DAVID D. THOMPSON, JR., M.D.
BRUCE COOPER, M.D.
ROBERT P. GOLDBERG, M.D.
ABEL A. DONKA, M.D.
Practice of Internal Medicine
22 WEST MAIN STREET
NIANTIC, CT 06357-2340
Tel (860) 739-4431 - Fax (860) 739-9461

April 26, 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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for Lawrence + Memorial Hospital's (L+M) certificate of need application (CON) to establish an elective angioplasty program. An elective angioplasty program at L+M would increase access for southeastern Connecticut patients who typically travel 50-60 miles to receive services. This high travel time places an undue burden on our community, particularly since L+M has been providing angioplasty on an emergent basis for several years with excellent outcomes and has high quality interventionalists, equipment, staff, and facilities already in place. The emergency angioplasty program, in collaboration with Yale School of Medicine, has run successfully since 2008.

For the elective program, L+M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been released. In addition, the recent reclassification of elective angioplasty without on-site surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when 1) rigorous patient selection criteria is used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L+M's proposed program meets each of these requirements. Plus, in the rare instance that a patient requires a transfer, L+M's transfer protocol and agreement with Yale-New Haven Hospital is in place as part of the emergency angioplasty service and can be utilized, when necessary, for elective cases.

I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families.

Sincerely,

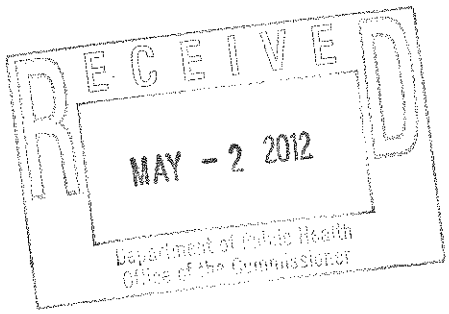
MD
MD
MD

Primary Care *for* WOMEN, LLC

8 Vista Drive – Eastport North Business Park – Old Lyme, CT 06371
860-434-8847 / FAX 434-0428

Mary Cummings Satti, M.D. • Anisha Parekh, M.D. • Christina McLean, M.D. • Mary C. Colpoys, M.D.

April 26, 2012



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Anisha Parekh, M.D.

Primary Care *for* WOMEN, LLC

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860-434-8847 / FAX 434-0428

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April 26, 2012

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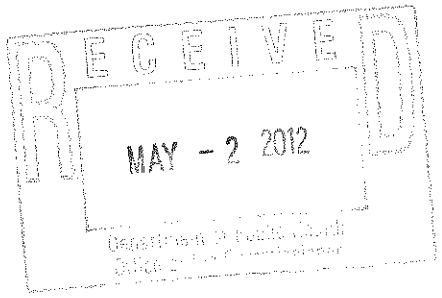

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I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families.

Sincerely,

Ch Mclean

Your Shoreline Solution for Women's Healthcare

Christina Mclean MD

Primary Care *for* WOMEN, LLC

8 Vista Drive – Eastport North Business Park – Old Lyme, CT 06371
860-434-8847 / FAX 434-0428

Mary Cummings Satti, M.D. • Anisha Parekh, M.D. • Christina McLean, M.D. • Mary C. Colpoys, M.D.

April 26, 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

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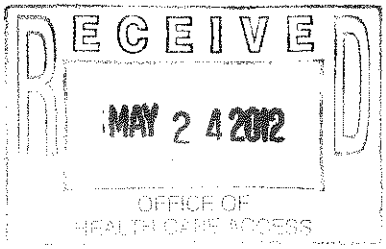
Sincerely,

Mary Cummings Satti, MD

Your Shoreline Solution for Women's Healthcare

L&M Physicians Cardiology at Waterford



Deputy Commissioner Davis
Office of The Health Care Access Department of Public Health
410 Capitol Ave, MS #138CA, PO Box 340308
Hartford, CT 06134

Dear Sir:

I am writing this letter to express my support for Lawrence & Memorial Hospital's certificate in need to establish an elective angioplasty program.

Currently, I am the Chief of Cardiology and was instrumental several years ago in helping the hospital attain emergency angioplasty. This has been an extremely busy, active, and successful, and safe program. An elective angioplasty program at L&M would increase our access for Southeastern Connecticut patients, who typically have to travel long distances under stress to Yale for this procedure. This puts an undue burden on both our patients and their family members.

Recent Seaport study suggests that it is safe to do elective angioplasty in selected patients without surgical onsite facilities. Our current program is in conjunction with the Yale-New Haven Hospital and we maintain a close working relationship with both the cardiologists as well as the thoracic surgeons, therefore having a rapid emergency access to cardiothoracic surgery if needed. An elective program would help us with continuity care and having a local cardiologist follow our angioplasty people.

Sincerely,

Peter S. Milstein, M.D., F.A.C.C.

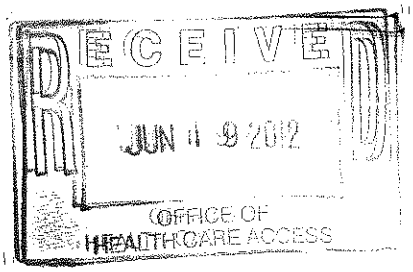
PSM/SAP/krn

DD: 05/14/2012
DT: 05/15/2012

196 Parkway South, Suite 103, Waterford, Connecticut 06385
Telephone (860) 443-4383 Fax (860) 443-3980

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

Table of Contents

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)

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: SC **Date:** 12/19/12

☒ **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
		TOTALS	500.00	0.00	500.00

VENDOR NO: L010882 ACCOUNTS PAYABLE

FORM 811CO4 REV (10-11)

VERIFY THE AUTHENTICITY OF THIS MULTI-TONE SECURITY DOCUMENT. CHECK BACKGROUND AREA CHANGES COLOR GRADUALLY FROM TOP TO BOTTOM.

LAWRENCE & MEMORIAL HOSPITAL
New London, CT 06320

51-57
119

DATE 05/29/12

CHECK NUMBER **288995**

AMOUNT
*****$500.00

VOID OVER 60 DAYS

PAY FIVE HUNDRED 00/100

TO THE ORDER OF TREASURER, STATE OF CONNECTICUT
....
.....,

CITIZENS BANK

AUTHORIZED SIGNATURE

Details on back. Security Features Included

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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

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.

Mary Labasi

Subscribed and sworn to before me

This Wednesday, May 02, 2012

Maryellen Golinsky

Notary Public

My commission expires 5/31/14

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49 Rope Ferry 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
ORDER 415595
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.

415595
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 860-444-5824

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 A&G GROUP, LLC. Entertainment will consist of the following: Acoustics (Not Amplified) . Objections must be filed by: 06/10/2012.
ANDREW C BELL

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announcements

Notes of Interest

CT SCRAP:Will buy your scrap steel, copper & aluminum. 33 Pequot Rd, Uncasville 860-848-3366

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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 (91,600). $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 quadro trac,nice jeep,needs a little tlc,runs good,$2700 860 501 4592

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pink and — wite moped all eletric 675 or best offer 860-7018516

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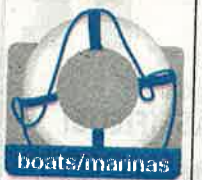
Labrador Retriever — Puppies-AKC,1st shots,Vet Checked,Chocolate & Black,$650,860-884-5040


boats/marinas

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ORIGINAL UNPUBLIISHED — PHOTO,CIRCA 1920'S, FOOTBALL PLAYER, ,V.G.COND.$135 OBO.401-596-1314

ORIGINAL UNPUBLIISHED — PHOTO,CIRCA 1920'S, FOOTBALL PLAYER, ,V.G.COND.$135 OBO.401-596-1314

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Anthony's Tree Removal — Licensed #0633737 & Insured. We remove any tree. Bucket truck service. Free Est.Call 860-625-6633

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E.J. TREE SERVICE No Tree Too Large / Small Free Estimates, Land Clearing, Firewood. Insured Lic#0610990.860-464-2032

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Year Round Tree Work — Owner operated tree service. Tree removals, tree trimming & pruning. Climbing & Bucket Truck services. All jobs cleaned up. Lic#

community classifieds

AMOUNT OF $97,253,000 FOR THE FISCAL YEAR BEGINNING JULY 1, 2012.

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

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

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

Mopeds

pink and — wite moped all eletric 675 or best offer 860-7018516

Motorcycles / Dirtbikes

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

Stearns New — 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 UNPUBLIISHED — 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, 100GB, 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 Covering, Rugs

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/ 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

TV/DVD STAND — -dark cherry-24" X 24"-very nice-$25-860-941-8954

Household Goods

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 ck-eck.See pics online Never Used,$15.00,860-535-1759

BRUNO'S Washers: $150, Dryers: $125, Frigs: $150, Stoves: $125 BEST DEALS! 369 Bank St. New London Call 860-439-1998

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community

ed 5' 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. Kepple, 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. Millovitsch, 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 06/04/2012
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

Lost & Found

Reward Cannon — DSLR camera in bag with accessories. I left it on the roof of my car in Mystic

Heavy Equipment

— John Deere 2009 4105 4x4 compact tractor. 41hp, hydrostatic, 183 hours. Comes with front loader and ballast box. Very clean homeowner use. $18500 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 / Dirtbikes

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 860-464-0211

Homecare / Eldercare

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 860-985-5838 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, 18 Thames St, Groton, CT 06340 EOE, AA**

Hotel / Restaurant / Food

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 31 Vauxhall St., New London, CT 06320

Painting/Papering

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 171 Boston Post Rd Old Lyme 06371

Career & Vocational Training

FREE TRAINING - Income-Eligible. MS Office/Clerical, Culinary, CNA, Employment Prep. OIC @ 860-447-1731.

Business Opportunities

25HP, Short shaft, w/gas tank & motorstand. Nice cond. $600. 860-941-9322

Swampscott Dory Built in 1997, 16', copper riveted, oars & trailer, make offer. 860-867-6821 —

Marinas

DOCK SLIP RENTALS Starting at $500 Don's Dock, Stonington, CT 860-535-0077 www.dons-dock.com

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 baitcasters,small,med spinning reels. $ 175. 860-884-3014

Mustang 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, 100GB, 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, more!, $100, 860-941-9331

Dell 5650 — 100 watt 5.1 surround sound speakers with subwoofer, phenominal sound for just $75, 860-941-9331

able)

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 lg pillows, like new, $150 call 860-535-9986

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

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 860-434-3181.

KitchenAid Slide — In Electric Range - glass top. Asking $225.00 Call 860-434-3181.

MIRROR -large(30"X42") — walnut stained frame--very nice---$40-860-941-8954

MIRROR -large(30"X42") — walnut stained frame--very nice---$40-860-941-8954

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 Items

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 cttrees.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 $300. 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 Ligature, 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

Other Miscellaneous

Antonio Stradivari — A. Stradivari Advertisement & Informational B&W Framed Print. $5. Call 860.917.6364

DIRECTORY OF businesses AND 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:

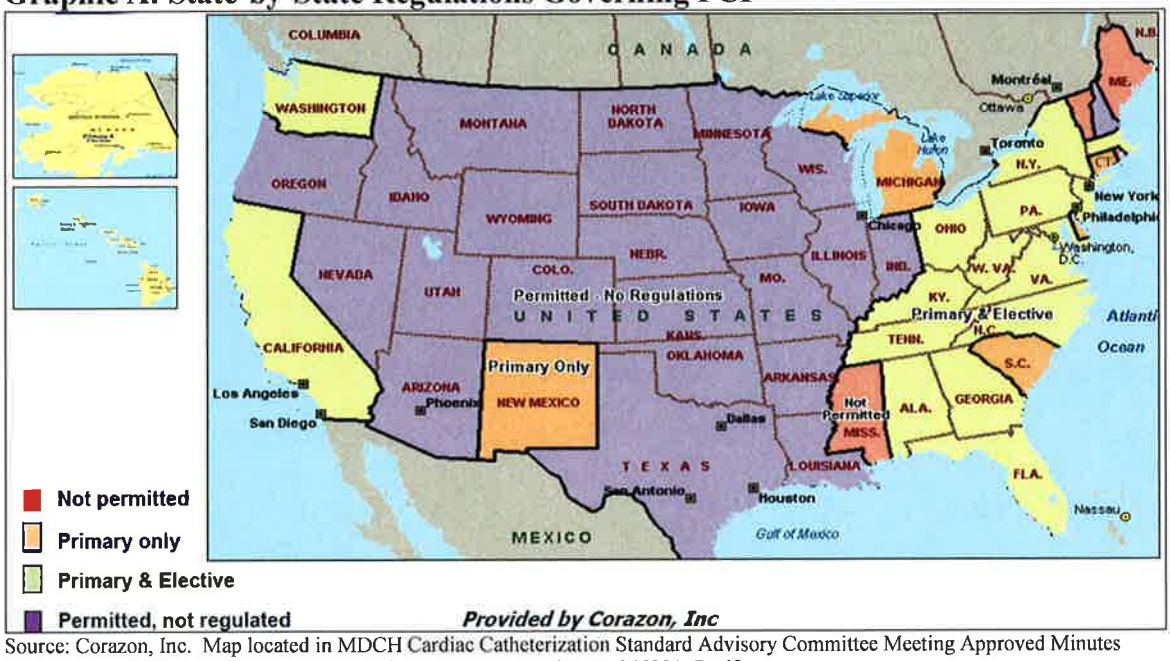
- Elective PCI without on-site surgery should be fostered in markets where access to this "higher level of cardiovascular care" is limited
- Elective PCI without on-site surgery is appropriate when patients are appropriately selected and backup precautions are in place, and
- Patients who are high risk 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

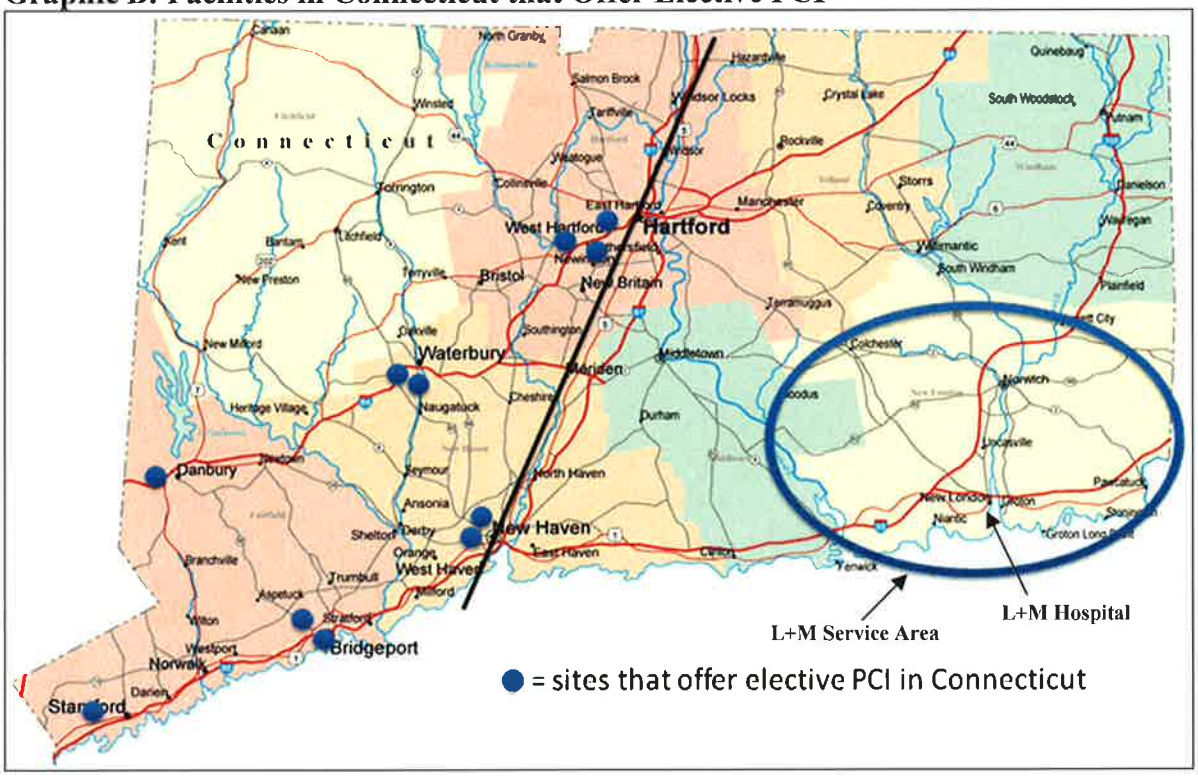


Table B below presents a tabulation of mileage and drive time estimates from L+M Hospital to the closest facilities within Connecticut and Rhode Island that provide elective PCI. Metrics were sourced from Google Maps and assume no delay during transit due to traffic or construction.

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

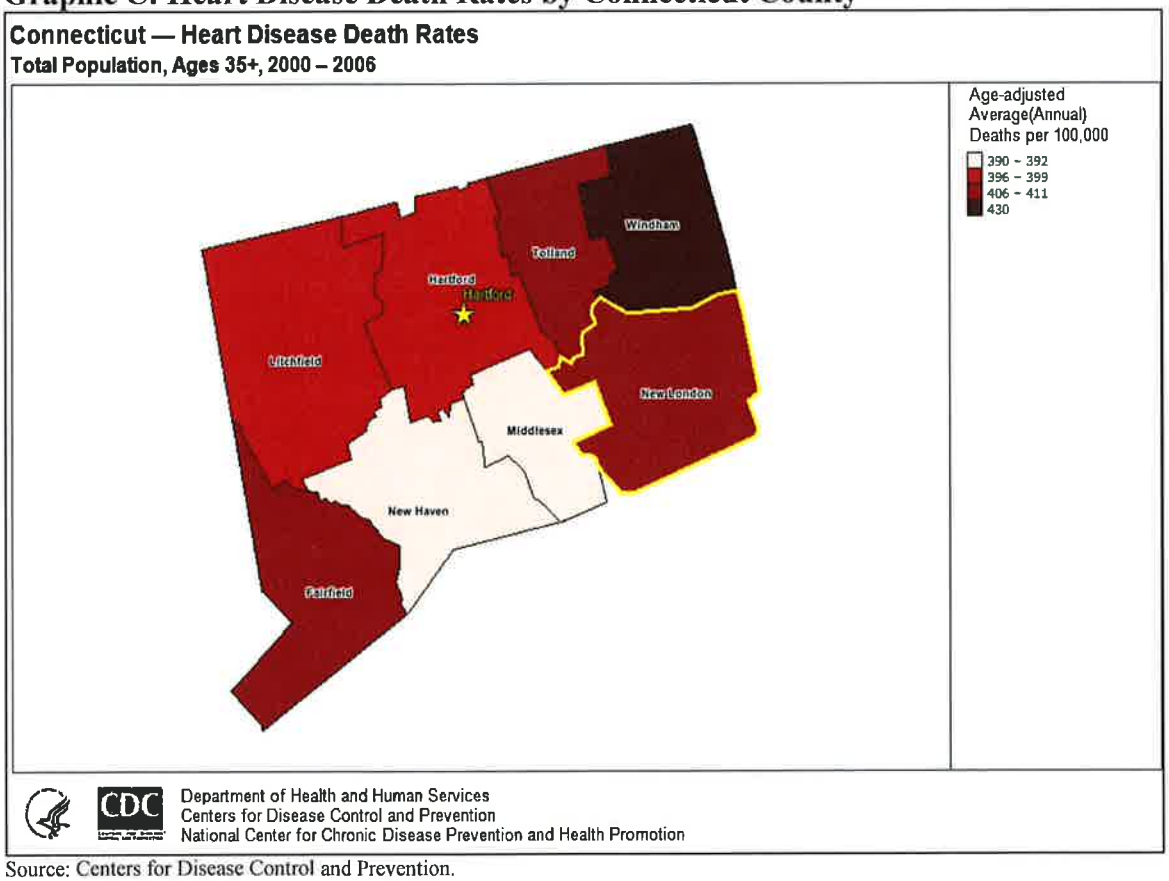
Source: Robert Wood Johnson Foundation, County Health Rankings & Roadmaps (http://www.countyhealthrankings.org/#app/).

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.

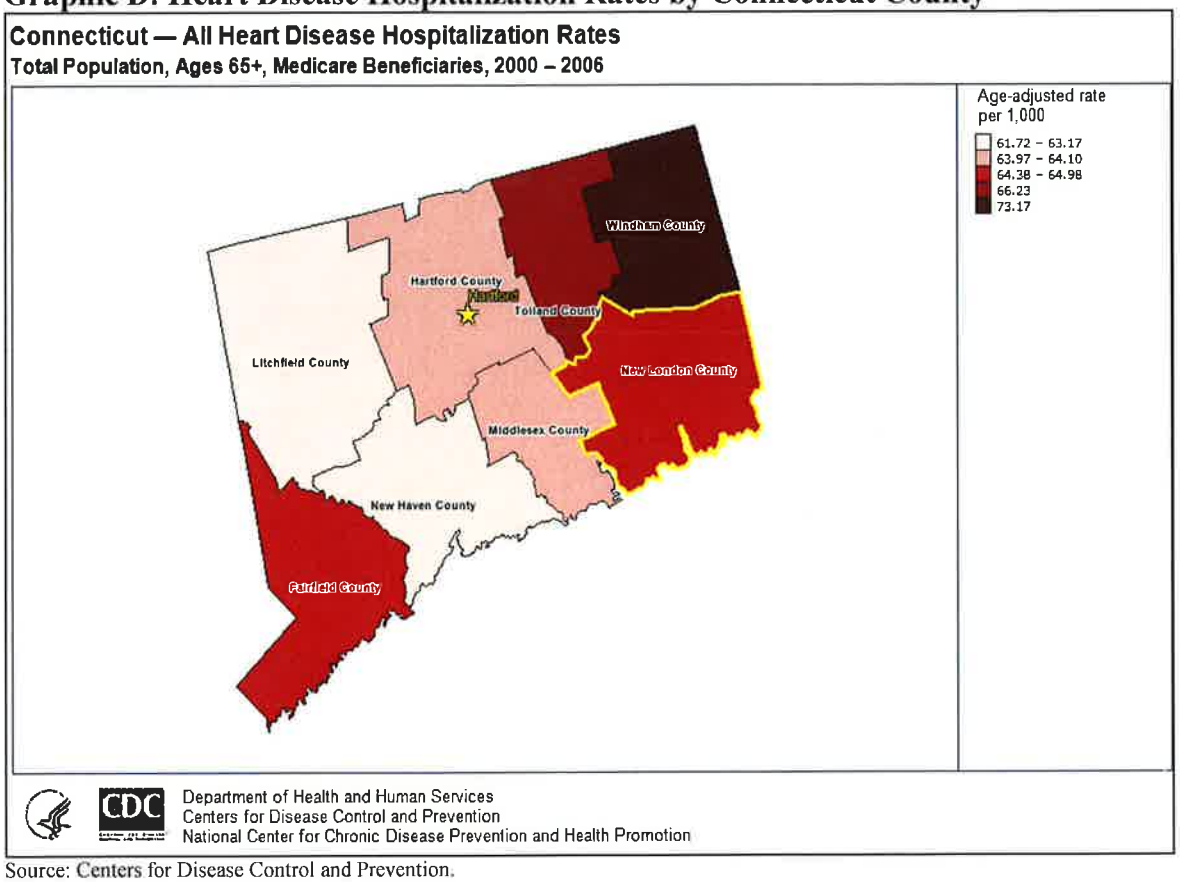
Furthermore, according to data provided by the Centers for Disease Control and Prevention (CDC), New London County has a higher heart disease death rate and hospitalization rate than most other counties in the state. Graphics C and D display this and further demonstrate that cardiac services such as 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 ($\leq$ 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.

Attachment A

Letters of Support

LAWRENCE & MEMORIAL
Physicians

April 26, 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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for Lawrence + Memorial Hospital's (L+M) certificate of need application (CON) to establish an elective angioplasty program. An elective angioplasty program at L+M would increase access for southeastern Connecticut patients who typically travel 50-60 miles to receive services. This high travel time places an undue burden on our community, particularly since L+M has been providing angioplasty on an emergent basis for several years with excellent outcomes and has high quality interventionalists, equipment, staff, and facilities already in place. The emergency angioplasty program, in collaboration with Yale School of Medicine, has run successfully since 2008.

For the elective program, L+M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been released. In addition, the recent reclassification of elective angioplasty without on-site surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when 1) rigorous patient selection criteria is used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L+M's proposed program meets each of these requirements. Plus, in the rare instance that a patient requires a transfer, L+M's transfer protocol and agreement with Yale-New Haven Hospital is in place as part of the emergency angioplasty service and can be utilized, when necessary, for elective cases.

I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families.

Sincerely,

Gina Williams, MD

LAWRENCE & MEMORIAL
Physicians

April 26, 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

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I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families.

Sincerely,

B. Williams MD

LAWRENCE+MEMORIAL HOSPITAL
100
1912-2012

June 6, 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

Dear Deputy Commissioner Davis:

Since its inception in the late 70's and early 80's, the safety and efficacy of Percutaneous Coronary Intervention (PCI) has improved dramatically. Improving technology, pharmacology, and operator experience have all contributed to rising success rates to greater than 95% and lowering the need for emergency surgery during a PCI to 0.3%. These improvements have led many to perform PCI at centers without surgical backup. Data supporting such procedures in the setting of acute MI are robust and led to the approval of primary angioplasty programs for STEMI. More recently, data have emerged demonstrating acceptable safety and efficacy endpoints for elective PCI in carefully selected patients at such "off-site" centers. This has led to another change in the ACC/AHA guidelines from a Class III level of recommendation to a Class IIb level of recommendation. This change was supported recently in an executive summary in the Journal of the American College of Cardiology. These recommendations emphasize several attributes of model programs. I believe L+M Hospital is emblematic of these "ideal programs" and is well suited to offer elective PCI without on-site surgical backup.

The greatest benefit of developing such a program is the improved access offered to patients of an underserved region. L+M is geographically located in southeastern Connecticut. We are the only facility providing angioplasty services in the eastern half of the state. On the western side of the state there are at least 14 such centers (of which 11 offer elective angioplasty). Often patients have to travel upwards of 50 miles to Yale-New Haven Hospital (YNHH) or another tertiary center to receive their elective PCI. Providing the service within their community would result in multiple benefits for our patients. It would avoid additional, unnecessary trips to the cath lab necessitating multiple arterial punctures. It would reduce the complication rates associated with prolonged indwelling arterial catheters and those associated with inter-hospital transfers. It would help fray health care costs by reducing hospital stay and costs associated with transfer. It would reduce the emotional and financial burden of families having to travel significant distance to be with their loved ones.

From a quality standpoint, offering elective PCI at L+M Hospital would allow for the cardiologist performing the PCI to also be the one providing post-procedure follow-up visit, thereby improving continuity of care and patient satisfaction. Furthermore having the procedure performed within a patients' "medical home" would allow for better communication and collaboration among a patient's various physicians. This would certainly enhance communication among subspecialists and help ensure delivery of the highest quality care.

Before beginning an elective PCI program, a well run primary PCI program for acute heart attack must already be in place. Since 2008 we have been running a very successful Primary angioplasty program with an annual volume of approximately 78 cases. Our door to balloon times put us among the best centers of our kind and our quality/safety metrics are on par with national standards. We have a long standing relationship with the cardiothoracic surgery program at YNHH and in the rare event of complications, transportation and communication occur seamlessly and quickly. Angiograms can be transmitted and viewed real-time in the YNHH cardiac catheterization lab. This gives us the ability to have consensus opinion from multiple interventional cardiologists/surgeons during complex cases.

These years of experience with a primary PCI program make us a model site to begin an elective program. Our staff is well trained and experienced. Our policies and protocols are in place and elaborated in the body of the CON application. As current Medical Director of the Primary Angioplasty Program at L+M, I am confident we are poised to fulfill a local need and enhance the delivery of high quality cardiac care to the patients of southeastern Connecticut.

Sincerely,

Brian Cambi, MD FACC FSCAI
Medical Director of the Primary Angioplasty Program at L+M Hospital

Eastern Connecticut Cardiology Group, P.C.

Brian S. Ehrlich MD FACC

Peter S. Milstein MD FACC

Richard P. Fazio MD FACC

Francis J. Mirecki MD FACC

Mark N. Fiengo DO FACC FSCAI

Valerie B. Popkin MD FACC

Mark J. Somers MD FACC

Robert J. Kupis MS PA-C

Kim Chemacki MHS PA-C

April 21, 2012

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

RE:
Patient ID #:
Date of Birth:

Dear Deputy Commissioner Davis:

As Director of Cardiac Catheterization Services at Lawrence & Memorial Hospital in New London and a longstanding practicing cardiologist in the New London County Community, I am writing this letter to express my strong support for Lawrence & Memorial Hospital's Certificate of Need application to establish an elective angioplasty program. This program would increase access for Southeastern Connecticut patients who otherwise have typically had to travel 50-60 miles to receive services at university settings. This high travel time does place an undue burden on our community, particularly since Lawrence & Memorial Hospital has been providing angioplasty on emergent basis for several years. The existing emergency angioplasty program can be proud of excellent outcomes, this in part due to the high quality of interventionists as well as equipment staff and facilities already in place. Emergency angioplasty program in a collaborative effort with Yale School of Medicine has been successfully in process since 2008.

In consideration for an elective angioplasty program, Lawrence & Memorial Hospital plans to institute strict criteria for patient selection based on the Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, in view of the large amount of supportive medical literature that has been released on this subject. Additionally, the recent re-classification of elective angioplasty without on-site surgery from Class III (should not be performed) to Class IIB (may be considered) is an example demonstrating growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable under the following situations:

1. When rigorous patient selection criteria is used.
2. When planning for program development is accomplished.
3. When procedures are performed by experienced operators.
4. When the program fills a void in the healthcare needs of the community.

Lawrence & Memorial's proposed program, each of the requirements as outlined above. Also, in a rare instance that a patient requires a transfer, Lawrence Memorial Hospital's transfer protocol in agreement with Yale New Heaven Hospital has been in place as part of the emergency angioplasty service and has been shown to be successfully utilized when necessary and can be utilized for elective cases should the need arise.

196 Parkway South, Suite 103, Waterford, Connecticut 06385
Telephone (860) 443-4383 Fax (860) 443-3980

Eastern Connecticut Cardiology Group, P.C.

Brian S. Ehrlich
MD FACC

Peter S. Milstein
MD FACC

Richard P. Fazio
MD FACC

Francis J. Mirecki
MD FACC

Mark N. Fiengo
DO FACC FSCAI

Valerie B. Popkin
MD FACC

Mark J. Somers
MD FACC

Robert J. Kupis
MS PA-C

Kim Chemacki
MHS PA-C

Once again, I strongly encourage you to approve the Certificate of Need application promoted by Lawrence & Memorial Hospital to establish elective angioplasty at our institution. I believe the program would improve care in our region and increase access for our patients and their families.

Respectfully,

Brian S. Ehrlich, M.D., F.A.C.C.

BSE/UKM/AHR/KA

DD: 04/21/2012
DT: 04/23/2012

Electronically signed by **Brian S. Ehrlich, M.D., F.A.C.C.**, 4/23/12 11:54 AM

196 Parkway South, Suite 103, Waterford, Connecticut 06385
Telephone (860) 443-4383 Fax (860) 443-3980

L&M Physicians Cardiology at Waterford

Deputy Commissioner Davis
Office of The Health Care Access Department of Public Health
410 Capitol Ave, MS #138CA, PO Box 340308
Hartford, CT 06134

Dear Sir:

I am writing this letter to express my support for Lawrence & Memorial Hospital's certificate in need to establish an elective angioplasty program.

Currently, I am the Chief of Cardiology and was instrumental several years ago in helping the hospital attain emergency angioplasty. This has been an extremely busy, active, and successful, and safe program. An elective angioplasty program at L&M would increase our access for Southeastern Connecticut patients, who typically have to travel long distances under stress to Yale for this procedure. This puts an undue burden on both our patients and their family members.

Recent Seaport study suggests that it is safe to do elective angioplasty in selected patients without surgical onsite facilities. Our current program is in conjunction with the Yale-New Haven Hospital and we maintain a close working relationship with both the cardiologists as well as the thoracic surgeons, therefore having a rapid emergency access to cardiothoracic surgery if needed. An elective program would help us with continuity care and having a local cardiologist follow our angioplasty people.

Sincerely,

Peter S. Milstein, M.D., F.A.C.C.

PSM/SAP/krn

DD: 05/14/2012
DT: 05/15/2012

LAWRENCE & MEMORIAL HOSPITAL

May 11, 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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for Lawrence + Memorial Hospital's (L+M) certificate of need application (CON) to establish an elective angioplasty program. An elective angioplasty program at L+M would increase access for southeastern Connecticut patients who typically travel 50-60 miles to receive these services. This high travel time places an undue burden on our community. L+M has been providing angioplasty on an emergent basis for several years with excellent outcomes. We already have in place the needed staff which includes high quality interventionalists, operating in a well equipped facility. Our emergency angioplasty program, in collaboration with Yale School of Medicine, has run successfully since 2008.

For the elective program, L+M plans to institute strict criteria for patient selection using The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully. This is supported by the C-Port E trial and other published literature. In addition, the recent reclassification of elective angioplasty without on-site surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates the growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when 1) rigorous patient selection criteria is used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L+M's proposed program meets each one of these requirements. Also, we currently utilize a transfer protocol based on an agreement with Yale-New Haven Hospital to transfer patients when needed to them. We would continue to operate under the same protocol, if necessary, for elective cases.

I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region by increasing access for our patients and their families to this service. Should you have any questions, please feel free to contact me at jgadbaw@lmhosp.org or by calling my office at 860-444-3722.

Sincerely,

Joseph J. Gadbaw, Jr, MD, FIDSA
Chair, Department of Medicine
Lawrence +Memorial Hospital
365 Montauk Avenue
New London, CT 06320
860-444-3722

LAWRENCE & MEMORIAL HOSPITAL

April 20, 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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for Lawrence + Memorial Hospital's (L+M) certificate of need application (CON) to establish an elective angioplasty program. An elective angioplasty program at L+M would increase access for southeastern Connecticut patients who typically travel 50-60 miles to receive services. This high travel time places an undue burden on our community, particularly since L+M has been providing angioplasty on an emergent basis for several years with excellent outcomes and has high quality interventionalists, equipment, staff and facilities already in place. The emergency angioplasty program, in collaboration with the Yale School of Medicine, has run successfully since 2008.

For the elective program, L+M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been released. In addition, the recent reclassification of elective angioplasty without on-site surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when 1) rigorous patient selection criteria is used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L+M's proposed program meets each of these requirements. Plus, in the rare instance that a patient requires a transfer, L+M's transfer protocol and agreement with Yale-New Haven Hospital is in place as part of the emergency angioplasty service and can be utilized, when necessary, for elective cases.

I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families. Should you have any questions, please feel free to contact me at omayorga@lmhosp.org.

Sincerely,

Oliver Mayorga, M.D.
Chairman & Medical Director, Emergency Services

April 20, 2012

The Hospitalist Company

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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for Lawrence + Memorial Hospital's (L+M) certificate of need application (CON) to establish an elective angioplasty program. An elective angioplasty program at L+M would increase access for southeastern Connecticut patients who typically travel 50-60 miles to receive services. This high travel time places an undue burden on our community, particularly since L+M has been providing angioplasty on an emergent basis for several years with excellent outcomes and has high quality interventionalists, equipment, staff, and facilities already in place. The emergency angioplasty program, in collaboration with Yale School of Medicine, has run successfully since 2008. In my role as director of the Hospitalist program at L+M, I have had the pleasure of working with this team of dedicated professionals on many occasions.

For the elective program, L+M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been released. In addition, the recent reclassification of elective angioplasty without on-site surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when 1) rigorous patient selection criteria is used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L+M's proposed program meets each of these requirements. Plus, in the rare instance that a patient requires a transfer, L+M's transfer protocol and agreement with Yale-New Haven Hospital is in place as part of the emergency angioplasty service and can be utilized, when necessary, for elective cases.

I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families. As a life long resident of the community, I am in strong support of this L+M initiative. Should you have any questions, please feel free to contact me at XXX@lmhosp.org.

Sincerely,

Kenneth Donovan, MD FHM
Medical Director
IPC Hospitalists of New London

LAWRENCE & MEMORIAL
Physicians

CARDIOLOGY
Roshanak Bagheri, MD
Jon C. Gaudio, MD

FAMILY MEDICINE
Brenda Applegate, MD
Luanne Benshimol, APRN
Robert Ciotola, MD
Suresh D'Mello, MD
Jay Graves, MD
William H. Kober, MD
Michael Lang, DO
Bridget Mejza, APRN
Elizabeth Nelligan, MD
Kathy Parker, APRN
Robert J. Perry, MD
Brian L. Williams, MD
Gina Williams, MD

INTERNAL MEDICINE
Jenny Hyppolite, MD
Myriam I. Jones, MD
Robert Meikle, MD
Katherine Obara, APRN
Neil Palker, MD
Nimesh Patel, DO
Scott Credit, MS, APRN
Bruce A. Patterson, APRN

NEI URGERY
Patn ıerty, MD
Stanley Pugsley, MD
Victoria Samuels, MD
Arthur Welch, PA-C

OB/GYN
Henry S. Amdur, MD
Edward J. Watson, MD
Janet Rufo, CNM

SURGERY
General, Bariatric, Laparoscopic, Breast, Plastic & Reconstructive
Elizabeth A. Arguelles, MD
Garth H. Ballantyne, MD, FACS
Heidi L. Elliott, MD
John C. Lee, MD
David F. Reisfeld, MD, FACS
Eric A. Sommer, MD
Dean N. Willis, MD, FACS

PHYSICAL MEDICINE & REHABILITATION
Mustapha Kemal, MD
Joseph F. O'Keefe, MD
Joseph W. Peters, MD

ISLAND HEALTH PROJECT
Christopher Ingram, MD

May 3, 2012

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

Dear Deputy Commissioner Davis:

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For the elective program, L+M plan to institute strict criteria for patient selections per The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been released. In addition, the recent reclassification of elective angioplasty with on-sited surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when I) rigorous patient selection criteria is used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L+M's proposed program meets each of these requirements. Plus, in the rare instance that a patient requires a transfer, L+M's transfer protocol and agreement with Yale-New Haven Hospital is in a place as part of the emergency angioplasty services and can be utilized, when necessary, for elective cases.

I strongly encourage you to approve L+M's Con application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families. Should you have any questions, please feel free to contact me at wkober@lmhosp.org.

Sincerely,

William Kober, MD
L+M Physicians, Stonington

LAWRENCE & MEMORIAL
Physicians

April 20, 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

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I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families. Should you have any questions, please feel free to contact me at bapplegate@lmhosp.org.

Sincerely,

Brenda Applegate, MD
L+M Physicians, Stonington

April 20, 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

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Sincerely,

Name
Title

EDWARD J. MCDERMOTT, M.D.
276-R MONTAUK AVENUE
NEW LONDON, CT 06320
860-447-1475 TEL
860-447-8598 FAX

E-MAIL
EJMCDERMOTTMD
@MEDSCAPE.COM

April 20, 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

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Sincerely,

Name
Title

April 20, 2012

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Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
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Sincerely,

Name
Title MD

April 20, 2012

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Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

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Sincerely,

E. S

Name Eugene SAPOZHNIKOV, MD
Title

April 20, 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

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Sincerely,

J. L. D.

Name
Title MD

April 20, 2012

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

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860 - 442 - 0290

Sincerely,

Amzad Khan, MD

Name Amzad Khan, MD
Title M.D.

LAWRENCE & MEMORIAL
Physicians

April 20, 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

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Sincerely,

Michael Lang, DO
L+M Physicians, Ledyard

LAWRENCE & MEMORIAL
Physicians

April 20, 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

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Sincerely,

Robert Ciotola, MD
L+M Physicians, Ledyard

April 20, 2012

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Deputy Commissioner
Office of Health Care Access
Department of Public Health
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Sincerely,

Sanford Greenhouse, MD
Gales Ferry Medical Group
Gales Ferry, CT

April 20, 2012

Lisa Davis
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Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
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Sincerely,

Mary Murphy-Fiengo, DO
Gales Ferry Medical Group
Gales Ferry, CT

April 20, 2012

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John Hennessey, MD
Gales Ferry Medical Group
Gales Ferry, CT

April 20, 2012

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Sincerely,

Gary Bertman, MD
GP Family 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

May 3, 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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for the CON application for an elective angioplasty program at Lawrence & Memorial (L&M) Hospital. The program will be a joint effort between L&M Hospital and the Yale-New Haven Heart and Vascular Center (YNHH HVC). The director of the program and all of the participating interventional cardiologists will be members of the Yale School of Medicine full-time faculty. This is the way the current PAMI angioplasty program has operated since 2008 and the outcomes have been excellent by national benchmarks. We view the proposed elective program as an extension of that program.

An elective angioplasty program at L&M would increase access for southeastern Connecticut patients who currently must travel 50-60 miles to receive these services. For the elective program, L&M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been recently released. In addition, the recent reclassification of elective angioplasty without on-site surgery from Class III ("should not be performed") to Class IIb ("may be considered") further demonstrates growing support for this service. Clinical guidelines specifically note that elective angioplasty without on-site surgery may be reasonable when 1) rigorous patient selection criteria are used, 2) planning for program development is accomplished, 3) procedures are performed by experienced operators, and 4) the program fills a void in the health care needs of the community. L&M's proposed program meets each of these requirements. Additionally, in the rare instance that a patient requires a transfer, L&M's transfer protocol and agreement with Yale-New Haven Hospital is already in place as part of the PAMI angioplasty program.

I strongly encourage you to approve L&M's CON application to establish a joint YNHH HVC/ L&M elective angioplasty program. Should you have any questions, please feel free to contact me.

Sincerely,

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

Yale SCHOOL OF MEDICINE
Department of Surgery

Section of Cardiac Surgery
DAVID D. YUH, MD
Section Chief, Cardiac Surgery

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courier
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Room 204
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New Haven CT 06510

May 4, 2012

Ms. 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 Lawrence & Memorial (L & M) Hospital's application to provide elective angioplasty to the community of patients it serves. As the chief of cardiac surgery at Yale-New Haven Hospital (YNHH), I have been working closely with Dr. Brian Cambi and his cardiologist colleagues who practice at L & M to build upon an already robust, well-established relationship with us. This relationship has been fostered by excellent outcomes achieved in the medical and surgical treatment of acute heart failure and coronary ischemia by Yale's accomplished staff of cardiologists and cardiac surgeons. Growing out of this, we have developed a streamlined referral mechanism to facilitate the immediate transfer of unstable patients from L & M Hospital to the state-of-the-art tertiary cardiac care facilitates offered at YNHH.

Given that Lawrence and Memorial Hospital is geographically isolated from other hospitals offering elective angioplasty, establishing this service at L & M Hospital will provide a large community of patients with local access to high-quality interventional cardiology services that would otherwise only be obtainable by traveling significant distances. Fortunately, physicians, staff, and facilities already in place for L & M's approved *emergency* angioplasty program would greatly facilitate the development of an *elective* angioplasty program in a cost-effective manner. Yale faculty will be prominent in the management of this program, including overseeing quality assurance and performance improvement mechanisms. Furthermore, the aforementioned close relationship between YNHH and L & M would readily provide high-quality, responsive cardiac surgical backup for this program.

Thank you for your consideration of Lawrence & Memorial Hospital's application to conduct elective angioplasty. I believe that adding this capability will go a long ways towards improving the continuity of care available to cardiac patients at L & M Hospital and providing advanced tertiary care when required.

Sincerely,

David D. Yuh, MD

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

Branford Office
11 Harrison Avenue
Branford CT 06405
TEL: 203 483-8300 · FAX: 203 483-8314

Guilford Office
111 Goose Lane, Suite 2400
Guilford CT 06437
TEL: 203 458-2097 · FAX: 203 458-1592

Michael W. Cleman, MD
Director
Cardiac Catheterization Laboratory

JOSEPH BRENNAN, MD
HENRY S. CABIN, MD
BRIAN CAMBI, MD
JEPTHA CURTIS, MD
FRANK GIORDANO, MD
HOWARD HARONIAN, MD
FAISAL HASAN, MD
CHRISTOPHER HOWES, MD
CARLOS MENA-HURTADO, MD
STEVEN PFAU, MD
MICHAEL REMETZ, MD
REBECCA SCANDRETT, MD
JOHN F. SETARO, MD
CRAIG A. THOMPSON, MD

JOY SAUNDERS, APRN

May 3, 2012

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
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I am writing this letter to express my support for the CON application for an elective angioplasty program at Lawrence & Memorial (L&M) Hospital. The program will be a joint effort between L&M Hospital and the Yale-New Haven Heart and Vascular Center (YNHH HVC). The director of the program and all of the participating interventional cardiologists will be members of the Yale School of Medicine full-time faculty. The current PAMI angioplasty program has operated using this model since 2008 and the outcomes have been excellent by national benchmarks. We view the proposed elective program as an extension of that program.

An elective angioplasty program at L&M would increase access for southeastern Connecticut patients who currently must travel 50-60 miles to receive these services. For the elective program, L&M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been recently released. In the rare instance that a patient requires emergent transfer, L&M's transfer protocol and agreement with Yale-New Haven Hospital is already in place as part of the PAMI angioplasty program.

I strongly encourage you to approve L&M's CON application to establish a joint YNHH HVC/ L&M elective angioplasty program. Should you have any questions, please feel free to contact me.

Sincerely,

Michael W. Cleman, M.D.

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May 1, 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

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for Lawrence + Memorial Hospital's (L+M) certificate of need application (CON) to establish an elective angioplasty program. An elective angioplasty program at L+M would increase access for southeastern Connecticut patients who typically travel 50-60 miles to receive services. This high travel time places an undue burden on our community, particularly since L+M has been providing angioplasty on an emergent basis for several years with excellent outcomes and has high quality interventionalists, equipment, staff, and facilities already in place. The emergency angioplasty program, in collaboration with Yale School of Medicine, has run successfully since 2008. I have played an active role in that program. The past four years have given the staff adequate training and exposure to now allow elective cases.

For the elective program, L+M plans to institute strict criteria for patient selection per The Society for Cardiovascular Angiography and Interventions guidelines. Therefore, I strongly believe that elective angioplasty without on-site surgery can be performed successfully, given the large amount of supporting medical literature that has been released. In the rare instance that a patient requires a transfer, L+M's transfer protocol and agreement with Yale-New Haven Hospital is in place as part of the emergency angioplasty service and can be utilized, when necessary, for elective cases.

I strongly encourage you to approve L+M's CON application to establish an elective angioplasty program. I believe the program would improve care in our region and increase access for our patients and their families. Should you have any questions, please feel free to contact me at howard.haronian@yale.edu.

Sincerely,

Howard L. Haronian, MD FACC

Associate Clinical Professor of Medicine
Yale School of Medicine
Attending Interventional Cardiologist
The Westerly Hospital
L+M Hospital
Yale-New Haven Hospital

Attachment 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"

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PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: Executive Summary

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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*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, up-

dating, 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.

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 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 required 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

Table 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE 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.

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 are cited as being compliant with many of the proposed standards. 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, 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, 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, multivessel, myocardial infarction, non–ST-elevation myocardial infarction (NSTEMI), no-reflow, optical coherence tomography, proton pump inhibitor, 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.

Because the executive summary contains only the recommendations, the reader is encouraged to consult the full-text guideline (4) for additional detail on the recommendations and guidance on the care of the patient undergoing PCI.

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 Guideline Scope

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 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 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.

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

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 (4). The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms. The following text contains recommendations for revascularization to improve survival and symptoms, and they are presented in Tables 2 and 3.

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.

2.1. Heart Team Approach to Revascularization Decisions

CLASS I

1. A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD (5–7). *(Level of Evidence: C)*

CLASS IIa

1. Calculation of the Society of Thoracic Surgeons and SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) scores is reasonable in patients with unprotected left main and complex CAD (7–14). *(Level of Evidence: B)*

2.2. Revascularization to Improve Survival

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 (15–21). *(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., Society of Thoracic Surgeons–predicted risk of operative mortality ≥5%) (8,10,11,22–40,106) *(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 (11,27,29–31,36,37,39–41). *(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 (24,42,43). *(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; Society of Thoracic Surgeons–predicted risk of operative mortality >2%) (8,10,11,22–40,44). *(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 (8,10,11,15–23). *(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]) or in the proximal LAD plus 1 other major coronary artery (17,21,45–48). *(Level of Evidence: B)*
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* [49–51]; *PCI Level of Evidence: C* [49]*)*

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 (52–55). *(Level of Evidence: B)*
2. 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 (21,56–60). *(Level of Evidence: B)*
3. CABG with a left internal mammary artery graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia (21,48,61,62). *(Level of Evidence: B)*

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	(5–7)
CABG and PCI	IIa—Calculation of STS and SYNTAX scores	B	(7–14)
UPLM*			
CABG	I	B	(15–21)
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	(8,10,11,22–40,106)
	IIa—For UA/NSTEMI if not a CABG candidate	B	(11,27,29–31,36,37,39–41)
	IIa—For STEMI when distal coronary flow is TIMI flow grade <3 and PCI can be performed more rapidly and safely than CABG	C	(24,42,43)
	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	(8,10,11,22–40,44)
	III: Harm—For SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI and who are good candidates for CABG	B	(8,10,11,15–23)
3-vessel disease with or without proximal LAD artery disease*			
CABG	I	B	(17,21,45–48)
	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	(23,38,48,63,64)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
2-vessel disease with proximal LAD artery disease*			
CABG	I	B	(17,21,45–48)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
2-vessel disease without proximal LAD artery disease*			
CABG	IIa—With extensive ischemia	B	(52–55)
	IIb—Of uncertain benefit without extensive ischemia	C	(48)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
1-vessel proximal LAD artery disease			
CABG	IIa—With LIMA for long-term benefit	B	(21,48,61,62)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
1-vessel disease without proximal LAD artery involvement			
CABG	III: Harm	B	(21,45,52,53,86–90)
PCI	III: Harm	B	(21,45,52,53,86–90)
LV dysfunction			
CABG	IIa—EF 35% to 50%	B	(21,56–60)
CABG	IIb—EF <35% without significant left main CAD	B	(21,56–60,75,76)
PCI	Insufficient data		N/A
Survivors of sudden cardiac death with presumed ischemia-mediated VT			
CABG	I	B	(49–51)
PCI	I	C	(49)
No anatomic or physiologic criteria for revascularization			
CABG	III: Harm	B	(21,45,52,53,86–90)
PCI	III: Harm	B	(21,45,52,53,86–90)

In patients with multivessel disease who also have diabetes, it is reasonable to choose CABG (with LIMA) over PCI (54,66–73) *(Class 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.

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	(74,91–100)
≥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	(78,81,84)
	IIb—CABG	C	(85)
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	(23,38,48,63,64)
Viable ischemic myocardium that is perfused by coronary arteries that are not amenable to grafting	IIb—TMR as an adjunct to CABG	B	(101–105)
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.

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 (23,38,48,63,64). *(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 left internal mammary artery graft can be anastomosed to the LAD artery (54,66–73). *(Level of Evidence: B)*

CLASS IIb

1. 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 (48). *(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 (17,45,48,74). *(Level of Evidence: B)*
3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe left ventricular systolic dysfunction (ejection fraction <35%) whether or not viable myocardium is present (21,56–60,75,76). *(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 (77–85). *(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 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 (21,45,52,53,86–90). *(Level of Evidence: B)*

2.3. Revascularization to Improve Symptoms

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 (74,91–100). *(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 (78,81,84). *(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 (23,38,48,63,64). *(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 (85). *(Level of Evidence: C)*
2. 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 (101–105). *(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% left main or ≥70% non–left main stenosis) or physiological (e.g., abnormal fractional flow reserve) criteria for revascularization. *(Level of Evidence: C)*

2.4. Clinical Factors That May Influence the Choice of Revascularization

2.4.1. Dual Antiplatelet Therapy Compliance and Stent Thrombosis

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 dual antiplatelet therapy (DAPT) for the appropriate duration of treatment based on the type of stent implanted (107–110). *(Level of Evidence: B)*

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	(118,119)
Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.	I	B	(120–123)
In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized.	I	B	(124–126)
Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.	III: No Benefit	A	(127–131)
Anaphylactoid reactions			
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate prophylaxis before repeat contrast administration.	I	B	(132–135)
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	(136–138)
Statins			
Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.	IIa	A: Statin naive	(139–145)
		B: Chronic statin therapy	(146)
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	(147–149)
Aspirin			
Patients already on daily aspirin therapy should take 81 mg to 325 mg before PCI.	I	B	(150–153)
Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.	I	B	(150,152,153)

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.

2.5. Hybrid Coronary Revascularization

CLASS IIa

1. Hybrid coronary revascularization (defined as the planned combination of left internal mammary artery-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following (111–117) *(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 or PCI (i.e., excessive vessel tortuosity or chronic total occlusion).

CLASS IIb

1. Hybrid coronary revascularization (defined as the planned combination of left internal mammary artery-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)*

3. Preprocedural Considerations: Recommendations

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

3.1. Radiation Safety

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)*

3.2. Contrast-Induced Acute Kidney Injury

CLASS I

1. Patients should be assessed for risk of contrast-induced acute kidney injury before PCI (118,119). *(Level of Evidence: C)*
2. Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration (120–123). *(Level of Evidence: B)*
3. In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized (124–126). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced acute kidney injury (127–131). *(Level of Evidence: A)*

3.3. Anaphylactoid Reactions

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 (132–135). *(Level of Evidence: B)*

Table 5. Indications for Coronary Angiography in STEMI

Indications	COR	LOE	References
Immediate coronary angiography			
Candidate for primary PCI	I	A	(155,175–178)
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	I	B	(179,180)
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	IIa	B	(181,182)
Coronary angiography 3 to 24 h after fibrinolysis			
Hemodynamically stable patients with evidence for successful fibrinolysis	IIa	A	(183–187)
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.

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 (136–138). *(Level of Evidence: C)*

3.4. Statin Treatment

CLASS IIa

1. Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural myocardial infarction. *(Level of Evidence: A for statin-naive patients* [139–145]*; Level of Evidence: B for those on chronic statin therapy* [146]*)*

3.5. Bleeding Risk

CLASS I

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

3.6. PCI in Hospitals Without On-Site Surgical Backup

CLASS IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished (155,156). *(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 (156–158). *(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)*

4. Procedural Considerations: Recommendations

4.1. Vascular Access

CLASS IIa

1. The use of radial artery access can be useful to decrease access site complications (159–167). *(Level of Evidence: A)*

4.2. PCI in Specific Clinical Situations

4.2.1. Unstable Angina/Non–ST-Elevation Myocardial Infarction

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) (168–170). *(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 (169–172). *(Level of Evidence: A)*
3. The selection of PCI or CABG as the means of revascularization in the patient with acute coronary syndrome (ACS) should generally be based on the same considerations as those without ACS (45,170,173,174). *(Level of Evidence: B)*

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.

4.2.2. ST-Elevation Myocardial Infarction

Table 5 contains indications for coronary angiography in STEMI.

4.2.2.1. CORONARY ANGIOGRAPHY STRATEGIES IN STEMI

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 (155,175–178). *(Level of Evidence: A)*

b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization (179,180). *(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 (181,182). *(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 (183–187). *(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)*

4.2.2.2. PRIMARY PCI OF THE INFARCT ARTERY

CLASS I

1. Primary PCI should be performed in patients within 12 hours of onset of STEMI (175–178). *(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 (188,189). *(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 (190–192). *(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 (179,180). *(Level of Evidence: B)*
5. Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with ischemic symptoms for less than 12 hours (193,194). *(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 (195–197). *(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 (198–202). *(Level of Evidence: B)*

4.2.2.3. DELAYED OR ELECTIVE PCI IN PATIENTS WITH STEMI

CLASS IIa

1. PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion (181,182). *(Level of Evidence: B)*
2. PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy (186,187). *(Level of Evidence: B)*
3. PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing (203,204). *(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 (205–209). *(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 (210–212). *(Level of Evidence: B)*

Table 6 contains indications for PCI in STEMI.

4.2.3. Cardiogenic Shock

CLASS I

1. PCI is recommended for patients with acute myocardial infarction who develop cardiogenic shock and are suitable candidates (180,213–215). *(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 (180,216–219). *(Level of Evidence: B)*

4.2.4. Revascularization Before Noncardiac Surgery

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 (220–226). *(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 (222,227). *(Level of Evidence: C)*

CLASS III: HARM

1. Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery (228,229). *(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 (107,225,230,231). *(Level of Evidence: B)*

Table 6. Indications for PCI in STEMI

Indications	COR	LOE	References
Primary PCI*			
STEMI symptoms within 12 h	I	A	(175–178)
Severe heart failure or cardiogenic shock	I	B	(179,180)
Contraindications to fibrinolytic therapy with ischemic symptoms <12 h	I	B	(193,194)
Clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 h after symptom onset	IIa	B	(195–197)
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	(198–202)
Delayed or elective PCI in patients with STEMI			
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	IIa	B	(181,182)
Patent infarct artery 3 to 24 h after fibrinolytic therapy	IIa	B	(186,187)
Ischemia on noninvasive testing	IIa	B	(203,204)
Hemodynamically significant stenosis in a patent infarct artery >24 h after STEMI	IIb	B	(205–209)
Totally occluded infarct artery >24 h after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	B	(210–212)

*Systems goal of performing primary PCI within 90 min of first medical contact when the patient presents to a hospital with PCI capability (188,189) (*Class I; LOE: B*) and within 120 min when the patient presents to a hospital without PCI capability (190–192) (*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.

4.3. Coronary Stents

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 (232). *(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 [233–237]; *Level of Evidence: C* for UA/NSTEMI [235]; *Level of Evidence: A* for STEMI [235,236,238–240]).
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 (107,241–243). *(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 (107–110). *(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 (107,241–243). *(Level of Evidence: B)*

4.4. Adjunctive Diagnostic Devices

4.4.1. Fractional Flow Reserve

CLASS IIa

1. Fractional flow reserve 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 (89,244–247). *(Level of Evidence: A)*

4.4.2. Intravascular Ultrasound

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (248–250). *(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 (251–253). *(Level of Evidence: B)*
3. IVUS is reasonable to determine the mechanism of stent restenosis (254). *(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) (248,255,256). *(Level of Evidence: B)*
2. IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting (249,254,257). *(Level of Evidence: B)*
3. IVUS may be reasonable to determine the mechanism of stent thrombosis (254). *(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)*

4.5. Adjunctive Therapeutic Devices

4.5.1. Coronary Atherectomy

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 (258,259). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis (260–263). *(Level of Evidence: A)*

4.5.2. Thrombectomy

CLASS IIa

1. Aspiration thrombectomy is reasonable for patients undergoing primary PCI (264–266). *(Level of Evidence: B)*

4.5.3. Laser Angioplasty

CLASS IIb

1. Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (267). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Laser angioplasty should not be used routinely during PCI (260,262,268). *(Level of Evidence: A)*

4.5.4. Cutting Balloon Angioplasty

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 (269). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Cutting balloon angioplasty should not be performed routinely during PCI (260,269,270). *(Level of Evidence: A)*

4.5.5. Embolic Protection Devices

CLASS I

1. Embolic protection devices should be used during saphenous vein graft PCI when technically feasible (271–274). *(Level of Evidence: B)*

4.6. Percutaneous Hemodynamic Support Devices

Table 7 contains recommendations for antiplatelet and antithrombin pharmacotherapy at the time of PCI.

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)*

4.6.1. Oral Antiplatelet Therapy

CLASS I

1. Patients already taking daily aspirin therapy should take 81 mg to 325 mg before PCI (150–153). *(Level of Evidence: B)*
2. Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI (150,152,153). *(Level of Evidence: B)*
3. After PCI, use of aspirin should be continued indefinitely (275-278). *(Level of Evidence: A)*
4. A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting (279–283) *(Level of Evidence: A)*. Options include
   a. Clopidogrel 600 mg (ACS and non-ACS patients) (279–281). *(Level of Evidence: B)*
   b. Prasugrel 60 mg (ACS patients) (282). *(Level of Evidence: B)*
   c. Ticagrelor 180 mg (ACS patients) (283). *(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 (280,284). *(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 (107). *(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 (285), prasugrel 10 mg daily (282), and ticagrelor 90 mg twice daily (283). *(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 (107,232,286). *(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) (107,287). *(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 (151,288–291). *(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 (282,283). *(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 (282). *(Level of Evidence: B)*

4.6.2. Intravenous Antiplatelet Therapy

STEMI

CLASS IIa

1. In patients undergoing primary PCI treated with unfractionated heparin (UFH), it is reasonable to administer a glycoprotein (GP) IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not patients were pretreated with clopidogrel (292–298). *(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 (297,299–312). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. 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 (313–320). *(Level of Evidence: B)*

UA/NSTEMI

CLASS I

1. In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) not treated with bivalirudin and not adequately pre-

Table 7. Recommendations for Antiplatelet and Antithrombin Pharmacotherapy at the Time of PCI

	COR	LOE	References	Relevant Caveats/Comments
Oral antiplatelet agents				
Aspirin	I	B	(150–153,275–278)	N/A
$P2Y_{12}$ inhibitors	I	A	(279–283)	• A loading dose of a $P2Y_{12}$ inhibitor should be given to patients undergoing PCI with stenting.
• Clopidogrel	I	B	(279–281)	• 600-mg loading dose now recommended.
• Prasugrel	I	B	(282)	• Contraindicated in patients with prior TIA/CVA: ***Class III: Harm; LOE: B.*** • Generally not recommended in patients >75 years of age (see Section 5.7.2 in full text). • Consideration of using a lower maintenance dose in persons weighing <60 kg suggested by FDA (Section 5.7.2 in full text).
• Ticagrelor	I	B	(283)	• 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	(292–298)	• 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	(321–326)	
	SIHD: IIa	B	(327–329)	
• Clopidogrel pretreatment	STEMI: IIa	C	(292–298)	
	UA/NSTEMI: IIa	B	(324,327)	
	SIHD: IIb	B	(327,330–332)	
Antithrombin agents				
UFH	I	C	N/A	• Dosing based on whether or not GPI was administered
Bivalirudin	I	B	(333–342)	• Lower bleeding rates associated with bivalirudin are mitigated when used concomitantly with a GPI.
Enoxaparin	IIb	B	(343–347)	• 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	(348,349)	• 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.

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 (321–326). *(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) (324,327). *(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) (327–329). *(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) (327,330–332). *(Level of Evidence: B)*

4.6.3. Anticoagulant Therapy

4.6.3.1. USE OF PARENTERAL ANTICOAGULANTS DURING PCI

CLASS I

1. An anticoagulant should be administered to patients undergoing PCI. *(Level of Evidence: C)*

4.6.3.2. UNFRACTIONATED HEPARIN

CLASS I

1. Administration of IV UFH is useful in patients undergoing PCI. *(Level of Evidence: C)*

4.6.3.3. ENOXAPARIN

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 subcutaneous doses (e.g., 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to 12 hours before PCI (346,350–353). *(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 (343–347). *(Level of Evidence: B)*

CLASS III: HARM

1. UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin (346,354). *(Level of Evidence: B)*

4.6.3.4. BIVALIRUDIN AND ARGATROBAN

CLASS I

1. For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH (333–342). *(Level of Evidence: B)*
2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH (355,356). *(Level of Evidence: B)*

4.6.3.5. FONDAPARINUX

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 (348,349). *(Level of Evidence: C)*

4.6.4. No-Reflow Pharmacological Therapies

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 (357–372). *(Level of Evidence: B)*

4.7. PCI in Specific Anatomic Situations

4.7.1. Chronic Total Occlusions

CLASS IIa

1. PCI of a chronic total occlusion in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise (373–377). *(Level of Evidence: B)*

4.7.2. Saphenous Vein Grafts

CLASS I

1. Embolic protection devices should be used during saphenous vein graft PCI when technically feasible (271–274). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during saphenous vein graft PCI (232,286,378,379). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI is not recommended for chronic saphenous vein graft occlusions (380–382). *(Level of Evidence: C)*

4.7.3. Bifurcation Lesions

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 (383–386). *(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 (387–390). *(Level of Evidence: B)*

4.7.4. Aorto-Ostial Stenoses

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (391,392). *(Level of Evidence: B)*
2. Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis (393,394). *(Level of Evidence: B)*

4.7.5. Calcified Lesions

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 (258,259,395). *(Level of Evidence: C)*

4.8. PCI in Specific Patient Populations

4.8.1. Chronic Kidney Disease

CLASS I

In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted (147–149). *(Level of Evidence: B)*

4.9. Periprocedural Myocardial Infarction Assessment

CLASS I

1. In patients who have signs or symptoms suggestive of myocardial infarction 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)*

4.10. Vascular Closure Devices

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 (396–399). *(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 (396–401). *(Level of Evidence: B)*

5. Postprocedural Considerations: Recommendations

Postprocedural considerations in patients undergoing PCI are discussed below and summarized in Table 8. Some recommendations and text regarding DAPT in Section 5.7.2 of the full-text guideline (4) are intentionally repeated in this section for reader ease of use.

5.1. Postprocedural Antiplatelet Therapy

CLASS I

1. After PCI, use of aspirin should be continued indefinitely (275–278). *(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 (285), prasugrel 10 mg daily (282), and ticagrelor 90 mg twice daily (283). *(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 (107,232,286). *(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) (287). *(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 (107). *(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 (151,288–291). *(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 (282,283). *(Level of Evidence: C)*

5.1.1. Proton Pump Inhibitors and Antiplatelet Therapy

CLASS I

1. Proton pump inhibitors should be used in patients with a history of prior gastrointestinal bleeding who require DAPT (402). *(Level of Evidence: C)*

CLASS IIa

1. Use of proton pump inhibitors is reasonable in patients with an increased risk of gastrointestinal bleeding (e.g., advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection) who require DAPT (402). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine use of a proton pump inhibitor is not recommended for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy (402). *(Level of Evidence: C)*

5.1.2. Clopidogrel Genetic Testing

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 (434). *(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 (434). *(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 (434). *(Level of Evidence: C)*

5.1.3. Platelet Function Testing

CLASS IIb

1. Platelet function testing may be considered in patients at high risk for poor clinical outcomes (434). *(Level of Evidence: C)*
2. In patients treated with clopidogrel with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered (434). *(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 (434). *(Level of Evidence: C)*

5.2. Restenosis

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 (435). *(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

Table 8. Postprocedural Recommendations for Patients Undergoing PCI

Recommendations		COR	LOE	References
Aspirin				
After PCI, use of aspirin should be continued indefinitely.		I	A	(275–278)
After PCI, it is reasonable to use aspirin 81 mg/d in preference to higher maintenance doses.		IIa	B	(151,288–291)
$P2Y_{12}$ 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	(282,283,285)
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	(107,232,286)
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	(287)
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	(107)
PPIs should be used in patients with a history of prior GI bleeding who require DAPT.		I	C	(402)
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	(402)
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.		IIb	C	(282,283)
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	(402)
Exercise testing				
For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.		IIa	C	N/A
Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.		III: No Benefit	C	(403)
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	(404–412)
Secondary prevention (recommendations included from the 2011 AHA/ACCF Secondary Prevention and Risk Reduction Therapy Guideline) (413)				
Lipid management with lifestyle modification and lipid-lowering pharmacotherapy	Lifestyle modification	I	B	(414,415)
	Statin therapy	I	A	(414,416–419,419a)
	Statin therapy which lowers LDL cholesterol to <100 mg/dL and achieves at least a 30% lowering of LDL cholesterol	I	C	(414–419,419a)
	Statin therapy which lowers LDL cholesterol to <70 mg/dL in very high-risk* patients	IIa	C	(416–418,419a,420–422)
Blood pressure control (with a blood pressure goal of <140/90 mm Hg)	Lifestyle modification	I	B	(423–427)
	Pharmacotherapy	I	A	(423,428,429)
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	(430–433)

*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.

is able to comply with and tolerate DAPT (436–438). *(Level of Evidence: A)*

CLASS IIa

1. IVUS is reasonable to determine the mechanism of stent restenosis (254). *(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 (254). *(Level of Evidence: C)*

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5.2.1. Exercise Testing

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 (403). *(Level of Evidence: C)*

5.2.2. Cardiac Rehabilitation

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 (404–412). *(Level of Evidence: A)*

6. Quality and Performance Considerations: Recommendations

6.1. Quality and Performance

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)*

6.2. Certification and Maintenance of Certification

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)*

6.3. Operator and Institutional Competency and Volume

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 (439,440). *(Level of Evidence: C)*
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 (439,441–444). *(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 (439). *(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. *(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 (439). *(Level of Evidence: C)*

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Key Words: ACCF/AHA Practice Guidelines ■ acute coronary syndromes ■ anticoagulants ■ antiplatelet agents ■ arrhythmias, cardiac ■ coronary angiography ■ coronary artery revascularization interventions: stents ■ drug therapy ■ heart diseases ■ myocardial revasularization ■ platelet aggregation inhibitor ■ ultrasound.

APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

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This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

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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. Section numbers apply to the full-text guideline. †Significant relationship.

APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

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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)	None	None
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Sidney C. Smith	Content Reviewer	None	None	None	None	None	None
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This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

According to the ACCF/AHA, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) The *person or a member of the person's household* has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document*.

*Significant relationship. †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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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

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*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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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).

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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

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.

Attachment C

"Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery"

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

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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.)

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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.

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-

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-

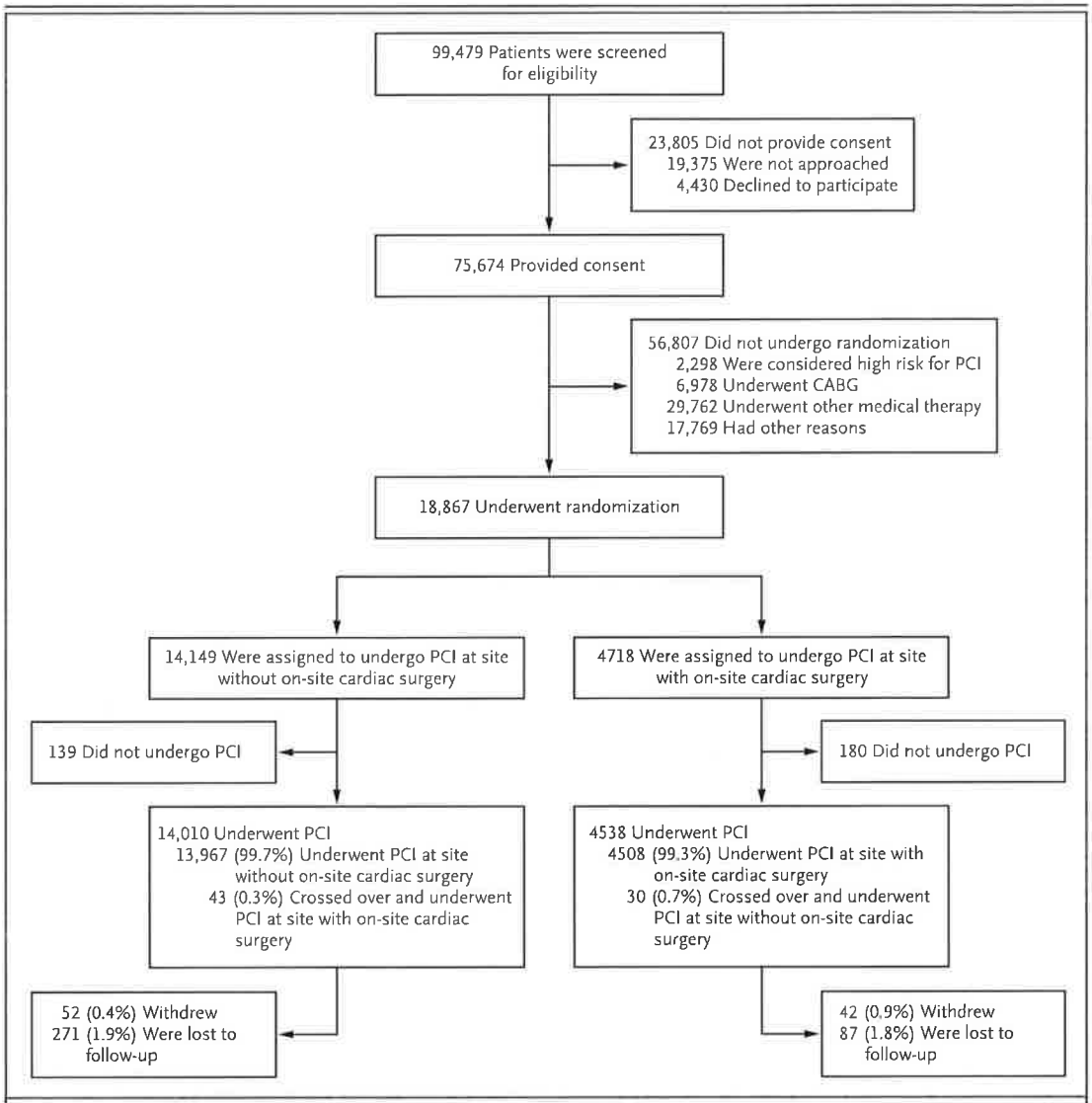

Figure 1. Enrollment and Randomization of the Study Patients.

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

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.

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-

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-

Table 4. Adverse Events.

Event	6 Wk			9 Mo		
	On-Site Cardiac Surgery (N=14,149)	No On-Site Cardiac Surgery (N=4718)	P Value	On-Site Cardiac Surgery (N=14,149)	No 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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Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Aversano T, Lemmon CC, Liu L. Outcomes of PCI at hospitals with or without on-site cardiac surgery. N Engl J Med 2012. DOI: 10.1056/NEJMoa1114540.

(PDF updated March 29, 2012.)

Contents

C-PORT PCI Development Program

The C-PORT PCI development program is usually a 3 to 4 month effort that involves many individuals at multiple levels at the participating hospital and the hospital's tertiary partner. Individuals involved include administrators, physicians, nurses, technical staff, social workers, pharmacists, and other providers. This is a detailed and detail-oriented undertaking involving multiple care areas within the institution including the emergency room, catheterization laboratory, coronary care unit and step-down unit. Overall, program development includes setting of standards, training of staff, development of local logistics, and development of a quality and error management program that provides for a high-quality program both during implementation and after completion of the clinical trial. A summary outline is presented below. Importantly, so-called "political" issues which can affect patient care are identified, addressed and resolved during program development. While applied standards are uniform and follow national guidelines, the details of program development and implementation are unique to each participating institution.

The program is implemented by creating four committees at the participating site: the Steering Committee, the Emergency Department (ED) Subcommittee, Catheterization Laboratory Subcommittee, and the Coronary Care Unit (CCU)/Step-down Unit Subcommittee. The Steering Committee is composed of physician, nursing, administrative and, when appropriate, technical representatives from each of the care areas. In addition, representatives from the local Emergency Medical System (EMS) provider (field-to-hospital and inter-hospital transport), pharmacy and social services are helpful. The purpose of the Steering Committee is to provide overall guidance and integration of the process of program development across the several care areas involved in delivering PCI

care. The care area subcommittees are composed of physician, nursing, administrative, technical staff. Participation by caregivers including nurse practitioners, case managers and floor nurses, as well as nurse educators is encouraged. The care area subcommittees are responsible for actual program implementation including the development of any required policies and procedures, care plans, order sheets, checklists, the acquisition of any new required equipment and scheduling of any required didactic, observational or hands-on training of staff.

I. Standards

Facilities: Hospitals should be performing *primary* PCI's per State guidelines, including both thrombolytic-eligible and thrombolytic-ineligible patients. While local State regulations may provide alternative minimum numbers, in no case should the number of primary PCI performed fall below 36 per year, the ACC/AHA guideline. While primary PCI patients are *not* randomized in the trial, outcomes data are placed in a parallel registry (in States where primary PCI is not already approved at hospitals without on-site cardiac surgery). In addition to conventional primary PCI patients, the registry (non-randomized) will include patients undergoing rescue PCI (PCI following failed thrombolytics) and STEMI patients with cardiogenic shock.

Hospitals should be capable of performing a minimum of 200 PCI's per year (the sum of primary and non-primary PCI). State regulations may provide alternative minimum volume numbers for specific reasons (eg. geographic isolation) or may allow a more

gradual "ramping up" during the initial phase of the trial. Failure to comply with State and C-PORT case volume guidelines may lead to termination of an institution's participation.

Care Providers - general: The employment and privileges granted to physicians and nurses at a facility certified by the State will serve as evidence of competence of physician and nursing personnel practicing in each of these environments. This ensures that community standards are applied where no national standards exist.

Care Providers - interventional cardiology: The American Heart Association/American College of Cardiology Joint Task Force guidelines for PCI serve as the basis for practitioner standards.

These standards set $\geq$ 75 angioplasty cases per year as the minimum number required to maintain clinical competence. The C-PORT trial requires that appropriately trained practitioner-investigators meet the current AHA/ACC competency criteria.

Laboratory Standards:

The guidelines and policies defined by the Society for Cardiac Angiography and Intervention guide development of laboratory standards. All centers involved will have as a minimum a diagnostic cardiac catheterization laboratory. The existence of such a catheterization laboratory and its certification by the relevant State authority will constitute evidence of adequacy as a catheterization laboratory.

All participating site cardiac catheterization laboratories must meet the following requirements:

i. documentation of *adequate training of catheterization laboratory staff*, including nurses and technicians

ii. documentation of adequate training of physician-practitioners

iii. documentation of *adequate supplies*

iv. documentation of *adequate support facilities*

v. completion of any required program development (for primary and elective PCI)

II. Training

Catheterization Laboratory Staff: Employment of staff (nurses and technicians) at a State-certified diagnostic catheterization and/or angioplasty laboratory will constitute evidence of competency to work in a diagnostic cardiac catheterization laboratory.

Hospital Staff: In hospitals in which angioplasty is *not* currently performed, the nursing and technical staff in both the catheterization laboratory and in the pre-procedure and post-procedure care units require additional training. This training is part of the primary and elective PCI development program.

Additional training includes familiarization with: angioplasty equipment (guide

catheters, guide wires and angioplasty catheters including balloons and stents, distal protection devices, closure devices); commonly used drugs, such as heparin, clopidogrel, and GpIIb/IIIa antagonists, assessment and monitoring of the state of anticoagulation; intra-aortic balloon counterpulsation equipment; patient transfer to and from the laboratory; and the multitude of issues related to pre-procedure, intra-procedure and post-procedure care. Development of care algorithms, provision of equipment and expertise for care of the patient who sustains a coronary perforation or who requires emergency cardiac surgery will be implemented and practiced.

The C-PORT trial has developed a formal training program for technical and nursing staff working at hospitals without angioplasty capability. At a minimum this training will include:

1. local didactic presentations (eg. physician/nurse lectures, vendor in-services, etc)
2. minimum of 2 days (16 hours) – *one or more weeks is encouraged* -of "one-on-one" observational training for all nurse-level caregivers in the catheterization laboratory and post-procedure care area (CCU and step-down unit) and catheterization technical staff at an affiliated tertiary facility
3. detailed development of hospital policy and procedures in the emergency room, cardiac catheterization laboratory, step-down unit and coronary care unit for patients with acute myocardial infarction treated with primary angioplasty and for elective angioplasty patients

4. detailed development of the logistics required to assure prompt, appropriate and effective application of primary angioplasty and elective angioplasty
5. detailed development of order sheets and checklists used in the care of PCI patients (pre and post procedure)
6. detailed development of a quality and error management strategy
7. minimum one "dry run" or "run-through" by study staff at the participating hospital supervised by the Study Director and Study Nurse Coordinator for primary angioplasty
8. minimum one "dry run" by study staff at the participating hospital supervised by the Study Director and Study Nurse Coordinator for coronary perforation and emergency ambulance transport
9. regularly scheduled meetings among Coordinating Center staff and representative of involved departments (including nurses, physicians and technicians) for the duration of study enrollment to discuss study progress and identify and address problem areas, changes in protocol, and new treatment strategies or methods.

These elements are supplemented with physician, nurse and vendor-supplied in-services and other continuing education programs.

In addition to defining minimum criteria for nurse and technician competency in the various care areas involved in PCI procedures, defined requirements for competency maintenance will be developed and written.

Catheterization laboratory technical staff, catheterization unit nurses, and step-down and CCU unit nurses from each participating institution that currently does not perform angioplasty must attend (1) and (2) above. Participation of all staff members from these care areas is strongly encouraged.

If a member of the nursing or technical staff is to serve as a "second operator" during the angioplasty procedure, that individual must undergo additional training. This training requires "hands-on" experience performing elective angioplasty at a tertiary center under the supervision of the local principal investigator from his or her institution or his designee. Competence to perform as second operator will be determined by the training physician. Participation in at least 25 elective angioplasty procedures at a tertiary institution before assisting in a procedure performed at the participating site is a suggested guideline.

Completion of training procedures does not constitute certification of competency by any individual, institution or the C-PORT study staff of any individuals completing that training. Training means only that certain material has been reviewed and does not attest to the competency or experience of any individual undergoing that training.

III. Logistics

Care Plan Development: An important factor in the successful development of primary and elective angioplasty capability in a hospital which does not currently perform

angioplasty involves nursing care. Familiarity with the course of the angioplasty procedure itself, the devices, including stents and drugs, including GpIIb/IIIa antagonists, utilized, anticoagulation regimens and their management, potential procedure-related complications, sheaths and intra-aortic balloon pumps, closure devices, and all the many pre-procedure, intra-procedure and post-procedure care issues is critically important to successful development of safe and effective angioplasty capability. While there is no substitute for experience, the didactic and observational training required for participation facilitates the transition to a PCI-capable facility.

Development of pre-procedure, intra-procedure and post-procedure nursing care plans and pathways is also important to successful management of the angioplasty patient. Care plans and pathways and staff training (including definition of competency requirements and competency maintenance) must be in place before angioplasty begins. Sample plans and critical pathways are reviewed at staff training sessions and are available from the C-PORT trial staff.

C-PORT study personnel assist participating hospital technical and nursing personnel develop detailed care plans and pathways for angioplasty patients. Model care plans and pathways are provided by the Clinical Coordinating Center and modified by the participating hospital staff as appropriate for their facility. This is done through direct contact supplemented by email, telephone and fax communication over a several week (typically 12-14 week) period. Formal and informal discussions and meetings between study personnel (particularly the nurse coordinator) occur during this period concerning

pre-angioplasty, intra-procedure and post-procedure care, sheath pulling, monitoring, and complications, as care plans and procedures are developed at the participating institution. Subsequently, at least weekly contact is continued to answer the many questions and address the many issues that require resolution during initiation of a new clinical program and commencement of a clinical trial.

Logistics Development for Primary PCI: For hospitals not currently performing primary PCI, that program must be established prior to beginning the non-primary PCI randomized trial. This requires development of detailed, local logistics. The logistical goal is for all patients to have primary angioplasty within 90 minutes of Emergency Room arrival. The specific issues that must be addressed to assure the prompt, appropriate and effective application of primary angioplasty in the treatment of AMI is the goal of logistics development. The specific plans required in each participating institution are specific to that institution, although the goal remains the same. Logistical issues that need to be addressed include: hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after the primary angioplasty, plans for failed angioplasty, fall-back plans for primary angioplasty system failure, and many additional issues. Specific "political" issues that can affect patient care must be identified, addressed and resolved prior to implementing the PCI program. These are all addressed during the primary angioplasty development program.

Logistics Development for Elective PCI: All logistical issues addressed for primary PCI must be addressed for non-primary PCI, as well. A critical aspect of elective PCI development at hospitals without on-site cardiac surgery is creation of detailed algorithm for management of coronary perforation and for emergency transfer of patient who require care at a tertiary facility for any reason. Algorithms for management of both coronary perforation and emergency transfer are created and practiced during the PCI development program. Continued practice during the course of the clinical trial is mandatory, involves the entire catheterization laboratory staff and takes place at least every 6 months.

On-going training: After trial start-up, on-going supplementation of initial training with frequent face-to-face meetings and telephone contact with nursing and physician study personnel continues. Experience to date suggests that at study initiation frequent telephone contact is required; after several weeks, contact is less frequent but is maintained as needed by telephone and/or email. Regular meetings between study personnel from the Coordinating Center and the participating facility to discuss identified problem areas, to resolve such problems, to provide on-going feedback regarding study progress and quality of care, and to provide on-going training in new techniques, drugs or procedures related to the treatment of PCI patients are important and occur at least every 6 months during the trial.

IV. Quality and Error Management

Quality and Error Management: An important aspect of the C-PORT primary and

elective angioplasty program development alluded to above is quality and error management. Outcomes data are available to participating sites through the Sextant data management system, which is provided by the Clinical Coordinating Center. Review of outcomes on a regular basis is important to identify problem areas. Plans for addressing problem areas will be developed in collaboration with the Clinical Coordinating Center and plans for short and long-term monitoring to assess remedial efforts are made. Special emphasis is given to minimizing, discovering, reporting and correcting error in the system of PCI care developed at participating institutions.

Outcomes data are also available to State regulatory authorities for their State's participating institutions through the Sextant data management system.

Two important elements of quality and error management include creating a mechanism for local peer-review and on-going, regularly scheduled multiple care-area meetings.

Local peer-review (catheterization/intervention or "M&M" conferences) may be difficult to develop because of a small number of staff. An alternative to local peer-review is review of cases at the affiliated tertiary hospital's interventional case review meetings on a regular basis. Weekly peer-review (e.g. cath/intervention conference) is required at participating institutions. Attendance of at least 60% of such meetings by catheterization laboratory personnel (including physicians, nurses and technicians) is required for participation in the study.

It is important for physician, nursing and administrative representatives from the care areas involved in the primary and elective angioplasty systems (emergency room, catheterization laboratory, coronary care unit and step-down unit) to meet on a regular (eg. monthly) basis to improve procedures, identify problem areas and develop solutions, and to plan for continuing medical education for all groups. EMS and the affiliated tertiary hospital are important partners in this effort. Representatives from both of these groups should be encouraged to attend participating site care area meetings.

Tertiary Partner: As noted above, the functions of the tertiary partner includes accepting emergent transfers from the participating site, serving as a training center for participating site staff, serving as an on-going resource for participating site staff, and providing model care plans, pathways and order sets for the participating site. Participating sites may, however, transfer patients for emergent or elective care to any hospital the physician or patient requests or the patient's insurance requires.

The Heart Team approach to considering revascularization strategy based on objective risk / benefit assessment through collaborative review of particularly high risk (unprotected left main or complex coronary anatomy) cases with interventionalist, clinical cardiologist and cardiac surgeon participation has recently been promoted by the ACCF/ACC/SCAI guidelines (2). Use of objective risk scoring systems such as SYNTAX is similarly promoted. Current technology, particularly web-based technologies, allow for real-time or near real-time remote review of cineangiograms. In addition, risk assessment systems such as SYNTAX are available on the web, as well. The role of the tertiary hospital should be expanded to include use of these resources to implement the Heart Team

approach at partner hospitals without on-site cardiac surgery.

Study Definitions

Except as noted, definitions of data elements followed the American College of Cardiology National Cardiovascular Data Registry Cardiac Catheterization Module v3.02 Data Definitions (3)

Bleeding was defined as any blood transfusion regardless of cause, other than required for cardiac surgery. Vascular surgery or vascular repair included thrombin injection and ultrasound guided compression of pseudoaneurysms, as well as direct surgical repair of an access site.

Target vessel revascularization was defined as any revascularization intervention (whether PCI or CABG) occurring in any part of a study-treated any time after the index intervention whether within the same segment or not. In patients who received no index PCI, any revascularization performed after randomization was considered a TVR.

A PCI was considered "staged" if completing all index PCIs required more than the initial diagnostic catheterization laboratory visit. A successful *lesion PCI* was defined as a PCI following which the target vessel residual coronary stenosis was 20% or less and there was TIMI 3 flow. Depending on whether all, some or none of the lesions were treated successfully during the index PCI procedure, *PCI patient* level outcome was defined as *complete success, partial success or failure.*

Figures

Figure S1

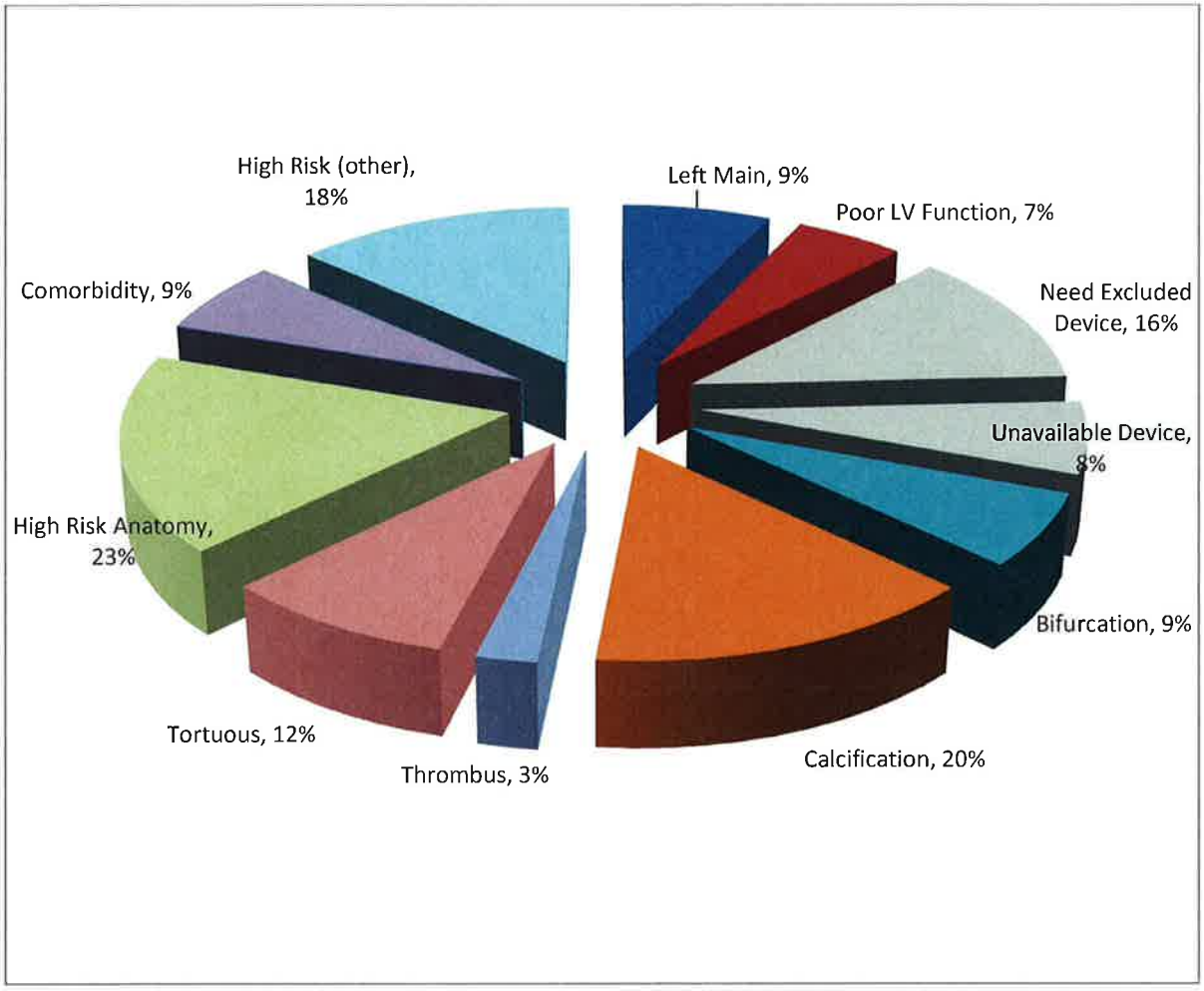

Figure S1: Reasons Registry Patients Considered High Risk for PCI. LV= left ventricular. Figures are percent of the 2298 consented patients who were not randomized.

Tables

Table S1. Inclusion and Exclusion Criteria

Inclusions	Exclusions
Patient	**Patient**
Pre-catheterization	***Pre-catheterization***
Able to give informed consent	Unable to give informed consent
Age > 18 years	ST-segment elevation myocardial infarction
Negative pregnancy test or not of childbearing potential	pregnancy
Post-catheterization	***Post-catheterization***
Significant CAD (≥ 50% stenosis) requiring PCI	No need for PCI or need for CABG
All required PCI can be performed with devices available at no-SOS hospital (***Device*** below)	Any PCI requires device unavailable at no-SOS hospital (***Device*** below)
procedure judged to be not high risk*	High risk procedure*
Device	**Device**
Balloons, stents	Directional atherectomy
Thrombectomy devices	Rotational atherectomy
Cutting balloons for instent restenosis	Cutting balloons for *de novo* lesions
Distal protection devices	
Institutional	
Capability to perform ≥ 200 PCIs annually (elective + primary)	
Complete formal PCI development program	
Adhere to CPORT patient and device inclusion, exclusion requirements and data requirements	
Formal agreement with tertiary partner for training and acceptance of emergency transfers	
Formal agreement with emergency transport service (arrival time ≤ 30 min from call)	
24/7 primary PCI program	
Inteventionalist	
Meets AHA/ACC competency criteria (1)	
Coronary perforation management plan – covered stent and coils	

* *High procedural risk* criteria are
1. PCI of unprotected left main coronary artery
2. poor left ventricular function (EF≤ 20%) *and* need to perform PCI in a vessel supplying significant myocardium
3. interventionalist assessment of high risk

Table S1 Abbreviations: PCI=percutaneous coronary intervention; CABG = coronary artery bypass surgery; CPORT=Cardiovascular Patient Outcomes Research Team; AHA=American Heart Association: ACC=American College of Cardiology

Table S2 - Comparative Baseline Characteristics

Characteristics	Randomized N=18867 n(%)	Consented But Not Randomized N= 56807 n(%)	Not Consented Not Randomized N= 23805 n(%)
Demographics			
Age (years) (mean±SD)	64.0±12.0	62.2 ± 13.0	*
Male	12016 (63.9)	29738 (52.5)	12373(53.2)
Caucasian	14963 (79.3)	43508 (76.8)	16382 (68.8)
Medical History			
Hypertension	15974 (84.7)	43930 (77.6)	18786 (78.9)
Hypercholesterolemia	15432 (81.8)	37737 (66.7)	15142 (63.6)
Smoking (Current & Former)	11683 (61.9)	33252 (58.7)	12962 (54.4)
Diabetes	10353 (38.9)	19456 (34.4)	8855 (37.2)
Family History of CAD	7730 (54.9)	30302 (53.5)	10363 (43.5)
Heart Failure	2049 (10.9)	7316 (12.9)	5095 (21.4)
Prior MI	8041 (42.6)	7318 (12.9)	5367 (22.5)
Prior PCI	5936 (31.5)	10283 (18.2)	4865 (20.4)
Prior CABG	2484 (13.2)	5982 (10.6)	2794 (11.7)
Prior Stroke or PVD	3315 (17.6)	7651 (13.5)	4281 (18.0)
Laboratory and physical exam			
Creatinine (mg/dL) (median(IQR))	1.0 (0.8-1.2)	1.0 (0.8-1.2)	1.0 (0.8-1.3)
Baseline angiography			
One Vessel CAD	6742 (35.7)	8185 (14.5)	4465 (18.8)
Two Vessel CAD	6828 (36.2)	5551 (9.8)	3087 (13.0)
Three Vessel CAD	5285 (28.0)	9349 (16.5)	4184 (17.6)
Left Main Disease	643 (3.4)	2415 (4.3)	912 (3.8)
LV function (EF %)	54.2 +/- 10.6	54.0 +/- 13.7	51.3+/- 27.2

*=age cannot be included in this limited data set of patients who do not sign informed consent

Table S3 – Reasons for No Index PCI

	Without SOS N (%)	With SOS N (%)
CABG	24 (18)	34 (19)
Medical therapy	21 (16)	32 (18)
Lesion resolution	45 (34)	43 (24)
No reason	8 (6)	18 (1)
Withdrew	18 (13)	21 (12)
Other	17 (13)	26 (14)
Death	4 (3)	2 (1)
Complication	2 (1)	4 (2)

Table S3 Abbreviations: CABG = coronary artery bypass surgery; SOS = surgery on-site
Percentages are percent of total subjects in each group who did not receive index PCI after randomization.

Table S4 - Comparison of CPORT E and NCDR Patient Characteristics

	CPORT E		NCDR	
	Without SOS	**With SOS**	**Without SOS**	**With SOS**
Age (years) (mean+/-SD)	64+/-12	64+/-12	64.2	64 ± 12
Male Gender (%)	64.0	63.2	65	66
Hypertension (%)	84.6	85.3	76	77
Hypercholesterolemia (%)	82.2	82.2	71	76
Diabetes (%)	39.0	39.7	32	33
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

Abbreviations for Table S4: SD=standard deviation; MI=myocardial infarction; CABG=coronary artery bypass surgery; PCI = percutaneous coronary intervention; SOS=surgery on-site;

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Attachment D

Other Relevant Articles, Studies, or Reports

REVIEW

Percutaneous Coronary Intervention at Centers With and Without On-site Surgery
A Meta-analysis

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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.[1,8-12]

This unresolved clinical issue has implications for the delivery of clinical care

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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

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

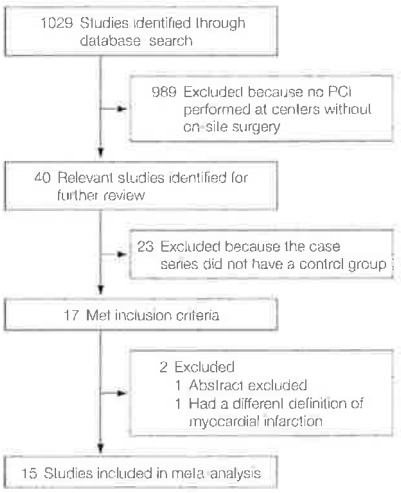
Primary PCI. The pooled OR for in-hospital mortality in patients undergoing primary PCI was derived from 124 074 patients. The average mortality rate across studies was 4.6% (range, 2.1%-11.3%) for sites without on-site surgery and 5.1% (range, 1.0%-12.2%) for sites with on-site surgery. Pooling all 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

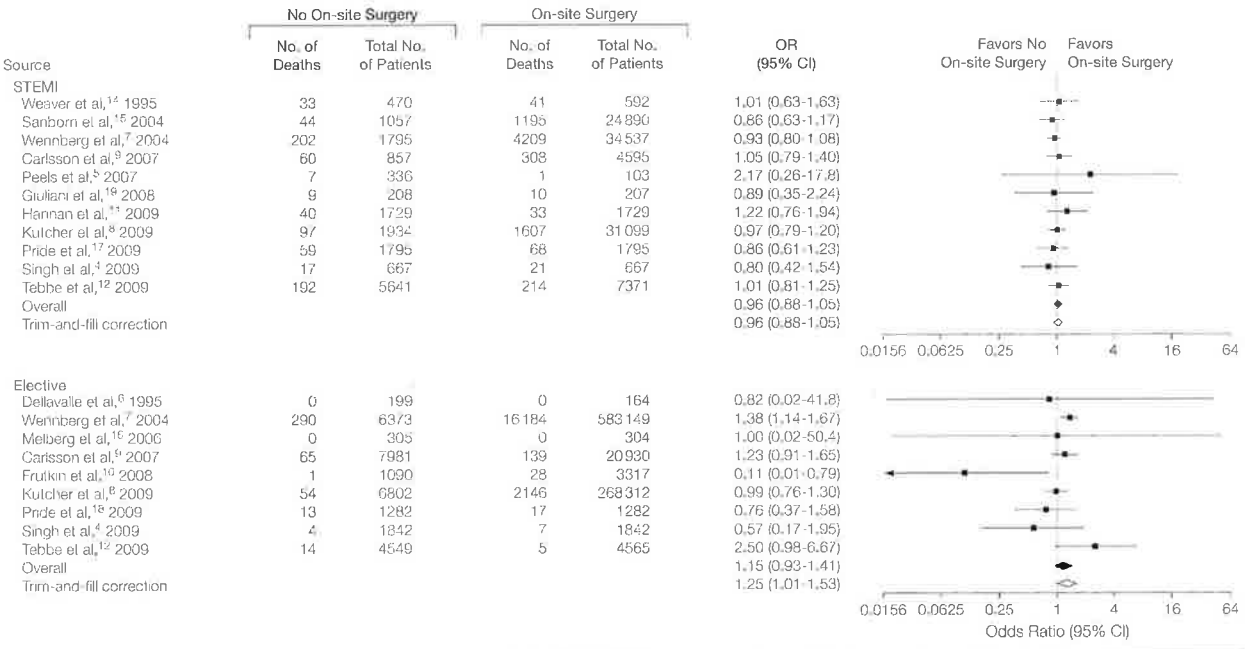
for emergency CABG surgery after primary PCI for STEMI were similar at centers with and without on-site surgical backup. The narrow funnel plot and consistent individual and combined effect estimates for mortality support the safety of performing primary PCI at these centers. No significant publication 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, Without On-site Surgery	No. of Patients: STEMI, With On-site Surgery	No. of Patients: Elective or Non-STEMI, Without On-site Surgery	No. of Patients: Elective or Non-STEMI, 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



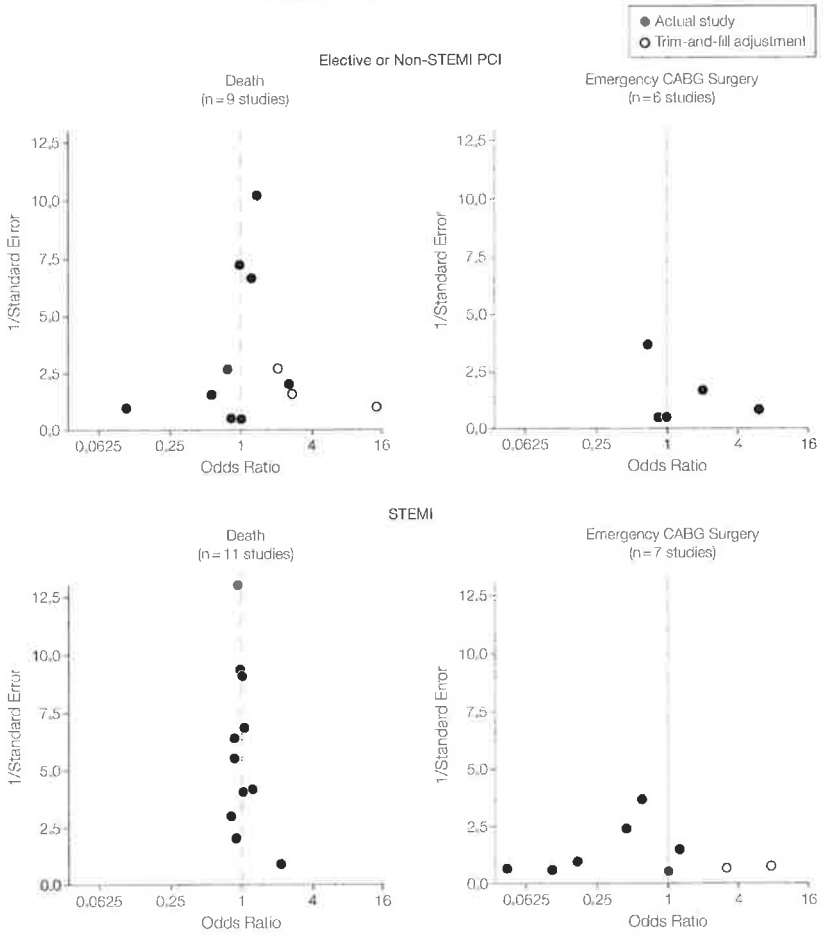
Odds ratio (OR) estimates with 95% CIs of all studies for the outcomes of death by indication for percutaneous coronary intervention. In the case of 0 counts, ORs were calculated by adding 0.5 to all cell counts from the study to avoid division by 0. STEMI indicates ST-elevation myocardial infarction.

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



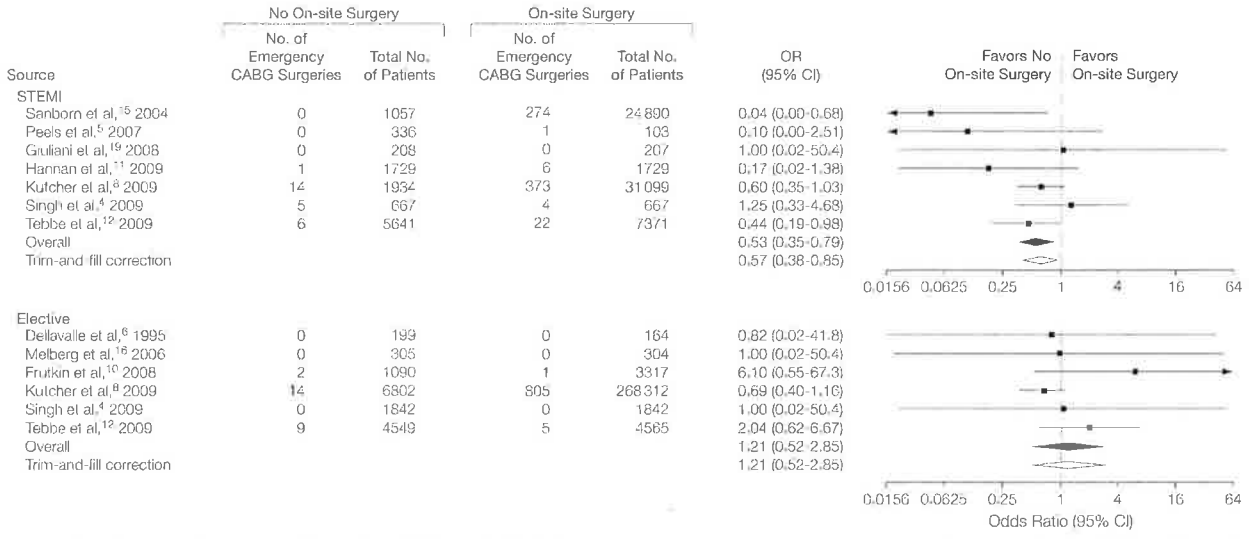
Studies comparing in-hospital mortality and emergency coronary artery bypass grafting (CABG) surgery after nonprimary (elective for patients without ST elevation myocardial infarction [STEMI]) and primary (patients with STEMI) percutaneous coronary intervention. Trim-and–based estimates of unpublished studies are also shown.

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.

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.[1] 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

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

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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

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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.

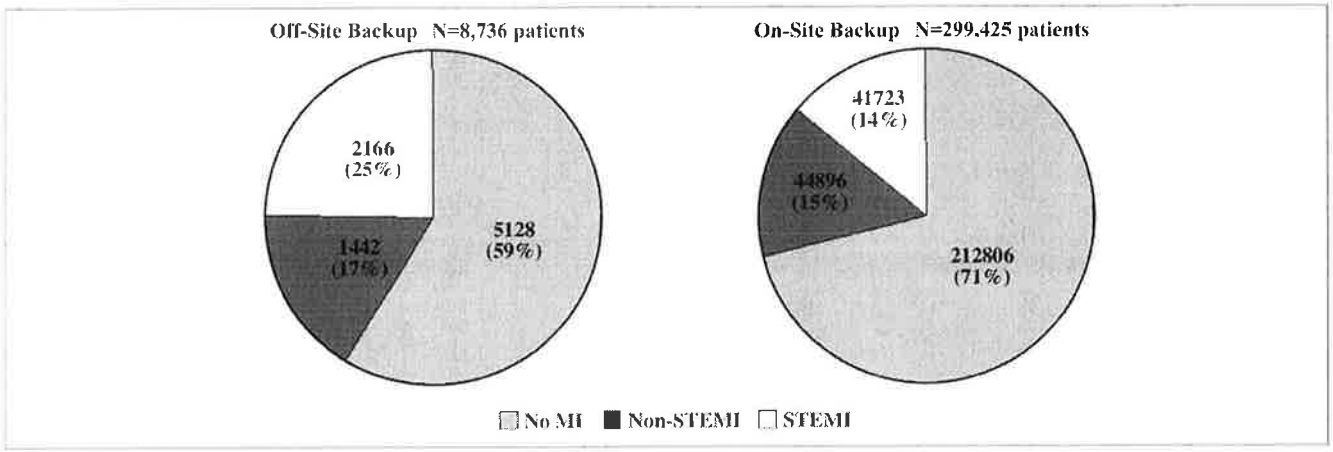
Table 3 Off-Site Capabilities Survey

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.

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).

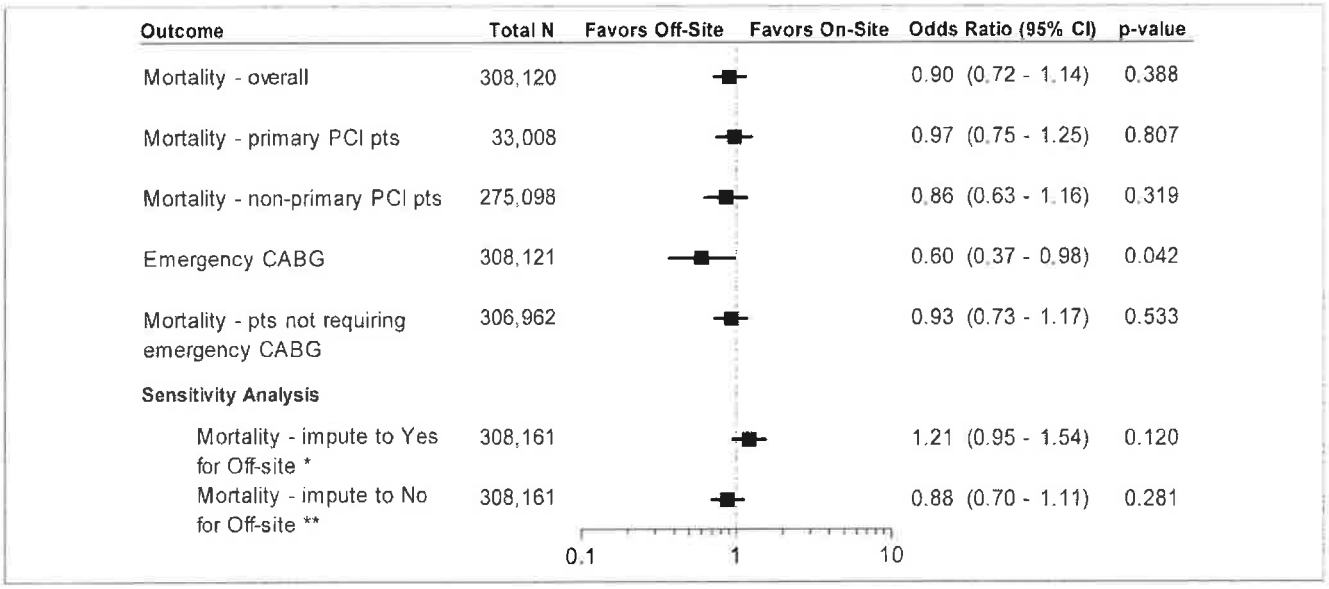
There have been concerns that off-site PCI facilities may tend to keep some borderline stable patients with suboptimal procedural results rather than initiate the logistics of emergency transfer to an outside surgical center. These patients may have adverse outcomes, as seems to be suggested by the aggregate 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).

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

APPENDIX

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

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EXPERT CONSENSUS DOCUMENT

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

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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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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

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

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

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

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.

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

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 $\times$ 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

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-

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

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.

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.

Table 1. Complication Rates for PCI Reported From the ACC-NCDR Database

	Percutaneous Coronary Intervention			
	ACS		Non-ACS	
Variable	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.

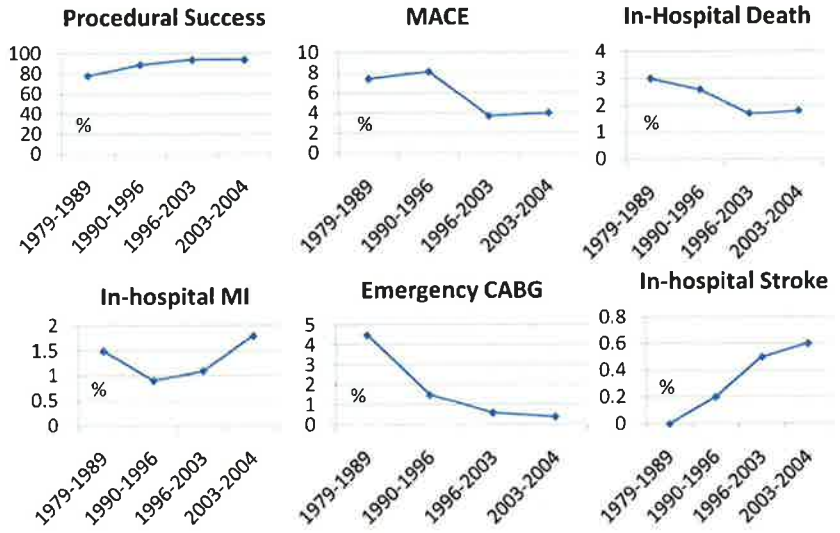

Figure 1. Trends in In-Hospital Outcomes Following PCI: The Mayo Clinic Experience

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

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.

2.4.1. Patients Acceptable for Diagnostic Cardiac Catheterization at a Facility Without Cardiovascular Surgical Capability

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.

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

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.

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.

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

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.

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.

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

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.

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.

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 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-

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

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

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

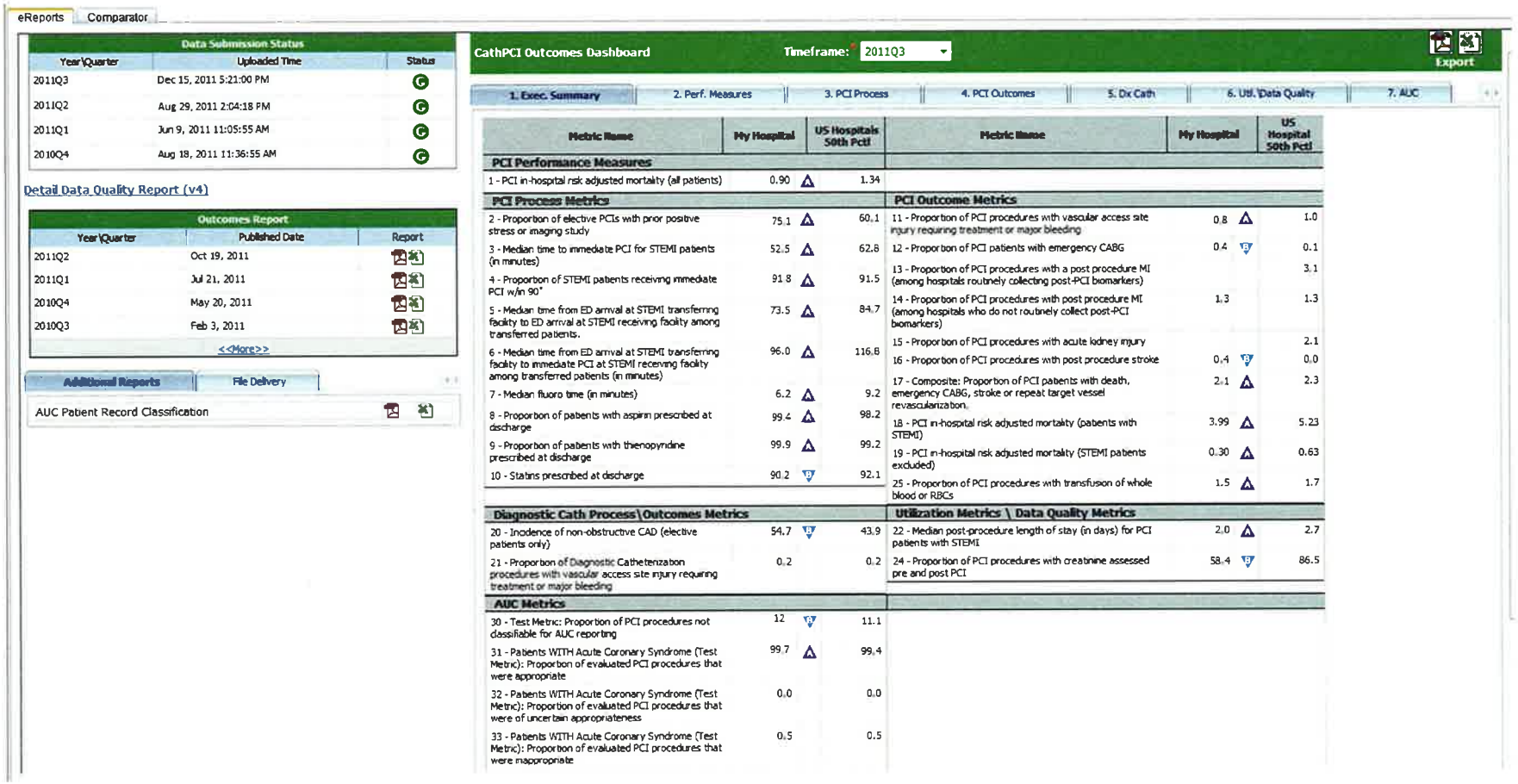

Figure 2. Example of the NCDR CathPCI Executive Summary Quality Dashboard

NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention.

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 $\times$ 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

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.

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

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-

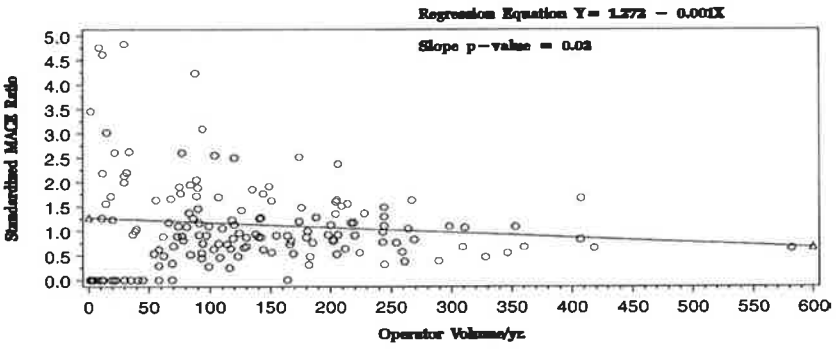

Figure 3. Linear Plot of Standardized MACE Ratios (Observed/Predicted Rates) Versus Annual Operator Volume

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).

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-

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-

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).

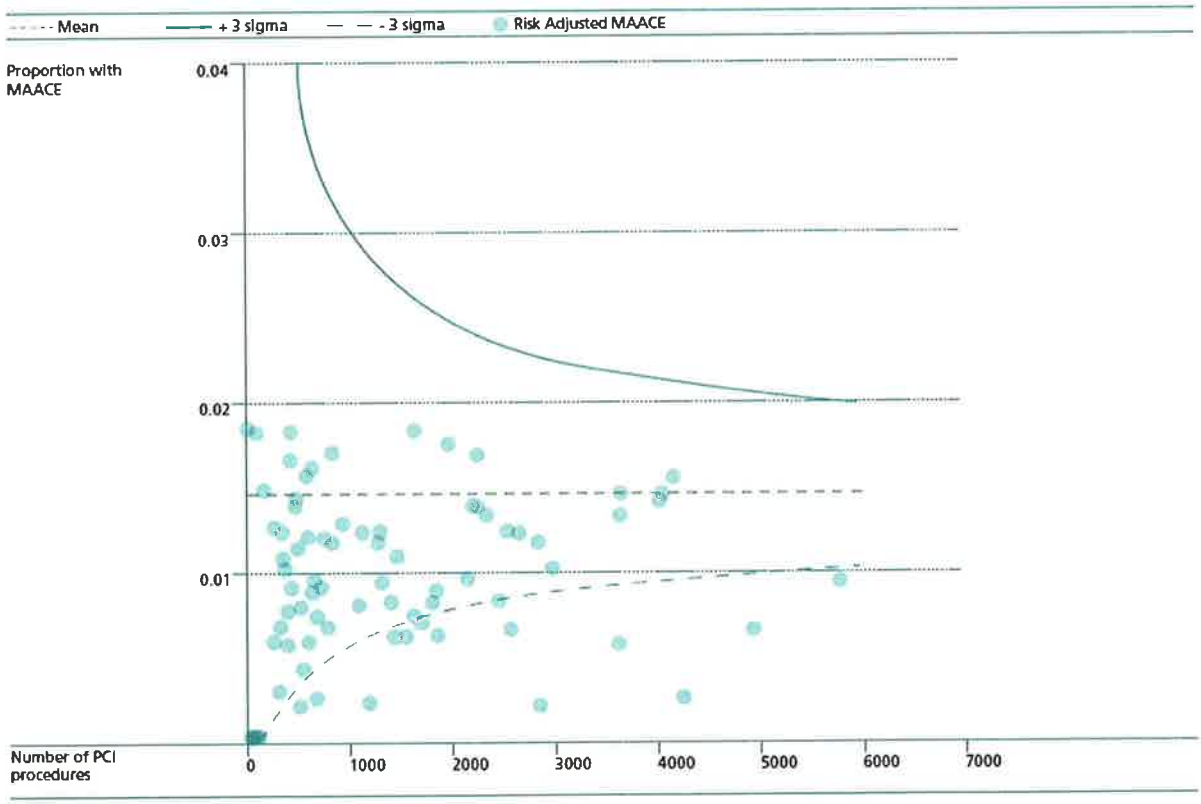

Figure 4. Relationship Between MACCE and Institutional Volume

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.

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.

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.

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-

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 m^2)
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

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 m^2
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

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

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-

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-

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

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

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

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-

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.

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

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-

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

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.

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-

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

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

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.

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).

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.

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-

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

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.

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	Translent 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.

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

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,

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

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.

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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
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*Recused from writing initial text and voting on document recommendations due to relevant relationships with industry to this document. †Significant relationship.

APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHERS ENTITIES (RELEVANT)—2012 ACCF/SCAI 2012 CLINICAL EXPERT CONSENSUS DOCUMENT ON CARDIAC CATHETERIZATION LABORATORY STANDARDS UPDATE

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

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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. Fera	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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Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Spencer B. King	Content Reviewer—ACCF Interventional Scientific Council	• Celonova Biosciences Inc.	None	None	None	None	None
Lloyd W. Klein	Content Reviewer—SCAI Quality Improvement Committee	None	None	None	None	None	None
Shrihari Naidu	Organizational Reviewer—SCAI	• Abbott Vascular • Abiomed*	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	• Paieon			• 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

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Steven J. Yakubov	Organizational Reviewer—SCAI	None	None	None	None	None	• Defendant, adequacy and decision process of a PCI, 2010 • Defendant, stress testing evaluation, 2010

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*Significant relationship.

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

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

Survey says: Most cardiologists support elective PCI sans on-site CABG . . . with caveats

DECEMBER 13, 2011 Steve Stiles

New York, NY and Washington DC - If resistance isn't futile, perhaps it's slipping?

In a survey conducted jointly this month by **theheart.org** and *US News & World Report*, two-thirds of respondents say that elective angioplasty at centers without cardiothoracic surgery on-site (SOS) can be done safely and effectively.

Of note, however, respondents were split as to who should decide what hospitals should have PCI capability, although almost all felt that outcomes monitoring and public reporting should be mandated for all sites performing elective procedures.

The nearly one-third of respondents who gave elective PCI without on-site surgery a thumbs down did so in spite of the survey's stipulations that such programs be "properly developed," adhere to strict patient-selection criteria, and have an annual volume of ≥200 cases; that they include only "**AHA/ACC**-qualified" operators; and that outcomes be monitored.

"It's all about the money. Period. Greed is king. Period," wrote one responder anonymously. Another, reflecting the tone taken by quite a few of the survey's minority respondents, provided a fairly dry take on it: "Ask any cardiologist where they would prefer their PCI to be performed."

But others, in support of elective PCI without on-site surgery pointed out that this had been done "**for a very long time**," as one respondent put it. "The whole subject is utterly superfluous and unnecessary to even discuss!"

A "no-brainer"?

The survey results may reflect some thawing in the US cardiology establishment's take on the practice also reflected in **new guidelines on coronary revascularization unveiled last month** [1]. Previously relegated to class 3 ("not useful/effective and may be harmful"), the practice was upgraded to class 2b ("may be considered"). Primary PCI at such centers, a different question, was upgraded to class 2a ("is reasonable to perform").

Remaining in class 3 (useless or harmful) was *any* kind of non-SOS PCI in the absence of "a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer"—a condition some rural centers can't meet.

Perhaps, as well, many respondents had recently seen results of the **Cardiovascular Patient Outcomes Research Team Elective** (C-PORT E) study, reported at the **AHA 2011 Scientific Sessions** and covered by **heartwire**. With >18 500 patients undergoing elective PCI randomized at centers with or without SOS, the trial saw no significant mortality (<1% in both groups) or safety differences at six weeks. Emergency bypass surgery was needed in 0.2% of cases at centers with SOS and 0.1% of non-SOS centers.

Surgical backup is rarely needed and has not been a requirement in Europe for years.

"C-PORT E is likely to establish a new standard of care for PCI in the US. Surgical backup is rarely needed and has not been a requirement in Europe for years," wrote **Dr Henry Altszuler** (Robert Wood Johnson Medical School, New Brunswick, NJ) in response to the survey. "As a participant in the trial, I can attest to the benefits. . . . With intelligent case selection and experienced staff and physicians, [non-SOS elective PCI] is a seamless process and a 'win-win' for patients and hospitals."

"This is a no-brainer," wrote **Dr Martin Albornoz** (MidAtlantic Cardiovascular Associates, Baltimore MD). "PCI can be safely performed at hospitals without SOS. Case selection, physician experience, and careful oversight are key."

Nearly all responders who commented favorably on the practice had caveats, which were generally consistent with those in the new guidelines.

Topping the list was the need for high-level operator experience and skill: "I have been doing PCI without surgical backup since 2003. I also perform PCI at a site with surgery on-site," wrote **Dr Jean-Pierre Geagea** (Tufts University, Boston, MA). "For a successful program, physicians need to know their limitations. This is the golden rule. Rule #2, the program needs to know that complications will happen, so they need to get familiar with how to deal with them (pressing the panic button will not help the program). A well-experienced interventionalist should be available 24/7 to lead every new program."

"PCI without surgical backup can be safe if cases are chosen 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," wrote **Dr Mark Friedman** (University of Arizona Medical Center, Tucson).

Surgery at every PCI site degrades the volume of surgery to the point that it cannot be done with a high degree of competence.

Dr Timothy A Sanborn (North Shore University Health System, Evanston, IL) agreed: "If there is a multihospital healthcare system with a good plan for transfer to a hospital with cardiothoracic surgery, then selected cases of elective PCI should be allowed, provided there is participation in a national database such as the ACC [National Cardiovascular Data Registry] NCDR."

Others were concerned that an insistence on SOS would spread surgeons and their experience too thinly. "The safety of PCI in today's setting is very good. The surgical volume necessary to maintain reasonable team competence is such that surgery at every PCI site degrades the volume of surgery to the point that it cannot be done with a high degree of competence, particularly in the situation of an emergent patient coming out of the cath lab," according to **Dr John C Alexander** (North Shore University Health System, Evanston, IL).

Dr Kim Eagle (University of Michigan, Ann Arbor), responding to the survey, observed: "Volumes fall due to success of medical and preventive therapy; hospitals and cardiologists are desperate to do as many PCIs as possible. I believe that much of this is fueled by greed, not need. The geographic-access argument does not fly for the majority of those seeking to do this. Also, indication drift leading to 'discretionary' procedures is a real issue if and when this is opened up. By making PCI available at every hospital in the nation, we will not only drive up costs, we will reduce quality due to exposing patients to unnecessary risky procedures."

"The greatest factor that increased the number of surgical programs has been compliance with state regulations so that PCI can be done. These small surgical programs are expensive and fragment surgery in our communities," wrote **Dr W Douglas Weaver** (Henry Ford Hospital, Detroit, MI).

Family matters

More than a few skeptics of the strategy expressed their objections by making it personal. Most did this anonymously, including those who wrote, "If I ever needed a coronary intervention, I would choose a hospital with surgical backup available" and "Would you let your family have PCI without standby?"

But **Dr George Broderick** (Good Samaritan Hospital, Dayton, OH) owned what he wrote: "Ask the interventional cardiologists doing these procedures at hospitals without surgical backup to remember their last patient who had to go to emergency surgery after an unexpected complication, and then would they do that to their parents? We all have had these experiences, and the limited randomized trial that suggests this is not an issue is backing this activity up. Very spooky."

Would you let your family have PCI without standby?

According to **Dr Scott Woodfield** (Lowcountry Cardiology Associates, North Charleston, SC), "PCI needs to be more limited. Fewer facilities with more experience mean better outcomes."

Which hospitals? What outcomes? Whose oversight?

Other survey questions probed the issues of who should be performing elective PCIs in the absence of surgical backup, how their results should be tracked, and by whom.

In all, **36.6**% of survey respondents said that professional groups like the ACC and AHA should decide which hospitals have elective PCI capability, **29.7**% said that state and/or local regulators should be in charge of that decision, **27.4**% said that job should fall to local physicians and hospitals; only **6.3**% believed federal regulators should have final say.

A full **97.7**% of respondents supported outcomes monitoring and public reporting, and of those, the majority (**46.3**%) said professional groups like the ACC and AHA should be responsible. Roughly **24%** felt state policymakers should provide this oversight, with local physician input, while **18.3**% said it should happen at a national level, with the help of the professional societies. Just **11.7**% felt "individual hospitals" should oversee their own outcomes and reporting.

There were additional nuances provided in the comments section.

Dr James de Lemos (University of Texas Southwestern Medical Center, Dallas) said, "I support reporting of outcomes to regulators but not yet to the public."

Also, **Dr Ralph Brindis** (Oakland Kaiser Medical Center, CA) observed, "Ideally these stand-alone programs would be created due to local patient care needs rather than a financial driver per se. Close evaluation of outcomes and quality through participation and transparency of results from the NCDR registry is essential for quality oversight."

Of the non-SOS skeptics as well, **59.7**% believed that at the non-SOS centers, referrals for inappropriate PCI "to keep institutional volume up" will increase. "A bad idea" that will "increase the number of nonindicated procedures," concurred **Dr Jacob Shani** (Heart Institute at Maimonides Medical Center, Brooklyn, NY). "Those hospitals rarely use [fractional flow reserve] FFR for confirmation of lesion severity. All the high-risk patients are referred out, creating an unfair burden on other institutions. . . . The only reason results are 'good' is patient selection, including angioplasty of vessels and lesions that should be treated medically." And at centers without SOS, he wrote, "operators don't have the same skill level as in the surgery-backed institutions."

Indeed, almost as popular a reason not to consider non-SOS elective PCI safe and effective, selected by **57.1**% of respondents, was that the centers with cardiothoracic surgery "tend to attract the most highly qualified cardiologists."

"Judgment, the appropriate case mix, equipment, surgical decisions, and long-term outcomes all are derived from a combination of skill and experience," writes **Dr Michael Kelberman** (Mohawk Valley Heart Institute, Utica, NY) "Small stand-alone programs simply will fall short on most of these measures by virtue of their very nature. These are elective cases—there is no reason to subject patients to these risks."

The fourth most common response was that there are too many non-SOS programs already: "this will dilute the volume at established centers." That was selected by **37.8**% of respondents.

Writes **Dr Joseph Carrozza** (St Elizabeth's Medical Center, Boston, MA), "Although the data suggest that PCI at non-SOS hospitals can be performed safely, low-volume operators in low-volume institutions perform consistently below appropriate thresholds."

"Volume and quality are closely linked. The problem is there are a lot of diagnostic-only cath labs that are trying to transition to unbacked PCIs," according to **Dr David A Portugal** (Cardiology of Houston, TX) "This is at a time that overall PCI volume is dropping. This divides the overall 'pie' of PCIs further, making it more difficult for quality centers to maintain their volume. There needs to be better regulation, limiting PCI centers to high-volume labs."

Anachronism or malpractice fears?

Dr Gary S Roubin (Lenox Hill Heart and Vascular Institute, New York, NY): "Backup CT surgery is an anachronism from the early days of coronary angioplasty before the era of the modern coronary stent."

Dr Nate Lebowitz (Advanced Cardiology Institute, Fort Lee, NJ): "The only valid reason we have *avoided* performing PCI at a hospital without cardiac surgery is fear of malpractice and fear of local newspaper persecution. With an acute MI, you often do not know the patient and family [and] so are more likely to get sued."

And **31.1**% of non-SOS center skeptics indicated that elective PCI raises healthcare expenses. "With careful selection, PCI without surgical backup can be safe, but it is increasing healthcare costs for no benefits to the healthcare system," wrote **Dr Kenneth M Kent** (Washington Hospital Center, Washington, DC).

Those who provided comments in the survey indicated some other reasons, not included as survey options, for coming down against a non-SOS strategy. Several touted the advantages of a team approach in many patients who need revascularization.

Kelberman also wrote, "There is an increasing push to make revascularization decisions in concert with surgeons, including for hybrid procedures. This is an important trend that is making all revascularization decisions safer and better for patients. It makes no sense to take a step backward and encourage an environment where this can simply not take place."

All about the money?

Survey participants were also asked their explanation for why there is "a push to allow PCI at more hospitals" without SOS. "The issue is much more about money and marketing than MDs and hospitals want to admit," commented one anonymously, although speaking for those giving the highest-ranked response, at **45.4%**.

> This is about cardiologists and hospitals wanting more money. Quality and patient care have a secondary, if any, role.

On the record, **Dr Michael Nellestein** (Heartland Health, St Joseph, MO) similarly wrote, "This is about cardiologists and hospitals wanting more money. Quality and patient care have a secondary, if any, role. Doctors want [relative value units] RVUs and hospitals want facility fees, period. It's all about the money."

Dr Howard C Herrmann (University of Pennsylvania, Philadelphia) added: "Although I think it is generally safe, the rare complications will likely have better outcomes at hospitals with surgical backup. I suspect most physicians would not choose to have their own PCI at a hospital without surgical backup. Although there are legitimate reasons to do PCI without surgery at remote hospitals where patients otherwise might not have local access, and in emergent situations, I believe that much of the driving pressure is financial by the hospitals that want to offer this profitable procedure."

According to **Dr Michael Mirro** (Fort Wayne Cardiology, IN), "This is about money most places—small hospitals trying to compete and bottom-feeder interventionalists. Some rural areas in the West do need to do this but should be granted a waiver."

On that note, **35.7%** of the respondents indicated that the push is at least partly about increasing access to PCI in areas of need. "The limitation of the number of centers in rural US able to do PCI (primary and lower-risk elective) I feel makes it imperative that more centers be available even without surgical backup," wrote **Dr Richard A Leff** (Marshall Hospital Center Sparks, NV).

"We have all known for a very long time that the data and real-world practice show that in appropriately selected patients and cases, there is no need for on-site surgical programs," wrote **Dr Andrey Espinoza** (Hunterdon Medical Center, Flemington, NJ).

"You have to remember that it is not as though if there is a major complication during an elective PCI, a surgical team is just sitting around ready to take the patient into an open room," he added. "Sometimes the delay can be just as lengthy as [with] a transferred patient."

There were several other comments along the same lines, including this one from a discouraged anonymous writer: "The last time I really needed surgical backup, it failed to appear."

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CONNECTICUT DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

STATEWIDE HEALTH CARE FACILITIES AND SERVICES PLAN

JUNE 2012

410 CAPITOL AVENUE
HARTFORD, CT 06134

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 addition study to examine patient migration patterns to confirm or refute this assertion. As can be seen in the table below, the DEMHS 4 region (see below) is an example of an area that may be in need of additional cardiac service capacity. It appears there is greater demand for cardiac services in the DEMHS 4 region (Eastern CT) than there is capacity to serve. (add table - crosstab of patient residence to cardiac discharge region)

Table 4.7: 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	7,589	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 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	37,646	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 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 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	28,483
			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 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	14,865	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. Utilize outpatient data to evaluate cardiac catheterizations and angioplasties.
2. Conduct research into cardiac utilization and quality by examining institutional versus operator performance.
3. 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.
4. Further examine cardiac capacity on a regional basis to assess capacity and access.

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.[12] According to the CT Cancer Partnership, 67% of acute care hospitals in Connecticut are ACoS accredited.[13].

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

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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

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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.

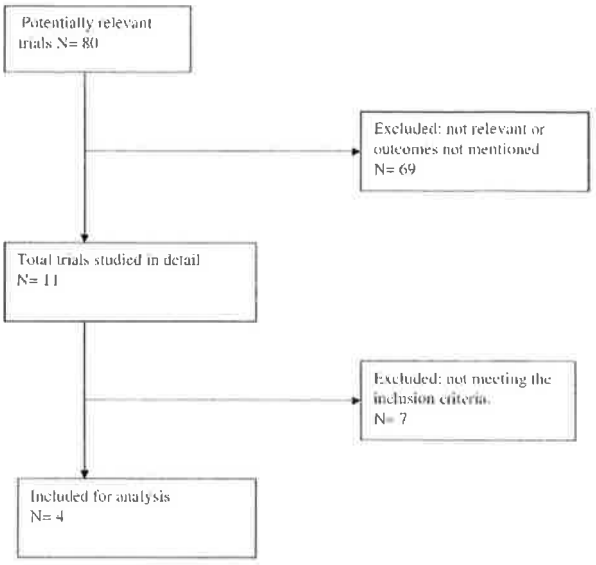

FIGURE 1. Trial selection and inclusion flow diagram.

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

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).

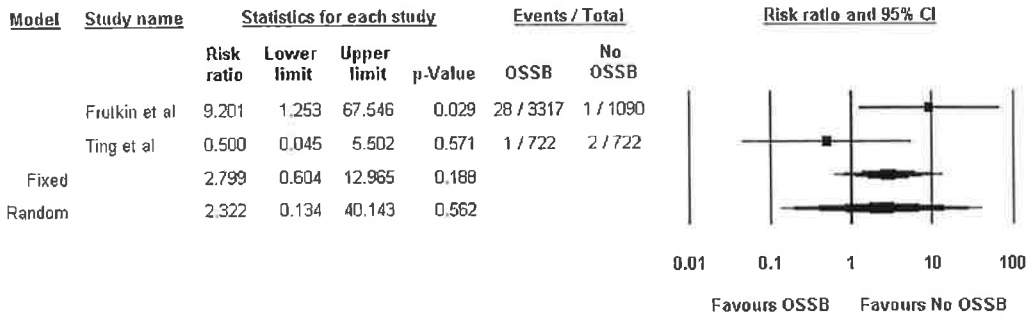

FIGURE 2. Risk of in-hospital death with on-site surgical backup versus no backup.

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

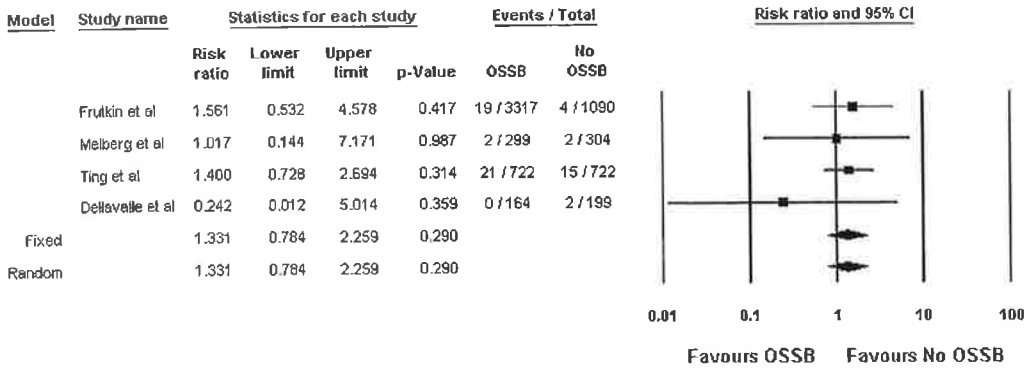

FIGURE 3. Risk of nonfatal myocardial infarction with on-site surgical backup versus no backup.

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

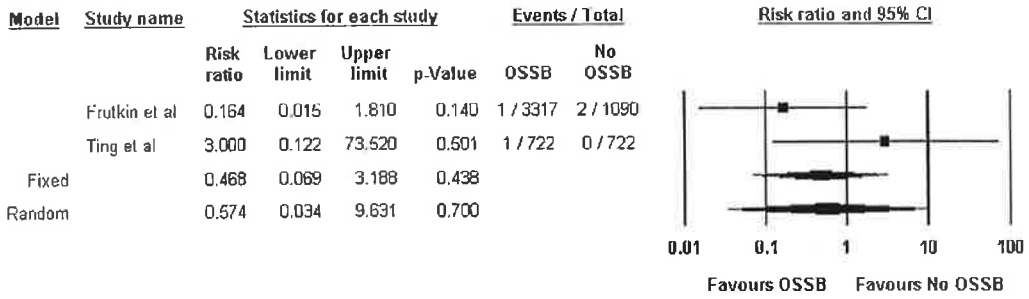

FIGURE 4. Risk of emergency coronary artery bypass graft with on-site surgical backup versus no backup.

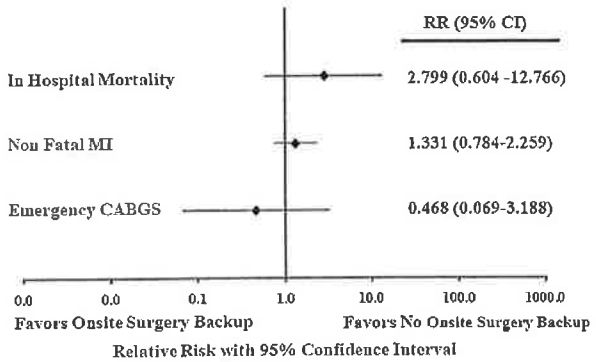

FIGURE 5. Summary figure.

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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Outcomes of 1,090 Consecutive, Elective, Nonselected Percutaneous Coronary Interventions at a Community Hospital Without Onsite Cardiac Surgery

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We evaluated the efficacy and safety of elective percutaneous coronary intervention (PCI) at a hospital without onsite cardiac surgery. A growing number of hospitals without onsite cardiac surgery perform elective PCI. Few hospitals have reported outcomes, despite controversy surrounding this practice. From August 2003 to December 2005, 1,090 elective PCI were performed at Saint Luke's South Hospital (SLS), a hospital without onsite cardiac surgery, for which the referral center is the Mid America Heart Institute (MAHI). The elective PCI program used experienced interventionalists, technicians, and nurses; a tested helocopter transport protocol; a well-equipped catheterization laboratory; and a quality assurance process. Baseline characteristics, procedural success, and adverse clinical outcomes were compared. Observed frequencies of in-hospital death, a combined end point of Q-wave myocardial infarction (MI)/emergency coronary artery bypass grafting (CABG) surgery, and vascular complications were compared with prediction models. SLS, with lower risk characteristics than MAHI, had unadjusted frequencies of procedural success (93% vs 94%, p = NS), Q-wave MI (0.3% vs 0.3%, p = NS), emergency CABG surgery (0.2% vs 0.03%, p = 0.09), vascular complications (0.6% vs 0.6%, p = NS), and in-hospital death (0.1% vs 0.8%, p = 0.002) that compared favorably with MAHI. Two patients transferred from SLS to MAHI for emergency CABG surgery without adverse effects. Fewer in-hospital deaths and vascular complications were observed at SLS than predicted by models. In conclusion, favorable clinical outcomes were achieved for elective PCI at a hospital without onsite cardiac surgery that used strict program requirements. **(Am J Cardiol 2008;101:53–57)**

The American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions guidelines for percutaneous coronary intervention (PCI) recommend against elective PCI at hospitals without onsite cardiac surgery.[1] Nonetheless, an increasing number of hospitals without onsite cardiac surgery in the United States have developed programs for elective PCI.[2] Acknowledging this trend, the Society for Cardiac Angiography and Interventions recently issued an expert consensus statement that provides practice standards for elective PCI at hospitals without onsite cardiac surgery.[3] However, only a limited number of studies have reported favorable outcomes for PCI programs at hospitals without onsite cardiac surgery.[4–7] We sought to determine whether elective PCI can be performed effectively and safely at a community hospital without onsite cardiac surgery using an experienced team of cardiologists, nurses, and technicians, a well-equipped catheterization laboratory, a rapid transport system, a quality assurance process, and no prespecified patient selection criteria. We compared the outcomes of elective PCI at this community hospital with those of a regional, affiliated, tertiary hospital with onsite cardiac surgery. We also compared the observed frequencies of major adverse outcomes at both hospitals with the expected frequencies of these outcomes predicted by externally developed models.

Methods

The Saint Luke's Health System services a 100-mile radius of Kansas City, Missouri. Saint Luke's Hospital is a 629-bed, tertiary care facility that includes the Mid America Heart Institute (MAHI) with 3 cardiac catheterization labs and onsite vascular and cardiac surgery. Saint Luke's South Hospital (SLS) is an 86-bed hospital in Johnson County, Kansas, 15 miles from MAHI. SLS has 1 catheterization laboratory and no onsite cardiac surgery. Encompass software (Heartlab, Westerly, Rhode Island) captures the angiographic images that are transmitted to MAHI via a T-1 line. The elective PCI program at SLS started in August 2003 after approval by the Saint Luke's Health Care Practice Committee. The SLS catheterization lab was staffed by the same highly experienced interventionalists, technicians, and nurses who practiced at MAHI. The 7 interventionalists performed an average of 220 PCIs annually (range 116 to 358). All technicians had Registered Catheterization Inva-

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Table 1
Clinical and angiographic characteristics of elective percutaneous coronary intervention (PCI) at Saint Luke's South Hospital (SLS) and Mid America Heart Institute (MAHI)

Variable	SLS (n = 1,090)	MAHI (n = 3,317)	p Value
Age (yrs)	66 ± 12	66 ± 13	1.0
Men	790 (73%)	2,188 (66%)	<0.001
Caucasian	1,022 (94%)	2,790 (84%)	<0.001
Diabetes mellitus	310 (28%)	1,110 (34%)	0.002
Hypertension	820 (75%)	2,527 (76%)	0.5
Dyslipidemia	972 (89%)	2,834 (85%)	0.002
Body mass index (kg/m^2)	29.3 ± 5.6	29.4 ± 6.2	0.7
Smoker	694 (64%)	2,251 (68%)	0.01
Previous MI	319 (29%)	1,320 (40%)	<0.001
Previous PCI	477 (44%)	1,583 (48%)	0.02
Previous CABG surgery	220 (20%)	728 (22%)	0.2
Previous heart failure	65 (6%)	346 (10%)	<0.001
Peripheral vascular disease	125 (11%)	421 (13%)	0.3
Stroke or transient ischemic attack	163 (15%)	603 (18%)	0.01
Renal failure (Creatinine >2 mg/dl)	29 (3%)	193 (6%)	<0.001
Atypical chest pain	174 (16%)	458 (14%)	0.08
Stable angina pectoris	254 (23%)	507 (15%)	<0.001
Unstable angina pectoris	404 (37%)	1,357 (41%)	0.025
Non–ST-elevation MI	63 (6%)	582 (18%)	<0.001
Creatinine (mg/dl)	1.14 ± 0.93	1.2 ± 0.9	0.021
Left ventricular ejection fraction*	0.55 ± 0.11	0.50 ± 0.14	<0.001
Left ventricular ejection fraction <0.4*	59 (9%)	374 (19%)	<0.001
No. of narrowed coronary arteries†			
1	299 (27%)	999 (30%)	0.09
2	356 (33%)	1,079 (33%)	0.9
3	434 (40%)	1,231 (37%)	0.1
No. of coronary arteries treated per coronary angioplasty			
1	773 (71%)	2,244 (68%)	0.04
2	250 (23%)	710 (21%)	0.3
3	32 (3%)	142 (4%)	0.05
Unprotected left main attempted	4 (0.4%)	27 (0.8%)	0.1
Chronic total occlusions attempted	78 (7%)	391 (12%)	<0.001
Vein graft attempted	60 (6%)	263 (8%)	0.008
No. of stents	1.8 ± 1.1	1.7 ± 1.3	0.2
Glycoprotein IIb/IIIa use	309 (28%)	710 (21%)	<0.001
Intra-aortic balloon pump	2 (0.2%)	57 (2%)	<0.001

* Left ventricular ejection fraction was available in 64% of patients at SLS and 60% at MAHI.
† Coronary artery narrowing was defined as >70% stenosis in the target vessel and >50% stenosis in the other vessels.

Table 2
Unadjusted clinical outcomes of elective percutaneous coronary intervention (PCI) at Saint Luke's South Hospital (SLS) and Mid America Heart Institute (MAHI)

Variable	SLS (n = 1,090)	MAHI (n = 3,317)	p Value
Angiographic success	1,013 (93%)	3,143 (95%)	0.02
Procedural success	1,012 (93%)	3,111 (94%)	0.2
Postprocedure in-hospital Q-wave MI	4 (0.5%)	19 (0.9%)	0.3
Repeat urgent PCI	3 (0.3%)	10 (0.3%)	0.9
Emergency CABG surgery	2 (0.2%)	1 (0.03%)	0.09
Vascular complications	7 (0.6%)	21 (0.6%)	1.0
Bleeding at site other than arteriotomy	4 (0.8%)	24 (1.5%)	0.3
Stroke	0 (0%)	11 (0.3%)	0.06
In-hospital death	1 (0.09%)	28 (0.8%)	0.002
30-d death	3 (0.3%)	55 (1.7%)	<0.001
1-yr death	29 (2.7%)	155 (4.7%)	0.004

sive Specialist certification with an average of 10 years experience. Case selection was at the discretion of the operator. Patients at SLS provided informed consent for PCI and expressed understanding of benefits and risks, including the potential need for transfer to MAHI for emergency coronary artery bypass grafting (CABG) surgery.

The rapid transport protocol used a helicopter (Lifeflight Eagle, Kansas City, Missouri) that was redesigned to accommodate an intra-aortic balloon pump and a mechanical ventilator and was staffed by a registered flight nurse. In an unscheduled, unrehearsed test case, a mock patient was transported within 45 minutes from the SLS catheterization laboratory to the MAHI operating room. Quality assurance included a review by the interventionalists of all PCI outcomes at SLS, initially monthly for 6 months and then quarterly. Outcomes were reported annually to the Saint Luke's Health Care Practice Committee.

Data are reported for elective PCI at SLS and MAHI from August 1, 2003 through December 31, 2005. All pa-

Table 3
Observed versus expected adverse outcomes for elective percutaneous coronary intervention

Saint Luke's South Hospital				
Outcome	Observed	Predicted*	95% CI*	p Value
In-hospital death	1 (0.1%)	4 (0.4%)	1–10 (0.1–0.9)	<0.05
MI/emergency CABG surgery	6 (0.6%)	5 (0.5%)	2–2 (0.2–1.1)	NS
Vascular complication	6 (0.6%)	17 (1.6%)	10–27 (0.9–25)	<0.05
Mid America Heart Institute				
Outcome	Observed	Predicted	95% CI*	p Value
In-hospital death	29 (0.9%)	22 (0.6%)	13–32 (0.4–1.0)	NS
MI/emergency CABG surgery	20 (0.6%)	19 (0.6%)	12–30 (0.4–0.9)	NS
Vascular complication	29 (0.9%)	52 (1.6%)	40–70 (1.2–2.1)	<0.05

* Predicted values and confidence interval (CI) range in parentheses are based on the Northern New England Cardiovascular Disease Study Group models.

tients who underwent PCI at SLS and MAHI were followed prospectively in the MAHI Catheterization/PCI Registry.[8] Within the Saint Luke's Health Care System, patients who have ST-elevation myocardial infarction (MI) are preferentially transferred to MAHI for primary PCI. Therefore, primary PCI performed at SLS (n = 20) and at MAHI (n = 425) are excluded from the analysis. Primary outcomes included angiographic success (technical success in all lesions attempted during a PCI), procedural success (angiographic success without in-hospital death, Q-wave MI, or emergency CABG surgery), transfer from SLS to MAHI because of a PCI complication (postprocedural Q-wave MI or emergency CABG surgery), vascular complications, and in-hospital death. Secondary outcomes included death at 30 days and 1 year as extrapolated from the Social Security Death Master File.[9]

Emergency CABG surgery was defined as unplanned surgical revascularization within 48 hours of PCI. Vascular complications included retroperitoneal bleed, occlusion, dissection, pseudoaneurysm, atrioventricular fistula, or hematoma that required transfusion or vascular closure. Postprocedural non–ST-elevation MI was not analyzed because cardiac enzymes were not uniformly collected for all patients after PCI. For the specified time periods, detailed angiographic data, including lesion complexity, were not recorded in the registry database.

We report continuous variables as mean ± SD and categorical variables as frequencies and percentages. *t* Tests, chi-square tests, and Wilcoxon rank-sum test were used when appropriate. Statistical tests were 2-sided, and p values <0.05 were considered significant. The baseline clinical and angiographic characteristics of the SLS and MAHI cohorts differed greatly and precluded a meaningful adjusted analysis. Therefore, we used models developed by the Northern New England Cardiovascular Disease Study Group to calculate for each cohort the expected frequencies of in-hospital mortality,[10] a combined end point of MI/CABG surgery, and vascular complications.[11] For these analyses all PCIs were coded as having type A lesions because our database lacked American College of Cardiology angiographic information, potentially creating a lower estimate for each adverse outcome. SAS version 9.1 (SAS Institute Inc., Cary, North Carolina) was used for all analyses.

Results

At SLS, 1,090 consecutive elective PCIs were performed on 982 patients. An additional 36 patients (3%) underwent diagnostic angiography at SLS but then underwent PCI within 90 days at MAHI. These patients were referred to MAHI for PCI because of complex anatomy (chronic total occlusions or unprotected left main stenoses) or the anticipated need for hemodynamic support or rotational atherectomy. None of these 36 patients sustained significant adverse events. During the same time period, 3,317 elective PCI procedures were performed on 2,863 patients at MAHI.

The clinical and angiographic characteristics of the elective PCI procedures at SLS and MAHI are listed in Table 1. Patients who underwent elective PCI at SLS and MAHI were similar in terms of age, history of hypertension, previous CABG surgery, peripheral vascular disease, and body mass index. In general, the SLS PCI cohort had lower risk clinical and angiographic characteristics than the MAHI cohort.

Angiographic success of PCI was significantly lower in the SLS cohort than the MAHI cohort, but procedural success was similar between the groups (Table 2). The SLS and MAHI cohorts had similar unadjusted frequencies of postprocedural Q-wave MI, emergency CABG surgery, urgent, repeat PCI, and vascular complications (Table 2). The PCI cohort at SLS, compared with MAHI, had significantly lower unadjusted rates of in-hospital, 30-day, and 1-year death (Table 2).

Because baseline characteristics of the SLS and MAHI cohorts differed significantly, we compared the frequency of major adverse PCI outcomes at both SLS and MAHI against external benchmarks. The observed frequencies of in-hospital death, MI/emergency CABG surgery, and vascular complications at SLS were less than or within the confidence intervals of the Northern New England Cardiovascular Disease Study Group models (Table 3).

After PCI at SLS, 2 patients (0.2%) were transferred from the catheterization laboratory to MAHI for emergency CABG surgery. One patient had sustained dissection and perforation of the right coronary artery. The patient arrived at the MAHI intensive care unit 43 minutes after the call for transport. The patient underwent CABG surgery the next day. The second patient sustained a left main coronary

artery dissection. Within 56 minutes of the call for transport, the patient arrived at the MAHI operating room. Both patients were living 1 year after emergency CABG surgery. Six additional patients were transferred electively after PCI at SLS to MAHI. One patient had acute stent thrombosis requiring repeat PCI. Another had transient ST-elevation due to transient hypotension during sheath removal. The remaining patients had unsuccessful dilation of a target vessel without complications; 2 patients were transferred for elective CABG surgery of a chronic total occlusion, and 2 required use of rotational atherectomy.

Discussion

An elective PCI program was established at SLS, a community hospital without onsite cardiac surgery. The program employed several features that likely improve procedural quality and minimize adverse outcomes[3,5]: (1) high-volume experienced interventionalists and catheterization laboratory personnel who also practiced at the affiliated, tertiary care hospital; (2) a cardiac catheterization laboratory with a full range of equipment for coronary interventions and hemodynamic support; (3) a proven protocol for rapid transport to hospital with cardiac surgery; and (4) a quality assurance process that included data collection, analysis, and review. The program at SLS did not use patient selection criteria, and a substantial proportion of patients at SLS had higher risk features such as acute coronary syndrome, reduced ejection fraction, and intervention on multiple vessels. The unadjusted frequencies of procedural success and adverse outcomes at SLS compared favorably with MAHI, the affiliated, tertiary hospital with onsite cardiac surgery. Due to referral patterns and operator discretion, the SLS cohort had lower risk characteristics than MAHI, biasing any comparison in favor of SLS. Thus, we compared the frequencies of in-hospital death, Q-wave MI/emergency CABG surgery, and vascular complications at both hospitals with Northern New England Cardiovascular Disease Study Group predictive models. The observed frequencies of these adverse outcomes at SLS were less or within the confidence intervals of these models. The results at SLS suggest that elective PCI without onsite cardiac surgery can be effective and safe when program standards are employed.

Our observational cohort adds to a growing body of reports that suggest elective PCI can be performed safely and effectively at hospitals without onsite cardiac surgery.[4–7,12–14] However, there is considerable disagreement whether elective PCI should be performed at hospitals without onsite cardiac surgery.[1,3] The benefits of an elective PCI program without onsite cardiac surgery are largely theoretical and not necessarily patient-centered. The practice may allow more uniform distribution of advanced cardiac care, especially to medically underserved regions. Performance of elective PCI without onsite cardiac surgery permits operators and hospitals to hone PCI skills and maintain a primary PCI program.[1,15] This practice may limit patient transfer to another institution, thereby reducing test duplication and medical error.[15] Patients may find an elective PCI program at a nearby hospital more convenient than commuting to a regional PCI center. An elective PCI program without onsite cardiac surgery may serve as a means by which institutions establish or retain patient referrals.

The danger in performing elective PCI at facilities without onsite cardiac surgery is that a small, but real, number of patients will sustain complications that require immediate surgery. In order to reduce the likelihood of PCI complications, some programs have employed selection criteria that exclude higher risk patients from elective PCI.[5,6,14] The Society for Cardiac Angiography and Interventions expert consensus statement recommends this strategy.[3] However, the low incidence of severe PCI complications in the stent era makes it difficult to identify who will require emergency cardiac surgery.[16] Therefore, selection criteria are unlikely to eliminate the occurrence of PCI complications or the rare need for emergency CABG surgery.

Patients who require emergency CABG surgery for PCI complications are already at an increased risk of death.[17,18] The lack of onsite cardiac surgery at a PCI program may exacerbate this risk and may herald other deficiencies in advanced cardiac care.[1] Transfer between hospitals may delay access to emergency CABG surgery[12] for patients who need immediate care.[19] Delay to surgery after failed PCI has been associated with increased periprocedural infarction and death,[20] emphasizing the need for immediate access to cardiac surgery.

An analysis of Medicare claims data demonstrated greater mortality for patients undergoing elective PCI at hospitals without cardiac surgery,[21] reinforcing concerns about this practice. The adjusted in-hospital and 30-day mortality for Medicare enrollees who underwent elective PCI was 38% higher at hospitals without onsite cardiac surgery versus hospitals with surgical backup (4.6% vs 2.8%, $p = 0.001$). The increase in mortality was confined to hospitals without onsite cardiac surgery performing <50 PCIs per year. The relation between lower hospital volume and adverse PCI outcomes is well documented.[22] Proliferation of PCI programs without onsite cardiac surgery could increase the number of programs with low procedural volumes. Practice standards for elective PCI programs without onsite cardiac surgery may curtail exposure of patients to such low-volume programs.

This study has a number of limitations. Because patient characteristics at SLS and MAHI differed, we used Northern New England Cardiovascular Disease Study Group predictive models to compare observed versus expected frequencies of adverse outcomes for each hospital. These models, generated from a different patient population and era, may have less predictive accuracy when applied to SLS and MAHI. However, the in-hospital mortality model has predictive value in other cohorts.[23,24] The low incidence of adverse outcomes after elective PCI suggests that a study using 2 well-matched cohorts would require a large number of observations to find a difference between institutions with and without onsite cardiac surgery. For example, we estimate that had our cohorts been better matched, 18,030 patients at SLS and 54,090 patients at MAHI would be needed to detect a 50% mortality difference with 80% power at $\alpha = 0.05$. Because only 2 patients required transfer from SLS, we cannot definitively conclude that the transport system is adequate. Finally, we report results from a higher volume suburban, community hospital (450 PCIs per year)

and a high-volume, tertiary care center that are both integrated within a health care system using a single cardiology group and catheterization laboratory team. As such, the results from SLS may not be readily generalized to other health care systems, particularly institutions with lower volume and without a nearby, affiliated PCI program that provides high-volume experienced interventional cardiologists and ancillary personnel.

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Nonemergent coronary angioplasty without on-site surgical backup: A randomized study evaluating outcomes in low-risk patients

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Background Percutaneous coronary intervention (PCI) in nonemergent patients with coronary artery disease in hospitals without on-site cardiac surgery backup is still controversial. To prospectively evaluate a set of low procedural risk criteria for PCI, patients with stable or unstable angina were randomized to treatment in either a community hospital, which had all supportive services except for on-site cardiac surgery, or a regional surgical hospital 213 km away.

Methods and results During a 4-year period, 609 (57%) of 1064 consecutive patients with stable or unstable angina who underwent coronary angiography at a teaching community hospital in Norway fulfilled the predefined low-risk criteria for PCI. The patients were randomized to treatment at either the community hospital (n = 305) or at the regional hospital (n = 304). The angiographic success rate (96% at both hospitals) and number of major periprocedural complications (overall 0.3%) were equal at the 2 hospitals. In particular, there were no deaths or need for urgent transfer to cardiac surgery. At 6 months of clinical follow-up, there was a significant higher major adverse cardiac event rate at the community hospital, compared with the regional hospital (6.9% vs 2.3%, respectively, $P = .03$) because of more repeat target vessel revascularizations. Improvement in angina functional class and exercise capacity was similar in both groups. The excluded high-risk PCI patients had higher 6-month major adverse cardiac event rate compared with all low-risk patients (8.4% vs 4.3%, respectively, $P = .01$).

Conclusion Selected nonemergent patients can, based on angiography, safely undergo PCI at hospitals without cardiac surgery backup. The angiographic selection criteria identified high-risk patients, which had worsened outcome at 6 months of follow-up. (Am Heart J 2006;152:888-95.)

Percutaneous coronary interventions (PCI) were previously only performed at hospitals with emergency cardiac surgical capability. However, major progress in PCI techniques, in particular, the introduction of intracoronary stents,[1] has significantly reduced the risk of periprocedural complications mandating urgent cardiac surgery. As a result, the number of PCI procedures has increased worldwide,[2] and an increasing proportion of the procedures are performed at centers without surgical backup.[3] Revascularization with primary PCI is often preferred to thrombolytic therapy in patients with acute myocardial infarction (MI) at centers both with[4] and without[5] on-site cardiac surgical service. Despite major advances in the PCI technique, the current American College of Cardiology/American Heart Association/Society of Cardiovascular Angiography and Interventions guidelines[6] discourage performance of PCI at centers without on-site cardiac surgery service because the risk of an acute serious complication still may outweigh the inconvenience of referring the patients to a tertiary hospital. Current risk models predict fairly accurately subgroups with low-risk for complication requiring emergency coronary artery bypass grafting (CABG).[7] But these models have not been tested prospectively in the actual setting of low-volume nonsurgical hospitals.[8] Moreover, prediction of risk in the individual patient has become more difficult because the overall procedural risk has diminished.[9]

We therefore conducted a prospective randomized trial to compare the outcomes in selected low-risk patients with stable or unstable angina undergoing PCI at 2 hospitals, 1 with on-site cardiac surgery and 1 with a distance of 213 km to the nearest surgical service. The primary aim of our trial was to demonstrate the safety of nonemergent PCI without on-site surgical backup by

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Table I. Angiographic procedural high-risk criteria

- Unprotected LMS*, IMA, or SVG supplying critical part of the myocardium (functional LMS)
- Proximal LAD stenosis†
- LAD luminal diameter <2.5 mm‡
- In patients with previous MI, target vessel supplies most of the remaining viable myocardium.§
- LVEF <35% in any patient irrespective of other criteria

LMS, Left main stenosis; *LAD*, left anterior descending artery; *RCX*, left circumflex artery; *RCA*, right coronary artery; *LVEF*, left ventricular ejection fraction; *IMA*, internal mammary artery graft; *SVG*, saphenous vein graft.
*Only PCI to LMS in patients with IMA to LAD.
†Ostial or the proximal 2 cm of the artery.
‡Deemed unsuitable for bail-out stenting.
§If large anterior wall infarction, dominant RCA supplying viable inferior wall should not be dilated, and vice versa.

comparing the rate of major acute complications during PCI at the 2 hospitals. Secondly, we evaluated the efficacy of the procedure by comparing the interhospital rates of major cardiac events, symptomatic relief, and exercise capacity at 6 months.

Methods

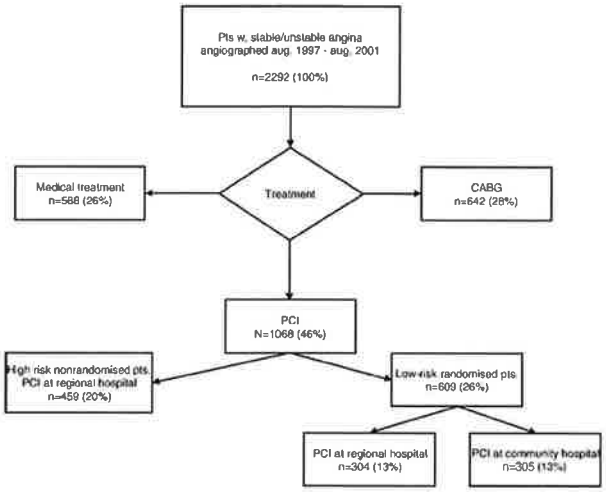
Patients

All patients with stable or unstable angina undergoing diagnostic coronary angiography at the Stavanger University Hospital from September 1997 to August 2001 were considered for inclusion in the study whenever PCI was indicated. This community teaching hospital has performed all catheterization procedures in Rogaland County (360 000 inhabitants) since 1993 and has no on-site surgical backup. The present study marked the start of the PCI program. Inclusion was based on the clinically and angiographically assessed periprocedural risk of death or nonfatal MI, which could possibly be alleviated by emergency CABG, should the event occur. Patients were excluded if they had acute MI with ST elevation in the electrocardiogram, cardiogenic shock, ejection fraction <35%, or significant valvular disease in need for surgery. The angiographic criteria for high procedural risk are listed in Table I. The inclusion and exclusion criteria were based on previously reported risk factors for acute ischemic complications[10,11] and a recent analysis of our own angioplasty database of 3312 angioplasty procedures.[12] Generally, the main purpose of the angiographic criteria was to avoid jeopardizing large areas of myocardium by periprocedural vessel closure.[13] Patients were not selected on anticipated procedural success or technical difficulty.

Among the patients randomized to the regional hospital, 2 patients were offered CABG instead of PCI upon hospital admission, and 3 were advised to continue medical therapy alone instead of undergoing PCI. Percutaneous coronary intervention was undertaken according to randomization at the community hospital.

Ergometer stress testing was performed on stable patients at baseline and on all included patients at 6 months of clinical follow-up. Acute MI was diagnosed according to conventional electrocardiogram criteria and measurement of creatine kinase-MB mass or troponin.

Figure 1



Treatment strategy for all patients with stable or unstable angina undergoing coronary angiography at the community hospital during the study period. Percentages of the total number of patients are shown.

Design and patient logistics

Informed consent was obtained after angiography. Those who were not included in the study were offered treatment at the regional hospital. The interventionalists and clinicians caring for the patients reviewed all angiograms performed the preceding week. Allocation to treatment was then performed according to Figure 1. Patients referred either to surgery or PCI at the regional hospital were routinely reassessed jointly by cardiac surgeons and interventionalists.

Patients were randomized in blocks of 4 using sealed opaque envelopes. The study was approved by the regional ethics committee.

Procedural safety program

The community hospital PCI program was ascertained to measure up to the same standards and outcomes as those of the regional hospital. The catheterization laboratory had identical staffing (nurses and technicians) and equipment as the regional hospital, and a 24-hour on-call service was established to deal with any emergencies related to patients who had undergone PCI. The nurses were adept in hemodynamic monitoring and intra-aortic balloon pump management. A PCI training program for 1 cardiologist experienced in cardiac catheterization was initiated at the commencement of the study. This cardiologist participated in all the procedures at the community hospital and additional 3 to 5 procedures weekly at the regional hospital. The training was supervised throughout the study at both hospitals by experienced (>1000 PCI) interventionalists. Parallel to this, 4 other cardiologists were trained in coronary angiography at the community hospital and, gradually, also in PCI at both hospitals. A consensus among the study steering

Table II. Patient characteristics at baseline for randomized low-risk patients and for high-risk patients

	Low-risk patients (n = 609)		High-risk patients (n = 459)	
Treatment group	**Regional hospital (n = 304)**	**Community hospital (n = 305)**	**Regional hospital (n = 459)**	***P****
Female sex (%)	20	21	19	NS
Age (mean ± SD)	58 ± 10	59 ± 10	60 ± 11	.05
Unstable angina (%)	20	26†	36	<.001
Family history of CAD (%)	40	39	39	NS
Hypertension (%)	25	24	25	NS
Hypercholesterolemia (%)	70	71	64	.04
Smoker (%)	33	32	24	.002
Diabetes mellitus (%)	5	9	7	NS
Positive exercise test (%)‡	74	75	81	.05
Previous MI (%)	39	39	32	.01
Recent MI (%)	5	8	7	NS
Previous PCI (%)	9	6	11	.02
Previous CABG (%)	6	5	11	.001

Family history of CAD, Known CAD in primary relatives.
**P* values for difference between all randomized patients versus nonrandomized patients referred to PCI. No significant difference between randomized groups except †.
†$P < .05$.
‡Exercise induced chest pain and/or ST depression in patients with stable angina.

committee was that 500 PCI procedures were necessary for each cardiologist to be allowed to perform procedures at the community hospital without supervision after termination of the study.

The pre-, peri-, and postprocedural check lists of the regional hospital were implemented at both hospitals. In brief, the check lists contained information on mandatory drug treatment, blood chemistry and blood group, surgical risk factors, how to deal with clinical signs and symptoms post procedure, arterial sheath removal, bleeding, and other complications. The distance between the community hospital and the regional hospital is approximately 213 km (~4-hour drive). Ambulance helicopter service was available at the community hospital at all time, and PCI was performed only if the weather conditions would allow air transport (1-hour flight time). Emergency transfer to surgery should be considered if the patient experienced sustained occlusion of a vital coronary artery or became hemodynamically unstable during the procedure.

Data analysis

Clinical characteristics, the findings at coronary angiography, and the results of PCI for all patients at both hospitals were entered into an identical database management system by the cardiologist who performed the procedure. All clinical events during the follow-up period and clinical status for each patient were captured in the PCI database or from the hospitals' patient information systems. Comparisons were done between the procedural low-risk patient groups at both hospitals. Data at the regional hospital for the procedural high-risk PCI patients, who were excluded from randomization, were also captured for comparison. After independent assessment at the regional hospital, 5 randomized patients did not receive PCI as their final treatment. We decided not to include these patients in the outcome analysis because the purpose of the study was to evaluate efficacy and safety of PCI.[14] Continuous data are presented as means ± SD and were compared with the t test. Categorical variables with nominal or ordinal data were compared with the χ^2 test or Mann-Whitney rank-sum test, respectively. A Cox proportional hazards model with adjustment for differences at baseline was used for comparison of the major adverse cardiac event (MACE) rates in each study group at follow-up. Major adverse cardiac events consisted of the combined rate of the primary end point (procedure-related death, MI, or emergency CABG) and the secondary end point (need for repeat revascularization).

$P < .05$ was considered statistically significant.

Sample size estimates. The study intended to show an equivalent outcome at the 2 hospitals during the PCI procedure and at 6 months of clinical follow-up. During the last 6 years, only 10 of 3312 unselected patients (0.3%) undergoing PCI at the regional center needed emergency CABG. Only 1 (0.05%) of 1715 low-risk patients treated, who experienced cardiac tamponade due to coronary perforation, was a low-risk patient according to our criteria. If need for emergent surgery should occur, the study should be stopped and the inclusion criteria reevaluated. Furthermore, the combined rate of death, MI, or repeat revascularization in the low-risk patients during 6 months of follow-up was <5% in recent years. Based on these figures and using the methods outlined in Jones et al,[15] we calculated that 322 patients had to be treated at each hospital to show an equivalent combined outcome at 6 months (event rate 4%, range of difference <5%, and with a power of 90%). Using our standard bicycle ergometer protocol with 20-W incremental increase in workload per minute, low-risk patients in our database exercised 6.4 ± 2.4 minutes before treatment. Assuming a 1-minute average increase in exercise time at 6 months of follow-up and that 50% of the included patients had stable angina and were tested before and after PCI, 180 patients in each group were required to show a difference of <1 minute between the 2 groups in exercise tolerance. Based on the preliminary results of the study, routine use of PCI at the community hospital without surgical backup was approved by the Ministry of Health.

Table III. Use of medication before angiography

	Low-risk patients (n = 609)		High-risk patients (n = 459)	
Treatment group	**Regional hospital (n = 304)**	**Community hospital (n = 305)**	**Regional hospital (n = 459)**	***P****
Aspirin (%)	85	87	78	.003
β-Blocker (%)	79	79	72	.004
Calcium antagonist (%)	16	17	20	NS
Long-acting nitrates (%)	37	36	41	NS
ACE inhibitors (%)	21	25	24	NS
Intravenous heparin (%)	15	20	21	.05
Warfarin (%)	3	3	5	NS
Statins (%)	79	79	73	.03

ACE, Angiotensin-converting enzyme.
**P* values for difference between all low- versus high-risk patients referred to PCI. There were no significant differences between the 2 low-risk patient groups.

Table IV. Findings at angiography in low- and high-risk patients undergoing PCI (%)

	Low-risk patients		High-risk patients	
	Regional hospital (n = 304)	**Community hospital (n = 305)**	**Regional hospital (n= 459)**	***P****
Extent of CAD				<.001
1-vessel disease	39	39	28	
2-vessel disease	35	37	36	
3-vessel disease	26	24	36	
No. of segments with stenosis†	2.3 ± 1.3	2.3 ± 1.2	2.9 ± 1.6	<.001
Angiographic MI				
Anterior wall	7	10	18	<.001
Apical segment	6	12‡	20	<.001
Inferior wall	16	16	20	<.001
LVEF	68 ± 10	67 ± 10	66 ± 13	.05

Extent of CAD, No. of epicardial vessel territories with significant stenosis.
**P* values for differences between low-risk vs high-risk patients referred to PCI. No significant difference between the two low-risk groups except †.
†Lesions with ≥50% diameter stenosis (mean ± STD).
‡$P < .05$.

Results

A total of 2352 patients with stable or unstable angina, who underwent coronary angiography at the community hospital, were found to have significant coronary artery disease (CAD). Of these, 642 (30%) were referred to coronary artery bypass grafting and 1064 (45%) to PCI (Figure 1). Medical therapy alone was preferred in 588 patients (25%).

Among patients with low-risk angiographic criteria, 2 refused to participate; thus, 609 patients (304 to the regional hospital and 305 to the community hospital) were randomized and constituted 57% of all patients eligible for PCI. The remaining 43% had high-risk procedural criteria and were referred directly for PCI at the regional center.

The randomized low-risk groups were well balanced at baseline with regard to patient characteristics (Table II), medication (Table III), and findings at angiography (Table IV). More patients had unstable angina in the group treated in the community hospital, and intravenous heparin was administered more often pre and post procedure at this hospital. There were no differences in the therapeutic management between the 2 hospitals when treating low-risk patients. The average number of lesions treated and percentage stented were equal at both centers. In addition, in stented patients, the mean total length and mean diameter of the stents deployed were similar (Table V).

Procedural complications

In randomized patients, there were no deaths, emergency CABG, or cerebral strokes (Table VI). One patient at the community hospital experienced a retrograde dissection into the aortic root after angioplasty of the right coronary artery. The dissection was immediately and successfully sealed with a stent in the coronary ostium. In the high-risk group, 1 patient died during the PCI procedure at the regional hospital, and 1 acute life-threatening dissection was successfully treated by emergency CABG. Serious periprocedural complications

Table V. Characteristics of all lesions treated and the outcome after the PCI procedure

	All low-risk patients (n = 603)	High-risk patients (n = 459)	P
Average no. of lesions treated per session (range)	1.3 (1-4)	1.5 (1-8)	<.001
Restenotic lesions (%)	2.3	3.8	NS
Coronary lesion site (%)			<.001
LAD	25	53	
RCX	29	17	
RCA	44	22	
LMS	0	2	
Graft	3	6	
ACC/AHA lesion class (%)			<.001
A	14	2	
B1	45	45	
B2	19	34	
C	22	19	
Bifurcation lesion (%)	10	20	<.001
Chronic occlusion (%)	15	9	.001
Stented lesion (%)	74	75	NS
Stent reason (%)			.003
Primary/residual stenosis after angioplasty	87	91	
Bail-out/local dissection	13	9	
Total stent length per procedure (mm) (mean ± SD)	21 ± 11	24 ± 14	<.001
Average stent diameter (mm) (mean ± SD)	3.0 ± 0.4	3.0 ± 0.4	NS
Max inflation pressure stent (mm Hg)	14 ± 2	14 ± 3	NS
Max inflation pressure balloon (mm Hg)	9 ± 3	9 ± 3	NS
Glycoprotein IIb/IIIa used (%)	7	21	<.001
TIMI flow pre procedure(%)			.01
0	19	14	
1	13	18	
2	1	1	
3	67	67	
TIMI flow post procedure* (%)			NS
0	3	3	
1	0	0	
2	1	0	
3	96	97	
Overall success rate (%)	96	96	NS

All numbers are percentages unless otherwise stated. *Graft*, degenerated vein graft; *ACC/AHA*, American College of Cardiology/American Heart Association.
*A significant ($P < .001$) improvement in TIMI flow after the procedure was achieved in both the low- and high-risk groups.

were infrequent, with a total of 4 major coronary events (0.6%).

