Charlotte Hungerford Hospital
540 LITCHFIELD STREET, PO BOX 988, TORRINGTON, CT 06790-0988 (860)496-6666

April 3, 2015

Ms. Kimberly Martone
Director of Operations
Office of Health Care Access
410 Capital Avenue
MS #13HCA
P.O. Box 340308
Hartford, CT 06106

RE: Charlotte Hungerford Hospital
Certificate of Need Application
Acquisition of a CT Scanner for the
Hungerford Emergency and Medical
Care Center in Winsted

Dear Ms. Martone:

Enclosed please find the original and four hard copies in report binders, as well as an electronic copy on CD of Charlotte Hungerford's Certificate of Need application regarding the acquisition of a CT Scanner for our Winsted Emergency Facility. A check for the filing fee of $500.00 is also enclosed herein.

Please do not hesitate to contact me with any questions or concerns.

Thank you for your time.

Sincerely,

John J. Capobianco
Vice President of Operations
The Charlotte Hungerford Hospital

Enclosures

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.: 15-31989 **Check No.:** 27427
OHCA Verified by: [illegible] **Date:** 4/8/15

☑ **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) 418-7053, 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 signed 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.**

NEW HAVEN REGISTER THE REGISTER CITIZEN The Middletown Press Farmington Valley Times CONNECTICUT
SHORELINE TIMES The Foothills Trader WEST HARTFORD NEWS MINUTEMAN Newspapers Connecticut Bride
Milford-Orange Bulletin THE GRANBY NEWS the Dolphin THE LITCHFIELD COUNTY TIMES Post-Chronicle

Proof of Ad **03/02/15**

Account:	**152622**
Name:	
Company:	**CHARLOTTE HUNGERFORD HOSPITAL**
Address:	**540 LITCHFIELD ST** **C/O TIM LEBOUTHILLIER** **TORRINGTON, CT 06790**
Telephone:	**(860) 496-6666**
Ad ID:	**525456**
Description:	**Public Notice Filing for Charlotte H**
Run Dates:	**03/03/15 to 03/05/15**
Class:	**1201**
Orig User:	**CRCGILSON**
Words:	**77**
Lines:	**31**
Agate Lines:	**34**
Column width:	**1**
Depth:	**3.722**
Blind Box:	

Public Notice
Filing for Charlotte Hungerford Hospital
Hungerford Emergency and Medical Center
16 slice Computed Tomography Scanner

Statutory Reference: Connecticut General Statutes 19a-638

Applicant: Charlotte Hungerford Hospital, Hungerford Emergency and Medical Center

Project Address: Located at Hungerford Emergency and Medical Center, 115 Spencer Street, Winsted Connecticut, 06098

Proposal: The Applicant intends to file a Certificate of Need application with the State of Connecticut Office of Health Care Access for the purchase of a 16 slice CT scanner.

We Appreciate Your Business!
Thank You !

21ST CENTURY media

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LEGAL NOTICES

NOTICE OF INTENT TO FILE FOR FEDERAL FINANCIAL ASSISTANCE

The Canaan Fire District proposes to file an Application for Federal Financial Assistance with the USDA, Rural Development. This application for financial assistance will be for funding under the Rural Utilities Service, Part 1780, Water and Waste Loans and Grants (CFDA 10.760) and is anticipated to be submitted by March 20, 2015. The specific elements of the project include the rehabilitation of certain of the District's municipal sewer lines and manholes. The project is anticipated to cost $2,513,080.00. Any comments regarding this application should be submitted to Anthony J. Nania, the District's Warden at PO Box 22, Canaan, CT 06018, or by email at ajn@ajnania.us within fifteen days of this publication.

The Canaan Fire District
By Anthony J. Nania, its Warden

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APARTMENTS FOR RENT (UNFURNISHED)

BEAUTIFULLY RENOVATED APTS.

Laundry on site, on-site Maintenance. Heat & hot water included.

1-Bedroom flat, $825.

2-bedroom flat, $920.

2-bedroom Townhouse, $975,

3-bedroom Townhouse, $1075.

Georgetown Apts Torrington Call 860-482-1941.

The Mill at Still River
101 Whiting St. WINSTED, CT 06098

Has elegant brick & beam. **1 & 2 bedrooms.** Every Apartment has River views, dishwasher, garbage disposal, gas heat, cathedral ceilings. Laundry & elevator on premises.

"SMOKE FREE ENVIROMENT"

"Move-In Special"

Call Paula

978-821-6880.

TORRINGTON, 2 BR, 1st fl, front porch. W/D. Residential neighborhood. Garage. $750. **Call 860-567-2435.**

HELP WANTED FULL TIME

LINE WORKER NEEDED
at Commercial Bakery. Job requires standing long hours, manipulating dough as it is fed through conveyor, some cleaning. Apply between 9am & 3pm Monday through Friday. Please Do Not Call.
BriCins Inc.
347 Technology Park Dr. Torrington, CT

BARGAINS!