Clinical outcome at 6 months

All major cardiac events during the hospital stay and up to 6 months of follow-up are shown in Table VII. One patient randomized to the community hospital died of a noncardiac cause after treatment. No further mortality occurred. At 6 months of follow-up, the MACE rate was 2.3% versus 6.9% ($P = .033$) (Figure 2), and including a target vessel revascularization rate (TVR) of 1.7% versus 5.6% ($P = .01$) in the regional and community hospitals, respectively. There was no difference between the study groups at 30 days of follow-up. Canadian Cardiovascular Society (CCS) angina grade improved by 2.0 versus 1.7 classes from baseline to 6 months for patients treated at the regional versus the community hospital ($P < .05$ within group, P = nonsignificant [NS] between group comparison)(Table VIII). Exercise time also increased significantly during follow-up in both groups. Patients treated in the community hospital used significantly less antianginal drugs during follow-up (Table VIII).

Table VI. Serious periprocedural complications during PCI in randomized patients

	Low-risk patients		
	Regional hospital (n = 299)	Community hospital (n = 304)	P
Death	0	0	NS
Emergency CABG	0	0	NS
Nonfatal MI	2	2	NS
Cardiac tamponade	0	0	NS
Aortic dissection	0	1	NS
Pseudoaneurysm	1	1	NS
CVA	0	1	NS

Analysis was performed on the patients who underwent PCI after randomization. *CVA*, cerebrovascular accident.

Procedural high-risk patients

The angiographically assessed high-risk PCI procedure patients had more risk factors (Table V), and more proximal lesions were treated. The event rate at 6 months of follow-up was significantly higher in the high risk group, compared with all low-risk patients (MACE rate at 6 months was 8.5% vs 4.3% in the nonrandomized vs randomized group of patients, $P = .01$) (Figure 2).

Discussion

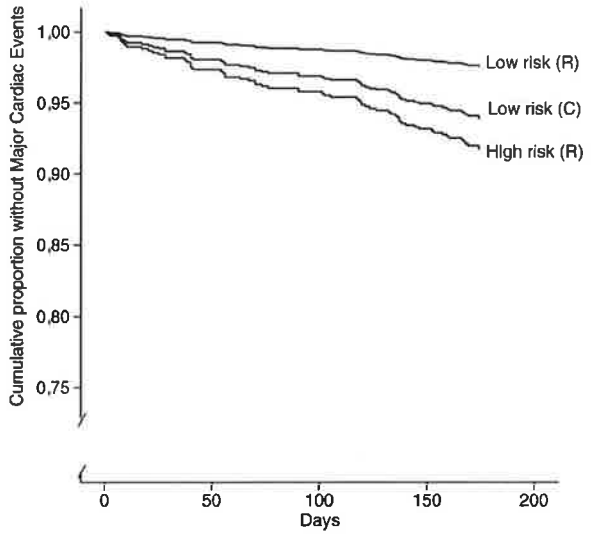
More than half of the patients referred to PCI fulfilled the inclusion criteria. Low-risk patients, in contrast to the high-risk patients, did not experience serious complications during the PCI procedure, and there was no need for emergency CABG. Furthermore, the absence of onsite cardiac surgical service did not affect the therapeutic management. Symptomatic relief and increase in exercise capacity at 6 months of follow-up were also similar. The overall incidence of repeat revascularization was low, and it should be emphasized that the study was run before the introduction of drug-eluting stents. The slightly higher TVR rate in patients treated at the community hospital, as compared with the regional hospital, may be due to a lower threshold for reangiography of PCI patients treated at the

Table VII. Clinical outcome measures at 6 months of follow-up

	Regional hospital (n = 299)		Community hospital (n = 304)			All low-risk patients (n = 603)		High-risk patients (n = 459)		
	n	%	n	%	P	n	%	n	%	P
Death	0	0	1 (1*)	0.3	.32	1 (1*)	0.2	5 (3*)	1.1	.047
Myocardial infarction	3	1.0	3	1.0	.99	6	1.0	7	1.5	.44
Readmission with unstable angina	7	2.3	12	3.9	.26	19	3.2	19	4.1	.39
Repeat angiography without PCI	8	2.7	15	4.9	.15	23	3.8	18	3.9	.93
Repeat PCI	5	1.7	17	5.6	.01	21	3.8	21	4.6	.54
CABG after PCI	1	0.3	2	0.7	.57	3	0.5	6	1.3	.15

Analysis performed on patients who underwent PCI after randomization. Some patients had >1 event.
*Noncardiac death.

Figure 2



Proportion of patients without major cardiac events during 6 months of follow-up. The data were analyzed with the use of a Cox proportional hazards model adjusting for diagnosis (stable or unstable angina). The cumulative event rate for low-risk patients treated at the regional hospital (2.3%) was significantly lower than for patients treated at the community hospital (6.9%) ($P = .033$) and for high-risk patients treated at the regional hospital (8.5%) ($P = .04$). The difference in event rate for patients treated at the community hospital and for high-risk patients at the regional hospital was nonsignificant. *C*, Community hospital; *R*, regional hospital.

Table VIII. Angina grade and ergometer stress test results before and after PCI in randomized patients

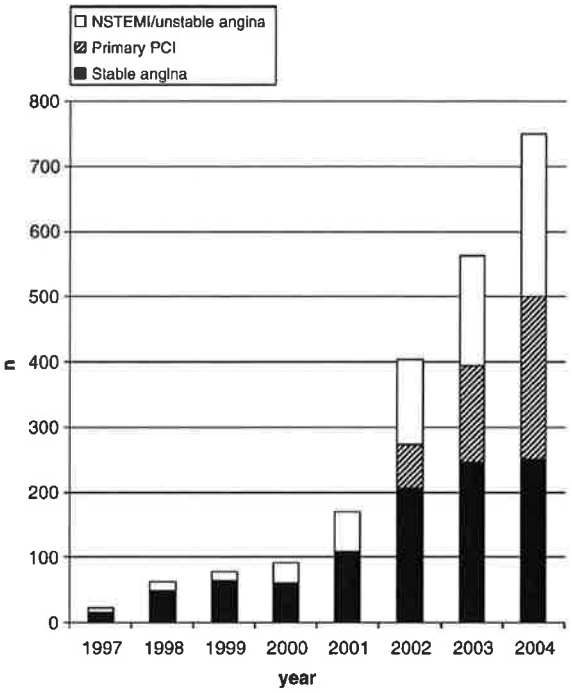
	Regional hospital	Community hospital
CCS (mean ± SD)		
Before PCI	2.7 ± 0.9	2.5 ± 0.8
At 6-m follow-up	0.7 ± 0.9	0.8 ± 0.8
No. of antiangina drugs (mean ± SD)	0.9 ± 0.7	0.7 ± 0.7†
Exercise time before PCI (min)†	7.2 ± 2.1	7.1 ± 2.1
Exercise time at 6-m follow-up (min)	8.5 ± 2.3‡	8.5 ± 2.2‡
Exercise induced ischemia (%)		
Before PCI	61.8	59.3
At 6-m follow-up	12.5	12.3

Significant decrease in CCS grade ($P < .01$) within both groups compared with baseline.
†Significant differences between the groups ($P = .003$).
‡Significant increase in exercise time ($P < .005$) within both study groups after PCI. Exercise results analyzed for stable patients who had tests before and after PCI (n = 183 and n = 187 for patients treated at regional and community hospital, respectively).

community center. This study marked the beginning of the PCI program at the community hospital. However, a possible influence of a learning curve on the rate of TVR seems unlikely as the clinical recurrence rate of 5.6% at the community hospital is lower than reported in the general literature. As anticipated, high-risk patients experienced more cardiac events during the PCI procedure and at follow-up, compared with low-risk patients.

Emergency CABG today occurs mostly unexpectedly[16] and may include other clinical situations than earlier.[1] Most complications previously mandating urgent CABG can now be treated with percutaneous techniques.[17] Left main stem dissection, one of the prime reasons for emergency CABG can, at least temporarily, be treated with stents or a perfusion balloon catheter. Furthermore, a covered stent may effectively control coronary artery rupture. Patients who undergo emergency surgery after failed PCI generally have a worse prognosis than after elective CABG in both inhouse and transferred patients.[18,19] The mortality rate after emergency CABG has not declined.[20] This is probably, in part, because more patients with extensive CAD undergo PCI and partly because of an increase in the time delay for urgent

Figure 3



Volumes and indication for PCI at the community hospital from September 1997 to December 2004. The study period ended in September 2001. Primary PCI service 24 hours, 7 days a week was established January 2004.

operations, as most centers provide backup on a "next operating room available" basis. Serious complications necessitating CABG may also occur during PCI in low-risk patients or even during diagnostic angiography, and how many events can be avoided or limited by emergency CABG service on site is questionable.[21] The availability of other on-site supportive services is also of importance for the final outcome.

The ability to perform PCI, in conjunction to the initial diagnostic catheterization at the patient's local hospital instead of referral to a distant regional center, has several clinical, practical, as well as economical advantages.[22] Based on the preliminary results of our study, routine use of PCI in low-risk nonemergent as well as primary PCI at the community hospital without surgical backup was approved by the Ministry of Health in 2001. As a consequence, the procedure volumes have increased significantly and have ensured adequate volumes for 4 operators (Figure 3). The community hospital now has a 24-hour, 7-days-a-week primary PCI service.

The ability to perform primary PCI in a timely fashion is currently the prime reason for establishing a PCI program at nonsurgical community hospitals.[22] To ensure adequate efficiency and safety during an emergency procedure, a regular elective PCI program at a fully equipped catheterization laboratory with adequate institutional and operator volume is needed. A strict set of elective patient selection criteria should be used, and a continuously updated program for operator training, urgent patient transfer plan, and outcome evaluation must be established. Before establishing a regular PCI program at a community hospital, a test period in collaboration with a tertiary center should confirm acceptable safety and efficacy of the procedure. The present study exemplifies this.

Limitations

The assessment of outcome after PCI was restricted to 1064 consecutive patients. Of these, 609 were considered to have low periprocedural risk and suited for PCI at a community center. A vast number of patients would need to be included to perform an equivalent study with sufficient statistical power to rule out any need for surgical backup in low-risk patients with the current emergency CABG rate.

Because outcome after PCI is dependent on operator experience and skills, the present patient selection criteria should also be evaluated at other nonsurgical centers.

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Outcomes Following Elective Percutaneous Coronary Intervention Without On-Site Surgical Backup in a Community Hospital

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Despite guidelines to the contrary, limited numbers of elective percutaneous coronary intervention (PCI) procedures without on-site surgical backup are being performed, particularly in Europe and Canada. In the United States, many hospitals are considering establishing on-site surgical programs, in part to facilitate PCI. At a hospital with only off-site surgical backup, 562 elective PCI procedures were performed on 489 consecutive patients. Of these, 551 (98.0%) were successfully completed without major in-hospital complications; 5 patients (1.0%) had in-hospital complications, and 4 (0.8%) were urgently transferred. It is concluded that elective PCI with off-site surgical backup is feasible and safe for selected patients under specific conditions. ©2005 by Excerpta Medica Inc.

(Am J Cardiol 2005;95:1091–1093)

Even before the use of stents became widespread, emergency percutaneous coronary intervention (PCI) during acute myocardial infarction without on-site surgical backup was found to be feasible and safe.[1–5] In Europe and Canada, this paradigm has been extended in many institutions to elective PCI. Although not endorsed by guidance committees,[6] similar programs now also exist in the United States.[7,8] The main criticism of these programs has not been that they are unsafe but that they are unnecessary: there are nearly 800 open-heart surgical programs throughout the United States.[9] About 500 additional centers have catheterization laboratories but no open-heart programs[10]; although many perform only diagnostic catheterizations, those that do perform PCI without on-site surgical facilities are considered by some not to have legitimate interventional programs. To add to the debate on whether it is wise to expend health care resources to establish on-site cardiac surgery programs, we sought to determine whether elective PCI with off-site surgical backup might be feasible and safe in selected patients, given a well-developed transfer plan.

• • •

From February 1998 to October 2002, we performed 562 PCI procedures on 489 patients. All patients provided standard clinical informed consent, which included information that only off-site surgical backup was being provided; as an alternative, patients were offered PCI at Duke University Medical Center. To identify patients at lower risk for cardiovascular complications, patients selected for PCI met exclusion criteria agreed on by Alamance Regional Medical Center and Duke University Medical Center; specifically, no patient's age was >75 years, and no patient had class III or IV heart failure, left ventricular function <30%, acute myocardial infarction, cardiogenic shock, PCI immediately after thrombolytic therapy, refractory unstable angina, left main or 3-vessel disease, PCI of ≥2 major vessels, collaterals originating from the vessel targeted for intervention, complex lesion morphology (ostial location, bifurcation, heavy calcification, intracoronary thrombus, or total occlusion), or vein grafts. These characteristics have been shown to be associated with a moderate to high risk for in-hospital adverse events.[6,11,12] Data on patients excluded were not systematically collected during the

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TABLE 1 Clinical and Procedural Characteristics

Characteristic	Value
Clinical (n = 489)	
Age (mean) (yrs)	58.6
Men	62%
>1-vessel disease	15%
Ejection fraction ≤35%	1.4%
Admission from emergency room	53%
Procedural (n = 562)	
Stent use	87%
Glycoprotein IIb/IIIa inhibitor use	93%

TABLE 2 Procedural Success* (562 Procedures)

Procedural Outcome	n	%
Successful	551	98.0
Unsuccessful	11	2.0
Unable to cross	6	1.1
Major complications	5	0.9

*Defined as <20% residual stenosis without a major in-hospital complication (coronary artery bypass graft, transmural myocardial infarction, or death).

TABLE 3 Adverse Cardiac Events

Adverse Event	n	% (95% confidence interval)
Transmural myocardial infarction	0	0.0 (0.0–0.0)
Emergency revascularization	4	0.7 (0.01–1.41)
In-hospital death	1	0.2 (0.17–0.52)
Enzyme elevation to 3 times the upper limit of normal	11	2.0 (0.80–3.10)
Groin complication	6	1.1 (0.21–1.91)
Total	22	3.9 (2.3–5.5)

study except from January to November 2003, when an average of 16.1 patients per month were excluded by these criteria. On average, 11.1 patients per month underwent PCI at Alamance during the study.

To ensure quality and compliance with the specified exclusion criteria, the first 20 patients were previewed prospectively with interventionalists from Duke. In addition, the first 50 patients were reviewed retrospectively to assess procedural success and complications. All procedures were performed by 2 fellowship-trained, board-eligible interventional cardiologists; since their fellowship training, the 2 operators had maintained caseloads of ≥75 PCI procedures per year. Procedural success was defined as a residual stenosis <20% without in-hospital major complications (emergency coronary bypass surgery, transmural myocardial infarction, or death). Myocardial infarction after PCI was defined as the elevation of creatine kinase-MB levels to >3 times the upper limit of normal. If patients arrived with elevated enzymes, myocardial infarction was defined as a further 50% increase from baseline after PCI. All major complications were reviewed by a performance improvement committee comprising representatives from the 2 institutions.

PCI was performed through the femoral artery using standard techniques. All patients received aspirin and intracoronary nitroglycerin. In coronary stent cases, patients received either ticlopidine or clopidogrel. Heparin was administered to achieve an activated clotting time of 300 to 350 seconds or 200 to 250 seconds when glycoprotein IIb/IIIa inhibitors were given. Before October 2001, abciximab was the glycoprotein IIb/IIIa inhibitor of choice; subsequently, virtually all patients received eptifibatide. All patients were monitored overnight in the coronary care unit.

Off-site surgical backup was provided by Duke University Medical Center, located 34 miles (mostly Interstate highway) from Alamance Regional Medical Center. A Duke mobile intensive care ambulance was always present on-site during a PCI procedure, and in cases of transfer to Duke, patients were accompanied by the interventional cardiologist. An operating room at Duke was also required to be on standby. Before initiation of this program, we rehearsed the transfer of mock patients to Duke to ensure that transfer could be accomplished smoothly and quickly. After the program began, mock transfers continued to be practiced every 6 months.

Demographic and angiographic characteristics as well as in-hospital events were captured in Alamance's PCI database for quality. Cases in the quality database were verified with appropriate charge codes in Alamance's cost accounting system. Angiographic characteristics were also tabulated in the Duke Information System for Cardiac Care database. In-hospital events were captured by case managers, staff members, and medical records coders. Vascular access site complications, including retroperitoneal bleeds, psuedoaneurysms, and arteriovenous fistulae, were verified by comparing event data in the quality database with *International Classification of Diseases,* Ninth Revision, Clinical Modification diagnosis codes.

Descriptive statistics were performed on demographic characteristics, vessel disease, and in-hospital events. Data analysis was performed using statistical software from SAS Institute. Inc. (Cary, North Carolina).

Table 1 lists the clinical and procedural characteristics of the 489 patients who underwent elective PCI during the study. Most of the patients were men with single-vessel disease. With rare exceptions, patients had ejection fractions >35%. Most patients were inpatients admitted to the emergency department with acute ischemic syndromes. As Table 1 indicates, 87% of patients received intracoronary stents, and 93% were treated with glycoprotein IIb/IIIa receptor antagonists.

Of the 562 procedures, 551 (98.0%) were successful (Table 2). There were 11 unsuccessful procedures (2.0%). In 6 patients (1.1%), we were unable to cross the lesion with a guidewire. Three of these patients were referred to Duke, where they eventually underwent successful PCI. The other 3 patients were treated medically without sequelae.

Major in-hospital complications were observed in 5 patients (0.9%); overall, there were 22 major and minor complications, for an event rate of 3.9% (Table 3). Four patients (0.7%) were urgently transferred

without incident and underwent successful bypass surgery. One patient who was urgently transferred underwent further attempts at PCI at Duke University Medical Center but eventually required a bypass graft the following day. The mean door-to-door time (from departure from the Alamance catheterization suite to arrival in the Duke catheterization suite in preparation for surgery) for the transferred patients was 40 minutes; the mean time from departure from Alamance to the operating room at Duke was 83 minutes.

One in-hospital death occurred, although not as a result of acute vessel closure. The patient had a successful PCI with an excellent angiographic result. However, the patient developed acute renal failure believed to be multifactorial in origin secondary to a combination of newly initiated angiotensin-converting enzyme inhibitor therapy, transient hypotension, and contrast nephropathy. The patient died at another institution while awaiting emergency dialysis.

Two deaths (0.4%) occurred out of the hospital several days after PCI. We assume that these patients likely experienced in-stent thrombosis, although the exact nature of their deaths is unknown. Over the entire study, only 30 patients (5.3%, with 100% follow-up) were readmitted during the first 6 months for clinical restenosis within the same vessel (although not necessarily the same lesion).

• • •

Using selective criteria coupled with attention to logistics, we found PCI with off-site surgical backup to be safe and very successful. We observed a 98.0% PCI procedural success rate, comparable with rates found in the Stent Restenosis Study and the Belgian Netherlands Stent Study (96.1% and 92.7%, respectively),[13,14] and the total event rate for major and minor in-hospital complications was only 3.9%. The rate of major in-hospital complications was only 0.9%. We did not observe a single case of vessel closure after successful PCI over 4.5 years of follow-up.

The evolution of stent technology and adjunctive pharmacology has contributed to the improved success of PCI,[15] emboldening sites to perform PCI without surgical backup. Concurrently, some argue that PCI without on-site surgical backup is not warranted because of the abundance of open-heart programs in the United States. The impetus to establish a proportion of these programs may have been to legitimize an interventional program rather than to serve actual patient demand.[16,17] Studies have associated worse patient outcomes with small-volume open-heart programs versus institutions that perform greater volumes of surgical procedures.[18–20] In the report of Ting and colleagues,[8] a 99.5% success rate (195 of 196 consecutive patients) was achieved at an institution at which surgical backup, even off-site, was not considered. The success of the program appeared to be largely due to rigorous selection criteria and the availability of immediate consultation using telemedicine. As an alternative, on the basis of our experience, we conclude that PCI can be safely performed with off-site surgical backup and may obviate the need for a small-volume open-heart program at every site that performs PCI while facilitating the performance of PCI (in controlled circumstances) in the community.

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Emergency Coronary Artery Bypass Surgery for Percutaneous Coronary Interventions

Changes in the Incidence, Clinical Characteristics, and Indications From 1979 to 2003

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OBJECTIVES The purpose of the current study was to evaluate the changes in incidence, clinical characteristics, and indications for emergency coronary artery bypass grafting (CABG) in patients undergoing percutaneous coronary intervention (PCI) from 1979 to 2003.

BACKGROUND Emergency CABG after PCI is associated with significant morbidity and mortality.

METHODS Data from 23,087 patients who underwent PCI at Mayo Clinic from 1979 to 2003 were analyzed. Patients were divided into three groups: the "pre-stent" era, 1979 to 1994 (n = 8,905); the "initial stent era," 1995 to 1999 (n = 7,605); and the "current stent era," 2000 to 2003 (n = 6,577).

RESULTS Although patients undergoing PCI in the recent time periods had more high-risk features, there was a significant decrease in the incidence of emergency CABG from 2.9% to 0.7% to 0.3% across the groups ($p < 0.001$). Patients requiring emergency surgery in the recent time periods had a higher prevalence of hypertension, prior revascularization, and left ventricular dysfunction (ejection fraction <40%), as well as more complex coronary lesions. Fewer patients in the current stent era had coronary artery dissections and abrupt vessel closure requiring emergency CABG. The in-hospital mortality rate for emergency CABG patients remains unchanged and ranges from 10% to 14%.

CONCLUSIONS The current study demonstrates that despite the increase in high-risk patients undergoing PCI, there has been a marked decrease in the incidence of patients requiring emergency CABG. However, the in-hospital mortality rate for those requiring emergency CABG remains high and unchanged. (J Am Coll Cardiol 2005;46:2004–9) © 2005 by the American College of Cardiology Foundation

Many technologic and pharmacologic advances in percutaneous coronary intervention (PCI) have been made over the past 25 years. Steerable guide wires, coronary artery stents, and new anti-platelet therapies have resulted in an increase in the success rate of PCI procedures (1–3). In addition, high-risk patients who in the past would have undergone surgical revascularization are now undergoing PCI (4,5).

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Despite the increase in the number of PCI procedures performed, the need for emergency coronary bypass grafting (CABG) has been decreasing (6). Emergency CABG, however, still occurs and is associated with significant morbidity and mortality (7–9). The impact of improvements in technology and the inclusion of high-risk patients on the need and outcome of emergency CABG following PCI are not well known.

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We hypothesized that improvements in PCI technology and the inclusion of high-risk patients have resulted in a change in the incidence, clinical characteristics, and indications for emergency CABG in patients undergoing PCI from 1979 to 2003.

METHODS

Study patients. Patients undergoing PCI at the Mayo Clinic have been followed in a prospective registry since 1979. Patients in this registry have undergone follow up at 6 months, 1 year, and then annually since their PCI. A total of 23,087 patients undergoing PCI from 1979 to 2003 were included in the study. Patients were divided into three groups on the basis of the time period of their PCI. Group 1 consisted of 8,905 patients who underwent PCI from 1979 to 1994 and represents the "pre-stent era." During this period, the technology for percutaneous transluminal angioplasty was being developed and operator experience was being gained. Group 2 consisted of 7,605 patients undergoing PCI from 1995 to 1999 and is considered the "early-stent era." This was a transition period where stents and new parentral anti-platelet agents were introduced. Group 3 included 6,577 patients who underwent PCI from

Abbreviations and Acronyms

ACC/AHA = American College of Cardiology/American Heart Association
CABG = coronary artery bypass grafting
CCS = Canadian Cardiovascular Society
PCI = percutaneous coronary intervention

2000 to 2003 and represents the "current-stent era." In this recent time period, there was more frequent use of bare-metal stents, parentral glycoprotein IIb/IIIa inhibitors, and dual oral anti-platelet therapy.

Definitions. Emergency CABG was defined as cardiac surgery performed within hours of PCI to avoid unnecessary morbidity or death. This surgery takes precedence over elective cases. Indications for emergency CABG included abrupt vessel closure, extensive coronary artery dissection, incomplete revascularization, coronary perforation, unsuccessful dilation, and other situations resulting in hemodynamic instability and requiring surgical intervention. Unstable angina was defined as new onset of chest pain at rest or progression of stable angina to an increased Canadian Cardiovascular Society (CCS) score. Patients presenting with chest pain within two months of coronary revascularization were also considered to have unstable angina if the last episode of pain occurred within one week of the PCI.

The indication for the index PCI was classified as elective, urgent, or emergent. Emergent cases were those that required PCI within hours of presentation in order to avoid significant morbidity and mortality. Urgent cases required PCI before discharge from the hospital and usually occurred within one to three days after presentation with chest pain. All other cases were considered elective. Coronary lesions were classified according to the American College of Cardiology/American Heart Association (ACC/AHA) scoring system (10).

Statistical analysis. Data are presented as mean ± SD for continuous variables and frequency for discrete variables. Kaplan-Meier methods were used to estimate long-term survival. Group comparisons were made using one-way analysis of variance for continuous data and Pearson's chi-square test for nominal data. Discrete ordinal data were compared with the Wilcoxon rank-sum test. For pairwise comparisons, a Bonferroni-adjusted significance level of 0.0167 was used so that the total Type 1 error rate from the pairwise comparisons was no more than 0.05. Predictors of emergency CABG were determined by using a backwards selection method with multiple logistic regression. Significant predictors ($p < 0.05$) were reported as odds ratios and 95% confidence intervals (CI).

RESULTS

Characteristics of patients undergoing PCI. The baseline characteristics of the 23,087 patients who underwent PCI from 1979 to 2003 are shown in Table 1. Compared to Group 1, patients in Groups 2 and 3 were older (63.8 ± 11.4 years vs. 65.5 ± 11.9 years and 66.9 ± 12.1 years for Group 1 versus Groups 2 and 3, respectively, $p < 0.001$), and more likely to have diabetes (17% vs. 22% and 26%, respectively, $p < 0.001$), hypertension (49% vs. 61% and 74%, respectively, $p < 0.001$), and a greater body mass index (27.8 ± 4.6 kg/m^2 vs. 29.0 ± 5.2 kg/m^2 and 29.7 ± 5.7 kg/m^2, respectively, $p < 0.001$). Patients in the recent time periods were also more likely to have undergone prior PCI (23% vs. 32% and 36% for Group 1 vs. Groups 2 and 3, respectively, $p < 0.001$) or CABG (19% vs. 21% and 22%, respectively, $p < 0.001$) and were more likely to have

Table 1. Characteristics of Patients Undergoing Percutaneous Coronary Intervention

	Group 1 1979 to 1994 (n = 8,905)	Group 2 1995 to 1999 (n = 7,605)	Group 3 2000 to 2003 (n = 6,577)
Age (yrs)	63.8 ± 11.4	65.5 ± 11.9*	66.9 ± 12.1*
Male gender (%)	6,453 (72)	5,380 (71)	4,260 (70)
Diabetes mellitus (%)	1,531 (17)	1,700 (22)*	1,697 (26)*
Hypertension (%)	4,347 (49)	4,559 (61)*	4,613 (74)*
Body mass index (kg/m^2)	27.8 ± 4.6	29.0 ± 5.2*	29.7 ± 5.7*
Prior PCI (%)	2,067 (23)	2,429 (32)*	2,369 (36)*
Prior CABG (%)	1,664 (19)	1,619 (21)*	1,474 (22)*
Unstable angina (%)	6,460 (73)	5,084 (67)*	3,739 (57)*
Ejection fraction <40%	408 (5)	750 (10)*	753 (11)*
Type of PCI		*	*
Elective	7,287 (82)	2,966 (39)	2,204 (34)
Urgent	708 (8)	3,355 (44)	3,142 (48)
Emergent	909 (10)	1,276 (17)	1,228 (19)
Calcification in lesion (%)	2,032 (24)	2,918 (41)*	1,991 (33)*
ACC/AHA type C lesion	1,074 (32)	3,169 (46)*	2,532 (42)*
Total number of stents placed	0.1 ± .3	1.2 ± 1.1*	1.4 ± 1*
Glycoprotein IIb/IIIa used (%)	0 (0)	2,593 (34)*	3,907 (59)*

*$p < 0.001$ versus Group 1.
ACC/AHA = American College of Cardiology/American Heart Association; CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention.

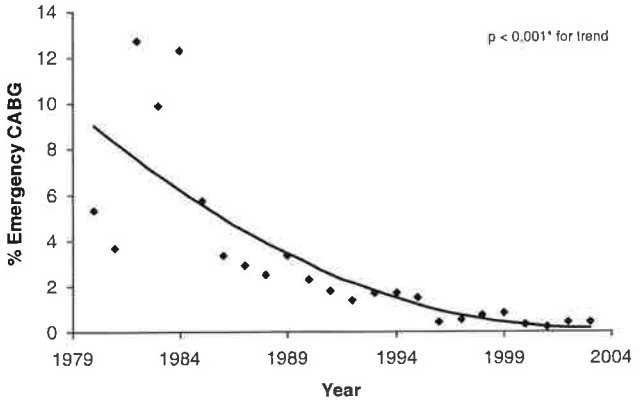

Figure 1. Percentage of patients requiring emergency coronary artery bypass grafting (CABG) after percutaneous coronary intervention from 1979 to 2003 (n = 23,087). *Armitage test for trend.

an ejection fraction <40% (5% vs. 10% and 11%, respectively, $p < 0.001$). Patients in Groups 2 and 3 were also more likely to have calcified (24% vs. 41% and 33% for Group 1 vs. Groups 2 and 3, respectively, $p < 0.001$) and type C coronary lesions (32% vs. 46% and 42%, respectively, $p < 0.001$). Despite a greater percentage of patients presenting with unstable angina (57% vs. 73% and 67%, respectively, $p < 0.001$), patients in Group 1 were less likely than those in Groups 2 and 3 to undergo urgent (8% vs. 44% and 48%, respectively, $p < 0.001$) or emergent procedures (10% vs. 17% and 19%, respectively, $p < 0.001$). There were a significantly greater proportion of stents used (0.1 ± 0.3 stents/patient vs. 1.2 ± 1.1 and 1.4 ± 1 stents/patient, respectively, $p < 0.001$) and glycoprotein IIb/IIIa inhibitors (0% vs. 34% and 59%, respectively, $p < 0.001$) in Groups 2 and 3.

In-lab death. The incidences of in-lab death were 35 (0.39%) in Group 1, 22 (0.29%) in Group 2, and 15 (0.23%) in Group 3 ($p = 0.06$ for trend).

Characteristics of patients requiring emergency CABG. Temporal trends in the proportion of patients requiring emergency CABG are shown in Figure 1. A significant decrease in the incidence of emergency CABG from 2.9% to 0.7% to 0.3% ($p < 0.001$ Armitage test for trend) was observed across the three groups. As shown in Table 2, patients requiring emergency CABG in the recent time periods had a higher prevalence of hypertension (39% vs. 56% and 65% for Group 1 vs. Groups 2 and 3, respectively, $p = 0.010$), prior PCI (19% vs. 3% and 24%, $p = 0.039$), and left ventricular dysfunction (5% vs. 13% and 24%, respectively, $p = 0.004$). These patients were also more likely than those in Group 1 to have undergone urgent (4% vs. 30% and 38% for Group 1 vs. Groups 2 and 3, respectively, $p < 0.001$) and emergent (15% vs. 45% and 38%, respectively, $p < 0.001$) procedures and have more complex coronary lesions.

During the study period, there was a significant change in reasons for emergency CABG (Table 2). Compared with the patients in Group 1, those in Groups 2 and 3 had a significantly lower incidence of abrupt vessel closure (21%

Table 2. Characteristics of Patients Requiring Emergency Coronary Bypass Surgery After Percutaneous Coronary Intervention

	Group 1 1979 to 1994 (n = 258)	Group 2 1995 to 1999 (n = 56)	Group 3 2000 to 2003 (n = 21)
Age (yrs)	62.4 ± 10.7	64.6 ± 10.0	53.5 ± 14.9
Male gender (%)	181 (70)	36 (64)	16 (76)
Diabetes mellitus (%)	23 (9)	3 (5)	2 (10)
Hypertension (%)	98 (39)	28 (56)*	13 (65)*
Body mass index (kg/m^2)	27.0 ± 4.1	28.4 ± 3.9	30.4 ± 4.3*
Prior PCI (%)	48 (19)	19 (34)*	5 (24)*
Prior CABG (%)	25 (10)	3 (5)	0 (0)
Unstable angina (%)	187 (72)	31 (55)*	13 (62)*
Ejection fraction <40% (%)	14 (5)	7 (13)*	5 (24)*
Type of PCI		*	*
Elective	210 (81)	14 (25)	5 (24)
Urgent	10 (4)	17 (30)	8 (38)
Emergent	38 (15)	25 (45)	8 (38)
Calcification in lesion (%)	54 (22)	30 (61)*	11 (65)*
ACC/AHA type C lesion	15 (29)	24 (56)*	9 (50)*
Total number of stents placed	0.1 ± 0.4	0.9 ± 1.1*	1.1 ± 1.4*
Glycoprotein IIb/IIIa used (%)	0 (0)	16 (29)*	11 (52)*
Indication for emergency CABG			
Abrupt vessel closure	55 (21)	2 (4)*	3 (14)*
Dissection	88 (34)	12 (22)*	3 (14)*
Incomplete revascularization	26 (10)	7 (13)	4 (19)
Perforation	1 (0.5)	1 (2)	2 (9)
Unsuccessful dilation	67 (26)	28 (50)	7 (33)
Other	21 (8)	6 (10)	2 (9)

*$p < 0.05$ versus Group 1.
Abbreviations as in Table 1.

Table 3. Predictors for Emergency Coronary Artery Bypass Grafting During the Pre-Stent Era (1979 to 1994)

	Odds Ratio	95% CI
Pre-procedure shock	2.35	1.33–4.13
Acute myocardial infarction	1.82	1.31–2.53
Canadian Cardiovascular Society angina class ≥3	1.81	1.35–2.42
Angulated segment (>45°)	1.66	1.27–2.17
Multi-vessel coronary disease	1.55	1.18–2.04

CI = confidence interval.

vs. 4% and 14% for Group 1 vs. Groups 2 and 3, respectively, $p < 0.001$) and coronary artery dissection (34% vs. 22% and 14%, respectively, $p < 0.001$) requiring emergency CABG. Patients requiring emergency CABG in Groups 2 and 3 were also more likely to have coronary artery stents placed (0.1 ± 0.4 stents/patient vs. 0.9 ± 1.1 and 1.1 ± 1.4 stents/patient, respectively, $p < 0.001$) and receive glycoprotein IIb/IIIa inhibitors (0% vs. 29% and 52%, respectively, $p < 0.001$).

Predictors of emergency CABG. During the pre-stent era (1979 to 1994) the strongest predictor for emergency CABG was pre-procedure shock (OR 2.35, 95% confidence interval 1.33 to 4.13). Other significant predictors (Table 3) included acute myocardial infarction, CCS score ≥3, lesion in an angulated segment (>45°), and multi-vessel coronary disease.

During the stent-era (1995 to 2003) the strongest predictor for emergency CABG was an emergent indication for PCI (odds ratio 3.77, 95% confidence interval 2.02 to 7.02). Other significant predictors (Table 4) were multi-vessel coronary artery disease, the presence of peripheral vascular disease, lesion in an angulated segment (>45°), and history of tobacco abuse.

Mortality rate of emergency CABG. Forty-one patients (31 in Group 1, 8 in Group 2, and 2 in Group 3) who had emergency CABG died during hospitalization. The in-hospital mortality rates of patients undergoing emergency bypass surgery are shown in Figure 2 and range from 10% to 14%. There was no significant difference in the mortality rates between the three groups. The most common causes of death (Table 5) were postoperative myocardial infarction (56%) and respiratory failure from pneumonia, acute lung injury, acute respiratory distress syndrome, or pulmonary embolism (19.5%). An unsuccessful PCI attempt was the most common indication for emergency CABG in these patients (53.7%).

Table 4. Predictors for Emergency Coronary Artery Bypass Grafting During the Stent Era (1995 to 2003)

	Odds Ratio	95% CI
Emergent PCI	3.77	2.02–7.02
Multi-vessel coronary disease	2.40	1.44–4.0
Peripheral vascular disease	2.28	1.24–4.17
Angulated segment (>45°)	1.90	1.19–3.03
History of smoking	1.88	1.07–3.28

CI = confidence interval; PCI = percutaneous coronary intervention.

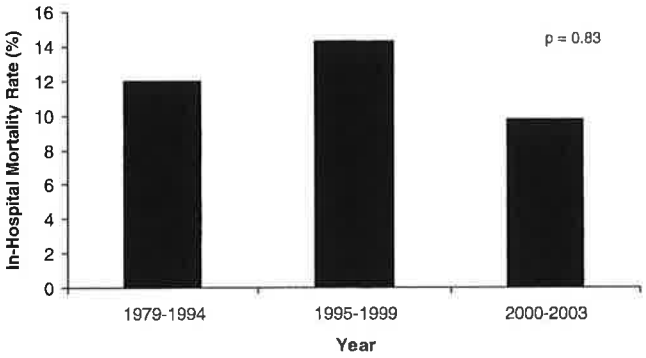

Figure 2. In-hospital mortality rates of patients requiring emergency coronary artery bypass grafting after percutaneous coronary intervention from 1979 to 2003 (n = 335).

One-year outcomes. In Groups 1, 2, and 3, respectively, 227, 48, and 19 patients who had emergency CABG survived to hospital discharge. The 1-year survival rates were similar in these patients (94.3%, 97.9%, and 87.7%).

DISCUSSION

The current study demonstrates that despite the increase in high-risk patients undergoing PCI, there has been a significant and sustained decrease in the incidence of emergency CABG. There has also been a change in the indication for emergency CABG, with fewer abrupt vessel closures and coronary artery dissections. These changes are likely due to improvements in interventional technology and medical therapy. The in-hospital mortality rate for those requiring emergency CABG, however, is unchanged and remains high.

Characteristics of patients undergoing PCI. Our results show that older and sicker patients are undergoing PCI. Patients in the more recent time periods were more likely to have hypertension, diabetes, and left ventricular dysfunction. Angiographically, these patients also had higher risk coronary disease with greater calcification and more severe ACC/AHA lesion scores. Similar findings were noted in a prior study involving patients from the National, Heart, Lung, and Blood Institute Registry (4). A possible explanation for the increase in high-risk patients is that the

Table 5. Cause of Death and Indication for Bypass Surgery in 41 Patients With In-Hospital Death After Emergency Surgery

Cause of death	
Postoperative myocardial infarction	23 (56)
Cardiac arrhythmia	8 (19.5)
Respiratory failure	5 (12.1)
Heart failure	3 (7.3)
Cerebrovascular accident	1 (2.4)
Ventricular rupture	1 (2.4)
Indication for CABG	
Unsuccessful dilation	22 (53.7)
Dissection	5 (12.2)
Incomplete revascularization	5 (12.2)
Abrupt vessel closure	3 (7.1)

Values are n (%). Respiratory failure includes pneumonia, acute lung injury, acute respiratory distress syndrome, and pulmonary embolism.

widespread use of coronary artery stenting has resulted in an improvement in PCI outcomes. These improvements may have allowed more high-risk patients to undergo PCI.

Although more high-risk patients are undergoing PCI, the in-lab death rate has remained the same. This finding, along with the decrease in emergency PCI rates, suggests that improvements in PCI have resulted in fewer complications, but if a major complication occurs, the mortality rate remains unchanged by the newer technologies.

Incidence of emergency CABG. Despite the increase in high-risk patients undergoing PCI, we found a 10-fold reduction in the incidence of emergency CABG, from 2.9% to 0.3%. These data are similar to the rates reported by Seshadri et al. (6) from the Cleveland Clinic, who reported a rate of 0.61%. Our results are also consistent with those from six trials comparing coronary artery stenting to angioplasty. This analysis demonstrated that 0.31% of patients in the most recent time period undergoing primary PCI required emergency CABG (11). The decline in the incidence of emergency CABG is most likely due to the development of coronary artery stents and glycoprotein IIb/IIIa inhibitors (12,13).

The patients requiring emergency CABG in the current-stent era were also older and sicker than the patients in the pre-stent era. This may be a reflection of the increase in high-risk patients undergoing PCI.

Indications for emergency CABG. There was a significant change in the indications for emergency CABG after PCI, with a decrease in the incidence of abrupt vessel closure and coronary artery dissection resulting in the need for emergency CABG. Both of these changes are most likely due to the increased use of coronary artery stents and glycoprotein IIb/IIIa inhibitors, which reduce the risk of abrupt vessel closure and can be used to treat coronary artery dissections (14).

There has also been a change in the predictors of emergency CABG. In the pre-stent era, the presence of pre-procedural shock was the strongest predictor. In the stent era, shock is no longer a significant predictor and again may be due to improvements in PCI technology.

Outcomes of emergency CABG. Although there has been a change in the characteristics and indications for emergency CABG, the in-hospital and one-year mortality rate for these patients remains the same, underscoring the need to recognize variables associated with higher incidence of emergent CABG, and tailor strategies to avoid or reduce such complication. We observed a mortality rate of 10% to 14%, which is similar to the rate of 15% reported by Seshadri et al. (6). These rates are much higher than those for elective CABG, and a previous study suggests that the high mortality rate may be due to the hemodynamic instability that is present at the time of emergency surgery (15). This instability can lead to a lower probability of receiving an internal mammary graft and a greater requirement for inotropic support and blood products (15,16). The most common causes of death in these patients were postoperative myocardial infarction and cardiac arrhythmias. Emergency CABG has also been associated with longer hospital stays, increased risk of postoperative myocardial infraction, and a greater prevalence of ventricular arrhythmias (16).

Study limitations. A limitation of the current study is that it was a retrospective review of outcomes at a single high-volume center. The results may therefore not be applicable to other centers with lower volumes.

Conclusions. In conclusion, the results of the current study show that despite the increase in high-risk patients undergoing PCI, there has been a dramatic decrease in the incidence of patients requiring emergency CABG. In addition, there has been a change in the indication for emergency CABG, with a decrease in the incidence of coronary artery dissections and abrupt vessel closure. The mortality rate associated with emergency CABG, however, remains high and unchanged.

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Safety of elective—including "high risk"—percutaneous coronary interventions without on-site cardiac surgery

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Background Current guidelines (American College of Cardiology/American Heart Association) for percutaneous coronary intervention (PCI) limit the performance of elective cases to hospitals with the capability for cardiac surgery. The number of hospitals in the United States with this capability is limited, which restricts availability of this proven technology.

Objective To determine the safety of performing elective, nonselected PCI in hospitals without cardiac surgery capability.

Design, setting, and patients A single-center retrospective analysis of the first 1000 patients undergoing elective, including "high-risk," PCI in the county hospital in Phoenix, Arizona.

Main outcome measures A database (Access Microsoft Windows) was established to follow patient characteristics, indications for the procedure, technical aspects of the procedure, outcomes and complications. The Quality Improvement Committee followed each case closely to independently assess the adequacy of indications and patient management, with a monthly case review of every patient who had a periprocedural or postprocedural complication.

Results Failure to complete target vessel revascularization occurred in 68 of the total 1756 vessels (3.8%). Seven patients (0.7%), required elective referral for coronary artery bypass graft surgery after failed PCI. Coronary perforations occurred in 9 patients (0.9%); all resolved with percutaneous techniques. Postprocedure myocardial infarction was diagnosed in 21 patients (2.1%). Two patients (0.2%) developed a stroke. Periprocedural death (within 48 hours of the procedure) occurred in 2 patients (0.2%). Out of the 1000 interventions performed, none required emergency coronary artery bypass graft surgery.

Conclusions Technical advances in interventional cardiology allow for safe performance of PCI in hospitals without on-site cardiac surgery facilities if proposed conditions are met. Our results together with the vast experience in other countries supports a paradigm change that would increase the number of hospitals that can offer interventional cardiology procedures with a corresponding increase in the number of patients that would benefit. (Am Heart J 2004;148:676–83.)

Current guidelines from the American College of Cardiology/American Heart Association (ACC/AHA) for percutaneous coronary intervention (PCI) recommend the performance of elective PCI only in hospitals with cardiac surgery capabilities.

The performance of primary PCI for patients with acute ST-elevation myocardial infarction or new left bundle-branch block in the clinical setting of acute myocardial infarction is considered a class IIb indication if high-volume operators and an institution with a high volume are available along with an established proven plan for rapid access to cardiac surgery at a nearby facility within 1 hour.[1]

Since the first coronary angioplasty by Gruentzig in 1977, the role of emergency coronary artery bypass graft (CABG) surgery following failed PCI has changed dramatically. Increasing operator expertise together with significant technical advances including generalized use of intracoronary stents and new antiplatelet therapies have reduced the need for emergency CABG surgery to <0.5%.[2–5] We report our observational experience in the first 1000, elective, nonselected PCI procedures in a hospital without on-site cardiac surgery capability.

Methods

Maricopa Medical Center (MMC) is the county hospital in Phoenix, Arizona. It is a full-service, 541-bed hospital that sees nearly 20,000 inpatient admissions every year.

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Maricopa Integrated Health System (MIHS) is the health care safety net for citizens of Maricopa County. The health system serves people of many races and nationalities who come from diverse cultures and speak several different languages. Many of the patients face major challenges, such as lack of health insurance, complex medical problems, and difficult socioeconomic situations.

In August 1998 we opened our diagnostic cardiac catheterization laboratory,

staffed from the beginning by 2 experienced interventional cardiologists who routinely performed PCI at nearby facilities that have on-site cardiac surgery. The technical and nursing staff was also experienced in periprocedural and postprocedural care.

Over 4000 diagnostic procedures have been performed since then, requiring the addition of another interventional cardiologist to the full-time staff. During the first 2 years, patients requiring coronary intervention were transferred to a nearby hospital for either CABG surgery or elective PCI, performed by our own cardiology staff. In October of 2000, we launched the interventional program at MMC.

Patient eligibility protocols were developed and approved by the internal review board at MMC. During the first 3 months, only "low-risk" cases were approved for PCI, but with the growing demand and enormous success of the program, a decision was made to perform all cases at MMC. Patients were given the option to be transferred to nearby hospitals for their intervention after thorough explanation of the procedure and clear understanding that emergency cardiac surgery could not be performed on-site. Only 11 patients elected the alternative option. Eighty-three patients had their procedure, diagnostic and/or interventional, at the surgical facility, due to overload of our own cardiac catheterization laboratory.

From the beginning, a database (Access Microsoft Windows) was established to follow patients characteristics, indications for the procedure, technical aspects of the procedure, outcomes and complications. The Quality Improvement (QI) committee followed each case closely and collected the data to independently assess the adequacy of indications and patient management, and conducted a monthly case review of every patient who had a peri- or postprocedural complication.

Immediate transfer for emergency CABG surgery was ensured with an arrangement with emergency medical services to transport patients to a nearby medical center, located 1.5 miles away. The cardiac catheterization laboratory was fully equipped, including intra-aortic balloon pumps (IABP), thrombectomy equipment, and polytetrafluoroethylene (PTFE)-covered stents to provide necessary support to manage complications and provide safe transfer in case of need.

The first 1000 elective cases are the subject of this report. During this period, 89 primary angioplasties (in patients with acute ST-elevation myocardial infarction) were performed with excellent outcomes, but are not considered in this report since the focus of this paper is on elective PCI.

Interventional procedure

PCI was performed during the initial diagnostic catheterization (ad hoc) in most cases (96%). Use of eptifibatide or tirofiban was routine except when clear contraindications existed and overall were used in 978 patients (97.8%). Heparin was used as a 60 units per kilogram body weight bolus before the intervention. Activated clotting time was measured only during very prolonged and complicated interventions when the operator considered that extra heparin might be necessary.

All patients received clopidogrel 300 mg after completion of the procedure and 75 mg per day at least during the first month postprocedure, along with aspirin 81 mg. Stents were used in most interventions, with 1636 stents used in a total of 1759 vessels that were intervened (93%). Prophylactic IABP was used at the discretion of the operator for high-risk intervention in patients with poor left ventricular function undergoing multivessel stenting or unprotected left main intervention. Only 19 patients (1.9%) received the IABP.

Patient characteristics

The clinical characteristics of our population showed a significant predominance of male patients (632; 63%) versus female patients. The mean age was 63 years (range 35-92). Main comorbidities are depicted in Figure 1.

Angiographic characteristics

Interventions were performed in 1759 vessels in our first 1000 patients, with an average of 1.7 vessels per patient. Distribution of revascularized vessels is depicted in Figure 2. In 49 patients with previous CABG surgery, the left main coronary artery was intervened (4.9% of patients). Nineteen patients (1.9% of all patients) had unprotected left main intervention. PCI was performed in these patients either because of patient preference with refusal to undergo CABG surgery or because the patient was considered not eligible for surgery after consultation with cardiac surgery.

Single-vessel intervention was performed in 469 patients (46.9%). Two-vessel intervention was performed in 348 patients (34.8%), and 3-vessel intervention was performed in 156 patients (15.6%). Four or more vessels were revascularized in 27 patients (2.7%). Chronic total occlusions (CTOs) were successfully revascularized in 28 patients (2.8%) and failed in 35 vessels. Overall success rate, considered as target vessel revascularization with <30% residual stenosis, was 96.2% (Figure 2).

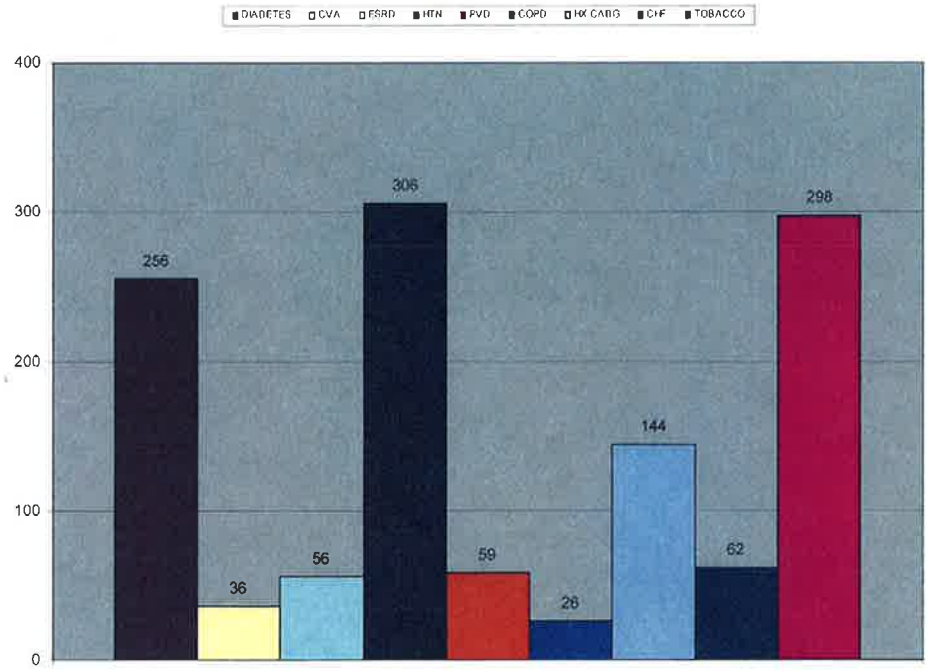
Analysis of the type of lesions (ACC/AHA classification) that were revascularized showed 27% were type A lesions, 22% type B1, 31% type B2, and 20% type C (Figure 3).

Complications

Failure to complete target vessel revascularization (TVR) occurred in 68 of the total 1756 vessels (3.8%), with a majority occurring in CTOs (35 vessels). Seven patients (0.7%) required elective referral for CABG surgery after failed PCI, with the remaining patients opting for medical treatment (32 patients). Non-planned IABP placement due to hemodynamic instability occurred in 7 patients (0.7%), with all of them ending up having successful revascularization and uneventful recovery.

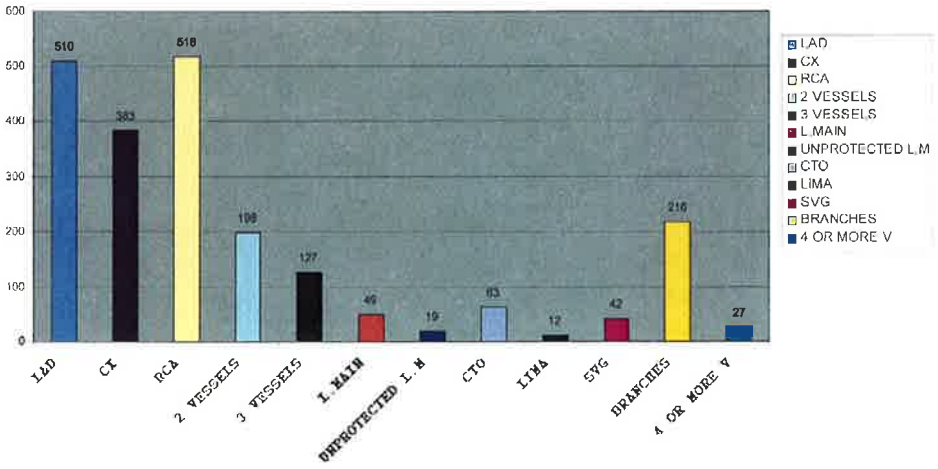
Coronary perforations occurred in 9 patients (0.9%). Four of these patients required emergent pericardiocentesis due to tamponade. Five vessels were successfully treated with a covered stent (Jomed stent), and in 3 patients the perfo-

Figure 1



Patient comorbidities.

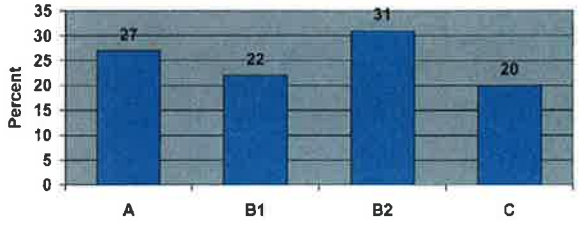
Figure 2



Vessels intervened.

ration was treated with reversal of anticoagulation together with prolonged perfusion balloon inflation. One patient had a perforation involving the distal segment of the vessel and required treatment with coil embolization. Two of these patients with perforation had enzyme elevation postprocedure that was diagnostic of periprocedural myocardial infarction. Three patients (0.3%) required cardiopulmonary resuscitation and intubation during the interventional procedure with successful results and uneventful recovery.

Figure 3



Lesion types, ACC/AHA classification.

Postprocedure MI was diagnosed when the creatine phosphokinase-MB was >3 times the baseline level; this occurred in 21 patients (2.1%), including the patients already described that had coronary perforations. Two patients (0.2%) developed a stroke after their PCI (within 48 hours) with no evidence of intracranial bleed on computed tomography (CT). Each patient required an extended hospital stay with residual neurologic sequelae. In 39 patients (3.9%), access site hematomas (>3 cm in size) were diagnosed that did not require blood transfusion or further intervention, with all of them recovering uneventfully. In 6 patients (0.6%), major access site complications occurred, including need for transfusion (5 patients), surgical revision (2 cases of femoral artery pseudoaneurysm and 1 case of brachial artery occlusion) or percutaneous intervention (1 to treat an occlusive dissection in an iliac artery treated with stent placement and 1 case with iliac perforation treated with a covered stent [Wallgraft]). Two patients (0.2%), developed progressive renal failure attributed to the procedure that stabilized with medical management not requiring dialysis.

Periprocedural death (within 48 hours of the procedure) occurred in two patients (0.2%), with 11 inhospital deaths (1.1%). The deaths of 9 other patients during the same hospitalization when the PCI was performed were considered unrelated to the procedure; they occurred as the result of other multiple medical or surgical conditions. The 2 cases of periprocedural death were related to bleeding complications while on tirofiban, without evidence of vascular injury on emergent angiography.

Of significant interest is the fact that out of the 1000 interventions performed, no case required emergency CABG surgery (Figure 4).

Discussion

The early experience with PCI was characterized by frequent complications, including coronary dissection, acute recoil, coronary perforation, and coronary thrombosis.[6] The early years demanded "surgical standby" for emergency CABG surgery, which was frequently required to salvage patients from these dreaded complications. The performance of PCI was predicated on the availability of on-site cardiac surgery.

In many foreign countries, the formal requirement for on-site cardiac surgery for the performance of PCI has slowly changed. In the British Cardiac Society Guidelines, of 20,511 PCI procedures performed in the United Kingdom in 1996, 1382 (7%) were performed in 6 centers without on-site cardiac surgical capabilities.[7] Emergency CABG within 24 hours was required in 1.5% of patients. Surgical backup, whether on-site or off-site, was recommended for all coronary angioplasty procedures.[7]

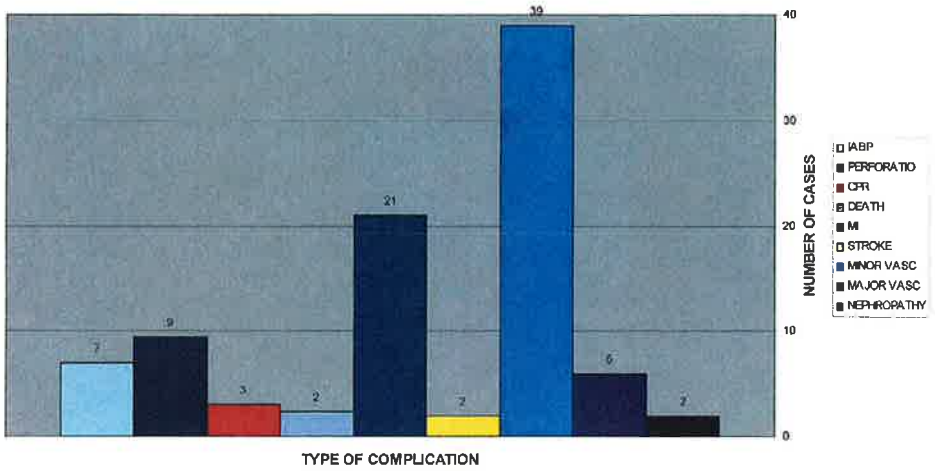
In Israel, a recent publication[8] reports 11 years of experience of performing PCI without surgical support. In Canada, the Cardiac Care Network of Ontario[9] has recommended to the Ontario Ministry of Health that pilot programs be set up in Ontario to perform coronary angioplasty (both primary and elective) at hospitals without on-site surgical backup.

Increasing experience in PCI as well as several technical improvements, primarily the routine use of stents, has dramatically reduced the need for emergency surgical revascularization. The role of heart surgery has switched from the emergency treatment of the frequent complications of PCI to the timely revascularization of subjects not suitable for percutaneous interventions. Thus, the performance of PCI at centers without on-site surgical facilities is gaining widespread acceptance.

Loubeyre et al[2] reported a retrospective (1995) and prospective (1996) registry that analyzed the incidence, indication, and results of emergency CABG surgery performed within 24 hours of PCI in 68 and 57 centers, respectively, accounting for nearly half of all angioplasty procedures in France. Over the 2 years, 26,885 and 27,497 procedures were investigated, with a stenting rate of 46% and 64%, respectively. The observed need for emergency surgery was constantly low throughout this period (0.38% and 0.32%, respectively). Indications for surgery included complications directly due to PCI in 37% of cases in the 2-year period. Outcome remained poor, with inhospital mortality in 10% and 17% and myocardial infarction in 27% and 25% of cases, respectively. A comparison of the results in centers with and without surgical facilities showed no differences in outcome, despite a longer time to surgery (359 min ± 406 min vs 170 min ± 205 min, $P = .0001$) and a lower incidence of emergency surgery (0.25% versus 0.44%, $P = .0001$) in centers without on-site surgery backup. The French multicenter registry revealed an increase in the use of stents together with a dramatic decrease in the incidence of emergency CABG surgery (below 0.5%) following PCI.

In the United States, Ting et al[10] studied the safety and efficacy of performing low-risk elective and acute infarct PCI at a community hospital without cardiac surgical capability. Procedural success was achieved in 195 (99.5%) patients, with 1 (0.5%) inhospital death.

Figure 4



Complications.

No patients required transfer to another facility for emergent cardiac surgery for a procedure-related complication. They conclude that low-risk elective and acute infarct PCI can be performed with safety and efficacy at a community hospital without cardiac surgical capability by following rigorous standards.

The complications of PCI that can lead to emergency surgery are: 1) flow limiting dissection; 2) abrupt closure; 3) occlusion of a large side branch during the procedure, with an inability to restore patency percutaneously; and 4) coronary artery perforation. In recent years, there has been a steady decline in the frequency of dissections and abrupt closures. The explanations are multifactorial, but the use of coronary artery stents has been the most important factor.[11] Glycoprotein IIb/IIIa receptor inhibitors also reduce the need for emergency CABG in patients undergoing PCI.[12] In an analysis of pooled data from 2 trials (Evaluation of Platelet IIb/IIIa Inhibitor for Stenting and Evaluation of Percutaneous Transluminal Coronary Angioplasty to Improve Long-term Outcome With Abciximab Glycoprotein IIb/IIIa Blockade), the incidence of cardiac surgical procedures was 1.28% in patients receiving abciximab, which is substantially lower than the incidence of 2.17% in the placebo group (relative risk reduction 41%, $P = .021$).[12]

Coronary perforations, particularly if they are severe or occur in patients treated with glycoprotein IIb/IIIa inhibitors, may not respond to prolonged balloon inflation or pericardiocentesis and may require emergency CABG surgery, but this complication is rare.[13] Use of a coronary stent covered with PTFE membrane reduces the need for CABG in such cases.[14]

The establishment of cardiac surgery programs for the sole purpose of supporting PCI is quite controversial. The surgical volume will most likely be insufficient to be cost-effective but also outcomes might be jeopardized. Immediate death rates (death during the hospital admission) with CABG surgery vary widely, from lows of 1% to highs approaching 15% and perhaps higher. Research from the United States demonstrates clearly that there is a volume effect. Centers and surgeons with higher volumes have lower immediate mortality. The volume effect persists even at relatively high levels, that is, >650 procedures a year for a hospital and >116 procedures a year for a physician. This fact strongly supports regulation to centralize CABG surgery facilities.[15] A recent study[16] showed how mortality decreased ($P < .001$) with increasing volume (3.6% in low [<500 cases], 3.0% in moderate [500-1000 cases], and 2.0% in high [>1000 cases] volume hospitals).

The impact of new technology, specifically the availability of drug-eluting stents, will clearly have an impact on CABG surgery volume. Surgical indications will be further reduced to the technical pitfalls of stenting (complex or tortuous anatomy, chronic occlusions, multiple tandem lesions).

An important question is whether the availability of on-site cardiac surgery influences the interventionist in deciding for surgical referral against a more aggressive PCI approach to solve the complication. Results of emergency CABG surgery after PCI complications are poor even in hospitals with on-site cardiac surgery.[2] In a recent review,[17] emergency CABG surgery for failed PCI is still associated with important morbidity and

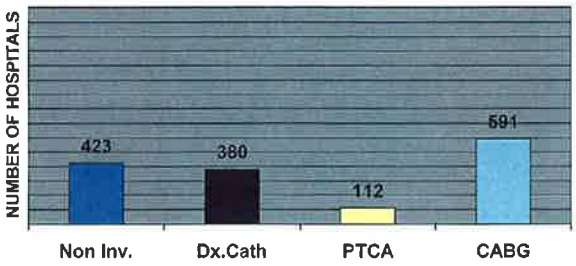
mortality. In 18,593 PCI procedures performed from 1992 through 2000, there was a need for emergency CABG surgery in 113 (0.61%) cases. The major indications were extensive dissection (n = 61, 54%), perforation/tamponade (n = 23, 20%), and recurrent acute closure (n = 23, 20%). Prevalence of emergency CABG surgery decreased from 1.5% of PCI cases in 1992 to 0.14% in 2000 ($P < .001$) In patients undergoing emergency CABG surgery, there were 17 (15%) inhospital deaths, 14 (12%) perioperative Q-wave myocardial infarctions, and 6 (5%) strokes.

The experience and competency of the interventionist is clearly an important factor. There is clearly an association between institutional and individual procedural volumes and clinical outcome, including mortality.[18] Current American College of Cardiology/American Heart Association (ACC/AHA) recommendations suggest that an individual operator should perform at least 75 cases annually to remain competent.[1] Hamad et al[19] studied the results of 781 PCI procedures performed at 1 institution by either high- (>100 procedures per year) or low-volume operators (<100 procedures per year) and concluded that low-volume operators had poorer outcomes when more complex lesions were involved. Another study[20] involving 2350 PCIs performed by high- (>50/y) and low-volume operators (<50/y) at a single institution found differences in the rates of emergency CABG surgery (2.1% for high-volume, 3.9% for low-volume operators .

Jollis et al[21] studied 1992 Medicare discharge abstracts for 97,478 patients who had PCI performed by 6115 physicians. The rates for inhospital CABG surgery were 3.8%, 3.4%, and 2.6% for patients treated by physicians with an average volume of <25, 25-50, and >50 PCI procedures per year, respectively ($P < .001$). A study of the 1991 to 1994 New York State experience,[22] with 62,670 patients treated by >100 physicians, discovered significant differences in patients undergoing PCI performed by cardiologists with annual volumes <75/year. These patients had a risk-adjusted mortality rate of 1.03%, compared with 0.90% for all patients, and a same-stay risk-adjusted CABG surgery rate of 3.95%, compared with 3.43% for all patients. Ellis et al[23] analyzed databases from 5 high-volume centers involving 12,985 patients undergoing PCIs during 1993 to 1994 and also found a significant, inverse relation between operator volume and the combined end point of death, Q-wave myocardial infarction, or the need for emergency CABG surgery.

The relationship of appropriate revascularization to the availability of PCI capability has been reported. Women, ethnic minorities, and uninsured persons receive fewer cardiac procedures than affluent white male patients do.[24] Hospitals that provided on-site revascularization had higher use rates (76%) than hospitals that did not provide it (59%). In hospitals that did not provide on-site revascularization, uninsured patients were less likely to have revascularization recommended to them (52%).

Figure 5



NMRI registry. Among the 1506 participating registry hospitals, 423 (28.1%) were classified as noninvasive, 380 (25.2%) as cath-capable, 112 (7.4%) as percutaneous coronary angiography-capable and 591 (39.2%) as CABG-capable. From Rogers et al.[26]

The availability of qualified hospitals and operators is the chief limitation to the widespread application of PCI in patients who require it. Approximately 840 community hospitals in the United States that have cardiac catheterization laboratories do not have cardiac surgery facilities.[25] A report of the National Registry of Myocardial Infarction (NRMI-2) showed that among the 1506 participating registry hospitals, 423 (28.1%) were classified as noninvasive, 380 (25.2%) as catheterization-capable, 112 (7.4%) as percutaneous transluminal coronary angioplasty-capable, and 591 (39.2%) as CABG-capable (Figure 5).[26] Many of these hospitals are staffed by experienced and active interventionalists. In view of the growing population in need of PCI and the decreasing role of CABG surgery to revascularize these patients, the established requirement to have on-site cardiac surgical capability has to be reviewed to evaluate whether PCI can be extended safely and effectively to these primary care hospitals.

This paper reports for the first time in the United States the safety of performing elective, non selected, including high-risk cases of PCI in a hospital without cardiac surgery capability. Our experience is significant since it mimics the conditions present in many hospitals in this country, where experienced interventionalists are available and where diagnostic cardiac catheterization laboratories are underutilized due to the dogma of the requirement for surgical back-up.

We believe that our results together with the vast experience in other countries supports a paradigm change that would increase the number of hospitals that can offer interventional cardiology procedures with a corresponding increase in the number of patients that would benefit.

We suggest the following standards for the performance of elective and primary angioplasty at community hospitals without cardiac surgery:

- The operators must be experienced interventionalists who regularly perform elective intervention.
- The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated angioplasty laboratories at a surgical center. They must participate in a 24-hour 365-day 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.
- Formalized written protocols for immediate and efficient transfer of patients to the nearest cardiac surgical facility must be in place.
- The volume of yearly procedures performed by each operator should be high enough (according to ACC/AHA guidelines) to ensure continued competency.
- Primary intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction, to ensure streamlined care paths and increased case volumes.
- There must be an ongoing program of outcomes analysis and formalized periodic case review.

Limitations

This is a single-center experience. Conditions required to establish a safe elective PCI program might be difficult to meet at other hospitals. We believe, however, that results similar to ours can be achieved by cardiologists and institutions that establish programs that adopt rigorous standards such as those proposed. Our data were collected retrospectively, although complications were followed on a daily basis by an experienced nurse with expertise in quality assurance programs. The hospital quality assurance committee evaluated each complicated case during monthly meetings. A team of independent consultants was assigned by the hospital administration to evaluate the appropriateness of the interventional program. Their findings supported the continuation of the program.

We thank the hospital administration at Maricopa Medical Center without whose enthusiastic support this work would not have been possible. The excellent work of Ellen Horton, RN, in data collection and Curt Bay, PhD, in statistical analysis is paramount to the publication of our work. We particularly wish to acknowledge the invaluable contributions of the catheterization laboratory team, Jeff Weddle, RN, Ann Kelly, RN, Kelly Johansen, RN, and David Pigg, RT, whose dedicated service and commitment to an intensive work schedule were integral to the success of our program. Special mention must be made of our cardiovascular technician, Vincent Romero, who contributed his experience and skills to the excellent outcomes achieved.

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heartwire

INTERVENTIONAL/SURGERY

C-PORT E: Elective PCI doesn't require surgical backup

NOVEMBER 14, 2011 Lisa Nainggolan

Orlando, FL - Patients who had elective PCI at experienced US hospitals without on-site cardiac surgery fared no worse than those who had the same procedure at institutions with surgical backup, a new study shows.


Dr Thomas Aversano

The mortality rate after six weeks was almost the same for each group, at just under 1%, said **Dr Thomas Aversano** (Johns Hopkins Medical Institute, Baltimore, MD), who presented the findings of the **Cardiovascular Patient Outcomes Research Team Elective** (C-PORT E) study during a late-breaking clinical trial session here today at the **American Heart Association (AHA) 2011 Scientific Sessions.**

"The key finding is that the patient-related medical outcomes, at least the short-term safety outcomes, of elective angioplasty are the same, regardless of the hospital type," Aversano told **heartwire.** He added that his team will have data on how patients fared nine months after the procedure early next year. And he stressed: "The purpose of the trial was not to expand the number of centers doing angioplasty but to give healthcare policy makers—who can make rational decisions about access, quality, and cost of angioplasty care in their state—some information on which to base their decision."

The discussant of the findings, surgeon **Dr Loren F Hiratzka** (Bethesda North and Good Samaritan Hospitals, Cincinnati, OH), said the results are important, but it has to be borne in mind that very specific conditions were in place in this study. He and others warned that there could be "unintended consequences" of moving elective PCI out into the community. "The real central question is, 'Can these results be reproduced in general community practice?' " noted Hiratzka.

> The purpose of the trial was not to expand the number of centers doing angioplasty but to give healthcare policy makers some information.

Speaking during the press briefing, **Dr Robert Harrington** (Duke Clinical Research Institute, Durham, NC) agreed: "The issue of unintended consequences is worth pausing on. In the angioplasty world, the **American College of Cardiology** (ACC)/**AHA** recommendations recommend 75 cases a year as the minimum volume. There are states in this country where the median volume for an interventional cardiologist is 50 cases a year. We need to ask ourselves, is that really what we want?

> The real central question is, 'Can these results be reproduced in general community practice?'

"What we need to insist upon as we embark upon broadening the use of these procedures in the community is that all those steps [employed in C-PORT E] don't get forgotten in the zeal. This is an incredibly important topic that has both medical-care and policy implications attached to it."

Guidelines committee will consider the evidence

Asked by **heartwire** to comment on the C-PORT E data, **Dr Alice Jacobs** (Boston, MA)—who is the principal investigator of a very similar ongoing trial called MASSCOMM—said: "I think this is an important study. The practice across the country—absent data—is moving toward performing nonemergency PCI in hospitals without on-site surgery. Now we have the evidence."


Dr Alice Jacobs

"If you can show that you provide the same outcomes and do it in the fashion that C-PORT E is doing it—which is high-volume physicians, well-trained staff, specific criteria about things that you should tackle and you shouldn't tackle without on-site surgery—and if it appears to be safe, for which we'll wait for Dr Aversano's long-term outcomes and the MASSCOMM study, then I think the guidelines committees will consider the evidence."

She added that the new ACCF/AHA guidelines on PCI and CABG, released only last week, did update the recommendations on elective PCI without on-site surgery, which "is now class IIb from a class III recommendation, which means it's reasonable to consider it."

New studies such as C-PORT E will be considered on a case-by-case basis to see if they warrant updating the

New mitral-repair therapies face obstacles
FEB 10, 2012 16:30 EST

recommendations, she noted.

However, she too cautioned that many things need to be taken into consideration when looking at this issue. "It's not the focus on having on-site surgery available in 2011, because the emergency surgery rate is very low. What on-site surgery has represented in the past is a surrogate for volume and quality. If you have a patient with complex disease, it's taking that step back and calling the surgeons to the cath lab and getting that combined opinion, which is critically important."

Another issue that hasn't been addressed, she says, is, "How will we maintain the volume in tertiary sites to train our young interventionalists when the care moves into the community?"

Bridge to ICD Implantation

Making Same-Day Discharge after PCI a Reality: What You Need to Know

A Balanced Approach to PCI: Treating Ischemia and Eliminating Bleeding

More

A 77-Year-Old Man With Prior DES PCI of Culprit RCA Undergoes FFR-Guided PCI of LAD and/or LMCA

An 86-Year-Old Woman With Prior DES PCI of Mid-LAD Undergoes Rotablation and DES of Complex Calcified Lesions

C-PORT E details

Aversano said one of the motivating factors for conducting the trial was that, as more and more centers have started to perform primary PCI for ST-elevation myocardial infarction (STEMI) without cardiac surgery backup, they have discovered that sustaining the volume of patients required to keep a program viable is difficult, so they have started to add elective PCIs.

In the C-PORT E trial, more than 18 500 patients were randomized on a 3:1 basis to PCI centers with cardiac-surgery capabilities or hospitals without surgical backup. The 60 institutions without surgery capabilities had to be able to perform at least 200 PCIs per year, although a "startup" figure of 100 was allowed in the first year, he noted, with a median of 150 annual procedures.

In a panel discussion that followed his presentation, he noted that some hospitals had been asked to leave the study because they had not performed enough procedures, but he did not yet have data on outcomes from those institutions.

Dr Robert Harrington

The interventionalists in the study were required to perform more than 75 PCI cases per year, and all centers underwent a formally developed PCI program.

Mortality at six weeks was 0.93% in the surgical-backup group, compared with 0.91% in the no-surgical-backup group (p=0.94).

PCI success was >90% in both groups but lower in those randomized to hospitals without surgery on-site (success rate difference of 1.1% on a per patient basis). Emergency CABG was rare but occurred more frequently in those randomized to hospitals with surgery on-site compared with those with no surgical backup (0.2% vs 0.1%). The incidence of bleeding, vascular repair, stroke, and renal failure was similar in both groups.

Access vs convenience; should states limit the number of PCI centers?

During a panel discussion following his presentation, Aversano was asked whether PCI centers had to be a certain distance from a tertiary centers as a study requirement. This was the case in some states, but not others, he said.

Dr Eric Peterson (Duke Clinical Research Institute, Durham, NC) wondered whether there should be a requirement that, if there is a program close by, "we would not institute another program," as his colleague **Dr Manesh Patel** (Duke Clinical Research Institute), observed that, "in some cities and places, there are 30 or 40 centers performing PCI that are not that far apart."

"Yes, I completely agree," noted Aversano. He added that one of the main reasons for doing this study was that "the colocation" requirement, whereby it is recommended that PCI centers are backed up by surgical facilities, "tends to spur on a kind of metastases of surgical programs just to back up angioplasty. So if there is evidence that we can separate them, it doesn't mean having more angioplasty programs, it means they don't have to be colocated necessarily."

> In some cities and places, there are 30 or 40 centers performing PCI that are not that far apart.

Dr Loren F Hiratzka

Hiratzka, the surgeon, commented: "It clearly is an issue going forward. As a patient, is it better to take the 20-minute trip to a place that has surgery or a 10-minute trip to a place that does not, provided you can provide the same level of service for PCI in both?"

Aversano noted: "I want to dispel this 'convenience myth,' because it sort of irks me a little bit. There is an access issue, not just a convenience issue, especially for those in more rural areas. They are not 20 minutes away [from big tertiary centers], they are an hour or an hour and a half away. That's the big town, with doctors they don't know, at a great cost to their family when they have to come to visit them. There are a lot of factors that go into making that decision about where they want to go."

> I want to dispel this 'convenience myth,' because it sort of irks me a little bit. There is an access issue, not just a convenience issue.

Jacobs agreed: "There are multiple motivations for moving care into community hospitals. A lot of it is not necessarily access to care but convenience of care, and that's important as well."

Peterson said another unintended outcome might derive from the volume question, "which might have the unexpected consequence of driving more procedures to be done, maybe in cases where the appropriateness is borderline, just in order to reach the volume targets."

Aversano agreed: "My hope in this study was to create information that would be used by regulators to inform those decisions. It's up to the policy makers to decide in the end."

Hiratzka declared no conflicts of interest.

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Whither ATP 4? JNC 8? Obesity 2? AHA gets guideline updates, not answers
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NEXT HEARTWIRE ARTICLE »
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Related links

- **New PCI, CABG guidelines emphasize team approach** [*Interventional/Surgery* > *Interventional/Surgery*; Nov 07, 2011]
- **The ABCs of the impact of the C-PORT E study**

Attachment E

Demographic Information

L+M Service Area by Zip Code and Town

PSA = primary service area, SSA = secondary service area

Postal Service Zip Code and Town	CHA Town (1)	Service Area
06320 New London	New London	PSA
06333 East Lyme	East Lyme	PSA
06335 Gales Ferry	Ledyard	PSA
06338 Mashantucket	Ledyard	PSA
06339 Ledyard	Ledyard	PSA
06340 Groton	Groton	PSA
06349 Groton	Groton	PSA
06353 Montville	Montville	PSA
06355 Mystic	Groton	PSA
06357 Niantic	East Lyme	PSA
06359 North Stonington	North Stonington	PSA
06370 Oakdale	Montville	PSA
06371 Old Lyme	Old Lyme	PSA
06372 Old Mystic	Stonington	PSA
06375 Quaker Hill	Waterford	PSA
06376 South Lyme	Old Lyme	PSA
06378 Stonington	Stonington	PSA
06379 Pawcatuck	Stonington	PSA
06382 Uncasville	Montville	PSA
06385 Waterford	Waterford	PSA
06386 Waterford	Waterford	PSA
06388 West Mystic	Groton	PSA
06439 Hadlyme	Lyme	PSA
02891 Westerly	Westerly	SSA
06254 North Franklin	Franklin	SSA
06334 Bozrah	Bozrah	SSA
06336 Gilman	Bozrah	SSA
06337 Griswold + Lisbon	Griswold + Lisbon	SSA
06351 Jewett City	Griswold + Lisbon	SSA
06360 Norwich	Norwich	SSA
06365 Preston	Preston	SSA
06380 Taftville	Norwich	SSA
06384 Voluntown	Voluntown	SSA
06389 Yantic	Norwich	SSA
06415 Colchester	Colchester	SSA
06420 Salem	Salem	SSA
06474 North Westchester	Colchester	SSA
06475 Old Saybrook	Old Saybrook	SSA

(1) CHA, or the Connecticut Hospital Association, consolidates the postal zip codes and towns. These consolidated towns are listed in the CON as L+M's service area towns.

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06320 New London								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	25,667		14,839	5,042	167	1,074	24	2,803	1,718
2010 Estimate	25,665		15,339	4,953	187	889	23	2,648	1,626
2000 Census	25,687		16,317	4,783	225	544	21	2,342	1,455
1990 Census	28,547		20,287	4,441	178	512	53	1,945	1,131
Growth 1990 - 2000	-10.02%		-19.57%	7.70%	26.40%	6.25%	-60.38%	20.41%	28.65%
2000 Census Population by Age	**25,687**		**16,317**	**4,783**	**225**	**544**	**21**	**2,342**	**1,455**
Age 0 to 4	1,708	6.65%	748	421	20	31	2	239	247
Age 5 to 9	1,683	6.55%	731	464	32	15	2	248	191
Age 10 to 14	1,624	6.32%	692	474	11	26	0	263	158
Age 15 to 17	842	3.28%	385	234	10	23	0	125	65
Age 18 to 20	2,274	8.85%	1,680	249	16	62	2	157	108
Age 21 to 24	2,236	8.70%	1,581	285	14	66	2	176	112
Age 25 to 34	3,845	14.97%	2,359	702	29	110	1	441	203
Age 35 to 44	3,762	14.65%	2,381	762	33	88	7	352	139
Age 45 to 49	1,606	6.25%	1,076	308	15	40	3	109	55
Age 50 to 54	1,277	4.97%	906	197	14	29	0	86	45
Age 55 to 59	984	3.83%	698	174	11	18	0	51	32
Age 60 to 64	733	2.85%	520	133	4	10	0	42	24
Age 65 to 74	1,431	5.57%	1,088	246	9	14	2	31	41
Age 75 to 84	1,210	4.71%	1,047	107	5	11	0	19	21
Age 85 and over	472	1.84%	425	27	2	1	0	3	14
Age 18 and over	19,830	77.20%	13,761	3,190	152	449	17	1,467	794
Age 21 and over	17,556	68.35%	12,081	2,941	136	387	15	1,310	686
Age 65 and over	3,113	12.12%	2,560	380	16	26	2	53	76
Median Age	31.3		34.93	28.77	28.28	29.45	37.14	24.16	19.85
Average Age	34.91		38.38	31.08	30.99	32.11	32.83	26.14	24.39
2010 Estimated Population by Age	**25,665**		**15,339**	**4,953**	**187**	**889**	**23**	**2,648**	**1,626**
Age 0 to 4	1,584	6.17%	685	383	12	40	3	249	212
Age 5 to 9	1,545	6.02%	658	440	25	25	0	232	165
Age 10 to 14	1,613	6.28%	691	449	17	38	0	269	149
Age 15 to 17	922	3.59%	405	252	5	30	0	168	62
Age 18 to 20	2,464	9.60%	1,820	239	13	141	0	153	98
Age 21 to 24	1,947	7.59%	1,351	222	14	115	4	140	101
Age 25 to 34	3,550	13.83%	1,993	690	24	148	1	450	244
Age 35 to 44	3,812	14.85%	2,228	821	28	119	11	429	176
Age 45 to 49	1,683	6.56%	1,003	374	11	66	0	144	85
Age 50 to 54	1,549	6.04%	1,016	265	13	58	0	125	72
Age 55 to 59	1,163	4.53%	742	212	12	36	1	91	69
Age 60 to 64	950	3.70%	622	181	7	21	1	71	47
Age 65 to 74	1,286	5.01%	847	248	4	33	2	72	80
Age 75 to 84	1,034	4.03%	799	121	1	17	0	52	44
Age 85 and over	563	2.19%	479	56	1	2	0	3	22
Age 18 and over	20,001	77.93%	12,900	3,429	128	756	20	1,730	1,038
Age 21 and over	17,537	68.33%	11,080	3,190	115	615	20	1,577	940
Age 65 and over	2,883	11.23%	2,125	425	6	52	2	127	146
Median Age	33.07		35.3	32.12	28.13	28.75	38.18	27.51	26.07
Average Age	35.57		38.18	33.26	30.6	32.86	34.83	29.36	30.16
2015 Projected Population by Age	**25,667**		**14,839**	**5,042**	**167**	**1,074**	**24**	**2,803**	**1,718**
Age 0 to 4	1,566	6.10%	652	391	13	43	2	250	215
Age 5 to 9	1,514	5.90%	645	397	23	31	2	242	174
Age 10 to 14	1,513	5.89%	627	416	16	33	0	282	139
Age 15 to 17	950	3.70%	412	256	5	32	0	174	71
Age 18 to 20	2,694	10.50%	1,932	257	6	203	1	182	113
Age 21 to 24	2,144	8.35%	1,420	228	14	148	5	202	127
Age 25 to 34	2,764	10.77%	1,432	564	18	146	2	381	221
Age 35 to 44	3,758	14.64%	2,069	842	24	154	6	468	195
Age 45 to 49	1,680	6.55%	959	373	11	87	1	160	89
Age 50 to 54	1,577	6.14%	968	307	13	64	0	136	89
Age 55 to 59	1,424	5.55%	863	310	11	53	2	107	78
Age 60 to 64	1,085	4.23%	679	228	7	30	0	89	52
Age 65 to 74	1,446	5.63%	948	288	4	36	3	81	86
Age 75 to 84	963	3.75%	735	125	2	12	0	46	43
Age 85 and over	589	2.29%	498	60	0	2	0	3	26
Age 18 and over	20,124	78.40%	12,503	3,582	110	935	20	1,855	1,119
Age 21 and over	17,430	67.91%	10,571	3,325	104	732	19	1,673	1,006
Age 65 and over	2,998	11.68%	2,181	473	6	50	3	130	155
Median Age	34		36.45	35.14	28.61	28.22	35	26.82	25.9
Average Age	36.12		38.72	34.87	30.87	32.72	33.17	29.64	30.68

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06333 East Lyme								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or Al. Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	7,943		6,253	360	35	1,059	2	62	172
2010 Estimate	7,679		6,295	328	35	805	3	57	156
2000 Census	7,101		6,256	269	33	372	1	51	119
1990 Census	6,240		5,798	207	16	106	1	38	74
Growth 1990 - 2000	13.80%		7.90%	29.95%	106.25%	250.94%	0.00%	34.21%	60.81%
2000 Census Population by Age	**7,101**		**6,256**	**269**	**33**	**372**	**1**	**51**	**119**
Age 0 to 4	410	5.77%	353	2	3	31	0	6	15
Age 5 to 9	579	8.15%	515	8	2	38	0	5	11
Age 10 to 14	650	9.15%	569	9	1	45	0	5	21
Age 15 to 17	337	4.75%	310	3	0	21	0	1	2
Age 18 to 20	167	2.35%	144	15	2	1	0	2	3
Age 21 to 24	192	2.70%	133	38	3	7	0	5	6
Age 25 to 34	676	9.52%	517	84	4	40	0	8	23
Age 35 to 44	1,445	20.35%	1,230	71	10	101	1	12	20
Age 45 to 49	668	9.41%	617	14	1	29	0	3	4
Age 50 to 54	547	7.70%	505	11	2	25	0	0	4
Age 55 to 59	443	6.24%	431	2	0	7	0	1	2
Age 60 to 64	307	4.32%	285	4	1	13	0	0	4
Age 65 to 74	424	5.97%	402	5	3	12	0	0	2
Age 75 to 84	198	2.79%	187	3	1	2	0	3	2
Age 85 and over	58	0.82%	58	0	0	0	0	0	0
Age 18 and over	5,125	72.17%	4,509	247	27	237	1	34	70
Age 21 and over	4,958	69.82%	4,365	232	25	236	1	32	67
Age 65 and over	680	9.58%	647	8	4	14	0	3	4
Median Age	38.69		39.77	32.08	36.5	35.3	40	26.88	25.65
Average Age	36.76		37.49	33.2	35.09	31.29	42.5	28.4	26.6
2010 Estimated Population by Age	**7,679**		**6,295**	**328**	**35**	**805**	**3**	**57**	**156**
Age 0 to 4	432	5.63%	334	3	4	71	0	5	15
Age 5 to 9	459	5.98%	364	5	1	76	0	8	5
Age 10 to 14	546	7.11%	429	5	1	89	0	3	19
Age 15 to 17	477	6.21%	394	8	0	68	0	2	5
Age 18 to 20	286	3.72%	239	21	4	11	1	1	9
Age 21 to 24	469	6.11%	352	59	4	23	1	11	19
Age 25 to 34	765	9.96%	566	106	6	49	0	6	32
Age 35 to 44	904	11.77%	661	73	11	125	0	9	25
Age 45 to 49	748	9.74%	630	21	0	84	0	7	6
Age 50 to 54	698	9.09%	597	13	0	79	1	2	6
Age 55 to 59	581	7.57%	541	2	0	35	0	0	3
Age 60 to 64	426	5.55%	378	3	1	39	0	2	3
Age 65 to 74	530	6.90%	484	4	1	32	0	0	9
Age 75 to 84	277	3.61%	249	3	2	22	0	1	0
Age 85 and over	81	1.05%	77	2	0	2	0	0	0
Age 18 and over	5,765	75.07%	4,774	307	29	501	3	39	112
Age 21 and over	5,479	71.35%	4,535	286	25	490	2	38	103
Age 65 and over	888	11.56%	810	9	3	56	0	1	9
Median Age	40.48		42.1	30.94	30.83	36.24	23	24.45	26.88
Average Age	38.2		39.41	32.77	31.61	33.59	32.17	28.09	29.12
2015 Projected Population by Age	**7,943**		**6,253**	**360**	**35**	**1,059**	**2**	**62**	**172**
Age 0 to 4	455	5.73%	326	3	2	102	1	6	15
Age 5 to 9	456	5.74%	336	4	4	92	0	9	11
Age 10 to 14	475	5.98%	342	4	0	111	0	3	15
Age 15 to 17	440	5.54%	331	9	0	93	0	2	5
Age 18 to 20	304	3.83%	258	20	4	11	1	2	8
Age 21 to 24	564	7.10%	419	71	6	34	0	12	22
Age 25 to 34	1,027	12.93%	740	116	5	118	0	9	39
Age 35 to 44	653	8.22%	438	73	11	101	0	8	22
Age 45 to 49	595	7.49%	471	19	1	94	0	3	7
Age 50 to 54	717	9.03%	584	15	1	103	0	1	13
Age 55 to 59	654	8.23%	598	3	0	50	0	0	3
Age 60 to 64	538	6.77%	456	7	1	71	0	1	2
Age 65 to 74	653	8.22%	579	11	0	52	0	3	8
Age 75 to 84	304	3.83%	273	2	0	24	0	3	2
Age 85 and over	108	1.36%	102	3	0	3	0	0	0
Age 18 and over	6,117	77.01%	4,918	340	29	661	1	42	126
Age 21 and over	5,813	73.18%	4,660	320	25	650	0	40	118
Age 65 and over	1,065	13.41%	954	16	0	79	0	6	10
Median Age	39.26		43.55	30.95	28	32.33	5	24	27.56
Average Age	39.03		40.68	33.71	28.71	33.54	11.5	28.26	29.71

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06335 Gales Ferry								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	6,482		5,698	173	55	296	1	71	188
2010 Estimate	6,490		5,803	159	53	241	2	60	172
2000 Census	6,536		6,023	133	54	140	1	42	143
1990 Census	6,797		6,494	93	13	91	2	10	94
Growth 1990 - 2000	-3.84%		-7.25%	43.01%	315.38%	53.85%	-50.00%	320.00%	52.13%
2000 Census Population by Age	**6,536**		**6,023**	**133**	**54**	**140**	**1**	**42**	**143**
Age 0 to 4	355	5.43%	317	6	6	5	0	3	18
Age 5 to 9	576	8.81%	513	18	5	10	0	6	24
Age 10 to 14	568	8.69%	522	12	5	12	0	6	11
Age 15 to 17	330	5.05%	296	7	3	4	0	4	16
Age 18 to 20	170	2.60%	152	7	2	3	0	1	5
Age 21 to 24	194	2.97%	168	6	3	6	0	2	9
Age 25 to 34	714	10.92%	658	12	6	14	0	9	15
Age 35 to 44	1,309	20.03%	1,213	31	10	31	0	9	15
Age 45 to 49	556	8.51%	515	12	4	15	0	0	10
Age 50 to 54	496	7.59%	470	4	4	11	0	1	6
Age 55 to 59	369	5.65%	342	8	3	13	1	0	2
Age 60 to 64	275	4.21%	264	5	0	5	0	0	1
Age 65 to 74	391	5.98%	368	4	2	10	0	1	6
Age 75 to 84	192	2.94%	186	1	0	1	0	0	4
Age 85 and over	41	0.63%	39	0	1	0	0	0	1
Age 18 and over	4,707	72.02%	4,375	90	35	109	1	23	74
Age 21 and over	4,537	69.42%	4,223	83	33	106	1	22	69
Age 65 and over	624	9.55%	593	5	3	11	0	1	11
Median Age	37.8		38.18	33.75	30	40.16	57.5	23	19.5
Average Age	36.25		36.66	31.63	30.72	37.62	57.5	24.15	26.52
2010 Estimated Population by Age	**6,490**		**5,803**	**159**	**53**	**241**	**2**	**60**	**172**
Age 0 to 4	339	5.22%	292	9	4	9	0	5	20
Age 5 to 9	359	5.53%	309	13	2	13	0	5	17
Age 10 to 14	428	6.59%	384	7	6	17	0	6	8
Age 15 to 17	383	5.90%	345	11	3	5	0	5	14
Age 18 to 20	229	3.53%	201	12	2	4	0	1	9
Age 21 to 24	338	5.21%	277	9	5	17	0	8	22
Age 25 to 34	711	10.96%	628	15	9	27	0	13	19
Age 35 to 44	901	13.88%	809	25	3	28	0	13	23
Age 45 to 49	643	9.91%	581	16	5	25	0	0	16
Age 50 to 54	573	8.83%	527	8	4	25	0	3	6
Age 55 to 59	469	7.23%	424	17	4	21	2	0	1
Age 60 to 64	355	5.47%	328	10	3	12	0	1	1
Age 65 to 74	465	7.16%	415	5	0	33	0	0	12
Age 75 to 84	232	3.57%	221	2	3	5	0	0	1
Age 85 and over	65	1.00%	62	0	0	0	0	0	3
Age 18 and over	4,981	76.75%	4,473	119	38	197	2	39	113
Age 21 and over	4,752	73.22%	4,272	107	36	193	2	38	104
Age 65 and over	762	11.74%	698	7	3	38	0	0	16
Median Age	40.84		40.75	36.4	30	45.1	57.5	25	24.27
Average Age	38.75		39.19	35.31	33.7	41.15	57.5	25.63	29.3
2015 Projected Population by Age	**6,482**		**5,698**	**173**	**55**	**296**	**1**	**71**	**188**
Age 0 to 4	336	5.18%	279	5	5	13	0	11	23
Age 5 to 9	344	5.31%	293	15	1	14	0	5	16
Age 10 to 14	362	5.58%	318	7	5	16	0	7	9
Age 15 to 17	315	4.86%	284	5	2	7	0	2	15
Age 18 to 20	219	3.38%	186	9	3	10	0	2	9
Age 21 to 24	405	6.25%	318	15	5	26	0	12	29
Age 25 to 34	777	11.99%	675	18	9	32	0	18	25
Age 35 to 44	686	10.58%	608	20	5	25	0	10	18
Age 45 to 49	573	8.84%	511	15	3	29	1	0	14
Age 50 to 54	582	8.98%	524	12	4	35	0	2	5
Age 55 to 59	544	8.39%	488	24	4	25	0	0	3
Age 60 to 64	454	7.00%	410	16	4	19	0	1	4
Age 65 to 74	546	8.42%	485	7	2	38	0	1	13
Age 75 to 84	257	3.96%	243	4	1	7	0	0	2
Age 85 and over	82	1.27%	76	1	2	0	0	0	3
Age 18 and over	5,125	79.07%	4,524	141	42	246	1	46	125
Age 21 and over	4,906	75.69%	4,338	132	39	236	1	44	116
Age 65 and over	885	13.65%	804	12	5	45	0	1	18
Median Age	42.2		43.16	41.25	32.22	45.86	47.5	23.83	24.03
Average Age	40.22		40.79	39.39	35.79	41.22	47.5	23.49	29.29

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06339 Ledyard								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	8,547		6,726	340	526	417	14	136	388
2010 Estimate	8,395		6,783	301	515	332	12	115	337
2000 Census	8,107		6,894	234	459	182	9	82	247
1990 Census	7,818		7,298	156	67	118	9	39	131
Growth 1990 - 2000	3.70%		-5.54%	50.00%	585.07%	54.24%	0.00%	110.26%	88.55%
2000 Census Population by Age	**8,107**		**6,894**	**234**	**459**	**182**	**9**	**82**	**247**
Age 0 to 4	560	6.91%	427	13	59	13	2	8	38
Age 5 to 9	603	7.44%	477	22	52	12	0	8	32
Age 10 to 14	721	8.89%	603	15	54	13	0	9	27
Age 15 to 17	427	5.27%	342	14	43	7	2	6	13
Age 18 to 20	243	3.00%	179	3	23	9	0	5	24
Age 21 to 24	316	3.90%	249	12	25	12	1	3	14
Age 25 to 34	997	12.30%	823	34	54	31	0	19	36
Age 35 to 44	1,522	18.77%	1,346	41	58	30	1	15	31
Age 45 to 49	677	8.35%	598	23	28	15	2	0	11
Age 50 to 54	566	6.98%	508	15	22	14	0	1	6
Age 55 to 59	477	5.88%	435	15	10	12	0	1	4
Age 60 to 64	308	3.80%	280	7	4	8	0	6	3
Age 65 to 74	455	5.61%	414	13	17	5	1	1	4
Age 75 to 84	198	2.44%	176	7	10	1	0	0	4
Age 85 and over	37	0.46%	37	0	0	0	0	0	0
Age 18 and over	5,796	71.49%	5,045	170	251	137	5	51	137
Age 21 and over	5,553	68.50%	4,866	167	228	128	5	46	113
Age 65 and over	690	8.51%	627	20	27	6	1	1	8
Median Age	36.21		37.58	35.98	20.8	33.06	23	26.05	19.69
Average Age	35.09		36.21	35.14	26.63	33.18	29.61	26.54	23.77
2010 Estimated Population by Age	**8,395**		**6,783**	**301**	**515**	**332**	**12**	**115**	**337**
Age 0 to 4	535	6.37%	385	13	58	22	2	11	44
Age 5 to 9	570	6.79%	418	34	56	13	2	13	34
Age 10 to 14	605	7.21%	478	14	49	28	0	11	25
Age 15 to 17	425	5.06%	321	22	43	14	3	7	15
Age 18 to 20	263	3.13%	183	9	25	10	0	3	33
Age 21 to 24	443	5.28%	332	15	39	26	1	9	21
Age 25 to 34	1,048	12.48%	813	46	60	52	0	26	51
Age 35 to 44	1,192	14.20%	1,008	34	59	40	0	20	31
Age 45 to 49	734	8.74%	621	21	33	24	4	0	31
Age 50 to 54	682	8.12%	602	10	27	24	0	7	12
Age 55 to 59	559	6.66%	487	17	16	29	0	1	9
Age 60 to 64	450	5.36%	382	14	9	28	0	5	12
Age 65 to 74	550	6.55%	464	33	27	15	0	2	9
Age 75 to 84	266	3.17%	216	19	14	7	0	0	10
Age 85 and over	73	0.87%	73	0	0	0	0	0	0
Age 18 and over	6,260	74.57%	5,181	218	309	255	5	73	219
Age 21 and over	5,997	71.44%	4,998	209	284	245	5	70	186
Age 65 and over	889	10.59%	753	52	41	22	0	2	19
Median Age	37.81		39.58	34.46	23.72	35.25	17	26.35	24.33
Average Age	37.13		38.39	37.31	28.91	36.33	23.58	27.02	28.53
2015 Projected Population by Age	**8,547**		**6,726**	**340**	**526**	**417**	**14**	**136**	**388**
Age 0 to 4	553	6.47%	381	18	62	31	5	7	49
Age 5 to 9	555	6.49%	386	33	49	30	2	17	38
Age 10 to 14	572	6.69%	434	21	53	24	0	13	27
Age 15 to 17	418	4.89%	302	18	45	20	0	8	25
Age 18 to 20	273	3.19%	182	8	28	14	0	8	33
Age 21 to 24	478	5.59%	339	20	39	39	2	11	28
Age 25 to 34	1,026	12.00%	763	56	72	52	0	24	59
Age 35 to 44	1,064	12.45%	863	40	47	45	0	28	41
Age 45 to 49	635	7.43%	516	28	31	31	3	0	26
Age 50 to 54	711	8.32%	621	13	28	31	0	8	10
Age 55 to 59	655	7.66%	573	14	17	35	0	3	13
Age 60 to 64	535	6.26%	448	18	9	42	0	6	12
Age 65 to 74	682	7.98%	580	33	31	18	2	3	15
Age 75 to 84	289	3.38%	244	16	15	5	0	0	9
Age 85 and over	101	1.18%	94	4	0	0	0	0	3
Age 18 and over	6,449	75.45%	5,223	250	317	312	7	91	249
Age 21 and over	6,176	72.26%	5,041	242	289	298	7	83	216
Age 65 and over	1,072	12.54%	918	53	46	23	2	3	27
Median Age	38.84		41.67	34.29	23.67	34.71	10	26.67	24.14
Average Age	38.29		40.02	36.91	28.98	35.58	25.86	28.33	28.78

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06340 Groton								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	34,609		25,297	3,298	229	3,100	100	996	1,589
2010 Estimate	33,675		25,600	3,060	245	2,370	85	867	1,448
2000 Census	31,655		25,732	2,606	282	1,145	58	630	1,202
1990 Census	37,729		32,627	2,576	227	677	77	512	1,033
Growth 1990 - 2000	-16.10%		-21.13%	1.16%	24.23%	69.13%	-24.68%	23.05%	16.36%
2000 Census Population by Age	**31,655**		**25,732**	**2,606**	**282**	**1,145**	**58**	**630**	**1,202**
Age 0 to 4	2,785	8.80%	2,015	290	34	96	4	77	269
Age 5 to 9	2,414	7.63%	1,822	256	25	73	11	49	178
Age 10 to 14	1,918	6.06%	1,433	198	22	60	4	51	150
Age 15 to 17	912	2.88%	696	90	4	33	6	24	59
Age 18 to 20	1,761	5.56%	1,344	185	25	44	4	86	73
Age 21 to 24	2,534	8.01%	2,022	229	23	77	8	90	85
Age 25 to 34	5,995	18.94%	4,773	580	54	298	9	126	155
Age 35 to 44	4,658	14.71%	3,871	373	33	200	9	70	102
Age 45 to 49	1,613	5.10%	1,360	105	25	61	3	19	40
Age 50 to 54	1,418	4.48%	1,227	90	13	56	0	14	18
Age 55 to 59	1,101	3.48%	973	55	5	42	0	8	18
Age 60 to 64	873	2.76%	775	41	5	35	0	8	9
Age 65 to 74	1,740	5.50%	1,586	67	5	53	0	4	25
Age 75 to 84	1,364	4.31%	1,295	35	9	13	0	2	10
Age 85 and over	569	1.80%	540	12	0	4	0	2	11
Age 18 and over	23,626	74.64%	19,766	1,772	197	883	33	429	546
Age 21 and over	21,865	69.07%	18,422	1,587	172	839	29	343	473
Age 65 and over	3,673	11.60%	3,421	114	14	70	0	8	46
Median Age	30.49		32.4	25.95	26.48	31.36	21	22.24	15.2
Average Age	33.81		35.48	27.46	28.48	32.33	22.19	24	20.6
2010 Estimated Population by Age	**33,675**		**25,600**	**3,060**	**245**	**2,370**	**85**	**867**	**1,448**
Age 0 to 4	2,521	7.49%	1,674	314	27	168	8	91	239
Age 5 to 9	2,178	6.47%	1,501	263	19	141	18	59	177
Age 10 to 14	2,073	6.16%	1,406	248	12	136	9	67	195
Age 15 to 17	1,162	3.45%	847	125	1	65	12	24	88
Age 18 to 20	2,099	6.23%	1,497	247	26	92	2	138	97
Age 21 to 24	2,225	6.61%	1,638	237	17	129	8	104	92
Age 25 to 34	5,509	16.36%	3,989	595	46	522	7	163	187
Age 35 to 44	5,158	15.32%	3,948	477	36	440	9	110	138
Age 45 to 49	2,267	6.73%	1,805	149	20	174	10	32	77
Age 50 to 54	1,877	5.57%	1,538	135	8	138	0	31	27
Age 55 to 59	1,458	4.33%	1,216	65	8	119	0	16	34
Age 60 to 64	1,193	3.54%	994	59	8	93	2	18	19
Age 65 to 74	1,770	5.26%	1,532	74	12	107	0	7	38
Age 75 to 84	1,440	4.28%	1,328	47	5	34	0	5	21
Age 85 and over	745	2.21%	687	25	0	12	0	2	19
Age 18 and over	25,741	76.44%	20,172	2,110	186	1,860	38	626	749
Age 21 and over	23,642	70.21%	18,675	1,863	160	1,768	36	488	652
Age 65 and over	3,955	11.74%	3,547	146	17	153	0	14	78
Median Age	33.45		35.63	26.61	29.46	33.7	16.88	23.1	18.77
Average Age	35.67		37.69	28.71	31.14	34.44	22.16	26.07	24.22
2015 Projected Population by Age	**34,609**		**25,297**	**3,298**	**229**	**3,100**	**100**	**996**	**1,589**
Age 0 to 4	2,466	7.13%	1,561	326	18	223	8	84	246
Age 5 to 9	2,166	6.26%	1,412	276	21	174	17	69	197
Age 10 to 14	1,973	5.70%	1,258	254	11	172	10	76	192
Age 15 to 17	1,253	3.62%	881	138	2	87	10	39	96
Age 18 to 20	2,338	6.76%	1,591	285	26	141	5	179	111
Age 21 to 24	2,530	7.31%	1,803	297	19	170	11	120	110
Age 25 to 34	4,579	13.23%	3,129	510	41	542	11	170	176
Age 35 to 44	4,996	14.44%	3,574	484	34	594	16	125	169
Age 45 to 49	2,367	6.84%	1,789	171	20	248	11	41	87
Age 50 to 54	2,254	6.51%	1,747	208	11	203	0	40	45
Age 55 to 59	1,876	5.42%	1,517	100	7	183	0	16	53
Age 60 to 64	1,424	4.11%	1,159	83	4	137	1	21	19
Age 65 to 74	2,086	6.03%	1,765	87	9	171	0	12	42
Age 75 to 84	1,432	4.14%	1,317	46	6	39	0	3	21
Age 85 and over	869	2.51%	794	33	0	16	0	1	25
Age 18 and over	26,751	77.29%	20,185	2,304	177	2,444	55	728	858
Age 21 and over	24,413	70.54%	18,594	2,019	151	2,303	50	549	747
Age 65 and over	4,387	12.68%	3,876	166	15	226	0	16	88
Median Age	35		37.84	26.43	29.27	35.69	21	22.7	19.72
Average Age	36.81		39.14	29.74	31.19	35.49	23.79	26.29	25.33

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06349 Groton								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	1		1	0	0	0	0	0	0
2010 Estimate	1		1	0	0	0	0	0	0
2000 Census	1		1	0	0	0	0	0	0
1990 Census	4		4	0	0	0	0	0	0
Growth 1990 - 2000	-75.00%		-75.00%						
2000 Census Population by Age	**1**		**1**	**0**	**0**	**0**	**0**	**0**	**0**
Age 0 to 4	0	0.00%	0	0	0	0	0	0	0
Age 5 to 9	0	0.00%	0	0	0	0	0	0	0
Age 10 to 14	0	0.00%	0	0	0	0	0	0	0
Age 15 to 17	0	0.00%	0	0	0	0	0	0	0
Age 18 to 20	0	0.00%	0	0	0	0	0	0	0
Age 21 to 24	0	0.00%	0	0	0	0	0	0	0
Age 25 to 34	1	*****%	1	0	0	0	0	0	0
Age 35 to 44	0	0.00%	0	0	0	0	0	0	0
Age 45 to 49	0	0.00%	0	0	0	0	0	0	0
Age 50 to 54	0	0.00%	0	0	0	0	0	0	0
Age 55 to 59	0	0.00%	0	0	0	0	0	0	0
Age 60 to 64	0	0.00%	0	0	0	0	0	0	0
Age 65 to 74	0	0.00%	0	0	0	0	0	0	0
Age 75 to 84	0	0.00%	0	0	0	0	0	0	0
Age 85 and over	0	0.00%	0	0	0	0	0	0	0
Age 18 and over	1	*****%	1	0	0	0	0	0	0
Age 21 and over	1	*****%	1	0	0	0	0	0	0
Age 65 and over	0	0.00%	0	0	0	0	0	0	0
Median Age	27.5		30						
Average Age	27.5		27.5						
2010 Estimated Population by Age	**1**		**1**	**0**	**0**	**0**	**0**	**0**	**0**
Age 0 to 4	0	0.00%	0	0	0	0	0	0	0
Age 5 to 9	0	0.00%	0	0	0	0	0	0	0
Age 10 to 14	0	0.00%	0	0	0	0	0	0	0
Age 15 to 17	0	0.00%	0	0	0	0	0	0	0
Age 18 to 20	0	0.00%	0	0	0	0	0	0	0
Age 21 to 24	1	*****%	1	0	0	0	0	0	0
Age 25 to 34	0	0.00%	0	0	0	0	0	0	0
Age 35 to 44	0	0.00%	0	0	0	0	0	0	0
Age 45 to 49	0	0.00%	0	0	0	0	0	0	0
Age 50 to 54	0	0.00%	0	0	0	0	0	0	0
Age 55 to 59	0	0.00%	0	0	0	0	0	0	0
Age 60 to 64	0	0.00%	0	0	0	0	0	0	0
Age 65 to 74	0	0.00%	0	0	0	0	0	0	0
Age 75 to 84	0	0.00%	0	0	0	0	0	0	0
Age 85 and over	0	0.00%	0	0	0	0	0	0	0
Age 18 and over	1	*****%	1	0	0	0	0	0	0
Age 21 and over	1	*****%	1	0	0	0	0	0	0
Age 65 and over	0	0.00%	0	0	0	0	0	0	0
Median Age	23.5		23						
Average Age	23.5		23.5						
2015 Projected Population by Age	**1**		**1**	**0**	**0**	**0**	**0**	**0**	**0**
Age 0 to 4	0	0.00%	0	0	0	0	0	0	0
Age 5 to 9	0	0.00%	0	0	0	0	0	0	0
Age 10 to 14	0	0.00%	0	0	0	0	0	0	0
Age 15 to 17	1	*****%	1	0	0	0	0	0	0
Age 18 to 20	0	0.00%	0	0	0	0	0	0	0
Age 21 to 24	0	0.00%	0	0	0	0	0	0	0
Age 25 to 34	0	0.00%	0	0	0	0	0	0	0
Age 35 to 44	0	0.00%	0	0	0	0	0	0	0
Age 45 to 49	0	0.00%	0	0	0	0	0	0	0
Age 50 to 54	0	0.00%	0	0	0	0	0	0	0
Age 55 to 59	0	0.00%	0	0	0	0	0	0	0
Age 60 to 64	0	0.00%	0	0	0	0	0	0	0
Age 65 to 74	0	0.00%	0	0	0	0	0	0	0
Age 75 to 84	0	0.00%	0	0	0	0	0	0	0
Age 85 and over	0	0.00%	0	0	0	0	0	0	0
Age 18 and over	0	0.00%	0	0	0	0	0	0	0
Age 21 and over	0	0.00%	0	0	0	0	0	0	0
Age 65 and over	0	0.00%	0	0	0	0	0	0	0
Median Age	16.5		16.5						
Average Age	17.5		16.5						

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06353 Montville								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	97		89	2	0	2	0	2	2
2010 Estimate	93		85	3	1	1	0	1	2
2000 Census	84		79	1	1	1	0	1	1
1990 Census	72		70	0	0	1	0	0	1
Growth 1990 - 2000	16.67%		12.86%			0.00%			0.00%
2000 Census Population by Age	**84**		**79**	**1**	**1**	**1**	**0**	**1**	**1**
Age 0 to 4	9	10.71%	8	0	0	0	0	1	0
Age 5 to 9	6	7.14%	6	0	0	0	0	0	0
Age 10 to 14	6	7.14%	4	0	1	1	0	0	0
Age 15 to 17	4	4.76%	3	1	0	0	0	0	0
Age 18 to 20	2	2.38%	1	0	0	0	0	0	1
Age 21 to 24	3	3.57%	3	0	0	0	0	0	0
Age 25 to 34	10	11.90%	10	0	0	0	0	0	0
Age 35 to 44	17	20.24%	17	0	0	0	0	0	0
Age 45 to 49	7	8.33%	7	0	0	0	0	0	0
Age 50 to 54	6	7.14%	6	0	0	0	0	0	0
Age 55 to 59	5	5.95%	5	0	0	0	0	0	0
Age 60 to 64	2	2.38%	2	0	0	0	0	0	0
Age 65 to 74	4	4.76%	4	0	0	0	0	0	0
Age 75 to 84	3	3.57%	3	0	0	0	0	0	0
Age 85 and over	0	0.00%	0	0	0	0	0	0	0
Age 18 and over	59	70.24%	58	0	0	0	0	0	1
Age 21 and over	57	67.86%	57	0	0	0	0	0	0
Age 65 and over	7	8.33%	7	0	0	0	0	0	0
Median Age	36		37.65	16.5	12.5	12.5		2.5	19.5
Average Age	34.2		35.54	16.5	12.5	12.5		2.5	19
2010 Estimated Population by Age	**93**		**85**	**3**	**1**	**1**	**0**	**1**	**2**
Age 0 to 4	5	5.38%	5	0	0	0	0	0	0
Age 5 to 9	7	7.53%	6	0	1	0	0	0	0
Age 10 to 14	7	7.53%	6	1	0	0	0	0	0
Age 15 to 17	5	5.38%	4	0	0	0	0	0	1
Age 18 to 20	2	2.15%	1	0	0	1	0	0	0
Age 21 to 24	4	4.30%	3	0	0	0	0	1	0
Age 25 to 34	9	9.68%	7	1	0	0	0	0	1
Age 35 to 44	16	17.20%	15	1	0	0	0	0	0
Age 45 to 49	8	8.60%	8	0	0	0	0	0	0
Age 50 to 54	7	7.53%	7	0	0	0	0	0	0
Age 55 to 59	6	6.45%	6	0	0	0	0	0	0
Age 60 to 64	3	3.23%	3	0	0	0	0	0	0
Age 65 to 74	8	8.60%	8	0	0	0	0	0	0
Age 75 to 84	4	4.30%	4	0	0	0	0	0	0
Age 85 and over	2	2.15%	2	0	0	0	0	0	0
Age 18 and over	69	74.19%	64	2	0	1	0	1	1
Age 21 and over	67	72.04%	63	2	0	0	0	1	1
Age 65 and over	14	15.05%	14	0	0	0	0	0	0
Median Age	40.28		42	30	7.5	19.5		23	18
Average Age	38.93		40.45	27.5	7.5	19		21.5	24.5
2015 Projected Population by Age	**97**		**89**	**2**	**0**	**2**	**0**	**2**	**2**
Age 0 to 4	9	9.28%	9	0	0	0	0	0	0
Age 5 to 9	6	6.19%	5	1	0	0	0	0	0
Age 10 to 14	7	7.22%	6	0	0	0	0	1	0
Age 15 to 17	6	6.19%	5	0	0	1	0	0	0
Age 18 to 20	4	4.12%	2	0	0	1	0	0	1
Age 21 to 24	5	5.15%	4	1	0	0	0	0	0
Age 25 to 34	9	9.28%	7	0	0	0	0	1	1
Age 35 to 44	11	11.34%	11	0	0	0	0	0	0
Age 45 to 49	8	8.25%	8	0	0	0	0	0	0
Age 50 to 54	8	8.25%	8	0	0	0	0	0	0
Age 55 to 59	7	7.22%	7	0	0	0	0	0	0
Age 60 to 64	6	6.19%	6	0	0	0	0	0	0
Age 65 to 74	7	7.22%	7	0	0	0	0	0	0
Age 75 to 84	3	3.09%	3	0	0	0	0	0	0
Age 85 and over	1	1.03%	1	0	0	0	0	0	0
Age 18 and over	69	71.13%	64	1	0	1	0	1	2
Age 21 and over	65	67.01%	62	1	0	0	0	1	1
Age 65 and over	11	11.34%	11	0	0	0	0	0	0
Median Age	38.13		40.91	10		18		15	21
Average Age	36.48		38.03	15.5		18.5		20	25.75

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06355 Mystic								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	14,240		12,934	207	42	625	18	85	329
2010 Estimate	13,528		12,423	199	45	480	16	75	290
2000 Census	12,085		11,318	191	59	235	9	51	222
1990 Census	11,215		10,642	189	47	151	10	30	146
Growth 1990 - 2000	7.76%		6.35%	1.06%	25.53%	55.63%	-10.00%	70.00%	52.05%
2000 Census Population by Age	**12,085**		**11,318**	**191**	**59**	**235**	**9**	**51**	**222**
Age 0 to 4	624	5.16%	564	7	3	16	1	4	29
Age 5 to 9	751	6.21%	674	11	4	14	1	6	41
Age 10 to 14	802	6.64%	737	12	4	13	2	12	22
Age 15 to 17	430	3.56%	393	8	3	4	1	4	17
Age 18 to 20	263	2.18%	245	3	1	2	0	4	8
Age 21 to 24	338	2.80%	313	6	0	6	0	2	11
Age 25 to 34	1,453	12.02%	1,347	18	8	44	1	11	24
Age 35 to 44	2,102	17.39%	1,954	46	7	58	2	6	29
Age 45 to 49	1,016	8.41%	960	15	10	19	0	0	12
Age 50 to 54	972	8.04%	937	9	3	15	0	1	7
Age 55 to 59	765	6.33%	729	6	3	19	0	1	7
Age 60 to 64	609	5.04%	577	13	4	10	1	0	4
Age 65 to 74	973	8.05%	927	23	2	13	0	0	8
Age 75 to 84	708	5.86%	686	12	6	2	0	0	2
Age 85 and over	279	2.31%	275	2	1	0	0	0	1
Age 18 and over	9,478	78.43%	8,950	153	45	188	4	25	113
Age 21 and over	9,215	76.25%	8,705	150	44	186	4	21	105
Age 65 and over	1,960	16.22%	1,888	37	9	15	0	0	11
Median Age	41.76		42.09	41.63	44.29	38.19	16.5	17.63	18.75
Average Age	41.07		41.55	42.25	41.06	36.67	25.83	21.17	25.37
2010 Estimated Population by Age	**13,528**		**12,423**	**199**	**45**	**480**	**16**	**75**	**290**
Age 0 to 4	651	4.81%	564	10	2	37	1	2	35
Age 5 to 9	703	5.20%	611	10	4	24	4	11	39
Age 10 to 14	787	5.82%	700	9	7	30	0	13	28
Age 15 to 17	561	4.15%	501	11	3	11	2	8	25
Age 18 to 20	381	2.82%	344	8	2	6	0	6	15
Age 21 to 24	579	4.28%	513	8	0	30	0	6	22
Age 25 to 34	1,290	9.54%	1,144	22	8	68	7	9	32
Age 35 to 44	1,967	14.54%	1,801	30	6	85	0	10	35
Age 45 to 49	1,198	8.86%	1,111	19	2	40	2	3	21
Age 50 to 54	1,217	9.00%	1,150	17	4	37	0	3	6
Age 55 to 59	1,019	7.53%	943	7	4	50	0	1	14
Age 60 to 64	821	6.07%	773	16	3	28	0	0	1
Age 65 to 74	1,129	8.35%	1,064	20	0	30	0	3	12
Age 75 to 84	807	5.97%	790	10	0	4	0	0	3
Age 85 and over	418	3.09%	414	2	0	0	0	0	2
Age 18 and over	10,826	80.03%	10,047	159	29	378	9	41	163
Age 21 and over	10,445	77.21%	9,703	151	27	372	9	35	148
Age 65 and over	2,354	17.40%	2,268	32	0	34	0	3	17
Median Age	44.27		45.15	42.17	30.63	39	26.43	19.75	21.55
Average Age	42.55		43.33	41.22	31.62	37.13	22.06	24.89	26.67
2015 Projected Population by Age	**14,240**		**12,934**	**207**	**42**	**625**	**18**	**85**	**329**
Age 0 to 4	681	4.78%	573	9	6	43	1	4	45
Age 5 to 9	714	5.01%	594	11	7	47	4	10	41
Age 10 to 14	749	5.26%	649	13	3	42	1	12	29
Age 15 to 17	564	3.96%	499	8	4	12	4	5	32
Age 18 to 20	400	2.81%	365	4	0	11	0	6	14
Age 21 to 24	715	5.02%	629	11	1	38	0	10	26
Age 25 to 34	1,347	9.46%	1,179	19	5	86	6	19	33
Age 35 to 44	1,692	11.88%	1,516	30	3	95	0	9	39
Age 45 to 49	1,138	7.99%	1,046	17	4	47	1	1	22
Age 50 to 54	1,319	9.26%	1,233	14	2	55	0	7	8
Age 55 to 59	1,195	8.39%	1,101	7	4	66	0	1	16
Age 60 to 64	993	6.97%	928	23	3	36	1	0	2
Age 65 to 74	1,399	9.82%	1,315	28	0	40	0	1	15
Age 75 to 84	843	5.92%	821	11	0	6	0	0	5
Age 85 and over	491	3.45%	486	2	0	1	0	0	2
Age 18 and over	11,532	80.98%	10,619	166	22	481	8	54	182
Age 21 and over	11,132	78.17%	10,254	162	22	470	8	48	168
Age 65 and over	2,733	19.19%	2,622	41	0	47	0	1	22
Median Age	46.13		47.21	44.5	25	38.53	17.25	23.2	21.54
Average Age	43.61		44.57	43.07	27.8	36.86	21.78	25.16	26.93

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06357 Niantic								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	11,818		9,323	1,500	48	288	10	335	314
2010 Estimate	11,485		9,382	1,268	46	236	10	269	274
2000 Census	11,006		9,548	886	44	140	6	169	213
1990 Census	9,089		8,516	312	29	86	3	49	94
Growth 1990 - 2000	21.09%		12.12%	183.97%	51.72%	62.79%	100.00%	244.90%	126.60%
2000 Census Population by Age	**11,006**		**9,548**	**886**	**44**	**140**	**6**	**169**	**213**
Age 0 to 4	478	4.34%	447	8	0	7	0	0	16
Age 5 to 9	557	5.06%	522	8	0	13	0	2	12
Age 10 to 14	624	5.67%	580	9	3	18	0	2	12
Age 15 to 17	338	3.07%	310	13	1	8	0	1	5
Age 18 to 20	318	2.89%	235	48	3	0	2	15	15
Age 21 to 24	472	4.29%	323	107	2	3	1	18	18
Age 25 to 34	1,797	16.33%	1,305	328	15	23	0	63	63
Age 35 to 44	2,124	19.30%	1,699	295	13	31	1	45	40
Age 45 to 49	865	7.86%	793	38	3	8	0	13	10
Age 50 to 54	741	6.73%	697	17	2	12	1	5	7
Age 55 to 59	622	5.65%	606	5	0	6	0	2	3
Age 60 to 64	468	4.25%	457	4	1	3	1	1	1
Age 65 to 74	878	7.98%	856	6	1	5	0	1	9
Age 75 to 84	570	5.18%	566	0	0	3	0	1	0
Age 85 and over	154	1.40%	152	0	0	0	0	0	2
Age 18 and over	9,009	81.86%	7,689	848	40	94	6	164	168
Age 21 and over	8,691	78.97%	7,454	800	37	94	4	149	153
Age 65 and over	1,602	14.56%	1,574	6	1	8	0	2	11
Median Age	39.18		41.19	32.62	33.67	34.13	25	32.38	29.52
Average Age	40.05		41.19	32.78	34.48	32.58	37.17	33.45	30.22
2010 Estimated Population by Age	**11,485**		**9,382**	**1,268**	**46**	**236**	**10**	**269**	**274**
Age 0 to 4	444	3.87%	399	7	0	13	0	2	23
Age 5 to 9	481	4.19%	427	14	0	22	0	2	16
Age 10 to 14	518	4.51%	462	14	1	23	0	1	17
Age 15 to 17	397	3.46%	362	13	0	14	0	3	5
Age 18 to 20	408	3.55%	265	87	5	5	3	21	22
Age 21 to 24	701	6.10%	436	188	4	11	3	34	25
Age 25 to 34	1,735	15.11%	1,031	470	19	39	0	101	75
Age 35 to 44	1,958	17.05%	1,410	371	12	52	2	60	51
Age 45 to 49	888	7.73%	779	55	1	18	0	23	12
Age 50 to 54	876	7.63%	813	20	1	20	1	9	12
Age 55 to 59	766	6.67%	745	6	0	8	0	3	4
Age 60 to 64	576	5.02%	561	7	1	3	1	3	0
Age 65 to 74	859	7.48%	829	14	2	3	0	3	8
Age 75 to 84	621	5.41%	610	2	0	5	0	4	0
Age 85 and over	257	2.24%	253	0	0	0	0	0	4
Age 18 and over	9,645	83.98%	7,732	1,220	45	164	10	261	213
Age 21 and over	9,237	80.43%	7,467	1,133	40	159	7	240	191
Age 65 and over	1,737	15.12%	1,692	16	2	8	0	7	12
Median Age	40.34		44.28	31.62	31.84	32.69	23.67	32.08	28.87
Average Age	41.18		43.22	32.28	34.07	31.55	33.3	33.8	29.57
2015 Projected Population by Age	**11,818**		**9,323**	**1,500**	**48**	**288**	**10**	**335**	**314**
Age 0 to 4	442	3.74%	396	9	2	14	0	3	18
Age 5 to 9	463	3.92%	416	7	0	15	0	2	23
Age 10 to 14	490	4.15%	423	12	1	32	0	4	18
Age 15 to 17	383	3.24%	343	14	0	18	0	1	7
Age 18 to 20	429	3.63%	260	102	6	3	4	32	22
Age 21 to 24	785	6.64%	486	213	1	17	2	35	31
Age 25 to 34	1,812	15.33%	987	554	20	45	0	119	87
Age 35 to 44	1,823	15.43%	1,183	437	13	57	1	79	53
Age 45 to 49	868	7.34%	727	74	2	18	0	30	17
Age 50 to 54	854	7.23%	756	39	2	26	2	12	17
Age 55 to 59	848	7.18%	822	5	0	13	0	4	4
Age 60 to 64	714	6.04%	689	7	1	9	1	6	1
Age 65 to 74	980	8.29%	935	21	0	10	0	5	9
Age 75 to 84	621	5.25%	608	4	0	6	0	3	0
Age 85 and over	306	2.59%	292	2	0	5	0	0	7
Age 18 and over	10,040	84.96%	7,745	1,458	45	209	10	325	248
Age 21 and over	9,611	81.33%	7,485	1,356	39	206	6	293	226
Age 65 and over	1,907	16.14%	1,835	27	0	21	0	8	16
Median Age	41.03		46.15	32.09	32	35	23	32.61	29.37
Average Age	41.9		44.27	33.01	32.68	34.73	34	34.16	30.74

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06359 North Stonington								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	5,271		4,874	37	107	108	0	23	122
2010 Estimate	5,172		4,813	34	109	89	0	18	109
2000 Census	4,993		4,708	30	103	53	0	12	87
1990 Census	4,884		4,741	24	22	39	0	2	56
Growth 1990 - 2000	2.23%		-0.70%	25.00%	368.18%	35.90%		500.00%	55.36%
2000 Census Population by Age	**4,993**		**4,708**	**30**	**103**	**53**	**0**	**12**	**87**
Age 0 to 4	288	5.77%	253	2	18	5	0	3	7
Age 5 to 9	329	6.59%	302	1	11	2	0	0	13
Age 10 to 14	376	7.53%	346	3	14	4	0	1	8
Age 15 to 17	261	5.23%	246	3	6	1	0	0	5
Age 18 to 20	157	3.14%	146	0	1	1	0	0	9
Age 21 to 24	162	3.24%	150	0	3	4	0	1	4
Age 25 to 34	524	10.49%	488	6	12	5	0	3	10
Age 35 to 44	968	19.39%	930	7	15	6	0	2	8
Age 45 to 49	511	10.23%	477	1	9	11	0	1	12
Age 50 to 54	378	7.57%	364	2	2	6	0	0	4
Age 55 to 59	309	6.19%	300	1	3	4	0	0	1
Age 60 to 64	212	4.25%	206	0	3	2	0	1	0
Age 65 to 74	334	6.69%	320	4	6	0	0	0	4
Age 75 to 84	155	3.10%	151	0	0	2	0	0	2
Age 85 and over	29	0.58%	29	0	0	0	0	0	0
Age 18 and over	3,739	74.88%	3,561	21	54	41	0	8	54
Age 21 and over	3,582	71.74%	3,415	21	53	40	0	8	45
Age 65 and over	518	10.37%	500	4	6	2	0	0	6
Median Age	39.51		39.55	35	23	42.5		28.33	22.5
Average Age	37.51		37.95	35.57	26.79	36.6		27.92	28.48
2010 Estimated Population by Age	**5,172**		**4,813**	**34**	**109**	**89**	**0**	**18**	**109**
Age 0 to 4	270	5.22%	227	5	18	8	0	6	6
Age 5 to 9	297	5.74%	261	0	16	5	0	1	14
Age 10 to 14	338	6.54%	309	6	10	4	0	1	8
Age 15 to 17	236	4.56%	222	2	5	0	0	1	6
Age 18 to 20	167	3.23%	145	4	4	2	0	1	11
Age 21 to 24	233	4.51%	210	1	6	9	0	1	6
Age 25 to 34	602	11.64%	556	3	12	11	0	2	18
Age 35 to 44	675	13.05%	638	5	8	6	0	4	14
Age 45 to 49	578	11.18%	536	3	10	17	0	1	11
Age 50 to 54	460	8.89%	438	0	3	13	0	0	6
Age 55 to 59	386	7.46%	371	2	4	8	0	0	1
Age 60 to 64	293	5.67%	286	1	5	1	0	0	0
Age 65 to 74	372	7.19%	358	2	8	0	0	0	4
Age 75 to 84	208	4.02%	202	0	0	3	0	0	3
Age 85 and over	57	1.10%	54	0	0	2	0	0	1
Age 18 and over	4,031	77.94%	3,794	21	60	72	0	9	75
Age 21 and over	3,864	74.71%	3,649	17	56	70	0	8	64
Age 65 and over	637	12.32%	614	2	8	5	0	0	8
Median Age	42.03		42.47	21	22	44.17		18	26.94
Average Age	39.53		40.2	28.35	27.68	37.54		20.53	29.9
2015 Projected Population by Age	**5,271**		**4,874**	**37**	**107**	**108**	**0**	**23**	**122**
Age 0 to 4	274	5.20%	230	3	18	8	0	7	8
Age 5 to 9	280	5.31%	243	1	14	6	0	0	16
Age 10 to 14	324	6.15%	290	5	12	6	0	2	9
Age 15 to 17	232	4.40%	213	5	3	2	0	1	8
Age 18 to 20	170	3.23%	151	0	2	1	0	1	15
Age 21 to 24	254	4.82%	223	1	4	14	0	4	8
Age 25 to 34	614	11.65%	557	5	12	18	0	3	19
Age 35 to 44	570	10.81%	536	5	11	6	0	2	10
Age 45 to 49	503	9.54%	463	1	9	17	0	0	13
Age 50 to 54	480	9.11%	458	1	2	10	0	1	8
Age 55 to 59	449	8.52%	434	3	3	9	0	0	0
Age 60 to 64	370	7.02%	354	1	6	7	0	2	0
Age 65 to 74	451	8.56%	434	6	9	0	0	0	2
Age 75 to 84	219	4.15%	213	0	0	3	0	0	3
Age 85 and over	81	1.54%	75	0	2	1	0	0	3
Age 18 and over	4,161	78.94%	3,898	23	60	86	0	13	81
Age 21 and over	3,991	75.72%	3,747	23	58	85	0	12	66
Age 65 and over	751	14.25%	722	6	11	4	0	0	8
Median Age	43.56		44.89	32	25.42	34.44		21.5	23.5
Average Age	40.81		41.59	34.55	29.56	36.06		22.87	28.95

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06370 Oakdale								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	7,709		7,113	103	44	180	4	63	202
2010 Estimate	7,375		6,818	114	48	152	3	60	180
2000 Census	6,689		6,207	129	52	98	4	56	143
1990 Census	6,509		6,057	155	38	91	5	60	103
Growth 1990 - 2000	2.77%		2.48%	-16.77%	36.84%	7.69%	-20.00%	-6.67%	38.83%
2000 Census Population by Age	**6,689**		**6,207**	**129**	**52**	**98**	**4**	**56**	**143**
Age 0 to 4	400	5.98%	360	8	8	5	0	3	16
Age 5 to 9	513	7.67%	463	10	3	7	0	8	22
Age 10 to 14	567	8.48%	517	6	6	10	0	10	18
Age 15 to 17	316	4.72%	288	5	5	6	0	2	10
Age 18 to 20	209	3.12%	192	6	2	1	0	1	7
Age 21 to 24	210	3.14%	184	5	2	4	1	3	11
Age 25 to 34	844	12.62%	797	16	8	11	2	7	3
Age 35 to 44	1,385	20.71%	1,291	28	9	17	0	11	29
Age 45 to 49	554	8.28%	526	5	2	8	0	5	8
Age 50 to 54	439	6.56%	407	11	2	10	0	3	6
Age 55 to 59	395	5.91%	374	12	1	2	1	0	5
Age 60 to 64	283	4.23%	269	4	1	8	0	0	1
Age 65 to 74	388	5.80%	365	9	1	6	0	1	6
Age 75 to 84	158	2.36%	147	4	2	2	0	2	1
Age 85 and over	28	0.42%	27	0	0	1	0	0	0
Age 18 and over	4,893	73.15%	4,579	100	30	70	4	33	77
Age 21 and over	4,684	70.03%	4,387	94	28	69	4	32	70
Age 65 and over	574	8.58%	539	13	3	9	0	3	7
Median Age	37.05		37.34	38.04	25	37.94	30	26.43	20.36
Average Age	35.72		36.03	37.11	27.28	36.59	35.25	27.96	26.38
2010 Estimated Population by Age	**7,375**		**6,818**	**114**	**48**	**152**	**3**	**60**	**180**
Age 0 to 4	402	5.45%	359	7	9	10	0	2	15
Age 5 to 9	432	5.86%	389	7	3	7	0	7	19
Age 10 to 14	487	6.60%	439	3	6	11	0	13	15
Age 15 to 17	363	4.92%	330	7	2	14	0	0	10
Age 18 to 20	273	3.70%	250	4	0	3	0	2	14
Age 21 to 24	362	4.91%	308	9	3	13	0	3	26
Age 25 to 34	840	11.39%	779	18	5	15	3	12	8
Age 35 to 44	1,178	15.97%	1,096	15	14	19	0	9	25
Age 45 to 49	715	9.69%	679	4	1	8	0	4	19
Age 50 to 54	616	8.35%	582	8	1	15	0	3	7
Age 55 to 59	483	6.55%	457	13	0	4	0	3	6
Age 60 to 64	399	5.41%	376	3	1	13	0	0	6
Age 65 to 74	520	7.05%	488	9	1	13	0	2	7
Age 75 to 84	243	3.29%	229	5	2	5	0	0	2
Age 85 and over	62	0.84%	57	2	0	2	0	0	1
Age 18 and over	5,691	77.17%	5,301	90	28	110	3	38	121
Age 21 and over	5,418	73.46%	5,051	86	28	107	3	36	107
Age 65 and over	825	11.19%	774	16	3	20	0	2	10
Median Age	40.22		40.06	36.33	27	36.58	30	27.5	23.62
Average Age	38.32		38.74	38.53	27.18	37.3	30.83	28.23	29.73
2015 Projected Population by Age	**7,709**		**7,113**	**103**	**44**	**180**	**4**	**63**	**202**
Age 0 to 4	411	5.33%	361	7	5	16	0	3	19
Age 5 to 9	428	5.55%	383	6	1	9	0	8	21
Age 10 to 14	451	5.85%	403	5	7	11	0	12	13
Age 15 to 17	331	4.29%	299	5	1	10	0	1	15
Age 18 to 20	278	3.61%	251	6	0	8	0	1	12
Age 21 to 24	424	5.50%	357	7	4	13	2	5	36
Age 25 to 34	907	11.77%	845	20	6	14	2	10	10
Age 35 to 44	980	12.71%	906	11	9	19	0	10	25
Age 45 to 49	694	9.00%	656	6	0	9	0	5	18
Age 50 to 54	684	8.87%	642	6	3	20	0	4	9
Age 55 to 59	619	8.03%	594	10	0	7	0	1	7
Age 60 to 64	487	6.32%	457	0	2	23	0	0	5
Age 65 to 74	635	8.24%	603	7	3	14	0	1	7
Age 75 to 84	298	3.87%	282	4	3	6	0	0	3
Age 85 and over	82	1.06%	74	3	0	1	0	2	2
Age 18 and over	6,088	78.97%	5,667	80	30	134	4	39	134
Age 21 and over	5,810	75.37%	5,416	74	30	126	4	38	122
Age 65 and over	1,015	13.17%	959	14	6	21	0	3	12
Median Age	41.8		42.26	32.75	31.67	39.74	25	26.5	23.33
Average Age	39.85		40.38	36.54	33.26	38.23	26.75	28.64	29.24

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06371 Old Lyme								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	9,258		8,888	17	15	232	1	33	72
2010 Estimate	9,305		8,984	15	14	194	0	33	65
2000 Census	9,422		9,187	20	22	113	1	25	54
1990 Census	8,484		8,320	35	23	68	2	7	29
Growth 1990 - 2000	11.06%		10.42%	-42.86%	-4.35%	66.18%	-50.00%	257.14%	86.21%
2000 Census Population by Age	**9,422**		**9,187**	**20**	**22**	**113**	**1**	**25**	**54**
Age 0 to 4	530	5.63%	496	0	2	16	0	4	12
Age 5 to 9	645	6.85%	618	1	1	12	0	4	9
Age 10 to 14	680	7.22%	658	3	2	8	0	4	5
Age 15 to 17	334	3.54%	328	0	0	3	0	2	1
Age 18 to 20	159	1.69%	150	1	1	4	0	1	2
Age 21 to 24	170	1.80%	162	0	3	4	0	0	1
Age 25 to 34	744	7.90%	719	0	3	11	0	4	7
Age 35 to 44	1,654	17.55%	1,609	3	4	26	1	5	6
Age 45 to 49	841	8.93%	819	3	3	11	0	1	4
Age 50 to 54	799	8.48%	789	3	2	4	0	0	1
Age 55 to 59	704	7.47%	697	0	1	5	0	0	1
Age 60 to 64	521	5.53%	511	5	0	3	0	0	2
Age 65 to 74	925	9.82%	916	1	0	6	0	0	2
Age 75 to 84	558	5.92%	557	0	0	0	0	0	1
Age 85 and over	158	1.68%	158	0	0	0	0	0	0
Age 18 and over	7,233	76.77%	7,087	16	17	74	1	11	27
Age 21 and over	7,074	75.08%	6,937	15	16	70	1	10	25
Age 65 and over	1,641	17.42%	1,631	1	0	6	0	0	3
Median Age	43.82		44.09	48.33	31.67	33.64	40	15.75	18
Average Age	41.86		42.16	43.13	31.41	30.67	37.5	20.28	24.71
2010 Estimated Population by Age	**9,305**		**8,984**	**15**	**14**	**194**	**0**	**33**	**65**
Age 0 to 4	488	5.24%	433	0	1	23	0	7	24
Age 5 to 9	535	5.75%	494	0	2	28	0	3	8
Age 10 to 14	595	6.39%	558	8	3	12	0	7	7
Age 15 to 17	445	4.78%	423	0	1	18	0	3	0
Age 18 to 20	259	2.78%	239	4	1	8	0	2	5
Age 21 to 24	419	4.50%	402	0	3	11	0	0	3
Age 25 to 34	690	7.42%	663	0	1	16	0	4	6
Age 35 to 44	988	10.62%	943	1	0	30	0	5	9
Age 45 to 49	839	9.02%	818	0	1	18	0	2	0
Age 50 to 54	908	9.76%	899	1	1	7	0	0	0
Age 55 to 59	834	8.96%	826	0	0	8	0	0	0
Age 60 to 64	622	6.68%	616	1	0	4	0	0	1
Age 65 to 74	920	9.89%	909	0	0	10	0	0	1
Age 75 to 84	556	5.98%	556	0	0	0	0	0	0
Age 85 and over	207	2.22%	205	0	0	1	0	0	1
Age 18 and over	7,242	77.83%	7,076	7	7	113	0	13	26
Age 21 and over	6,983	75.05%	6,837	3	6	105	0	11	21
Age 65 and over	1,683	18.09%	1,670	0	0	11	0	0	2
Median Age	46.39		47.06	14.69	18	23.91		14.64	10.36
Average Age	42.58		43.22	22.3	20.61	28.54		19.02	17.34
2015 Projected Population by Age	**9,258**		**8,888**	**17**	**15**	**232**	**1**	**33**	**72**
Age 0 to 4	503	5.43%	440	0	4	31	0	7	21
Age 5 to 9	500	5.40%	455	1	2	32	0	3	7
Age 10 to 14	539	5.82%	498	5	5	19	0	6	6
Age 15 to 17	417	4.50%	401	0	0	12	0	3	1
Age 18 to 20	262	2.83%	244	3	0	10	0	2	3
Age 21 to 24	502	5.42%	474	0	3	19	0	0	6
Age 25 to 34	874	9.44%	841	0	0	20	0	6	7
Age 35 to 44	685	7.40%	639	2	1	27	1	2	13
Age 45 to 49	620	6.70%	601	1	0	13	0	3	2
Age 50 to 54	900	9.72%	889	1	0	10	0	0	0
Age 55 to 59	901	9.73%	884	0	0	16	0	0	1
Age 60 to 64	732	7.91%	723	3	0	5	0	0	1
Age 65 to 74	1,049	11.33%	1,031	0	0	16	0	0	2
Age 75 to 84	544	5.88%	544	0	0	0	0	0	0
Age 85 and over	230	2.48%	224	1	0	2	0	1	2
Age 18 and over	7,299	78.84%	7,094	11	4	138	1	14	37
Age 21 and over	7,037	76.01%	6,850	8	4	128	1	12	34
Age 65 and over	1,823	19.69%	1,799	1	0	18	0	1	4
Median Age	47.8		48.76	20.5	11.5	23.53	40	15.5	19
Average Age	43.19		43.86	34.81	13.37	29.1	37.5	20.74	22.86

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06375 Quaker Hill								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	4,498		3,814	156	26	297	3	79	123
2010 Estimate	4,420		3,834	145	28	234	3	65	111
2000 Census	4,317		3,897	127	31	123	1	41	97
1990 Census	3,812		3,580	90	15	59	0	7	61
Growth 1990 - 2000	13.25%		8.85%	41.11%	106.67%	108.47%		485.71%	59.02%
2000 Census Population by Age	**4,317**		**3,897**	**127**	**31**	**123**	**1**	**41**	**97**
Age 0 to 4	211	4.89%	174	10	1	8	0	4	14
Age 5 to 9	276	6.39%	236	8	4	10	0	4	14
Age 10 to 14	240	5.56%	204	7	4	13	0	6	6
Age 15 to 17	142	3.29%	123	6	3	5	0	1	4
Age 18 to 20	409	9.47%	366	11	1	8	0	8	15
Age 21 to 24	264	6.12%	237	8	1	11	0	4	3
Age 25 to 34	395	9.15%	357	14	4	10	0	5	5
Age 35 to 44	661	15.31%	602	16	6	24	0	2	11
Age 45 to 49	295	6.83%	264	11	1	11	1	1	6
Age 50 to 54	251	5.81%	227	9	1	7	0	3	4
Age 55 to 59	254	5.88%	240	4	1	4	0	1	4
Age 60 to 64	195	4.52%	177	7	2	3	0	2	4
Age 65 to 74	348	8.06%	330	7	2	7	0	0	2
Age 75 to 84	293	6.79%	280	8	0	1	0	0	4
Age 85 and over	83	1.92%	80	1	0	1	0	0	1
Age 18 and over	3,448	79.87%	3,160	96	19	87	1	26	59
Age 21 and over	3,039	70.40%	2,794	85	18	79	1	18	44
Age 65 and over	724	16.77%	690	16	2	9	0	0	7
Median Age	38.39		39.18	34.64	28.75	31.5	47.5	20.06	20.1
Average Age	39.3		40.09	36.06	30.85	32.34	47.5	24.32	28.49
2010 Estimated Population by Age	**4,420**		**3,834**	**145**	**28**	**234**	**3**	**65**	**111**
Age 0 to 4	198	4.48%	158	11	0	12	0	4	13
Age 5 to 9	210	4.75%	168	11	3	15	0	1	12
Age 10 to 14	260	5.88%	204	9	8	25	0	7	7
Age 15 to 17	204	4.62%	174	11	1	6	0	0	12
Age 18 to 20	482	10.90%	417	10	2	23	0	18	12
Age 21 to 24	356	8.05%	298	7	3	34	1	6	7
Age 25 to 34	321	7.26%	268	9	3	20	2	14	5
Age 35 to 44	493	11.15%	430	21	2	32	0	2	6
Age 45 to 49	324	7.33%	278	9	0	23	0	1	13
Age 50 to 54	307	6.95%	268	16	3	10	0	6	4
Age 55 to 59	277	6.27%	257	4	1	9	0	2	4
Age 60 to 64	243	5.50%	213	13	2	8	0	1	6
Age 65 to 74	334	7.56%	311	6	0	11	0	3	3
Age 75 to 84	297	6.72%	281	7	0	4	0	0	5
Age 85 and over	114	2.58%	109	1	0	2	0	0	2
Age 18 and over	3,548	80.27%	3,130	103	16	176	3	53	67
Age 21 and over	3,066	69.37%	2,713	93	14	153	3	35	55
Age 65 and over	745	16.86%	701	14	0	17	0	3	10
Median Age	39.26		40.35	37.14	21	26	27.5	22.67	20.88
Average Age	39.73		40.85	36.15	26.88	32.47	26.17	27.94	30.69
2015 Projected Population by Age	**4,498**		**3,814**	**156**	**26**	**297**	**3**	**79**	**123**
Age 0 to 4	204	4.54%	153	11	0	19	0	9	12
Age 5 to 9	203	4.51%	157	7	4	22	0	3	10
Age 10 to 14	230	5.11%	168	8	7	32	0	9	6
Age 15 to 17	196	4.36%	163	9	2	10	0	1	11
Age 18 to 20	541	12.03%	456	10	1	30	0	27	17
Age 21 to 24	427	9.49%	353	13	0	50	1	4	6
Age 25 to 34	330	7.34%	271	20	2	17	1	11	8
Age 35 to 44	371	8.25%	308	15	1	30	0	5	12
Age 45 to 49	282	6.27%	236	12	0	21	1	2	10
Age 50 to 54	323	7.18%	283	15	1	17	0	4	3
Age 55 to 59	310	6.89%	280	6	3	17	0	0	4
Age 60 to 64	276	6.14%	236	15	3	9	0	2	11
Age 65 to 74	385	8.56%	351	6	2	17	0	2	7
Age 75 to 84	288	6.40%	273	7	0	3	0	0	5
Age 85 and over	132	2.93%	126	2	0	3	0	0	1
Age 18 and over	3,665	81.48%	3,173	121	13	214	3	57	84
Age 21 and over	3,124	69.45%	2,717	111	12	184	3	30	67
Age 65 and over	805	17.90%	750	15	2	23	0	2	13
Median Age	38.66		41.04	35	18	23.84	30	19.94	24.67
Average Age	40.1		41.5	36.98	31.5	31.52	32.83	23.71	33.25

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06378 Stonington								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	5,421		5,195	12	9	108	5	24	68
2010 Estimate	5,457		5,259	13	9	86	5	23	62
2000 Census	5,501		5,359	17	10	46	3	16	50
1990 Census	5,186		5,093	22	6	28	2	8	27
Growth 1990 - 2000	6.07%		5.22%	-22.73%	66.67%	64.29%	50.00%	100.00%	85.19%
2000 Census Population by Age	**5,501**		**5,359**	**17**	**10**	**46**	**3**	**16**	**50**
Age 0 to 4	257	4.67%	238	0	0	6	0	4	9
Age 5 to 9	311	5.65%	297	2	0	2	0	0	10
Age 10 to 14	339	6.16%	327	1	0	5	0	2	4
Age 15 to 17	184	3.34%	179	0	0	1	0	2	2
Age 18 to 20	96	1.75%	91	0	0	3	0	1	1
Age 21 to 24	142	2.58%	138	1	0	2	0	0	1
Age 25 to 34	550	10.00%	528	0	2	10	1	5	4
Age 35 to 44	907	16.49%	879	2	2	12	1	0	11
Age 45 to 49	522	9.49%	512	2	0	3	0	2	3
Age 50 to 54	462	8.40%	454	1	1	2	1	0	3
Age 55 to 59	405	7.36%	402	2	1	0	0	0	0
Age 60 to 64	334	6.07%	330	2	2	0	0	0	0
Age 65 to 74	561	10.20%	554	4	1	0	0	0	2
Age 75 to 84	322	5.85%	321	0	1	0	0	0	0
Age 85 and over	109	1.98%	109	0	0	0	0	0	0
Age 18 and over	4,410	80.17%	4,318	14	10	32	3	8	25
Age 21 and over	4,314	78.42%	4,227	14	10	29	3	7	24
Age 65 and over	992	18.03%	984	4	2	0	0	0	2
Median Age	44.63		45.02	52.5	55	29	40	18	18
Average Age	42.95		43.28	47.32	53.3	26.78	40.83	21.53	24.55
2010 Estimated Population by Age	**5,457**		**5,259**	**13**	**9**	**86**	**5**	**23**	**62**
Age 0 to 4	236	4.32%	211	0	0	9	0	4	12
Age 5 to 9	262	4.80%	241	5	0	3	2	1	10
Age 10 to 14	298	5.46%	273	0	1	10	0	3	11
Age 15 to 17	228	4.18%	213	0	1	6	0	4	4
Age 18 to 20	125	2.29%	113	1	0	10	0	1	0
Age 21 to 24	224	4.10%	220	1	0	0	0	2	1
Age 25 to 34	487	8.92%	455	0	3	15	2	4	8
Age 35 to 44	683	12.52%	658	1	0	16	0	0	8
Age 45 to 49	476	8.72%	464	3	0	6	0	2	1
Age 50 to 54	537	9.84%	525	1	0	7	1	2	1
Age 55 to 59	497	9.11%	488	1	2	3	0	0	3
Age 60 to 64	387	7.09%	386	0	1	0	0	0	0
Age 65 to 74	548	10.04%	544	0	1	1	0	0	2
Age 75 to 84	343	6.29%	343	0	0	0	0	0	0
Age 85 and over	126	2.31%	125	0	0	0	0	0	1
Age 18 and over	4,433	81.24%	4,321	8	7	58	3	11	25
Age 21 and over	4,308	78.94%	4,208	7	7	48	3	10	25
Age 65 and over	1,017	18.64%	1,012	0	1	1	0	0	3
Median Age	46.95		47.65	23	33.33	28.33	27.5	17.63	14.09
Average Age	44		44.66	28.69	39.83	28.26	24.5	22.48	22.67
2015 Projected Population by Age	**5,421**		**5,195**	**12**	**9**	**108**	**5**	**24**	**68**
Age 0 to 4	240	4.43%	207	0	2	11	0	2	18
Age 5 to 9	244	4.50%	217	4	0	7	3	2	11
Age 10 to 14	273	5.04%	240	2	1	14	0	3	13
Age 15 to 17	212	3.91%	197	0	0	10	0	2	3
Age 18 to 20	130	2.40%	114	1	0	11	0	4	0
Age 21 to 24	264	4.87%	260	0	1	1	0	1	1
Age 25 to 34	494	9.11%	462	0	1	16	2	6	7
Age 35 to 44	566	10.44%	540	1	0	18	0	0	7
Age 45 to 49	373	6.88%	364	1	0	6	0	1	1
Age 50 to 54	528	9.74%	512	2	1	9	0	3	1
Age 55 to 59	535	9.87%	527	0	1	4	0	0	3
Age 60 to 64	464	8.56%	464	0	0	0	0	0	0
Age 65 to 74	620	11.44%	615	1	2	0	0	0	2
Age 75 to 84	328	6.05%	328	0	0	0	0	0	0
Age 85 and over	150	2.77%	148	0	0	1	0	0	1
Age 18 and over	4,452	82.13%	4,334	6	6	66	2	15	23
Age 21 and over	4,322	79.73%	4,220	5	6	55	2	11	23
Age 65 and over	1,098	20.25%	1,091	1	2	1	0	0	3
Median Age	48.85		49.95	15	30	25	9.17	20.25	11.92
Average Age	44.9		45.77	28.46	35.06	27.01	15.5	24.65	19.81

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06379 Pawcatuck								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	8,797		7,945	86	40	390	11	81	244
2010 Estimate	8,717		8,010	81	41	292	9	69	215
2000 Census	8,617		8,159	70	48	128	5	48	159
1990 Census	8,231		8,046	53	27	20	2	13	70
Growth 1990 - 2000	4.69%		1.40%	32.08%	77.78%	540.00%	150.00%	269.23%	127.14%
2000 Census Population by Age	**8,617**		**8,159**	**70**	**48**	**128**	**5**	**48**	**159**
Age 0 to 4	549	6.37%	490	17	5	11	0	3	23
Age 5 to 9	591	6.86%	529	7	5	11	1	5	33
Age 10 to 14	596	6.92%	551	9	2	11	0	8	15
Age 15 to 17	359	4.17%	345	1	1	4	0	6	2
Age 18 to 20	237	2.75%	226	1	1	6	1	0	2
Age 21 to 24	302	3.50%	274	2	5	10	0	4	7
Age 25 to 34	1,107	12.85%	1,048	7	8	22	0	1	21
Age 35 to 44	1,504	17.45%	1,419	8	5	31	3	12	26
Age 45 to 49	634	7.36%	607	5	5	9	0	3	5
Age 50 to 54	579	6.72%	564	1	2	3	0	1	8
Age 55 to 59	477	5.54%	469	2	1	3	0	0	2
Age 60 to 64	352	4.08%	346	1	1	3	0	0	1
Age 65 to 74	674	7.82%	653	6	4	3	0	3	5
Age 75 to 84	515	5.98%	501	0	3	1	0	2	8
Age 85 and over	141	1.64%	137	3	0	0	0	0	1
Age 18 and over	6,522	75.69%	6,244	36	35	91	4	26	86
Age 21 and over	6,285	72.94%	6,018	35	34	85	3	26	84
Age 65 and over	1,330	15.43%	1,291	9	7	4	0	5	14
Median Age	38.67		39.34	21	31.25	30	36.67	23	23.57
Average Age	38.92		39.47	28.17	34.02	29.76	29.8	29.29	27.09
2010 Estimated Population by Age	**8,717**		**8,010**	**81**	**41**	**292**	**9**	**69**	**215**
Age 0 to 4	524	6.01%	451	11	2	30	0	2	28
Age 5 to 9	562	6.45%	490	5	4	21	2	14	26
Age 10 to 14	593	6.80%	534	12	1	10	0	9	27
Age 15 to 17	371	4.26%	343	7	0	10	0	8	3
Age 18 to 20	263	3.02%	240	3	0	13	1	0	6
Age 21 to 24	381	4.37%	333	2	4	25	0	6	11
Age 25 to 34	995	11.41%	902	10	14	41	5	4	19
Age 35 to 44	1,309	15.02%	1,181	13	4	60	1	17	33
Age 45 to 49	730	8.37%	674	7	3	33	0	5	8
Age 50 to 54	665	7.63%	636	1	3	9	0	3	13
Age 55 to 59	541	6.21%	520	4	1	7	0	0	9
Age 60 to 64	465	5.33%	446	0	0	16	0	0	3
Age 65 to 74	627	7.19%	593	5	5	11	0	0	13
Age 75 to 84	508	5.83%	492	0	0	6	0	1	9
Age 85 and over	183	2.10%	175	1	0	0	0	0	7
Age 18 and over	6,667	76.48%	6,192	46	34	221	7	36	131
Age 21 and over	6,404	73.47%	5,952	43	34	208	6	36	125
Age 65 and over	1,318	15.12%	1,260	6	5	17	0	1	29
Median Age	40.45		41.03	25.5	31.79	34.02	28	22	28.42
Average Age	39.69		40.39	28.48	34.18	33.19	23.78	25.88	32.21
2015 Projected Population by Age	**8,797**		**7,945**	**86**	**40**	**390**	**11**	**81**	**244**
Age 0 to 4	531	6.04%	445	17	2	37	0	2	28
Age 5 to 9	543	6.17%	443	5	12	25	2	13	43
Age 10 to 14	569	6.47%	493	11	0	26	0	9	30
Age 15 to 17	392	4.46%	359	2	2	15	0	9	5
Age 18 to 20	285	3.24%	261	0	0	14	3	0	7
Age 21 to 24	444	5.05%	374	1	5	40	0	11	13
Age 25 to 34	919	10.45%	810	13	10	53	5	5	23
Age 35 to 44	1,130	12.85%	984	13	2	83	1	17	30
Age 45 to 49	693	7.88%	628	8	2	37	0	7	11
Age 50 to 54	723	8.22%	693	0	0	7	0	8	15
Age 55 to 59	646	7.34%	625	5	1	9	0	0	6
Age 60 to 64	519	5.90%	493	1	0	24	0	0	1
Age 65 to 74	727	8.26%	688	7	3	16	0	0	13
Age 75 to 84	465	5.29%	446	0	1	4	0	0	14
Age 85 and over	211	2.40%	203	3	0	0	0	0	5
Age 18 and over	6,762	76.87%	6,205	51	24	287	9	48	138
Age 21 and over	6,477	73.63%	5,944	51	24	273	6	48	131
Age 65 and over	1,403	15.95%	1,337	10	4	20	0	0	32
Median Age	41.57		43	30.38	24.2	32.17	26	23.73	23.77
Average Age	40.35		41.37	30.99	25.96	32.24	22.91	27.34	30.25

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06382 Uncasville								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	12,518		8,903	1,546	191	609	5	713	551
2010 Estimate	12,187		9,130	1,311	198	472	5	580	491
2000 Census	11,541		9,470	882	212	239	3	354	381
1990 Census	9,889		9,145	266	89	115	4	78	192
Growth 1990 - 2000	16.71%		3.55%	231.58%	138.20%	107.83%	-25.00%	353.85%	98.44%
2000 Census Population by Age	**11,541**		**9,470**	**882**	**212**	**239**	**3**	**354**	**381**
Age 0 to 4	592	5.13%	487	7	17	23	0	9	49
Age 5 to 9	723	6.26%	604	25	11	13	0	18	52
Age 10 to 14	744	6.45%	646	19	16	11	0	24	28
Age 15 to 17	449	3.89%	379	24	8	10	0	14	14
Age 18 to 20	459	3.98%	300	85	12	9	0	24	29
Age 21 to 24	674	5.84%	413	138	13	14	0	59	37
Age 25 to 34	1,852	16.05%	1,291	295	36	47	0	114	69
Age 35 to 44	2,152	18.65%	1,769	185	45	37	0	69	47
Age 45 to 49	781	6.77%	685	41	13	18	0	9	15
Age 50 to 54	669	5.80%	612	21	8	15	1	4	8
Age 55 to 59	577	5.00%	536	10	9	7	0	6	9
Age 60 to 64	458	3.97%	414	15	4	16	0	2	7
Age 65 to 74	763	6.61%	718	8	11	12	0	2	12
Age 75 to 84	490	4.25%	467	7	7	4	2	0	3
Age 85 and over	158	1.37%	149	2	2	3	0	0	2
Age 18 and over	9,033	78.27%	7,354	807	160	182	3	289	238
Age 21 and over	8,574	74.29%	7,054	722	148	173	3	265	209
Age 65 and over	1,411	12.23%	1,334	17	20	19	2	2	17
Median Age	36.21		38.48	29.85	33.06	33.4	77.5	27.54	23
Average Age	37.29		38.79	31.38	33.86	34.6	72.5	27.98	25.53
2010 Estimated Population by Age	**12,187**		**9,130**	**1,311**	**198**	**472**	**5**	**580**	**491**
Age 0 to 4	578	4.74%	440	17	14	42	0	11	54
Age 5 to 9	615	5.05%	488	20	11	30	0	20	46
Age 10 to 14	673	5.52%	554	18	13	20	0	32	36
Age 15 to 17	493	4.05%	400	30	3	26	0	20	14
Age 18 to 20	547	4.49%	305	133	18	13	0	44	34
Age 21 to 24	890	7.30%	461	238	3	29	0	108	51
Age 25 to 34	1,829	15.01%	1,062	412	37	68	0	163	87
Age 35 to 44	1,929	15.83%	1,417	246	29	66	0	107	64
Age 45 to 49	958	7.86%	789	70	14	35	0	24	26
Age 50 to 54	848	6.96%	725	39	11	40	5	18	10
Age 55 to 59	640	5.25%	567	20	7	17	0	13	16
Age 60 to 64	587	4.82%	502	32	3	31	0	8	11
Age 65 to 74	788	6.47%	693	11	20	24	0	12	28
Age 75 to 84	528	4.33%	474	22	8	16	0	0	8
Age 85 and over	284	2.33%	253	3	7	15	0	0	6
Age 18 and over	9,828	80.64%	7,248	1,226	157	354	5	497	341
Age 21 and over	9,281	76.15%	6,943	1,093	139	341	5	453	307
Age 65 and over	1,600	13.13%	1,420	36	35	55	0	12	42
Median Age	37.57		41.03	29.84	35	36.21	52.5	28.37	26.21
Average Age	38.72		40.75	32.32	38.04	37.01	52.5	30.26	29.7
2015 Projected Population by Age	**12,518**		**8,903**	**1,546**	**191**	**609**	**5**	**713**	**551**
Age 0 to 4	580	4.63%	409	14	13	62	0	17	65
Age 5 to 9	599	4.79%	467	29	10	22	0	23	48
Age 10 to 14	625	4.99%	498	22	11	30	0	33	31
Age 15 to 17	481	3.84%	365	28	5	34	0	29	20
Age 18 to 20	577	4.61%	290	163	11	19	0	56	38
Age 21 to 24	1,013	8.09%	483	276	8	37	0	142	67
Age 25 to 34	1,809	14.45%	949	459	31	86	0	195	89
Age 35 to 44	1,763	14.08%	1,161	300	31	75	0	136	60
Age 45 to 49	928	7.41%	728	91	11	40	0	28	30
Age 50 to 54	938	7.49%	781	58	9	53	4	16	17
Age 55 to 59	809	6.46%	700	26	10	24	1	18	30
Age 60 to 64	628	5.02%	514	35	7	53	0	10	9
Age 65 to 74	911	7.28%	794	16	16	43	0	10	32
Age 75 to 84	525	4.19%	465	24	11	16	0	0	9
Age 85 and over	332	2.65%	299	5	7	15	0	0	6
Age 18 and over	10,233	81.75%	7,164	1,453	152	461	5	611	387
Age 21 and over	9,656	77.14%	6,874	1,290	141	442	5	555	349
Age 65 and over	1,768	14.12%	1,558	45	34	74	0	10	47
Median Age	38.34		43.53	30.25	37.1	36.93	53.13	27.9	25.73
Average Age	39.54		42.2	32.74	39.6	37.61	53.5	29.81	30.15

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06385 Waterford								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	14,806		13,157	310	48	853	2	162	274
2010 Estimate	14,783		13,355	307	49	679	2	141	250
2000 Census	14,820		13,785	302	59	357	1	101	215
1990 Census	14,107		13,459	255	36	166	6	50	135
Growth 1990 - 2000	5.05%		2.42%	18.43%	63.89%	115.06%	-83.33%	102.00%	59.26%
2000 Census Population by Age	**14,820**		**13,785**	**302**	**59**	**357**	**1**	**101**	**215**
Age 0 to 4	726	4.90%	637	13	7	29	0	8	32
Age 5 to 9	946	6.38%	855	21	4	26	0	8	32
Age 10 to 14	1,050	7.09%	942	33	6	40	0	8	21
Age 15 to 17	592	3.99%	529	19	0	18	0	8	18
Age 18 to 20	352	2.38%	317	14	1	8	0	6	6
Age 21 to 24	341	2.30%	302	17	2	7	1	7	5
Age 25 to 34	1,507	10.17%	1,384	35	7	43	0	14	24
Age 35 to 44	2,527	17.05%	2,361	34	12	75	0	14	31
Age 45 to 49	1,218	8.22%	1,129	33	4	34	0	8	10
Age 50 to 54	1,022	6.90%	965	19	4	18	0	9	7
Age 55 to 59	900	6.07%	864	9	0	17	0	4	6
Age 60 to 64	729	4.92%	702	9	1	11	0	1	5
Age 65 to 74	1,456	9.82%	1,388	24	10	20	0	5	9
Age 75 to 84	1,087	7.33%	1,050	18	1	8	0	1	9
Age 85 and over	367	2.48%	360	4	0	3	0	0	0
Age 18 and over	11,506	77.64%	10,822	216	42	244	1	69	112
Age 21 and over	11,154	75.26%	10,505	202	41	236	1	63	106
Age 65 and over	2,910	19.64%	2,798	46	11	31	0	6	18
Median Age	42.57		43.16	34.71	37.08	36	23	28.93	20.25
Average Age	42.11		42.76	36.9	35.93	34.18	23.5	31.05	27.44
2010 Estimated Population by Age	**14,783**		**13,355**	**307**	**49**	**679**	**2**	**141**	**250**
Age 0 to 4	684	4.63%	572	16	3	56	0	3	34
Age 5 to 9	744	5.03%	645	15	4	37	0	11	32
Age 10 to 14	870	5.89%	751	23	5	58	0	8	25
Age 15 to 17	665	4.50%	573	19	1	34	0	14	24
Age 18 to 20	465	3.15%	405	11	2	22	0	11	14
Age 21 to 24	622	4.21%	535	36	2	25	2	12	10
Age 25 to 34	1,350	9.13%	1,201	27	4	66	0	22	30
Age 35 to 44	1,882	12.73%	1,688	27	14	114	0	16	23
Age 45 to 49	1,274	8.62%	1,138	26	5	79	0	14	12
Age 50 to 54	1,262	8.54%	1,168	27	3	38	0	15	11
Age 55 to 59	1,079	7.30%	1,017	12	0	34	0	4	12
Age 60 to 64	862	5.83%	805	13	1	38	0	0	5
Age 65 to 74	1,419	9.60%	1,311	30	5	53	0	10	10
Age 75 to 84	1,121	7.58%	1,072	22	0	19	0	1	7
Age 85 and over	484	3.27%	474	3	0	6	0	0	1
Age 18 and over	11,820	79.96%	10,814	234	36	494	2	105	135
Age 21 and over	11,355	76.81%	10,409	223	34	472	2	94	121
Age 65 and over	3,024	20.46%	2,857	55	5	78	0	11	18
Median Age	45.43		46.35	37.41	37.5	38.64	23	30.23	20.14
Average Age	43.51		44.39	38.99	34.38	36.91	23.5	33.15	27.42
2015 Projected Population by Age	**14,806**		**13,157**	**310**	**48**	**853**	**2**	**162**	**274**
Age 0 to 4	678	4.58%	546	17	3	69	0	7	36
Age 5 to 9	716	4.84%	602	17	6	44	0	13	34
Age 10 to 14	786	5.31%	656	27	6	63	0	13	21
Age 15 to 17	598	4.04%	492	17	1	54	0	6	28
Age 18 to 20	475	3.21%	409	6	2	23	0	17	18
Age 21 to 24	717	4.84%	612	36	2	34	0	18	15
Age 25 to 34	1,481	10.00%	1,282	40	5	98	0	27	29
Age 35 to 44	1,445	9.76%	1,267	26	12	106	0	11	23
Age 45 to 49	1,094	7.39%	951	24	3	93	2	11	10
Age 50 to 54	1,303	8.80%	1,181	24	3	59	0	21	15
Age 55 to 59	1,239	8.37%	1,151	12	0	56	0	9	11
Age 60 to 64	1,040	7.02%	973	10	0	47	0	1	9
Age 65 to 74	1,579	10.66%	1,449	26	5	75	0	8	16
Age 75 to 84	1,110	7.50%	1,058	23	0	21	0	0	8
Age 85 and over	545	3.68%	528	5	0	11	0	0	1
Age 18 and over	12,028	81.24%	10,861	232	32	623	2	123	155
Age 21 and over	11,553	78.03%	10,452	226	30	600	2	106	137
Age 65 and over	3,234	21.84%	3,035	54	5	107	0	8	25
Median Age	47.32		48.75	33.75	33	38.92	47.5	27.59	21
Average Age	44.52		45.64	37.99	31.3	37.7	47.5	31.69	28.62

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	02891 Westerly								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	21,848		20,105	241	148	878	0	112	364
2010 Estimate	21,717		20,223	205	139	724	0	93	333
2000 Census	21,363		20,314	154	118	447	0	71	259
1990 Census	20,056		19,500	115	59	205	3	26	148
Growth 1990 - 2000	6.52%		4.17%	33.91%	100.00%	118.05%	-100.00%	173.08%	75.00%
2000 Census Population by Age	**21,363**		**20,314**	**154**	**118**	**447**	**0**	**71**	**259**
Age 0 to 4	1,270	5.94%	1,153	10	15	34	0	11	47
Age 5 to 9	1,401	6.56%	1,284	7	9	52	0	10	39
Age 10 to 14	1,350	6.32%	1,259	15	13	30	0	5	28
Age 15 to 17	822	3.85%	767	13	3	24	0	2	13
Age 18 to 20	636	2.98%	597	9	2	14	0	2	12
Age 21 to 24	853	3.99%	798	14	7	20	0	3	11
Age 25 to 34	2,721	12.74%	2,588	20	16	48	0	21	28
Age 35 to 44	3,557	16.65%	3,379	27	20	90	0	7	34
Age 45 to 49	1,464	6.85%	1,396	8	8	36	0	5	11
Age 50 to 54	1,407	6.59%	1,351	9	9	22	0	3	13
Age 55 to 59	1,178	5.51%	1,137	5	7	21	0	2	6
Age 60 to 64	907	4.25%	892	4	1	7	0	0	3
Age 65 to 74	1,737	8.13%	1,684	7	4	34	0	0	8
Age 75 to 84	1,466	6.86%	1,441	4	4	12	0	0	5
Age 85 and over	594	2.78%	588	2	0	3	0	0	1
Age 18 and over	16,520	77.33%	15,851	109	78	307	0	43	132
Age 21 and over	15,884	74.35%	15,254	100	76	293	0	41	120
Age 65 and over	3,797	17.77%	3,713	13	8	49	0	0	14
Median Age	39.59		40.06	29.5	31.25	35.17		26.19	18.63
Average Age	40.28		40.77	32.74	31.32	33.99		24.62	24.88
2010 Estimated Population by Age	**21,717**		**20,223**	**205**	**139**	**724**	**0**	**93**	**333**
Age 0 to 4	1,066	4.91%	936	11	16	41	0	12	50
Age 5 to 9	1,163	5.36%	1,018	13	15	67	0	13	37
Age 10 to 14	1,318	6.07%	1,190	18	13	44	0	9	44
Age 15 to 17	844	3.89%	759	16	5	34	0	11	19
Age 18 to 20	683	3.15%	617	13	4	25	0	5	19
Age 21 to 24	1,022	4.71%	938	23	8	34	0	1	18
Age 25 to 34	2,392	11.01%	2,225	26	20	65	0	23	33
Age 35 to 44	3,070	14.14%	2,855	28	22	117	0	5	43
Age 45 to 49	1,703	7.84%	1,588	16	12	69	0	6	12
Age 50 to 54	1,629	7.50%	1,526	13	9	53	0	7	21
Age 55 to 59	1,438	6.62%	1,364	11	2	49	0	1	11
Age 60 to 64	1,390	6.40%	1,356	2	2	18	0	0	12
Age 65 to 74	1,793	8.26%	1,697	13	7	68	0	0	8
Age 75 to 84	1,471	6.77%	1,427	2	4	36	0	0	2
Age 85 and over	735	3.38%	727	0	0	4	0	0	4
Age 18 and over	17,326	79.78%	16,320	147	90	538	0	48	183
Age 21 and over	16,643	76.64%	15,703	134	86	513	0	43	164
Age 65 and over	3,999	18.41%	3,851	15	11	108	0	0	14
Median Age	42.82		43.51	28.27	29.25	39.44		18.9	20.61
Average Age	42.24		42.91	31.82	30.46	38.3		23.15	26.73
2015 Projected Population by Age	**21,848**		**20,105**	**241**	**148**	**878**	**0**	**112**	**364**
Age 0 to 4	1,075	4.92%	930	8	11	54	0	16	56
Age 5 to 9	1,084	4.96%	920	13	13	78	0	13	47
Age 10 to 14	1,183	5.41%	1,037	21	21	58	0	7	39
Age 15 to 17	834	3.82%	735	22	4	45	0	10	18
Age 18 to 20	659	3.02%	588	18	3	29	0	4	17
Age 21 to 24	986	4.51%	889	25	4	50	0	2	16
Age 25 to 34	2,640	12.08%	2,440	38	23	75	0	26	38
Age 35 to 44	2,619	11.99%	2,396	26	24	127	0	6	40
Age 45 to 49	1,576	7.21%	1,437	15	16	79	0	11	18
Age 50 to 54	1,658	7.59%	1,529	16	8	65	0	13	27
Age 55 to 59	1,653	7.57%	1,551	9	7	63	0	3	20
Age 60 to 64	1,499	6.86%	1,453	8	3	23	0	1	11
Age 65 to 74	2,177	9.96%	2,054	18	6	90	0	0	9
Age 75 to 84	1,416	6.48%	1,367	4	5	38	0	0	2
Age 85 and over	789	3.61%	779	0	0	4	0	0	6
Age 18 and over	17,672	80.89%	16,483	177	99	643	0	66	204
Age 21 and over	17,013	77.87%	15,895	159	96	614	0	62	187
Age 65 and over	4,382	20.06%	4,200	22	11	132	0	0	17
Median Age	44.45		45.41	28.55	32.83	38.94		26.54	22.25
Average Age	43.24		44.04	32.97	32.71	37.85		26.83	27.86