Old wood 6' folding carpenter rules, $5 each. Call 8603794761

STEEL DOOR w/ hinges, $90. **2 COACH BAGS,** $90 ea. (1) new, (1) used once. **2 ANTIQUE FRAMED SCENIC**

DONATE YOUR CAR, TRUCK, RV OR BOAT to the SPCA and receive the maximum tax deduction and quick, free pick up. See our adoptable dogs and cats or donate online at SPCACT.ORG. Call 203-445-9978

MATERIAL HANDLERS/SORTERS - Shifts – 6:30 p.m. – 7:00 a.m. and 3:00 p.m. -11:30 p.m. - Canaan

ACCOUNTS RECEIVEABLE/COLLECTIONS – working knowledge of PEACHTREE/SAGE software required. Temp to hire opportunity in Torrington.

QUALITY INSPECTORS NEEDED - Various electrical/electronic and non-electrical inspection positions available!

INDUSTRIAL SEWING MACHINE OPERATORS NEEDED!! Must be experienced - 1st shift

ALL POSITIONS REQUIRED RELIABLE TRANSPORTATION CALL OUR OFFICE FOR MORE INFORMATION! 860-482-1171 Email resumes: 1725@kellyservices.com

KELLY SERVICES

FIREWOOD

FIREWOOD: Seasoned, Cut, Split, Delievered. **(860)485-0693**

TREE SERVICE: Brush Chipping, Storm Damage, Building Lot **(860)485-0693** Log Length Green Fully Insured. Free Estimate.

CATS

BLACK CAT, female, Free to good home. Can't keep her already have too many animals. 860-238-7852 or 860-294-2063

Attention Getters draw ATTENTION to your Classified Ad. Add one for just a few dollars extra. There are many to choose from.
1-800-922-7066

HAULING

Attics - Basements
Garages Cleared
Trash Removed
Dump Runs
860-496-7853 or 860-309-7496
Howard Nodine

HAULING

DUMP RUNS!
Lumber, Furniture, Construction Debris, Appliances Clothes, Paper, Glass, Pools, Sheds, Decks, Fences, Brush, leaves, & More.
Call 860-304-6740.

SNOW REMOVAL

Roof Shoveling exp., insured 860-459-6407 Matt

Roof snow removal. snow plowing, salt and clean walk ways, free estimates, reasonable rates. call Ed 860-201-4560 cell 860-491-8375

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Advertise it here in The Register Citizen "At Your Service" Directory. We'll help you put together an ad to reach

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RIVERTON SELF STORAGE will sell at a PUBLIC ONLINE AUCTION at www.storagebattles.com, all the personal property stored in its facility, by: Estate of Elizabeth Van Why in Unit #111 & Unit #115 consisting of; Furniture, shelving, cabinets, boxes, clothing and other personal property Preview begins online on March 1, 2015 at www.storagebattles.com. Auction goes through March 21, 2015. **Riverton Self Storage reserves the following rights: (1) to bid at the public online auction; (2) to refuse any and all bids; (3) to cancel the auction at any time for any reason.**

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Georgetown Apts Torrington Call 860-482-1941.

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"Move-In Special"

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978-821-6880.

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STEEL DOOR w/ hinges, $90.
2 COACH BAGS, $90 ea. (1) new, (1) used once.
2 ANTIQUE FRAMED SCENIC PICTURES on canvas, $50 each. Call 860-489-6177

FIREWOOD

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Log Length Green
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Turn unwanted Items into CASH!

Place an Article For Sale ad TODAY!

Call us at 1-800-922-7066 and place your ad today!

BANTAM VILLAGE APARTMENTS
48 BANTAM VILLAGE BANTAM, CT . 06750
Now accepting applications for one bedroom units

for qualified elderly and/or disabled individuals. Rent will be approximately 30% of income. Call 860-567-4438 Monday through Friday 9am-1pm for more details. Applications are accepted on a first come first serve basis.
Financed by USDA rural development.
The institution is an Equal Opportunity Provider and Employer
The TDD Number: 1-800-833-8134

MATERIAL HANDLERS/SORTERS - Shifts – 6:30 p.m. – 7:00 a.m. and 3:00 p.m. -11:30 p.m. - Canaan

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QUALITY INSPECTORS NEEDED - Various electrical/electronic and non-electrical inspection positions available!

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Garages Cleared
Trash Removed
Dump Runs
860-496-7853 or 860-309-7496
Howard Nodine

LOOK!
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HAULING

DUMP RUNS!
Lumber, Furniture, Construction Debris, Appliances Clothes, Paper, Glass, Pools, Sheds, Decks, Fences, Brush, leaves, & More.
Call 860-304-6740.

SNOW REMOVAL

Roof Shoveling exp., insured 860-459-6407 Matt

Roof snow removal. snow plowing, salt and clean walk ways, free estimates, reasonable rates. call Ed 860-

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978-821-6880.

CAN'T FIND what you're looking for? Find it the fast & easy, effective way by using the classifieds! Call and place a low cost classified ad under "Wanted To Buy" in next week's paper.

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REMEMBER - when placing a classified to get fast results be sure to include:
1) all the details
2) include the price
3) be available to callers
As easy as 1 - 2 - 3!

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TREE SERVICE:
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Log Length Green
Fully Insured.
Free Estimate.

FLEA MARKETS

GOSHEN:
14th Annual Flea Market
at St. Thomas' Hall
Rt 63N Sat. Mar. 7,
8:30 am - 2:30 pm.
55 TABLES
New & Old vendors
Bake Sale
Lunch Available.