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06254 North Franklin								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	1,884		1,826	25	1	0	1	2	29
2010 Estimate	1,865		1,815	20	1	1	1	2	25
2000 Census	1,835		1,798	13	1	1	1	1	20
1990 Census	1,810		1,790	2	1	3	2	1	11
Growth 1990 - 2000	1.38%		0.45%	550.00%	0.00%	-66.67%	-50.00%	0.00%	81.82%
2000 Census Population by Age	**1,835**		**1,798**	**13**	**1**	**1**	**1**	**1**	**20**
Age 0 to 4	99	5.40%	96	1	0	0	0	0	2
Age 5 to 9	120	6.54%	116	2	0	0	0	0	2
Age 10 to 14	131	7.14%	129	0	0	0	0	0	2
Age 15 to 17	93	5.07%	90	1	0	0	0	0	2
Age 18 to 20	53	2.89%	49	2	1	0	0	0	1
Age 21 to 24	56	3.05%	53	3	0	0	0	0	0
Age 25 to 34	204	11.12%	199	0	0	0	0	1	4
Age 35 to 44	342	18.64%	340	0	0	0	0	0	2
Age 45 to 49	170	9.26%	167	0	0	0	1	0	2
Age 50 to 54	134	7.30%	132	2	0	0	0	0	0
Age 55 to 59	107	5.83%	107	0	0	0	0	0	0
Age 60 to 64	92	5.01%	90	1	0	1	0	0	0
Age 65 to 74	132	7.19%	129	1	0	0	0	0	2
Age 75 to 84	83	4.52%	82	0	0	0	0	0	1
Age 85 and over	19	1.04%	19	0	0	0	0	0	0
Age 18 and over	1,392	75.86%	1,367	9	1	1	1	1	12
Age 21 and over	1,339	72.97%	1,318	7	0	1	1	1	11
Age 65 and over	234	12.75%	230	1	0	0	0	0	3
Median Age	39.92		39.91	21.67	19.5	62.5	47.5	30	27.5
Average Age	38.73		38.9	29.27	20.5	63.5	47.5	32.5	30.27
2010 Estimated Population by Age	**1,865**		**1,815**	**20**	**1**	**1**	**1**	**2**	**25**
Age 0 to 4	91	4.88%	88	2	0	0	0	0	1
Age 5 to 9	102	5.47%	92	3	1	1	0	0	5
Age 10 to 14	112	6.01%	110	0	0	0	0	0	2
Age 15 to 17	86	4.61%	78	3	0	0	0	0	5
Age 18 to 20	55	2.95%	51	3	0	0	0	0	1
Age 21 to 24	85	4.56%	82	2	0	0	0	0	1
Age 25 to 34	218	11.69%	211	2	0	0	0	2	3
Age 35 to 44	259	13.89%	255	3	0	0	0	0	1
Age 45 to 49	188	10.08%	186	1	0	0	1	0	0
Age 50 to 54	159	8.53%	158	0	0	0	0	0	1
Age 55 to 59	140	7.51%	139	1	0	0	0	0	0
Age 60 to 64	110	5.90%	110	0	0	0	0	0	0
Age 65 to 74	143	7.67%	142	0	0	0	0	0	1
Age 75 to 84	82	4.40%	79	0	0	0	0	0	3
Age 85 and over	35	1.88%	34	0	0	0	0	0	1
Age 18 and over	1,474	79.03%	1,447	12	0	0	1	2	12
Age 21 and over	1,419	76.09%	1,396	9	0	0	1	2	11
Age 65 and over	260	13.94%	255	0	0	0	0	0	5
Median Age	42.5		42.67	20	7.5	7.5	47.5	30	17.7
Average Age	40.52		40.9	23.82	7.5	7.5	47.5	32.5	30.51
2015 Projected Population by Age	**1,884**		**1,826**	**25**	**1**	**0**	**1**	**2**	**29**
Age 0 to 4	89	4.72%	83	5	0	0	0	0	1
Age 5 to 9	95	5.04%	87	3	0	0	0	0	5
Age 10 to 14	104	5.52%	102	0	0	0	0	0	2
Age 15 to 17	81	4.30%	71	6	0	0	0	0	4
Age 18 to 20	57	3.03%	50	3	0	0	0	0	4
Age 21 to 24	91	4.83%	88	3	0	0	0	0	0
Age 25 to 34	221	11.73%	212	3	0	0	0	2	4
Age 35 to 44	220	11.68%	215	2	1	0	0	0	2
Age 45 to 49	170	9.02%	168	0	0	0	1	0	1
Age 50 to 54	170	9.02%	168	0	0	0	0	0	2
Age 55 to 59	154	8.17%	153	0	0	0	0	0	1
Age 60 to 64	137	7.27%	137	0	0	0	0	0	0
Age 65 to 74	172	9.13%	171	0	0	0	0	0	1
Age 75 to 84	86	4.56%	85	0	0	0	0	0	1
Age 85 and over	37	1.96%	36	0	0	0	0	0	1
Age 18 and over	1,515	80.41%	1,483	11	1	0	1	2	17
Age 21 and over	1,458	77.39%	1,433	8	1	0	1	2	13
Age 65 and over	295	15.66%	292	0	0	0	0	0	3
Median Age	44.29		45.15	17.25	40		47.5	30	19.88
Average Age	41.77		42.31	17.76	37.5		47.5	32.5	29.44

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06334 Bozrah								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	2,557		2,407	14	20	46	4	23	43
2010 Estimate	2,521		2,392	15	22	34	3	17	38
2000 Census	2,471		2,374	16	22	16	1	11	31
1990 Census	2,419		2,369	15	9	3	0	5	18
Growth 1990 - 2000	2.15%		0.21%	6.67%	144.44%	433.33%		120.00%	72.22%
2000 Census Population by Age	**2,471**		**2,374**	**16**	**22**	**16**	**1**	**11**	**31**
Age 0 to 4	131	5.30%	121	1	1	2	0	4	2
Age 5 to 9	169	6.84%	155	2	3	1	0	0	8
Age 10 to 14	178	7.20%	169	2	2	2	1	0	2
Age 15 to 17	104	4.21%	97	1	2	1	0	1	2
Age 18 to 20	71	2.87%	67	0	3	0	0	0	1
Age 21 to 24	73	2.95%	71	0	1	1	0	0	0
Age 25 to 34	281	11.37%	266	2	2	2	0	2	7
Age 35 to 44	460	18.62%	448	1	6	2	0	2	1
Age 45 to 49	216	8.74%	212	1	0	0	0	2	1
Age 50 to 54	187	7.57%	181	4	1	0	0	0	1
Age 55 to 59	166	6.72%	163	1	0	1	0	0	1
Age 60 to 64	98	3.97%	93	0	1	3	0	0	1
Age 65 to 74	171	6.92%	169	1	0	0	0	0	1
Age 75 to 84	127	5.14%	124	0	0	0	0	0	3
Age 85 and over	39	1.58%	38	0	0	1	0	0	0
Age 18 and over	1,889	76.45%	1,832	10	14	10	0	6	17
Age 21 and over	1,818	73.57%	1,765	10	11	10	0	6	16
Age 65 and over	337	13.64%	331	1	0	1	0	0	4
Median Age	40.05		40.38	35	21	30	12.5	27.5	25.71
Average Age	39.23		39.62	33.75	26.61	33.89	12.5	23.77	29.24
2010 Estimated Population by Age	**2,521**		**2,392**	**15**	**22**	**34**	**3**	**17**	**38**
Age 0 to 4	124	4.92%	112	0	1	3	0	5	3
Age 5 to 9	137	5.43%	119	3	3	5	0	0	7
Age 10 to 14	154	6.11%	144	2	2	2	0	1	3
Age 15 to 17	110	4.36%	99	1	1	2	0	4	3
Age 18 to 20	83	3.29%	81	1	0	0	0	0	1
Age 21 to 24	115	4.56%	112	0	1	1	0	0	1
Age 25 to 34	271	10.75%	244	3	1	5	3	2	13
Age 35 to 44	350	13.88%	331	0	8	9	0	2	0
Age 45 to 49	241	9.56%	238	0	0	0	0	3	0
Age 50 to 54	234	9.28%	228	3	1	0	0	0	2
Age 55 to 59	194	7.70%	188	1	1	3	0	0	1
Age 60 to 64	148	5.87%	142	0	3	3	0	0	0
Age 65 to 74	179	7.10%	176	1	0	1	0	0	1
Age 75 to 84	125	4.96%	124	0	0	0	0	0	1
Age 85 and over	56	2.22%	54	0	0	0	0	0	2
Age 18 and over	1,996	79.17%	1,918	9	15	22	3	7	22
Age 21 and over	1,913	75.88%	1,837	8	15	22	3	7	21
Age 65 and over	360	14.28%	354	1	0	1	0	0	4
Median Age	42.97		43.61	26.67	37.5	33	30	16.88	25.77
Average Age	40.93		41.56	30.2	33.45	31.04	27.5	21.68	27.74
2015 Projected Population by Age	**2,557**		**2,407**	**14**	**20**	**46**	**4**	**23**	**43**
Age 0 to 4	126	4.93%	105	0	0	6	0	9	6
Age 5 to 9	130	5.08%	109	0	4	7	0	0	10
Age 10 to 14	141	5.51%	127	3	4	2	0	1	4
Age 15 to 17	102	3.99%	90	3	0	3	0	3	3
Age 18 to 20	90	3.52%	87	1	1	0	0	0	1
Age 21 to 24	131	5.12%	127	0	1	2	0	0	1
Age 25 to 34	280	10.95%	254	0	0	5	4	6	11
Age 35 to 44	280	10.95%	263	1	7	7	0	1	1
Age 45 to 49	225	8.80%	221	1	0	0	0	3	0
Age 50 to 54	242	9.46%	238	3	0	1	0	0	0
Age 55 to 59	226	8.84%	218	1	0	7	0	0	0
Age 60 to 64	179	7.00%	170	0	2	6	0	0	1
Age 65 to 74	221	8.64%	219	1	0	0	0	0	1
Age 75 to 84	113	4.42%	111	0	0	0	0	0	2
Age 85 and over	71	2.78%	68	0	1	0	0	0	2
Age 18 and over	2,058	80.48%	1,976	8	12	28	4	10	20
Age 21 and over	1,968	76.97%	1,889	7	11	28	4	10	19
Age 65 and over	405	15.84%	398	1	1	0	0	0	5
Median Age	44.95		45.94	21	25	31	30	16.5	16.5
Average Age	42.02		42.92	34.54	30.29	30.83	27.5	19.11	24.48

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06336 Gilman								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	70		66	0	1	2	0	0	1
2010 Estimate	68		64	1	0	1	0	1	1
2000 Census	65		63	0	0	1	0	0	1
1990 Census	63		63	0	0	0	0	0	0
Growth 1990 - 2000	3.17%		0.00%						
2000 Census Population by Age	**65**		**63**	**0**	**0**	**1**	**0**	**0**	**1**
Age 0 to 4	5	7.69%	5	0	0	0	0	0	0
Age 5 to 9	7	10.77%	6	0	0	1	0	0	0
Age 10 to 14	3	4.62%	3	0	0	0	0	0	0
Age 15 to 17	5	7.69%	4	0	0	0	0	0	1
Age 18 to 20	2	3.08%	2	0	0	0	0	0	0
Age 21 to 24	1	1.54%	1	0	0	0	0	0	0
Age 25 to 34	8	12.31%	8	0	0	0	0	0	0
Age 35 to 44	12	18.46%	12	0	0	0	0	0	0
Age 45 to 49	5	7.69%	5	0	0	0	0	0	0
Age 50 to 54	4	6.15%	4	0	0	0	0	0	0
Age 55 to 59	3	4.62%	3	0	0	0	0	0	0
Age 60 to 64	2	3.08%	2	0	0	0	0	0	0
Age 65 to 74	4	6.15%	4	0	0	0	0	0	0
Age 75 to 84	3	4.62%	3	0	0	0	0	0	0
Age 85 and over	1	1.54%	1	0	0	0	0	0	0
Age 18 and over	45	69.23%	45	0	0	0	0	0	0
Age 21 and over	43	66.15%	43	0	0	0	0	0	0
Age 65 and over	8	12.31%	8	0	0	0	0	0	0
Median Age	36.25		37.08			7.5			16.5
Average Age	35.7		36.47			7.5			16.5
2010 Estimated Population by Age	**68**		**64**	**1**	**0**	**1**	**0**	**1**	**1**
Age 0 to 4	5	7.35%	4	0	0	0	0	1	0
Age 5 to 9	4	5.88%	4	0	0	0	0	0	0
Age 10 to 14	6	8.82%	6	0	0	0	0	0	0
Age 15 to 17	3	4.41%	3	0	0	0	0	0	0
Age 18 to 20	2	2.94%	2	0	0	0	0	0	0
Age 21 to 24	3	4.41%	3	0	0	0	0	0	0
Age 25 to 34	7	10.29%	5	1	0	0	0	0	1
Age 35 to 44	9	13.24%	8	0	0	1	0	0	0
Age 45 to 49	6	8.82%	6	0	0	0	0	0	0
Age 50 to 54	6	8.82%	6	0	0	0	0	0	0
Age 55 to 59	5	7.35%	5	0	0	0	0	0	0
Age 60 to 64	4	5.88%	4	0	0	0	0	0	0
Age 65 to 74	4	5.88%	4	0	0	0	0	0	0
Age 75 to 84	3	4.41%	3	0	0	0	0	0	0
Age 85 and over	1	1.47%	1	0	0	0	0	0	0
Age 18 and over	50	73.53%	47	1	0	1	0	0	1
Age 21 and over	48	70.59%	45	1	0	1	0	0	1
Age 65 and over	8	11.76%	8	0	0	0	0	0	0
Median Age	39		41.25	30		40		2.5	30
Average Age	37.88		38.81	27.5		37.5		2.5	27.5
2015 Projected Population by Age	**70**		**66**	**0**	**1**	**2**	**0**	**0**	**1**
Age 0 to 4	3	4.29%	2	0	0	0	0	0	1
Age 5 to 9	3	4.29%	1	0	0	2	0	0	0
Age 10 to 14	4	5.71%	3	0	1	0	0	0	0
Age 15 to 17	2	2.86%	2	0	0	0	0	0	0
Age 18 to 20	5	7.14%	5	0	0	0	0	0	0
Age 21 to 24	3	4.29%	3	0	0	0	0	0	0
Age 25 to 34	7	10.00%	7	0	0	0	0	0	0
Age 35 to 44	7	10.00%	7	0	0	0	0	0	0
Age 45 to 49	7	10.00%	7	0	0	0	0	0	0
Age 50 to 54	6	8.57%	6	0	0	0	0	0	0
Age 55 to 59	6	8.57%	6	0	0	0	0	0	0
Age 60 to 64	5	7.14%	5	0	0	0	0	0	0
Age 65 to 74	6	8.57%	6	0	0	0	0	0	0
Age 75 to 84	3	4.29%	3	0	0	0	0	0	0
Age 85 and over	3	4.29%	3	0	0	0	0	0	0
Age 18 and over	58	82.86%	58	0	0	0	0	0	0
Age 21 and over	53	75.71%	53	0	0	0	0	0	0
Age 65 and over	12	17.14%	12	0	0	0	0	0	0
Median Age	45.71		47.14		12.5	7.5			2.5
Average Age	42.71		44.91		12.5	7.5			2.5

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06351 Jewett City								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	15,899		14,725	255	125	279	12	140	363
2010 Estimate	15,541		14,520	223	128	218	10	120	322
2000 Census	14,867		14,115	164	133	113	5	86	251
1990 Census	14,163		13,768	97	53	54	2	43	146
Growth 1990 - 2000	4.97%		2.52%	69.07%	150.94%	109.26%	150.00%	100.00%	71.92%
2000 Census Population by Age	**14,867**		**14,115**	**164**	**133**	**113**	**5**	**86**	**251**
Age 0 to 4	878	5.91%	802	12	15	16	0	10	23
Age 5 to 9	1,114	7.49%	1,037	8	12	8	0	10	39
Age 10 to 14	1,158	7.79%	1,082	10	17	7	0	9	33
Age 15 to 17	678	4.56%	627	16	7	1	1	2	24
Age 18 to 20	425	2.86%	398	9	8	2	0	2	6
Age 21 to 24	562	3.78%	536	9	4	2	0	3	8
Age 25 to 34	1,988	13.37%	1,877	25	24	16	1	13	32
Age 35 to 44	2,887	19.42%	2,747	35	16	30	1	18	40
Age 45 to 49	1,178	7.92%	1,130	12	7	9	0	5	15
Age 50 to 54	1,040	7.00%	996	11	12	6	1	3	11
Age 55 to 59	785	5.28%	757	4	6	7	0	4	7
Age 60 to 64	486	3.27%	468	8	3	1	0	3	3
Age 65 to 74	911	6.13%	894	3	2	2	0	3	7
Age 75 to 84	594	4.00%	581	2	0	6	1	1	3
Age 85 and over	183	1.23%	183	0	0	0	0	0	0
Age 18 and over	11,039	74.25%	10,567	118	82	81	4	55	132
Age 21 and over	10,614	71.39%	10,169	109	74	79	4	53	126
Age 65 and over	1,688	11.35%	1,658	5	2	8	1	4	10
Median Age	37.22		37.54	32.2	26.46	36.5	40	30.38	21.25
Average Age	36.76		37.15	32.16	27.73	33.31	45.3	29.63	26.43
2010 Estimated Population by Age	**15,541**		**14,520**	**223**	**128**	**218**	**10**	**120**	**322**
Age 0 to 4	848	5.46%	755	18	13	30	0	11	21
Age 5 to 9	906	5.83%	814	10	12	17	0	18	35
Age 10 to 14	1,016	6.54%	926	11	14	17	1	14	33
Age 15 to 17	752	4.84%	674	21	8	1	2	7	39
Age 18 to 20	514	3.31%	471	15	5	8	0	4	11
Age 21 to 24	723	4.65%	662	18	11	9	0	4	19
Age 25 to 34	1,901	12.23%	1,766	24	22	27	3	23	36
Age 35 to 44	2,481	15.96%	2,321	35	14	46	0	26	39
Age 45 to 49	1,442	9.28%	1,372	18	8	21	0	3	20
Age 50 to 54	1,288	8.29%	1,226	12	4	15	1	3	27
Age 55 to 59	1,032	6.64%	988	7	8	9	0	2	18
Age 60 to 64	782	5.03%	744	17	0	6	1	5	9
Age 65 to 74	965	6.21%	935	10	7	4	0	0	9
Age 75 to 84	615	3.96%	597	6	1	6	2	0	3
Age 85 and over	276	1.78%	269	1	1	2	0	0	3
Age 18 and over	12,019	77.34%	11,351	163	81	153	7	70	194
Age 21 and over	11,505	74.03%	10,880	148	76	145	7	66	183
Age 65 and over	1,856	11.94%	1,801	17	9	12	2	0	15
Median Age	39.81		40.14	32.71	25.45	35	31.67	25.87	25.83
Average Age	38.78		39.33	34.46	28.82	32.29	41.9	25.45	30.32
2015 Projected Population by Age	**15,899**		**14,725**	**255**	**125**	**279**	**12**	**140**	**363**
Age 0 to 4	861	5.42%	757	15	16	28	0	16	29
Age 5 to 9	886	5.57%	781	11	9	20	0	19	46
Age 10 to 14	923	5.81%	836	15	6	19	3	9	35
Age 15 to 17	703	4.42%	626	26	7	3	3	4	34
Age 18 to 20	523	3.29%	473	18	9	5	0	6	12
Age 21 to 24	856	5.38%	794	19	13	11	0	2	17
Age 25 to 34	1,821	11.45%	1,662	27	22	42	4	27	37
Age 35 to 44	2,205	13.87%	2,032	39	13	57	0	26	38
Age 45 to 49	1,337	8.41%	1,265	14	4	27	0	9	18
Age 50 to 54	1,401	8.81%	1,320	19	9	19	0	5	29
Age 55 to 59	1,236	7.77%	1,172	8	7	18	0	5	26
Age 60 to 64	1,006	6.33%	944	26	1	12	1	7	15
Age 65 to 74	1,224	7.70%	1,180	10	9	6	0	3	16
Age 75 to 84	593	3.73%	573	6	0	9	1	0	4
Age 85 and over	324	2.04%	310	2	0	3	0	2	7
Age 18 and over	12,526	78.78%	11,725	188	87	209	6	92	219
Age 21 and over	12,003	75.50%	11,252	170	78	204	6	86	207
Age 65 and over	2,141	13.47%	2,063	18	9	18	1	5	27
Median Age	41.42		42.05	33.7	26.14	37.02	18	30.19	27.3
Average Age	40.09		40.66	35.47	29.43	35.26	29.42	29.65	31.8

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06360 Norwich								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	33,697		24,990	3,230	375	1,853	18	1,386	1,845
2010 Estimate	33,649		25,967	2,936	397	1,463	11	1,214	1,661
2000 Census	33,486		27,665	2,395	428	746	10	918	1,324
1990 Census	34,493		30,889	1,689	206	358	11	517	823
Growth 1990 - 2000	-2.92%		-10.44%	41.80%	107.77%	108.38%	-9.09%	77.56%	60.87%
2000 Census Population by Age	**33,486**		**27,665**	**2,395**	**428**	**746**	**10**	**918**	**1,324**
Age 0 to 4	2,155	6.44%	1,481	239	34	59	1	101	240
Age 5 to 9	2,282	6.81%	1,639	261	60	48	0	92	182
Age 10 to 14	2,296	6.86%	1,691	257	43	45	0	102	158
Age 15 to 17	1,317	3.93%	1,048	108	17	25	0	50	69
Age 18 to 20	1,128	3.37%	892	82	13	26	0	54	61
Age 21 to 24	1,841	5.50%	1,424	160	26	47	0	97	87
Age 25 to 34	4,670	13.95%	3,786	342	72	163	2	142	163
Age 35 to 44	5,386	16.08%	4,475	433	61	120	2	134	161
Age 45 to 49	2,435	7.27%	2,081	155	29	61	2	53	54
Age 50 to 54	2,092	6.25%	1,843	92	25	58	2	29	43
Age 55 to 59	1,523	4.55%	1,352	81	19	37	1	15	18
Age 60 to 64	1,167	3.49%	1,039	46	11	27	0	19	25
Age 65 to 74	2,443	7.30%	2,260	96	8	21	0	17	41
Age 75 to 84	2,033	6.07%	1,957	33	8	6	0	11	18
Age 85 and over	718	2.14%	697	10	2	3	0	2	4
Age 18 and over	25,436	75.96%	21,806	1,530	274	569	9	573	675
Age 21 and over	24,308	72.59%	20,914	1,448	261	543	9	519	614
Age 65 and over	5,194	15.51%	4,914	139	18	30	0	30	63
Median Age	36.95		39.18	27.65	27.92	32.55	45	23.47	18.64
Average Age	38.1		40.18	29.45	29.57	33.06	40.5	26.34	23.87
2010 Estimated Population by Age	**33,649**		**25,967**	**2,936**	**397**	**1,463**	**11**	**1,214**	**1,661**
Age 0 to 4	2,041	6.07%	1,279	278	21	112	1	94	256
Age 5 to 9	2,128	6.32%	1,359	324	49	85	0	121	190
Age 10 to 14	2,232	6.63%	1,499	303	35	87	0	125	183
Age 15 to 17	1,306	3.88%	966	131	16	50	0	57	86
Age 18 to 20	1,063	3.16%	779	88	12	38	0	67	79
Age 21 to 24	1,494	4.44%	1,083	139	26	58	0	91	97
Age 25 to 34	4,839	14.38%	3,600	452	71	302	4	194	216
Age 35 to 44	5,088	15.12%	3,931	494	64	212	0	189	198
Age 45 to 49	2,517	7.48%	2,013	200	16	121	2	79	86
Age 50 to 54	2,470	7.34%	2,029	147	26	146	3	61	58
Age 55 to 59	1,961	5.83%	1,650	119	14	96	1	35	46
Age 60 to 64	1,539	4.57%	1,283	62	23	70	0	57	44
Age 65 to 74	2,157	6.41%	1,857	115	14	59	0	27	85
Age 75 to 84	1,869	5.55%	1,741	55	8	16	0	14	35
Age 85 and over	945	2.81%	898	29	2	11	0	3	2
Age 18 and over	25,942	77.10%	20,864	1,900	276	1,129	10	817	946
Age 21 and over	24,879	73.94%	20,085	1,812	264	1,091	10	750	867
Age 65 and over	4,971	14.77%	4,496	199	24	86	0	44	122
Median Age	38.29		41.15	29.54	30.56	34.98	46.25	27.68	22.51
Average Age	39.16		41.6	30.84	32.24	35.57	39.77	29.74	27.34
2015 Projected Population by Age	**33,697**		**24,990**	**3,230**	**375**	**1,853**	**18**	**1,386**	**1,845**
Age 0 to 4	2,060	6.11%	1,182	300	26	149	1	118	284
Age 5 to 9	2,065	6.13%	1,244	348	47	99	0	112	215
Age 10 to 14	2,112	6.27%	1,308	318	35	104	0	150	197
Age 15 to 17	1,348	4.00%	939	157	17	64	0	75	96
Age 18 to 20	1,134	3.37%	777	115	12	52	0	85	93
Age 21 to 24	1,670	4.96%	1,165	162	18	94	0	115	116
Age 25 to 34	4,011	11.90%	2,811	393	54	333	5	198	217
Age 35 to 44	5,042	14.96%	3,705	557	62	271	1	217	229
Age 45 to 49	2,393	7.10%	1,814	213	19	162	5	87	93
Age 50 to 54	2,480	7.36%	1,965	166	25	171	3	80	70
Age 55 to 59	2,338	6.94%	1,915	173	14	142	3	44	47
Age 60 to 64	1,838	5.45%	1,510	85	20	101	0	64	58
Age 65 to 74	2,435	7.23%	2,075	152	12	81	0	28	87
Age 75 to 84	1,705	5.06%	1,578	53	12	15	0	10	37
Age 85 and over	1,066	3.16%	1,002	38	2	15	0	3	6
Age 18 and over	26,112	77.49%	20,317	2,107	250	1,437	17	931	1,053
Age 21 and over	24,978	74.13%	19,540	1,992	238	1,385	17	846	960
Age 65 and over	5,206	15.45%	4,655	243	26	111	0	41	130
Median Age	39.77		43.28	30.47	31.02	36.16	47	26.92	22.29
Average Age	39.96		42.94	31.75	32.2	35.98	42.22	29.55	27.39

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06365 Preston								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	4,986		4,703	19	40	112	1	40	71
2010 Estimate	4,886		4,629	27	40	91	1	33	65
2000 Census	4,699		4,494	35	39	53	1	24	53
1990 Census	5,014		4,814	95	12	42	1	12	38
Growth 1990 - 2000	-6.28%		-6.65%	-63.16%	225.00%	26.19%	0.00%	100.00%	39.47%
2000 Census Population by Age	**4,699**		**4,494**	**35**	**39**	**53**	**1**	**24**	**53**
Age 0 to 4	214	4.55%	202	1	1	2	0	1	7
Age 5 to 9	296	6.30%	272	4	9	2	0	5	4
Age 10 to 14	330	7.02%	308	3	2	2	0	8	7
Age 15 to 17	217	4.62%	205	3	3	5	0	0	1
Age 18 to 20	136	2.89%	131	0	0	4	0	0	1
Age 21 to 24	142	3.02%	135	1	1	2	1	0	2
Age 25 to 34	534	11.36%	513	3	4	5	0	1	8
Age 35 to 44	845	17.98%	815	4	4	14	0	4	4
Age 45 to 49	425	9.04%	392	9	8	10	0	0	6
Age 50 to 54	325	6.92%	317	2	2	1	0	0	3
Age 55 to 59	298	6.34%	293	0	3	1	0	0	1
Age 60 to 64	281	5.98%	271	0	1	1	0	5	3
Age 65 to 74	385	8.19%	373	3	1	4	0	0	4
Age 75 to 84	219	4.66%	215	2	0	0	0	0	2
Age 85 and over	52	1.11%	52	0	0	0	0	0	0
Age 18 and over	3,642	77.51%	3,507	24	24	42	1	10	34
Age 21 and over	3,506	74.61%	3,376	24	24	38	1	10	33
Age 65 and over	656	13.96%	640	5	1	4	0	0	6
Median Age	41.02		40.9	41.25	33.75	38.21	23	13.75	30.63
Average Age	39.91		40.19	36.4	32.09	35.67	23.5	26.67	33.3
2010 Estimated Population by Age	**4,886**		**4,629**	**27**	**40**	**91**	**1**	**33**	**65**
Age 0 to 4	216	4.42%	199	1	3	5	0	0	8
Age 5 to 9	229	4.69%	206	2	8	8	0	2	3
Age 10 to 14	265	5.42%	233	2	3	2	0	10	15
Age 15 to 17	209	4.28%	191	5	2	10	0	1	0
Age 18 to 20	153	3.13%	145	1	0	5	0	1	1
Age 21 to 24	218	4.46%	204	0	6	2	1	1	4
Age 25 to 34	561	11.48%	537	10	1	3	0	2	8
Age 35 to 44	683	13.98%	648	1	6	18	0	4	6
Age 45 to 49	459	9.39%	432	3	4	15	0	0	5
Age 50 to 54	443	9.07%	429	1	1	4	0	3	5
Age 55 to 59	362	7.41%	359	0	2	1	0	0	0
Age 60 to 64	347	7.10%	327	0	0	9	0	8	3
Age 65 to 74	399	8.17%	382	1	4	7	0	1	4
Age 75 to 84	258	5.28%	255	0	0	1	0	0	2
Age 85 and over	84	1.72%	82	0	0	1	0	0	1
Age 18 and over	3,967	81.19%	3,800	17	24	66	1	20	39
Age 21 and over	3,814	78.06%	3,655	16	24	61	1	19	38
Age 65 and over	741	15.17%	719	1	4	9	0	1	7
Median Age	43.78		44.25	27.5	23.67	40.83	23	32.5	26.88
Average Age	41.9		42.37	27.31	29.7	37.29	23.5	34.76	31.73
2015 Projected Population by Age	**4,986**		**4,703**	**19**	**40**	**112**	**1**	**40**	**71**
Age 0 to 4	215	4.31%	193	1	1	6	0	0	14
Age 5 to 9	228	4.57%	194	0	11	12	0	7	4
Age 10 to 14	238	4.77%	216	2	3	1	0	8	8
Age 15 to 17	183	3.67%	166	4	0	12	0	0	1
Age 18 to 20	153	3.07%	145	0	0	5	0	1	2
Age 21 to 24	236	4.73%	216	1	7	4	1	0	7
Age 25 to 34	573	11.49%	549	2	3	8	0	2	9
Age 35 to 44	604	12.11%	561	1	4	24	0	6	8
Age 45 to 49	401	8.04%	375	3	4	15	0	0	4
Age 50 to 54	468	9.39%	454	1	1	3	0	3	6
Age 55 to 59	425	8.52%	420	0	2	2	0	1	0
Age 60 to 64	405	8.12%	381	0	0	10	0	12	2
Age 65 to 74	487	9.77%	469	3	4	8	0	0	3
Age 75 to 84	259	5.19%	255	0	0	1	0	0	3
Age 85 and over	111	2.23%	109	1	0	1	0	0	0
Age 18 and over	4,122	82.67%	3,934	12	25	81	1	25	44
Age 21 and over	3,969	79.60%	3,789	12	25	76	1	24	42
Age 65 and over	857	17.19%	833	4	4	10	0	0	6
Median Age	45.79		46.49	32.5	23.86	38.33	23	38.33	24.71
Average Age	43.3		43.89	37.44	29.68	35.88	23.5	35.65	29.04

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06380 Taftville								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	2,727		2,293	112	8	45	1	133	135
2010 Estimate	2,701		2,320	98	9	36	1	116	121
2000 Census	2,690		2,407	75	13	18	0	84	93
1990 Census	2,926		2,758	45	12	10	0	48	53
Growth 1990 - 2000	-8.07%		-12.73%	66.67%	8.33%	80.00%		75.00%	75.47%
2000 Census Population by Age	**2,690**		**2,407**	**75**	**13**	**18**	**0**	**84**	**93**
Age 0 to 4	170	6.32%	140	1	0	2	0	8	19
Age 5 to 9	183	6.80%	159	5	1	1	0	12	5
Age 10 to 14	203	7.55%	165	11	1	1	0	11	14
Age 15 to 17	113	4.20%	101	1	1	0	0	4	6
Age 18 to 20	104	3.87%	92	2	1	0	0	6	3
Age 21 to 24	146	5.43%	119	7	0	1	0	10	9
Age 25 to 34	394	14.65%	346	18	4	5	0	11	10
Age 35 to 44	485	18.03%	436	17	2	3	0	15	12
Age 45 to 49	171	6.36%	160	1	1	0	0	2	7
Age 50 to 54	134	4.98%	127	2	0	1	0	2	2
Age 55 to 59	145	5.39%	139	3	1	0	0	1	1
Age 60 to 64	85	3.16%	81	1	1	0	0	1	1
Age 65 to 74	178	6.62%	169	2	0	4	0	0	3
Age 75 to 84	149	5.54%	144	3	0	0	0	1	1
Age 85 and over	30	1.12%	29	1	0	0	0	0	0
Age 18 and over	2,021	75.13%	1,842	57	10	14	0	49	49
Age 21 and over	1,917	71.26%	1,750	55	9	14	0	43	46
Age 65 and over	357	13.27%	342	6	0	4	0	1	4
Median Age	35.63		36.87	30.83	31.25	33		21.4	20.5
Average Age	36.63		37.69	33.02	33.12	35.97		23.9	24.32
2010 Estimated Population by Age	**2,701**		**2,320**	**98**	**9**	**36**	**1**	**116**	**121**
Age 0 to 4	159	5.89%	123	5	0	2	1	7	21
Age 5 to 9	166	6.15%	139	7	0	4	0	8	8
Age 10 to 14	177	6.55%	142	10	0	0	0	16	9
Age 15 to 17	108	4.00%	91	3	0	0	0	5	9
Age 18 to 20	93	3.44%	75	2	0	1	0	8	7
Age 21 to 24	123	4.55%	95	5	1	4	0	11	7
Age 25 to 34	413	15.29%	347	23	2	6	0	20	15
Age 35 to 44	450	16.66%	395	20	2	5	0	17	11
Age 45 to 49	225	8.33%	204	4	1	2	0	6	8
Age 50 to 54	194	7.18%	173	5	0	5	0	8	3
Age 55 to 59	125	4.63%	116	6	1	0	0	2	0
Age 60 to 64	128	4.74%	114	1	1	2	0	3	7
Age 65 to 74	166	6.15%	144	3	0	5	0	0	14
Age 75 to 84	129	4.78%	118	3	1	0	0	5	2
Age 85 and over	45	1.67%	44	1	0	0	0	0	0
Age 18 and over	2,091	77.42%	1,825	73	9	30	0	80	74
Age 21 and over	1,998	73.97%	1,750	71	9	29	0	72	67
Age 65 and over	340	12.59%	306	7	1	5	0	5	16
Median Age	37.43		38.75	32.39	42.5	37	2.5	26.5	24.71
Average Age	38.02		38.99	33.73	45.5	37.14	2.5	30.03	30.48
2015 Projected Population by Age	**2,727**		**2,293**	**112**	**8**	**45**	**1**	**133**	**135**
Age 0 to 4	162	5.94%	117	3	2	4	0	10	26
Age 5 to 9	162	5.94%	126	11	1	6	0	12	6
Age 10 to 14	169	6.20%	134	9	0	0	0	15	11
Age 15 to 17	112	4.11%	92	4	0	0	0	7	9
Age 18 to 20	92	3.37%	69	4	1	0	0	7	11
Age 21 to 24	134	4.91%	99	7	1	3	0	12	12
Age 25 to 34	321	11.77%	253	22	2	7	1	23	13
Age 35 to 44	468	17.16%	402	22	0	5	0	23	16
Age 45 to 49	214	7.85%	190	5	1	3	0	7	8
Age 50 to 54	221	8.10%	195	6	0	8	0	9	3
Age 55 to 59	189	6.93%	175	11	0	2	0	0	1
Age 60 to 64	119	4.36%	109	0	0	2	0	3	5
Age 65 to 74	194	7.11%	172	3	0	5	0	2	12
Age 75 to 84	114	4.18%	104	5	0	0	0	3	2
Age 85 and over	56	2.05%	56	0	0	0	0	0	0
Age 18 and over	2,122	77.81%	1,824	85	5	35	1	89	83
Age 21 and over	2,030	74.44%	1,755	81	4	35	1	82	72
Age 65 and over	364	13.35%	332	8	0	5	0	5	14
Median Age	39.39		41.38	33.18	21	40	30	26.52	22.5
Average Age	39.03		40.58	34.31	20.94	36.9	32.5	28.91	28.4

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06384 Voluntown								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	2,660		2,545	21	27	7	0	19	41
2010 Estimate	2,624		2,518	18	27	8	0	16	37
2000 Census	2,564		2,477	14	25	8	0	9	31
1990 Census	2,135		2,097	6	4	10	0	1	17
Growth 1990 - 2000	20.09%		18.12%	133.33%	525.00%	-20.00%		800.00%	82.35%
2000 Census Population by Age	**2,564**		**2,477**	**14**	**25**	**8**	**0**	**9**	**31**
Age 0 to 4	159	6.20%	148	1	1	2	0	0	7
Age 5 to 9	215	8.39%	205	2	4	1	0	0	3
Age 10 to 14	193	7.53%	187	1	3	0	0	1	1
Age 15 to 17	116	4.52%	113	0	1	0	0	1	1
Age 18 to 20	73	2.85%	71	0	1	0	0	1	0
Age 21 to 24	64	2.50%	58	1	3	0	0	0	2
Age 25 to 34	405	15.80%	393	1	2	3	0	2	4
Age 35 to 44	538	20.98%	528	2	2	1	0	3	2
Age 45 to 49	196	7.64%	186	2	4	0	0	1	3
Age 50 to 54	165	6.44%	160	1	0	0	0	0	4
Age 55 to 59	125	4.88%	122	0	1	0	0	0	2
Age 60 to 64	71	2.77%	67	1	2	0	0	0	1
Age 65 to 74	137	5.34%	134	1	0	1	0	0	1
Age 75 to 84	87	3.39%	86	0	1	0	0	0	0
Age 85 and over	20	0.78%	19	1	0	0	0	0	0
Age 18 and over	1,881	73.36%	1,824	10	16	5	0	7	19
Age 21 and over	1,808	70.51%	1,753	10	15	5	0	6	19
Age 65 and over	244	9.52%	239	2	1	1	0	0	1
Median Age	36.03		36.2	40	24.33	28.33		32.5	28.75
Average Age	35.41		35.57	38.13	30.64	26.38		30.89	29.45
2010 Estimated Population by Age	**2,624**		**2,518**	**18**	**27**	**8**	**0**	**16**	**37**
Age 0 to 4	148	5.64%	134	0	2	1	0	1	10
Age 5 to 9	160	6.10%	143	2	4	4	0	2	5
Age 10 to 14	182	6.94%	174	3	1	0	0	3	1
Age 15 to 17	131	4.99%	126	0	1	0	0	1	3
Age 18 to 20	95	3.62%	91	1	0	0	0	3	0
Age 21 to 24	113	4.31%	100	2	8	0	0	0	3
Age 25 to 34	285	10.86%	275	1	3	2	0	4	0
Age 35 to 44	504	19.21%	491	6	1	1	0	2	3
Age 45 to 49	250	9.53%	241	0	3	0	0	0	6
Age 50 to 54	206	7.85%	204	0	1	0	0	0	1
Age 55 to 59	159	6.06%	156	1	0	0	0	0	2
Age 60 to 64	128	4.88%	123	2	2	0	0	0	1
Age 65 to 74	148	5.64%	146	0	0	0	0	0	2
Age 75 to 84	86	3.28%	85	0	1	0	0	0	0
Age 85 and over	29	1.11%	29	0	0	0	0	0	0
Age 18 and over	2,003	76.33%	1,941	13	19	3	0	9	18
Age 21 and over	1,908	72.71%	1,850	12	19	3	0	6	18
Age 65 and over	263	10.02%	260	0	1	0	0	0	2
Median Age	39.18		39.4	35	23.75	8.75		19	17.5
Average Age	37.63		38.13	31.78	28.24	15.63		20.53	26.01
2015 Projected Population by Age	**2,660**		**2,545**	**21**	**27**	**7**	**0**	**19**	**41**
Age 0 to 4	153	5.75%	140	0	1	1	0	0	11
Age 5 to 9	153	5.75%	141	2	2	3	0	1	4
Age 10 to 14	158	5.94%	148	4	1	0	0	4	1
Age 15 to 17	124	4.66%	116	1	0	0	0	4	3
Age 18 to 20	100	3.76%	97	0	0	0	0	2	1
Age 21 to 24	147	5.53%	131	1	13	0	0	0	2
Age 25 to 34	281	10.56%	267	3	3	3	0	3	2
Age 35 to 44	423	15.90%	413	3	3	0	0	3	1
Age 45 to 49	235	8.83%	229	0	1	0	0	0	5
Age 50 to 54	231	8.68%	222	1	2	0	0	2	4
Age 55 to 59	200	7.52%	197	0	0	0	0	0	3
Age 60 to 64	151	5.68%	145	4	1	0	0	0	1
Age 65 to 74	192	7.22%	189	1	0	0	0	0	2
Age 75 to 84	80	3.01%	80	0	0	0	0	0	0
Age 85 and over	32	1.20%	30	1	0	0	0	0	1
Age 18 and over	2,072	77.89%	2,000	14	23	3	0	10	22
Age 21 and over	1,972	74.14%	1,903	14	23	3	0	8	21
Age 65 and over	304	11.43%	299	2	0	0	0	0	3
Median Age	40.9		40.63	33.33	23.92	9.17		18.75	22
Average Age	38.81		39.28	36.7	27.19	15.36		25.08	29.35

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06415 Colchester								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	16,881		15,854	252	53	181	4	216	321
2010 Estimate	16,383		15,487	229	56	152	3	177	279
2000 Census	15,360		14,687	203	64	90	2	114	200
1990 Census	11,651		11,306	149	32	55	3	29	77
Growth 1990 - 2000	31.83%		29.90%	36.24%	100.00%	63.64%	-33.33%	293.10%	159.74%
2000 Census Population by Age	**15,360**		**14,687**	**203**	**64**	**90**	**2**	**114**	**200**
Age 0 to 4	1,291	8.40%	1,218	11	5	9	0	15	33
Age 5 to 9	1,367	8.90%	1,279	18	3	5	0	19	43
Age 10 to 14	1,245	8.11%	1,189	21	6	6	0	3	20
Age 15 to 17	630	4.10%	597	10	3	3	0	5	12
Age 18 to 20	344	2.24%	324	7	2	1	0	2	8
Age 21 to 24	390	2.54%	365	9	3	4	0	4	5
Age 25 to 34	2,222	14.47%	2,124	25	16	22	1	22	12
Age 35 to 44	3,345	21.78%	3,226	31	14	18	1	17	38
Age 45 to 49	1,120	7.29%	1,073	21	0	8	0	9	9
Age 50 to 54	934	6.08%	907	11	3	1	0	6	6
Age 55 to 59	614	4.00%	600	4	1	1	0	1	7
Age 60 to 64	443	2.88%	421	8	4	3	0	3	4
Age 65 to 74	702	4.57%	676	9	3	5	0	6	3
Age 75 to 84	506	3.29%	484	17	0	4	0	1	0
Age 85 and over	207	1.35%	204	1	1	0	0	1	0
Age 18 and over	10,827	70.49%	10,404	143	47	67	2	72	92
Age 21 and over	10,483	68.25%	10,080	136	45	66	2	70	84
Age 65 and over	1,415	9.21%	1,364	27	4	9	0	8	3
Median Age	35.58		35.77	35.16	31.25	32.73	35	29.09	16
Average Age	34.52		34.7	36.11	32.34	33.71	35	29.41	23.07
2010 Estimated Population by Age	**16,383**		**15,487**	**229**	**56**	**152**	**3**	**177**	**279**
Age 0 to 4	1,234	7.53%	1,150	18	3	13	0	15	35
Age 5 to 9	1,249	7.62%	1,149	19	1	9	0	24	47
Age 10 to 14	1,332	8.13%	1,259	15	9	11	0	7	31
Age 15 to 17	856	5.22%	802	12	1	10	0	10	21
Age 18 to 20	517	3.16%	484	7	3	6	0	1	16
Age 21 to 24	725	4.43%	670	18	7	7	0	14	9
Age 25 to 34	1,536	9.38%	1,415	28	8	34	2	25	24
Age 35 to 44	2,990	18.25%	2,865	23	12	23	1	27	39
Age 45 to 49	1,500	9.16%	1,432	21	2	13	0	16	16
Age 50 to 54	1,247	7.61%	1,201	14	3	3	0	13	13
Age 55 to 59	888	5.42%	866	10	3	0	0	3	6
Age 60 to 64	725	4.43%	695	8	3	5	0	5	9
Age 65 to 74	817	4.99%	762	19	1	10	0	15	10
Age 75 to 84	491	3.00%	468	14	0	8	0	0	1
Age 85 and over	276	1.68%	269	3	0	0	0	2	2
Age 18 and over	11,712	71.49%	11,127	165	42	109	3	121	145
Age 21 and over	11,195	68.33%	10,643	158	39	103	3	120	129
Age 65 and over	1,584	9.67%	1,499	36	1	18	0	17	13
Median Age	37.88		37.84	34.11	30	30.88	32.5	32	19.03
Average Age	36.03		36.28	36.8	31.37	33.04	34.17	32.65	26.19
2015 Projected Population by Age	**16,881**		**15,854**	**252**	**53**	**181**	**4**	**216**	**321**
Age 0 to 4	1,237	7.33%	1,140	13	6	21	0	24	33
Age 5 to 9	1,257	7.45%	1,148	15	1	6	0	26	61
Age 10 to 14	1,299	7.70%	1,217	25	7	12	0	7	31
Age 15 to 17	879	5.21%	810	12	1	15	0	16	25
Age 18 to 20	575	3.41%	533	8	2	7	0	7	18
Age 21 to 24	912	5.40%	834	22	3	15	0	26	12
Age 25 to 34	1,603	9.50%	1,469	31	12	37	2	21	31
Age 35 to 44	2,372	14.05%	2,241	28	8	21	2	38	34
Age 45 to 49	1,386	8.21%	1,314	28	1	13	0	11	19
Age 50 to 54	1,415	8.38%	1,364	19	3	2	0	14	13
Age 55 to 59	1,199	7.10%	1,159	14	1	3	0	1	21
Age 60 to 64	855	5.06%	826	3	4	8	0	5	9
Age 65 to 74	1,077	6.38%	1,019	17	4	12	0	14	11
Age 75 to 84	504	2.99%	483	14	0	7	0	0	0
Age 85 and over	311	1.84%	297	3	0	2	0	6	3
Age 18 and over	12,209	72.32%	11,539	187	38	127	4	143	171
Age 21 and over	11,634	68.92%	11,006	179	36	120	4	136	153
Age 65 and over	1,892	11.21%	1,799	34	4	21	0	20	14
Median Age	39.05		38.46	35	30.42	28.92	35	25.95	19.75
Average Age	37.02		37.38	36.8	32.14	32.41	35	30.62	26.97

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06420 Salem								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	4,255		3,984	34	24	134	0	13	66
2010 Estimate	4,140		3,902	34	22	107	0	13	62
2000 Census	3,913		3,739	31	24	57	0	11	51
1990 Census	3,353		3,245	27	8	31	0	10	32
Growth 1990 - 2000	16.70%		15.22%	14.81%	200.00%	83.87%		10.00%	59.38%
2000 Census Population by Age	**3,913**		**3,739**	**31**	**24**	**57**	**0**	**11**	**51**
Age 0 to 4	259	6.62%	237	0	0	8	0	3	11
Age 5 to 9	360	9.20%	334	4	1	4	0	0	17
Age 10 to 14	362	9.25%	343	4	1	8	0	2	4
Age 15 to 17	171	4.37%	164	3	2	1	0	0	1
Age 18 to 20	121	3.09%	114	2	2	0	0	0	3
Age 21 to 24	87	2.22%	83	0	2	0	0	0	2
Age 25 to 34	432	11.04%	413	3	4	7	0	3	2
Age 35 to 44	853	21.80%	822	5	3	16	0	1	6
Age 45 to 49	367	9.38%	351	5	4	5	0	1	1
Age 50 to 54	294	7.51%	288	1	1	3	0	0	1
Age 55 to 59	244	6.24%	240	0	0	1	0	0	3
Age 60 to 64	107	2.73%	102	1	0	3	0	1	0
Age 65 to 74	149	3.81%	143	2	4	0	0	0	0
Age 75 to 84	79	2.02%	77	1	0	1	0	0	0
Age 85 and over	28	0.72%	28	0	0	0	0	0	0
Age 18 and over	2,761	70.56%	2,661	20	20	36	0	6	18
Age 21 and over	2,640	67.47%	2,547	18	18	36	0	6	15
Age 65 and over	256	6.54%	248	3	4	1	0	0	0
Median Age	37.19		37.21	33.33	35	35.31		26.67	9.26
Average Age	34.62		34.93	33.48	37.9	30.43		25.32	17.53
2010 Estimated Population by Age	**4,140**		**3,902**	**34**	**22**	**107**	**0**	**13**	**62**
Age 0 to 4	258	6.23%	227	0	0	15	0	1	15
Age 5 to 9	275	6.64%	252	2	1	6	0	1	13
Age 10 to 14	325	7.85%	295	5	0	17	0	2	6
Age 15 to 17	214	5.17%	208	4	2	0	0	0	0
Age 18 to 20	184	4.44%	174	4	3	0	0	0	3
Age 21 to 24	197	4.76%	186	0	3	0	0	0	8
Age 25 to 34	389	9.40%	373	1	3	7	0	3	2
Age 35 to 44	635	15.34%	594	4	5	24	0	1	7
Age 45 to 49	420	10.14%	396	6	1	13	0	3	1
Age 50 to 54	354	8.55%	341	0	1	10	0	1	1
Age 55 to 59	314	7.58%	304	0	0	5	0	0	5
Age 60 to 64	221	5.34%	207	3	1	9	0	1	0
Age 65 to 74	234	5.65%	228	4	2	0	0	0	0
Age 75 to 84	89	2.15%	87	1	0	1	0	0	0
Age 85 and over	31	0.75%	30	0	0	0	0	0	1
Age 18 and over	3,068	74.11%	2,920	23	19	69	0	9	28
Age 21 and over	2,884	69.66%	2,746	19	16	69	0	9	25
Age 65 and over	354	8.55%	345	5	2	1	0	0	1
Median Age	40.12		38.97	37.5	31.67	38.54		33.33	12.5
Average Age	36.77		37.16	36.07	35.2	32.86		32.96	20.13
2015 Projected Population by Age	**4,255**		**3,984**	**34**	**24**	**134**	**0**	**13**	**66**
Age 0 to 4	265	6.23%	226	2	0	19	0	2	16
Age 5 to 9	269	6.32%	245	0	0	11	0	0	13
Age 10 to 14	285	6.70%	256	3	0	20	0	4	2
Age 15 to 17	199	4.68%	190	4	3	0	0	0	2
Age 18 to 20	191	4.49%	181	4	3	0	0	0	3
Age 21 to 24	246	5.78%	233	0	3	0	0	0	10
Age 25 to 34	471	11.07%	446	1	4	14	0	2	4
Age 35 to 44	446	10.48%	417	3	1	20	0	1	4
Age 45 to 49	401	9.42%	375	4	5	13	0	2	2
Age 50 to 54	372	8.74%	354	0	1	14	0	1	2
Age 55 to 59	356	8.37%	343	0	0	6	0	0	7
Age 60 to 64	286	6.72%	266	5	1	13	0	1	0
Age 65 to 74	334	7.85%	325	6	3	0	0	0	0
Age 75 to 84	99	2.33%	94	2	0	3	0	0	0
Age 85 and over	35	0.82%	33	0	0	1	0	0	1
Age 18 and over	3,237	76.08%	3,067	25	21	84	0	7	33
Age 21 and over	3,046	71.59%	2,886	21	18	84	0	7	30
Age 65 and over	468	11.00%	452	8	3	4	0	0	1
Median Age	40.62		40.16	45	32.5	36.5		27.5	18
Average Age	38.1		38.54	40.6	38.06	33.06		28.35	21.87

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	06475 Old Saybrook								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	10,684		10,119	59	13	284	10	54	145
2010 Estimate	10,546		10,025	73	13	246	8	51	130
2000 Census	10,365		9,925	104	8	178	7	47	96
1990 Census	9,550		9,234	137	7	87	3	32	50
Growth 1990 - 2000	8.53%		7.48%	-24.09%	14.29%	104.60%	133.33%	46.88%	92.00%
2000 Census Population by Age	**10,365**		**9,925**	**104**	**8**	**178**	**7**	**47**	**96**
Age 0 to 4	589	5.68%	540	2	0	22	0	9	16
Age 5 to 9	690	6.66%	653	2	2	16	0	6	11
Age 10 to 14	624	6.02%	588	7	2	10	0	4	13
Age 15 to 17	347	3.35%	328	1	0	5	0	3	10
Age 18 to 20	216	2.08%	195	6	0	5	2	2	6
Age 21 to 24	204	1.97%	193	3	0	3	0	0	5
Age 25 to 34	953	9.19%	887	12	1	39	0	5	9
Age 35 to 44	1,658	16.00%	1,570	16	2	49	3	6	12
Age 45 to 49	776	7.49%	758	3	0	8	0	5	2
Age 50 to 54	800	7.72%	779	11	1	7	0	1	1
Age 55 to 59	723	6.98%	699	14	0	4	0	4	2
Age 60 to 64	560	5.40%	540	11	0	6	0	0	3
Age 65 to 74	1,153	11.12%	1,141	6	0	2	1	1	2
Age 75 to 84	728	7.02%	719	4	0	1	0	0	4
Age 85 and over	344	3.32%	335	6	0	1	1	1	0
Age 18 and over	8,115	78.29%	7,816	92	4	125	7	25	46
Age 21 and over	7,899	76.21%	7,621	86	4	120	5	23	40
Age 65 and over	2,225	21.47%	2,195	16	0	4	2	2	6
Median Age	44.43		45.06	50	15	32.18	40	20.25	17.4
Average Age	43.35		43.84	46.17	26.25	29.97	44.76	26.96	24.42
2010 Estimated Population by Age	**10,546**		**10,025**	**73**	**13**	**246**	**8**	**51**	**130**
Age 0 to 4	545	5.17%	487	1	1	31	0	10	15
Age 5 to 9	583	5.53%	532	4	4	23	0	1	19
Age 10 to 14	634	6.01%	590	7	4	12	0	6	15
Age 15 to 17	424	4.02%	395	1	0	12	0	9	7
Age 18 to 20	301	2.85%	252	11	0	12	4	7	15
Age 21 to 24	398	3.77%	378	4	0	12	0	0	4
Age 25 to 34	802	7.60%	725	10	0	45	0	4	18
Age 35 to 44	1,221	11.58%	1,122	10	3	57	4	5	20
Age 45 to 49	801	7.60%	780	0	0	13	0	3	5
Age 50 to 54	798	7.57%	779	9	1	4	0	2	3
Age 55 to 59	894	8.48%	877	6	0	8	0	2	1
Age 60 to 64	757	7.18%	736	4	0	13	0	0	4
Age 65 to 74	1,215	11.52%	1,207	4	0	2	0	0	2
Age 75 to 84	770	7.30%	766	1	0	1	0	0	2
Age 85 and over	403	3.82%	399	1	0	1	0	2	0
Age 18 and over	8,360	79.27%	8,021	60	4	168	8	25	74
Age 21 and over	8,059	76.42%	7,769	49	4	156	4	18	59
Age 65 and over	2,388	22.64%	2,372	6	0	4	0	2	4
Median Age	47.28		48.41	33.5	11.88	29.67	21	17.83	19.8
Average Age	44.52		45.36	36.39	20.19	29.09	28.88	24.35	24.81
2015 Projected Population by Age	**10,684**		**10,119**	**59**	**13**	**284**	**10**	**54**	**145**
Age 0 to 4	565	5.29%	501	2	1	29	0	9	23
Age 5 to 9	556	5.20%	509	2	5	22	0	3	15
Age 10 to 14	591	5.53%	549	2	1	16	0	5	18
Age 15 to 17	431	4.03%	399	2	0	8	0	9	13
Age 18 to 20	317	2.97%	263	8	0	15	5	8	18
Age 21 to 24	482	4.51%	456	5	0	12	0	0	9
Age 25 to 34	923	8.64%	823	12	1	64	0	8	15
Age 35 to 44	926	8.67%	838	4	4	59	5	1	15
Age 45 to 49	690	6.46%	665	0	0	16	0	3	6
Age 50 to 54	796	7.45%	775	8	1	5	0	3	4
Age 55 to 59	903	8.45%	879	6	0	9	0	5	4
Age 60 to 64	889	8.32%	862	2	0	20	0	0	5
Age 65 to 74	1,409	13.19%	1,401	6	0	2	0	0	0
Age 75 to 84	764	7.15%	760	0	0	4	0	0	0
Age 85 and over	442	4.14%	439	0	0	3	0	0	0
Age 18 and over	8,541	79.94%	8,161	51	6	209	10	28	76
Age 21 and over	8,224	76.97%	7,898	43	6	194	5	20	58
Age 65 and over	2,615	24.48%	2,600	6	0	9	0	0	0
Median Age	48.99		50.36	32.08	12.5	31.25	21	18.38	18.58
Average Age	45.19		46.11	36.36	22.88	31.42	28.25	23.31	22.61

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	Connecticut								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	3,574,974		2,750,629	357,758	12,141	140,649	2,175	209,334	102,288
2010 Estimate	3,514,291		2,762,041	340,349	11,240	119,546	1,881	186,873	92,361
2000 Census	3,405,565		2,780,355	309,843	9,639	82,313	1,366	147,201	74,848
1990 Census	3,287,116		2,829,481	264,297	6,328	46,426	1,374	91,092	48,118
Growth 1990 - 2000	3.60%		-1.74%	17.23%	52.32%	77.30%	-0.58%	61.60%	55.55%
2000 Census Population by Age	**3,405,565**		**2,780,355**	**309,843**	**9,639**	**82,313**	**1,366**	**147,201**	**74,848**
Age 0 to 4	223,344	6.56%	163,673	26,277	776	6,923	124	15,206	10,365
Age 5 to 9	244,144	7.17%	183,455	29,289	866	5,806	97	15,571	9,060
Age 10 to 14	241,587	7.09%	184,621	28,343	792	5,475	108	14,885	7,363
Age 15 to 17	132,613	3.89%	101,188	15,571	465	3,168	66	8,285	3,870
Age 18 to 20	124,416	3.65%	91,513	15,353	520	3,759	92	9,258	3,921
Age 21 to 24	147,169	4.32%	106,224	17,978	597	5,457	129	12,015	4,769
Age 25 to 34	451,640	13.26%	343,527	48,168	1,531	18,268	226	28,764	11,156
Age 35 to 44	581,049	17.06%	482,359	49,992	1,654	14,757	215	21,804	10,268
Age 45 to 49	252,754	7.42%	217,710	18,541	696	5,451	83	6,627	3,646
Age 50 to 54	228,053	6.70%	198,579	16,356	523	4,398	66	5,171	2,960
Age 55 to 59	176,961	5.20%	155,824	12,258	340	3,027	43	3,374	2,095
Age 60 to 64	131,652	3.87%	115,346	9,919	247	2,170	37	2,392	1,541
Age 65 to 74	231,565	6.80%	210,791	13,195	383	2,521	46	2,494	2,135
Age 75 to 84	174,345	5.12%	164,323	6,533	192	939	24	1,055	1,279
Age 85 and over	64,273	1.89%	61,222	2,070	57	194	10	300	420
Age 18 and over	2,563,877	75.28%	2,147,418	210,363	6,740	60,941	971	93,254	44,190
Age 21 and over	2,439,461	71.63%	2,055,905	195,010	6,220	57,182	879	83,996	40,269
Age 65 and over	470,183	13.81%	436,336	21,798	632	3,654	80	3,849	3,834
Median Age	37.37		39.48	29.59	30.25	30.79	27.96	24.46	23.39
Average Age	37.74		39.55	31.43	31.61	31.35	30.6	26.32	26.88
2010 Estimated Population by Age	**3,514,291**		**2,762,041**	**340,349**	**11,240**	**119,546**	**1,881**	**186,873**	**92,361**
Age 0 to 4	211,091	6.01%	147,546	25,967	960	9,003	182	17,237	10,196
Age 5 to 9	216,816	6.17%	155,262	26,902	1,034	7,751	142	16,594	9,131
Age 10 to 14	232,718	6.62%	169,499	28,530	1,037	7,593	154	17,423	8,482
Age 15 to 17	156,243	4.45%	117,933	17,147	605	5,008	114	10,402	5,034
Age 18 to 20	147,036	4.18%	106,429	17,329	675	5,975	117	11,338	5,173
Age 21 to 24	180,923	5.15%	133,150	19,431	793	7,850	183	13,670	5,846
Age 25 to 34	400,919	11.41%	281,501	48,644	1,755	22,500	310	33,627	12,582
Age 35 to 44	503,752	14.33%	386,057	54,339	1,798	19,171	265	29,426	12,696
Age 45 to 49	287,797	8.19%	238,444	23,324	776	8,892	127	10,840	5,394
Age 50 to 54	269,836	7.68%	228,086	20,544	556	7,440	94	8,488	4,628
Age 55 to 59	229,775	6.54%	197,603	16,272	368	5,933	54	5,785	3,760
Age 60 to 64	189,854	5.40%	162,057	14,507	316	4,985	55	4,937	2,997
Age 65 to 74	244,129	6.95%	214,272	16,034	362	5,003	52	4,647	3,759
Age 75 to 84	163,209	4.64%	149,519	7,893	134	1,864	22	1,834	1,943
Age 85 and over	80,193	2.28%	74,683	3,486	71	578	10	625	740
Age 18 and over	2,697,423	76.76%	2,171,801	241,803	7,604	90,191	1,289	125,217	59,518
Age 21 and over	2,550,387	72.57%	2,065,372	224,474	6,929	84,216	1,172	113,879	54,345
Age 65 and over	487,531	13.87%	438,474	27,413	567	7,445	84	7,106	6,442
Median Age	39.52		41.99	32.17	27.94	32.37	26.56	27.01	26.84
Average Age	38.99		40.92	33.52	30.09	33.51	29.44	28.89	30.17
2015 Projected Population by Age	**3,574,974**		**2,750,629**	**357,758**	**12,141**	**140,649**	**2,175**	**209,334**	**102,288**
Age 0 to 4	213,069	5.96%	145,208	26,285	1,002	10,480	209	18,713	11,172
Age 5 to 9	211,361	5.91%	146,670	26,707	1,114	8,732	174	18,062	9,902
Age 10 to 14	218,150	6.10%	154,070	27,434	1,035	8,423	152	18,278	8,758
Age 15 to 17	153,334	4.29%	112,420	17,200	677	5,952	116	11,452	5,517
Age 18 to 20	152,954	4.28%	107,848	18,253	724	7,261	134	12,924	5,810
Age 21 to 24	201,394	5.63%	145,753	21,499	868	9,970	205	16,202	6,897
Age 25 to 34	407,207	11.39%	287,704	45,934	1,808	24,494	344	33,855	13,068
Age 35 to 44	433,786	12.13%	309,006	54,963	1,891	21,058	324	33,161	13,383
Age 45 to 49	267,181	7.47%	211,669	25,361	856	10,236	159	12,954	5,946
Age 50 to 54	283,376	7.93%	233,245	23,708	622	9,521	112	10,626	5,542
Age 55 to 59	262,538	7.34%	220,601	20,430	477	8,123	74	7,996	4,837
Age 60 to 64	220,526	6.17%	187,115	16,648	362	6,662	68	6,007	3,664
Age 65 to 74	301,446	8.43%	262,590	20,614	468	6,818	67	6,228	4,661
Age 75 to 84	159,983	4.48%	144,919	8,606	151	2,078	26	2,082	2,121
Age 85 and over	88,669	2.48%	81,811	4,116	86	841	11	794	1,010
Age 18 and over	2,779,060	77.74%	2,192,261	260,132	8,313	107,062	1,524	142,829	66,939
Age 21 and over	2,626,106	73.46%	2,084,413	241,879	7,589	99,801	1,390	129,905	61,129
Age 65 and over	550,098	15.39%	489,320	33,336	705	9,737	104	9,104	7,792
Median Age	40.62		43.92	34.03	28.6	32.96	27.83	27.67	27.36
Average Age	39.91		42.01	34.85	30.84	34.28	30.25	29.8	30.93

Population by Age and Race Trend

Source: Claritas, 2012.

Population by Age and Race Trend	The United States								
	Total Population	%	White Alone	Black or Af. American Alone	Amer. Indian or AL Native Alone	Asian Alone	Nat. Hawaii or Pac. Isl. Alone	Some Oth. Race Alone	Two or More Races
Population									
2015 Projection	322,320,436		228,659,078	40,616,189	3,096,872	15,561,068	531,419	23,722,350	10,133,460
2010 Estimate	306,624,699		222,311,945	38,203,182	2,859,788	13,486,064	479,920	20,433,721	8,850,079
2000 Census	281,421,906		211,460,626	34,658,190	2,475,956	10,242,998	398,835	15,359,073	6,826,228
1990 Census	248,709,873		197,075,070	29,405,314	1,848,368	6,443,727	366,754	9,277,563	4,293,077
Growth 1990 - 2000	13.15%		7.30%	17.86%	33.95%	58.96%	8.75%	65.55%	59.01%
2000 Census Population by Age	**281,421,906**		**211,460,626**	**34,658,190**	**2,475,956**	**10,242,998**	**398,835**	**15,359,073**	**6,826,228**
Age 0 to 4	19,175,798	6.81%	12,859,892	2,804,786	213,052	670,406	33,391	1,646,056	948,215
Age 5 to 9	20,549,505	7.30%	13,944,882	3,205,512	239,007	680,536	36,503	1,613,292	829,773
Age 10 to 14	20,528,072	7.29%	14,322,638	3,121,530	245,677	684,525	35,772	1,414,466	703,464
Age 15 to 17	12,040,437	4.28%	8,470,877	1,753,868	142,576	429,532	21,513	846,637	375,434
Age 18 to 20	12,228,901	4.35%	8,496,868	1,757,152	132,486	479,064	23,940	973,556	365,835
Age 21 to 24	14,914,553	5.30%	10,264,294	2,047,285	155,299	654,367	30,568	1,330,033	432,707
Age 25 to 34	39,891,724	14.18%	28,320,559	5,167,570	372,761	1,935,640	68,353	3,030,214	996,627
Age 35 to 44	45,148,527	16.04%	34,297,488	5,526,779	391,214	1,755,557	61,791	2,224,292	891,406
Age 45 to 49	20,092,404	7.14%	15,810,626	2,275,191	159,422	749,777	23,675	735,465	338,248
Age 50 to 54	17,585,548	6.25%	14,213,875	1,805,457	128,303	626,255	18,938	524,104	268,616
Age 55 to 59	13,469,237	4.79%	11,107,247	1,306,641	90,531	433,749	13,428	328,970	188,671
Age 60 to 64	10,805,447	3.84%	8,945,842	1,063,469	67,189	342,795	10,142	232,984	143,026
Age 65 to 74	18,390,986	6.54%	15,688,418	1,613,172	85,897	494,151	13,227	293,569	202,552
Age 75 to 84	12,361,180	4.39%	10,938,616	896,489	40,254	244,148	5,769	128,261	107,643
Age 85 and over	4,239,587	1.51%	3,778,504	313,289	12,288	62,496	1,825	37,174	34,011
Age 18 and over	209,128,094	74.31%	161,862,337	23,772,494	1,635,644	7,777,999	271,656	9,838,622	3,969,342
Age 21 and over	196,899,193	69.97%	153,365,469	22,015,342	1,503,158	7,298,935	247,716	8,865,066	3,603,507
Age 65 and over	34,991,753	12.43%	30,405,538	2,822,950	138,439	800,795	20,821	459,004	344,206
Median Age	35.3		37.64	30.11	27.95	32.87	27.59	24.57	22.76
Average Age	36.31		38.22	32.09	30.16	34.08	29.84	26.44	26.61
2010 Estimated Population by Age	**306,624,699**		**222,311,945**	**38,203,182**	**2,859,788**	**13,486,064**	**479,920**	**20,433,721**	**8,850,079**
Age 0 to 4	21,028,358	6.86%	13,414,761	3,114,008	256,763	902,388	41,427	2,177,575	1,121,436
Age 5 to 9	20,206,144	6.59%	13,153,357	3,082,814	257,258	844,090	40,064	1,890,281	938,280
Age 10 to 14	20,380,552	6.65%	13,459,000	3,122,618	265,421	860,715	40,454	1,781,969	850,375
Age 15 to 17	13,033,952	4.25%	8,818,338	1,895,503	163,699	572,032	25,330	1,073,177	485,873
Age 18 to 20	13,223,088	4.31%	8,845,781	1,903,397	155,546	613,783	28,250	1,204,349	471,982
Age 21 to 24	16,740,249	5.46%	11,328,391	2,226,352	192,218	799,457	36,467	1,608,129	549,235
Age 25 to 34	40,883,505	13.33%	27,761,961	5,420,812	442,044	2,188,708	81,925	3,775,287	1,212,768
Age 35 to 44	42,659,236	13.91%	30,305,659	5,646,807	399,510	2,120,958	69,992	3,004,546	1,111,764
Age 45 to 49	22,725,034	7.41%	17,166,612	2,662,197	184,270	1,039,316	28,940	1,152,209	491,490
Age 50 to 54	21,620,286	7.05%	16,879,596	2,318,935	158,825	929,503	24,161	885,099	424,167
Age 55 to 59	19,055,756	6.21%	15,280,945	1,898,722	122,521	767,571	19,381	623,456	343,160
Age 60 to 64	15,490,345	5.05%	12,512,989	1,517,523	91,323	631,597	15,182	449,871	271,860
Age 65 to 74	20,707,408	6.75%	17,118,975	1,884,966	103,043	742,080	17,160	498,685	342,499
Age 75 to 84	13,131,796	4.28%	11,286,775	1,046,161	47,158	349,808	7,793	226,400	167,701
Age 85 and over	5,738,990	1.87%	4,978,805	462,367	20,189	124,058	3,394	82,688	67,489
Age 18 and over	231,975,693	75.65%	173,466,489	26,988,239	1,916,647	10,306,839	332,645	13,510,719	5,454,115
Age 21 and over	218,752,605	71.34%	164,620,708	25,084,842	1,761,101	9,693,056	304,395	12,306,370	4,982,133
Age 65 and over	39,578,194	12.91%	33,384,555	3,393,494	170,390	1,215,946	28,347	807,773	577,689
Median Age	36.88		39.74	31.93	28.14	34.83	28.41	26.28	25.06
Average Age	37.6		39.7	33.66	30.69	35.73	30.79	28.27	28.98
2015 Projected Population by Age	**322,320,436**		**228,659,078**	**40,616,189**	**3,096,872**	**15,561,068**	**531,419**	**23,722,350**	**10,133,460**
Age 0 to 4	22,171,235	6.88%	13,778,764	3,258,113	277,187	1,022,002	45,741	2,499,177	1,290,251
Age 5 to 9	21,335,112	6.62%	13,425,502	3,299,286	278,922	978,218	45,875	2,220,369	1,086,940
Age 10 to 14	20,723,380	6.43%	13,267,463	3,209,997	275,082	962,829	43,637	2,011,709	952,663
Age 15 to 17	12,971,566	4.02%	8,516,285	1,893,771	168,480	627,416	27,018	1,200,150	538,446
Age 18 to 20	13,532,815	4.20%	8,815,513	1,952,712	163,145	682,332	30,704	1,360,946	527,463
Age 21 to 24	17,568,530	5.45%	11,626,711	2,357,607	204,595	894,656	39,757	1,825,818	619,386
Age 25 to 34	41,627,112	12.91%	27,825,482	5,505,003	468,535	2,347,708	86,891	4,079,543	1,313,950
Age 35 to 44	41,489,532	12.87%	28,145,889	5,822,621	425,141	2,294,384	76,198	3,494,563	1,230,736
Age 45 to 49	22,042,812	6.84%	15,913,079	2,760,528	192,191	1,176,191	31,757	1,410,079	558,987
Age 50 to 54	22,769,813	7.06%	17,270,264	2,524,057	177,284	1,132,808	27,599	1,129,217	508,584
Age 55 to 59	21,464,608	6.66%	16,830,414	2,209,525	145,142	986,412	22,730	840,681	429,704
Age 60 to 64	18,618,888	5.78%	14,822,496	1,844,315	112,233	863,865	18,537	607,529	349,913
Age 65 to 74	25,684,662	7.97%	21,059,099	2,330,787	127,165	1,035,739	21,401	673,036	437,435
Age 75 to 84	13,807,257	4.28%	11,777,046	1,114,359	53,115	401,874	8,464	261,302	191,097
Age 85 and over	6,513,114	2.02%	5,585,071	533,508	28,655	154,634	5,110	108,231	97,905
Age 18 and over	245,119,143	76.05%	179,671,064	28,955,022	2,097,201	11,970,603	369,148	15,790,945	6,265,160
Age 21 and over	231,586,328	71.85%	170,855,551	27,002,310	1,934,056	11,288,271	338,444	14,429,999	5,737,697
Age 65 and over	46,005,033	14.27%	38,421,216	3,978,654	208,935	1,592,247	34,975	1,042,569	726,437
Median Age	37.74		41.07	32.88	28.86	36.16	28.8	26.82	25.39
Average Age	38.4		40.69	34.44	31.42	36.76	31.31	28.98	29.54

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06320 New London		06333 East Lyme		06335 Gales Ferry		06339 Ledyard	
Population								
2015 Projection	25,667		7,943		6,482		8,547	
2010 Estimate	25,665		7,679		6,490		8,395	
2000 Census	25,687		7,101		6,536		8,107	
1990 Census	28,547		6,240		6,797		7,818	
Growth 2010-2015	0.01%		3.44%		-0.12%		1.81%	
Growth 2000-2010	-0.09%		8.14%		-0.70%		3.55%	
Growth 1990-2000	-10.02%		13.80%		-3.84%		3.70%	
2010 Estimated Population by Single Race Classification	**25,665**		**7,679**		**6,490**		**8,395**	
White Alone	15,339	59.77%	6,295	81.98%	5,803	89.41%	6,783	80.80%
Black or African American Alone	4,953	19.30%	328	4.27%	159	2.45%	301	3.59%
American Indian and Alaska Native Alone	187	0.73%	35	0.46%	53	0.82%	515	6.13%
Asian Alone	889	3.46%	805	10.48%	241	3.71%	332	3.95%
Native Hawaiian and Other Pacific Islander Alone	23	0.09%	3	0.04%	2	0.03%	12	0.14%
Some Other Race Alone	2,648	10.32%	57	0.74%	60	0.92%	115	1.37%
Two or More Races	1,626	6.34%	156	2.03%	172	2.65%	337	4.01%

Demographic Snapshot (Part 2)	06320 New London		06333 East Lyme		06335 Gales Ferry		06339 Ledyard	
Households								
2015 Projection	9,874		2,687		2,451		3,135	
2010 Estimate	10,014		2,585		2,432		3,050	
2000 Census	10,187		2,364		2,393		2,876	
1990 Census	10,718		2,042		2,325		2,630	
Growth 2010-2015	-1.40%		3.95%		0.78%		2.79%	
Growth 2000-2010	-1.70%		9.35%		1.63%		6.05%	
Growth 1990-2000	-4.95%		15.77%		2.92%		9.35%	
2010 Estimated Families by Poverty Status*	**5,288**		**2,128**		**1,870**		**2,384**	
Income At or Above Poverty Level	4,525	85.57%	2,102	98.78%	1,798	96.15%	2,327	97.61%
Married-Couple Family	2,858	54.05%	1,902	89.38%	1,600	85.56%	1,912	80.20%
With own children	1,288	24.36%	1,001	47.04%	787	42.09%	889	37.29%
No own children	1,570	29.69%	901	42.34%	813	43.48%	1,023	42.91%
Male Householder	406	7.68%	42	1.97%	63	3.37%	110	4.61%
With own children	290	5.48%	20	0.94%	12	0.64%	77	3.23%
No own children	116	2.19%	22	1.03%	51	2.73%	33	1.38%
Female Householder	1,261	23.85%	158	7.42%	135	7.22%	305	12.79%
With own children	865	16.36%	104	4.89%	99	5.29%	201	8.43%
No own children	396	7.49%	54	2.54%	36	1.93%	104	4.36%
Income Below Poverty Level	763	14.43%	26	1.22%	72	3.85%	57	2.39%
Married-Couple Family	160	3.03%	5	0.23%	14	0.75%	42	1.76%
With own children	86	1.63%	0	0.00%	0	0.00%	33	1.38%
No own children	74	1.40%	5	0.23%	14	0.75%	9	0.38%
Male Householder	63	1.19%	9	0.42%	0	0.00%	0	0.00%
With own children	56	1.06%	7	0.33%	0	0.00%	0	0.00%
No own children	7	0.13%	2	0.09%	0	0.00%	0	0.00%
Female Householder	540	10.21%	12	0.56%	58	3.10%	15	0.63%
With own children	509	9.63%	12	0.56%	58	3.10%	15	0.63%
No own children	31	0.59%	0	0.00%	0	0.00%	0	0.00%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06340 Groton		06349 Groton		06353 Montville		06355 Mystic	
Population								
2015 Projection	34,609		1		97		14,240	
2010 Estimate	33,675		1		93		13,528	
2000 Census	31,655		1		84		12,085	
1990 Census	37,729		4		72		11,215	
Growth 2010-2015	2.77%		0.00%		4.30%		5.26%	
Growth 2000-2010	6.38%		0.00%		10.71%		11.94%	
Growth 1990-2000	-16.10%		-75.00%		16.67%		7.76%	
2010 Estimated Population by Single Race Classification	**33,675**		**1**		**93**		**13,528**	
White Alone	25,600	76.02%	1	*****%	85	91.40%	12,423	91.83%
Black or African American Alone	3,060	9.09%	0	0.00%	3	3.23%	199	1.47%
American Indian and Alaska Native Alone	245	0.73%	0	0.00%	1	1.08%	45	0.33%
Asian Alone	2,370	7.04%	0	0.00%	1	1.08%	480	3.55%
Native Hawaiian and Other Pacific Islander Alone	85	0.25%	0	0.00%	0	0.00%	16	0.12%
Some Other Race Alone	867	2.57%	0	0.00%	1	1.08%	75	0.55%
Two or More Races	1,448	4.30%	0	0.00%	2	2.15%	290	2.14%

Demographic Snapshot (Part 2)	06340 Groton		06349 Groton		06353 Montville		06355 Mystic	
Households								
2015 Projection	13,564		0		39		5,969	
2010 Estimate	13,112		0		37		5,641	
2000 Census	12,135		0		32		4,960	
1990 Census	11,988		0		27		4,437	
Growth 2010-2015	3.45%				5.41%		5.81%	
Growth 2000-2010	8.05%				15.63%		13.73%	
Growth 1990-2000	1.23%				18.52%		11.79%	
2010 Estimated Families by Poverty Status*	**8,231**		**0**		**26**		**3,722**	
Income At or Above Poverty Level	7,712	93.69%	0		23	88.46%	3,660	98.33%
Married-Couple Family	6,116	74.30%	0		20	76.92%	3,092	83.07%
With own children	3,120	37.91%	0		9	34.62%	1,254	33.69%
No own children	2,996	36.40%	0		11	42.31%	1,838	49.38%
Male Householder	431	5.24%	0		2	7.69%	175	4.70%
With own children	249	3.03%	0		2	7.69%	74	1.99%
No own children	182	2.21%	0		0	0.00%	101	2.71%
Female Householder	1,165	14.15%	0		1	3.85%	393	10.56%
With own children	800	9.72%	0		0	0.00%	254	6.82%
No own children	365	4.43%	0		1	3.85%	139	3.73%
Income Below Poverty Level	519	6.31%	0		3	11.54%	62	1.67%
Married-Couple Family	150	1.82%	0		1	3.85%	44	1.18%
With own children	113	1.37%	0		1	3.85%	27	0.73%
No own children	37	0.45%	0		0	0.00%	17	0.46%
Male Householder	26	0.32%	0		0	0.00%	1	0.03%
With own children	25	0.30%	0		0	0.00%	1	0.03%
No own children	1	0.01%	0		0	0.00%	0	0.00%
Female Householder	343	4.17%	0		2	7.69%	17	0.46%
With own children	335	4.07%	0		2	7.69%	7	0.19%
No own children	8	0.10%	0		0	0.00%	10	0.27%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06357 Niantic		06359 North Stonington		06370 Oakdale		06371 Old Lyme	
Population								
2015 Projection	11,818		5,271		7,709		9,258	
2010 Estimate	11,485		5,172		7,375		9,305	
2000 Census	11,006		4,993		6,689		9,422	
1990 Census	9,089		4,884		6,509		8,484	
Growth 2010-2015	2.90%		1.91%		4.53%		-0.51%	
Growth 2000-2010	4.35%		3.59%		10.26%		-1.24%	
Growth 1990-2000	21.09%		2.23%		2.77%		11.06%	
2010 Estimated Population by Single Race Classification	**11,485**		**5,172**		**7,375**		**9,305**	
White Alone	9,382	81.69%	4,813	93.06%	6,818	92.45%	8,984	96.55%
Black or African American Alone	1,268	11.04%	34	0.66%	114	1.55%	15	0.16%
American Indian and Alaska Native Alone	46	0.40%	109	2.11%	48	0.65%	14	0.15%
Asian Alone	236	2.05%	89	1.72%	152	2.06%	194	2.08%
Native Hawaiian and Other Pacific Islander Alone	10	0.09%	0	0.00%	3	0.04%	0	0.00%
Some Other Race Alone	269	2.34%	18	0.35%	60	0.81%	33	0.35%
Two or More Races	274	2.39%	109	2.11%	180	2.44%	65	0.70%

Demographic Snapshot (Part 2)	06357 Niantic		06359 North Stonington		06370 Oakdale		06371 Old Lyme	
Households								
2015 Projection	4,141		2,001		2,875		3,833	
2010 Estimate	4,068		1,945		2,725		3,830	
2000 Census	3,940		1,834		2,414		3,812	
1990 Census	3,458		1,670		2,196		3,380	
Growth 2010-2015	1.79%		2.88%		5.50%		0.08%	
Growth 2000-2010	3.25%		6.05%		12.88%		0.47%	
Growth 1990-2000	13.94%		9.82%		9.93%		12.78%	
2010 Estimated Families by Poverty Status*	**2,662**		**1,509**		**2,111**		**2,776**	
Income At or Above Poverty Level	2,581	96.96%	1,458	96.62%	2,046	96.92%	2,724	98.13%
Married-Couple Family	2,150	80.77%	1,257	83.30%	1,756	83.18%	2,420	87.18%
With own children	860	32.31%	559	37.04%	844	39.98%	968	34.87%
No own children	1,290	48.46%	698	46.26%	912	43.20%	1,452	52.31%
Male Householder	100	3.76%	65	4.31%	79	3.74%	95	3.42%
With own children	70	2.63%	41	2.72%	37	1.75%	63	2.27%
No own children	30	1.13%	24	1.59%	42	1.99%	32	1.15%
Female Householder	331	12.43%	136	9.01%	211	10.00%	209	7.53%
With own children	214	8.04%	109	7.22%	137	6.49%	123	4.43%
No own children	117	4.40%	27	1.79%	74	3.51%	86	3.10%
Income Below Poverty Level	81	3.04%	51	3.38%	65	3.08%	52	1.87%
Married-Couple Family	16	0.60%	20	1.33%	3	0.14%	7	0.25%
With own children	0	0.00%	14	0.93%	2	0.09%	0	0.00%
No own children	16	0.60%	6	0.40%	1	0.05%	7	0.25%
Male Householder	11	0.41%	18	1.19%	26	1.23%	6	0.22%
With own children	6	0.23%	18	1.19%	20	0.95%	5	0.18%
No own children	5	0.19%	0	0.00%	6	0.28%	1	0.04%
Female Householder	54	2.03%	13	0.86%	36	1.71%	39	1.40%
With own children	52	1.95%	13	0.86%	29	1.37%	30	1.08%
No own children	2	0.08%	0	0.00%	7	0.33%	9	0.32%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06375 Quaker Hill		06378 Stonington		06379 Pawcatuck		06382 Uncasville	
Population								
2015 Projection	4,498		5,421		8,797		12,518	
2010 Estimate	4,420		5,457		8,717		12,187	
2000 Census	4,317		5,501		8,617		11,541	
1990 Census	3,812		5,186		8,231		9,889	
Growth 2010-2015	1.76%		-0.66%		0.92%		2.72%	
Growth 2000-2010	2.39%		-0.80%		1.16%		5.60%	
Growth 1990-2000	13.25%		6.07%		4.69%		16.71%	
2010 Estimated Population by Single Race Classification	**4,420**		**5,457**		**8,717**		**12,187**	
White Alone	3,834	86.74%	5,259	96.37%	8,010	91.89%	9,130	74.92%
Black or African American Alone	145	3.28%	13	0.24%	81	0.93%	1,311	10.76%
American Indian and Alaska Native Alone	28	0.63%	9	0.16%	41	0.47%	198	1.62%
Asian Alone	234	5.29%	86	1.58%	292	3.35%	472	3.87%
Native Hawaiian and Other Pacific Islander Alone	3	0.07%	5	0.09%	9	0.10%	5	0.04%
Some Other Race Alone	65	1.47%	23	0.42%	69	0.79%	580	4.76%
Two or More Races	111	2.51%	62	1.14%	215	2.47%	491	4.03%

Demographic Snapshot (Part 2)	06375 Quaker Hill		06378 Stonington		06379 Pawcatuck		06382 Uncasville	
Households								
2015 Projection	1,495		2,444		3,804		4,189	
2010 Estimate	1,496		2,455		3,739		4,101	
2000 Census	1,495		2,447		3,614		3,896	
1990 Census	1,489		2,263		3,275		3,653	
Growth 2010-2015	-0.07%		-0.45%		1.74%		2.15%	
Growth 2000-2010	0.07%		0.33%		3.46%		5.26%	
Growth 1990-2000	0.40%		8.13%		10.35%		6.65%	
2010 Estimated Families by Poverty Status*	**1,100**		**1,563**		**2,411**		**2,864**	
Income At or Above Poverty Level	1,093	99.36%	1,537	98.34%	2,303	95.52%	2,731	95.36%
Married-Couple Family	905	82.27%	1,317	84.26%	1,840	76.32%	2,213	77.27%
With own children	382	34.73%	496	31.73%	862	35.75%	1,006	35.13%
No own children	523	47.55%	821	52.53%	978	40.56%	1,207	42.14%
Male Householder	69	6.27%	63	4.03%	112	4.65%	173	6.04%
With own children	25	2.27%	29	1.86%	44	1.82%	93	3.25%
No own children	44	4.00%	34	2.18%	68	2.82%	80	2.79%
Female Householder	119	10.82%	157	10.04%	351	14.56%	345	12.05%
With own children	69	6.27%	52	3.33%	204	8.46%	207	7.23%
No own children	50	4.55%	105	6.72%	147	6.10%	138	4.82%
Income Below Poverty Level	7	0.64%	26	1.66%	108	4.48%	133	4.64%
Married-Couple Family	7	0.64%	11	0.70%	47	1.95%	38	1.33%
With own children	0	0.00%	11	0.70%	31	1.29%	4	0.14%
No own children	7	0.64%	0	0.00%	16	0.66%	34	1.19%
Male Householder	0	0.00%	0	0.00%	18	0.75%	13	0.45%
With own children	0	0.00%	0	0.00%	18	0.75%	10	0.35%
No own children	0	0.00%	0	0.00%	0	0.00%	3	0.10%
Female Householder	0	0.00%	15	0.96%	43	1.78%	82	2.86%
With own children	0	0.00%	15	0.96%	33	1.37%	82	2.86%
No own children	0	0.00%	0	0.00%	10	0.41%	0	0.00%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06385 Waterford		02891 Westerly		06254 North Franklin		06334 Bozrah	
Population								
2015 Projection	14,806		21,848		1,884		2,557	
2010 Estimate	14,783		21,717		1,865		2,521	
2000 Census	14,820		21,363		1,835		2,471	
1990 Census	14,107		20,056		1,810		2,419	
Growth 2010-2015	0.16%		0.60%		1.02%		1.43%	
Growth 2000-2010	-0.25%		1.66%		1.63%		2.02%	
Growth 1990-2000	5.05%		6.52%		1.38%		2.15%	
2010 Estimated Population by Single Race Classification	**14,783**		**21,717**		**1,865**		**2,521**	
White Alone	13,355	90.34%	20,223	93.12%	1,815	97.32%	2,392	94.88%
Black or African American Alone	307	2.08%	205	0.94%	20	1.07%	15	0.60%
American Indian and Alaska Native Alone	49	0.33%	139	0.64%	1	0.05%	22	0.87%
Asian Alone	679	4.59%	724	3.33%	1	0.05%	34	1.35%
Native Hawaiian and Other Pacific Islander Alone	2	0.01%	0	0.00%	1	0.05%	3	0.12%
Some Other Race Alone	141	0.95%	93	0.43%	2	0.11%	17	0.67%
Two or More Races	250	1.69%	333	1.53%	25	1.34%	38	1.51%

Demographic Snapshot (Part 2)	06385 Waterford		02891 Westerly		06254 North Franklin		06334 Bozrah	
Households								
2015 Projection	6,170		9,346		729		980	
2010 Estimate	6,129		9,217		715		958	
2000 Census	6,039		8,883		687		920	
1990 Census	5,458		7,961		648		862	
Growth 2010-2015	0.67%		1.40%		1.96%		2.30%	
Growth 2000-2010	1.49%		3.76%		4.08%		4.13%	
Growth 1990-2000	10.64%		11.58%		6.02%		6.73%	
2010 Estimated Families by Poverty Status*	**4,177**		**5,928**		**549**		**725**	
Income At or Above Poverty Level	4,046	96.86%	5,686	95.92%	542	98.72%	710	97.93%
Married-Couple Family	3,348	80.15%	4,531	76.43%	474	86.34%	606	83.59%
With own children	1,352	32.37%	1,971	33.25%	215	39.16%	259	35.72%
No own children	1,996	47.79%	2,560	43.18%	259	47.18%	347	47.86%
Male Householder	203	4.86%	315	5.31%	28	5.10%	45	6.21%
With own children	140	3.35%	133	2.24%	13	2.37%	7	0.97%
No own children	63	1.51%	182	3.07%	15	2.73%	38	5.24%
Female Householder	495	11.85%	840	14.17%	40	7.29%	59	8.14%
With own children	247	5.91%	443	7.47%	25	4.55%	31	4.28%
No own children	248	5.94%	397	6.70%	15	2.73%	28	3.86%
Income Below Poverty Level	131	3.14%	242	4.08%	7	1.28%	15	2.07%
Married-Couple Family	59	1.41%	71	1.20%	3	0.55%	2	0.28%
With own children	24	0.57%	39	0.66%	0	0.00%	2	0.28%
No own children	35	0.84%	32	0.54%	3	0.55%	0	0.00%
Male Householder	24	0.57%	37	0.62%	1	0.18%	0	0.00%
With own children	17	0.41%	17	0.29%	1	0.18%	0	0.00%
No own children	7	0.17%	20	0.34%	0	0.00%	0	0.00%
Female Householder	48	1.15%	134	2.26%	3	0.55%	13	1.79%
With own children	47	1.13%	122	2.06%	3	0.55%	13	1.79%
No own children	1	0.02%	12	0.20%	0	0.00%	0	0.00%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06336 Gilman		06351 Jewett City		06360 Norwich		06365 Preston	
Population								
2015 Projection	70		15,899		33,697		4,986	
2010 Estimate	68		15,541		33,649		4,886	
2000 Census	65		14,867		33,486		4,699	
1990 Census	63		14,163		34,493		5,014	
Growth 2010-2015	2.94%		2.30%		0.14%		2.05%	
Growth 2000-2010	4.62%		4.53%		0.49%		3.98%	
Growth 1990-2000	3.17%		4.97%		-2.92%		-6.28%	
2010 Estimated Population by Single Race Classification	**68**		**15,541**		**33,649**		**4,886**	
White Alone	64	94.12%	14,520	93.43%	25,967	77.17%	4,629	94.74%
Black or African American Alone	1	1.47%	223	1.43%	2,936	8.73%	27	0.55%
American Indian and Alaska Native Alone	0	0.00%	128	0.82%	397	1.18%	40	0.82%
Asian Alone	1	1.47%	218	1.40%	1,463	4.35%	91	1.86%
Native Hawaiian and Other Pacific Islander Alone	0	0.00%	10	0.06%	11	0.03%	1	0.02%
Some Other Race Alone	1	1.47%	120	0.77%	1,214	3.61%	33	0.68%
Two or More Races	1	1.47%	322	2.07%	1,661	4.94%	65	1.33%

Demographic Snapshot (Part 2)	06336 Gilman		06351 Jewett City		06360 Norwich		06365 Preston	
Households								
2015 Projection	27		6,285		14,332		2,019	
2010 Estimate	26		6,096		14,262		1,960	
2000 Census	25		5,715		13,988		1,841	
1990 Census	23		5,171		13,885		1,624	
Growth 2010-2015	3.85%		3.10%		0.49%		3.01%	
Growth 2000-2010	4.00%		6.67%		1.96%		6.46%	
Growth 1990-2000	8.70%		10.52%		0.74%		13.36%	
2010 Estimated Families by Poverty Status*	**19**		**4,353**		**8,500**		**1,450**	
Income At or Above Poverty Level	16	84.21%	4,221	96.97%	7,794	91.69%	1,429	98.55%
Married-Couple Family	14	73.68%	3,381	77.67%	5,592	65.79%	1,219	84.07%
With own children	6	31.58%	1,630	37.45%	2,464	28.99%	517	35.66%
No own children	8	42.11%	1,751	40.23%	3,128	36.80%	702	48.41%
Male Householder	1	5.26%	258	5.93%	533	6.27%	75	5.17%
With own children	0	0.00%	123	2.83%	330	3.88%	40	2.76%
No own children	1	5.26%	135	3.10%	203	2.39%	35	2.41%
Female Householder	1	5.26%	582	13.37%	1,669	19.64%	135	9.31%
With own children	1	5.26%	391	8.98%	1,056	12.42%	73	5.03%
No own children	0	0.00%	191	4.39%	613	7.21%	62	4.28%
Income Below Poverty Level	3	15.79%	132	3.03%	706	8.31%	21	1.45%
Married-Couple Family	1	5.26%	28	0.64%	123	1.45%	15	1.03%
With own children	1	5.26%	11	0.25%	56	0.66%	7	0.48%
No own children	0	0.00%	17	0.39%	67	0.79%	8	0.55%
Male Householder	0	0.00%	39	0.90%	88	1.04%	5	0.34%
With own children	0	0.00%	36	0.83%	81	0.95%	3	0.21%
No own children	0	0.00%	3	0.07%	7	0.08%	2	0.14%
Female Householder	2	10.53%	65	1.49%	495	5.82%	1	0.07%
With own children	2	10.53%	65	1.49%	465	5.47%	1	0.07%
No own children	0	0.00%	0	0.00%	30	0.35%	0	0.00%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06380 Taftville		06384 Voluntown		06415 Colchester		06420 Salem	
Population								
2015 Projection	2,727		2,660		16,881		4,255	
2010 Estimate	2,701		2,624		16,383		4,140	
2000 Census	2,690		2,564		15,360		3,913	
1990 Census	2,926		2,135		11,651		3,353	
Growth 2010-2015	0.96%		1.37%		3.04%		2.78%	
Growth 2000-2010	0.41%		2.34%		6.66%		5.80%	
Growth 1990-2000	-8.07%		20.09%		31.83%		16.70%	
2010 Estimated Population by Single Race Classification	**2,701**		**2,624**		**16,383**		**4,140**	
White Alone	2,320	85.89%	2,518	95.96%	15,487	94.53%	3,902	94.25%
Black or African American Alone	98	3.63%	18	0.69%	229	1.40%	34	0.82%
American Indian and Alaska Native Alone	9	0.33%	27	1.03%	56	0.34%	22	0.53%
Asian Alone	36	1.33%	8	0.30%	152	0.93%	107	2.58%
Native Hawaiian and Other Pacific Islander Alone	1	0.04%	0	0.00%	3	0.02%	0	0.00%
Some Other Race Alone	116	4.29%	16	0.61%	177	1.08%	13	0.31%
Two or More Races	121	4.48%	37	1.41%	279	1.70%	62	1.50%

Demographic Snapshot (Part 2)	06380 Taftville		06384 Voluntown		06415 Colchester		06420 Salem	
Households								
2015 Projection	1,180		1,033		6,072		1,550	
2010 Estimate	1,159		1,010		5,914		1,494	
2000 Census	1,129		965		5,541		1,379	
1990 Census	1,152		783		4,145		1,137	
Growth 2010-2015	1.81%		2.28%		2.67%		3.75%	
Growth 2000-2010	2.66%		4.66%		6.73%		8.34%	
Growth 1990-2000	-2.00%		23.24%		33.68%		21.28%	
2010 Estimated Families by Poverty Status*	**736**		**746**		**4,521**		**1,182**	
Income At or Above Poverty Level	651	88.45%	722	96.78%	4,420	97.77%	1,176	99.49%
Married-Couple Family	473	64.27%	616	82.57%	3,755	83.06%	1,023	86.55%
With own children	208	28.26%	294	39.41%	2,116	46.80%	555	46.95%
No own children	265	36.01%	322	43.16%	1,639	36.25%	468	39.59%
Male Householder	59	8.02%	40	5.36%	186	4.11%	53	4.48%
With own children	18	2.45%	39	5.23%	110	2.43%	28	2.37%
No own children	41	5.57%	1	0.13%	76	1.68%	25	2.12%
Female Householder	119	16.17%	66	8.85%	479	10.60%	100	8.46%
With own children	72	9.78%	44	5.90%	312	6.90%	87	7.36%
No own children	47	6.39%	22	2.95%	167	3.69%	13	1.10%
Income Below Poverty Level	85	11.55%	24	3.22%	101	2.23%	6	0.51%
Married-Couple Family	20	2.72%	9	1.21%	46	1.02%	6	0.51%
With own children	20	2.72%	3	0.40%	18	0.40%	6	0.51%
No own children	0	0.00%	6	0.80%	28	0.62%	0	0.00%
Male Householder	4	0.54%	11	1.47%	2	0.04%	0	0.00%
With own children	2	0.27%	11	1.47%	2	0.04%	0	0.00%
No own children	2	0.27%	0	0.00%	0	0.00%	0	0.00%
Female Householder	61	8.29%	4	0.54%	53	1.17%	0	0.00%
With own children	56	7.61%	4	0.54%	44	0.97%	0	0.00%
No own children	5	0.68%	0	0.00%	9	0.20%	0	0.00%

Demographic Snapshot

Source: Claritas, 2012.

Demographic Snapshot (Part 1)	06475 Old Saybrook		Connecticut		The United States	
Population						
2015 Projection	10,684		3,574,974		322,320,436	
2010 Estimate	10,546		3,514,291		306,624,699	
2000 Census	10,365		3,405,565		281,421,906	
1990 Census	9,550		3,287,116		248,709,873	
Growth 2010-2015	1.31%		1.73%		5.12%	
Growth 2000-2010	1.75%		3.19%		8.96%	
Growth 1990-2000	8.53%		3.60%		13.15%	
2010 Estimated Population by Single Race Classification	**10,546**		**3,514,291**		**306,624,699**	
White Alone	10,025	95.06%	2,762,041	78.59%	222,311,945	72.50%
Black or African American Alone	73	0.69%	340,349	9.68%	38,203,182	12.46%
American Indian and Alaska Native Alone	13	0.12%	11,240	0.32%	2,859,788	0.93%
Asian Alone	246	2.33%	119,546	3.40%	13,486,064	4.40%
Native Hawaiian and Other Pacific Islander Alone	8	0.08%	1,881	0.05%	479,920	0.16%
Some Other Race Alone	51	0.48%	186,873	5.32%	20,433,721	6.66%
Two or More Races	130	1.23%	92,361	2.63%	8,850,079	2.89%

Demographic Snapshot (Part 2)	06475 Old Saybrook		Connecticut		The United States	
Households						
2015 Projection	4,380		1,371,101		121,279,475	
2010 Estimate	4,307		1,346,850		115,306,103	
2000 Census	4,183		1,301,670		105,480,101	
1990 Census	3,752		1,230,479		91,947,410	
Growth 2010-2015	1.69%		1.80%		5.18%	
Growth 2000-2010	2.96%		3.47%		9.32%	
Growth 1990-2000	11.49%		5.79%		14.72%	
2010 Estimated Families by Poverty Status*	**3,008**		**911,593**		**78,712,346**	
Income At or Above Poverty Level	2,949	98.04%	858,517	94.18%	71,479,360	90.81%
Married-Couple Family	2,549	84.74%	687,301	75.40%	57,477,586	73.02%
With own children	1,026	34.11%	327,240	35.90%	27,632,854	35.11%
No own children	1,523	50.63%	360,061	39.50%	29,844,732	37.92%
Male Householder	108	3.59%	42,245	4.63%	3,939,275	5.00%
With own children	67	2.23%	21,391	2.35%	2,259,423	2.87%
No own children	41	1.36%	20,854	2.29%	1,679,852	2.13%
Female Householder	292	9.71%	128,971	14.15%	10,062,499	12.78%
With own children	170	5.65%	78,109	8.57%	6,233,220	7.92%
No own children	122	4.06%	50,862	5.58%	3,829,279	4.86%
Income Below Poverty Level	59	1.96%	53,076	5.82%	7,232,986	9.19%
Married-Couple Family	10	0.33%	15,920	1.75%	2,882,746	3.66%
With own children	5	0.17%	9,034	0.99%	1,878,626	2.39%
No own children	5	0.17%	6,886	0.76%	1,004,120	1.28%
Male Householder	13	0.43%	6,191	0.68%	776,244	0.99%
With own children	10	0.33%	4,695	0.52%	591,002	0.75%
No own children	3	0.10%	1,496	0.16%	185,242	0.24%
Female Householder	36	1.20%	30,965	3.40%	3,573,996	4.54%
With own children	10	0.33%	27,652	3.03%	3,159,911	4.01%
No own children	26	0.86%	3,313	0.36%	414,085	0.53%

Attachment F

Policies & Procedures for PCI Procedure

LAWRENCE+MEMORIAL HOSPITAL

Title: Non Emergent Angioplasty procedure	Reference Number:
File Location: PCS/Cardiopulmonary/Cath lab	Issuing Department: Cath lab
Latest Review/Revision Date: 5-12	Original Date: 5-12
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date:	
Medical Director, Angioplasty program — Date: 5/31/12	
Vice President Patient Care Services/CNO — Date: 5/30/2012	

PURPOSE: To establish procedures for the safe care of the patient having a non-emergent angioplasty procedure upon CON Approval.

POLICY:

1. Interventional cardiologists verify patient meets criteria for performance of non-emergent angioplasty in a non surgical on site cath lab (Non SOS).
2. Informed consent and discussion with patient and family by Interventional cardiologists.

PROCEDURE:

Patient selection: See ACC guideline *Table I.*

Patient Preparation:

A. Pre –procedure
   a. Cath lab nurse verifies patient identity, allergies and completes standard pre procedure documentation process
   b. Cath lab is set up using standard procedures for femoral or radial access.

B. Intra- procedure
   a. Completes standard diagnostic procedure.
   b. Physician determines the need for angioplasty. If meet criteria, procedure performed same day or as a staged procedure. If does not meet criteria, patient is referred to tertiary center with on site surgery available.
   c. Prepares patient and equipment for non emergent angioplasty.
   d. Explain procedure to patient and family.
   e. Assure patient given any pre-ordered antiplatelet medication such as Plavix or Prasugrel.
   f. Obtains/prepares the following additional medication such as but not limited to: GPIIb/IIIa inhibitors, heparin, and antiplatelet medications.

g. Assures correct angioplasty supplies (wires, guides, stents, catheters) available.
h. Prepare for use of IVUS, FFR, and IABP, hands off defibrillation, temporary pacing and IV vasopressors.
i. Assures emergency equipment is available such as but not limited to:
    1.Temporary pacemaker supplies
    2.Pericardiocentesis tray
    3.JoMed Stent Grafts
    4.Perfusion balloons
    5.Pressors
j. Baseline ACT performed.
k. Maintain ACT to appropriate level based on type of anticoagulation ordered.
l. Be prepared to quickly response to complications such as perforation, tamponade, arrhythmias or dissection. See coronary perforation algorithm *Table 2*.
m. If an Emergent/Primary angioplasty patient arrives during an elective PCI procedure, consult the physician and refer to the bumping protocol.

C. Post-Procedure
    a. Post procedure transfer to appropriate telemetry or critical care unit with written post procedure orders.
    b. Report given to RN on receiving unit using SBAR method.
    c. Post unit to monitor for and report to physician any new onset of chest pain, access site issues, and vital sign changes by 20% from baseline.
    d. Assure follow up consult with cardiac rehabilitation.
    e. Provide post care visit by cath lab staff to monitor post recovery and access site and provide education information such as what type of stent implanted.

D. Transferring guidelines
    a. Immediate decision on therapeutic action if emergent transfer for surgery is needed. See Patient transfer to higher level of care facility guidelines
    b. The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program
    c. Physician contacts referring interventionalist and cardiac surgeon.
    d. Physician chooses the appropriate form of transportation.

PROTOCOL

Reference:
1. Brilakis et al. A Percutaneous Treatment Algorithm for Crossing Coronary Chronic Total Occlusions. JACC: Cardiovascular Intervention, Vol 5,No 4, 2012.
2. Ellis, Stephen. Strategic Approaches in Coronary Intervention. LWW. 3rd ed. 2006.

Archive Dates
Reviewed Date:
Revised:
Supersedes:

Table 1:

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:

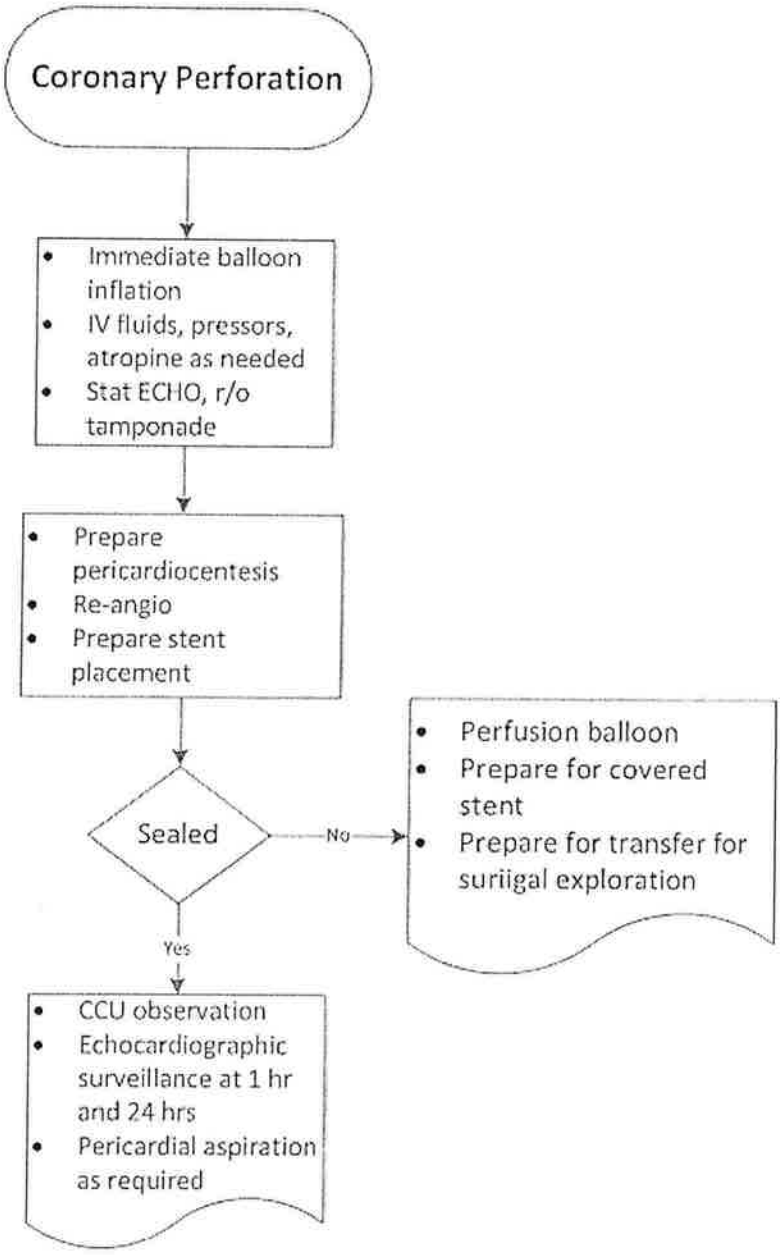
- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification at a stenosis or proximal segment
- Location in an extremely angulated segment (>90°)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- 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.**

Table 2


Coronary Perforation
Immediate balloon inflation
IV fluids, pressors, atropine as needed
Stat ECHO, r/o tamponade
Prepare pericardiocentesis
Re-angio
Prepare stent placement
Sealed
No
Perfusion balloon
Prepare for covered stent
Prepare for transfer for suriigal exploration
Yes
CCU observation
Echocardiographic surveillance at 1 hr and 24 hrs
Pericardial aspiration as required

LAWRENCE+MEMORIAL HOSPITAL

Title: Bumping Protocol for Interventional Services	Reference Number: Click here to enter text.
File Location: Pt. Care Services / Cardio Pulmonary	Issuing Department: Cath Lab
Latest Review/Revision Date: 5/12	Original Date: 1/06
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date:	

Medical Director, Primary Angioplasty — Date: 5/29/12

Chairman, Department of Radiology — Date

Lauren Williams, RN
Vice President Patient Care Services/CNO — Date: 5/30/2012

PURPOSE

To ensure primary angioplasty is available with a time frame that meets ACC/AHA guidelines (≤ 90 minutes). Bumping means the postponement of elective procedures. It does not mean interruption of a procedure already in progress even if elective.

POLICY

1. All physicians agree in advance to adhere to this acuity based bumping protocol.
2. Interventional Cardiologist to consult with physician whose case is affected by this bumping protocol.

PROCEDURE

1. In the event that there is a scheduling conflict related to the availability of appropriate staff and/or clinical setting, the following classification of priority is followed:
   First Priority:
   - Acute STEMI (Immediate transfer to Cardiac Cath lab)
   - Non Emergent PCI when physician has crossed the lesion/balloon inflated.
   - Suspected pulmonary embolus with hemodynamic instability (Immediate transfer to Interventional procedures)
   - Acute aortic dissection requiring angiography (Immediate transfer to Interventional procedures)..

   Emergent Priority

- Acute limb ischemia (Transfer to Interventional procedure within 30 minutes)

Urgent Priority

- Unstable angina within 24 hours (Transfer to Cardiac Cath lab on completion of the case in progress)
- Inferior vena cava filters or venography for deep venous thrombosis (Transfer to Interventional radiology on completion of the case in progress)
- Non Emergent PCI when physician has not crossed the lesion

2. Procedure to follow: See attached PCI bumping algorithm

First Priority patients:

- Delay in start for non-first priority patients. Bumped patient procedure performed after completion of emergency procedure.

Emergency Priority patients:

- Procedure in progress to be finished as soon as possible (asap)

Urgent Priority patients:

- Procedure done upon completion of the case in progress.

Two First Priorities AMI arrive at the same time or Non Emergent PCI in progress and lesion has been crossed

- Interventional Cardiologists to prioritize the Cases. Case not able to be done are transferred to another facility that can perform primary angioplasty or invasive cardiologist to start diagnostic part of cath as determined by interventional cardiologist.

PCI BUMPING ALGORITHM

SCHEDULING CONFLICT
ON CALL NURSE #2 CONSULTS WITH INTERVENTIONAL CARDIOLOGIST

Conflict in Procedure	Conflict in staffing
Interventional Cardiologist consult with physician whose case is affected Physicians determine priority of patient Either delay in start of procedure or transfer patient If Non Emergent PCI procedure in progress, arrange for invasive cardiologist to start the procedure.	Nurse 2 calls in available off duty staff If unable to meet staffing requirements, contact Interventional Cardiology to determine next step Either delay in start of procedure or transfer patient

Bumping Protocol for Interventional Services

PROTOCOL

Reference:

Archive Dates Reviewed Date: Revised: 03/08, 12/09, 5/12 Supersedes:

LAWRENCE + MEMORIAL HOSPITAL

Title: Patient transfer to higher level of care guidelines	Reference Number:
File Location: Departmental	Issuing Department: Cath lab
Latest Review/Revision Date: 5-12	Original Date: 5-12
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date: Medical Director, Angioplasty 5/31/12 Date Director, Patient care Services 5/31/12 Date	

PURPOSE: To provide guidelines for when the need arises for emergent transportation for a PCI patient from the Cardiac Catheterization lab.

POLICY

PROCEDURE:
The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program at Lawrence + Memorial Hospital (L+M) as described below:

1. A CT Surgeon is on-call 24/7 to arrange for patient transfers through the Y-Access system and to receive the patient at YNHH.
2. All YNHH on-call CT Surgeons are privileged to provide CABG or other procedures expected as a result of complications associated with performing elective PCI at Lawrence & Memorial Hospital.
3. YNHH maintains one operating room open every day for emergency transfers that is CT Surgery capable. The on-call CT Surgeon remains in-house during the hours of 7:30am through 4:00pm, Monday through Friday to accommodate the Lawrence & Memorial elective PCI schedule.
4. The receiving surgeon and team obtain consent for surgery from patient or surrogate.
5. The Yale-New Haven Heart & Vascular Center agrees that L+ M may represent to patients that YNHVC provides surgical backup to elective PCI in its patient consent process.
6. YNHVC and L+M maintain computer systems interface or direct access to L+M systems for the YNHVC receiving surgeon to review real-time images and hemodynamic data, as well as audio and video images for consulting on treatment options and transfer decisions.

7. L+M Hospital employ the Yale-New Haven Hospital Y-Access transfer system to expedite the process of surgical consultation and transfer.
8. All other provisions of the Transfer Agreement will remain in effect for heart and vascular patients
9. When choosing the appropriate form of transportation, the patient's stability and equipment needs is assessed and relayed to the proposed transportation team. Patients requiring a Balloon Pump during transport require air medical transport or a nurse to accompany the patient if ground transport does not have the appropriate staff to monitor the pump.
10. In the event air medical transport is preferred but unavailable due to weather, staff should inquire if the team is available to provide the trip by ground.

Below is the transport option in order of use:

1. Lifestar (Air Medical) transportation – Crew configuration will consist of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
2. Lifestar (Ground) transportation – Crew configuration will consist of an American Ambulance EMT and a second American Technician which may be an EMT or Paramedic and the Lifestar Crew consisting of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
3. American Ambulance (Ground) transportation - Crew configuration will consist of an American Ambulance EMT and a Paramedic.

The following option must only be used if other transportation is unavailable and transportation must occur immediately.

4. New London Fire Department Ambulance (Ground) transportation - Crew configuration will consist of 2 Firefighter/EMT's and a Lawrence & Memorial Hospital Paramedic.

Contact Information

Lifestar – (800)437-4378
American Ambulance – (860)886-1463
New London Fire Department – (860)442-4444/911

PROTOCOL

Reference:
1. Hospital L+M Policy Patient transfer to Higher level of care facility.
2. YNHH transfer agreement

Archive Dates
Reviewed Date:
Revised: 5/12
Supersedes:

LAWRENCE+MEMORIAL HOSPITAL

Title: Quality Assurance Plan: Cath Lab	Reference Number:
File Location: Departmental	Issuing Department: Cath lab
Latest Review/Revision Date: 4/12	Original Date: 9/90
Endorsing Departments/Committees/Dates: Cardiology Service	
Authorizing Signature/Title/Date: Medical Director, Cath lab 5/23/12 Max Gorski 5/23/2012 Director, Patient care services	

PURPOSE:
To establish an ongoing quality assurance plan for maintaining high-quality performance and providing high-quality patient care through a systematic process of ongoing evaluation of patient outcomes and process reviews.

Unit Scope of Care:
The cath lab provides for the diagnostic/therapeutic services of cardiac catheterization. It provides for the insertion, and replacement of permanent pacemakers/ICD and for the insertion of an intra-aortic balloon and temporary pacemakers. It provides for the performance of primary angioplasty for STEMI patients that meet the ACC/AHA patient selection criteria. Pending CON approval will provide for the performance of non emergent angioplasty patients that meet the ACC patient selection criteria for non surgical on site criteria. It also provides for tilt studies and other arrhythmia related services. These services are provided in areas of the hospital specifically designed and equipped to achieve the above in a quality manner.

Staffing consists of a cath lab trained registered nurse, a CV trained registered nurse or technologist, an x-ray technologist and an invasive cardiologist. For pacemaker/ICD insertion, the physician may be a thoracic surgeon or an invasive cardiologist with privileges for pacemaker/ICD insertion. For primary PCI, the cardiologist must be an interventional cardiologist with privileges.

Staffing for tilt studies consist of a nurse and a cardiologist or Health professional affiliate (HPA) experienced in tilt table testing.

Scope of care includes nursing coverage for interventional radiology and other areas in radiology.

POLICY:
Standard: Quality Assurance

PROCEDURE:

Procedural volume:

1. Physician and laboratory procedure volume statistics are recorded and kept on file in Cath lab office based on a fiscal year.
   a. Minimal benchmark per ACC guidelines per lab is: 300 caths per year; 36 primary PCI per year.
   b. Minimal benchmark per physician is: 75 Diagnostic studies per year; 75 angioplasty procedures per year must include 11 primary PCI per interventional cardiologist.
   c. If a physician operates in more than one adult laboratory, he/she should perform no fewer than 50 studies at each of the respective facilities unless the operation principles are identical in all laboratories utilized.
   d. Physicians responsible for maintaining their own volume records.

Equipment Maintenance:

1. Equipment is maintained in good operating condition and tested daily/monthly as indicated. See appropriate documentation forms.
2. Planned Preventive Maintenance is performed on equipment used in cathlab including but not limited to imaging system, hemodynamic system, IABP consoles, power injectors, IVUS, defibrillators by Hospital trained Biomedical Engineering department and/or contract preventive maintenance by appropriate manufacturer.
3. Records are maintained in Hospitals Biomed department.
4. Point of care testing: Daily QC performed as per POC policy and monitored by POC Coordinator.
5. Hemodynamic transducer(s) are zeroed prior to each procedure.
6. Imaging system tested daily when lab is open. If a complaint of poor image quality occurs, technologist performs QC check and/or call for service. Yearly check by Health Physicist with records in Biomed dept.

Radiation Safety Guidelines:

1. Follow hospital wide Radiation policy and Alara program.
2. Annual lead apron inspection.

Credentialing/Recredentialing of Physicians: See Medical staff credentialing guidelines

Validation/revalidation of clinical staff: See individual's orientation record and health stream educational records.

Adverse Outcomes:

1. Adverse outcomes for caths and pacer procedures are collected on a case-by-case basis. Adverse Outcomes are defined according to ACC /PCI Registry and Heart Rhythm Society. See Appendix A & B.
2. Adverse occurrence requiring physician peer review is reviewed at cath lab peer review meeting and documentation forwarded to Chairman, Dept of Medicine or to other quality/hospital committees. Peer review process follows Medical department peer review guidelines.
3. Individual physician's adverse outcome rate is documented and reported to Medical Director Cath lab & Chairman, Dept. of Medicine as requested.
4. The cardiologist assures that all adverse outcomes occurring during the cath lab visit or after lab visit until discharge (or before any subsequent lab visits) is communicated to the CCL staff for QA documentation.
5. All major adverse outcomes are reported to Quality/Risk Management Department.

Troubleshooting:

1. The Medical Director of Cath Lab/designee is on call for assistance and trouble shooting in the event a problem arises during a study and for QA and monitoring of results. In the event of his absence, an assigned cardiologist is made available.

Quality/Appropriateness Criteria:

1. The percentage of diagnostic cases found to be without significant heart disease should not exceed **27% -36%** of the total patients studied by any physician or by the laboratory as a whole. Significant heart disease is defined as a **70% stenosis** of at least one major arterial vessel or at least **50%** occlusion of the left main coronary artery as defined by ACC. ***If > 50% of diagnostic caths do not have flow limiting CAD, the non –invasive testing algorithm used to select patients for angiography should be reevaluated.***
2. No more than **1%** of the studies should require repetition because of inadequate data or image quality.
3. Inadequate or incomplete < 1%
4. Complication rates greater than (>) 5% considered excessive and cause for review.
5. **Correlation and Confirmation of results.** Quarterly correlation of cath results and other diagnostic procedure and operative findings are collected, tabulated and kept on file in cath lab office. These results are distributed to the interpreting physician, reviewed with cath lab medical director and at appropriate meetings.
6. Participate in ACC Cath-PCI registry.
7. Conduct cath conferences (See related QA conference plan: Cardiac cath lab). Special attention to PCI cases Primary and non-Emergent, if approved, to review for quality, results of individual operators and outcomes.

Monitoring and Evaluation Process:

1. Clinical indicators based on **structural, process and outcomes** domains are developed, monitored, and revised as indicated. All aspects of the continuum of patient care services, from pre-entry through exit phases, are reviewed for opportunities for improvement relative to efficacy (desired outcomes), **appropriateness** (relevant patients clinical needs), timeliness, effectiveness (correct manner & outcomes), continuity, safety, efficiency, respect and caring, report variability & completeness and **correlation** with other imaging modalities. (See Quality Assurance Conference plan: Cath lab)
    a. **Structural Domain**
        1. Credentialing criteria
    b. **Process Domain**
        1. Direct patient- care activities: Quality of angiography studies, generation and completeness of reports, handling of complications
        2. System-related activities: Procedural checklist, lab results, response time in emergencies
        3. Guidelines-related activities: Procedure indications, radiation safety, contrast, infection control
        4. Cost and utilization activities: Availability and quality of supplies, length of stay, staffing and personnel
    c. **Outcome Domain**
        1. Monitoring of complication (30 days)
        2. Aggregate or physician specific data
        3. Cath lab statistics

2. Collected data is systematically assessed internally (levels, patterns, trends), externally (reference databases) or with standards (practice guidelines) or best practice (benchmarks) to ascertain if improvement/goals, actions are met. Opportunities for improvement are prioritized based on the data.

3. Data source: Daily logs, computer databases, Hemo system queries, Written/oral complaints, Quality referral reports.

4. Methodology: Review of patterns and trends. Retrospective or concurrent review of 5% of total volume, 30 charts, or 100% sampling as indicated and determined by the indicator being monitored. Record on appropriate quality form. Each form reviewed by nurse manager. Trends are discussed at the cardiology services meeting and/or quality assurance cath lab conferences. (See related Quality Assurance Plan: Cath lab)

5. Reviewer: Manager or Medical director or designee. Trends are reviewed at Cardiology services meetings/quality assurance quality conferences. Major adverse occurrences reviewed at cardiac cathlab Peer review meetings.

6. Frequency of review and reporting: Quality reporting a minimum of **two** times per year. Statistical reporting of volume statistics is **quarterly** at cardiology service meetings and cath lab staff meeting and/or unit base practice council meetings. Quality monitoring results are reported at cardiology services, peer review meetings or cath conference meetings and cathlab staff/unit based meetings as appropriate.

Reference:

1. American College of Cardiology/Society for Cardiac Angiography and Interventions clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update, *JACC*, Vol 59, 0735-1097, 2012.
2. ACC/AHA/SCAI 2005 Guidelines Update for Percutaneous Coronary Intervention, *JACC*, 47, 2006.
3. AHA et al. 2012 Appropriate Use Criteria for Diagnostic Catheterization, **JACC**,Vol 59,2012.
4. AHA.SCAI 2009 Appropriateness Criteria for Coronary Revascularization. *JACC*,2009 53:530-553.
5. Naidu,S et al. Clinical Expert Consensus Statement on Best Practices in the Cardiac Catheterization Laboratory: Society for Cardiovascular Angiography and Intervention, ***Catheterization and Cardiovascualr interventions*** 00:000-000 (2012)
6. Grossman's Cardiac Catheterization, Angiography and Intervention. Chapter 3, Complications and the Optimal Use of Adjunctive Pharmacology. 7th edition. 2006.
7. ACC-NCDR Cath PCI Registry 2011 for benchmarks. American College of Cardiology Foundation.
8. Recommendations from the Heart Rhythm Society Task Force on Device Performance Polices and Guidelines. HRTHM 2006.
9. ACC-NCDR ICD Registry Benchmark 2011. American College of Cardiology Foundation.
10. SCAI Quality Improvement Toolkit, www.scai.org/qit, 2012.
11. Medical department current peer review hospital policy/procedures.
12. Quality Assessment and Improvement in Interventional Cardiology: A Position Statement of the Society of Cardiovascular Angiography and Interventions,Part 1: Standards for Quality Assessment and Improvement in Interventional Cardiology, ***Catheterization and Cardiovascular Interventions*** 00-000-000 2011.
13. Quality Assessment and Improvement in Interventional Cardiology: A Position Statement of the Society of Cardiovascular Angiography and Interventions,Part 2: Public Reporting and risk adjustment, ***Catheterization and Cardiovascular Interventions*** 00-000-000 2011
14. **Cath lab quality assurance forms**
15. **Quality Assurance Conference plan**

Archive Dates
Reviewed Date: 11/02
Revised: 11/95,12/96,2/98,11/99,4/00,10/00,10/01,7/03,11/04,10/01,1/08. 3/11, 5/12
Supersedes: Unit based Quality & Performance Quality Plan
Invasive Services Volume and Standards Indicators.

Appendix A: Pacemaker adverse outcomes

List of pacer adverse outcomes monitored are:

- ☐ Pneumo/Hemothorax < 2%
- ☐ Lead displacement < 1%
- ☐ Embolus < 2%
- ☐ Death < 0.1%
- ☐ Infection < 1%
- ☐ Pocket Hematoma < 0.3%
- ☐ Arrhythmias requiring Defibrillation < 0.1%
- ☐ Other < 2%
- ☐

Overall complication rate should be < 2%.

Appendix B: Adverse Outcome Defined according to ACC/PCI Registry 2011.

Overall adverse outcome rate should be:

- Diagnostic cath < 1%
- PCI < 2%
- Primary PCI < 4%
- MACE < 0.1%

- ☐ **Death:** < 0.1% Any death in the lab or within 24 hrs of procedure. Any death owing to an adverse outcome is recorded as a cath-related death no matter when it occurs. (< 2% per CON)
  - Diagnostic cath 0.6% (SCAI 2012 QA toolkit)
  - PCI STEMI ~~5.38%~~ 4.8-1%
  - PCI NSTEMI 0.65%
  - Over all PCI 1.39%

Predisposing factors, which might increase TFA for death

- Age: Elderly (>75 y/o)
- Class IV CHF
- Severity of coronary obstruction (Left main)
- Valvular heart disease esp when combined with coronary disease
- LV ejection (<30%)
- Severe Non-cardiac diseases: Patients with renal insufficiency, insulin-requiring diabetes, advanced CV or peripheral vascular disease

- ☐ **Myocardial Infarction:** < 0.3%
  A significant rise in cardiac enzymes (3 X upper limit) or Evolutionary ST segment elevations.

- CVA/Stroke: < 0.2% (0.06%) Documented by loss of neurological function with residual symptoms lasting at least 24 hours after onset or leading to death.

- Arrhythmias: VF/VT requiring treatment. < 2%

- Contrast allergic reaction: Major (Anaphylactic or Hypotension)
- Contrast induced Renal Failure: < 0.5% Increase Cr > 2 or 2x baseline or new requirement for dialysis

- Cardiogenic shock: Hemodynamic compromise: Sustained (>30 mins) episode of Systolic BP < 90 mmhg and/or requirement of vasopressor or IABP.

- Emergency PCI: Complication of diagnostic cath

- Unplanned CAB:

- **Abrupt closure**: Vessel intervened upon demonstrates ischemic changes, chest pain or hemodynamic compromise

- **Bleeding: -Access site : Local Vascular injury requiring surgical/transfusion** (hematomas, retroperitoneal bleed) and/or major access site related injury (access site occlusion, peripheral embolization, loss of pulse ,dissection, psuedoaneurysm, AV fistulas)

  Diagnostic (0.4%) PCI (< 3%)
  - Requiring treatment
  - Developing within 72 hours of procedure
  - Associated with hemoglobin drop of > 3 g/dl; transfusion of blood or a procedural intervention/surgery at the bleeding site to reverse/stop or correct bleeding.

- **Other**: < 0.5% any other complication not listed above that requires treatment and may prolong patient's stay

LAWRENCE+MEMORIAL HOSPITAL

Title: Quality Assurance Conference Plan – Cardiac Cath Lab	Reference Number: Click here to enter text.
File Location: Departmental	Issuing Department: Cath Lab
Latest Review/Revision Date: 5-12	Original Date: 6/08
Endorsing Departments/Committees/Dates: Cardiology Service meeting	
Authorizing Signature/Title/Date: Medical director, Cath lab 5/25/12 Date Director, Primary Angioplasty 5/24/12 Date Director, Patient care Service 5/23/2012 Date	

Purpose:
Quality Assurance Cath Lab Conferences are for the purposes of evaluation and improving the quality of procedures rendered in the cardiac cath lab and enforcing guidelines designed to optimize resource utilization.

Plan:

1. Cardiac Catheterization Conferences consists of three components:
   - Cardiac Catheterization conferences: (Angio review, Quality review, Educational topics)
   - Angioplasty (PCI) conferences: (Angio review of primary PCI and if approved Non-Emergent PCI, Quality review, Morbidity & Mortality (M&M)
   - Peer review conferences: M&M
2. All documents and discussion that are part of the process are appropriately protected from "discover" consistent with Connecticut General Statutes.
3. All minutes and other records of the proceedings that involve peer review and quality improvement are maintained separately from the other business minutes.
4. Attendance is documented at all conferences.

Cardiac Cath Conferences:

1. A minimum of **two** cath lab quality assurance conferences are held each calendar year.
2. The purpose is to review the results of comparative studies, to address discrepancies, to discuss difficult cases and laboratory issues. It also provides continuing education credits.
3. Includes open review of at least 5 random cases per conference. Reviews each case for Technical quality (quality of images, Interpretive quality (Agreement with reading) and Administrative quality (Appropriate diagnosis).
4. Attendance of all medical staff is required for at least one meeting.

5. Attendance is open to all clinical staff.
6. Tertiary interventional cardiologists and cardiac surgeons attendance is encouraged either in person or by conference call.
7. All Cath lab staff and Physician can recommend cases for review.

Angioplasty (PCI) Conferences: Primary and Non Emergent PCI as approved.

1. A minimum of **two** PCI quality assurance conferences are held each calendar year. At least one is held at Yale. (May be combined with above cath conference)
2. Primary review is performed on all primary and non-emergent PCI for appropriateness, medical necessity and adverse outcomes by cath lab nurse manager or designee.
3. Secondary review is performed when criteria is not met as dictated by PCI Medical director. Refer following outcomes for review, but not limited to:
    a. Restudy or reshooting required
    b. Death
    c. Subacute thrombosis
    d. Emergency bypass
    e. Unsuccessful procedure
    f. Complications
    g. Staff request
4. Peer review at Yale for all deaths and sub-acute thrombosis.
5. Minimum of two board certified interventional cardiologist reviews each case together for quality assurance.
6. Debriefing of select PCI cases as requested by case review or staff.

Peer Review Conferences:

1. The peer review process follows the standards as established in the hospital's Medical staff policy entitled "Peer Review". The peer review process in the cath lab assures that:
    a. A thorough, credible deliberation of the standard of care occurs
    b. Opportunities for improvement are identified and implemented.
    c. Education is provided.
2. Peer review conference is held minimally **two** times per year.
3. Medical Director assigns a physician to review the case, and notifies the physician whose case is being reviewed.
4. Case selection = all death within 30 days of procedure and major complication as defined by ACC Cath-PCI registry and other internal, state or regulatory reporting requirements.
5. Peer review conference must insure at least three (3) practitioners are in attendance. If there is insufficient numbers of physicians specializing in the involved practitioner's field to objectively and expertly review the case, an expert in the field may provide input through an external review.

Reference:
1. L&M policies: "Peer Review" policy & Quality Assurance-Cath lab policy
2. 2007 Focused ACC/AHA/SCAI 2005 Guidelines Update for Percutaneous Coronary Intervention: ***JACC*** 2008; 51:172-209.
3. Dehner,G et al. 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, **Catheterization and Cardiovascular Interventions**. 69:471-478 (2007).
4. Cardiac cath lab standards, JACC, Vol 37,2001.
5. HRS 2006 Guidelines.
6. The Joint Commission Standard, 2011. WWW. Joint commission.org/Standards
7. WWW. ACGME.org 3-2011.

Archive Dates
Reviewed Date:
Revised: 6/08, 5-12
Supersedes:

LAWRENCE+MEMORIAL HOSPITAL

Educational Plan for Non –Emergent Angioplasty w/o SOS

Description of the program:
The education program meets all the education guidelines as recommended by CPORT. The program will be offered to staff working in all areas affected by the addition of Non-Emergent Angioplasty at L+M hospital. The educational process to prepare the clinical staff involves varied learning methodologies: self learning modules, formal lectures, clinical experience at Yale as needed, observation in our cath lab, vendor sponsored in-services and dry run simulations for cath lab and post care units. It will also include clinical validation via the L+M Simulation (SIMS) computer learning system. Each educational offering is designed to meet the needs of the particular unit/staff expertise i.e. Cardiac Cath lab, CCU, Med-surg telemetry (Post cardiac care) unit or ambulatory medical unit (AMU). Yale-New Haven hospital (YNHH) is being contacted to provide on site educational program and optional clinical experience in the treatment and post procedural management of patients undergoing angioplasty. Competency verification is determined on initial training and on an annual basis.

Course Objectives:

1. To care for patient having non emergent angioplasty competently.
2. To list and manage potential complications.
3. Demonstrate ability to rapidly transfer (within 30 mins) patients to tertiary canter for emergency bypass (CABG).
4. Demonstrate ability to care for patients with various vascular closure devices or arterial sheaths.
5. Demonstrate ability to care for patient with various access sites. i.e. Radial vs Femoral
6. Demonstrate ability to operate specialized devices such as IVUS /FFR devices use to access stent deployment and gradients across the lesion.
7. To provide pre and post educational instructions to patients and their families including discharge instructions.

Course Content:

Training will include familiarization with: angioplasty equipment (wires, stent, IVUS, FFR, angioplasty catheters), commonly used drugs, assessment and monitoring of the state of anticoagulation, Intra aortic balloon counterpulsation equipment, patient transfer to and from lab/ referral hospital, and all issues related to pre-procedure, intra-procedure, and post-procedure care.

Department (Who)	Topic (What)	Method (How)
Cardiac cath lab staff	✓ Patient preparation	✓ Pre clinical assessment

Department (Who)	Topic (What)	Method (How)
(RN's and techs)	✓ Indications/contraindications ✓ Review access site set up ie radial/femoral ✓ Equipment & supplies (stents, balloons, specialty wires) ✓ FFR how to set up, interpret ✓ IVUS how to set up, interpret ✓ Anticoagulation methods ✓ Review of IABP set up/maintenance ✓ Review complications management including perforation ✓ Intra- procedure care ✓ Hematoma management ✓ Hypothermia management ✓ Post care (closure device) ✓ Advanced pharmacotherapy review ✓ Emergent transfer procedure with mock drills ✓ Charging process ✓ Documentation guideline review with Philips hemosystem	✓ Pre knowledge assessment ✓ Formal inservices/lectures by interventional cardiologists (Minimal 8-10 hrs) ✓ Vendor in-services on equipment ✓ Simulation lab case reviews (SIMS lab) (Minimal 1-2 hrs)
Intermediate care units (AMU/Post cardiac care/CCU)	✓ Preparation of patient including educational tips ✓ Post care ✓ Access site management ✓ Review of what happens in the lab. ✓ Complication management and assessment (hematoma, recurrent chest pain, tamponade..) ✓ Emergent transfer back to lab or tertiary procedure ✓ Case reviews ✓ Pharmacotherapy review ✓ Documentation guideline with McKesson HED system	✓ Pre clinical assessment ✓ Pre knowledge assessment ✓ Formal in-services/lectures by interventional cardiologists or clinical specialist. (Minimal 2 hrs) ✓ Simulation lab case reviews (SIMS lab) (Minimal 1 hrs)
All staff	✓ **Mock drills** of care of process for patients re *post care* or need *transfer* or have *complications* ✓ **Clinical experience** on site cath lab. Based on learning assessment each person.	✓ **Post clinical sign off** (see separate form) ✓ **Simulation lab** case reviews (SIMS lab) (Minimal 1-2 hrs) ✓ **Mock drills** for

Department (Who)	Topic (What)	Method (How)
	○ Cath lab nurse/tech minimum 1 days or minimal 2 procedures ("one on one" observational training) if needed based on learning needs of individual at YNHH. ○ Post care unit nurses (core group) minimum of 1 days or 2 procedures observation on site L+M cath lab.	transfer/complications ✓ **Clinical experience** of non- emergent PCI on site at L+M. ✓ **Optional available** observation training at YNHH if needed.
Ongoing all post care units and cath lab area.	✓ **On-going** retrospective case review of protocols and case processes.	**Case review/debriefing** as close to patient procedure for all cath lab and post care staff. (Quarterly) **Annual competency assessment** for all post care units and cath lab.

Reference:

1. Grossoman's "Cardiac Catheterization,Angiography and Intervention. Seventh ed. LWW. 2006.
2. Kerns, Morton. The Cardiac Catheterization Handbook. Saunders. 5th edition.2011.
3. Ellis, Stephen et al. Strategic approaches in Coronary Intervention. LWW. 3rd edition.
4. Mehta,Sameer. Textbook of STEMI Intervention.

#	Planning for Non-Emergent PCI with No SOS	Weeks																	
	Steps	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	1st month post	Completed date
	Planning																		
	Set Multi disciplinary meeting																		
	Invite attendees																		
	VSA-REI to plan scope of project																		
	Establish task list																		
	Operational :Patient Access : Scheduling																		
	Create scheduling categories ie Non emergent angio I/O																		
	Admission algorithm for bed assignment esp with high census																		
	Patient Scheduling																		
	Staff Scheduling																		
	Education																		
	Planning outlines & dates																		
	Planning clinical experience schedule for cathlab/post care unit staff																		
	Pre - Intra - Post care lectures																		
	Include: Transfer procedure;Hypothermia mgt, FFR;Chronic total occulsion, Perforation mgt, Hematoma mgt ...																		
	Policy/Protocol																		
	Review/Revise current order set to include non emergent PCI orders																		
	Review/develop current policies to include non emergent PCI standard of care																		
	Finance: Equipment/charging																		
	Review/Revise inventory par levels																		
	Review/revise chargemasterCPT codes																		
	Order FFR related catheters																		
	Review CCL charge slip																		
	Education staff re charging process/changes																		
	Quality Metrics																		
	Review current/Determination for changes																		
	Review/Revise Quality plan																		
	Marketing																		
	Website update																		
	Internal communicatin announcements																		
	External communication announcements: Newspaper, physician liason ..																		
	IS systems																		

#	Planning for Non-Emergent PCI with No SOS	Weeks																
	Steps	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	1st month post	Completed date
	Discuss videoconference needs																		
	Configure all CPACS to transmit images to Yale (current two are set)																		
	Evaluation																		
	Case reviews in Simulation lab/Mock Drills																		
	Post planning/evaluation meeting																		
	Go live																		
	Follow up Assessement post Go Live																		

Attachment G

Results of 2007 Community Needs Assessment

HEALTH STATUS PROFILE

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
GENERAL HEALTH STATUS										
Total Population 2005 Estimates	26,111	77,605	40,631	36,975	9,819	75,737	77,145	266,418	3,503,185	290,850,005
Annual Household Income (1999)	$33,809	$42,715	$46,154	$39,181	$69,477	$53,434	$62,898	$51,301	$57,483	$43,318.0
% of Labor Force Unemployed	4.5	3.1	2.6	3.7	1.5	2.3	2.1	2.7	3.5	5.7
% Population Not Attaining H.S. Diploma (>25 yrs)	21.4	15.9	11.3	20.8	5.5	14.3	10.2	13.8	15.9	15.4
% Population Under the Age of 18	22.3	23.9	24.3	23.4	22.2	22.4	25.2	23.6	23.9	25.2
% Population Between Ages 18-44	45.4	40.3	43.0	37.4	27.2	35.5	36.4	37.8	36.4	38.8
% Population Between Ages 45-64	20.3	22.4	20.7	24.2	33.4	27.5	27.7	25.6	26.0	23.7
% Population Age 65 and Over	11.9	13.4	12.0	15.0	17.3	14.6	10.7	13.0	13.7	12.4
% Uninsured (< 65yrs)	19.2	14.0	3.0	15.6	NA	6.3	10.5	11.0	10.6	17.6
% Projected Population Change (2000-2010)									4.8	NA
% Projected Population Change (2000-2015)									6.3	NA
FUNCTIONAL HEALTH STATUS										
% Health Fair to Poor	17.8	19.8	12.7	24.2	NA	11.4	9.3	13.8	12.2	14.8
% Limited Activity	26.0	24.6	21.6	26.4	NA	21.8	23.5	23.8	15.1	NA
% Need for Personal Care Assistance (Household)	8.4	6.8	4.2	8.5	NA	5.4	3.8	5.7	NA	NA
% Need and Use Special Equipment for Health Problem	10.3	10.1	9.0	11.0	NA	6.7	5.0	7.6	NA	NA
% 11+ Days Physical Health Not Good	13.5	12.7	11.2	13.6	NA	10.5	7.7	10.3	8.8	NA
% 11+ Days Mental Health Not Good	14.9	14.7	11.0	17.0	NA	8.9	11.6	12.0	9.2	NA
% 11+ Days Lost due to Poor Mental or Physical Health	6.7	7.3	7.2	7.4	NA	6.8	5.2	6.3	8.2	NA
% 3+ Chronic Conditions	25.1	24.9	16.9	29.8	NA	20.7	19.7	22.2	NA	NA
Wellness Categories:										
Well	38.7	43.4	50.6	39.1	NA	35.6	40.8	40.3	34.1	NA
At Risk for Future Medical Problems	8.8	8.2	8.6	7.9	NA	11.6	13.4	10.8	7.4	NA
Some Health Problems	36.0	31.2	30.0	32.0	NA	40.4	38.1	36.1	44.9	NA
Not Well	16.6	17.2	10.7	21.2	NA	12.5	7.6	12.9	13.7	NA

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
PRIMARY CARE										
% Without Usual Source of Primary Care	26.4	22.3	18.3	24.7	NA	22.7	19.2	21.2	12.5	12.1
Males	34.0	24.1	14.9	29.1	NA	28.8	23.9	26.1	16.3	15.5
Females	19.3	20.6	21.2	20.3	NA	16.8	14.8	16.7	9.0	8.9
% Named a clinic or doctor's office as primary source of care	74.9	82.6	85.4	80.9	NA	79.0	83.1	81.5	NA	NA
% Named hospital or emergency room as primary source of care	17.7	11.0	6.3	13.8	NA	10.9	9.1	10.6	NA	NA
% Not Having a Checkup Within the Past 2 Years	11.0	9.2	4.9	11.8	NA	14.2	12.8	12.0	14.1	NA
Males	17.4	10.7	2.5	15.2	NA	18.7	16.2	15.1	16.1	NA
Females	5.0	7.8	6.9	8.3	NA	9.8	9.7	9.1	12.2	NA
% Received Flu Shot (past 12 months)	29.0	29.7	40.3	23.4	NA	29.3	24.9	28.9	27.8	NA
Ages 45-64	26.9	27.3	31.5	25.2	NA	32.4	28.4	30.3	22.7	NA
Ages 65+	52.9	55.1	55.3	54.7	NA	51.0	50.3	53.2	71.1	65.7
Males	24.1	29.4	45.6	20.7	NA	24.8	24.9	24.8	26.4	NA
Females	33.6	30.1	35.7	26.3	NA	33.7	24.9	26.1	29.2	NA
% Received Pneumoccal Shot (ever)	23.1	26.0	27.1	25.3	NA	23.7	26.3	25.5	23.1	NA
Ages 45-64	18.8	23.8	24.8	23.3	NA	20.5	24.1	22.6	15.9	NA
Ages 65+	67.8	58.0	52.9	65.6	NA	62.3	66.5	63.8	69.3	65.9
Males	22.5	28.0	29.2	27.3	NA	19.5	25.5	24.8	22.3	NA
Females	23.7	24.0	25.3	23.2	NA	27.4	27.0	26.1	23.9	NA
% Could not see a doctor because of cost	10.7	12.4	8.6	14.7	NA	5.4	7.7	8.7	9.2	15.6
ED Visits per 100,000 population	71,509	57,772	61,779	53,369	26,849	30,706	30,930	42,512	32,384	38,200.0
Ages <18	72,080	53,013	59,632	45,475	19,160	28,416	28,723	39,478	31,910	NA
Ages 18-44	81,901	68,645	65,411	72,739	30,797	39,113	37,630	52,680	40,042	NA
Ages 45-64	64,862	46,695	51,826	41,880	23,102	24,279	23,744	32,927	24,355	30,600.0
Ages 65+	42,187	52,040	70,270	36,014	37,752	25,890	31,930	37,278	28,046	45,400.0

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
PRIMARY CARE cont.										
Hospitalizations per 100,000 Population	12,125	12,263	10,879	13,782	8,152	9,242	8,530	10,158	10,384	11,923.0
Ages <18	4,228	2,908	2,619	3,237	1,423	2,173	1,779	2,432	2,879	NA
Ages 18-44	8,351	8,927	7,981	10,120	5,639	6,341	6,650	7,448	8,104	NA
Ages 45-64	16,905	13,477	11,091	15,709	6,947	9,066	8,549	10,536	9,688	11,789.0
Ages 65+	33,117	36,928	37,651	36,293	23,076	27,521	30,801	31,430	30,889	36,299.0
Ambulatory Care Sensitive (ACS), Hospital Admission Rate	2121.7	2117.8	1762.2	2508.5	931.8	1476.8	1163.4	1600.3	1562.7	NA
Ages 0-17	1106.3	642.1	618.1	669.3	45.9	444.6	345.0	517.9	565.8	NA
Ages 18-44	695.9	608.7	449.0	811.0	281.0	444.5	400.3	503.4	486.6	NA
Ages 45-64	3492.1	2556.5	1885.3	3186.3	778.7	1341.4	1159.8	1708.1	1410.8	NA
Ages 65+	7111.5	8550.0	8583.6	8520.5	3389.2	5835.8	5703.9	6567.4	6457.9	NA
ACS Respiratory Admissions	781.3	940.7	771.6	1126.4	478.6	652.3	498.4	698.0	672.4	NA
ACS Cardiovascular Admissions	779.4	794.4	606.7	1000.7	295.3	561.8	443.3	591.6	553.0	NA
ACS Pediatric Admissions	226.0	130.8	123.1	139.3	0.0	87.1	75.2	106.4	112.5	NA
ACS Medicine Admissions	335.1	251.9	260.9	242.1	157.9	175.6	146.5	204.4	224.9	NA
ED Visits for ACS Conditions	9072.6	7535.6	9286.1	5611.9	2021.5	3141.2	3348.9	5021.4	2978.2	NA

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
CARDIOVASCULAR HEALTH										
% Current Smokers (Age 18+)	27.2	25.5	18.5	29.8	NA	24.9	23.3	24.5	16.5	20.6
% Sedentary Lifestyle (measured by no physical activity)	27.9	23.3	13.8	28.9	NA	20.9	21.5	21.9	21.2	23.8
% Physical Activity (5 times a week at 30 min)	17.5	19.1	20.5	18.4	NA	24.4	22.3	21.1	NA	49.1
% Physical Activity (>=150 minutes week)	49.3	50.7	64.1	42.5	NA	57.7	55.7	54.5	NA	NA
% Overweight (Ages 18+)	34.5	35.4	41.1	32.1	NA	31.9	37.5	34.8	38.1	36.7
% Obesity (Ages 18+)	26.6	21.1	15.6	24.4	NA	28.4	22.9	24.1	20.1	24.4
% Overweight/Obesity Problem (% of households with O/O Youth 0-17)	10.2	0.9	1.7	0.6	NA	3.6	3.9	3.5	NA	NA
% High Cholesterol	23.2	26.8	21.5	30.0	NA	30.4	24.5	27	28.4	35.6
% High Blood Pressure	29.8	23.8	19.6	26.4	NA	28.1	21.3	25.1	23.8	25.5
% Heart Disease	3.7	5.0	3.6	5.8	NA	1.6	2.4	2.9	4.3	NA
% Having Cholesterol Checked (within the past year)	60.6	63.2	67.9	60.3	NA	63.9	62.8	63.5	59.0	NA
% Advised to quit smoking in the past year	63.8	67.2	62.1	69.2	NA	73.9	65.6	67.7	NA	63.5
% Rehab following Heart Attack or Stroke Hospitalization	36.7	55.0	52.2	57.3	NA	32.7	59.6	47.1	41.1	NA
Male	24.7	64.6	40.6	91.3	NA	47.9	61.9	55.2	44.2	NA
Female	44.3	40.6	78.0	20.3	NA	7.3	56.5	36.1	37.4	NA
% Take Aspirin to Reduce Heart Attack (age 35+)	27.7	23.1	25.7	21.4	NA	23.2	18.5	22.6	NA	NA
Male	31.3	30.0	33.2	28.3	NA	21.6	19.5	25.2	NA	NA
Female	24.3	16.8	20.4	13.7	NA	24.8	17.7	20.3	NA	NA
Congestive Heart Failure, Hospital Admissions	9.6	4.5	1.2	8.1	5.1	2.6	1.3	3.6	2.0	NA
Ages 45-64	18.8	11.5	0.0	22.3	15.3	0.0	2.3	5.9	2.3	NA
Ages 65+	16.1	4.8	10.3	0.0	0.0	18.1	6.1	10.1	7.0	NA
AMI, Hospital Admission Rate	168.5	208.7	155.1	267.8	122.2	178.9	147.1	175.3	129.9	NA
Ages 45-64	263.6	215.9	243.8	189.7	76.3	120.0	166.0	168.0	98.8	NA
Ages 65+	834.8	1143.2	831.7	1417.1	559.9	965.1	892.0	969.7	734.6	NA

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
CARDIOVASCULAR HEALTH cont.										
Cerebrovascular Disease (stroke), Hospital Admission Rate	116.8	141.1	121.8	162.3	101.8	103.6	95.9	113.5	131.0	NA
Ages 45-64	178.8	115.2	124.9	106.0	45.8	74.4	65.5	88.7	101.8	NA
Ages 65+	561.9	826.2	770.1	875.5	471.5	557.3	673.5	662.4	724.2	NA
CABG, Hospital Admission Rate	15.3	30.9	19.7	43.3	35.6	21.8	31.1	27.0	37.1	NA
Ages 45-64	56.5	25.9	17.8	33.5	0.0	26.4	42.1	32.3	54.4	NA
Ages 65+	32.1	168.1	112.9	216.6	206.3	90.6	163.8	131.9	160.0	NA
Heart Disease, Mortality Rate	260.4	244.0	228.9	260.5	254.6	253.1	197.5	235.1	239.2	NA
Ages 45-64	200.8	147.8	122.9	171.1	50.9	110.4	104.4	122.2	110.1	NA
Ages 65+	1744.4	1498.7	1629.1	1384.0	1336.0	1486.1	1537.2	1518.1	1496.3	NA
AMI, Mortality Rate	40.9	51.1	58.2	43.3	50.9	51.1	43.2	47.8	44.2	58.7
Ages 45-64	25.1	26.9	23.8	29.8	0.0	27.2	23.4	24.4	22.3	NA
Ages 65+	289.0	320.2	431.2	222.6	275.1	287.0	343.9	310.2	275.9	NA
Cerebrovascular Disease (stroke), Mortality Rate	53.6	67.4	50.0	86.5	44.1	62.9	41.0	56.3	51.2	54.2
Ages 45-64	12.6	23.0	15.9	29.8	0.0	11.2	14.0	14.7	14.8	NA
Ages 65+	406.7	451.5	376.5	517.5	255.4	410.8	343.9	399.1	338.1	NA

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
RESPIRATORY HEALTH										
% Current Smokers	27.2	25.5	18.5	29.8	NA	24.9	23.3	24.5	16.5	20.6
Male	29.0	25.1	16.1	29.8	NA	23.1	25.4	24.8	17.0	NA
Female	25.4	26.0	20.4	29.7	NA	26.6	21.3	24.1	16.2	NA
% Former Smokers	22.0	27.5	33.8	23.8	NA	29.1	28.4	28.1	29.4	24.8
% Current Asthma (Ages 18+)	11.0	12.9	7.7	16.2	NA	6.9	7.3	9.1	8.0	8.0
% COPD	3.6	2.9	1.8	3.5	NA	3.9	1.9	2.8	NA	NA
Lung Cancer, Males, Incidence Rate*	91.5	85.2	NA	NA	82.5	73.1	80.7	81.0	80.4	78.5
Lung Cancer, Females, Incidence Rate*	54.9	106.9	NA	NA	60.3	61.6	70.7	76.7	68.9	51.3
% Advised to quit smoking in the past year	63.8	67.2	62.1	69.2	NA	73.9	65.6	67.7	NA	63.5
% Received Flu Shot (past 12 months)	29.0	29.7	40.3	23.4	NA	29.3	24.9	28.9	27.8	NA
Ages 45-64	26.9	27.3	31.5	25.2	NA	32.4	28.4	30.3	22.7	NA
Ages 65+	52.9	55.1	55.3	54.7	NA	51.0	50.3	53.2	71.1	65.7
Males	24.1	29.4	45.6	20.7	NA	24.8	24.9	24.8	26.4	NA
Females	33.6	30.1	35.7	26.3	NA	33.7	24.9	26.1	29.2	NA
% Received Pneumoccal Shot (ever)	23.1	26.0	27.1	25.3	NA	23.7	26.3	25.5	23.1	NA
Ages 45-64	18.8	23.8	24.8	23.3	NA	20.5	24.1	22.6	15.9	NA
Ages 65+	67.8	58.0	52.9	65.6	NA	62.3	66.5	63.8	69.3	65.9
Males	22.5	28.0	29.2	27.3	NA	19.5	25.5	24.8	22.3	NA
Females	23.7	24.0	25.3	23.2	NA	27.4	27.0	26.1	23.9	NA
Bronchitis and Asthma, Hospital Admission Rate										NA
Ages 0-17	591.7	326.4	293.9	363.5	0.0	220.8	185.4	267.7	284.4	NA
Ages 18-44	101.2	86.3	51.5	130.3	37.5	40.9	55.2	66.0	78.7	NA
Ages 45-64	141.2	115.2	53.5	173.0	61.1	57.6	53.8	77.7	78.1	NA
Ages 65+	144.5	120.1	143.7	99.3	29.5	108.7	78.9	104.4	138.1	NA
Bronchitis and Asthma, ED Visit Rate	2447.2	2124.9	2062.5	2193.4	743.4	926.9	1050.0	1453.7	965.5	NA
Ages <18	2255.5	1740.0	1626.3	1869.5	481.9	815.6	692.7	1171.7	1004.1	NA
Ages 18-44	2889.2	2650.6	2342.0	3041.3	843.0	1329.9	1435.7	1939.9	1283.2	NA
Ages 45-64	2306.1	2006.7	2081.6	1936.4	748.2	731.9	919.0	1238.8	728.4	NA
Ages 65+	1364.5	1426.6	1909.7	1001.9	913.6	484.8	916.3	972.6	501.5	NA

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
RESPIRATORY HEALTH cont										
COPD, Hospital Admission Rate	287.2	321.5	291.7	354.3	132.4	214.6	143.9	229.3	168.5	NA
Ages 45-64	574.2	454.9	333.1	569.2	137.4	208.8	128.6	271.4	175.7	NA
Ages 65+	1187.9	1513.1	1796.8	1263.6	501.0	1037.6	922.3	1140.7	849.9	NA
COPD, ED Visit Rate	1451.5	1346.6	1957.9	674.8	371.7	557.2	585.9	876.3	384.0	NA
Ages 45-64	1882.5	1586.3	2313.5	904.0	274.8	597.5	579.9	928.5	415.1	NA
Ages 65+	2456.1	2949.3	4271.3	1787.1	1031.5	1078.4	1286.4	1814.7	918.4	NA
Adult Pneumonia, Hospital Admission Rate	331.3	380.9	337.2	563.9	254.6	303.0	252.1	330.7	326.6	NA
Ages 45-64	480.0	373.0	249.8	613.8	168.0	201.6	184.7	276.5	237.0	NA
Ages 65+	1589.3	2512.0	2115.1	2545.3	1061.0	1540.5	1674.8	1795.9	1744.9	NA
Pneumonia, Hospital Admission Rate (0-17)	377.3	196.9	177.3	219.3	0.0	153.1	92.7	161.3	140.1	NA
Lung Cancer, Males, Mortality Rate	62.7	63.5	49.8	79.6	48.1	63.4	59.7	61.7	59.2	62.9
Lung Cancer, Females, Mortality Rate	44.9	61.1	58.7	63.6	46.9	62.4	53.6	57.2	49.7	46.1
COPD, Mortality Rate	39.6	59.3	57.4	61.3	40.7	58.5	40.2	50.9	41.4	43.5
Ages 45-64	31.4	26.9	19.8	33.5	0.0	25.6	9.4	20.0	15.0	NA
Ages 65+	256.8	384.3	438.1	337.0	216.1	353.4	339.8	344.0	270.0	NA
Pneumonia/Influenza, Mortality Rate	24.3	14.6	12.3	17.1	13.6	25.1	16.9	19.1	25.1	NA
Smoking Related Neoplasms, Mortality Rate	120.0	138.3	129.6	147.8	142.6	147.9	121.0	134.4	131.5	NA
Male	138.5	145.2	130.2	163.0	158.2	164.8	136.9	148.3	146.1	NA
Female	102.3	131.5	129.0	134.1	127.4	131.0	105.6	120.8	117.9	NA

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
DIABETES										
% Sedentary Lifestyle (measured by no physical activity)	27.9	23.3	13.8	28.9	NA	20.9	21.5	21.9	21.2	23.8
% Overweight (Ages 18+)	34.5	35.4	41.1	32.1	NA	31.9	37.5	34.8	38.1	36.7
% Obesity (Ages 18+)	26.6	21.1	15.6	24.4	NA	28.4	22.9	24.1	20.1	24.4
% Diagnosed Diabetes (All Adults 18+)	11.2	9.1	6.8	10.6	NA	9.9	6.8	8.7	6.5	7.3
Ages 18-44	7.2	3.8	3.2	4.0	NA	7.1	4.5	5.1	2.3	NA
Ages 45-64	14.3	10.6	6.2	12.8	NA	8.1	6.9	8.8	8.8	NA
Ages 65+	22.9	23.9	13.2	41.4	NA	20.7	15.6	19.6	13.2	NA
% Hemoglobin A1c measurement (at least once) in past year (Age 18+)	65.5	70.3	82.7	65.8	NA	98.5	97.4	84.7	90.7	90.4
% Lipid profile in past 2 years (Age 18+)	87.1	91.7	86.7	93.8	NA	100.0	91.0	93.6	91.0	95.0
% Retinal eye exam in past year (Age 18+)	68.5	75.4	53.6	83.7	NA	79.9	54.9	72	79.9	67.6
% Foot examination in past year (Age 18+)	59.2	58.7	50.6	62.1	NA	85.6	75.4	70.5	73.2	71.7
% Influenza immunization in past year (Age 65+)	40.5	45.4	30.5	51.3	NA	42.8	40.3	42.4	59.8	34.3
Diabetes, ED Rate	352.3	280.9	210.4	358.4	91.7	136.0	110.2	190.3	170.3	NA
Ages 45-64	630.6	420.3	261.7	569.2	106.9	170.4	161.4	264.0	223.4	NA
Ages 65+	610.0	610.0	544.2	667.9	235.8	353.4	358.0	449.3	403.0	NA
Diabetes, Hospital Admission Rate	109.1	89.6	68.0	79.8	50.9	53.5	44.7	66.8	76.2	NA
Ages 45-64	197.7	123.8	107.1	139.5	0.0	69.6	77.2	92.4	83.0	NA
Ages 65+	192.6	153.7	195.1	117.3	176.8	90.6	54.6	114.5	181.3	NA
Short-term Complications, Admission Rate	53.6	50.9	54.1	47.3	25.5	32.3	29.2	38.7	36.2	NA
Long-term Complications, Admissions Rate	93.8	90.2	102.1	77.1	20.4	48.9	39.5	61.6	82.2	NA
Lower Extremity Amputations, Admissions Rate	5.7	5.2	7.4	9.5	0.0	2.0	5.2	4.1	6.3	NA
Diabetes, Mortality Rate	21.7	23.6	12.3	36.1	20.4	22.4	16.0	20.8	20.0	25.5
Ages 45-64	18.8	19.2	19.8	18.6	10.2	17.6	14.0	16.6	13.9	NA
Ages 65+	149.8	134.5	68.4	192.6	78.6	120.8	97.1	119.8	115.3	NA

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
REPRODUCTIVE HEALTH										
Teen Birth Rate (10-17 yrs) Per 1,000 Female Population by Age	16.4	5.2	4.7	5.5	0.0	0.8	1.6	3.6	5.1	4.1
% Inadequate Prenatal Care	0.2	0.3	0.2	0.4	0.0	0.1	0.1	0.2	0.5	NA
Ages 10-17	1.6	0.0	0.0	0.0	0.0	0.0	0.0	0.8	2.0	NA
Ages 18-49	0.1	0.3	0.2	0.4	0.0	0.1	0.1	0.2	0.5	NA
% Adequate Prenatal Care	78.4	82.8	85.1	80.4	92.6	88.9	87.8	83.4	81.5	NA
Ages 10-17	62.3	61.0	88.5	39.3	0.0	50.0	59.1	60.8	59.2	NA
Ages 18-49	79.5	83.3	85.1	81.4	92.6	89.4	88.2	84.1	82.0	NA
% Pregnant Women Receiving Prenatal Care in First Trimester	89.3	86.0	89.1	82.8	95.7	91.9	91.5	88.3	87.0	83.7
High Risk, Hospital Admission Rate (10-49 year old females)	1076.1	721.6	887.3	573.1	104.5	307.4	307.5	483.7	480.1	NA
Ages 10-17	201.8	65.6	27.3	100.9	0.0	12.7	10.9	42.7	77.9	NA
Ages 18-49	708.9	614.6	699.2	523.5	138.9	313.8	256.4	424.9	433.8	NA
C-Section Rate per 100 births	28.1	26.3	28.9	24.6	29.6	26.5	28.1	26.8	28.0	28.9
Primary C-Section Rate per 100 births	17.8	16.2	16.8	16.0	17.0	17.1	17.2	16.7	17.5	18.0
VBAC rate per 100 births	1.6	1.3	1.2	1.4	2.6	2.2	0.9	1.6	1.3	1.1
% Low Birthweight (<2500 grams)	6.0	5.5	4.8	6.2	3.0	4.6	5.3	5.3	6.2	8.1
Ages 10-17	13.1	5.1	0.0	9.1	0.0	20.0	13.6	10.0	8.0	NA
Ages 18-49	5.6	5.5	4.8	6.1	3.0	4.4	5.1	5.2	6.1	NA
% Prematurity (< 37 weeks)	16.7	16.0	15.0	17.0	17.4	13.8	17.1	16.2	17.1	7.8
Ages 10-17	29.5	13.6	7.7	18.2	0.0	20.0	18.2	21.1	17.8	NA
Ages 18-49	15.9	16.0	15.1	17.0	17.4	13.8	17.1	16.1	17.1	NA
Infant Mortality Rate per 1,000 births	4.0	1.9	1.8	1.9	1.4	4.2	3.7	3.0	2.0	6.8
Neonatal Mortality Rate per 1,000 births	3.0	1.2	1.1	1.2	1.4	3.8	2.2	2.1	1.5	4.6

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
CANCER										
% Current Smokers (Age 18+)	27.2	25.5	18.5	29.8	NA	24.9	23.3	24.5	16.5	20.6
% Sedentary Lifestyle (measured by no physical activity)	27.9	23.3	13.8	28.9	NA	20.9	21.5	21.9	21.2	23.8
% Obesity (Ages 18+)	26.6	21.1	15.6	24.4	NA	28.4	22.9	24.1	20.1	24.4
% Advised to quit smoking in the past year	63.8	67.2	62.1	69.2	NA	73.9	65.6	67.7	NA	63.5
Malignant Neoplasms, Incidence Rate	504.3	627.1	NA	NA	845.3	481.1	566.5	564.0	600.8	459.6
Male	488.7	594.0	NA	NA	983.6	457.4	575.5	553.6	604.8	540.0
Female	519.1	659.4	NA	NA	710.5	504.7	557.7	574.3	597.1	404.1
% Stage All Cancers Female, Local	48.9	45.2	NA	NA	58.1	45.8	45.4	46.3	39.4	NA
% Stage All Cancers Female, Distant	21.9	23.8	NA	NA	11.8	22.6	24.4	23.0	18.7	NA
% Stage All Cancers Male, Local	39.1	46.6	NA	NA	52.8	46.2	50.3	47.3	46.7	NA
% Stage All Cancers Male, Distant	26.8	23.3	NA	NA	21.3	23.9	19.1	22.4	20.9	NA
Malignant Neoplasms, Mortality Rate	168.5	208.7	196.9	221.8	230.8	219.2	190.1	203.2	205.6	191.5
Ages 45-64	251.0	180.4	182.4	178.6	152.7	168.0	207.3	189.2	181.4	NA
Ages 65+	963.2	1197.6	1266.3	1137.3	1041.3	1123.7	1177.2	1140.2	1107.7	NA
Male	175.1	195.7	178.4	216.1	240.7	228.2	202.7	206.7	212.7	201.3
Ages 45-64	256.4	185.5	194.9	176.7	142.4	172.7	208.1	192.1	191.9	NA
Ages 65+	1282.9	1410.7	1473.3	1352.5	1190.7	1387.7	1415.3	1381.6	1362.3	NA
Female	162.2	221.5	216.2	226.9	221.2	210.1	177.9	199.8	198.9	182.0
Ages 45-64	245.8	175.6	170.4	180.4	163.0	163.2	206.5	186.4	172.4	NA
Ages 65+	757.0	1062.5	1128.6	1006.4	913.0	930.7	983.3	967.2	933.6	NA
Respiratory:										
Lung Cancer, Incidence Rate	72.8	96.2	NA	NA	71.3	67.3	75.6	78.8	74.5	62.7
% Stage Lung Local	15.8	21.0	NA	NA	28.6	19.6	19.4	20.0	17.2	NA
Male	11.4	19.4	NA	NA	^	25.3	20.7	20.3	16.0	NA
Female	22.7	22.2	NA	NA	^	12.9	18.1	19.7	18.4	NA
% Stage Lung Distant	57.9	48.2	NA	NA	42.9	49.7	50.9	50.0	50.5	NA
Male	62.9	48.0	NA	NA	^	41.0	47.8	47.8	51.9	NA
Female	50.0	48.4	NA	NA	^	60.0	54.2	52.3	49.1	NA
Lung Cancer, Mortality Rate	53.6	62.3	54.1	71.2	^	62.9	56.6	59.4	54.3	54.4

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
CANCER cont.										
Other:										
Melanoma, Incidence Rate	46.0	49.8	NA	NA	122.2	40.1	57.0	51.4	42.1	18.7
Melanoma, Mortality Rate	^	^	^	^	^	^	^	^	3.1	2.7
Gastrointestinal:										
Colorectal, Incidence Rate	63.8	81.2	NA	NA	^	48.9	50.1	62.1	69.3	49.5
Male	60.1	79.1	NA	NA	^	46.7	46.5	60.0	71.7	58.0
Female	67.4	83.2	NA	NA	^	51.0	53.6	64.1	67.0	42.8
% Stage Colorectal, Local	31.9	36.4	NA	NA	50.0	41.5	39.6	38.7	41.6	NA
Male	18.2	38.2	NA	NA	^	42.9	35.4	37.5	44.0	NA
Female	44.0	34.7	NA	NA	^	40.4	42.9	39.7	39.3	NA
% Stage Colorectal, Distant	17.0	21.2	NA	NA	7.1	15.1	18.9	18.1	16.1	NA
Male	13.6	22.5	NA	NA	^	16.3	16.7	17.9	15.5	NA
Female	20.0	20.0	NA	NA	^	14.0	20.6	18.3	16.8	NA
% Colo-Rectal Exam Past Year (Age 40+)	52.9	42.6	48.1	38.7	NA	52.1	48.7	49.0	NA	NA
% Reported Blood Stool Test Past Year (Age 50+)	25.2	20.5	26.2	15.6	NA	20.1	23.5	22.2	21.8	NA
% Reported Having Sigmoid/Colonoscopy Past 5 Years (Age 50+)	59.6	65.5	68.3	62.8	NA	63.5	50.6	60.6	55.7	NA
Colorectal, Mortality Rate	^	23.6	21.3	26.1	^	18.5	20.3	20.9	20.2	19.2
Male	^	22.6	20.9	24.6	^	16.7	19.3	19.0	20.1	19.6
Female	^	24.6	21.8	27.5	^	20.2	21.3	22.8	20.3	18.9
Female Breast:										
Female Breast Cancer, Incidence Rate	162.2	210.5	NA	NA	227.9	166.2	181.4	185.4	204.0	124.2
% Stage Female Breast, Local	72.0	70.8	NA	NA	73.1	64.9	64.0	67.6	63.4	NA
% Stage Female Breast, Distant	1.9	3.6	NA	NA	0.0	4.1	5.5	3.9	4.4	NA
% Reported Mammogram past year, Age 40+	68.4	67.9	73.6	63.0		75.3	70.6	71.0	66.5	NA
% Reported Mammogram past year, Age 50+	68.2	75.9	17.9	21.6		75.7	69.8	73.1	68.6	NA
Female Breast Cancer, Mortality Rate	^	28.9	35.2	22.3	^	29.0	27.2	27.0	30.1	28.2

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
CANCER cont.										
Reproductive:										
Cervix Uteri, Incidence Rate	^	^	NA	NA	^	^	^	7.2	7.1	7.1
% Stage Cervix Uteri Female, Local	^	^	NA	NA	^	^	^	37.9	45.8	NA
% Stage Cervix Uteri Female, Distant	^	^	NA	NA	^	^	^	6.9	12.2	NA
% Reported Pap Smear past 2 years	85.2	82.7	80.5	84.5	NA	85.7	78.2	82.8	79.2	NA
Ages 18-44	89.7	86.5	97.3	81.5	NA	92.9	82.5	87.6	86.6	NA
Ages 45-64	90.6	91.1	90.7	91.5	NA	85.6	82.3	87.4	82.7	NA
Ages 65+	63.0	62.3	50.1	82.8	NA	69.3	53.5	61.8	57.0	NA
Female Cervix Uteri, Mortality Rate	^	^	3.4	3.4	^	^	^	1.5	2.0	2.7
Prostate:										
Male Prostate Gland, Incidence Rate	120.2	135.7	NA	NA	316.4	110.2	149.1	137.4	213.6	164.9
% Stage Prostate, Local	80.4	77.6	NA	NA	89.1	79.2	79.4	79.7	83.0	NA
% Stage Prostate, Distant	2.2	1.9	NA	NA	2.2	2.4	2.4	2.2	4.2	NA
% Males (<50) Testicular Cancer Exam (Past 2 yrs)	29.5	36.4	64.8	67.4	NA	36.6	39.4	36.5	NA	NA
% Prostate Exam (PSA test) past 2 yrs (Age 50+)	79.1	72.6	72.4	72.7	NA	74.7	76.4	76.1	70.2	NA
% Digital Rectal Exam past 2 years (Age 50+)	65.7	51.2	54.8	47.1	NA	55.2	63.9	56.4	77.1	NA
Male Prostate Gland, Mortality Rate	^	19.1	19.3	19.0	6.9	21.1	20.2	18.2	24.1	20.7

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MENTAL HEALTH										
% 11+ Days Mental Health Not Good	14.9	14.7	11.0	17.0	NA	8.9	11.6	12.0	9.2	NA
Ages 18-44	16.4	19.7	16.4	21.2	NA	9.0	11.8	14.7	10.5	NA
Ages 45-64	16.4	11.7	12.3	11.4	NA	12.0	12.5	11.6	9.8	NA
Ages 65+	7.3	3.3	1.3	7.2	NA	1.6	9.3	4.6	4.8	NA
% Depression	25.0	28.9	20.8	33.8	NA	22.6	28.7	26.5	NA	NA
Ages 18-64	25.4	30.8	27.2	32.6	NA	25.2	30.4	28.4	NA	NA
Ages 65+	23.0	20.4	6.0	44.0	NA	11.4	17.8	17.4	NA	NA
% Psychiatric Disorder	16.7	18.7	11.1	23.3	NA	12.4	14.2	15.1	NA	NA
Ages 18-64	17.7	21.5	15.8	24.2	NA	13.7	15.9	17.0	NA	NA
Ages 65+	11.2	5.7	0.0	15.4	NA	6.7	3.3	5.6	NA	NA
% HH with child with Emotional/Behavioral Problem (Ages 0-17)	11.9	8.0	5.9	8.9	NA	6.0	12.4	9.4	NA	NA
%HH with child with Learning Disability/Attention Disorder (Ages 0-17)	19.1	9.0	4.3	11.0	NA	17.2	17.2	15.2	NA	NA
% Adults with Outpatient Mental Health Treatment (past year)	14.2	13.7	7.4	17.4	NA	10.3	16.1	13.7	NA	NA
Psychoses, Hospital Admission Rate	725.7	623.7	425.8	841.1	244.4	299.7	265.1	423.8	482.2	NA
Ages 0-17	51.5	145.7	81.1	219.3	22.9	94.2	77.2	97.7	158.9	NA
Ages 18-44	830.9	874.0	551.9	1281.7	468.3	435.2	414.5	613.1	706.3	NA
Ages 45-64	1515.4	935.7	666.1	1188.6	274.8	316.7	285.3	555.9	572.2	NA
Ages 65+	240.8	201.7	256.7	153.4	117.9	253.7	145.6	204.4	280.2	NA
Senility and Organic Mental Disorders, Hospital Admission Rate	26.8	20.0	19.7	20.3	15.3	17.2	13.6	17.8	27.7	NA
Ages 18-64	8.7	8.4	0.0	8.8	16.8	4.2	5.1	5.3	6.2	NA
Ages 65+	176.6	124.9	164.3	90.3	29.5	99.7	97.1	110.2	172.6	NA
Major Depressive Disorder, Hospital Admission Rate	185.7	268.0	184.6	359.7	106.9	136.0	127.7	175.9	191.8	NA
Ages 0-17	17.2	62.0	15.2	115.4	22.9	44.2	36.0	43.7	76.6	NA
Ages 18-64	262.1	387.4	262.6	529.2	159.8	178.1	170.8	244.1	246.2	NA
Ages 65+	80.3	76.9	112.9	45.1	29.5	95.1	85.0	82.6	144.8	NA
Bipolar Disorder, Hospital Admission Rate	166.6	173.3	137.8	212.3	71.3	87.8	81.7	118.0	116.5	NA
Ages 0-17	8.6	59.3	40.5	80.8	0.0	38.3	38.6	40.5	44.1	NA
Ages 18-64	235.9	240.4	183.5	305.2	100.9	111.1	110.1	160.4	158.0	NA
Ages 65+	80.3	62.4	92.4	36.1	58.9	63.4	12.1	52.2	53.6	NA

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	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
MENTAL HEALTH cont.										
Schizophrenia and Related Disorders, Hospital Admission Rate	321.7	319.6	177.2	476.0	10.2	61.4	47.3	156.1	137.8	NA
Ages 18-64	477.7	489.1	251.0	759.8	16.8	76.5	64.7	230.5	205.1	NA
Ages 65+	48.2	67.2	102.7	36.1	0.0	81.6	48.5	62.3	46.8	NA
Anxiety Disorders, Hospital Admission Rate	40.2	26.4	20.9	32.5	15.3	21.1	25.9	25.7	29.0	NA
Ages 0-17	8.6	40.5	25.3	57.7	22.9	20.6	18.0	24.6	29.2	NA
Ages 18-64	49.5	24.7	21.2	28.5	16.8	21.0	27.3	26.6	31.3	NA
Ages 65+	48.2	9.6	10.3	9.0	0.0	22.7	36.4	23.2	17.8	NA
Other Mental Conditions, Hospital Admission Rate	82.3	36.1	34.5	37.9	30.6	23.1	20.1	32.1	65.9	NA
Ages 0-17	51.5	40.5	25.3	57.7	0.0	29.4	15.4	29.4	69.1	NA
Ages 18-64	99.0	40.1	40.6	39.5	50.5	25.1	20.2	36.4	74.5	NA
Ages 65+	48.2	9.6	20.5	0.0	0.0	4.5	30.3	15.9	20.8	NA
Senility and Organic Mental Disorders, ED Visit Rate	36.4	61.2	51.7	71.7	50.9	42.3	33.7	45.0	30.3	NA
Ages 18-64	26.2	21.6	13.5	30.7	33.6	21.5	21.2	22.8	13.5	NA
Ages 65+	144.5	336.2	338.8	334.0	176.8	185.8	139.6	216.0	136.1	NA
Major Depressive Disorder, ED Visit Rate	239.4	291.2	178.4	415.1	66.2	167.0	129.0	195.6	85.8	NA
Ages 0-17	94.3	132.2	81.1	190.4	22.9	164.9	128.7	132.7	76.6	NA
Ages 18-64	323.3	396.6	231.7	584.1	100.9	190.7	139.4	245.3	101.7	NA
Ages 65+	48.2	81.7	92.4	72.2	0.0	68.0	66.7	66.7	29.1	NA
Bipolar Disorder, ED Visit Rate	176.2	257.1	145.2	380.0	40.7	99.7	87.5	147.3	61.7	NA
Ages 0-17	154.4	337.2	233.1	455.8	45.9	167.8	87.5	187.5	50.0	NA
Ages 18-64	215.5	277.4	137.1	437.0	42.1	95.3	99.0	159.2	76.1	NA
Ages 65+	0.0	19.2	10.3	27.1	29.5	13.6	18.2	15.9	13.9	NA

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MENTAL HEALTH cont.										
Schizophrenia and Related Disorders, ED Visit Rate	283.4	152.1	64.0	248.8	50.9	54.1	35.0	99.5	74.4	NA
Ages 18-64	416.5	223.0	85.0	379.9	84.1	75.4	46.5	144.4	111.1	NA
Ages 65+	32.1	52.8	61.6	45.1	0.0	40.8	42.5	42.0	19.3	NA
Anxiety, Personality, and Other Disorders, ED Visit Rate	511.3	463.9	385.2	550.4	178.2	208.0	215.8	313.4	262.9	NA
Ages 0-17	154.4	167.3	152.0	184.6	45.9	141.3	79.8	127.9	118.9	NA
Ages 18-64	667.0	637.1	515.6	775.1	260.8	264.0	275.8	415.7	342.3	NA
Ages 65+	321.1	182.5	164.3	198.6	58.9	68.0	176.0	150.7	152.7	NA
Other Mental Conditions, ED Visit Rate	574.5	520.6	397.5	655.9	178.2	262.8	218.4	352.5	331.6	NA
Ages 0-17	377.3	528.8	445.8	623.2	229.4	409.3	267.8	391.6	346.2	NA
Ages 18-64	728.2	599.0	428.7	792.7	201.9	253.6	227.3	391.8	376.4	NA
Ages 65+	96.3	139.3	133.5	144.4	29.5	77.0	48.5	88.4	102.1	NA
Suicide, Mortality Rate	7.7	9.4	9.8	9.0	3.4	13.6	18.1	12.8	7.8	10.8
Males	15.7	13.0	9.6	17.1	6.9	20.3	26.3	19.0	12.6	17.6
Females	0.0	5.9	10.1	1.7	0.0	7.0	10.2	6.7	3.4	4.3

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SUBSTANCE ABUSE										
% Chronic Heavy Drinking (Past Month)	3.0	5.8	6.8	5.1	NA	6.5	6.8	5.8	3.5	4.9
Ages 18-64	3.1	6.7	8.7	5.8	NA	6.5	7	6.2	3.4	NA
Ages 65+	2.7	1.3	2.1	0.0	NA	6.4	5.4	3.8	3.7	NA
% Binge Drinking (Past Month)	12.6	15.9	14.7	16.6	NA	15.4	18.2	15.8	14.8	14.4
Ages 18-64	14.2	18.6	19.5	18.2	NA	18.2	20.7	18.3	17.5	NA
Ages 65+	4.1	3.4	3.4	3.3	NA	3.4	2.6	3.5	3.0	NA
Substance Abuse, Hospital Admission Rate	24.9	8.4	12.3	4.1	0.0	5.3	1.9	6.9	9.9	NA
Ages 18-64	35.0	13.4	19.3	6.6	0.0	7.3	3.0	10.4	15.3	NA
Ages 65+	16.1	0.0	0.0	0.0	0.0	4.5	0.0	2.9	2.3	NA
Acute Alcohol-Related Mental Disorders, Hospital Admission Rate	7.7	11.6	13.5	9.5	10.2	6.6	1.9	6.9	31.3	NA
Ages 18-64	11.6	16.4	17.4	15.4	16.8	7.3	2.0	9.2	44.2	NA
Ages 65+	0.0	9.6	20.5	0.0	0.0	13.6	6.1	8.7	23.3	NA
Alcohol-Related Psychoses, Hospital Admission Rate	109.1	50.9	43.1	59.5	25.5	33.7	24.0	43.0	49.5	NA
Ages 18-64	157.3	74.0	57.9	92.2	42.1	49.2	33.3	62.4	71.9	NA
Ages 65+	48.2	33.6	51.3	18.1	0.0	18.1	24.3	26.1	33.3	NA
Acute Drug-Related Mental Disorders, Hospital Admission Rate	11.5	1.9	3.7	0.0	5.1	2.0	2.6	3.2	11.3	NA
Ages 18-64	17.5	3.1	5.8	0.0	8.4	3.1	4.0	5.0	17.7	NA
Ages 65+	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	NA
Drug-Related Psychoses, Hospital Admission Rate	36.4	19.3	17.2	21.6	35.6	15.2	16.2	19.5	33.8	NA
Ages 0-17	8.6	2.7	0.0	5.8	0.0	5.9	2.6	4.0	1.7	NA
Ages 18-64	52.4	20.6	13.5	28.5	8.4	17.8	19.2	22.2	46.3	NA
Ages 65+	0.0	43.2	71.9	18.1	176.8	18.1	30.3	34.8	32.7	NA
Acute Alcohol-Related Mental Disorders, ED Visit Rate	1432.3	903.9	403.6	1453.7	341.2	327.5	281.9	591.0	534.9	NA
Ages 0-17	94.3	113.3	81.1	150.0	91.8	53.0	59.2	77.8	73.0	NA
Ages 18-64	2094.2	1350.1	575.5	2231.0	496.3	485.1	401.1	873.5	794.9	NA
Ages 65+	289.0	225.8	143.7	297.9	117.9	68.0	91.0	143.5	156.3	NA

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SUBSTANCE ABUSE cont.										
Alcohol-Related Psychoses, ED Visit Rate	30.6	22.6	16.0	29.8	10.2	9.9	12.3	16.3	17.9	NA
Ages 18-64	46.6	33.9	21.2	48.3	16.8	13.6	18.2	24.3	27.6	NA
Ages 65+	0.0	9.6	20.5	0.0	0.0	9.1	6.1	7.2	4.9	NA
Acute Drug-Related Mental Disorders, ED Visit Rate	114.9	108.9	55.4	167.7	45.8	67.3	59.0	80.9	116.2	NA
Ages 0-17	34.3	45.9	15.2	80.8	22.9	32.4	30.9	35.7	28.6	NA
Ages 18-64	163.1	155.2	79.2	241.5	67.3	94.3	79.8	113.6	174.7	NA
Ages 65+	0.0	4.8	10.3	0.0	0.0	4.5	0.0	2.9	2.4	NA
Drug-Related Psychoses, ED Visit Rate	76.6	51.5	35.7	69.0	10.2	35.6	26.6	40.7	39.6	NA
Ages 0-17	8.6	2.7	0.0	5.8	0.0	0.0	0.0	1.6	2.4	NA
Ages 18-64	113.6	69.9	50.2	92.2	16.8	53.4	41.4	59.5	60.2	NA
Ages 65+	0.0	52.8	30.8	72.2	0.0	13.6	0.0	20.3	10.4	NA
Alcohol-Related Mortality Rate	24.3	9.0	7.4	10.8	17.0	14.1	8.6	12.1	9.9	NA
Males	34.0	8.7	4.8	13.3	27.5	22.0	10.5	16.2	13.3	NA
Females	15.0	9.3	10.1	8.6	6.7	6.2	6.8	8.2	6.7	NA
Alcohol Liver Disease, Mortality Rate	17.9	7.3	7.4	7.2	17.0	12.8	7.3	10.3	8.8	NA
Motor Vehicle Accidents, Mortality Rate	12.8	10.7	6.6	15.3	13.6	12.8	11.7	11.9	10.1	16.5
Males	15.7	13.9	8.0	20.9	27.5	15.9	16.7	15.9	15.1	23.3
Females	10.0	7.6	5.0	10.3	0.0	9.7	6.8	7.9	5.5	10.0

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ACCIDENTS/SAFETY										
% Always use seatbelts	84.8	91.8	94.2	90.3	NA	88.9	86.6	88.9	NA	NA
Total Accidents, Mortality Rate	47.2	32.3	20.5	45.1	27.2	35.6	32.0	34.4	34.0	37.6
Male	62.7	40.0	22.5	60.7	41.3	52.0	40.4	45.8	45.3	49.3
Female	32.4	24.6	18.4	30.9	13.4	19.3	23.8	23.3	23.3	26.2
Motor Vehicle Accidents, Mortality Rate	12.8	10.7	6.6	15.3	13.6	12.8	11.7	11.9	10.1	16.5
Male	15.7	13.9	8.0	20.9	27.5	15.9	16.7	15.9	15.1	23.3
Female	10.0	7.6	5.0	10.3	0.0	9.7	6.8	7.9	5.5	10.0
YOUTH HEALTH										
% Ever Been Diagnosed with Asthma (Ages 0-17)	12.4	12.9			NA	9.9	11.1	11.5	NA	NA
% Overweight/Obesity Problem (Ages 0-17)	8.1	1.1	1.7	0.6	NA	2.4	2.9	2.8	NA	NA
% Emotional/Behavioral Problem (Ages 0-17)	9.4	6.7	5.9	8.9	NA	4.0	9.1	7.5	NA	NA
% Learning Disability/Attention Disorder (Ages 0-17)	12.6	7.4	4.3	11.0	NA	13.8	14.0	11.7	NA	NA
Teen Birth Rate (10-17 yrs) Per 1,000 Female Population by Age	16.4	5.2	4.7	5.5	0.0	0.8	1.6	3.6	5.1	4.1
% Adequate Prenatal Care, Ages 10-17	62.3	61.0	88.5	39.3	0.0	50.0	59.1	60.8	59.2	NA
% Adequate Prenatal Care, Ages 18-20	69.4	76.8	80.1	73.7	60.0	81.3	77.8	75.4	67.3	NA
% Inadequate Prenatal Care, Ages 10-17	1.6	0.0	0.0	0.0	0.0	0.0	0.0	0.8	2.0	NA
% Inadequate Prenatal Care, Ages 18-20	0.0	0.6	0.0	1.1	0.0	0.0	0.0	0.4	1.2	NA
Asthma and Bronchitis, Hospital Admission Rate (Ages 0-17)	591.7	326.4	293.9	363.5	0.0	220.8	185.4	267.7	284.4	NA
Pneumonia, Hospital Admission Rate (Ages 0-17)	377.3	196.9	177.3	219.3	0.0	153.1	92.7	161.3	140.1	NA
Psychoses Hospital Admission Rate (Ages 0-17)	51.5	145.7	81.1	219.3	22.9	94.2	77.2	97.7	158.9	NA
Major Depressive Disorder, Hospital Admission Rate (Ages 0-17)	17.2	62.0	15.2	115.4	22.9	44.2	36.0	43.7	76.6	NA
Bipolar Disorder, Hospital Admission Rate (Ages 0-17)	8.6	59.3	40.5	80.8	0.0	38.3	38.6	40.5	44.1	NA
Anxiety, Personality, and Other Disorders, Hospital Admit Rate (Ages 0-17)	8.6	40.5	25.3	57.7	22.9	20.6	18.0	24.6	29.2	NA

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YOUTH HEALTH cont.										
Other Mental Conditions, Hospital Admission Rate (Ages 0-17)	51.5	40.5	25.3	57.7	0.0	29.4	15.4	29.4	69.1	NA
Acute Alcohol-Related Mental Disorders, Hospital Admission Rate (Ages 0-17)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	NA
Acute Drug-Related Mental Disorders, Hospital Admission Rate (Ages 0-17)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.9	NA
Drug-Related Psychoses, Hospital Admission Rate (Ages 0-17)	8.6	2.7	0.0	5.8	0.0	5.9	2.6	4.0	1.7	NA
Pediatric gastroenteritis, Hospital Admissions (Ages 0-17)	68.6	40.5	35.5	46.2	0	41.2	38.6	41.4	41.5	98.1
ACS Conditions, Hospital Admission Rate (0-17)	1106.3	642.1	618.1	669.3	45.9	444.6	345.0	517.9	565.8	NA
ED Asthma/Bronchitis Visits per 100,000 Population	2447.2	2124.9	2062.5	2193.4	743.4	926.9	1050.0	1453.7	965.5	NA
Ages < 18	2255.5	1740.0	1626.3	1869.5	481.9	815.6	692.7	1171.7	1004.1	NA
ED Pneumonia Visits per 100,000 Population	522.7	426.5	406.1	449.0	259.7	224.5	267.7	326.4	253.6	NA
Ages < 18	951.9	547.6	526.9	571.2	91.8	250.3	293.5	410.7	331.7	NA
ED Otitis Visits per 100,000 Population	4298.9	3356.7	4649.2	1936.5	555.0	1296.6	1335.2	2174.8	1204.9	NA
Ages < 18	11809.0	8009.5	10457.1	5222.0	1147.3	2962.0	2007.1	5188.0	3348.4	NA
High Risk Antepartum Hospitalizations, Ages 10-17	201.8	65.6	27.3	100.9	0.0	12.7	10.9	42.7	77.9	NA
% Low Birthweight (<2500 grams) Ages 10-17	13.1	5.1	0.0	9.1	0.0	20.0	13.6	10.0	8.0	NA
% Prematurity (< 37 weeks), Ages 10-17	29.5	13.6	7.7	18.2	0.0	20.0	18.2	21.1	17.8	NA
ORAL HEALTH										
% Reporting not visiting Dentist past year	31.8	29.4	22.9	33.5	NA	21.7	16.6	22.8	20.7	29.3
ORTHOPEDICS										
% Diagnosed Arthritis	16.5	24.2	20.9	26.1	NA	19.8	19.9	20.9	25.5	27.0
Ages 45-64	20.3	36.8	31.7	39.3	NA	25.9	31.2	29.8	19.2	NA
Ages 65+	40.3	52.5	43.0	67.9	NA	37.4	39.8	44.1	53.4	NA
% Diagnosed Osteoporosis (65+)	10.8	15.9	17.4	13.3	NA	19.4	24.8	18.4		NA
Orthopedics, Hospital Admissions Rate	589.8	687.5	643.6	735.6	743.4	678.7	606.0	653.9	707.9	NA
Hip Procedures, Hospital Admission Rate	57.4	79.2	62.8	97.4	81.5	68.7	53.1	66.6	80.3	NA
Ages 65+	417.4	461.1	410.7	505.5	412.6	416.8	406.6	427.6	486.1	NA
Joint Procedure Hospital Admission Rate	208.7	279.0	268.3	290.7	381.9	296.4	255.4	274.0	251.7	NA
Ages 65+	1139.8	1253.7	1437.4	1092.1	1473.5	1191.6	1438.1	1278.4	1174.5	NA

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

	New London	Diverse Suburbs	Groton	Norwich	The Lymes	Mill Towns	Rural Towns	New London County	Connecticut	US
INFECTIOUS DISEASE										
HIV-Infection, Hospital Admissions Rate	67.0	25.8	7.4	43.3	10.2	9.2	6.5	19.0	27.9	NA
HIV-Infection Mortality Rate	10.2	3.9	3.3	4.5	0.0	3.1	1.7	3.5	5.4	4.7
Hepatitis C, Incidence Rate	254.7	149.5	91.5	213.2	79.8	97.3	96.6	127.2	146.2	NA
Sexually Transmitted Disease Incidence Rate:										NA
Gonorrhea	197.2	79.7	57.8	103.7	10.2	21.6	21.6	55.3	77.9	NA
Chlamydia	570.6	268.9	199.8	344.8	20.4	84.7	81.4	182.7	261.2	NA

Diverse Suburbs: Groton, Norwich; The Lymes: Lyme, Old Lyme; Mill Towns: Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns: Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, Voluntown

DATA SOURCES

Data Type	Years Used	Source
Birth	2002-2004	Connecticut Dept. of Public Health - Office of Vital Records
Mortality	2002-2004	Connecticut Dept. of Public Health - Office of Vital Records
Hospital Inpatient	FY 2004,2005	ChimeData – Connecticut Hospital Asociation
Hospital ED	FY 2004, 2005	ChimeData – Connecticut Hospital Asociation
Adult Household Survey	2006	CHPPR
Cancer Incidence and Staging	2001-2003	Connecticut Dept. of Public Health - Tumor Registry
Infectious Disease: Hepatitis C, Chlamydia/ Gonorrhea	2000-2005	Connecticut Dept. of Public Health – Bureau of Community Health
Population, Income, and Education	1990, 2000, 2005 Estimate	US Census Bureau

Attachment H

SCAI Requirements for Elective PCI without On-Site Surgery & L+M Compliance

Table 5. SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	
SCAI Requirement	**L+M's Status**
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	L+M maintains highly trained nursing and technical laboratory staff through its existing primary PCI and peripheral angiography services. Staff are highly experienced; no staff has less than 2 years experience. Staff is competent to treat acutely ill patients with hemodynamic and electrical instability. An education plan for non-emergent angioplasty without on-site surgery for staff is provided in Attachment F.
On-call schedule with operation of laboratory 24 h/d, 365 d/y.	L+M has an agreement with YNHH/YSOM to provide 24 h/d, 365 d/y call coverage of its PCI service. Ten total physicians provide coverage. The Medical Director of L+M's PCI service resides within L+M's PSA and is the primary covering physician. Other covering physicians stay at a hotel 5 minutes from the hospital when on-call. A policy is in place for cath lab staff and technicians to provide on-call 24 h/d, 365 d/y coverage.
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.	L+M maintains coronary care unit staff with experience and competency in invasive hemodynamic monitoring, operations of temporary pacemaker, and management of IABP through its existing primary PCI program. Personnel are capability of intubation and ventilator management on-site and during transfer.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank)	L+M's administration is fully supportive of the proposed elective PCI program. The appropriate support services are already in place due to L+M's existing emergent service.
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 refer to Attachment I for the written transfer agreement between L+M and YNHH.
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	L+M maintains two fully-equipped, state-of-the-art catheterization labs in which emergent or elective PCI cases can be performed. Both L+M Philips cardiac imaging systems are capable of transmitting real-time 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.	audio/video to YNHH for consultation with other interventionalists or cardiac surgeons while the patient is still on the table. L+M also has remote access to YNHH's GE electronic imaging storage system to view past patient images.
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.	L+M maintains a full complement of interventional equipment for its primary PCI program and will maintain the same for the proposed program. L+M maintains fractional flow reserve (FFR) and IVUS equipment. Rotational or other atherectomy devices will not be utilized.
Meticulous clinical and angiographic selection criteria for PCI.	Please refer to Section 2d of the application for the patient selection criteria that will be utilized.
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.	Through its existing program, L+M offers primary PCI as the treatment of choice for STEMI patients. L+M participates in the CathPCI Registry through the ACC NCDR and door-to-balloon (D2B) times are tracked (please refer to Table K in the application for recent statistics). Cases that exceed the 90 minute D2B best practice are reviewed internally by the Medical Director and Cath Lab Manager. Cases are also presented at Quality Assurance Cath Lab Conferences (please refer to Attachment F).
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.	L+M meets the requirements for data collection, outcomes analysis, benchmarking, and quality improvement. L+M participates in the CathPCI Registry through the ACC NCDR. Formalized periodic case reviews are completed and 2 times per year, case reviews are completed at Quality Assurance Cath Lab Conferences (please refer to Attachment F).
Participation in a national data registry where available, such as the ACC NCDR in the United States.	L+M participates in the CathPCI Registry through the ACC NCDR (please refer to Attachment N for Executive Summary).