DEADLINE for the REGISTER CITIZEN is 4 p.m.
Tuesday through Friday.
To advertise weekends and Mondays the deadline is Friday at 3 p.m.
Call 1-800-922-7066

DONATE YOUR CAR, TRUCK, RV OR BOAT to the SPCA and receive the maximum tax deduction and quick, free pick up. See our adoptable dogs and cats or donate online at SPCACT.ORG. Call 203-445-9978

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Call 1-800-922-7066 Today!

Weekly

Netanyahu, the other Israelis and Robbie Burns

In The Public Interest
Ralph Nader

Apart from inadvertently making the case for equal time by his Israeli pre-election opposition, the spectacle of Benjamin Netanyahu's wild diatribe at the joint session of Congress amidst the feral cheers of his congressional yahoos will be remembered as a textbook case of propaganda unhinged from reality.

Starting from his preposterous premise that Iran, a poor country of 77 million people with an economy nearly the size of Massachusetts', is planning a caliphate to conquer the world, Netanyahu builds his case on belligerent words by Iranian leaders, who believe they are responding to Israeli belligerence backed by its ultra-modern, U.S.-equipped military machine and its repeated threats of preemptive attacks against Tehran.

Unwilling, unlike his Israeli opponents, to subject himself to questions before congressional committees, this three-time soliloquist at joint congressional sessions (1996, 2011 and 2015) was received with hoopla quite different from his reception in a much more critical Knesset. The prime minister's 42 minute speech was punctuated by 23 standing ovations and sitting applauses that took up 10 minutes.

◆ ◆ ◆

The U.S. Israeli lobby has made Congress a rubber stamp for lopsided policies in the Middle East.

Only about 50 Democrats boycotted his address.

It is as if Israel doesn't frighten Iran with its 200 nuclear weapons and its rejection of the Nuclear Non-Proliferation Treaty whose international inspections are required for all other signatory nations on Earth, including Iran.

It is as if Israel has not threatened Iran with annihilation, sent spies to sabotage and slay Iranian scientists and worked with its Arab allies to undermine the Iranian regime;

It is as if Iranians do not remember that the United State overthrew their popularly elected Prime Minister Mossadegh in 1953 to reinstate the Shah's dictatorship for 26 years;

It is as if the Iranians do not mourn the loss of hundreds of thousands of soldiers and civilians killed by Saddam Hussein's brutal invasion of their country from 1980 to 1988 with the military, intelligence and diplomatic support of the United States;

It is as if Iranians were not frightened into thinking they were next when George W. Bush named Iran as part of the "axis of evil" (along with Iraq and North Korea), and proceeded to destroy Iraq and surround Iran with U.S. armed forces that are still in place to this day;

It is as if the Iranian people are not suffering from economic boycotts which, by impacting disproportionately civilian health and safety there. (See Public Citizen's Health Letter) violate international law;

It is as if Iran should accept a wide sphere of influence by the United States and not try to expand its sphere of influence for its own defense;

It is as if Iran had not proposed a serious plan to George W. Bush over 10 years ago to settle disputes and establish a nuclear-weapons free zone in the Middle East, which Mr. Bush completely ignored;

It is as if Iran is not, in the words of former Obama adviser, Vali R. Nasr, carrying "most of the weight" in the "battles on the ground" against ISIS in Iraq, thereby saving the U.S. from committing again U.S. soldiers to avert a complete rout of those left behind after our deadly debacle in Iraq since 2003;

It is as if Iran is not claiming it is building nuclear power plants for electricity (a foolishly dangerous move for its own people) and not building an atomic bomb, has not been in full compliance with the Geneva interim accord (November 2013) with the P5+1 countries, as these parties, led by the United States, strive to conclude a complete agreement this year;

It is as if Israel has not illegally occupied, colonized and stolen Palestinian land and water over the decades (including regularly invading a blockaded Gaza, invading Lebanon five times and attacking other nearby countries pre-emptively) and caused hundreds of thousands of civilian casualties;

It is as if Israel, while complaining about Iranian behavior, does not continue their Palestinian policies that violate several United Nations' resolutions, while goading the U.S. toward war against Iran;

It is as if the Arab League, with 22 member nations, has not offered repeatedly since 2002 a comprehensive peace treaty in return to Israel returning to its 1967 borders that was also rejected by Israel;

It is as if Iran has forgotten the shooting down of a scheduled Iranian civilian Airbus by the U.S. Navy in 1988 with a loss of 290 innocent lives, including 66 children;

It is as if Iran, a country that hasn't invaded any country for over 250 years, should remain cool in the face of such attacks, threats, infiltrations, boycotts, U.S. Navy in the Persian Gulf, and not engage in any military alliances; and

It is as if Iran's authoritarian leaders are not preoccupied enough with pressures inside their country that are both internally and externally driven without also planning to conquer the world.

◆ ◆ ◆

The pop-up lawmakers in Congress on Tuesday have not shown any interest in their own government's causal responsibility for Iranian animosities. The priority for many in Congress is marching to the drumbeat of whatever the U.S. Israeli lobby wants from the Pentagon, the State Department and the American taxpayers. (Some members of Congress have spoken up in the past, notably Republican Congressmen Ron Paul and Paul Findley and Senators Chuck Percy and James Abourezk.)

Why does a large majority of Congress block the viewpoints and policies that could lead to peace as advocated by many former chiefs of Israel's security, intelligence, military and political institutions? They have spoken up repeatedly in Israel but are never allowed to testify before congressional committees. This entrenched anti-Semitism on Capitol Hill against the "other Israeli" Jews needs to be challenged by peace and justice-loving Americans who want to avoid future blowbacks and war quagmires for our soldiers.

A way to clarify jingoistic biases in foreign policy is to ask the questions: who was the initial aggressor? Who is the invader, the occupier, the ever hovering armed drone operator? Who has backed and armed dictators to repress their people who want no more such nation-building by the U.S.?

For a century, is it we, with the British and French, who have been over there or is it they who have been over here? Brutish conditions breed brutish behavior in all directions.

The poetic wisdom of the great Scottish poet Robbie Burns teaches the crucial empathy: "O would some power the giftie gie us to see ourselves as others see us."

Consumer advocate and former presidential candidate Ralph Nader grew up in Winsted and is a graduate of The Gilbert School.

Where's my Gig, and how do I get it if I want it, as I should?

Broadband Banter
Frank Shinneman

The previous Broadband Banter ("What's a 'Gig'… and why do I want one?") described the basics of Internet connection speed and the value of Gbps (gigabit per second) connections. So what options are available to get Gbps speeds here the Northwest Corner?

Luckily, there is one gigabit service that runs through the main highways of all five towns of the Northwest Corner. It is CEN (the Connecticut Education Network) and it's connected to all public schools and to one of our libraries, the David M. Hunt Library in Falls Village. Plans are underway for municipal and library connections in Salisbury and other towns are actively exploring connection. The short answer is: your gig, and the ultra-high speed it provides, is coming first to a library near you.

CEN provides guaranteed 1 Gbps download and upload speeds with no data caps. This is a great benefit for public services and public Wi-Fi, but it will only benefit businesses located near the main arteries that are willing to pay to extend fiber optic cable to their locations. Recently, New Haven initiated a general request for bids to build a citywide gigabit network. Today, 45 other towns have joined the initiative and the state of Connecticut is now calling for a "Gigabit Economic Development Movement," encouraging towns to participate and use CEN as their key link for connectivity. If successful, we may reach the gigabit speeds and low costs already available outside the United States.

For our home connections, only cellular and cable can meet the new FCC definition of "broadband," which is 25 Mbps (Megabits per second) download and 3 Mbps upload. You can read the news, watch a few videos clips and stream an occasional movie without broadband, but for distance learning, video conferencing and a growing number of business applications, broadband speed is a minimum. Upload speed was previously not very important for home applications, but with most smartphones now automatically streaming megabit photos to the cloud and back to our other devices, we'll be noticing our low upload speeds, just as we have with video chat services like FaceTime and Skype.

Originally, cable TV/Internet providers bid for and received from the state the exclusive rights to provide service in defined territories. Connecticut is divided into 24 former "franchise" territories, served by five companies. Comcast controls 58 percent of these, including the one covering the five towns of northwest Connecticut (Salisbury, Sharon, Falls Village, North Canaan and Norfolk). While these franchise boundaries no longer exist legally, the cost of stringing new lines effectively prevents a provider other than Comcast from coming in unless they sold all the infrastructure of a territory. Where service is available, Comcast can generally provide a cable connection with speeds that exceed the FCC's definition of broadband (up to 150 Mbps "Actual speeds vary and are not guaranteed"). Download speeds of up to 500 Mbps for residences and one gigabit for businesses have been announced for 2015. But here's the rub: If you're not on a street with Comcast cable now, you're not likely to ever get it, since Comcast has extended cable service by, on average, only six miles in each of the last 10 years across the 300 miles of roads in their northwest Connecticut service area. To their credit, Comcast also provides over 40 public hot spots across our five towns with limited free access and unlimited paid access.

Those of us on a street with neither cable nor a strong cellular 4G signal have to make do with download speeds of 1 to18 Mbps from DSL (depending on how far you are from the main office) or with satellite speeds of up to 15 Mbps. Almost all of these are fast enough to stream a movie, but cellular and satellite data plans will have a cap on the monthly amount you can upload or download before you start paying around $15 per gigabit (comparable to paying around $45 for a 90-minute movie) and/or have your speed greatly reduced.

Some of us see our towns as "Shangri-La" refuges from the hyper-connectedness and pressure of the outside world. For all those for whose lives are led primarily or entirely within the perimeter of the Northwest Corner — particularly if they have children and/or businesses — continuing to adopt socially and economically enhancing technologies is essential. We cannot limit our Internet resources to the ability to simply stream a movie or use email. Gigabit connectivity can also attract new businesses and create new jobs. Examples include medical image analysis, genetic sequencing for personalized medicine, HD video conferencing, financial analysis, remote video presentations, transmission of large architectural blueprints, home/business security monitoring, insurance claims processing and remote medical consulting.

A significant number of Region One students do not have access to high-speed Internet, let alone broadband, putting them at a competitive disadvantage compared to their peers with broadband connections. A gigabit network enables top level education and would help level the playing field between our public and private school students. We regularly bemoan the lack of high paying local jobs and the dwindling of our tax base, but we don't want malls or manufacturing. A developed gigabit infrastructure can attract desirable high tech businesses, raise the tax base and still conserve our country way of life. Let's give all our citizens, our businesses and our children the resources and opportunities they deserve.