Table 6. SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	
SCAI Requirement	**L+M's Status**
1. Interventional cardiologists establish working relations with cardiac surgeons at the receiving facility.	YNHH/YSOM interventional cardiologists provide coverage for L+M's PCI program. As affiliates of YNHH/YSOM, each physician has a working relationship with the cardiac surgeons at YNHH, the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.	Due to L+M's existing primary PCI program, L+M is already capable of real-time transfer of images and review of treatment options with cardiac surgeons and other interventionalists at YNHH using audio/video equipment through L+M's Philips cardiac imaging systems. These capabilities are in place and will be utilized as appropriately with an elective PCI program.
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.	YNHH shall maintain one operating room open every day for emergency transfers that is cardiothoracic surgery capable. The on-call cardiothoracic surgery will be in-house at YNHH during the hours of 7:30am to 4pm, Monday through Friday to accommodate the L+M elective PCI schedule (please refer to Attachment I).
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.	YNHH on-call cardiothoracic surgeons will be privileged to provide CABG or other procedures, as necessary, in the event of complication resulting from elective PCI at L+M (please refer to Attachment I). Per item #3 above, YNHH will maintain operation room and surgical capacity to ensure patients requiring transfer from L+M can be accommodated at YNHH.
5. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	In the event of a complication, L+M's Philips cardiac imaging systems are capable of transmitting real-time images and audio/video to YNHH for consultation with other interventionalists or cardiac surgeons while the patient is still on the table. Together the team can assess the needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse the transfer agreement.	Administrations from L+M and YNHH support and endorse the transfer agreement.
7. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.	Please refer to Attachment F and Attachment I for the protocols for rapid transfer of patients.

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.	American Ambulance has committed to provide ground transport within 20 minutes of notification. Life Star Air Transportation which originates from Norwich, typically arrives at L+M within 12 minutes once contacted. Please refer to Attachment J for letter from transport vendor.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.	Per YNHH, the receiving surgeon and team will obtain consent for surgery from patient or surrogate. L+M will inform patients that YNHH will provide surgical backup, if needed, in its patient consent process for elective PCI.
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.	Informed consent will include disclosure that the procedure is being completed without on-site surgical backup, the potential risks related to transfer, the risk of urgent surgery (0.3%), and 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.	Please refer to Attachment F. Per the Quality Program outlined in the attachment, L+M will review all cases where a patient was transferred for emergency surgery.

Attachment I

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 Lawrence & Memorial Hospital, whose principle office is located at 365 Montauk Avenue, New London, Connecticut, to provide the transfer of patients from Lawrence & Memorial 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, Lawrence & Memorial 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 Lawrence & Memorial Hospital, the "parties" to this transfer protocol and Agreement ("Agreement") hereby agreed as follows:

A. The Decision

1. Lawrence & Memorial 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 Lawrence & Memorial Hospital's physician determines that a transfer to YNHH is medically necessary and/or appropriate in accordance with state and federal statutes and regulations, Lawrence & Memorial 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. Lawrence & Memorial Hospital's transferring physician shall provide necessary medical treatment within the capabilities of the staff and facilities available at Lawrence & Memorial 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. Lawrence & Memorial 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, Lawrence & Memorial 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, Lawrence & Memorial 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 Lawrence & Memorial Hospital may have.

2. In the event full patient information is not provided at the time of transfer and subsequently becomes available, Lawrence & Memorial Hospital shall promptly transmit to YNHH.

3. Lawrence & Memorial 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 Lawrence & Memorial Hospital, YNHH shall provide the information to Lawrence & Memorial Hospital to assist it to properly bill for Lawrence & Memorial Hospital's services.

4. If the patient is to be transferred back to Lawrence & Memorial Hospital subsequent to treatment at YNHH, YNHH shall promptly provide Lawrence & Memorial 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, Lawrence & Memorial 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 Lawrence & Memorial 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 Lawrence & Memorial Hospital do hereby execute this Transfer Protocol and Agreement.

Lawrence & Memorial Hospital

Date 10/6/08

Name: Bruce Cummings
Title: President & CEO

Date 10/8/08

Name: ~~Michael Alpher~~ Peter Later, DO
Title: Director, Emergency Department

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 HOSPITAL

Heart and Vascular Addendum

The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program at Lawrence & Memorial Hospital as described below:

1. A CT Surgeon will be on-call 24/7 to arrange for patient transfers through the Y-Access system and to receive the patient at YNHH.

2. All YNHH on-call CT Surgeons will be privileged to provide CABG on other procedures expected as a result of complications associated with performing elective PCI at Lawrence & Memorial Hospital.

3. YNHH shall maintain one operating room open every day for emergency transfers that is CT Surgery capable. The on-call CT Surgeon will be in-house during the hours of 7:30am through 4:30pm, Monday through Friday to accommodate the Lawrence & Memorial elective PCI schedule.

4. The receiving surgeon and team will obtain consent for surgery from patient or surrogate.

5. The Yale-New Haven Heart & Vascular Center agrees that Lawrence & Memorial may represent to patients that YNHVC will provide surgical backup to elective PCI in its patient consent process.

6. YNHVC and L&M will maintain computer systems interface or direct access to L&M systems for the YNHVC receiving surgeon to review real-time images and hemo dynamic data, as well as audio and video images for consulting on treatment options and transfer decisions.

7. Lawrence & Memorial Hospital will employ the Yale-New Haven Hospital Y-Access transfer system to expedite the process of surgical consultation and transfer.

8. Yale-New Haven Hospital will transfer the patients, once medically stabilized and suitable for transport, back to Lawrence & Memorial to receive any rehabilitation and ongoing care.

9. All other provisions of the Transfer Agreement will remain in effect for heart and vascular patients.

TL/cmn.SSA443

20 York Street
New Haven, CT 06504

Agreement Regarding Comprehensive Primary Angioplasty Program Coverage
between
Yale University and Eastern Conn. Cardiology Group, P.C.

This Agreement is entered by and between Eastern Conn. Cardiology Group, P.C. (the "Practice") and Yale University, through its School of Medicine, Department of Internal Medicine, Section of Cardiovascular Medicine ("Yale") as of the 31st day of January, 2008. This Agreement supersedes in its entirety that certain agreement by and between the Practice and Yale dated as of January 23, 2006 regarding On-Call Coverage of Primary Angioplasty Services.

WHEREAS, the Practice has been engaged to provide full time primary (STEMI) angioplasty services at Lawrence & Memorial Hospital ("L&M") and, pursuant to an agreement dated as of January 23, 2006, Yale has provided primary angioplasty on-call coverage to assist the Practice in meeting its obligations;

WHEREAS, the Practice has a need for additional interventional cardiology expertise;

WHEREAS, the Practice wishes to enter into an agreement with Yale for comprehensive coverage of primary angioplasty care for the Practice's patients at L&M;

WHEREAS, Yale, through its faculty, is engaged in patient care, research, and teaching in the field of interventional cardiology and such a coverage arrangement would provide potential additional research and teaching opportunities; and

WHEREAS, Yale and the Practice desire to provide such services for the Practice pursuant to the terms of this Agreement.

NOW THEREFORE, in consideration of the foregoing recitals, which form part of the substance of this Agreement, the mutual agreements set forth in this Agreement, and other good and valuable consideration, the receipt and the sufficiency of which are hereby acknowledged, the parties agree as follows:

Section I. Yale Responsibilities

1. Scope of Services.

A. Subject to the terms and conditions of this Agreement, the Practice hereby engages Yale to provide through its faculty professional the professional services described in Section 1.B (the "Services") to Practice Patients (as that term is defined in Section 1.B).

B. The Services shall consist of:

i. All primary (STEMI) angioplasty services for Practice Patients on a 24/7 basis and cardiac catheterization procedures with or without coronary artery angioplasty procedures for Practice Patients performed at Yale.

ii. Diagnostic catheterizations and (to the extent the individual Specialists are certified to provide them) general cardiology services at L&M for Practice Patients, but only during

normal weekday office hours (excluding holidays and weekends), if the Specialist is available.

iii. Director services for the PCI program, guidance for the L&M PCI program's quality reviews, and guidance in satisfying all applicable regulatory and L&M requirements

Yale will provide the Services through one or more physician members of Yale's full-time faculty who are trained and experienced in angioplasty (each, a "Specialist").

For purposes of this Agreement, the term "Practice Patients" means (i) patients seen at L&M or at the Practice's offices and (ii) patients referred by the Practice (or by the Specialist while working at the Practice) for cardiac catheterizations or coronary artery angioplasty procedures to be performed by a Specialist at Yale-New Haven Hospital.

C. One Specialist assigned by Yale as the principal provider of the Services (the "Principal Specialist") will live in the general New London area. When the Principal Specialist is unavailable (due to sickness, vacation, etc. or while performing Services at Yale), Yale will make another Specialist from its full-time faculty available on-site or within 40 minutes of L&M at all times.

D. Yale's obligations hereunder to provide Services shall in no way affect the Practice's commitments to L&M, as stated in the Certificate of Need Application and related materials pertaining to the primary angioplasty program at L&M.

2. **Designation of Specialist.**

Yale will notify the Practice in advance of the name and qualifications of the Principal Specialist and each other Specialist and will promptly notify the Practice if Yale wishes to assign a different Principal Specialist. The Principal Specialist and the other Specialists must be acceptable to the Practice. The Practice's acceptance of the Specialists shall not be unreasonably withheld.

3. **Documentation; Access to Records.**

Yale shall require each Specialist to appropriately and accurately document all clinical services performed under this Agreement. Consistent with applicable Federal and state law, Yale and the Specialists may access the Practice's medical and billing records related to the Services. This right to access records shall survive termination of this Agreement for any reason.

4. **Specialist Qualifications.**

Yale represents and warrants that each Specialist providing Services under this Agreement will:

(a) be licensed by the State of Connecticut to perform his or her professional duties;

(b) obtain and maintain medical staff privileges at L&M;

(c) truthfully and accurately maintain and preserve patient records;

(d) provide care to all patients in need of the Services as assigned to such individual without regard to a patient's ability to pay and without regard to the patient's race, color, national origin, sex, age,

religion, ancestry, marital status, sexual orientation, handicap or any other status prohibited by applicable statute or regulation;

(e) maintain Board Certification by the ABMS in cardiology or if not Board Certified, shall become so within three (3) years of the Specialist being assigned to provide Services under this Agreement;

(f) not engage in conduct that is harmful or disruptive to the operations or reputation of L&M or the Practice, nor that constitutes a threat to the safety or welfare of any person, including without limitation, L&M patients and personnel; and

(g) not be excluded or debarred from participation in any federal health care program, including Medicare or Medicaid.

5. **Insurance.**

Yale will carry malpractice insurance with limits of not less than one million ($1,000,000) dollars per occurrence and three million ($3,000,000) dollars annual aggregate, covering the Specialists for their activities under this Agreement. This obligation shall survive termination of this Agreement for any reason.

Section II. Compensation

As full compensation for providing the Services described herein, including all professional services rendered to Practice Patients hereunder, for the first twelve months of the Initial Term the Practice will pay Yale One Million Four Hundred Fifty Thousand Dollars ($1,450,000) (the "Base Compensation") payable by monthly payments of One Hundred Twenty Thousand Eight Hundred Thirty-Three Dollars ($120,833) each at the beginning of each month (provided that if in any month Yale fails to furnish the Services (e.g. call coverage) as required under Section I.B of this Agreement, the payment for such month will be reduced by a fraction the denominator of which is the number of days in the month and the numerator of which is the number of days in which the Services were not furnished). The total compensation for each subsequent 12-month term of this Agreement, as well as for any one-year renewals of this Agreement, will be the previous year's total compensation plus three percent (3%) of such total compensation (the "Compensation Adjustment"), provided that payment of the Compensation Adjustments for the second and third years of the Initial Term will be deferred to the fourth and fifth years of the Initial Term and then paid in monthly installments, provided that if this Agreement is terminated early, any unpaid deferred Compensation Adjustments shall be paid upon termination. Payment during the second, third, fourth and fifth years of the Initial Term and any renewal terms will also be made in twelve equal installments at the beginning of each month. The compensation set forth under this Section II is due and payable to Yale regardless of any amounts billed and collected by the Practice for these Services.

Checks should be made payable to and sent to: Yale University, Financial Operations, Yale University, School of Medicine, P.O. Box 208092, New Haven, CT 06520-8092, Attention: Director, Business Services.

Section III. Billing and Credentialing

Yale shall require each Specialist to reassign his/her billing rights to the Practice for the Services rendered

to Practice Patients pursuant to this Agreement. The Practice shall bill and collect for such Services and Yale shall have no right to share in any of the proceeds of such billing. The Practice shall be solely responsible for compliance with billing requirements of all payors, including Medicare and Medicaid. The Practice shall be responsible for compliance with all contractual obligations relating to billing and collection of the Services. The indemnification obligations set forth in Section VII shall extend to any claim, liability or loss arising out of the Practice's collection of such revenues, including the failure by the Practice to complete and file necessary forms or otherwise conform to the requirements of any governmental or other third-party payor. The Practice's ability or inability to bill and successfully collect for the Services shall not affect the compensation due to Yale pursuant to Section II. Yale shall require each Specialist to execute and deliver to the Practice a separate assignment to the Practice in the form attached as **Exhibit A.**

Yale shall require each Specialist to apply to be credentialed as a participating physician with the payors with which the Practice is credentialed for managed care contracting purposes. For avoidance of doubt, Yale shall be free to bill and collect for professional services provided to Practice Patients at Yale to the extent those services fall outside the definition of Services in Section I.B.

Section IV. Term and Termination

The initial term of this Agreement shall begin on May 1, 2008 (the "Effective Date") and end April 30, 2013 ("Initial Term"). This Agreement shall automatically renew for two additional one-year terms unless either party provides written notice at least ninety (90) days prior to the start of a subsequent one-year term of its intent not to renew the Agreement.

Either party may terminate this Agreement upon thirty (30) days prior written notice to the other party if the other party materially breaches this Agreement and fails to cure within said thirty (30) day period, or, if the breach is not subject to immediate cure, fails to take substantial steps to cure such breach within such thirty (30) day period and to continue thereafter to diligently cure such breach to the reasonable satisfaction of the non-breaching party.

Either party may terminate this Agreement for any reason upon one (1) year's prior written notice given no earlier than the beginning of the third year of the Initial Term (i.e., not effective until the beginning of the fourth year of the Initial Term or later).

Notwithstanding anything herein to the contrary, the Practice may terminate this Agreement on thirty days' written notice if L&M loses its State certification to perform emergency angioplasty procedures.

Section V. Responsibilities of the Practice

1. Practice Setting.

The Practice shall provide at its sole cost and expense all necessary technical and clerical personnel, nursing support and administrative services at the Practice's facilities. The Practice shall maintain adequate space, facilities, equipment and supplies for the safe and proper operation of the Practice. The Practice, at its sole cost and expense, shall make available a furnished apartment or other housing, including utilities, cleaning and linen services, in the vicinity of L&M to the Specialists (other than the Primary Specialist who will live permanently in the general New London area) providing the Services under this Agreement.

2. Licensure and Certifications.

The Practice shall ensure that its physicians and all non-physician personnel are properly certified and licensed and that all Practice equipment meets applicable standards.

3. Research.

The Practice understands and agrees that the Specialists may be involved in clinical research activities. Subject to all regulatory requirements and approval by Institutional Review Boards, the Practice agrees to facilitate Yale's clinical research activities at the Practice and L&M.

4. Compliance.

The Practice will be responsible for complying with all laws, regulations and ordinances relating to the Services and the operation of its practice. The Practice shall obtain and maintain during the term of this Agreement any federal, state or local license, certificate, approval or authorization that is legally required to be held by the Practice in order to operate the practice and comply materially with all applicable federal, state and local laws.

5. Insurance.

The Practice will, at its expense, maintain its normal and customary professional liability insurance coverage with respect to the Practice as well as workers' compensation insurance and general liability insurance coverage in an amount reasonably necessary to cover all activities of the Practice and its physicians. Such coverage shall insure it, its employees and agents (but excluding Yale and the Specialists) against claims and liabilities arising out of or relating to this Agreement and the operation of the Practice's practice. In the event such coverage is written on a claims-made basis, the Practice shall arrange for appropriate tail coverage consistent with the requirements of this Section in the event such claims-made policy is canceled or not renewed. This obligation shall survive termination of this Agreement for any reason.

6. Access to Records.

The Practice shall ensure that Practice records pertaining to the provision of the Services or the performance of this Agreement are available at reasonable times and upon reasonable notice to Yale or its designees, consistent with applicable Federal and state laws and regulations. This obligation shall survive termination of this Agreement for any reason.

7. Notice.

The Practice agrees to notify Yale upon the occurrence of any of the following events: (i) the making of any claim or institution of a lawsuit against the Practice relating to the provision of the Services or the activities of Yale under this Agreement; (ii) the loss, suspension or relinquishment of any license, certificate, approval or authorization described in Section V.4 above; (iii) the loss of insurance coverage as described above; or (iv) any regulatory or administrative proceeding that may affect the ability of the Practice to continue to perform its obligations under this Agreement.

Section VI. Use of Name

Neither party may use the name of, or any symbol or mark identified with, the other party in connection with any advertising, promotional or similar materials, written or oral, without the prior written permission of the other party.

Section VII. Indemnification

1. Yale agrees to indemnify, defend and hold harmless the Practice and its officers, directors, trustees, employees and agents (not including the Specialists when providing Services pursuant to this Agreement except to the extent they are otherwise indemnifiable under Yale's policies) from any claim, liability or loss (including reasonable attorneys' fees) arising out of or resulting from the acts or omissions of Yale or any of its employees or agents (not including the Specialists when providing Services pursuant to this Agreement) in connection with this Agreement.

2. The Practice agrees to indemnify, defend and hold harmless Yale and its officers, directors, trustees, employees and agents (including the Specialists) from any claim, liability or loss (including reasonable attorneys' fees) arising out of or resulting from the acts or omissions of the Practice or any of its employees or agents (including the Specialists when providing Services pursuant to this Agreement) in connection with this Agreement; provided that this indemnification shall not apply to medical professional liability claims based on the alleged acts or omissions of the Specialists or to other liability claims based on the alleged gross negligence or willful misconduct of the Specialists.

3. Each party shall notify the other immediately in writing of any claim of injury or damage related to activities performed pursuant to this Agreement. The parties shall cooperate with each other in the investigation and disposition of any claim arising out of the activities of this Agreement, provided that nothing shall require either party to disclose any documents, records or communications that are protected under the peer review privilege, the attorney client privilege or the attorney work-product privilege.

4. The provisions of this Section VII shall survive termination of this Agreement for any reason.

Section VIII. Limitation of Liability

1. Limitation of Liability.

EXCEPT AS EXPRESSLY PROVIDED IN SECTION VII ("INDEMNIFICATION"), IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR ITS TERMINATION, REGARDLESS OF THE FORM OF ACTION (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY, BUT NOT INCLUDING MEDICAL PROFESSIONAL LIABILITY) AND IRRESPECTIVE OF WHETHER SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE.

2. Money Damages.

With the exception of the obligations in Section II ("Compensation") and Section VII ("Indemnification") and except for claims of medical professional liability, in no event shall either party be liable to the other for money damages.

Section IX. Miscellaneous

1. **Independent Contractors.**

Yale and the Practice shall be considered independent contractors for all purposes, and nothing in this Agreement shall be deemed to make Yale and the Practice partners or joint venturers or (notwithstanding the provisions of Section VII with respect to indemnification) to make either party the employee of the other.

2. **Physician Compensation.**

Yale shall be exclusively responsible for payment of compensation to the Specialists, including but not limited to employment taxes, withholding payments, fringe benefits, professional licensing fees, social security obligations and professional liability insurance premiums and contributions to deferred compensation plans.

3. **Provision of Additional Coverage.**

The Practice recognizes that Yale has made and will continue to make investments and commitments to physician staffing based in part on its obligations under this Agreement. In consideration of those investments and commitments, the Practice agrees that, during the term of this Agreement and for a period of two (2) years after its expiration or termination, the Practice will not add any physicians to the Practice (as members, employees, independent contractors or otherwise) to provide interventional cardiology services in addition to (or instead of) those provided by Yale under this Agreement, or arrange for any other person or organization to provide such additional services on behalf of the Practice or in satisfaction of the Practice's contractual obligations, unless:

(i) it has first offered to Yale in writing the opportunity to provide such additional services (on terms and conditions appropriate to the nature and scope of the services) and Yale has declined the offer in writing or has failed to respond within thirty (30) days after receiving the offer in writing, and

(ii) the terms and conditions offered to such physician or other person or organization (after Yale has declined or failed to respond to the Practice's offer) are no more favorable than those offered to Yale.

This obligation shall not apply if ECCG has rightfully terminated this Agreement for cause, or if upon the expiration of this Agreement ECCG has offered to renew or extend it on substantially the same terms and Yale has declined the offer.

4. **Confidentiality.**

In the performance of work for the practice, Yale and the Specialist may have access to patient's medical records, including but not limited to patient assessment instruments, and other confidential information. Yale and the Specialist shall comply with all state and federal laws governing the confidentiality of patient information, including all HIPAA requirements. Yale agrees that both during and after the term of this Agreement, neither it nor any Specialist will, except insofar as is permitted by law, directly or indirectly, disclose or make available to any person, firm, corporation, association or other entity for any reason or purpose whatsoever, any such confidential information.

5. **Amendment; Binding Agreement.**

This Agreement may not be amended or modified except by a written instrument signed by both parties, and may not be assigned by either party without the prior written consent of the other party. This Agreement supersedes all prior agreements between the parties on the subject hereof. This Agreement is binding on and inures to the benefit of the parties and their successors, assigns, heirs, administrators, and executors.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the date first written above.

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By_____
Brian S. Ehrlich, M.D.
Its: President

Dated: 2/27, 2008

YALE UNIVERSITY, through its SCHOOL OF MEDICINE

By_____

Its_____

Dated: 2/7, 2008

Penrhyn E. Cook
Executive Director
Grant & Contract Administration

By_____

Its_____

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between EASTERN CONN. CARDIOLOGY GROUP, P.C., a Connecticut professional corporation, (the "Practice"), and JOSEPH BRENNAN, M.D. ("Physician"), a member of the full time faculty of Yale University, School of Medicine ("Yale"), and is effective as of MAY 1, 2008.

Pursuant to the Agreement between Yale and the Practice effective MAY 1, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: J BRENNAN

Date: 2/5/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: B S EHRLICH

Title: PRESIDENT

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between EASTERN CONN. CARDIOLOGY GROUP, P.C., a Connecticut professional corporation, (the "Practice"), and Henry Cabin, M.D. ("Physician"), a member of the full time faculty of Yale University School of Medicine ("Yale"), and is effective as of 5/1/, 2008.

Pursuant to the Agreement between Yale and the Practice effective 5/1/, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: Henry Cabin

Date: 2/5/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between **EASTERN CONN. CARDIOLOGY GROUP, P.C.**, a Connecticut professional corporation, (the "Practice"), and Brian Cambi, M.D. ("Physician"), a member of the full time faculty of Yale University, School of Medicine ("Yale"), and is effective as of 5/1, 2008.

Pursuant to the Agreement between Yale and the Practice effective _____, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: Brian Cambi

Date: 2/6/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between EASTERN CONN. CARDIOLOGY GROUP, P.C., a Connecticut professional corporation, (the "Practice"), and Michael Cleman, M.D. ("Physician"), a member of the full time faculty of Yale University, School of Medicine ("Yale"), and is effective as of 5/1, 2008.

Pursuant to the Agreement between Yale and the Practice effective _____, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: Michael Cleman

Date: 2/7/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between EASTERN CONN. CARDIOLOGY GROUP, P.C., a Connecticut professional corporation, (the "Practice"), and Jeptha Curtis, M.D. ("Physician"), a member of the full time faculty of Yale University, School of Medicine ("Yale"), and is effective as of 5/1, 2008.

Pursuant to the Agreement between Yale and the Practice effective _____, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: Jeptha Curtis

Date: 2/5/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between **EASTERN CONN. CARDIOLOGY GROUP, P.C.**, a Connecticut professional corporation, (the "Practice"), and Frank Giordano, M.D. ("Physician"), a member of the full time faculty of Yale University, School of Medicine ("Yale"), and is effective as of 5/1, 2008.

Pursuant to the Agreement between Yale and the Practice effective _____, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: Frank Giordano

Date: 2/8/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between **EASTERN CONN. CARDIOLOGY GROUP, P.C.**, a Connecticut professional corporation, (the "Practice"), and Hagop L. Haroutunian, M.D. ("Physician"), a part time faculty member of Yale University, School of Medicine ("Yale"), and is effective as of 5/1, 2008.

Pursuant to the Agreement between Yale and the Practice effective 5/1/, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: H. L. Haroutunian MD.

Date: 2/26/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

EXHIBIT A

THIS REASSIGNMENT AGREEMENT is entered into by and between **EASTERN CONN. CARDIOLOGY GROUP, P.C.**, a Connecticut professional corporation, (the "Practice"), and MICHAEL REMETZ M.D. ("Physician"), a member of the full time faculty of Yale University, School of Medicine ("Yale"), and is effective as of MAY, 2008.

Pursuant to the Agreement between Yale and the Practice effective MAY, 2008 (the "Agreement"), Yale has agreed to assign the Physician to provide professional cardiology services to patients of the Practice.

The Physician hereby reassigns to the practice all of Physician's rights, if any, to bill and receive payment for Physician's services furnished to the Practice's patients as defined in the Agreement ("Services").

The Practice shall be jointly and severally responsible for any Medicare overpayment relating to claims for the Services. The Physician shall cooperate with the Practice to the extent reasonably required to process claims for the Services with Medicare and/or other insurance carriers.

The Practice agrees that Yale and the Physician shall have access to claims submitted by the Practice for the Services provided by the Physician to the extent allowed by law.

This Reassignment Agreement shall terminate upon termination of the Agreement for any reason or upon termination of Physician's employment at Yale for any reason.

AGREED AND ACCEPTED.

PHYSICIAN

By _____

Printed Name: Michael Remetz

Date: 2/6/08

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By _____

Printed Name: Brian Ehrlich

Title: _____

Date: 2/27/08

ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT (this "**Agreement**") is made and entered into as of January 1, 2012, by and between EASTERN CONN. CARDIOLOGY GROUP, P.C. ("**Transferor**"), a Connecticut professional corporation, and L&M PHYSICIAN ASSOCIATION, INC., a Connecticut nonstock corporation and medical foundation ("**Transferee**") to become effective upon the closing of the transactions contemplated by that certain Letter of Intent, dated May, 12, 2011, between Transferor and Transferee (the "**Closing**").

WHEREAS, Transferor wishes to assign, transfer and convey to Transferee all of its rights and obligations under that certain Agreement Regarding Comprehensive Primary Angioplasty Program Coverages, dated January 31, 2008, between Yale University and Eastern Conn. Cardiology Group, P.C. (the "**Assigned Contract**"); and

WHEREAS, Transferor is executing and delivering this Agreement for the purpose of assigning and transferring to the Transferee all of its rights and liabilities under the Assigned Contract; and Transferee is executing and delivering this Agreement for the purpose of assuming all of the liabilities of the Transferor under the Assigned Contract arising on or after the Closing, but only to the extent that the obligations of Transferor under the Assigned Contract remain unperformed or unfulfilled on, or by their terms continue after the Closing (the "**Assumed Liabilities**");

NOW, THEREFORE, in consideration of the payment of $1.00 and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by Transferor, the parties agree as follows:

1. Sale and Transfer of Assets. Effective at the Closing, Transferor does hereby grant, bargain, transfer, convey, assign and deliver to Transferee all of Transferor's right, title and interest, of whatever kind and character, in and to the Assigned Contract.

2. Assumption of Liability. Effective at the Closing, Transferee hereby assumes and agrees to discharge or perform, as appropriate, all of the Assumed Liabilities, and specifically excluding any obligations resulting from, arising out of, related to, or are caused by, any one or more of the following: (a) a breach of the Assigned Contract occurring prior to the Closing; or (b) an event or condition occurring or existing prior to the Closing which would constitute a breach or default by Transferor under the Assigned Contract. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, TRANSFEREE DOES NOT ASSUME AND SHALL NOT BE LIABLE FOR ANY OF THE DEBTS, OBLIGATIONS OR LIABILITIES OF TRANSFEROR, WHENEVER ARISING AND OF WHATEVER TYPE OR NATURE. Transferor shall be and remain liable for all of its responsibilities, liabilities, obligations, costs and expenses, fixed or contingent, arising out of the performance of the Assigned Contract prior to Closing or accruing prior to Closing but known after the date of this Agreement. Transferee shall be liable for all of the Assumed Liabilities and all responsibilities,

liabilities, obligations, costs and expenses, fixed or contingent, arising out of the performance of the Assigned Contract after the Closing.

3. Transferor's Representations. Transferor represents and warrants to Transferee that: (i) there are no consents required or necessary for Transferor to transfer the Assigned Contract to Transferee, other than the Consent of Yale University; and (ii) there are currently no defaults or threatened defaults by Transferor or the knowledge of Transferor, any other party under the Assigned Contract.

4. Further Actions. Transferor, for itself and its successors and assigns, hereby covenants and agrees to execute and deliver to Transferee, its successors and assigns, such other instruments of conveyance, assignment and transfer as Transferee, its successors and assigns, may reasonably request in order to (i) more fully vest in Transferee, its successors and assigns, all and singular the rights and properties hereby granted, bargained, sold, transferred, conveyed, assigned and delivered; (ii) to protect the right, title and interest of Transferee, its successors and assigns, in and to, the Assumed Liabilities; and (iii) to carry out, as may be otherwise appropriate, the transactions contemplated hereby, all at the sole cost of Transferor.

Indemnification. Transferor agrees to indemnify and hold Transferee and its successors and assigns harmless from and against any claim, action, proceeding, damage, loss, expense or obligation actually incurred by Transferee which arises or results from (i) the breach of any representation, warranty, covenant or obligation of the Transferor in this Agreement; (ii) except for Assumed Liabilities any liabilities, obligations, expenses or debts related to the Transferor or Transferor's medical practice incurred prior to the Closing. The Transferee will be responsible for purchase of an extended reporting endorsement, so called "tail" insurance, for acts and omissions of, or caused by, Transferor that may have occurred prior to the closing.

5. No Third Party Beneficiary. This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. The Transferee's assumption of the Assumed Liabilities is not intended by the parties hereto to expand the rights or remedies of any third party against Transferee as compared to the rights and remedies that such third party would have had against Transferor had the parties not consummated the transactions contemplated hereby.

6. Governing Law. This Agreement shall be deemed to have been executed and delivered in the State of Connecticut, and shall be governed by and construed in accordance with the internal laws, as opposed to the rules governing conflicts of laws, of the State of Connecticut.

7. Severability. The invalidity or unenforceability of any term or provision in this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

8. Amendment. This Agreement supersedes all prior discussions, negotiations and amendments between the parties concerning the subject matter hereof and no change, amendment, qualification or cancellation of this Agreement shall be effective unless in writing and executed by each of the parties hereto.

9. Counterparts. This Agreement may be executed in two or more counterparts and delivered via facsimile or other electronic means, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be signed in its name by its proper and duly authorized representative.

EASTERN CONN.CARDIOLOGY GROUP, P.C.

By: _____
Name: Valerie Popken
Title: Vice President

L&M PHYSICIAN ASSOCIATION, INC.

By: _____
Name:
Title:

Consented and agreed to:

YALE UNIVERSITY, through its SCHOOL OF MEDICINE

By _____
Name: Janet Linder ~~Linder~~ LINDNER
Title: Associate Vice President for Administration

Dated: 2/21/12

LAWRENCE & MEMORIAL HOSPITAL

May 7, 2012

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

Re: Certificate of Need - Docket Number 04-30297

Dear Ms. Roberts:

This will advise you of a change in the contractual arrangements relating to Lawrence & Memorial Hospital's Primary Interventional Cardiac Service Program (the "PCI Program"), which was established pursuant to Docket Number 04-30297-CON and modified by Docket Numbers 06-30297-MDF and 08-30297-MDF.

The following agreements were executed in January of 2008 in connection with the implementation of the PCI Program:

1. Agreement Regarding Comprehensive Primary Angioplasty Program Coverage between Yale University and Eastern Conn. Cardiology Group, P.C. ("ECCG"); and

2. Call and Service Agreement between Lawrence & Memorial Hospital and ECCG.

On May 1,2012, the obligations of ECCG under the foregoing agreements were assigned to and assumed by L&M Physician Association, Inc. ("L&MPA"), which is a tax-exempt medical foundation affiliated with Lawrence & Memorial Hospital. The assignment was made in connection with the acquisition of ECCG's cardiology practice by L&MPA and the employment by L&MPA of all of the physicians and staff of L&MPA. These transactions will not result in any significant changes to the PCI Program.

Please feel free to contact me directly if you have any questions.

Very truly yours,

Daniel Rissi, M.D.
Vice President & Chief Medical
& Clinical Operations Officer

cc: Maureen Anderson, General Counsel
John H. Lawrence, Jr., Shipman & Goodwin LLP

2275480v2

EXECUTION VERSION

PRACTICE TRANSITION AGREEMENT

by and among

LAWRENCE & MEMORIAL HOSPITAL, INC. and
L&M PHYSICIAN ASSOCIATION, INC.

and

EASTERN CONN. CARDIOLOGY GROUP, P.C., EASTERN CT CARDIOLOGY DIAGNOSTICS, LLC and BRIAN S. EHRLICH, M.D., PETER S. MILSTEIN, M.D., RICHARD P. FAZIO, M.D., FRANCIS J. MIRECKI, M.D., MARK N. FIENGO, D.O., VALERIE B. POPKIN, M.D., and MARK J. SOMERS, M.D.

Dated as of May 1, 2012

PRACTICE TRANSITION AGREEMENT

THIS PRACTICE TRANSITION AGREEMENT is entered into as of May 1, 2012, by and among LAWRENCE & MEMORIAL HOSPITAL, INC., a Connecticut nonstock corporation and licensed acute care general hospital (the "Hospital"); L&M PHYSICIAN ASSOCIATION, INC., a Connecticut medical foundation ("L&MPA"); EASTERN CONN. CARDIOLOGY GROUP, P.C., a Connecticut professional corporation (the "Practice Group"); EASTERN CT CARDIOLOGY DIAGNOSTICS, LLC, a Connecticut limited liability company ("ECCD"); and BRIAN S. EHRLICH, M.D., PETER S. MILSTEIN, M.D., RICHARD P. FAZIO, M.D., FRANCIS J. MIRECKI, M.D., MARK N. FIENGO, D.O., VALERIE B. POPKIN, M.D., and MARK J. SOMERS, M.D. (collectively, the "Physician Owners"). The Hospital and L&MPA are sometimes referred to herein as the "Hospital Parties" and the Practice Group, ECCD and the Physician Owners are sometimes referred to herein as the "Practice Group Parties." Capitalized terms used herein and not otherwise defined herein shall have the respective meanings set forth in Article 9.

W I T N E S S E T H:

WHEREAS, the Hospital is a licensed acute care hospital located in New London, Connecticut:

WHEREAS, L&MPA is a medical foundation that is affiliated with the Hospital;

WHEREAS, the Practice Group is engaged in the practice of cardiology and internal medicine (the "Cardiology Practice") at 196 Parkway South, Suite 103, Waterford, Connecticut 06385 (the "Medical Office");

WHEREAS, ECCD owns and operates a cardiac diagnostic laboratory which provides stress testing, electrocardiogram and echocardiography services at the Medical Office (the "Cardiac Lab");

WHEREAS, the Physician Owners are the sole shareholders of the Practice Group and the sole members of ECCD; and

WHEREAS, the Parties desire to ensure the availability of high quality cardiology services in the New London area, and have entered into this Agreement in order to: (i)) provide for the sale of certain of the assets related to the Cardiology Practice to L&MPA and provide for the transition of the Cardiology Practice to L&MPA, (ii) provide for the sale of certain of the assets related to the Cardiac Lab to the Hospital and provide for the transition of the Cardiology Lab operations to the Hospital; and (iii) collaborate in order to enhance access to cardiac care for all area residents, achieve clinical quality and outcomes that meet or exceed national standards, and achieve outstanding patient satisfaction;

NOW, THEREFORE, in consideration of the premises and the mutual agreements contained herein, the Parties hereby covenant and agree as follows:

ARTICLE 1

TRANSACTIONS

Section 1.1 General. Upon the terms and subject to all of the conditions contained herein and the performance by each of the Parties of their respective obligations hereunder, the Parties hereby enter into the following transactions (the "Transactions"):

(a) The Practice Group hereby assigns to the Hospital all of the Practice Group's rights as a tenant under that certain Lease Agreement, dated July 20, 2004, between Waterford Real Estate Holdings, LLC, as landlord, and Waterford Cardiology Realty Group, LLC (as assignee of the Practice Group), as tenant, of the Medical Office (the "Office Lease").

(b) The Practice Group hereby enters into the following transactions in order to transfer the Cardiology Practice to L&MPA, free and clear of all liens, claims, leases, security interests, pledges, hypothecations, charges, chattel mortgages, conditional sales contracts, collateral security arrangements and other title or interest retention arrangements and other encumbrances and restrictions of any type or nature whatsoever ("Encumbrances"):

(1) The Practice Group hereby sells, transfers, conveys, assigns and delivers to L&MPA all furniture, fixtures, equipment and other tangible personal property used or held for use by the Practice Group in the Cardiology Practice (the "Cardiology Practice Tangible Assets");

(2) The Practice Group hereby sells, transfers, conveys, assigns and delivers to L&MPA all inventories of medical and office supplies on hand and used or held for use in the Cardiology Practice (the "Cardiology Practice Supplies");

(3) The Practice Group hereby assigns and transfers to L&MPA the exclusive right to use all other tangible and intangible rights and property of the Practice Group used or held for use in the Cardiology Practice, including all Intellectual Property that is either owned or used by or licensed to the Practice Group and all telephone numbers and the right to bill under the name of the Practice Group and under the names of its physicians and Allied Health Professionals (the "Providers") and under its and their respective provider identification numbers;

(4) The Practice Group hereby assigns and transfers to L&MPA all books, business and medical records, files, data bases and other information, whether in hard copy or electronic media, related to the Cardiology Practice, including policy and procedure manuals, patient lists, personnel records, records and data bases related to third party payers;

(5) The Practice Group hereby assigns and transfers to L&MPA all of the rights, claims and benefits of the Practice Group arising on and after the

Closing under (i) the Agreement Regarding Comprehensive Primary Angioplasty Program Coverage, dated January 31, 2008, between Yale University and the Practice Group, and (ii) the Call and Service Agreement, dated January 4, 2008, between the Hospital and the Practice Group (together, the "Yale Agreements");

(6) The Practice Group hereby assigns and transfers to L&MPA (i) all of the rights, claims and benefits of the Practice Group arising on and after the Closing under the agreements, contracts and other commitments listed in Schedule 1.1(b)(6) related to the Cardiology Practice (together with the Yale Agreements, the "Cardiology Practice Assigned Agreements"); (ii) if and to the extent that the same are assignable, all computer software and programs, including all source codes, object codes and documentation, and all licenses relating thereto, used in connection with the Cardiology Practice; (iii) subject to applicable laws and regulations, all transferable health and safety and other permits, licenses, authorizations, certificates, exemptions and approvals of any governmental or regulatory authority necessary for or incident to the operation of the Cardiology Practice; and (iv) all of the Practice Group's right, title and interest on in, to and under all other assets, rights and claims of every kind and nature used or intended to be used in connection with the Cardiology Practice; and

(7) The Practice Group hereby assigns and transfers to L&MPA the trained and assembled work force in place for the Cardiology Practice.

All of the rights and assets hereby transferred and conveyed to L&MPA with respect to the Cardiology Practice are referred to herein as the "Cardiology Practice Assets."

(c) The Practice Group and ECCD hereby enter into the following transactions in order to sell and transfer the Cardiac Lab to the Hospital, free and clear of all Encumbrances:

(1) The Practice Group and ECCD hereby sell, transfer, convey, assign and deliver to the Hospital all of the properties and assets related to the Cardiac Lab, including all furniture, fixtures, equipment, medical and business records, and other tangible personal property used or held for use by the Practice Group and ECCD for the Cardiology Lab (the "Cardiac Lab Tangible Assets");

(2) The Practice Group and ECCD hereby sell, transfer, convey, assign and deliver to the Hospital all inventories of medical and office supplies on hand and used or held for use in the Cardiac Lab (the "Cardiac Lab Supplies");

(3) The Practice Group and ECCD hereby assign and transfer to the Hospital all books, business and medical records, files, data bases and other information, whether in hard copy or electronic media, related to the Cardiac Lab, including policy and procedure manuals, patient lists, personnel records, records and data bases related to third party payers;

(4) The Practice Group and ECCD hereby assign and transfer to the Hospital the exclusive right to use all other tangible and intangible rights and

property of the Practice Group and ECCD used or held for use in the Cardiac Lab, including all Intellectual Property that is either owned or used by or licensed to the Practice Group or ECCD for the Cardiac Lab and all telephone numbers and the right to bill under the name of the Cardiac Lab;

(5) The Practice Group and ECCD hereby assign and transfer to the Hospital (i) all of the rights, claims and benefits of the Practice Group and ECCD arising on and after the Closing under the agreements, contracts and other commitments listed in Schedule 1.1(c)(5) related to the Cardiac Lab (the "Cardiac Lab Assigned Agreements" and together with the Cardiology Practice Assigned Agreements, the "Assigned Agreements"); (ii) if and to the extent that the same are assignable, all computer software and programs, including all source codes, object codes and documentation, and all licenses relating thereto, used in connection with the Cardiac Lab; (iii) subject to applicable laws and regulations, all transferable health and safety and other permits, licenses, authorizations, certificates, exemptions and approvals of any governmental or regulatory authority necessary for or incident to the operation of the Cardiac Lab; and (iv) all of the Practice Group's and ECCD's right, title and interest on in, to and under all other assets, rights and claims of every kind and nature used or intended to be used in connection with the Cardiac Lab; and

(6) The Practice Group and ECCD hereby assign and transfer to the Hospital the trained and assembled work force in place for the Cardiac Lab.

All of the rights and assets to be transferred and conveyed to the Hospital with respect to the Cardiac Lab are referred to herein as the "Cardiac Lab Assets."

(d) Each of the eight cardiologists currently employed by ECCG (each a "physician" and collectively the "physicians") has entered into an employment agreement with L&MPA which will become effective at the Closing Date (the "Employment Agreement"); and

(e) The Parties will enter into such other agreements as may be necessary to effectuate the objectives of this Agreement.

All of the rights and assets to be transferred and conveyed to the Hospital and L&MPA hereunder are referred to herein as the "Transferred Assets." Notwithstanding the foregoing, there shall be excluded from the Transferred Assets: (i) cash, cash equivalents and bank accounts, (ii) certificates of deposit and any other investment securities, (iii) accounts and loans receivable; (iv) the minute books, Tax Returns and other organizational documents of the Practice Group and ECCD, and the financial and accounting books and records of the Practice Group and ECCD; (v) any contracts, agreements or rights between the Practice Group and ECCD and any of its Affiliates or the Physician Owners; (vi) the tangible personal property of each physician as shown on a separate listing previously furnished to the Hospital Parties; and (vii) all contracts and leases that are not Assigned Agreements (collectively, the "Excluded Assets").

Section 1.2 Assignment of the Assigned Contracts; No Assumption of Liabilities and Obligations.

(a) The assignment of the Practice Group's and ECCD's right, title and interest in and to all rights, claims and benefits under the Assigned Agreements shall not be effective with respect to any Assigned Agreement which, by its terms, may not be assigned without the prior consent of any other party, until the Practice Group or ECCD has obtained a written consent from such other party. If written consent to the assignment of any such contract is not received prior to the Closing, the Practice Group and ECCD shall make available to the Hospital and L&MPA following the Closing the benefits of any such Assigned Agreement as contemplated by this Agreement and shall use commercially reasonable efforts to obtain such consent.

(b) Neither the Hospital nor L&MPA assume or otherwise agree to pay, discharge or perform, any liabilities, obligations or undertakings of the Practice Group or ECCD (whether accrued, absolute, contingent or otherwise, whether or not disputed, or whether or not disclosed to the Hospital Parties), except for liabilities arising after the Closing under the Assigned Agreements.

(c) The Practice Group and ECCD shall be responsible for the payment of all of their liabilities, obligations and undertakings and all other liabilities, obligations and undertakings relating to the Cardiology Practice and the Cardiac Lab, except for liabilities arising after the Closing under the Assigned Agreements, including any obligations under or relating to any Employee Plan, and neither the Hospital nor L&MPA.

Section 1.3 Purchase Price.

(a) Subject to the terms and conditions hereof:

(i) In consideration of the sale of the Cardiology Practice Assets to L&MPA, L&MPA agrees to pay to the Practice Group the sum of One Hundred Seventy-three Thousand Five Hundred Fifty-two and 800/100 Dollars ($173,552.89) (the "Practice Purchase Price"); and

(ii) In consideration of the sale of the Cardiac Lab Assets to the Hospital, the Hospital agrees to pay to ECCD the sum of Three Hundred Forty-five Thousand One Hundred Twenty-three and 46/100 Dollars ($345,123.46) (the "Cardiac Lab Purchase Price" and together with the Practice Purchase Price, the "Purchase Price")[1].

(b) Subject to the terms and conditions hereof, in consideration of the sale, transfer, conveyance, assignment and delivery of the Transferred Assets at the Closing and the other undertakings of Practice Group Parties hereunder, the Hospital Parties agree to pay the Purchase Price as follows: an amount equal to ten percent (10%) of Purchase Price by wire transfer of immediately to Shipman & Goodwin LLP (the "Escrow Agent") to be held in escrow by the Escrow Agent pursuant to the terms of an escrow agreement in form and substance satisfactory to the Parties (the "Escrow Agreement"), and the remainder by wire transfer of immediately

available funds to an account or accounts designated by the Practice Group and ECCD in writing prior to the Closing.

(c) The Parties agree that the Purchase Price shall be allocated among the Transferred Assets as determined by the Hospital Parties in accordance with Section 1060 of the Code and the regulations thereunder. Each of the Parties shall prepare and submit Internal Revenue Form 8594 prepared in accordance with such allocation and this Section 1.3(c), and each of the Parties shall file all Tax Returns consistent with this Section 1.3(c).

ARTICLE 2
THE CLOSING

Section 2.1 Date and Place. The closing of the Transactions (the "Closing") shall take place at the executive offices of the Hospital simultaneously with the execution and delivery of this Agreement (the "Closing Date").

Section 2.2 Deliveries at the Closing. At the Closing:

(a) The Parties have executed and delivered the following

(i) Bills of sale and instruments of assignment and such other instruments, in form and substance satisfactory to the Parties, as may be requested by such parties to transfer the applicable Transferred Assets to such parties;

(ii) the Employment Agreements; and

(iii) the Escrow Agreement.

(b) The Practice Group and ECCD have delivered or caused to be delivered to the Hospital Parties the following:

(1) A receipt for the Purchase Price;

(3) Possession and control of the Transferred Assets, free and clear of any Encumbrances;

(4) A certificate of the Practice Group, dated as of the Closing, certifying as to the resolutions adopted by its Board of Directors and shareholders approving this Agreement and the other Transaction Documents to which it is a party and the incumbency of those persons signing on behalf of the Practice Group; and

(5) A certificate of ECCD, dated as of the Closing, certifying as to the resolutions adopted by its managers and members approving this Agreement and the other Transaction Documents to which it is a party and the incumbency of those persons signing on behalf of ECCD.

(c) The Hospital Parties shall deliver or cause to be delivered to the Practice Group Parties the following:

(1) The Purchase Price as described in Section 1.3(a);

(2) A certificate of the Hospital, dated as of the Closing, certifying as to the approval of this Agreement and the other Transaction Documents to which it is a party by its Board of Directors and the incumbency of those persons signing on behalf of the Hospital; and

(3) A certificate of L&MPA, dated as of the Closing, certifying as to the approval of this Agreement and the other Transaction Documents to which it is a party by its sole member and the incumbency of those persons signing on behalf of L&MPA.

(d) To the extent that any of the Transferred Assets are subject to any Encumbrances, the Practice Group and ECCD shall obtain releases of such Encumbrances, which releases shall be in form and substance acceptable to the Hospital Parties and their counsel.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES OF THE PRACTICE GROUP PARTIES

The Practice Group Parties, jointly and severally, make the following representations and warranties to the Hospital Parties. Nothing in the Practice Group Disclosure Schedule attached hereto shall be deemed adequate to disclose an exception to a representation or warranty made herein unless the specific section of the Disclosure Schedule identifies the exception with reasonable particularity and describes the relevant facts in reasonable detail or unless a cross reference to another section of the Disclosure Schedules is made with reasonable particularity.

Section 3.1 Due Organization. The Practice Group is a professional corporation duly organized and validly existing under the laws of the State. ECCD is a limited liability company duly organized and validly existing under the laws of the State. The Practice Group and ECCD each has full power and authority to carry on its business as it is now being conducted and to own the properties and assets it now owns.

Section 3.2 Power and Authority; Due Authorization and Execution. Each of the Practice Group and ECCD has the power and authority to execute, deliver and perform this Agreement and the other Transaction Documents to be executed and delivered by it, to consummate the Transactions, and to perform all of the terms and conditions of the Transaction Documents to be performed by it. The execution and delivery of this Agreement and the other Transaction Documents to be executed and delivered by the Practice Group and ECCD, the performance of all the terms and conditions of the Transaction Documents to be performed by the Practice Group and ECCD, and the consummation of the Transactions have been duly authorized and approved by the Practice Group and ECCD. This Agreement and the other Transaction Documents to be executed and delivered by the Practice Group Parties have been duly executed and delivered by the Practice Group Parties and constitute the valid and binding obligations of the Practice Group Parties enforceable against each of them in accordance with their respective terms.

Section 3.3 No Violation. Subject to receipt of the consents and approvals listed in Section 3.3 of the Practice Group Disclosure Schedule, neither the execution and delivery by the

Practice Group Parties of this Agreement or the other Transaction Documents to be executed by them nor the consummation by the Practice Group Parties of the Transactions will:

(a) conflict with or violate any provision of the organizational documents of the Practice Group or ECCD;

(b) violate, conflict with, constitute a default (or an event which, with or without notice, lapse of time or both, or the occurrence of any other event, would constitute a default) under, result in the termination of, accelerate the performance required by, cause the acceleration of the maturity of any debt or other obligation pursuant to, or result in the creation or imposition of any Encumbrance upon any of the Transferred Assets under any agreement, contract or commitment to which any Practice Group Party is a party or by which any Practice Group Party is bound or to which the Transferred Assets are subject; or

(c) violate any federal, state or local law or any judgment, decree, order, regulation or rule of any court or governmental authority.

Section 3.4 Subsidiaries and Affiliates. None of the Practice Group Parties owns an equity or other financial interest in or controls, directly or indirectly, any Person other than the Practice Group or ECCD which provides health care services or supplies in the Service Area, and none of the Practice Group Parties is a party to any joint venture or partnership which provides health care services or supplies in the Service Area.

Section 3.5 Ownership of the Practice Group and ECCG. The Physician Owners own beneficially and of record all of the issued and outstanding shares of capital stock of the Practice Group and all of the membership interests in ECCD, free and clear of any Encumbrances. There are no commitments, options, rights or warrants to issue any capital stock of the Practice Group or any membership interests in ECCD or to issue any securities of the Practice Group or ECCD convertible or exchangeable into such capital stock or membership interests.

Section 3.6 Permits, Licenses and Governmental Authorizations. All building and other permits, certificates of occupancy, concessions, grants, franchises, licenses and other governmental authorizations and approvals necessary for the operation of the Medical Office and the conduct of the Cardiology Practice and the Cardiac Lab have been duly obtained and are in full force and effect, and there are no proceedings pending or, to the knowledge of the Practice Group Parties, threatened, which may result in the revocation, cancellation or suspension, or any adverse modification, of any thereof.

Section 3.7 Financial Statements; Books and Records.

(a) The Practice Group and ECCD have each furnished the Hospital Parties with: (i) its annual financial statements for each of the fiscal years ended on December 31, 2009, 2010 and 2011 and (ii) its interim financial statements as of March 31, 2012 (the "Financial Statements"). In addition, the Practice Group Parties have furnished the Hospital Parties with certain operational data relating to the Cardiology Practice and the Cardiac Lab (the "Operational Data"). Copies of the Financial Statements and the Operational Data are included in Section 3.7

of the Practice Group Disclosure Schedule. The Financial Statements (w) were prepared in accordance with the books of account and other financial records of the Practice Group and ECCD, respectively; (x) present fairly the financial condition and results of operations of the Practice Group and ECCD, respectively, as of the dates thereof or for the periods covered thereby; (y) have been prepared in accordance with the cash receipts and disbursements method of accounting applied on a basis consistent with the past practices of the Practice Group and ECCD, respectively; and (z) include all material adjustments (consisting only of normally recurring accruals) that are necessary for a fair presentation of the financial condition and the results of the operations of the Practice Group and ECCD, respectively, as of the dates thereof or for the periods covered thereby. During the periods covered by the Financial Statements, neither the Practice Group nor ECCD has changed any principle or practice with respect to the recordation of any assets or liabilities or any revenue or expenses.

(b) The books of account and other financial records of the Practice Group and ECCD: (i) reflect, in all material respects, all items of revenue and expense and all assets and liabilities required to be reflected therein, applied on a basis consistent with their past practices; (ii) are in all material respects complete and correct, and do not contain or reflect any material inaccuracies or discrepancies; and (iii) have been maintained in accordance with good business and accounting practices.

Section 3.8 No Undisclosed Liabilities. Neither the Practice Group nor ECCD has any material liabilities or other obligations of any nature (whether absolute, accrued, contingent or otherwise, and whether due or to become due) relating to the Cardiology Practice, the Cardiac Lab or the Transferred Assets, except for liabilities and other obligations that are reflected in the Financial Statements or identified in Section 3.8 of the Practice Group Disclosure Schedule.

Section 3.9 Absence of Changes. Since December 31, 2011, the Practice Group and ECCD have conducted their respective businesses in all material respects only in the ordinary course, and during such period there has been no:

(a) transactions by the Practice Group or ECCD that individually or in the aggregate, have had or would reasonably be expected to have a material adverse effect on the Cardiology Practice, the Cardiac Lab or the Transferred Assets;

(b) amendment, termination, breach or violation of any of the Assigned Agreements; and all of such agreements are valid and in full force and effect and are transferable to the Hospital Parties, as applicable;

(c) amendment or termination of any material agreement, contract, license or other commitment to which the Practice Group is a party (other than the Assigned Agreements) affecting the Cardiology Practice, the Cardiac Lab or the Transferred Assets;

(d) waiver of any right of material value with respect to the Cardiology Practice, the Cardiac Lab or the Transferred Assets;

(e) Encumbrance of any of the Transferred Assets;

(f) creation, incurrence, assumption or guarantee by the Practice Group or ECCD of any indebtedness impacting, affecting or that could form an Encumbrance on the Transferred Assets; or

(vii) other event or condition of any character that has or might reasonably have a material adverse effect on the Cardiology Practice, the Cardiac Lab or any of the Transferred Assets.

Section 3.10 Title to Transferred Assets; Encumbrances. The Practice Group and ECCD each has complete and unrestricted power and authority and the unqualified right to sell, transfer, convey, assign and deliver to the Hospital Parties; and upon consummation of the Transactions, L&MPA will acquire good, valid and marketable title to the Cardiology Practice Assets, and the Hospital will acquire good, valid and marketable title to the Cardiac Lab Assets, free and clear of all Encumbrances. The bills of sale, assignments and assumption agreements and other documents of conveyance executed and delivered to the Hospital Parties by the Practice Group and ECCD at the Closing will be valid and binding obligations of the Practice Group and ECCD enforceable in accordance with their terms.

Section 3.11 Contracts.

(a) The Practice Group Parties have delivered to the Hospital Parties true and complete copies of all material written, and have disclosed to the Hospital Parties all material oral, contracts, leases, agreements and other commitments ("Contracts") of the Practice Group and ECCD, all of which are listed on Section 3.11 of the Practice Group Disclosure Schedule. Except as listed on such Section, neither the Practice Group nor ECCD is a party to any material written or oral Contract which relates to the Cardiology Practice, the Cardiac Lab or the Transferred Assets.

(b) Each of the Assigned Agreements is valid and enforceable in accordance with its terms. Neither the Practice Group nor ECCD or, to the knowledge of the Practice Group Parties, any other party thereto is, in default in the performance, observance or fulfillment of any obligation, covenant, condition or other term in any Assigned Agreement and neither the Practice Group nor ECCD has given notice to, or received notice from, any Person relating to any alleged or potential default thereunder. No event has occurred which (with or without the giving of notice or lapse of time, or both) may conflict with or result in a violation or breach of, or give any Person the right to exercise any remedy under or accelerate the maturity or performance of, or cancel, terminate or modify any Assigned Agreement.

Section 3.12 Real Property.

(a) Neither the Practice Group nor ECCD owns or leases any real property other than the Medical Office.

(b) There is no violation of any law (including any building, planning or zoning law) relating to the Medical Office. The Practice Group Parties have furnished to the Hospital Parties true and complete copies of all surveys, certificates of occupancy, environmental reports and audits, appraisals, permits, and other documents within the possession or control of the Practice

Group Parties relating to or otherwise affecting the Medical Office and the uses thereof. The Practice Group and ECCD are in peaceful and undisturbed possession of the Medical Office and there are no contractual or legal restrictions that preclude or restrict the use of the Medical Office for the purposes for which it is currently being used. All existing water, sewer, steam, gas, electricity, telephone and other utilities required for the use, occupancy, operation and maintenance of the Medical Office are adequate for the use, occupancy, operation and maintenance of the Medical Office as it has been and is currently being used and occupied. There are no material latent defects or material adverse physical conditions affecting the Medical Office or any of the improvements, fixtures, fixed assets or personalty of a permanent nature annexed, affixed or attached to the Medical Office. Neither the Practice Group nor ECCD has leased or subleased any parcel or any portion of the Medical Office to any other Person.

(c) There are no condemnation proceedings or eminent domain proceedings of any kind pending or threatened against the Medical Office.

(d) The Medical Office is occupied under a valid and current certificate of occupancy or similar permit, the Transactions will not require the issuance of any new or amended certificate of occupancy and there are no facts that would prevent the Medical Office from being leased and used by the Hospital Parties after the Closing in the same manner as leased and used by the Practice Group and ECCD immediately prior to the Closing.

(e) To the best knowledge of the Practice Group Parties, the Medical Office was constructed in compliance in all material respects with applicable laws (including all applicable building, planning and zoning laws), and no asbestos is contained in the Medical Office.

(f) The Medical Office and none of the current uses and conditions thereof violate in any material respects any applicable deed restrictions or other applicable covenants, restrictions, agreements, existing site plan approvals, zoning or subdivision regulations or urban redevelopment plans as modified by any duly issued variances, and no permits, licenses or certificates pertaining to the ownership or operation of the Medical Office are required by any governmental authority having jurisdiction over the Medical Office.

Section 3.13 Equipment and Condition. All equipment and other tangible personal property owned, used or leased by the Practice Group or ECCD and used in the Medical Office or for the Cardiology Practice or the Cardiac Lab is in good condition and repair (except ordinary wear and tear, which are not such as to materially and adversely affect the conduct of the Cardiology Practice or the Cardiac Lab) and is suitable for the uses intended.

Section 3.14 Intellectual Property Rights. Neither the Practice Group nor ECCD has any right, title or interest in or to any patents, patent rights, processes, trade names, trademarks, service marks, inventions, specialized treatment protocols, copyrights, formulas or trade secrets, except as set forth on Section 3.14 of the Practice Group Disclosure Schedule. Except for off-the-shelf software licenses, neither the Practice Group nor ECCD is a licensee in respect to any patents, trademarks, service marks, trade names, copyrights or applications therefor, or processes, formulas or trade secrets.

Section 3.15 Insurance.

(a) The Practice Group and ECCD have maintained insurance policies with financially sound insurance companies of such types (including general liability, professional liability, worker's compensation and property damage) and such amounts as are adequate for the ownership and operation of the Cardiology Practice, the Cardiac Lab, the Medical Office and the Transferred Assets, as currently operated and conducted (and as previously operated and conducted).

(b) None of the Practice Group Parties has received within the last two (2) years any notice of cancellation (except for those received during renewal periods), termination or reduction in coverage for any insurance policy maintained by the Practice Group, ECCD or their Providers.

Section 3.16 Compliance with Laws. The Practice Group has conducted the Cardiology Practice and ECCD has operated the Cardiac Lab, and they have conducted their other activities, in accordance with all applicable laws, rules, regulations, judgments, orders and other requirements of all courts, administrative agencies, or governmental authorities having jurisdiction over them, including applicable laws, rules, regulations and requirements relating to occupational safety and health (OSHA), ERISA, Americans with Disabilities Act, employment, environmental law, clean air, labor, wage and hour and pension matters. None of the Practice Group Parties has received within the last two (2) years any notification of any asserted present or past failure by it to comply with such laws, rules or regulations that relate in any way to the Cardiology Practice, the Cardiac Lab or the Transferred Assets, except as disclosed in Section 3.16 of the of the Practice Group Disclosure Schedule.

Section 3.17 Employment Matters.

(a) The Practice Group and ECCD have reviewed (i) the "Fair Market Appraisal of Eastern Connecticut Cardiology Diagnostics, LLC's Work Force in Place," dated April 18, 2012, prepared by Kaufman Strategic Advisors, LLC and (ii) the "Fair Market Appraisal of Eastern Connecticut Cardiology Group, P.C.'s Work Force in Place," dated April 18, 2012, prepared by Kaufman Strategic Advisors, LLC (together, the "Work Force in Place Valuation Reports"). To the best knowledge of the Practice Group and ECCD, the employee related information contained in the Work Force in Place Valuation Reports is true, accurate and complete in all material respects.

(b) The Practice Group Parties have provided to the Hospital Parties a copy of all (i) employment agreements and other agreements or arrangements relating to the terms and conditions of employment with the Practice Group or ECCD that are currently in effect with respect to any employee; and (ii) professional service agreements and other agreements and arrangements that are currently in effect for independent contractors who are providing health care services on behalf of the Practice Group or ECCD.

(c) The Practice Group and ECCD are in compliance with all federal, state, local and other applicable laws, ordinances and regulations respecting employment practices, including all terms and conditions of employment, wages and hours, and discrimination or harassment

(relating to sex, age, religion, race, national origin, ethnicity, disability, veteran status or any other protected category), and is not engaging and has not engaged in any unfair labor practice in respect of the operations of the Cardiology Practice or the Cardiac Lab. There is no unfair labor practice complaint, charge or claim or any complaint, charge or claim alleging a failure to comply with any other employment-related laws, ordinances and regulations against the Practice Group or ECCD pending or threatened in respect of the operation of the Cardiology Practice or the Cardiac Lab. There is no retaliation complaint, charge or claim relating to an employee's exercise of a legal right, opposition to unlawful conduct, participation in filing a charge, or cooperation in an investigation into an employment complaint pending or threatened before any federal, state or local agency, authority, judicial forum or arbitration body against the Practice Group or ECCD in respect of the operations of the Cardiology Practice or the Cardiac Lab and there is no basis therefor.

(d) The Practice Group and ECCD has each paid in full to all of its employees and former employees who performed services for the Cardiology Practice and the Cardiac Lab all wages, salaries, commissions, bonuses, benefits, compensation, overtime, cash-outs of accrued unused paid time off or leave, and severance or any other amounts due upon termination of employment that are due and payable. The Practice Group and ECCD has each withheld and paid when due to the applicable governmental authorities all employment taxes (including unemployment compensation contributions) payable with respect to its employees and former employees. The Practice Group and ECCD has each paid when due all workers' compensation premiums with respect to its employees, and otherwise has complied with all applicable workers' compensation laws.

(e) Neither the Practice Group nor ECCD is a party to, bound by or negotiating in respect of any collective bargaining agreement with any labor union or other association of employees, and no attempt has been made to organize or certify any of its employees as or as part of a bargaining unit affecting the Cardiology Practice or the Cardiac Lab.

(f) Neither the Practice Group nor ECCD has been the subject of any inspection or investigation relating to its compliance with or violation of the Immigration Reform and Control Act of 1986 and the rules and regulations promulgated thereunder, nor has it been fined or otherwise penalized by reason of any failure to comply with such immigration laws, nor is any such proceeding pending or threatened in respect of the Cardiology Practice or the Cardiac Lab.

Section 3.18 Employee Plans and Arrangements.

(a) Section 3.18(a) of the Practice Group Disclosure Schedule contains a complete and accurate list of all Employee Plans.

(b) A complete and accurate copy of each Employee Plan as in effect as of the date of this Agreement has been delivered or made available to the Hospital Parties (or, to the extent no such copy exists, a description of the terms).

(c) Neither the Practice Group or ECCD nor any trade or business, whether or not incorporated, under common control with the Practice Group or ECCD within the meaning of Section 414(b), (c), (m) or (o) of the Code has incurred any unsatisfied liability with respect to

an Employee Plan (other than Pension Benefit Guaranty Corporation (PBGC) premiums) to the PBGC or the Internal Revenue Service under Title IV of ERISA or Section 412 of the Code that could reasonably be expected to result in the imposition of any liability on the Hospital Parties or any of their affiliates or the imposition of any Encumbrance on the Transferred Assets.

Section 3.19 Taxes. All Taxes due and payable by the Practice Group or ECCD with respect to the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Assets on or before the date hereof have been paid (or the Practice Group and ECCD have made adequate provision for the payment thereof), and the Practice Group and ECCD has each filed all tax returns and reports required to be filed by them with all applicable taxing authorities ("Tax Returns") that could affect the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Assets. The Practice Group and ECCD have paid (or has made adequate provision for the payment of) all Taxes that could create an Encumbrance on any of the Transferred Assets. Neither the Practice Group nor ECCD has any outstanding or unsatisfied deficiency assessments with respect to any material Taxes, and there are no current audits or investigations by or disputes with any authority with respect to any Taxes that may affect the Practice Group or ECCD or create an Encumbrance on any of the Transferred Assets. None of the Practice Group Parties has received notice that an examination of or proceeding concerning any Tax Return is pending or threatened that may affect any of them or create an Encumbrance on any of the Transferred Assets. There are no Encumbrances for Taxes on any of the Transferred Assets.

Section 3.20 Litigation. Except as set forth in Section 3.20 of the Practice Group Disclosure Schedule, there is no action, suit, claim, inquiry, proceeding or investigation pending, involving or threatened against the Practice Group Parties which affects the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Assets, or which questions or challenges the validity of this Agreement or the other Transaction Documents or any action taken or to be taken pursuant to this Agreement or the other Transaction Documents, and there are no reasonable grounds for believing that there is any basis for any such action, suit, claim, inquiry, proceeding or investigation. None of the Practice Group Parties is subject to any judgment, order or decree entered in any proceeding or investigation which may materially affect the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Asserts.

Section 3.21 Governmental Consents. No consent, approval or authorization of, notice to, or declaration, filing or registration with, any governmental or regulatory authority, domestic or foreign, is required in connection with the execution, delivery and performance of the Transaction Documents by the Practice Group Parties or the consummation of the Transactions by any of the Practice Group Parties.

Section 3.22 Other Consents. Except as set forth in Section 3.3 of the Practice Group Disclosure Schedule, no consent, approval or authorization of, or notice to, any other Person, including parties to loans, leases, agreements, contracts or other commitments, is required in connection with the execution, delivery and performance of the Transaction Documents by the Practice Group Parties or the consummation of the Transactions by the Practice Group Parties.

Section 3.23 Regulatory Compliance. None of the Practice Group Parties has engaged in any activities which are prohibited under the Physician Anti-Referral Laws or which are prohibited by rules of professional conduct, including the following: (a) knowingly and willfully

making or causing to be made a false statement or representation of a material fact in any application for any benefit or payment or for use in determining rights to any benefit or payment; (b) any failure by a claimant to disclose knowledge of the occurrence of any event affecting the initial or continued right to any benefit or payment on its own behalf or on behalf of another, with the intent to fraudulently secure such benefit or payment; or (c) knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, or offering to pay or receive such remuneration (i) in return for referring an individual to a Person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part by Medicare or Medicaid or any other governmental health benefit program, or (ii) in return for purchasing, leasing or ordering or arranging for, or recommending, purchasing, lease or ordering any good, facility, service or item for which payment may be made in whole or in part by Medicare or Medicaid or any other health benefit program.

Section 3.24 Medicare and Medicaid. The Practice Group, ECCD and the Providers are participants in good standing with the Medicare and Medicaid programs. There are no claims, actions or appeals pending before any commission, board or agency, including any intermediary or carrier, the Provider Reimbursement Review Board or the Administrator of the Centers for Medicare & Medicaid Services (CMS), with respect to any federal or state Medicare or Medicaid claims filed by the Practice Group, or any disallowances by any commission, board or agency in connection with any audit or review of such claims, which would materially adversely affect the Practice Group or ECCD or their operations or the consummation of the Transactions. To the knowledge of the Practice Group Parties, no validation review, program integrity review or other investigation related to the Practice Group or ECCD or their operations has been conducted by any commission, board or agency, including the HHS Office of Inspector General, the U.S. Department of Justice or the Attorney General of the State, in connection with any Medicare or Medicaid program and no such reviews or investigations are scheduled, pending or threatened against or affecting the Practice Group or ECCD or any of the Providers, the Cardiology Practice, the Cardiac Lab or the consummation of the Transactions.

Section 3.25 Environmental, Health and Safety Matters. Neither the Practice Group nor ECCD has generated, treated, stored, disposed of, transported or released, or arranged for or permitted the generation, treatment, storage, disposal, transportation or release of any substance, or owned or operated any property in a manner that has given or could reasonably be expected to give rise to any liability pursuant to any environmental, health or safety laws or regulations, including any liability for response costs. None of the Practice Group Parties has received any written or oral notice or report regarding any actual or alleged violation of any environmental, health or safety law or regulation, or any liability, relating to any of its past or presently owned or leased properties or any safety law or regulation for response costs, corrective action or natural resource damages (as those terms are defined under such laws and regulations) at any location. The Practice Group has provided the Hospital Parties with correct and complete copies of all reports and studies within its possession or control with respect to past or present environmental, health or safety conditions or events related to the Cardiology Practice or the Cardiac Lab or the past or present business or assets of the Practice Group or ECCD.

Section 3.26 Brokers or Finders. There are no claims for brokerage commissions or finder's or similar fees in connection with the Transactions which may be now or hereafter asserted against any of the Hospital Parties resulting from any action taken by any of the Practice Group Parties or their agents or employees.

Section 3.27 No Untrue Representations; Full Disclosure. No representation or warranty by any of the Practice Group Parties in this Agreement or in any other Transaction Document, and no schedule or certificate issued by any officer, directors or manager of the Practice Group or ECCD and furnished or to be furnished to the Hospital Parties pursuant hereto, or in connection with the Transactions, contains any untrue statement of a material fact, or omits to state a material fact necessary in order to make the statements or facts contained therein not misleading. There is no fact which the Practice Group Parties have not disclosed to the Hospital Parties in writing that materially and adversely affects or, so far as the Practice Group Parties can now reasonably foresee, could materially and adversely affect the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Assets or the ability of the Practice Group Parties to perform their obligations under this Agreement and the other Transaction Documents.

ARTICLE 4

REPRESENTATIONS AND WARRANTIES OF THE HOSPITAL PARTIES

The Hospital Parties hereby, jointly and severally, represent and warrant to the Practice Group as follows:

Section 4.1 Due Organization. The Hospital is a corporation duly organized and validly existing under the laws of the State. L&MPA is a medical foundation duly organized and validly existing under the laws of the State. Each of the Hospital Parties has all necessary corporate power and authority to own all of its assets and to carry on its business as such business is now being conducted.

Section 4.2 Power and Authority for Transactions. Each of the Hospital Parties has the corporate power and authority to execute, deliver and perform this Agreement and the other the Transaction Documents to be executed and delivered by it, to consummate the Transactions and to perform all of the terms and conditions of the Transaction Documents to be performed by it. The execution and delivery of this Agreement and the other Transaction Documents to be executed and delivered by the Hospital Parties, the performance of all the terms and conditions of the Transaction Documents to be performed by the Hospital Parties, and the consummation of the Transactions have been duly authorized and approved by the Hospital Parties. This Agreement and the other Transaction Documents to be executed and delivered by the Hospital Parties have been duly executed and delivered by the Hospital Parties and constitute the valid and binding obligations of the Hospital Parties and are enforceable against them in accordance with their respective terms.

Section 4.3 No Violation. Subject to receipt of the consents and approvals listed in Schedule 4.3, neither the execution and delivery by the Hospital Parties of this Agreement or the

other Transaction Documents to be executed by them nor the consummation of the Transactions by the Hospital Parties will:

(a) conflict with or violate any provision of the organizational documents of the Hospital or L&MPA;

(b) violate, conflict with, constitute a default (or an event which, with or without notice, lapse of time or both, or the occurrence of any other event, would constitute a default) under, result in the termination of any agreement, contract or commitment to which any Hospital Party is a party or by which any Hospital Party is bound; or

(c) violate any federal, state or local law or any judgment, decree, order, regulation or rule of any court or governmental authority.

Section 4.4 Litigation. There is no action, suit, claim, inquiry, proceeding or investigation pending, involving or threatened against any Hospital Party which questions or challenges the validity of this Agreement or the other Transaction Documents or any action taken or to be taken pursuant to this Agreement or the other Transaction Documents, and there are no reasonable grounds for believing that there is any basis for any such action, suit, claim, inquiry, proceeding or investigation.

Section 4.5 Governmental Consents. No consent, approval or authorization of, notice to, or declaration, filing or registration with, any governmental or regulatory authority, domestic or foreign, is required in connection with the execution, delivery and performance of the Transaction Documents by the Hospital Parties or the consummation of the Transactions by the Hospital Parties.

Section 4.6 Other Consents. Except as set forth in Schedule 4.3, no consent, approval or authorization of, or notice to, any other Person, including parties to loans, leases, agreements, contracts or other commitments, is required in connection with the execution, delivery and performance of the Transaction Documents by the Hospital Parties or the consummation of the Transactions by the Hospital Parties.

Section 4.7 Commissions and Fees. There are no valid claims for brokerage commissions or finder's or similar fees in connection with the Transactions which may be now or hereafter asserted against the Practice Group Parties resulting from any action taken by any of the Hospital Parties or their agents or employees.

ARTICLE 5

COVENANTS AND AGREEMENTS

Section 5.1 Payment of Taxes and Expenses.

(a) The Practice Group and ECCD shall pay any Taxes, fees or similar charges payable in connection with the conveyance of the Transferred Assets contemplated by this

Agreement. In the event that a Tax is attributable to a period that begins before Closing and ends after Closing, the Parties will negotiate in good faith to fairly allocate such Tax between the Parties.

(b) Except as otherwise explicitly provided herein, whether or not the Transactions are consummated, each of the Parties shall pay its own expenses and costs, including legal and accounting fees, incurred by it in connection with the negotiation, execution and performance of this Agreement.

Section 5.2 Access and Cooperation.

(a) After the date hereof, the Hospital Parties shall afford the Practice Group Parties and their representatives access to the properties, books, contracts and records of the Hospital Parties and, shall furnish promptly to the Practice Group Parties, all information and records formerly owned by the Practice Group and ECCD concerning the Cardiology Practice and the Cardiac Lab as may be reasonably requested by the Practice Group Parties to collect outstanding receivables and windup the Practice Group and ECCD.

(b) After the date hereof, each of the Practice Group Parties and the Hospital Parties shall in a timely manner: (i) provide the other Parties with such assistance as may reasonably be requested by either of them in connection with the preparation of any Tax Return or response to any audit or other examination by any taxing authority or judicial or administrative proceeding relating to liability for Taxes; (ii) retain and provide access to any records or other information that may be relevant to such return, audit or examination, proceeding, or determination; and (iii) provide notice to the other Parties of any final determination of any such audit or examination proceeding, or determination that affects any amount required to be shown on any Tax Return of any other Party.

Section 5.3 Cessation of Business. As soon as practical after the Closing, the Practice Group and ECCD shall cease the active practice of medicine and all other business operations and shall be dissolved and thereafter shall liquidate their assets and pay their respective liabilities.

Section 5.4 Employment.

(a) The sponsorship and liabilities of each Practice Group Employee Plan shall be retained by the Practice Group and specifically shall not be assumed by any of the Hospital Parties, and the Hospital Parties shall not be responsible for any of the benefits under or other liabilities relating to such plans.

(b) To the extent permitted by applicable law, the original personnel files of any staff member of the Practice Group or ECCD who accepts an offer of employment from L&MPA shall be transferred to L&MPA or the Hospital, as the case may be, as of the Closing or as soon as practicable thereafter. The original personnel records of all former employees of the Practice Group and any employees who do not become employees of L&MPA or the Hospital pursuant to an offer of employment described in Section 5.6(a) shall remain with the Practice Group or ECCD; provided that L&MPA or the Hospital shall be provided with a copy of all employee

health and safety records required by applicable law, and the Practice Group Parties shall permit L&MPA and the Hospital and their respective authorized representatives to have full access to all such personnel records to the extent reasonably necessary in order for any of the Hospital Parties to respond to a subpoena, court order, audit, investigation or otherwise as required by applicable law or in connection with any pending or threatened lawsuit, action, arbitration, claim, complaint, investigation or other proceeding.

Section 5.5 Publicity. Neither the Practice Group Parties nor the Hospital Parties shall publicly disclose the terms of this Agreement, except (i) with the prior written consent of the other Parties; (ii) to its employees, accountants, attorneys, lenders and advisors who have a need to know such information to advise such Party in connection with the transactions contemplated hereby and to enable it to consummate the transactions contemplated hereby; (iii) if such disclosure is compelled by an order of a court or governmental agency having competent jurisdiction, and after consultation by the disclosing Party with the other Parties; (iv) if such disclosure is required by lawful discovery in any judicial proceeding, in which case the disclosing Party will give notice to the other Parties; or (v) in any action by such Party to enforce this Agreement. The Parties agree that, to the maximum extent feasible, they will advise and confer with each other before the issuance of any other reports, statements or press releases pertaining to the transactions contemplated hereunder.

Section 5.6 Further Assurances. After the Closing, each Party will, from time to time, at the request of any other Party and without further cost or expense to the requesting Party, execute, acknowledge, deliver and perform such other instruments of conveyance and transfer, and take such other actions as any other Party may reasonably request, to implement the Transactions.

ARTICLE 6

SURVIVAL OF REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

Section 6.1 Survival of Representations and Warranties. All representations and warranties made by the Parties in this Agreement or in any certificate, schedule, statement, document or instrument furnished hereunder or in connection with the negotiation, execution and performance of this Agreement shall survive the Closing. Notwithstanding any investigation conducted or any knowledge acquired by any Party, whether before or after the Closing, or the decision of any Party to complete the Closing, each Party shall be entitled to rely upon the representations and warranties set forth herein and therein.

Section 6.2 Indemnification by the Practice Group Parties. The Practice Group Parties will defend, reimburse, indemnify and hold harmless the Hospital Parties and their respective affiliates, successors, assigns, employees and agents (the "Hospital Indemnitees") against and in respect of:

(a) Any and all damages, losses, deficiencies, liabilities, costs and expenses ("Losses") incurred or suffered by any of the Hospital Indemnities that result from, relate to or arise out of: (i) any and all liabilities and obligations of any of the Practice Group Parties of any nature whatsoever except to the extent expressly assumed by a Hospital

Party hereunder; (ii) any and all actions, suits, claims, or legal, administrative, arbitration, governmental or other proceedings or investigations against any Hospital Indemnitee that relate to the Practice Group Parties or the Cardiology Practice or the Cardiac Lab (except to the extent expressly assumed by a Hospital Party hereunder); (iii) any breach of the representations or warranties of the Practice Group Parties or nonfulfillment of any of agreements or covenants of the Practice Group Parties under any of the Transaction Documents, or any certificate, schedule, statement, document or instrument furnished to the Hospital Parties pursuant hereto or in connection with the negotiation, execution or performance of this Agreement or the Transactions; or (iv) Taxes that are attributable to the Practice Group Parties, the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Assets for the period prior to the Closing and any Taxes imposed on any Practice Group Party or any affiliate of the Practice Group or ECCD; and

(b) Any and all actions, suits, claims, proceedings, investigations, demands, assessments, audits, fines, judgments, costs and other expenses, including interest, penalties and reasonable attorneys fees and expenses incident to any of the foregoing or incurred in the enforcement of the indemnification rights under this Section 6.2 (including reasonable attorneys fees and expenses at both the trial and appellate level, regardless of whether incurred in an action with a third-party or between the Parties).

Section 6.3 Indemnification by the Hospital Parties. The Hospital Parties will defend, reimburse, indemnify and hold harmless the Practice Group Parties and their respective successors, assigns, shareholders, members, officers, employees and agents (the "Practice Group Indemnitees") against and in respect of:

(a) Any and all Losses incurred or suffered by any of the Practice Group Indemnitees or other obligations that result from, relate to or arise out of: (i) any and all obligations of the Hospital Parties under this Agreement of any nature whatsoever; (ii) any and all actions, suits, claims, or legal, administrative, arbitration, governmental or other proceedings or investigations against any of the Practice Group Indemnitees that relate to the Medical Office, the Cardiology Practice, the Cardiac Lab or the Transferred Assets in which the principal event giving rise thereto occurred after the Closing or which result from or arise out of any action or inaction by or on behalf of any of the Hospital Parties on or after the Closing relating to the Medical Office, Cardiology Practice, the Cardiac Lab or the Transferred Assets; or (iii) any breach of the representations or warranties of the Hospital Parties or nonfulfillment of any of agreements or covenants of the Hospital Parties under any of the Transaction Documents, any certificate, schedule, statement, document or instrument furnished to the Practice Group Parties pursuant hereto or in connection with the negotiation, execution or performance of this Agreement or the Transactions; and

(b) any and all actions, suits, claims, proceedings, investigations, demands, assessments, audits, fines, judgments, costs and other expenses, including interest, penalties and reasonable attorneys fees and expenses incident to any of the foregoing or incurred in the enforcement of the indemnification rights under this Section 6.3 (including reasonable attorneys fees and expenses at both the trial and appellate level, regardless of whether incurred in an action with a third-party or between the Parties).

Section 6.4 Notice of Claims.

(a) Claims by Third Parties. Promptly after receipt by an indemnified party of written notice of the commencement of any investigation, claim, proceeding or other action in respect of which indemnity may be sought from an indemnitor under either Section 6.2 or 6.3 (each, an "Action"), such indemnified party shall immediately notify the indemnitor in writing of the commencement of such Action; but the failure to so notify the indemnitor shall not relieve it from any liability that it may otherwise have to such indemnified party, except to the extent that the indemnitor is materially prejudiced or forfeits substantive rights or defenses as a result of such failure. In connection with any Action in which the indemnitor and any indemnified party are parties, the indemnitor shall be entitled to participate therein, and may assume the defense thereof. Notwithstanding the assumption of the defense of any such Action by the indemnitor, each indemnified party shall have the right to employ separate counsel and to participate in the defense of such Action, and the indemnitor shall bear the reasonable fees, costs and expenses of such separate counsel to such indemnified party if: (i) the indemnitor shall have agreed to the retention of such separate counsel; (ii) the defendants in, or target of, any such Action include more than one indemnified party or both an indemnified party and the indemnitor shall have concluded that representation of such indemnified party by the same counsel would be inappropriate due to actual or, as reasonably determined by such indemnified party's counsel, potential differing interests between them in the conduct of the defense of such Action, or if there may be legal defenses available to such indemnified party that are different from or additional to those available to the other indemnified party or to the indemnitor; or (iii) the indemnitor shall have failed to employ counsel reasonably satisfactory to such indemnified party within a reasonable period of time after notice of the institution of such Action. If such indemnified party retains separate counsel in cases other than as described in clause (i), (ii) or (iii) above, such counsel shall be retained at the expense of such indemnified party. Except as provided above, it is hereby agreed and understood that the indemnitor shall not, in connection with any Action in the same jurisdiction, be liable for the fees and expenses of more than one counsel for all such indemnified parties (together with appropriate local counsel). The Party from whom indemnification is sought shall not, without the written consent of the party seeking indemnification (which consent shall not be unreasonably withheld), settle or compromise any claim or consent to entry of any judgment that relates to Taxes or does not include an unconditional release of the party seeking indemnification from all liabilities with respect to such claim.

(b) Other Claims. In the event one Party should have a claim for indemnification that does not involve a claim or demand being asserted by a third party, the party seeking indemnification shall promptly send notice of such claim to the Party from whom indemnification is sought.

Section 6.5 Offset Rights and Limitations.

(a) The Hospital Parties shall have the right to offset against any amounts due under the Transaction Documents the amount of any indemnity claim of any Hospital Party pursuant to this Article 6 for which a claim notice was timely delivered.

(b) Neither the exercise nor the failure to exercise such right of setoff or to give a notice of claim will constitute an election of remedies or limit the Hospital Parties in any manner in the enforcement of any other remedies that may be available to it.

ARTICLE 7

DEFINITIONS AND INTERPRETATION

Section 7.1 Definitions. For purposes of this Agreement, the following terms shall have the respective meanings set forth below:

"Action" shall have the meaning set forth in Section 6.4(a).

"Agreement" means this Agreement.

"Allied Health Professional" means a licensed nurse practitioner or physicians assistant who is employed by or under contract with the Practice Group or ECCD and is directly engaged in the treatment of patients of the Cardiology Practice or at the Cardiac Lab and whose services are or may be billable.

"Assigned Agreements" shall have the meaning set forth in Section 1.1(c)(5).

"Cardiac Lab" shall have the meaning set forth in the recitals.

"Cardiac Lab Assets" shall have the meaning set forth in Section 1.1(c).

"Cardiac Lab Assigned Agreements" shall have the meaning set forth in Section 1.1(c)(5).

"Cardiac Lab Purchase Price" shall have the meaning set forth in Section 1.3(a)(ii).

"Cardiac Lab Supplies" shall have the meaning set forth in Section 1.1(c)(2).

"Cardiac Lab Tangible Assets" shall have the meaning set forth in Section 1.1(c)(1).

"Cardiology Practice" shall have the meaning set forth in the recitals.

"Cardiology Practice Assets" shall have the meaning set forth in Section 1.1(b).

"Cardiology Practice Assigned Agreements" shall have the meaning set forth in Section 1.1(b)(6).

"Cardiology Practice Supplies" shall have the meaning set forth in Section 1.1(b)(2).

"Cardiology Practice Tangible Assets" shall have the meaning set forth in Section 1.1(b)(1).

"Closing" shall have the meaning set forth in Section 2.1.

"Closing Date" shall have the meaning set forth in Section 2.1.

"Code" means the Internal Revenue Code of 1986.

"Contracts" shall have the meaning set forth in Section 3.11(a).

"ECCD" means Eastern CT Cardiology Diagnostics, LLC, a Connecticut limited liability company.

"Employee Plans" means (i) all "employee benefit plans," as defined in Section 3(3) of ERISA, (ii) all other severance pay, salary continuation, bonus, incentive, stock option, retirement, pension, profit sharing or deferred compensation plans, contracts, programs, funds or arrangements of any kind, and (iii) all other employee benefit plans, contracts, programs, funds, or arrangements in respect of any employees of the Practice Group and ECCD that are sponsored by the Practice Group and ECCD or any of their affiliates.

"Employment Agreement" shall have the meaning set forth in Section 1.1(d).

"Encumbrances" shall have the meaning set forth in Section 1.1(b)(1).

"ERISA" means the Employee Retirement and Income Security Act of 1974.

"Excluded Assets" shall have the meaning set forth in Section 1.1.

"Office Lease" shall have the meaning set forth in Section 1.1(a).

"Financial Statements" shall have the meaning set forth in Section 3.7(a)

"Hospital" means Lawrence & Memorial Hospital, Inc., a Connecticut nonstock corporation and licensed acute care general hospital.

"Hospital Indemnitees" shall have the meaning set forth in Section 6.2.

"Hospital Party" or the "Hospital Parties" means either the Hospital or L&MPA or, collectively, the Hospital and L&MPA.

"Intellectual Property" means all of the following: all trademarks, tradenames (including the right to use the name "Eastern Conn. Cardiology Group" or "Eastern CT Cardiology Diagnostics" and all variations and derivatives thereof), patents, copyrights, proprietary information, domain names, the web site of the Practice Group and ECCG and all content, source codes and URLs related thereto, all designs and any registrations and applications therefore, all databases and data collections and all rights therein; all software; any and all other intellectual property rights and proprietary rights relating to any of the foregoing; all immunities, covenants not to sue and the like relating to the foregoing; all books and records describing or used in

connection with the foregoing, including all agreements, contracts, licenses, and other arrangements to which the Practice Group or ECCD or any of their affiliates is a party or by which any of them is bound either as licensee or licensor relating to any intellectual property described above; and all goodwill, going concern value, franchises, permits, consents, approvals, and claims or causes of action arising out of or related to infringement or misappropriation, of any of the foregoing.

"L&MPA" means L&M Physician Association, Inc., a Connecticut medical foundation.

"Losses" shall have the meaning set forth in Section 6.2(a).

"Medical Office" shall have the meaning set forth in the recitals.

"Operational Data" shall have the meaning set forth in Section 3.7(a).

"Party" or "Parties" means a party (or the parties) to this Agreement.

"Person" means an individual, a partnership, a corporation, a limited liability company, an association, a joint stock company, a trust, a joint venture, an unincorporated organization or any governmental agency or authority.

"Physician Anti-Referral Laws" all federal and state requirements and restrictions governing physician referrals, specifically including the Section 1877 of the Social Security Act, as amended, codified at 42 U.S.C. §1395nn (the "Stark Amendment") and the regulations promulgated thereunder, and Section 1128B(b) of the Social Security Act, codified at 42 U.S.C. §1320a-7b(b).

"Physician Owners" means Brian S. Ehrlich, M.D., Peter S. Milstein, M.D., Richard P. Fazio, M.D., Francis J. Mirecki, M.D., Mark N. Fiengo, D.O., Valerie B. Popkin, M.D., and Mark J. Somers, M.D., as the shareholders of the Practice Group and the members of ECCD.

"Practice Group Indemnitees" shall have the meaning set forth in Section 6.3.

"Practice Purchase Price" shall have the meaning set forth in Section 1.3(a)(i).

"Purchase Price" shall have the meaning set forth in Section 1.3(a)(ii).

"Practice Group" means Eastern Conn. Cardiology Group, P.C., a Connecticut professional corporation.

"Practice Group Party" or the "Practice Group Parties" means the Practice Group, ECCD or the Physician Owners or, collectively, the Practice Group, ECCD and the Physician Owners.

"Providers" shall have the meaning set forth Section 1.1(b)(3).

"Schedule" means a schedule attached and appended to this Agreement.

"Service Area" means the cities and towns of Bozrah, Colchester, East Lyme, Franklin, Griswold, Groton, Ledyard, Lisbon, Lyme, Montville, New London, North Stonington, Norwich, Old Lyme, Old Saybrook, Preston, Salem, Stonington, Voluntown and Waterford, Connecticut, and Westerly, Rhode Island.

"State" means the State of Connecticut.

"Taxes" all federal, state, county, local and other taxes, including income, gross receipts, corporate, franchise, stamp, transfer, sales and use, license, severance, excise, employment (including unemployment compensation contributions), withholding, property, escheat or unclaimed property, ad valorem, or any other taxes, assessments, charges or levies, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties.

"Tax Returns" shall have the meaning set forth in Section 3.19.

"Transactions" shall have the meaning set forth in Section 1.1.

"Transaction Documents" shall mean this Agreement, the Office Lease, the Employment Agreements, and the other documents and instruments referred to herein and therein.

"Transferred Assets" shall have the meaning set forth in Section 1.1.

"Treasury Regulations" means regulations promulgated by the United States Department of the Treasury.

"Yale Agreements" shall have the meaning set forth in Section 1.1(b)(4)

Section 7.2 Interpretation.

(a) When a reference is made in this Agreement to an Article or to a Section, Subsection, Exhibit or Schedule, such reference shall be to an Article of, a Section or Subsection of, or an Exhibit or Schedule to, this Agreement unless otherwise indicated. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of any provision of this Agreement. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation." The words "hereof," "herein" and "hereunder" and words of similar import when used in this Agreement shall refer to this Agreement as a whole (including the Schedules) and not to any particular provision of this Agreement. The words "date hereof" shall refer to the date of this Agreement. The term "or" is not exclusive. The word "extent" in the phrase "to the extent" shall mean the degree to which a subject or other thing extends, and such phrase shall not mean simply "if." The definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms. Any agreement or instrument defined or referred to herein or in any agreement or instrument that is referred to herein means such agreement or instrument as from time to time amended, modified or supplemented. Reference to

any law or regulation means such law or regulation as amended, modified, codified, replaced or reenacted, in whole or in part, and in effect from time to time, including rules and regulations promulgated thereunder, and reference to any section or other provision of any law or regulation means that provision of such law or regulation from time to time in effect and constituting the substantive amendment, modification, codification, replacement or reenactment of such section or other provision. References to a Person are also to its successors and permitted assigns and reference to a Person in a particular capacity excludes such Person in any other capacity or individually.

(b) This Agreement was negotiated by the Parties with the benefit of legal representation, and any rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against any Party shall not apply to any construction or interpretation hereof. In the event of an ambiguity or a question of intent or interpretation, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement or to the extent to which any such Party's counsel participated in the drafting of any provision hereof or by virtue of the extent to which any such provision is inconsistent with any prior draft hereof

ARTICLE 8

MISCELLANEOUS

Section 8.1 No Payments for Referrals. The Parties agree that the benefits to the Hospital Parties under this Agreement do not require, are not payment for, and are not in any way contingent upon the admission, referral or any other arrangement for the provision of any item or service offered by the Hospital Parties or any of their affiliates to any patient.

Section 8.2 Assignment. This Agreement and the rights and obligations created hereunder shall not be assignable by the Parties, either voluntarily or by operation of the law, without the prior written consent of the other Parties; provided, however, the Hospital or L&MPA may assign this Agreement or any rights or interests hereunder to their respective affiliates without the prior written consent of the Practice Group or any of the Providers.

Section 8.3 Governing Law. This Agreement shall be governed by and construed under the laws of the State. Each party hereto (i) submits to the exclusive jurisdiction of the courts of the State of Connecticut, the United States District Court for the District of Connecticut and any corresponding appellate courts in any legal action or proceeding relating to the Transaction Documents; (ii) consents that any such action or proceeding may be brought in such courts; (iii) waives any objection that it may have to the venue of any such action or proceeding in any such court or that such action or proceeding was brought in an inconvenient court and agrees not to plead or claim the same; and (iv) agrees that service of process in any such action or proceeding may be effected by giving written notice in accordance with the provisions of Section 8.7.

Section 8.4 Waiver. No failure by any Party to insist upon the strict performance of any covenant, agreement, term or condition of this Agreement or to exercise any right or remedy hereunder shall constitute a waiver. No waiver of any breach shall affect or alter this Agreement,

but each and every covenant, condition, agreement and term of this Agreement shall continue in full force and effect with respect to any other existing or subsequent breach.

Section 8.5 Amendment. No amendment of this Agreement shall be binding on any Party unless in writing and executed by the duly authorized representatives of all Parties.

Section 8.6 Entire Agreement. This Agreement, together with all Schedules and exhibits hereto, constitutes the entire agreement between the Parties relating to the subject matter hereof, and supersedes all prior agreements or understandings, whether written or oral, and whether explicit or implicit, which have been entered into before the execution hereof.

Section 8.7 Notices. Any notice or other communication required or which may be given hereunder shall be in writing and shall be delivered personally, telexed or sent by facsimile or other electronic medium, or sent by certified, registered or express mail, postage prepaid, and shall be deemed given when so delivered personally, telexed or sent by facsimile or other electronic medium, or if mailed, two (2) days after the date of mailing, to the following addresses:

(i) If to the Hospital Parties:

Lawrence & Memorial Hospital, Inc.
365 Montauk Avenue
New London, CT 06320-4700
Attention:

With a copy (which shall not constitute notice) to:

John H. Lawrence, Jr., Esq.
Shipman & Goodwin LLP
One Constitution Plaza
Hartford, CT 06103-1919

(ii) If to Practice Group Parties:

Eastern Conn. Cardiology Group, P.C.
196 Parkway South, Suite 103
Waterford, CT 06385-1234
Attention:

Any Party may change its address for notice purposes by giving written notice thereof pursuant to this Section.

Section 8.8 Severability. If any provision of this Agreement or any portion hereof is held to be invalid or unenforceable, such invalidity or unenforceability shall not affect or impair the validity and enforceability of the remainder of this Agreement. In such event, all Parties

agree that the court making such determination shall have the power to alter or amend such provision so that it shall be enforceable.

Section 8.9 Construction. Whenever the singular number is used in this Agreement and when required by the context, the same shall include the plural and vice versa, and the masculine gender shall include the feminine and neuter genders and vice versa. Any reference in this Agreement to any section of the Treasury Regulations or the Code shall be construed to include any amendment to such section or to any corresponding provisions of succeeding law.

Section 8.10 Rights and Remedies Cumulative. The rights and remedies provided by this Agreement are cumulative and the use of any one right or remedy by any Party shall not preclude or waive the right to use any or all other remedies. Said rights and remedies are given in addition to any other rights the Parties may have by law, statute, ordinance or otherwise.

Section 8.11 No Third Party Beneficiaries. Except as specifically set forth or referred to herein, nothing expressed or implied herein is intended or shall be construed to confer upon or give to any Person other than the Parties hereto, and their successors or permitted assigns, any rights or remedies under or by reason of this Agreement.

Section 8.12 Counterparts. This Agreement may be executed in any number of counterparts and delivered via facsimile or other electronic means, with the same effect as if the signatures thereto and hereto were upon the same instrument but all of such counterparts taken together shall be deemed to constitute one and the same instrument.

Section 8.13 Binding Effect. Subject to the provisions contained herein, this Agreement shall be binding upon and inure to the benefit of the Parties hereto and upon their respective successors and permitted assigns.

Section 8.14 Arbitration. The Parties agree that any controversy, dispute or claim arising out of or relating to this Agreement, which cannot be resolved by the Parties within thirty (30) days after written notice thereof from another Party, shall be settled by binding arbitration by a single arbitrator in New London, Connecticut. The arbitration shall be administered by JAMS pursuant to its Streamlined Arbitration Rules and Procedures. The arbitrator shall state in writing the reasons for his or her award and the legal and factual conclusions underlying the award. The award of the arbitrator shall be final, and judgment upon the award may be entered in any state or federal court located in the State. Notwithstanding the foregoing, either Party may seek equitable relief, including an injunction or specific performance, in the event of a breach or threatened breach of any of the covenants herein. The costs of such arbitration proceeding shall be borne equally by the Hospital Parties and the Practice Group Parties. The Parties agree that all of the negotiations and proceedings relating to such disputes and all testimony, transcripts and other documents relating to such arbitration shall be treated as confidential and will not be disclosed or otherwise divulged to any other Person except as necessary in connection with such negotiations.

Section 8.15 Equitable Relief. Each Party acknowledges and agrees that the remedies at law of the other Party for any breach of this Agreement would be inadequate and agrees that in

addition to any remedy at law which it may have, the other Party may be granted temporary, preliminary and permanent injunctive relief in any proceeding which may be brought to enforce such provisions, without the necessity of proving that there is no adequate remedy at law or the filing of a bond or provision of other security therefor. The Parties also agree that terms of this Agreement shall be enforceable by a decree of specific performance. Each Party further acknowledges and agrees that any proceeding to enforce the covenants set forth in this Section may be adjudicated in a court of competent jurisdiction and that the court shall have all the necessary authority to issue the injunctive relief described herein.

Section 8.16 Existing Physician Employment Agreements. The Practice Group and each of the physician employees of the Practice Group hereby agree to terminate all employment agreements by and between the Practice Group and such physician employees effective at the Closing and such agreements shall have no force and effect except for obligations and liabilities that arose prior to the termination thereof.

[*The remainder of this page is left intentionally blank.*]

IN WITNESS WHEREOF, the Parties have caused this Practice Transition Agreement to be executed as of the date first written above, either individually or by their duly authorized representative.

LAWRENCE & MEMORIAL HOSPITAL, INC.

By: _____
Name: Brian Cummings
Title: President + CEO

L&M PHYSICIAN ASSOCIATION, INC.

By: _____
Name: Pamela Kane
Title: Executive Director

EASTERN CONN. CARDIOLOGY GROUP, P.C.

By: _____
Name: Valerie Popkin
Title: Vice President

EASTERN CT CARDIOLOGY DIAGNOSTICS, LLC

By: _____
Name: Valerie Popkin
Title: Vice President

PHYSICIAN OWNERS:

_____
Brian S. Ehrlich, M.D.

_____
Richard P. Fazio, M.D.

_____
Mark N. Fiengo, D.O.

_____
Mark J. Somers, M.D.

_____
Peter S. Milstein, M.D.

_____
Francis J. Mirecki, M.D.

_____
Valerie B. Popkin, M.D.

LIST OF SCHEDULES

Schedule 1.1(b)(6)	Cardiolgy Practice Assigned Agreements
Schedule 1.1(c)(5)	Cardiac Lab Assigned Agreements
Schedule 4.3	Hospital Party Consents and Approvals

Schedule 1.1(b)(6)

Cardiolgy Practice Assigned Agreements

1. Transtelephonic Pacemaker Monitoring Agreement between Philips Remote Cardiac Services and ECCG dated 1/7/2010.

2. St. Jude Medical Merlin.™net Patient Care Network User Agreement between Pacesetter, Inc. d/b/a St. Jude Medical Cardiac Rhythm Management Division and ECCG dated 10/26/2009.

3. Monthly Service Agreement between Interbridge.net and ECCG dated 12/1/2009.

4. Medtronic Carelink® Network Agreement between Medtronic, Inc. and ECCG dated 10/6/2007.

5. Amendment to Service Agreement for Integrated Services Digital Network Primary Rate Interface between AT&T Connecticut and ECCG dated 5/5/2011.

6. Lease Agreement between Leaf Financial Corporation and ECCG dated 5/4/2009 (Konica Minolta Bizhub 200 Digital Copier (new)).

7. Lease Agreement between Leaf Financial Corporation and ECCG dated 4/24/2009 (Konica Minolta Bizhub 200 Digital Copier (new)). [handwritten notation on copy says: copier - front desk Wtfd]

8. Lease Agreement between Bank of America and ECCG [no date] for Konica Minolta Bizhub 200 Digital Copier, Serial # 31137215, with attached sales order from Copy Rite Business Systems dated 1/16/2009. [handwritten notation on copy says "3 yr lease Grtn"]

9. Lease Agreement between Bank of America and ECCG [no date] for Konica Minolta Bizhub 200 Digital Copier, Serial # 31137954, with attached sales order from Copy Rite Business Systems dated 1/10/08. [handwritten notation on copy says "3 yr lease Wtfd"]

10. The Yale Agreements.

Schedule 1.1(c)(5)

Cardiac Lab Assigned Agreements

1. Philips Medical Systems Gold Customer Service Agreement, effective date of 9/1/2008, service expiration date of 8/31/2012 between Philips Medical Systems N.A. and ECCG.

2. First Amendment of the Triad Isotopes, Inc. Provider Agreement dated 3/1/2011 between Triad Isotopes, Inc. and ECCD, effective as of 9/1/2011.

3. Equipment and Service Support Agreement between GE Healthcare and ECCG dated 10/17/2008 (Billing account # 060003316).

4. Ultrasound and BMD Products Sale and Services Agreement between GE Healthcare (GE Ultrasound OTR) and ECCG dated 10/2/2008.

5. Extended maintenance agreement of Billing Acct # 00263302 between GE Healthcare and ECCG dated 8/9/2011 (period of 10/15/2011 - 10/14/2014).

6. Ultrasound Products Sale and Services Agreement between GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC) and ECCG dated 9/25/2007.

Schedule 4.3

Hospital Party Consents and Approvals

None.

Execution Version

PRACTICE GROUP DISCLOSURE SCHEDULE

In connection with the Practice Transition Agreement, dated as of May 1, 2012 (the "Agreement"), by and among Lawrence & Memorial Hospital, Inc., a Connecticut nonstock corporation and licensed acute care general hospital; L&M Physician Association, Inc., a Connecticut medical foundation; Eastern Conn. Cardiology Group, P.C., a Connecticut professional corporation ("ECCG"); Eastern CT Cardiology Diagnostic, LLC, a Connecticut limited liability company ("ECCD"); and Brian S. Ehrlich, M.D., Peter S. Milstein, M.D., Richard P. Fazio, M.D., Francis J. Mirecki, M.D., Mark N. Fiengo, D.O., Valerie B. Popkin, M.D., and Mark J. Somers, M.D. Capitalized terms used herein and not otherwise defined herein shall have the respective meanings set forth in the Agreement.

The Practice Group Parties hereby deliver these Disclosure Schedules to the Hospital Parties with respect to the representations and warranties given by the Practice Group Parties in the Agreement.

The Section headings in these Disclosure Schedules are for reference purposes only and shall not affect in any way the express description of the Schedules as set forth in the Agreement. Nothing in this Disclosure Schedule shall be deemed adequate to disclose an exception to a representation or warranty of the Practice Group Parties unless the specific Section identifies the exception with reasonable particularity and describes the relevant facts in reasonable detail or unless a cross reference to another Section is made with reasonable particularity.

Section 3.3	Consents and Approvals for the Practice Group Parties
Section 3.7	Financial Statements and Operational Data
Section 3.8	Liabilities
Section 3.11	Contracts
Section 3.14	Intellectual Property
Section 3.16	Compliance with Laws
Section 3.18(a)	List of Employee Plans
Section 3.20	Litigation

Section 3.3

Consents and Approvals for the Practice Group Parties

- Third party consents to the assignment of the Assigned Contracts
- Nuclear Regulatory Commission consent to transferring control of Materials License 06-30826-01 to the Hospital
- Shareholder and board of director approvals of the Practice Group
- Member and manager approvals of ECCD

Section 3.7

Financials Statements and Operational Data

Financial statements: See attached
Operational Data: None

Section 3.8

Liabilities

None, other than as shown in the Financial Statements.

Section 3.11

Contracts

1. Shareholders' Stock Purchase Agreement, effective as of July 1, 1996 by and among Brian S. Ehrlich, Peter S. Milstein, C. Wallace Andrias, Richard Fazio and Francis J. Mirecki and ECCG.

2. Amendment of Shareholders' Stock Purchase Agreement effective as of July 1, 1998 by and among Brian S. Ehrlich, Peter S. Milstein, C. Wallace Andrias, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo and ECCG.

3. Amendment of Shareholders' Stock Purchase Agreement effective as of October 1, 2003 by and among Brian S. Ehrlich, Peter S. Milstein, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo, Valerie Popkin and ECCG.

4. Amendment of Shareholders' Stock Purchase Agreement effective as of August ___, 2004 by and among Brian S. Ehrlich, Peter S. Milstein, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo, Valerie Popkin, Mark J. Somers and ECCG.

5. Supplemental Agreement effective as of January 1, 1989, by and among Brian S. Ehrlich, Peter S. Milstein, Walter P. Paladino, C. Wallace Andrias, Richard Fazio and ECCG.

6. Agreement and Amendment of Supplemental Agreement effective as of July 1, 1996, by and among Brian S. Ehrlich, Peter S. Milstein, C. Wallace Andrias, Richard Fazio and Francis J. Mirecki and ECCG.

7. Agreement and Amendment of Supplemental Agreement effective as of July 1, 1998, by and among Brian S. Ehrlich, Peter S. Milstein, C. Wallace Andrias, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo and ECCG.

8. First Amendment and Restatement of Supplemental Agreement effective as of July 1, 2003, by and among Brian S. Ehrlich, Peter S. Milstein, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo, Valerie Popkin and ECCG.

9. Second Amendment and Restatement of Supplemental Agreement effective as of July 1, 2004, by and among Brian S. Ehrlich, Peter S. Milstein, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo, Valerie Popkin, Mark J. Somers and ECCG.

10. Third Amendment and Restatement of Supplemental Agreement effective as of July 1, 2005, by and among Brian S. Ehrlich, Peter S. Milstein, Richard Fazio, Francis J. Mirecki, Mark N. Fiengo, Valerie Popkin, Mark J. Somers, Jon C. Gaudio and ECCG.

11. Amendment to Employment Contract effective as of January 1, 2002 by and between ECCG and Brian S. Ehrlich.

12. Amendment to Employment Contract effective as of January 1, 2002 by and between ECCG and Peter S. Milstein.

13. Amendment to Employment Contract effective as of January 1, 2002 by and between ECCG and Richard Fazio.

14. Amendment to Employment Contract effective as of November 1, 1999 by and among ECCG and Mark N. Fiengo.

15. Amendment to Employment Contract effective as of January 1, 2002 by and between ECCG and Francis J. Mirecki.

16. Employment Contract effective as of October 1, 2003 by and between ECCG and Valerie Popkin (term of contract shall begin on August 1, 2003).

17. Employment Contract effective as of August 1, 2004 by and between ECCG and Mark J. Somers.

18. Contract as of June 8, 1999 by and between ECCG and Robert Kupis.

19. Contract as of December 4, 2000 by and between ECCG and Kimberly Guzzio (now Chemacki).

20. Lease Agreements relating to office space located at 481 Gold Star Highway, Groton, Connecticut.

21. Philips Medical Systems Gold Customer Service Agreement, effective date of 9/1/2008, service expiration date of 8/31/2012 between Philips Medical Systems N.A. and ECCG.

22. First Amendment of the Triad Isotopes, Inc. Provider Agreement dated 3/1/2011 between Triad Isotopes, Inc. and ECCD, effective as of 9/1/2011.

23. Transtelephonic Pacemaker Monitoring Agreement between Philips Remote Cardiac Services and ECCG dated 1/7/2010.

24. St. Jude Medical Merlin.™net Patient Care Network User Agreement between Pacesetter, Inc. d/b/a St. Jude Medical Cardiac Rhythm Management Division and ECCG dated 10/26/2009.

25. Monthly Service Agreement between Interbridge.net and ECCG dated 12/1/2009.

26. Equipment and Service Support agreement between GE Healthcare and ECCG dated 10/17/2008 (Billing account # 060003316).

27. Ultrasound and BMD Products Sale and Services Agreement between GE Healthcare (GE Ultrasound OTR) and ECCG dated 10/2/2008.

28. Extended maintenance agreement of Billing Acct # 00263302 between GE Healthcare and ECCG dated 8/9/2011 (period of 10/15/2011 - 10/14/2014).

29. Ultrasound Products Sale and Services Agreement between GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC) and ECCG dated 9/25/2007.

30. Medtronic Carelink® Network Agreement between Medtronic, Inc. and ECCG dated 10/6/2007.

31. Purchased Services Agreement for Non-Medicare and Technical Component Agreement for Medicare of 30-Day Transtelephonic Arrhythmia Monitoring between Raytel Cardiac Services, Inc. dba Philips Cardiac Systems and ECCG dated 6/16/2009 (Acct # 6GOB and 2 DBP).

32. Amendment to Service Agreement for Integrated Services Digital Network Primary Rate Interface between AT&T Connecticut and ECCG dated 5/5/2011.

33. Lease Agreement between Leaf Financial Corporation and ECCG dated 5/4/2009 (Konica Minolta Bizhub 200 Digital Copier (new)).

34. Lease Agreement between Leaf Financial Corporation and ECCG dated 4/24/2009 (Konica Minolta Bizhub 200 Digital Copier (new)). [handwritten notation on copy says: copier - front desk Wtfd]

35. Lease Agreement between Bank of America and ECCG [no date] for Konica Minolta Bizhub 200 Digital Copier, Serial # 31137215, with attached sales order from Copy Rite Business Systems dated 1/16/2009. [handwritten notation on copy says "3 yr lease Grtn"]

36. Lease Agreement between Bank of America and ECCG [no date] for Konica Minolta Bizhub 200 Digital Copier, Serial # 31137954, with attached sales order from Copy Rite Business Systems dated 1/10/08. [handwritten notation on copy says "3 yr lease Wtfd"]

37. Lease Agreement dated as of July 20, 2004 between Waterford Real Estate Holdings, LLC and ECCG; assigned from ECCG to Waterford Cardiology Realty Group, LLC as of November 1, 2005.

Section 3.14

Intellectual Property Rights

None.

Section 3.16

Compliance with Laws

1. Evaluation and Management Medicare review in March 2011 was done against Dr. Brian Cambi, M.D. Additional training was provided to Dr. Cambi post review by both SSMED (the billing company) and a NGS (Medicare) teleconference on August 4, 2011. Status is resolved and all owed monies paid.

Section 3.18(a)

List of Employee Plans

Dental insurance
Medical insurance
Life insurance
Employee health program
Pharmacy benefit program
401(K) profit-sharing plan and trust.

Section 3.20

Litigation

Pending case in Appellate Court:

Karen Guerri, Administrator of the Estate of Craig S. Guerri v. Mark Fiengo, D.O.; Superior Court, JD of New London at New London; CV09-5011115-S. Verdict in favor of Dr. Fiengo issued on September 30, 2010. The Plaintiff then filed a Motion to Set Aside the Verdict and For a New Trial; Judge Cosgrove denied the motion and request for a new trial on December 30, 2010. The Plaintiff filed an appeal to the Appellate Court on January 19, 2011. Status: argued (on January 17, 2012), no decision.

Attachment J

Letter from Local Emergency Medical Services (EMS) & Guideline for Rapid Transport of Patients Requiring Urgent Surgery

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

May 17, 2012

Lawrence & Memorial Hospital
Attn: Shraddha Patel
Director of Business Development and Planning
365 Montauk Avenue
New London, CT 06320

Dear Ms. Patel,

For many years, American Ambulance has been the preferred provider for Lawrence & Memorial. We take great pride in the fact that we have this long standing relationship.

It is my understanding that Lawrence and Memorial is moving forward with their plans to become a facility that can provide non-emergent elective angioplasty. Please consider this letter our commitment to have an ambulance at your facility, no later than 20 minutes from when the ambulance is requested, should the need for transport arise. We clearly understand that a request of this nature would be one that requires immediate transport to a tertiary care center.

In the event that you need an American Ambulance representative at any future planning meetings in relation to this process, or any other, please feel free to contact me at 860.886.1463 ext. 301 or via emailing me at gallard@americanamb.com..

Respectfully,

Gregory B. Allard
Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

LAWRENCE+MEMORIAL HOSPITAL

Title: Patient transfer to higher level of care guidelines	Reference Number:
File Location: Departmental	Issuing Department: Cath lab
Latest Review/Revision Date: 5-12	Original Date: 5-12
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date: Medical Director, Angioplasty 5/31/12 Date Director, Patient care Services 5/31/12 Date	

PURPOSE: To provide guidelines for when the need arises for emergent transportation for a PCI patient from the Cardiac Catheterization lab.

POLICY

PROCEDURE:
The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program at Lawrence + Memorial Hospital (L+M) as described below:

1. A CT Surgeon is on-call 24/7 to arrange for patient transfers through the Y-Access system and to receive the patient at YNHH.
2. All YNHH on-call CT Surgeons are privileged to provide CABG or other procedures expected as a result of complications associated with performing elective PCI at Lawrence & Memorial Hospital.
3. YNHH maintains one operating room open every day for emergency transfers that is CT Surgery capable. The on-call CT Surgeon remains in-house during the hours of 7:30am through 4:00pm, Monday through Friday to accommodate the Lawrence & Memorial elective PCI schedule.
4. The receiving surgeon and team obtain consent for surgery from patient or surrogate.
5. The Yale-New Haven Heart & Vascular Center agrees that L+ M may represent to patients that YNHVC provides surgical backup to elective PCI in its patient consent process.
6. YNHVC and L+M maintain computer systems interface or direct access to L+M systems for the YNHVC receiving surgeon to review real-time images and hemodynamic data, as well as audio and video images for consulting on treatment options and transfer decisions.

7. L+M Hospital employ the Yale-New Haven Hospital Y-Access transfer system to expedite the process of surgical consultation and transfer.
8. All other provisions of the Transfer Agreement will remain in effect for heart and vascular patients
9. When choosing the appropriate form of transportation, the patient's stability and equipment needs is assessed and relayed to the proposed transportation team. Patients requiring a Balloon Pump during transport require air medical transport or a nurse to accompany the patient if ground transport does not have the appropriate staff to monitor the pump.
10. In the event air medical transport is preferred but unavailable due to weather, staff should inquire if the team is available to provide the trip by ground.

Below is the transport option in order of use:

1. Lifestar (Air Medical) transportation – Crew configuration will consist of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
2. Lifestar (Ground) transportation – Crew configuration will consist of an American Ambulance EMT and a second American Technician which may be an EMT or Paramedic and the Lifestar Crew consisting of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
3. American Ambulance (Ground) transportation - Crew configuration will consist of an American Ambulance EMT and a Paramedic.

The following option must only be used if other transportation is unavailable and transportation must occur immediately.

4. New London Fire Department Ambulance (Ground) transportation - Crew configuration will consist of 2 Firefighter/EMT's and a Lawrence & Memorial Hospital Paramedic.

Contact Information

Lifestar – (800)437-4378
American Ambulance – (860)886-1463
New London Fire Department – (860)442-4444/911

PROTOCOL

Reference:
1. Hospital L+M Policy Patient transfer to Higher level of care facility.
2. YNHH transfer agreement

Archive Dates
Reviewed Date:
Revised: 5/12
Supersedes:

Attachment K

Connecticut Department of Public Health New Mandate Regarding STEMI Patients

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel Malloy
Governor

Date: January 23, 2012

To: EMS Chiefs of Service
EMS Medical Directors
EMS Pre-hospital Care Coordinators
CMED/Regional Communication Centers

From: Jewel Mullen, MD, MPH, MPA, and Commissioner

Re: DPH Policy Guidance for STEMI patients

The Department of Public Health approved the attached ST Elevation Myocardial Infarction (STEMI) guidelines to close gaps that may delay appropriate treatment for STEMI patients. Connecticut's Emergency Medical Services (EMS) Advisory Board and Medical Advisory Committee collaborated to develop this guidance.

The goals of the guidance are to ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI, thereby increasing the likelihood they will be transported for treatment with percutaneous coronary intervention within 90 minutes of first medical contact.

PHONE: (860) 509-7101 FAX: (860) 509-7111
410 CAPITOL AVENUE - MS#13COM, P.O. BOX 340308, HARTFORD, CONNECTICUT 06134-0308

Connecticut EMS STEMI Guideline

CEMSMAC 2011

Goals:

Authorized transporting EMS personnel obtain a 12-lead ECG in the field on all patients with suspected Acute Coronary Syndrome.

ECG findings are obtained by properly trained, equipped and authorized EMS personnel and communicated to direct medical oversight via paramedic interpretation, automated computer algorithm interpretation, wireless transmission with subsequent physician interpretation or any combination of these three strategies to the receiving hospital.

Goal – to receive primary PCI within 90 minutes from first medical contact.

Definitions: patient with STEMI

1. Active chest pain or equivalent symptoms (nausea, SOB)
2. 12-lead ECG of good quality showing STEMI:
    a. ST-elevation
        i. ≥2 mm in 2 contiguous leads (V1-V4) and/or
        ii. ≥1 mm in 2 contiguous leads (limb, lateral)
    b. QRS duration ≤0.12 seconds
    c. ***Acute MI*** or equivalent prints on 12-lead ECG; paramedic agrees
3. No major bleeding (e.g., vomiting frank blood)
4. No significant trauma

Guidelines:

1. Transport patients with prehospital-diagnosed STEMI (as defined above) according to the following protocol:
    a. <30 min transport time interval
        i. Directly to a primary PCI hospital under direct or indirect medical oversight
    b. ≥30 min transport time
        ii. Decision regarding appropriate destination hospital should be made in conjunction with indirect and/or direct medical oversight

2. Interfacility transfer
   a. Non-PCI hospitals should have an established process developed to ensure timely transfer of STEMI patients to a PCI center. Interfacility transfer care should be in conjunction with direct and/or indirect medical oversight, consistent with local EMS policies and protocols.

3. If anticipated time to primary PCI > 90 minutes, administration of fibrinolytic therapy at a non-PCI capable hospital, for fibrinolytic-eligible patients

Approved by CEMSMAC 3/11
Approved by CT EMS Advisory Board and referred back to CEMSMAC for reconciliation. 5/11.
Board position accepted by CEMSMAC. 9/11

Attachment L

New Policy Guideline from Backus EMS Regarding Transfer of Patients with STEMI to Facility Capable of Performing Primary PCI

From: Potter, Fred [mailto:FPotter@wwbh.org]
Sent: Thursday, January 26, 2012 3:16 PM
Subject: WWBH - STEMI Guidance ALS

Hello,

As you are probably already aware, a subject that we've been talking about for some time now has been addressed yesterday by the State. A communication was issued yesterday by Dr. Jewell Mullen, Commissioner of Public Health titled *"DPH Policy Guidance for STEMI Patients"* that deals with the destination hospital of ST Elevation Myocardial Infarctions (STEMI's) which along with the actual CEMSMAC Guideline is attached. Dr. McClaine & I have thoroughly analyzed the guidance from Commissioner Mullen, and we feel that it must be followed, effective immediately.

The guideline has defined a STEMI as:

1) Active chest pain or equivalent symptoms (nausea, SOB)
2) 12-lead ECG of good quality showing STEMI:
    i) ST-elevation
        (a) 2 mm in $\geq$2 contiguous leads (V1-V4) and/or
        (b) 1 mm in $\geq$2 contiguous leads (limb, lateral)
    ii) QRS duration $\leq$0.12 seconds
    iii) ***Acute MI*** or equivalent prints on 12-lead ECG; paramedic agrees
3) No major bleeding
4) No significant trauma

Our analysis is that patients with a pre-hospital diagnosed STEMI (by a paramedic or a physician) requires the following action: That if the transport time to a hospital capable of primary percutaneous coronary intervention (PCI) is less than 30 minutes, you must transport the patient there. The hospitals capable of this procedure that affect Backus sponsored services include Lawrence & Memorial Hospital, Hartford Hospital, & St. Francis Hospital. If the Transport time is 30 minutes or longer, you should transport to the closest appropriate hospital just as you do now.

While compliance with this guidance from the CT DPH Commissioner is your responsibility, we've done some research based on station location utilizing Google directions. We've found the following stations fall within the 30 minute requirement (Lawrence & Memorial):

Mohegan 20 min
East Great Plain (Norwich) 22 min
Mohegan Sun 24 min
Laurel Hill (Norwich) 24 min
Oakdale 25
Salem 26 min
Yantic (Norwich) 26 min
Bozrah 27 min

Taftville (Norwich) 29 min
Foxwoods 30 min

Basically, it appears that everything in Norwich and south is under 30 minutes of Lawrence & Memorial Hospital. However, you may have to rely on the BLS crews in the individual Towns if you have any question.

Colchester to Hartford Hospital is 27 minutes, & 29 minutes to St. Francis Hospital.

Lawrence & Memorial: Contact Station "W" on Med 9. Request a "Code PCI" early in your patch
Hartford Hospital/St. Francis Contact North Central CMED on Med 10

Please note: This guidance is only for pre-hospital diagnosed STEMI's, not for other ST deviations (ie: ST-depression) and not simply chest pain. *Therefore, there must be a STEMI diagnosed by either a paramedic or a physician for this guideline to apply.* Otherwise, you should follow the same criteria that you currently use (closest hospital or patient choice.) We will be doing a 100% case review of all STEMI's.

Additionally, Lawrence & Memorial Hospital has offered to provide a training session on PCI's one evening in the near future which will also include a tour of their cardiac catheterization lab (which of course we will give full CME credit for.) We'll share that information with you once it is set up.

If you should have any questions about this, please feel free to contact either Dr. McClaine or myself.

Fred K. Potter; Paramedic, EMSI
EMS Coordinator
The William W. Backus Hospital
326 Washington Street
Norwich, CT 06360
860-889-8331 x4455
Fax: 860-892-2744
http://www.backushospital.org/ems.html

Attachment M

Curriculum Vitae

Lawrence & Memorial Hospital

President / Chief Executive Officer

Bruce D. Cummings

Mr. Cummings was named Chief Executive Officer at Lawrence & Memorial Hospital on October 31, 2005. Prior to that, he served as President and Chief Executive Officer of Olean General Hospital in Olean, New York. From September 1990 to March 2002, Mr. Cummings served as the CEO of Blue Hill Memorial Hospital in Maine. Mr. Cummings also spent 10 years at Mid-Maine Medical Center in Waterville, Maine as Director of Ambulatory Care; and from November 1985 to 1990 as Vice President for Strategic Planning, Marketing and Corporate Development. From 1978 to 1980, Mr. Cummings served as the City of Danbury's first full-time Director of Health.

Mr. Cummings received a Bachelor of Arts in Sociology from Colby College and a Master of Public Health degree from Yale University School of Medicine, Department of Epidemiology and Public Health. He is board-certified in healthcare management through the American College of Healthcare Executives, a member of the Board of Directors of the Connecticut Hospital Association, a director of the Visiting Nurse Association of Southeastern Connecticut, and a delegate to the American Hospital Association's Regional (New England) Policy Board.

Daniel Rissi, MD
365 Montauk Avenue
New London, CT 06320
(860) 442-0711

Professional Experience

Febuary 2008 to present; Lawrence & Memorial Hospital; Vice President/Chief Medical & Clinical Operations Officer
June 2006 to February 2008; Lawrence and Memorial Hospital; Vice President and Chief Operating Officer
October 2005 to January 2006; Olean General Hospital; Interim President and Chief Executive Officer
January 2003 to June 2006; Olean General Hospital; Vice President for Medical Affairs
March 2002 to August 2002: Blue Hill Memorial Hospital; Interim Chief Executive Officer
1990 to 2002: Blue Hill Memorial Hospital; Medical Director (full time since 1998); Chief of Staff
1996 to 2002: Maine Network for Health; Medical Director (1998-2002)

Additional Professional Activities

2003-2006: Olean General Hospital, Olean, New York; active medical staff
1980-2003: Blue Hill Memorial Hospital, Blue Hill, Maine; active medical staff
1980-2003: Eastern Maine Medical Center, Bangor, Maine; affiliate medical staff
1980-1994: Island Medical Center Doctors, Stonington, Maine; physician, managing partner

Education and Training

American Board of Family Medicine; certified 1980, recertified 1986,1992, 1998, 2004
Certificate of added Qualification in Geriatrics, AAFP; certified 1988; recertified 1998
Medical Review Officer; certified by AAMRO 2003
Aviation Medical Examiner (FAA); certified 1981, recertified 1986, 1991
State of Maine Medical Examiner; certified 1977
1977-1980 Eastern Maine Medical Center; Residency in Family Medicine
1973-1977 Johns Hopkins University School of Medicine; MD
1969-1973 Yale University; BA

Professional Memberships

American College of Physician Executives; member since 1996
American Academy of Family Physicians; member since 1980; Fellowship 1994
American Geriatrics Society; member since 1989
National Board of Medical Examiners; diplomate 1977
American College of Healthcare Executives; member since 2006

Lawrence & Memorial Hospital

Vice President / Chief Financial Officer

Lugene Inzana, MBA, CPA

Mr. Inzana became Vice President/Chief Financial Officer at Lawrence & Memorial Hospital in January 2008. Prior to joining Lawrence & Memorial, he served as Vice President of Finance/CFO 2004-2007 at Olean General Hospital, a 186 bed Rural Referral Center located in Olean, NY. From 2002-2004, Mr. Inzana was Vice President Finance – MIS/CFO at Jones Memorial Hospital in Wellsville, NY. From 1991 to 2002 he served as Controller of Olean General Hospital and from 1989 to 1991 he served as Controller of St. Francis Hospital in Olean, NY.

Mr. Inzana holds an Associate's Degree in Accounting from the State University of New York, a Bachelors Degree in Accounting and a Masters Degree in Finance, both from St. Bonaventure University and is a Certified Public Accountant.

Mr. Inzana is the Past President of the Western New York Chapter of Healthcare Financial Management Association, representing approximately 200 financial executives across Western New York.

PAMELA J. KANE, MBA
83 Hewitt Road
Mystic, CT 06355
Residence: 860.415.9538
Cellular: 860.235.9538
Email: kanesfive@gmail.com

EDUCATION

2009 — MBA-Whittemore School of Business and Economics
University of New Hampshire, Durham, New Hampshire

2002 — Health Policy and Management courses, Muskie School of Public Service
University of Southern Maine, Portland, Maine

1991 — BS-Business Administration, Minor: English (Cum Laude)
Whittemore School of Business and Economics
University of New Hampshire, Durham, New Hampshire

PROFESSIONAL EXPERIENCE

03/2010 To Present — **LAWRENCE & MEMORIAL HOSPITAL**, New London, Connecticut
(A not-for-profit, general, acute care, private hospital serving the residence of Eastern Connecticut, Fisher's Island New York and Southern Rhode Island)

Vice President of Physician Practice Management (03/2010 to present)
Executive Director, L&M Physician Assoc./Associated Specialist of Southeastern CT

Responsibilities: Senior executive responsible for managing hospital owned physician practices; practice held by Associated Specialist of Southeastern Connecticut, a subsidiary of the Hospital; and L&M Physician Association, a not-for-profit medical group practice which is a subsidiary of Lawrence and Memorial Corporation and "sister" entity to the Hospital.

- Effectively recruit and retain physicians interested in health system employment
- Utilize analytical, operation, and financial infrastructure necessary and sufficient to successfully operate the practices in a fiscally sound manner
- Provide appropriate, timely date and other feedback to employed physicians in a manner which advanced the provision of safe, high quality, cost-effective care
- Hire, direct, evaluate, and compensate the management and support personnel who support the practices
- As a member of the hospital Senior Management Group, participate in strategic planning and annual system wide initiatives to further the success of the health system

06/1998 to 03/2010 — **CHEST MEDICINE ASSOCIATES**, Portland, Maine
(A professional services corporation providing healthcare within the specialties of pulmonary, critical care and sleep medicine serving Southern Maine)

Practice Administrator (01/1004 to 03/2010)

Responsibilities: Management of various service lines utilizing thirty two providers, including seventeen employed physicians, fifteen subcontracted critical care electronic intensive care unit (eICU) physician specialists, and a nurse practitioner. Serve on the

Board of Directors, Executive Committee and Finance Committee, report to the organization's President.

Accomplishments:

- Negotiated and participated in formulation of proposal resulting in 15% and 17% remuneration increases in the 2008 and 2009 professional services agreements with a partner healthcare system.
- Selected and implemented Electronic Health Record automated monitoring and submission of pulmonary medicine related CMS PQRI (Physician Quality Reporting Initiatives), as well as additional quality measures leading to awards and monetary recognition from the Community Physicians and Hospital Organization.
- Gained a 25% increase in provider efficiency and a 62% decreased in patient no-shows with an enhanced and thorough pre-evaluation process.
- Created the criteria and directed the software programming of a customized electronic Balance Scorecard to provide daily status updates on pertinent quality and productivity measures resulting in continuous advances toward targeted goals.
- Improved patient average length of time in days between a request for a consultation with a physician and the third available appointment by 37.5% without increasing providers.
- Successfully reached the prior twelve month's recruitment goal of hiring four physicians and one nurse practitioner with a more innovative compensation package and employment structure.

Practice Manager (06/1998 to 12/2003)

Responsibilities: Direct the day to day operations of two outpatient facilities as well as two satellite clinics.

Accomplishments:

- Facility lease negotiation, plan design and move for outpatient satellite office.
- Reduced transcription costs by close to 50% and reduced turn-around time from over one month to less than one week.
- Acquired new practice management system which facilitated electronic claims submission and provider scheduling allowing for a 23% growth in activity without increasing staff.
- Added a pulmonary function lab which was at 85% capacity and profitable within the first few months of operations due to improved processes increasing access.

PRIOR EXPERIENCE

04/1994 to 05/1998 — **OBOC**, South Portland, Maine
(Fitness services and products provider)
Owner/Operator

Entrepreneurial accomplishments:

- Secured a trademark patent for fitness apparel and services.
- Opened first Spinning© studio in the State of Maine.

04/1994 to 05/1998 — **JKLC**, South Portland, Maine
(Landscape business)
Operations Manager

12/1992 to 04/1994 — **CBE TECHNOLOGIES, INC.**, Boston, Massachusetts
(Information Technology solutions company)
Technical Support Coordinator

09/1991 to 08/1992 **WANG LABORATORIES, INC.,** Lowell, Massachusetts
(Computer hardware manufacturer)
Regional Support Specialist –Personal Computer Division

PROFESSIONAL AFFILIATIONS

American College of Healthcare Executives (ACHE)
American College of Chest Physicians (ACCP)
Medical Group Management Association (MGMA)
Connecticut Medical Group Management Association (CMGMA)

AWARDS

2009 Beta Gamma Sigma (honor society of business programs accredited by AACSB)
2009 Golden Key International Honor Society

REFERENCES

Available Upon Request

Brian Christopher Cambi, MD FACC FSCAI

2 Rocco Drive
East Lyme, CT 06333
860-691-0619 (Home)
203-623-3988 (Cell)
203-370-2177 (Beeper)
brian.cambi@yale.edu

EMPLOYMENT

2008 - **Assistant Professor**
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

- ***Director*** – Primary Angioplasty Program at Lawrence and Memorial Hospital
- ***Director*** – Stress Echocardiography at Lawrence and Memorial Hospital

2007-2008 **Attending Cardiologist**
West Haven Veteran's Administration Hospital

2007-2008 **Clinical Instructor**
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

PROFESSIONAL TRAINING

2006-2007 **Advanced Fellowship in Interventional Cardiology.**
Yale University School of Medicine, New Haven, CT

2005-2006 **Advanced Fellowship in Non-invasive Cardiac Imaging.**
Yale University School of Medicine, New Haven, CT

- Level II training in echocardiography
- Level II training in nuclear cardiology

2003-2005 **Clinical Cardiology Fellowship.** Yale University School of Medicine.

2002-2003 **Chief Resident, Internal Medicine**. Yale University School of Medicine.

1999-2002 **Intern and Resident, Internal Medicine**. Yale University School of Medicine.

EDUCATION

1995-1999 Doctor of Medicine, State University of New York at Buffalo, School of Medicine and Biomedical Sciences, Buffalo, NY.
- ***Summa Cum Laude***

1991-1995 Bachelor of Science, Biology. The College of William and Mary, Williamsburg, VA.
- ***Magna Cum Laude***

LICENSURE AND CERTIFICATION

2007 Board certified - Interventional Cardiology
2006 Board certified - Cardiology
2006 Board certified - Nuclear Cardiology
2006 Board certified - Echocardiography
2002 Board certified - Diplomate, American Board of Internal Medicine.

ACADEMIC ACTIVITIES

2006 Speaker, Grand Rounds, Cardiology. Yale University School of Medicine.
- "CT Angiography: A Novel Clinical Application"

2005-2006 Research: CT Angiography in the Non-Invasive Detection of Revascularizable Cardiomyopathy.

2002-2003 Director, Morbidity and Mortality conference. Yale University School of Medicine, Section of Internal Medicine.

HONORS AND AWARDS

1999 **The John Watson Award in Medicine.** SUNY at Buffalo School of Medicine.
- Outstanding achievement and leadership in Internal Medicine

1999 **Association of Pathology Chairs Award**. SUNY at Buffalo School of Medicine.
- Academic excellence in Pathology

1998 **Alpha Omega Alpha Honor Medical Society**. SUNY at Buffalo School of Medicine.

1997 **James Gibson Anatomical Honor Society**. SUNY at Buffalo School of Medicine.
- Academic excellence in Gross Anatomy

1995 **Phi Sigma National Honor Society**. The College of William and Mary.
- Academic excellence in biology

REFERENCES – *available on request*

40 Courtland Drive
Groton, CT 06340

(C) 860 908-9657
(W) 860 442-0711 X 5078
E-Mail Maxgorski@att.net

Max J. Gorski

Summary

Over twenty years of progressive management experience in health care and human services, supported by graduate degrees in Rehabilitation Services and Business Administration. Work experience includes but is not exclusively limited to: strategic planning and program development, budget preparation and fiscal management, facility and human resource administration, quality improvement and program evaluation, marketing, public relations and fundraising, contracting, grant writing, advocacy, accreditation and licensure.

Experience

03/2000 – present — **Lawrence & Memorial Hospital**
New London, Connecticut

Director of Patient Care Services within a 280 bed multi-service community hospital, serving the southeastern region of Connecticut. Responsibilities include administrative oversight of four clinical service lines with over 200 employees and a combined operating budget in excess of $50M.

07/99 – 02/2000 — **Horizon Mental Health Management, Inc.**
Lewisville, Texas

Interim Program Director for behavioral health services at ***North Adams Regional Hospital*** in North Adams, Massachusetts.

02/97 - 06/99 — **Orange County ARC, Inc.**
Anaheim, California

Vice-President Specialized Programs for this fifty year old non-profit habilitation organization which provides vocational and educational services to adults diagnosed with a developmental disability, residing in the greater Orange County area.

01/95 - 01/97 — **Chestnut Hill Mental Health Center, Inc.**
Greenville, South Carolina

President/Chief Executive Officer for a proprietary owned, for profit, 88 bed, inpatient/outpatient hospital and residential treatment facility, offering comprehensive psychiatric and substance abuse services to children, adolescents, adults and geriatric patients.

12/90 - 1/95 — **Harbor Foundation, Inc.**
Harbor City, California

President/Chief Executive Officer for this fifty five year old non-profit human service organization which provides educational and vocational services to developmentally challenged children and adults residing in the greater South Bay area of the city of Los Angeles.

09/89 - 12/90 — **Horizon Mental Health Management, Inc.**
Lewisville, Texas

Program Director for behavioral health services located at ***Coastal***

Communities Hospital in Costa Mesa, CA.

10/87 - 08/89 **Monarch Health Corporation, Inc.**
Marblehead, Massachusetts

Administrative Director for the Department of Psychiatry at ***Saint Vincent Hospital***, a 568 bed affiliated teaching hospital of the University of Massachusetts Medical School, in Worcester, Massachusetts. The department consisted of a 20 bed, secure unit and a 31 bed, adult unlocked unit. Additionally, outpatient and crisis intervention services are offered.

07/84 - 09/87 **Mental Health Management, Inc.**
McLean, Virginia

Program Manager for the adult inpatient psychiatric program at ***Noble Hospital in Westfield, Massachusetts***. The program consists of a 20 bed secure unit located within a 162 bed acute care general hospital.

07/79 – 07/84 **Greater Enfield ARC, Inc.**
Enfield, Connecticut

Program Administrator for the Counseling and Placement Center, a supported work program serving a six town area with a population of over 1200 developmentally challenged children, adolescents and adults.

1980 - 1981 **Chicopee Boy's Club**
Chicopee, Massachusetts

Residential Manager for a group home housing six developmentally challenged adolescent boys

1977 - 1980 **Chicopee Boy's Club**
Chicopee, Massachusetts

Residential Aid (part time) for a group home housing seven developmentally challenged children

1976 - 1977 **Friend's of the Retarded, Inc.**
Chicopee, Massachusetts

Production Supervisor for 15 developmentally challenged adults in a sheltered workshop setting.

Education

MBA - Marketing/Finance **American International College**
Springfield, Massachusetts

M.Ed. – R ehabilitation Services **Springfield College**
Springfield, Massachusetts

BA - Rehabilitation Services **Springfield College**
Springfield, Massachusetts

CURRICULUM VITAE

Name: Gerry Mulholland
Address: 21 Milton Road
Quaker Hill, Ct. 06375
Telephone: Work 860 442-077 x2699
Email: gmulholland@lmhosp.org

Professional Education:

MSN
University of Rhode Island
Kingston, Rhode Island 02881
September 1978 - May 1981

BSN
University of Connecticut
Storrs, Connecticut 06268
January 1973 - May 1976

Diploma
Hospital of St. Raphael's School of Nursing
New Haven, Connecticut 06500
September 1967 - June 1970

Professional Work Experiences:

May 1989 - Present	Manager, Invasive & Non Invasive Cardiology Lawrence & Memorial Hospital New London, Connecticut 06320
June 1980 - May 1989	Critical Care Instructor Staff Development Department Lawrence & Memorial Hospital
July 1978 - June 1980	Staff Nurse, ICU Lawrence & Memorial Hospital
Dec. 1976 - July 1978	Staff Nurse, ICU Hospital of St. Raphael New Haven, Connecticut 06500

Jan. 1973 - Dec. 1976	IV and ICU Nurse (PT) (To complete BSN)	Lawrence & Memorial Hospital
Sept. 1972 - Jan. 1973	Assistant Head Nurse, ICU	Lawrence & Memorial Hospital
July 1970 - Sept. 1972	Staff Nurse, ICU	Lawrence & Memorial Hospital

Memberships:

1. Sigma Theta Tau
2. American Association of Critical Care (AACN)
3. American Nurses Association (ANA)
4. Heart Rhythm Society (HRS)
5. Affiliate member of American College of Cardiology (ACC)
6. American Organization of Nurse Executive (AONE)
7. Association of perioperative Registered Nurses (AORN)

Certificates:

1. Coronary Care Nursing Completed 1971
2. Respiratory Care Nursing Completed 1971
3. Nursing Management from Fairfield University Completed in December 1988.

Certifications:

1. Certified in Adult Critical Care Nursing (CCRN)
2. Certified in AHA Basic Cardiac Life Support (BCLS)
3. Certified in AHA Advanced Cardiac Life Support (ACLS)
4. Certified Nurse Manager and Leader AONE (CNML)

Lectures + Publications:

1. Mulholland, Gerry. Pocket Guide in 12-Lead ECG Interpretation. Williams & Wilkins.1998 (Textbook)

2. Mulholland and Brewer. Improving Your Skills in 12-Lead ECG Interpretation. Williams & Wilkins. 1990. (Textbook)

3. "The Role of the IABP in a Community Hospital" presented at the National Teaching Conference of the American Association of Critical Care Nurses May 1987 in New Orleans. (Lecture)

4. Regional Advanced Cardiac Life Support Resource Consortium Concept" presented at the Emergency Cardiac Care Conference on ACLS Education June 15-16,1984 in Providence, R.I. (Lecture)

Attachment N

National Cardiovascular Data Registry Measures for L+M

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.99	1.51	0.78

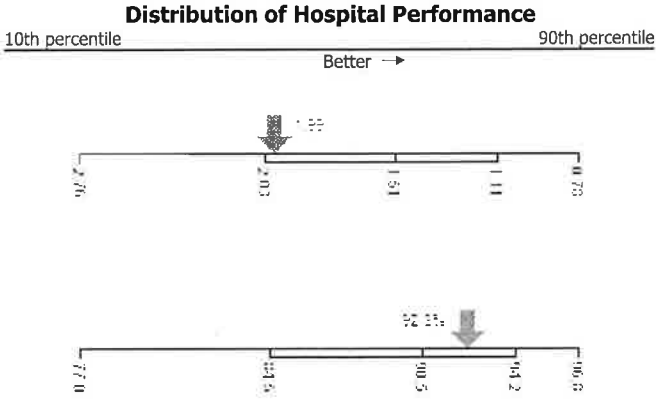
Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2017]

38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.3%	90.5%	96.8%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:1988]

Distribution of Hospital Performance



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.

Aggregation Date: Apr 16, 2012 11:59:59 PM
Publish Date: May 11, 2012

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	60.0%	80.6%

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:1513]

3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
57.0	62.5	50.0

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:1502]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90"**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.2%	91.9%	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:1503]

5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	83.7	55.2

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
44.5	115.2	83.2

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:1506]

7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.5	9.2	6.8

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:1633]

8 **Proportion of patients with aspirin prescribed at discharge**

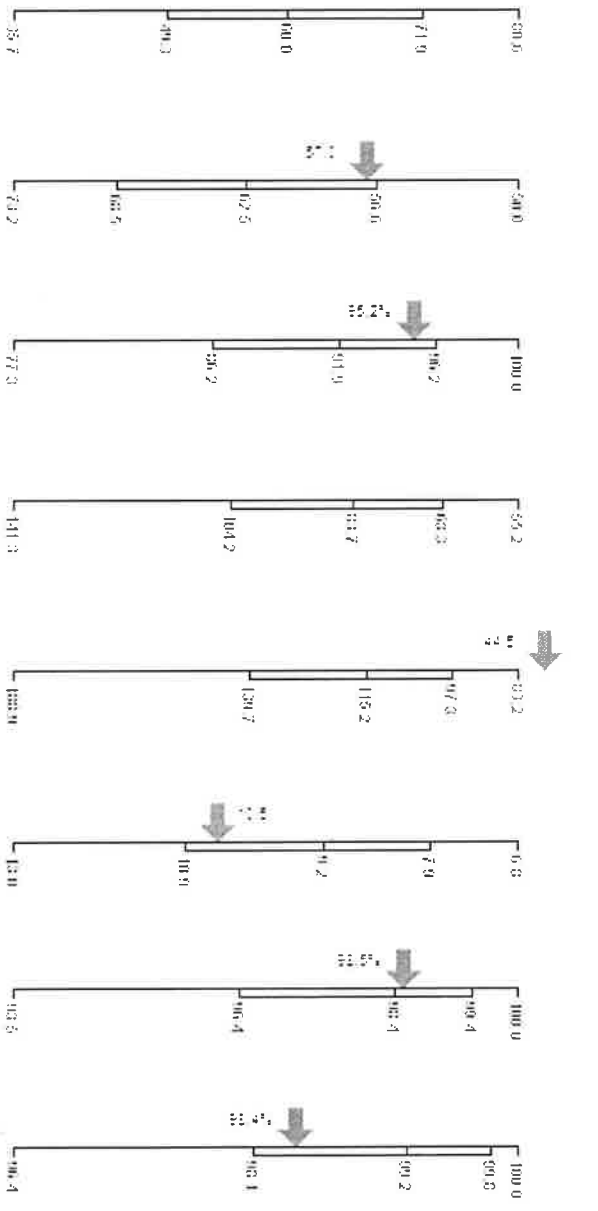
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.5%	98.4%	100.0%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1978]

9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.4%	99.2%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:1987]



Aggregation Date: Apr 16, 2012 11:59:59 PM
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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.3%	92.5%	97.7%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:1983]

PCI Outcome Metrics

Distribution of Hospital Performance

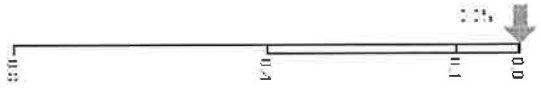
10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

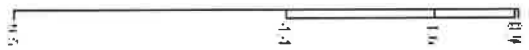
Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1960]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.6%	0.0%

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:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

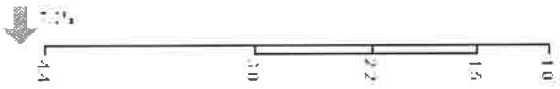
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.5%	0.0%

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:1804]

15 **Proportion of PCI procedures with acute kidney injury*****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.0%	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:1952]



16 **Proportion of PCI procedures with post procedure stroke**

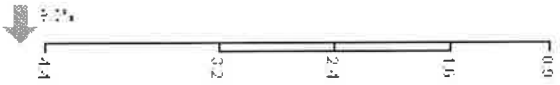
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.3%	0.0%	0.0%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]

17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9.0%	2.4%	0.9%

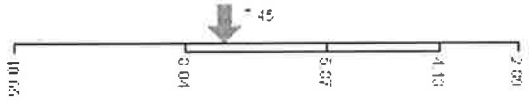
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.45	5.87	2.89

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2026]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.89	0.72	0.31

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:2035]

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

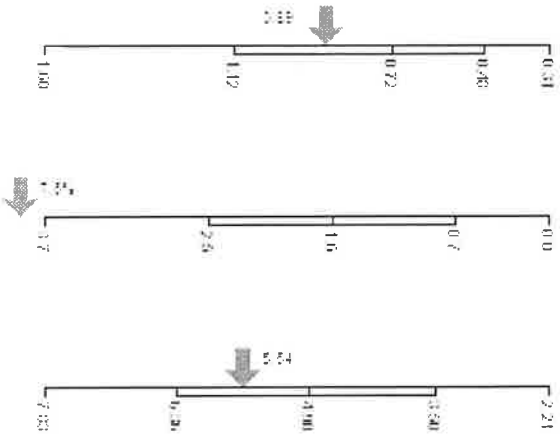
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.6%	1.6%	0.0%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
5.64	4.90	2.21

Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]

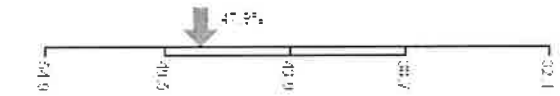


Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
47.9%	43.9%	32.1%

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]

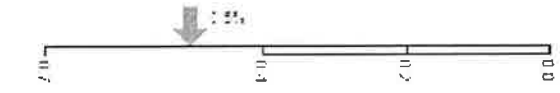


Diagnostic Cath Outcomes Metrics

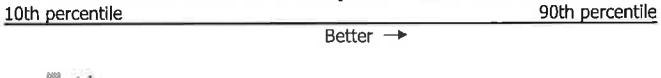
21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.5%	0.2%	0.0%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



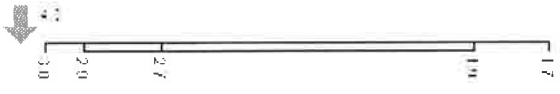
Utilization Metrics



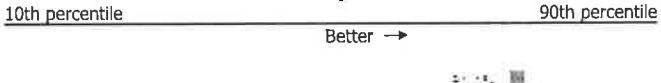
22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.0	2.7	1.7

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2091]



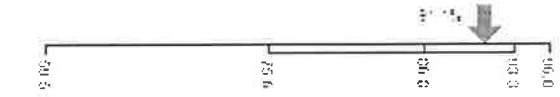
Data Quality Metrics



24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
91.1%	86.8%	96.0%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



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Executive Summary

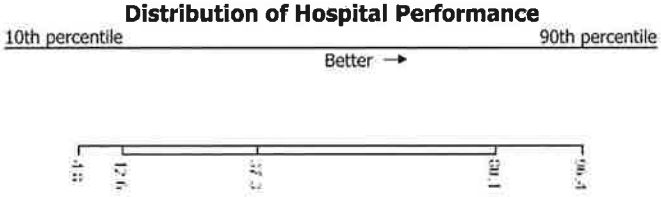
CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

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



26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	37.3%	96.4%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

Section III: PCI Appropriate Use Criteria (AUC) 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 metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level. PCI AUC metrics are not appropriate for public/external reporting.

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

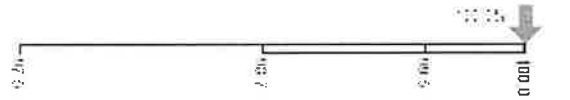
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	10.2%	2.3%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	99.5%	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:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

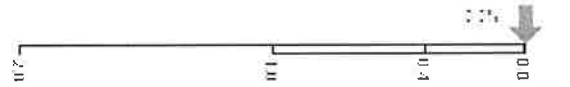
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.6%

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:1582]

33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.4%	0.0%

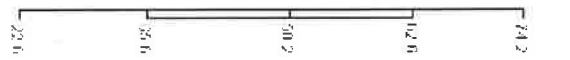
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	50.2%	74.2%

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:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	38.0%	60.5%

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:1586]

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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2011Q4

Section III: PCI Appropriate Use Criteria (AUC) 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 metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level. PCI AUC metrics are not appropriate for public/external reporting.

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	9.1%	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:1587]

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.

Aggregation Date: Apr 16, 2012 11:59:59 PM
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Attachment O

Documentation of Non-Profit Status

Internal Revenue Service

Department of the Treasury

Washington, DC 20224

Person to Contact:

Telephone Number:

Refer Reply to:
OP:E:EO:R:3-CCH

Date:
FEB 27 1985

Lawrence and Memorial Hospitals
365 Montauk Avenue
New London, CT 06320

Employer Identification Number: 06-0646704

Legend:

M = Lawrence and Memorial Hospitals
N = Lawrence and Memorial Corporation
O = Lawrence and Memorial Foundation, Inc.
P = L & M Health Care, Inc.
Q = L & M Systems, Inc.

Dear Applicant:

This letter is in reference to your joint request for rulings, with three other organizations, regarding a proposed corporate reorganization and proposed transactions relating thereto.

Currently, M, N, O, and P are organizations recognized as exempt from federal income tax under section 501(c)(3) of the Internal Revenue Code. M is a public charity described in sections 170(b)(1)(A)(iii) and 509(a)(1) of the Code. N is a supporting organization described in section 509(a)(3). O is a public charity described in sections 170(b)(1)(A)(vi) and 509(a)(1). P is a public charity described in section 509(a)(2). Q is a for-profit organization.

M is a voluntary and not-for-profit hospital considering a reorganization. M's plan of reorganization is proposed in order to:

(1) assure M's continued leadership role in the community and continued capacity to provide patient care at a lower cost;

(2) facilitate compliance with governmental reporting requirements;

(3) segregate hospital assets from non-hospital assets so as to limit third party liability;

(4) separate regulated and non-regulated activities;

(5) isolate unrelated business activities from exempt activities;

(6) remove the management of non-hospital activities and assets from hsopital management;

(7) increase investment opportunitites;

(8) improve recruitment opportunities;

(9) increase flexibility in undertaking capital expenditure projects; and

(10) facilitate long range planning.

After the proposed reorganization, M, N, O, P, and Q will, as a group, conduct the activities formerly conducted by M alone.

In order to implement the proposed reorganization, M will amend its organizing instruments to designate N as its sole member. M will continue to operate the general acute care hospital and provide medical and hospital care. N was formed to benefit, perform the functions of, carry out the purposes of, and uphold, promote, and further the welfare, programs, and activities of M. All of N's members are currently persons who are members of M. In the future, a majority of N's trustees will also be trustees of M. N will function as the parent corporation in the new structure and will provide overall direction and control to M, O, P, and Q.

O was formed to assist M, N, and other section 501(c)(3) organizations associated with M and N, by soliciting and receiving contributions, grants, donations, bequests, and devises, and to make distributions to such organizations for proper purposes. P was formed, among other purposes, to operate and maintain programs directed toward improving the efficiency of utilization of health care facilities, including the education for health professionals, the public, nursing, and residency training, and delivery of health care services. P may assume certain of the outpatient medical care programs or community health education programs previously performed by M, as well as outpatient programs unexplored by M. N is the sole member of both O and P.

Q is a stock corporation with N as its sole shareholder. Q's primary purpose is to render health care related and other services which M has avoided since such services would constitute an unrelated business activity. It is not anticipated that M, N, O, or P will provide any services to Q, but if services are provided, an arm's-length fee will be charged.

M will transfer sufficient cash to provide working capital to N, O, and P at the consummation of the reorganization. Following the initial transfer, it is anticipated that there will be further cash transfers among the exempt organizations. M may also transfer philanthropic monies previously raised

by M to O on the condition that O hold these dollars in a separate, segregated fund that will be used solely for the benefit of M. After the reorganization, M, N, O, and P will share some assets, personnel, and services in an effort to reduce, through economies of scale, the overall cost of providing health care services. To the extent there are transactions between the exempt organizations and Q, such transactions will be conducted on an arm's-length basis and it is anticipated that the charges for goods or services provided in connection with such transactions would be at fair market value.

Section 501(c)(3) of the Code provides for the exemption from federal income tax of organizations that are organized and operated exclusively for charitable purposes.

Section 1.501(c)(3)-1(d)(2) of the Income Tax Regulations provides that the term "charitable" is used in section 501(c)(3) of the Code in its generally accepted legal sense. In the law of charity, the promotion of health is considered to be a charitable purpose.

Section 509(a)(1) of the Code provides that organizations described in section 170(b)(1)(A) (other than in clauses (vii) and (viii)) are excepted from classification as private foundations.

Section 170(b)(1)(A)(iii) of the Code, in part, describes an organization the principal purpose or functions of which are the providing of medical education or medical research, if the organization is a hospital.

Section 170(b)(1)(A)(vi) of the Code describes an organization which normally receives a substantial part of its support (exclusive of income received in the exercise or performance by such organization of its charitable, educational, or other purpose or function constituting the basis for its exemption under section 501(a)) from a governmental unit referred to in section 170(c)(1) or from direct or indirect contributions from the general public.

Section 1.170A-9(e)(6)(ii) of the regulations provides that unusual grants may be excluded from the calculation used to determine whether an organization is normally supported by direct or indirect contributions from the general public. Section 1.170A-9(e)(6)(iii) provides that all pertinent facts and circumstances will be taken into consideration to determine whether a particular contribution may be excluded.

Section 509(a)(2)(A) of the Code provides that an organization which normally receives more than one-third of its support from any combination of gifts, grants, contributions, or membership fees; and gross receipts from admissions, sales of merchandise, performance of services, or furnishing of facilities, in an activity which is not an unrelated trade or business, is excepted from classification as a private foundation.

Lawrence and Memorial Hospitals

Section 509(a)(3) of the Code, in part, provides for exception from classification as private foundations for organizations organized and operated exclusively for the benefit of, to perform the functions of, or to carry out the purposes of organizations described in section 509(a)(1), and which are operated, supervised, or controlled by or in connection with one or more organizations described in section 509(a)(1).

Section 511(a) of the Code imposes a tax on the unrelated business taxable income of organizations described in section 501(c).

Section 512(a)(1) of the Code defines the term "unrelated business taxable income" as the gross income derived by any organization from any unrelated trade or business regularly carried on by it, less certain allowable deductions and modifications. Section 512(b)(1) provides that dividends are excluded from this definition.

Section 513(a) of the Code defines the term "unrelated trade or business" as any trade or business the conduct of which is not substantially related (aside from the need of such organization for income or funds or the use it makes of the profits derived) to the exercise or performance by such organization of the functions constituting the basis for its exemption.

Section 1.513-1(d)(2) of the regulations provides that trade or business is "related" to exempt purposes, in the relevant sense, only where the conduct of the business activities has causal relationship to the achievement of exempt purposes; and it is "substantially related" only if the causal relationship is a substantial one. The regulation continues that for the conduct of trade of business from which a particular amount of gross income is derived to be substantially related to purposes for which exemption is granted, the production or distribution of the goods or the performance of the services from which the gross income is derived must contribute importantly to the accomplishment of those purposes.

Section 514 of the Code provides for the taxation under section 512 of income from debt-financed property. Section 514(b)(1)(A)(i), however, provides that the definition of debt-financed property does not include any property substantially all the use of which is substantially related to the exercise or performance by such organization of its charitable purpose constituting the basis for its exemption under section 501.