Frank Shinneman is a retired technology entrepreneur currently researching Internet connectivity in the Northwest Corner and posting news on Twitter @Fiber4NWCT. He and his wife, Cindy, live in Lakeville.

PHOTO FROM THE WINSTED JOURNAL ARCHIVES

Remember when?

This is a picture from The Winsted Journal's archive from December 1997. Do you know the story behind the picture? If so, write to editor@winstedjournal.com or call Shaw Israel Izikson at 860-738-4418.

Legal Notices

LEGAL NOTICE
Public Notice
Filing for Charlotte Hungerford Hospital
Hungerford Emergency and Medical Center
16 Slice Computed Tomography Scanner

Statutory Reference: Connecticut General Statues 19a-638

Applicant: Charlotte Hungerford Hospital, Hungerford Emergency and Medical Center

Project Address: Located at Hungerford Emergency and Medical Center, 115 Spencer Street, Winsted Connecticut, 06098

Proposal: The Applicant intends to file a Certificate of Need application with the State of Connecticut Office of Health Care Access for the purchase of a 16 slice CT scanner.

03-13-15

AFFIDAVIT

Applicant: **The Charlotte Hungerford Hospital**

Project Title: **Acquisition of a CT Scanner for the Hungerford Emergency and Medical Care Center in Winsted.**

I, **Daniel J McIntyre** (Individual's Name), **President and Executive Director** (Position Title – CEO or CFO)

of **The Charlotte Hungerford Hospital** (Hospital or Facility Name) being duly sworn, depose and state that

The Charlotte Hungerford Hospital s information submitted in this Certificate of (Hospital or Facility Name)
Need Application is accurate and correct to the best of my knowledge.

Signature 3/26/2015 Date

Subscribed and sworn to before me on 26th day of March, 2015

ANNAMARIE CORROLO
Notary Public/~~Commissioner of Superior Court~~

My commission expires: 4/30/2016

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

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

Docket Number:	
Applicant:	The Charlotte Hungerford Hospital
Applicant's Facility ID*:	**07011**
Contact Person:	John J Capobianco
Contact Person's Title:	Vice President for Operations
Contact Person's Address:	540 Litchfield Street Torrington, CT 06790
Contact Person's Phone Number:	**860-496-6611**
Contact Person's Fax Number:	**860-482-8627**
Contact Person's Email Address:	**jcapobianco@hungerford.org**
Project Town:	**Winsted**
Project Name:	**Acquisition of a CT Scanner for the Hungerford Emergency and Medical Care Center in Winsted**
Statute Reference:	Section 19a-638, C.G.S.
Estimated Total Capital Expenditure:	

*Please provide either the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier.

- **Project Description: Acquisition of Equipment**

  a. Please provide a narrative detailing the proposal.

  Hungerford Emergency and Medical Care (HEMC) located at 115 Spencer Street in Winsted, Connecticut is an off campus satellite fully functioning Type B Emergency Department which is a part of The Charlotte Hungerford Hospital (CHH). Winsted is a rural northwestern Connecticut town. HEMC offers emergency medical care to the surrounding communities, seven days a week, twelve hours per day. Access to emergency medical treatment in this rural area is limited to HEMC and Charlotte Hungerford Hospital. Patients from the surrounding communities rely on the emergency medical care they receive at Hungerford Emergency and Medical Care.

  CHH proposes to acquire, install and operate a Toshiba Aquilion 16 slice whole body scanner at HEMC. This would be the second CT scanner for Emergency Department patients, one on campus at the main hospital, the proposed being off campus at HEMC.

  The proposal is based on the following:

  - **Computed Tomography (CT) imaging has increasingly become valuable in treating patients in emergency medical situations, specifically for stroke care. Patients presenting to the Emergency Department at HEMC fall within the same time constraints as our patients who present at the CHH main campus Emergency Department. Standard of care for stroke patients is door to CT scan within 25 minutes. In order to function as a true emergency department, HEMC needs to meet the same standards of care. CT availability is necessary to provide the level of care necessary to timely diagnose, treat and transfer these stroke patients.**
  - **CT imaging continues to be the standard imaging modality for Emergency Department patients, especially in a rural setting.**
  - **Clinical practice guidelines and evidence based practice demonstrates the role of CT in timely diagnosis (Abdominal pain and pulmonary embolism).**
  - **The current practice at Hungerford Emergency and Medical Care is to transfer patients twelve miles via ambulance service to Charlotte Hungerford Hospital in order to complete the CT examination. Not only does this prevent our HEMC physicians from fully assessing our patients, but the transfer itself displaces a scarce resource of ambulance personnel and vehicles to provide the transfer.**
  - **This CT scanner installation at HEMC will prevent delays in treatment, promote faster diagnosis and contribute to the safety of our patients.**
  - **The scanner at HEMC will act as a backup when the scanner at the CHH Main Campus is down, decreasing the need to cancel exams,**

delay treatment or more importantly transfer or divert ED patients to other facilities for CT scans.