Subsequent to the proposed reorganization and transfer of activities and funds, M, N, O, and P will operate exclusively for the charitable purpose of promotion of health within the meaning of section 501(c)(3) of the Code. The transfers and sharing of assets, personnel, and services described, in themselves, will have no adverse effect on a determination of exempt status or exception from private foundation status.

Further, the proposed transfers and sharing of assets, personnel, and services do not involve the regular carrying on of unrelated trade or business within the meaning of section 513 of the Code, and do not involve the use of assets other than substantially in furtherance of exempt purposes within the meaning of section 514.

Based on the above, we rule as follows:

(1) M, after its amendments of its organizing instruments and the proposed reorganization, will continue to qualify as an organization described in sections 501(c)(3), 509(a)(1), and 170(b)(1)(A)(iii) of the Code.

(2) N, after the proposed reorganization, will continue to qualify as an organization described in sections 501(c)(3) and 509(a)(3) of the Code.

(3) O, after the proposed reorganization, will continue to qualify as an organization described in section 501(c)(3) of the Code and, provided the requisite public support is received, sections 509(a)(1) and 170(b)(1)(A)(vi).

(4) P, after the proposed reorganization, will continue to qualify as an organization described in section 501(c)(3) of the Code and, provided it meets the support tests thereunder, section 509(a)(2).

(5) N's ownership of 100% of the issued and outstanding voting stock of Q and N's receipt of dividends from Q will have no adverse effect on N's status under sections 501(c)(3) and 509(a)(3) of the Code, and the taxable income of Q will not be construed to be unrelated business income to N.

(6) The proposed transfers of cash and other assets and the sharing of personnel, services, facilities, and expenses by and between M, N, O, and P will not:

(a) jeopardize the continued status of M, N, O, and P as organizations described in section 501(c)(3) of the Code;

(b) adversely affect the status of M, N, O, and P as organizations described in section 509(a); or

(c) give rise to unrelated business taxable income under sections 511-514 to M, N, O, or P.

(7) M's transfer of philanthropic monies to O will qualify as an unusual grant within the meaning of section 1.170A-9(e)(6)(ii) of the regulations and may be excluded from the calculation used to determine public support for purposes of section 170(b)(1)(A)(vi) of the Code.

(8) After the amendments to M's organizing instruments and the proposed reorganization, contributions to M, N, O, and P will continue to be deductible by donors as provided in section 170 of the Code.

These rulings are based on the understanding that there will be no material changes in the facts upon which they are based. Any such change should be reported to your key District Director. A copy of this ruling is being sent to your key District Director. Because it could help resolve questions concerning your federal income tax status, this ruling should be kept in your permanent records.

This ruling is directed only to the organization that requested it. Section 6110(j)(3) of the Code provides that it may not be used or cited as precedent.

Sincerely yours,

(Signed) J. E. Griffith

J. E. Griffith
Chief, Exempt Organizations
Rulings Branch

Attachment P

Hospital License

STATE OF CONNECTICUT

Department of Public Health

License No. 0047

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

Lawrence and Memorial Corporation of New London, CT, d/b/a Lawrence and Memorial Hospital is hereby licensed to maintain and operate a General Hospital.

Lawrence and Memorial Hospital is located at 365 Montauk Avenue, New London, CT 06320

The maximum number of beds shall not exceed at any time:

28 Bassinets
280 General Hospital beds

This license expires **March 31, 2013** and may be revoked for cause at any time.

Dated at Hartford, Connecticut, April 1, 2011. RENEWAL.

Satellites

Joslin Diabetes Center, 14 Clara Drive, Mystic, CT
Outpatient Surgery Center, 52 Hazelnut Hill Road, 2nd Floor, Groton, CT
Pequot Health Center, 52 Hazelnut Hill Road, 1st Floor, Groton, CT

Jewel Mullen, MD, MPH, MPA
Commissioner

Attachment Q

Financial Attachments I and II

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	$167,087,081	$167,087,081		$167,087,081	$167,312,475	$534,182	$167,846,657	$167,312,475	$947,818	$168,260,293	$167,312,475	$985,323	$168,297,798
Medicare	$99,961,313	$99,961,313		$99,961,313	$100,064,210	$189,827	$100,254,037	$100,064,210	$340,572	$100,404,782	$100,064,210	$351,738	$100,415,948
Medicaid and Other Medical Assistance	$38,586,934	$38,586,934		$38,586,934	$38,602,178	$12,342	$38,614,520	$38,602,178	$22,920	$38,625,098	$38,602,178	$24,683	$38,626,861
Other Government	$13,177,882	$13,177,882		$13,177,882	$13,177,882	$0	$13,177,882	$13,177,882	$0	$13,177,882	$13,177,882	$0	$13,177,882
Total Net Patient Patient Revenue	$318,813,210	$318,813,210	$0	$318,813,210	$319,156,745	$736,351	$319,893,096	$319,156,745	$1,311,310	$320,468,055	$319,156,745	$1,361,745	$320,518,490
Other Operating Revenue	$15,662,907	$15,662,907		$15,662,907	$15,662,907		$15,662,907	$15,662,907		$15,662,907	$15,662,907		$15,662,907
Revenue from Operations	$334,476,117	$334,476,117	$0	$334,476,117	$334,819,652	$736,351	$335,556,003	$334,819,652	$1,311,310	$336,130,962	$334,819,652	$1,361,745	$336,181,397
OPERATING EXPENSES													
Salaries and Fringe Benefits	$182,889,063	$182,889,063		$182,889,063	$182,889,063		$182,889,063	$182,889,063		$182,889,063	$182,889,063		$182,889,063
Professional / Contracted Services	$22,304,506	$22,304,506		$22,304,506	$22,304,506	$0	$22,304,506	$22,304,506	$0	$22,304,506	$22,304,506	$0	$22,304,506
Supplies and Drugs	$45,460,595	$45,460,595		$45,460,595	$45,521,360	$230,388	$45,751,748	$45,521,360	$410,280	$45,931,640	$45,521,360	$426,060	$45,947,420
Bad Debts	$13,865,210	$13,865,210		$13,865,210	$13,865,210		$13,865,210	$13,865,210		$13,959,266	$13,865,210		$13,865,210
Other Operating Expense	$25,578,267	$25,578,267		$25,578,267	$25,578,267	$82,078	$25,660,345	$25,578,267	$94,056	$25,672,323	$25,578,267	$97,212	$25,675,479
Subtotal	$290,097,641	$290,097,641	$0	$290,097,641	$290,158,406	$312,466	$290,470,872	$290,158,406	$504,336	$290,756,798	$290,158,406	$523,272	$290,681,678
Depreciation/Amortization	$17,199,566	$17,199,566		$17,199,566	$17,199,566		$17,199,566	$17,199,566		$17,199,566	$17,199,566		$17,199,566
Interest Expense	$2,212,181	$2,212,181		$2,212,181	$2,212,181		$2,212,181	$2,212,181		$2,212,181	$2,212,181		$2,212,181
Lease Expense	$2,426,892	$2,426,892		$2,426,892	$2,426,892		$2,426,892	$2,426,892		$2,426,892	$2,426,892		$2,426,892
Total Operating Expense	$311,936,280	$311,936,280	$0	$311,936,280	$311,997,045	$312,466	$312,309,511	$311,997,045	$504,336	$312,595,437	$311,997,045	$523,272	$312,520,317
Gain/(Loss) from Operations	$22,539,837	$22,539,837	$0	$22,539,837	$22,822,607	$423,885	$23,246,492	$22,822,607	$806,974	$23,535,525	$22,822,607	$838,473	$23,661,080
Plus: Non-Operating Revenue	$4,137,772	$4,137,772		$4,137,772	$4,137,772		$4,137,772	$4,137,772		$4,137,772	$4,137,772		$4,137,772
Revenue Over/(Under) Expense	$26,677,609	$26,677,609	$0	$26,677,609	$26,960,379	$423,885	$27,384,264	$26,960,379	$806,974	$27,673,297	$26,960,379	$838,473	$27,798,852
FTEs	1939.04	1939.04		1939.04	1939.04		1939.04	1939.04		1939.04	1939.04		1939.04
*Volume Statistics:	74	74		74	89	73	162	89	130	219	89	135	224

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.

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: PCI Elective
Type of Unit Description: Cases
# of Months in Operation: 12

FY 2013 **FY Projected Incremental** Total Incremental Expenses:	(1) **$312,466**	(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		$29,385	34	$999,090	$809,263			$189,827	$145,532	$44,295
Medicaid		$29,385	7	$205,695	$193,353			$12,342	$29,962	($17,621)
CHAMPUS/TriCare		$29,385	0	$0				$0	$0	$0
Total Governmental			41	$1,204,785	$1,002,616	$0	$0	$202,169	$175,495	$26,674
Commericial Insurers		$29,385	31	$910,935	$376,753			$534,182	$132,691	$401,491
Uninsured		$29,385	1	$29,385		$14,693	$14,693	$0	$4,280	($4,280)
Total NonGovernment		$29,385	32	$940,320	$376,753	$14,693	$14,693	$534,182	$136,971	$397,211
Total All Payers		$29,385	73	$2,145,105	$1,379,369	$14,693	$14,693	$736,351	$312,466	$423,885

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	PCI Elective
Type of Unit Description:	Cases
# of Months in Operation	12

FY 2014 **FY Projected Incremental** Total Incremental Expenses: **$504,336** **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		$29,385	61	$1,792,485	$1,451,913			$340,572	$236,650	$103,922
Medicaid		$29,385	13	$382,005	$359,085			$22,920	$50,434	($27,513)
CHAMPUS/TriCare		$29,385	0	$0				$0	$0	$0
Total Governmental			74	$2,174,490	$1,810,998	$0	$0	$363,492	$287,084	$76,409
Commericial Insurers		$29,385	54	$1,586,790	$638,972			$947,818	$209,493	$738,325
Uninsured		$29,385	2	$58,770		$29,385	$29,385	$0	$7,759	($7,759)
Total NonGovernment		$29,385	56	$1,645,560	$638,972	$29,385	$29,385	$947,818	$217,252	$730,566
Total All Payers		$29,385	130	$3,820,050	$2,449,970	$29,385	$29,385	$1,311,310	$504,336	$806,974

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: PCI Elective
Type of Unit Description: Cases
# of Months in Operation: 12

FY 2015 **FY Projected Incremental** Total Incremental Expenses: **$523,272**	(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		$29,385	63	$1,851,255	$1,499,517			$351,738	$244,194	$107,545
Medicaid		$29,385	14	$411,390	$386,707			$24,683	$54,265	($29,582)
CHAMPUS/TriCare		$29,385	0	$0				$0	$0	$0
Total Governmental			77	$2,262,645	$1,886,223	$0	$0	$376,422	$298,459	$77,963
Commericial Insurers		$29,385	56	$1,645,560	$660,237			$985,323	$217,061	$768,262
Uninsured		$29,385	2	$58,770		$29,385	$29,385	$0	$7,752	($7,752)
Total NonGovernment		$29,385	58	$1,704,330	$660,237	$29,385	$29,385	$985,323	$224,813	$760,510
Total All Payers		$29,385	135	$3,966,975	$2,546,460	$29,385	$29,385	$1,361,745	$523,272	$838,473

Attachment R

Financial Attachment Assumptions

Lawrence & Memorial Hospital
Project: Cardiac Cath Angioplasty Expansion for Elective Cases
Forecasted Profit and Loss Statement

ASSUMPTIONS:
Implementation Date October 1,2012

VOLUME	FY 2013	FY 2014	FY 2015					
					Rate Per			
Cases	73	130	135		Procedure	Cases		
Diagnostic Caths(Current Volume)	-73	-130	-135		$ 12,838			
Elective Angioplasty	73	130	135		$ 22,925			
Average Rate/Procedures	$ 10,087	$ 10,087	$ 10,087		$ 10,087			
REVENUES								
Procedures	$736,351	$1,311,310	$1,361,745					
OPERATING EXPENSES								
Direct Expenses								
Salaries & Wages	-	-	-					
Professional Fees	-	-	-					
Nonsalary	260,388	420,280	436,060					
Total Direct Expenses	260,388	420,280	436,060					
Indirect Expenses								
Fringe Benefits	-	-	-		27.00%	percent of total salaries		
Other indirect	52,078	84,056	87,212		20.00%	percent of total expenses		
Depreciation	-	-	-					
Total Indirect Expense	52,078	84,056	87,212					
Total Operating								
Expenses	312,466	504,336	523,272					
OPERATING INCOME(LOSS)	423,885	806,974	838,473					
CUMULATIVE								
INCOME(LOSS)	423,885	1,230,859	2,069,332					
							relief	
Salary Detail:				Base Salary		FTE's		W/Diff.
RN	0	0	0	$79,000	per FTE	0.00	Y*	$90,850
On call Angioplasty Tech Staff	0	0	0					

				Total FTE's		0.00		
					Includes	15.00%	relief	
	0	0	0					
Non Salary Detail:								
Med./Surg Supplies-Angio	(65,335)	(116,350)	(120,825)	$895.00	per case			
Med./Surg Supplies-Angio	295,723	526,630	546,885	$4,051.00	per case			
Training & Education *	5,000	5,000	5,000					
Advertising & Mkting *	25,000	5,000	5,000					
* Denotes Start\Up Costs	---	---	---					
	260,388	420,280	436,060					
Depreciation:				Amount	Years of Service			
Renovations/ New Construction				-	15			
Fixed Equipment				-	10			
Movable Equipment	-	-	-	-	5			
Total	-	-	-	-				

Attachment S

Rate Schedule

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810 LMH CATH LAB As of Date

Dept	Mnemonic	Description	CHG
01.6810	1603004	LOW OSM CONT 300-399 50 ML	$328.00
01.6810	1603015	LOW OSM CONT 300-399 125 ML	$376.00
01.6810	1603017	LOW OSM CONT 300-399 75 ML	$449.00
01.6810	1701823CL	PAD MONITOR/DEFIB HP	$18.00
01.6810	1706004	BASIC CATH SUPPLY TRAY	$323.00
01.6810	1706010	ARTERIAL INTRODUCERS	$73.00
01.6810	1706011	TEMP BALLOON PACING WIRE	$336.00
01.6810	1706012	CARDIAC CATHETERS DIAGNOSTIC	$465.00
01.6810	1706013	GUIDE WIRE DIAGNOSTIC	$66.00
01.6810	1706016	VENOUS INTR PERM PACE	$97.00
01.6810	1706019	CATHETER SWAN GANZ 7F	$619.00
01.6810	1706025	TEMP PACING WIRE SEMI FLOAT	$252.00
01.6810	1706027	BASIC PACER SUPPLY TRAY	$94.00
01.6810	1706029	DISP PRESSURE INFUSOR BAG	$38.00
01.6810	1706040	WHOLEY WIRE	$265.00
01.6810	1706042	FEMSTOP/EXTERNAL CLOSURE DEVIC	$213.00
01.6810	1706043	VASCULAR CLOSURE DEVICE	$525.00
01.6810	1706920	SMART NEEDLE	$266.00
01.6810	1706922	PREMANANT PACING LEAD	$2,360.00
01.6810	1706926	DDDR PACEMAKER	$14,776.00
01.6810	1706928	VVIR PACEMAKER	$12,461.00
01.6810	1706932	DDD PACEMAKER	$12,954.00
01.6810	1706952	VVI PACCEMAKER	$10,335.00
01.6810	1706966	MICROPUNCTURE NEEDLE SET	$87.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	1706967	GUIDING CATHETER	$260.00
01.6810	1706968	INDEFLATOR	$366.00
01.6810	1706969	CORONARY/SPECIAL/STEERABLE WIR	$352.00
01.6810	1706970	GUARD WIRE/FILTER WIRE	$3,740.00
01.6810	1706971	PTCA BALLOONS	$880.00
01.6810	1706972	CUTTING BALLOONS	$1,440.00
01.6810	1706973	EXPORT/PRONTO CATHETER	$1,496.00
01.6810	1706974	BARE METAL STENT W/DEL	$3,784.00
01.6810	1706976	DRUG ELUTING STENT W/DEL	$6,384.00
01.6810	1706978	ANGIOJECT CATHETER/X SIZER	$2,293.00
01.6810	1706980	CATHETER, ULTRASOUND	$1,359.00
01.6810	1706981	TRANSIT CATHETER	$1,359.00
01.6810	1706983	GENERATOR,PICD-DUAL (DDD)	$50,562.00
01.6810	1706984	LEAD,LV/CS	$7,540.00
01.6810	1706985	CRT-DEFIBRILLATOR	$59,807.00
01.6810	1706986	CRT-PACEMAKER	$28,600.00
01.6810	1706987	LEAD, PACER/ICD COMBO	$5,436.00
01.6810	1706988	GENERATOR,PICD-SINGLE (VVI)	$44,141.00
01.6810	1706990	LEAD, SINGLE ICD COIL	$10,534.00
01.6810	1706991	LEAD,DUAL ICD COIL	$15,296.00
01.6810	1706992	LEAD,OTHER ICD	$7,540.00
01.6810	1706994	ELECTROSURGICAL PEN/ELECTRODE	$179.00
01.6810	1706996	RADIAL COMPRESSION BAND	$132.00
01.6810	1706997	RADIAL SPECIALTY GLIDE WIRE	$260.00
01.6810	1718010	TORGUE GLIDE WIRE	$117.00
01.6810	1718100	MRI DDDR PACEMAKER	$13,650.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	1718101	MRI PACEMAKER LEAD	$1,890.00
01.6810	2013998	CARDIAC FLUOROSCOPY	$514.00
01.6810	2901015	INSERT/DUALPAC/ICD LEADS	$1,583.00
01.6810	2901018	PERC INSERTION IABP CATHETE	$2,128.00
01.6810	2901023	RIGHT HEART CATH ONLY	$6,087.00
01.6810	2901026	THROMBOLYSIS INTRACORONARY	$1,183.00
01.6810	2901029	OXYGEN SATURATION RUN	$341.00
01.6810	2901056	INSERT TEMP PACER	$2,792.00
01.6810	2901057	THROMBOLYSIS CORONARY BY IV	$508.00
01.6810	2901063	LHC ONLY +/- VGRAM	$8,099.00
01.6810	2901068	REMOVE PERM PM GENERATOR	$2,439.00
01.6810	2901069	REVISION PACEMAK POCKE	$2,285.00
01.6810	2901072	REPOSITION PAC/ICD LEAD	$2,885.00
01.6810	2901073	INS PM W/ EXISTING SING LEAD	$3,908.00
01.6810	2901074	INS/REP PERM PM W/ATR/VENT LEA	$5,907.00
01.6810	2901075	INS/REP PERM PM W/VENT LEADS	$5,174.00
01.6810	2901076	INS/REP PERM PM W/ATRIAL	$4,910.00
01.6810	2901078	INS PM W/EXISTING DUAL LEAD	$5,954.00
01.6810	2901079	UPGRADE PACER SYSTEM	$6,348.00
01.6810	2901080	INSERT PAC/ICS LEAD	$4,158.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	2901083	PULSE OXIMETRY	$73.00
01.6810	2901085	RHLH +/- VGRAM	$11,252.00
01.6810	2901086	CARDIOVERSION	$1,035.00
01.6810	2901115	CS SAME MD>=5YR 1ST 30 MIN	$304.00
01.6810	2901115A	CS SAME MD EA ADDL 15 MIN	$40.00
01.6810	2901119	IV CONTRAST INJECTION	$514.00
01.6810	2901121	S&I VENOGRAPHY	$1,173.00
01.6810	2901123	FLOWDIRECTED CATHET MONITORING	$2,500.00
01.6810	2901124	IMPL PAT ACTIV EVENT REC	$3,379.00
01.6810	2901125	REMOV IMPL PAT CARDI REC	$1,594.00
01.6810	2901126	INTERNAL EVENT RECORDER DEVICE	$9,089.00
01.6810	2901128	REMOV PACEMAKER SING LEAD	$1,468.00
01.6810	2901129	REMOV PACEMAKER DUAL LEAD	$1,302.00
01.6810	2901130	INS SINGLE ICD GENERATOR	$12,060.00
01.6810	2901131	INSERT DUAL ICD GENERATOR	$12,252.00
01.6810	2901132	INS/REP ICD W/SING LEAD SYSTEM	$23,327.00
01.6810	2901133	INS DUAL ICD LEADS & PICD	$23,500.00
01.6810	2901134	TESTING ICD SINGLE/DUAL GENER	$2,001.00
01.6810	2901135	REMOVAL ICD GENERATOR ONLY	$2,175.00
01.6810	2901136	REMOVAL ICD LEAD(TRANSV)	$2,175.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	2901137	REV POCKET PACING ICD(S)	$2,336.00
01.6810	2901138	IMPLANT LV LEAD AT TIME OF GEN	$6,645.00
01.6810	2901139	REPOSITIONING OF LV LEAD	$2,934.00
01.6810	2901140	INS LV LEAD ATT TO EXIST DEV	$7,524.00
01.6810	2901141	CS SAME MD <5YR 1ST 30 MIN	$98.00
01.6810	2901142	IV PUSH INITIAL DRUG	$143.00
01.6810	2901144	IV INFUSION DRUG 1ST HOUR	$234.00
01.6810	2901145	IV TRANSFUSION BLOOD PROD	$772.00
01.6810	2901146	IM/SC INJECTION	$93.00
01.6810	2901147	OXYGEN PER HOUR	$48.00
01.6810	2901148	HAND NEB RX INITIAL	$101.00
01.6810	2901149	HAND NEB RX SUBSEQUENT	$76.00
01.6810	2901150	PLACEMENT OF OCC CLOSE DEVICE	$432.00
01.6810	2901153	BARE METAL STENT PROCEDURE	$9,005.00
01.6810	2901154	BARE METAL STENT ADDL VESSEL	$5,792.00
01.6810	2901155	OUTPATIENT VISIT LEVEL 1	$120.00
01.6810	2901158	NO CHARGE TEE (STATS)	$0.00
01.6810	2901159	NO CHARGE ABI NRS ASSES (STAT)	$0.00
01.6810	2901160	NO CHARGE BUBBLE STUDY (STATS)	$0.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	2901161	NO CHG PRE PROC ASSES (STATS)	$0.00
01.6810	2901162	NO CHG IVP CONT ECHO (STATS)	$0.00
01.6810	2901163	MISC CATH LAB PROC (UNLISTED)	$1,050.00
01.6810	2901164	PERC TRANS CATH RETRIVAL FB	$1,574.00
01.6810	2901165	INTRO OF CATH INTO AORTA	$1,129.00
01.6810	2901166	PERC INTRAVASC FB RETRIEVAL	$1,982.00
01.6810	2901167	CORONARY ANGIOGRAPHY ONLY	$8,408.00
01.6810	2901168	CORONARY + ART + VENOUS GRAFTS	$9,450.00
01.6810	2901169	RHC + CORONARY	$6,863.00
01.6810	2901170	RHC + CORONARY + ART + VEN GFT	$8,154.00
01.6810	2901171	CORONARY + LHC +/- VGRAM	$10,066.00
01.6810	2901172	COR+LHC+ART+VEN GFTS +/- VGRAM	$11,356.00
01.6810	2901173	RLHC + COR +/- VGRAM	$8,741.00
01.6810	2901174	RLHC+COR+ART+VEN GFTS+/- VGRAM	$12,570.00
01.6810	2901175	PHARM ASSESSMENT WITH RHC	$183.00
01.6810	2901176	EXERCISE ASSISSMENT WITH RHC	$183.00
01.6810	2901177	ULTRASOUND GUIDANCE PERICARDIO	$333.00
01.6810	2901178	INJ SUPRA VALVULAR AORTOGRAPHY	$443.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	2901179	INJ PULMONARY ANGIOGRAPHY	$466.00
01.6810	2901180	INJ RIGHT VENT OR RA ANGIO	$503.00
01.6810	2901181	TILT TABLE STUDY	$1,142.00
01.6810	2901182	MISC PACER PROC (UNLISTED)	$1,050.00
01.6810	2901183	INS PERM PM ONLY W/EXT MUL LEA	$4,122.00
01.6810	2901184	REM PM W/REPL PM W/SING LEAD	$5,378.00
01.6810	2901185	REM PM W/REPLAC PM W/DUAL LEAD	$5,487.00
01.6810	2901186	REM PM W/REPLAC PM W/DUAL LEAD	$5,799.00
01.6810	2901187	INS ICD ONLY W/EXIST DUAL LEAD	$6,023.00
01.6810	2901188	INS ICD ONLY W/EXIST MULT LEAD	$6,251.00
01.6810	2901189	REM ICD W/REPL ICD W/SING LEAD	$5,805.00
01.6810	2901190	REM ICD W/REPL ICD W/DUAL LEAD	$6,033.00
01.6810	2901191	REM ICD W/REPL ICD W/MULT LEAD	$6,262.00
01.6810	2903001	INJECT & IMAG RENAL ARNGIOGRAP	$2,039.00
01.6810	2903002	INJ & IMAG ILIAC ANGIOGRAPHY	$2,611.00
01.6810	2903003	SINGLE VESSEL	$7,472.00
01.6810	2903004	PTCA: ADDITIONAL VESSEL	$4,827.00
01.6810	2903005	STENT:INSERTION DES	$9,324.00
01.6810	2903006	STENT ADDITIONAL VESSEL	$5,792.00

CHARGE MASTER DETAIL BY DEPARTMENT

01.6810	2903007	CORONARY THROMBECTOMY	$1,437.00
01.6810	2903008	IVUS ULTRASOUND	$2,400.00
01.6810	2903009	IVUS ULTRASOUND: ADDITION VESS	$1,206.00
01.6810	2903010	PERICARDIOCENTESIS	$630.00
01.6810	2903011	PRESSURE/FLOW WIRE	$3,073.00
01.6810	2903012	PRESSURE/FLOW WIRE: ADDIT VESS	$801.00
01.6810	2903013	CARDIAC OUTPUT(SEPARATE PROCED	$305.00
01.6810	2903014	CARDIAC OUTPUT (ADDITIONAL)	$213.00
01.6810	2903015	REMOVE INTRA AORTIC BALLOON	$1,773.00
01.6810	2903017	AORTOGRAPHY,ABD	$2,837.00
01.6810	2903018	DECLOT THROMBOL AGENT	$413.00
01.6810	2903019	ANGIO BRACH RETROGRAD	$1,773.00
01.6810	2903020	INTRO NEEDLE RETRO BRACH	$782.00
01.6810	2903021	ANGIO BRACH RETROGRADE (P)	$0.00
01.6810	2903022	INSERT CENTRAL LINE > 5YRS	$1,221.00
01.6810	2903023	INSERT PICC > 5 YEARS	$1,362.00
01.6810	2903024	FLUORO GUIDANCE CV ACCESS	$356.00
01.6810	2903025	US GUIDANCE VASCULAR ACCESS	$457.00

L&M Physicians Cardiology at Waterford

Deputy Commissioner Davis
Office of The Health Care Access Department of Public Health
410 Capitol Ave, MS #138CA, PO Box 340308
Hartford, CT 06134

Dear Madam:

I am writing this letter to express my support for Lawrence & Memorial Hospital's certificate in need to establish an elective angioplasty program.

Currently, I am the Chief of Cardiology and was instrumental several years ago in helping the hospital attain emergency angioplasty. This has been an extremely busy, active, and successful, and safe program. An elective angioplasty program at L&M would increase our access for Southeastern Connecticut patients, who typically have to travel long distances under stress to Yale for this procedure. This puts an undue burden on both our patients and their family members.

Recent C-Port E study suggests that it is safe to do elective angioplasty in selected patients without surgical onsite facilities. Our current program is in conjunction with the Yale-New Haven Hospital and we maintain a close working relationship with both the cardiologists as well as the thoracic surgeons, therefore having a rapid emergency access to cardiothoracic surgery if needed. An elective program would help us with continuity care and having a local cardiologist follow our angioplasty people.

Sincerely,

Peter S. Milstein, M.D., F.A.C.C.

PSM/SAP/krn

DD: 05/14/2012
DT: 05/15/2012

196 Parkway South, Suite 103, Waterford, Connecticut 06385
Telephone (860) 443-4383 Fax (860) 443-3980

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

July 19, 2012 VIA FAX & EMAIL ONLY

Ms. Shraddha Patel
Director of Business Development & Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

RE: Certificate of Need Application; Docket Number: 12-31768-CON
Lawrence & Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

Dear Ms. Patel:

On June 19, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need application filing on behalf of Lawrence & Memorial Hospital ("Applicant" or "Hospital") to establish and operate an elective angioplasty program at Lawrence & Memorial Hospital in New London, Connecticut.

OHCA has reviewed the CON application and requests the following additional information pursuant to General Statutes §19a-639a(c):

1. Describe the process and criteria for patients requiring elective PCI that are being transferred to Yale (and other facilities).

2. Please describe the Hospital's current process for a patient who may require surgical backup during a primary PCI procedure. Additionally, please explain if this will be the same procedure utilized for a similar situation for the proposed service. If not, please explain, what procedural changes will be made?

3. Describe the Hospital's proposed step-by-step process/protocol regarding patient transfers to a full cardiac service provider in case of an emergency during the elective PCI procedure.

4. Please provide the mortality rate of the Applicant's Primary PCI program since its inception. Please discuss the Applicant's mortality rate compared to the recommended mortality rate in the 2011 ACCF/AHA/SCAI guidelines.

5. Discuss and describe the existing referral base (physicians and physician practices, specifically the interventionalists) in the region and the service area that is associated with the Hospital. Provide a list of physicians and the associated practices that are currently providing Primary PCI services at the Hospital.

6. Does the Applicant expect the physician referral base to expand given the proposed service? Additionally, please provide copies of all contracts the Applicants have with all new healthcare providers.

7. Please provide for each physician (table on pg. 40) their individual annual PCI volume including volume from all facilities where they delivered services.

8. Provide a detailed discussion regarding the following:

    a. Options the Applicants considered prior to deciding to move forward with their plans to apply for Elective PCI without Open Heart Surgery backup.
    b. Did the Applicant consider any collaboration with any other healthcare providers in the region and the service area?

9. In the table on page 40 of the Application, the Applicant anticipates volume for FY13, FY14 and FY15 to be 162, 219 and 224, respectively. Please address the following questions:

    a. How does the Applicant plan to meet the increased demand? Do you plan to hire more physicians/nurses? Explain in detail.

    b. Do you anticipate having any referrals from either the Backus Hospital or any other healthcare provider from the state of Rhode Island? Please explain.

10. In regard to the Attachment B: 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 and 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 does the Hospital's transport agreement with YNHH (where a majority of the patients have been transferred in the past) relate to or meet the guidelines?

    d. What is the Hospital's median time to immediate PCI for STEMI patients?

e. How does the Hospital's median time meet to the ACCF/AHA/SCAI guidelines published in November 2011?

11. Discuss the incidence of cardiac disease in the Applicant's service area and provide evidence.

12. Please provide a list of ICD-9 codes used to calculate the Hospital's historical and current volume.

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 (e.g., completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Please begin your submission using Page 518 and reference "Docket Number: 12-31768-CON." Submit one (1) original and six (6) hard copies of your response. In addition, please submit a scanned copy of your response, in an Adobe format (pdf) including all attachments, on CD. If available, a copy of the response in MS Word should also be provided on the CD.

If you have any questions concerning this letter, please feel free to contact Steve Lazarus at (860) 418-7012 or Alla Veyberman (860) 418-7007.

Sincerely,

A. Veyberman

Alla Veyberman
Health Care Analyst

****
*** TX REPORT ***
****

TRANSMISSION OK

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RECIPIENT ADDRESS	918604443716
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PAGES SENT	4
RESULT	OK

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MS.PATEL

FAX: 860.444.3716

AGENCY: L&M HOSPITAL

FROM: OHCA

DATE: 07/19/2012 **Time:**

NUMBER OF PAGES: 4
(including transmittal sheet

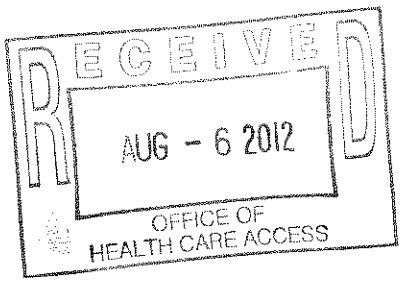
Comments:

Completeness Letter
Docket Number: 12-31768-CON
Establish and Operate an Elective Angioplasty Program at L&M Hospital

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

August 3, 2012



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

RE: Certificate of Need Application Docket Number: 12-31768-CON
Proposal to Establish and Operate an Elective Angioplasty Program at Lawrence + Memorial Hospital in New London, CT

Dear Ms. Martone:

Enclosed please find our responses to OHCA's questions received in a letter dated July 19, 2012 pertaining to Certificate of Need Application Docket Number: 12-31768-CON. As requested, we have included an original and six copies of our response along with electronic files in Adobe (.pdf) and MS Word formats.

Please do not hesitate to contact me at (860) 442-0711, extension 2073, if you have any questions.

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
Certificate of Need Application; Docket Number: 12-31768

Responses to Completeness Questions

Table of Contents

Responses to OHCA Completeness Letter Dated July 19, 2012 for Certificate of Need Application Docket Number: 12-31768-CON

1. Describe the process and criteria for patients requiring elective PCI that are being transferred to Yale (and other facilities).

Response:
Currently, patients at Lawrence + Memorial Hospital (L+M) who receive a diagnostic catheterization and meet the criteria for elective PCI are either transferred the same day to Yale-New Haven Hospital (YNHH) (or another facility) or are sent home and the elective procedure is scheduled at YNHH (or another facility) on another date. The criteria utilized to determine the appropriateness of elective PCI is stated in the "2012 Appropriate Use Criteria for Coronary Revascularization Focused Update" published by the American College of Cardiology Foundation (ACCF). When evaluating the appropriateness of elective PCI, the L+M performing physician adheres to the criteria outlined in Table 4 of the report (please refer to Attachment 1 for a copy of the report). If the patient meets the criteria for elective PCI, the performing physician, patient, and patient's family collaborate to determine whether the procedure will occur the same day as the diagnostic catheterization or on a different date.

For patients who have the elective PCI procedure on the same date as their diagnostic catheterization, the transfer process occurs as follows:
- Patient undergoes diagnostic catheterization at L+M
- Results immediately available and performing physician evaluates patient to determine if patient meets criteria for elective PCI
- If criteria is met for elective PCI and patient consents to procedure at YNHH the same day, the YNHH transfer protocol and agreement process is initiated (please refer to Attachment I of L+M's initial certificate of need (CON) filing for agreement). L+M contacts YNHH to coordinate transfer. If YNHH is able to accept the transfer, all available information regarding the patient is submitted to YNHH. L+M staff contact the transport vendor to initiate ground ambulance transportation.
- Patient is then transferred from L+M to YNHH via ground ambulance for their elective PCI procedure.

In FY 2012, all transfers for elective PCI have been made to YNHH; the above process was initiated for each of these patients.

2. Please describe the Hospital's current process for a patient who may require surgical backup during a primary PCI procedure. Additionally, please explain if this will be the same procedure utilized for a similar situation for the proposed service. If not, please explain what procedural changes will be made?

Response:
Currently, if during a primary PCI procedure a complication arises that warrants urgent surgical intervention, the performing interventionalist at L+M contacts the Cardiothoracic (CT) Surgery Department at YNHH. The CT Surgery Department at YNHH is on-call 24/7 so contact with a CT surgeon is immediate. The L+M interventionalist communicates the

patient's name, history, and other relevant information to the CT surgeon. The CT surgeon then initiates the YNHH Y-Access transfer system which is designed to facilitate and expedite the hospital-to-hospital transfer of patients. Additionally, a YNHH operating room is held open for the transferred patient.

While contact is being made with YNHH's CT Surgery Department, L+M staff is simultaneously notifying the air transport vendor Life Star of the need for immediate transfer of a patient. Life Star air transport is equipped with hemodynamic support (such as an intra-aortic balloon pump (IABP)) and a crew configuration of critical care nurse/paramedic and respiratory therapist/emergency medical services (EMS) certified individual. Life Star air transport can be on-site at L+M in 12 minutes once notified. During this time, the patient at L+M is prepped for transport. Once airborne, travel time to YNHH is 20 minutes.

The current process outlined above will also be utilized for the proposed elective PCI program if, similarly, urgent surgical intervention is required.

Please refer to pages 360-361 and pages 402-405 in the initial CON filing for L+M's transfer policy and YNHH's policy as the receiving facility.

3. Describe the Hospital's proposed step-by-step process/protocol regarding patient transfers to a full cardiac service provider in case of an emergency during the elective PCI procedure.

Response:
As noted in Response #2 of this letter, the process to transfer a patient requiring urgent surgical intervention will be the same regardless of whether the PCI procedure at L+M was emergent or elective. YNHH, a full cardiac service provider, will be the receiving facility for patients that require surgical intervention.

4. Please provide the mortality rate of the Applicant's Primary PCI program since its inception. Please discuss the Applicant's mortality rate compared to the recommended mortality rate in the 2011 ACCF/AHA/SCAI guidelines.

Response:
As noted in the initial CON filing on page 47, since the inception of L+M's primary PCI program, 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 as L+M completed 316 total procedures during the same time period. According to data from the 2011 ACCF/AHA/SCAI guidelines, an analysis of data from the National Cardiovascular Data Registry (NCDR) showed an in-hospital mortality rate of 4.81% in ST-segment elevation myocardial infarction (STEMI) patients that required primary PCI intervention. L+M's mortality rate compares favorably to the expected mortality rate published in the 2011 ACCF/AHA/SCAI guidelines.

5. Discuss and describe the existing referral base (physicians and physician practices, specifically the interventionalists) in the region and the service area that is associated with the Hospital. Provide a list of physicians and the associated practices that are currently providing Primary PCI services at the Hospital.

Response:
Several physician practices exist in the region and service area of L+M that serve as the referral base for L+M cardiac services. Ten cardiologists in L+M's primary service area (service area defined on page 27 of the initial CON filing) are employed by L+M's parent company, L+M Corporation. Eight other cardiologists practice in L+M's service area and each is affiliated with L+M. The following table profiles the existing referral base and includes the cardiology practices and cardiologists that are affiliated with L+M's medical staff:

Practice Name	Location(s)	Cardiologists	Notes
L+M Physician Association Cardiology*	New London, CT	Jon Gaudio, MD Roshanak Bagheri, MD	
L+M Physician Association Cardiology*	Waterford, CT	Wally Andrias, MD Richard Fazio, MD Mark Fiengo, DO Mark Somers, MD Peter Milstein, MD Frank Mirecki, MD Valerie Popkin, MD Brian Ehrlich, MD	
Cardiology Associates of Norwich, LLC	Norwich, CT	Jeffrey Seltzer, MD James Healy, MD Faisal Hasan, MD**	There are five other cardiologists in this practice; however, they are not affiliated with L+M's medical staff. Dr. Hasan is an interventional cardiologist also affiliated with YNHH/Yale School of Medicine (YSM).
Cardiology Specialists, LTD	Westerly, RI Mystic, CT	Howard Haronian, MD** Stephen Kutz, MD Jon Scheiber, MD	Dr. Haronian is an interventional cardiologist also affiliated with YNHH/YSM.
Joseph R. Dotolo, Inc.	Westerly, RI	Joseph Dotolo, MD	
Cardiovascular Institute of New England	Westerly, RI	George Bourganos, MD	There are two other cardiologists in this practice; however, they are not affiliated with L+M's medical staff.

* Note: Physicians in L+M Physician Association Cardiology are employed by L+M Corporation.
** Note: Drs. Hasan and Haronian are interventional cardiologists that practice at Cardiology Associates of Norwich and Cardiology Specialists, respectively, and are also affiliated with YNHH/YSM. As noted in the table below, these physicians provide on-call coverage for L+M's primary angioplasty service.

PCI is lifesaving in patients with acute STEMI. Per Attachment K in the initial CON filing, the Connecticut Department of Health requires that for patients with a pre-hospital 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. The interventional cardiologists listed in the table below are affiliated with YNHH/YSM and L+M's medical staff and currently provide on-call coverage of L+M's existing primary PCI program.

Practice Name	Interventional Cardiologist	Primary Office Location(s)	Notes
Yale University Cardiovascular Medicine	Brian Cambi, MD	New London, CT	Dr. Cambi is the Medical Director of L+M's Primary Angioplasty Program.
Yale University Cardiovascular Medicine	Carlos Mena, MD	New Haven, CT	
Yale University Cardiovascular Medicine	Frank Giordano, MD	New Haven, CT	
Yale University Cardiovascular Medicine	Rebecca Scandrett, MD	New Haven, CT	
Yale University Cardiovascular Medicine	Steven Pfau, MD	New Haven, CT	
Yale University Cardiovascular Medicine	Joseph Brennan Jr., MD	New Haven, CT	
Yale University Cardiovascular Medicine	Faisal Hasan, MD	Norwich, CT	
Yale University Cardiovascular Medicine	Howard Haronian, MD	Westerly, RI Mystic, CT	

6. Does the Applicant expect the physician referral base to expand given the proposed service? Additionally, please provide copies of all contracts the Applicants have with all new healthcare providers.

Response:
L+M does not anticipate an expansion in the physician referral base either geographically or in terms of quantity of physicians in the service area. As noted in Response #9 of this letter, L+M's volume projections in the initial CON filing were not based on assumptions regarding new physicians in the market or an expansion of L+M's geographic reach beyond the existing service area. Rather L+M's volume projections were based on actual data of transfers from L+M's catheterization lab to YNHH for elective PCI and, in the future, the retention of select patients (i.e., non-high risk patients) that could remain at L+M for their elective PCI procedure. L+M maintains employment contracts with physicians that are employed by L+M Physician Association Cardiology. These contracts contain confidential information including compensation and benefits and for these reasons cannot be submitted with this response letter.

7. Please provide for each physician (table on pg. 40) their individual annual PCI volume including volume from all facilities where they delivered services.

Response:
The physicians listed on page 40 of the initial CON filing perform PCI procedures at both L+M and YNHH. These physicians' 2011 calendar year volume is provided in the table below.

	Calendar Year 2011		
Physician Identifier	**Volume at L+M***	**Volume at YNHH****	**Total Volume**
A	33	74	107
B	12	129	141
C	11	77	88
D	13	40	53
E	9	92	101
F	1	98	99
G	0	100	100
H	0	150	150
Total	**79**	**760**	**839**

* Note: Please note that volumes by physician identifier shown above are different than volumes shown on page 40 of the initial CON filing. This is due to the different time periods shown (i.e., fiscal year 2011 in the initial CON filing versus calendar year 2011 shown above). Volume at L+M includes primary PCI procedures.
** Note: Volume at YNHH includes both primary and elective PCI procedures.

8. Provide a detailed discussion regarding the following:

a. Options the Applicants considered prior to deciding to move forward with their plans to apply for Elective PCI without Open Heart Surgery backup

Response:
An alternative to filing the application to add elective PCI at L+M was to maintain the status quo and continue to send patients out of the region and service area for this service (as there are no other providers of elective PCI in eastern Connecticut as noted in the initial CON application on page 20 and in Response #8b of this letter). The option to maintain the status quo, as demonstrated in the initial CON filing, is not in the best interest of the patient.

Currently, patients who require elective PCI are either transferred the same day to Yale-New Haven Hospital (YNHH) (or another facility) or are sent home and the elective procedure is scheduled at YNHH (or another facility) on another date.

As stated in the initial CON filing, the rationale behind L+M pursuing elective PCI services at this time rather than maintaining the status quo includes the following:

- November 2011 ACCF/AHA/SCAI Clinical Practice Guidelines for PCI raised the indication for elective PCI without onsite cardiac surgery from Class III ("should not be performed") to Class IIb ("may be considered") based upon results of several landmark

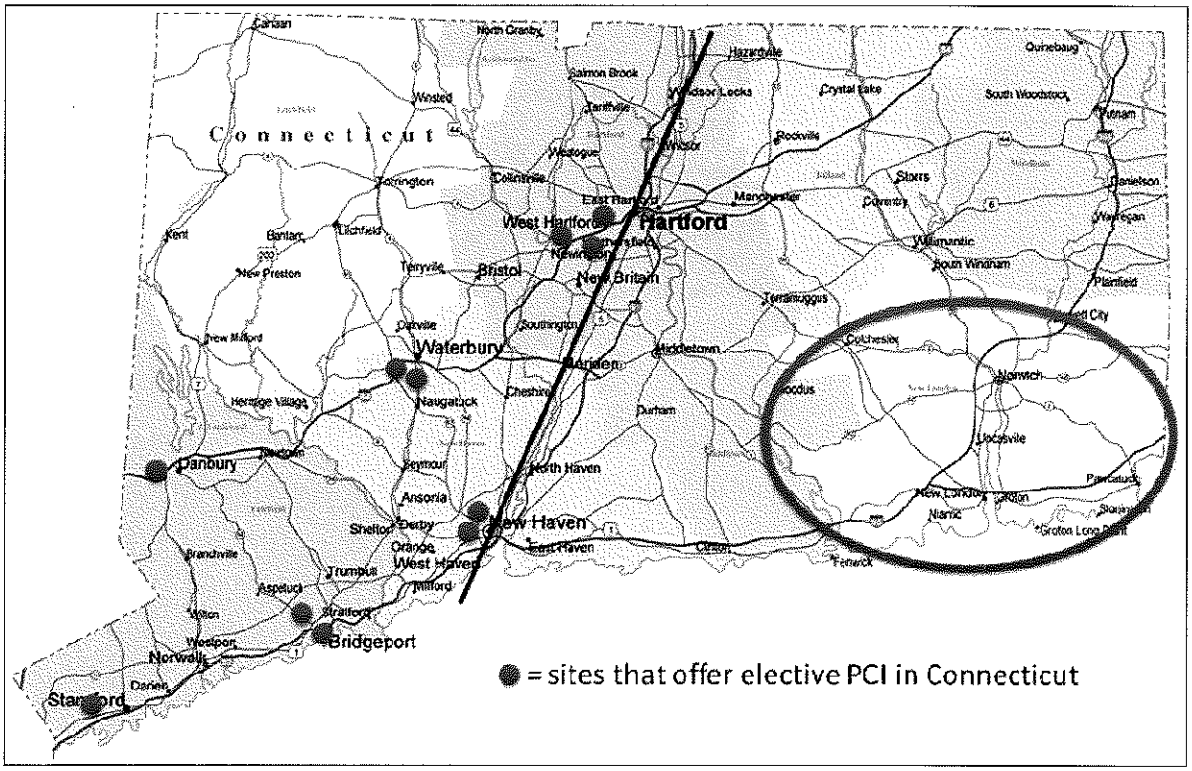
studies (please refer to Response #10a of this letter for information on how L+M meets the criteria for Class IIb)

- Results released in May 2012 for key randomized, controlled study CPORT-E (Cardiovascular Patient Outcomes Research Team Elective) demonstrated that elective PCI at facilities without on-site surgery was non-inferior from an outcomes perspective compared to facilities with on-site surgery
- The number of states that allow elective PCI without on-site cardiac surgery continues to increase
- Nationally, physician support for elective PCI without on-site cardiac surgery has increased according to recent surveys of practicing cardiologists
- L+M's geographic location makes it an ideal site for elective PCI without on-site surgery as there is a regional lack of providers and a clear need for cardiac services (as demonstrated in the Response #11 of this letter)
    - As noted on page 20 of the initial CON application, the closest providers of elective PCI services are 48-61 miles and a 58-64 minute drive time from L+M
    - The November 2011 Practice Guidelines and the 2012 Cath Lab Standards Update report both note an ideal location for elective PCI without on-site surgery is a location that "will clearly fill a void in the healthcare needs of the community" and "the cardiology community [should] 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"
    - In OHCA's Agreed Settlement for L+M's CON filing to Establish Primary Interventional Cardiac Service at Lawrence and Memorial Hospital in New London (Docket Number: 04-30297-CON), OHCA notes that "L+M is located in a geographic pocket or outlying area where its residents have to travel over 45 miles for emergent angioplasty" and "as a result of this geographic isolation, L+M's area residents are currently not receiving the treatment of choice for STEMI patients." Although the current proposal seeks to establish an elective PCI program, OHCA's prior findings still hold true and L+M, as noted in Response #8b of this letter, is still in a "geographic pocket or outlying area" and patients are not able to easily access elective PCI services. (please refer to Attachment 2 for OHCA's Agreed Settlement for Docket Number: 04-30297-CON).
- There is a high and increasing demand for cardiovascular services such as elective PCI in L+M's service area due to the aging population and poor health statistics and health status of residents in the region compared to state and national averages (please refer to Response #11 of this letter for additional information)
- Strict patient selection criteria will be utilized to ensure only non-high risk patients receive elective PCI at L+M; non-high risk patients are the best candidates for elective PCI without on-site surgery according to the November 2011 ACCF/AHA/SCAI Practice Clinical Guidelines
    - According to the November 2011 Practice Guidelines, studies have indicated the expected emergency cardiac surgery rate for elective PCI is 0.3%
    - Through its patient selection process and capture of only non-high risk patients, L+M can potentially achieve rates even lower than 0.3%

- L+M has provided primary or emergent PCI services successfully since 2008 and has excellent outcomes and quality statistics; significant program development is already complete and the addition of elective PCI services would be seamless
- L+M's proposed elective PCI program would utilize the same YNHH/YSM interventionalists that currently provide emergent PCI at L+M
- L+M'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 with high success and low complication rates
- L+M's proposed elective PCI program would utilize the same clinical staff (catheterization laboratory technicians, nurses, etc.) that currently support the emergent PCI program
- L+M's proposed elective PCI program would utilize the same state-of-the-art facilities and technologies that currently support the emergent PCI program
- For its primary PCI program, L+M has established a streamlined referral mechanism to facilitate the immediate transfer of unstable patients from L+M to cardiac surgery facilities at YNHH; the proposed elective PCI program at L+M would utilize the same system
- Elective PCI at L+M would increase quality of care as patients who are currently transferred from L+M 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
    - 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
- Elective PCI at L+M would reduce the burden on patients. Patients who are currently transferred from L+M to another facility for elective PCI often face an undue emotional and financial burden due to multiple moves from stretchers to beds to tables, multiple sheath exchanges which increase the risk of infection, and separation from local and familiar physicians and health care settings.
- Elective PCI at L+M would reduce the burden on families. Patient's families face a financial burden as they often incur costs of travel, parking, and, at times, hotel accommodations when the patient is admitted to the hospital.
- Elective PCI at L+M would allow patients to stay within their medical home and increase continuity of care
- Establishing an elective PCI program would increase PCI volume at L+M, thus enhancing hospital and team experience and, in turn, quality and safety of all PCI procedures performed
- Eliminating transfers for elective PCI would reduces costs to the health care system from duplicate testing and redundant costs for dyes, catheters, surgical trays, and other supplies

b. Did the Applicant consider any collaboration with any other healthcare providers in the region and the service area?

Response:
There are no providers of elective PCI in L+M's service area, within New London County, or in eastern Connecticut as shown in the map below (the map was included in the initial CON filing on page 20) (L+M service area is located within blue oval on the map).



The lack of proximate partners in Connecticut and also in Rhode Island (where the closest provider of elective PCI is Miriam Hospital in Providence, RI which is 61 miles from L+M) makes collaboration with other health care providers in the region and the service area to provide elective PCI to L+M's service area patients impossible.

Due to L+M's existing relationship with YNHH/YSM to perform primary PCI at L+M, collaboration with YNHH/YSM for the proposed elective service is appropriate. The same high quality cardiac interventionalists that perform primary PCI at L+M will perform elective cases as well. As shown in Response #7 of this letter, these physicians have significant PCI procedural experience. Also, as noted in Response #2 and #10b of this letter, L+M and YNHH have an established, streamlined referral mechanism to facilitate the immediate transfer of unstable patients who require surgical intervention from L+M to YNHH.

Although, other providers of elective PCI with onsite cardiac surgery exist in the state of CT and RI, the existing relationship with YNHH makes it L+M's preferred partner for the proposed service. In addition, the travel distance and time between L+M and YNHH are

comparable to distances and times between L+M and these other facilities; therefore patient safety is in no manner compromised when unstable patients are transferred to YNHH.

9. In the table on page 40 of the Application, the Applicant anticipates volume for FY 13, FY 14 and FY 15 to be 162, 219, and 224, respectively. Please address the following questions:

    a. How does the Applicant plan to meet the increased demand? Do you plan to hire more physicians/nurses? Explain in detail.

Response:
The incremental volume expected from the elective PCI program can be accommodated by the existing staff and facilities. No additional catheterization laboratory staff, nursing unit staff, or other clinical personnel will be needed to meet the increase in volume. In addition, through L+M's relationship with YNHH, the elective PCI program will be staffed by YNHH/YSM physicians and no additional physicians will be required to meet the volume targets.

    b. Do you anticipate having any referral from either Backus Hospital or any healthcare provider from the state of Rhode Island? Please explain.

Response:
L+M's volume projections were based on retaining volume at L+M that historically had been transferred to YNHH. The projections do not consider capturing elective PCI volume from Backus Hospital or Rhode Island providers as assumptions made to that effect would have been purely speculative.

As outlined on pages 41-44 of the initial CON filing, L+M's elective PCI volume projections were based on the retention of non-high risk elective PCI patients. Non-high risk patients, per the 2011 ACCF/AHA/SCAI Guidelines for PCI, are the best candidates for elective PCI without on-site cardiac surgery backup. For the initial CON filing, a patient chart review and the CPORT-E trial patient selection process were utilized to project the number of previously transferred cases that could be safely performed at L+M.

L+M's volume projection methodology was built upon a patient base that actually exists; however, due to the lack of elective PCI services at L+M, patients are being sent outside the region for care. As noted in the initial CON filing, volume projections will increase PCI volume at L+M and decrease volume transferred to YNHH; however, even after a shift in volume, YNHH will still complete 1,000+ PCI cases per year. Therefore, the impact to the quality and strength of YNHH's program is minimal and YNHH would still be considered a high volume institution. As demonstrated in the letters of support in Attachment A of the initial CON filing, YNHH and YSM physicians support L+M's application to establish an elective PCI program despite the volume shift.

Although not assumed, if referrals from Backus Hospital or any health care provider in Rhode Island are generated, this volume would be above and beyond the projections L+M is

anticipating. Should this situation arise, L+M is prepared to accommodate this volume but would evaluate its available resources and make adjustments to its resource allocation as necessary.

10. In regard to the Attachment B: 2011 ACCF/AHA/SCAI Guidelines for PCI, please address the following questions:

    a. How does the Hospital meet each of the criteria listed in Class IIa, IIb, III and tables 5 and 6?

Response:
With regard to Section 4.8 of the 2011 ACCF/AHA/SCAI Guidelines for PCI, Class IIa refers to primary or emergent PCI and is not applicable to this application. L+M has completed over 300 emergent PCI procedures for patients with STEMI since program inception with excellent outcomes.

According to the 2011 Guidelines' Class III classification, "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 for transfer." As demonstrated in Responses #2, #3, and #10b of this letter, L+M maintains a proven plan for rapid transport to YNHH, the closest facility from a travel time perspective that offers cardiac surgery. In addition, hemodynamic support such as IABP is available for the patient transfer and can be utilized as needed. Therefore, Class III does not apply to L+M for these reasons.

L+M Hospital meets the criteria listed in IIb of the 2011 ACCF/AHA/SCAI Guidelines for PCI. Class IIb states:

> "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."

Due to the program development and patient selection process, L+M is the ideal site for elective PCI without on-site surgery.

As stated in the initial CON filing on page 13, 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 of the initial CON filing 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

Also, 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 of the initial CON filing). 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.

Tables 5 and 6 in the 2011 ACCF/AHA/SCAI Guidelines list the SCAI expert consensus document requirements for PCI programs without on-site surgical backup. As demonstrated in the table below, L+M and its surgical backup partner YNHH, meet each of the criteria listed.

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

SCAI Requirement	L+M's Status
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	L+M maintains highly trained nursing and technical laboratory staff through its existing primary PCI and peripheral angiography services. Staff are highly experienced; no staff has less than 2 years experience. Staff is competent to treat acutely ill patients with hemodynamic and electrical instability. An education plan for non-emergent angioplasty without on-site surgery for staff is provided in Attachment F of the initial CON filing.
On-call schedule with operation of laboratory 24 h/d, 365 d/y.	L+M has an agreement with YNHH/YSM to provide 24 h/d, 365 d/y call coverage of its PCI service. The Medical Director of L+M's PCI service resides within L+M's PSA and is the primary covering physician. Other covering physicians stay at a hotel 5 minutes from the hospital when on-call. A policy is in place for catheterization laboratory staff and technicians to provide on-call 24 h/d, 365 d/y coverage.
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	L+M maintains coronary care unit staff with experience and competency in invasive hemodynamic monitoring, operations of temporary pacemaker, and management of IABP through its existing primary PCI program. Personnel are capability of

necessary.	intubation and ventilator management on-site and during transfer.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank)	L+M's administration is fully supportive of the proposed elective PCI program. The appropriate support services are already in place due to L+M's existing emergent service.
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 refer to Attachment I of the initial CON filing for the written transfer agreement between L+M and YNHH.
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.	L+M maintains two fully-equipped, state-of-the-art catheterization labs in which emergent or elective PCI cases can be performed. Both L+M Philips cardiac imaging systems are capable of transmitting real-time images and audio/video to YNHH for consultation with other interventionalists or cardiac surgeons while the patient is still on the table. L+M also has remote access to YNHH's GE electronic imaging storage system to view past patient images.
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.	L+M maintains a full complement of interventional equipment for its primary PCI program and will maintain the same for the proposed program. L+M maintains fractional flow reserve (FFR) and IVUS equipment. Rotational or other atherectomy devices will not be utilized.
Meticulous clinical and angiographic selection criteria for PCI.	Please refer to Section 2d of the initial CON filing for the patient selection criteria that will be utilized.
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.	Through its existing program, L+M offers primary PCI as the treatment of choice for STEMI patients. L+M participates in the CathPCI Registry through the ACC NCDR and door-to-balloon (D2B) times are tracked (please refer to Table K of the initial CON filing for recent statistics). Cases that exceed the 90 minute D2B best practice are reviewed internally by the Medical Director and Cath Lab Manager. Cases are also presented at Quality Assurance Cath Lab Conferences (please refer to Attachment F of the initial

	CON filing).
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.	L+M meets the requirements for data collection, outcomes analysis, benchmarking, and quality improvement. L+M participates in the CathPCI Registry through the ACC NCDR. Formalized periodic case reviews are completed and 2 times per year, case reviews are completed at Quality Assurance Cath Lab Conferences (please refer to Attachment F of the initial CON filing).
Participation in a national data registry where available, such as the ACC NCDR in the United States.	L+M participates in the CathPCI Registry through the ACC NCDR (please refer to Attachment N of the initial CON filing for Executive Summary).

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

SCAI Requirement	L+M/YNHH's Status
1. Interventional cardiologists establish working relations with cardiac surgeons at the receiving facility.	YNHH/YSM interventional cardiologists provide coverage for L+M's PCI program. As affiliates of YNHH/YSM, each physician has a working relationship with the cardiac surgeons at YNHH, the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.	Due to L+M's existing primary PCI program, L+M is already capable of real-time transfer of images and review of treatment options with cardiac surgeons and other interventionalists at YNHH using audio/video equipment through L+M's Philips cardiac imaging systems. These capabilities are in place and will be utilized as appropriately with an elective PCI program.
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.	YNHH shall maintain one operating room open every day for emergency transfers that is cardiothoracic surgery capable. The on-call cardiothoracic surgery will be in-house at YNHH during the hours of 7:30am to 4pm, Monday through Friday to accommodate the L+M elective PCI schedule (please refer to Attachment I of the initial CON filing).
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	YNHH on-call cardiothoracic surgeons will be privileged to provide CABG or other procedures, as necessary, in the event of complication resulting from elective PCI at L+M (please refer to Attachment I of the initial CON filing). Per item #3 above, YNHH will maintain operation room and surgical capacity

this time.	to ensure patients requiring transfer from L+M can be accommodated at YNHH.
5. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	In the event of a complication, L+M's Philips cardiac imaging systems are capable of transmitting real-time images and audio/video to YNHH for consultation with other interventionalists or cardiac surgeons while the patient is still on the table. Together the team can assess the needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse the transfer agreement.	Administrations from L+M and YNHH support and endorse the transfer agreement.
7. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.	Please refer to Attachment F and Attachment I of the initial CON filing for the protocols for rapid transfer of patients.
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.	American Ambulance has committed to provide ground transport within 20 minutes of notification. Life Star Air Transportation which originates from Norwich, typically arrives at L+M within 12 minutes once contacted. Please refer to Attachment J of the initial CON filing for letter from transport vendor.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.	Per YNHH, the receiving surgeon and team will obtain consent for surgery from patient or surrogate. L+M will inform patients that YNHH will provide surgical backup, if needed, in its patient consent process for elective PCI.
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.	Informed consent will include disclosure that the procedure is being completed without on-site surgical backup, the potential risks related to transfer, the risk of urgent surgery (0.3%), and 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.	Please refer to Attachment F of the initial CON filing. Per the Quality Program outlined in the attachment, L+M will review all cases where a patient was transferred for emergency surgery.

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:
For its primary PCI program, L+M has established a streamlined referral mechanism to facilitate the immediate transfer of unstable patients who require surgical intervention from L+M to a cardiac surgery operating room at YNHH. The same process and procedures for the primary PCI program will be utilized for the proposed elective PCI program at L+M. If rapid transport is required, as described in Responses #2 and #3 of this letter, the performing interventionalist at L+M will contact the on-call CT surgeon at YNHH. The Y-Access transfer system will be initiated by YNHH and an operating room will be held open. Concurrently, L+M staff will contact air transport.

L+M has access to air transport through Life Star. Life Star air transport is equipped with the appropriate hemodynamic support (e.g., IABP) and this equipment will be utilized on an as needed basis. In addition, all paramedics are IABP certified and capable of safely using the equipment. As noted in the initial CON filing on pages 37-38, L+M has had conversations with local EMS providers and air transport can be available within 12 minutes of contact and travel time to YNHH is 20 minutes. L+M is well equipped to meet the recommended timeframe of 90 minutes between "initial decision to transport" and "actual time of initiating [emergency cardiac surgery] at the receiving surgical center" stated in the Journal of the American College of Cardiology (JACC) 2009 study referenced on page 38 of the initial CON filing.

c. How does the Hospital's transport agreement with YNHH (where a majority of the patients have been transferred in the past) relate to or meet the guidelines?

Response:
According to distances in miles and travel times in minutes noted on page 20 of the initial CON filing, YNHH is the closest elective PCI provider from a travel time perspective to L+M. Therefore, YNHH is indeed the "nearby" hospital to receive patients requiring urgent surgical intervention. The transport agreement located in Attachment I of the initial CON filing details the nature of the partnership between L+M and YNHH. The longstanding, collaborative, and well-established relationship between YNHH and L+M and its physicians makes the transfer process truly efficient and seamless.

d. What is the Hospital's median time to immediate PCI for STEMI patients?

Response:
As noted on page 48 of the initial CON filing, L+M's median time to immediate PCI for STEMI patients was 57.0 minutes for the rolling four quarters ending 2011 Quarter 4 (data published by the National Cardiovascular Data Registry).

e. How does the Hospital's median time to meet the ACCF/AHA/SCAI guidelines published in November 2011?

Response:
According to the ACCF/AHA/SCAI guidelines published in November 2011, "primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first contact as a systems goal." As demonstrated in Response #8d of this letter, L+M's primary PCI program compares favorably to this recommended timeframe also known as door-to-balloon time.

11. Discuss the incidence of cardiac disease in the Applicant's service area and provide evidence.

Response:
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 (please refer to Attachment 3 for a listing of towns in New London County and information on which towns are included in L+M's service area). Contributing to the poorer cardiovascular health includes 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. 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)

Key information from pages 27 through 32 of the initial CON filing are provided below:

> 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[1] (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[2] accounted for 49% of all CVD deaths

[1] 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.
[2] Coronary heart disease is a form of heart disease resulting from impaired circulation in one or more coronary arteries.

- 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[3] 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[4] 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 A below and Attachment G in the initial CON filing 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 A below). In addition, mortality rates for heart disease are higher in New London County than state averages for both residents 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.

[3] Premature mortality is defined as the "years of potential life lost before age 75."
[4] New London County comprises most of L+M's service area.

Table A: 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).

The same 2007 community health assessment also subdivided New London County and provided information on prevalence of heart disease. The table below provides additional detailed information regarding L+M's service area and proportion of residents with heart disease.

	% Heart Disease
Town of New London	3.7%
Diverse Suburbs	5.0%
The Lymes	NA
Mill Towns	1.6%
Rural Towns	2.4%

Note: Diverse Suburbs include Groton and Norwich; The Lymes includes Lyme and Old Lyme; Mill Towns includes Griswold, Lisbon, Montville, Sprague, Stonington, Waterford; Rural Towns includes Bozrah, Colchester, East Lyme, Franklin, Lebanon, Ledyard, North Stonington, Preston, Salem, and Voluntown
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 B below.

Table B: Health Status Profile from RWJF Study

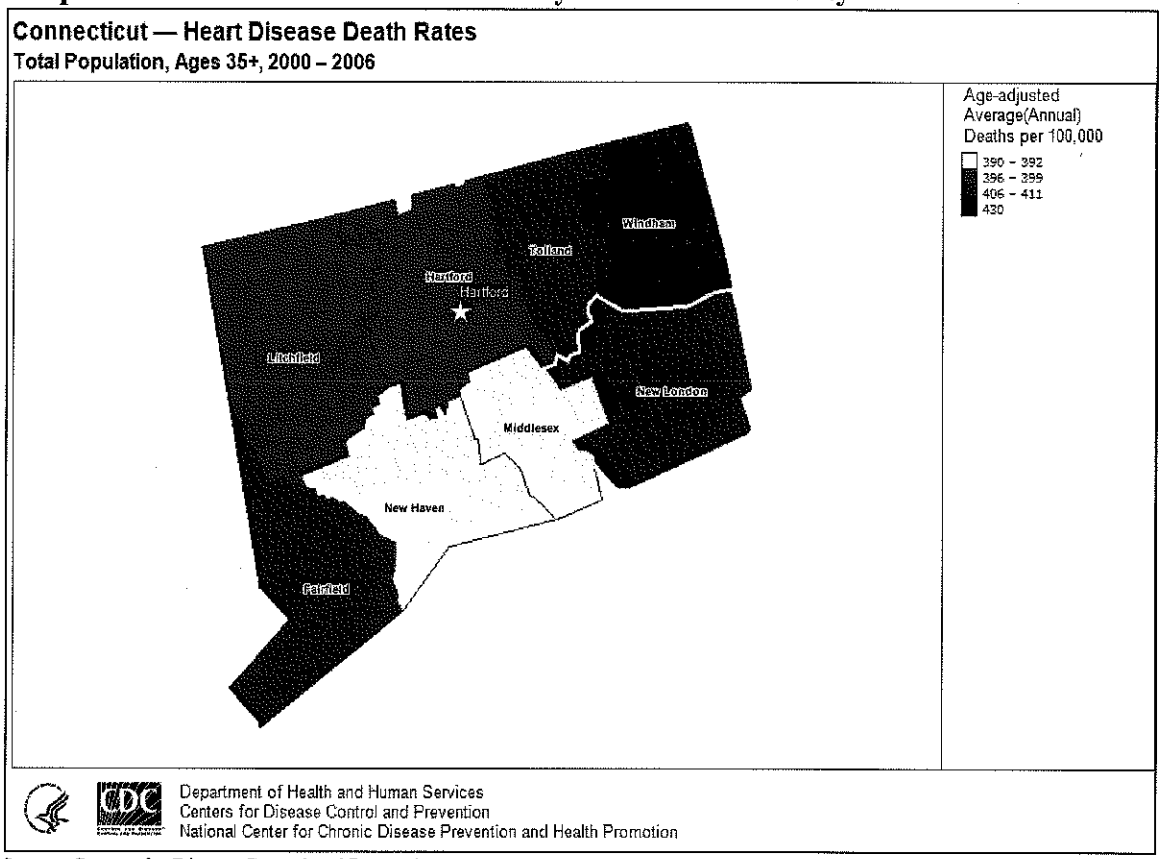
	New London County	Connecticut	United States Benchmark
Health Behaviors			
Adult Smoking	19%	16%	14%
Adult Obesity	24%	23%	21%
Clinical Care			
Primary Care Physicians	1,098:1	729:1	631:1
Preventable Hospital Stays	70	63	49

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.

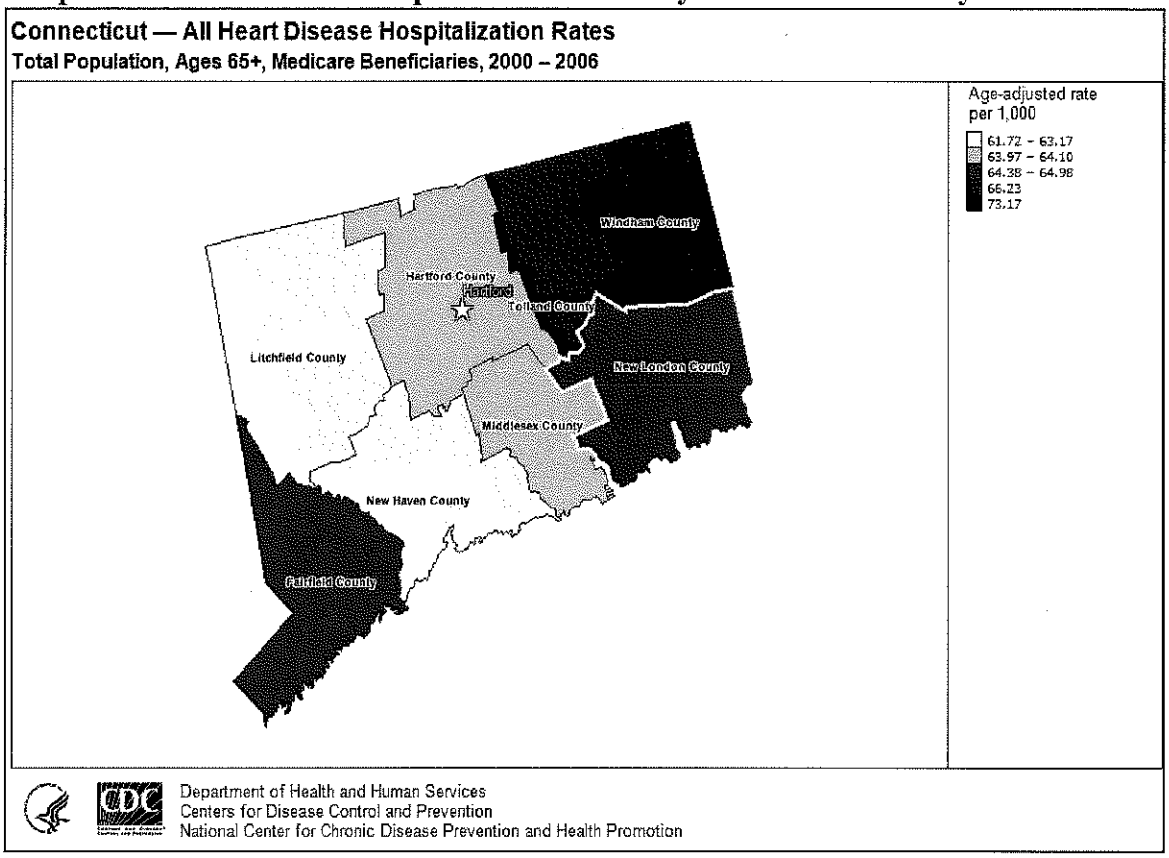
Furthermore, according to data provided by the Centers for Disease Control and Prevention (CDC), New London County has a higher heart disease death rate and hospitalization rate than most other counties in the state. Graphics A and B display this and further demonstrate that cardiac services such as elective PCI is much needed in New London County and the proposed service area.

Graphic A: Heart Disease Death Rates by Connecticut County



Source: Centers for Disease Control and Prevention.

Graphic B: 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 C below and please refer to Attachment E in the initial CON filing for detailed demographic information).

Table C: 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)[5], have a higher proportion of residents that are black non-Hispanic compared to the statewide proportion of 9.7% (please refer to Attachment E in the initial CON filing 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. As demonstrated in the initial CON filing, the benefits of offering elective PCI at L+M to patients are significant.

[5] Zip code and town as follows: 06320 New London, 06340 Groton, 06357 Niantic, and 06382 Uncasville.

12. Please provide a list of ICD-9 codes used to calculate the Hospital's historical and current volume.

Response:

The following ICD-9 codes were included to calculate L+M's historic and current volume:

- 00.66 Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy
- 36.03 Open chest coronary artery angioplasty
- 36.04 Intracoronary artery thrombolytic infusion
- 36.06 Insertion of non-drug-eluting coronary artery stent(s)
- 36.07 Insertion of drug-eluting coronary artery stent(s)
- 36.09 Other removal of coronary artery obstruction

Attachment 1

"ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update"

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ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography

Endorsed by the American Society of Echocardiography and the Heart Rhythm Society

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Abstract

The American College of Cardiology Foundation (ACCF), Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, and the American Association for Thoracic Surgery, along with key specialty and subspecialty societies, conducted an update of the appropriate use criteria (AUC) for coronary revascularization frequently considered. In the initial document, 180 clinical scenarios were developed to mimic patient presentations encountered in everyday practice and included information on symptom status, extent of medical therapy, risk level as assessed by noninvasive testing, and coronary anatomy. This update provides a reassessment of clinical scenarios the writing group felt to be affected by significant changes in the medical literature or gaps from prior criteria. The methodology used in this update is similar to the initial document, and the definition of appropriateness was unchanged. The technical panel scored the clinical scenarios on a scale of 1 to 9. Scores of 7 to 9 indicate that revascularization is considered appropriate and likely to improve patients' health outcomes or survival. Scores of 1 to 3 indicate revascularization is

considered inappropriate and unlikely to improve health outcomes or survival. Scores in the mid-range (4 to 6) indicate a clinical scenario for which the likelihood that coronary revascularization will improve health outcomes or survival is uncertain.

In general, as seen with the prior AUC, the use of coronary revascularization for patients with acute coronary syndromes and combinations of significant symptoms and/or ischemia is appropriate. In contrast, revascularization of asymptomatic patients or patients with low-risk findings on noninvasive testing and minimal medical therapy are viewed less favorably. The technical panel felt that based on recent studies, coronary artery bypass grafting remains an appropriate method of revascularization for patients with high burden of coronary artery disease (CAD). Additionally, percutaneous coronary intervention may have a role in revascularization of patients with high burden of CAD. The primary objective of the appropriate use criteria is to improve physician decision making and patient education regarding expected benefits from revascularization and to guide future research.

Preface

The American College of Cardiology Foundation (ACCF), in collaboration with the Society for Cardiovascular Angiography and Interventions (SCAI), the Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and other societies, developed and published in 2009 appropriate use criteria (AUC) for certain clinical scenarios in which coronary revascularization could be used in an effort to address the rational use of coronary revascularization in the delivery of high-quality care. This document is the first focused update of the original document and includes new literature published since the original document and gaps noted during implementation.

The publication of AUC reflects one of several ongoing efforts by the ACCF and its partners to assist clinicians caring for patients with cardiovascular diseases and in support of high-quality cardiovascular care. The ACCF/American Heart Association (AHA) clinical practice guidelines provide a foundation for summarizing evidence-based cardiovascular care and, when evidence is lacking, provide expert consensus opinion that is approved in review by the ACCF and AHA. However, in many areas, variability remains in the use of cardiovascular procedures, raising questions of over- or underuse. The AUC provide a practical standard upon which to assess and better understand variability.

We are grateful to the technical panel and its chair, Frederick A. Masoudi, MD, MSPH, FACC, FAHA, a professional group with a wide range of skills and insights, for their thoughtful and thorough deliberation of the merits of coronary revascularization for various clinical scenarios. We would also like to thank the parent AUC Task Force and the ACCF staff, Joseph M. Allen and Lea Binder, for their exceptionally skilled support in the generation of this document.

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Introduction

This report is a focused update of the AUC for coronary revascularization published in 2009 (1). The increasing prevalence of coronary artery disease (CAD), continued advances in surgical and percutaneous techniques for revascularization and concomitant medical therapy for CAD, and the costs of revascularization have resulted in heightened interest regarding the appropriate use of coronary revascularization. Clinicians, payers, and patients are interested in the specific benefits of revascularization. Inappropriate revascularization may be harmful to patients and generate unwarranted costs to the healthcare system, whereas appropriate revascularization procedures can improve patients' clinical outcomes.

As in the original AUC document, the same classification scheme with ratings of appropriate, uncertain, and inappropriate was used. The uncertain category can cause confusion in the interpretation of the AUC and can imply several meanings within its definition. First, the rating of uncertain is used when pertinent literature is either not available or when true discrepancies exist. Second, it is impossible to include every relevant piece of clinical information (e.g., age, sex, diabetes) in the individual clinical scenarios. Attempting to do that may result in an unmanageable number of clinical scenarios and thus compromise the usefulness of the AUC in daily practice. The practice of medicine is full of uncertainties that require a thoughtful clinician to use his or her best judgment about each patient to reach decisions about management. Therefore, a rating of uncertain may be assigned by members of the technical panel if clinical information not provided might affect their individual rating, causing a shift into either the appropriate or inappropriate category.

A rating of uncertain means simply what the name implies, and depending on additional factors, it can be appropriate or inappropriate to perform revascularization. The writing group emphasizes that uncertain indications are not inappropriate. Rather, they reflect clinical scenarios that are reasonable for performing revascularization, but additional clinical factors should be considered or further research is needed to more definitively define the benefits of treatment for patients.

All prior AUC publications have reflected an ongoing effort to critically and systematically create, review, and categorize the appropriateness of certain cardiovascular

diagnostic tests, whereas the AUC for coronary revascularization remains the only document addressing treatment. The writing group and technical panel members for this update are identical to the initial AUC (with only 1 exception) and comprised of members from relevant professional societies including both practicing interventional cardiologists and a cardiothoracic surgeon.

For the majority of clinical scenarios, the technical panel only considered the appropriate use of revascularization irrespective of whether this was accomplished by percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG). However, in a select subgroup of clinical scenarios in which revascularization is generally considered appropriate, the appropriateness of PCI and CABG, individually, was considered. In this subgroup, it was recognized that a focused update could be necessary following publication of the SYNTAX (Synergy Between PCI With TAXUS and Cardiac Surgery) trial (2). Therefore, in this update, the writing group identified 4 indications possibly affected by results of the SYNTAX trial for reexamination. The writing group also split 2 of the indications to represent levels of disease burden, recognizing, however, that the ability to reproducibly quantify the SYNTAX score in routine clinical practice has challenges. Also in this subgroup, the variables of diabetes and depressed left ventricular function were included in the initial AUC, but these were combined for the update because all indications with these variables were rated the same in the previous scores by the technical panel.

In addition, since the publication of the original document, efforts to implement data collection protocols related to the AUC indications identified a gap in the clinical scenarios related to lower-risk unstable angina/non–ST-segment elevation myocardial infarction (UA/NSTEMI) patients and asymptomatic patients with 1- or 2-vessel CAD not involving the proximal left anterior descending artery (LAD) in whom no noninvasive testing had been performed. Although limited new evidence is available for these patient populations since publication, the writing group developed indications to address these previous omissions.

Methods

A detailed description of the methods used for rating the selected clinical indications is found in a previous publication, "ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging" (3). Briefly, this process combines evidence-based medicine and practice experience by engaging a technical panel in a modified Delphi exercise. The technical panel is created from nominations given by multiple relevant professional societies and provider-led organizations as well as from health policy and payer communities. To preserve objectivity, technical panels are created so as to not include a majority of individuals whose livelihood is tied to the technology under evaluation.

In making its appropriate use determinations, the technical panel is provided with summaries of the relevant evidence from the medical literature and practice guidelines. Panelists are first asked individually, and then collectively, to assess the benefits and risks of a test or procedure in the context of the potential benefits to patients' outcomes and an implicit understanding of the associated resource use and costs. After the rating process, the final appropriate use ratings are summarized using an established rigorous methodology (4).

Indication Development

Appropriate use criteria are based on current understanding of the technical capabilities and potential patient benefits of the procedures examined. The AUC are also developed to identify common clinical scenarios—but they cannot possibly include every conceivable patient presentation. The term *indication* is used interchangeably with *clinical scenario* in the document for brevity and does not imply that a procedure should necessarily be performed. Some patients seen in clinical practice are not represented in these appropriate use criteria or have additional extenuating features that would alter the appropriateness of treatment as compared with the clinical scenarios presented. Additionally, although AUC indications and ratings are shaped by the guidelines, the AUC often contain more detailed clinical scenarios than the more generalized situations covered in clinical practice guidelines, and thus, subtle differences between these 2 guidance tools may be possible. To minimize this possibility, the coronary revascularization criteria were updated in conjunction with members of the ACCF/AHA PCI and CABG revascularization guideline committees.

Appropriate use criteria are intended to assist patients and clinicians, but are not intended to diminish the acknowledged difficulty or uncertainty of clinical decision making and cannot act as substitutes for sound clinical judgment and practice experience. Rather, the aim of these criteria is to allow assessment of utilization patterns for a test or procedure. Comparing utilization patterns across a large subset of provider's patients can allow for an assessment of a provider's management strategies with those of his/her peers. The ACCF and its collaborators believe that an ongoing review of one's practice using these criteria will help guide a more effective, efficient, and equitable allocation of healthcare resources, and ultimately, better patient outcomes.

The indications went through external review by multisociety and specialty representation for the 2009 document. Because of the narrow focus, the indications were not sent for external review for this update.

Scope of Indications

As previously described, the indications for coronary revascularization were developed considering the following common variables:

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a. The clinical presentation (e.g., acute coronary syndrome, stable angina);
b. Severity of angina (asymptomatic, Canadian Cardiovascular Society [CCS] Class I, II, III, or IV);
c. Extent of ischemia on noninvasive testing and the presence or absence of other prognostic factors, such as congestive heart failure, depressed left ventricular function, or diabetes;
d. Extent of medical therapy; and
e. Extent of anatomic disease (1-, 2-, 3-vessel disease, with or without proximal LAD or left main coronary disease).

The clinical scenarios developed include coronary anatomy, as this is the focus of much of the previous literature on coronary revascularization. However, the writing group recognizes that for everyday patient care, symptom status, ischemic burden, and level of medical therapy often play a critical role in decision making even before the coronary anatomy has been defined by angiography. It is important to note that the indications focus on revascularization, percutaneous or surgical, and do not address diagnostic catheterization or coronary angiography; these criteria are currently under development.

Technical Panel Selection

Stakeholders were given the opportunity to participate in the AUC process by submitting nominees from their organizations through a call for nominations announced in the summer of 2006. From this list of nominees, the AUC Task Force and writing group selected technical panel members to ensure an appropriate balance with respect to expertise. The 17-member technical panel was composed of 4 interventional cardiologists, 4 cardiovascular surgeons, 8 members representing noninterventional cardiologists, other physicians who treat patients with cardiovascular disease, health outcome researchers, and 1 medical officer from a health plan. For the update of the AUC for coronary revascularization, the same technical panelists (with 1 exception) from the original document published in 2009 were reconvened to rerate the 15 clinical scenarios included in the focused update.

Rating Process and Scoring

The technical panel members first rated indications independently. Then, the technical panel participated in 2 conferences calls for a discussion of each indication. After the discussion, panelists independently provided their final scores for each indication. Each panelist had equal weight in producing the final result for the indications and was not forced into consensus. For each indication, the median numerical score was determined and then assigned to an appropriate use category.

For the conference calls, each technical panelist received a personalized rating form that indicated his/her rating for each indication and the distribution of de-identified ratings of other members of the panel. In addition, the moderator received a summary rating form with similar information (including panelist identification), along with other statistics reflecting the level of agreement among technical panel members. The level of agreement among panelists, as defined by RAND, was analyzed for each indication based on the BIOMED rule for a panel of 14 to 16 (a simplified RAND method for determining disagreement) (4). Per the BIOMED definition, agreement was defined as an indication where 4 or fewer panelists' ratings fell outside the 3-point region containing the median score. Disagreement was defined as a situation where at least 5 panelists' ratings fell in both the appropriate and the inappropriate categories. Because the technical panel had 17 representatives, which exceeded the 16 addressed in this rule, an additional level of agreement analysis as described by RAND was performed that examined the interpercentile range compared with interpercentile range adjusted for symmetry (4). This information was used by the moderator to guide the technical panel's discussion by highlighting areas of differences among the panelists.

In developing these appropriate use criteria for coronary revascularization, the technical panel was asked to assess whether coronary revascularization for each indication was appropriate, uncertain, or inappropriate using the following definition of appropriate use:

Coronary revascularization is appropriate when the expected benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life) exceed the expected negative consequences of the procedure.

The technical panel scored each indication on a scale from 1 to 9 as follows:

Median Score 7 to 9

Appropriate procedure for specific indication (procedure **is** generally acceptable and **is** a reasonable approach for the indication).

Median Score 4 to 6

Uncertain for specific indication (procedure **may** be generally acceptable and **may** be a reasonable approach for the indication). Uncertainty implies that more research and/or patient information is needed to classify the indication definitively.

Median Score 1 to 3

Inappropriate procedure for that indication (procedure **is not** generally acceptable and **is not** a reasonable approach for the indication).

The division of these scores into 3 levels of appropriateness is somewhat arbitrary, and the numeric designations should be viewed as a continuum. Further, there is diversity in clinical opinion for particular clinical scenarios, such that scores in the intermediate level of appropriateness should be labeled uncertain, because critical patient or research data may be lacking or discordant. This designation serves as a prompt to the field to carry out definitive research investigations whenever possible. It is anticipated that the AUC reports will continue to be revised as further data are

generated and information from the implementation of the criteria is accumulated.

To prevent bias in the scoring process, care was taken in providing objective, nonbiased information, including guidelines and key references, to the technical panel.

General Assumptions

Specific assumptions are provided that were considered by the technical panel in rating the relevant clinical scenarios for the appropriate use of revascularization:

1. Each clinical scenario includes the patient's clinical status/symptom complex, ischemic burden by noninvasive functional testing when presented, burden of coronary atherosclerosis as determined by angiography, and intensity of medical therapy in the determination of the appropriate use of coronary revascularization.
2. Assume coronary angiography has been performed when these findings are presented in the indications. The technical panel should rate the appropriateness of revascularization based upon the clinical features and coronary findings, and not the appropriateness of diagnostic coronary angiography.
3. Assume left main coronary artery stenosis (greater than or equal to 50% luminal diameter narrowing) or proximal LAD stenosis (greater than or equal to 70% luminal diameter narrowing) is not present unless specifically noted. Assume no other significant coronary artery stenoses are present except those noted in the clinical scenario.
4. The clinical scenarios should be rated based on the published literature regarding the risks and benefits of percutaneous and surgical coronary revascularization. Note that specific patient groups not well represented in the literature are not presented in the current clinical scenarios. However, the writing group recognizes that decisions about coronary artery revascularization in such patients are frequently required. Examples of such patients include those with end-stage renal disease or advanced age.
5. Clinical outcome is related to the extent of coronary artery disease (Table A1) (5). Based on this observation and clinical guideline recommendations regarding "borderline" angiographic stenosis (50% to 60%) in epicardial (non-left main) locations, a significant coronary stenosis for the purpose of the clinical scenarios is defined as:
   - Greater than or equal to 70% luminal diameter narrowing, by visual assessment, of an epicardial stenosis measured in the "worst view" angiographic projection.
   - Greater than or equal to 50% luminal diameter narrowing, by visual assessment, of a left main stenosis measured in the "worst view" angiographic projection.

Table A1. CAD Prognostic Index

Extent of CAD	Prognostic Weight (0–100)	5-Year Survival Rate (%)*
1-vessel disease, 75%	23	93
>1-vessel disease, 50% to 74%	23	93
1-vessel disease, ≥95%	32	91
2-vessel disease	37	88
2-vessel disease, both ≥95%	42	86
1-vessel disease, ≥95% proximal LAD	48	83
2-vessel disease, ≥95% LAD	48	83
2-vessel disease, ≥95% proximal LAD	56	79
3-vessel disease	56	79
3-vessel disease, ≥95% in at least 1	63	73
3-vessel disease, 75% proximal LAD	67	67
3-vessel disease, ≥95% proximal LAD	74	59

*Assuming medical treatment only. Reprinted with permission from Califf et al. (5).
CAD = coronary artery disease; LAD = left anterior descending coronary artery.

6. All patients are receiving standard care, including guideline-based risk factor modification for primary or secondary prevention in cardiovascular patients unless specifically noted (6–10).
7. Despite the best efforts of the clinician, all patients may not achieve target goals for risk factor modification. However, a plan of care to address risk factors is assumed to be occurring in patients represented in the indications. For patients with chronic stable angina, the writing group recognizes that there is a wide variance in the medical therapy for angina. The specific definition of maximal anti-ischemic medical therapy is presented in the definition section and includes the use of 2 or more antianginal medications.
8. Operators performing percutaneous or surgical revascularization have appropriate clinical training and experience and have satisfactory outcomes as assessed by quality assurance monitoring (11–13).
9. Revascularization by either percutaneous or surgical methods is performed in a manner consistent with established standards of care (11–13).
10. In the clinical scenarios, no unusual extenuating circumstances exist (such as inability to comply with antiplatelet agents, do not resuscitate status, patient unwilling to consider revascularization, technically not feasible to perform revascularization, or comorbidities likely to markedly increase procedural risk substantially) unless specifically noted.

Definitions

A complete set of definitions of terms used throughout the clinical scenarios is listed in Appendix A. These definitions were provided to and discussed with the technical panel prior to the rating of indications.

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Maximal Anti-Ischemic Medical Therapy

As previously stated, the indications assume that patients are receiving risk factor modification according to guideline-based recommendations. For the purposes of the clinical scenarios presented, **maximal antianginal medical therapy is defined as the use of at least 2 classes of therapies to reduce anginal symptoms.**

Stress Testing and Risk of Findings on Noninvasive Testing

Stress testing is commonly used for both diagnosis and risk stratification of patients with coronary artery disease. Using criteria defined for traditional exercise stress tests (14):

Low-risk stress test findings: associated with a cardiac mortality of less than 1% per year

Intermediate-risk stress test findings: associated with a 1% to 3% per year cardiac mortality

High-risk stress test findings: associated with a greater than 3% per year cardiac mortality

Examples of findings from noninvasive studies and their associated level of risk for cardiac mortality are presented in Table A2 (13). As noted in the footnote to this table, for certain low-risk findings, there may be additional findings that alter the assessment of risk, but these relationships have not been well studied. Implicit in these risk definitions is a measure of the amount of myocardium at risk, or ischemic myocardium. For the purpose of the indications for coronary revascularization, stress test findings are presented by these risk criteria. For patients without stress test findings, please refer to the note below on invasive methods of determining hemodynamic significance. Assume that when prior testing (including an imaging procedure) is referenced in an indication, the testing was performed correctly and with sufficient quality so as to produce a meaningful and accurate result within the limits of the test performance.

For the purposes of the clinical scenarios in this document, patients with both typical and atypical angina are classified by the feature of the CCS grading system presented below. Patients with noncardiac chest pain should be considered to be asymptomatic.

Grading of Angina Pectoris by the Canadian Cardiovascular Society Classification System (15)

Class I: Ordinary physical activity does not cause angina, such as walking, climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.

Class II: Slight limitation of ordinary activity. 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 in normal condition.

Class III: Marked limitations of ordinary physical activity. Angina occurs on walking 1 or 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace.

Class IV: Inability to carry on any physical activity without discomfort—anginal symptoms may be present at rest.

High-Risk Features for Short-Term Risk of Death or Nonfatal MI for UA/NSTEMI (16)

At least 1 of the following:

- History—accelerating tempo of ischemic symptoms in preceding 48 hours
- Character of pain—prolonged ongoing (greater than 20 minutes) rest pain
- Clinical findings
  - Pulmonary edema, most likely due to ischemia
  - New or worsening mitral regurgitation murmur
  - S_3 or new/worsening rales
  - Hypotension, bradycardia, tachycardia
  - Age greater than 75 years
- Electrocardiogram
  - Angina at rest with transient ST-segment changes greater than 0.5 mm
  - Bundle-branch block, new or presumed new
  - Sustained ventricular tachycardia
- Cardiac marker
  - Elevated cardiac TnT, TnI, or CK-MB (e.g., TnT or TnI greater than 0.1 ng per mL)

TIMI Risk Score—for Patients With Suspected ACS (17)

Variables (1 point each)

- Age ≥65 years
- ≥3 risk factors (hypertension, diabetes mellitus, family history, lipids, smoking)
- Known CAD (stenosis ≥50%)
- Aspirin use in past 7 days
- Severe angina (≥2 episodes within 24 hours)
- ST-segment deviation ≥0.5 mm
- Elevated cardiac markers

Risk of death or ischemic event through 14 days

- Low: 0–2 (<8.3% event rate)
- Intermediate: 3–4 (<19.3% event rate)
- High: 5–7 (41% event rate)

Abbreviations

CABG = coronary artery bypass grafting
CAD = coronary artery disease
CCS = Canadian Cardiovascular Society
CTO = chronic total occlusion
FFR = fractional flow reserve
HF = heart failure

Table A. Focused Update: New or Revised Indications

	Indication	Appropriate Use Score (1–9)	
	Patients With Acute Coronary Syndromes		
9.	• UA/NSTEMI and low-risk features (e.g., TIMI score ≤2) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	U (6)	
10.	• UA/NSTEMI and intermediate-risk features (e.g., TIMI score 3–4) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	A (8)	
	Patients Without Prior Bypass Surgery **Asymptomatic**		
20.	• One- or 2-vessel CAD without involvement of proximal LAD • No noninvasive testing performed	I (3)	
	Method of Revascularization: Multivessel CAD, CCS Angina Greater Than or Equal to Class III, and/or Evidence of Intermediate- to High-Risk Findings on Noninvasive Testing		
		PCI	CABG
62.	• Two-vessel CAD with proximal LAD stenosis	A (7)	A (8)
63.	• Three-vessel CAD with low CAD burden (i.e., 3 focal stenoses, low SYNTAX score)	A (7)	A (9)
64.	• Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	U (4)	A (9)
65.	• Isolated left main stenosis	U (6)	A (9)
66.	• Left main stenosis and additional CAD with low CAD burden (i.e., 1- to 2-vessel additional involvement, low SYNTAX score)	U (5)	A (9)
67.	• Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., 3-vessel involvement, presence of CTO, or high SYNTAX score)	I (3)	A (9)

A = appropriate; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; LAD = left anterior descending coronary artery; MI = myocardial infarction; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery; TIMI = Thrombolysis In Myocardial Infarction; U = uncertain; UA/NSTEMI = unstable angina/non–ST-segment elevation myocardial infarction.

IVUS = intravascular ultrasound
LAD = left anterior descending artery
LIMA = left internal mammary artery
LV = left ventricular
LVEF = left ventricular ejection fraction
MI = myocardial infarction
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction
TIMI = Thrombolysis In Myocardial Infarction
UA/NSTEMI = unstable angina/non–ST-segment elevation myocardial infarction

Results of Updated Ratings

The writing group evaluated the previous 180 clinical scenarios and identified those where reevaluation, expansion, or consolidation was felt necessary (Table A). Nine of the 15 updated indications met the definition of agreement as described above. There were no ratings where the technical panel held such opposing viewpoints that the technical panel's votes were determined to be in "disagreement" as defined by the strict RAND definitions and described previously in the Methods section.

As the majority of the original clinical scenarios and ratings were not rerated in this update, Table A represents the focused update indications. In addition, the entire list of 171 clinical scenarios and their appropriateness scores are shown below in Tables 1, 2, 3, and 4. Figures 1, 2, 3, 4, and 5 demonstrate gradients in appropriate use rating by increasingly severe symptom status and ischemic risk, and by the method of revascularization. These are also presented in a format similar to the original document. In addition to the changes reflected in Table A, the fractional flow reserve (FFR) cut point was updated from 0.75 to 0.80 in indication 22 to reflect new literature since the publication of the original document and to maintain consistency with guidelines (18).

Coronary Revascularization Appropriate Use Criteria (by Indication)

Table 1. Patients With Acute Coronary Syndromes

Indication		Appropriate Use Score (1–9)
1.	• STEMI • Less than or equal to 12 hours from onset of symptoms • Revascularization of the culprit artery	A (9)
2.	• STEMI • Onset of symptoms within the prior 12 to 24 hours • Severe HF, persistent ischemic symptoms, or hemodynamic or electrical instability present	A (9)
3.	• STEMI • Greater than 12 hours from symptom onset • Asymptomatic; no hemodynamic instability and no electrical instability	I (3)
4.	• STEMI with presumed successful treatment with fibrinolysis • Evidence of HF, recurrent ischemia, or unstable ventricular arrhythmias present • One-vessel CAD presumed to be the culprit artery	A (9)
5.	• STEMI with presumed successful treatment with fibrinolysis • Asymptomatic; no HF or no recurrent ischemic symptoms, or no unstable ventricular arrhythmias • Normal LVEF • One-vessel CAD presumed to be the culprit artery	U (5)
6.	• STEMI with presumed successful treatment with fibrinolysis • Asymptomatic; no HF, no recurrent ischemic symptoms, or no unstable ventricular arrhythmias at time of presentation • Depressed LVEF • Three-vessel CAD • Elective/semielective revascularization	A (8)
7.	• STEMI with successful treatment of the culprit artery by primary PCI or fibrinolysis • Asymptomatic; no HF, no evidence of recurrent or provokable ischemia, or no unstable ventricular arrhythmias during index hospitalization • Normal LVEF • Revascularization of a non-infarct-related artery during index hospitalization	I (2)
8.	• STEMI or NSTEMI and successful PCI of culprit artery during index hospitalization • Symptoms of recurrent myocardial ischemia and/or high-risk findings on noninvasive stress testing performed after index hospitalization • Revascularization of ≥1 additional coronary arteries	A (8)
9.	• UA/NSTEMI and low-risk features (e.g., TIMI score ≤2) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	U (6)
10.	• UA/NSTEMI and intermediate-risk features (e.g., TIMI score 3–4) for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	A (8)
11.	• UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery	A (9)
12.	• UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI • Revascularization of multiple coronary arteries when the culprit artery cannot clearly be determined	A (9)
13.	• Patients with acute myocardial infarction (STEMI or NSTEMI) • Evidence of cardiogenic shock • Revascularization of ≥1 coronary arteries	A (8)

New and updated indications are shaded blue.

A = appropriate; CAD = coronary artery disease; HF = heart failure; I = inappropriate; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NSTEMI = non–ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI =ST-segment elevation myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction; U = uncertain; UA = unstable angina.

Table 2. Patients Without Prior Bypass Surgery

Indication		Appropriate Use Score (1–9)		
	CCS Angina Class	Asymptomatic	I or II	III or IV
14.	• One- or 2-vessel CAD without involvement of proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (1)	I (2)	U (5)
15.	• One- or 2-vessel CAD without involvement of proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	I (2)	U (5)	A (7)
16.	• One- or 2-vessel CAD without involvement of proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (5)	U (6)
17.	• One- or 2-vessel CAD without involvement of proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	A (7)	A (8)
18.	• One- or 2-vessel CAD without involvement of proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (6)	A (7)	A (8)
19.	• One- or 2-vessel CAD without involvement of proximal LAD • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (7)	A (8)	A (9)
20.	• One- or 2-vessel CAD without involvement of proximal LAD • No noninvasive testing performed	I (3)	U (5)	A (7)
21.	• One- or 2-vessel CAD with borderline stenosis "50% to 60%" • No noninvasive testing performed • No further invasive evaluation performed (i.e., FFR, IVUS)	Not rated	I (2)	I (3)
22.	• One- or 2-vessel CAD with borderline stenosis "50% to 60%" • No noninvasive testing performed or equivocal test results present • FFR less than or equal to 0.80* and/or IVUS with significant reduction in cross-sectional area	I (3)	U (6)	A (7)
23.	• One- or 2-vessel CAD with borderline stenosis "50% to 60%" • No noninvasive testing performed or equivocal test results present • FFR or IVUS findings do not meet criteria for significant stenosis	I (1)	I (2)	I (2)
24.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (1)	I (2)	I (3)
25.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	I (1)	U (4)	U (6)
26.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (4)	U (6)
27.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Intermediate-risk criteria on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	U (5)	A (7)
28.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (5)	A (7)
29.	• Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • High-risk criteria on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (7)	A (8)
30.	• One-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (5)	A (7)

Continued on next page

Table 2. Continued

Indication		Appropriate Use Score (1–9)		
	CCS Angina Class	Asymptomatic	I or II	III or IV
31.	• One-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	U (4)	A (7)	A (8)
32.	• One-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (6)	A (7)
33.	• One-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	U (5)	A (8)	A (9)
34.	• One-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (8)	A (9)
35.	• One-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	A (7)	A (9)	A (9)
36.	• Two-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (6)	A (7)
37.	• Two-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (7)	A (8)
38.	• Two-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (5)	A (7)	A (8)
39.	• Two-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (6)	A (7)	A (9)
40.	• Two-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (8)	A (9)
41.	• Two-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (8)	A (9)	A (9)
42.	• Three-vessel CAD (no left main) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	U (5)	U (6)	A (7)
43.	• Three-vessel CAD (no left main) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (7)	A (8)
44.	• Three-vessel CAD (no left main) • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (7)	A (8)
45.	• Three-vessel CAD (no left main) • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (7)	A (8)	A (9)
46.	• Three-vessel CAD (no left main) • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	A (7)	A (8)	A (9)
47.	• Three-vessel CAD (no left main) • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (8)	A (9)	A (9)
48.	• Three-vessel CAD (no left main) • Abnormal LV systolic function	A (8)	A (9)	A (9)
49.	• Left main stenosis	A (9)	A (9)	A (9)

New and updated indications are shaded blue. *FFR cut point updated from 0.75 to 0.80 to reflect new literature since publication of the original document and to maintain consistency with guidelines (18).

A = appropriate; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; I = inappropriate; LAD = left anterior descending coronary artery; LV = left ventricular; LVEF = left ventricular ejection fraction; U = uncertain.

Table 3. Patients With Prior Bypass Surgery (Without Acute Coronary Syndrome)

Indication		Appropriate Use Score (1–9)		
	CCS Angina Class	Asymptomatic	I or II	III or IV
50.	• One or more stenoses in saphenous vein graft(s) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (4)	U (6)
51.	• One or more stenoses in saphenous vein graft(s) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	U (4)	U (6)	A (7)
52.	• One or more stenoses in saphenous vein graft(s) • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (4)	U (6)	A (7)
53.	• One or more stenoses in saphenous vein graft(s) • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	A (7)	A (8)
54.	• One or more stenoses in saphenous vein graft(s) • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (6)	A (7)	A (7)
55.	• One or more stenoses in saphenous vein graft(s) • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	A (7)	A (8)	A (9)
56.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	Not rated	I (3)	U (6)
57.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	I (3)	U (5)	A (7)
58.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	I (3)	U (5)	A (7)
59.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (4)	U (6)	A (8)
60.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	U (6)	A (7)	A (8)
61.	• One or more lesions in native coronary arteries without bypass grafts • All bypass grafts patent and without significant disease • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	U (5)	A (8)	A (9)

A = appropriate; CCS = Canadian Cardiovascular Society; I = inappropriate; LV = left ventricular; U = uncertain.

Table 4. Method of Revascularization: Multivessel CAD, CCS Angina Greater Than or Equal to Class III, and/or Evidence of Intermediate- to High-Risk Findings on Noninvasive Testing*

Indication		Appropriate Use Score (1–9)	
		PCI	CABG
62.	• Two-vessel CAD with proximal LAD stenosis	A (7)	A (8)
63.	• Three-vessel CAD with low CAD burden (i.e., 3 focal stenoses, low SYNTAX score)	A (7)	A (9)
64.	• Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	U (4)	A (9)
65.	• Isolated left main stenosis	U (6)	A (9)
66.	• Left main stenosis and additional CAD with low CAD burden (i.e., 1- to 2-vessel additional involvement, low SYNTAX score)	U (5)	A (9)
67.	• Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., 3-vessel involvement, presence of CTO, or high SYNTAX score)	I (3)	A (9)
68.	• Prior bypass surgery with native 3-vessel disease and failure of multiple bypass grafts • LIMA remains patent to a native coronary artery • Depressed LVEF	U (6)	A (7)
69.	• Prior bypass surgery with native 3-vessel disease and failure of multiple bypass grafts • LIMA was used as a graft but is no longer functional • Depressed LVEF	A (8)	U (6)

New and updated indications are shaded blue. *The 2009 appropriate use criteria (1) separated out diabetes and normal or depressed LVEF for the indications in this table, but they were combined for the focused update because these clinical variables did not affect the ratings.

A = appropriate; CABG = coronary artery bypass graft; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; LAD = left anterior descending coronary artery; LIMA = left internal mammary artery; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery; U = uncertain.

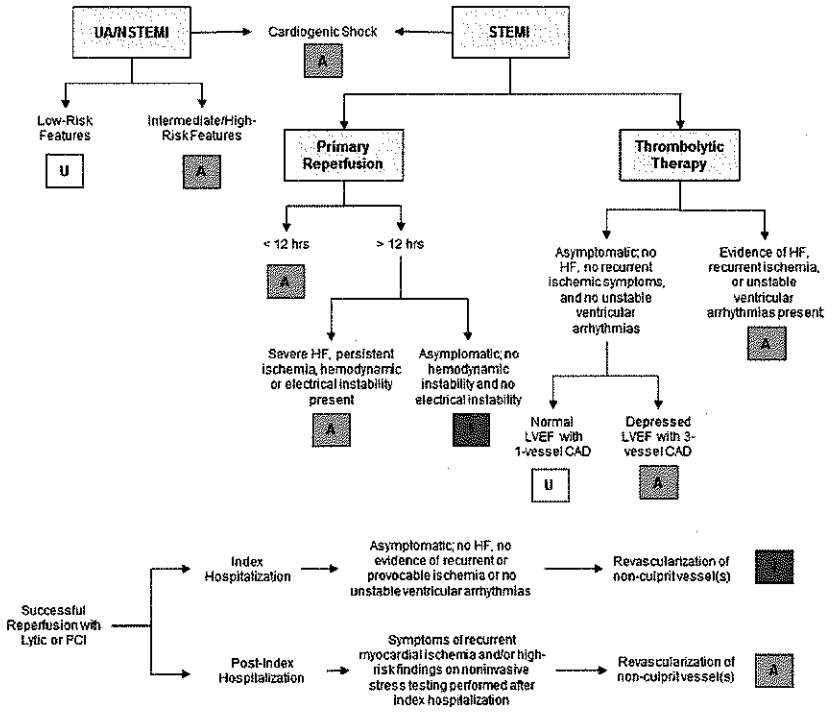

Figure 1. Appropriate Use Ratings for Revascularization in Acute Coronary Syndromes*

*The fact that the use of coronary revascularization for a particular condition is listed in this figure (appropriate, uncertain, inappropriate) does not preclude the use of other therapeutic modalities that may be equally effective. See the most current ACCF/AHA UA/NSTEMI and STEMI guidelines (16,23). A = appropriate; CAD = coronary artery disease; HF = heart failure; I = inappropriate; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; U = uncertain; UA/NSTEMI = unstable angina/non–ST-elevation myocardial infarction.

Low-Risk Findings on Noninvasive Study						Asymptomatic					
Symptoms Med. Rx						**Stress Test Med. Rx**					
Class III or IV Max Rx	U	A	A	A	A	High Risk Max Rx	U	A	A	A	A
Class I or II Max Rx	U	U	A	A	A	High Risk No/min Rx	U	U	A	A	A
Asymptomatic Max Rx	I	I	U	U	U	Int. Risk Max Rx	U	U	U	U	A
Class III or IV No/min Rx	I	U	A	A	A	Int. Risk No/min Rx	I	I	U	U	A
Class I or II No/min Rx	I	I	U	U	U	Low Risk Max Rx	I	I	U	U	U
Asymptomatic No/min Rx	I	I	U	U	U	Low Risk No/min Rx	I	I	U	U	U
Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main	**Coronary Anatomy**	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main

Figure 2. Appropriate Use Ratings by Low-Risk Findings on Noninvasive Imaging Study and Asymptomatic (Patients Without Prior Bypass Surgery)

A = appropriate; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

Intermediate Risk Findings on Noninvasive Study						CCS Class I or II Angina					
Symptoms Med. Rx						**Stress Test Med. Rx**					
Class III or IV Max Rx	A	A	A	A	A	High Risk Max Rx	A	A	A	A	A
Class I or II Max Rx	U	A	A	A	A	High Risk No/min Rx	U	A	A	A	A
Asymptomatic Max Rx	U	U	U	U	A	Int. Risk Max Rx	U	A	A	A	A
Class III or IV No/min Rx	U	U	A	A	A	Int. Risk No/min Rx	U	U	U	A	A
Class I or II No/min Rx	U	U	U	A	A	Low Risk Max Rx	U	U	A	A	A
Asymptomatic No/min Rx	I	I	U	U	A	Low Risk No/min Rx	I	I	U	U	U
Coronary Anatomy	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz. disease; no Left Main	**Coronary Anatomy**	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz disease; no Left Main

Figure 3. Appropriate Use Ratings by Intermediate-Risk Findings on Noninvasive Imaging Study and CCS Class I or II Angina (Patients Without Prior Bypass Surgery)

A = appropriate; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

High-Risk Findings on Noninvasive Study						CCS Class III or IV Angina					
Symptoms Med. Rx						**Stress Test Med. Rx**					
Class III or IV Max Rx	A	A	A	A	A	High Risk Max Rx	A	A	A	A	A
Class I or II Max Rx	A	A	A	A	A	High Risk No/min Rx	A	A	A	A	A
Asymptomatic Max Rx	U	A	A	A	A	Int. Risk Max Rx	A	A	A	A	A
Class III or IV No/min Rx	A	A	A	A	A	Int. Risk No/min Rx	U	U	A	A	A
Class I or II No/min Rx	U	A	A	A	A	Low Risk Max Rx	U	A	A	A	A
Asymptomatic No/min Rx	U	U	A	A	A	Low Risk No/min Rx	I	U	A	A	A
Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main	Coronary Anatomy	CTO of 1-vz.; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main

Figure 4. Appropriate Use Ratings by High-Risk Findings on Noninvasive Imaging Study and CCS Class III or IV Angina (Patients Without Prior Bypass Surgery)

A = appropriate; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

	CABG	PCI
Two-vessel CAD with proximal LAD stenosis	A	A
Three-vessel CAD with low CAD burden (i.e., three focal stenosis, low SYNTAX score)	A	A
Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	A	U
Isolated left main stenosis	A	U
Left main stenosis and additional CAD with low CAD burden (i.e., one to two vessel additional involvement, low SYNTAX score)	A	U
Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., three vessel involvement, presence of CTO, or high SYNTAX score)	A	I

Figure 5. Method of Revascularization of Multivessel Coronary Artery Disease

A = appropriate; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CTO = chronic total occlusion; I = inappropriate; LAD = left anterior descending artery; PCI = percutaneous coronary intervention; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery; U = uncertain.

Rating Revascularization Methods

Mode of Revascularization (Indications 62 to 69)

Recognizing that variability in revascularization methods is often based upon patient factors and local practice patterns, the majority of indications are not intended to distinguish between the specific modes of revascularization (i.e., PCI vs. CABG). However, the writing group recognized that among patients with extensive or complex atherosclerosis, the mode of revascularization is also of interest when revascularization is deemed appropriate. Therefore, Table 4 presents clinical scenarios where the technical panelists were asked to consider the appropriate use of PCI and CABG as the revascularization method independently of each other (such that each modality would receive separate scores based on each specific clinical indication). These ratings are not intended to be a competitive ranking of PCI versus CABG, or to prioritize a specific approach when both are rated to have the same level of appropriateness.

Many of the known clinical factors that increase the risk of revascularization are shared between CABG and percutaneous methods. In the original AUC for revascularization, clinical scenarios were developed that included diabetes and LV function to stratify patients, but when rated, these features did not result in different ratings and thus were not used in this focused update. However, in an attempt to further stratify patients, the SYNTAX score is used in some of the new clinical scenarios.

The clinical scenarios below specifically apply to patients with multivessel CAD. It is assumed for these clinical scenarios that all patients have unacceptable levels of symptoms despite appropriate medical therapy and evidence of intermediate- to high-risk findings on noninvasive testing. In other words, the technical panel assumed that revascularization is appropriate and focused on rating the merit of the different modes with the intent of complete coronary revascularization for each indication.

In addition, it is assumed that no unusual extenuating circumstances exist (inability to comply with antiplatelet agents, patient is do not resuscitate status, patient preference strongly favoring 1 therapy or comorbidities likely to markedly increase procedural risk substantially). As such, the technical panel rated the appropriateness of PCI and CABG based on the information in the indication alone, assuming other variables are not present that would impact the decision.

Discussion

The ultimate objective of AUC is to improve patient care and health outcomes. The ACCF and its collaborators believe that careful blending of a broad range of clinical experiences and available evidence-based information will help guide a more efficient and equitable allocation of healthcare resources in cardiovascular revascularization. This approach is not intended to diminish the acknowledged difficulty or uncertainty of clinical decision making. Appropriate use criteria are not substitutes for sound clinical judgment and practice experience. It is acknowledged that some patients seen in clinical practice may not be represented in the AUC or have extenuating features when compared with the clinical scenarios presented.

Since the publication of the original coronary revascularization AUC, there has been substantial national focus on the variability and appropriateness of coronary revascularization. The 2009 AUC specifically for coronary revascularization by PCI has been mapped to the National Cardiovascular Data, Registry (NCDR) CathPCI registry data, and each institution's benchmarked results are now provided to member facilities in quarterly reports as a test quality metric. This initial assessment of PCI appropriateness within the NCDR data was also published by Chan and colleagues (19). Hospitals and operators are encouraged to review their specific reports as part of a quality improvement program to ensure data accuracy and increase the use of appropriate revascularization. Additionally, the SYNTAX trial, which was not formally published until 2009, was anticipated to possibly have an impact on the AUC. Despite calls for earlier updates of specific clinical scenarios, such as the isolated left main coronary artery revascularization, the writing group awaited the peer-reviewed publication of both the original trial data and the intermediate-term follow-up.

This focused update highlights 2 specific areas that were felt to require reconsideration: 1) specific indications that represent gaps identified when mapping the 2009 AUC to the CathPCI registry; and 2) re-evaluation of the indications for the treatment of multivessel CAD with symptoms by method (PCI and CABG) of revascularization as a result of data from the SYNTAX trial.

New Clinical Scenarios to Address Gaps

The 2009 AUC document only had 1 clinical scenario for UA/NSTEMI and high-risk features, which was graded as appropriate. The ratings for these new clinical scenarios (Indications 9 and 10) focus on patients with UA/NSTEMI and low- or intermediate-risk features as determined by the TIMI score. Revascularization in such patients with a low-risk score was graded as uncertain, meaning that revascularization may be reasonable, with the caveat that there is limited data on clinical benefit. For patients with an intermediate-risk score, revascularization was rated appropriate as it was for patients at high risk (Fig. 1).

In the 2009 AUC document, the clinical scenario of an asymptomatic patient without prior bypass surgery and with 1- or 2-vessel disease not involving the proximal LAD in whom no noninvasive testing had been performed was not evaluated because this clinical scenario was felt to be uncommon. However, for future mapping of the AUC to the CathPCI registry, the appropriateness of this clinical scenario was graded

in this focused update and determined to be inappropriate. This did not affect the appearance of Figures 2, 3, and 4 below because they include indications that were not updated.

PCI and CABG in Patients With Multivessel CAD

In this group of ratings, it is assumed that revascularization is appropriate, and the technical panel rated the appropriateness of the mode of revascularization independently for CABG and PCI (Fig. 5). The writing group and technical panel felt some quantification of CAD burden, either by description or SYNTAX score, could be helpful to clinicians. CABG was rated as appropriate in all of the new clinical scenarios developed, whereas PCI was rated as appropriate only in patients with 2-vessel CAD with involvement of the proximal LAD and in patients with 3-vessel disease with a low CAD burden. PCI for 3-vessel disease with a high CAD burden, however, was rated as uncertain. PCI for isolated left main stenosis is now graded as uncertain, as are scenarios with 3-vessel CAD with intermediate to high CAD burden and left main stenosis and additional CAD with low CAD burden. PCI is considered inappropriate for left main stenosis and additional CAD with intermediate to high CAD burden.

Clinical Judgment and Understanding the AUC Ratings

Although the appropriate use ratings reflect a general assessment of when revascularization may or may not be useful for specific patient populations, physicians and other stakeholders should continue to acknowledge the pivotal role of clinical judgment in determining whether revascularization is indicated for an individual patient. For example, the rating of a revascularization indication as inappropriate or uncertain should not preclude a provider from performing revascularization procedures when there are patient- and condition-specific data to support that decision. Indeed, this may reflect optimal clinical care, if supported by mitigating patient characteristics. Likewise, uncertain indications require individual physician judgment and understanding of the patient to better determine the usefulness of revascularization for a particular clinical scenario. The ranking of uncertain (4 to 6) **should not be viewed as excluding the use of revascularization for such patients**. Finally, there may be clinical scenarios in which the use of coronary revascularization for an indication considered to be appropriate does not always represent reasonable practice, such that the benefit of the procedure does not outweigh the risks. Accordingly, the AUC are intended to evaluate overall patterns of care regarding revascularization rather than adjudicating specific cases. In situations where there is substantial variation between the appropriate use rating and what the clinician believes is the best recommendation for the patient, further considerations or actions such as a second opinion may be appropriate. It is not anticipated that all physicians or facilities will have 100% of their revascularization procedures deemed appropriate. However, related to the overall patterns of care, if the national average of appropriate procedure ratings is 80%, e.g., and a physician or facility has only a 40% rate of appropriate procedures, further examination of the patterns of care may be warranted and helpful.

Stable Ischemic Heart Disease *With* Prior CABG

The writing group did not feel the focused update needed to address any clinical scenarios in patients with stable ischemic heart disease and prior CABG. These indications from the prior document show a pattern similar to that seen in patients without prior CABG; the presence of high-risk findings on noninvasive testing, higher severity of symptoms, or an increasing burden of disease in either the bypass grafts or native coronaries increased the likelihood of an appropriate rating. The only inappropriate ratings in patients with prior CABG were noted in patients receiving no or minimal anti-ischemic therapy or having low-risk findings on noninvasive testing. More uncertain ratings occurred in this group of patients, reflecting their higher complexity, higher risk, and the limited availability of published evidence regarding management outcome.

Application of Criteria

There are many potential applications for the AUC. Clinicians can use the ratings for decision support or as an educational tool when considering the need for revascularization. Moreover, these criteria can be used to facilitate discussion with patients and/or referring physicians about the need for revascularization. Facilities and payers may choose to use these criteria either prospectively in the design of protocols or pre-authorization procedures, or retrospectively for quality reports. It is hoped that payers would use these criteria to ensure that their members receive necessary, beneficial, and cost-effective cardiovascular care, rather than for other purposes.

It is expected that services performed for appropriate indications will receive reimbursement. In contrast, services performed for inappropriate indications may require additional documentation to justify payment because of the unique circumstances or the clinical profile that may exist in such a patient. This additional documentation should not be required for uncertain indications. It is critical to emphasize that the writing group, technical panel, AUC Task Force, and clinical community do not believe an uncertain rating justifies denial of reimbursement for revascularization. Rather, uncertain ratings are those in which the available data vary and many other factors exist that may affect the decision to perform or not perform revascularization. The opinions of the technical panel often varied for these indications, reflecting that additional research is needed. Indications with high clinical volume that are rated as uncertain identify important areas for further research. The AUC writing group and technical panel favor the collaborative interaction of cardiac surgeons and interventional cardiologists Heart Team approach regarding revascularization decisions in complex patients or coronary anatomy.

When evaluating physician or facility performance, AUC should be used in conjunction with efforts that lead to quality improvement. Prospective pre-authorization procedures, if put in place, are most effective once a retrospective review has identified a pattern of potential inappropriate use. Because these criteria are based on current scientific evidence and the deliberations of the technical panel, they should be used prospectively to generate future discussions about reimbursement, but should not be applied retrospectively to cases completed before issuance of this report or documentation of centers/providers performing an unexpectedly high proportion of inappropriate cases as compared with their peers.

The writing group recognizes that these criteria will be evaluated during routine clinical care. To that end, specific data fields such as symptom status, presence or absence of acute coronary syndrome, history of bypass surgery, extent of ischemia on noninvasive imaging, CAD burden, and degree of antianginal therapy are anticipated to provide sufficient detail to determine individual appropriate use ratings. Because a reasonable and tolerated dose of antianginal therapy may vary significantly among different patients, the writing group continues to recommend the use of 2 classes of antianginal therapies as a minimum standard for medical therapy. The writing group also recognizes all data (e.g., visual assessment of stenosis severity, interpretation of noninvasive imaging, symptom severity) collected to assess appropriate use relies on its content accurately reflecting actual patient characteristics. Any current variability in these data points need to be addressed before accurate determination of appropriate use can be provided.

The primary objective of this report is to provide guidance regarding the suitability of coronary revascularization for diverse clinical scenarios. As with previous AUC documents, consensus among the technical panel members was desirable, but an attempt to achieve complete agreement within this diverse panel would have been artificial and was not the goal of the process. Two rounds of ratings with substantial discussion among the technical panel members between the ratings did lead to some consensus among panelists. However, further attempts to drive consensus would have diluted true differences in opinion among panelists and, therefore, was not undertaken. Moreover, remarkable concordance between the appropriateness ratings from the original criteria and 85 cardiologists not participating in the process, and blinded to the initial results, has been documented (20).

Future research analyzing patient outcomes for indications rated as appropriate will help ensure the equitable and efficient allocation of resources for coronary revascularization. Review of appropriateness patterns may also improve understanding of regional variations in the use of revascularization as highlighted in the Dartmouth Atlas Project (21). Further exploration of the indications rated as uncertain will help generate the information required to further define the appropriate use of coronary revascularization. Additionally, the criteria will need to be updated with the publication of ongoing trials in coronary revascularization and new clinical practice guidelines. For additional information and discussion of the literature, please see the ACCF/AHA PCI and CABG guidelines (12,13).

In conclusion, this document represents the current understanding of the clinical benefit of coronary revascularization with respect to health outcomes and survival. It is intended to provide a practical guide to clinicians and patients when considering revascularization. As with other AUC, the results of some of these ratings will require research and further evaluation to provide the greatest information and benefit to clinical decision making.

Appendix A: Additional Coronary Revascularization Definitions

Angina/Chest Pain Classification

Angina is a syndrome typically noted to include discomfort in the chest, jaw, shoulder, back, or arm that is aggravated by exertion or emotional stress and relieved by nitroglycerin. The quality of the discomfort, provoking factors, and relieving factors are used to define typical, atypical, and noncardiac chest pain. Atypical angina is generally defined by 2 of the above 3 characteristics, and noncardiac chest pain is generally defined as chest pain that meets 1 or none of the above criteria. These definitions are presented below.

Clinical Classification of Chest Pain (22):

- ***Typical* Angina (Definite):** Defined as 1) substernal chest pain or discomfort that is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.
- ***Atypical* Angina (Probable):** Chest pain or discomfort that **lacks 1** of the characteristics of definite or typical angina.
- ***Nonanginal* Chest Pain:** Chest pain or discomfort that **meets 1 or none** of the typical angina characteristics.

The writing group assumes that noninvasive assessments of coronary anatomy (i.e., cardiac computed tomography, cardiac magnetic resonance angiography) provide anatomic information that is potentially similar to x-ray angiography. However, these modalities do not currently provide information on ischemic burden and are not assumed to be present in the clinical scenarios.

Invasive Methods of Determining Hemodynamic Significance

The writing group recognizes that not all patients referred for revascularization will have previous noninvasive testing. In fact, there are several situations in which patients may be appropriately referred for coronary angiography based on symptom presentation and a high pretest probability of coronary artery disease. In these settings, there may be

Table A2. Noninvasive Risk Stratification

High-risk (>3% annual mortality rate)
1. Severe resting left ventricular dysfunction (LVEF <35%)
2. High-risk treadmill score (score ≤−11)
3. Severe exercise left ventricular dysfunction (exercise LVEF <35%)
4. Stress-induced large perfusion defect (particularly if anterior)
5. Stress-induced multiple perfusion defects of moderate size
6. Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201)
7. Stress-induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201)
8. Echocardiographic wall motion abnormality (involving >2 segments) developing at low dose of dobutamine (≤10 mg/kg/min) or at a low heart rate (<120 beats/min)
9. Stress echocardiographic evidence of extensive ischemia
Intermediate-risk (1% to 3% annual mortality rate)
1. Mild/moderate resting left ventricular dysfunction (LVEF 35% to 49%)
2. Intermediate-risk treadmill score (score between −11 and <5)
3. Stress-induced moderate perfusion defect without LV dilation or increased lung intake (thallium-201)
4. Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of dobutamine involving less than or equal to 2 segments
Low-risk (<1% annual mortality rate)
1. Low-risk treadmill score (score ≥5)
2. Normal or small myocardial perfusion defect at rest or with stress*
3. Normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress*

*Although the published data are limited, patients with these findings will probably not be at low risk in the presence of either a high-risk treadmill score or severe resting left ventricular dysfunction (LVEF <35%). Reprinted with permission from Patel et al. (1).
LV = left ventricular; LVEF = left ventricular ejection fraction.

situations where angiography shows a coronary narrowing of questionable hemodynamic importance in a patient with symptoms that can be related to myocardial ischemia. In such patients, the use of additional invasive measurements (such as fractional flow reserve or intravascular ultrasound) at the time of diagnostic angiography may be very helpful in further defining the need for revascularization and substituted for stress test findings (Table A2).

Appendix B: Additional Methods

See the earlier Methods section of the report for a description of technical panel selection, indication development, scope of indications, and rating process.

Relationships With Industry and Other Entities

The American College of Cardiology Foundation and its partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the technical panel. Specifically, all panelists are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the AUC Task Force, discussed with all members of the technical panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by all participants, who are listed in Appendix C, in the Appropriate Use Criteria for Coronary Revascularization can be found in Appendix D. In addition, to ensure complete transparency, complete disclosure information—including relationships not pertinent to this document—is available online as a document supplement.

Literature Review

The technical panel members were asked to refer to the relevant guidelines for a summary of the relevant literature, guideline recommendation tables, and reference lists provided for each indication table when completing their ratings (Online Appendix).

Appendix C: ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update Participants

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†Participated in the 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update only

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Appendix D. ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 APPROPRIATE USE CRITERIA FOR CORONARY REVASCULARIZATION FOCUSED UPDATE WRITING GROUP, TECHNICAL PANEL, INDICATION REVIEWERS,* AND TASK FORCE—RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (IN ALPHABETICAL ORDER)

Participant	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Manesh R. Patel	None	None	None	None	None	None
Gregory J. Dehmer	None	None	None	None	None	None
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Peter K. Smith	• Eli Lilly	None	None	None	None	None
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Peter K. Smith	• Eli Lilly	None	None	None	None	None
Karen J. Beckman	None	None	None	None	None	None
Charles E. Chambers	None	None	None	None	None	None
T. Bruce Ferguson	None	None	None	None	None	None
Mario J. Garcia	None	None	None	None	None	None
Frederick L. Grover	None	None	None	None	None	None
David R. Holmes Jr.	None	None	None	None	None	None
Lloyd W. Klein	None	None	None	None	None	None
Marian C. Limacher	None	None	None	None	None	None
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Lee M. Arcement	None	None	None	None	None	None
R. Morton Bolman	None	None	None	None	None	None
Javed Butler	None	None	None	None	None	None
Jun R. Chiong	None	None	None	None	None	None
G. William Dec	None	None	None	None	None	None
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Raymond J. Gibbons	None	None	None	None	None	None
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Lloyd W. Klein	None	None	None	None	None	None
Michael J. Mack	None	None	None	None	None	None
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William C. Nugent	None	None	None	None	None	None
Myung H. Park	None	None	None	None	None	None
Michael Poon	None	None	None	None	None	None
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Christopher M. Kramer	None	None	None	None	None	None
James K. Min	None	• GE Healthcare	None	None	None	None
Manesh R. Patel	None	None	None	None	None	None
Leslee Shaw	None	None	None	None	None	None
Raymond F. Stainback	None	None	None	None	None	None
Joseph M. Allen	None	None	None	None	None	None

This table represents the relevant relationships with industry and other entities that were disclosed by participants at the time of participation. It does not necessarily reflect relationships at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation does not imply endorsement of this document. *Relationships were recorded at the time of review for the 2009 publication. Because the reviewers did not review the focused update, their information was not updated for this document. †Significant relationship.

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Key Words: ACCF Appropriate Use Criteria ■ coronary artery bypass graft surgery ■ percutaneous coronary interventions ■ revascularization.

Attachment 2

OHCA Agreed Settlement for Docket Number: 04-30297-CON Establish Primary Interventional Cardiac Service at Lawrence and Memorial Hospital in New London

Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Applicants:	**Lawrence and Memorial Hospital and Yale-New Haven Hospital**
Docket Number:	**04-30297-CON**
Project Title:	**Establish Primary Interventional Cardiac Service at Lawrence and Memorial Hospital in New London**
Statutory Reference:	**Section 19a-638, Connecticut General Statutes**
Filing Date:	**December 28, 2004**
Hearing Dates:	**March 10, 2005**
Presiding Officer:	**Cristine Vogel, Commissioner**
Decision Date:	**June 1, 2005**
Default Date:	**Not Applicable**
Staff:	**Paolo Fiducia**

Project Description: Lawrence and Memorial Hospital and Yale-New Haven Hospital ("Applicants") propose to establish a primary interventional cardiac service, to be located at Lawrence and Memorial Hospital, at a total capital expenditure of $7,500.

Nature of Proceedings: On December 28, 2004, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish a primary interventional cardiac service, to be located at Lawrence and Memorial Hospital. The proposal has a total capital expenditure of $7,500. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A public hearing regarding the CON Application was held on March 10, 2005. The Applicants were notified of the date, time, and place of the hearing and notices to the public were published prior to the hearings in *The Day Publishing Company* (New London). Commissioner Cristine Vogel served as presiding 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 Connecticut General Statutes) and Section 19a-638, C.G.S.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Applicants and in rendering this decision, considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Section 19a-638, C.G.S. The provisions of this section, 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 Applicants' Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. Lawrence and Memorial Hospital ("L&M") is a not-for-profit 280-bed acute care hospital located in New London, Connecticut. L&M currently operates two diagnostic cardiac catheterization laboratories[1]. *(December 28, 2004, CON Application, page 25)*

2. Yale-New Haven Hospital ("YNHH") is a not-for-profit, 944-bed acute care hospital located in New Haven, Connecticut. YNHH is a full service (i.e. cardiac catheterization, angioplasty and open-heart surgery) cardiac provider. *(Department of Public Health License)*

[1] 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.

3. The Applicants propose to establish a primary angioplasty[2] service for acute myocardial infarction ("PAMI") patients at L&M presenting with ST-segment elevation (STEMI) and left bundle branch blockage (LBBB). *(December 28, 2004, CON Application, page 25)*

4. The Applicants have submitted two agreements for the implementation of the proposed PAMI program at L&M, as follows:
   - A Clinical Participant Agreement which states that L&M becomes a clinical participant of the Yale-New Haven Health Services Corporation Network and shall obtain certain services including: training, strategic and service line planning, outcome, and marketing.
   - A Primary Intervention Program Training Agreement which states that YNHH will support the establishment of the primary interventional cardiac services at L&M in a number of ways including: providing or arranging consultative services with respect to the development of proposed care standards, quality assurance programs and policies, procedures and protocols, consulting with respect to the collection and analysis of quality data, and arranging training for nursing and technical staff who will be serving the primary interventional cardiac service.

   (December 28, 2004, CON Application, pages 13, 339 & 340 and Attachment C)

5. The Applicants have had a primary tertiary cardiac referral relationship since 1985. Out of 144 transfers from L&M to other acute care hospitals for advanced cardiac services in FY 2003, 125 were transferred to YNHH. *(December 28, 2004, CON Application, page 27)*

6. The proposed program will be developed and managed by L&M in collaboration with Eastern Connecticut Cardiology Group, PC ("ECCG"), which is the primary cardiology group servicing L&M. ECCG consists of nine board certified cardiologists and one interventional cardiologist with offices in New London and Groton. *(December 28, 2004, CON Application, page 25)*

7. The Hospital stated that ECCG will open a third office in Waterford, CT within the next 12 months and anticipate adding at least one more board certified cardiologist. *(December 28, 2004, CON Application, page 26)*

8. The proposed primary angioplasty service will be performed in L&M's two existing diagnostic cardiac catheterization laboratories by interventional cardiologists on staff at L&M and the Yale School of Medicine. The service will be available twenty-four hours per day, seven days per week. *(December 28, 2004, CON Application, page 25)*

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[2] Primary (or 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.

9. The proposed primary angioplasty program will augment existing inpatient and outpatient cardiac services at L&M which include: *(December 28, 2004, CON Application, page 25)*
   - Diagnostic cardiac catheterization
   - 10-bed cardiac care unit
   - 31-bed cardiac step down telemetry unit
   - Direct fiber-optic video link between L&M and YNHH
   - Cardiac Rehabilitation
   - Exercise stress testing
   - Pharmacological and exercise nuclear stress testing
   - Electrocardiograms and holter and event monitoring
   - Echocardiograms
   - Transesophageal echocardiograms
   - Tilt table studies
   - Pacemaker insertions
   - Cardiac homecare
   - Community education programs
   - Paramedic intercept program.

10. The Applicants based the need for the proposed primary angioplasty service at L&M on the following: *(December 28, 2004 CON Application, page 25)*
   - Existing cardiac volume
   - Improved accessibility for patients
   - Reduction in mortality and morbidity in service areas
   - Reduction in time to treatment

11. The Applicants' proposed service areas ("PSA") for the proposed PAMI program consist of the following towns:

Table 1: L&M's Proposed Primary Angioplasty Program's Service Areas

Towns	Primary	Secondary	Total	
	East Lyme	Bozrah	Bozrah	Montville
	Groton	Colchester	Colchester	New London
	Ledyard	Franklin	East Lyme	North Stonington
	Lyme	Griswold	Franklin	Norwich
	Montville	Lisbon	Griswold	North Stonington
	New London	Norwich	Ledyard	Old Lyme
	North Stonington	Preston	Lisbon	Preston
	Old Lyme	Salem		Salem
	Stonington	Voluntown		Stonington
	Waterford			Voluntown
				Waterford
L&M's Share of Area's Inpatient Diagnostic Cardiac Caths	48.8%	5.5%	33.2%	
Area's Share of L&M's Inpatient Diagnostic Cardiac Caths	87.4%	5.5%	92.9%	

Source: Cardiac catheterization volume from *OHCA Acute Care Hospital Inpatient Discharge Database*. Service area from *December 28, 2004 CON Application*, pages 32-33).

12. The demographic characteristics of L&Ms' PSA for the proposed PAMI program are as follows:

Table 2: Demographic Characteristics of L&M's PSA

		Population			
Service Area	**Total**	**Adults (15+)**	**15 – 44 (%)**	**45 – 64 (%)**	**65+ (%)**
Primary	168,400	134,872	43.9	22.9	13.4
Secondary	80,810	63,470	43.4	22.4	12.7
Total Service Area	249,210	198,342	43.7	22.7	13.2
Connecticut	**3,405,565**	**2,696,490**	**42.2**	**23.2**	**13.8**

Source: Census 2000.

13. L&M's historical volume of diagnostic cardiac catheterizations for Fiscal Years ("FY") 2000-2003 is as follows:

Table 3: L&M's Historical Cardiac Catheterization Volume (FYs 2000 – 2003)

CT Service Area	**2000**	**2001**	**2002**	**2003***
Inpatient	470	516	420	474
Outpatient	649	675	558	475
Total	1,119	1,191	978	949

* Diagnostic cardiac catheterization laboratories opened at The William W. Backus Hospital and Westerly Hospital (Rhode Island).

Source: *OHCA Acute Care Hospital Inpatient Discharge Database* and self-reported outpatient figures from *CON Application, December 28, 2004 page 40).*

14. In Connecticut from FYs 2000 through 2003, patients 65 years and older received 55% of all inpatient diagnostic cardiac catheterizations and angioplasty procedures. *(OHCA Acute Care Hospital Inpatient Discharge Database)*

15. Physician participation in the primary interventional cardiac service will be strictly limited to experienced interventional cardiologists who meet or exceed the volume standards set forth in the American College of Cardiology ("ACC") and the American Heart Association ("AHA") guidelines. *(September 16, 2004, CON Application, page 25)*

16. The 2001 ACC/AHA Guidelines for PCI recommend criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. These criteria and standards will be utilized by the Applicants and are specified in **Attachment I.** *(June 15, 2001, JACC Vol.37, No. 8, page 2226&2227)*

17. The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Trial's Manual of Operations for the Primary Angioplasty Registry contains patient eligibility and identification criteria, guidelines for clinical care, standards for facilities and care providers and staff training, including care plan and logistics

development and quality and error management. These criteria and standards will be utilized by the Applicants and are specified in **Attachment I.** *(September 3, 2003, The Atlantic C-PORT Trial Primary Angioplasty Registry, Manual of Operations)*

18. The Hospital stated that during FY 2003, sixty-five of the 246 patients with a primary diagnosis of Acute Myocardial Infarction ("AMI") were diagnosed with STEMI. The Chief of Cardiology reviewed the medical records meeting the C-PORT inclusion criteria and determined that all of the patients met the criteria and would have been candidates for primary angioplasty. *(December 28, 2004, CON Application, pages 26&27)*

19. The Hospital stated that the proposed angioplasty service is planned to meet the ACC/AHA practice guidelines and the C-PORT requirements for care standards, staff training and competency, physician competency, surgical back-up logistics, and quality monitoring and reporting. *(December 28, 2004, CON Application, page 54)*

20. The Applicants stated that primary angioplasty would be performed at L&M safely and efficiently by meeting the ACC/AHA criteria and standards and C-PORT guidelines through the following:
    a. Patient entry points (e.g., the Emergency Department) will be continuously staffed by personnel competent in performing electrocardiogram ("ECG"), initial evaluation and treatment of patients with acute ischemic syndromes, including MI and unstable angina. The same personnel will have training in cardiac, monitoring and advanced cardiac life support ("ACLS");
    b. The critical care unit and cardiac service unit will have cardiac monitoring, immediate access to persons trained in ACLS and capabilities for arterial line and pulmonary artery catheter placement, temporary pacemaker replacement, mechanical ventilation and intra-aortic balloon placement;
    c. The specialty care unit and future cardiac services unit will be able to provide continuous ECG monitoring and prompt access to ACLS trained staff;
    d. Nursing staff monitoring post-operative PAMI patients will meet all applicable training requirements;
    e. Credentialing and privileging of interventionalists will be conducted in accordance with the policies and procedures set forth in the Medical Staff Bylaws; and
    f. Nursing and technical staff involved in the PAMI Program will take part in a formal training program arranged through YNHH.
    (December 28, 2004, CON Application, page 107)

22. Numerous studies have demonstrated that primary PCI is a more effective therapeutic alternative to pharmaceutical therapy resulting in lower morbidity and mortality, as follows:
    - PCI for acute myocardial infarction can be performed safely and effectively at a community hospital without on-site cardiac surgical facilities. *(Ting, et.al,Mayo Clinic, 2004, "Percutaneous coronary intervention for ST-segment and non-ST-segment elevation myocardial infarction at hospitals with and without on-site cardiac surgical capability")*

- The C-PORT trial found that community hospitals performing primary angioplasty without cardiac surgical backup had better outcomes based on a six-month composite measure of mortality and adverse outcomes than those who received pharmaceutical therapy. *(Aversano, et.al., "Thrombolytic Therapy vs. Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery")*

23. The average ischemic heart disease and AMI discharges and deaths in L&M's PSA for FYs 1999-2003 are as follows:

Table 5: Average Annual Ischemic Heart Disease and AMI Discharges and Deaths in L&M's Proposed CT Service Areas, (FYs 2000 – 2003[1])

	Hospital Discharges				Mortality	
	Ischemic Heart Disease[2]		AMI		Ischemic Heart Disease	
Service Area	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate
Primary	1,202	8.9	484	3.6	242	1.8
Secondary	774	12.2	328	5.2	129	2.0
Total Service Area	1,976	10.0	812	4.1	371	1.9
Connecticut	-	**8.2**	-	**3.2**	-	**2.1**

Mortality figures are from CT Department of Public Health Vital Records.
Population figures are from Census 2000.
[1]Deaths were from calendar years 2000 through 2003. AMI discharges were from Hospital Fiscal Years 2000 through 2004 (Hospital Fiscal Year from October 1st through September 30th).
[2]Includes discharges with a primary diagnosis of either coronary atherosclerosis or acute myocardial infarction (AMI).
ICD-9 codes: Ischemic Heart Disease 410 - 414; AMI 410.
ICD-10 codes: Ischemic Heart Disease Mortality I20 – I25.
(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases.)

Note: The adult rate was calculated by dividing the average annual total number of ischemic or AMI discharges or ischemic deaths originating in the service area by the adult population (age 15 and older) in that area and multiplying this by 1,000. Therefore, it is interpreted as the number of discharges or death per 1,000 adults in the service area (e.g. 7.1 ischemic heart disease discharges per 1,000 adults in L&M's total service area).

24. Travel distances from L&M to the nearest existing PAMI and full-service cardiac providers are as follows:

Table 4: Area PAMI and Full-Service Cardiac Providers

Hospital	Miles to L&M Hospital
Hartford	48
St. Francis	49
Yale	49

Source: Travel miles from Yahoo maps.

25. The ACC/AHA guidelines for PCI recommend formalized written protocols in place for immediate (within 1 hour) and efficient transfer of patients to the nearest full-service cardiac center. The ACC/AHA guidelines also state that procedures must be done in a timely fashion (balloon inflations within 90±30 minutes of ED admission). *(JACC, 2001, Vol. 37, No.8, pg. 2239)*

26. The Applicants stated that patients who require CABG or other cardiac surgery will be transferred on an urgent basis to YNNH. The Applicants have executed a transfer agreement. *(December 28, 2004 CON Application, page 334)*

27. The transportation of patients to L&M for PAMI services will be supported primarily by American Ambulance Service. *(December 28, 2004 CON Application, page 52)*

28. L&M will be responsible for the facilities, equipment and day-to-day operations of the PAMI program. YNNH will ensure that all staff are expertly trained in the art of acute coronary interventional procedures and will also provide ongoing training as necessary and appropriate. *(March 3, 2005 Responses to Interrogatories, page 4)*

29. The Applicants project the following number of diagnostic cardiac catheterizations and primary angioplasties in L&M's PSA for FYs 2005, 2006, and 2007: *(December 28, 2004 CON Application, page 45)*

Table 6: Projected Cardiac Volume

Service	FY 2005	FY 2006	FY 2007
Diagnostic Cardiac Catheterizations*	919	928	937
Primary Angioplasties	52	73	77

Projections based on a 4.18% compounded annual growth rate and historical market share.
(December 28, 2004 CON Application, pages 48-50)

30. The Applicants stated that Dr. Fiengo will perform the substantial majority of the 60-70 projected procedures per year, with the remainder provided by Yale affiliated interventional cardiologists. *(December 28, 2004 CON Application, page 51)*

31. The Applicants stated that the proposed PAMI program and call system is staffed by Dr. Fiengo (54% of covered time), the on-site interventional cardiologist from ECCG, and eight interventionalists (46% of covered time) from Yale University School of Medicine, Cardiology Interventional Group ("YSMCG"). The burden of coverage is shared among the nine (9) doctors, and all participants have agreed to the call schedule. *(December 28, 2004 CON Application, page 2)*

32. The Applicants stated that if L&M is approved for PAMI, YSMCG is committed to recruiting an additional interventional cardiologist to help support the L&M program. *(March 3, 2005 Responses to Interrogatories, page 2)*

33. To ensure seven days per week, 24 hours per day program availability, the Applicants have proposed the following operating call schedule:

- Dr. Fiengo would cover Monday, Tuesday, Wednesday day and night, and every third weekend. YSMCG would cover Thursday, Friday, and two out of three weekends.
- Interventionalists from YSMCG will be providing coverage to L&M from their Branford office during the daytime.
- During the nighttime, coverage will be provided from the physician homes. Several of the covering physicians live on the shoreline east of New Haven (two live in Madison and two live in Guilford) and will be readily available to L&M. In addition, L&M will provide one on-site call room for an interventional cardiologist who wants to spend the night at L&M.
- L&M has assured that there will not be delays in treatment when the interventional cardiologist is traveling to L&M as one of the ECCG cardiologists will also be on-call and will be preparing the patient for the angioplasty procedure prior to the arrival of the interventional cardiologist. The ECCG cardiologist will perform the diagnostic catheterization and identify the culprit lesion causing the AMI. By having the ECCG cardiologist on-call in addition to the on-call interventional cardiologist, the care process will be expedited.
  (December 28, 2004 CON Application, page 342 and March 3, 2005 Responses to Interrogatories, page 2)

34. Dr. Henry Cabin from the Yale School of Medicine testified at the hearing on March 10, 2005 to the following:

- "It takes about 50 minutes from New Haven to L&M.
- Its about 35 to 40 minutes from Guilford/Madison to L&M".

Financial Feasibility of the Proposal and its Impact on the Applicant's Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services

35. The proposal has a total expenditure of $7,500 for medical equipment which will be financed through operating funds. *(December 28, 2004, CON Application, page 67)*

36. L&M projects the implementation of the proposal will result in incremental losses in operations of $(504,082), $(524,171) and $(513,692) for FYs 2005, 2006 and 2007, respectively. *(December 28, 2004, CON Application, page 132)*

37. L&M projects gains in total operations with the project of $762,351, $760,696, and $769,975 for FYs 2005, 2006, and 2007, respectively. *(December 28, 2004, CON Application, page 132)*

38. L&M does not anticipating hiring any additional FTEs as a result of this CON. *(December 28, 2004, CON Application, page 72)*

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

The following findings are made pursuant to principles and guidelines set forth in Section 19a-637, C.G.S.:

39. There is no State Health Plan in existence at this time. *(December 28, 2004 CON Application, page 30)*

40. The Applicants have adduced evidence that this proposal is consistent with L&M's long-range plan. *(December 28, 2004 CON Application, page 30)*

41. L&M has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and applications of technology. *(December 28, 2004 CON Application, page 64)*

42. The Applicants' proposal will not impact L&M's teaching and research responsibilities. *(December 28, 2004 CON Application, page 65)*

43. There are no distinguishing characteristics of L&M's patient/physician mix. *(December 28, 2004 CON Application, page 65)*

44. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(December 28, 2004 CON Application, page 63 and Attachment VIII)*

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 even though L&M's service area has a younger population and a lower mortality rate than the Connecticut rate average, OHCA determined that geographic isolation, as well as the high cardiac volume at L&M, are significant factors in determining need.

L&M and Yale-New Haven Hospital ("Applicants") propose to expand the cardiovascular services at L&M to include primary angioplasty for acute myocardial infarction ("PAMI") patients presenting with ST-segment elevation ("STEMI") or left bundle branch blockage ("LBBB"). L&M will be responsible for the day-to-day operations of the PAMI program, including facilities and equipment. YNHH will ensure that all staff are expertly trained in acute coronary interventional procedures and will provide tertiary back-up services as an existing full-service cardiac provider. The service area for the proposed program consists of 18 towns, and L&M is geographically positioned to address the needs of the residents in the proposed service areas.

The Applicants based the need for the proposed primary interventional cardiac service on existing cardiac volume, improved accessibility for patients, reduction in mortality and morbidity in the service area, and reduction in time to treatment. Numerous studies have demonstrated that primary PCI is a more effective therapeutic alternative to pharmaceutical therapy resulting in lower morbidity and mortality. According to medical literature, primary PCI can be performed safely without cardiac surgery when rigorous program criteria are established through the American College of Cardiology/American Heart Association ("ACC/AHA") criteria and standards and C-PORT guidelines, as specified in Attachment I. Current medical literature supports primary angioplasty in community hospitals without on-site cardiac surgery for patients presenting with STEMI or LBBB myocardial infarction.

The ACC/AHA guidelines for PCI recommends that formalized written protocols be in place for immediate (within 1 hour) and efficient transfer of patients to the nearest full-service cardiac center. Currently, residents of L&M's proposed service areas travel over 45 miles to full-service cardiac centers for PAMI services. Out of 144 transfers from L&M to other acute care hospitals for advanced cardiac services in FY 2003, 125 were transferred to YNHH. Implementation of the proposal will allow primary angioplasty procedures to be done in a timely fashion (balloon inflations within 90±30 minutes of admission). Primary intervention will be performed routinely as the treatment of choice around the clock (e.g. 24 hours per day/7 days a week) for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes. These are all

salubrious results from improved access to patient care.

The proposal has the potential to improve the quality of care and continuity of cardiac services in the region. Studies have shown that acute infarct PCI can be performed safely and effectively at a community hospital without cardiac surgical capability by following rigorous standards as specified in Attachment I. The Applicants stated that primary angioplasty would be performed at L&M safely and efficiently by meeting the ACC/AHA criteria and standards and C-PORT guidelines through a fully equipped cardiac catheterization laboratory with access to a full range of interventional equipment.

Furthermore, physicians participating in the program will be experienced interventional cardiologists who meet or exceed the minimum volume standards put forth in the ACC/AHA guidelines. The proposed program will be developed and managed by L&M in collaboration with Eastern Connecticut Cardiology Group, which is the primary cardiology group servicing L&M, consisting of nine board certified cardiologists and one interventional cardiologist, Dr. Fiengo. The proposed PAMI program at L&M will be covered by Dr. Fiengo and eight interventional cardiologists from the Yale School of Medicine Cardiology Group ("YSMCG"). YSMCG is committed to recruiting an additional interventional cardiologist to help support the L&M program.

To ensure seven days per week, 24 hours per day program availability at L&M, all nine interventionalists for the PAMI program agreed to an operating schedule at L&M. Dr. Fiengo would cover Monday, Tuesday, Wednesday day and night, and every third weekend. YSMCG would cover Thursday, Friday, and two out of three weekends. Interventionalists from YSMCG will be providing coverage to L&M from their Branford office during the daytime. During the nighttime, coverage will be provided from the physician homes. Several of the covering physicians live on the shoreline east of New Haven and will be readily available to L&M. In addition, L&M will provide one on-site call room for an interventional cardiologist who wants to spend the night at L&M. In addition, L&M has assured that there will not be delays in treatment when the interventional cardiologist is traveling to L&M as one of the ECCG cardiologists will also be on-call and will be preparing the patient for the angioplasty procedure prior to the arrival of the interventional cardiologist. The ECCG cardiologist will perform the diagnostic catheterization and identify the culprit lesion causing the AMI. By having the ECCG cardiologist on-call in addition to the on-call interventional cardiologist, the care process will be expedited.

L&M currently is operating two diagnostic cardiac catheterization laboratories performing 1,119, 1,191, 978 and 949 studies in Fiscal Years ("FY") 2000, 2001, 2002, and 2003, respectively. Based on historical volumes and service area market share rates, OHCA estimates that L&M could potentially perform 52, 73 and 77 PAMIs for FYs 2005, 2006 and 2007, respectively. Dr. Fiengo will perform the substantial majority of the 60-70 procedures per year, with the remainder provided by Yale-affiliated interventional cardiologists. In FY 2003, sixty-five of the 246 patients with a primary diagnosis of AMI at L&M were diagnosed with STEMI. The Chief of Cardiology reviewed the medical records meeting the C-PORT inclusion criteria and determined that

all of the STEMI patients met the criteria and would have been candidates for primary angioplasty. Based on the above, OHCA finds that the proposed PAMI program at L&M would meet or exceed the minimum volume standard of 36 PAMIs per year as stated in the ACC/AHA Guidelines.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure of $7,500 for medical equipment which will be financed through operating funds. L&M projects the implementation of the proposal will result in incremental losses in operations of $(504,082), $(524,171) and $(513,692) for FYs 2005, 2006 and 2007, respectively. However, L&M projects gains in total hospital operations with the project of $762,351, $760,696, and $769,975 for FYs 2005, 2006, and 2007, respectively. L&M's volume and financial projections upon which they are based appear to be reasonable and achievable. Therefore, the CON proposal will not adversely impact the interests of consumers and payers of such services.

The Applicants' proposed primary angioplasty service is differentiated from other cardiac-related proposals in the following ways. First, L&M is located in a geographic pocket or outlying area where its residents have to travel over 45 miles for emergent angioplasty; thereby potentially not meeting the recommended door-to-balloon time of 90-120 minutes and increasing the risk of mortality and morbidity for its population. As a result of this geographic isolation, L&M's area residents are currently not receiving the treatment of choice for its STEMI patients. L&M's proposal will bring appropriate access to high quality cardiac services within a reasonable travel time. Second, L&M currently operates a high volume diagnostic cardiac catheterization program, and currently performs approximately 950 diagnostic cardiac catheterizations per year and is projecting to perform 60-70 PAMIs per year. Additionally, the proposed arrangement between L&M, ECCG, and YSMCG will provide full physician coverage by experienced interventional cardiologists for the PAMI program ensuring seven days a week, 24 hours per day program availability. Therefore, L&M's program will be able to achieve PAMI volumes in excess of those stated in the ACC/AHA Guidelines. Finally, L&M's strong collaborative relationship with YNHH will enhance the accessibility of high quality, community-based medical services offered by L&M. Implementation of the proposal will bring appropriate access to high quality cardiac services to the residents of the service areas within a reasonable travel time. In summary, the proposal will result in enhanced cardiac services in the New London region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and Lawrence and Memorial Hospital and Yale-New Haven Hospital ("Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish a primary interventional cardiac service to be located at L&M at a total capital expenditure of $7,500, as follows:

1. The Applicants' request for a CON to establish a primary interventional cardiac service to be located at L&M at a total capital expenditure of $7,500 is hereby approved.

2. L&M 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 L&M in writing of its evaluation. If OHCA finds questionable material, L&M 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 L&M does not submit the above data to the Cardiac Data Registry on a quarterly basis, the primary angioplasty program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstitution of the program.

3. If L&M and/or the physicians do not perform the ACC/AHA recommended minimum number of annual institutional or operator volumes, as specified in Attachment I within 12 months of commencement of the primary PCI program (first 12-month period), L&M shall submit monthly reports of primary angioplasty volume arrayed by physician to OHCA until such time as the minimum volumes are met by both institution and physician. If by the end of the second 12-month period, the ACC/AHA institutional and operator annual volumes are not met, the Applicants' primary PCI program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstitution of the program.

4. L&M shall participate in the C-PORT registry and is required to comply with the patient eligibility and identification, guidelines for clinical care, standards for facilities and care providers and staff training, including care plan and logistics

development and quality and error management, as stated in the Manual of Operation. L&M shall provide OHCA quarterly data reports through such registry for the purposes of monitoring and quality assurance. If L&M determines not to participate in the C-PORT registry or the C-PORT registry no longer exists, L&M shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.

5. L&M shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. L&M shall provide OHCA quarterly data reports from the ACC-NCDR. These reports shall be submitted to OHCA at the same time that the Connecticut Cardiac Data Registry data is filed. L&M is required to comply with all the ACC/AHA criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. If L&M determines not to participate in the ACC-NCDR, L&M shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards.

6. L&M shall report to OHCA documenting compliance with the ACC/AHA general exclusion criteria for invasive procedures, performance of primary PCI in hospitals without cardiac surgery capabilities, and selection of patients appropriate for primary PCI or transfer to a full-service cardiac center. If the ACC/AHA criteria and standards and/or the C-PORT guidelines are not met, Lawrence and Memorial Hospital's primary PCI program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstitution of the program.

7. The Applicants will contract with a second on-site interventional cardiologist for the proposed PAMI program who will begin performing PAMIs' at L&M upon Dr. Fiengo performing 70 cumulative angioplasty procedures at L&M. The interventional cardiologist must be fully credentialed and have the following qualifications:
   - Board-Certified in interventional cardiology
   - Maintains a Connecticut license and admitting privileges at both L&M and YNHH
   - Meets or exceeds the AHA/ACC minimum operator volume standards for PCI for the past 2 years.

   The Applicants shall provide the CV of the additional interventional cardiologist prior to performance of primary angioplasties at L&M. OHCA shall acknowledge receipt and acceptance of the CV prior to performance of PAMIs by the physician.

8. The Applicants shall report to OHCA documenting compliance with the operating call schedule. The Applicants shall provide documentation that on call YSMCG cardiologists initiate the procedure within 40 minutes of call.

9. OHCA and L&M and YNHH agree that this Agreed Settlement represents a final agreement between OHCA and L&M and YNHH with respect to this request. The

signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Applicants with regard to Docket Number 04-30297-CON.

10. This authorization shall expire on June 1, 2007. Should the Applicants' primary interventional cardiac service not be implemented by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.

11. 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 L&M's expense, if the Applicants fail to comply with its terms.

5/31/05
Date

Duly Authorized Agent for
Lawrence and Memorial Hospital

Date

Duly Authorized Agent for
Yale-New Haven Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on June 1, 2005.

Date Signed:
June 1, 2005

Signed by:
Cristine A. Vogel
Commissioner
Office of Health Care Access

CAV:pf

Attachment 3

New London County Towns and Overlap with L+M Service Area

New London County Towns and Overlap with L+M Service Area

Towns in New London County	L+M Service Area
Bozrah	SSA
Colchester	SSA
East Lyme	PSA
Franklin	SSA
Griswold+Lisbon	SSA
Groton	PSA
Lebanon	excluded from service area
Ledyard	PSA
Lyme	PSA
Montville	PSA
New London	PSA
North Stonington	PSA
Norwich	SSA
Old Lyme	PSA
Preston	SSA
Salem	SSA
Sprague	excluded from service area
Stonington	PSA
Voluntown	SSA
Waterford	PSA

Key:
PSA = primary service area
SSA = secondary service area

Note: Other towns included in L+M's secondary service area include Old Saybrook, CT and Westerly, RI.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

August 31, 2012 Via Fax and Regular Mail

Ms. Shraddha Patel
Director of Business Development & Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

RE: Certificate of Need Application; Docket Number: 12-31768-CON
Lawrence & Memorial Hospital Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

Dear Ms. Patel:

This letter is to inform you that, pursuant to Section 19a-639a(d) of the Connecticut General Statutes, the Office of Health Care Access has determined that the above-referenced application has been deemed complete as of August 31, 2012. The date of August 31, 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) 418-7007.

Sincerely,

A. Veyberman

Alla Veyberman
OHCA Health Care Analyst

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3032
RECIPIENT ADDRESS	98604443716
DESTINATION ID	
ST. TIME	08/31 10:08
TIME USE	00'18
PAGES SENT	2
RESULT	OK

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: SHRADDHA PATEL

FAX: 860.444.3716

AGENCY: L&M HOSPITAL

FROM: OHCA

DATE: 08/31/2012 **Time:**

NUMBER OF PAGES: 2
(including transmittal sheet

Comments:

Deemed Complete Letter
Docket Number: 12-31768-CON

PLEASE PHONE ***IF THERE ARE ANY***

Greer, Leslie

From: Olejarz, Barbara
Sent: Thursday, November 08, 2012 2:20 PM
To: Lazarus, Steven; Greer, Leslie; Veyberman, Alla; Riggott, Kaila
Cc: Martone, Kim
Subject: FW: From Michele Volpe re Lawrence & Memorial Hospital (CON Application- Docket Number: 12-31768-CON)
Attachments: Letter to OHCA Re Declaratory Ruling on 911 (FINAL 11.8.12).pdf

11/8/12

Please see below.

The attached is also going to be sent in by fax.

Barbara

From: Bettyanne Toole [mailto:bettyanne@bvmlaw.com]
Sent: Thursday, November 08, 2012 2:02 PM
To: Martone, Kim
Cc: Olejarz, Barbara; Michele AOL
Subject: From Michele Volpe re Lawrence & Memorial Hospital (CON Application- Docket Number: 12-31768-CON)

Dear Kim: Attached please find correspondence regarding Lawrence & Memorial Hospital's pending Certificate of Need Application (Docket Number: 12-31768-CON). Please feel free to contact me with any additional questions.

Thank you,
Michele M. Volpe
michelemvolpe@aol.com

Sent by:
Betty Anne Toole-Teasley
Paralegal
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511-6957
Telephone: (203) 777-5800 (ext. 104)
Facsimile: (203) 777-5806

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET, THIRD FLOOR
NEW HAVEN, CONNECTICUT 06511
203-777-5800
Fax: 203-777-5806

Michele M. Volpe
Direct Dial: (203) 777-6995
michelemvolpe@aol.com

November 8, 2012
Via Facsimile # (860) 418 7053, Electronic Mail
and First Class USPS Mail

Deputy Commissioner Lisa Davis
State of Connecticut
Department of Public Health
Division of Office of Health Care Access
410 Capitol Avenue
MS #13HCA
Hartford, CT 06134-0308

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Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

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When the Declaratory Ruling is read in context, it is clear that it applies only to long term care facilities, not acute care hospitals transferring patients to other acute care hospitals. Indeed, if the Declaratory Ruling is read overly broadly so that it applies to both long term care facilities and acute care hospitals, it conflicts with State and Federal Statutes and places an enormous strain on Connecticut's emergency medical system ("EMS"). The Applicant's current patient transfer protocols—which reflect the standard industry-wide practice for acute care hospitals in Connecticut—fully comply with all applicable law.

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emergencies that are reported to them privately by long term care facilities or private individuals. On February 14, 2003, the DPH issued a written opinion (the "Declaratory Ruling"), in which it concluded:

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The Declaratory Ruling also held that ambulance services and other providers of emergency medical transport ("Providers") cannot provide emergency medical services to long term care facilities and individuals in areas where they are not Primary Service Area Responders ("PSARs"), except under very limited circumstances, and that Providers cannot contract directly with long term care facilities for the provision of emergency medical services. *Id.* at p. 25-26 and p. 34-35. In the Declaratory Ruling, the DPH interpreted Connecticut General Statutes §§ 19a-175 and 19a-179, and the accompanying regulations, which are known as the Emergency Medical Services Assistance Act ("EMSAA"). The Declaratory Ruling addressed only the practices and procedures of: (1) long term care facilities; and (2) EMS providers providing services to long term care facilities and private individuals. It did not address at all the transfer of patients between two acute care hospitals.

II. The DPH Intended the Declaratory Ruling to Apply Only to Emergency Transfers of Patients From Long Term Care Facilities to Hospitals

The context of the Declaratory Ruling, as well as the language used by the DPH in the opinion, indicate that the ruling does not apply when a hospital transfers a patient to another hospital during an emergency. In its opinion, the DPH discussed the historical practices and procedures of long term care facilities, and interpreted DPH's prior policy directives to long term care facility administrators. *E.g.*, DPH Declaratory Ruling, at p. 18 (clarifying the DPH's prior statements, which "defined the term, 'emergency,' for long term care facilities"). The terminology used throughout the Declaratory Ruling makes it clear that the DPH meant for the Declaratory Ruling to apply only to long term care facilities, not hospitals. For example, in each section of the ruling that regulates the conduct of facilities, the DPH's conclusions specifically refer to long term care facilities. *E.g.*, *id*, at p. 30 (concluding that "**long term care facilities** are required to call 911when there is an emergency")(Emphasis added); *id.*, at p. 35 ("[F]or **long term care facilities** to enter into such [private patient transport] agreements with providers would undermine the entire regulatory scheme creating the emergency medical services system as it exists today . . .")(Emphasis added).

While the Declaratory Ruling is replete with references to "long term care facilities," it makes no mention of interhospital transfers—either in general terms, or by using specific terms of art, such as "interfacility critical care transport" ("ICCT"), a term of art in the industry that was added to General Statutes § 19a-175 in 2009. If the DPH intended that the Declaratory Ruling apply to ICCTs, it presumably would have used the proper term of art in its opinion or, at the very least, explained in general terms that the opinion applied to acute care hospitals, which are fundamentally different from long term care facilities. The language selected by the DPH for its ruling, which focuses on "long term care facilities" and omits any mention of hospitals or ICCTs activating the 911 system, plainly indicates that the opinion does not apply to interhospital patient transfer protocols.

III. Even if the Declaratory Ruling Applied to Interhospital Transfers, Such Application Was Superceded by Statute, and Would Conflict With State and Federal Laws

The Declaratory Ruling interpreted the EMSAA as it existed in 2003. In 2009, the legislature enacted General Statutes § 19a-179c, which directly regulates ICCTs. It provides:

> Any ambulance used for interfacility critical care transport shall meet the requirements for a basic level ambulance, as prescribed in regulations adopted pursuant to section 19a-179, including requirements concerning medically necessary supplies and services, and may be supplemented by a licensed registered nurse, advanced practice registered nurse, physician assistant or respiratory care practitioner, provided such licensed professionals shall have current training and certification in pediatric or adult advanced life support, or from the Neonatal Resuscitation Program of the American Academy of Pediatrics, as appropriate, based on the patient's condition.

Thus, even if the Declaratory Ruling applied to interhospital transfers in 2003, the legislature's enactment of § 19a-179c in 2009 created new rules that specifically regulate interhospital transfers, and, therefore, abrogated the Declaratory Ruling as it applies to acute care hospitals. Furthermore, a hospital may not be able to comply with § 19a-179c if it must dial "911" to arrange interhospital transfers because it will have very limited control over the EMS provider that the 911 dispatcher sends.

OHCA's interpretation of the Declaratory Ruling also conflicts with the Federal Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd(c)(2), which states:

> An appropriate transfer to a medical facility is a transfer-- . . . (D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer. . .

Hospitals and physicians who fail to comply with the EMTALA are subject to fines and, in some instances, exclusion from federal and state health care programs. 42 U.S.C. § 1395dd(d). If hospitals must dial "911" to procure emergency patient transfers, they will be unable to comply with their duty to provide a transfer that is "effected through qualified personnel and transportation equipment." The foregoing conflicts with State and Federal law, which expose the Declaratory Ruling to a legal challenge, can be avoided if the Declaratory Ruling is read to apply to long term care facilities, but not hospitals such as the Applicant.

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The Connecticut Supreme Court has held: "specific terms covering the given subject matter will prevail over general language of the same or another statute which might otherwise prove controlling. . . . The provisions of one statute which specifically focus on a particular problem will

always, in the absence of express contrary legislative intent, be held to prevail over provisions of a different statute more general in its coverage." *Housatonic Railroad Co., Inc.* v. *Commissioner of Revenue Services*, 301 Conn. 268, 302 (2011). Furthermore, in cases "in which more than one statutory provision is involved, a court presumes that the legislature intended those provisions to be read together to create a harmonious body of law and the court construes the provisions, if possible, to avoid conflict between them." *Tomlinson v. Tomlinson*, 305 Conn. 529, 552 (2012). The Declaratory Ruling interprets the generalized Emergency Medical Services Assistance Act of 1974, not the specific statute pertaining to ICCTs, General Statutes § 19a-179c. Because General Statutes § 19a-179c applies specifically to interhospital transfers and is in tension with the Declaratory Ruling, it prevails.

V. Application of the Declaratory Ruling to Interhospital Transfers Would Unnecessarily Strain the Emergency Medical System

As the DPH explained in the Declaratory Ruling, calls to 911 set off a tiered response:

> [W]hen 911 is accessed, first responders, typically fire or law enforcement agencies, are dispatched to provide basic intervention such [as] cardiopulmonary resuscitation and control of bleeding. Basic ambulances then provide more advanced skills and transportation of the sick and injured. Paramedics provide advanced life support and may function as a part of the ambulance or intercept with the ambulance. (DPH Declaratory Ruling, at p. 14).

Hospitals do not require 911 dispatchers to provide them with first aid instructions, nor do they need first responders to render basic first aid. If hospitals accessed the 911 system for every interhospital transfer in the State of Connecticut, it would unnecessarily divert multiple public safety resources to organizations that do not require their assistance, at great cost to the cities and towns that must pay for these resources. As a matter of public policy, it does not make sense to require hospitals to utilize the 911 system for emergency interhospital transfers, which occur on a regular basis throughout the State. To do so would divert EMS resources away from situations where such assistance is truly needed.

For all the foregoing reasons, the Declaratory Ruling should not be applied to the Applicant. Please do not hesitate to contact me at 203-777-6995 if you have any additional questions or concerns.

Sincerely,

Michele M. Volpe

MMV/bt

cc: Kimberly Martone, Director of Operations, via email: Kimberly.Martone@ct.gov

FAX TRANSMISSION

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET
THIRD FLOOR
NEW HAVEN, CT 06511
(203) 777-5800 Fax: (203) 777-5806

FAX #: (860) 418-7053

DATE: November 8, 2012

TO: Deputy Commissioner Lisa Davis
Director of Operations, Kimberly Martone
State of Connecticut
Department of Public Health
Division of Office of Health Care Access

PAGES: 5 , including this page

FROM: Michele M. Volpe

MATTER #: 115481

SUBJECT: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

COMMENTS:

Please see the attached correspondence.

Thank you.

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET, THIRD FLOOR
NEW HAVEN, CONNECTICUT 06511
203-777-5800
Fax: 203-777-5806

Michele M. Volpe
Direct Dial: (203) 777-6995
michelemvolpe@aol.com

November 8, 2012
Via Facsimile # (860) 418 7053, Electronic Mail
and First Class USPS Mail

Deputy Commissioner Lisa Davis
State of Connecticut
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November 8, 2012
Via Facsimile # (860) 418 7053, Electronic Mail
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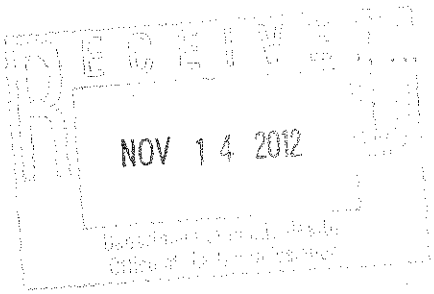

Deputy Commissioner Lisa Davis
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Department of Public Health
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Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

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III. Even if the Declaratory Ruling Applied to Interhospital Transfers, Such Application Was Superceded by Statute, and Would Conflict With State and Federal Laws

The Declaratory Ruling interpreted the EMSAA as it existed in 2003. In 2009, the legislature enacted General Statutes § 19a-179c, which directly regulates ICCTs. It provides:

> Any ambulance used for interfacility critical care transport shall meet the requirements for a basic level ambulance, as prescribed in regulations adopted pursuant to section 19a-179, including requirements concerning medically necessary supplies and services, and may be supplemented by a licensed registered nurse, advanced practice registered nurse, physician assistant or respiratory care practitioner, provided such licensed professionals shall have current training and certification in pediatric or adult advanced life support, or from the Neonatal Resuscitation Program of the American Academy of Pediatrics, as appropriate, based on the patient's condition.

Thus, even if the Declaratory Ruling applied to interhospital transfers in 2003, the legislature's enactment of § 19a-179c in 2009 created new rules that specifically regulate interhospital transfers, and, therefore, abrogated the Declaratory Ruling as it applies to acute care hospitals. Furthermore, a hospital may not be able to comply with § 19a-179c if it must dial "911" to arrange interhospital transfers because it will have very limited control over the EMS provider that the 911 dispatcher sends.

OHCA's interpretation of the Declaratory Ruling also conflicts with the Federal Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd(c)(2), which states:

> An appropriate transfer to a medical facility is a transfer-- . . . (D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . .

Hospitals and physicians who fail to comply with the EMTALA are subject to fines and, in some instances, exclusion from federal and state health care programs. 42 U.S.C. § 1395dd(d). If hospitals must dial "911" to procure emergency patient transfers, they will be unable to comply with their duty to provide a transfer that is "effected through qualified personnel and transportation equipment." The foregoing conflicts with State and Federal law, which expose the Declaratory Ruling to a legal challenge, can be avoided if the Declaratory Ruling is read to apply to long term care facilities, but not hospitals such as the Applicant.

IV. Well Settled Principles of Statutory Interpretation Support the Applicant's Reading of the Declaratory Ruling

The Connecticut Supreme Court has held: "specific terms covering the given subject matter will prevail over general language of the same or another statute which might otherwise prove controlling. . . . The provisions of one statute which specifically focus on a particular problem will

always, in the absence of express contrary legislative intent, be held to prevail over provisions of a different statute more general in its coverage." *Housatonic Railroad Co., Inc.* v. *Commissioner of Revenue Services*, 301 Conn. 268, 302 (2011). Furthermore, in cases "in which more than one statutory provision is involved, a court presumes that the legislature intended those provisions to be read together to create a harmonious body of law and the court construes the provisions, if possible, to avoid conflict between them." *Tomlinson v. Tomlinson*, 305 Conn. 529, 552 (2012). The Declaratory Ruling interprets the generalized Emergency Medical Services Assistance Act of 1974, not the specific statute pertaining to ICCTs, General Statutes § 19a-179c. Because General Statutes § 19a-179c applies specifically to interhospital transfers and is in tension with the Declaratory Ruling, it prevails.

V. Application of the Declaratory Ruling to Interhospital Transfers Would Unnecessarily Strain the Emergency Medical System

As the DPH explained in the Declaratory Ruling, calls to 911 set off a tiered response:

> [W]hen 911 is accessed, first responders, typically fire or law enforcement agencies, are dispatched to provide basic intervention such [as] cardiopulmonary resuscitation and control of bleeding. Basic ambulances then provide more advanced skills and transportation of the sick and injured. Paramedics provide advanced life support and may function as a part of the ambulance or intercept with the ambulance. (DPH Declaratory Ruling, at p. 14).

Hospitals do not require 911 dispatchers to provide them with first aid instructions, nor do they need first responders to render basic first aid. If hospitals accessed the 911 system for every interhospital transfer in the State of Connecticut, it would unnecessarily divert multiple public safety resources to organizations that do not require their assistance, at great cost to the cities and towns that must pay for these resources. As a matter of public policy, it does not make sense to require hospitals to utilize the 911 system for emergency interhospital transfers, which occur on a regular basis throughout the State. To do so would divert EMS resources away from situations where such assistance is truly needed.

For all the foregoing reasons, the Declaratory Ruling should not be applied to the Applicant. Please do not hesitate to contact me at 203-777-6995 if you have any additional questions or concerns.

Sincerely,

Michele M. Volpe

MMV/bt

cc: Kimberly Martone, Director of Operations, via email: Kimberly.Martone@ct.gov

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

November 21, 2012

Ms. Shraddha Patel
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

RE: Certificate of Need Application, Docket Number 12-31768-CON
Lawrence & Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

Dear Ms. Patel,

With the receipt of the completed Certificate of Need ("CON") application information submitted by Lawrence & Memorial Hospital ("Applicant") on August 31, 2012, the Office of Health Care Access ("OHCA") has initiated its review of the CON application identified above.

Pursuant to General Statutes § 19a-639a (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:	Lawrence & Memorial Hospital
Docket Number:	12-31768-CON
Proposal:	Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital with no capital expenditure

Notice is hereby given of a public hearing to be held in this matter to commence on:

Date: December 13, 2012

Time: 10:00 a.m.

Place: Department of Public Health, Office of Health Care Access
Third Floor Hearing Room, 410 Capitol Avenue
Hartford, CT 06134

The Applicant is designated as a 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 Day* 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
Kevin Hansted, 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

November 21, 2012 Requisition # 123456

The Day Publishing Co.
47 Eugene O'Neill Drive
New London, CT 06360

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 **Monday, November 26, 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 Kaila Riggott 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

The Day Publishing Co., **November 21, 2012**
Notice of Public Hearing, Docket Number 12-31768-CON

PLEASE INSERT THE FOLLOWING:

Office of Health Care Access Public Hearing

Statute Reference:	19a-639
Applicant:	Lawrence & Memorial Hospital.
Town:	New London
Docket Number:	12-31768-CON
Proposal:	Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital with no capital expenditure
Date:	December 13, 2012
Time:	10:00 a.m.
Place:	Department of Public Health, Office of Health Care Access Third Floor Hearing Room, 410 Capitol Avenue Hartford, CT 06134

Any person who wishes to request status in the above listed public hearing may file a written petition no later than December 7, 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.

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3170
RECIPIENT ADDRESS	98604443716
DESTINATION ID	
ST. TIME	11/21 15:28
TIME USE	00'37
PAGES SENT	5
RESULT	OK

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MS. PATEL

FAX: 860-44-3716

AGENCY: L & M HOSPITAL

FROM: OHCA

DATE: 11/20/12 **Time:**

NUMBER OF PAGES: 4
(including transmittal sheet

Comments:

Re: 31768

PLEASE PHONE Barbara K. Olejarz IF THERE ARE ANY TRANSMISSION PROBLEMS.

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: Kevin Hansted, Hearing Officer

FROM: Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner

DATE: November 28, 2012

RE: Certificate of Need Application; Docket Number: 12-31768-CON
Lawrence and Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial 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 34038
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Greer, Leslie

From: ADS <ADS@graystoneadv.com>
Sent: Wednesday, November 21, 2012 2:33 PM
To: Greer, Leslie
Subject: Re: Hearing Notice DN: 12-31768-CON

Good day!