As CT technology has continued to advance and improve, it is critical that we offer this service to our patients at the time of greatest need, closest to the time of injury or medical issue, at Hungerford Emergency and Medical Care.

b. Provide letters that have been received in support of the proposal.

Please see Attachment A: Dr. Gregg Grinspan MD, HEMC Medical Director
State Representative Jay Case, 63rd District
State Senator Clark Chapin, 30th District
Christopher Battista, Winsted Health Center Board President
Connecticut Office of Rural Health

c. Provide the Manufacturer, Model, Number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

The hospital plans to acquire and install a CT similar to the Toshiba Aquilion 16 slice whole body scanner at the Hungerford Emergency and Medical Care, 115 Spencer Street, Winsted, CT 06098. The total expenditure will include an injector and UPS system.

d. List each of the Applicant's sites and the imaging modalities and other services currently offered by location.

Site Location	Imagining Modalities
Charlotte Hungerford Hospital	X-ray, CT, Nuclear Medicine, Interventional Radiology, Ultrasound, Mammography, MRI, Echo
Kennedy Drive	Mammography, PET
Winsted	X-ray, Mammography
Dr. Freccero	X-ray
Cardiology Office	Nuclear Medicine, Echo
Walk-In	X-ray

- **Clear Public Need**

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

Clear public need is demonstrated by the imperative to increase the quality of care and safety of the patients who require CT Imaging along with emergency medical care in our community. It is essential to quickly and accurately diagnose and treat patients within the community.

In order to position Hungerford Emergency and Medical Care (HEMC) as a full service Emergency Department we must prevent the delays inherent in transferring patients elsewhere for CT scanning.

Evidence suggests that rural emergency departments need to have readily accessible CT imaging equipment in order to accurately and timely diagnose and treat patients in their community, specifically as it relates to potentially life threatening illnesses and accidents, such as stroke and other embolic events, head and spinal injury, and abdominal pain and trauma.

Rapid diagnosis and treatment are key in preventing morbidity and mortality, thus CT scanning capability at HEMC would further the goals of *Healthy Connecticut 2020*, specifically targeting reducing deaths from stroke, falls, and motor vehicle crashes.

References Provided: Please see attachment B.

b. Complete **Table 1** for each piece of equipment of the type proposed currently operated by the Applicant at each of the Applicant's sites.

TABLE 1
EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Service*	Days/Hours of Operation **	Utilization***
Charlotte Hungerford Hospital 540 Litchfield Street Torrington, CT 06790	AQ64/V-AR Toshiba Aquilion 64 slice CT Scanner	24/7 364 days per year. Routine scheduled and emergency services	Oct 1, 2014 to September 30,2014 Scans/exams: 9,435

*Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)
**Days of the week unit is operational, and start and end time for each day
***Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

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

i. The rationale for locating the proposed equipment at the proposed site;

The CT scanner will be located at HEMC, 115 Spencer Street, Winsted, as a part of the Emergency Department. The community of Winsted and the surrounding towns need access to CT imaging technology to ensure quality and safety of the patient population. A CT imaging scanner located at HEMC will provide faster more accurate diagnosis of emergency department patients, so decisions can be made regarding treatment quickly and effectively.

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

The population includes the greater Winsted/Winchester community and the surrounding rural areas. See the Table below for specific ED utilization data by Town Served. We believe that CT utilization data will not differ from current HEMC Emergency Department population.

HEMC E.D. Service Area Utilization 6/30/2013-11/20/2014			
ZIP CODE	Town/City	State	# Visits
06098	WINSTED	CT	5477
06790	TORRINGTON	CT	958
06063	BARKHAMSTED	CT	561
06058	NORFOLK	CT	475
06057	NEW HARTFORD	CT	449
06021	COLEBROOK	CT	267
06065	RIVERTON	CT	156
06018	CANAAN	CT	120

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

The proposed patient population is currently being served at HEMC, with transfers to CHH for CT imaging, increasing the time to diagnosis and treatment of potentially life threatening medical issues. See data below for information related to patients that have required transfer from HEMC for CT scanning at other sites, primarily at CHH. This data does not include patients who bypassed HEMC and were taken directly to the CT equipped CHH E.D.

HEMC	13-Nov	13-Dec	Jan-14	Feb-14	Mar-14	Apr-14
Transfers for CT Scanning	10	17	9	3	11	5
Percent of Transfers	55.56%	70.83%	50.00%	42.86%	68.75%	29.41%

HEMC	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14
Transfers for CT Scanning	7	9	10	8	6	14
Percent of Transfers	43.75%	50%	47.62%	44.44%	35.29%	66.66%

Total Transfers for CT Scanning	109
Percent of Transfers	50.43%
Range	29.41%-70.83%

The data above demonstrates that 50% of transfers from the HEMC facility were due to a need for advanced diagnostic imaging for definitive diagnosis. In addition we have evidence that ambulances transporting patients who have a high likelihood of needing CT services are diverted to the CHH Main Campus ED or another closer Hospital.

iv. Identify the name and location (name, facility ID, address, service, hours of operation) of existing providers in the service area and within close proximity, provide the utilization of these services for the most recently completed year;

TABLE 2
EXISTING SERVICE PROVIDERS

Facility Name	Facility ID*	Facility Address	Service	Utilization**	Days/Hours of Operation
		No other ED or Hospital Based CT Scanners in our Service Area.			