Thanks so much for your ad submission.
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.

We sincerely appreciate your business.

PLEASE NOTE: New Department of Labor guidelines allow web base advertising when hiring foreign nationals. To provide required documentation Graystone will retrieve & archive verification for the 1st and 30th days of posting for $115.00/web site. If required, notify Graystone when ad placement is approved.

Thank you,
Graystone Group Advertising

2710 North Avenue
Bridgeport, CT 06604
Phone: 800-544-0005
Fax: 203-549-0061

E-mail new ad requests to: ads@graystoneadv.com
http://www.graystoneadv.com/

From: <Greer>, Leslie <Leslie.Greer@ct.gov>
Date: Wednesday, November 21, 2012 2:21 PM
To: ads <ads@graystoneadv.com>
Subject: Hearing Notice DN: 12-31768-CON

Please run the attached hearing notice no later than November 26, 2012. I will provide a requisition number for billing purposes within the next few days. If you have any questions, please call myself or Barbara Olejarz @ (860) 418-7001.

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

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

December 4, 2012

Ms. Shraddha Patel
Director of Business Development & Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

RE: Certificate of Need Application, Docket Number 12-31768-CON
Lawrence & Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital
Request for Prefile Testimony and Issues

Dear Ms. Patel:

The Office of Health Care Access ("OHCA") will hold a public hearing on Thursday, December 13, 2012, at 10:00 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. Lawrence & Memorial Hospital ("Applicant") must submit prefiled testimony to OHCA no later than 12:00 p.m. on December 7, 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 Issues outlining the topics that will be discussed at the hearing.

Please contact Alla Veyberman at (860) 418-7007, if you have any questions concerning this request.

Sincerely,

Kevin Hansted SAVE

Kevin Hansted
Hearing Officer

Attachment

ISSUES FOR PUBLIC HEARING:

Certificate of Need Application, Docket Number: 12-31768-CON

Proposal to Establish and Operate an Elective Angioplasty Program Without Onsite Surgical Backup at Lawrence & Memorial Hospital

Please be fully prepared to discuss the following issues:

1. Page 360 of Exhibit A provides Lawrence & Memorial Hospital's guidelines for emergent transportation for a PCI patient from the Cardiac Catheterization lab. The guidelines do not include contacting 911 for such emergent transportation. Lawrence & Memorial Hospital has taken the position that acute care hospitals are not subject to the Department of Public Health's Declaratory Ruling, dated February 14, 2003, which requires that 911 be contacted for all emergency patient transfers (the "Declaratory Ruling"). In support of its position, Lawrence & Memorial Hospital claims that it would not be able to comply with Connecticut General Statutes § 19a-179c if it was required to call 911 for emergency transports. During the initial contact with the 911 dispatcher, could the hospital request an immediate response by a basic level ambulance with the exclusion of fire and police response?

2. Assuming the response to No. 1 is in the affirmative, are there situations in which the 911 dispatcher would send something less than a basic level ambulance?

3. In what way would the hospital be unable to comply with 42 U.S.C. § 1395dd(c)(2) if it were to call 911 for an emergency transfer?

4. Page 360 of Exhibit A states that the New London Fire Department Ambulance will be used if other transportation is unavailable and transportation must occur immediately. Is a distinction being made between "immediately" and "emergency"?

5. Page 32 of the Declaratory Ruling concludes that, in an emergency situation, a provider is required to forward an emergency call to the 911 system if it has been contacted outside of the 911 system. Given this conclusion, explain in what way(s) contacting the provider directly, as instructed in Lawrence & Memorial Hospital's guidelines, results in a decreased response time by the provider given the provider must forward the call to the 911 system.

****
*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	3187
RECIPIENT ADDRESS	98604443716
DESTINATION ID	
ST. TIME	12/04 15:43
TIME USE	00'35
PAGES SENT	4
RESULT	OK

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MS. SHRADDHA PATEL

FAX: 860.444.3716

AGENCY: LAWRENCE & MEMORIAL HOSPITAL

FROM: OHCA

DATE: 12/04/2012 **Time:**

NUMBER OF PAGES: 4
(including transmittal sheet

Comments:
Docket Number: 12-31768-CON

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS

Phone: (860) 418-7001 Fax: (860) 418-7053

Greer, Leslie

From: Lazarus, Steven
Sent: Tuesday, December 04, 2012 2:39 PM
To: michelemvolpe@aol.com
Cc: Riggott, Kaila; Martone, Kim; Hansted, Kevin; Veyberman, Alla; Greer, Leslie
Subject: Copy of Request for Prefile Testimony and Issues (re: 12-31768-CON)
Attachments: 12_31768_Request for Prefile & Issues.pdf

Dear Attorney Volpe,

Attached you will find a scanned copy of the Request for Prefile Testimony and Issues related to the upcoming public hearing under Docket Number 12-31768. Please feel free to contact Alla Veyberman if you have any questions.

Sincerely,
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

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

December 4, 2012

Ms. Shraddha Patel
Director of Business Development & Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

RE: Certificate of Need Application, Docket Number 12-31768-CON
Lawrence & Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital
Request for Prefile Testimony and Issues

Dear Ms. Patel:

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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 Issues outlining the topics that will be discussed at the hearing.

Please contact Alla Veyberman at (860) 418-7007, if you have any questions concerning this request.

Sincerely,

Kevin Hansted SAVE

Kevin Hansted
Hearing Officer

Attachment

ISSUES FOR PUBLIC HEARING:

Certificate of Need Application, Docket Number: 12-31768-CON

Proposal to Establish and Operate an Elective Angioplasty Program Without Onsite Surgical Backup at Lawrence & Memorial Hospital

Please be fully prepared to discuss the following issues:

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3. In what way would the hospital be unable to comply with 42 U.S.C. § 1395dd(c)(2) if it were to call 911 for an emergency transfer?

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5. Page 32 of the Declaratory Ruling concludes that, in an emergency situation, a provider is required to forward an emergency call to the 911 system if it has been contacted outside of the 911 system. Given this conclusion, explain in what way(s) contacting the provider directly, as instructed in Lawrence & Memorial Hospital's guidelines, results in a decreased response time by the provider given the provider must forward the call to the 911 system.

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*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	3187
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ST. TIME	12/04 15:43
TIME USE	00'35
PAGES SENT	4
RESULT	OK

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MS. SHRADDHA PATEL

FAX: 860.444.3716

AGENCY: LAWRENCE & MEMORIAL HOSPITAL

FROM: OHCA

DATE: 12/04/2012 **Time:**

NUMBER OF PAGES: 4
(including transmittal sheet

Comments:
Docket Number: 12-31768-CON

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS

Phone: (860) 418-7001 Fax: (860) 418-7053

Greer, Leslie

From: Katherine Hagmann <khh@bvmlaw.com>
Sent: Tuesday, December 04, 2012 4:57 PM
To: Hansted, Kevin
Cc: Lazarus, Steven; Riggott, Kaila; Martone, Kim; Veyberman, Alla; Greer, Leslie; Michele AOL; Bettyanne Toole
Subject: Lawrence & Memorial Hospital CON Application (Docket # 12-317-68-CON)

Dear Mr. Hansted,

This afternoon, we entered an appearance on behalf of Lawrence & Memorial Hospital for the above-captioned matter. We received your letter listing the issues that will be considered at the December 13, 2012 hearing at 2:39 PM this afternoon. The letter states that the deadline for my client's submission of prefiled testimony is this Friday at noon, which gives the Applicant less than three days to prepare its responses to the five questions set forth in the letter.

OHCA's standard practice has been to set a deadline of five days prior to the hearing for submission of the Applicant's prefiled testimony. This deadline tracks the deadline for an intervenor's submissions, which is also five days prior to the hearing, and ensures that the applicant is not placed at a disadvantage vis a vis intervenors. We respectfully request that you grant an extension of time until 5:00 PM on Monday, December 10, 2012. Monday is fair and equitable in light of the short time frame for a response to OHCA's specific questions, and the deadline for intervenors' submissions, which is also Monday. *See* Regs., Conn. State Agencies 19a-9-27(a) (setting the deadline for intervenors) and 19a-9-8 (setting a due date of the next business day when a deadline falls when the department is closed).

Respectfully submitted,

Kate Hsu Hagmann
Attorney at Law
Bershtein, Volpe & McKeon, P.C.
105 Court Street, 3rd Floor
New Haven, CT 06511
Tel: (203) 777-5800
Fax: (203) 777-5806
www.bvmlaw.com

FAX TRANSMISSION

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET
THIRD FLOOR
NEW HAVEN, CT 06511
(203) 777-5800 Fax: (203) 777-5806

FAX #: (860) 418-7053	**DATE:** December 5, 2012
TO: Kevin Hansted, Hearing Officer Steven W. Lazarus, Associate Health Care Analyst State of Connecticut Department of Public Health Division of Office of Health Care Access	**PAGES:** 3, including this page
FROM: Michele M. Volpe	**MATTER #:** 115491

SUBJECT: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

COMMENTS:

Please see the attached Notice of Appearance.

Thank you.

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET, THIRD FLOOR
NEW HAVEN, CONNECTICUT 06511
203-777-5800
Fax: 203-777-5806

Michele M. Volpe
Direct Dial (203) 777-6995

December 5, 2012
Via Facsimile (860) 418-7053
and USPS 1st Class Mail

Kevin Hansted, Hearing Officer
Steven W. Lazarus, Associate Health Care Analyst
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, Connecticut 06134-0308

Re: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

Dear Mr. Hansted and Mr. Lazarus:

Enclosed please find an original and five (5) copies of our Notice of Appearance in the above captioned matter.

Thank you.

Very truly yours,

Michele M. Volpe

MMV/bt
Enclosures

S:\doc\[5451-5500\115491 L & M Hosp re OHCA\Docs\Elective Angioplasty (CON Application)\Letters\OHCA (Appearance) 12.05.12.doc

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS : **DOCKET NO. 12-31768-CON**

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : **DECEMBER 5, 2012**

NOTICE OF APPEARANCE

Please enter the appearance of Bershtein, Volpe & McKeon P.C. as counsel on behalf of Lawrence & Memorial Hospital in the above-captioned proceeding.

Respectfully Submitted,

By: _____
Michèle M. Volpe
Juris No. 412124
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor, New Haven, CT 06511
Tel. No. (203) 777-5800
Fax No. (203) 777-5806

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

December 5, 2012 Via FAX

Michelle M. Volpe
Attorney at Law
Bershtein, Volpe & McKeon, P.C.
105 Court Street
New Haven, CT 06511

RE: Certificate of Need, Docket Number 12-31768-CON
Lawrence & Memorial Hospital
Establishment and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital
Request for Prefile Testimony Time Extension

Dear Attorney Volpe:

On December 4, 2012, the Office of Health Care Access ("OHCA") requested that Lawrence & Memorial Hospital ("Applicant") pre-file its testimony for the hearing scheduled for December 13, 2012, to be filed no later than Friday, December 7, 2012. The Applicant has requested that OHCA extend the filing of the pre-file testimony with OHCA to December 10, 2012, by 4:30 pm.

OHCA hereby grants your request and orders that the pre-file testimony by the Applicant be filed with OHCA no later than December 10, 2012, 4:30 pm.

If you have any questions concerning this matter, please feel free to contact Alla Veyberman at (860) 418-7007.

Sincerely,

Kevin Hansted
Hearing Officer

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3191
RECIPIENT ADDRESS	912037775806
DESTINATION ID	
ST. TIME	12/05 16:19
TIME USE	00'43
PAGES SENT	2
RESULT	OK

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: MICHELLE VOLPE, ESQ.

FAX: (203) 777-5806

AGENCY: BERSHTEIN, VOLPE & MCKEON, P.C.

FROM: STEVEN LAZARUS

DATE: 12/5/12 **TIME:**

NUMBER OF PAGES: 2
(including transmittal sheet

Comments: DN: 12-31768-CON Prefile Testimony Time Extension

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET, THIRD FLOOR
NEW HAVEN, CONNECTICUT 06511
203-777-5800
Fax: 203-777-5806

Michele M. Volpe
Direct Dial (203) 777-6995

December 5, 2012
Via Facsimile (860) 418-7053
and USPS 1st Class Mail

Kevin Hansted, Hearing Officer
Steven W. Lazarus, Associate Health Care Analyst
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, Connecticut 06134-0308

Re: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

Dear Mr. Hansted and Mr. Lazarus:

Enclosed please find an original and five (5) copies of our Notice of Appearance in the above captioned matter.

Thank you.

Very truly yours,

Michele M. Volpe

MMV/bt
Enclosures

S:\doc\11 5451-5500\11549 L & M Hosp re OHCA\Docs\Elective Angioplasty (CON Application)\Letters\OHCA (Appearance) 12.05.12.doc

STATE OF CONNECTICUT : **DOCKET NO. 12-31768-CON**
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : **DECEMBER 5, 2012**

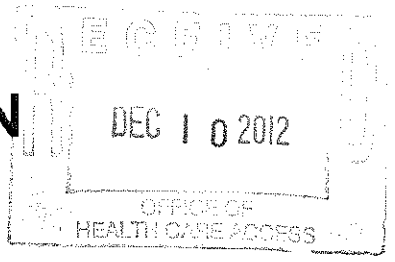
NOTICE OF APPEARANCE

Please enter the appearance of Bershtein, Volpe & McKeon P.C. as counsel on behalf of Lawrence & Memorial Hospital in the above-captioned proceeding.

Respectfully Submitted,

By: _____

Michèle M. Volpe
Juris No. 412124
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor, New Haven, CT 06511
Tel. No. (203) 777-5800
Fax No. (203) 777-5806



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FAX #: (860) 418-7053	**DATE:** December 10, 2012
TO: Kevin Hansted, Hearing Officer Steven W. Lazarus, Associate Health Care Analyst State of Connecticut Department of Public Health Division of Office of Health Care Access	**PAGES:** 65, including this page
FROM: Michele M. Volpe	**MATTER #:** 115491

SUBJECT: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

COMMENTS:

Please see the attached. Thank you.

LAWRENCE +MEMORIAL HOSPITAL
365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

December 10, 2012
Via Federal Express
Via Facsimile (860) 418-7053
Via Electronic Mail: Steven.Lazarus@ct.gov

Kevin Hansted, Hearing Officer
Steven W. Lazarus, Associate Health Care Analyst
State of Connecticut
Department of Public Health
Division of Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06106-1367

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Dear Hearing Officer Hansted and Mr. Lazarus:

In connection with the Public Hearing scheduled for Thursday, December 13, 2012 at 10:00 a.m. on the above-captioned CON Application, enclosed please find an original and four (4) copies of the following:

1. Applicant's Brief in Support of its Patient Transfer Protocol
2. Prefile Testimony of Brian Cambi, MD, FACC, FSCAI
3. Prefile Testimony of Ron Kersey

Also enclosed is a CD containing a scanned version of each document listed above.

Please do not hesitate to contact me with any questions.

Thank you.

Crista Durand, Vice President
Strategic Planning, Marketing & Business Development

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

APPLICANT'S BRIEF IN SUPPORT OF ITS
PATIENT TRANSFER PROTOCOL

Lawrence & Memorial Hospital (the "Applicant" or "L+M") respectfully submits that its patient transfer protocol for the elective angioplasty program ("Protocol")[1] does not conflict with the Department of Public Health's ("DPH") February 14, 2003 Declaratory Ruling (the "Declaratory Ruling" or "Ruling"), which recognizes that a clinician's "clinical judgment should be used in determining whether the 911 system should be activated." Declaratory Ruling, at p. 18. This brief sets forth the legal and policy bases for the Applicant's position, and responds to the five hearing issues that the Office of Health Care Access ("OHCA") submitted to the Applicant on December 4, 2012.

If the DPH disagrees and maintains that the 911 system must be activated each time an elective angioplasty patient who develops a procedurally related complication that requires surgical intervention is transferred to another hospital, L+M respectfully submits that the Ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving "long term care facilities" and members of the public, as well as the EMS providers who respond to their calls. An interpretation of the Ruling that deprives treating physicians in hospitals of the ability to exercise discretion over whether to activate the 911 system and how patients should be transported conflicts with the Ruling itself, and subsequently-enacted State

[1] The Protocol is attached hereto as Exhibit A.

law, and Federal law. It also places an unnecessary strain on community EMS resources, and jeopardizes patient safety.

I. The Declaratory Ruling

The Declaratory Ruling addresses three major topics. First, the Ruling requires "long term care facilities" and members of the public to dial 911 to facilitate the transportation of urgently ill or injured individuals to hospitals during "medical emergencies, which require an immediate response." *See* Declaratory Ruling, at p. 13, #68 and p. 30. Second, it regulates the conduct of the local EMS providers, called Primary Service Area Responders ("PSARs"), who respond to emergency calls made by members of the public and long term care facilities. *See id.* at pp. 20, 25, 31-34. Third, the Declaratory Ruling specifically addresses the role of acute care hospitals within the EMS system, and explains that their purpose is to assist EMS providers to safely transfer patients into Connecticut's hospital system. *See id.* at pp. 8-12 and p.21-25. This third point is most pertinent to the issues at hand.

As the Ruling explains, a patient's care is entrusted to the highly trained professionals at Connecticut's acute care hospitals as soon as the 911 system is activated. Each EMS provider is sponsored by an acute care hospital, which provides "medical control," administered by staff physicians who serve as "medical directors" to the PSAR units. *Id.* at p. 8, #36. Medical control by a sponsor hospital is necessary because "emergency medical technicians and paramedics provide invasive medical care, including starting IV lines, using defibrillators, performing endotracheal intubations, and administering medications." *Id.* If EMTs or paramedics have treatment questions or run into complications in the field, they can contact a physician at the sponsor hospital to obtain medical direction. *Id.* at p. 9, #38.

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As the Ruling explains, a patient's care is entrusted to the highly trained professionals at Connecticut's acute care hospitals as soon as the 911 system is activated. Each EMS provider is sponsored by an acute care hospital, which provides "medical control," administered by staff physicians who serve as "medical directors" to the PSAR units. *Id.* at p. 8, #36. Medical control by a sponsor hospital is necessary because "emergency medical technicians and paramedics provide invasive medical care, including starting IV lines, using defibrillators, performing endotracheal intubations, and administering medications." *Id.* If EMTs or paramedics have treatment questions or run into complications in the field, they can contact a physician at the sponsor hospital to obtain medical direction. *Id.* at p. 9, #38.

Sponsor hospitals are also responsible for monitoring the quality of the care provided by PSARs. *Id.*, at p. 9, #37. "Medical directors may withhold medical authorization from emergency personnel or a provider if the medical director believes the EMS staff or service has demonstrated incompetence or negligence, poses a threat to public health or safety, or has acted contrary to medical direction." *Id.* at p.8, #36. If a PSAR travels outside its regular service area, the sponsor hospital must continue to be responsible for quality assurance. *Id.*at p. 11, #52. Thus, the Ruling makes clear that acute care hospitals form the lynchpin of the EMS system, furnishing the PSARs who bring patients to the hospitals with expert medical advice. The EMS system operates safely because of sponsor hospitals applying their medical training and expertise.

II. L+M's Protocol Complies with the Declaratory Ruling

The Declaratory Ruling not only recognizes the medical training and judgment of physicians, it defines "emergency" so that clinicians, such as physicians, are *required* to exercise their independent medical judgment when deciding whether to activate 911. For purposes of the Ruling, DPH adopted a definition of the term "emergency," which was set forth in two guidance letters that it sent to long term care facility operators in 2002. *Id.* at p. 12-14, and p. 18. The letters explain that a medical emergency is a situation that requires an immediate response, which "**as determined by appropriate licensed staff at a transferring facility, necessitates the activation of the 911 response system.**" *Id*, at p. 13, #68 (Emphasis added). Although the letters set forth three specific examples of medical emergencies (i.e. the "rapidly deteriorating condition of a resident;" "[a]n accident resulting in serious injury," and "[a] life threatening emergency"), the 2002 letters, and an earlier 1987 letter, *always* allow the transferring facility to exercise discretion regarding whether 911 is activated. *Id.*, at p. 12, #65; p. 13, #68; and p. 14,

#71. When the Ruling adopted the definition of "emergency" set forth in the 2002 letters, it emphasized again that "**clinical judgment should be used in determining whether the 911 system should be activated.**" *Id.*, at 18 (Emphasis added). The 2002 letters also explain: "If non-emergency transportation is desired, any ambulance service may be utilized." *Id.* at 14, #71.

The Ruling's emphasis on the judgment of clinicians makes perfect sense. Just as a hospital staff physician must have discretion when determining whether a patient should travel from the emergency department to surgery in a wheelchair or on a gurney, a physician must have discretion to determine whether a patient travels from the cathcterization laboratory at L +M to an operating room at Yale via Lifestar, American Ambulance, or, when presented with an emergency that "necessitates the activation of the 911 response system," through the 911 system. *See id.*, at p. 13, #68.

L+M's Protocol is identical in all material respects to the protocol that it submitted in connection with its successful CON application for the emergency angioplasty program. [2] Both protocols fully comply with the mandates described above. They recognize that most critical care inter-hospital transfers will not constitute a "medical emergency," which "as determined by appropriate licensed staff at a transferring facility, necessitates the activation of the 911 response system." *See id.* The Protocol is utilized only when, due to complications during the procedure, the interventional cardiologist decides that the patient requires a level of care found at the transferee hospital. The interventional cardiologist makes sure the patient is medically stable, and L+M staff obtains the patient's or family's informed consent for the transfer. In the vast majority of cases, which involve transferring a medically stable patient within the hospital

[2] When L+M applied to OHCA for approval of its emergency angioplasty program, OHCA requested a copy of L+M's patient transfer protocol in the completeness questions. The emergency angioplasty patient transfer protocol advised L+M's staff to contact EMS providers directly, and it included Lifestar's direct1-800 number in the protocol. *See* Emergency Transfer Protocol (attached hereto as Exhibit B). That CON application was approved by OHCA.

system, this will not, in the clinician's judgment, constitute a medical emergency that is best served by activating the 911 system. That is why both protocols make no mention of 911. If, in the attending physician's opinion the best means of facilitating the patient's transfer to another acute care hospital is by activating 911, 911 will be activated. If the Department will find it useful, L+M certainly is willing to state this in its Protocol.

III. Mandated Activation of the 911 System for Each Urgent or Emergent Patient Transfer Will Gravely Impair Public Safety, and Conflict with the Ruling Itself, as Well as State and Federal Law

A. Activation of the 911 System for Each Urgent, Emergent, or Critical Care Patient Transfer Jeopardizes Patient Safety

If DPH is taking the position that the Ruling requires L+M to activate 911 for all emergent, urgent, and critical care inter-hospital transfers, specifically transfers of elective angioplasty patients who develop a complication to Yale, the following process, which is diagramed in Exhibit C (attached hereto), will occur each time an urgent, emergent, or critical care patient is transferred to Yale. The treating physician is required to dial 911 and relay the patient's needs to the dispatcher, who is required to activate the Primary Service Area Responder (PSAR) for New London, the New London Fire Department ("NLFD") ambulance. If the NLFD ambulance is unavailable, the call will result in the dispatch of a PSAR from another community. This procedure adds links in the chain of communication, creating multiple opportunities for miscommunications and mistakes. It also results in the dispatch of a Basic Level (BL) ambulance, as well as fire fighters or police officers, who are first responders. OHCA's second enumerated question queries whether a 911 dispatcher will send something less than a BL ambulance. Because, upon information and belief, all PSARs are equipped with BL ambulances, 911 will dispatch a BL unit. However, this question fails to address L+M's concern, which is patient safety. A BL ambulance will not, in this instance, be the clinically appropriate mode of

transportation for an elective angioplasty patient with a complication. Under Section 19a-179-18 of the Connecticut Agency Regulations, a BL ambulance is not always equipped with the supplies that these medically complex patients need and the NLFD ambulances are staffed only with EMTs. If the Department requires NLFD's BL ambulance to perform these transfers, it will need to be supplemented with L&M staff, such as paramedics, nursing, and/or respiratory therapists to ensure the safe transfer of patients. Without an appropriately equipped ambulance, transferred patients risk complications due to lack of necessary equipment and experienced trained health care providers, all of which could have been easily and efficiently provided under L+M's proposed transfer system. As Dr. Cambi explains in his testimony, the providers in L+M's protocol arrive pre-equipped with the medically appropriate staff and equipment for these transferees. Thus, if the ruling is applied to hospitals, they may find themselves in a position where the least desirable provider must become the first provider for inter-hospital transfers of critically ill patients.

Although the Lifestar helicopter is available if L+M is required to activate 911, the procedure for dispatching the helicopter is more complicated. **New London's 911 dispatchers cannot initiate Lifestar absent a request from the PSAR, which is the NLFD.** Therefore, rather than making a single phone call, the treating physician is required to call 911, the dispatcher is required to contact the PSAR, and the PSAR is required to activate Lifestar and travel to L+M, even though the hospital has no need for the services of a PSAR. This chain of command makes sense when the EMS system deals with members of the general public or long term care facilities that may not have physicians on staff, because the PSAR must assess the severity of the patient's condition and decide whether Lifestar is necessary. In the hospital setting, it is not necessary for the PSAR to assess the patient as this is already done by the

transferring hospital, and the patient is stabilized. Activating the 911 system in unnecessary cases adds complexity and delay to inter-hospital transfers, which are initiated at the request of highly trained physicians. Indeed, in L+M's case, the PSAR will arrive to render assistance that is not needed at the very institution that sponsors it and provides it with medical direction and control.

B. Activation of the 911 System for Each Urgent, Emergent, or Critical Care Patient Transfer Strips the Community of Much Needed EMS Resources

Using the NLFD ambulance for inter-hospital transfers will also strip the community of both an ambulance and a L+M paramedic for the time it takes to make the round trip, which could exceed two hours. Although the likelihood of a transfer of elective angioplasty patients to Yale for urgent cardiac surgery is very low due to L&M's strict patient selection process, requiring the hospital to activate the 911 system for all other specialties will result in a severe drain on community resources. As Ron Kersey explains in his pre-filed testimony, L+M's emergency department transferred 450 patients to Yale in Fiscal Year 2012. If all of those transfers are considered emergencies, that could equate to nearly 40 trips per month, which will take the NLFD Ambulance out of its service area for hours at a time, and require New London to rely on PSARs from neighboring communities to fill the gap.

Involving local 911 dispatchers in emergent, urgent, and critical care inter-hospital transfers will also waste local resources, with no benefit to the patients. Unlike members of the public, who may need first aid instructions while they are waiting for a first responder to arrive, physicians do not require the assistance of a 911 dispatcher to assess patient needs and provide basic first aid instructions. More important, the physicians and hospital staff have already stabilized the patient for transfer. As NLFD Deputy Chief Henry Kydd explains in his letter, calls to 911 may also result in police or fire vehicles being dispatched to the hospital, which will

draw these resources away from the community members who need them. *See* Letter by NLFD Deputy Chief Henry Kydd (attached to Prefiled Testimony of R. Kersey).

Finally, because application of the Declaratory Ruling to emergent, urgent, and critical care inter-hospital transfers will represent a marked departure from the current practices of every Connecticut hospital, as well as the industry standard for hospitals throughout the United States,[3] it will have a significant financial impact on cities and towns throughout Connecticut, and can very well collapse the 911 system in the State. The problems described above can be avoided if the Declaratory Ruling is read in its proper context to defer to the transferring hospital and treating physician's judgment as to whether the 911 system is activated.

C. The Declaratory Ruling Does Not Apply to This Patient Transfer Protocol

If the Department is of the opinion that L+Mmust activate the 911 system for *all* emergent, urgent, and critical care interhospital transfers, *even if the treating physician concludes that accessing 911 is unnecessary or clinically inappropriate*, L+Margues, in the alternative, that the Ruling does not apply to its Protocol at all. This DPH interpretation of the Ruling ignores its plain language, as well as its context because, by its terms, the Ruling applies only to long term care facilities, members of the public, and the EMS providers who serve them during medical emergencies before they arrive at a hospital. In addition, this DPH interpretation is at odds with the Ruling's emphasis on the independent judgment of clinicians, which is described above. *See supra* at pp. 1, 3-4.

The language used throughout the Declaratory Ruling—in particular the hearing officer's repeated use of the term "long term care facilities" in the factual findings and conclusions of

[3] *See* Jonathan Warren, MD, FCCM, FCCP et al., Guidelines for the inter- and intrahospital transport of critically ill patients, 32 Crit. Care Med No. 1, at pp. 256-262 (2004).

law—indicates that the Ruling applies only to nursing homes and other long term care facilities, not acute care hospitals which are fundamentally different health care institutions.[4]

The context in which the Ruling arose also supports L+M's interpretation. The Petition for the Declaratory Ruling ("Petition") was filed for the purpose of dispelling confusion among the operators of *long term care facilities* regarding when they must dial 911, as well as confusion amongst EMS providers servicing them. The Ruling specifically references three letters which the Department issued to long-term care facility administrators as guidance on the proper procedures for the emergency transfers of patients to hospitals. Declaratory Ruling, at p. 12, # 65-66; p. 13, # 68-69, and p. 70, #70-72. The Ruling explains that the second letter, issued in May 2002, had produced confusion within the long-term care industry, and that the Department therefore had issued a December 2002 statement to **"long-term care facility operators and EMS providers** . . . reiterating that when a medical emergency exists in the judgment of a clinician, the 911 system must be activated." (Emphasis added; internal quotation marks omitted.) *Id.*, at p.14, #70 and 71.

[4] Chapter 368v of the General Statutes, which regulates health care institutions, describes the differences between long term care facilities, also known as nursing homes, and acute care hospitals. The former are defined as "any nursing home or residential care home as defined in section 19a-490 or any rest home with nursing supervision which provides, in addition to personal care required in a residential care home, nursing supervision under a medical director twenty-four hours per day, or any chronic and convalescent nursing home which provides skilled nursing care under medical supervision and direction to carry out nonsurgical treatment and dietary procedures for chronic diseases, convalescent stages, acute diseases or injuries . . ." *See* Conn. Gen. Stat. § 19a-521. On the other hand, "Hospital" is defined as "an establishment for the lodging, care and treatment of persons suffering from disease or other abnormal physical or mental conditions and includes inpatient psychiatric services in general hospitals." Conn. Gen. Stat. § 19a-490(b).

Hospitals and long term care facilities are also subject to different sets of regulations. For example, hospitals are required to maintain a medical staff of not fewer than five (5) physicians. *See* Regs., Conn. State Agencies §§ 19-13-D3(c)(1) and 19-13-D5(c)(1). Hospitals also are required to maintain, at a minimum, facilities such as clinical laboratories, blood banks, radiology departments and operating rooms. *See* Regs., Conn. State Agencies §§ 19a-13-D3(f) and 19-13-D5(f). Homes for the aged and nursing homes, however, are not required to maintain a medical staff. *See* Regs., Conn. State Agencies § 19-13-D6(d).

Furthermore, other factual findings contained within the Ruling almost exclusively refer to the practices of long-term care facilities or ambulance services treating patients during medical emergencies before they reach the hospital.[5] The only factual findings that specifically refer to acute care hospitals pertain to the hospitals' role as sponsors of emergency medical service providers. *See id.*, at pp. 8-12. It is telling that the Ruling does not contain a single factual finding about procedures for transferring patients after they have entered the hospital system. If the Petition addressed inter-hospital transfers, DPH surely would have heard separate testimony about the hospitals' patient transfer protocols.

Not only does the limited scope of the factual findings demonstrate that inter-hospital transfers were well beyond the purview of the Declaratory Ruling, the legal conclusions set forth within the Ruling exclusively pertain to long-term care facilities and the EMS providers that service them, as well as members of the public, during medical emergencies. Each conclusion of law that regulates the conduct of a health care institution makes a specific reference to long-term care facilities—not acute care hospitals. As noted above, the Hearing Officer specifically defines the term "emergency" in the context of *long-term care facilities*, and goes on to apply that defined term throughout the remainder of the opinion. *See id.*, at p. 17-18. Subsection C of the Ruling, which addresses the question of whether an EMS provider may provide emergency

[5]For example, on Page 6, at Finding #14, DPH states: "Advertising was also prohibited by the Emergency Medical Services Assistance Act to prevent the public, **including long term care facilities**, from calling ambulances other than the PSAR to provide service." (Emphasis added). At Page 14, Finding #75, DPH states: "In addition to the need for emergency and non-emergency transports to and from **long term care facilities, long term care facilities** also request transports that are not pre-scheduled and do not require a full three tiered response . . . ." (Emphasis added).

Although the Ruling sometimes uses the words "facility" or "health care facility," instead of "long term care facility," when these references to "facilities" are read in context, it is clear that they are shorthand references to long term care facilities. For example, while Factual Finding #84 states that "a small percentage of requests for emergency service have been made by facilities directly to non-PSA providers . . .," the next finding is a specific example of Montowese Health and Rehabilitation Center's use of the non-PSAR provider Nelson Ambulance Service for medical emergencies. Declaratory Ruling, at p. 16, # 84 and 85.

medical services in an area in which it has not been designated as the Primary Service Area Responder ("PSAR"), provides in relevant part:

> [T]he preponderance of evidence and a reasonable construction of the statutes and regulations establishes that **long term care facilities** are required to call 911 when there is an emergency, and non-PSAR providers may *not* respond to emergency calls made directly to them.

Id, at p. 30 (Emphasis added). Finally, Subsection H prohibits "long term care facilities" from entering into contracts with providers for the provision of emergency medical services. *Id.* at 35.

DPH makes factual findings regarding the historical practices and procedures of long-term care facilities, interprets DPH's prior policy directives to long-term care facility administrators, and makes no factual findings or conclusions of law pertaining to acute care hospitals' patient transfer protocols. The context of the Declaratory Ruling, as well as the language employed therein, indicate that it does not address urgent, emergent, and critical care inter-hospital patient transfers.

D. Even if the Ruling Once Governed Urgent, Emergent, and Critical Care Inter-Hospital Transfers, it is Premised Upon an Earlier Version of the Emergency Medical Services Assistance Act

The Declaratory Ruling is premised upon DPH's interpretation of the Emergency Medical Services Assistance Act ("EMSAA"), General Statutes §§ 19a-175, et seq., as it existed on February 14, 2003. At that time, EMSAA did not contain a provision that specifically governed inter-hospital transfers. In 2009, the legislature amended EMSAA by enacting General Statutes § 19a-179c, which specifically addresses all inter-hospital transfers, and does not require hospitals to activate 911. Section 19a-179c does not distinguish between "emergency" transfers and "non-emergency" transfers of patients between hospitals. It governs all inter-hospital transfers, and, as the legislative history makes clear, it was enacted to endorse transfers *exactly* like the transfer at issue here utilizing providers outside the 911 system.

Section 19a-179c provides:

> Any ambulance used for **interfacility critical care transport** shall meet the requirements for a basic level ambulance, as prescribed in regulations adopted pursuant to section 19a-179, including requirements concerning medically necessary supplies and services, and may be supplemented by a licensed registered nurse, advanced practice registered nurse, physician assistant or respiratory care practitioner, provided such licensed professionals shall have current training and certification in pediatric or adult advanced life support, or from the Neonatal Resuscitation Program of the American Academy of Pediatrics, as appropriate, based on the patient's condition.

(Emphasis added.) The 2009 legislation also added the term "interfacility critical care transport" ("ICCT") to the definitions section of EMSAA. ICCT means "the interfacility transport of a patient between licensed **hospitals**."[6] (Emphasis added).

Under Connecticut's rules of statutory interpretation, "specific terms covering the given subject matter will prevail over general language of the same or another statute which might otherwise prove controlling." *Tomlinson* v. *Tomlinson*, 305 Conn. 529, 552 (2012). Thus, the terms of § 19a-179c, which apply specifically to all transfers between hospitals, control over the more generalized statutes that DPH interpreted in its 2003 Ruling, as well as the generalized terms of the Ruling itself.

Finally, the legislative history demonstrates that § 19a-179c was enacted to endorse hospitals' industry-wide practice of using providers, not PSARs dispatched by 911, to transport

[6] The definition of ICCT does not distinguish between "emergency" and "non-emergency" transfers. It encompasses all transports of patients between licensed hospitals. In addition, the legislature's use of the word "critical" in ICCT suggests that § 19a-179c specifically applies to "emergency" transfers between hospitals. Our Supreme Court has determined that "[i]n the construction of the statutes, words and phrases shall be construed according to the commonly approved usage of the language. . . . [Courts] ordinarily look to the dictionary definition of a word to ascertain its commonly approved usage." *Director of Health Affairs Policy Planning v. Freedom of Information Commission*, 293 Conn. 164, 184 (2009) (Citation omitted; internal quotation marks omitted.). The word "critical" is defined as "being or relating to an illness or condition involving danger of death" and "relating to or being the stage of a disease at which an abrupt change for better or worse may be expected." Merriam-Webster's Collegiate Dictionary (10th Ed. 1993). The legislature's use of the word "critical" demonstrates its intent that the statute apply to emergency transfers of patients.

critically ill patients to other hospitals. Section 19a-179c stems from House Bill No. 6599 of the 2009 legislative session, which was enacted as Public Acts of 2009, No. 09-16. During a public hearing concerning House Bill No. 6599, the Joint Standing Committee on Public Health heard testimony from Dr. Jim Parker, an emergency medical physician and the director of Connecticut Children's Hospital's ("CCH") Critical Care Transport Team. *See* Conn. Joint Standing Committee Hearings, Public Health, Pt. 6, 2009 Sess., pp. 1610–14 (Attached hereto as Exhibit D). Dr. Parker testified in favor of an amendment to House Bill No. 6599, which would allow CCH to run its Critical Care Transport Team without jeopardizing its clinicians' licenses:

> **Connecticut Children's needs to operate a critical care transport team to bring critically ill or injured children/newborns from community hospitals to our facility when they need tertiary care services that are not available at a community facility.**
>
> Current Office of Emergency Medical Services regulations require that every individual providing care to a patient in an ambulance must be licensed . . . as an EMT. This regulation prevents our team of trained pediatric critical care clinicians from providing specialized services that these newborns and children need.
>
> Connecticut Children's is not—currently not operating this service because of potential liability for our clinicians' licenses. As a result, children who need our transport services do not have access to them. . . .
>
> When enacted, [House Bill No. 6599] will allow Connecticut Children's to resume operation of its critical care transport service, providing our patients with access to **the specialized healthcare transport services they need** in a safe environment.

Id., at 1610–11 (Emphasis added). Dr. Parker identified two additional services that would benefit from House Bill No. 6599: Yale's pediatric specialty transport service and John Dempsey's neonatal specialty transport service. *Id.*, at 1612. As Dr. Parker's testimony made clear, these are specialized transport services which do not make use of the 911 system or local PSARs to accomplish transports of critically ill patients. The amendment propounded by Dr.

Parker, which allowed these hospitals to arrange for transport services for critically ill patients, was adopted. By enacting § 19a-179c, the legislature implicitly endorsed the standard industry practice of arranging direct transport services to convey critically ill patients between licensed hospitals—the exact type of transfer at issue here.

Even if the Declaratory Ruling applied to hospitals in 2003, the legislature subsequently expressed an intent to narrow its scope, so that it applies only to prehospital transfers, such as for members of the public, including long term care facilities. **The Ruling does not apply to transfers *after* the patient has entered the hospital system—those transfers are governed by § 19a-179c. If the Ruling is applied to hospitals now, after the legislature's enactment of § 19a-179c, it will conflict with the purpose and intent of the 2009 legislation.**

E. Application of the Ruling to All Urgent, Emergent, and Critical Care Inter-Hospital Transfers Creates a Direct Conflict with Federal Law

Finally, if physicians are required to activate 911 for all urgent, emergent, and critical care inter-hospital transfers, the Ruling will directly conflict with the Federal Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd. This conflict with federal law can—and must—be avoided if the Declaratory Ruling is applied correctly, so that it does not mandate the activation of 911 for all urgent, emergent, and critical care inter-hospital transfers. EMTALA closely regulates the transfer of emergency department patients between acute care hospitals. It states:

> An appropriate transfer to a medical facility is a transfer-- . . . (D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . . 42 U.S.C. § 1395dd(c)(2).

Hospitals and physicians who fail to comply with EMTALA are subject to fines and, in some instances, exclusion from federal and state health care programs. 42 U.S.C. § 1395dd(d). EMTALA also has a preemption provision, which states: "The provisions of this section do not preempt any State or local law requirement, **except to the extent that the requirement directly conflicts with a requirement of this section**." 42 U.S.C. § 1395dd(f)(Emphasis added).

"When state law conflicts with federal law, courts are bound to follow federal law." *Pac. Capital Bank, N.A. v. Connecticut*, 542 F.3d 341, 348 (2d Cir. 2008) (Internal quotation marks omitted). State and federal law directly conflict where it is impossible for a party to comply with both state and federal requirements. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011). Direct conflict preemption does not require impossibility to arise in each and every instance, it requires only that "compliance with both federal and state regulations may in some circumstances be impossible . . ." *County of Suffolk v. Long Island Lighting Co.*, 728 F.2d 52, 57 (2d Cir. 1984). A direct conflict will also arise where state law "may impede the execution of the full purposes and objectives of Congress." *Id.* "State law is in 'irreconcilable conflict' with federal law, and hence preempted by federal law, when compliance with the state statute would frustrate the purposes of the federal scheme." *Pac. Capital Bank, N.A.*, 542 F.3d, at 351.

If the Declaratory Ruling is read to require 911 to be activated for all emergent, urgent, and critical care inter-hospital transfers, which necessarily include transfers of Emergency Department ("ED") patients between hospitals, hospitals and physicians will be unable to comply with EMTALA in many instances. Under EMTALA, a hospital and treating physician must ensure that transfers of ED patients are "effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . ." 42 U.S.C. § 1395dd(c)(2)(D). Hospitals must, for

example, ensure that the transport team is properly staffed. *See Lopes v. Kapiolani Medical Center for Women & Children*, 410 F. Supp.2d 939 (D. Hawaii 2005) (transport team for a neonatal patient may not have been adequately staffed under EMTALA where it consisted of transport RNs but not a respiratory therapist). The hospitals and treating physicians must also be able to carefully select the "transportation equipment." 42 U.S.C. § 1395dd(c)(2)(D). If L+M dials 911 and activates the local PSAR—not the pre-screened better-equipped vehicles with specially trained providers —for all ED ground transfers, L+M will be unable to ensure that all ED patients are transferred by "qualified personnel and transportation equipment." If L+M contacts an ambulance directly to set up the transfer to ensure compliance with the above, it will violate the Department's broad interpretation of the Declaratory Ruling. Thus, it will be impossible to comply with both state and federal law.

This conflict can—and must—be avoided by reading the Ruling appropriately. "[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter." *Jones v. United States*, 529 U.S. 848, 857 (2000) (Internal quotation marks omitted). A recent Second Circuit case applied this principle when it considered a Connecticut statute that caps the interest rate banks may charge for tax refund anticipation loans (RALs). *Pac. Capital Bank, N.A.*, 542 F.3d, at 347. The Connecticut Attorney General had issued a formal opinion, which stated that the Connecticut law applied to the "facilitators" who sell tax refund loans made by national banks. *Id.*, at 346. The plaintiff, a California-based national bank, filed a federal declaratory judgment action, claiming that the Connecticut statute conflicted with the Federal National Bank Act, which allows a bank to charge the maximum interest rates permitted by its home state. *Id.* at 347. The Second Circuit held that the interest rate provisions

of the Connecticut statute are preempted by the National Bank Act if they are applied to facilitators who make RAL loans offered by national banks. *Id.* at 353. If, however, the statute is construed so that it excludes facilitators making loans on behalf of national banks, it may stand. *See id.*, at 354. The Second Circuit affirmed the latter interpretation of the statute, which avoided constitutional problems and was not contrary to the intent of the legislature. *Id.* In short, the Second Circuit invalidated the Attorney General's formal interpretation of the RAL statute in order to adopt an interpretation that was not preempted by federal law.

In the present case, EMSAA and the Declaratory Ruling are most appropriately interpreted in a manner that does not conflict with EMTALA. If the Ruling is interpreted so that it applies only to prehopsital transfers, such as transfers of long term care facility residents and members of the public to acute care hospitals, the conflict can be avoided. Pursuant to *Jones* and *Pac. Capital Bank, N.A.*, this interpretation must be adopted. To do otherwise creates a direct conflict with Federal law, and subjects both EMSAA and the Declaratory Ruling to constitutional challenge.

IV. Responses to OHCA's List of Issues

Question:

1. **Page 360 of Exhibit A provides Lawrence & Memorial Hospital's guidelines for emergent transportation for a PCI patient from the Cardiac Catheterization lab. The guidelines do not include contacting 911 for such emergent transportation. Lawrence & Memorial Hospital has taken the position that acute care hospitals are not subject to the Department of Public Health's Declaratory Ruling, dated February 14, 2003, which requires that 911 be contacted for all emergency patient transfers (the "Declaratory Ruling"). In support of its position, Lawrence & Memorial Hospital claims that it would not be able to comply with Connecticut General Statutes § 19a-179c if it was required to call 911 for emergency transports. During the initial contact with the 911 dispatcher, could the hospital request an**

immediate response by a basic level ambulance with the exclusion of fire and police response?

Answer:

Although Lawrence & Memorial Hospital can *request* that the 911 dispatcher only send a basic level ambulance without fire and police response, it cannot *require* that the 911 dispatcher send only a basic level ambulance. The Declaratory Ruling explicitly recognizes that "there are different standards for the daily operation of [Coordinated Medical Emergency Direction Centers] and [Public Safety Answering Points ("PSAPs")]/dispatchers, including different protocols [and] different operational procedures . . . ." Declaratory Ruling, at p. 6, # 20. As NLFD Deputy Chief Henry Kydd explains in his letter (attached to Ron Keresy's Pre-filed Testimony) , the City of New London's protocols and policies mandate that the New London Fire Department send a fire truck to the scene whenever the 911 system is activated for life threatening problems. Unlike long term care facilities, many of which do not have physicians on staff, and members of the public, hospitals do not require the assistance of first responders, such as fire fighters, to render basic first aid, assess the patient's condition, and stabilize the patient. Sending a fire truck to L+M hospital for each urgent, emergent and critical care transport will be an unnecessary waste of resources, and it will divert public safety resources away from members of the community who truly need them.

Question:

2. **Assuming the response to No. 1 is in the affirmative, are there situations in which the 911 dispatcher would send something less than a basic level ambulance?**

Answer:

Most likely not since, upon information and belief, all PSARs must operate "basic level ambulances." However, as L+M explained in detail, the question ignores three central concerns that L+M has expressed during these proceedings. First, dispatching BL ambulances for every urgent, emergent, and critical care inter-hospital transport will waste valuable community resources. The 911 dispatcher will send a basic level ambulance staffed by EMTs, as well as other local resources such as a fire and police personnel. When members of the public or long term care facilities dial 911, these first responders play an important role. They assess the patient's condition, determine whether more advanced EMS providers need to be dispatched, such as Lifestar or L+M's paramedic intercept team, and render basic first aid. At L+M, the patient has already been assessed and stabilized by the treating physician, who is in the best position to determine the clinically appropriate mode of transportation. Deploying local EMS resources to L+M for all urgent, emergent, and critical care patient transfers will unnecessarily waste community resources, at great cost to the City of New London.

Second, a BL ambulance staffed only with EMTs is not clinically appropriate for medically complex inter-hospital transfer patients. As Dr. Cambi explains in his pre-filed testimony, elective angioplasty patients who develop a complication and must be transferred to Yale require the assistance of personnel with years of experience in transferring patients with

complex intravenous medications and mechanical life support systems. If the Department requires a BL ambulance to perform these transfers, it will need to be supplemented with L+M staff, such as paramedics, nursing, and/or respiratory therapists to ensure the safe transfer of patients. The providers in L+M's protocol arrive pre-equipped with the medically appropriate staff and equipment for these transferees.

Third, accessing the 911 system for inter-hospital transfers of urgent, emergent, and critical care patients unnecessarily adds delay and complexity to the patient transfer process. Even if L+M can ultimately secure the services of the Lifestar helicopter by calling the 911 dispatcher, the call to 911 adds additional unnecessary links in the chain of communication. As Ron Kersey explains in his pre-filed testimony, the following chain of events, which are diagramed in greater detail in Exhibit C, will unfold. Rather than making a single phone call, the treating physician and hospital staff are required to call 911, the dispatcher is required to contact the PSAR, and the PSAR is required to activate Lifestar and travel to the hospital, even though the hospital has no need for the services of the NLFD EMTs or the BL ambulance. These additional links in the chain of communications only add cost to the community, increase response time, as well as the potential for miscommunications and mistakes. Furthermore, this procedure does not benefit public safety and has the potential to gravely impact patient care.

Question:

3. **In what way would the hospital be unable to comply with 42 U.S.C. § 1395dd(c)(2) if it were to call 911 for an emergency transfer?**

Answer:

Under the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, a hospital may not transfer an individual who arrives at its emergency department to another hospital unless the transfer is "appropriate." 42 U.S.C. § 1395dd(c)(2). Pursuant to 42 U.S.C. § 1395dd(c)(2)(D), a transfer is "appropriate" only where it "is effected through qualified personnel and transportation equipment . . . including the use of necessary and medically appropriate life support measures during the transfer . . . ." Failure to ensure that a transfer is "appropriate" within the meaning of EMTALA, may subject the hospital and the treating physician to civil penalties, and repeated violations could result in exclusion from state and federal healthcare programs. *See* 42 U.S.C. § 1395dd(d).

Under DPH's broad interpretation of the Declaratory Ruling, L+M will be required to dial 911 in order to transfer urgent, emergent and critical care patients to other hospitals from its emergency department. Although it is a sponsor hospital, L+M does not have the authority to dictate the manner in which a 911 dispatcher responds. In particular, if L+M dials 911 and asks for a mobile intensive care ("MIC") unit to provide ground transportation, L+M will receive a BL ambulance which it must supplement with L+M paramedics and other staff, not a provider that is already equipped with clinically appropriate equipment and personnel. If the local EMS provider is unavailable, L+M will receive a MIC PSAR from another community, selected by the 911 dispatcher in accordance with local EMS policies and protocols. L+M will not even know in advance which provider will arrive, let alone be able to ensure that the provider's personnel and

equipment are "appropriate" under EMTALA. If L+M must call 911 for all urgent, emergent, and critical care inter-hospital transfers, including transfers from its ED department, it will be unable to perform its duty under EMTALA to ensure that the ED transfers are "appropriate."

Question:

4. **Page 360 of Exhibit A states that the New London Fire Department Ambulance will be used if other transportation is unavailable and transportation must occur immediately. Is a distinction being made between "immediately" and "emergency"?**

Answer:

The words "emergent" and "immediately" in the L+M Guideline for Emergent Transportation of Elective PCI Patient Protocol do not have the same meaning as the term "emergency" as it is defined in the Declaratory Ruling. "Emergent" and "immediate" mean within the industry standard of ninety (90) to one hundred twenty (120) minutes from the initial decision to transport elective angioplasty patients to initiating surgery at the receiving surgical center. These patients are stabilized at L+M and ready to be transported to Yale.

Question:

5. **Page 32 of the Declaratory Ruling concludes that, in an emergency situation, a provider is required to forward an emergency call to the 911 system if it has been contacted outside of the 911 system. Given this conclusion, explain in what way(s) contacting the provider directly, as instructed in Lawrence & Memorial Hospital's guidelines, results in a decreased response time by the provider given the provider must forward the call to the 911 system.**

Answer:

The Declaratory Ruling concludes that providers who receive emergency ***prehospital*** calls from members of the general public, including long term care facilities, must transfer them into the 911 system. It does not require first responder providers to contact 911 when they receive calls from hospitals to arrange interhospital transfers of stable patients. These calls are to move patients *within* hospitals, and are not "emergencies," as that word is defined in the Declaratory Ruling.

Upon information and belief, providers of inter-hospital transportation do not forward requests for inter-hospital transfers to the 911 system because they are not "emergency" calls for the transportation of patients *into* the hospital system, which is the purpose of the 911 system. As Gregory B. Allard, Vice President of American Ambulance, Inc. explains in his letter, which is attached to the Pre-filed Testimony of Dr. Cambi, it is common practice within the medical transport industry for providers to dispatch ambulances directly to hospitals. In fact, the Lifestar helicopter is licensed by OCHA to directly respond to patient transfer calls from hospitals.

V. Conclusion

The Department of Public Health's requirement that hospitals dial 911 will set policy which will ultimately create inferior standards in the community than that which exist today. It will have grave ramifications for local fire and police departments and hospitals. It will collapse the 911 system, create hardships for resources in cities and towns, and usurp the medical judgment of sponsor hospitals and staff. Finally and most importantly, it will have an adverse impact on patient care.

Respectfully Submitted,

By: _____
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Exhibit A

LAWRENCE+MEMORIAL HOSPITAL

Title: Patient transfer to higher level of care guidelines	Reference Number:
File Location: Departmental	Issuing Department: Cath lab
Latest Review/Revision Date: 5-12	Original Date: 5-12
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date: Medical Director, Angioplasty 5/31/12 Date Director, Patient care Services 5/31/12 Date	

PURPOSE: To provide guidelines for when the need arises for emergent transportation for a PCI patient from the Cardiac Catheterization lab.

POLICY

PROCEDURE:
The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program at Lawrence + Memorial Hospital (L+M) as described below:

1. A CT Surgeon is on-call 24/7 to arrange for patient transfers through the Y-Access system and to receive the patient at YNHH.
2. All YNHH on-call CT Surgeons are privileged to provide CABG or other procedures expected as a result of complications associated with performing elective PCI at Lawrence & Memorial Hospital.
3. YNHH maintains one operating room open every day for emergency transfers that is CT Surgery capable. The on-call CT Surgeon remains in-house during the hours of 7:30am through 4:00pm, Monday through Friday to accommodate the Lawrence & Memorial elective PCI schedule.
4. The receiving surgeon and team obtain consent for surgery from patient or surrogate.
5. The Yale-New Haven Heart & Vascular Center agrees that L+ M may represent to patients that YNHVC provides surgical backup to elective PCI in its patient consent process.
6. YNHVC and L+M maintain computer systems interface or direct access to L+M systems for the YNHVC receiving surgeon to review real-time images and hemodynamic data, as well as audio and video images for consulting on treatment options and transfer decisions.

7. L+M Hospital employ the Yale-New Haven Hospital Y-Access transfer system to expedite the process of surgical consultation and transfer.
8. All other provisions of the Transfer Agreement will remain in effect for heart and vascular patients
9. When choosing the appropriate form of transportation, the patient's stability and equipment needs is assessed and relayed to the proposed transportation team. Patients requiring a Balloon Pump during transport require air medical transport or a nurse to accompany the patient if ground transport does not have the appropriate staff to monitor the pump.
10. In the event air medical transport is preferred but unavailable due to weather, staff should inquire if the team is available to provide the trip by ground.

Below is the transport option in order of use:

1. Lifestar (Air Medical) transportation – Crew configuration will consist of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
2. Lifestar (Ground) transportation – Crew configuration will consist of an American Ambulance EMT and a second American Technician which may be an EMT or Paramedic and the Lifestar Crew consisting of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
3. American Ambulance (Ground) transportation - Crew configuration will consist of an American Ambulance EMT and a Paramedic.

   The following option must only be used if other transportation is unavailable and transportation must occur immediately.
4. New London Fire Department Ambulance (Ground) transportation - Crew configuration will consist of 2 Firefighter/EMT's and a Lawrence & Memorial Hospital Paramedic.

Contact Information

Lifestar – (800)437-4378
American Ambulance – (860)886-1463
New London Fire Department – (860)442-4444/911

PROTOCOL

Reference:
1. Hospital L+M Policy Patient transfer to Higher level of care facility.
2. YNHH transfer agreement

Archive Dates
Reviewed Date:
Revised: 5/12
Supersedes:

Exhibit B

Policy: Emergency Transfer Protocol to Cardiac Surgery Center Page 1 of 2

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LAWRENCE & MEMORIAL HOSPITAL

Effective Date: 10/04
Reviewed:
Revised:
Supersedes: New

Section: Pt Care Services/Rights
Subsection: Medical Services/Invasive Procedures
Resource:Cath lab

Purpose: To ensure a safe and expedient transfer in the event that any patient is in need of emergent transfer to a tertiary center for immediate Cardiac Surgery or other interventional procedures.

If Cardiologist determines the need for an immediate transfer:

1. Physician will make arrangements with physician receiving the patient and assuming responsibility at the new hospital. Discusses clinical information with receiving physicians/surgeon. Digital images are transmitted as appropriate
2. Physician will have obtained consent of patient and/or family for transfer.
3. Patient shall not be transferred until the receiving hospital has consented to accept the patient.
4. Reason for transfer should be documented in chart.
5. Members of the Cath lab staff as appropriate initiates the following calls:
    a. To Receiving unit at receiving hospital center to give telephone report
    b. To Admissions /registration staff at receiving center to get a bed assignment
    c. Contact appropriate EMS system to activate immediate transport (preferable by air). Give them the receiving facility name/unit and physician for the patient and brief report.
    d. For ground transport, contact appropriate pre arranged critical care transport ambulance on standby during primary angioplasty procedures.
    e. For helicopter transport, contact LIFE Star center at 1 800 437-4378 and L&M security.
6. Sheathes and balloon pumps are sewn into place.
7. Level of care is determined and appropriate plans are made with transport team to ensure patients clinical safety.
8. Patient is prepared for transport and transferred to transport vehicle/helicopter.
9. All care documentation is copied including copy of cath images (per Cath Lab Policy: Transportation Internal-External) and is sent with patient including transfer orders and Inter-facility patient transfer form.
10. Interventional cardiologist may accompany unstable patient, or stays in contact with transferring team until patient is received at cardiac surgical center. Nurse may accompany patient with IABP (See related IABP policy). Transport is via Critical care transport ambulance with paramedic service or Helicopter service.

References: Sinclair, McNamara and Wharton, Critical Pathways in Cardiology: Vol 1. No 2, Lippincott Williams & Wilkins, 2002.

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Policy: Emergency Transfer Protocol to Cardiac Surgery Center

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Approved By: _____ Date: 10-25-04
Mark Fiorigo, DO
Director, Angioplasty service

Approved By: _____ Date: 10/26/04
Brian Ehrlich, MD
Medical Director, Cath lab

Approved By: J Bonardi RN Date: 10/25/04
Francis Bonardi, RN
Vice President, Patient Care Services

Exhibit C

12/10/12 L+M Transfer Process
L+M Transfer Protocol With DPH 911 Policy
Cardiologists determines need for critical care transfer
1. Patient is stabilized and prepared for transport
2. Cardiologist contacts admitting physician at receiving hospital to arrange transfer
Cath lab staff calls 911 dispatcher to request transport
Patient disposition communicated directly to 911 dispatch
911 dispatches NLFD (New London PSAP)
1 of 2 NLFD BLS transport units and fire engine dispatched to L+M
NLFD BLS transport arrives at L+M along with fire engine
Cardiologist identifies most appropriate mode of transport (air or ground) and communicates such to NLFD BLS response
911 dispatcher contacts air medical transport or ground transport.
Is air medical transport available?
Yes
No
Cath lab staff call air medical transport to give key information re transport needs
Air medical transport arrives and transferred from cath lab to transport provider
Air medical transport transports patient to receiving hospital
NLFD BLS returns to base (Fire engine)
Transfer process stops
L+M Paramedic, L+M nurse and other L+M resources accompany patient during transport
Leaves L+M + Para area without critical care coverage for at least 2 hours
NLFD ambulance transport patient to receiving hospital
NLFD BLS returns to base (Fire engine)
Transfer process stops
NLFD ambulance transports patient to receiving hospital.
EMS sources from neighboring town to provide coverage.
L+M Industry Standard Transfer Protocol
Cardiologists determines need for critical care transfer
1. Patient is stabilized and prepared for transport
2. Cardiologist contacts admitting physician at receiving hospital to arrange transfer
Cardiologist identifies most appropriate mode of transport (air or ground) and communicates such to cath lab staff
Cath lab staff contacts air medical transport or commercial ground ambulance to initiate patient transport
Patient disposition + Medical history communicated directly to preferred transport provider
Air medical transport or commercial ground ambulance arrives at L+M
Patient transferred from cath lab to transport provider
Air medical transport or commercial ground ambulance transports patient to receiving hospital
Transfer process stops

Exhibit D

001610

JIM PARKER: Thank you. Senator Harris, members of the Public Health Committee, thank you for the opportunity to testify regarding House Bill 6599, An Act Concerning Public Safety.

My name's Jim Parker, I'm an emergency medical physician at Connecticut Children's Medical Center. I serve as the chair for Connecticut EMS for Children, and I'm also the medical director of the Connecticut Children's Critical Care Transport Team.

Connecticut Children's needs to operate a critical care transport team to bring critically ill or injured children/newborns from community hospitals to our facility when they need tertiary care services that are not available at a community facility.

Current Office of Emergency Medical Services regulations require that every individual providing care to a patient in an ambulance must be licensed actually as an EMT. This regulation prevents our team of trained pediatric critical care clinicians from providing the specialized services that these newborns and children need.

Connecticut Children's is not -- currently not operating this service because of potential liability for our clinicians' licenses. As a result, children who need our transport services do not have access to them.

I'm asking today that you amend House Bill 6599 to include a section that defines neonatal and pediatric specialty care transport, the verbiage of which is worked out on reverse of the sheet you've been provided.

The language should promote patient safety by requiring the use of a basic level ambulance

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with a licensed EMT on board. The language should also recognize that critically ill neonates and children need ongoing care that must be furnished by certified or licensed health professionals who specialize in neonatology or pediatrics.

Current standards established by the American Heart Association and the American Academy of Pediatrics define the qualifications for members of the neonatal and pediatric transport team. It is important that this amendment be written so that it will be effective upon passage, since Connecticut Children's is not currently offering critical care transport services pending the statutory change.

When enacted, this amendment will allow Connecticut Children's to resume operation of its critical care transport service, providing our patients with access to the specialized healthcare transport services they need in a safe environment.

I urge you to support amending House Bill 6599 to include a definition of neonatal and pediatric specialty care transports. Thank you for your time and your attention to this matter.

SENATOR HARRIS: Thank you, Doctor. Any questions?

Now, this is a piece, just for clarification, that we had in another bill, right, and your request is that we put it in this particular bill?

JIM PARKER: This is a piece that, to my knowledge, was being proposed in another bill but felt that it -- it was felt that it's best to go

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through the Department of Public Health than through us, within this.

SENATOR HARRIS: And is the reason for that because time is of the essence to get a bill passed so you can resume your services?

JIM PARKER: Absolutely. I speak specifically to Connecticut Children's, but there are three services that are impacted by this in the state. Yale runs a pediatric specialty transport service, and John Dempsey runs a neonatal specialty transport service.

Technically, any transports currently occurring with those services are operating outside their scope of practice and putting though clinicians at risk.

SENATOR HARRIS: Because there is no EMT aboard during those transports?

JIM PARKER: It's not having the EMT aboard. It's actually every person providing care must carry prehospital credentials.

SENATOR HARRIS: So everybody, and that's the problem.

Okay, and -- I thought I had another question, but.

Have you tried to work with the Department of Public Health to be able to accomplish this goal without the need for legislation, the need for expedited legislation?

JIM PARKER: We've had meetings with the Department of Public Health and Office of EMS over the last six to eight months, with an ongoing discussion of this issue, and the feeling both through them and in discussion with the

assistant AG was that this could not be something that was going to be fixed without changing the statute.

SENATOR HARRIS: Thank you very much. Any -- Representative Esty.

REP. ESTY: Thank you. And thank you, Dr. Parker. What -- do you know what the origin, then, was of the Office of Emergency Medical Services' decision to put this in place? Presumably, this is -- this was language that was put in there.

What was the rationale and were you consulted at that time? Were any of the neonates were consulted in did they talk to the Academy of Pediatrics, or how did they -- how did this get through, causing what would clearly not seem to make any sense from a layperson's point of view, even less from a clinician's point of view?

JIM PARKER: From my understanding, this is a statute that's long been on the books, and probably preceded the American Academy of Pediatrics' development of recommendations with regard to pediatric specialty transport.

It is a regulation that more -- is aimed toward the level of care necessary for operating an ambulance, and as these niches have grown and as these subspecialties have developed, the regulation has not been acknowledged or not been amended to change with those developments.

REP. ESTY: So this is artifact of the field having developed and these regs have not been updated, and I presume lawyers took a look at them and said you can't --

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JIM PARKER: That's -- that's my understanding.

REP. ESTY: It's always back to the lawyers who look at it.

JIM PARKER: Our lawyers took a look at it, but it was to the point that we asked the Department of Public Health to take it to the Assistant Attorney General who did provide us an interpretation that, yes, Department of Public Health was interpreting that regulation correctly.

REP. ESTY: So you would be outside of the scope of the practice and therefore be put in --

JIM PARKER: And therefore each person putting their license at risk.

REP. ESTY: All right. Thank you very much.

SENATOR HARRIS: Thank you, Doctor.

Next we have Gary O'Connor -- excuse me, Greg Allard. Gary O'Connor, I'm sorry, followed by Greg Allard.

GARY O'CONNOR: Thank you, Mr. Chairman.

Good morning. Actually, it's afternoon now. Time flies. My name is Gary O'Connor. I'm a partner with the law firm of Pepe & Hazard, and I'm here on behalf of the Association of Commercial Ambulance Providers. We call it ACAP. And I'd like to thank you for the opportunity to speak in support of Raised Bill 6599.

This bill in its present form addresses a very important patient safety issue in the State of Connecticut, namely, the transportation of patients who are confined to stretchers.

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

PRE-FILED TESTIMONY
OF LAWRENCE & MEMORIAL HOSPITAL
BY BRIAN CAMBI, MD, FACC, FSCAI

Good Morning Hearing Officer Hansted and members of the Department of Public Health. My name is Brian Cambi, MD, FACC, FSCAI, and I am the Medical Director of the Primary Angioplasty Program at Lawrence + Memorial Hospital ("L+M").[1] I thank you for this opportunity to appear before you today. As stated in our brief, L+M's protocol for inter-hospital transfers of elective angioplasty patients who develop a procedurally related complication that requires surgical intervention (the "Protocol") is a clinically appropriate transfer protocol that is typical in the industry, in that it preserves the treating physician's discretion to select the most medically appropriate means of transportation for the patient, based on the recommendations of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

A. L+M's Transfer Policy Comports with the Medical Community's Recommendations for Elective Angioplasty Programs.

In the early years, patients undergoing elective angioplasty developed procedural complications that required coronary artery bypass grafting (often on the same day) at rates quoted anywhere from 6-10%. Over the years, advances in technology and adjunctive medical therapy in combination with operator experience has led to a dramatic reduction in

[1] A copy of my Curriculum Vitae is attached hereto as Exhibit 1.

complications. Fortunately, the rate of procedural complications rendering a patient critically ill necessitating the need for same day surgery is rare with numbers in the literature described as low as 0.3%. With these changes and the release of recent studies in the medical literature, it is clear that we can now provide elective angioplasty services to carefully-selected low risk patients in a safe way that enhances the delivery of medical services to our local community. The rationale behind our desire for L+M to have such a program is outlined extensively in our application.

An important part of such a program is developing a sound policy for the transfer of an elective angioplasty patient in the rare event he or she develops a procedurally related complication that requires surgical intervention. The American College of Cardiology (ACC), as well as the American Heart Association (AHA) and the Society for Cardiovascular Angiography and Interventions (SCAI), has recommended in their consensus statement[2] that elective angioplasty programs without on-site surgical backup be able to acquire transportation services for critically ill patients within 20 minutes. Furthermore, the consensus statement states that these transportation services should be equipped with appropriately trained medical personnel and equipment such as intra-aortic balloon pump capability and mechanical ventilator support. L+M's transfer policy satisfies these requirements by selecting Lifestar and American ambulance as the preferred providers in the rare event that an elective angioplasty patient is transferred to Yale.

[2] A copy of the consensus statement can be found in L+M's CON application, at p. 35 (Table H).

B. Lifestar and American are the Preferred Providers Because Their Vehicles and Transport Teams are Pre-equipped to Handle Patients with Complex Medical Needs.

When patients develop a procedurally related complication and become critically ill in the L+M catheterization laboratory, they receive multiple interventions to stabilize their acute de-compensation such as mechanical ventilator support, intra-aortic balloon pump implantation, and a variety of inotropic and vasopressor medications designed to enhance and maintain cardiovascular function. Typically, this results in a stabilized, but critically ill patient that requires urgent transfer to a tertiary level facility to receive advanced level medical care not provided at our community hospital. These are not pre-hospital patients with an emergency that requires conventional 911 services to bring them to the nearest medical facility. Rather, these are patients who have a stabilized medical condition but remain critically ill and require sophisticated transport to a tertiary facility for advanced care. Relying on highly trained, experienced medical personnel who have the appropriate equipment and manpower to handle these transfers is the most prudent course of action to ensure the best outcome of our critically ill patients. I believe, as the attending interventional cardiologist and sponsoring institution, it is well within our scope of practice to make the most appropriate medical decision to ensure the highest quality, safest, and most expeditious mechanism of transport of these patients to our collaborating tertiary facility. To take that decision away from the attending interventional cardiologist and leave it in the hands of a 911 dispatcher jeopardizes patient safety.

It is my opinion that Lifestar Air Transport or American Ambulance both have the capability to provide not only qualified paramedics but personnel with years of experience in transferring these unique critically ill patients with complex intravenous medications as well as

their mechanical life support systems.[3] Local basic level EMS services are ill-equipped to deal with the challenges of these patients. If the New London Fire Department, which maintains a basic level ambulance, were to transfer our critically ill patients, a safe transfer may be possible, but it will most definitely be much more difficult to arrange. L+M would need to provide multiple staff like paramedics, nursing, and/or respiratory therapists to ensure the safe transport of patients. Although we support this process as a last resort in our transfer policy, following this procedure for all inter-facility transfers will strip our community and L+M of critical clinical resources for an extended period of time which is not ideal.

The most efficient mechanism for these transports is to request Lifestar Air Transport or ground transport through Lifestar or American Ambulance via direct contact with these providers. Direct contact expedites the relay of critical patient-related information to the provider responsible for the transport. A call to 911 that initiates a response by the PSAR to travel to the hospital prior to activating Lifestar or American Ambulance results in unnecessary waiting and delay, potential for miscommunication due to multiple patient information hand-offs, and can ultimately harm patient safety.

We maintain that L+M's transfer protocol complies with the 2003 Declaratory Ruling, in that it preserves the clinician's clinical judgment regarding when 911 should be activated. If the Department of Public Health disagrees and maintains that 911 must be activated each time an elective angioplasty patient is transferred to Yale, I respectfully submit that the ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving long term care facilities and members of the public, and the EMS providers who

[3] American Ambulance, Inc. Vice President Gregory B. Allard describes the sophisticated equipment maintained by his company, as well as the higher level of training provided to its personnel. *See* Letter by Gregory B. Allard (attached hereto as Exhibit 2).

respond to their calls. If L+M is robbed of its discretion to determine whether 911 is activated and/or the most appropriate mode of transportation for patients traveling from one hospital to another hospital , I strongly feel a quality and safety issue will emerge putting our patients at risk, not just in the elective angioplasty program, but in the emergency department and all other hospital specialties. There is no question local EMS is an important part of the emergency services system in our region. As Ron Kersey explains in his statement, keeping local EMS local is as important as getting our critically ill patients safely to a tertiary care facility for the advanced medical care they require.

I respectfully submit that L&M's Transfer Protocol meets all of the quality and clinically appropriate industry standards. We urge the Department of Public Health, Division of Office of Health Care Access to approve our CON application.

[SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The undersigned witness hereby submits all of the above testimony as his own testimony, and will adopt it at the hearing.

12-6-12

Brian Cambi, M.D., FACC, FSCAI

Exhibit 1

Brian Christopher Cambi, MD FACC FSCAI

2 Rocco Drive
East Lyme, CT 06333
860-691-0619 (Home)
203-623-3988 (Cell)
203-370-2177 (Beeper)
brian.cambi@yale.edu

EMPLOYMENT

2008 - Assistant Professor
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

- ***Director*** – Primary Angioplasty Program at Lawrence and Memorial Hospital
- ***Director*** – Stress Echocardiography at Lawrence and Memorial Hospital

2007-2008 Attending Cardiologist
West Haven Veteran's Administration Hospital

2007-2008 Clinical Instructor
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

PROFESSIONAL TRAINING

2006-2007 Advanced Fellowship in Interventional Cardiology.
Yale University School of Medicine, New Haven, CT

2005-2006 Advanced Fellowship in Non-invasive Cardiac Imaging.
Yale University School of Medicine, New Haven, CT

- Level II training in echocardiography
- Level II training in nuclear cardiology

2003-2005 Clinical Cardiology Fellowship. Yale University School of Medicine.

2002-2003 Chief Resident, Internal Medicine. Yale University School of Medicine.

1999-2002 Intern and Resident, Internal Medicine. Yale University School of Medicine.

EDUCATION

1995-1999 Doctor of Medicine, State University of New York at Buffalo, School of Medicine and Biomedical Sciences, Buffalo, NY.
- ***Summa Cum Laude***

1991-1995 Bachelor of Science, Biology. The College of William and Mary, Williamsburg, VA.
- ***Magna Cum Laude***

LICENSURE AND CERTIFICATION

2007 Board certified - Interventional Cardiology
2006 Board certified - Cardiology
2006 Board certified - Nuclear Cardiology
2006 Board certified - Echocardiography
2002 Board certified - Diplomate, American Board of Internal Medicine.

ACADEMIC ACTIVITIES

2006 Speaker, Grand Rounds, Cardiology. Yale University School of Medicine.
- "CT Angiography: A Novel Clinical Application"

2005-2006 Research: CT Angiography in the Non-Invasive Detection of Revascularizable Cardiomyopathy.

2002-2003 Director, Morbidity and Mortality conference. Yale University School of Medicine, Section of Internal Medicine.

HONORS AND AWARDS

1999 **The John Watson Award in Medicine.** SUNY at Buffalo School of Medicine.
- Outstanding achievement and leadership in Internal Medicine

1999 **Association of Pathology Chairs Award.** SUNY at Buffalo School of Medicine.
- Academic excellence in Pathology

1998 **Alpha Omega Alpha Honor Medical Society.** SUNY at Buffalo School of Medicine.

1997 **James Gibson Anatomical Honor Society.** SUNY at Buffalo School of Medicine.
- Academic excellence in Gross Anatomy

1995 **Phi Sigma National Honor Society.** The College of William and Mary.
- Academic excellence in biology

REFERENCES – *available on request*

Exhibit 2

AMERICAN
AMBULANCE
SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

December 7, 2012

Hearing Officer Kevin Hansted
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Dear Mr. Hansted,

The intent of this letter is to provide details about our ambulances, in particular the Advanced Life Support (ALS) equipment used by our Paramedics, and the training our Paramedics receive, as well as to point out that American Ambulance Service, Inc. (AASI) is not a PSAR for the Lawrence + Memorial service area.

AASI is supportive of Lawrence + Memorial obtaining approval to perform non-emergent angioplasty even though this approval will have a negative financial impact on our business. By providing an elective angioplasty service to residents of Eastern Connecticut this approval will reduce the number of ALS transports that we currently do out of Lawrence + Memorial. We support this initiative because having non-emergent angioplasty available in Eastern Connecticut is in the best interest of the people residing in and passing through Eastern Connecticut.

AASI currently has an ambulance fleet of 24 and they all exceed the basic minimum vehicle standards set forth in the CT EMS Statutes. Our basic ambulances are built to our specifications and are built on a chassis of our choice. Within those specifications are several safety minded items that exceed the basic requirements. We also have Epi-Pens, AED's, and baby aspirin which are not standard equipment.

We currently have 11 sets of ALS gear. So 11 of those 24 ambulances could be operating at the ALS level on any given day at any given time depending on Paramedics being scheduled, without any impact whatsoever on the communities we serve as a first responder PSAR.

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

Our ALS gear includes a ZOLL CCT M-series Cardiac Monitor, an ALS equipment bag, ALS equipment restock bag, portable ventilators, and a small IGLOO cooler. Our Cardiac Monitors have the following functions; biphasic defibrillator, external pacing, non-invasive vital sign monitoring including, SpO2, EtCO2, NIBP, and fully interpretive 12-lead ECG. The ALS equipment bag has several items in it. The first is our ALS medications that can be given, orally, intramuscularly, intravenously. Some of the medications we carry are controlled substances that are used for sedation and pain management. Another thing we have is our intravenous supplies such as needles, tubing, fluids, and blood glucose monitor. Another route of infusion is intraosseous and we carry a specific device called and EZ-IO drill. It is a cordless drill used to bore a hole in a patient's bone. We also carry advanced airway equipment such as LMAs, CPAP devices, endotracheal tubes and laryngoscopes. Our portable ventilator is used during transports when a patient is sedated to a point where they can't control their own airway. The IGLOO cooler contains intravenous fluids that are temperature controlled and are used to induce a hypothermic state.

The paramedics are trained to use a lot of this equipment in school but upon being hired they need site specific training based on the equipment used. Our paramedics need to learn things such as our portable ventilator, our cardiac monitors, BGL monitors, CPAP device. Our sponsor hospital requires all paramedics have ACLS, PALS, PHTLS, and CPR training which is not required at some other sponsor hospitals. They also undergo continuing education monthly at our sponsor hospital. The continuing education topics vary from month to month. Annually the sponsor hospital requires all of them to go through a skills training session where they review things such as infusion pumps, medications, STEMI protocols, 12-and lead ECG recognition. Also reviewed routinely are the guidelines set forth by our sponsor hospital. Some examples of guidelines include induced hypothermia, STEMI, and Stroke.

It is usual and customary practice for a hospital such as Lawrence + Memorial to have a working relationship with an organization such as AASI for emergent and non-emergent ALS inter-facility transfers. These transfers are performed by our paramedics that have been given medical control by a sponsor hospital. The sponsor hospital physician has determined that these paramedics have undergone enough training and have the skill set required to perform inter-facility transfers of medically complex patients. Transfer requests from all area hospitals come directly into our dispatch center via a seven digit telephone line. Our highly trained dispatchers understand the urgency some of these requests may need. We never pass on any of these ALS transfer requests to the local PSAR service as they are not equipped nor are they trained to perform this level of service. Our service is equipped, trained, and has enough resources to do this. A local 911 PSAR service is limited, usually 1 or 2

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

ambulances, in its resources. They are obligated by law to be available to respond to the emergency requests within the town boundaries. That is their primary function. Being utilized to perform transfers like this is again not within their capabilities and it strips whatever emergency resources from their town.

I hope that the information obtained within this letter is useful and in the event it has led to more questions please feel free to contact me.

Respectfully,

Gregory B. Allard, Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

PRE-FILED TESTIMONY
OF LAWRENCE & MEMORIAL HOSPITAL
BY RON KERSEY

Good Morning Hearing Officer Hansted and members of the Department of Public Health. My name is Ron Kersey and I am E.M.S. Coordinator at Lawrence + Memorial Hospital ("L+M").[1] I thank you for this opportunity to appear before you today. As stated in our brief, L+M's protocol for inter-hospital transfers of elective angioplasty patients who develop a procedurally related complication that requires surgical intervention (the "Protocol") is a clinically appropriate transfer protocol that is typical in the industry, in that it preserves the treating physician's discretion to select the most medically appropriate means of transportation for the patient, based on the recommendations of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

The protocol that L+M uses for critical care inter-hospital transfer of angioplasty patients is a carefully organized approach to providing our patients with the highest quality, most appropriate mode of transportation with minimal impact to the community EMS system. L+M's policy for the inter-hospital transfer of a patient for advanced medical care represents the industry standard process for ensuring safe patient transport in the most efficient and timely manner. Dr. Cambi highlighted the clinical and medical benefits of our transfer protocol. I

[1] A copy of my Curriculum Vitae is attached hereto as Exhibit 1.

would like to discuss the implications of utilizing 911 for L+M's critical care transfers and the negative impact that process will have on patients, our local EMS system and the community.

If L+M were to call 911 for critical care transportation of patients to Yale or another tertiary care facility, it will place significant strain on the resources of our local EMS system. Dr. Cambi noted the infrequency of critical care transfers expected with the proposed elective angioplasty program; however, if the use of 911 for inter-facility transports were implemented hospital-wide, it will cripple our local resources. In Fiscal Year 2012, 450 patients were transferred to Yale alone from L+M's emergency department for emergent and urgent issues. This total climbs significantly when you consider tertiary facilities such as Hartford Hospital, as well as specialized care facilities such as Connecticut Children's. As New London Fire Department Deputy Chief Henry Kydd explains in his letter[2], the local EMS system cannot absorb this added responsibility nor is it the best equipped provider to do so.

The PSAR for the town of New London is the New London Fire Department (NLFD). The NLFD is equipped with two basic level support (BLS) transport units to handle all community 911 responses. As outlined in Deputy Chief Kydd's letter, the NLFD is not prepared clinically to handle the complex needs of the patients requiring critical care transport from L+M to a tertiary care facility. The NLFD is staffed with emergency medical technicians (EMTs) who are trained to provide basic medical care until the patient can be transferred to a hospital for advanced medical care. The skill level of some of the first responder EMTs is not specialized to manage cardiac patients requiring transfer to Yale. Deputy Chief Kydd supports L+M's plan for critical care transportation of elective angioplasty patients and agrees with the utilization of NLFD only as a last resort should the providers outlined in L+M's protocol not be unavailable.

[2] New London Fire Department Deputy Chief Henry Kydd's letter is attached hereto as Exhibit 2.

Utilizing NLFD for critical care transport to Yale will take one of two BLS units completely out of the community for an extended period of time stripping local residents of their 911 resource. In order to accommodate this, New London will be forced to rely on neighboring communities to fill in 911 calls in their area while the town ambulance is providing inter-facility transports, hence creating a potential ripple effect among an extended service area of first responder providers.

Activating 911 to dispatch NLFD means an L+M paramedic will need to accompany the NLFD EMT staff in the transport to Yale, and another local resource will be unavailable to the community for an extended period of time. A single transport, on average, will require the local ambulance and paramedic to be out of their primary response area for greater than 2 hours at a time. In addition, depending on the needs of the patient, an L+M nurse and respiratory therapist may also need to accompany the patient to Yale further depleting L+M and the community of resources. If Lifestar and/or American Ambulance were utilized rather than local EMS, L+M is able to maintain its much needed resources to support other hospital patients. Unlike local EMS, the providers in L+M's protocol have been vetted and have equipped their ambulances specifically to handle these calls and have given their crews additional education to provide the complex care required for these patients.

L+M supports the legal argument presented to this Department that the 2003 Declaratory Ruling does not apply to the inter-hospital transfer process. As L+M notes in its brief, the Ruling fails to mention inter-hospital transports and solely comments on transports to acute care facilities from long term care facilities or private citizens. The Ruling deals exclusively with pre-hospital transfers and is in place to ensure timely access for the community to the services of an acute care facility such as L+M. Despite the merits of this Ruling, to broadly extend its

application to all transfers is a mistake. I do not know of a hospital in the state of Connecticut that accesses the 911 system to move a patient from one acute care facility to another, whether in an emergent, urgent, critical condition or otherwise. It is in the best interest of the patient that L+M and other acute care facilities in the state follow a procedure to work directly with transport providers.

It should be highlighted that L+M is the sponsor hospital for the town of New London and adjacent communities. As the sponsor hospital, L+M is involved in the system development of the local EMS system. As the responsible party, we are willing to prescribe a process in which other providers are contacted directly by acute care hospitals for inter-hospital transports and the 911 service is not utilized at all unless these providers are unavailable. As the sponsor hospital in our community, L+M has the authority to determine this course of action as outlined in the 2003 Declaratory Ruling.

We maintain that L+M's transfer protocol complies with the 2003 Declaratory Ruling, in that it preserves the clinician's clinical judgment regarding when 911 should be activated. If the Department of Public Health disagrees and maintains that 911 must be activated each time an elective angioplasty patient who develops a complication is transferred to Yale, I respectfully submit that the ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving long term care facilities and members of the public, and the EMS providers who respond to their calls. If L+M is robbed of its discretion to determine whether 911 is activated and/or the most appropriate mode of transportation for patients traveling from one hospital to another hospital, I strongly feel a quality and safety issue will emerge putting our patients at risk, not just in the elective angioplasty program, but in the emergency department and all other hospital specialties. There is no question local EMS is an

important part of the emergency services system in our region. As explained above, keeping local EMS local is as important as getting our critically ill patients safely to a tertiary care facility for the advanced medical care they require.

I respectfully submit that L&M's Transfer Protocol meets all of the quality and clinically appropriate industry standards. We urge the Department of Public Health, Division of Office of Health Care Access to approve our CON application.

[SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The undersigned witness hereby submits all of the above testimony as his own testimony, and will adopt it at the hearing.

12-6-12

Ron Kersey

Exhibit 1

Ronald Kersey
117 Riverview Avenue
New London, CT 06320
(860)442-8737
rkersey@lmhosp.org

Areas of Effectiveness: Advanced emergency medical treatment, firefighting, emergency response and public preparedness, leadership, drill, exercise, and simulation design, business management, human body system knowledge, medical education, communication and public speaking, customer service skills.

Education

1989 – present **Three Rivers Community College**
574 New London Turnpike, Norwich, CT 06360
Currently pursuing an Associates in Liberal Arts and Science

02/93 – 05/93 **Capital Community College**
950 Main Street, Hartford CT 06103
Six credits in EMT-Paramedic III obtained

Career Experience

01/11 – present **Simulation Laboratory Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Coordinate the development of clinical simulation center
- Develop computer clinical simulation programs and scenarios
- Train clinical simulation operators
- Conduct clinical simulation for all levels of healthcare providers
- Troubleshoot and repair simulation equipment and manikins
- Manage American Heart Association Community Training Center Staff and activities

- Provide educational debriefing sessions for simulations

01/92 – present **Emergency Management Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Develop hospital emergency response plan
- Respond to and mitigate emergency situations
- Train staff in emergency preparedness and response
- Conduct emergency response drills and exercises
- Lead hospital through emergency events and situations
- Acquire grant funding to support emergency preparedness activities
- Perform radiological monitoring during nuclear contamination events
- Coordinate hospital emergency preparedness activities with the community

03/89 – present **EMS Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Direct Community EMS system development and quality oversight
- Plan and perform EMS related training for community EMS services
- Provide administrative supervision for hospital paramedic program
- Develop annual budget and manage department expenses
- Train, hire, and council employees
- Coordinate hospital and EMS interaction
- Conduct advanced medical training classes for hospital and physician staff

03/88 – 03/89 **Chief Paramedic**, Lawrence & Memorial Hospital Paramedic program, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Provide advanced emergency medical treatment
- Oversee daily operations and employee supervision
- Manage fleet maintenance
- Provide employee scheduling
- Employee counseling and coaching
- Conduct employee performance reviews
- Promote positive community relations

06/10 – present **Emergency Medical Technician**, Town of Ledyard, 1 Fairway Drive, Ledyard, CT 06339

Responsibilities Include:

- Respond to emergency calls
- Operate emergency vehicles
- Administer emergency medical treatment
- Conduct public education and awareness classes
- Perform daily checks and maintenance of emergency equipment
- Provide electronic patient care documentation report for each patient's medical record

04/08 – present **Emergency Medical Service – Instructor**, Emergency Training Services Incorporated, 45 Spring valley Road, Mystic, CT 06355

Responsibilities Include:

- Develop and Conduct EMS lectures
- Provide EMS skill training
- Train on proper use and maintenance of EMS equipment
- Manage classroom environment and activities
- Coach, remediate, and encourage student participation
- Manage class records

01/00 – 1/03 **Firefighter/Emergency Medical Technician**, Pinkerton's Incorporated, Pfizer New London location, 4330 Park Terrace Drive, Westlake Village, CA 91361

Responsibilities Include:

- Participate in emergency response activities

- Conduct site safety inspections
- Assist with facility security
- Monitor and maintain fire alarm and protection systems
- Train staff on fire suppression techniques

6/92 – 6/98 **Emergency Medical Technician**, Health Resources Incorporated Millstone Nuclear Power Facility 136 Berlin Rd. Cromwell, CT 06416

Responsibilities Include:

- Conduct air quality monitoring
- Provide safe work permit assessment and authorization
- Perform radiologic monitoring
- Manage hazardous materials events
- Respond to confined space rescue situations

10/81 – 3/88 **Paramedic/Associate Supervisors/Advanced Life Support Coordinator**, American Ambulance Service Inc. One American Way Norwich, CT 06360

Responsibilities Include:

- Provide advanced life support patient care
- Supervise daily staff activities
- Conduct public speaking events on the EMS system
- Coordinate advanced life support training

Volunteer Experience

06/92 – 01/94 **Firefighter/EMT**, New London Fire Department 89 Bank Street, New London, CT 06320

Responsibilities Include:

- Assist with fire ground activities
- Promote positive volunteer and career staff interactions

08/88 – present **Firefighter/EMT**, Goshen Fire Department, Shore Road, Waterford CT 06385

Responsibilities Include:

- Respond to marine emergencies
- Provide basic life support care

06/88 – present **Emergency Medical Technician**, Waterford Ambulance Association 89 Rope Ferry Road, Waterford CT 06385

Responsibilities Include:

- Administer emergency medical treatment
- Conduct public education and awareness classes
- Provide electronic patient care documentation report for each patient's medical record

06/88 – present **Firefighter/EMT**, Jordan Fire Company, 89 Rope Ferry Road, Waterford CT 06385

Responsibilities Include:

- Respond to emergency calls
- Mitigate hazardous materials incidents
- Maintain emergency equipment

References available upon request

Exhibit 2

City of New London
Fire Department

Hearing Officer Kevin Hansted
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Lawrence + Memorial Hospital's Patient Transfer Protocol for Elective Angioplasty Patients

Dear Mr. Hansted::

The City of New London Fire Department ("NLFD") has reviewed and supports the Lawrence + Memorial Hospital plan for "Emergent Transportation of Elective Angioplasty Patients" (the "Protocol").

NLFD is the Primary Service Area Responder ("PSAR") for New London. We staff two BLS transport units with EMTs to handle community 911 responses and transport injured individuals to L+M Hospital. The EMTs are trained to provide basic medical care until the patient can be transferred to a hospital for advanced medical care. In addition, we utilize a paramedic intercept unit from L+M for all life and limb threatening emergencies. The NLFD is required to follow certain policies and procedures each time it is contacted by the local 911 dispatcher. In addition to the BLS ambulance, we dispatch a fire engine to the scene of the emergency for all life threatening problems. The fire fighters assess the situation and render basic first aid if the NLFD ambulance has not arrived. When the ambulance or paramedic intercept team arrive, they assess the severity of the emergency and call for additional EMS resources, such as the Lifestar air medical transport helicopter, if necessary. If L+M Hospital is required to go through the 911 system each time the hospital calls Lifestar, the fire engine and BLS ambulance will be dispatched to the hospital each time Lifestar is called, even though their services are not needed.

As identified in the Protocol, NLFD ambulances, supplemented by L+M paramedics and other staff, may at times be required to assist in the transportation of critically ill patients from Lawrence + Memorial to Yale New Haven Hospital. We understand, however, that in most instances other providers will perform this service. Those other providers are better equipped to handle the transfers because, unlike our EMTs, their staff have been given additional training to manage medically complex cardiac patients. In addition, if the NLFD is called upon to assist L+M with its 450+ urgent, emergent, and critical care patient transfers per year, it will draw resources away from the community for extended periods of time and cripple the local EMS system. The projected volume is well above the NLFD's capacity, and would require me to draw additional EMS resources away from neighboring communities to fill the gap for community 911 responses. To preserve the stability of New London's community EMS system, L+M

Reginald J. Samuel, Sr., Fire Chief
289 Bank Street
New London, CT 06320-5521
(860) 447-5291 • FAX (860) 447-5293
Email: rsamul@ci.new-london.ct.us

CITY OF NEW LONDON
FIRE DEPARTMENT

and its medical staff should be permitted to determine the most appropriate mode of transportation for their patients, which will most often be via air medical transport or another provider that is specially equipped to handle inter-facility critical care transports.

In the event that the preferred resources outlined in L+M's Protocol are not available or they deem them unnecessary for clinical reasons, the NLFD will provide an ambulance for transportation. However, the NLFD should not and cannot become the primary first responder for all of L+M's inter-hospital patient transfer calls.

Please feel free to contact me with any questions or concerns at (860) 447-5291.

Sincerely,

Henry Kydd, Deputy Chief
New London Fire Department

Ronald J. Samul, Sr., Fire Chief
289 Bank Street
New London, CT 06320-5521
(860) 447-5291 • FAX (860) 447-5293
Email: rsamul@ci.new-london.ct.us

Greer, Leslie

From: Lazarus, Steven
Sent: Tuesday, December 11, 2012 7:12 AM
To: Greer, Leslie
Cc: Hansted, Kevin; Martone, Kim; Riggott, Kaila
Subject: FW: Lawrence & Memorial Hospital (Docket #12-31768-CON)
Attachments: DPH.CON PCI (Brief, Cambi Prefile, Kersey Prefile) Docket #12-31768-CON.pdf

Leslie,

Please add to the original file.

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: Bettyanne Toole [mailto:bettyanne@bvmlaw.com]
Sent: Monday, December 10, 2012 3:50 PM
To: Lazarus, Steven
Cc: Michele AOL; Katherine Hagmann
Subject: Lawrence & Memorial Hospital (Docket #12-31768-CON)

Steven: Please see the attached file containing the following:

1. Lawrence & Memorial Hospital transmittal letter to OHCA;
2. Applicant's Brief in Support of its Patient Transfer Protocol;
3. Prefile Testimony of Brian Cambi, MD, FACC, FSCAI; and
4. Prefile Testimony of Ron Kersey.

Thank you,

Betty Anne Toole-Teasley
Paralegal
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor
New Haven, Connecticut 06511-6957
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LAWRENCE +MEMORIAL HOSPITAL

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December 10, 2012
Via Federal Express
Via Facsimile (860) 418-7053
Via Electronic Mail: Steven.Lazarus@ct.gov

Kevin Hansted, Hearing Officer
Steven W. Lazarus, Associate Health Care Analyst
State of Connecticut
Department of Public Health
Division of Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06106-1367

Re: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

Dear Hearing Officer Hansted and Mr. Lazarus:

In connection with the Public Hearing scheduled for Thursday, December 13, 2012 at 10:00 a.m. on the above-captioned CON Application, enclosed please find an original and four (4) copies of the following:

1. Applicant's Brief in Support of its Patient Transfer Protocol
2. Prefile Testimony of Brian Cambi, MD, FACC, FSCAI
3. Prefile Testimony of Ron Kersey

Also enclosed is a CD containing a scanned version of each document listed above.

Please do not hesitate to contact me with any questions.

Thank you.

Crista Durand, Vice President
Strategic Planning, Marketing & Business Development

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

APPLICANT'S BRIEF IN SUPPORT OF ITS PATIENT TRANSFER PROTOCOL

Lawrence & Memorial Hospital (the "Applicant" or "L+M") respectfully submits that its patient transfer protocol for the elective angioplasty program ("Protocol")[1] does not conflict with the Department of Public Health's ("DPH") February 14, 2003 Declaratory Ruling (the "Declaratory Ruling" or "Ruling"), which recognizes that a clinician's "clinical judgment should be used in determining whether the 911 system should be activated." Declaratory Ruling, at p. 18. This brief sets forth the legal and policy bases for the Applicant's position, and responds to the five hearing issues that the Office of Health Care Access ("OHCA") submitted to the Applicant on December 4, 2012.

If the DPH disagrees and maintains that the 911 system must be activated each time an elective angioplasty patient who develops a procedurally related complication that requires surgical intervention is transferred to another hospital, L+M respectfully submits that the Ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving "long term care facilities" and members of the public, as well as the EMS providers who respond to their calls. An interpretation of the Ruling that deprives treating physicians in hospitals of the ability to exercise discretion over whether to activate the 911 system and how patients should be transported conflicts with the Ruling itself, and subsequently-enacted State

[1] The Protocol is attached hereto as Exhibit A.

law, and Federal law. It also places an unnecessary strain on community EMS resources, and jeopardizes patient safety.

I. The Declaratory Ruling

The Declaratory Ruling addresses three major topics. First, the Ruling requires "long term care facilities" and members of the public to dial 911 to facilitate the transportation of urgently ill or injured individuals to hospitals during "medical emergencies, which require an immediate response." *See* Declaratory Ruling, at p. 13, #68 and p. 30. Second, it regulates the conduct of the local EMS providers, called Primary Service Area Responders ("PSARs"), who respond to emergency calls made by members of the public and long term care facilities. *See id.* at pp. 20, 25, 31-34. Third, the Declaratory Ruling specifically addresses the role of acute care hospitals within the EMS system, and explains that their purpose is to assist EMS providers to safely transfer patients into Connecticut's hospital system. *See id.* at pp. 8-12 and p.21-25. This third point is most pertinent to the issues at hand.

As the Ruling explains, a patient's care is entrusted to the highly trained professionals at Connecticut's acute care hospitals as soon as the 911 system is activated. Each EMS provider is sponsored by an acute care hospital, which provides "medical control," administered by staff physicians who serve as "medical directors" to the PSAR units. *Id.* at p. 8, #36. Medical control by a sponsor hospital is necessary because "emergency medical technicians and paramedics provide invasive medical care, including starting IV lines, using defibrillators, performing endotracheal intubations, and administering medications." *Id.* If EMTs or paramedics have treatment questions or run into complications in the field, they can contact a physician at the sponsor hospital to obtain medical direction. *Id.* at p. 9, #38.

Sponsor hospitals are also responsible for monitoring the quality of the care provided by PSARs. *Id.*, at p. 9, #37. "Medical directors may withhold medical authorization from emergency personnel or a provider if the medical director believes the EMS staff or service has demonstrated incompetence or negligence, poses a threat to public health or safety, or has acted contrary to medical direction." *Id.* at p.8, #36. If a PSAR travels outside its regular service area, the sponsor hospital must continue to be responsible for quality assurance. *Id.*at p. 11, #52. Thus, the Ruling makes clear that acute care hospitals form the lynchpin of the EMS system, furnishing the PSARs who bring patients to the hospitals with expert medical advice. The EMS system operates safely because of sponsor hospitals applying their medical training and expertise.

II. L+M's Protocol Complies with the Declaratory Ruling

The Declaratory Ruling not only recognizes the medical training and judgment of physicians, it defines "emergency" so that clinicians, such as physicians, are *required* to exercise their independent medical judgment when deciding whether to activate 911. For purposes of the Ruling, DPH adopted a definition of the term "emergency," which was set forth in two guidance letters that it sent to long term care facility operators in 2002. *Id.* at p. 12-14, and p. 18. The letters explain that a medical emergency is a situation that requires an immediate response, which "**as determined by appropriate licensed staff at a transferring facility, necessitates the activation of the 911 response system.**" *Id*, at p. 13, #68 (Emphasis added). Although the letters set forth three specific examples of medical emergencies (i.e. the "rapidly deteriorating condition of a resident;" "[a]n accident resulting in serious injury," and "[a] life threatening emergency"), the 2002 letters, and an earlier 1987 letter, *always* allow the transferring facility to exercise discretion regarding whether 911 is activated. *Id.*, at p. 12, #65; p. 13, #68; and p. 14,

#71. When the Ruling adopted the definition of "emergency" set forth in the 2002 letters, it emphasized again that "**clinical judgment should be used in determining whether the 911 system should be activated.**" *Id.*, at 18 (Emphasis added). The 2002 letters also explain: "If non-emergency transportation is desired, any ambulance service may be utilized." *Id.* at 14, #71.

The Ruling's emphasis on the judgment of clinicians makes perfect sense. Just as a hospital staff physician must have discretion when determining whether a patient should travel from the emergency department to surgery in a wheelchair or on a gurney, a physician must have discretion to determine whether a patient travels from the catheterization laboratory at L +M to an operating room at Yale via Lifestar, American Ambulance, or, when presented with an emergency that "necessitates the activation of the 911 response system," through the 911 system. *See id.*, at p. 13, #68.

L+M's Protocol is identical in all material respects to the protocol that it submitted in connection with its successful CON application for the emergency angioplasty program.[2] Both protocols fully comply with the mandates described above. They recognize that most critical care inter-hospital transfers will not constitute a "medical emergency," which "as determined by appropriate licensed staff at a transferring facility, necessitates the activation of the 911 response system." *See id.* The Protocol is utilized only when, due to complications during the procedure, the interventional cardiologist decides that the patient requires a level of care found at the transferee hospital. The interventional cardiologist makes sure the patient is medically stable, and L+M staff obtains the patient's or family's informed consent for the transfer. In the vast majority of cases, which involve transferring a medically stable patient within the hospital

[2] When L+M applied to OHCA for approval of its emergency angioplasty program, OHCA requested a copy of L+M's patient transfer protocol in the completeness questions. The emergency angioplasty patient transfer protocol advised L+M's staff to contact EMS providers directly, and it included Lifestar's direct1-800 number in the protocol. *See* Emergency Transfer Protocol (attached hereto as Exhibit B). That CON application was approved by OHCA.

system, this will not, in the clinician's judgment, constitute a medical emergency that is best served by activating the 911 system. That is why both protocols make no mention of 911. If, in the attending physician's opinion the best means of facilitating the patient's transfer to another acute care hospital is by activating 911, 911 will be activated. If the Department will find it useful, L+M certainly is willing to state this in its Protocol.

III. Mandated Activation of the 911 System for Each Urgent or Emergent Patient Transfer Will Gravely Impair Public Safety, and Conflict with the Ruling Itself, as Well as State and Federal Law

A. Activation of the 911 System for Each Urgent, Emergent, or Critical Care Patient Transfer Jeopardizes Patient Safety

If DPH is taking the position that the Ruling requires L+M to activate 911 for all emergent, urgent, and critical care inter-hospital transfers, specifically transfers of elective angioplasty patients who develop a complication to Yale, the following process, which is diagramed in Exhibit C (attached hereto), will occur each time an urgent, emergent, or critical care patient is transferred to Yale. The treating physician is required to dial 911 and relay the patient's needs to the dispatcher, who is required to activate the Primary Service Area Responder (PSAR) for New London, the New London Fire Department ("NLFD") ambulance. If the NLFD ambulance is unavailable, the call will result in the dispatch of a PSAR from another community. This procedure adds links in the chain of communication, creating multiple opportunities for miscommunications and mistakes. It also results in the dispatch of a Basic Level (BL) ambulance, as well as fire fighters or police officers, who are first responders. OHCA's second enumerated question queries whether a 911 dispatcher will send something less than a BL ambulance. Because, upon information and belief, all PSARs are equipped with BL ambulances, 911 will dispatch a BL unit. However, this question fails to address L+M's concern, which is patient safety. A BL ambulance will not, in this instance, be the clinically appropriate mode of

transportation for an elective angioplasty patient with a complication. Under Section 19a-179-18 of the Connecticut Agency Regulations, a BL ambulance is not always equipped with the supplies that these medically complex patients need and the NLFD ambulances are staffed only with EMTs. If the Department requires NLFD's BL ambulance to perform these transfers, it will need to be supplemented with L&M staff, such as paramedics, nursing, and/or respiratory therapists to ensure the safe transfer of patients. Without an appropriately equipped ambulance, transferred patients risk complications due to lack of necessary equipment and experienced trained health care providers, all of which could have been easily and efficiently provided under L+M's proposed transfer system. As Dr. Cambi explains in his testimony, the providers in L+M's protocol arrive pre-equipped with the medically appropriate staff and equipment for these transferees. Thus, if the ruling is applied to hospitals, they may find themselves in a position where the least desirable provider must become the first provider for inter-hospital transfers of critically ill patients.

Although the Lifestar helicopter is available if L+M is required to activate 911, the procedure for dispatching the helicopter is more complicated. **New London's 911 dispatchers cannot initiate Lifestar absent a request from the PSAR, which is the NLFD.** Therefore, rather than making a single phone call, the treating physician is required to call 911, the dispatcher is required to contact the PSAR, and the PSAR is required to activate Lifestar and travel to L+M, even though the hospital has no need for the services of a PSAR. This chain of command makes sense when the EMS system deals with members of the general public or long term care facilities that may not have physicians on staff, because the PSAR must assess the severity of the patient's condition and decide whether Lifestar is necessary. In the hospital setting, it is not necessary for the PSAR to assess the patient as this is already done by the

transferring hospital, and the patient is stabilized. Activating the 911 system in unnecessary cases adds complexity and delay to inter-hospital transfers, which are initiated at the request of highly trained physicians. Indeed, in L+M's case, the PSAR will arrive to render assistance that is not needed at the very institution that sponsors it and provides it with medical direction and control.

B. Activation of the 911 System for Each Urgent, Emergent, or Critical Care Patient Transfer Strips the Community of Much Needed EMS Resources

Using the NLFD ambulance for inter-hospital transfers will also strip the community of both an ambulance and a L+M paramedic for the time it takes to make the round trip, which could exceed two hours. Although the likelihood of a transfer of elective angioplasty patients to Yale for urgent cardiac surgery is very low due to L&M's strict patient selection process, requiring the hospital to activate the 911 system for all other specialties will result in a severe drain on community resources. As Ron Kersey explains in his pre-filed testimony, L+M's emergency department transferred 450 patients to Yale in Fiscal Year 2012. If all of those transfers are considered emergencies, that could equate to nearly 40 trips per month, which will take the NLFD Ambulance out of its service area for hours at a time, and require New London to rely on PSARs from neighboring communities to fill the gap.

Involving local 911 dispatchers in emergent, urgent, and critical care inter-hospital transfers will also waste local resources, with no benefit to the patients. Unlike members of the public, who may need first aid instructions while they are waiting for a first responder to arrive, physicians do not require the assistance of a 911 dispatcher to assess patient needs and provide basic first aid instructions. More important, the physicians and hospital staff have already stabilized the patient for transfer. As NLFD Deputy Chief Henry Kydd explains in his letter, calls to 911 may also result in police or fire vehicles being dispatched to the hospital, which will

draw these resources away from the community members who need them. *See* Letter by NLFD Deputy Chief Henry Kydd (attached to Prefiled Testimony of R. Kersey).

Finally, because application of the Declaratory Ruling to emergent, urgent, and critical care inter-hospital transfers will represent a marked departure from the current practices of every Connecticut hospital, as well as the industry standard for hospitals throughout the United States,[3] it will have a significant financial impact on cities and towns throughout Connecticut, and can very well collapse the 911 system in the State. The problems described above can be avoided if the Declaratory Ruling is read in its proper context to defer to the transferring hospital and treating physician's judgment as to whether the 911 system is activated.

C. The Declaratory Ruling Does Not Apply to This Patient Transfer Protocol

If the Department is of the opinion that L+Mmust activate the 911 system for *all* emergent, urgent, and critical care interhospital transfers, *even if the treating physician concludes that accessing 911 is unnecessary or clinically inappropriate*, L+Margues, in the alternative, that the Ruling does not apply to its Protocol at all. This DPH interpretation of the Ruling ignores its plain language, as well as its context because, by its terms, the Ruling applies only to long term care facilities, members of the public, and the EMS providers who serve them during medical emergencies before they arrive at a hospital. In addition, this DPH interpretation is at odds with the Ruling's emphasis on the independent judgment of clinicians, which is described above. *See supra* at pp. 1, 3-4.

The language used throughout the Declaratory Ruling—in particular the hearing officer's repeated use of the term "long term care facilities" in the factual findings and conclusions of

[3] *See* Jonathan Warren, MD, FCCM, FCCP et al., Guidelines for the inter- and intrahospital transport of critically ill patients, 32 Crit. Care Med No. 1, at pp. 256-262 (2004).

law—indicates that the Ruling applies only to nursing homes and other long term care facilities, not acute care hospitals which are fundamentally different health care institutions.[4]

The context in which the Ruling arose also supports L+M's interpretation. The Petition for the Declaratory Ruling ("Petition") was filed for the purpose of dispelling confusion among the operators of *long term care facilities* regarding when they must dial 911, as well as confusion amongst EMS providers servicing them. The Ruling specifically references three letters which the Department issued to long-term care facility administrators as guidance on the proper procedures for the emergency transfers of patients to hospitals. Declaratory Ruling, at p. 12, # 65-66; p. 13, # 68-69, and p. 70, #70-72. The Ruling explains that the second letter, issued in May 2002, had produced confusion within the long-term care industry, and that the Department therefore had issued a December 2002 statement to "**long-term care facility operators and EMS providers** . . . reiterating that when a medical emergency exists in the judgment of a clinician, the 911 system must be activated." (Emphasis added; internal quotation marks omitted.) *Id.*, at p.14, #70 and 71.

[4] Chapter 368v of the General Statutes, which regulates health care institutions, describes the differences between long term care facilities, also known as nursing homes, and acute care hospitals. The former are defined as "any nursing home or residential care home as defined in section 19a-490 or any rest home with nursing supervision which provides, in addition to personal care required in a residential care home, nursing supervision under a medical director twenty-four hours per day, or any chronic and convalescent nursing home which provides skilled nursing care under medical supervision and direction to carry out nonsurgical treatment and dietary procedures for chronic diseases, convalescent stages, acute diseases or injuries . . ." *See* Conn. Gen. Stat. § 19a-521. On the other hand, "Hospital" is defined as "an establishment for the lodging, care and treatment of persons suffering from disease or other abnormal physical or mental conditions and includes inpatient psychiatric services in general hospitals." Conn. Gen. Stat. § 19a-490(b).

Hospitals and long term care facilities are also subject to different sets of regulations. For example, hospitals are required to maintain a medical staff of not fewer than five (5) physicians. *See* Regs., Conn. State Agencies §§ 19-13-D3(c)(1) and 19-13-D5(c)(1). Hospitals also are required to maintain, at a minimum, facilities such as clinical laboratories, blood banks, radiology departments and operating rooms. *See* Regs., Conn. State Agencies §§ 19a-13-D3(f) and 19-13-D5(f). Homes for the aged and nursing homes, however, are not required to maintain a medical staff. *See* Regs., Conn. State Agencies § 19-13-D6(d).

Furthermore, other factual findings contained within the Ruling almost exclusively refer to the practices of long-term care facilities or ambulance services treating patients during medical emergencies before they reach the hospital.[5] The only factual findings that specifically refer to acute care hospitals pertain to the hospitals' role as sponsors of emergency medical service providers. *See id.*, at pp. 8-12. It is telling that the Ruling does not contain a single factual finding about procedures for transferring patients after they have entered the hospital system. If the Petition addressed inter-hospital transfers, DPH surely would have heard separate testimony about the hospitals' patient transfer protocols.

Not only does the limited scope of the factual findings demonstrate that inter-hospital transfers were well beyond the purview of the Declaratory Ruling, the legal conclusions set forth within the Ruling exclusively pertain to long-term care facilities and the EMS providers that service them, as well as members of the public, during medical emergencies. Each conclusion of law that regulates the conduct of a health care institution makes a specific reference to long-term care facilities—not acute care hospitals. As noted above, the Hearing Officer specifically defines the term "emergency" in the context of *long-term care facilities*, and goes on to apply that defined term throughout the remainder of the opinion. *See id.*, at p. 17-18. Subsection C of the Ruling, which addresses the question of whether an EMS provider may provide emergency

[5]For example, on Page 6, at Finding #14, DPH states: "Advertising was also prohibited by the Emergency Medical Services Assistance Act to prevent the public, **including long term care facilities**, from calling ambulances other than the PSAR to provide service." (Emphasis added). At Page 14, Finding #75, DPH states: "In addition to the need for emergency and non-emergency transports to and from **long term care facilities, long term care facilities** also request transports that are not pre-scheduled and do not require a full three tiered response . . . ." (Emphasis added).

Although the Ruling sometimes uses the words "facility" or "health care facility," instead of "long term care facility," when these references to "facilities" are read in context, it is clear that they are shorthand references to long term care facilities. For example, while Factual Finding #84 states that "a small percentage of requests for emergency service have been made by facilities directly to non-PSA providers . . .," the next finding is a specific example of Montowese Health and Rehabilitation Center's use of the non-PSAR provider Nelson Ambulance Service for medical emergencies. Declaratory Ruling, at p. 16, # 84 and 85.

medical services in an area in which it has not been designated as the Primary Service Area Responder ("PSAR"), provides in relevant part:

> [T]he preponderance of evidence and a reasonable construction of the statutes and regulations establishes that **long term care facilities** are required to call 911 when there is an emergency, and non-PSAR providers may *not* respond to emergency calls made directly to them.

Id, at p. 30 (Emphasis added). Finally, Subsection H prohibits "long term care facilities" from entering into contracts with providers for the provision of emergency medical services. *Id.* at 35.

DPH makes factual findings regarding the historical practices and procedures of long-term care facilities, interprets DPH's prior policy directives to long-term care facility administrators, and makes no factual findings or conclusions of law pertaining to acute care hospitals' patient transfer protocols. The context of the Declaratory Ruling, as well as the language employed therein, indicate that it does not address urgent, emergent, and critical care inter-hospital patient transfers.

D. Even if the Ruling Once Governed Urgent, Emergent, and Critical Care Inter-Hospital Transfers, it is Premised Upon an Earlier Version of the Emergency Medical Services Assistance Act

The Declaratory Ruling is premised upon DPH's interpretation of the Emergency Medical Services Assistance Act ("EMSAA"), General Statutes §§ 19a-175, et seq., as it existed on February 14, 2003. At that time, EMSAA did not contain a provision that specifically governed inter-hospital transfers. In 2009, the legislature amended EMSAA by enacting General Statutes § 19a-179c, which specifically addresses all inter-hospital transfers, and does not require hospitals to activate 911. Section 19a-179c does not distinguish between "emergency" transfers and "non-emergency" transfers of patients between hospitals. It governs all inter-hospital transfers, and, as the legislative history makes clear, it was enacted to endorse transfers *exactly* like the transfer at issue here utilizing providers outside the 911 system.

Section 19a-179c provides:

> Any ambulance used for **interfacility critical care transport** shall meet the requirements for a basic level ambulance, as prescribed in regulations adopted pursuant to section 19a-179, including requirements concerning medically necessary supplies and services, and may be supplemented by a licensed registered nurse, advanced practice registered nurse, physician assistant or respiratory care practitioner, provided such licensed professionals shall have current training and certification in pediatric or adult advanced life support, or from the Neonatal Resuscitation Program of the American Academy of Pediatrics, as appropriate, based on the patient's condition.

(Emphasis added.) The 2009 legislation also added the term "interfacility critical care transport" ("ICCT") to the definitions section of EMSAA. ICCT means "the interfacility transport of a patient between licensed **hospitals**."[6] (Emphasis added).

Under Connecticut's rules of statutory interpretation, "specific terms covering the given subject matter will prevail over general language of the same or another statute which might otherwise prove controlling." *Tomlinson* v. *Tomlinson*, 305 Conn. 529, 552 (2012). Thus, the terms of § 19a-179c, which apply specifically to all transfers between hospitals, control over the more generalized statutes that DPH interpreted in its 2003 Ruling, as well as the generalized terms of the Ruling itself.

Finally, the legislative history demonstrates that § 19a-179c was enacted to endorse hospitals' industry-wide practice of using providers, not PSARs dispatched by 911, to transport

[6] The definition of ICCT does not distinguish between "emergency" and "non-emergency" transfers. It encompasses all transports of patients between licensed hospitals. In addition, the legislature's use of the word "critical" in ICCT suggests that § 19a-179c specifically applies to "emergency" transfers between hospitals. Our Supreme Court has determined that "[i]n the construction of the statutes, words and phrases shall be construed according to the commonly approved usage of the language. . . . [Courts] ordinarily look to the dictionary definition of a word to ascertain its commonly approved usage." *Director of Health Affairs Policy Planning v. Freedom of Information Commission*, 293 Conn. 164, 184 (2009) (Citation omitted; internal quotation marks omitted.). The word "critical" is defined as "being or relating to an illness or condition involving danger of death" and "relating to or being the stage of a disease at which an abrupt change for better or worse may be expected." Merriam-Webster's Collegiate Dictionary (10th Ed. 1993). The legislature's use of the word "critical" demonstrates its intent that the statute apply to emergency transfers of patients.

critically ill patients to other hospitals. Section 19a-179c stems from House Bill No. 6599 of the 2009 legislative session, which was enacted as Public Acts of 2009, No. 09-16. During a public hearing concerning House Bill No. 6599, the Joint Standing Committee on Public Health heard testimony from Dr. Jim Parker, an emergency medical physician and the director of Connecticut Children's Hospital's ("CCH") Critical Care Transport Team. *See* Conn. Joint Standing Committee Hearings, Public Health, Pt. 6, 2009 Sess., pp. 1610–14 (Attached hereto as Exhibit D). Dr. Parker testified in favor of an amendment to House Bill No. 6599, which would allow CCH to run its Critical Care Transport Team without jeopardizing its clinicians' licenses:

> **Connecticut Children's needs to operate a critical care transport team to bring critically ill or injured children/newborns from community hospitals to our facility when they need tertiary care services that are not available at a community facility.**
>
> Current Office of Emergency Medical Services regulations require that every individual providing care to a patient in an ambulance must be licensed . . . as an EMT. This regulation prevents our team of trained pediatric critical care clinicians from providing specialized services that these newborns and children need.
>
> Connecticut Children's is not—currently not operating this service because of potential liability for our clinicians' licenses. As a result, children who need our transport services do not have access to them. . . .
>
> When enacted, [House Bill No. 6599] will allow Connecticut Children's to resume operation of its critical care transport service, providing our patients with access to **the specialized healthcare transport services they need** in a safe environment.

Id., at 1610–11 (Emphasis added). Dr. Parker identified two additional services that would benefit from House Bill No. 6599: Yale's pediatric specialty transport service and John Dempsey's neonatal specialty transport service. *Id.*, at 1612. As Dr. Parker's testimony made clear, these are specialized transport services which do not make use of the 911 system or local PSARs to accomplish transports of critically ill patients. The amendment propounded by Dr.

Parker, which allowed these hospitals to arrange for transport services for critically ill patients, was adopted. By enacting § 19a-179c, the legislature implicitly endorsed the standard industry practice of arranging direct transport services to convey critically ill patients between licensed hospitals—the exact type of transfer at issue here.

Even if the Declaratory Ruling applied to hospitals in 2003, the legislature subsequently expressed an intent to narrow its scope, so that it applies only to prehospital transfers, such as for members of the public, including long term care facilities. **The Ruling does not apply to transfers *after* the patient has entered the hospital system—those transfers are governed by § 19a-179c. If the Ruling is applied to hospitals now, after the legislature's enactment of § 19a-179c, it will conflict with the purpose and intent of the 2009 legislation.**

E. Application of the Ruling to All Urgent, Emergent, and Critical Care Inter-Hospital Transfers Creates a Direct Conflict with Federal Law

Finally, if physicians are required to activate 911 for all urgent, emergent, and critical care inter-hospital transfers, the Ruling will directly conflict with the Federal Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd. This conflict with federal law can—and must—be avoided if the Declaratory Ruling is applied correctly, so that it does not mandate the activation of 911 for all urgent, emergent, and critical care inter-hospital transfers. EMTALA closely regulates the transfer of emergency department patients between acute care hospitals. It states:

> An appropriate transfer to a medical facility is a transfer-- . . . (D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . . 42 U.S.C. § 1395dd(c)(2).

Hospitals and physicians who fail to comply with EMTALA are subject to fines and, in some instances, exclusion from federal and state health care programs. 42 U.S.C. § 1395dd(d). EMTALA also has a preemption provision, which states: "The provisions of this section do not preempt any State or local law requirement, **except to the extent that the requirement directly conflicts with a requirement of this section**." 42 U.S.C. § 1395dd(f)(Emphasis added).

"When state law conflicts with federal law, courts are bound to follow federal law." *Pac. Capital Bank, N.A. v. Connecticut*, 542 F.3d 341, 348 (2d Cir. 2008) (Internal quotation marks omitted). State and federal law directly conflict where it is impossible for a party to comply with both state and federal requirements. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011). Direct conflict preemption does not require impossibility to arise in each and every instance, it requires only that "compliance with both federal and state regulations may in some circumstances be impossible . . ." *County of Suffolk v. Long Island Lighting Co.*, 728 F.2d 52, 57 (2d Cir. 1984). A direct conflict will also arise where state law "may impede the execution of the full purposes and objectives of Congress." *Id.* "State law is in 'irreconcilable conflict' with federal law, and hence preempted by federal law, when compliance with the state statute would frustrate the purposes of the federal scheme." *Pac. Capital Bank, N.A.*, 542 F.3d, at 351.

If the Declaratory Ruling is read to require 911 to be activated for all emergent, urgent, and critical care inter-hospital transfers, which necessarily include transfers of Emergency Department ("ED") patients between hospitals, hospitals and physicians will be unable to comply with EMTALA in many instances. Under EMTALA, a hospital and treating physician must ensure that transfers of ED patients are "effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . ." 42 U.S.C. § 1395dd(c)(2)(D). Hospitals must, for

example, ensure that the transport team is properly staffed. *See Lopes v. Kapiolani Medical Center for Women & Children*, 410 F. Supp.2d 939 (D. Hawaii 2005) (transport team for a neonatal patient may not have been adequately staffed under EMTALA where it consisted of transport RNs but not a respiratory therapist). The hospitals and treating physicians must also be able to carefully select the "transportation equipment." 42 U.S.C. § 1395dd(c)(2)(D). If L+M dials 911 and activates the local PSAR—not the pre-screened better-equipped vehicles with specially trained providers —for all ED ground transfers, L+M will be unable to ensure that all ED patients are transferred by "qualified personnel and transportation equipment." If L+M contacts an ambulance directly to set up the transfer to ensure compliance with the above, it will violate the Department's broad interpretation of the Declaratory Ruling. Thus, it will be impossible to comply with both state and federal law.

This conflict can—and must—be avoided by reading the Ruling appropriately. "[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter." *Jones v. United States*, 529 U.S. 848, 857 (2000) (Internal quotation marks omitted). A recent Second Circuit case applied this principle when it considered a Connecticut statute that caps the interest rate banks may charge for tax refund anticipation loans (RALs). *Pac. Capital Bank, N.A.*, 542 F.3d, at 347. The Connecticut Attorney General had issued a formal opinion, which stated that the Connecticut law applied to the "facilitators" who sell tax refund loans made by national banks. *Id.*, at 346. The plaintiff, a California-based national bank, filed a federal declaratory judgment action, claiming that the Connecticut statute conflicted with the Federal National Bank Act, which allows a bank to charge the maximum interest rates permitted by its home state. *Id.* at 347. The Second Circuit held that the interest rate provisions

of the Connecticut statute are preempted by the National Bank Act if they are applied to facilitators who make RAL loans offered by national banks. *Id.* at 353. If, however, the statute is construed so that it excludes facilitators making loans on behalf of national banks, it may stand. *See id.*, at 354. The Second Circuit affirmed the latter interpretation of the statute, which avoided constitutional problems and was not contrary to the intent of the legislature. *Id.* In short, the Second Circuit invalidated the Attorney General's formal interpretation of the RAL statute in order to adopt an interpretation that was not preempted by federal law.

In the present case, EMSAA and the Declaratory Ruling are most appropriately interpreted in a manner that does not conflict with EMTALA. If the Ruling is interpreted so that it applies only to prehopsital transfers, such as transfers of long term care facility residents and members of the public to acute care hospitals, the conflict can be avoided. Pursuant to *Jones* and *Pac. Capital Bank, N.A.*, this interpretation must be adopted. To do otherwise creates a direct conflict with Federal law, and subjects both EMSAA and the Declaratory Ruling to constitutional challenge.

IV. Responses to OHCA's List of Issues

Question:

1. **Page 360 of Exhibit A provides Lawrence & Memorial Hospital's guidelines for emergent transportation for a PCI patient from the Cardiac Catheterization lab. The guidelines do not include contacting 911 for such emergent transportation. Lawrence & Memorial Hospital has taken the position that acute care hospitals are not subject to the Department of Public Health's Declaratory Ruling, dated February 14, 2003, which requires that 911 be contacted for all emergency patient transfers (the "Declaratory Ruling"). In support of its position, Lawrence & Memorial Hospital claims that it would not be able to comply with Connecticut General Statutes § 19a-179c if it was required to call 911 for emergency transports. During the initial contact with the 911 dispatcher, could the hospital request an**

immediate response by a basic level ambulance with the exclusion of fire and police response?

Answer:

Although Lawrence & Memorial Hospital can *request* that the 911 dispatcher only send a basic level ambulance without fire and police response, it cannot *require* that the 911 dispatcher send only a basic level ambulance. The Declaratory Ruling explicitly recognizes that "there are different standards for the daily operation of [Coordinated Medical Emergency Direction Centers] and [Public Safety Answering Points ("PSAPs")]/dispatchers, including different protocols [and] different operational procedures . . . ." Declaratory Ruling, at p. 6, # 20. As NLFD Deputy Chief Henry Kydd explains in his letter (attached to Ron Keresy's Pre-filed Testimony) , the City of New London's protocols and policies mandate that the New London Fire Department send a fire truck to the scene whenever the 911 system is activated for life threatening problems. Unlike long term care facilities, many of which do not have physicians on staff, and members of the public, hospitals do not require the assistance of first responders, such as fire fighters, to render basic first aid, assess the patient's condition, and stabilize the patient. Sending a fire truck to L+M hospital for each urgent, emergent and critical care transport will be an unnecessary waste of resources, and it will divert public safety resources away from members of the community who truly need them.

Question:

2. **Assuming the response to No. 1 is in the affirmative, are there situations in which the 911 dispatcher would send something less than a basic level ambulance?**

Answer:

Most likely not since, upon information and belief, all PSARs must operate "basic level ambulances." However, as L+M explained in detail, the question ignores three central concerns that L+M has expressed during these proceedings. First, dispatching BL ambulances for every urgent, emergent, and critical care inter-hospital transport will waste valuable community resources. The 911 dispatcher will send a basic level ambulance staffed by EMTs, as well as other local resources such as a fire and police personnel. When members of the public or long term care facilities dial 911, these first responders play an important role. They assess the patient's condition, determine whether more advanced EMS providers need to be dispatched, such as Lifestar or L+M's paramedic intercept team, and render basic first aid. At L+M, the patient has already been assessed and stabilized by the treating physician, who is in the best position to determine the clinically appropriate mode of transportation. Deploying local EMS resources to L+M for all urgent, emergent, and critical care patient transfers will unnecessarily waste community resources, at great cost to the City of New London.

Second, a BL ambulance staffed only with EMTs is not clinically appropriate for medically complex inter-hospital transfer patients. As Dr. Cambi explains in his pre-filed testimony, elective angioplasty patients who develop a complication and must be transferred to Yale require the assistance of personnel with years of experience in transferring patients with

complex intravenous medications and mechanical life support systems. If the Department requires a BL ambulance to perform these transfers, it will need to be supplemented with L+M staff, such as paramedics, nursing, and/or respiratory therapists to ensure the safe transfer of patients. The providers in L+M's protocol arrive pre-equipped with the medically appropriate staff and equipment for these transferees.

Third, accessing the 911 system for inter-hospital transfers of urgent, emergent, and critical care patients unnecessarily adds delay and complexity to the patient transfer process. Even if L+M can ultimately secure the services of the Lifestar helicopter by calling the 911 dispatcher, the call to 911 adds additional unnecessary links in the chain of communication. As Ron Kersey explains in his pre-filed testimony, the following chain of events, which are diagramed in greater detail in Exhibit C, will unfold. Rather than making a single phone call, the treating physician and hospital staff are required to call 911, the dispatcher is required to contact the PSAR, and the PSAR is required to activate Lifestar and travel to the hospital, even though the hospital has no need for the services of the NLFD EMTs or the BL ambulance. These additional links in the chain of communications only add cost to the community, increase response time, as well as the potential for miscommunications and mistakes. Furthermore, this procedure does not benefit public safety and has the potential to gravely impact patient care.

Question:

3. **In what way would the hospital be unable to comply with 42 U.S.C. § 1395dd(c)(2) if it were to call 911 for an emergency transfer?**

Answer:

Under the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, a hospital may not transfer an individual who arrives at its emergency department to another hospital unless the transfer is "appropriate." 42 U.S.C. § 1395dd(c)(2). Pursuant to 42 U.S.C. § 1395dd(c)(2)(D), a transfer is "appropriate" only where it "is effected through qualified personnel and transportation equipment . . . including the use of necessary and medically appropriate life support measures during the transfer . . . ." Failure to ensure that a transfer is "appropriate" within the meaning of EMTALA, may subject the hospital and the treating physician to civil penalties, and repeated violations could result in exclusion from state and federal healthcare programs. *See* 42 U.S.C. § 1395dd(d).

Under DPH's broad interpretation of the Declaratory Ruling, L+M will be required to dial 911 in order to transfer urgent, emergent and critical care patients to other hospitals from its emergency department. Although it is a sponsor hospital, L+M does not have the authority to dictate the manner in which a 911 dispatcher responds. In particular, if L+M dials 911 and asks for a mobile intensive care ("MIC") unit to provide ground transportation, L+M will receive a BL ambulance which it must supplement with L+M paramedics and other staff, not a provider that is already equipped with clinically appropriate equipment and personnel. If the local EMS provider is unavailable, L+M will receive a MIC PSAR from another community, selected by the 911 dispatcher in accordance with local EMS policies and protocols. L+M will not even know in advance which provider will arrive, let alone be able to ensure that the provider's personnel and

equipment are "appropriate" under EMTALA. If L+M must call 911 for all urgent, emergent, and critical care inter-hospital transfers, including transfers from its ED department, it will be unable to perform its duty under EMTALA to ensure that the ED transfers are "appropriate."

Question:

4. **Page 360 of Exhibit A states that the New London Fire Department Ambulance will be used if other transportation is unavailable and transportation must occur immediately. Is a distinction being made between "immediately" and "emergency"?**

Answer:

The words "emergent" and "immediately" in the L+M Guideline for Emergent Transportation of Elective PCI Patient Protocol do not have the same meaning as the term "emergency" as it is defined in the Declaratory Ruling. "Emergent" and "immediate" mean within the industry standard of ninety (90) to one hundred twenty (120) minutes from the initial decision to transport elective angioplasty patients to initiating surgery at the receiving surgical center. These patients are stabilized at L+M and ready to be transported to Yale.

Question:

5. **Page 32 of the Declaratory Ruling concludes that, in an emergency situation, a provider is required to forward an emergency call to the 911 system if it has been contacted outside of the 911 system. Given this conclusion, explain in what way(s) contacting the provider directly, as instructed in Lawrence & Memorial Hospital's guidelines, results in a decreased response time by the provider given the provider must forward the call to the 911 system.**

Answer:

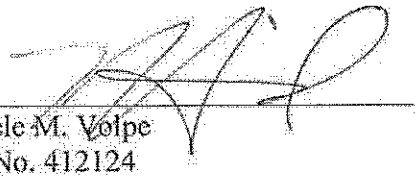
The Declaratory Ruling concludes that providers who receive emergency ***prehospital*** calls from members of the general public, including long term care facilities, must transfer them into the 911 system. It does not require first responder providers to contact 911 when they receive calls from hospitals to arrange interhospital transfers of stable patients. These calls are to move patients *within* hospitals, and are not "emergencies," as that word is defined in the Declaratory Ruling.

Upon information and belief, providers of inter-hospital transportation do not forward requests for inter-hospital transfers to the 911 system because they are not "emergency" calls for the transportation of patients *into* the hospital system, which is the purpose of the 911 system. As Gregory B. Allard, Vice President of American Ambulance, Inc. explains in his letter, which is attached to the Pre-filed Testimony of Dr. Cambi, it is common practice within the medical transport industry for providers to dispatch ambulances directly to hospitals. In fact, the Lifestar helicopter is licensed by OCHA to directly respond to patient transfer calls from hospitals.

V. Conclusion

The Department of Public Health's requirement that hospitals dial 911 will set policy which will ultimately create inferior standards in the community than that which exist today. It will have grave ramifications for local fire and police departments and hospitals. It will collapse the 911 system, create hardships for resources in cities and towns, and usurp the medical judgment of sponsor hospitals and staff. Finally and most importantly, it will have an adverse impact on patient care.

Respectfully Submitted,



By:_____

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Exhibit A

LAWRENCE+MEMORIAL HOSPITAL

Title: Patient transfer to higher level of care guidelines	Reference Number:
File Location: Departmental	Issuing Department: Cath lab
Latest Review/Revision Date: 5-12	Original Date: 5-12
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date: Medical Director, Angioplasty 5/31/12 Date Director, Patient care Services 5/31/12 Date	

PURPOSE: To provide guidelines for when the need arises for emergent transportation for a PCI patient from the Cardiac Catheterization lab.

POLICY

PROCEDURE:

The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program at Lawrence + Memorial Hospital (L+M) as described below:

1. A CT Surgeon is on-call 24/7 to arrange for patient transfers through the Y-Access system and to receive the patient at YNHH.
2. All YNHH on-call CT Surgeons are privileged to provide CABG or other procedures expected as a result of complications associated with performing elective PCI at Lawrence & Memorial Hospital.
3. YNHH maintains one operating room open every day for emergency transfers that is CT Surgery capable. The on-call CT Surgeon remains in-house during the hours of 7:30am through 4:00pm, Monday through Friday to accommodate the Lawrence & Memorial elective PCI schedule.
4. The receiving surgeon and team obtain consent for surgery from patient or surrogate.
5. The Yale-New Haven Heart & Vascular Center agrees that L+ M may represent to patients that YNHVC provides surgical backup to elective PCI in its patient consent process.
6. YNHVC and L+M maintain computer systems interface or direct access to L+M systems for the YNHVC receiving surgeon to review real-time images and hemodynamic data, as well as audio and video images for consulting on treatment options and transfer decisions.

7. L+M Hospital employ the Yale-New Haven Hospital Y-Access transfer system to expedite the process of surgical consultation and transfer.
8. All other provisions of the Transfer Agreement will remain in effect for heart and vascular patients
9. When choosing the appropriate form of transportation, the patient's stability and equipment needs is assessed and relayed to the proposed transportation team. Patients requiring a Balloon Pump during transport require air medical transport or a nurse to accompany the patient if ground transport does not have the appropriate staff to monitor the pump.
10. In the event air medical transport is preferred but unavailable due to weather, staff should inquire if the team is available to provide the trip by ground.

Below is the transport option in order of use:

1. Lifestar (Air Medical) transportation – Crew configuration will consist of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
2. Lifestar (Ground) transportation – Crew configuration will consist of an American Ambulance EMT and a second American Technician which may be an EMT or Paramedic and the Lifestar Crew consisting of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
3. American Ambulance (Ground) transportation - Crew configuration will consist of an American Ambulance EMT and a Paramedic.

The following option must only be used if other transportation is unavailable and transportation must occur immediately.

4. New London Fire Department Ambulance (Ground) transportation - Crew configuration will consist of 2 Firefighter/EMT's and a Lawrence & Memorial Hospital Paramedic.

Contact Information

Lifestar – (800)437-4378
American Ambulance – (860)886-1463
New London Fire Department – (860)442-4444/911

PROTOCOL

Reference:
1. Hospital L+M Policy Patient transfer to Higher level of care facility.
2. YNHH transfer agreement

Archive Dates
Reviewed Date:
Revised: 5/12
Supersedes:

Exhibit B

Policy: Emergency Transfer Protocol to Cardiac Surgery Center

LAWRENCE & MEMORIAL HOSPITAL

Effective Date: 10/04
Reviewed:
Revised:
Supersedes: New

Section: Pt Care Services/Rights
Subsection: Medical Services/Invasive Procedures
Resource:Cath lab

Purpose: To ensure a safe and expedient transfer in the event that any patient is in need of emergent transfer to a tertiary center for immediate Cardiac Surgery or other interventional procedures.

If Cardiologist determines the need for an immediate transfer:

1. Physician will make arrangements with physician receiving the patient and assuming responsibility at the new hospital. Discusses clinical information with receiving physicians/surgeon. Digital images are transmitted as appropriate
2. Physician will have obtained consent of patient and/or family for transfer.
3. Patient shall not be transferred until the receiving hospital has consented to accept the patient.
4. Reason for transfer should be documented in chart.
5. Members of the Cath lab staff as appropriate initiates the following calls:
    a. To Receiving unit at receiving hospital center to give telephone report
    b. To Admissions /registration staff at receiving center to get a bed assignment
    c. Contact appropriate EMS system to activate immediate transport (preferable by air). Give them the receiving facility name/unit and physician for the patient and brief report.
    d. For ground transport, contact appropriate pre arranged critical care transport ambulance on standby during primary angioplasty procedures.
    e. For helicopter transport, contact LIFE Star center at 1 800 437-4378 and L&M security.
6. Sheathes and balloon pumps are sewn into place.
7. Level of care is determined and appropriate plans are made with transport team to ensure patients clinical safety.
8. Patient is prepared for transport and transferred to transport vehicle/helicopter.
9. All care documentation is copied including copy of cath images (per Cath Lab Policy: Transportation Internal-External) and is sent with patient including transfer orders and Inter-facility patient transfer form.
10. Interventional cardiologist may accompany unstable patient, or stays in contact with transferring team until patient is received at cardiac surgical center. Nurse may accompany patient with IABP (See related IABP policy). Transport is via Critical care transport ambulance with paramedic service or Helicopter service.

References: Sinclair, McNamara and Wharton, Critical Pathways in Cardiology: Vol 1, No 2, Lippincott Williams & Wilkins, 2002.

Approved By: _____ Date: 10-25-04
Mark Fiengo, DO
Director, Angioplasty service

Approved By: _____ Date: 10/26/04
Brian Ehrlich, MD
Medical Director, Cath lab

Approved By: F Bonardi RN Date: 10/25/04
Francis Bonardi, RN
Vice President, Patient Care Services

Exhibit C

12/10/12 L+M Transfer Process
L+M Transfer Protocol with DPH 911 Policy
Cardiologists determines need for critical care transfer
1. Patient is stabilized and prepared for transport
2. Cardiologist contacts admitting physician at receiving hospital to arrange transfer
Cath lab staff calls 911 dispatcher to request transport
Patient disposition communicated directly to 911 dispatch
911 dispatches NLFD (New London PSAP)
1 of 2 NLFD BLS transport units and fire engine dispatched to L+M
NLFD BLS transport arrives at L+M along with fire engine
Cardiologist identifies most appropriate mode of transport (air transport) and communicates such to NLFD BLS response
911 dispatcher contacts air medical transport or ground transport.
Is air medical transport available?
Yes
No
Cath lab staff call air medical transport to give key information re transport needs
Air medical transport arrives and transferred from cath lab to transport provider
Air medical transport transports patient to receiving hospital
NLFD BLS returns to base (Fire engine)
Transfer process stops
NLFD ambulance transports patient to receiving hospital. EMS sources from neighboring towns to provide coverage
L+M Paramedic, L+M nurse and other L+M resources accompanied patient during transport
Leaves L+M + Pare area without critical care coverage for at least 2 hours
NLFD ambulance transport patient to receiving hospital
NLFD BLS returns to base (Fire engine)
Transfer process stops
L+M Industry standard Transfer Protocol
Cardiologists determines need for critical care transfer
1. Patient is stabilized and prepared for transport
2. Cardiologist contacts admitting physician at receiving hospital to arrange transfer
Cardiologist identifies most appropriate mode of transport (air or ground) and communicates such to cath lab staff
Cath lab staff contacts air medical transport or commercial ground ambulance to initiate patient transport.
Patient disposition + Medical history communicated directly to preferred transport provider
Air medical transport or commercial ground ambulance arrives at L+M.
Patient transferred from cath lab to transport provider
Air medical transport or commercial ground ambulance transports patient to receiving hospital
Transfer process stops

Exhibit D

JIM PARKER: Thank you. Senator Harris, members of the Public Health Committee, thank you for the opportunity to testify regarding House Bill 6599, An Act Concerning Public Safety.

My name's Jim Parker, I'm an emergency medical physician at Connecticut Children's Medical Center. I serve as the chair for Connecticut EMS for Children, and I'm also the medical director of the Connecticut Children's Critical Care Transport Team.

Connecticut Children's needs to operate a critical care transport team to bring critically ill or injured children/newborns from community hospitals to our facility when they need tertiary care services that are not available at a community facility.

Current Office of Emergency Medical Services regulations require that every individual providing care to a patient in an ambulance must be licensed actually as an EMT. This regulation prevents our team of trained pediatric critical care clinicians from providing the specialized services that these newborns and children need.

Connecticut Children's is not -- currently not operating this service because of potential liability for our clinicians' licenses. As a result, children who need our transport services do not have access to them.

I'm asking today that you amend House Bill 6599 to include a section that defines neonatal and pediatric specialty care transport, the verbiage of which is worked out on reverse of the sheet you've been provided.

The language should promote patient safety by requiring the use of a basic level ambulance

with a licensed EMT on board. The language should also recognize that critically ill neonates and children need ongoing care that must be furnished by certified or licensed health professionals who specialize in neonatology or pediatrics.

Current standards established by the American Heart Association and the American Academy of Pediatrics define the qualifications for members of the neonatal and pediatric transport team. It is important that this amendment be written so that it will be effective upon passage, since Connecticut Children's is not currently offering critical care transport services pending the statutory change.

When enacted, this amendment will allow Connecticut Children's to resume operation of its critical care transport service, providing our patients with access to the specialized healthcare transport services they need in a safe environment.

I urge you to support amending House Bill 6599 to include a definition of neonatal and pediatric specialty care transports. Thank you for your time and your attention to this matter.

SENATOR HARRIS: Thank you, Doctor. Any questions?

Now, this is a piece, just for clarification, that we had in another bill, right, and your request is that we put it in this particular bill?

JIM PARKER: This is a piece that, to my knowledge, was being proposed in another bill but felt that it -- it was felt that it's best to go

through the Department of Public Health than through us, within this.

SENATOR HARRIS: And is the reason for that because time is of the essence to get a bill passed so you can resume your services?

JIM PARKER: Absolutely. I speak specifically to Connecticut Children's, but there are three services that are impacted by this in the state. Yale runs a pediatric specialty transport service, and John Dempsey runs a neonatal specialty transport service.

Technically, any transports currently occurring with those services are operating outside their scope of practice and putting though clinicians at risk.

SENATOR HARRIS: Because there is no EMT aboard during those transports?

JIM PARKER: It's not having the EMT aboard. It's actually every person providing care must carry prehospital credentials.

SENATOR HARRIS: So everybody, and that's the problem.

Okay. and -- I thought I had another question, but.

Have you tried to work with the Department of Public Health to be able to accomplish this goal without the need for legislation, the need for expedited legislation?

JIM PARKER: We've had meetings with the Department of Public Health and Office of EMS over the last six to eight months, with an ongoing discussion of this issue, and the feeling both through them and in discussion with the

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assistant AG was that this could not be something that was going to be fixed without changing the statute.

SENATOR HARRIS: Thank you very much. Any -- Representative Esty.

REP. ESTY: Thank you. And thank you, Dr. Parker. What -- do you know what the origin, then, was of the Office of Emergency Medical Services' decision to put this in place? Presumably, this is -- this was language that was put in there.

What was the rationale and were you consulted at that time? Were any of the neonates were consulted in did they talk to the Academy of Pediatrics, or how did they -- how did this get through, causing what would clearly not seem to make any sense from a layperson's point of view, even less from a clinician's point of view?

JIM PARKER: From my understanding, this is a statute that's long been on the books, and probably preceded the American Academy of Pediatrics' development of recommendations with regard to pediatric specialty transport.

It is a regulation that more -- is aimed toward the level of care necessary for operating an ambulance, and as these niches have grown and as these subspecialties have developed, the regulation has not been acknowledged or not been amended to change with those developments.

REP. ESTY: So this is artifact of the field having developed and these regs have not been updated, and I presume lawyers took a look at them and said you can't --

JIM PARKER: That's -- that's my understanding.

REP. ESTY: It's always back to the lawyers who look at it.

JIM PARKER: Our lawyers took a look at it, but it was to the point that we asked the Department of Public Health to take it to the Assistant Attorney General who did provide us an interpretation that, yes, Department of Public Health was interpreting that regulation correctly.

REP. ESTY: So you would be outside of the scope of the practice and therefore be put in --

JIM PARKER: And therefore each person putting their license at risk.

REP. ESTY: All right. Thank you very much.

SENATOR HARRIS: Thank you, Doctor.

Next we have Gary O'Connor -- excuse me, Greg Allard. Gary O'Connor, I'm sorry, followed by Greg Allard.

GARY O'CONNOR: Thank you, Mr. Chairman.

Good morning. Actually, it's afternoon now. Time flies. My name is Gary O'Connor. I'm a partner with the law firm of Pepe & Hazard, and I'm here on behalf of the Association of Commercial Ambulance Providers. We call it ACAP. And I'd like to thank you for the opportunity to speak in support of Raised Bill 6599.

This bill in its present form addresses a very important patient safety issue in the State of Connecticut, namely, the transportation of patients who are confined to stretchers.

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

PRE-FILED TESTIMONY
OF LAWRENCE & MEMORIAL HOSPITAL
BY BRIAN CAMBI, MD, FACC, FSCAI

Good Morning Hearing Officer Hansted and members of the Department of Public Health. My name is Brian Cambi, MD, FACC, FSCAI, and I am the Medical Director of the Primary Angioplasty Program at Lawrence + Memorial Hospital ("L+M").[1] I thank you for this opportunity to appear before you today. As stated in our brief, L+M's protocol for inter-hospital transfers of elective angioplasty patients who develop a procedurally related complication that requires surgical intervention (the "Protocol") is a clinically appropriate transfer protocol that is typical in the industry, in that it preserves the treating physician's discretion to select the most medically appropriate means of transportation for the patient, based on the recommendations of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

A. L+M's Transfer Policy Comports with the Medical Community's Recommendations for Elective Angioplasty Programs.

In the early years, patients undergoing elective angioplasty developed procedural complications that required coronary artery bypass grafting (often on the same day) at rates quoted anywhere from 6-10%. Over the years, advances in technology and adjunctive medical therapy in combination with operator experience has led to a dramatic reduction in

[1] A copy of my Curriculum Vitae is attached hereto as Exhibit 1.

complications. Fortunately, the rate of procedural complications rendering a patient critically ill necessitating the need for same day surgery is rare with numbers in the literature described as low as 0.3%. With these changes and the release of recent studies in the medical literature, it is clear that we can now provide elective angioplasty services to carefully-selected low risk patients in a safe way that enhances the delivery of medical services to our local community. The rationale behind our desire for L+M to have such a program is outlined extensively in our application.

An important part of such a program is developing a sound policy for the transfer of an elective angioplasty patient in the rare event he or she develops a procedurally related complication that requires surgical intervention. The American College of Cardiology (ACC), as well as the American Heart Association (AHA) and the Society for Cardiovascular Angiography and Interventions (SCAI), has recommended in their consensus statement[2] that elective angioplasty programs without on-site surgical backup be able to acquire transportation services for critically ill patients within 20 minutes. Furthermore, the consensus statement states that these transportation services should be equipped with appropriately trained medical personnel and equipment such as intra-aortic balloon pump capability and mechanical ventilator support. L+M's transfer policy satisfies these requirements by selecting Lifestar and American ambulance as the preferred providers in the rare event that an elective angioplasty patient is transferred to Yale.

[2] A copy of the consensus statement can be found in L+M's CON application, at p. 35 (Table H).

B. Lifestar and American are the Preferred Providers Because Their Vehicles and Transport Teams are Pre-equipped to Handle Patients with Complex Medical Needs.

When patients develop a procedurally related complication and become critically ill in the L+M catheterization laboratory, they receive multiple interventions to stabilize their acute de-compensation such as mechanical ventilator support, intra-aortic balloon pump implantation, and a variety of inotropic and vasopressor medications designed to enhance and maintain cardiovascular function. Typically, this results in a stabilized, but critically ill patient that requires urgent transfer to a tertiary level facility to receive advanced level medical care not provided at our community hospital. These are not pre-hospital patients with an emergency that requires conventional 911 services to bring them to the nearest medical facility. Rather, these are patients who have a stabilized medical condition but remain critically ill and require sophisticated transport to a tertiary facility for advanced care. Relying on highly trained, experienced medical personnel who have the appropriate equipment and manpower to handle these transfers is the most prudent course of action to ensure the best outcome of our critically ill patients. I believe, as the attending interventional cardiologist and sponsoring institution, it is well within our scope of practice to make the most appropriate medical decision to ensure the highest quality, safest, and most expeditious mechanism of transport of these patients to our collaborating tertiary facility. To take that decision away from the attending interventional cardiologist and leave it in the hands of a 911 dispatcher jeopardizes patient safety.

It is my opinion that Lifestar Air Transport or American Ambulance both have the capability to provide not only qualified paramedics but personnel with years of experience in transferring these unique critically ill patients with complex intravenous medications as well as

their mechanical life support systems.[3] Local basic level EMS services are ill-equipped to deal with the challenges of these patients. If the New London Fire Department, which maintains a basic level ambulance, were to transfer our critically ill patients, a safe transfer may be possible, but it will most definitely be much more difficult to arrange. L+M would need to provide multiple staff like paramedics, nursing, and/or respiratory therapists to ensure the safe transport of patients. Although we support this process as a last resort in our transfer policy, following this procedure for all inter-facility transfers will strip our community and L+M of critical clinical resources for an extended period of time which is not ideal.

The most efficient mechanism for these transports is to request Lifestar Air Transport or ground transport through Lifestar or American Ambulance via direct contact with these providers. Direct contact expedites the relay of critical patient-related information to the provider responsible for the transport. A call to 911 that initiates a response by the PSAR to travel to the hospital prior to activating Lifestar or American Ambulance results in unnecessary waiting and delay, potential for miscommunication due to multiple patient information hand-offs, and can ultimately harm patient safety.

We maintain that L+M's transfer protocol complies with the 2003 Declaratory Ruling, in that it preserves the clinician's clinical judgment regarding when 911 should be activated. If the Department of Public Health disagrees and maintains that 911 must be activated each time an elective angioplasty patient is transferred to Yale, I respectfully submit that the ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving long term care facilities and members of the public, and the EMS providers who

[3] American Ambulance, Inc. Vice President Gregory B. Allard describes the sophisticated equipment maintained by his company, as well as the higher level of training provided to its personnel. *See* Letter by Gregory B. Allard (attached hereto as Exhibit 2).

respond to their calls. If L+M is robbed of its discretion to determine whether 911 is activated and/or the most appropriate mode of transportation for patients traveling from one hospital to another hospital , I strongly feel a quality and safety issue will emerge putting our patients at risk, not just in the elective angioplasty program, but in the emergency department and all other hospital specialties. There is no question local EMS is an important part of the emergency services system in our region. As Ron Kersey explains in his statement, keeping local EMS local is as important as getting our critically ill patients safely to a tertiary care facility for the advanced medical care they require.

I respectfully submit that L&M's Transfer Protocol meets all of the quality and clinically appropriate industry standards. We urge the Department of Public Health, Division of Office of Health Care Access to approve our CON application.

[SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The undersigned witness hereby submits all of the above testimony as his own testimony, and will adopt it at the hearing.

12-6-12

Brian Cambi, M.D., FACC, FSCAI

Exhibit 1

Brian Christopher Cambi, MD FACC FSCAI

2 Rocco Drive
East Lyme, CT 06333
860-691-0619 (Home)
203-623-3988 (Cell)
203-370-2177 (Beeper)
brian.cambi@yale.edu

EMPLOYMENT

2008 - **Assistant Professor**
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

- ***Director*** – Primary Angioplasty Program at Lawrence and Memorial Hospital
- ***Director*** – Stress Echocardiography at Lawrence and Memorial Hospital

2007-2008 **Attending Cardiologist**
West Haven Veteran's Administration Hospital

2007-2008 **Clinical Instructor**
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

PROFESSIONAL TRAINING

2006-2007 **Advanced Fellowship in Interventional Cardiology.**
Yale University School of Medicine, New Haven, CT

2005-2006 **Advanced Fellowship in Non-invasive Cardiac Imaging.**
Yale University School of Medicine, New Haven, CT

- Level II training in echocardiography
- Level II training in nuclear cardiology

2003-2005 **Clinical Cardiology Fellowship.** Yale University School of Medicine.

2002-2003 **Chief Resident, Internal Medicine.** Yale University School of Medicine.

1999-2002 **Intern and Resident, Internal Medicine.** Yale University School of Medicine.

EDUCATION

1995-1999 Doctor of Medicine, State University of New York at Buffalo, School of Medicine and Biomedical Sciences, Buffalo, NY.
- ***Summa Cum Laude***

1991-1995 Bachelor of Science, Biology. The College of William and Mary, Williamsburg, VA.
- ***Magna Cum Laude***

LICENSURE AND CERTIFICATION

2007 Board certified - Interventional Cardiology
2006 Board certified - Cardiology
2006 Board certified - Nuclear Cardiology
2006 Board certified - Echocardiography
2002 Board certified - Diplomate, American Board of Internal Medicine.

ACADEMIC ACTIVITIES

2006 Speaker, Grand Rounds, Cardiology. Yale University School of Medicine.
- "CT Angiography: A Novel Clinical Application"

2005-2006 Research: CT Angiography in the Non-Invasive Detection of Revascularizable Cardiomyopathy.

2002-2003 Director, Morbidity and Mortality conference. Yale University School of Medicine, Section of Internal Medicine.

HONORS AND AWARDS

1999 **The John Watson Award in Medicine.** SUNY at Buffalo School of Medicine.
- Outstanding achievement and leadership in Internal Medicine

1999 **Association of Pathology Chairs Award.** SUNY at Buffalo School of Medicine.
- Academic excellence in Pathology

1998 **Alpha Omega Alpha Honor Medical Society.** SUNY at Buffalo School of Medicine.

1997 **James Gibson Anatomical Honor Society.** SUNY at Buffalo School of Medicine.
- Academic excellence in Gross Anatomy

1995 **Phi Sigma National Honor Society.** The College of William and Mary.
- Academic excellence in biology

REFERENCES – *available on request*

Exhibit 2

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

December 7, 2012

Hearing Officer Kevin Hansted
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Dear Mr. Hansted,

The intent of this letter is to provide details about our ambulances, in particular the Advanced Life Support (ALS) equipment used by our Paramedics, and the training our Paramedics receive, as well as to point out that American Ambulance Service, Inc. (AASI) is not a PSAR for the Lawrence + Memorial service area.

AASI is supportive of Lawrence + Memorial obtaining approval to perform non-emergent angioplasty even though this approval will have a negative financial impact on our business. By providing an elective angioplasty service to residents of Eastern Connecticut this approval will reduce the number of ALS transports that we currently do out of Lawrence + Memorial. We support this initiative because having non-emergent angioplasty available in Eastern Connecticut is in the best interest of the people residing in and passing through Eastern Connecticut.

AASI currently has an ambulance fleet of 24 and they all exceed the basic minimum vehicle standards set forth in the CT EMS Statutes. Our basic ambulances are built to our specifications and are built on a chassis of our choice. Within those specifications are several safety minded items that exceed the basic requirements. We also have Epi-Pens, AED's, and baby aspirin which are not standard equipment.

We currently have 11 sets of ALS gear. So 11 of those 24 ambulances could be operating at the ALS level on any given day at any given time depending on Paramedics being scheduled, without any impact whatsoever on the communities we serve as a first responder PSAR.

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

Our ALS gear includes a ZOLL CCT M-series Cardiac Monitor, an ALS equipment bag, ALS equipment restock bag, portable ventilators, and a small IGLOO cooler. Our Cardiac Monitors have the following functions; biphasic defibrillator, external pacing, non-invasive vital sign monitoring including, SpO2, EtCO2, NIBP, and fully interpretive 12-lead ECG. The ALS equipment bag has several items in it. The first is our ALS medications that can be given, orally, intramuscularly, intravenously. Some of the medications we carry are controlled substances that are used for sedation and pain management. Another thing we have is our intravenous supplies such as needles, tubing, fluids, and blood glucose monitor. Another route of infusion is intraosseous and we carry a specific device called and EZ-IO drill. It is a cordless drill used to bore a hole in a patient's bone. We also carry advanced airway equipment such as LMAs, CPAP devices, endotracheal tubes and laryngoscopes. Our portable ventilator is used during transports when a patient is sedated to a point where they can't control their own airway. The IGLOO cooler contains intravenous fluids that are temperature controlled and are used to induce a hypothermic state.

The paramedics are trained to use a lot of this equipment in school but upon being hired they need site specific training based on the equipment used. Our paramedics need to learn things such as our portable ventilator, our cardiac monitors, BGL monitors, CPAP device. Our sponsor hospital requires all paramedics have ACLS, PALS, PHTLS, and CPR training which is not required at some other sponsor hospitals. They also undergo continuing education monthly at our sponsor hospital. The continuing education topics vary from month to month. Annually the sponsor hospital requires all of them to go through a skills training session where they review things such as infusion pumps, medications, STEMI protocols, 12-and lead ECG recognition. Also reviewed routinely are the guidelines set forth by our sponsor hospital. Some examples of guidelines include induced hypothermia, STEMI, and Stroke.

It is usual and customary practice for a hospital such as Lawrence + Memorial to have a working relationship with an organization such as AASI for emergent and non-emergent ALS inter-facility transfers. These transfers are performed by our paramedics that have been given medical control by a sponsor hospital. The sponsor hospital physician has determined that these paramedics have undergone enough training and have the skill set required to perform inter-facility transfers of medically complex patients. Transfer requests from all area hospitals come directly into our dispatch center via a seven digit telephone line. Our highly trained dispatchers understand the urgency some of these requests may need. We never pass on any of these ALS transfer requests to the local PSAR service as they are not equipped nor are they trained to perform this level of service. Our service is equipped, trained, and has enough resources to do this. A local 911 PSAR service is limited, usually 1 or 2

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

ambulances, in its resources. They are obligated by law to be available to respond to the emergency requests within the town boundaries. That is their primary function. Being utilized to perform transfers like this is again not within their capabilities and it strips whatever emergency resources from their town.

I hope that the information obtained within this letter is useful and in the event it has led to more questions please feel free to contact me.

Respectfully,

Gregory B. Allard, Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

PRE-FILED TESTIMONY
OF LAWRENCE & MEMORIAL HOSPITAL
BY RON KERSEY

Good Morning Hearing Officer Hansted and members of the Department of Public Health. My name is Ron Kersey and I am E.M.S. Coordinator at Lawrence + Memorial Hospital ("L+M").[1] I thank you for this opportunity to appear before you today. As stated in our brief, L+M's protocol for inter-hospital transfers of elective angioplasty patients who develop a procedurally related complication that requires surgical intervention (the "Protocol") is a clinically appropriate transfer protocol that is typical in the industry, in that it preserves the treating physician's discretion to select the most medically appropriate means of transportation for the patient, based on the recommendations of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

The protocol that L+M uses for critical care inter-hospital transfer of angioplasty patients is a carefully organized approach to providing our patients with the highest quality, most appropriate mode of transportation with minimal impact to the community EMS system. L+M's policy for the inter-hospital transfer of a patient for advanced medical care represents the industry standard process for ensuring safe patient transport in the most efficient and timely manner. Dr. Cambi highlighted the clinical and medical benefits of our transfer protocol. I

[1] A copy of my Curriculum Vitae is attached hereto as Exhibit 1.

would like to discuss the implications of utilizing 911 for L+M's critical care transfers and the negative impact that process will have on patients, our local EMS system and the community.

If L+M were to call 911 for critical care transportation of patients to Yale or another tertiary care facility, it will place significant strain on the resources of our local EMS system. Dr. Cambi noted the infrequency of critical care transfers expected with the proposed elective angioplasty program; however, if the use of 911 for inter-facility transports were implemented hospital-wide, it will cripple our local resources. In Fiscal Year 2012, 450 patients were transferred to Yale alone from L+M's emergency department for emergent and urgent issues. This total climbs significantly when you consider tertiary facilities such as Hartford Hospital, as well as specialized care facilities such as Connecticut Children's. As New London Fire Department Deputy Chief Henry Kydd explains in his letter[2], the local EMS system cannot absorb this added responsibility nor is it the best equipped provider to do so.

The PSAR for the town of New London is the New London Fire Department (NLFD). The NLFD is equipped with two basic level support (BLS) transport units to handle all community 911 responses. As outlined in Deputy Chief Kydd's letter, the NLFD is not prepared clinically to handle the complex needs of the patients requiring critical care transport from L+M to a tertiary care facility. The NLFD is staffed with emergency medical technicians (EMTs) who are trained to provide basic medical care until the patient can be transferred to a hospital for advanced medical care. The skill level of some of the first responder EMTs is not specialized to manage cardiac patients requiring transfer to Yale. Deputy Chief Kydd supports L+M's plan for critical care transportation of elective angioplasty patients and agrees with the utilization of NLFD only as a last resort should the providers outlined in L+M's protocol not be unavailable.

[2] New London Fire Department Deputy Chief Henry Kydd's letter is attached hereto as Exhibit 2.

Utilizing NLFD for critical care transport to Yale will take one of two BLS units completely out of the community for an extended period of time stripping local residents of their 911 resource. In order to accommodate this, New London will be forced to rely on neighboring communities to fill in 911 calls in their area while the town ambulance is providing inter-facility transports, hence creating a potential ripple effect among an extended service area of first responder providers.

Activating 911 to dispatch NLFD means an L+M paramedic will need to accompany the NLFD EMT staff in the transport to Yale, and another local resource will be unavailable to the community for an extended period of time. A single transport, on average, will require the local ambulance and paramedic to be out of their primary response area for greater than 2 hours at a time. In addition, depending on the needs of the patient, an L+M nurse and respiratory therapist may also need to accompany the patient to Yale further depleting L+M and the community of resources. If Lifestar and/or American Ambulance were utilized rather than local EMS, L+M is able to maintain its much needed resources to support other hospital patients. Unlike local EMS, the providers in L+M's protocol have been vetted and have equipped their ambulances specifically to handle these calls and have given their crews additional education to provide the complex care required for these patients.

L+M supports the legal argument presented to this Department that the 2003 Declaratory Ruling does not apply to the inter-hospital transfer process. As L+M notes in its brief, the Ruling fails to mention inter-hospital transports and solely comments on transports to acute care facilities from long term care facilities or private citizens. The Ruling deals exclusively with pre-hospital transfers and is in place to ensure timely access for the community to the services of an acute care facility such as L+M. Despite the merits of this Ruling, to broadly extend its

application to all transfers is a mistake. I do not know of a hospital in the state of Connecticut that accesses the 911 system to move a patient from one acute care facility to another, whether in an emergent, urgent, critical condition or otherwise. It is in the best interest of the patient that L+M and other acute care facilities in the state follow a procedure to work directly with transport providers.

It should be highlighted that L+M is the sponsor hospital for the town of New London and adjacent communities. As the sponsor hospital, L+M is involved in the system development of the local EMS system. As the responsible party, we are willing to prescribe a process in which other providers are contacted directly by acute care hospitals for inter-hospital transports and the 911 service is not utilized at all unless these providers are unavailable. As the sponsor hospital in our community, L+M has the authority to determine this course of action as outlined in the 2003 Declaratory Ruling.

We maintain that L+M's transfer protocol complies with the 2003 Declaratory Ruling, in that it preserves the clinician's clinical judgment regarding when 911 should be activated. If the Department of Public Health disagrees and maintains that 911 must be activated each time an elective angioplasty patient who develops a complication is transferred to Yale, I respectfully submit that the ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving long term care facilities and members of the public, and the EMS providers who respond to their calls. If L+M is robbed of its discretion to determine whether 911 is activated and/or the most appropriate mode of transportation for patients traveling from one hospital to another hospital, I strongly feel a quality and safety issue will emerge putting our patients at risk, not just in the elective angioplasty program, but in the emergency department and all other hospital specialties. There is no question local EMS is an

important part of the emergency services system in our region. As explained above, keeping local EMS local is as important as getting our critically ill patients safely to a tertiary care facility for the advanced medical care they require.

I respectfully submit that L&M's Transfer Protocol meets all of the quality and clinically appropriate industry standards. We urge the Department of Public Health, Division of Office of Health Care Access to approve our CON application.

[SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The undersigned witness hereby submits all of the above testimony as his own testimony, and will adopt it at the hearing.

12-6-12

Ron Kersey

Exhibit 1

Ronald Kersey
117 Riverview Avenue
New London, CT 06320
(860)442-8737
rkersey@lmhosp.org

Areas of Effectiveness: Advanced emergency medical treatment, firefighting, emergency response and public preparedness, leadership, drill, exercise, and simulation design, business management, human body system knowledge, medical education, communication and public speaking, customer service skills.

Education

1989 – present **Three Rivers Community College**
574 New London Turnpike, Norwich, CT 06360
Currently pursuing an Associates in Liberal Arts and Science

02/93 – 05/93 **Capital Community College**
950 Main Street, Hartford CT 06103
Six credits in EMT-Paramedic III obtained

Career Experience

01/11 – present **Simulation Laboratory Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Coordinate the development of clinical simulation center
- Develop computer clinical simulation programs and scenarios
- Train clinical simulation operators
- Conduct clinical simulation for all levels of healthcare providers
- Troubleshoot and repair simulation equipment and manikins
- Manage American Heart Association Community Training Center Staff and activities

- Provide educational debriefing sessions for simulations

01/92 – present **Emergency Management Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Develop hospital emergency response plan
- Respond to and mitigate emergency situations
- Train staff in emergency preparedness and response
- Conduct emergency response drills and exercises
- Lead hospital through emergency events and situations
- Acquire grant funding to support emergency preparedness activities
- Perform radiological monitoring during nuclear contamination events
- Coordinate hospital emergency preparedness activities with the community

03/89 – present **EMS Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Direct Community EMS system development and quality oversight
- Plan and perform EMS related training for community EMS services
- Provide administrative supervision for hospital paramedic program
- Develop annual budget and manage department expenses
- Train, hire, and council employees
- Coordinate hospital and EMS interaction
- Conduct advanced medical training classes for hospital and physician staff

03/88 – 03/89 **Chief Paramedic**, Lawrence & Memorial Hospital Paramedic program, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Provide advanced emergency medical treatment
- Oversee daily operations and employee supervision
- Manage fleet maintenance
- Provide employee scheduling
- Employee counseling and coaching
- Conduct employee performance reviews
- Promote positive community relations

06/10 – present **Emergency Medical Technician**, Town of Ledyard, 1 Fairway Drive, Ledyard, CT 06339

Responsibilities Include:

- Respond to emergency calls
- Operate emergency vehicles
- Administer emergency medical treatment
- Conduct public education and awareness classes
- Perform daily checks and maintenance of emergency equipment
- Provide electronic patient care documentation report for each patient's medical record

04/08 – present **Emergency Medical Service – Instructor**, Emergency Training Services Incorporated, 45 Spring valley Road, Mystic, CT 06355

Responsibilities Include:

- Develop and Conduct EMS lectures
- Provide EMS skill training
- Train on proper use and maintenance of EMS equipment
- Manage classroom environment and activities
- Coach, remediate, and encourage student participation
- Manage class records

01/00 – 1/03 **Firefighter/Emergency Medical Technician**, Pinkerton's Incorporated, Pfizer New London location, 4330 Park Terrace Drive, Westlake Village, CA 91361

Responsibilities Include:

- Participate in emergency response activities

- Conduct site safety inspections
- Assist with facility security
- Monitor and maintain fire alarm and protection systems
- Train staff on fire suppression techniques

6/92 – 6/98 **Emergency Medical Technician**, Health Resources Incorporated Millstone Nuclear Power Facility 136 Berlin Rd. Cromwell, CT 06416

Responsibilities Include:

- Conduct air quality monitoring
- Provide safe work permit assessment and authorization
- Perform radiologic monitoring
- Manage hazardous materials events
- Respond to confined space rescue situations

10/81 – 3/88 Paramedic/Associate Supervisors/Advanced Life Support Coordinator, American Ambulance Service Inc. One American Way Norwich, CT 06360

Responsibilities Include:

- Provide advanced life support patient care
- Supervise daily staff activities
- Conduct public speaking events on the EMS system
- Coordinate advanced life support training

Volunteer Experience

06/92 – 01/94 **Firefighter/EMT**, New London Fire Department 89 Bank Street, New London, CT 06320

Responsibilities Include:

- Assist with fire ground activities
- Promote positive volunteer and career staff interactions

08/88 – present **Firefighter/EMT**, Goshen Fire Department, Shore Road, Waterford CT 06385

Responsibilities Include:

- Respond to marine emergencies
- Provide basic life support care

06/88 – present **Emergency Medical Technician**, Waterford Ambulance Association 89 Rope Ferry Road, Waterford CT 06385

Responsibilities Include:

- Administer emergency medical treatment
- Conduct public education and awareness classes
- Provide electronic patient care documentation report for each patient's medical record

06/88 – present **Firefighter/EMT**, Jordan Fire Company, 89 Rope Ferry Road, Waterford CT 06385

Responsibilities Include:

- Respond to emergency calls
- Mitigate hazardous materials incidents
- Maintain emergency equipment

References available upon request

Exhibit 2

CITY OF NEW LONDON
FIRE DEPARTMENT

Hearing Officer Kevin Hansted
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Lawrence + Memorial Hospital's Patient Transfer Protocol for Elective Angioplasty Patients

Dear Mr. Hansted:

The City of New London Fire Department ("NLFD") has reviewed and supports the Lawrence + Memorial Hospital plan for "Emergent Transportation of Elective Angioplasty Patients" (the "Protocol").

NLFD is the Primary Service Area Responder ("PSAR") for New London. We staff two BLS transport units with EMTs to handle community 911 responses and transport injured individuals to L+M Hospital. The EMTs are trained to provide basic medical care until the patient can be transferred to a hospital for advanced medical care. In addition, we utilize a paramedic intercept unit from L+M for all life and limb threatening emergencies. The NLFD is required to follow certain policies and procedures each time it is contacted by the local 911 dispatcher. In addition to the BLS ambulance, we dispatch a fire engine to the scene of the emergency for all life threatening problems. The fire fighters assess the situation and render basic first aid if the NLFD ambulance has not arrived. When the ambulance or paramedic intercept team arrive, they assess the severity of the emergency and call for additional EMS resources, such as the Lifestar air medical transport helicopter, if necessary. If L+M Hospital is required to go through the 911 system each time the hospital calls Lifestar, the fire engine and BLS ambulance will be dispatched to the hospital each time Lifestar is called, even though their services are not needed.

As identified in the Protocol, NLFD ambulances, supplemented by L+M paramedics and other staff, may at times be required to assist in the transportation of critically ill patients from Lawrence + Memorial to Yale New Haven Hospital. We understand, however, that in most instances other providers will perform this service. Those other providers are better equipped to handle the transfers because, unlike our EMTs, their staff have been given additional training to manage medically complex cardiac patients. In addition, if the NLFD is called upon to assist L+M with its 450+ urgent, emergent, and critical care patient transfers per year, it will draw resources away from the community for extended periods of time and cripple the local EMS system. The projected volume is well above the NLFD's capacity, and would require me to draw additional EMS resources away from neighboring communities to fill the gap for community 911 responses. To preserve the stability of New London's community EMS system, L+M

Richard J. Samul, Sr., Fire Chief
209 Bank Street
New London, CT 06320-5521
(860) 447-5291 • FAX (860) 447-5293
Email: rsamul@ci.new-london.ct.us

CITY OF NEW LONDON
FIRE DEPARTMENT

and its medical staff should be permitted to determine the most appropriate mode of transportation for their patients, which will most often be via air medical transport or another provider that is specially equipped to handle inter-facility critical care transports.

In the event that the preferred resources outlined in L+M's Protocol are not available or they deem them unnecessary for clinical reasons, the NLFD will provide an ambulance for transportation. However, the NLFD should not and cannot become the primary first responder for all of L+M's inter-hospital patient transfer calls.

Please feel free to contact me with any questions or concerns at (860) 447-5291.

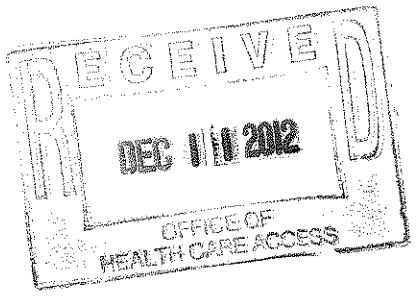
Sincerely,

Henry Kydd, Deputy Chief
New London Fire Department

Ronald J. Samul, Sr., Fire Chief
289 Bank Street
New London, CT 06320-5521
(860) 447-5291 • FAX (860) 447-5293
Email: rsamul@ci.new-london.ct.us

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org



December 10, 2012
Via Federal Express
Via Facsimile (860) 418-7053
Via Electronic Mail: Steven.Lazarus@ct.gov

Kevin Hansted, Hearing Officer
Steven W. Lazarus, Associate Health Care Analyst
State of Connecticut
Department of Public Health
Division of Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06106-1367

Re: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

Dear Hearing Officer Hansted and Mr. Lazarus:

In connection with the Public Hearing scheduled for Thursday, December 13, 2012 at 10:00 a.m. on the above-captioned CON Application, enclosed please find an original and four (4) copies of the following:

1. Applicant's Brief in Support of its Patient Transfer Protocol
2. Prefile Testimony of Brian Cambi, MD, FACC, FSCAI
3. Prefile Testimony of Ron Kersey

Also enclosed is a CD containing a scanned version of each document listed above.

Please do not hesitate to contact me with any questions.

Thank you.

Crista Durand, Vice President
Strategic Planning, Marketing & Business Development

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

APPLICANT'S BRIEF IN SUPPORT OF ITS PATIENT TRANSFER PROTOCOL

Lawrence & Memorial Hospital (the "Applicant" or "L+M") respectfully submits that its patient transfer protocol for the elective angioplasty program ("Protocol")[1] does not conflict with the Department of Public Health's ("DPH") February 14, 2003 Declaratory Ruling (the "Declaratory Ruling" or "Ruling"), which recognizes that a clinician's "clinical judgment should be used in determining whether the 911 system should be activated." Declaratory Ruling, at p. 18. This brief sets forth the legal and policy bases for the Applicant's position, and responds to the five hearing issues that the Office of Health Care Access ("OHCA") submitted to the Applicant on December 4, 2012.

If the DPH disagrees and maintains that the 911 system must be activated each time an elective angioplasty patient who develops a procedurally related complication that requires surgical intervention is transferred to another hospital, L+M respectfully submits that the Ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving "long term care facilities" and members of the public, as well as the EMS providers who respond to their calls. An interpretation of the Ruling that deprives treating physicians in hospitals of the ability to exercise discretion over whether to activate the 911 system and how patients should be transported conflicts with the Ruling itself, and subsequently-enacted State

[1] The Protocol is attached hereto as Exhibit A.

law, and Federal law. It also places an unnecessary strain on community EMS resources, and jeopardizes patient safety.

I. The Declaratory Ruling

The Declaratory Ruling addresses three major topics. First, the Ruling requires "long term care facilities" and members of the public to dial 911 to facilitate the transportation of urgently ill or injured individuals to hospitals during "medical emergencies, which require an immediate response." *See* Declaratory Ruling, at p. 13, #68 and p. 30. Second, it regulates the conduct of the local EMS providers, called Primary Service Area Responders ("PSARs"), who respond to emergency calls made by members of the public and long term care facilities. *See id.* at pp. 20, 25, 31-34. Third, the Declaratory Ruling specifically addresses the role of acute care hospitals within the EMS system, and explains that their purpose is to assist EMS providers to safely transfer patients into Connecticut's hospital system. *See id.* at pp. 8-12 and p.21-25. This third point is most pertinent to the issues at hand.

As the Ruling explains, a patient's care is entrusted to the highly trained professionals at Connecticut's acute care hospitals as soon as the 911 system is activated. Each EMS provider is sponsored by an acute care hospital, which provides "medical control," administered by staff physicians who serve as "medical directors" to the PSAR units. *Id.* at p. 8, #36. Medical control by a sponsor hospital is necessary because "emergency medical technicians and paramedics provide invasive medical care, including starting IV lines, using defibrillators, performing endotracheal intubations, and administering medications." *Id.* If EMTs or paramedics have treatment questions or run into complications in the field, they can contact a physician at the sponsor hospital to obtain medical direction. *Id.* at p. 9, #38.

Sponsor hospitals are also responsible for monitoring the quality of the care provided by PSARs. *Id.*, at p. 9, #37. "Medical directors may withhold medical authorization from emergency personnel or a provider if the medical director believes the EMS staff or service has demonstrated incompetence or negligence, poses a threat to public health or safety, or has acted contrary to medical direction." *Id.* at p.8, #36. If a PSAR travels outside its regular service area, the sponsor hospital must continue to be responsible for quality assurance. *Id.*at p. 11, #52. Thus, the Ruling makes clear that acute care hospitals form the lynchpin of the EMS system, furnishing the PSARs who bring patients to the hospitals with expert medical advice. The EMS system operates safely because of sponsor hospitals applying their medical training and expertise.