*Please provide either the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.
**Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

v. The effect of the proposal on existing providers; and

None

vi. If the proposal involves a new site of service, identify the service area towns and the basis for their selection.

Table 3

Not applicable: this is not a new service site.

Note: Provide basis for the selected towns.

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

There are no similar services, an Emergency Room with Cat Scan, within a 25 mile radius of the Hungerford Emergency and Medical Care Center in Winsted other than the Charlotte Hungerford main campus ED.

- **Actual and Projected Volume**

  a. Complete the following tables for the past three fiscal years ("FY"), current fiscal year ("CFY"), and first three projected FYs of the proposal, for each of the Applicant's existing and proposed pieces of equipment (of the type proposed, at the proposed location only). In Table 4a, report the units of service by piece of equipment, and in Table 4b, report the units of service by type of exam (e.g. if specializing in orthopedic, neurosurgery, or if there are scans that can be performed on the proposed scanner that the Applicant is unable to perform on its existing scanners).

TABLE 4A
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY EQUIPMENT UNIT

Equipment***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY 12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 18
AQ64/V-AR Toshiba Aquilion @ CHH (main site located in Torrington)	**Volume:** 9,577 Inpatient: 2,394 Outpatient: 7,183 12 months 10/1/11 to 9/30/12	**Volume:** 9,332 Inpatient: 2,520 Outpatient: 6,812 12 months 10/1/12 to 9/30/13	**Volume:** 9,435 Inpatient: 2,695 Outpatient: 6,740 12 months 10/1/13 to 9/30/14	**Volume:** 3,203 Inpatient: 841 Outpatient: 2,362 4 months 10/1/14 to 01/31/15	**Budget Volume:** 9,600 Inpatient: 2,520 Outpatient: 7,080 12 months 10/1/15 to 9/30/16	**Budget Volume:** 9,600 Inpatient: 2,520 Outpatient: 7,080 12 months 10/1/16 to 9/30/17	**Budget Volume:** 9,600 Inpatient: 2,520 Outpatient: 7,080 12 months 10/1/17 to 9/30/18
Proposed Winsted	0	0	0	0	Inpatient: 0 Outpatient: 260 ED: 400 **Proposed**	Inpatient: 0 Outpatient: 268 ED:412 **Proposed**	Inpatient: 0 Outpatient: 276 ED:424 **Proposed**
Total	**9,577**	**9,332**	**9,435**	**3,203**	**660**	**680**	**700**

*For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.
**If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
***Identify each scanner separately and add lines as necessary. Also break out inpatient/outpatient/ED volumes if applicable.
****Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

TABLE 4B

HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY TYPE OF SCAN/EXAM

Service***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY 12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 18
Head	3050	2,858	2,881	891	184	184	187
Temporal Bones	21	23	19	0	3	4	6
Maxofacial	277	244	268	96	20	21	22
Soft Tissue neck	144	162	160	44	13	13	14
Chest Thorax	951	1,102	1,169	495	73	73	75
Cervical spine	731	537	426	133	33	34	35
Thoracic spine	15	11	11	3	1	2	3
Lumbar Spine	69	66	80	33	5	6	7
Pelvis	92	93	120	55	6	7	8
Upper ext	43	58	81	31	5	5	6
Lower ext	141	160	171	86	28	28	29
Abdomen	166	151	116	50	10	10	11
Abscess drain	19	15	2	0	0	0	0
Cyst Aspiration	2	6	30	0	0	0	0
Angio-abd	8	4	3	5	0	0	0
Angio-chest	435	418	426	126	1	2	2
Angio-head	4	8	6	0	33	34	35
Angio(up/low)ext	5	0	4	0	3	4	4
Angio-neck	3	1	3	1	2	3	3
Angio pelvic	4	0	1	0	1	1	1
Needle LOC	2	1	3	12	1	1	1
Inj	8	6	15	3	0	0	0

Angio-abd-pelvis	3	11	17	2	5	6	7
Paracentesis	4	1	2	0	0	0	0
CTA-Abd	0	0	5	0	0	0	0
Abd &Pelv	3,380	3,396	3,416	1,134	233	242	244
	12 months	12 months	12 months	4 months	12 months	12 months	12 months
	10/1/11 to 9/30/12	10/1/12 to 9/30/13	10/1/13 to 9/30/14	10/1/14 to 1/31/15	10/1/15 to 9/30/16	10/1/16 to 9/30/17	10/1/17 to 9/30/18
Total	**9,577**	**9,332**	**9,435**	**3,203**	**660**	**680**	**700**

*For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.
**If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
***Identify each type of scan/exam (e.g. orthopedic, neurosurgery or if there are scans/exams that can be performed on the proposed piece of equipment that the Applicant is unable to perform on its existing equipment) and add lines as necessary.
****Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

Type of CT requiring Transfers from HEMC 11/13-10/14		
Type of CT	Number	%
Head	33	30%
Chest	12	11%
Abd/Pelvis	62	57%
Other	2	2%

b. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected volume by scanner and scan type.

Volume based on:

1. Review of ambulance run sheets to determine # of patients who would benefit from CT during the hours of 9 am and 9 pm from Winsted and the towns contiguous to Winsted.