II. L+M's Protocol Complies with the Declaratory Ruling

The Declaratory Ruling not only recognizes the medical training and judgment of physicians, it defines "emergency" so that clinicians, such as physicians, are *required* to exercise their independent medical judgment when deciding whether to activate 911. For purposes of the Ruling, DPH adopted a definition of the term "emergency," which was set forth in two guidance letters that it sent to long term care facility operators in 2002. *Id.* at p. 12-14, and p. 18. The letters explain that a medical emergency is a situation that requires an immediate response, which "**as determined by appropriate licensed staff at a transferring facility, necessitates the activation of the 911 response system.**" *Id*, at p. 13, #68 (Emphasis added). Although the letters set forth three specific examples of medical emergencies (i.e. the "rapidly deteriorating condition of a resident;" "[a]n accident resulting in serious injury," and "[a] life threatening emergency"), the 2002 letters, and an earlier 1987 letter, *always* allow the transferring facility to exercise discretion regarding whether 911 is activated. *Id.*, at p. 12, #65; p. 13, #68; and p. 14,

#71. When the Ruling adopted the definition of "emergency" set forth in the 2002 letters, it emphasized again that "**clinical judgment should be used in determining whether the 911 system should be activated.**" *Id.*, at 18 (Emphasis added). The 2002 letters also explain: "If non-emergency transportation is desired, any ambulance service may be utilized." *Id.* at 14, #71.

The Ruling's emphasis on the judgment of clinicians makes perfect sense. Just as a hospital staff physician must have discretion when determining whether a patient should travel from the emergency department to surgery in a wheelchair or on a gurney, a physician must have discretion to determine whether a patient travels from the catheterization laboratory at L +M to an operating room at Yale via Lifestar, American Ambulance, or, when presented with an emergency that "necessitates the activation of the 911 response system," through the 911 system. *See id.*, at p. 13, #68.

L+M's Protocol is identical in all material respects to the protocol that it submitted in connection with its successful CON application for the emergency angioplasty program.[2] Both protocols fully comply with the mandates described above. They recognize that most critical care inter-hospital transfers will not constitute a "medical emergency," which "as determined by appropriate licensed staff at a transferring facility, necessitates the activation of the 911 response system." *See id.* The Protocol is utilized only when, due to complications during the procedure, the interventional cardiologist decides that the patient requires a level of care found at the transferee hospital. The interventional cardiologist makes sure the patient is medically stable, and L+M staff obtains the patient's or family's informed consent for the transfer. In the vast majority of cases, which involve transferring a medically stable patient within the hospital

[2] When L+M applied to OHCA for approval of its emergency angioplasty program, OHCA requested a copy of L+M's patient transfer protocol in the completeness questions. The emergency angioplasty patient transfer protocol advised L+M's staff to contact EMS providers directly, and it included Lifestar's direct1-800 number in the protocol. *See* Emergency Transfer Protocol (attached hereto as Exhibit B). That CON application was approved by OHCA.

system, this will not, in the clinician's judgment, constitute a medical emergency that is best served by activating the 911 system. That is why both protocols make no mention of 911. If, in the attending physician's opinion the best means of facilitating the patient's transfer to another acute care hospital is by activating 911, 911 will be activated. If the Department will find it useful, L+M certainly is willing to state this in its Protocol.

III. Mandated Activation of the 911 System for Each Urgent or Emergent Patient Transfer Will Gravely Impair Public Safety, and Conflict with the Ruling Itself, as Well as State and Federal Law

A. Activation of the 911 System for Each Urgent, Emergent, or Critical Care Patient Transfer Jeopardizes Patient Safety

If DPH is taking the position that the Ruling requires L+M to activate 911 for all emergent, urgent, and critical care inter-hospital transfers, specifically transfers of elective angioplasty patients who develop a complication to Yale, the following process, which is diagramed in Exhibit C (attached hereto), will occur each time an urgent, emergent, or critical care patient is transferred to Yale. The treating physician is required to dial 911 and relay the patient's needs to the dispatcher, who is required to activate the Primary Service Area Responder (PSAR) for New London, the New London Fire Department ("NLFD") ambulance. If the NLFD ambulance is unavailable, the call will result in the dispatch of a PSAR from another community. This procedure adds links in the chain of communication, creating multiple opportunities for miscommunications and mistakes. It also results in the dispatch of a Basic Level (BL) ambulance, as well as fire fighters or police officers, who are first responders. OHCA's second enumerated question queries whether a 911 dispatcher will send something less than a BL ambulance. Because, upon information and belief, all PSARs are equipped with BL ambulances, 911 will dispatch a BL unit. However, this question fails to address L+M's concern, which is patient safety. A BL ambulance will not, in this instance, be the clinically appropriate mode of

transportation for an elective angioplasty patient with a complication. Under Section 19a-179-18 of the Connecticut Agency Regulations, a BL ambulance is not always equipped with the supplies that these medically complex patients need and the NLFD ambulances are staffed only with EMTs. If the Department requires NLFD's BL ambulance to perform these transfers, it will need to be supplemented with L&M staff, such as paramedics, nursing, and/or respiratory therapists to ensure the safe transfer of patients. Without an appropriately equipped ambulance, transferred patients risk complications due to lack of necessary equipment and experienced trained health care providers, all of which could have been easily and efficiently provided under L+M's proposed transfer system. As Dr. Cambi explains in his testimony, the providers in L+M's protocol arrive pre-equipped with the medically appropriate staff and equipment for these transferees. Thus, if the ruling is applied to hospitals, they may find themselves in a position where the least desirable provider must become the first provider for inter-hospital transfers of critically ill patients.

Although the Lifestar helicopter is available if L+M is required to activate 911, the procedure for dispatching the helicopter is more complicated. **New London's 911 dispatchers cannot initiate Lifestar absent a request from the PSAR, which is the NLFD.** Therefore, rather than making a single phone call, the treating physician is required to call 911, the dispatcher is required to contact the PSAR, and the PSAR is required to activate Lifestar and travel to L+M, even though the hospital has no need for the services of a PSAR. This chain of command makes sense when the EMS system deals with members of the general public or long term care facilities that may not have physicians on staff, because the PSAR must assess the severity of the patient's condition and decide whether Lifestar is necessary. In the hospital setting, it is not necessary for the PSAR to assess the patient as this is already done by the

transferring hospital, and the patient is stabilized. Activating the 911 system in unnecessary cases adds complexity and delay to inter-hospital transfers, which are initiated at the request of highly trained physicians. Indeed, in L+M's case, the PSAR will arrive to render assistance that is not needed at the very institution that sponsors it and provides it with medical direction and control.

B. Activation of the 911 System for Each Urgent, Emergent, or Critical Care Patient Transfer Strips the Community of Much Needed EMS Resources

Using the NLFD ambulance for inter-hospital transfers will also strip the community of both an ambulance and a L+M paramedic for the time it takes to make the round trip, which could exceed two hours. Although the likelihood of a transfer of elective angioplasty patients to Yale for urgent cardiac surgery is very low due to L&M's strict patient selection process, requiring the hospital to activate the 911 system for all other specialties will result in a severe drain on community resources. As Ron Kersey explains in his pre-filed testimony, L+M's emergency department transferred 450 patients to Yale in Fiscal Year 2012. If all of those transfers are considered emergencies, that could equate to nearly 40 trips per month, which will take the NLFD Ambulance out of its service area for hours at a time, and require New London to rely on PSARs from neighboring communities to fill the gap.

Involving local 911 dispatchers in emergent, urgent, and critical care inter-hospital transfers will also waste local resources, with no benefit to the patients. Unlike members of the public, who may need first aid instructions while they are waiting for a first responder to arrive, physicians do not require the assistance of a 911 dispatcher to assess patient needs and provide basic first aid instructions. More important, the physicians and hospital staff have already stabilized the patient for transfer. As NLFD Deputy Chief Henry Kydd explains in his letter, calls to 911 may also result in police or fire vehicles being dispatched to the hospital, which will

draw these resources away from the community members who need them. *See* Letter by NLFD Deputy Chief Henry Kydd (attached to Prefiled Testimony of R. Kersey).

Finally, because application of the Declaratory Ruling to emergent, urgent, and critical care inter-hospital transfers will represent a marked departure from the current practices of every Connecticut hospital, as well as the industry standard for hospitals throughout the United States,[3] it will have a significant financial impact on cities and towns throughout Connecticut, and can very well collapse the 911 system in the State. The problems described above can be avoided if the Declaratory Ruling is read in its proper context to defer to the transferring hospital and treating physician's judgment as to whether the 911 system is activated.

C. The Declaratory Ruling Does Not Apply to This Patient Transfer Protocol

If the Department is of the opinion that L+Mmust activate the 911 system for *all* emergent, urgent, and critical care interhospital transfers, *even if the treating physician concludes that accessing 911 is unnecessary or clinically inappropriate*, L+Margues, in the alternative, that the Ruling does not apply to its Protocol at all. This DPH interpretation of the Ruling ignores its plain language, as well as its context because, by its terms, the Ruling applies only to long term care facilities, members of the public, and the EMS providers who serve them during medical emergencies before they arrive at a hospital. In addition, this DPH interpretation is at odds with the Ruling's emphasis on the independent judgment of clinicians, which is described above. *See supra* at pp. 1, 3-4.

The language used throughout the Declaratory Ruling—in particular the hearing officer's repeated use of the term "long term care facilities" in the factual findings and conclusions of

[3] *See* Jonathan Warren, MD, FCCM, FCCP et al., Guidelines for the inter- and intrahospital transport of critically ill patients, 32 Crit. Care Med No. 1, at pp. 256-262 (2004).

law—indicates that the Ruling applies only to nursing homes and other long term care facilities, not acute care hospitals which are fundamentally different health care institutions.[4]

The context in which the Ruling arose also supports L+M's interpretation. The Petition for the Declaratory Ruling ("Petition") was filed for the purpose of dispelling confusion among the operators of *long term care facilities* regarding when they must dial 911, as well as confusion amongst EMS providers servicing them. The Ruling specifically references three letters which the Department issued to long-term care facility administrators as guidance on the proper procedures for the emergency transfers of patients to hospitals. Declaratory Ruling, at p. 12, # 65-66; p. 13, # 68-69, and p. 70, #70-72. The Ruling explains that the second letter, issued in May 2002, had produced confusion within the long-term care industry, and that the Department therefore had issued a December 2002 statement to "**long-term care facility operators and EMS providers** . . . reiterating that when a medical emergency exists in the judgment of a clinician, the 911 system must be activated." (Emphasis added; internal quotation marks omitted.) *Id.*, at p.14, #70 and 71.

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[4] Chapter 368v of the General Statutes, which regulates health care institutions, describes the differences between long term care facilities, also known as nursing homes, and acute care hospitals. The former are defined as "any nursing home or residential care home as defined in section 19a-490 or any rest home with nursing supervision which provides, in addition to personal care required in a residential care home, nursing supervision under a medical director twenty-four hours per day, or any chronic and convalescent nursing home which provides skilled nursing care under medical supervision and direction to carry out nonsurgical treatment and dietary procedures for chronic diseases, convalescent stages, acute diseases or injuries . . ." *See* Conn. Gen. Stat. § 19a-521. On the other hand, "Hospital" is defined as "an establishment for the lodging, care and treatment of persons suffering from disease or other abnormal physical or mental conditions and includes inpatient psychiatric services in general hospitals." Conn. Gen. Stat. § 19a-490(b).

Hospitals and long term care facilities are also subject to different sets of regulations. For example, hospitals are required to maintain a medical staff of not fewer than five (5) physicians. *See* Regs., Conn. State Agencies §§ 19-13-D3(c)(1) and 19-13-D5(c)(1). Hospitals also are required to maintain, at a minimum, facilities such as clinical laboratories, blood banks, radiology departments and operating rooms. *See* Regs., Conn. State Agencies §§ 19a-13-D3(f) and 19-13-D5(f). Homes for the aged and nursing homes, however, are not required to maintain a medical staff. *See* Regs., Conn. State Agencies § 19-13-D6(d).

Furthermore, other factual findings contained within the Ruling almost exclusively refer to the practices of long-term care facilities or ambulance services treating patients during medical emergencies before they reach the hospital.[5] The only factual findings that specifically refer to acute care hospitals pertain to the hospitals' role as sponsors of emergency medical service providers. *See id.*, at pp. 8-12. It is telling that the Ruling does not contain a single factual finding about procedures for transferring patients after they have entered the hospital system. If the Petition addressed inter-hospital transfers, DPH surely would have heard separate testimony about the hospitals' patient transfer protocols.

Not only does the limited scope of the factual findings demonstrate that inter-hospital transfers were well beyond the purview of the Declaratory Ruling, the legal conclusions set forth within the Ruling exclusively pertain to long-term care facilities and the EMS providers that service them, as well as members of the public, during medical emergencies. Each conclusion of law that regulates the conduct of a health care institution makes a specific reference to long-term care facilities—not acute care hospitals. As noted above, the Hearing Officer specifically defines the term "emergency" in the context of *long-term care facilities*, and goes on to apply that defined term throughout the remainder of the opinion. *See id.*, at p. 17-18. Subsection C of the Ruling, which addresses the question of whether an EMS provider may provide emergency

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[5]For example, on Page 6, at Finding #14, DPH states: "Advertising was also prohibited by the Emergency Medical Services Assistance Act to prevent the public, **including long term care facilities**, from calling ambulances other than the PSAR to provide service." (Emphasis added). At Page 14, Finding #75, DPH states: "In addition to the need for emergency and non-emergency transports to and from **long term care facilities, long term care facilities** also request transports that are not pre-scheduled and do not require a full three tiered response . . . ." (Emphasis added).

Although the Ruling sometimes uses the words "facility" or "health care facility," instead of "long term care facility," when these references to "facilities" are read in context, it is clear that they are shorthand references to long term care facilities. For example, while Factual Finding #84 states that "a small percentage of requests for emergency service have been made by facilities directly to non-PSA providers . . .," the next finding is a specific example of Montowese Health and Rehabilitation Center's use of the non-PSAR provider Nelson Ambulance Service for medical emergencies. Declaratory Ruling, at p. 16, # 84 and 85.

medical services in an area in which it has not been designated as the Primary Service Area Responder ("PSAR"), provides in relevant part:

> [T]he preponderance of evidence and a reasonable construction of the statutes and regulations establishes that **long term care facilities** are required to call 911 when there is an emergency, and non-PSAR providers may *not* respond to emergency calls made directly to them.

Id, at p. 30 (Emphasis added). Finally, Subsection H prohibits "long term care facilities" from entering into contracts with providers for the provision of emergency medical services. *Id.* at 35.

DPH makes factual findings regarding the historical practices and procedures of long-term care facilities, interprets DPH's prior policy directives to long-term care facility administrators, and makes no factual findings or conclusions of law pertaining to acute care hospitals' patient transfer protocols. The context of the Declaratory Ruling, as well as the language employed therein, indicate that it does not address urgent, emergent, and critical care inter-hospital patient transfers.

D. Even if the Ruling Once Governed Urgent, Emergent, and Critical Care Inter-Hospital Transfers, it is Premised Upon an Earlier Version of the Emergency Medical Services Assistance Act

The Declaratory Ruling is premised upon DPH's interpretation of the Emergency Medical Services Assistance Act ("EMSAA"), General Statutes §§ 19a-175, et seq., as it existed on February 14, 2003. At that time, EMSAA did not contain a provision that specifically governed inter-hospital transfers. In 2009, the legislature amended EMSAA by enacting General Statutes § 19a-179c, which specifically addresses all inter-hospital transfers, and does not require hospitals to activate 911. Section 19a-179c does not distinguish between "emergency" transfers and "non-emergency" transfers of patients between hospitals. It governs all inter-hospital transfers, and, as the legislative history makes clear, it was enacted to endorse transfers *exactly* like the transfer at issue here utilizing providers outside the 911 system.

Section 19a-179c provides:

> Any ambulance used for **interfacility critical care transport** shall meet the requirements for a basic level ambulance, as prescribed in regulations adopted pursuant to section 19a-179, including requirements concerning medically necessary supplies and services, and may be supplemented by a licensed registered nurse, advanced practice registered nurse, physician assistant or respiratory care practitioner, provided such licensed professionals shall have current training and certification in pediatric or adult advanced life support, or from the Neonatal Resuscitation Program of the American Academy of Pediatrics, as appropriate, based on the patient's condition.

(Emphasis added.) The 2009 legislation also added the term "interfacility critical care transport" ("ICCT") to the definitions section of EMSAA. ICCT means "the interfacility transport of a patient between licensed **hospitals**."[6] (Emphasis added).

Under Connecticut's rules of statutory interpretation, "specific terms covering the given subject matter will prevail over general language of the same or another statute which might otherwise prove controlling." *Tomlinson* v. *Tomlinson*, 305 Conn. 529, 552 (2012). Thus, the terms of § 19a-179c, which apply specifically to all transfers between hospitals, control over the more generalized statutes that DPH interpreted in its 2003 Ruling, as well as the generalized terms of the Ruling itself.

Finally, the legislative history demonstrates that § 19a-179c was enacted to endorse hospitals' industry-wide practice of using providers, not PSARs dispatched by 911, to transport

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[6] The definition of ICCT does not distinguish between "emergency" and "non-emergency" transfers. It encompasses all transports of patients between licensed hospitals. In addition, the legislature's use of the word "critical" in ICCT suggests that § 19a-179c specifically applies to "emergency" transfers between hospitals. Our Supreme Court has determined that "[i]n the construction of the statutes, words and phrases shall be construed according to the commonly approved usage of the language. . . . [Courts] ordinarily look to the dictionary definition of a word to ascertain its commonly approved usage." *Director of Health Affairs Policy Planning v. Freedom of Information Commission*, 293 Conn. 164, 184 (2009) (Citation omitted; internal quotation marks omitted.). The word "critical" is defined as "being or relating to an illness or condition involving danger of death" and "relating to or being the stage of a disease at which an abrupt change for better or worse may be expected." Merriam-Webster's Collegiate Dictionary (10th Ed. 1993). The legislature's use of the word "critical" demonstrates its intent that the statute apply to emergency transfers of patients.

critically ill patients to other hospitals. Section 19a-179c stems from House Bill No. 6599 of the 2009 legislative session, which was enacted as Public Acts of 2009, No. 09-16. During a public hearing concerning House Bill No. 6599, the Joint Standing Committee on Public Health heard testimony from Dr. Jim Parker, an emergency medical physician and the director of Connecticut Children's Hospital's ("CCH") Critical Care Transport Team. *See* Conn. Joint Standing Committee Hearings, Public Health, Pt. 6, 2009 Sess., pp. 1610–14 (Attached hereto as Exhibit D). Dr. Parker testified in favor of an amendment to House Bill No. 6599, which would allow CCH to run its Critical Care Transport Team without jeopardizing its clinicians' licenses:

> **Connecticut Children's needs to operate a critical care transport team to bring critically ill or injured children/newborns from community hospitals to our facility when they need tertiary care services that are not available at a community facility.**
>
> Current Office of Emergency Medical Services regulations require that every individual providing care to a patient in an ambulance must be licensed . . . as an EMT. This regulation prevents our team of trained pediatric critical care clinicians from providing specialized services that these newborns and children need.
>
> Connecticut Children's is not—currently not operating this service because of potential liability for our clinicians' licenses. As a result, children who need our transport services do not have access to them. . . .
>
> When enacted, [House Bill No. 6599] will allow Connecticut Children's to resume operation of its critical care transport service, providing our patients with access to **the specialized healthcare transport services they need** in a safe environment.

Id., at 1610–11 (Emphasis added). Dr. Parker identified two additional services that would benefit from House Bill No. 6599: Yale's pediatric specialty transport service and John Dempsey's neonatal specialty transport service. *Id.*, at 1612. As Dr. Parker's testimony made clear, these are specialized transport services which do not make use of the 911 system or local PSARs to accomplish transports of critically ill patients. The amendment propounded by Dr.

Parker, which allowed these hospitals to arrange for transport services for critically ill patients, was adopted. By enacting § 19a-179c, the legislature implicitly endorsed the standard industry practice of arranging direct transport services to convey critically ill patients between licensed hospitals—the exact type of transfer at issue here.

Even if the Declaratory Ruling applied to hospitals in 2003, the legislature subsequently expressed an intent to narrow its scope, so that it applies only to prehospital transfers, such as for members of the public, including long term care facilities. **The Ruling does not apply to transfers *after* the patient has entered the hospital system—those transfers are governed by § 19a-179c. If the Ruling is applied to hospitals now, after the legislature's enactment of § 19a-179c, it will conflict with the purpose and intent of the 2009 legislation.**

E. Application of the Ruling to All Urgent, Emergent, and Critical Care Inter-Hospital Transfers Creates a Direct Conflict with Federal Law

Finally, if physicians are required to activate 911 for all urgent, emergent, and critical care inter-hospital transfers, the Ruling will directly conflict with the Federal Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd. This conflict with federal law can—and must—be avoided if the Declaratory Ruling is applied correctly, so that it does not mandate the activation of 911 for all urgent, emergent, and critical care inter-hospital transfers. EMTALA closely regulates the transfer of emergency department patients between acute care hospitals. It states:

> An appropriate transfer to a medical facility is a transfer-- . . . (D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . . 42 U.S.C. § 1395dd(c)(2).

Hospitals and physicians who fail to comply with EMTALA are subject to fines and, in some instances, exclusion from federal and state health care programs. 42 U.S.C. § 1395dd(d). EMTALA also has a preemption provision, which states: "The provisions of this section do not preempt any State or local law requirement, **except to the extent that the requirement directly conflicts with a requirement of this section**." 42 U.S.C. § 1395dd(f)(Emphasis added).

"When state law conflicts with federal law, courts are bound to follow federal law." *Pac. Capital Bank, N.A. v. Connecticut*, 542 F.3d 341, 348 (2d Cir. 2008) (Internal quotation marks omitted). State and federal law directly conflict where it is impossible for a party to comply with both state and federal requirements. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011). Direct conflict preemption does not require impossibility to arise in each and every instance, it requires only that "compliance with both federal and state regulations may in some circumstances be impossible . . ." *County of Suffolk v. Long Island Lighting Co.*, 728 F.2d 52, 57 (2d Cir. 1984). A direct conflict will also arise where state law "may impede the execution of the full purposes and objectives of Congress." *Id.* "State law is in 'irreconcilable conflict' with federal law, and hence preempted by federal law, when compliance with the state statute would frustrate the purposes of the federal scheme." *Pac. Capital Bank, N.A.*, 542 F.3d, at 351.

If the Declaratory Ruling is read to require 911 to be activated for all emergent, urgent, and critical care inter-hospital transfers, which necessarily include transfers of Emergency Department ("ED") patients between hospitals, hospitals and physicians will be unable to comply with EMTALA in many instances. Under EMTALA, a hospital and treating physician must ensure that transfers of ED patients are "effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer . . ." 42 U.S.C. § 1395dd(c)(2)(D). Hospitals must, for

example, ensure that the transport team is properly staffed. *See Lopes v. Kapiolani Medical Center for Women & Children*, 410 F. Supp.2d 939 (D. Hawaii 2005) (transport team for a neonatal patient may not have been adequately staffed under EMTALA where it consisted of transport RNs but not a respiratory therapist). The hospitals and treating physicians must also be able to carefully select the "transportation equipment." 42 U.S.C. § 1395dd(c)(2)(D). If L+M dials 911 and activates the local PSAR—not the pre-screened better-equipped vehicles with specially trained providers —for all ED ground transfers, L+M will be unable to ensure that all ED patients are transferred by "qualified personnel and transportation equipment." If L+M contacts an ambulance directly to set up the transfer to ensure compliance with the above, it will violate the Department's broad interpretation of the Declaratory Ruling. Thus, it will be impossible to comply with both state and federal law.

This conflict can—and must—be avoided by reading the Ruling appropriately. "[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter." *Jones v. United States*, 529 U.S. 848, 857 (2000) (Internal quotation marks omitted). A recent Second Circuit case applied this principle when it considered a Connecticut statute that caps the interest rate banks may charge for tax refund anticipation loans (RALs). *Pac. Capital Bank, N.A.*, 542 F.3d, at 347. The Connecticut Attorney General had issued a formal opinion, which stated that the Connecticut law applied to the "facilitators" who sell tax refund loans made by national banks. *Id.*, at 346. The plaintiff, a California-based national bank, filed a federal declaratory judgment action, claiming that the Connecticut statute conflicted with the Federal National Bank Act, which allows a bank to charge the maximum interest rates permitted by its home state. *Id.* at 347. The Second Circuit held that the interest rate provisions

of the Connecticut statute are preempted by the National Bank Act if they are applied to facilitators who make RAL loans offered by national banks. *Id.* at 353. If, however, the statute is construed so that it excludes facilitators making loans on behalf of national banks, it may stand. *See id.*, at 354. The Second Circuit affirmed the latter interpretation of the statute, which avoided constitutional problems and was not contrary to the intent of the legislature. *Id.* In short, the Second Circuit invalidated the Attorney General's formal interpretation of the RAL statute in order to adopt an interpretation that was not preempted by federal law.

In the present case, EMSAA and the Declaratory Ruling are most appropriately interpreted in a manner that does not conflict with EMTALA. If the Ruling is interpreted so that it applies only to prehopsital transfers, such as transfers of long term care facility residents and members of the public to acute care hospitals, the conflict can be avoided. Pursuant to *Jones* and *Pac. Capital Bank, N.A.*, this interpretation must be adopted. To do otherwise creates a direct conflict with Federal law, and subjects both EMSAA and the Declaratory Ruling to constitutional challenge.

IV. Responses to OHCA's List of Issues

Question:

1. **Page 360 of Exhibit A provides Lawrence & Memorial Hospital's guidelines for emergent transportation for a PCI patient from the Cardiac Catheterization lab. The guidelines do not include contacting 911 for such emergent transportation. Lawrence & Memorial Hospital has taken the position that acute care hospitals are not subject to the Department of Public Health's Declaratory Ruling, dated February 14, 2003, which requires that 911 be contacted for all emergency patient transfers (the "Declaratory Ruling"). In support of its position, Lawrence & Memorial Hospital claims that it would not be able to comply with Connecticut General Statutes § 19a-179c if it was required to call 911 for emergency transports. During the initial contact with the 911 dispatcher, could the hospital request an**

immediate response by a basic level ambulance with the exclusion of fire and police response?

Answer:

Although Lawrence & Memorial Hospital can *request* that the 911 dispatcher only send a basic level ambulance without fire and police response, it cannot *require* that the 911 dispatcher send only a basic level ambulance. The Declaratory Ruling explicitly recognizes that "there are different standards for the daily operation of [Coordinated Medical Emergency Direction Centers] and [Public Safety Answering Points ("PSAPs")]/dispatchers, including different protocols [and] different operational procedures . . . ." Declaratory Ruling, at p. 6, # 20. As NLFD Deputy Chief Henry Kydd explains in his letter (attached to Ron Keresy's Pre-filed Testimony) , the City of New London's protocols and policies mandate that the New London Fire Department send a fire truck to the scene whenever the 911 system is activated for life threatening problems. Unlike long term care facilities, many of which do not have physicians on staff, and members of the public, hospitals do not require the assistance of first responders, such as fire fighters, to render basic first aid, assess the patient's condition, and stabilize the patient. Sending a fire truck to L+M hospital for each urgent, emergent and critical care transport will be an unnecessary waste of resources, and it will divert public safety resources away from members of the community who truly need them.

Question:

2. **Assuming the response to No. 1 is in the affirmative, are there situations in which the 911 dispatcher would send something less than a basic level ambulance?**

Answer:

Most likely not since, upon information and belief, all PSARs must operate "basic level ambulances." However, as L+M explained in detail, the question ignores three central concerns that L+M has expressed during these proceedings. First, dispatching BL ambulances for every urgent, emergent, and critical care inter-hospital transport will waste valuable community resources. The 911 dispatcher will send a basic level ambulance staffed by EMTs, as well as other local resources such as a fire and police personnel. When members of the public or long term care facilities dial 911, these first responders play an important role. They assess the patient's condition, determine whether more advanced EMS providers need to be dispatched, such as Lifestar or L+M's paramedic intercept team, and render basic first aid. At L+M, the patient has already been assessed and stabilized by the treating physician, who is in the best position to determine the clinically appropriate mode of transportation. Deploying local EMS resources to L+M for all urgent, emergent, and critical care patient transfers will unnecessarily waste community resources, at great cost to the City of New London.

Second, a BL ambulance staffed only with EMTs is not clinically appropriate for medically complex inter-hospital transfer patients. As Dr. Cambi explains in his pre-filed testimony, elective angioplasty patients who develop a complication and must be transferred to Yale require the assistance of personnel with years of experience in transferring patients with

complex intravenous medications and mechanical life support systems. If the Department requires a BL ambulance to perform these transfers, it will need to be supplemented with L+M staff, such as paramedics, nursing, and/or respiratory therapists to ensure the safe transfer of patients. The providers in L+M's protocol arrive pre-equipped with the medically appropriate staff and equipment for these transferees.

Third, accessing the 911 system for inter-hospital transfers of urgent, emergent, and critical care patients unnecessarily adds delay and complexity to the patient transfer process. Even if L+M can ultimately secure the services of the Lifestar helicopter by calling the 911 dispatcher, the call to 911 adds additional unnecessary links in the chain of communication. As Ron Kersey explains in his pre-filed testimony, the following chain of events, which are diagramed in greater detail in Exhibit C, will unfold. Rather than making a single phone call, the treating physician and hospital staff are required to call 911, the dispatcher is required to contact the PSAR, and the PSAR is required to activate Lifestar and travel to the hospital, even though the hospital has no need for the services of the NLFD EMTs or the BL ambulance. These additional links in the chain of communications only add cost to the community, increase response time, as well as the potential for miscommunications and mistakes. Furthermore, this procedure does not benefit public safety and has the potential to gravely impact patient care.

Question:

3. **In what way would the hospital be unable to comply with 42 U.S.C. § 1395dd(c)(2) if it were to call 911 for an emergency transfer?**

Answer:

Under the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, a hospital may not transfer an individual who arrives at its emergency department to another hospital unless the transfer is "appropriate." 42 U.S.C. § 1395dd(c)(2). Pursuant to 42 U.S.C. § 1395dd(c)(2)(D), a transfer is "appropriate" only where it "is effected through qualified personnel and transportation equipment . . . including the use of necessary and medically appropriate life support measures during the transfer . . . ." Failure to ensure that a transfer is "appropriate" within the meaning of EMTALA, may subject the hospital and the treating physician to civil penalties, and repeated violations could result in exclusion from state and federal healthcare programs. *See* 42 U.S.C. § 1395dd(d).

Under DPH's broad interpretation of the Declaratory Ruling, L+M will be required to dial 911 in order to transfer urgent, emergent and critical care patients to other hospitals from its emergency department. Although it is a sponsor hospital, L+M does not have the authority to dictate the manner in which a 911 dispatcher responds. In particular, if L+M dials 911 and asks for a mobile intensive care ("MIC") unit to provide ground transportation, L+M will receive a BL ambulance which it must supplement with L+M paramedics and other staff, not a provider that is already equipped with clinically appropriate equipment and personnel. If the local EMS provider is unavailable, L+M will receive a MIC PSAR from another community, selected by the 911 dispatcher in accordance with local EMS policies and protocols. L+M will not even know in advance which provider will arrive, let alone be able to ensure that the provider's personnel and

equipment are "appropriate" under EMTALA. If L+M must call 911 for all urgent, emergent, and critical care inter-hospital transfers, including transfers from its ED department, it will be unable to perform its duty under EMTALA to ensure that the ED transfers are "appropriate."

Question:

4. **Page 360 of Exhibit A states that the New London Fire Department Ambulance will be used if other transportation is unavailable and transportation must occur immediately. Is a distinction being made between "immediately" and "emergency"?**

Answer:

The words "emergent" and "immediately" in the L+M Guideline for Emergent Transportation of Elective PCI Patient Protocol do not have the same meaning as the term "emergency" as it is defined in the Declaratory Ruling. "Emergent" and "immediate" mean within the industry standard of ninety (90) to one hundred twenty (120) minutes from the initial decision to transport elective angioplasty patients to initiating surgery at the receiving surgical center. These patients are stabilized at L+M and ready to be transported to Yale.

Question:

5. **Page 32 of the Declaratory Ruling concludes that, in an emergency situation, a provider is required to forward an emergency call to the 911 system if it has been contacted outside of the 911 system. Given this conclusion, explain in what way(s) contacting the provider directly, as instructed in Lawrence & Memorial Hospital's guidelines, results in a decreased response time by the provider given the provider must forward the call to the 911 system.**

Answer:

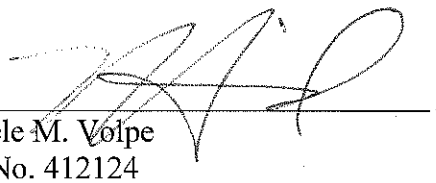
The Declaratory Ruling concludes that providers who receive emergency ***prehospital*** calls from members of the general public, including long term care facilities, must transfer them into the 911 system. It does not require first responder providers to contact 911 when they receive calls from hospitals to arrange interhospital transfers of stable patients. These calls are to move patients *within* hospitals, and are not "emergencies," as that word is defined in the Declaratory Ruling.

Upon information and belief, providers of inter-hospital transportation do not forward requests for inter-hospital transfers to the 911 system because they are not "emergency" calls for the transportation of patients *into* the hospital system, which is the purpose of the 911 system. As Gregory B. Allard, Vice President of American Ambulance, Inc. explains in his letter, which is attached to the Pre-filed Testimony of Dr. Cambi, it is common practice within the medical transport industry for providers to dispatch ambulances directly to hospitals. In fact, the Lifestar helicopter is licensed by OCHA to directly respond to patient transfer calls from hospitals.

V. Conclusion

The Department of Public Health's requirement that hospitals dial 911 will set policy which will ultimately create inferior standards in the community than that which exist today. It will have grave ramifications for local fire and police departments and hospitals. It will collapse the 911 system, create hardships for resources in cities and towns, and usurp the medical judgment of sponsor hospitals and staff. Finally and most importantly, it will have an adverse impact on patient care.

Respectfully Submitted,



By:_____
Michele M. Volpe
Juris No. 412124
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor, New Haven, CT 06511
Tel. No. (203) 777-5800
Fax No. (203) 777-5806

Exhibit A

LAWRENCE + MEMORIAL HOSPITAL

Title: Patient transfer to higher level of care guidelines	Reference Number:
File Location: Departmental	Issuing Department: Cath lab
Latest Review/Revision Date: 5-12	Original Date: 5-12
Endorsing Departments/Committees/Dates: Click here to enter text.	
Authorizing Signature/Title/Date: Medical Director, Angioplasty 5/31/12 Date Director, Patient care Services 5/31/12 Date	

PURPOSE: To provide guidelines for when the need arises for emergent transportation for a PCI patient from the Cardiac Catheterization lab.

POLICY

PROCEDURE:
The Cardiothoracic Surgery Section of the YNHH Department of Surgery will provide surgical backup to the elective PCI program at Lawrence + Memorial Hospital (L+M) as described below:

1. A CT Surgeon is on-call 24/7 to arrange for patient transfers through the Y-Access system and to receive the patient at YNHH.
2. All YNHH on-call CT Surgeons are privileged to provide CABG or other procedures expected as a result of complications associated with performing elective PCI at Lawrence & Memorial Hospital.
3. YNHH maintains one operating room open every day for emergency transfers that is CT Surgery capable. The on-call CT Surgeon remains in-house during the hours of 7:30am through 4:00pm, Monday through Friday to accommodate the Lawrence & Memorial elective PCI schedule.
4. The receiving surgeon and team obtain consent for surgery from patient or surrogate.
5. The Yale-New Haven Heart & Vascular Center agrees that L+ M may represent to patients that YNHVC provides surgical backup to elective PCI in its patient consent process.
6. YNHVC and L+M maintain computer systems interface or direct access to L+M systems for the YNHVC receiving surgeon to review real-time images and hemodynamic data, as well as audio and video images for consulting on treatment options and transfer decisions.

7. L+M Hospital employ the Yale-New Haven Hospital Y-Access transfer system to expedite the process of surgical consultation and transfer.
8. All other provisions of the Transfer Agreement will remain in effect for heart and vascular patients
9. When choosing the appropriate form of transportation, the patient's stability and equipment needs is assessed and relayed to the proposed transportation team. Patients requiring a Balloon Pump during transport require air medical transport or a nurse to accompany the patient if ground transport does not have the appropriate staff to monitor the pump.
10. In the event air medical transport is preferred but unavailable due to weather, staff should inquire if the team is available to provide the trip by ground.

Below is the transport option in order of use:

1. Lifestar (Air Medical) transportation – Crew configuration will consist of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
2. Lifestar (Ground) transportation – Crew configuration will consist of an American Ambulance EMT and a second American Technician which may be an EMT or Paramedic and the Lifestar Crew consisting of a Critical Care Nurse/Paramedic and a Respiratory Therapist/EMS certified Individual.
3. American Ambulance (Ground) transportation - Crew configuration will consist of an American Ambulance EMT and a Paramedic.

The following option must only be used if other transportation is unavailable and transportation must occur immediately.

4. New London Fire Department Ambulance (Ground) transportation - Crew configuration will consist of 2 Firefighter/EMT's and a Lawrence & Memorial Hospital Paramedic.

Contact Information

Lifestar – (800)437-4378
American Ambulance – (860)886-1463
New London Fire Department – (860)442-4444/911

PROTOCOL

Reference:
1. Hospital L+M Policy Patient transfer to Higher level of care facility.
2. YNHH transfer agreement

Archive Dates
Reviewed Date:
Revised: 5/12
Supersedes:

Exhibit B

Policy: Emergency Transfer Protocol to Cardiac Surgery Center

LAWRENCE & MEMORIAL HOSPITAL

Effective Date: 10/04
Reviewed:
Revised:
Supersedes: New

Section: Pt Care Services/Rights
Subsection: Medical Services/Invasive Procedures
Resource:Cath lab

Purpose: To ensure a safe and expedient transfer in the event that any patient is in need of emergent transfer to a tertiary center for immediate Cardiac Surgery or other interventional procedures.

If Cardiologist determines the need for an immediate transfer:

1. Physician will make arrangements with physician receiving the patient and assuming responsibility at the new hospital. Discusses clinical information with receiving physicians/surgeon. Digital images are transmitted as appropriate
2. Physician will have obtained consent of patient and/or family for transfer.
3. Patient shall not be transferred until the receiving hospital has consented to accept the patient.
4. Reason for transfer should be documented in chart.
5. Members of the Cath lab staff as appropriate initiates the following calls:
    a. To Receiving unit at receiving hospital center to give telephone report
    b. To Admissions /registration staff at receiving center to get a bed assignment
    c. Contact appropriate EMS system to activate immediate transport (preferable by air). Give them the receiving facility name/unit and physician for the patient and brief report.
    d. For ground transport, contact appropriate pre arranged critical care transport ambulance on standby during primary angioplasty procedures.
    e. For helicopter transport, contact LIFE Star center at 1 800 437-4378 and L&M security.
6. Sheathes and balloon pumps are sewn into place.
7. Level of care is determined and appropriate plans are made with transport team to ensure patients clinical safety.
8. Patient is prepared for transport and transferred to transport vehicle/helicopter.
9. All care documentation is copied including copy of cath images (per Cath Lab Policy: Transportation Internal-External) and is sent with patient including transfer orders and Inter-facility patient transfer form.
10. Interventional cardiologist may accompany unstable patient, or stays in contact with transferring team until patient is received at cardiac surgical center. Nurse may accompany patient with IABP (See related IABP policy). Transport is via Critical care transport ambulance with paramedic service or Helicopter service.

References: Sinclair, McNamara and Wharton, Critical Pathways in Cardiology: Vol 1. No 2, Lippincott Williams & Wilkins, 2002.

Approved By: _____ Date: 10-25-04

Mark Fiengo, DO
Director, Angioplasty service

Approved By: _____ Date: 10/26/04

Brian Ehrlich, MD
Medical Director, Cath lab

Approved By: J Bonardi RN Date: 10/25/04

Francis Bonardi, RN
Vice President, Patient Care Services

Exhibit C

12/10/12 L+M transfer Process
L+M Transfer Protocol with DPH 911 Policy
Cardiologists determines need for critical care transfer
1. Patient is stabilized and prepared for transport
2. Cardiologist contacts admitting physician at receiving hospital to arrange transfer
Cath lab staff calls 911 dispatcher to request transport
Patient disposition communicated directly to 911 dispatch
911 dispatches NLFD (New London PSAP) 1 of 2 NLFD BLS transport units and fire engine dispatched to L+M
NLFD BLS transport arrives at L+M along with fire engine
Cardiologist identifies most appropriate mode of transport (air or ground) and communicates such to NLFD BLS response
911 dispatcher contacts air medical transport or ground transport.
Is air medical transport available?
Yes
No
Cath lab staff call air medical transport to give key information re transport needs
Air medical transport arrives and transferred from cath lab to transport provider
Air medical transport transports patient to receiving hospital
NLFD BLS returns to base (Fire engine)
Transfer process stops
NLFD ambulance transports patient to receiving hospital EMS sources from neighboring towns to provide coverage
L+M Paramedic, L+M nurse and other L+M resources accompanies patient during transport
Leaves L+M + Pars area without critical care coverage for at least 2 hours
NLFD ambulance transport patient to receiving hospital
NLFD BLS returns to base (Fire engine)
Transfer process stops
L+M Industry standard Transfer Protocol
Cardiologists determines need for critical care transfer
1. Patient is stabilized and prepared for transport
2. Cardiologist contacts admitting physician at receiving hospital to arrange transfer
Cardiologist identifies most appropriate mode of transport (air or ground) and communicates such to cath lab staff
Cath lab staff contacts air medical transport or commercial or ground ambulance to initiate patient transport.
Patient disposition + Medical history communicated directly to preferred transport provider
Air medical transport or commercial ground ambulance arrives at L+M.
Patient transferred from cath lab to transport provider
Air medical transport or commercial ground ambulance transports patient to receiving hospital
Transfer process stops

Exhibit D

JIM PARKER: Thank you. Senator Harris, members of the Public Health Committee, thank you for the opportunity to testify regarding House Bill 6599, An Act Concerning Public Safety.

My name's Jim Parker, I'm an emergency medical physician at Connecticut Children's Medical Center. I serve as the chair for Connecticut EMS for Children, and I'm also the medical director of the Connecticut Children's Critical Care Transport Team.

Connecticut Children's needs to operate a critical care transport team to bring critically ill or injured children/newborns from community hospitals to our facility when they need tertiary care services that are not available at a community facility.

Current Office of Emergency Medical Services regulations require that every individual providing care to a patient in an ambulance must be licensed actually as an EMT. This regulation prevents our team of trained pediatric critical care clinicians from providing the specialized services that these newborns and children need.

Connecticut Children's is not -- currently not operating this service because of potential liability for our clinicians' licenses. As a result, children who need our transport services do not have access to them.

I'm asking today that you amend House Bill 6599 to include a section that defines neonatal and pediatric specialty care transport, the verbiage of which is worked out on reverse of the sheet you've been provided.

The language should promote patient safety by requiring the use of a basic level ambulance

with a licensed EMT on board. The language should also recognize that critically ill neonates and children need ongoing care that must be furnished by certified or licensed health professionals who specialize in neonatology or pediatrics.

Current standards established by the American Heart Association and the American Academy of Pediatrics define the qualifications for members of the neonatal and pediatric transport team. It is important that this amendment be written so that it will be effective upon passage, since Connecticut Children's is not currently offering critical care transport services pending the statutory change.

When enacted, this amendment will allow Connecticut Children's to resume operation of its critical care transport service, providing our patients with access to the specialized healthcare transport services they need in a safe environment.

I urge you to support amending House Bill 6599 to include a definition of neonatal and pediatric specialty care transports. Thank you for your time and your attention to this matter.

SENATOR HARRIS: Thank you, Doctor. Any questions?

Now, this is a piece, just for clarification, that we had in another bill, right, and your request is that we put it in this particular bill?

JIM PARKER: This is a piece that, to my knowledge, was being proposed in another bill but felt that it -- it was felt that it's best to go

through the Department of Public Health than through us, within this.

SENATOR HARRIS: And is the reason for that because time is of the essence to get a bill passed so you can resume your services?

JIM PARKER: Absolutely. I speak specifically to Connecticut Children's, but there are three services that are impacted by this in the state. Yale runs a pediatric specialty transport service, and John Dempsey runs a neonatal specialty transport service.

Technically, any transports currently occurring with those services are operating outside their scope of practice and putting though clinicians at risk.

SENATOR HARRIS: Because there is no EMT aboard during those transports?

JIM PARKER: It's not having the EMT aboard. It's actually every person providing care must carry prehospital credentials.

SENATOR HARRIS: So everybody, and that's the problem.

Okay. and -- I thought I had another question, but...

Have you tried to work with the Department of Public Health to be able to accomplish this goal without the need for legislation, the need for expedited legislation?

JIM PARKER: We've had meetings with the Department of Public Health and Office of EMS over the last six to eight months, with an ongoing discussion of this issue, and the feeling both through them and in discussion with the

00613

assistant AG was that this could not be something that was going to be fixed without changing the statute.

SENATOR HARRIS: Thank you very much. Any -- Representative Esty.

REP. ESTY: Thank you. And thank you, Dr. Parker. What -- do you know what the origin, then, was of the Office of Emergency Medical Services' decision to put this in place? Presumably, this is -- this was language that was put in there.

What was the rationale and were you consulted at that time? Were any of the neonates were consulted in did they talk to the Academy of Pediatrics, or how did they -- how did this get through, causing what would clearly not seem to make any sense from a layperson's point of view, even less from a clinician's point of view?

JIM PARKER: From my understanding, this is a statute that's long been on the books, and probably preceded the American Academy of Pediatrics' development of recommendations with regard to pediatric specialty transport.

It is a regulation that more -- is aimed toward the level of care necessary for operating an ambulance, and as these niches have grown and as these subspecialties have developed, the regulation has not been acknowledged or not been amended to change with those developments.

REP. ESTY: So this is artifact of the field having developed and these regs have not been updated, and I presume lawyers took a look at them and said you can't --

JIM PARKER: That's -- that's my understanding.

REP. ESTY: It's always back to the lawyers who look at it.

JIM PARKER: Our lawyers took a look at it, but it was to the point that we asked the Department of Public Health to take it to the Assistant Attorney General who did provide us an interpretation that, yes, Department of Public Health was interpreting that regulation correctly.

REP. ESTY: So you would be outside of the scope of the practice and therefore be put in --

JIM PARKER: And therefore each person putting their license at risk.

REP. ESTY: All right. Thank you very much.

SENATOR HARRIS: Thank you, Doctor.

Next we have Gary O'Connor -- excuse me, Greg Allard. Gary O'Connor, I'm sorry, followed by Greg Allard.

GARY O'CONNOR: Thank you, Mr. Chairman.

Good morning. Actually, it's afternoon now. Time flies. My name is Gary O'Connor. I'm a partner with the law firm of Pepe & Hazard, and I'm here on behalf of the Association of Commercial Ambulance Providers. We call it ACAP. And I'd like to thank you for the opportunity to speak in support of Raised Bill 6599.

This bill in its present form addresses a very important patient safety issue in the State of Connecticut, namely, the transportation of patients who are confined to stretchers.

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

PRE-FILED TESTIMONY
OF LAWRENCE & MEMORIAL HOSPITAL
BY BRIAN CAMBI, MD, FACC, FSCAI

Good Morning Hearing Officer Hansted and members of the Department of Public Health. My name is Brian Cambi, MD, FACC, FSCAI, and I am the Medical Director of the Primary Angioplasty Program at Lawrence + Memorial Hospital ("L+M").[1] I thank you for this opportunity to appear before you today. As stated in our brief, L+M's protocol for inter-hospital transfers of elective angioplasty patients who develop a procedurally related complication that requires surgical intervention (the "Protocol") is a clinically appropriate transfer protocol that is typical in the industry, in that it preserves the treating physician's discretion to select the most medically appropriate means of transportation for the patient, based on the recommendations of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

A. L+M's Transfer Policy Comports with the Medical Community's Recommendations for Elective Angioplasty Programs.

In the early years, patients undergoing elective angioplasty developed procedural complications that required coronary artery bypass grafting (often on the same day) at rates quoted anywhere from 6-10%. Over the years, advances in technology and adjunctive medical therapy in combination with operator experience has led to a dramatic reduction in

[1] A copy of my Curriculum Vitae is attached hereto as Exhibit 1.

complications. Fortunately, the rate of procedural complications rendering a patient critically ill necessitating the need for same day surgery is rare with numbers in the literature described as low as 0.3%.With these changes and the release of recent studies in the medical literature, it is clear that we can now provide elective angioplasty services to carefully-selected low risk patients in a safe way that enhances the delivery of medical services to our local community. The rationale behind our desire for L+M to have such a program is outlined extensively in our application.

An important part of such a program is developing a sound policy for the transfer of an elective angioplasty patient in the rare event he or she develops a procedurally related complication that requires surgical intervention. The American College of Cardiology (ACC), as well as the American Heart Association (AHA) and the Society for Cardiovascular Angiography and Interventions (SCAI), has recommended in their consensus statement[2] that elective angioplasty programs without on-site surgical backup be able to acquire transportation services for critically ill patients within 20 minutes. Furthermore, the consensus statement states that these transportation services should be equipped with appropriately trained medical personnel and equipment such as intra-aortic balloon pump capability and mechanical ventilator support. L+M's transfer policy satisfies these requirements by selecting Lifestar and American ambulance as the preferred providers in the rare event that an elective angioplasty patient is transferred to Yale.

[2] A copy of the consensus statement can be found in L+M's CON application, at p. 35 (Table H).

B. Lifestar and American are the Preferred Providers Because Their Vehicles and Transport Teams are Pre-equipped to Handle Patients with Complex Medical Needs.

When patients develop a procedurally related complication and become critically ill in the L+M catheterization laboratory, they receive multiple interventions to stabilize their acute de-compensation such as mechanical ventilator support, intra-aortic balloon pump implantation, and a variety of inotropic and vasopressor medications designed to enhance and maintain cardiovascular function. Typically, this results in a stabilized, but critically ill patient that requires urgent transfer to a tertiary level facility to receive advanced level medical care not provided at our community hospital. These are not pre-hospital patients with an emergency that requires conventional 911 services to bring them to the nearest medical facility. Rather, these are patients who have a stabilized medical condition but remain critically ill and require sophisticated transport to a tertiary facility for advanced care. Relying on highly trained, experienced medical personnel who have the appropriate equipment and manpower to handle these transfers is the most prudent course of action to ensure the best outcome of our critically ill patients. I believe, as the attending interventional cardiologist and sponsoring institution, it is well within our scope of practice to make the most appropriate medical decision to ensure the highest quality, safest, and most expeditious mechanism of transport of these patients to our collaborating tertiary facility. To take that decision away from the attending interventional cardiologist and leave it in the hands of a 911 dispatcher jeopardizes patient safety.

It is my opinion that Lifestar Air Transport or American Ambulance both have the capability to provide not only qualified paramedics but personnel with years of experience in transferring these unique critically ill patients with complex intravenous medications as well as

their mechanical life support systems.[3] Local basic level EMS services are ill-equipped to deal with the challenges of these patients. If the New London Fire Department, which maintains a basic level ambulance, were to transfer our critically ill patients, a safe transfer may be possible, but it will most definitely be much more difficult to arrange. L+M would need to provide multiple staff like paramedics, nursing, and/or respiratory therapists to ensure the safe transport of patients. Although we support this process as a last resort in our transfer policy, following this procedure for all inter-facility transfers will strip our community and L+M of critical clinical resources for an extended period of time which is not ideal.

The most efficient mechanism for these transports is to request Lifestar Air Transport or ground transport through Lifestar or American Ambulance via direct contact with these providers. Direct contact expedites the relay of critical patient-related information to the provider responsible for the transport. A call to 911 that initiates a response by the PSAR to travel to the hospital prior to activating Lifestar or American Ambulance results in unnecessary waiting and delay, potential for miscommunication due to multiple patient information hand-offs, and can ultimately harm patient safety.

We maintain that L+M's transfer protocol complies with the 2003 Declaratory Ruling, in that it preserves the clinician's clinical judgment regarding when 911 should be activated. If the Department of Public Health disagrees and maintains that 911 must be activated each time an elective angioplasty patient is transferred to Yale, I respectfully submit that the ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving long term care facilities and members of the public, and the EMS providers who

[3] American Ambulance, Inc. Vice President Gregory B. Allard describes the sophisticated equipment maintained by his company, as well as the higher level of training provided to its personnel. *See* Letter by Gregory B. Allard (attached hereto as Exhibit 2).

respond to their calls. If L+M is robbed of its discretion to determine whether 911 is activated and/or the most appropriate mode of transportation for patients traveling from one hospital to another hospital , I strongly feel a quality and safety issue will emerge putting our patients at risk, not just in the elective angioplasty program, but in the emergency department and all other hospital specialties. There is no question local EMS is an important part of the emergency services system in our region. As Ron Kersey explains in his statement, keeping local EMS local is as important as getting our critically ill patients safely to a tertiary care facility for the advanced medical care they require.

I respectfully submit that L&M's Transfer Protocol meets all of the quality and clinically appropriate industry standards. We urge the Department of Public Health, Division of Office of Health Care Access to approve our CON application.

[SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The undersigned witness hereby submits all of the above testimony as his own testimony, and will adopt it at the hearing.

12-6-12

Brian Cambi, M.D., FACC, FSCAI

Exhibit 1

Brian Christopher Cambi, MD FACC FSCAI

2 Rocco Drive
East Lyme, CT 06333
860-691-0619 (Home)
203-623-3988 (Cell)
203-370-2177 (Beeper)
brian.cambi@yale.edu

EMPLOYMENT

2008 - Assistant Professor
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

- ***Director*** – Primary Angioplasty Program at Lawrence and Memorial Hospital
- ***Director*** – Stress Echocardiography at Lawrence and Memorial Hospital

2007-2008 Attending Cardiologist
West Haven Veteran's Administration Hospital

2007-2008 Clinical Instructor
Yale University School of Medicine, Department of Internal Medicine, Section of Cardiology

PROFESSIONAL TRAINING

2006-2007 Advanced Fellowship in Interventional Cardiology.
Yale University School of Medicine, New Haven, CT

2005-2006 Advanced Fellowship in Non-invasive Cardiac Imaging.
Yale University School of Medicine, New Haven, CT

- Level II training in echocardiography
- Level II training in nuclear cardiology

2003-2005 Clinical Cardiology Fellowship. Yale University School of Medicine.

2002-2003 Chief Resident, Internal Medicine. Yale University School of Medicine.

1999-2002 Intern and Resident, Internal Medicine. Yale University School of Medicine.

EDUCATION

1995-1999 Doctor of Medicine, State University of New York at Buffalo, School of Medicine and Biomedical Sciences, Buffalo, NY.
- ***Summa Cum Laude***

1991-1995 Bachelor of Science, Biology. The College of William and Mary, Williamsburg, VA.
- ***Magna Cum Laude***

LICENSURE AND CERTIFICATION

2007 Board certified - Interventional Cardiology
2006 Board certified - Cardiology
2006 Board certified - Nuclear Cardiology
2006 Board certified - Echocardiography
2002 Board certified - Diplomate, American Board of Internal Medicine.

ACADEMIC ACTIVITIES

2006 Speaker, Grand Rounds, Cardiology. Yale University School of Medicine.
- "CT Angiography: A Novel Clinical Application"

2005-2006 Research: CT Angiography in the Non-Invasive Detection of Revascularizable Cardiomyopathy.

2002-2003 Director, Morbidity and Mortality conference. Yale University School of Medicine, Section of Internal Medicine.

HONORS AND AWARDS

1999 **The John Watson Award in Medicine.** SUNY at Buffalo School of Medicine.
- Outstanding achievement and leadership in Internal Medicine

1999 **Association of Pathology Chairs Award.** SUNY at Buffalo School of Medicine.
- Academic excellence in Pathology

1998 **Alpha Omega Alpha Honor Medical Society.** SUNY at Buffalo School of Medicine.

1997 **James Gibson Anatomical Honor Society.** SUNY at Buffalo School of Medicine.
- Academic excellence in Gross Anatomy

1995 **Phi Sigma National Honor Society.** The College of William and Mary.
- Academic excellence in biology

REFERENCES – *available on request*

Exhibit 2

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

December 7, 2012

Hearing Officer Kevin Hansted
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Dear Mr. Hansted,

The intent of this letter is to provide details about our ambulances, in particular the Advanced Life Support (ALS) equipment used by our Paramedics, and the training our Paramedics receive, as well as to point out that American Ambulance Service, Inc. (AASI) is not a PSAR for the Lawrence + Memorial service area.

AASI is supportive of Lawrence + Memorial obtaining approval to perform non-emergent angioplasty even though this approval will have a negative financial impact on our business. By providing an elective angioplasty service to residents of Eastern Connecticut this approval will reduce the number of ALS transports that we currently do out of Lawrence + Memorial. We support this initiative because having non-emergent angioplasty available in Eastern Connecticut is in the best interest of the people residing in and passing through Eastern Connecticut.

AASI currently has an ambulance fleet of 24 and they all exceed the basic minimum vehicle standards set forth in the CT EMS Statutes. Our basic ambulances are built to our specifications and are built on a chassis of our choice. Within those specifications are several safety minded items that exceed the basic requirements. We also have Epi-Pens, AED's, and baby aspirin which are not standard equipment.

We currently have 11 sets of ALS gear. So 11 of those 24 ambulances could be operating at the ALS level on any given day at any given time depending on Paramedics being scheduled, without any impact whatsoever on the communities we serve as a first responder PSAR.

AMERICAN AMBULANCE SERVICE, INC.

ONE AMERICAN WAY
NORWICH, CONNECTICUT 06360
860.886.1463 (V)
860.887.1138 (F)
americanamb.com

Our ALS gear includes a ZOLL CCT M-series Cardiac Monitor, an ALS equipment bag, ALS equipment restock bag, portable ventilators, and a small IGLOO cooler. Our Cardiac Monitors have the following functions; biphasic defibrillator, external pacing, non-invasive vital sign monitoring including, SpO2, EtCO2, NIBP, and fully interpretive 12-lead ECG. The ALS equipment bag has several items in it. The first is our ALS medications that can be given, orally, intramuscularly, intravenously. Some of the medications we carry are controlled substances that are used for sedation and pain management. Another thing we have is our intravenous supplies such as needles, tubing, fluids, and blood glucose monitor. Another route of infusion is intraosseous and we carry a specific device called and EZ-IO drill. It is a cordless drill used to bore a hole in a patient's bone. We also carry advanced airway equipment such as LMAs, CPAP devices, endotracheal tubes and laryngoscopes. Our portable ventilator is used during transports when a patient is sedated to a point where they can't control their own airway. The IGLOO cooler contains intravenous fluids that are temperature controlled and are used to induce a hypothermic state.

The paramedics are trained to use a lot of this equipment in school but upon being hired they need site specific training based on the equipment used. Our paramedics need to learn things such as our portable ventilator, our cardiac monitors, BGL monitors, CPAP device. Our sponsor hospital requires all paramedics have ACLS, PALS, PHTLS, and CPR training which is not required at some other sponsor hospitals. They also undergo continuing education monthly at our sponsor hospital. The continuing education topics vary from month to month. Annually the sponsor hospital requires all of them to go through a skills training session where they review things such as infusion pumps, medications, STEMI protocols, 12-and lead ECG recognition. Also reviewed routinely are the guidelines set forth by our sponsor hospital. Some examples of guidelines include induced hypothermia, STEMI, and Stroke.

It is usual and customary practice for a hospital such as Lawrence + Memorial to have a working relationship with an organization such as AASI for emergent and non-emergent ALS inter-facility transfers. These transfers are performed by our paramedics that have been given medical control by a sponsor hospital. The sponsor hospital physician has determined that these paramedics have undergone enough training and have the skill set required to perform inter-facility transfers of medically complex patients. Transfer requests from all area hospitals come directly into our dispatch center via a seven digit telephone line. Our highly trained dispatchers understand the urgency some of these requests may need. We never pass on any of these ALS transfer requests to the local PSAR service as they are not equipped nor are they trained to perform this level of service. Our service is equipped, trained, and has enough resources to do this. A local 911 PSAR service is limited, usually 1 or 2

AMERICAN AMBULANCE SERVICE, INC.

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NORWICH, CONNECTICUT 06360
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860.887.1138 (F)
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ambulances, in its resources. They are obligated by law to be available to respond to the emergency requests within the town boundaries. That is their primary function. Being utilized to perform transfers like this is again not within their capabilities and it strips whatever emergency resources from their town.

I hope that the information obtained within this letter is useful and in the event it has led to more questions please feel free to contact me.

Respectfully,

Gregory B. Allard, Vice President

Dedicated, Professional People Committed to Excellence, Caring for You.

STATE OF CONNECTICUT : DOCKET NO. 12-31768-CON
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 10, 2012

PRE-FILED TESTIMONY
OF LAWRENCE & MEMORIAL HOSPITAL
BY RON KERSEY

Good Morning Hearing Officer Hansted and members of the Department of Public Health. My name is Ron Kersey and I am E.M.S. Coordinator at Lawrence + Memorial Hospital ("L+M").[1] I thank you for this opportunity to appear before you today. As stated in our brief, L+M's protocol for inter-hospital transfers of elective angioplasty patients who develop a procedurally related complication that requires surgical intervention (the "Protocol") is a clinically appropriate transfer protocol that is typical in the industry, in that it preserves the treating physician's discretion to select the most medically appropriate means of transportation for the patient, based on the recommendations of the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography and Interventions.

The protocol that L+M uses for critical care inter-hospital transfer of angioplasty patients is a carefully organized approach to providing our patients with the highest quality, most appropriate mode of transportation with minimal impact to the community EMS system. L+M's policy for the inter-hospital transfer of a patient for advanced medical care represents the industry standard process for ensuring safe patient transport in the most efficient and timely manner. Dr. Cambi highlighted the clinical and medical benefits of our transfer protocol. I

[1] A copy of my Curriculum Vitae is attached hereto as Exhibit 1.

would like to discuss the implications of utilizing 911 for L+M's critical care transfers and the negative impact that process will have on patients, our local EMS system and the community.

If L+M were to call 911 for critical care transportation of patients to Yale or another tertiary care facility, it will place significant strain on the resources of our local EMS system. Dr. Cambi noted the infrequency of critical care transfers expected with the proposed elective angioplasty program; however, if the use of 911 for inter-facility transports were implemented hospital-wide, it will cripple our local resources. In Fiscal Year 2012, 450 patients were transferred to Yale alone from L+M's emergency department for emergent and urgent issues. This total climbs significantly when you consider tertiary facilities such as Hartford Hospital, as well as specialized care facilities such as Connecticut Children's. As New London Fire Department Deputy Chief Henry Kydd explains in his letter[2], the local EMS system cannot absorb this added responsibility nor is it the best equipped provider to do so.

The PSAR for the town of New London is the New London Fire Department (NLFD). The NLFD is equipped with two basic level support (BLS) transport units to handle all community 911 responses. As outlined in Deputy Chief Kydd's letter, the NLFD is not prepared clinically to handle the complex needs of the patients requiring critical care transport from L+M to a tertiary care facility. The NLFD is staffed with emergency medical technicians (EMTs) who are trained to provide basic medical care until the patient can be transferred to a hospital for advanced medical care. The skill level of some of the first responder EMTs is not specialized to manage cardiac patients requiring transfer to Yale. Deputy Chief Kydd supports L+M's plan for critical care transportation of elective angioplasty patients and agrees with the utilization of NLFD only as a last resort should the providers outlined in L+M's protocol not be unavailable.

[2] New London Fire Department Deputy Chief Henry Kydd's letter is attached hereto as Exhibit 2.

Utilizing NLFD for critical care transport to Yale will take one of two BLS units completely out of the community for an extended period of time stripping local residents of their 911 resource. In order to accommodate this, New London will be forced to rely on neighboring communities to fill in 911 calls in their area while the town ambulance is providing inter-facility transports, hence creating a potential ripple effect among an extended service area of first responder providers.

Activating 911 to dispatch NLFD means an L+M paramedic will need to accompany the NLFD EMT staff in the transport to Yale, and another local resource will be unavailable to the community for an extended period of time. A single transport, on average, will require the local ambulance and paramedic to be out of their primary response area for greater than 2 hours at a time. In addition, depending on the needs of the patient, an L+M nurse and respiratory therapist may also need to accompany the patient to Yale further depleting L+M and the community of resources. If Lifestar and/or American Ambulance were utilized rather than local EMS, L+M is able to maintain its much needed resources to support other hospital patients. Unlike local EMS, the providers in L+M's protocol have been vetted and have equipped their ambulances specifically to handle these calls and have given their crews additional education to provide the complex care required for these patients.

L+M supports the legal argument presented to this Department that the 2003 Declaratory Ruling does not apply to the inter-hospital transfer process. As L+M notes in its brief, the Ruling fails to mention inter-hospital transports and solely comments on transports to acute care facilities from long term care facilities or private citizens. The Ruling deals exclusively with pre-hospital transfers and is in place to ensure timely access for the community to the services of an acute care facility such as L+M. Despite the merits of this Ruling, to broadly extend its

application to all transfers is a mistake. I do not know of a hospital in the state of Connecticut that accesses the 911 system to move a patient from one acute care facility to another, whether in an emergent, urgent, critical condition or otherwise. It is in the best interest of the patient that L+M and other acute care facilities in the state follow a procedure to work directly with transport providers.

It should be highlighted that L+M is the sponsor hospital for the town of New London and adjacent communities. As the sponsor hospital, L+M is involved in the system development of the local EMS system. As the responsible party, we are willing to prescribe a process in which other providers are contacted directly by acute care hospitals for inter-hospital transports and the 911 service is not utilized at all unless these providers are unavailable. As the sponsor hospital in our community, L+M has the authority to determine this course of action as outlined in the 2003 Declaratory Ruling.

We maintain that L+M's transfer protocol complies with the 2003 Declaratory Ruling, in that it preserves the clinician's clinical judgment regarding when 911 should be activated. If the Department of Public Health disagrees and maintains that 911 must be activated each time an elective angioplasty patient who develops a complication is transferred to Yale, I respectfully submit that the ruling must be applied in accordance with its terms, so that it regulates prehospital emergency incidents involving long term care facilities and members of the public, and the EMS providers who respond to their calls. If L+M is robbed of its discretion to determine whether 911 is activated and/or the most appropriate mode of transportation for patients traveling from one hospital to another hospital, I strongly feel a quality and safety issue will emerge putting our patients at risk, not just in the elective angioplasty program, but in the emergency department and all other hospital specialties. There is no question local EMS is an

important part of the emergency services system in our region. As explained above, keeping local EMS local is as important as getting our critically ill patients safely to a tertiary care facility for the advanced medical care they require.

I respectfully submit that L&M's Transfer Protocol meets all of the quality and clinically appropriate industry standards. We urge the Department of Public Health, Division of Office of Health Care Access to approve our CON application.

[SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The undersigned witness hereby submits all of the above testimony as his own testimony, and will adopt it at the hearing.

12-6-12

Ron Kersey

Exhibit 1

Ronald Kersey
117 Riverview Avenue
New London, CT 06320
(860)442-8737
rkersey@lmhosp.org

==========

Areas of Effectiveness: Advanced emergency medical treatment, firefighting, emergency response and public preparedness, leadership, drill, exercise, and simulation design, business management, human body system knowledge, medical education, communication and public speaking, customer service skills.

Education

1989 – present **Three Rivers Community College**
574 New London Turnpike, Norwich, CT 06360
Currently pursuing an Associates in Liberal Arts and Science

02/93 – 05/93 **Capital Community College**
950 Main Street, Hartford CT 06103
Six credits in EMT-Paramedic III obtained

Career Experience

01/11 – present **Simulation Laboratory Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Coordinate the development of clinical simulation center
- Develop computer clinical simulation programs and scenarios
- Train clinical simulation operators
- Conduct clinical simulation for all levels of healthcare providers
- Troubleshoot and repair simulation equipment and manikins
- Manage American Heart Association Community Training Center Staff and activities

- Provide educational debriefing sessions for simulations

01/92 – present **Emergency Management Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Develop hospital emergency response plan
- Respond to and mitigate emergency situations
- Train staff in emergency preparedness and response
- Conduct emergency response drills and exercises
- Lead hospital through emergency events and situations
- Acquire grant funding to support emergency preparedness activities
- Perform radiological monitoring during nuclear contamination events
- Coordinate hospital emergency preparedness activities with the community

03/89 – present **EMS Coordinator**, Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Direct Community EMS system development and quality oversight
- Plan and perform EMS related training for community EMS services
- Provide administrative supervision for hospital paramedic program
- Develop annual budget and manage department expenses
- Train, hire, and council employees
- Coordinate hospital and EMS interaction
- Conduct advanced medical training classes for hospital and physician staff

03/88 – 03/89 **Chief Paramedic**, Lawrence & Memorial Hospital Paramedic program, 365 Montauk Avenue, New London, CT 06320

Responsibilities include:

- Provide advanced emergency medical treatment
- Oversee daily operations and employee supervision
- Manage fleet maintenance
- Provide employee scheduling
- Employee counseling and coaching
- Conduct employee performance reviews
- Promote positive community relations

06/10 – present **Emergency Medical Technician**, Town of Ledyard, 1 Fairway Drive, Ledyard, CT 06339

Responsibilities Include:

- Respond to emergency calls
- Operate emergency vehicles
- Administer emergency medical treatment
- Conduct public education and awareness classes
- Perform daily checks and maintenance of emergency equipment
- Provide electronic patient care documentation report for each patient's medical record

04/08 – present **Emergency Medical Service – Instructor**, Emergency Training Services Incorporated, 45 Spring valley Road, Mystic, CT 06355

Responsibilities Include:

- Develop and Conduct EMS lectures
- Provide EMS skill training
- Train on proper use and maintenance of EMS equipment
- Manage classroom environment and activities
- Coach, remediate, and encourage student participation
- Manage class records

01/00 – 1/03 **Firefighter/Emergency Medical Technician**, Pinkerton's Incorporated, Pfizer New London location, 4330 Park Terrace Drive, Westlake Village, CA 91361

Responsibilities Include:

- Participate in emergency response activities

- Conduct site safety inspections
- Assist with facility security
- Monitor and maintain fire alarm and protection systems
- Train staff on fire suppression techniques

6/92 – 6/98 **Emergency Medical Technician**, Health Resources Incorporated Millstone Nuclear Power Facility 136 Berlin Rd. Cromwell, CT 06416

Responsibilities Include:

- Conduct air quality monitoring
- Provide safe work permit assessment and authorization
- Perform radiologic monitoring
- Manage hazardous materials events
- Respond to confined space rescue situations

10/81 – 3/88 **Paramedic/Associate Supervisors/Advanced Life Support Coordinator**, American Ambulance Service Inc. One American Way Norwich, CT 06360

Responsibilities Include:

- Provide advanced life support patient care
- Supervise daily staff activities
- Conduct public speaking events on the EMS system
- Coordinate advanced life support training

Volunteer Experience

06/92 – 01/94 **Firefighter/EMT**, New London Fire Department 89 Bank Street, New London, CT 06320

Responsibilities Include:

- Assist with fire ground activities
- Promote positive volunteer and career staff interactions

08/88 – present **Firefighter/EMT**, Goshen Fire Department, Shore Road, Waterford CT 06385

Responsibilities Include:

- Respond to marine emergencies
- Provide basic life support care

06/88 – present **Emergency Medical Technician**, Waterford Ambulance Association 89 Rope Ferry Road, Waterford CT 06385

Responsibilities Include:

- Administer emergency medical treatment
- Conduct public education and awareness classes
- Provide electronic patient care documentation report for each patient's medical record

06/88 – present **Firefighter/EMT**, Jordan Fire Company, 89 Rope Ferry Road, Waterford CT 06385

Responsibilities Include:

- Respond to emergency calls
- Mitigate hazardous materials incidents
- Maintain emergency equipment

References available upon request

Exhibit 2

CITY OF NEW LONDON
FIRE DEPARTMENT

Hearing Officer Kevin Hansted
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Lawrence + Memorial Hospital's Patient Transfer Protocol for Elective Angioplasty Patients

Dear Mr. Hansted:

The City of New London Fire Department ("NLFD") has reviewed and supports the Lawrence + Memorial Hospital plan for "Emergent Transportation of Elective Angioplasty Patients" (the "Protocol").

NLFD is the Primary Service Area Responder ("PSAR") for New London. We staff two BLS transport units with EMTs to handle community 911 responses and transport injured individuals to L+M Hospital. The EMTs are trained to provide basic medical care until the patient can be transferred to a hospital for advanced medical care. In addition, we utilize a paramedic intercept unit from L+M for all life and limb threatening emergencies. The NLFD is required to follow certain policies and procedures each time it is contacted by the local 911 dispatcher. In addition to the BLS ambulance, we dispatch a fire engine to the scene of the emergency for all life threatening problems. The fire fighters assess the situation and render basic first aid if the NLFD ambulance has not arrived. When the ambulance or paramedic intercept team arrive, they assess the severity of the emergency and call for additional EMS resources, such as the Lifestar air medical transport helicopter, if necessary. If L+M Hospital is required to go through the 911 system each time the hospital calls Lifestar, the fire engine and BLS ambulance will be dispatched to the hospital each time Lifestar is called, even though their services are not needed.

As identified in the Protocol, NLFD ambulances, supplemented by L+M paramedics and other staff, may at times be required to assist in the transportation of critically ill patients from Lawrence + Memorial to Yale New Haven Hospital. We understand, however, that in most instances other providers will perform this service. Those other providers are better equipped to handle the transfers because, unlike our EMTs, their staff have been given additional training to manage medically complex cardiac patients. In addition, if the NLFD is called upon to assist L+M with its 450+ urgent, emergent, and critical care patient transfers per year, it will draw resources away from the community for extended periods of time and cripple the local EMS system. The projected volume is well above the NLFD's capacity, and would require me to draw additional EMS resources away from neighboring communities to fill the gap for community 911 responses. To preserve the stability of New London's community EMS system, L+M

Ronald J. Samul, Sr., Fire Chief
289 Bank Street
New London, CT 06320-5521
(860) 447-5291 • FAX (860) 447-5293
Email: rsamul@ci.new-london.ct.us

CITY OF NEW LONDON
FIRE DEPARTMENT

and its medical staff should be permitted to determine the most appropriate mode of transportation for their patients, which will most often be via air medical transport or another provider that is specially equipped to handle inter-facility critical care transports.

In the event that the preferred resources outlined in L+M's Protocol are not available or they deem them unnecessary for clinical reasons, the NLFD will provide an ambulance for transportation. However, the NLFD should not and cannot become the primary first responder for all of L+M's inter-hospital patient transfer calls.

Please feel free to contact me with any questions or concerns at (860) 447-5291.

Sincerely,

Henry Kydd, Deputy Chief
New London Fire Department

Ronald J. Samul, Sr., Fire Chief
289 Bank Street
New London, CT 06320-5521
(860) 447-5291 • FAX (860) 447-5293
Email: rsamul@ci.new-london.ct.us

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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: MICHELE VOLPE

FAX: 203 777-5806

AGENCY: BERSHTEIN, VOLPE & MCKEON P.C.

FROM: STEVEN LAZARUS

DATE: 12/12/12 **Time:**

NUMBER OF PAGES: 5
(including transmittal sheet

Comments:

Information for tomorrow's hearing regarding Docket Number 12-31768

Please contact Steven Lazarus at 860 418-7012 with any questions.

PLEASE PHONE Barbara K. Olejarz IF THERE ARE ANY TRANSMISSION PROBLEMS.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANT: **Lawrence and Memorial Hospital**

DOCKET NUMBER: **12-31768-CON**

PUBLIC HEARING: **December 13, 2012 at 10:00 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letters of support to OHCA various dates in the matter of the CON application under Docket Number 12-31768, received by OHCA inn May, 2012. (4 pages)
B	Letter from Lawrence and Memorial Hospital ("Applicant") dated June 18, 2012 enclosing the Certificate of Need to establish and operate an elective angioplasty program at Lawrence and Memorial Hospital receivedd by the Office of Health Care Access ("OHCA") on June 19, 2012. (518 pages)
C	OHCA's letter to the Applicant dated July 19, 2012 requesting additional information and/or clarification in the matter of the CON application under Docket Number 12-31768. (3 pages)
D	Applicant's responses to OHCA's letter of July 19, 2012, dated August 3, 2012, in the matter of the CON application under Docket Number 12-31768, received by OHCA on August 6, 2012.(70 pages)
E	OHCA's letter to the Applicant dated August 31, 2012 deeming the application complete in the matter of the CON application under Docket Number 12-31768.(1 page)
F	Applicant's letter to OHCA dated November 8, 2012 providing additional information in the matter of the CON application under Docket Number 12-31768, received by OHCA on November 6, 2012. (5 pages)
G	OHCA's request for legal notification in *The Day Publishing Company* and OHCA's Notice to the Applicant of the public hearing scheduled for December 13, 2012, in the matter of the CON application under Docket Number 12-31768, dated November 21, 2012. (4 pages)

H	Designation letter, dated November 28, 2012, designating Attorney Kevin Hansted as hearing officer in the matter of the CON application under Docket Number 12-31768. (1 page)
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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TENTATIVE AGENDA

PUBLIC HEARING

Docket Number: 12-31768-CON

Lawrence and Memorial Hospital

Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

December 13, 2012, at 10:00 a.m.

I. **Convening of the Public Hearing**

II. **Applicants' Direct Testimony (10 minutes each)**

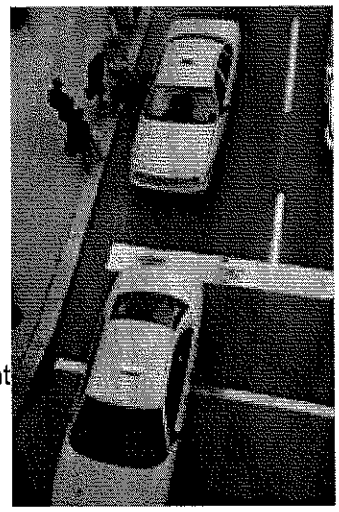
III. **OHCA's Questions**

IV. **Closing Remarks**

V. **Public Hearing Adjourned**

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

Directions to the Office of Health Care Access



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

Directions to Forest and Sisson (Lot C) for visitor shuttle service:

From I-91 (north or south) and from east of the river

In Hartford, take I-84 west. Take Exit 46, Sisson Avenue. At the end of the exit ramp, turn left at the signal light onto Sisson Avenue. Take your first left onto **Capitol Ave. Take your first left onto Forest Street. The parking lot is on your left and is labeled State of Connecticut. A shuttle bus to take you to our offices will either be waiting, or will appear in a few minutes.**

From the West

Take I-84 East to Exit 46, Sisson Avenue. At the end of the exit ramp, turn left at the light onto Sisson Avenue. Take you first left onto **Capitol Avenue. Take your first left onto Forest Street. The parking lot is on your left and is labeled State of Connecticut. A shuttle bus to take you to our offices will either be waiting, or will appear in a few minutes**

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

AGENDA

PUBLIC HEARING

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An Equal Opportunity Employer
410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

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OHCA HEARINGS - EXHIBIT AND LATE FILE FORM

Applicants: Lawrence & Memorial Hospital

DN: 12-31768-CON

Hearing Date: December 13, 2012

Time: 10:00 a.m.

Proposal: Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

OHCA Exhibit #	Description
1	The CT State Facilities + Services Plan (2012)
2	
3	
4	
5	

Applicant Exhibit #	Description
N	Correspondence relating to correction on other website
2	
3	
4	
5	

Administrative notice of submitted items

Applicant Exhibit N

received by other 12/13/12

BERSHTEIN, VOLPE & McKEON P.C.
ATTORNEYS AT LAW
105 COURT STREET, THIRD FLOOR
NEW HAVEN, CONNECTICUT 06511
203-777-5800
Fax: 203-777-5806

Michele M. Volpe
Direct Dial (203) 777-6995

December 12, 2012
Via Email: kaila.riggott@ct.gov
and Hand Delivery on December 13, 2012

Kaila Riggott
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, Connecticut 06134-0308

Re: Lawrence & Memorial Hospital - Certificate of Need Application
Establish and Operate an Elective Angioplasty Program
Docket Number: 12-31768-CON

Dear Ms. Riggott:

On the "Check the Calendar" section of the OHCA website, for December 13, 2012 at 10:00 a.m., there is a link entitled "Hearing on Docket # 12-31768-CON". When you click on the link, it lists the correct docket number for the Lawrence & Memorial Hospital Public Hearing that is scheduled for December 13; however it lists the Petitioner as "Greenwich Hospital" (please see attached).

We respectfully request that this error be corrected. The correct Petitioner should be "Lawrence & Memorial Hospital".

Thank you.

Very truly yours,

Michele M. Volpe

MMV/bt
Enclosure
cc: Kevin Hansted, Steven Lazarus
S:\doc\11 5451-5500\11549. L & M Hosp re OHCA\Docs\Elective Angioplasty (CON Application)\Letters\OHCA (Appearance) 12.12.12 (re Website Calendar).doc

Dec 13 2012

Hearing on Docket # 12-31768-CON

Petitioner(s):	Greenwich Hospital
Docket Number:	12-31768-CON
Proposal:	Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital with no capital expenditure.
Application Date:	December 13, 2012
Town:	New London

Location: Department of Public Health, Office of Health Care Access, Third Floor Hearing Room, 410 Capitol Avenue, Hartford
This event is 2 mile(s) from you (06106).

10 AM

Contact: Kaila Riggott
Email: kaila.riggott@ct.gov
Phone: 860-418-7037

Input your zip code to calculate the distance to the event: 06106 Go

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF OFFICE OF
HEALTH CARE ACCESS : DOCKET NO. 12-31768-CON

IN RE: LAWRENCE & MEMORIAL
HOSPITAL, ESTABLISH AND OPERATE
AN ELECTIVE ANGIOPLASTY PROGRAM : DECEMBER 13, 2012

REQUEST FOR ADMINISTRATIVE NOTICE

The Applicant, Lawrence & Memorial Hospital, respectfully requests that the Office of Healthcare Access take administrative notice of the following items:

United States Code:

- 42 U.S.C. § 1395dd

Code of Federal Regulations:

- 42 C.F.R. Part 413
- 42 C.F.R. Part 482
- 42 C.F.R. Part 489

United States Jurisprudence:

- *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011)
- *Jones* v. *United States*, 529 U.S. 848 (2000)
- *Pac. Capital Bank, N.A.* v. *Connecticut*, 542 F.3d 341 (2d Cir. 2008)
- *County of Suffolk* v. *Long Island Lighting Co.*, 728 F.2d 52 (2d Cir. 1984)
- *Lopes* v. *Kapiolani Medical Center for Women & Children*, 410 F. Supp.2d 939 (D. Hawaii 2005)

Connecticut General Statutes:

- General Statutes § 19a-175

- General Statutes § 19a-179c
- General Statutes § 19a-490
- General Statutes § 19a-521

Connecticut Jurisprudence:

- *Tomlinson* v. *Tomlinson*, 305 Conn. 539 (Conn. 2012)
- *Director of Health Affairs Policy Planning* v. *Freedom of Information Commission*, 293 Conn. 164 (Conn. 2009)

Regulations of Connecticut State Agencies:

- Regs., Conn. State Agencies §§ 19a-179-1 through 19a-179-21
- Regs., Conn. State Agencies §§ 19-13-D1 through 19-13-D8t

Decisions of Connecticut State Agencies:

- Declaratory Ruling, Connecticut Department of Public Health, February 14, 2003
- Lawrence and Memorial Hospital and Yale-New Haven Hospital's Certificate of Need Application, filed with the State of Connecticut, Office of Health Care Access (Docket #04-30297-CON) and Decision of the State of Connecticut, Department of Public Health, Office of Health Care Access regarding same
- Statewide Health Care Facilities and Services Plan, Connecticut Department of Public Health Office of Healthcare Access, October, 2012

Legislative Materials:

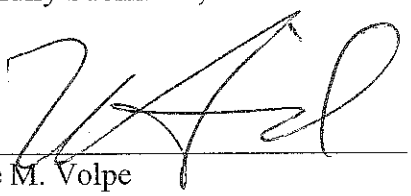
- Public Acts 2009, No. 09-16
- House Bill No. 6599, 2009 Sess., Connecticut General Assembly (File No. 378)
- House Bill No. 6599, 2009 Sess., Connecticut General Assembly (File No. 820)
- Conn. House of Representatives, 2009 Sess., pp. 2042–50

- Conn. Joint Standing Committee Hearings, Public Health, 2009 Sess., Pt. 6, pp. 1610–24, 1872–85
- OLR Analysis of House Bill 6599 as Amended by Amendment A, Connecticut General Assembly, Office of Legal Research

Other Materials:

- Lawrence & Memorial Hospital, Guideline for Emergent Transportation of Elective PCI Patient
- Definition of "Critical," Merriam-Webster's Collegiate Dictionary (10th Ed. 1993)
- Jonathan Warren, MD, FCCM, FCCP et al., Guidelines for the inter- and intrahospital transport of critically ill patients, 32 Crit. Care Med No. 1, at pp. 256-262 (2004)

Respectfully Submitted,



By: _____
Michele M. Volpe
Juris No. 412124
Bershtein, Volpe & McKeon P.C.
105 Court Street, 3rd Floor, New Haven, CT 06511
Tel. No. (203) 777-5800
Fax No. (203) 777-5806

PUBLIC HEARING
APPLICANT
SIGN UP SHEET

December 13, 2012
10:00 a.m.

Applicant: Docket Number: 12-31768-CON
Lawrence and Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

Name	Phone	Fax	Representing Organization/Self
Crista Durand	860-373-4735		L+M Hospital
Bruce Cummings	860-442-0711		" "
G Mulholland	860 442 0711 2659		" "
Mary Gonzales	860 442-0711 x5078		L+M Hospital
Shraddha Patel	860 9125324		L+M Hospital

Public Hearing
Lawrence and Memorial Hospital

Name	Phone	Fax	Representing Organization/Self
Brian Cambi	8604420711 5325		L+M Hosp
Kate Hagmann	203-777-5800		L+M Hosp
Ronald Kossey	860-444-5164		L+M Hosp.
Kevin Armstrong	860-442-0711		L+M Hosp.
Michele Volpe	203-7776955		L+M Hosp BVM Law Firm

PUBLIC HEARING
INFORMAL PARTICIPANT
SIGN UP SHEET

December 13, 2012
10:00 a.m.

Applicant: Docket Number: 12-31768-CON
Lawrence and Memorial Hospital
Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital

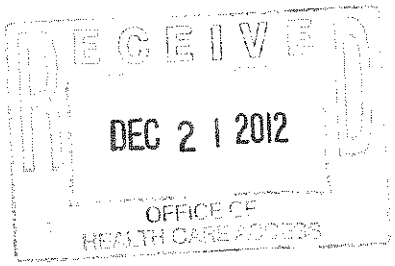
Name	Phone	Fax	Representing Organization/Self
~~Geraldine Mulholland~~	~~860 442 0311 x 2659~~		~~L+M~~
Henry Cabin	203 785-4129		Yale-New Haven Hospital
Michele Volpe	203-777-6995	203-777-5806	L+M Hosp BVM Law Firm

ORIGINAL

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

OFFICE OF HEALTH CARE ACCESS



LAWRENCE AND MEMORIAL HOSPITAL

APPLICATION TO ESTABLISH AND
OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT
LAWRENCE AND MEMORIAL HOSPITAL

DOCKET NO. 12-31768-CON

DECEMBER 13, 2012

10:02 A.M.

410 CAPITOL AVENUE
HARTFORD, CONNECTICUT

POST REPORTING SERVICE
HAMDEN, CT (800) 262-4102

HEARING RE: OFFICE OF HEALTH CARE ACCESS
DECEMBER 13, 2012

. . .Verbatim proceedings of a hearing before the State of Connecticut, Department of Public Health, Office of Health Care Access, in the matter of Application to Establish and Operate an Elective Angioplasty Program at Lawrence and Memorial Hospital, held at 410 Capitol Avenue, Hartford, Connecticut, on December 13, 2012 at 10:02 a.m. . . .

HEARING OFFICER KEVIN HANSTED: Good morning, everyone. Before we begin, would everyone please turn off any cell phones that are in the room? Thank you.

This public hearing before the Office of Health Care Access, identified by Docket No. 12-31768-CON, is being held on December 13, 2012 to consider Lawrence and Memorial Hospital's application to establish and operate an elective angioplasty program at Lawrence and Memorial Hospital.

This public hearing is being held pursuant to Connecticut 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.

My name is Kevin Hansted, and I've been designated by Commissioner Jewel Mullen of the Department of Public Health to serve as the Hearing Officer today.

The staff members assigned to assist me in this hearing are Kaila Riggott and Steven Lazarus. The hearing is being recorded by Post Reporting Services.

In making its decision, OHCA will consider and make written findings concerning the principles and guidelines set forth in Section 19a-639 of the Connecticut General Statutes.

The Applicant, Lawrence and Memorial Hospital, has been designated as a party in this proceeding.

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 the Record for reference purposes. Mr. Lazarus?

MR. STEVEN LAZARUS: Good morning. Steven Lazarus. OHCA would like to enter into the record Exhibits A through M.

HEARING OFFICER HANSTED: Thank you. Does staff have any additional exhibits?

MR. LAZARUS: Not at this point.

HEARING OFFICER HANSTED: Thank you. At this time, I would ask all the individuals that are going to testify here today to please stand, raise your right hand, and be sworn in.

(Whereupon, the parties were sworn.)

HEARING OFFICER HANSTED: Thank you. To all those individuals, who just took the oath, I ask that, when you first present testimony, please state your name and adopt your written testimony here today. Thank you.

At this time, Lawrence and Memorial Hospital, you may proceed.

MS. MICHELE VOLPE: Thank you.

HEARING OFFICER HANSTED: You're welcome.

MS. VOLPE: Good morning, Hearing Officer Hansted, Mr. Lazarus, Ms. Riggott. My name is Michele Volpe. I am legal counsel for the Applicant, Lawrence and Memorial, and I just have a couple of administrative housekeeping items.

In terms of the Table of Record, we'd like to enter into, as Table N, just a letter that was exchanged yesterday between Ms. Riggott and our office just regarding a correction on the website regarding the

hearing docket number and the Applicant.

HEARING OFFICER HANSTED: And these are just multiple copies?

MS. VOLPE: Yeah, five copies.

HEARING OFFICER HANSTED: Okay.

MS. VOLPE: The Commission usually likes to have an original and five copies.

HEARING OFFICER HANSTED: Right. Okay, thank you. We'll accept that.

MS. VOLPE: Okay and we'd also like to offer into the Table of Record a request to take administrative notice of the laws that are applicable in this proceeding specific to the questions presented by this Commission.

HEARING OFFICER HANSTED: Again, these are multiple copies?

MS. VOLPE: Correct.

HEARING OFFICER HANSTED: Thank you.

MS. VOLPE: We would offer that as Table of Record O.

HEARING OFFICER HANSTED: Let me just take a 10-minute break at this point.

MS. VOLPE: Sure.

HEARING OFFICER HANSTED: I just want to

review this, so I can decide if I want to take administrative notice of it.

MS. VOLPE: Very good.

HEARING OFFICER HANSTED: We'll go off the record for 10 minutes.

MS. VOLPE: Very good. Thank you.

HEARING OFFICER HANSTED: Thank you.

(Off the record)

HEARING OFFICER HANSTED: Okay. Attorney Volpe, you've asked that OHCA take administrative notice of several documents in your request for administrative notice. I will grant that request, with the understanding that OHCA is aware of the applicable laws in this matter and will apply them accordingly.

In addition to that, you've asked that OHCA take administrative notice of the Statewide Health Care Facilities and Services Plan.

I'm going to order that that be made OHCA Exhibit 1 in this matter.

MS. VOLPE: So, in addition to having the administrative notice of the Table of Record, you're going to also add your own facility's plan as an exhibit?

HEARING OFFICER HANSTED: Correct.

MS. VOLPE: Okay. Very good.

HEARING OFFICER HANSTED: Do you have any objection?

MS. VOLPE: None. Thank you.

HEARING OFFICER HANSTED: Thank you. You may proceed.

MS. VOLPE: Great. Thank you.

HEARING OFFICER HANSTED: You're welcome.

MS. VOLPE: To commence our Direct testimony, I'd like to introduce Mr. Bruce Cummings, President and Chief Executive Officer for Lawrence and Memorial Hospital.

MR. BRUCE CUMMINGS: Thank you, Michele. Good morning, Hearing Officer Hansted, Ms. Riggott, Mr. Lazarus.

HEARING OFFICER HANSTED: Good morning.

MR. CUMMINGS: Thank you for the opportunity to speak to you this morning about our Certificate of Need application.

My name is Bruce Cummings, and I'm CEO of L & M. L & M is proposing to build upon our existing successful emergency angioplasty service and to establish and operate an elective angioplasty program.

We've provided angioplasty services for patients with ST elevated myocardial infarctions since

2008, and we are proud of our high-quality outcomes. With the same infrastructure and staff in place, we're confident our proposed elective program will produce similar results.

Based on the list of issues provided by OHCA to L & M, we understand OHCA has questions regarding our policy for transfer of patients to tertiary care providers for advanced medical care.

Please be assured that L & M's primary goal is to conduct itself in a manner that puts patients first. Patient safety is a critical component of our organization's values, and we look forward to the opportunity to demonstrate that commitment to you today.

My colleagues will speak to you in more detail about our policy and the rationale for it, as stated. You've already been introduced to Michele Volpe, attorney at law.

With me today, also, to her left, is Dr. Brian Cambi. Dr. Cambi is the Medical Director for the Primary Angioplasty Program at L & M and assistant professor at Yale School of Medicine.

To my right is Ron Kersey, who is the EMS Coordinator at L & M. I'd also like to acknowledge in the audience today is Dr. Henry Cabin, Clinical Chief of

Cardiology and professor at Yale University School of Medicine and Medical Director of the Yale-New Haven Heart and Vascular Center.

Yale-New Haven and Yale School of Medicine are our allies, who support our commitment to providing advanced cardiovascular care to communities in Southeastern Connecticut.

Dr. Cabin will not be testifying, but is present today in support of our application and our position.

Also with me today in the audience are other members of the L & M Administrative and Clinical Staffs, who are available if you have specific technical or operational questions about our programming.

In conclusion, the proposed elective angioplasty program at L & M offers our community the opportunity to receive high-quality cardiac care locally, and I encourage OHCA to approve our CON application with all deliberate speed. Thank you.

HEARING OFFICER HANSTED: Thank you.

MS. VOLPE: Thank you, Bruce. All the testimony, the pre-filed testimony that has been submitted, supports the fact that L & M's patient transfer protocol for elective angioplasty program is

consistent with this Department, DPH's Declaratory Ruling issued in 2003, specifically, that great deference should be given to the clinical judgment of the transferring facility and its professional medical staff, as to whether or not to activate the 9-1-1 system.

Please take notice of the fact that the elective PCI patient transfer protocol at issue, which is the only set of issues before the hearing today, is materially identical to the protocol that L & M submitted in connection with its 2005 CON application for emergency angioplasty, and that application was approved by this Commission.

The Declaratory Ruling at issue here is intended to deal with pre-hospital emergency needs of the public to dial 9-1-1 and the role that should be played between EMS providers and sponsoring hospitals.

The Declaratory Ruling is not intended to apply to patients, who are already in an acute care setting, as that is covered by Connecticut General Statutes 19a-179c, which is titled Requirements Regarding Ambulance Used for Inter-facility, Crucial Care Transport.

If DPH is taking the position that 9-1-1 must be activated for all urgent, emergent and critical

care transports when a patient is in a hospital, this position represents a change in existing industry standards throughout Connecticut, which conflicts with the ruling, as well as the State and Federal law, and will gravely impact patient care and community resources.

If this is DPH's position, it is important that it directly conflicts with your own Declaratory Ruling. As we just explained, a mandate, that hospitals activate 9-1-1 for all urgent, emergent and critical care transports, conflicts with the ruling's deference to the medical expertise of sponsor hospitals.

It also conflicts with the ruling's expressed statement, that, and I quote from the ruling, "clinical judgment should be used in determining whether the 9-1-1 system should be activated."

It also conflicts with the language used in the ruling, itself. Every legal conclusion that relates to the conduct of the institution refers to long-term care facilities or members of the public and the EMS units that service them.

The factual findings relate to the conduct of long-term care facilities. The phrase, long-term care facility, does not encompass acute care hospitals.

This is recognized in the statutes and

Public Health Code, which are cited in our brief and offered today as administrative notice for the Table of Record.

It should not be lost on this Department that the position already directs conflicts with the first ever statewide health care plan.

For the first time in Connecticut, we are fortunate to have a statewide health plan, and we appreciate all the effort that was put into it by this Department, but our position is that that statewide health plan, if you read it in the context of the questions that are presented here at the hearing, are in direct conflict.

DPH's Connecticut Statewide Health Care Facilities and Services Plan treats acute care hospitals and long-term care facilities as entirely separate entities and defines the phrase long-term care as care and services over an extended period of time in settings, such as institutions, managed residential sites, or other sites within a community or home.

It is also very important to note that there are no factual findings in this Declaratory Ruling related to hospitals, protocols for transferring patients after they have entered the hospital system.

The context in which the ruling arose also supports L & M's interpretation. The ruling indicates that the petition for Declaratory Ruling was filed under the purpose of dispelling confusion among the operators of long-term care facilities and the general public regarding when they must dial 9-1-1, as well as confusion among EMS providers, who are servicing them.

The ruling specifically references three letters, which the Department issued to long-term care facility administrators, as guidance on the proper procedures for the emergency transfers of patients to hospitals.

It notes the confusion in these letters specifically addressed to the long-term care industry. Read appropriately, the ruling does not apply to acute care hospitals.

If it's DPH's position that it does apply, we feel we're in compliance, because it requires that all those construing the ruling to give great deference to the clinical judgment of the individuals within the sponsoring hospitals.

It also conflicts with the purpose and intent of the legislature when it enacted General Statutes 19a-179c, which came after the Declaratory

Ruling in 2009, and deals specifically with the issue at hand, which is an inter-facility transport of a critical care patient.

The ruling interpreted the Emergency Medical Services Assisting Act as it existed in 2003. In 2009, the legislature added Connecticut General Statutes 19a-179c, which applies specifically to inter-facility critical care transport, the exact type of transport at issue today and presented in OHCA's questions.

The statute provides hospitals with discretion to select the appropriate staff and vendor for these transports. Practitioners, RNs, PAs, whatever they feel is necessary to ride with a patient when they are having a transport from one acute care hospital to another in the state, this is left within the discretion of the sponsor hospitals and the practitioners, who are servicing patients in those hospitals.

It doesn't require them to dial 9-1-1 or use the local PSAR for these transfers. And it should be noted that this provision of the statute, which we reference is prevailing and supersedes the Declaratory Ruling, makes no reference of calling 9-1-1 or activating the 9-1-1.

If a basic level ambulance were to be

dispatched through the 9-1-1 call for these inter-facility transfers, this isn't the clinically-appropriate mode of transportation specifically for an elective angioplasty patient with complications.

As Dr. Cambi, who is here with us today, will explain in his testimony, the providers in the L & M's protocol arrive pre-equipped with the medically-appropriate staff and equipment for these transfers.

If the ruling is applied to hospitals, they find themselves in a position, where the least desirable provider must become the first provider for inter-hospital transfers of critically-ill patients.

As Ron Kersey, who is also here with us today, will explain in his testimony, L & M's Emergency Department transferred over 450 patients to Yale alone in fiscal year 2012, not to mention other hospitals, such as Hartford Hospital and Children's Hospital.

If this department will have every hospital in the state calling 9-1-1 for inter-facility transport, we suggest that that's going to be a tremendous waste of local resource and could potentially collapse the whole 9-1-1 system.

Involving local 9-1-1 dispatchers in emergent, urgent and critical care inter-hospital

transfers will also waste local resources, with no benefit to patients and no positive impact on the quality of care.

This position will have significant financial impact on cities and towns throughout Connecticut. The problems described above will be avoided if the Declaratory Ruling is read in its proper context to defer to the transferring hospital and the treating physician's judgment, as to whether the 9-1-1 system is ever even activated.

It's telling that the ruling does not contain a single factual finding about procedures for transferring patients after they have been entered into a hospital system.

The whole point of a 9-1-1 is to get a patient to the hospital. The scope of the factual findings demonstrate that inter-hospital transfers were well beyond the purview of the Declaratory Ruling.

The legal conclusion set forth in the ruling exclusively pertained to long-term care facilities and the EMS providers that service them, as well as the general public, when they are in need of emergency services.

Even if the ruling did govern urgent and

emergent and critical care inter-hospital transfers, it's premised upon an earlier version of the Emergency Medical Services Assistance Act, and it's superseded by Connecticut General Statutes 19a-179c, which I had already stated was enacted after, well after, in 2009.

As we pointed out already, that section of the statute does not distinguish between emergency and non-emergency transfers of patients. It doesn't speak at all of the 9-1-1 activation.

Any ambulance used for an inter-facility critical care transport shall meet the requirements for a basic level ambulance and may be supplemented by a licensed registered nurse, advanced practice registered nurse, and such other equipment as the transferring hospital deems appropriate, and that is crucial, because that's the type and level of care that is needed for these transfers.

So the terms of the statute that we feel prevails, which is 19a-179c, apply specifically to all transfers between hospitals, and it controls the more generalized provisions in the DPH Declaratory Ruling.

The legislative history, if you review the legislative history that's involved in Connecticut General Statutes 179, 19a-179c, it's clear that it was

enacted to address exactly the issue at hand.

If physicians are required to activate 9-1-1 for all emergent and critical care transports, we are concerned that this directly conflicts with the Federal Emergency Medical Treatment and Active Labor Act, better known as EMTALA.

EMTALA has a preemption provision, which states that the provisions in this section do not preempt any state or local law requirement, except to the extent that those requirements directly conflict with a requirement in this section.

If the Declaratory Ruling is read to require 9-1-1 to be activated, then it necessarily includes transfers from the Emergency Department, and if it includes transfers from the E.D., then the patients and the physicians servicing them were not able to comply with EMTALA in these instances.

Under EMTALA, a hospital and a treating physician must insure that transfers of E.D. patients are effective through qualified personnel and transportation equipment, as required, including the use of necessary and medical appropriate life support measures during the transfer. This conflict can and must be avoided if the ruling is read appropriately.

To deal, specifically, with this Commission's questions, the Department asked whether the hospital can request an immediate response by a basic level ambulance, with the exclusion of fire and police.

The answer is, yes, we can request it, but the Fire Department is going to follow its own protocol and established directives when responding to a 9-1-1 call and activating the system.

The Declaratory Ruling explicitly recognizes that there are different standards for the daily operation of coordinated medical emergency direct centers, and public safety answering points, and dispatchers, including different protocols in different operational procedures, a lot of which was outlined in the letter that was submitted on behalf of the New London Fire Department, Deputy Chief, Mr. Kydd, and he goes through this in his letter.

So could we ask for it as OHCA requests of us? Of course, we can ask. Are they going to be able to administer it? No, they're not. They get a 9-1-1 call, they're going to follow their own standards and protocols and procedures.

The Department also asks us whether 9-1-1 will dispatch something, other than the basic level

ambulance, but we submit that this Commission already knows the answer to that question you've asked us. The DPH knows that all PSRs must operate a basic level ambulance, so, to answer a question that we submit, that since all PSRs have to offer a basic level ambulance, then you know they're not going to send something less than that, but the question really ignores the three central concerns that the hospital has expressed during these proceedings.

First, that dispatching a basic level ambulance for every urgent, emergent and critical care transport will waste valuable community resources.

The patient has already been assessed and stabilized by a treating physician in the hospital. They're in the best position to determine the clinically-appropriate mode of transport, not somebody calling the 9-1-1 system and deploying the local EMS resources to an acute care hospital for all urgent, emergent, and critical care transfers.

So we submit that would be a tremendous waste of community resources at great cost to the City of New London. A basic level ambulance, staffed only with EMTs, is not clinically-appropriate for medically-complex inter-hospital patient transfers.

The providers in Lawrence and Memorial's protocol arrived pre-equipped, with medically-appropriate staff, and equipped for these type of transfers.

The additional links in the chain that we believe the Department is asking us to add will only cause concern for problems with direct communication, and it will also take away care right within our community.

The last question the Department asks is whether the hospital will be able to comply with EMTALA if we were to call 9-1-1 for an emergency transfer.

A transfer is appropriate only where it is effective through qualified personnel and transportation equipment, including the use of necessary and medical appropriate life support measures.

Failure to insure on our part, that is the hospital, the ability to appropriately transfer a patient could subject the hospital and the treating physician to civil penalties, and repeated violations could exclude us from the Federal Health Care Program.

If L & M is required to dial 9-1-1 in order to transfer urgent, emergent and critical care patients to other hospitals from its Emergency Department, then it's not able to insure that the properly-equipped medical transport provider will be the

one that shows up and, therefore, will be unable to perform its duties under EMTALA.

The Declaratory Ruling concludes that EMS providers, who receive emergency pre-hospital calls from members of the general public, including long-term care facilities, must transfer them to the 9-1-1 system.

It does not require first responder providers to contact 9-1-1 when they receive calls from hospitals to arrange for inter-hospital transfers.

These calls are to move patients within one hospital setting to another and are not emergencies, as that word is defined in the Declaratory Ruling.

Mr. Allard, Vice President of American Ambulance, explains in his letter, which was attached to the pre-filed testimony of Dr. Cambi, that it's common practice within the medical transport industry for providers to dispatch ambulances directly to hospitals.

In fact, the Life Star helicopter, which is licensed by OHCA, has the ability to directly respond to patient transfers from calls from hospitals.

Finally, what you've been waiting for. In conclusion, the Department of Public Health's requirement, that hospitals dial 9-1-1, will set policy, which will ultimately create inferior standards in the

community than that which exists today.

It will have grave ramifications for local fire and police departments and hospitals. It could potentially collapse the 9-1-1 system, create hardships for resources in cities and towns, and usurp the medical judgment of sponsor hospitals and staff.

Finally and most important, it will have an adverse impact on patient care and quality, therefore, the Applicant implores you to apply the appropriate reading of the Declaratory Ruling and to find that Lawrence and Memorial's patient transfer protocol for elective angioplasty program is in compliance with the law.

At this time, I want to introduce Mr. Ron Kersey, who is the EMS Coordinator at Lawrence and Memorial Hospital.

MR. RON KERSEY: Good morning, Hearing Officer Hansted and Ms. Riggott and Mr. Lazarus. My name is Ron Kersey. I'm the EMS Coordinator at Lawrence and Memorial Hospital. I am here to adopt my pre-filed testimony and answer any questions you may have.

As stated, transfer protocol for elective angioplasty patients is carefully organized, approached to providing our patients with the highest quality, most

appropriate mode of transportation, with minimal impact to the community EMS system.

As Michele Volpe noted in her statement, I am here to address the impact DPH's position will have on the EMS system and our local community.

I can speak to this point not only as L & M's EMS Coordinator, but also based on my extensive experience in the trenches as an EMT, a paramedic, and a volunteer firefighter in the New London community.

The basic level primary service area provider, or PSAR, for New London is the New London Fire Department, which maintains two basic level ambulances staffed with EMTs.

The Advanced Life Support PSAR for New London is the New London Fire Department ambulance, supplemented by a Lawrence and Memorial paramedic intercept team member.

If L & M were to call 9-1-1 for critical transportation of patients to Yale or another tertiary care facility, it would place a significant strain on the resources of our local EMS system.

Although the number of patients requiring critical care transportation from the elective angioplasty program is expected to be low, as Dr. Cambi

noted, if the use of 9-1-1 for inter-hospital transports were implemented house-wide, it would cripple our local resources.

The New London Fire Department Deputy Chief, Henry Kydd, in his letter included in pre-filed testimony outlines the negative impact on the local community and to his department if L & M were required to call 9-1-1 for every urgent, emergency or critical care inter-hospital transport.

The New London Fire Department cannot absorb this additional responsibility. As the PSAR for New London, the New London Fire Department is required to follow certain policies and procedures each time it is contacted by the 9-1-1 dispatcher.

In addition to Basic Life Support ambulances, New London dispatches fire engines, and often police are called to the scene.

For a typical 9-1-1 call, firefighters assess the severity of the situation and provide basic first aid if the ambulance has not arrived.

When the ambulance arrives, additional EMS resources, such as Life Star air medical transport, are requested, if necessary.

For L & M, a call to the 9-1-1 system for

inter-hospital transfers would initiate this exact response, stripping the community of key resources for a medical situation that cannot and should not be handled by local EMS.

Because New London Fire Department is equipped with two basic level transport units to handle all community 9-1-1 responses, in order to accommodate inter-hospital transports, New London would be forced to rely on neighboring communities to cover 9-1-1 calls in their area while town ambulances is out of the primary service area for an extended period of time, hence, creating the potential ripple effect among an extended service area of first responder.

In addition, activating 9-1-1 to dispatch New London Fire Department transports would require an L & M paramedic to accompany the New London Fire Department EMT staff to transport to Yale or another resource, and another resource would be unavailable for the community for an extended period of time.

Depending on a patient's needs, an L & M nurse, respiratory therapist may also be required to transport with the patient, further depleting L & M and the community of key clinical resources.

In our transfer policy, the performing

intervention cardiologist determines the appropriate mode of transportation, based on the needs of the patient. If Life Star and/or American Ambulance were utilized rather than the local PSAR, L & M is able to maintain valuable community resources, as well as provide the safest option for transporting our patients.

The providers in L & M's protocol have been vetted and have equipped their ambulances specifically to handle these calls.

These providers have given their crews additional training to provide the complex medical care required for these critically-ill patients.

In addition, our protocol, in which L & M initiates direct contact with the transport service, has fewer links in the chain of communication, which reduces the opportunity for miscommunications and mistakes.

L & M Hospital is the sponsor hospital for the New London Fire Department and the L & M paramedic team.

As the sponsor hospital in our community, we have the authority to determine the course of action to be taken for inter-hospital transports, as outlined in the 2003 Declaratory Ruling.

With this authority, it is our belief that

direct contact with commercial transport providers, such as Life Star and American Ambulance, provides patients the highest quality, safest and most expeditious method of transport to tertiary level facilities, as noted by Dr. Cambi.

We maintain that L & M's transfer policy complies with the 2003 Declaratory Ruling, in that it preserves the clinical judgment, the clinician's clinical judgment regarding when 9-1-1 should be activated.

If L & M is deprived of this discretion to determine whether 9-1-1 is activated and stripped of its -- to determine if the most appropriate mode of transportation for the patients traveling from one hospital to another hospital, I strongly feel a quality and safety issue will emerge, putting our patients at risk, not just in the elective angioplasty program, but in the hospital Emergency Department and other hospital specialties.

A safety issue will also arise within our community, which will be stripped of its EMS resources for extended periods of time. Thank you.

HEARING OFFICER HANSTED: Thank you, Mr. Kersey.

MS. VOLPE: Now we'd like to offer the

Direct testimony of Dr. Cambi, who is the Medical Director of our program at Lawrence and Memorial Hospital.

DR. BRIAN CAMBI: Good morning.

HEARING OFFICER HANSTED: Good morning.

DR. CAMBI: Hearing Officer Hansted, Mr. Lazarus, Ms. Riggott. As Michele noted, my name is Dr. Brian Cambi. I'm the Medical Director of the Primary Angioplasty Program at Lawrence and Memorial Hospital.

I'm here today to adopt my pre-filed testimony and answer any questions OHCA may have.

In the early years, patients undergoing elective angioplasty developed procedural complications that required coronary artery bypass grafting, often on the same day, at rates quoted anywhere from six to 10 percent.

Over the years, advances in technology and adjunctive medical therapy, in combination with operator experience, has led to a dramatic reduction in complications.

Fortunately, the rate of procedural complications rendering a patient critically ill and necessitating the need for same-day surgery is rare, with numbers in the literature described as low as 0.3

percent.

With these changes and the release of recent studies in the medical literature, it is clear that we can now safely provide elective angioplasty to carefully-selected low-risk patients.

The rationale behind our desire for L & M to have such a program is outlined extensively in our application and complies in full with a statewide facilities plan, Section 3.1, correction, Section 3.4.3.1, PCI without surgical backup, published by the Connecticut Department of Public Health's Office of Health Care Access in October of this year.

An important part of such a program is developing a sound policy for the expeditious transfer of patients in the rare event they become critically ill during the elective angioplasty procedure and require a higher level of care at a tertiary care hospital, including the potential need for urgent surgery.

The American College of Cardiology, as well as the American Heart Association and the Society for Cardiovascular Angiography and Interventions, have recommended in their 2011 Practice Guidelines that such programs, without on-site surgical backup, be able to acquire transportation services for critically-ill

patients within 20 minutes.

Furthermore, these transportation services should be equipped with appropriately-trained medical personnel and equipment, such as intra-aortic balloon pump capability and mechanical ventilatory support.

The Statewide Facilities Plan, once again, Section 3.4.3.1, PCI, without surgical backup, references these guidelines as requirements to be met by any facility seeking approval for elective programs. I believe L & M's transfer policy satisfies these requirements.

When patients develop a procedurally-related complication and become critically ill in the cath lab, they receive multiple interventions to stabilize their acute decompensation.

These include mechanical ventilatory support, intra-aortic balloon pump implantation, and a variety of inotropic and vasopressin intravenous medications designed to enhance and maintain cardiovascular function.

Typically, this results in a stabilized, but critically-ill patient, who requires transfer to a tertiary-level facility, in order to receive advanced medical care not provided at our community hospital.

These are not pre-hospital citizens with an acute medical emergency that requires conventional 9-1-1 services to bring them to the hospital, rather, these citizens are already patients within a hospital, who have a stabilized medical emergency, but remain critically-ill.

They require sophisticated inter-hospital transport to a tertiary facility for advanced care that is too complex for standard EMS services and first responders to adequately handle.

Relying on highly-trained, experienced medical personnel, who have the appropriate equipment and manpower to handle these transfers, is the most prudent course of action to insure the best outcome for our critically-ill patients.

In our region, Life Star and American Ambulance Services have the ideal resources and expertise to handle these situations in showing the highest quality outcome for our patients.

They have years of proven experience in executing these transfers and are better prepared to manage the complex intravenous drips and mechanical interventions these patients receive while in the hospital.

Basic EMS services and first responders are far better prepared to deal with pre-hospital emergencies and have less experience handling inter-hospital transfers of critically-ill patients.

In order for the New London Fire Department's basic level ambulance to perform these transfers safely, L & M will need to supplement the EMTs with multiple L & M staff, like paramedics, nurses, respiratory therapists, to insure safe transport of the patient.

The New London ambulance and these additional personnel will be unable to serve our community for an extended period of time, which is not ideal.

That is why the New London ambulance is the provider of last resort in our transfer protocol. Life Star and American can more efficiently accomplish these transfers, because their vehicles and staff arrive pre-equipped to handle them.

And if their personnel were absent from the community for an extended period, it will not deprive the community of the local EMS resources.

I believe, as the Attending Interventional Cardiologist and the Director of the sponsoring

institution, it is within our scope of practice to make the most appropriate medical decision to insure the highest quality, safest, and most expeditious mechanism of transport of these patients to our collaborating tertiary facility.

The guidelines set forth by the ACC, AHA and SKY, supported by the Statewide Facilities Plan, issued by this Department, support this assertion.

Thank you for your time and thoughtful consideration of our application.

HEARING OFFICER HANSTED: Thank you, Doctor.

MS. VOLPE: That concludes our Direct testimony, and we, Lawrence and Memorial, the Applicant, we welcome any questions that the Hearing Officer and members of the staff may have.

HEARING OFFICER HANSTED: Thank you. I just have a couple of follow-up questions, Attorney Volpe.

Do you know how long it would take the New London Fire Department ambulance to respond to a potential call in this situation versus American Ambulance?

MS. VOLPE: I want to make sure we

understand your question. You're talking about respond to the hospital if we were to call 9-1-1?

HEARING OFFICER HANSTED: Correct.

MS. VOLPE: Okay, so, if the hospital were to call 9-1-1, how long would it take the Fire Department ambulance to show up versus a pre-arranged American?

HEARING OFFICER HANSTED: Correct.

MS. VOLPE: Okay. We did submit a detailed chart, flowchart for your benefit that walks through what the procedures would be if we were to dial 9-1-1 versus arranging for transport directly.

In terms of the minutes, I may defer, to the extent that Mr. Kersey may know that answer. I don't know the answer.

Are you suggesting that, you know, would they come as quickly or not as quickly?

HEARING OFFICER HANSTED: No. I'm not suggesting anything. I'd just like to know the difference between the American Ambulance response versus the New London Fire Department response.

MS. VOLPE: Okay, well, if the New London Fire Department responds with a basic-level ambulance even quicker than the American fully-equipped one, the time, in terms of their response, isn't going to matter

in this particular patient transfer, because if we get the Fire Department ambulance there quicker than American, but they're not fully-equipped with what the patient needs for transport, we're going to have to run around the hospital and get the individuals and the medical equipment to outfit that ambulance, so I would, and I'll defer to Mr. Kersey, but I would believe, even assuming that the basic level ambulance from the New London Fire Department could get there quicker than American, there's still going to be a significant time lag, because we're going to have to run around and outfit the ambulance and the equipment and the professional practitioners to service that patient during transport.

I don't know if you know the exact time differential, Ron.

MR. KERSEY: The exact time differential is very difficult to say. I can tell you that the New London Fire Department ambulance has a very good 9-1-1 response time, however, it's hard to tell where American Ambulance would be coming from.

Their furthest away point is their home port in Norwich, which frequently isn't where they're dispatched from. They're often in our area, pre-staged in our area, and have the resources to respond quicker

than if they were coming from Norwich, so it's hard for me to say what the response time of American Ambulance would be, not knowing where that resource is coming from at the time.

MS. VOLPE: I think it would be safe to say that there's a chance that they could be there even quicker than 9-1-1. Would that be fair to say?

MR. KERSEY: Within the same response time, I would say. There is that opportunity.

DR. CAMBI: Could I expand on that?

HEARING OFFICER HANSTED: Certainly.

DR. CAMBI: I think that, you know, from the clinical side, from my perspective, the question I'd ask myself, as this patient became unstable and now we've stabilized him and we decide they need a higher level of care, is what's my fastest way to get that patient and the safest way down to Yale?

Sure, clearly, New London Fire would get there faster, five minutes let's say, but the total time it will take to get my patient down to the tertiary-level care needs is significantly longer by having New London Ambulance come first, because now I've wasted time.

They've got to come here, assess the situation, I've got to talk to them and explain what's

going on, and then they have to reach out and either get a higher level of support services, or we have to find them, and now the total time it's taken to get that patient down to Yale is delayed, even though that ambulance, the vehicle showed up sooner than perhaps one from American would have. Do you follow that logic?

HEARING OFFICER HANSTED: Yes, thank you.

DR. CAMBI: Okay.

HEARING OFFICER HANSTED: Thank you for that. Mr. Kersey, I just want to go back to you. The New London Fire Department, if they're faced with a situation, and I'm not saying a situation where L & M calls 9-1-1 and you arrive, but let's say an accident happens on the highway and the New London Fire Department ambulance arrives on the scene of that accident, and they need a higher-level ambulance than what you have, what happens in those cases?

MR. KERSEY: A paramedic from the hospital is dispatched to that life-threatening emergency, along with the New London Fire Department ambulance, and we would augment that crew to provide paramedic-level care en route to the acute care facility, the closest acute care facility.

In addition to that, if they arrive on the

scene with the paramedic from the hospital and they need air transportation via Life Star, they would initiate that call once they've assessed the patient's need for the air medical transportation, then they would decide on the landing point for the helicopter, place the patient in the helicopter, and the helicopter would transport the patient to a tertiary care facility.

HEARING OFFICER HANSTED: Okay, thank you. Attorney Volpe, you had mentioned in your brief the distinction between emergent and emergency, and you had defined emergency, or I shouldn't say you defined, but you stated in the brief that emergent relates to 90 to 120 minutes response time or transfer time.

What's the basis for that industry standard? Is there a reference that you have that defines emergent as this 90 to 120-minute response time?

MS. VOLPE: Yeah. I believe it's in the programs for the angioplasty programs, in terms of that response time.

From our purpose, we aren't making a distinction between -- in terms of defining emergent, urgent, critical care. I mean it's in the hospital. We've stabilized the patient. We feel we need to get them to the next tertiary care facility of a higher level

urgently.

From our perspective, we're not making a distinction. We referenced that, because that's good standard industry-wide standard practice, in terms of the time period, and that's in the angioplasty programs.

DR. CAMBI: I hate to keep doing this, but can I expand on that?

HEARING OFFICER HANSTED: No, go ahead, Doctor. That's fine.

DR. CAMBI: Sorry. You know, it's funny. Our jobs are so focused on time to doing something, and there's some confusion about this 90-minute thing, and I just want to try to clarify it.

On the one hand, in the angioplasty world, when someone arrives with a heart attack, we are tasked by our governing societies to open the blood vessel in 90 minutes or less. That's the so-called door to balloon time, and, so, everyone focuses on that 90 minutes.

There's another 90-minute time, though, as well, and that's been referenced in the medical literature, and that's the 90 to 120-minute time you just referenced. That's the suggested time to get a stabilized, but critically-ill patient after an angioplasty to the appropriate level of intervention.

For example, a bypass, a surgical intervention.

So in the Journal of the American College of Cardiology in 2009, study of offsite PCI, provided referenced earlier, that global standard from, quote, initial decision to transport to actual time of initiating CABG, or bypass operation, at the receiving surgical center is 90 minutes.

I think we included that study in our initial application under Attachment D, so that's where that 90 to 120 comes from, not referring to the emergency angioplasty that we do.

COURT REPORTER: I'm sorry.

DR. CAMBI: So the 90 to 120 references, once the medically-stabilized, but ill patient after an angioplasty, who requires surgery, not angioplasty, that's the 90 to 120-minute time frame.

HEARING OFFICER HANSTED: Okay, thank you, Doctor.

DR. CAMBI: Sure.

HEARING OFFICER HANSTED: Attorney Volpe, I just want to go back to your previous answer, just so I'm clear.

In your brief, the response to question four, OHCA's question four, I'm reading that as you're

making a distinction between the definition of emergent and emergency.

MS. VOLPE: In our response?

HEARING OFFICER HANSTED: Yes.

MS. VOLPE: Okay, just so we're all clear, your question is, page 360 of Exhibit A states that the New London Fire Department ambulance will be used if other transportation is unavailable and transportation must occur immediately.

That is what's in our protocol, and you're asking is the distinction being made between immediately and emergency, and we've said that the words emergent and immediately in our guideline for transportation on the elective PCI patient protocol do not have the same meaning as the term emergency, as defined in the Declaratory Ruling, so we are making a distinction that how the Department defined emergency for purposes of the Declaratory Ruling.

We said emergent and immediate mean within the industry standard of 90 to 120 minutes, and I think Dr. Cambi said that better than I can, in terms of the initial decision to transport elective angio, so there's two, sort of two tiers of time that becomes important.

For our purposes, we're not really making

a distinction between emergent, urgent, immediate, critical care. I mean we want to get the patient from one facility to the next through the best means available, and we've taken the position that the best means available means complying with the Declaratory Ruling and having the professional make a clinical decision on what is the best way to transport that patient and the most expeditious way within industry-wide standards.

I'm not even sure. Your question is is a distinction being made between immediately and emergency? I guess I would say no.

HEARING OFFICER HANSTED: Well let me ask you this, just outside of the brief. In terms of the emergent protocol that's been submitted to OHCA, is there an emergency transfer protocol that L & M has, or is it the same as the emergent transfer protocol?

MS. VOLPE: It's all the same for a patient, who we're dealing with in this. And correct me if I'm wrong, Dr. Cambi. The protocol we're going to follow is, when we have a patient in the angioplasty program, who needs to get transported to a higher level of care, we're going to follow that protocol.

Whether you want to call it emergency,

immediately, or urgent, it's the same protocol that we're going to follow.

HEARING OFFICER HANSTED: Doctor?

DR. CAMBI: Yeah. I would just echo what Michele said, and that is we've had such trouble wrestling with this word emergency since your questions arrived, and I think it's really a semantic problem.

The way I think about it is our team is at L & M to handle the true emergency. This patient is rolling in with a heart attack, or they become unstable after like an angioplasty. It's an emergency. Our team needs to act quickly to stabilize that emergency.

If we're successful, they, then, need urgent, imminent, expeditious transfer to Yale to get further care, but, if I'm unsuccessful in stabilizing that emergency, the patient is going to expire, so the true emergency, in the truest sense of the word emergency, is dealt with and stabilized on site at L & M.

It, then, becomes an urgent matter, if you will, to get that patient as quickly and as safely as possible with the right staff to an advanced level center to make sure that the stabilized medical emergency stays that way.

HEARING OFFICER HANSTED: Okay, so, the

distinction I'm hearing there is the stabilization of the patient, and if the patient is stabilized, the protocol that I have before me now for emergent transfer will be used, but it will also be used if the patient is not stabilized?

MS. VOLPE: If the patient is not stabilized, I'll defer to Dr. Cambi, they're going to die.

DR. CAMBI: Right.

MS. VOLPE: So I don't know that it's going to matter. If you're getting hung up on specific words in our protocol, we'd be happy to modify our protocol in accordance with whatever words the Commission would like to see.

From our perspective, we're saying that our protocol is we have a patient, who crashes during this procedure, they're going to get stabilized in the hospital, and then they're going to get transported to the next tertiary level of care.

So if there's a particular word that the Commission and this Department is not comfortable with in our protocol, we welcome the opportunity to work with you to get to a point where you're happy with the word selection, but it doesn't change the actual form and

content of the protocol and what's going to occur.

HEARING OFFICER HANSTED: Okay. I appreciate that. I won't ask you to change your protocol, and I certainly can't order that you change your protocol, but if you feel a subsequent submission of your protocol that may clarify things, you're certainly welcome to submit that.

MS. VOLPE: We're here today, Kevin, to clarify any questions you have in our protocol. From our perspective, the protocol is clear.

We've gone through painstaking detail to explain to you what happens during the protocol, so I would suggest that, if you're getting hung up on a specific word, we would welcome the opportunity for you to tell us.

I mean this is supposed to be a collaborative effort. We're not here to guess at what you want to see, so we would submit that we welcome you.

If you say, you know what? We'd feel more comfortable if you'd replace that word immediate with emergent or whatever, we want to hear it. We want to get it done.

We've gone in detail and provided you with very specific analysis on trying to figure out what it is

that this Commission is hung up on. I mean, if you have something specific, please share it with us here today. I mean that's why we're all here.

HEARING OFFICER HANSTED: Well I think, you know, again, I can't order you to change your protocol. You're certainly willing to submit whatever you want to submit as a late file.

MS. VOLPE: We don't want to submit any late file. We want to know what the Department wants.

HEARING OFFICER HANSTED: Okay, well, I think it's clear what the Department's concern is, based upon the issues we've already presented.

If what you're relying upon hasn't already been submitted to OHCA, then that's what we'll use in our decision-making, and I won't make any judgment calls on that at this point.

MS. VOLPE: I would suggest that it's not clear on what the Department's position is, and I think there's a huge amount of people in this room that would agree it's not clear on what the Department's position is.

We're trying to anticipate, by all of the pre-filed testimony that we've submitted, on what the Department's position is.

I mean is it the Department's position that the Applicant should be calling 9-1-1 if we have to make a transport, based on this program? Is that the Department's position?

HEARING OFFICER HANSTED: The Department's position is that it has before it at this point a Declaratory Ruling, which states that 9-1-1 should be called in emergency transfer situations.

However that is open to the Applicant's interpretation, that's how you are going to interpret it. We have possibly a different opinion and interpretation of that Declaratory Ruling, but we have that law before us, and we need to make our decision based upon that law.

MS. VOLPE: And I would present to you that that law states, very clearly, that it is the transferring facility, the sponsoring hospital's clinical determination on whether to activate the 9-1-1 system.

So if we're going to read that law in its proper context, there's great deference that should be given to the physician, who stabilized the patient, as to whether or not to activate the 9-1-1 system.

So we're prepared to tell you that we're in compliance with that law.

HEARING OFFICER HANSTED: Okay and your

brief has spelled that out very clearly for us, and I appreciate the brief. That has explained a lot for OHCA.

Again, I'm not arguing with you on this subject. I'm just clearly stating that I can't order you to change your protocol, so we'll base our decision on what we have, based upon what we have before us at this time.

I'm not going to tell you what to submit as evidence.

MS. VOLPE: It's not evidence. I mean we're talking about a hospital protocol that this Commission somehow has determined that we're not in compliance with the law.

I mean this is what we're here to decide today.

HEARING OFFICER HANSTED: Well let me make it very clear. OHCA hasn't made any determination that you're not in compliance with the law. OHCA has presented some issues for you to discuss today.

We haven't made any decision on this yet, or determination.

MS. VOLPE: Okay, so, our inference, based on your line of questioning, was somehow that we weren't in compliance with the Declaratory Ruling.

HEARING OFFICER HANSTED: No. That determination has not yet been made. Those are just questions that we had for discussion purposes today. That's all.

MS. VOLPE: I just think it's unfortunate and it's a tremendous waste of resources for everyone that if you have a specific issue with our protocol, that you don't provide it today to everyone who is here, so we can try and satisfy and address what it is that the Commission would like to see.

HEARING OFFICER HANSTED: Well I'm not saying you haven't satisfied us. I'm not saying you have satisfied us. Those are just some issues we had for you today, and we've discussed them.

I appreciate the discussion here today, I appreciate the brief, and we will make a decision on the CON application, based upon everything we have before us.

Doctor, did you want to add something?

DR. CAMBI: Can I ask another question? Is it okay with you?

HEARING OFFICER HANSTED: Well, no. I don't want to answer any questions. Attorney Volpe has pretty much fleshed this out for us.

DR. CAMBI: All right.

MS. VOLPE: It's OHCA's turn to ask questions.

DR. CAMBI: Okay.

HEARING OFFICER HANSTED: Thank you. Thank you. That was actually the -- well one more question for you. In terms of the transfers, it was mentioned here and, also, on the brief that there were 450 transfers from L & M to Yale.

How many, if you know, how many of those were from the current primary angioplasty program or stemming from issues with primary angioplasty?

MS. VOLPE: I'll defer, but probably zero to two.

DR. CAMBI: Yeah. Zero.

MS. VOLPE: Zero.

HEARING OFFICER HANSTED: Okay, thank you. Okay, those are the only questions I had.

MS. VOLPE: Before we move on to our closing remarks, can we just have a two-minute break?

HEARING OFFICER HANSTED: Oh, absolutely. Yes, we'll go off the record.

MS. VOLPE: Thank you.

(Off the record)

HEARING OFFICER HANSTED: Attorney Volpe,

did you -- if you wanted to make a closing statement, I'm fine with that, but I just want to get through the public portion, unless you wanted to add something in.

MS. VOLPE: I would like to just take two minutes and make a couple of closing remarks.

HEARING OFFICER HANSTED: Sure.

MS. VOLPE: Specifically, that our L & M's transfer protocol fully complies with the 2003 Declaratory Ruling and the directive that the clinician's medical judgment should prevail in determining whether the 9-1-1 system should be activated.

Physicians can't be deprived of the ability to exercise discretion over whether to activate the 9-1-1 system and how the patient should be transported.

A mandate, that hospitals must dial 9-1-1 for every urgent, emergent and critical care inter-hospital transfer, conflicts with the Declaratory Ruling, itself, as well as subsequently enacted State and Federal law, which we refer to today.

As Dr. Cambi explained in his testimony, it adversely impacts patient care and usurps the medical judgment of sponsor hospitals and their staff.

As Mr. Kersey explained in his testimony,

it also has the potential to collapse the 9-1-1 system and create hardships for resources in cities and towns.

The New London Deputy Fire Chief, Mr. Kydd, who speaks for the New London PSAR, supports our transfer protocol and explains that his department cannot become the primary first responder for all of L & M's transfers of critically-ill patients.

If that were to occur, it would impact not only his department, but first responders in all of the surrounding areas.

9-1-1, we submit, is getting a patient to the hospital, not transferring patients within the hospital system.

The Department's requirement, that hospitals dial 9-1-1, if that is, in fact, your position, really can set policy that will ultimately create inferior standards in the community than that which exists today.

I respectfully request that you approve L & M's patient transfer protocol for elective angioplasty and the CON that's before you today, and that we conform with OHCA's Statewide Health Care Facilities Plan, as outlined and referenced by Dr. Cambi.

Everything in our CON submission speaks to

the need analysis, and we respectfully request that you approve our application. That concludes our remarks.

HEARING OFFICER HANSTED: Thank you, Attorney Volpe. Is there anyone here from the public that wishes to give any public testimony?

Okay, well, let the record reflect that there are none, and, Attorney Volpe, unless you have anything else --

MS. VOLPE: We don't. Thank you.

HEARING OFFICER HANSTED: Thank you, and, with that, I will adjourn this hearing. Thank you, all.

(Whereupon, the hearing adjourned at 11:20 a.m.)

HEARING RE: OFFICE OF HEALTH CARE ACCESS
DECEMBER 13, 2012

AGENDA

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 19th day of December, 2012.

Paul Landman
President

Post Reporting Service
1-800-262-4102

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"):

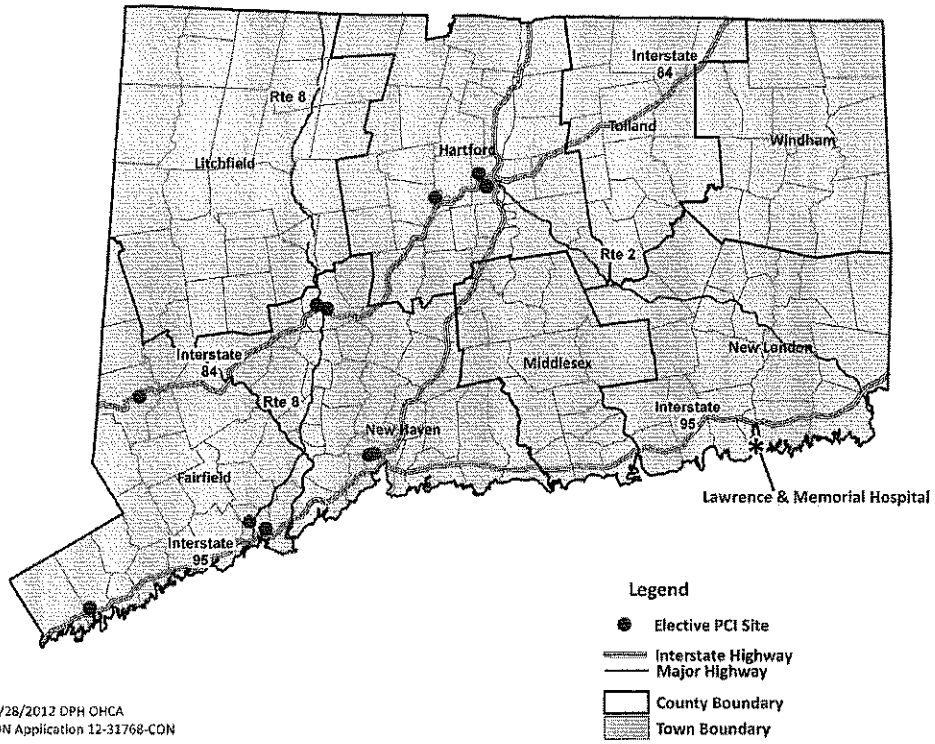
Table 1: Primary and secondary service area

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



Prepared 9/28/2012 DPH OHCA
Source: CON Application 12-31768-CON

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

	FY11			
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

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*** TX REPORT ***
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TO: Crista Durand

FAX: (860) 444-3716

AGENCY: L+N

FROM: Steven Lazarus

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Comments: Agreed Settlement for DN: 12-31768. Enclosed.

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

From: Patel, Shraddha [mailto:spatel@lmhosp.org]
Sent: Monday, April 29, 2013 1:29 PM
To: Fiducia, Paolo
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

- Fiscal Year 2013 Quarter 2 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2012Q3

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex tomorrow (04/30/13).

If you have any questions or concerns regarding this filing, please contact me at (860) 442-0711 x. 5185 or via email.

Thank you,
Shraddha Patel

Shraddha Patel, FACHE
Director of Business Development and Planning
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Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
East Lyme	1			1
Essex		1	1	2
Groton	2	1		3
Leydard	2	1		3
Mystic	1			1
New London	4	1	1	6
Niantic	2			2
Norwich	2	1		3
Oakdale		1		1
Old Lyme	1			1
Portsmouth, RI	1			1
Preston	2			2
Riverside, RI	2			2
Stonington		1		1
Waterbury	1			1
Waterford	2	2		4
Westerly, RI	2			2
Total PCI Procedures	25	9	2	36

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2013, Quarter 2

There were 0 transfers for cardiac surgery in FY 2013, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
National Cardiovascular Data Registry
CathPCI Registry
Version 4.4

Institutional Outcomes Report
2012Q3

Lawrence & Memorial Hospital
742173

Aggregation Date: Jan 10, 2013 11:59:59 PM

Publish Date: Jan 25, 2013

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

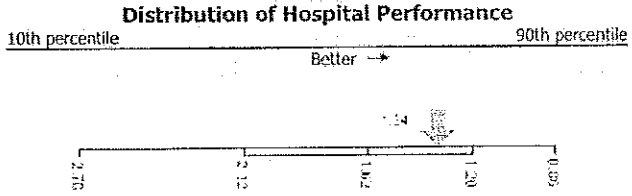
PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.34	1.62	0.86

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2017]

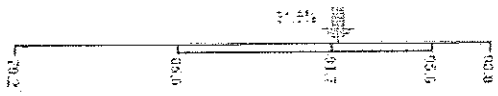
Distribution of Hospital Performance



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
91.9%	91.7%	98.0%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:1988]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	62.7%	85.4%

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:1513]

3 **Median time to immediate PCI for STEMI patients (in minutes)**

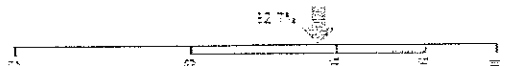
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
62.5	61.6	49.6

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:1502]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.7%	93.4%	100.0%

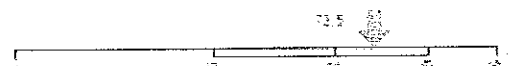
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
73.5	79.5	54.2

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
120.0	111.6	81.6

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:1506]

7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.0	9.3	6.9

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:1633]

8 **Proportion of patients with aspirin prescribed at discharge**

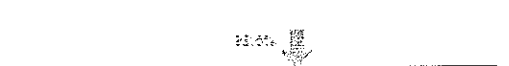
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.7%	98.7%	100.0%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1978]

9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.6%	99.3%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:1987]



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Executive Summary

CathPCI Registry®

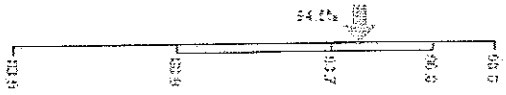
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.6%	93.7%	98.8%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:1983]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

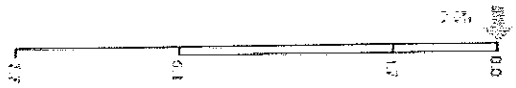
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1960]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	1.7%	0.0%

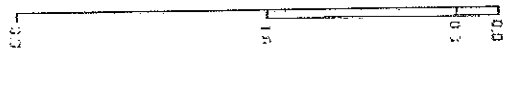
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.3%	0.0%

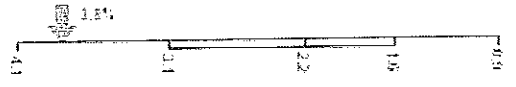
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



15 **Proportion of PCI procedures with acute kidney injury*****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.8%	2.2%	0.9%

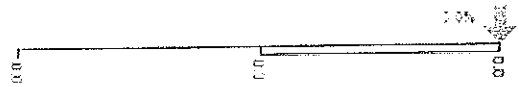
Your hospital's proportion of patients who had a rise of serum creatinine of > 50% over the pre-procedure baseline (excluding patients on dialysis pre-procedure). Inclusions: >= 90% of patients with a pre and post creatinine coded; LOS >=1 day. [Detail Line:1952]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

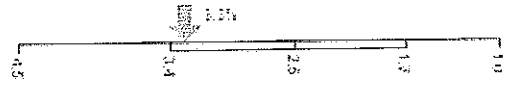
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.3%	2.5%	1.0%

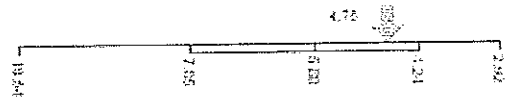
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.76	5.88	2.92

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2026]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.81	0.36

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:2035]

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.4%	1.4%	0.0%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.43	4.30	1.86

Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]

Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
48.4%	44.1%	30.3%

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

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US 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

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

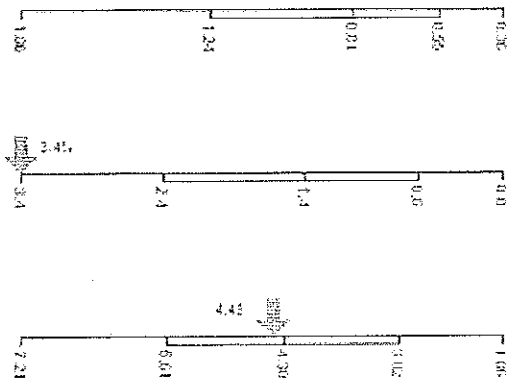
Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2091]

Data Quality Metrics

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.4%	90.6%	97.9%

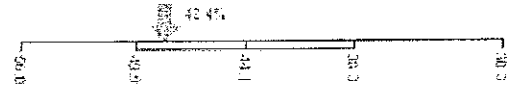
Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



Distribution of Hospital Performance

10th percentile — 90th percentile

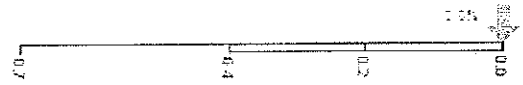
Better →



Distribution of Hospital Performance

10th percentile — 90th percentile

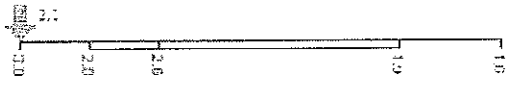
Better →



Distribution of Hospital Performance

10th percentile — 90th percentile

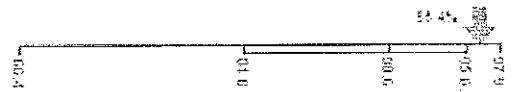
Better →



Distribution of Hospital Performance

10th percentile — 90th percentile

Better →



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

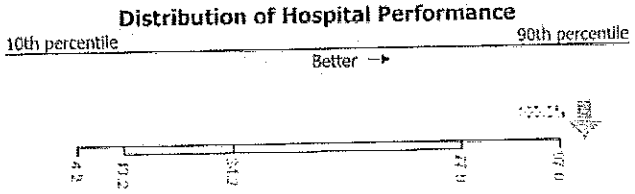
Test Metrics

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	34.2%	97.0%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Distribution of Hospital Performance



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	5.7%	1.0%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.1%	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:1581]

32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	1.3%	6.7%

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:1582]

33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.3%	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:1583]

34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	38.3%	67.0%

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:1585]

35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	37.6%	57.0%

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:1586]

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	19.6%	3.3%

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:1587]

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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Publish Date: Jan 25, 2013

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

April 29, 2013

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2013 Quarter 2 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2012Q3

If you have any questions or concerns regarding this filing, please contact me at (860) 442-0711 x. 5185 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
East Lyme	1			1
Essex		1	1	2
Groton	2	1		3
Leydard	2	1		3
Mystic	1			1
New London	4	1	1	6
Niantic	2			2
Norwich	2	1		3
Oakdale		1		1
Old Lyme	1			1
Portsmouth, RI	1			1
Preston	2			2
Riverside, RI	2			2
Stonington		1		1
Waterbury	1			1
Waterford	2	2		4
Westerly, RI	2			2
Total PCI Procedures	25	9	2	36

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2013, Quarter 2

There were 0 transfers for cardiac surgery in FY 2013, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

Version 4.4

Institutional Outcomes Report
2012Q3

Lawrence & Memorial Hospital
742173

Aggregation Date: Jan 10, 2013 11:59:59 PM

Publish Date: Jan 25, 2013

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.34	1.62	0.86

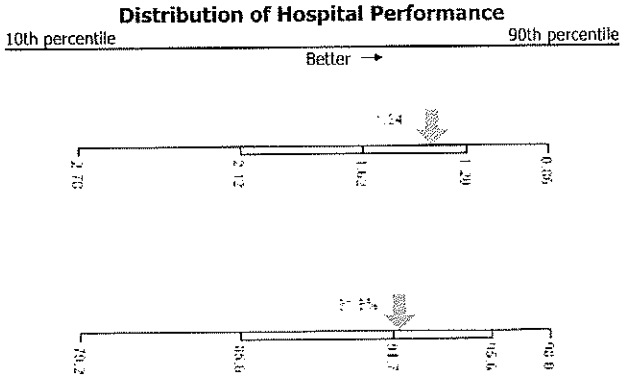
Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2017]

38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
91.9%	91.7%	98.0%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:1988]

Distribution of Hospital Performance



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	62.7%	85.4%

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:1513]

3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
62.5	61.6	49.6

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:1502]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.7%	93.4%	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:1503]

5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
73.5	79.5	54.2

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
120.0	111.6	81.6

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:1506]

7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.0	9.3	6.9

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:1633]

8 **Proportion of patients with aspirin prescribed at discharge**

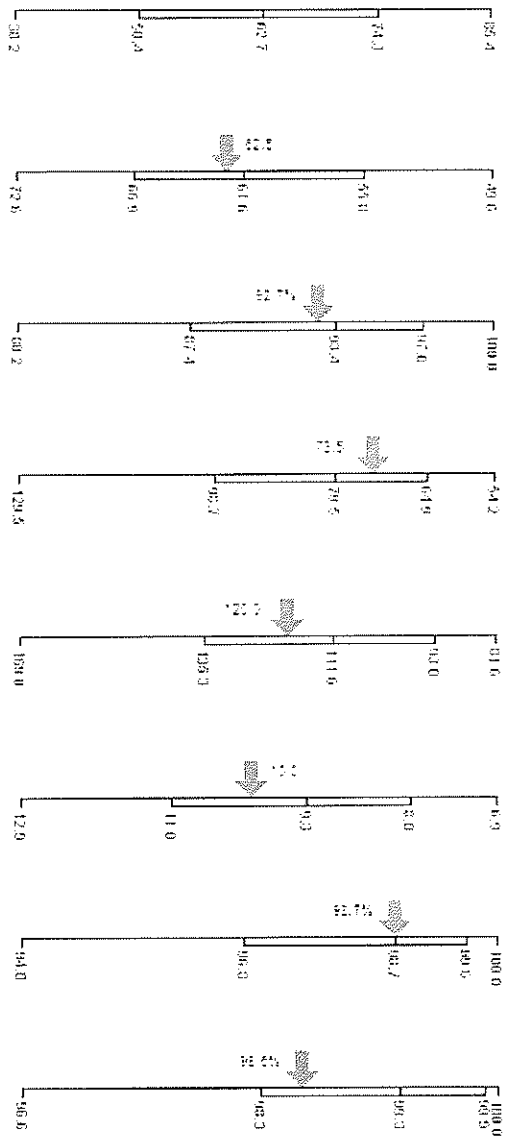
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.7%	98.7%	100.0%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1978]

9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.6%	99.3%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:1987]



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Executive Summary

CathPCI Registry®

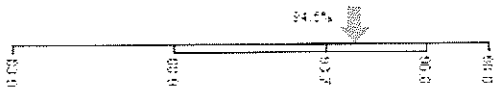
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.6%	93.7%	98.8%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:1983]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

My Hospital	US Hospitals 50th Pctl	US 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:1960]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	1.7%	0.0%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.3%	0.0%

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:1804]

15 **Proportion of PCI procedures with acute kidney injury*****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.8%	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:1952]

16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]

17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

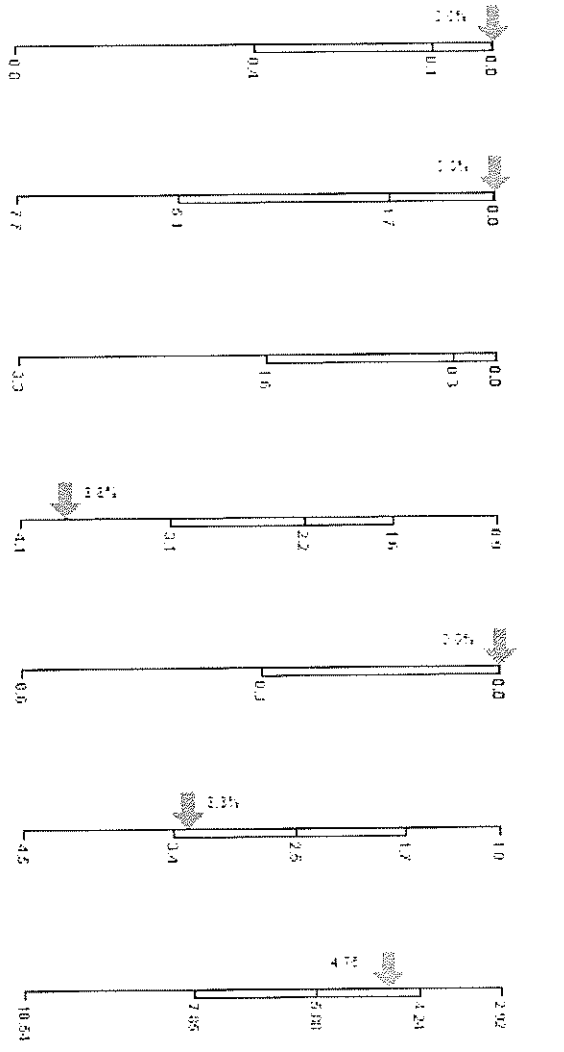
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.3%	2.5%	1.0%

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:1801]

18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.76	5.88	2.92

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2026]



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

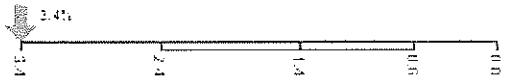
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.81	0.36

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:2035]

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.4%	1.4%	0.0%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.43	4.30	1.86

Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]

Diagnostic Cath Process Metrics

Distribution of Hospital Performance

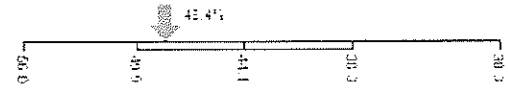
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
48.4%	44.1%	30.3%

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

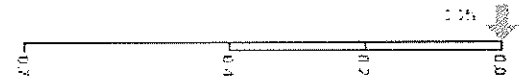
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US 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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2091]

Data Quality Metrics

Distribution of Hospital Performance

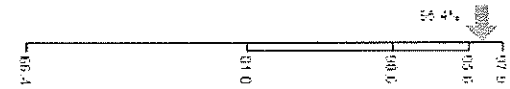
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.4%	90.6%	97.9%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

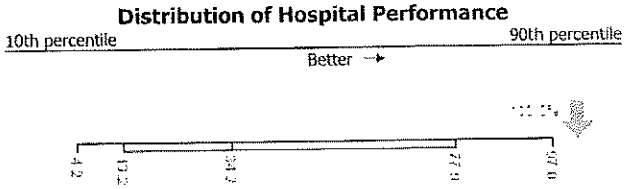
Test Metrics

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	34.2%	97.0%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Distribution of Hospital Performance



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

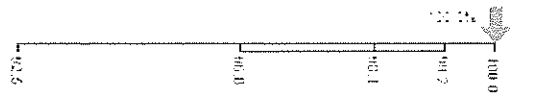
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	5.7%	1.0%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.1%	100.0%

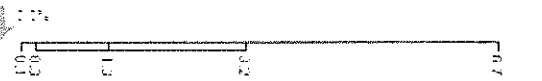
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	1.3%	6.7%

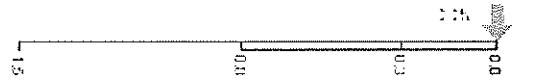
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.3%	0.0%

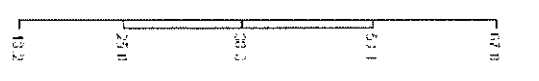
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	38.3%	67.0%

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:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	37.6%	57.0%

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:1586]

Executive Summary

CathPCI Registry®

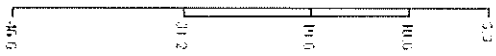
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q3

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	19.6%	3.3%

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:1587]



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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LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
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July 11, 2013

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Office of Health Care Access
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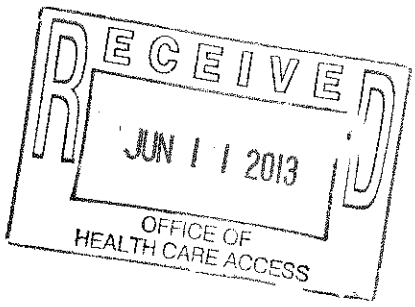
Hartford, CT 06134-0308



RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2013 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2012Q4

If you have any questions or concerns regarding this filing, please contact me at (860) 442-0711 x. 5185 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 3

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	1			1
Bozrah	1			1
Broad Brook	1			1
Cumberland, RI	1			1
East Lyme		2		2
Gales Ferry	2		1	3
Groton		3		3
Hope Valley, RI	1			1
Hopkinton, RI	1			1
Johnston, RI	1			1
Leydard		1		1
Mystic	2			2
New London	5	3	2	10
Niantic	1		3	4
North Stonington		1		1
Norwich	1	1		2
Oakdale		1		1
Salem	1	1		2
Stonington			1	1
Waterford	2			2
West Warwick, RI		1		1
Westerly, RI			1	1
Total PCI Procedures	21	14	8	43

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2013, Quarter 3

There were 0 transfers for cardiac surgery in FY 2013, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
National Cardiovascular Data Registry
CathPCI Registry®
Version 4.4

Institutional Outcomes Report
2012Q4

Lawrence & Memorial Hospital
742173

Aggregation Date: Apr 15, 2013 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q4

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.34	1.66	0.86

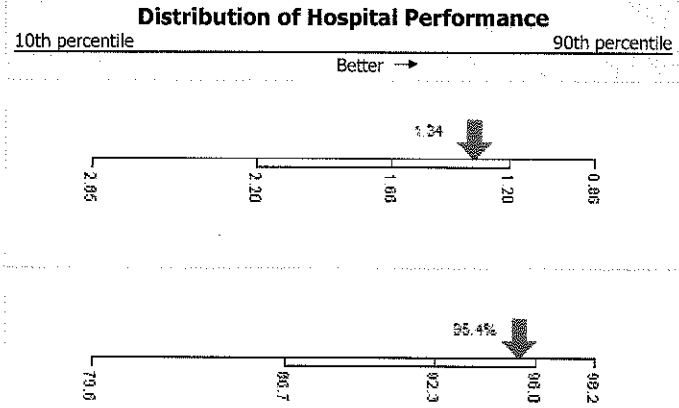
Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2017]

38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.4%	92.3%	98.2%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:1988]

Distribution of Hospital Performance



Note

Performance measures in the CathPCI Registry® have 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.

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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.

PCI Process Metrics

Distribution of Hospital Performance

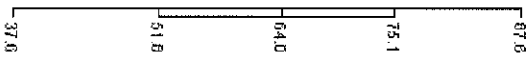
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	64.0%	87.6%

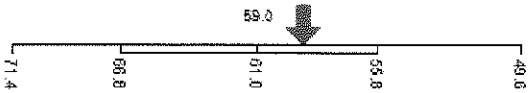
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
59.0	61.0	49.6

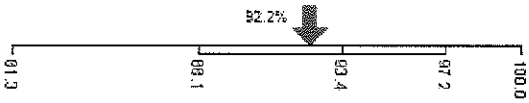
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.2%	93.4%	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:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

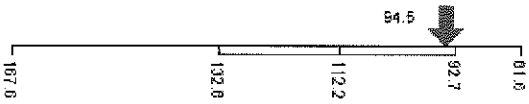
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
54.5	78.2	54.5

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.5	112.2	81.6

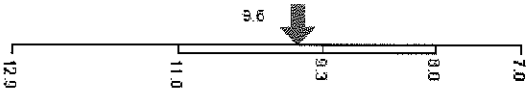
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9.6	9.3	7.0

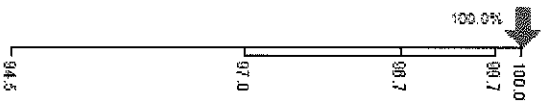
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.7%	100.0%

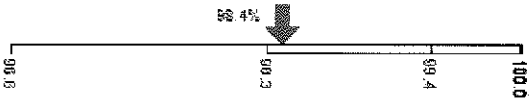
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1978]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.4%	99.4%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:1987]



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CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.9%	94.1%	98.9%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:1983]

PCI Outcome Metrics

Distribution of Hospital Performance

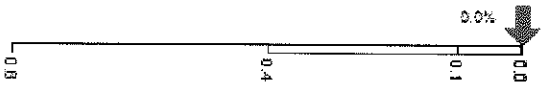
10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

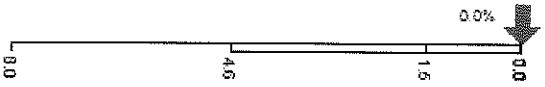
Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1960]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	1.5%	0.0%

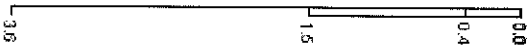
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.4%	0.0%

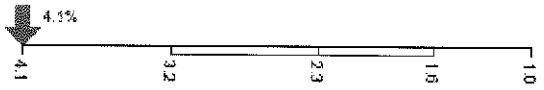
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



15 **Proportion of PCI procedures with acute kidney injury*****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.1%	2.3%	1.0%

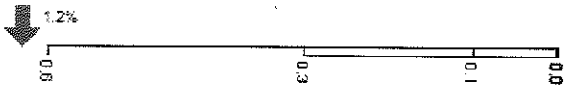
Your hospital's proportion of patients who had a rise of serum creatinine of > 50% over the pre-procedure baseline (excluding patients on dialysis pre-procedure). Inclusions: >= 90% of patients with a pre and post creatinine coded; LOS >=1 day. [Detail Line:1952]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.2%	0.1%	0.0%

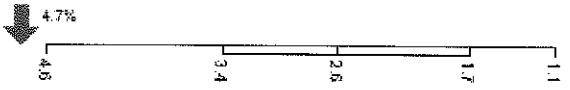
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.7%	2.6%	1.1%

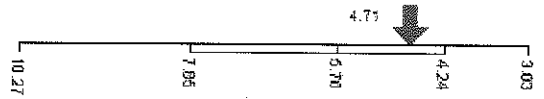
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.71	5.76	3.03

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2026]



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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.

19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

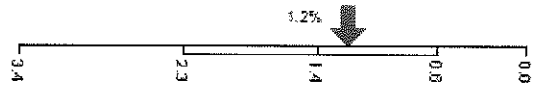
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.85	0.37

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:2035]

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.2%	1.4%	0.0%

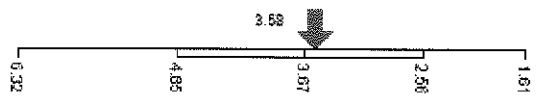
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.58	3.67	1.61

Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

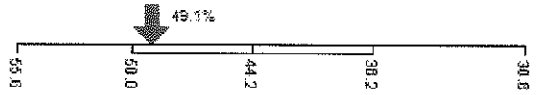
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
49.1%	44.2%	30.8%

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:1252]



Diagnostic Cath Outcomes Metrics

Distribution of Hospital Performance

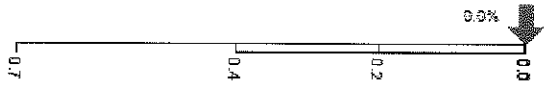
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US 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

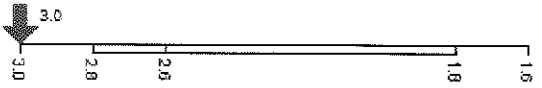
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2091]



Data Quality Metrics

Distribution of Hospital Performance

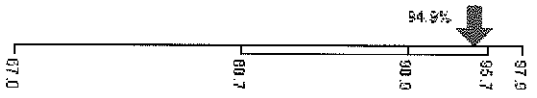
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.9%	90.9%	97.9%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



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Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Test Metrics

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

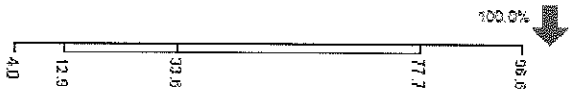
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	33.6%	96.6%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →



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Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

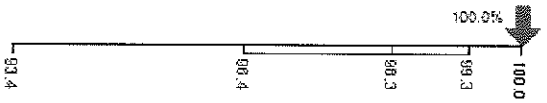
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	5.3%	0.9%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.3%	100.0%

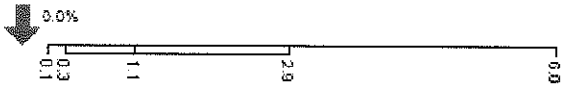
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	1.1%	6.0%

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:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

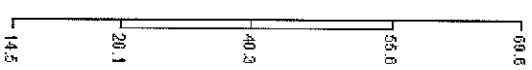
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.2%	0.0%

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:1583]

34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	40.3%	69.8%

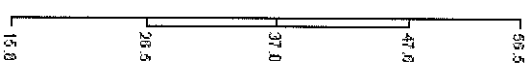
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	37.0%	56.5%

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:1586]



Aggregation Date: Apr 15, 2013 11:59:59 PM
Publish Date: May 4, 2013

Executive Summary

CathPCI Registry®

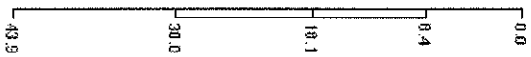
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2012Q4

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	18.1%	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:1587]



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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LAWRENCE +MEMORIAL HOSPITAL

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July 22, 2013

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2013Q1

If you have any questions or concerns regarding this filing, please contact me at (860) 442-0711 x. 5185 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

NCDR®
National Cardiovascular Data Registry
CathPCI Registry®
Version 4.4

Institutional Outcomes Report
2013Q1

Lawrence & Memorial Hospital
742173

Aggregation Date: Jul 1, 2013 11:59:59 PM

Publish Date: Jul 14, 2013

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q1

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

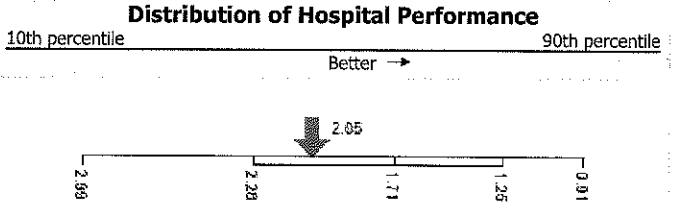
PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.05	1.71	0.91

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2035]

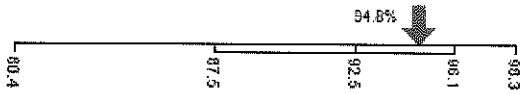
Distribution of Hospital Performance



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.8%	92.5%	98.3%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2006]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q1

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

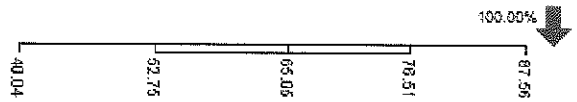
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	65.05%	87.56%

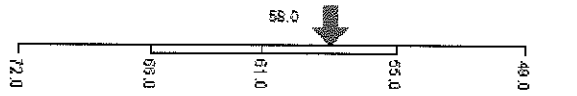
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
58	61	49

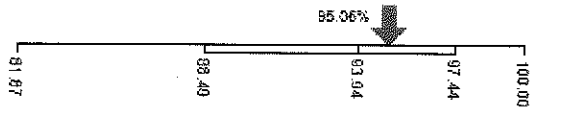
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.06%	93.94%	100.00%

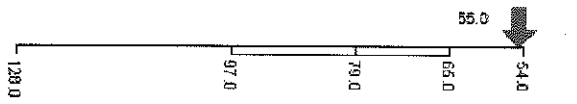
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
55	79	54

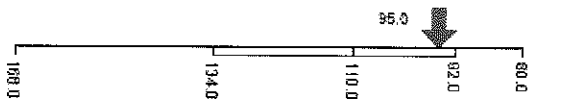
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95	110	80

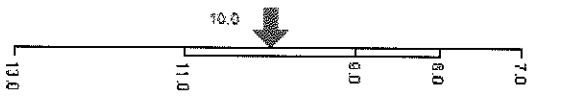
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10	9	7

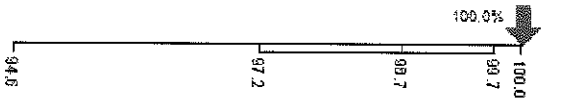
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.7%	100.0%

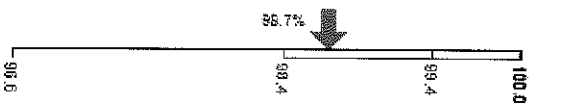
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1996]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.7%	99.4%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2005]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q1

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.1%	94.3%	99.0%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2001]

PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

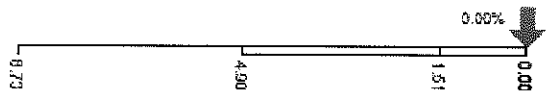
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1978]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	1.51%	0.00%

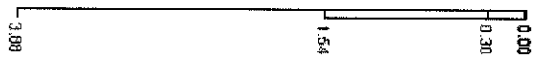
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.30%	0.00%

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:1804]



16 **Proportion of PCI procedures with post procedure stroke**

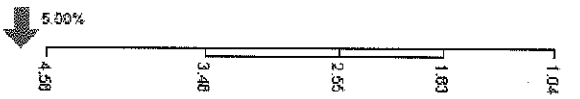
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.98%	0.08%	0.00%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]

17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
5.00%	2.55%	1.04%

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:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.18	5.91	3.03

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2044]

19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.89	0.41

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:2053]

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Executive Summary

CathPCI Registry®

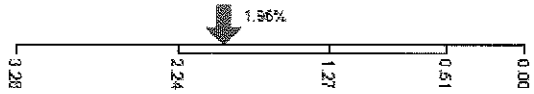
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.96%	1.27%	0.00%

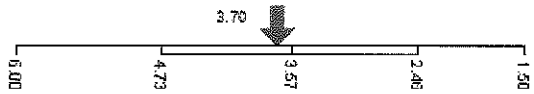
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.70	3.57	1.50

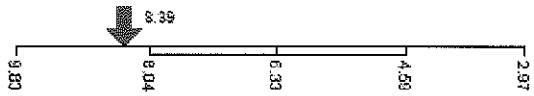
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8.39	6.33	2.97

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

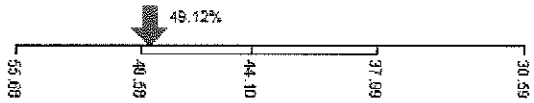
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
49.12%	44.10%	30.59%

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

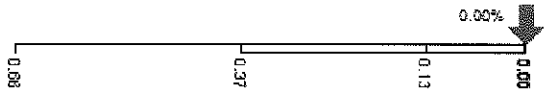
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.13%	0.00%

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

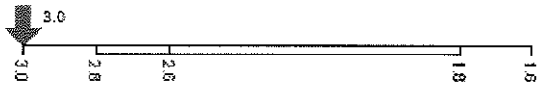
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2109]



Data Quality Metrics

Distribution of Hospital Performance

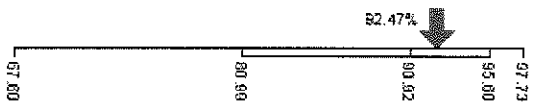
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.47%	90.92%	97.73%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

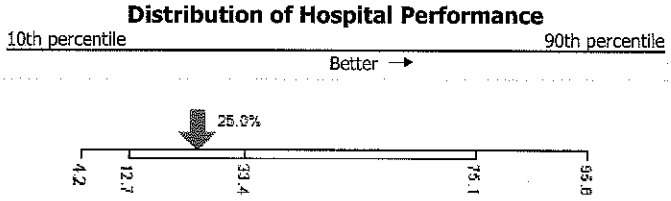
Test Metrics

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
25.0%	33.4%	95.8%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Distribution of Hospital Performance



Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

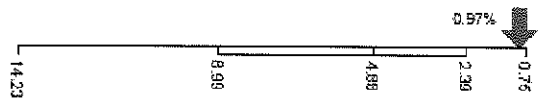
10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.97%	4.88%	0.75%

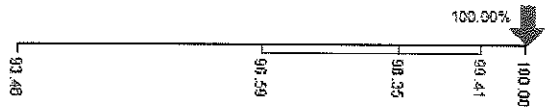
Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]



31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	98.35%	100.00%

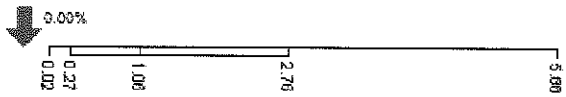
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	1.06%	5.88%

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:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

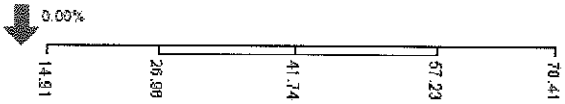
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.16%	0.00%

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:1583]

34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	41.74%	70.41%

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:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	36.36%	57.18%

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:1586]

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Executive Summary

CathPCI Registry®

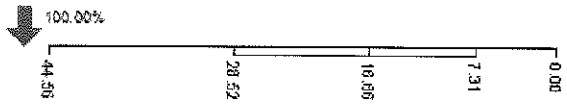
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	16.66%	0.00%

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:1587]



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.

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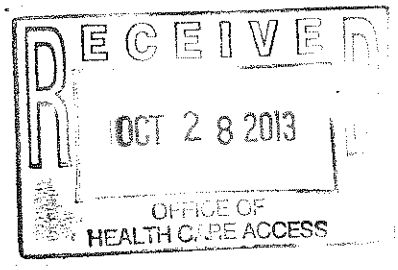


October 28, 2013

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2013 Quarter 4 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2013Q2

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 4

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI			1	1
Altoona , PA	1			1
Bradford, RI	2			2
Charleston, RI	1			1
East Haven	1			1
East Long Meadow, MA	1			1
East Lyme	1	2		3
Gales Ferry	1			1
Groton	3	3	3	9
Ledyard	1	1	1	3
Lyme	1	1		2
Milford	1			1
Mystic	3	2		5
New London	2	1	1	4
Newington	1			1
Niantic			1	1
North Stonington	1			1
Norwich	3	1		4
Oakdale	1			1
Ponta Gurda, FL	1			1
Quaker Hill		2		2
Salem	1			1
Sandy Hook	1			1
Saratoga, NY	1			1
Southwick, MA	1			1
Uncasville			1	1
Waterford	2	1		3
Westerly, RI	1			1
Wetherfield	1			1
Total PCI Procedures	34	14	8	56

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2013, Quarter 4

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Primary PCI procedure; non-urgent transfer to Yale for further treatment; operator was unable to cross lesion of STEMI patient due to chronic total occlusion	9/22/2013 00:23	9/22/2013 01:15	Yale operator unable to open culprit lesion; angioplasty with stent performed on another vessel: 9/22/2013 16:01
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
National Cardiovascular Data Registry
CathPCI Registry®
Version 4.4

Institutional Outcomes Report
2013Q2

Lawrence & Memorial Hospital
742173

Aggregation Date: Sep 30, 2013 11:59:59 PM

Publish Date: Oct 9, 2013

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q2

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

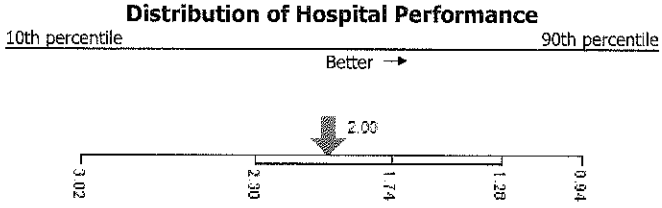
PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.00	1.74	0.94

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2035]

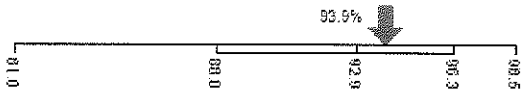
Distribution of Hospital Performance



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
93.9%	92.9%	98.5%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2006]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q2

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

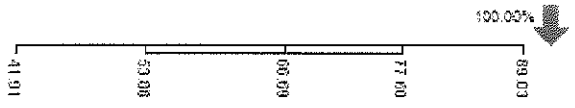
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	66.69%	89.03%

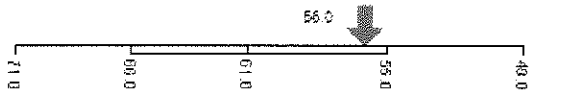
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
56	61	49

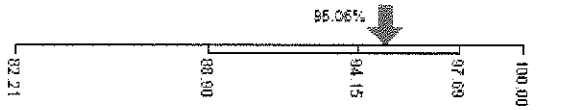
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.06%	94.15%	100.00%

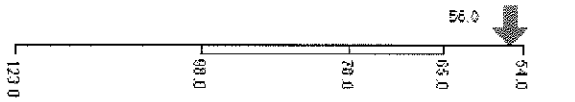
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
56	78	54

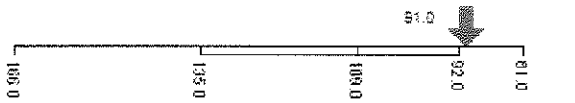
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
91	109	81

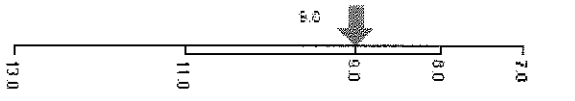
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	9	7

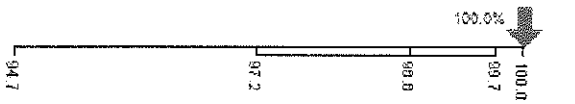
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.8%	100.0%

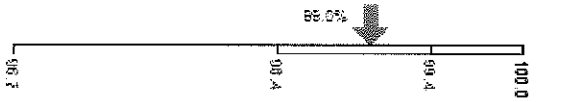
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1996]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.0%	99.4%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2005]



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Executive Summary

CathPCI Registry®

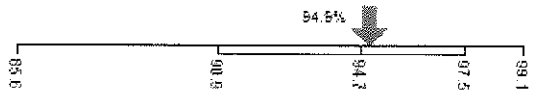
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q2

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.9%	94.7%	99.1%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2001]



PCI Outcome Metrics

Distribution of Hospital Performance

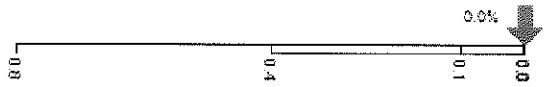
10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

My Hospital	US Hospitals 50th Pctl	US 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:1978]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

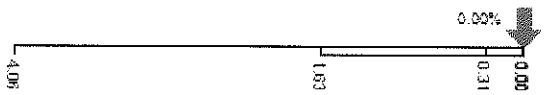
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.59%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.31%	0.00%

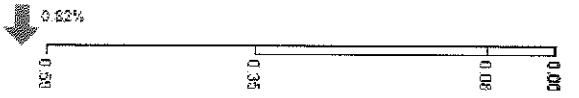
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.82%	0.08%	0.00%

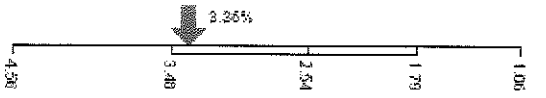
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.36%	2.54%	1.06%

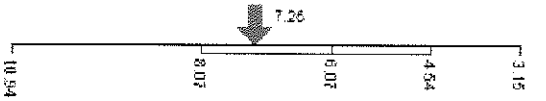
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.26	6.07	3.15

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2044]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.88	0.40

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:2053]

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Executive Summary

CathPCI Registry®

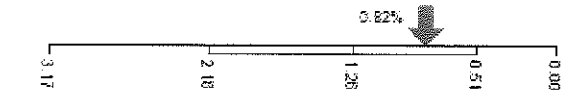
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.82%	1.28%	0.00%

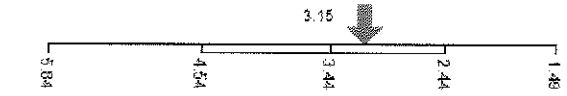
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.15	3.44	1.49

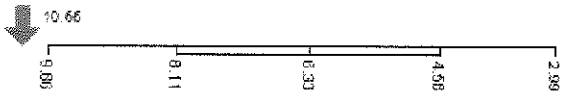
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.66	6.33	2.99

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.20%	43.67%	29.99%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.13%	0.00%

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

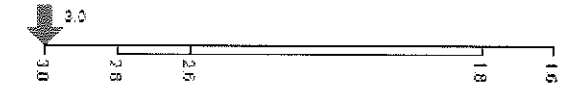
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2109]



Data Quality Metrics

Distribution of Hospital Performance

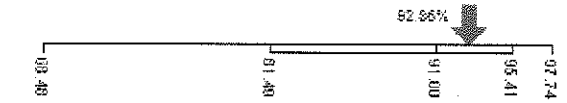
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.86%	91.00%	97.74%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



Aggregation Date: Sep 30, 2013 11:59:59 PM
Publish Date: Oct 9, 2013

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

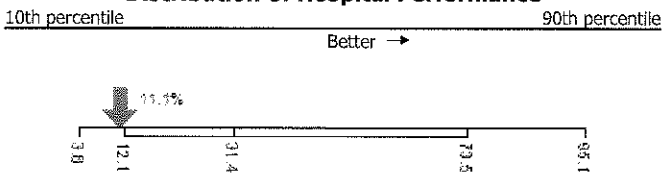
Test Metrics

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
11.1%	31.4%	95.1%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Distribution of Hospital Performance



Executive Summary

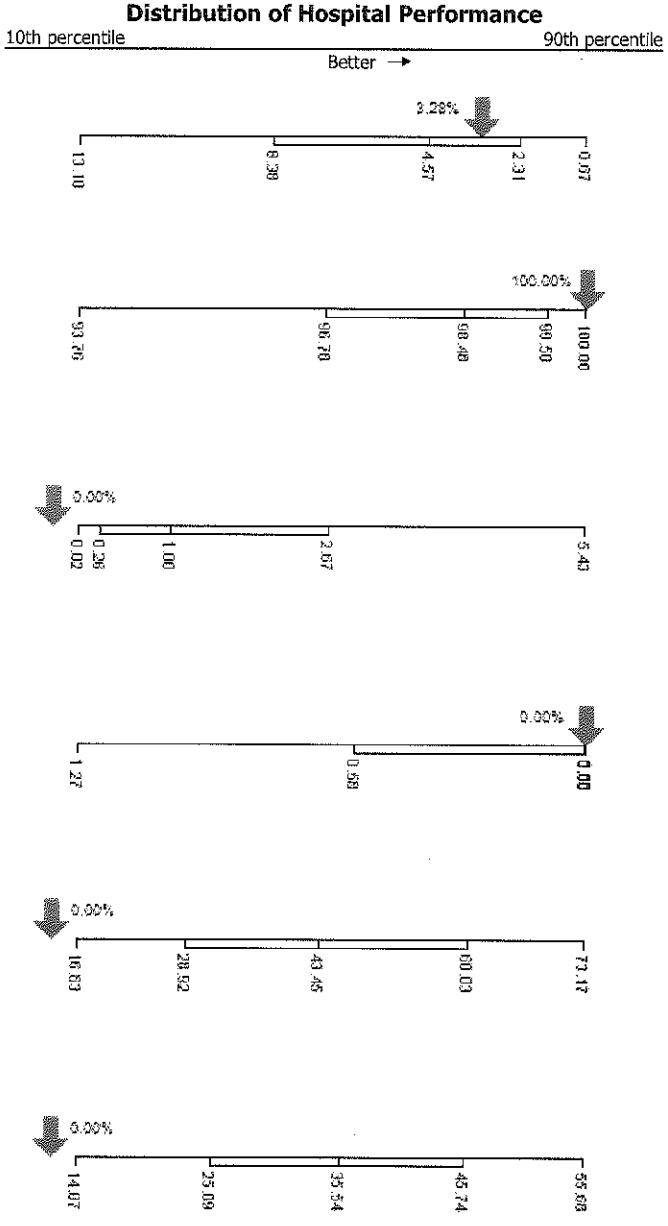
CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance



30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.28%	4.57%	0.67%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	98.48%	100.00%

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:1581]

32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	1.00%	5.43%

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:1582]

33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1583]

34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	43.45%	73.17%

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:1585]

35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	35.54%	55.68%

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:1586]

Aggregation Date: Sep 30, 2013 11:59:59 PM
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Executive Summary

CathPCI Registry®

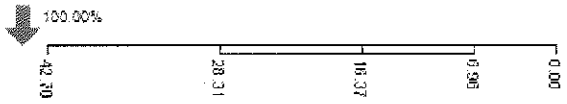
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	16.37%	0.00%

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:1587]



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.

Aggregation Date: Sep 30, 2013 11:59:59 PM
Publish Date: Oct 9, 2013

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2013, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
East Lyme	1			1
Essex		1	1	2
Groton	2	1		3
Leydard	2	1		3
Mystic	1			1
New London	4	1	1	6
Niantic	2			2
Norwich	2	1		3
Oakdale		1		1
Old Lyme	1			1
Portsmouth, RI	1			1
Preston	2			2
Riverside, RI	2			2
Stonington		1		1
Waterbury	1			1
Waterford	2	2		4
Westerly, RI	2			2
Total PCI Procedures	25	9	2	36

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Fiducia, Paolo

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Thursday, January 30, 2014 12:39 PM
To: Fiducia, Paolo
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2014 Q1 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

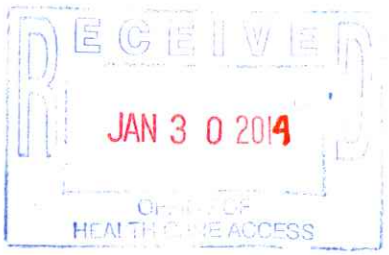
- Fiscal Year 2014 Quarter 1 PCI Volume by Patient's Town of Residence

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex tomorrow.

The latest ACC NCDR report has not been released yet. We will forward that document to you as soon as it becomes available.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel



Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 1

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Charleston, RI	1			1
Colchester			1	1
East Lyme		1		1
Groton	2	2		4
Jewett city			1	1
Ledyard	1			1
Middle Island, NY	1			1
Mystic	1	1	1	3
New London	2	2		4
Niantic		1		1
Norwich	1	1		2
Oakdale	2	1		3
Pawcatuck	2			2
Stonington			1	1
Uncasville		1		1
Waterford			1	1
Westerly, RI	1	1		2
Total PCI Procedures	14	11	5	30

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Note: Between 11/27/13 and 12/19/13, L+M's emergent PCI program was suspended due to the nursing/tech strike. Per the strike contingency plan provided to CT DPH, "emergent Percutaneous Coronary Intervention (PCI) will not be performed during strike."

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 1

Report 1. c.

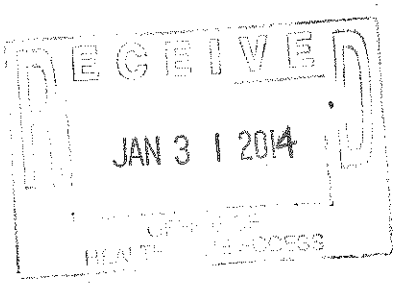
Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	None				
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

January 30, 2014



Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 1 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 1

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Charleston, RI	1			1
Colchester			1	1
East Lyme		1		1
Groton	2	2		4
Jewett city			1	1
Ledyard	1			1
Middle Island, NY	1			1
Mystic	1	1	1	3
New London	2	2		4
Niantic		1		1
Norwich	1	1		2
Oakdale	2	1		3
Pawcatuck	2			2
Stonington			1	1
Uncasville		1		1
Waterford			1	1
Westerly, RI	1	1		2
Total PCI Procedures	14	11	5	30

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Note: Between 11/27/13 and 12/19/13, L+M's emergent PCI program was suspended due to the nursing/tech strike. Per the strike contingency plan provided to CT DPH, "emergent Percutaneous Coronary Intervention (PCI) will not be performed during strike."

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	None				
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

February 3, 2014

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2013Q3

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Version 4.4

Institutional Outcomes Report
2013Q3

Lawrence & Memorial Hospital
742173

Aggregation Date: Jan 10, 2014 11:59:59 PM

Publish Date: Jan 29, 2014

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q3

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)**

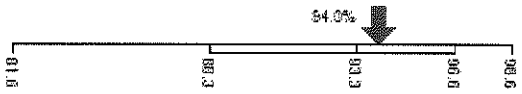
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.57	1.70	0.91

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2035]

38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.0%	93.3%	98.6%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2006]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q3

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

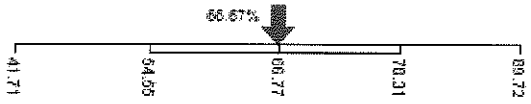
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
66.67%	66.77%	89.72%

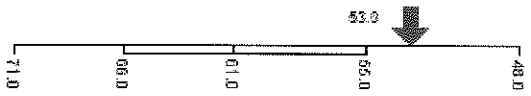
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
53	61	48

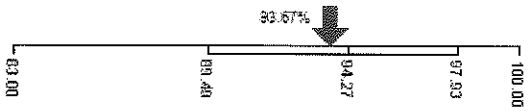
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
93.67%	94.27%	100.00%

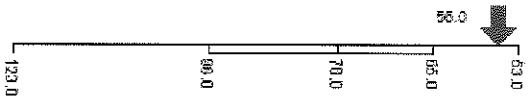
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
56	78	53

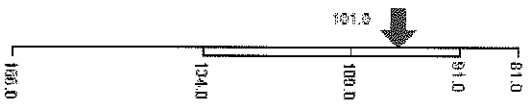
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
101	109	81

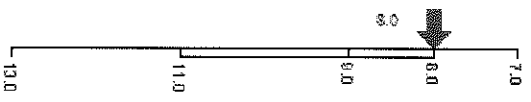
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8	9	7

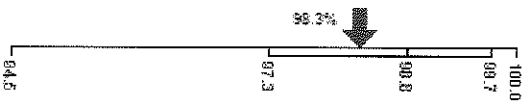
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.3%	98.8%	100.0%

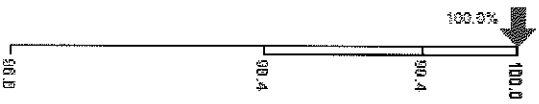
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1996]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	99.4%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2005]



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Executive Summary

CathPCI Registry®

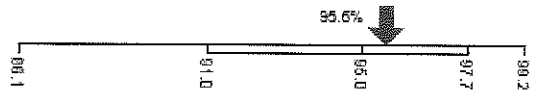
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.6%	95.0%	99.2%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2001]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

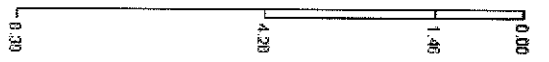
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1978]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.46%	0.00%

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:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

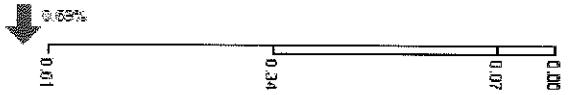
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.30%	0.00%

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:1804]

16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.69%	0.07%	0.00%

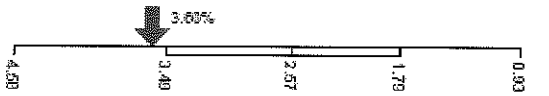
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.60%	2.57%	0.93%

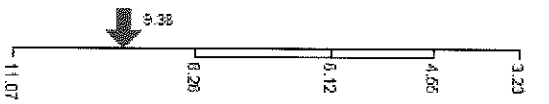
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9.38	6.12	3.23

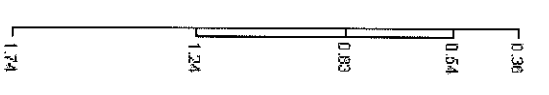
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2044]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.83	0.36

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:2053]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

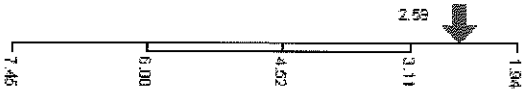
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.38%	1.30%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.59	4.52	1.94

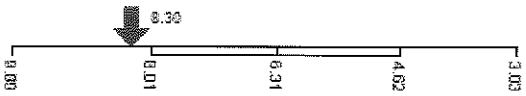
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8.30	6.31	3.03

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

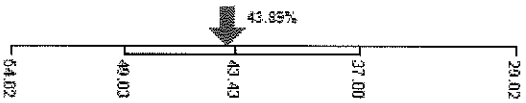
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.89%	43.43%	29.02%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.19%	0.13%	0.00%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2109]

Data Quality Metrics

Distribution of Hospital Performance

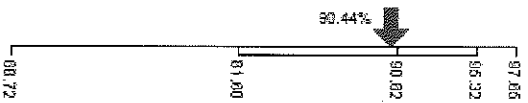
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
90.44%	90.82%	97.65%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q3

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 →

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
18.8%	30.3%	94.3%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

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Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.76%	4.42%	0.56%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

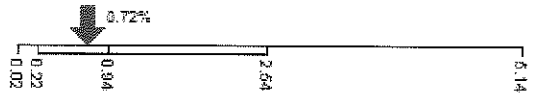
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.28%	98.58%	100.00%

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:1581]

32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.72%	0.94%	5.14%

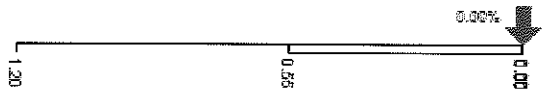
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

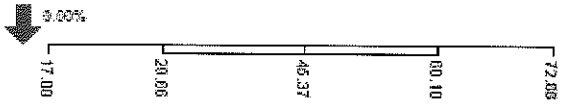
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	45.37%	72.88%

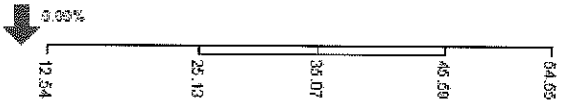
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	35.07%	54.55%

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:1586]



Executive Summary

CathPCI Registry®

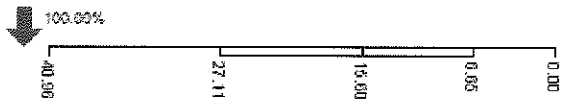
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	15.60%	0.00%

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:1587]



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.

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April 29, 2014

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 2 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Bristol	1			1
Brook Neal, VA	1			1
East Lyme	1		1	2
Essex	1			1
Gales Ferry		1	1	2
Groton	4	2	1	7
Ledyard	1			1
Mystic	2		1	3
New London	1	1	2	4
Niantic	2			2
Norwich			2	2
Pawcatuck	3			3
Plainfield			1	1
Quaker Hill		1	1	2
Sterling			1	1
Stonington		1		1
Uncasville			1	1
Waterford	3	2		5
Westerly, RI	5			5
Willimantic		1		1
Total PCI Procedures	25	9	12	46

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI procedure; non-urgent transfer to Yale for further treatment; operator was unable to cross partially chronic lesion in a SV graft. Patient transferred via routine ambulance. Case not included in elective PCI volume numbers.	2/28/2014 11:52	2/28/2014 12:44	Elective PCI 2/28/2014 12:50
2	Yale-New Haven Hospital	Primary PCI procedure; unable to accommodate as lab was busy with an unstable PCI patient. Both patients presented within 5 minutes of each other. Patient was not a candidate for thrombolytics. Transferred case not included in primary PCI volume numbers.	3/31/2014 11:03	3/31/2014 11:52	PCI 3/31/2014 11:53
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
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May 7, 2014

Paolo Fiducia
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Fiducia,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2013Q4

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2013Q4

Lawrence & Memorial Hospital
742173

Aggregation Date: Apr 15, 2014 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
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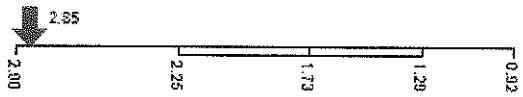
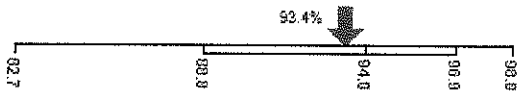
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q4

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: 2.85 | US Hospitals 50th Pctl: 1.73 | US Hospitals 90th Pctl: 0.92 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2035]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 93.4% | US Hospitals 50th Pctl: 94.0% | US Hospitals 90th Pctl: 98.8% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2006]	

Note

Performance measures in the CathPCI Registry® have 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.

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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q4

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

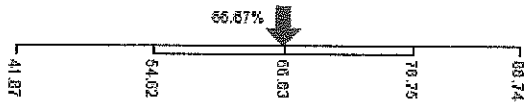
10th percentile ... 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
66.67%	66.83%	88.74%

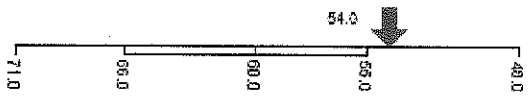
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
54	60	48

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:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

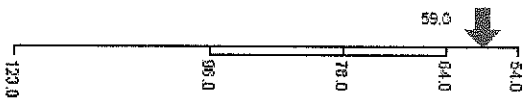
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
93.06%	94.63%	100.00%

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:1503]

5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
59	78	54

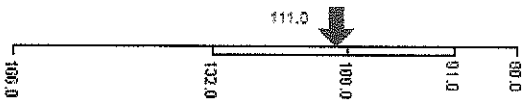
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
111	109	80

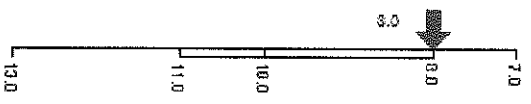
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8	10	7

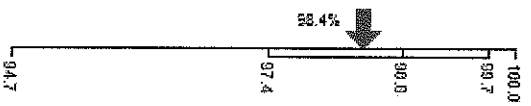
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.4%	98.8%	100.0%

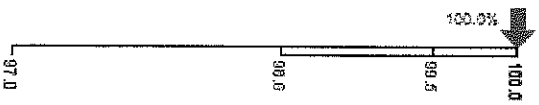
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1996]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	99.5%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2005]



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Executive Summary

CathPCI Registry®

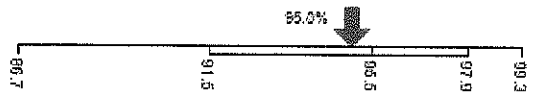
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.0%	95.5%	99.3%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2001]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

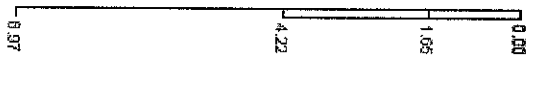
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1978]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.65%	0.00%

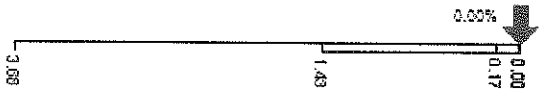
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.17%	0.00%

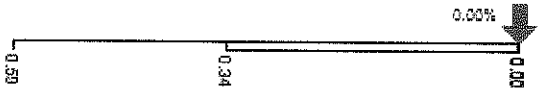
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

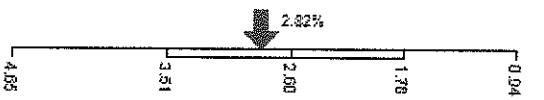
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.82%	2.60%	0.94%

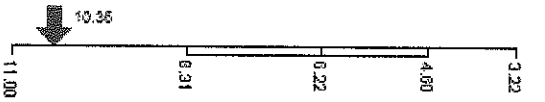
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.36	6.22	3.22

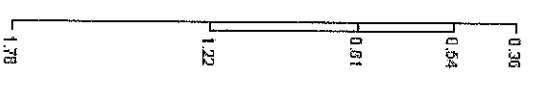
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2044]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.81	0.36

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:2053]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

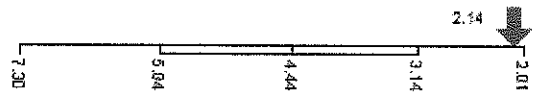
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.36%	1.24%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.14	4.44	2.01

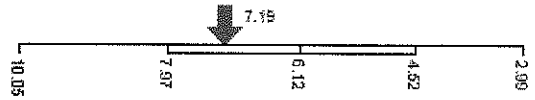
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.19	6.12	2.99

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

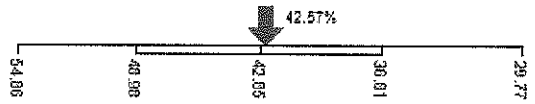
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.57%	42.85%	29.77%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.39%	0.13%	0.00%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2109]

Data Quality Metrics

Distribution of Hospital Performance

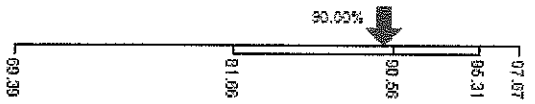
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
90.00%	90.56%	97.67%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2013Q4

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 →

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
16.7%	28.7%	94.2%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

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CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

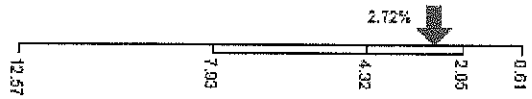
10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.72%	4.32%	0.61%

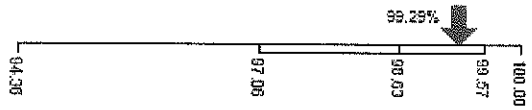
Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]



31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.29%	98.63%	100.00%

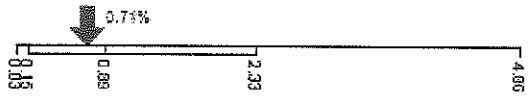
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.71%	0.89%	4.86%

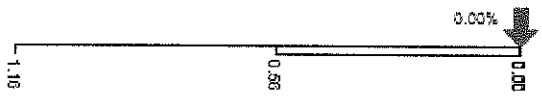
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

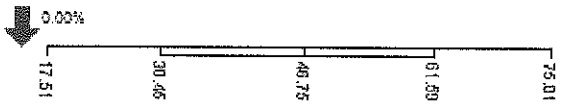
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	46.75%	75.01%

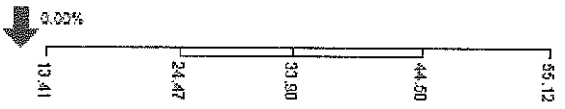
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	33.90%	55.12%

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:1586]



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Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	14.79%	0.00%

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:1587]

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.

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LAWRENCE +MEMORIAL HOSPITAL

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July 24, 2014

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2014Q1

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
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Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2014, Quarter 3

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Bozrah			1	1
Bradford, RI	1			1
East Lyme			1	1
Gales Ferry	1	1		2
Groton	2	1	1	4
Lady Lake, FL		1		1
Lebonan			1	1
Ledyard		2		2
Lyme	1			1
Mystic	2	2	1	5
New London	5	1	1	7
New Rochelle, NY	1			1
Niantic	1	1		2
North Franklin		2	1	3
Norwich			1	1
New York, NY			1	1
Oakdale	1			1
Old Lyme	1			1
Ponce, PR	1			1
Preston	1			1
Quaker Hill	1	1	1	3
Roxbury	1			1
Sarasota, FL	1			1
Stonington			1	1
Uncasville		1		1
Waterford	4	2	2	8
Westerly, RI	4			4
Total PCI Procedures	29	15	13	57

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Emergent PCI procedure: post-successful-stenting of difficult LAD lesion, patient proactively transferred via Helicopter with IABP to monitor more closely for any potential complications.	5/18/2014 7:14	5/18/2014 8:00	Not applicable; no procedure administered
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2014Q1

Lawrence & Memorial Hospital
742173

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National Cardiovascular Data Registry
CathPCI Registry®
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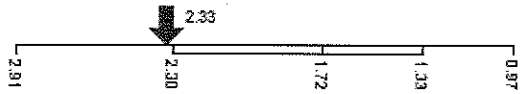
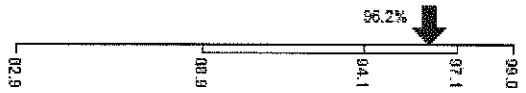
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

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: 2.33 | US Hospitals 50th Pctl: 1.72 | US Hospitals 90th Pctl: 0.97 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2035]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 96.2% | US Hospitals 50th Pctl: 94.1% | US Hospitals 90th Pctl: 99.0% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2006]	

Note

Performance measures in the CathPCI Registry® have 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.

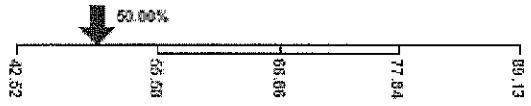
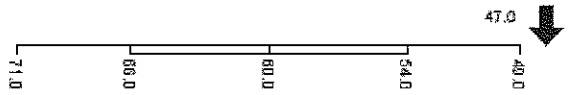
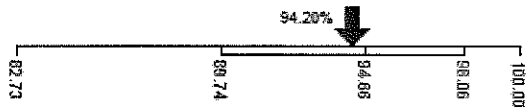
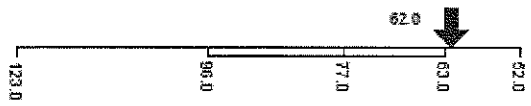
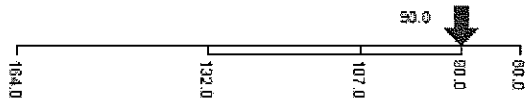
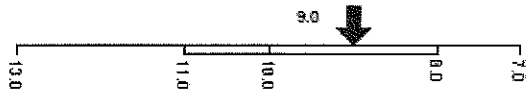
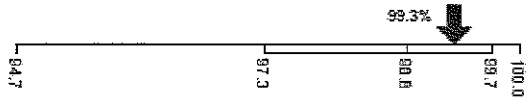
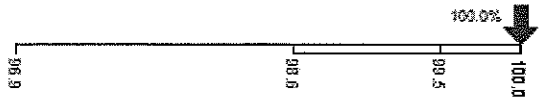
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

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: 50.00% | US Hospitals 50th Pctl: 66.86% | US Hospitals 90th Pctl: 89.13% 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:1513]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 47 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 49 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:1502]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 94.20% | US Hospitals 50th Pctl: 94.66% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 62 | US Hospitals 50th Pctl: 77 | US Hospitals 90th Pctl: 52 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 90 | US Hospitals 50th Pctl: 107 | US Hospitals 90th Pctl: 80 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:1506]	
7	**Median fluoro time (in minutes)** My Hospital: 9 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: 99.3% | US Hospitals 50th Pctl: 98.8% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1996]	
9	**Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 99.5% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2005]	

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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.9%	95.7%	99.4%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2001]

PCI Outcome Metrics

Distribution of Hospital Performance

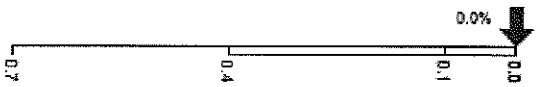
10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

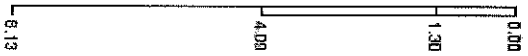
Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1978]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.30%	0.00%

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:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

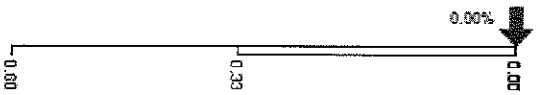
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1804]

16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

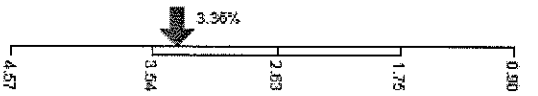
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.36%	2.63%	0.90%

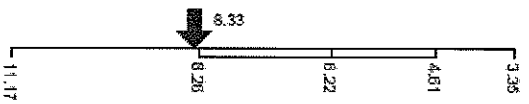
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8.33	6.22	3.35

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2044]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.83	0.35

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:2053]

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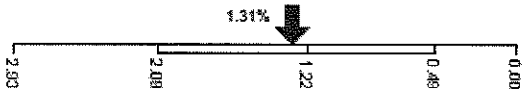
Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.31%	1.22%	0.00%

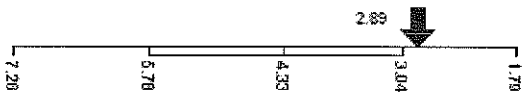
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.89	4.33	1.79

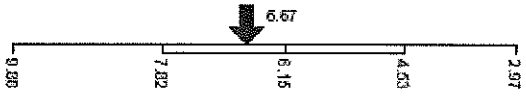
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.67	6.15	2.97

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]

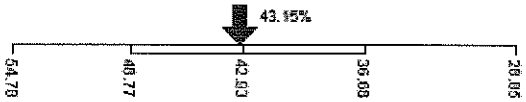


Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.15%	42.93%	28.85%

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

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.37%	0.13%	0.00%

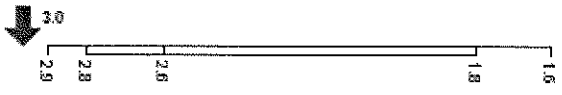
Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]

Utilization Metrics

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2109]

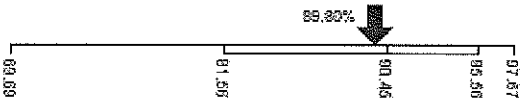


Data Quality Metrics

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
89.80%	90.45%	97.67%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



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Executive Summary

CathPCI Registry®

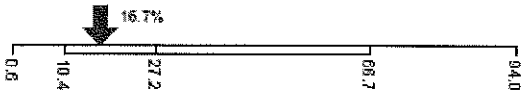
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

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
26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**	10th percentile … 90th percentile; Better →

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
16.7%	27.2%	94.0%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]



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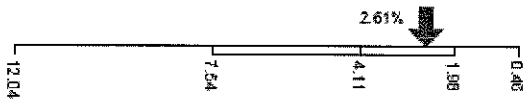
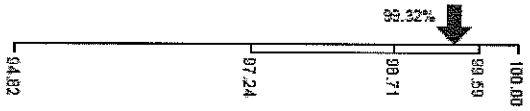
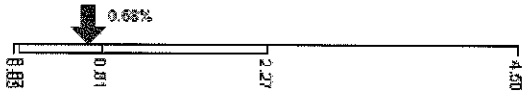
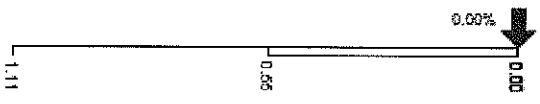
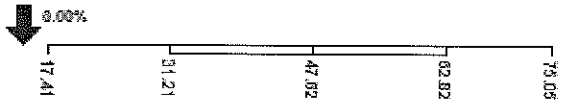
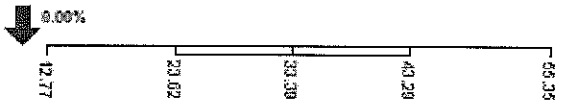
CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics	Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30 **Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 2.61% | US Hospitals 50th Pctl: 4.11% | US Hospitals 90th Pctl: 0.46% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]	
31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 99.32% | US Hospitals 50th Pctl: 98.71% | US Hospitals 90th Pctl: 100.00% 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:1581]	
32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.68% | US Hospitals 50th Pctl: 0.81% | US Hospitals 90th Pctl: 4.50% 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:1582]	
33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.00% | US Hospitals 90th Pctl: 0.00% 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:1583]	
34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 47.62% | US Hospitals 90th Pctl: 75.05% 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:1585]	
35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.00% | US Hospitals 50th Pctl: 33.39% | US Hospitals 90th Pctl: 55.35% 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:1586]	

Executive Summary

CathPCI Registry®

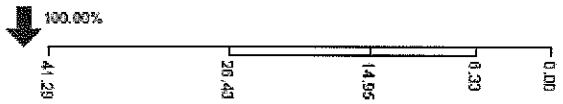
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	14.95%	0.00%

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:1587]



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.

Aggregation Date: Jun 30, 2014 11:59:59 PM
Publish Date: Jul 19, 2014

Huber, Jack

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Friday, July 25, 2014 8:38 PM
To: Huber, Jack
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2014 Q3 Compliance Format for 12-31768-CON (L+M Hospital).xlsx; ACC-NCDR 2014Q1 Report (L+M Hospital).pdf

Dear Mr. Huber,

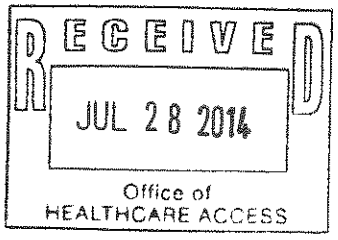
Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

- Fiscal Year 2014 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2014Q1

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex before July 31st.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel



Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Emergent PCI procedure: post-successful-stenting of difficult LAD lesion, patient proactively transferred via Helicopter with IABP to monitor more closely for any potential complications.	5/18/2014 7:14	5/18/2014 8:00	Not applicable; no procedure administered
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2014Q1

Lawrence & Memorial Hospital
742173

Aggregation Date: Jun 30, 2014 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

Distribution of Hospital Performance

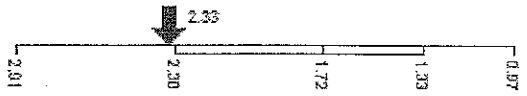
10th percentile — 90th percentile

Better →

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.33	1.72	0.97

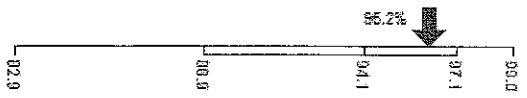
Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2035]



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.2%	94.1%	99.0%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2006]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

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

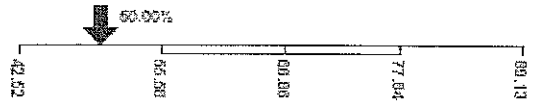
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
50.00%	66.86%	89.13%

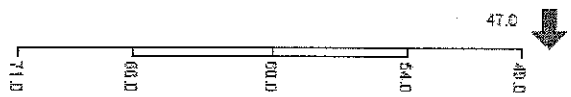
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
47	60	49

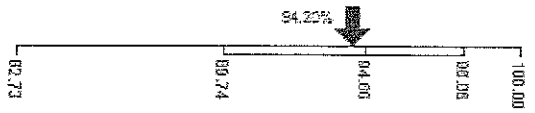
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.20%	94.66%	100.00%

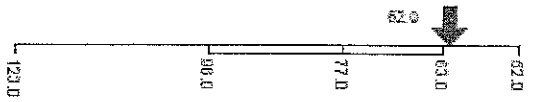
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
62	77	52

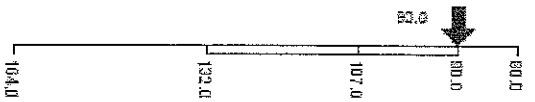
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
90	107	80

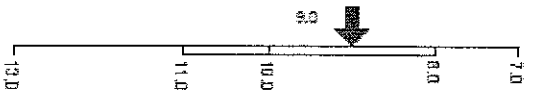
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

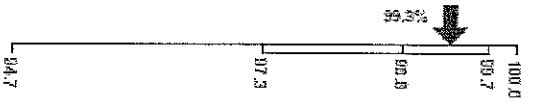
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.3%	98.8%	100.0%

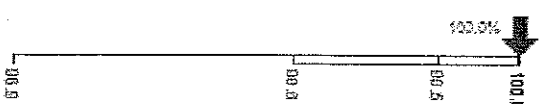
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1996]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	99.5%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2005]



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Executive Summary

CathPCI Registry®

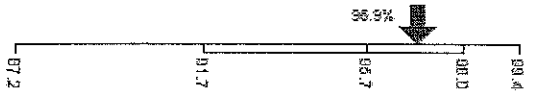
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.9%	95.7%	99.4%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2001]



PCI Outcome Metrics

Distribution of Hospital Performance

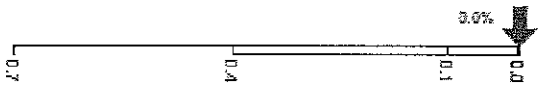
10th percentile — 90th percentile

Better →

12 **Proportion of PCI patients with emergency CABG**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.1%	0.0%

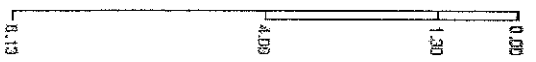
Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1978]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.30%	0.00%

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:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

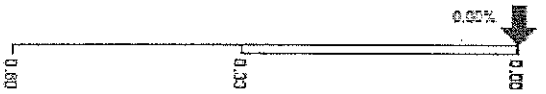
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1804]

16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

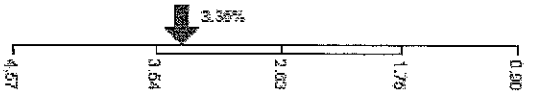
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.36%	2.63%	0.90%

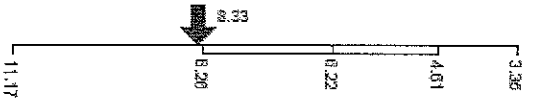
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8.33	6.22	3.35

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2044]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.83	0.35

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:2053]

Executive Summary

CathPCI Registry®

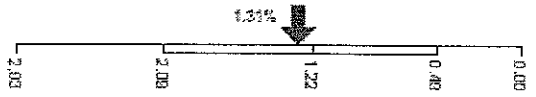
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.31%	1.22%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.89	4.33	1.79

Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]

39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.67	6.15	2.97

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]

Diagnostic Cath Process Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.15%	42.93%	28.85%

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

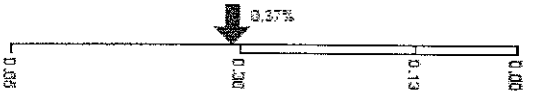
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.37%	0.13%	0.00%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.6	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2109]

Data Quality Metrics

Distribution of Hospital Performance

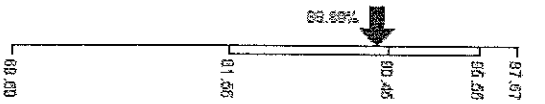
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
89.80%	90.45%	97.67%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1951]



Aggregation Date: Jun 30, 2014 11:59:59 PM
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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Test Metrics

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
16.7%	27.2%	94.0%

Proportion of elective procedures with biomarkers assessed post PCI.
Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient".
[Detail Line:1949]

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

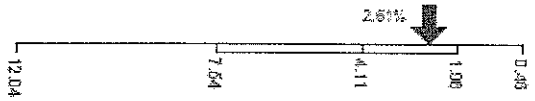
10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.61%	4.11%	0.46%

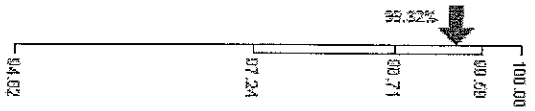
Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]



31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.32%	98.71%	100.00%

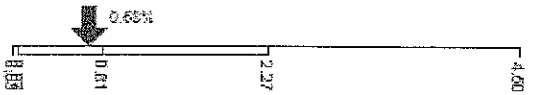
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.68%	0.81%	4.50%

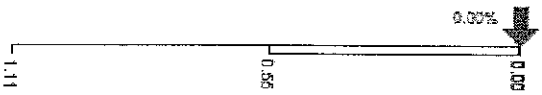
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

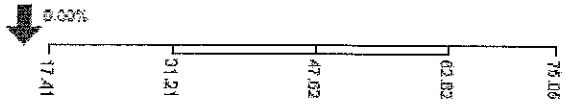
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	47.62%	75.05%

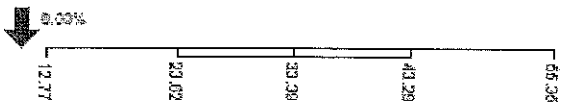
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	33.39%	55.35%

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:1586]



Executive Summary

CathPCI Registry®

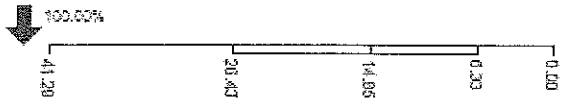
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	14.95%	0.00%

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:1587]



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.

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LAWRENCE +MEMORIAL HOSPITAL

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October 31, 2014

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2014 Quarter 4 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):				
Federal Fiscal Year 2014, Quarter 4				
Reports 1. a. and 1. b (combined)				
Town	**# of Primary* PCI Procedures**	**# of Elective PCI Procedures** (*Inpatient*)	**# of Elective PCI Procedures** (*Outpatient*)	**Total # of Procedures**
Ashaway, RI	2			2
Charleston, RI	2			2
East Lyme			1	1
Gales Ferry	3		1	4
Groton	3	2	1	6
Jewett City			1	1
Ledyard	1			1
Lyme		2		2
Mystic	2	1	2	5
New London	2	4	1	7
Niantic	1		1	2
North Franklin			1	1
Norwich			1	1
Old Lyme	2			2
Pawcatuck	1		1	2
Quaker Hill			1	1
Stonington	2		1	3
Waterford	4	5	2	11
West Warwick, RI	1			1
West Harford	1			1
Woonscoket, RI	1			1
Guilderland, NY	1			1
Voluntown		1	0	1
Danielson			1	1
Griswold			1	1
Brewster		1		1
Total PCI Procedures	29	16	17	62
*Assumed to be inpatient procedures				
** All towns in Connecticut unless otherwise noted				

Cardiac Transfers:

Federal Fiscal Year 2014, Quarter 4

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI procedure: unable to cross lesion, patient transferred for complex PCI	9/22/2014 12:22	9/22/2014 14:35	PCI procedure: 9/23/2014 11:10
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
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November 5, 2014

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2014Q2

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2014Q2

Lawrence & Memorial Hospital
742173

Aggregation Date: Sep 30, 2014 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q2

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

Distribution of Hospital Performance

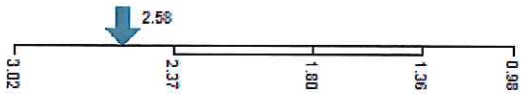
10th percentile — 90th percentile

Better →

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.58	1.80	0.98

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
97.9%	94.3%	99.0%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]

Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q2

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

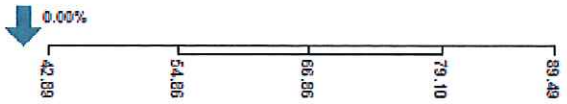
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	66.86%	89.49%

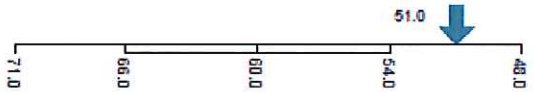
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
51	60	48

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:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.86%	94.91%	100.00%

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:1503]

5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

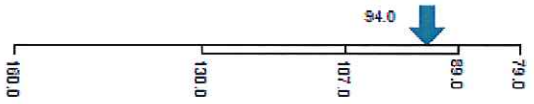
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
60	74	50

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94	107	79

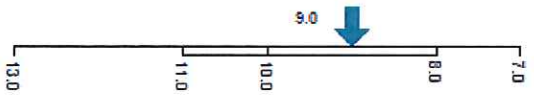
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

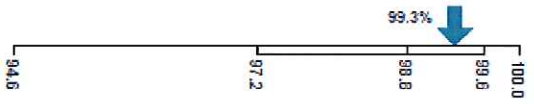
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.3%	98.8%	100.0%

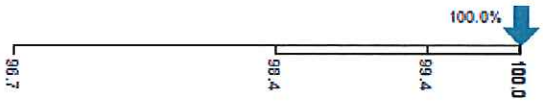
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	99.4%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q2

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.6%	95.8%	99.4%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]

PCI Outcome Metrics

Distribution of Hospital Performance

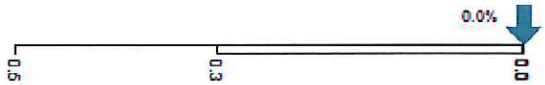
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

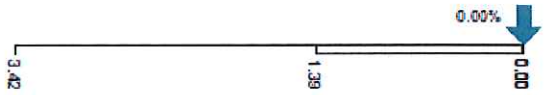
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.53%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

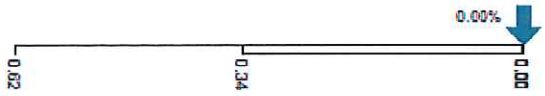
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

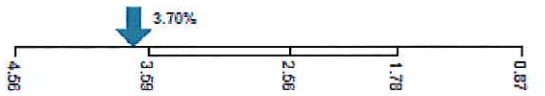
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.70%	2.56%	0.87%

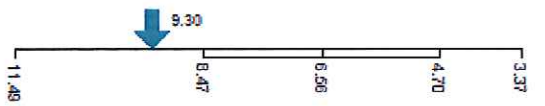
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9.30	6.56	3.37

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.86	0.38

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:2054]

Aggregation Date: Sep 30, 2014 11:59:59 PM
Publish Date: Oct 28, 2014

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

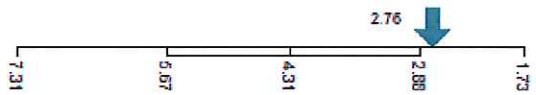
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.21%	1.19%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.76	4.31	1.73

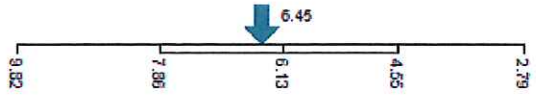
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.45	6.13	2.79

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



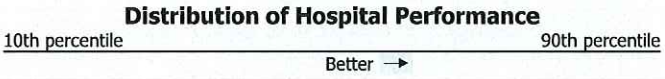
Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
45.20%	43.19%	29.27%

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]

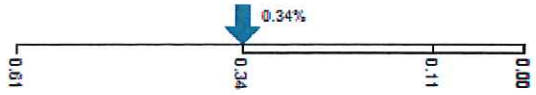
Diagnostic Cath Outcomes Metrics



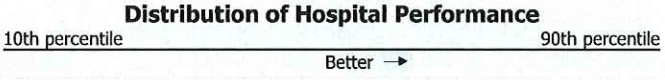
21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.34%	0.11%	0.00%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



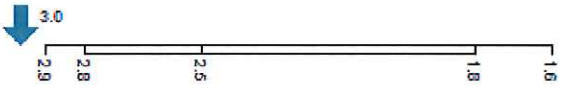
Utilization Metrics



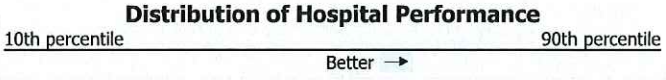
22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.5	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



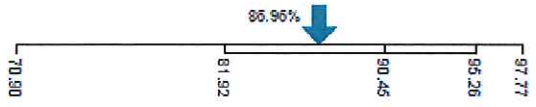
Data Quality Metrics



24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
86.96%	90.45%	97.77%

Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



Aggregation Date: Sep 30, 2014 11:59:59 PM
Publish Date: Oct 28, 2014

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q2

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

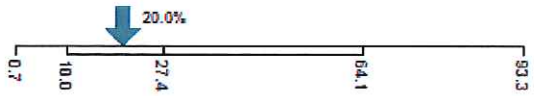
10th percentile 90th percentile

Better →

26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
20.0%	27.4%	93.3%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail Line:1949]



Aggregation Date: Sep 30, 2014 11:59:59 PM
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Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

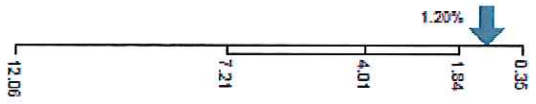
10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.20%	4.01%	0.35%

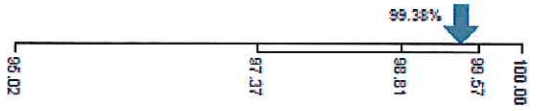
Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]



31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.38%	98.81%	100.00%

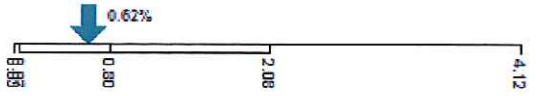
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.62%	0.80%	4.12%

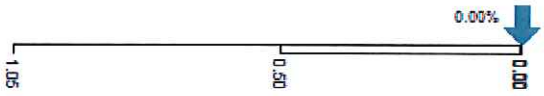
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

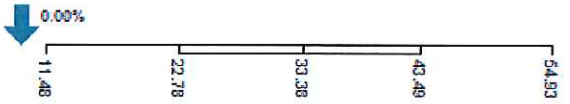
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	49.19%	75.84%

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:1585]

35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	33.38%	54.93%

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:1586]



Aggregation Date: Sep 30, 2014 11:59:59 PM
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Executive Summary

CathPCI Registry®

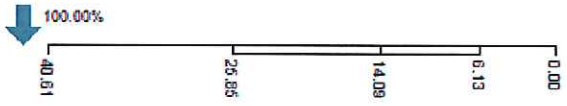
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	14.09%	0.00%

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:1587]



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.

Aggregation Date: Sep 30, 2014 11:59:59 PM
Publish Date: Oct 28, 2014

Huber, Jack

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Monday, January 26, 2015 12:31 PM
To: Huber, Jack
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2015 Q1 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

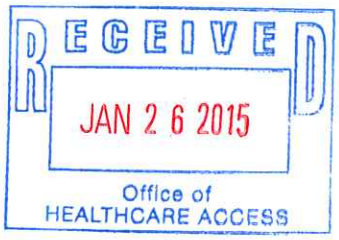
- Fiscal Year 2015 Quarter 1 PCI Volume by Patient's Town of Residence

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex before January 31st.

The ACC-NCDR Data Report for 2014Q3 will be sent separately, once the report is released to L+M.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel



Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 1

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Baltic	1			1
Coventry, RI	1			1
Griswold	1			1
Groton	7	1		8
Ledyard	1	1	2	4
Moodus	1		1	2
Mystic	2	1	2	5
New London	1	2		3
Niantic	2	2	2	6
North Franklin			1	1
Norwich	2			2
Oakdale		1	2	3
Old Lyme	1			1
Pawcatuck	3	1		4
Philadephia, PA	1			1
Preston		2		2
Quaker Hill			1	1
Sargus, MA	1			1
Seymore	1			1
Stonington	1		2	3
Taftville			1	1
Uncasville	1			1
Upper Marlboro	1			1
Waterford	2		2	4
Total PCI Procedures	31	11	16	58

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Patient had successful opening of culprit artery at L+M (via emergent PCI), but required further treatment (CABG) at YNHH for remaining disease.	10/19/2014 11:16	10/19/2014 14:13	10/20/2014 16:00
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

January 28, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 1 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 1

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Baltic	1			1
Coventry, RI	1			1
Griswold	1			1
Groton	7	1		8
Ledyard	1	1	2	4
Moodus	1		1	2
Mystic	2	1	2	5
New London	1	2		3
Niantic	2	2	2	6
North Franklin			1	1
Norwich	2			2
Oakdale		1	2	3
Old Lyme	1			1
Pawcatuck	3	1		4
Philadephia, PA	1			1
Preston		2		2
Quaker Hill			1	1
Sargus, MA	1			1
Seymore	1			1
Stonington	1		2	3
Taftville			1	1
Uncasville	1			1
Upper Marlboro	1			1
Waterford	2		2	4
Total PCI Procedures	31	11	16	58

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Patient had successful opening of culprit artery at L+M (via emergent PCI), but required further treatment (CABG) at YNHH for remaining disease.	10/19/2014 11:16	10/19/2014 14:13	10/20/2014 16:00
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

February 3, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2014Q3

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
M. Gorski
G. Mulholland

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2014Q3

Lawrence & Memorial Hospital
742173

Aggregation Date: Jan 12, 2015 11:59:59 PM

Publish Date: Jan 28, 2015

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

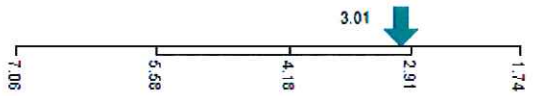
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q3

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: 2.13 | US Hospitals 50th Pctl: 1.80 | US Hospitals 90th Pctl: 0.99 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 3.01 | US Hospitals 50th Pctl: 4.18 | US Hospitals 90th Pctl: 1.74 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 98.7% | US Hospitals 50th Pctl: 94.5% | US Hospitals 90th Pctl: 99.1% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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.

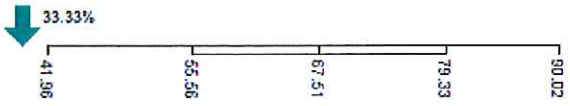
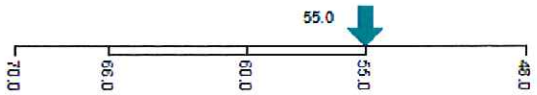
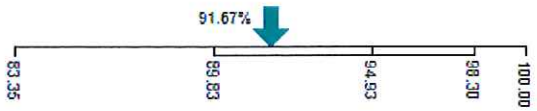
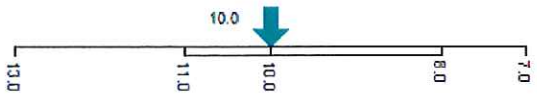
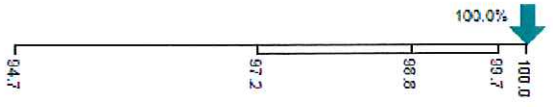
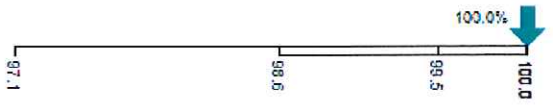
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q3

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: 33.33% | US Hospitals 50th Pctl: 67.51% | US Hospitals 90th Pctl: 90.02% 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:1513]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 55 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 48 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:1502]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 91.67% | US Hospitals 50th Pctl: 94.93% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 61 | US Hospitals 50th Pctl: 74 | US Hospitals 90th Pctl: 50 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 93 | US Hospitals 50th Pctl: 108 | US Hospitals 90th Pctl: 80 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:1506]	
7	**Median fluoro time (in minutes)** My Hospital: 10 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 98.8% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]	
9	**Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 99.5% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]	

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Executive Summary

CathPCI Registry®

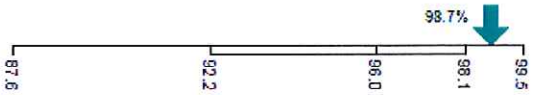
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.7%	96.0%	99.5%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

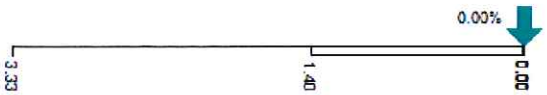
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.51%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

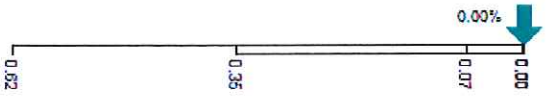
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.07%	0.00%

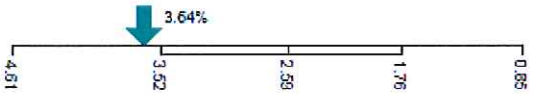
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.64%	2.59%	0.85%

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:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

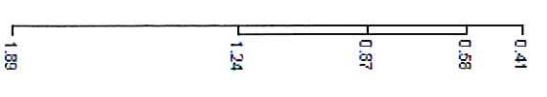
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.77	6.50	3.44

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]

19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.87	0.41

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:2054]



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Executive Summary

CathPCI Registry®

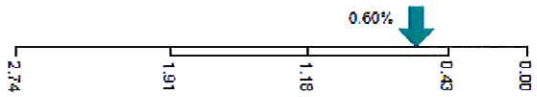
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.60%	1.18%	0.00%

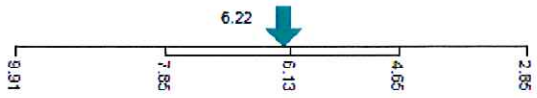
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.22	6.13	2.85

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]

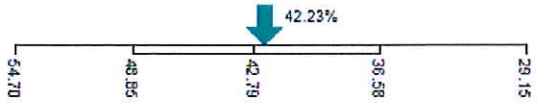


Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.23%	42.79%	29.15%

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]

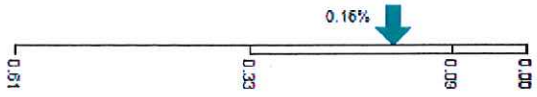


Diagnostic Cath Outcomes Metrics

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.16%	0.09%	0.00%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



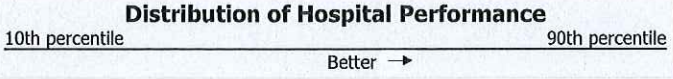
Utilization Metrics

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.5	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]

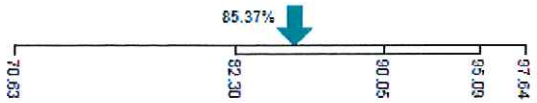
Data Quality Metrics



24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
85.37%	90.05%	97.64%

Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



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CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q3

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
26 **Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**	10th percentile … 90th percentile; Better →

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.3%	25.7%	91.2%

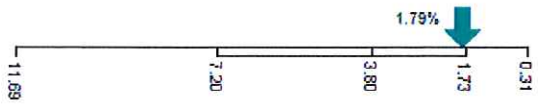
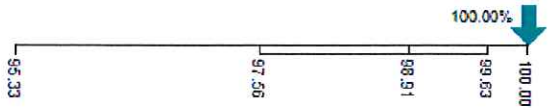
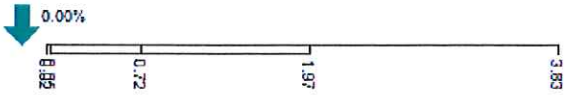
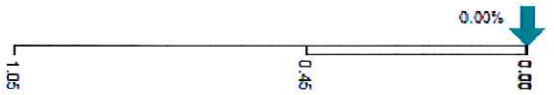
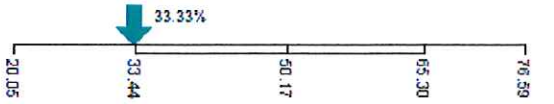
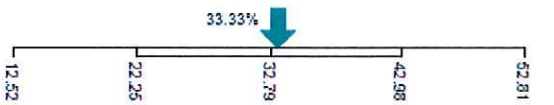
Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail Line:1949]

Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics		Distribution of Hospital Performance (10th percentile … 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 1.79% | US Hospitals 50th Pctl: 3.80% | US Hospitals 90th Pctl: 0.31% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]	
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 100.00% | US Hospitals 50th Pctl: 98.91% | US Hospitals 90th Pctl: 100.00% 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:1581]	
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.72% | US Hospitals 90th Pctl: 3.83% 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:1582]	
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.00% | US Hospitals 90th Pctl: 0.00% 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:1583]	
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 33.33% | US Hospitals 50th Pctl: 50.17% | US Hospitals 90th Pctl: 76.59% 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:1585]	
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 33.33% | US Hospitals 50th Pctl: 32.79% | US Hospitals 90th Pctl: 52.81% 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:1586]	

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CathPCI Registry®

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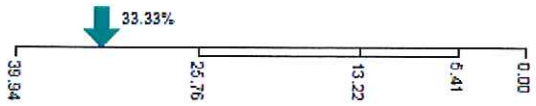
Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
33.33%	13.22%	0.00%

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:1587]



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.

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Huber, Jack

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Thursday, April 30, 2015 10:50 AM
To: Huber, Jack
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2015 Q2 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

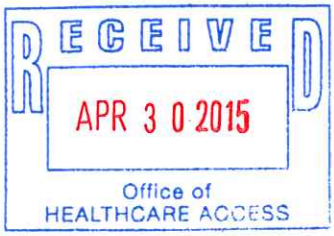
- Fiscal Year 2015 Quarter 2 PCI Volume by Patient's Town of Residence
- Patient transfer information

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex early next week.

The ACC-NCDR Data Report for 2014Q4 will be sent separately, once the report is released to L+M.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel



Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	1			1
Baltic	1			1
Centerfield, MA	1			1
East Lyme		1		1
Gales Ferry		1		1
Groton	6			6
Hope Valley, RI		1		1
Jewett City	2			2
Ledyard	3	1		4
Mystic		1	1	2
New London	5	2		7
Niantic		1		1
Noank		2		2
North Stonington	1			1
Norwich	3	1		4
Oakdale		2	2	4
Pawcatuck	1			1
Preston	1	1		2
Quaker Hill	1			1
Stonington	1	1		2
Uncasville	1			1
Verona, VA	1			1
Voluntown	1			1
Waterford	2		3	5
Westerly, RI	1			1
Westport	1			1
Total PCI Procedures	34	15	6	55

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI on patient with high grade lesion in LAD and RCA. Patient had a successful elective PCI on LAD system. When attempting to cross the RCA lesion with a wire, there was some difficluty in crossing the lesion and subsequent angiography showed what apeared to be a small dissection and reduced flow. Patient remained hemodynamically stable. Procedure aborted and Yale consulted. Decision to transfer to Yale for further treatment on this complex lesion. At Yale they were also unable to open artery.	1/15/2015 11:48	1/15/2015 12:46	Attempt at RCA PTCA was unscuccessful and patient was successfully managed medically. 1/15/2015 13:12
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

April 29, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 2 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
Karen Buck
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 2

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI	1			1
Baltic	1			1
Centerfield, MA	1			1
East Lyme		1		1
Gales Ferry		1		1
Groton	6			6
Hope Valley, RI		1		1
Jewett City	2			2
Ledyard	3	1		4
Mystic		1	1	2
New London	5	2		7
Niantic		1		1
Noank		2		2
North Stonington	1			1
Norwich	3	1		4
Oakdale		2	2	4
Pawcatuck	1			1
Preston	1	1		2
Quaker Hill	1			1
Stonington	1	1		2
Uncasville	1			1
Verona, VA	1			1
Voluntown	1			1
Waterford	2		3	5
Westerly, RI	1			1
Westport	1			1
Total PCI Procedures	34	15	6	55

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	Yale-New Haven Hospital	Elective PCI on patient with high grade lesion in LAD and RCA. Patient had a successful elective PCI on LAD system. When attempting to cross the RCA lesion with a wire, there was some difficluty in crossing the lesion and subsequent angiography showed what apeared to be a small dissection and reduced flow. Patient remained hemodynamically stable. Procedure aborted and Yale consulted. Decision to transfer to Yale for further treatment on this complex lesion. At Yale they were also unable to open artery.	1/15/2015 11:48	1/15/2015 12:46	Attempt at RCA PTCA was unscuccessful and patient was successfully managed medically. 1/15/2015 13:12
2					
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10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

Huber, Jack

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Wednesday, May 06, 2015 9:57 AM
To: Huber, Jack
Subject: RE: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: ACC-NCDR 2014Q4 Report (L+M Hospital).pdf

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

- ACC-NCDR Data Report for 2014Q4

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex early next week.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel

From: Patel, Shraddha
Sent: Thursday, April 30, 2015 10:50 AM
To: 'Huber, Jack'
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

- Fiscal Year 2015 Quarter 2 PCI Volume by Patient's Town of Residence
- Patient transfer information

We have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex early next week.

The ACC-NCDR Data Report for 2014Q4 will be sent separately, once the report is released to L+M.

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email.

Thank you,
Shraddha Patel

Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320

Phone: (860) 912-5324
Email: spatel@lmhosp.org

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®
Version 4.4

Institutional Outcomes Report
2014Q4

Lawrence & Memorial Hospital
742173

Aggregation Date: Apr 15, 2015 11:59:59 PM

Publish Date: Apr 30, 2015

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

Distribution of Hospital Performance

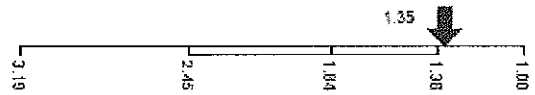
10th percentile — 90th percentile

Better →

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.35	1.84	1.00

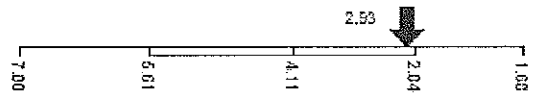
Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.93	4.11	1.68

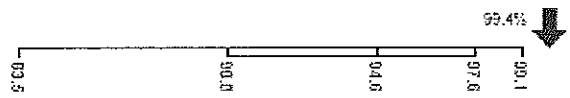
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	94.6%	99.1%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

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

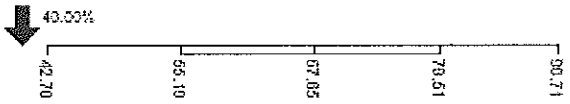
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
40.00%	67.65%	90.71%

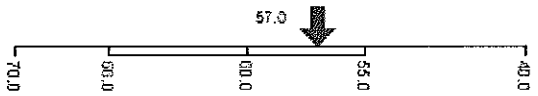
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
57	60	48

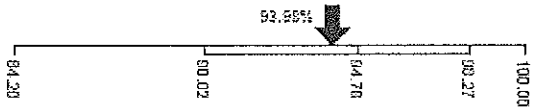
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
93.98%	94.78%	100.00%

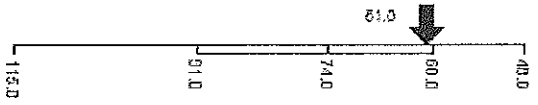
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
61	74	48

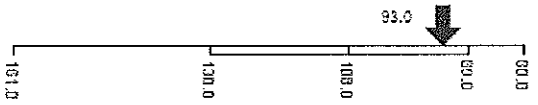
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
93	108	80

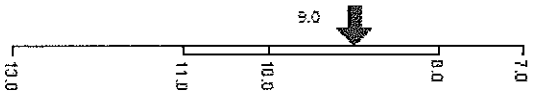
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

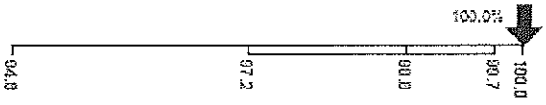
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.8%	100.0%

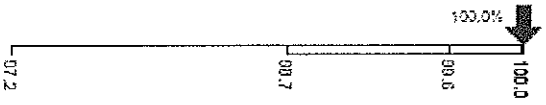
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	99.6%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]



Aggregation Date: Apr 15, 2015 11:59:59 PM
Publish Date: Apr 30, 2015

Executive Summary

CathPCI Registry®

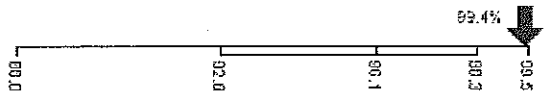
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	96.1%	99.5%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

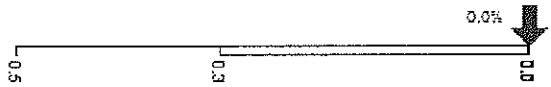
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

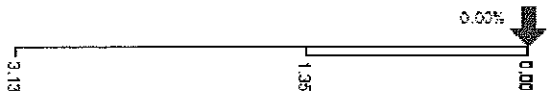
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.25%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

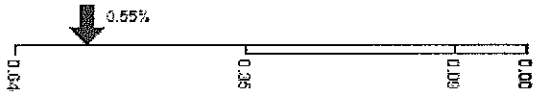
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.55%	0.09%	0.00%

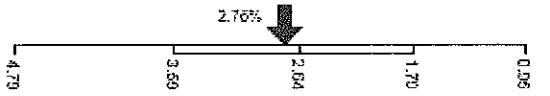
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.76%	2.64%	0.95%

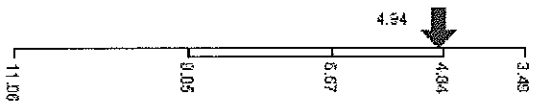
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.94	6.67	3.49

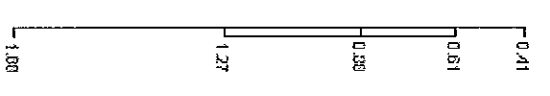
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.88	0.41

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:2054]



Executive Summary

CathPCI Registry®

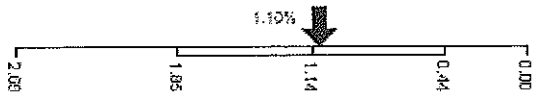
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.10%	1.14%	0.00%

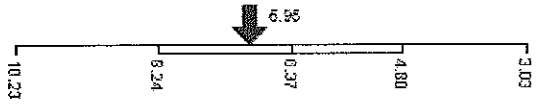
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.96	6.37	3.03

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

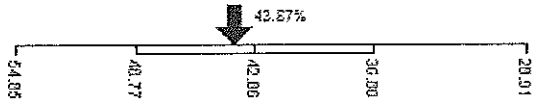
10th percentile 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.87%	42.86%	28.91%

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

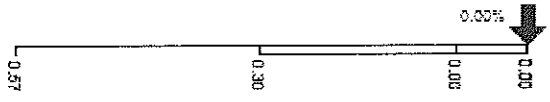
10th percentile 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.08%	0.00%

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.5	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]

Data Quality Metrics

Distribution of Hospital Performance

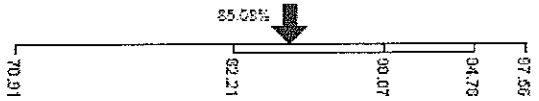
10th percentile 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
85.08%	90.07%	97.56%

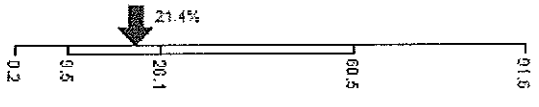
Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
21.4%	26.1%	91.6%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



Aggregation Date: Apr 15, 2015 11:59:59 PM
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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Line:1949]

Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

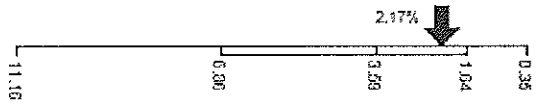
10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.17%	3.59%	0.35%

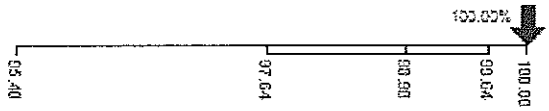
Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]



31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	98.90%	100.00%

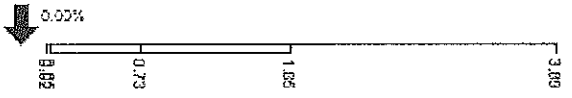
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.73%	3.89%

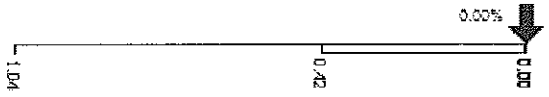
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

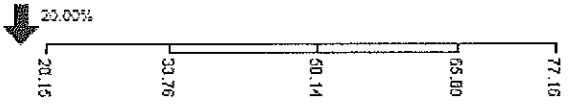
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
20.00%	50.14%	77.16%

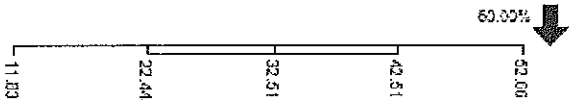
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
60.00%	32.51%	52.66%

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:1586]



Executive Summary

CathPCI Registry®

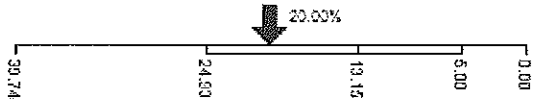
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
20.00%	13.15%	0.00%

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:1587]



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.

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LAWRENCE +MEMORIAL HOSPITAL

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May 6, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2014Q4

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
K. Buck
G. Mulholland

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2014Q4

Lawrence & Memorial Hospital
742173

Aggregation Date: Apr 15, 2015 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

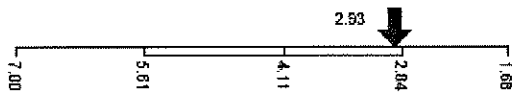
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

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: 1.35 | US Hospitals 50th Pctl: 1.84 | US Hospitals 90th Pctl: 1.00 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 2.93 | US Hospitals 50th Pctl: 4.11 | US Hospitals 90th Pctl: 1.68 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 99.4% | US Hospitals 50th Pctl: 94.6% | US Hospitals 90th Pctl: 99.1% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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.

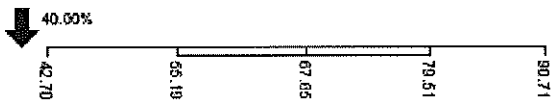
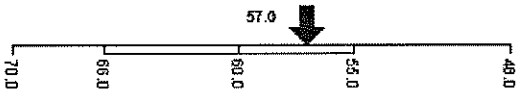
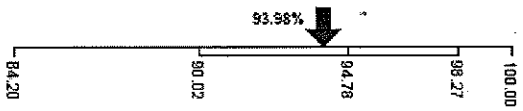
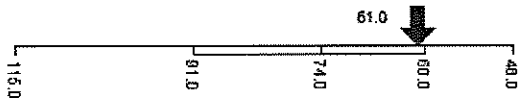
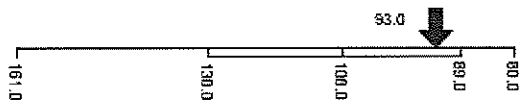
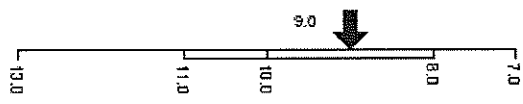
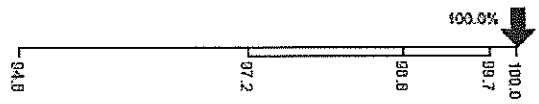
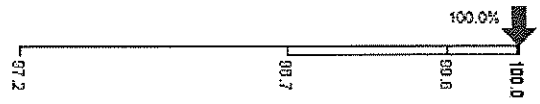
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

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: 40.00% | US Hospitals 50th Pctl: 67.65% | US Hospitals 90th Pctl: 90.71% 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:1513]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 57 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 48 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:1502]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 93.98% | US Hospitals 50th Pctl: 94.78% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 61 | US Hospitals 50th Pctl: 74 | US Hospitals 90th Pctl: 48 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 93 | US Hospitals 50th Pctl: 108 | US Hospitals 90th Pctl: 80 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:1506]	
7	**Median fluoro time (in minutes)** My Hospital: 9 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 98.8% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]	
9	**Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 99.6% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]	

Executive Summary

CathPCI Registry®

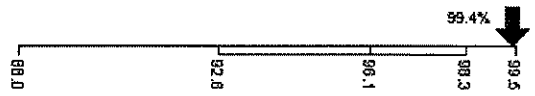
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	96.1%	99.5%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

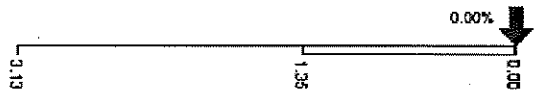
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.25%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

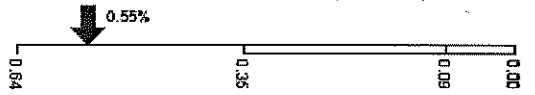
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.55%	0.09%	0.00%

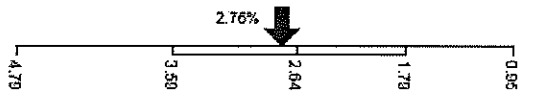
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.76%	2.64%	0.95%

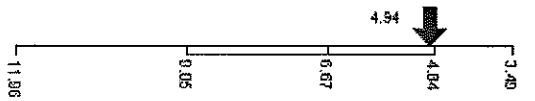
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.94	6.67	3.49

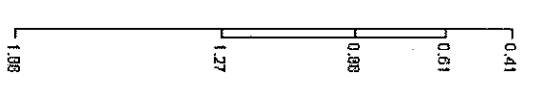
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.88	0.41

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:2054]



Executive Summary

CathPCI Registry®

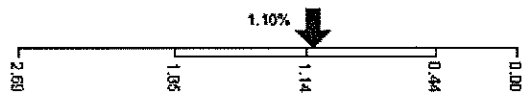
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.10%	1.14%	0.00%

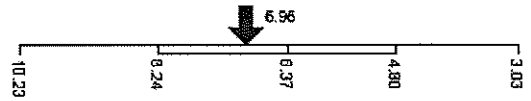
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.96	6.37	3.03

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

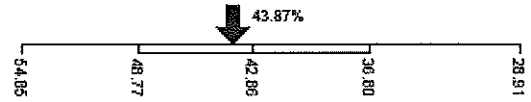
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.87%	42.86%	28.91%

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

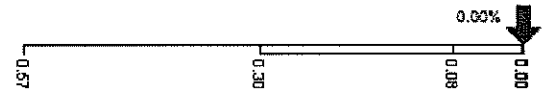
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.08%	0.00%

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

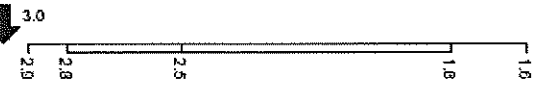
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.5	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

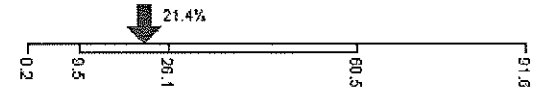
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
85.08%	90.07%	97.56%

Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]

26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
21.4%	26.1%	91.6%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2014Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

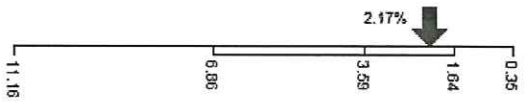
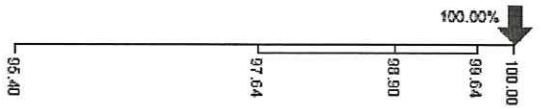
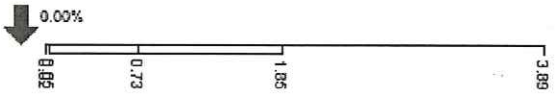
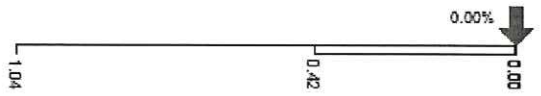
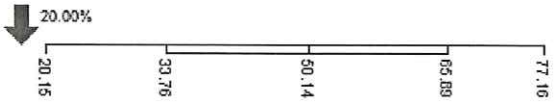
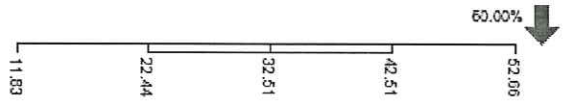
	Line:1949]	

Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

	PCI Appropriate Use Criteria (AUC) Metrics	Distribution of Hospital Performance (10th percentile — 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 2.17% | US Hospitals 50th Pctl: 3.59% | US Hospitals 90th Pctl: 0.35% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]	
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 100.00% | US Hospitals 50th Pctl: 98.90% | US Hospitals 90th Pctl: 100.00% 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:1581]	
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.73% | US Hospitals 90th Pctl: 3.89% 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:1582]	
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.00% | US Hospitals 90th Pctl: 0.00% 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:1583]	
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 20.00% | US Hospitals 50th Pctl: 50.14% | US Hospitals 90th Pctl: 77.16% 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:1585]	
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 60.00% | US Hospitals 50th Pctl: 32.51% | US Hospitals 90th Pctl: 52.66% 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:1586]	

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Publish Date: Apr 30, 2015

Executive Summary

CathPCI Registry®

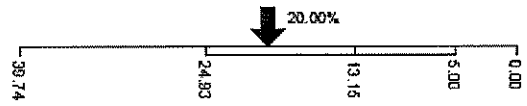
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
20.00%	13.15%	0.00%

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:1587]



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.

Aggregation Date: Apr 15, 2015 11:59:59 PM
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Greer, Leslie

Subject: FW: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)
Attachments: FY 2015 Q3 Compliance Format for 12-31768-CON (L+M Hospital).xlsx; ACC-NCDR 2015Q1 Report (L+M Hospital).pdf; FY 2015 Q3 Compliance Format for 12-31768-CON (L+M Hospital).pdf

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From: Patel, Shraddha [mailto:spatel@lmhosp.org]
Sent: Tuesday, July 28, 2015 9:24 AM
To: Huber, Jack
Subject: Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital)

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

- Fiscal Year 2015 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2015Q1

I have also submitted the attached in hardcopy and electronically on CD. You should receive these items via Fed Ex this week.

If you have any questions, please feel free to contact me.

Thanks,
Shraddha

Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

LAWRENCE +MEMORIAL HOSPITAL
365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

July 28, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2015Q1

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 3

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Canterbury	1			1
East Lyme		1		1
Gales Ferry	1	1		2
Groton	5	2	2	9
Jewett City			1	1
Kutztown, PA	1			1
Ledyard	1			1
Mystic	2		2	4
New London	2	6	1	9
Niantic	1		2	3
Oakdale	1	1		2
Old Lyme	2	1		3
Old Mystic	1			1
Quaker Hill	1	2	1	4
Troy, NY	1			1
Uncasville		1		1
Waterford			1	1
Total PCI Procedures	20	15	10	45

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
	NONE				

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2015Q1

Lawrence & Memorial Hospital
742173

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

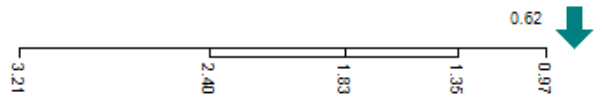
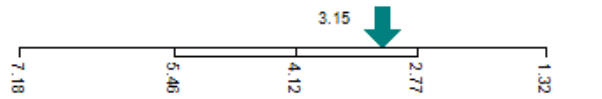
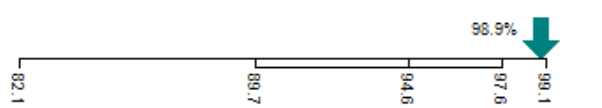
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

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: 0.62 | US Hospitals 50th Pctl: 1.83 | US Hospitals 90th Pctl: 0.97 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 3.15 | US Hospitals 50th Pctl: 4.12 | US Hospitals 90th Pctl: 1.32 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 98.9% | US Hospitals 50th Pctl: 94.6% | US Hospitals 90th Pctl: 99.1% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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.

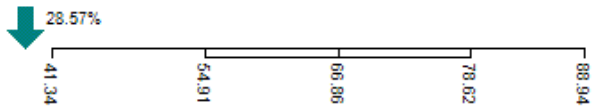
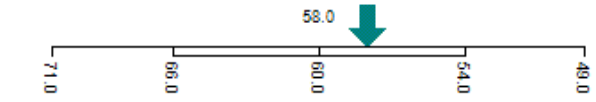
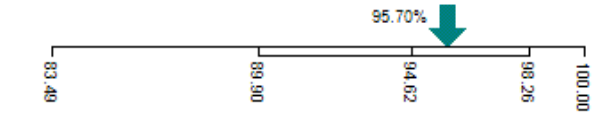
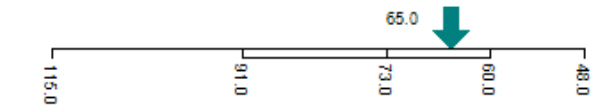
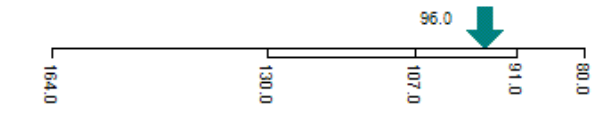
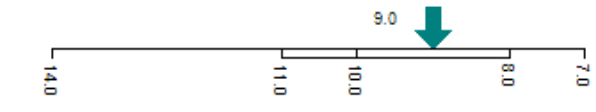
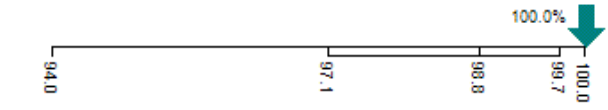
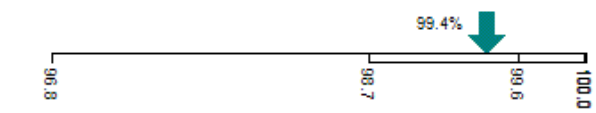
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

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: 28.57% | US Hospitals 50th Pctl: 66.86% | US Hospitals 90th Pctl: 88.94% 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:1513]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 58 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 49 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:1502]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 95.70% | US Hospitals 50th Pctl: 94.62% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 65 | US Hospitals 50th Pctl: 73 | US Hospitals 90th Pctl: 48 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 96 | US Hospitals 50th Pctl: 107 | US Hospitals 90th Pctl: 80 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:1506]	
7	**Median fluoro time (in minutes)** My Hospital: 9 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 98.8% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]	
9	**Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 99.4% | US Hospitals 50th Pctl: 99.6% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]	

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CathPCI Registry®

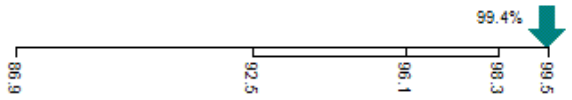
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	96.1%	99.5%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

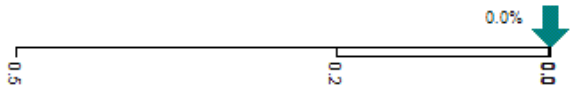
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

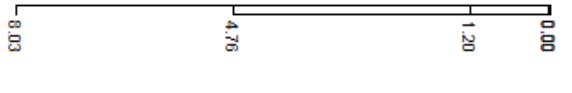
Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.20%	0.00%

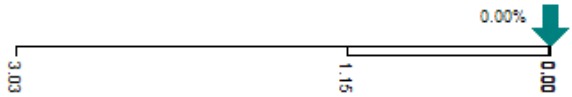
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

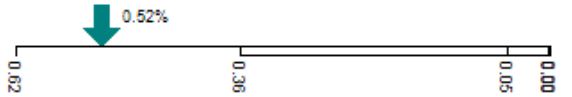
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.52%	0.05%	0.00%

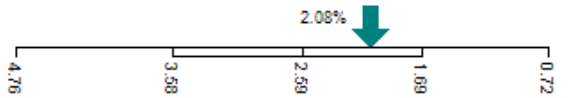
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.08%	2.59%	0.72%

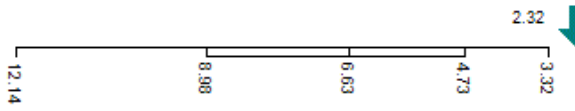
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.32	6.63	3.32

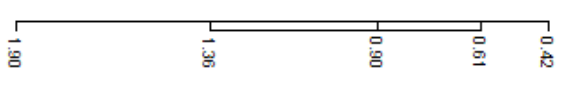
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.90	0.42

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:2054]



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CathPCI Registry®

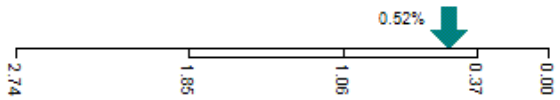
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.52%	1.06%	0.00%

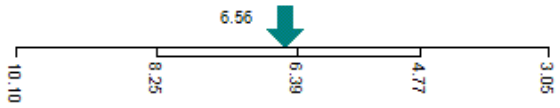
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.56	6.39	3.05

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

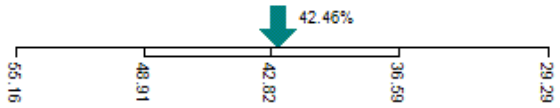
10th percentile 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.46%	42.82%	29.29%

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

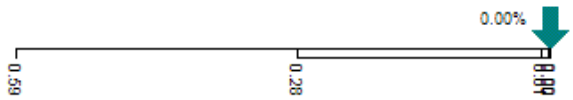
10th percentile 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.01%	0.00%

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

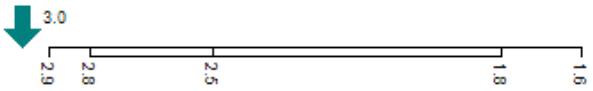
10th percentile 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.5	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

Distribution of Hospital Performance

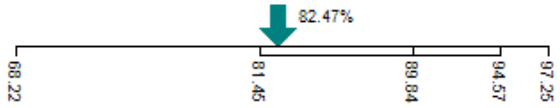
10th percentile 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
82.47%	89.84%	97.25%

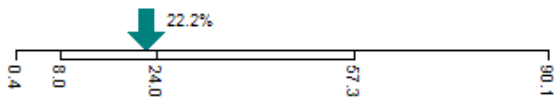
Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
22.2%	24.0%	90.1%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



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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.

	Line:1949]	

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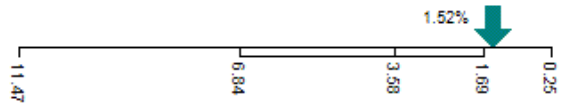
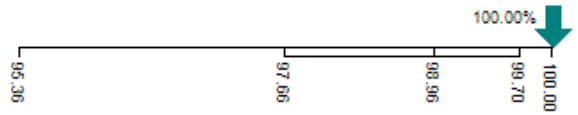
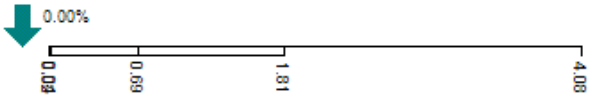
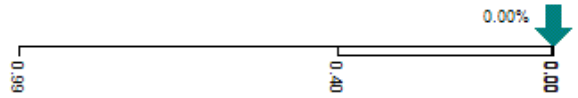
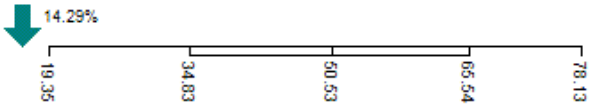
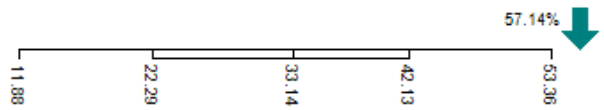
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics		Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 1.52% | US Hospitals 50th Pctl: 3.58% | US Hospitals 90th Pctl: 0.25% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]	
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 100.00% | US Hospitals 50th Pctl: 98.96% | US Hospitals 90th Pctl: 100.00% 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:1581]	
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.69% | US Hospitals 90th Pctl: 4.08% 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:1582]	
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.00% | US Hospitals 90th Pctl: 0.00% 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:1583]	
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 14.29% | US Hospitals 50th Pctl: 50.53% | US Hospitals 90th Pctl: 78.13% 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:1585]	
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 57.14% | US Hospitals 50th Pctl: 33.14% | US Hospitals 90th Pctl: 53.36% 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:1586]	

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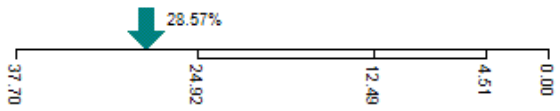
36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
28.57%	12.49%	0.00%

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:1587]



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.

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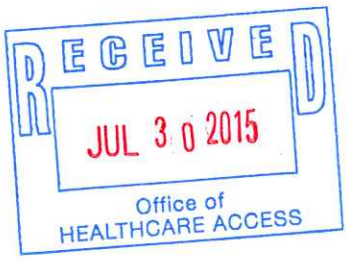


July 28, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 3 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2015Q1

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 3

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Canterbury	1			1
East Lyme		1		1
Gales Ferry	1	1		2
Groton	5	2	2	9
Jewett City			1	1
Kutztown, PA	1			1
Ledyard	1			1
Mystic	2		2	4
New London	2	6	1	9
Niantic	1		2	3
Oakdale	1	1		2
Old Lyme	2	1		3
Old Mystic	1			1
Quaker Hill	1	2	1	4
Troy, NY	1			1
Uncasville		1		1
Waterford			1	1
Total PCI Procedures	20	15	10	45

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 3

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
	NONE				

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2015Q1

Lawrence & Memorial Hospital
742173

Aggregation Date: Jun 30, 2015 11:59:59 PM

Publish Date: Jul 13, 2015

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

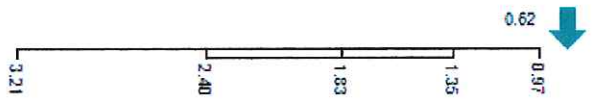
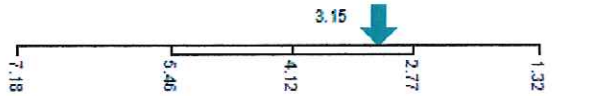
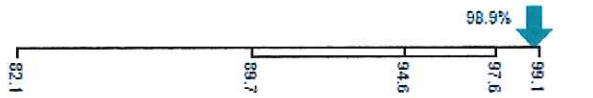
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

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: 0.62 | US Hospitals 50th Pctl: 1.83 | US Hospitals 90th Pctl: 0.97 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 3.15 | US Hospitals 50th Pctl: 4.12 | US Hospitals 90th Pctl: 1.32 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 98.9% | US Hospitals 50th Pctl: 94.6% | US Hospitals 90th Pctl: 99.1% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
28.57%	66.86%	88.94%

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:1513]

3 **Median time to immediate PCI for STEMI patients (in minutes)**

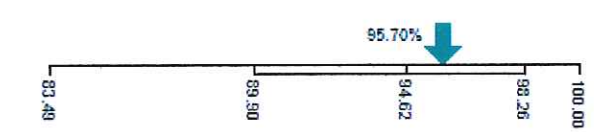
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
58	60	49

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:1502]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.70%	94.62%	100.00%

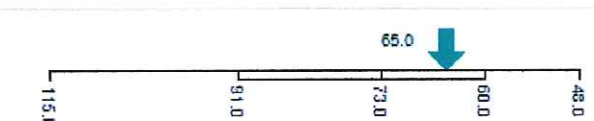
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
65	73	48

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

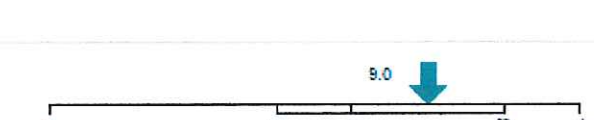
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96	107	80

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:1506]

7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

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:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

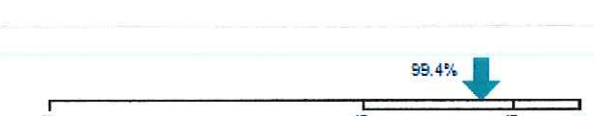
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.8%	100.0%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]

9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	99.6%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	96.1%	99.5%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]

PCI Outcome Metrics

Distribution of Hospital Performance

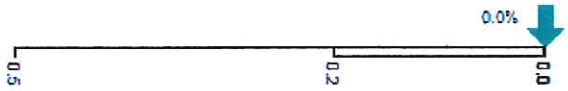
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

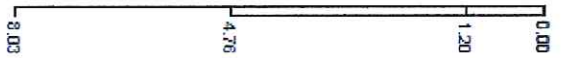
Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.20%	0.00%

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:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

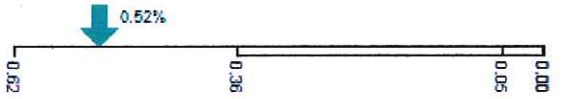
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1804]

16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.52%	0.05%	0.00%

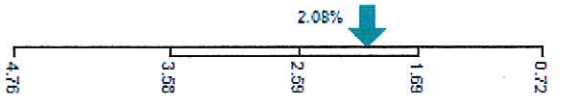
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.08%	2.59%	0.72%

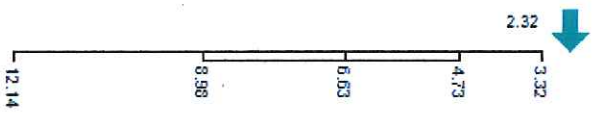
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.32	6.63	3.32

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.90	0.42

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:2054]

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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

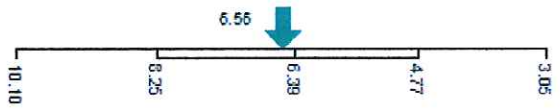
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.52%	1.06%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

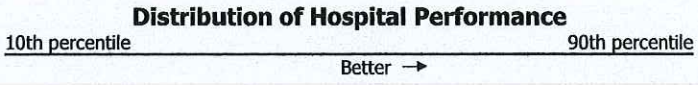
39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.56	6.39	3.05

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



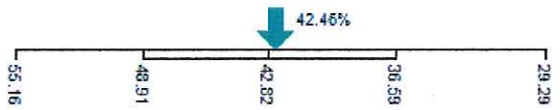
Diagnostic Cath Process Metrics



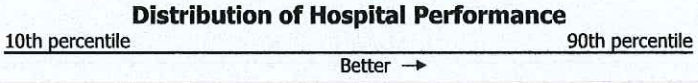
20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.46%	42.82%	29.29%

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]



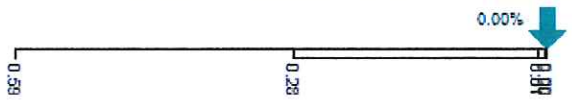
Diagnostic Cath Outcomes Metrics



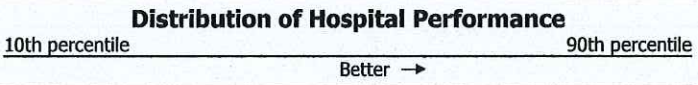
21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.01%	0.00%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



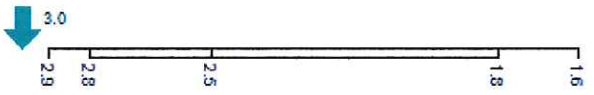
Utilization Metrics



22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.5	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]

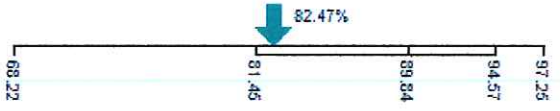


Data Quality Metrics

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
82.47%	89.84%	97.25%

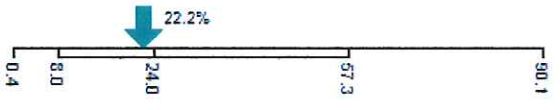
Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
22.2%	24.0%	90.1%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q1

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Line:1949]

Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

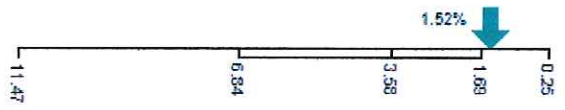
10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.52%	3.58%	0.25%

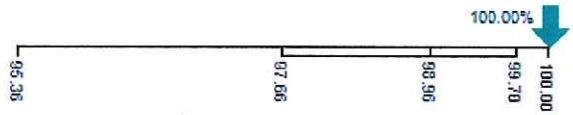
Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]



31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	98.96%	100.00%

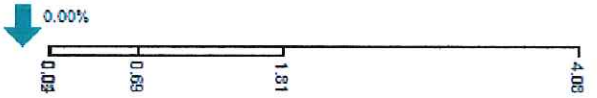
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.69%	4.08%

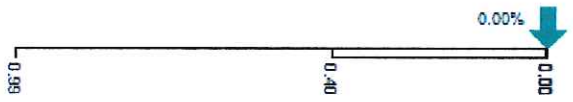
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

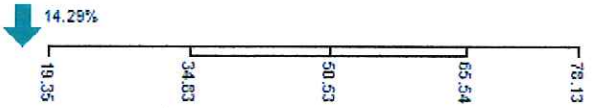
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.29%	50.53%	78.13%

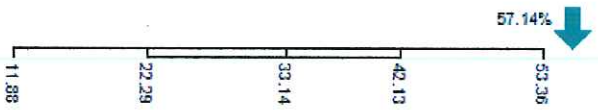
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
57.14%	33.14%	53.36%

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:1586]



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Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
28.57%	12.49%	0.00%

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:1587]

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.

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LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

October 30, 2015

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2015 Quarter 4 PCI Volume by Patient's Town of Residence
- ACC-NCDR Data Report for 2015Q2

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
G. Mulholland

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2015, Quarter 4

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI Procedures (*Inpatient*)	# of Elective PCI Procedures (*Outpatient*)	Total # of Procedures
Doylestown, PA	1			1
East Haddam			1	1
East Lyme		1	1	2
Gilman	1			1
Griswold	1			1
Groton	2	1	1	4
Harvard, MA	1			1
Islip, NY	1			1
Ledyard	1			1
Lyme		1		1
Mystic	1			1
New London	1	4	1	6
Niantic	1	1	1	3
North Stonington	1			1
Norwich	5			5
Oakdale	1	1	1	3
Old Saybrook	1			1
Pawcatuck	4			4
Plainfield			1	1
Quaker Hill	1	1		2
Salem	2			2
Stonington			1	1
Uncasville	1			1
Waterford	2	4		6
Westerly, RI	6			6
Yantic	1			1
Total PCI Procedures	36	14	8	58

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

Cardiac Transfers:

Federal Fiscal Year 2015, Quarter 4

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	YNHH	NSTEMI patient arrives via ambulance and urgently brought to cath lab. Patient had successful angioplasty, but it was determined patient required urgent surgical revascularization as well. Patient stable with IABP and intubation prior to transfer.	7/22/15 9:59	7/22/15 10:21	CABG 7/23/2015 10:58
2	YNHH	STEMI patient had PCI procedure to resolve acute issue; however, unable to completely restore normal coronary blood flow. After consultation with Yale the decision was to transfer to Yale for required bypass surgery.	8/13/15 11:53	8/13/15 12:16	CABG 8/13/2015 14:25

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2015Q2

Lawrence & Memorial Hospital
742173

Aggregation Date: Sep 30, 2015 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q2

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)**

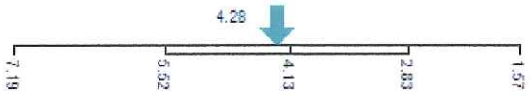
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.14	1.84	1.01

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.28	4.13	1.57

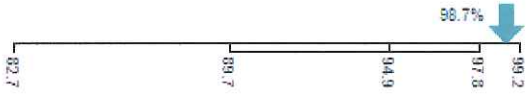
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.7%	94.9%	99.2%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]



Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q2

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

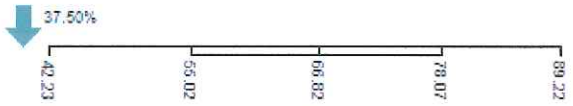
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
37.50%	66.82%	89.22%

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:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

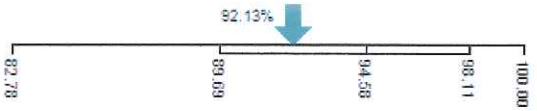
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
62	60	49

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:1502]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
92.13%	94.58%	100.00%

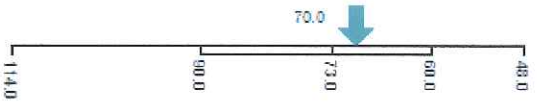
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
70	73	48

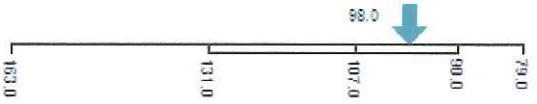
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98	107	79

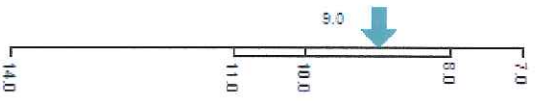
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

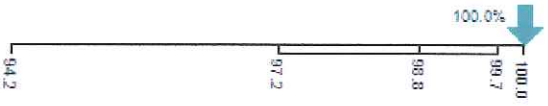
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	98.8%	100.0%

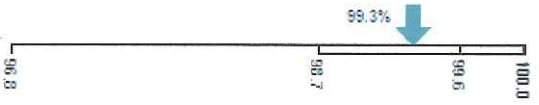
Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.3%	99.6%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]



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Executive Summary

CathPCI Registry®

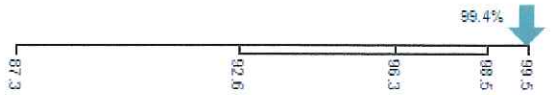
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q2

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.4%	96.3%	99.5%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

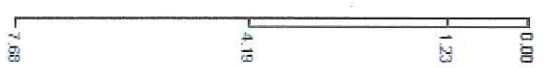
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.23%	0.00%

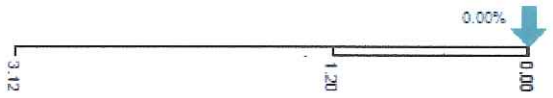
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

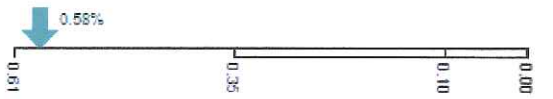
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.58%	0.10%	0.00%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

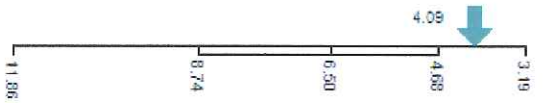
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.92%	2.62%	0.91%

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:1801]

18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.09	6.50	3.19

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.95	0.42

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:2054]

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Executive Summary

CathPCI Registry®

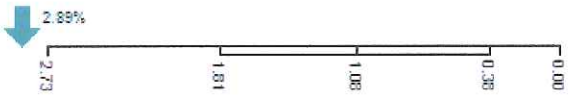
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.89%	1.08%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8.70	6.36	3.15

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]

Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.45%	42.62%	30.56%

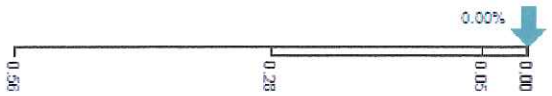
Patients with an elective diagnostic cath and coronary angiography with all native coronary territories <50% Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI". [Detail Line:1252]

Diagnostic Cath Outcomes Metrics

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.05%	0.00%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]

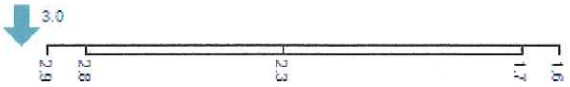


Utilization Metrics

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.3	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

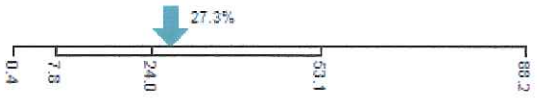
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
82.95%	89.71%	97.25%

Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]

26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
27.3%	24.0%	88.2%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



Aggregation Date: Sep 30, 2015 11:59:59 PM
Publish Date: Oct 15, 2015

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Line:1949]

Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

30 **Proportion of PCI procedures not classifiable for AUC reporting**

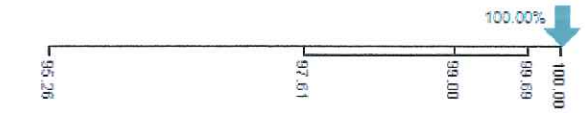
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.68%	3.62%	0.41%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	99.00%	100.00%

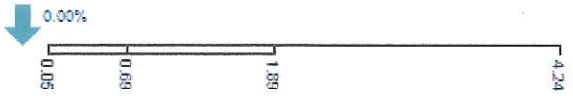
Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1581]



32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.69%	4.24%

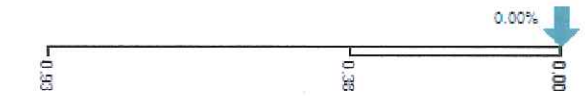
Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1582]



33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

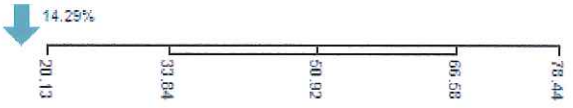
Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1583]



34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.29%	50.92%	78.44%

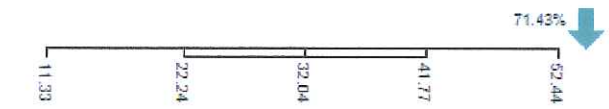
Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1585]



35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
71.43%	32.04%	52.44%

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:1586]



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Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.29%	13.12%	0.00%

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:1587]

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.

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Publish Date: Oct 15, 2015

LAWRENCE +MEMORIAL HOSPITAL

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February 1, 2016

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2016 Quarter 1 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
J. McDonald

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2016, Quarter 1

Reports 1. a. and 1. b (combined)

Town**	# of Primary* PCI Procedures	# of Elective PCI*** Procedures (*Inpatient*)	# of Elective PCI*** Procedures (*Outpatient*)	Total # of Procedures
East Lyme	1		2	3
Groton	1	1	2	4
Ledyard	1			1
Mystic	2	1	1	4
New London	4	1	2	7
Niantic			3	3
Norwich			1	1
Old Lyme	2			2
Pawcatuck		1	1	2
Preston		1		1
Salem	1			1
Sterling			1	1
Uncasville	1	1		2
Waterford		2	1	3
Westerly, RI	3	2	1	6
Griswold	1			1
Fishers Island, NY		1		1
South Kingston, RI	1			1
Ivoryton			1	1
Total PCI Procedures	18	11	16	45

*Assumed to be inpatient procedures

** All towns in Connecticut unless otherwise noted

***Quarterly reports submitted to OHCA since 2013 include FFR and IVUS procedures (ICD-9 code 00.59) which are considered interventional coronary procedures as described in the ACCF/AHA/SCAI Clinical Guidelines

Cardiac Transfers:

Federal Fiscal Year 2016, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	None				
2					
3					
4					
5					
6					
7					
8					
9					
10					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
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February 5, 2016

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- ACC-NCDR Data Report for 2015Q3

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
J. McDonald

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2015Q3

Lawrence & Memorial Hospital
742173

Aggregation Date: Jan 11, 2016 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

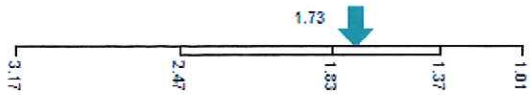
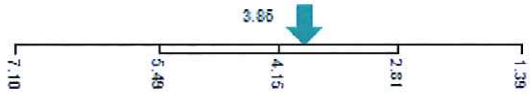
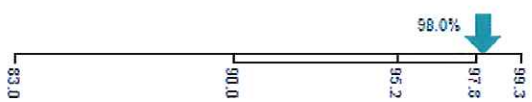
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q3

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: 1.73 | US Hospitals 50th Pctl: 1.83 | US Hospitals 90th Pctl: 1.01 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 3.86 | US Hospitals 50th Pctl: 4.15 | US Hospitals 90th Pctl: 1.39 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 98.0% | US Hospitals 50th Pctl: 95.2% | US Hospitals 90th Pctl: 99.3% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q3

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

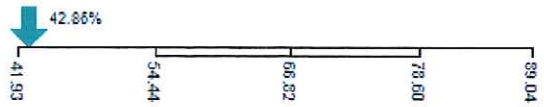
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.86%	66.82%	89.04%

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:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

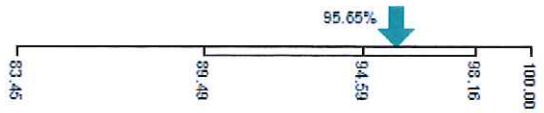
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
58	60	48

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:1502]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.65%	94.59%	100.00%

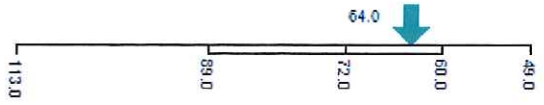
Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90'. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
64	72	49

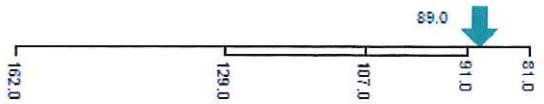
Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]



6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
89	107	81

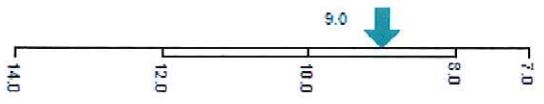
Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1506]



7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

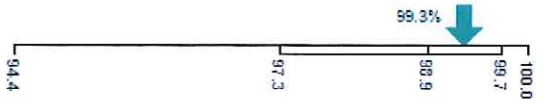
Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.3%	98.9%	100.0%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]



9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.6%	99.6%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]

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Executive Summary

CathPCI Registry®

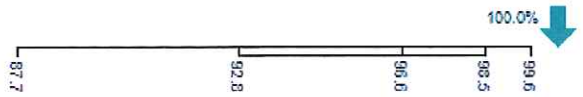
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.0%	96.6%	99.6%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

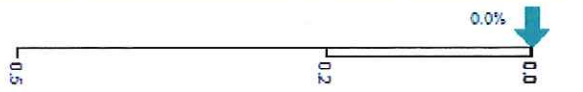
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

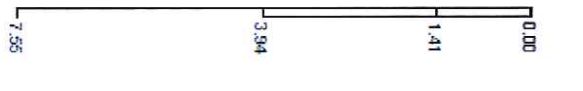
Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.41%	0.00%

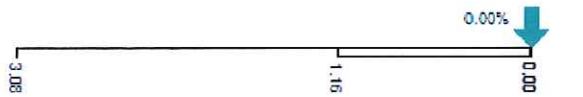
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

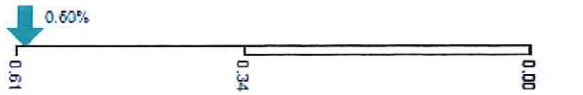
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.60%	0.00%	0.00%

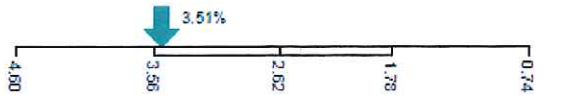
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.51%	2.62%	0.74%

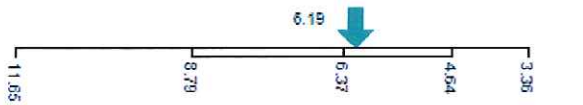
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.19	6.37	3.36

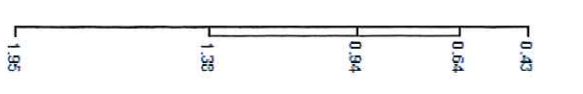
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.94	0.43

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:2054]



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

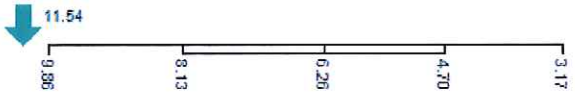
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.57%	1.05%	0.00%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]

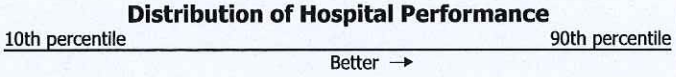
39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
11.54	6.26	3.17

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



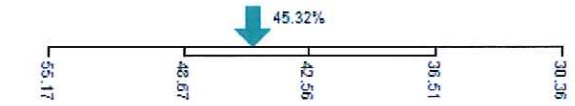
Diagnostic Cath Process Metrics



20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
45.32%	42.56%	30.36%

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]

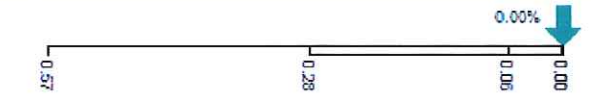


Diagnostic Cath Outcomes Metrics

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.06%	0.00%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



Utilization Metrics

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.0	1.6

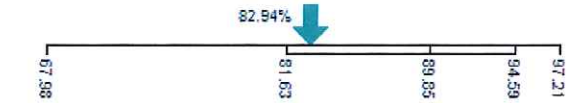
Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]

Data Quality Metrics

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
82.94%	89.85%	97.21%

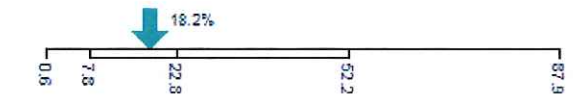
Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
18.2%	22.8%	87.9%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Line:1949]

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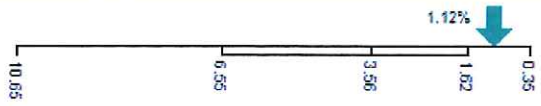
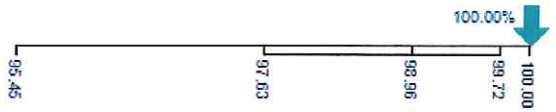
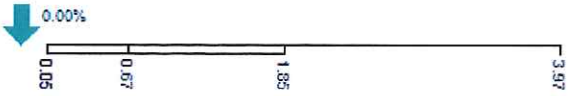
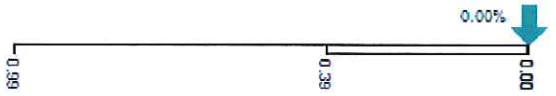
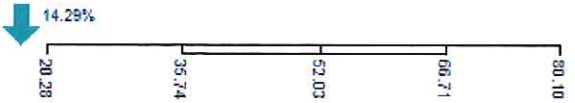
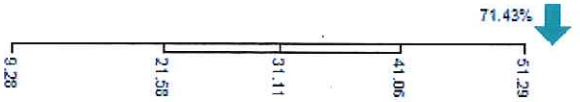
Executive Summary

CathPCI Registry®

(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics				Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	1.12%	3.56%	0.35%	
	Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]			
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	100.00%	98.96%	100.00%	
	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:1581]			
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	0.00%	0.67%	3.97%	
	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:1582]			
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	0.00%	0.00%	0.00%	
	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:1583]			
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	14.29%	52.03%	80.10%	
	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:1585]			
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	71.43%	31.11%	51.29%	
	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:1586]			

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Executive Summary

CathPCI Registry®

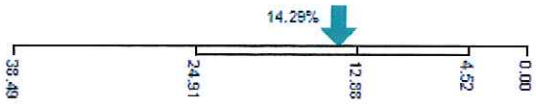
(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.29%	12.88%	0.00%

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:1587]



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.

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LAWRENCE +MEMORIAL HOSPITAL

365 Montauk Avenue | New London, CT 06320
860.442.0711 | lmhospital.org

April 30, 2016

Jack Huber
Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

RE: CON Docket Number 12-31768, Agreed Settlement
Establish and Operate an Elective Angioplasty Program at L+M Hospital

Dear Mr. Huber,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments in hardcopy and electronically on CD.

- Fiscal Year 2016 Quarter 2 PCI Volume by Patient's Town of Residence

If you have any questions or concerns regarding this filing, please contact me at (860) 912-5324 or via email at spatel@lmhosp.org.

Sincerely,

Shraddha Patel
Director of Business Development & Planning

Cc:
B. Cambi, MD
J. Goldberg
J. McDonald
L. Bagnati

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2016, Quarter 2

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI** Procedures (*Inpatient*)	# of Elective PCI** Procedures (*Outpatient*)	Total # of Procedures
Clinton, CT		1		1
East Lyme, CT	1			1
Gales Ferry, CT		2		2
Groton, CT		3	2	5
Haverhill, MA	1			1
Jewett City, CT	1		1	2
Kennesaw, GA	1			1
Ledyard, CT			1	1
Mystic, CT	1		1	2
New London, CT	3	3	1	7
Niantic, CT		2	1	3
Norwich, CT	2			2
Old Lyme, CT	1	1		2
Pawcatuck, CT			1	1
Quaker Hill, CT		1		1
Uncasville, CT		1		1
Waterford, CT	4		1	5
West Newbury, MA	1			1
Westerly, RI	1			1
Total PCI procedures	17	14	9	40

*Assumed to be inpatient procedures

**Quarterly reports submitted to OHCA since 2013 include FFR and IVUS procedures (ICD-9 code 00.59) which are considered interventional coronary procedures as described in the ACCF/AHA/SCAI Clinical Guidelines

Cardiac Transfers:

Federal Fiscal Year 2016, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	YNHH	After undergoing successful complex primary angioplasty at L+M, STEMI patient transferred to YNHH for additional angioplasty.	3/19/16 20:32	3/19/16 21:16	Procedure attempted but not completed.

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

Greer, Leslie

From: Roberts, Karen
Sent: Tuesday, May 10, 2016 9:02 AM
To: Patel, Shraddha
Cc: Cotto, Carmen; Greer, Leslie
Subject: RE: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)

To: Shraddha Patel
Director of Business Development & Planning
Lawrence + Memorial Hospital

RE: **Certificate of Need authorized under DN 12-31768-CON by the Office of Health Care Access (OHCA)**

Dear Shraddha:

Regarding the Certificate of Need (CON) for the Establishment of an Elective Angioplasty Program at Lawrence +Memorial Hospital issued under CON Docket Number 12-31768-CON, please submit any further filings or documentation related to the CON conditions via electronic mail by using the OHCA general email inbox which is OHCA@ct.gov. In addition, please reference the CON docket number in the subject line of the email when transmitting. Please be assured that any material that will be received in the general inbox will become part of the public record for this docket number.

If the submission is 20 pages in length or longer, please mail the document to the Office of Health Care Access using the mailing address below in addition to electronic transmission.

Thank you and let me know if you have any questions on this email.

Sincerely,

Karen Roberts
Principal Health Care Analyst
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13HCA, P.O. Box 340308, Hartford, CT 06134-0308
P: (860) 418-7041 / F: (860) 418-7053 / E: *karen.roberts@ct.gov*

Roberts, Karen

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Wednesday, May 18, 2016 12:51 PM
To: User, OHCA
Subject: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: ACC-NCDR 2015Q4 Report (L+M Hospital).pdf

Per the Agreed Settlement for CON Docket Number 12-31768 (L+M Hospital), please find the following attachments:

- ACC-NCDR Data Report for 2015Q4

If you have any questions, please feel free to contact me.

Thank you,
Shraddha

Shraddha Patel, FACHE
Director of Business Development & Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2015Q4

Lawrence & Memorial Hospital
742173

Aggregation Date: Apr 15, 2016 11:59:59 PM

Publish Date: May 11, 2016

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
2.64	1.86	1.01

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]

37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.61	4.16	1.61

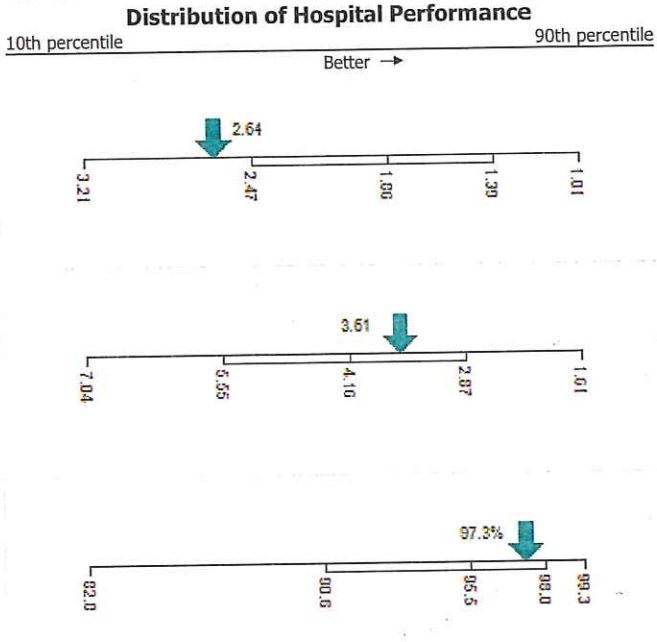
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]

38 **Composite: Discharge Medications in Eligible PCI Patients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
97.3%	95.5%	99.3%

Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]

Distribution of Hospital Performance



Note

Performance measures in the CathPCI Registry® have 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.

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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

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

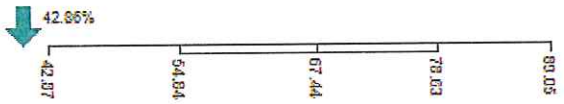
10th percentile — 90th percentile

Better →

2 **Proportion of elective PCIs with prior positive stress or imaging study**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
42.86%	67.44%	89.05%

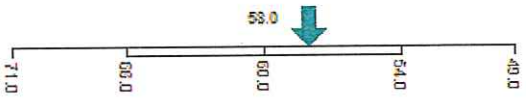
Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1513]



3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
58	60	49

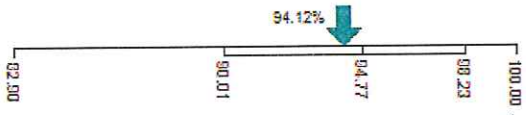
Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1502]



4 **Proportion of STEMI patients receiving immediate PCI w/in 90'**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
94.12%	94.77%	100.00%

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:1503]



5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
69	72	49

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

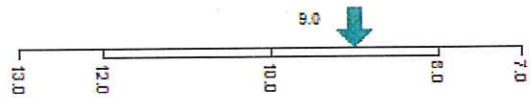
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
89	107	80

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:1506]

7 **Median fluoro time (in minutes)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
9	10	7

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:1633]



8 **Proportion of patients with aspirin prescribed at discharge**

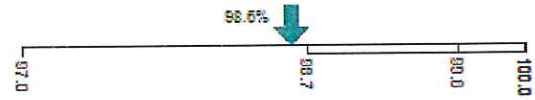
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.3%	98.9%	100.0%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]

9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
98.6%	99.6%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]



Aggregation Date: Apr 15, 2016 11:59:59 PM
Publish Date: May 11, 2016

Executive Summary

CathPCI Registry®

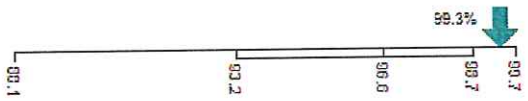
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
99.3%	96.6%	99.7%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

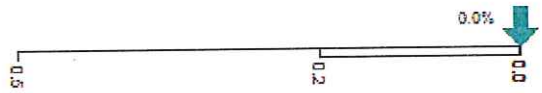
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	1.39%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

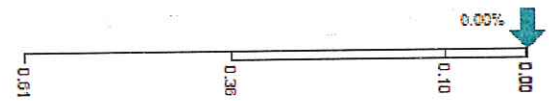
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1804]

16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.10%	0.00%

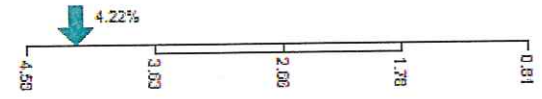
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.22%	2.66%	0.81%

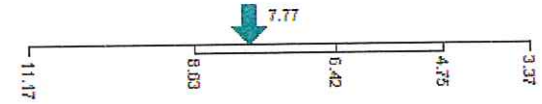
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.77	6.42	3.37

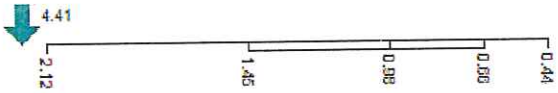
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.41	0.98	0.44

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:2054]



Aggregation Date: Apr 15, 2016 11:59:59 PM
Publish Date: May 11, 2016

Executive Summary

CathPCI Registry®

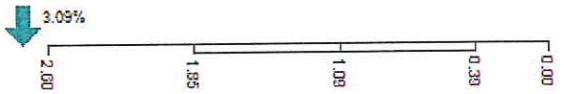
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.09%	1.09%	0.00%

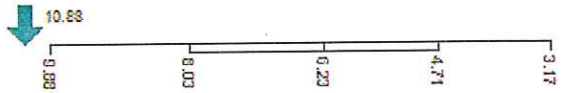
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.88	6.23	3.17

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
44.40%	42.22%	30.05%

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

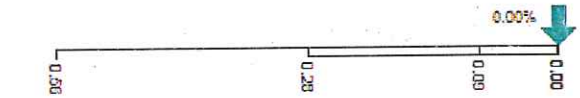
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.09%	0.00%

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

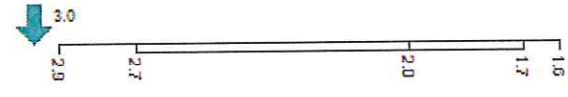
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.0	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

Distribution of Hospital Performance

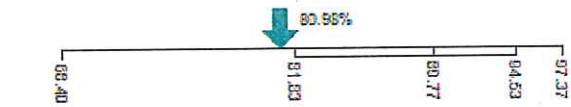
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
80.98%	89.77%	97.37%

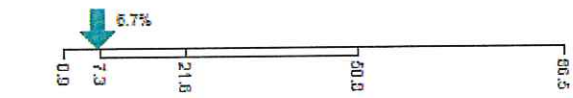
Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.7%	21.6%	86.5%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Line:1949]

Executive Summary

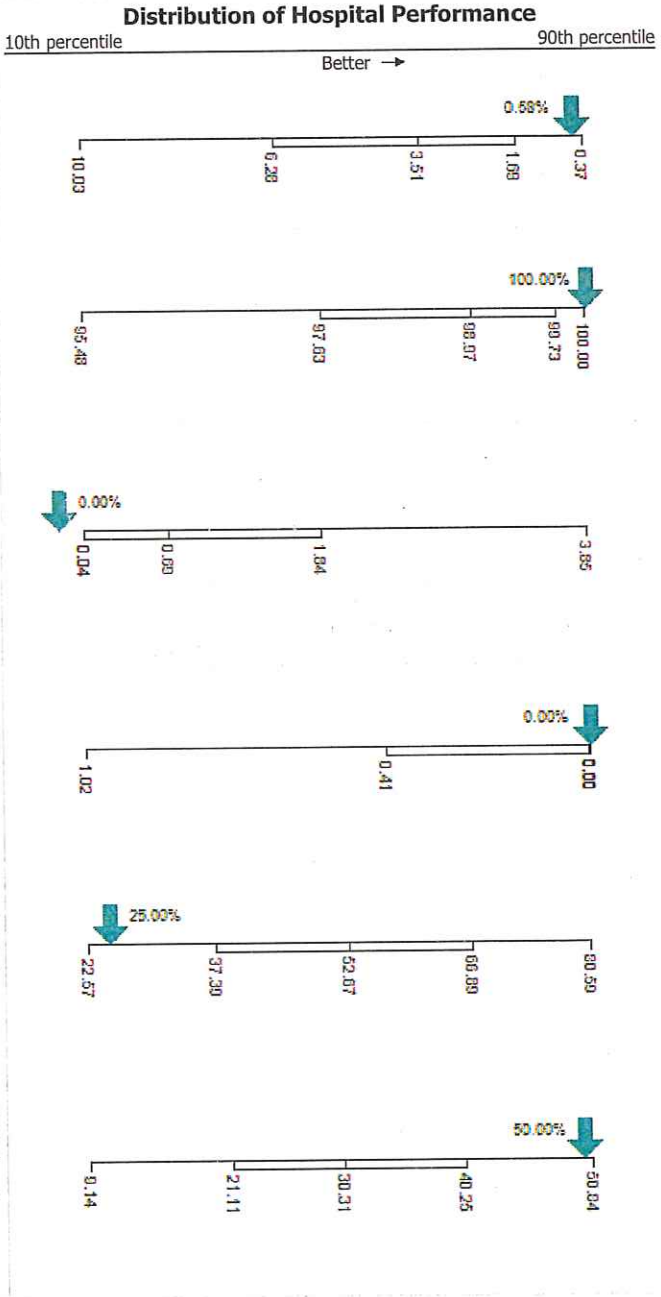
CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics

Distribution of Hospital Performance



30 **Proportion of PCI procedures not classifiable for AUC reporting**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.58%	3.51%	0.37%

Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]

31 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
100.00%	98.97%	100.00%

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:1581]

32 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.69%	3.85%

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:1582]

33 **Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

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:1583]

34 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
25.00%	52.67%	80.59%

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:1585]

35 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
50.00%	30.31%	50.84%

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:1586]

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Executive Summary

CathPCI Registry®

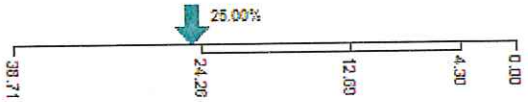
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2015Q4

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
25.00%	12.69%	0.00%

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:1587]



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.

Aggregation Date: Apr 15, 2016 11:59:59 PM
Publish Date: May 11, 2016

Greer, Leslie

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Wednesday, October 19, 2016 11:56 AM
To: User, OHCA
Cc: McDonald, Janine; Bagnati, Lynne; Cambi, Brian; Patel, Shraddha
Subject: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: FY 2016 Q4 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachments:

- Fiscal Year 2016 Quarter 4 PCI Volume by Patient's Town of Residence

The ACC-NCDR Data Report for 2016Q2 will be sent separately, once the report is released to L+M.

Thank you,
Shraddha Patel

Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2016, Quarter 4

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI** Procedures (*Inpatient*)	# of Elective PCI** Procedures (*Outpatient*)	Total # of Procedures
Ashaway, RI		1		1
Auburn, MA	1			1
Danielson, CT			1	1
East Granby, CT		1		1
East Lyme, CT	2			2
Gales Ferry, CT	1		1	2
Groton, CT	3	4		7
Jewett City, CT	1			1
Montpielier, VT	1			1
Moosup, CT			1	1
Mount Holly, NJ	1			1
Mystic, CT		1	1	2
New Hartford, CT	1			1
New London, CT	3	6	1	10
Niantic, CT	2	2		4
Noank, CT		1		1
Norwich, CT	3			3
Old Lyme, CT	1			1
Pawcatuck ,CT	1			1
Preston, CT	1			1
Putnam, CT		1		1
Quaker Hill, CT			1	1
Shelton, CT		2		2
Staten Island, NY	1			1
Stonington, CT	1			1
Waterford, CT	3		1	4
Total PCI procedures	27	19	7	53

*Assumed to be inpatient procedures

**Quarterly reports submitted to OHCA since 2013 include FFR and IVUS procedures (ICD-9 code 00.59) which are considered interventional coronary procedures as described in the ACCF/AHA/SCAI Clinical Guidelines

Cardiac Transfers:

Federal Fiscal Year 2016, Quarter 4

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
1	YNHH	Patient transferred for atherectomy procedure	8/26/16 6:10	8/26/16 7:31	Atherectomy and angioplasty 8/26/16 16:30

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

Greer, Leslie

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Tuesday, November 08, 2016 10:35 AM
To: User, OHCA
Cc: McDonald, Janine; Bagnati, Lynne; Cambi, Brian; Patel, Shraddha
Subject: RE: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: ACC-NCDR 2016Q2 Report (L+M Hospital).pdf

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachment:

- ACC-NCDR Data Report for 2016Q2

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Shraddha Patel

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Shraddha Patel

Shraddha Patel, FACHE
Director of Business Development and Planning
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Email: spatel@lmhosp.org

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2016Q2

Lawrence & Memorial Hospital
742173

Aggregation Date: Sep 30, 2016 11:59:59 PM

Publish Date: Nov 1, 2016

National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

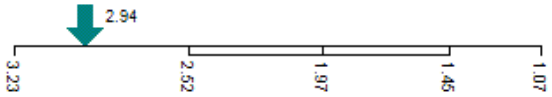
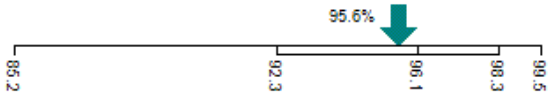
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q2

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: 2.94 | US Hospitals 50th Pctl: 1.97 | US Hospitals 90th Pctl: 1.07 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 95.6% | US Hospitals 50th Pctl: 96.1% | US Hospitals 90th Pctl: 99.5% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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.

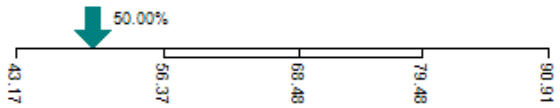
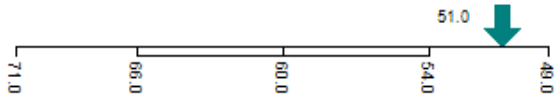
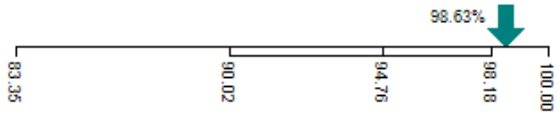
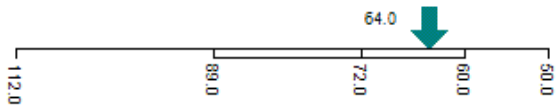
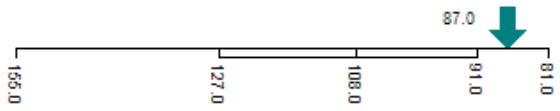
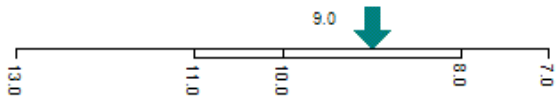
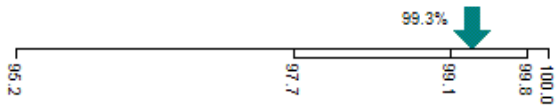
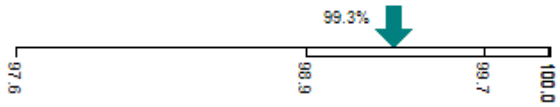
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q2

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: 50.00% | US Hospitals 50th Pctl: 68.48% | US Hospitals 90th Pctl: 90.91% 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:1513]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 51 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 49 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:1502]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 98.63% | US Hospitals 50th Pctl: 94.76% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 64 | US Hospitals 50th Pctl: 72 | US Hospitals 90th Pctl: 50 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 87 | US Hospitals 50th Pctl: 108 | US Hospitals 90th Pctl: 81 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:1506]	
7	**Median fluoro time (in minutes)** My Hospital: 9 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: 99.3% | US Hospitals 50th Pctl: 99.1% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]	
9	**Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 99.3% | US Hospitals 50th Pctl: 99.7% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]	

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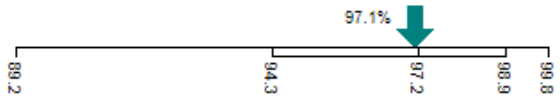
Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

10 **Statins prescribed at discharge**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
97.1%	97.2%	99.8%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

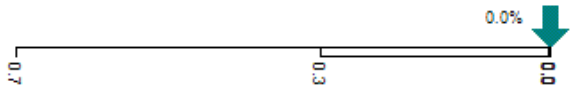
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

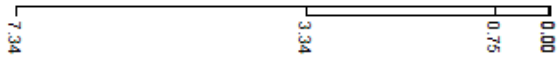
Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.75%	0.00%

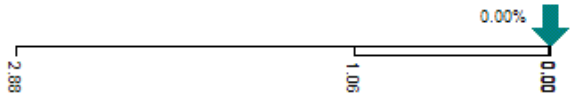
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1803]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

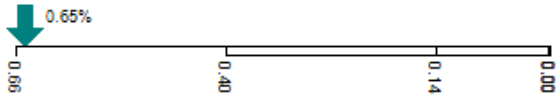
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.65%	0.14%	0.00%

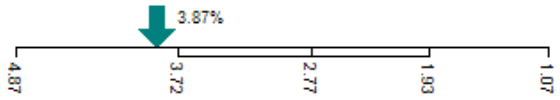
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.87%	2.77%	1.07%

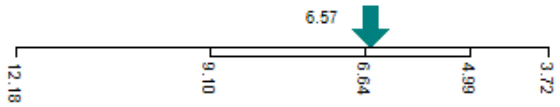
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.57	6.64	3.72

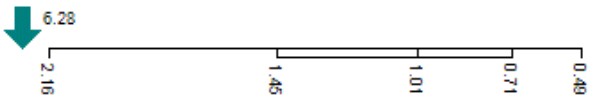
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
6.28	1.01	0.49

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:2054]



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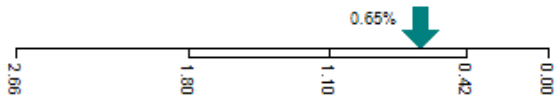
Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.65%	1.10%	0.00%

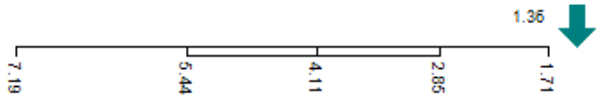
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



37 **PCI in-hospital risk adjusted rate of bleeding events (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.36	4.11	1.71

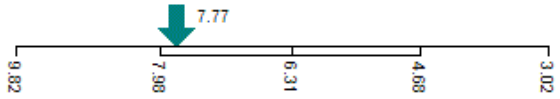
Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.77	6.31	3.02

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

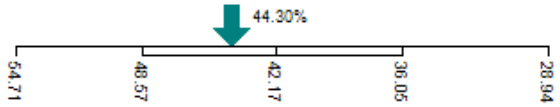
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
44.30%	42.17%	28.94%

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

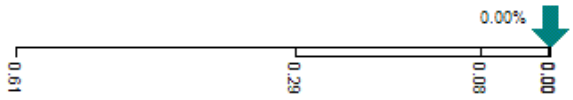
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.08%	0.00%

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

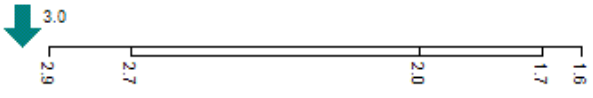
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.0	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

Distribution of Hospital Performance

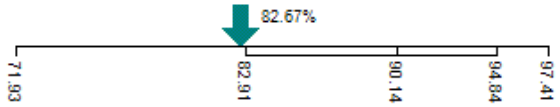
10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
82.67%	90.14%	97.41%

Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



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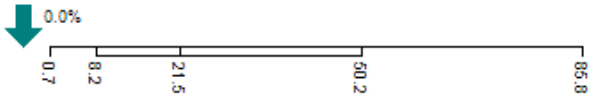
Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	21.5%	85.8%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail Line:1949]



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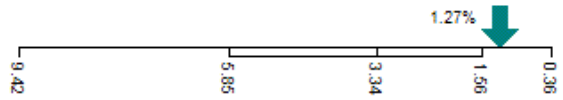
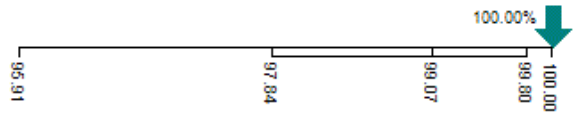
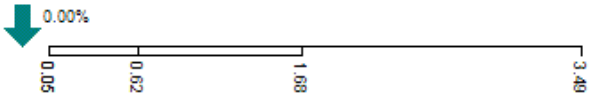
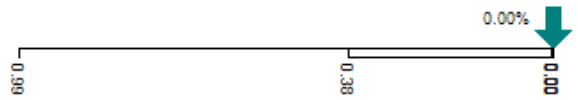
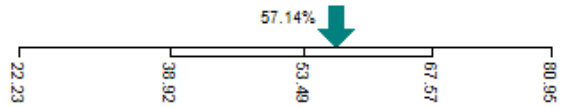
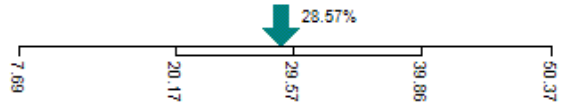
Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics		Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 1.27% | US Hospitals 50th Pctl: 3.34% | US Hospitals 90th Pctl: 0.36% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]	
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 100.00% | US Hospitals 50th Pctl: 99.07% | US Hospitals 90th Pctl: 100.00% 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:1581]	
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.62% | US Hospitals 90th Pctl: 3.49% 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:1582]	
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.00% | US Hospitals 90th Pctl: 0.00% 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:1583]	
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 57.14% | US Hospitals 50th Pctl: 53.49% | US Hospitals 90th Pctl: 80.95% 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:1585]	
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 28.57% | US Hospitals 50th Pctl: 29.57% | US Hospitals 90th Pctl: 50.37% 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:1586]	

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Executive Summary

CathPCI Registry®

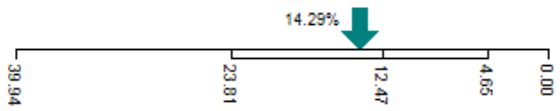
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q2

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.29%	12.47%	0.00%

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:1587]



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.

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Publish Date: Nov 1, 2016

Greer, Leslie

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Monday, January 09, 2017 12:21 PM
To: User, OHCA
Cc: McDonald, Janine; Bagnati, Lynne
Subject: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: FY 2017 Q1 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Good afternoon,

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachment:

- Fiscal Year 2017 Quarter 1 PCI Volume by Patient's Town of Residence

The ACC-NCDR Data Report for 2016Q3 will be sent separately, once the report is released to L+M.

Thank you,
Shraddha Patel

Shraddha Patel, FACHE
Director of Business Development and Planning
L+M Healthcare
365 Montauk Avenue
New London, CT 06320
Phone: (860) 912-5324
Email: spatel@lmhosp.org

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2017, Quarter 1

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI** Procedures (*Inpatient*)	# of Elective PCI** Procedures (*Outpatient*)	Total # of Procedures
Bozrah, CT	1			1
Bristol, CT		1		1
Brooklyn, CT			1	1
Danielson, CT	1			1
East Lyme, CT			1	1
Groton, CT	4	5	1	10
Jewett City, CT			1	1
Ledyard, CT	1	1	1	3
Morrisville, PA	1			1
Mystic, CT	1		2	3
New Britain, CT	1			1
New London, CT	2	1		3
Niantic, CT		1	1	2
North Stonington, CT	1			1
Norwich, CT	5		1	6
Oakdale, CT	2		2	4
Ocala, FL		1		1
Old Mystic, CT	1			1
Pawcatuck, CT	2			2
Salem, CT	1			1
Springfield, MA	1			1
Stonington, CT	1		1	2
Uncasville, CT		1		1
Waterford, CT	1	1	2	4
Westerly, RI	3	1		4
Total PCI procedures	30	13	14	57

*Assumed to be inpatient procedures

**Quarterly reports submitted to OHCA since 2013 include FFR and IVUS procedures (ICD-9 code 00.59) which are considered interventional coronary procedures as described in the ACCF/AHA/SCAI Clinical Guidelines

Cardiac Transfers:

Federal Fiscal Year 2017, Quarter 1

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
None					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

User, OHCA

From: Patel, Shraddha <spatel@lmhosp.org>
Sent: Thursday, February 09, 2017 3:17 PM
To: User, OHCA
Cc: McDonald, Janine; Bagnati, Lynne; Cambi, Brian
Subject: FW: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: ACC-NCDR 2016Q3 Report (L+M Hospital).pdf

Please note, this attachment includes data for 2016Q3. Below note was incorrectly stated.

From: Patel, Shraddha
Sent: Thursday, February 09, 2017 3:15 PM
To: 'OHCA@ct.gov'
Cc: McDonald, Janine; Bagnati, Lynne; Cambi, Brian
Subject: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachment:

- ACC-NCDR Data Report for 2016Q2

Thank you,
Shraddha Patel

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2016Q3

Lawrence & Memorial Hospital
742173

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

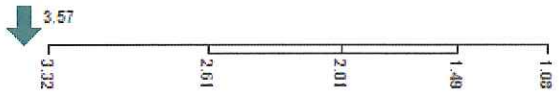
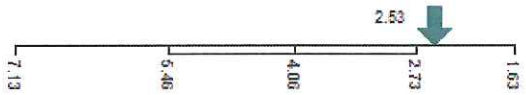
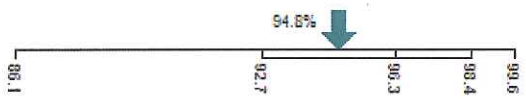
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

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: 3.57 | US Hospitals 50th Pctl: 2.01 | US Hospitals 90th Pctl: 1.08 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 2.53 | US Hospitals 50th Pctl: 4.06 | US Hospitals 90th Pctl: 1.63 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 94.8% | US Hospitals 50th Pctl: 96.3% | US Hospitals 90th Pctl: 99.6% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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.

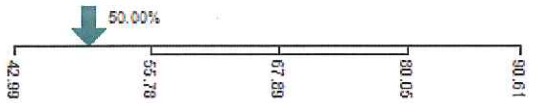
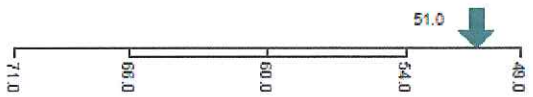
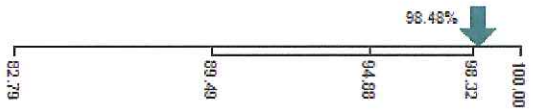
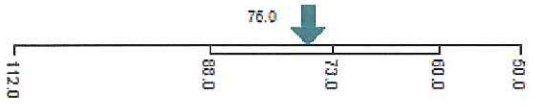
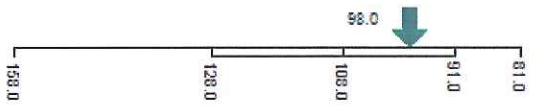
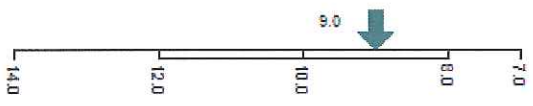
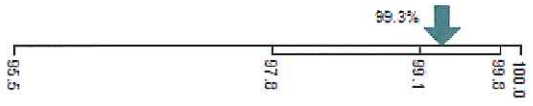
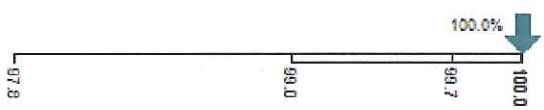
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

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: 50.00% | US Hospitals 50th Pctl: 67.89% | US Hospitals 90th Pctl: 90.61% 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:1513]	
3 **Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 51 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 49 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:1502]	
4 **Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 98.48% | US Hospitals 50th Pctl: 94.88% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 76 | US Hospitals 50th Pctl: 73 | US Hospitals 90th Pctl: 50 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 98 | US Hospitals 50th Pctl: 108 | US Hospitals 90th Pctl: 81 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:1506]	
7 **Median fluoro time (in minutes)** My Hospital: 9 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8 **Proportion of patients with aspirin prescribed at discharge** My Hospital: 99.3% | US Hospitals 50th Pctl: 99.1% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]	
9 **Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 99.7% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]	

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Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
96.3%	97.4%	100.0%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]

PCI Outcome Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]

13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

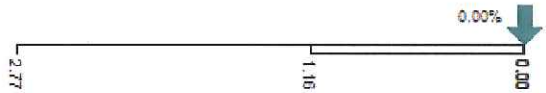
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.64%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

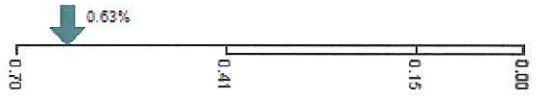
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.63%	0.15%	0.00%

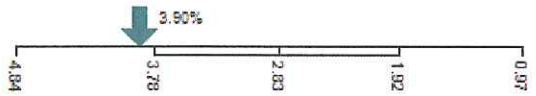
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.90%	2.83%	0.97%

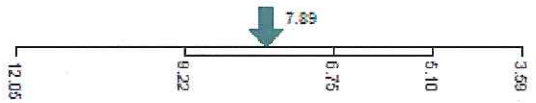
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
7.89	6.75	3.59

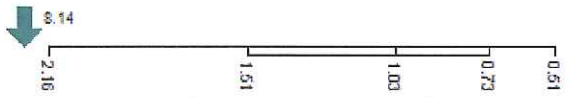
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
8.14	1.03	0.51

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:2054]



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CathPCI Registry®

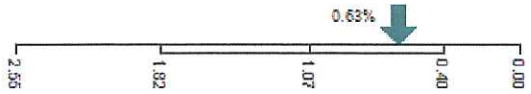
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.63%	1.07%	0.00%

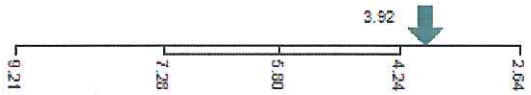
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.92	5.80	2.64

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]

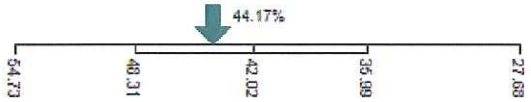


Diagnostic Cath Process Metrics

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
44.17%	42.02%	27.68%

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]

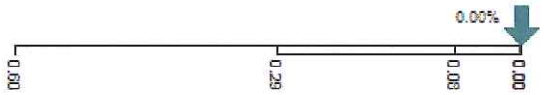


Diagnostic Cath Outcomes Metrics

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.08%	0.00%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]

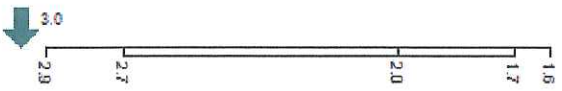


Utilization Metrics

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	2.0	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

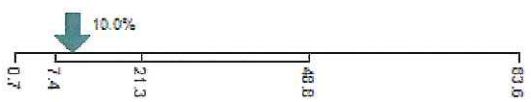
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
81.70%	90.14%	97.36%

Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]

26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.0%	21.3%	83.6%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



Aggregation Date: Jan 12, 2017 11:59:59 PM
Publish Date: Feb 4, 2017

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

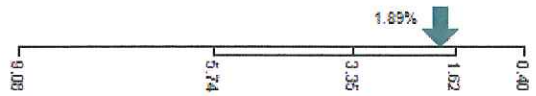
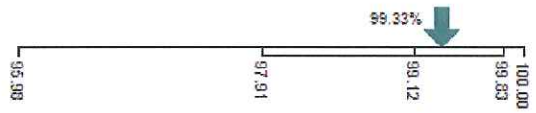
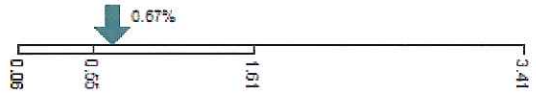
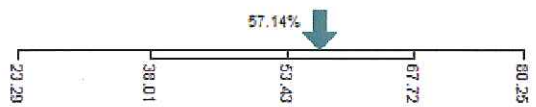
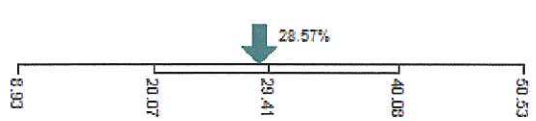
Line:1949]	

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics				Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	1.89%	3.35%	0.40%	
	Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]			
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	99.33%	99.12%	100.00%	
	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:1581]			
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	0.67%	0.55%	3.41%	
	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:1582]			
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	0.00%	0.00%	0.00%	
	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:1583]			
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	57.14%	53.43%	80.25%	
	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:1585]			
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness**			
	My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl	
	28.57%	29.41%	50.53%	
	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:1586]			

Executive Summary

CathPCI Registry®

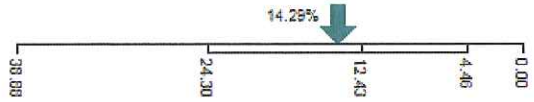
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q3

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.29%	12.43%	0.00%

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:1587]



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.

Aggregation Date: Jan 12, 2017 11:59:59 PM
Publish Date: Feb 4, 2017

User, OHCA

From: PATEL, SHRADDHA <SHRADDHA.PATEL@YNHH.ORG>
Sent: Friday, April 14, 2017 10:36 AM
To: User, OHCA
Cc: 'bcambi@lmhosp.org'; 'lbagnati@lmhosp.org'; McDonald, Janine (LMhosp); Smith, Diane
Subject: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: FY 2017 Q2 Compliance Format for 12-31768-CON (L+M Hospital).xlsx

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachment:

- Fiscal Year 2017 Quarter 2 PCI Volume by Patient's Town of Residence

The ACC-NCDR Data Report for 2016Q4 will be sent separately, once the report is released to L+M.

Thank you,
Shraddha

Shraddha Patel, FACHE
Director of Strategy and Regulatory Planning & Reporting
2 Howe 3rd Floor
New Haven, CT 06519
Phone: 860-912-5324
Email: shraddha.patel@ynhh.org

YaleNewHavenHealth

Percutaneous Coronary Intervention (PCI):

Federal Fiscal Year 2017, Quarter 2

Reports 1. a. and 1. b (combined)

Town	# of Primary* PCI Procedures	# of Elective PCI** Procedures (*Inpatient*)	# of Elective PCI** Procedures (*Outpatient*)	Total # of Procedures
Baltic, CT			1	1
Charlestown, RI	1			1
East Lyme, CT		1		1
Groton, CT	2	3	4	9
Jewett City, CT			1	1
Ledyard, CT	1		3	4
Mystic, CT	3	3	1	7
New Haven, CT		1		1
New London, CT	2	4	4	10
Niantic, CT	2	1		3
North Stonington, CT	1		1	2
Norwich, CT	5		1	6
Oakdale, CT	1			1
Old Lyme, CT	1	1		2
Pawcatuck, CT	1			1
Pawtucket, RI	1			1
Prospect, CT	1			1
Stonington, CT		1	1	2
Thompson, CT		1		1
Uncasville, CT	1			1
Vernon, CT		1		1
Waterford,CT	1	1		2
Westerly , RI	3		2	5
Wurtsboro, NY	1			1
Total PCI procedures	28	18	19	65

*Assumed to be inpatient procedures

**Quarterly reports submitted to OHCA since 2013 include FFR and IVUS procedures (ICD-9 code 00.59) which are considered interventional coronary procedures as described in the ACCF/AHA/SCAI Clinical Guidelines

Cardiac Transfers:

Federal Fiscal Year 2017, Quarter 2

Report 1. c.

Patient Transfer	Facility Receiving Transfer	Reason for Transfer	Patient Departure Date/Time*	Patient Arrival Date/Time*	Procedure Administered Date/Time*
None					

*Please provide Date/Time in the following format: mm/dd/yyyy hh:mm

User, OHCA

From: PATEL, SHRADDHA <SHRADDHA.PATEL@YNHH.ORG>
Sent: Thursday, May 25, 2017 2:35 PM
To: User, OHCA
Subject: RE: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)
Attachments: ACC-NCDR 2016Q4 Report (L+M Hospital).pdf

Per the Agreed Settlement for CON Docket Number 12-31768, please find the following attachment:

- ACC-NCDR report for 2016Q4

Thank you,
Shraddha

Shraddha Patel, FACHE
Director of Strategy and Regulatory Planning & Reporting
2 Howe 3rd Floor
New Haven, CT 06519
Phone: 860-912-5324
Email: shraddha.patel@ynhh.org

YaleNewHavenHealth

From: PATEL, SHRADDHA
Sent: Friday, April 14, 2017 10:36 AM
To: 'ohca@ct.gov' <ohca@ct.gov>
Cc: 'bcambi@lmhosp.org' <bcambi@lmhosp.org>; 'lbagnati@lmhosp.org' <lbagnati@lmhosp.org>; McDonald, Janine (LMhosp) <jmcdonald@lmhosp.org>; Smith, Diane <DIANE.SMITH2@YNHH.ORG>
Subject: Compliance Filings for CON Docket # 12-31768-CON (Elective Angioplasty)

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Thank you,
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Shraddha Patel, FACHE
Director of Strategy and Regulatory Planning & Reporting
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New Haven, CT 06519
Phone: 860-912-5324
Email: shraddha.patel@ynhh.org

YaleNewHavenHealth

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

CathPCI Registry®

Version 4.4

Institutional Outcomes Report
2016Q4

Lawrence & Memorial Hospital
742173

Aggregation Date: Apr 17, 2017 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org

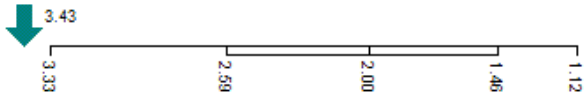
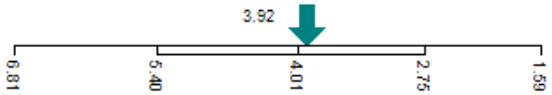
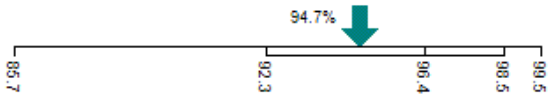
Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q4

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: 3.43 | US Hospitals 50th Pctl: 2.00 | US Hospitals 90th Pctl: 1.12 Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:2036]	
37	**PCI in-hospital risk adjusted rate of bleeding events (all patients)** My Hospital: 3.92 | US Hospitals 50th Pctl: 4.01 | US Hospitals 90th Pctl: 1.59 Your hospital's risk adjusted rate of bleeding events for patients with PCI procedures using the NCDR® PCI bleeding risk adjustment model. [Detail Line:1823]	
38	**Composite: Discharge Medications in Eligible PCI Patients** My Hospital: 94.7% | US Hospitals 50th Pctl: 96.4% | US Hospitals 90th Pctl: 99.5% Patients with a PCI procedure who receive prescriptions for all medications (aspirin, P2Y12 inhibitor, and statin) for which they are eligible for at discharge. [Detail Line:2007]	

Note

Performance measures in the CathPCI Registry® have 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.

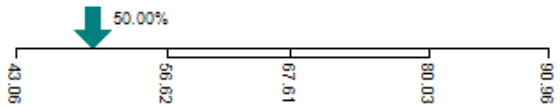
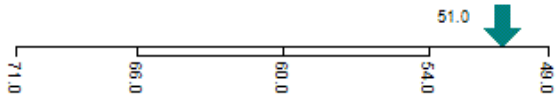
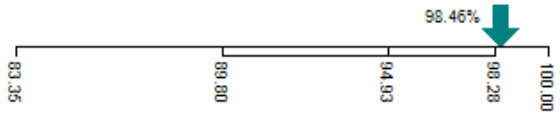
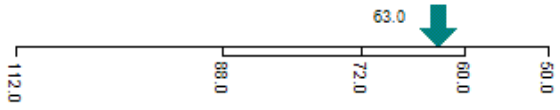
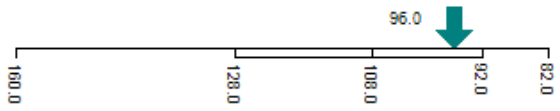
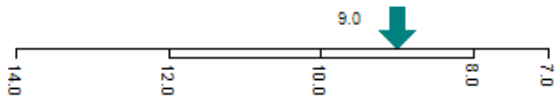
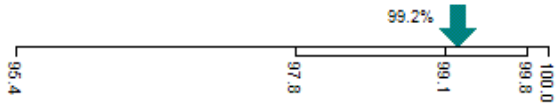
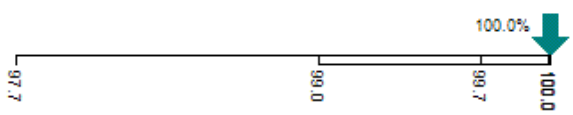
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American 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®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q4

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: 50.00% | US Hospitals 50th Pctl: 67.61% | US Hospitals 90th Pctl: 90.96% 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:1513]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 51 | US Hospitals 50th Pctl: 60 | US Hospitals 90th Pctl: 49 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:1502]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90'** My Hospital: 98.46% | US Hospitals 50th Pctl: 94.93% | US Hospitals 90th Pctl: 100.00% 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:1503]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: 63 | US Hospitals 50th Pctl: 72 | US Hospitals 90th Pctl: 50 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1505]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: 96 | US Hospitals 50th Pctl: 108 | US Hospitals 90th Pctl: 82 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:1506]	
7	**Median fluoro time (in minutes)** My Hospital: 9 | US Hospitals 50th Pctl: 10 | US Hospitals 90th Pctl: 7 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:1633]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: 99.2% | US Hospitals 50th Pctl: 99.1% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1997]	
9	**Proportion of patients with a P2Y12 inhibitor prescribed at discharge** My Hospital: 100.0% | US Hospitals 50th Pctl: 99.7% | US Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine/P2Y12 inhibitor prescribed at discharge. [Detail Line:2006]	

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Publish Date: May 20, 2017

Executive Summary

CathPCI Registry®

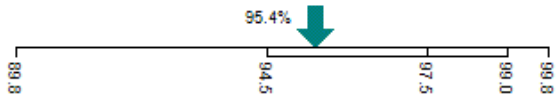
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q4

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	US Hospitals 50th Pctl	US Hospitals 90th Pctl
95.4%	97.5%	99.8%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:2002]



PCI Outcome Metrics

Distribution of Hospital Performance

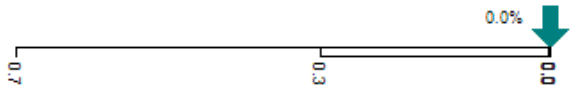
10th percentile — 90th percentile

Better →

12 **Emergency CABG post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.0%	0.0%	0.0%

Proportion of PCI patients with post procedure Emergency CABG. [Detail Line:1980]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

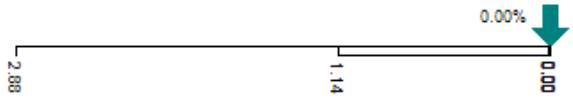
My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
	0.30%	0.00%

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:1803]

14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.00%	0.00%

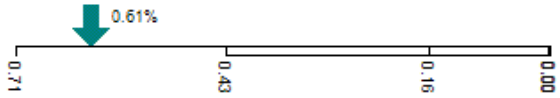
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1804]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.61%	0.16%	0.00%

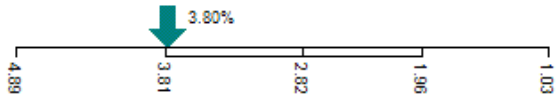
Your hospital's proportion of patients with stroke post procedure. [Detail Line:1811]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.80%	2.82%	1.03%

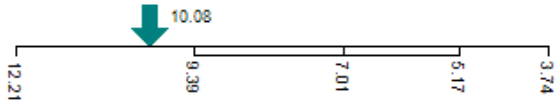
Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1801]



18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
10.08	7.01	3.74

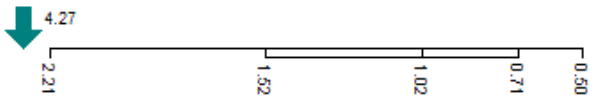
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2045]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
4.27	1.02	0.50

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:2054]



Aggregation Date: Apr 17, 2017 11:59:59 PM
Publish Date: May 20, 2017

Executive Summary

CathPCI Registry®

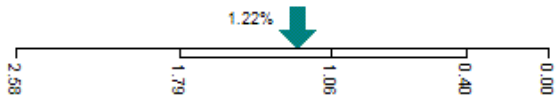
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q4

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

25 **Proportion of PCI procedures with transfusion of whole blood or RBCs**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.22%	1.06%	0.00%

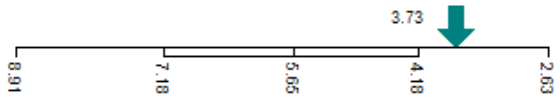
Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Inclusion: Patients with a pre-procedure hemoglobin >8 g/dL and patients with no CABG, and no other major surgery during the same admission. [Detail Line:1853]



39 **PCI in-hospital risk adjusted acute kidney injury (all patients)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.73	5.65	2.63

Your hospital's PCI in-hospital risk adjusted AKI rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1960]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

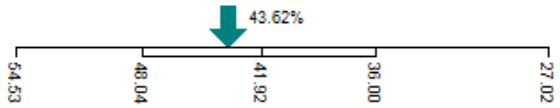
10th percentile 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
43.62%	41.92%	27.02%

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

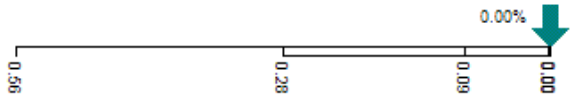
10th percentile 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
0.00%	0.09%	0.00%

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

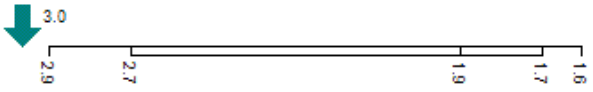
10th percentile 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
3.0	1.9	1.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2110]



Data Quality Metrics

Distribution of Hospital Performance

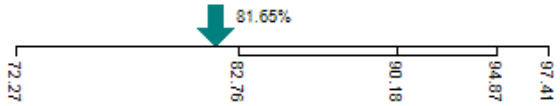
10th percentile 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
81.65%	90.18%	97.41%

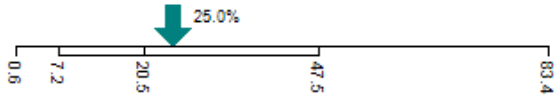
Proportion of PCI patients with creatinine assessed pre and post procedure. Exclusions: LOS<1 day and death in lab. [Detail Line:1951]



26 **Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
25.0%	20.5%	83.4%

Proportion of elective procedures with biomarkers assessed post PCI. Exclusions: LOS<1 day, or hospital status=outpatient, or death in lab. [Detail



Aggregation Date: Apr 17, 2017 11:59:59 PM
Publish Date: May 20, 2017

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

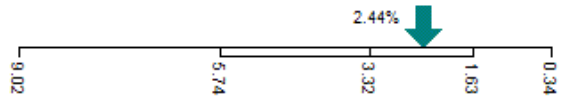
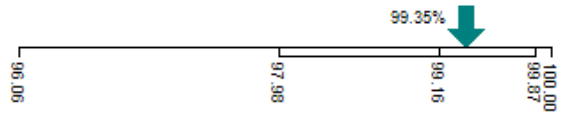
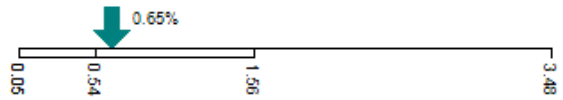
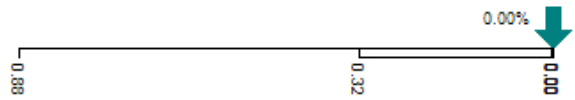
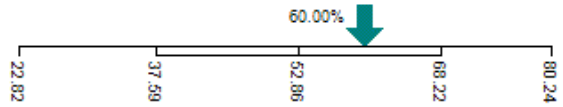
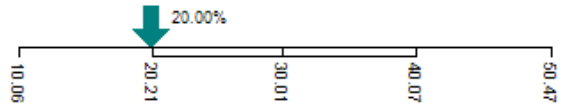
	Line:1949]	

Executive Summary

CathPCI Registry®

Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q4

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

PCI Appropriate Use Criteria (AUC) Metrics		Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30	**Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 2.44% | US Hospitals 50th Pctl: 3.32% | US Hospitals 90th Pctl: 0.34% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1589]	
31	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 99.35% | US Hospitals 50th Pctl: 99.16% | US Hospitals 90th Pctl: 100.00% 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:1581]	
32	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.65% | US Hospitals 50th Pctl: 0.54% | US Hospitals 90th Pctl: 3.48% 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:1582]	
33	**Patients WITH Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.00% | US Hospitals 50th Pctl: 0.00% | US Hospitals 90th Pctl: 0.00% 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:1583]	
34	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were appropriate** My Hospital: 60.00% | US Hospitals 50th Pctl: 52.86% | US Hospitals 90th Pctl: 80.24% 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:1585]	
35	**Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 20.00% | US Hospitals 50th Pctl: 30.01% | US Hospitals 90th Pctl: 50.47% 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:1586]	

Aggregation Date: Apr 17, 2017 11:59:59 PM
Publish Date: May 20, 2017

Executive Summary

CathPCI Registry®

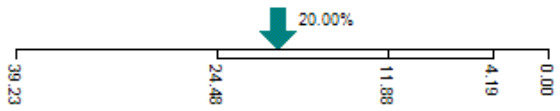
Lawrence & Memorial Hospital(742173) compared to Rolling Four Quarters (R4Q) for US Hospitals ending 2016Q4

Section III: PCI Appropriate Use Criteria (AUC) Metrics – These data are based upon the 2012 Appropriateness Criteria for Coronary Revascularization Focused Update (J Am Coll Cardiol 2012 59: 857-881) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level.PCI AUC metrics are not appropriate for public/external reporting

36 **Patients WITHOUT Acute Coronary Syndrome: Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
20.00%	11.88%	0.00%

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:1587]



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.

Aggregation Date: Apr 17, 2017 11:59:59 PM
Publish Date: May 20, 2017

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

August 8, 2017

Michele M. Volpe, Esq.
Bershtein, Volpe & McKeon, P.C.
105 Court Street
New Haven, CT 06511

RE: Docket Number 17-31768-MDF: Modification of the
Certificate of Need authorized under Docket Number 12-31768-CON
Lawrence & Memorial Hospital
Establishment and Operate an Elective Angioplasty Program

Dear Attorney Volpe:

Please be advised that, pursuant to Conn. Gen. Stat. § 4-181a(b), the Office of Health Care Access ("OHCA") intends to modify the CON issued in the above-referenced action to require annual filings rather than quarterly filings. Specifically: the Order will be modified to read as follows:

1. Lawrence & Memorial Hospital shall submit on an annual basis to OHCA the following reports which must be submitted within one (1) month following the end of the calendar year through the end of calendar year 2019:
   a. Elective and Emergency PCI performed annually by town of patient origin, in a format to be specified.
   b. Elective and Emergency PCI performed annually, 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 annual 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 to OHCA, a copy of the Executive Summary of the Institutional Outcomes Report it receives from ACC-NCDR. Each of the reports that the Hospital receives during the calendar year shall be submitted to OHCA one (1) month subsequent to the end of the calendar year through the end of calendar year 2019. 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

If you would like to submit any comments regarding this matter, please do so in writing to OHCA by 4:30 PM on Friday, August 25, 2017.

Sincerely,

Kimberly R Martone
Digitally signed by Kimberly Martone
Date: 2017.08.08 12:59:48 -04'00'

Kimberly R. Martone
Director of Operations

cc: Shraddha Patel, FACHE

Olejarz, Barbara

From: Microsoft Outlook
To: Michele Volpe; SHRADDHA.PATEL@YNHH.ORG
Sent: Tuesday, August 08, 2017 1:04 PM
Subject: Relayed: Lawrence + Memorial Hospital

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Michele Volpe (mmv@bvmlaw.com)

SHRADDHA.PATEL@YNHH.ORG (SHRADDHA.PATEL@YNHH.ORG)

Subject: Lawrence + Memorial Hospital

Olejarz, Barbara

From: Michele Volpe <mmv@bvmlaw.com>
Sent: Tuesday, October 03, 2017 12:51 PM
To: Hansted, Kevin
Cc: Martone, Kim; Olejarz, Barbara; Jennifer O'Donnell
Subject: RE: Modification of L&M decision

Thank you, Kevin. I hope this email finds you well. The information has been sent on to L+M and they will be in touch regarding getting back to you with a fully executed modification. Please feel free to contact me should you require anything further. Take care.

Michele M. Volpe
Bershtein, Volpe & McKeon P.C
105 Court Street
New Haven, CT 06511
Phone: (203) 777-6995
Fax: (203) 777-5806

From: Hansted, Kevin [mailto:Kevin.Hansted@ct.gov]
Sent: Friday, September 29, 2017 10:30 AM
To: Michele Volpe <mmv@bvmlaw.com>
Cc: Martone, Kim <Kimberly.Martone@ct.gov>; Olejarz, Barbara <Barbara.Olejarz@ct.gov>
Subject: Modification of L&M decision

Good morning Michele:

Attached is a modification of the decision originally rendered under Docket Number 12-31768-CON for L+M's elective angioplasty program. Please have your client review and execute the document and return the orginal to my attention for the Commissioners' signature.

Thank you,

Kevin T. Hansted
Staff Attorney
Office of Health Care Access

Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7044
kevin.hansted@ct.gov

User, OHCA

From: Patel, Shraddha <SHRADDHA.PATEL@YNHH.ORG>
Sent: Tuesday, October 10, 2017 4:41 PM
To: User, OHCA
Cc: Michele Volpe; Anderson, Maureen; Fiore, Denise; Cambi, Brian
Subject: Docket 17-31768-MDF - L+M Hospital
Attachments: CON Modification Docket 12-31768-CON.pdf

Good afternoon,

Attached please find the signed CON modification form 17-31768-MDF for Docket 12-31768-CON.

Please contact me if you have any questions.

Thank you,
Shraddha

Shraddha Patel, FACHE
Director of Strategy and Regulatory Planning & Reporting
2 Howe 3rd Floor
New Haven, CT 06519
Phone: 860-912-5324
Email: shraddha.patel@ynhh.org

YaleNewHavenHealth

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

Michele M. Volpe, Esq.
Bershtein, Volpe & McKeon, P.C.
105 Court Street
New Haven, CT 06511

RE: Docket Number 17-31768-MDF: Modification of the
Certificate of Need authorized under Docket Number 12-31768-CON
Lawrence & Memorial Hospital
Establishment and Operate an Elective Angioplasty Program

Dear Attorney Volpe:

On August 8, 2017 the Office of Health Care Access ("OHCA") notified Lawrence & Memorial Hospital that OHCA intended to modify certain conditions within the Certificate of Need ("CON") issued under Docket No.: 12-31768-CON. OHCA requested that Lawrence & Memorial Hospital submit any comments by August 25, 2017. OHCA received no comments from Lawrence & Memorial Hospital.

In accordance with Connecticut General Statutes § 4-181a(b), OHCA hereby modifies Conditions 1 through 5 of the Order issued under Docket No.: 12-31768-CON as follows:

1. Lawrence & Memorial Hospital shall submit on an annual basis to OHCA the following reports which must be submitted within one (1) month following the end of the calendar year through the end of calendar year 2019:
   a. Elective and Emergency PCI performed annually by town of patient origin, in a format to be specified.
   b. Elective and Emergency PCI performed annually, 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 annual 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 to OHCA, a copy of the Executive Summary of the Institutional Outcomes Report it receives from ACC-NCDR. Each of the reports that the Hospital receives during the calendar year shall be submitted to OHCA one (1) month subsequent to the end of the calendar year through the end of calendar year 2019. 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

All other conditions contained in the Order issued under Docket No.: 12-31768-CON remain in full force and effect.

Signed by Denise J. Fiore
(Print name)

SVP and COO
(Title)

10/10/17
Date

Duly Authorized Agent for
Lawrence & Memorial Hospital

Department of Public Health
Office of Health Care Access

Date:

Yvonne T. Addo, MBA
Deputy Commissioner

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

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Signed by Denise J. Fiore
(Print name)

SVP and COO
(Title)

10/10/17
Date

Denise J. Fiore
Duly Authorized Agent for
Lawrence & Memorial Hospital

Department of Public Health
Office of Health Care Access

10/11/2017
Date:

Yvonne T. Addo, MBA
Deputy Commissioner

Olejarz, Barbara

From: Olejarz, Barbara
Sent: Wednesday, October 11, 2017 10:07 AM
To: 'Michele Volpe'; 'SHRADDHA.PATEL@YNHH.ORG'
Subject: Modification
Attachments: CON Modification Docket 12-31768-CON.pdf

Tracking:

Recipient	Delivery
'Michele Volpe'	
'SHRADDHA.PATEL@YNHH.ORG'	
Martone, Kim	
Hansted, Kevin	
Riggott, Kaila	
Roberts, Karen	
McLellan, Rose	
Foreman, Rebecca	
Jensen, Dana	
Addo, Yvonne	Delivered: 10/11/2017 10:07 AM
Karen.Roberts@ct.gov	Delivered: 10/11/2017 10:07 AM
Kimberly.Martone@ct.gov	Delivered: 10/11/2017 10:07 AM
Kaila.Riggott@ct.gov	Delivered: 10/11/2017 10:07 AM
Kevin.Hansted@ct.gov	Delivered: 10/11/2017 10:07 AM
Rebecca.Foreman@ct.gov	Delivered: 10/11/2017 10:07 AM
Rose.C.McLellan@ct.gov	Delivered: 10/11/2017 10:07 AM
Dana.Jensen@ct.gov	Delivered: 10/11/2017 10:07 AM

10/11/17

Please see attached signed modification for Docket Number: 17-31768-MDF, modification of Certificate of Need authorized under Docket Number: 12-31768-CON

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov

Olejarz, Barbara

From: Microsoft Outlook
To: Michele Volpe; SHRADDHA.PATEL@YNHH.ORG
Sent: Wednesday, October 11, 2017 10:07 AM
Subject: Relayed: Modification

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Michele Volpe (mmv@bvmlaw.com)

SHRADDHA.PATEL@YNHH.ORG (SHRADDHA.PATEL@YNHH.ORG)

Subject: Modification

Olejarz, Barbara

From: Patel, Shraddha <SHRADDHA.PATEL@YNHH.ORG>
Sent: Wednesday, October 11, 2017 10:14 AM
To: Olejarz, Barbara; Michele Volpe
Subject: RE: Modification

Thank you Barbara.

From: Olejarz, Barbara [mailto:Barbara.Olejarz@ct.gov]
Sent: Wednesday, October 11, 2017 10:07 AM
To: Michele Volpe <mmv@bvmlaw.com>; Patel, Shraddha <SHRADDHA.PATEL@YNHH.ORG>
Subject: Modification

10/11/17

Please see attached signed modification for Docket Number: 17-31768-MDF, modification of Certificate of Need authorized under Docket Number: 12-31768-CON

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
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Email: Barbara.Olejarz@ct.gov