2. Outpatient volume based on discussion/survey with Primary Care Physicians in the Winsted area.

3. Assumes a 3% increase in CT volume per year.

c. Explain any increases and/or decreases in volume seen in the tables above.

Main Campus volume remains consistent. Increases associated in volume projected for the HEMC are due to the availability of a second scanner. This will increase the opportunity to provide emergent as well as outpatient cat scans which currently are located outside of the community.

d. Provide a breakdown, by town, of the volumes provided in Table 4a for the most recently completed FY.

TABLE 5
Utilization by Town

Town	Equipment	Utilization FY 14
ED Volumes Torrington: 1,967 Winsted: 333 Litchfield: 196 Harwinton: 124 Kent: 117 Surrounding towns: 1,660 **INPATIENT Volumes:** Torrington: 1,121 Winsted: 206 Litchfield: 128 Harwinton: 77 Kent: 52 Surrounding towns: 1,111 **OUTPATIENT Volumes:** Torrington: 1,192 Winsted: 271 Litchfield: 127 Harwinton: 122 Kent: 85 Surrounding towns: 546 Total: FY 149,435	AQ64/V-AR Toshiba Aquillon 64 Slice CT Scanner	10/1/13 to 9/30/14

*Identify each scanner separately and add lines as necessary. Also, break out inpatient/outpatient/ED volumes if applicable and include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI).
**Fill in year

e. Describe existing referral patterns in the area to be served by the proposal.

At present The Charlotte Hungerford Hospital captures over 90% of the Emergency Services market share in the greater Winsted area according to CHIME data. Patients do not need a referral to utilize the Emergency Department in Winsted at HEMC.

f. Explain how the existing referral patterns will be affected by the proposal.

We expect that there will be no significant change in referral patterns. Patients who were unable to receive definitive care at HEMC have been transported to the Hospital's Main Campus ED or brought directly to the Main Campus ED by EMS.

g. Provide a copy of any articles, studies, or reports that support the need to acquire the proposed scanner, along with a brief explanation regarding the relevance of the selected articles.

To increase the quality of care and safety of the patients who require emergency medical care in the Winsted area community, it is essential to quickly and accurately diagnose and treat patients within the community, and prevent delays inherent in transferring patients elsewhere for CT scanning.

Evidence suggests that rural emergency departments need to have readily accessible CT imaging equipment in order to accurately and timely diagnose and treat patients in their community, specifically as it relates to potentially life threatening illnesses and accidents, such as stroke and other embolic events, head and spinal injury, abdominal pain, and trauma.

References Provided: Please see Attachment B.

- **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.

See Attachment C

- **Neal Mandell, M.D.**
- **Maurice Defina, M.D.**
- **Gregg Grinspan, M.D.**
- **Michele Rainville RN**

b. Explain how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including but not limited to, (1) provision of or any change in the access to services for Medicaid recipients and indigent persons, and (2) the impact upon the cost effectiveness of providing access to services provided under the Medicaid program.

The population served by HEMC will have rapid access to CT scanning in emergency medical situations, reducing the need for EMS transport to CHH or other facilities. This reduction will assist in preventing periods of unavailability of services to the community when EMS is involved in such transfers, and will eliminate the cost of such transfers to all payors. Current Logisticare arrangement of transportation of Medicaid patients can add hours to the time between arrival in the Emergency Department and diagnosis and treatment. Due to the extremely limited access to any form of public transportation, conveyance out of town for services presents a

significant problem for the indigent population. Rapid and definitive diagnosis will improve and expedite treatment, and thus improve quality of care.

- **Organizational and Financial Information**

a. Identify the Applicant's ownership type(s) (e.g. Corporation, PC, LLC, etc.).
501 3 (c) Not for Profit Corporation

b. Does the Applicant have non-profit status?
X☐ Yes (Provide documentation) ☐ No

c. Provide a copy of the State of Connecticut, Department of Public Health license(s) currently held by the Applicant and indicate any additional licensure categories being sought in relation to the proposal.

Please see Attachment D

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.

Please see most recent audited financial statement on file.

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 6
TOTAL PROPOSAL CAPITAL EXPENDITURE

Purchase/Lease	Cost
Equipment (Medical, Non-medical Imaging)	370,000
Land/Building Purchase*	
Construction/Renovation**	275,000
Land/Building Purchase*	
Other (specify)	
Total Capital Expenditure (TCE)	**645,000**

Lease (Medical, Non-medical Imaging)***	
Total Capital Cost (TCO)	**645,000**
Total Project Cost (TCE+TCO)	**645,000**

*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.

See Attachment E.

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.

Funding for the project will come from the Hospital's annual capital budget.

g. Demonstrate how this proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant.

The proposal is consistent with the mission of the Hospital and will improve the quality and timeliness of care delivered to the patients at the HEMC.

- **Patient Population Mix: Current and Projected**

a. Provide the current and projected volume (and corresponding percentages) by patient population mix; including, but not limited to, access to services by Medicaid recipients and indigent persons for the proposed program.

TABLE 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX

Payer	Most Recently Completed FY14		Projected					
			FY16		FY17		FY18	
	Volume	%	Volume	%	Volume	%	Volume	%
Medicare*	0	0	145	24.1	164	24.1	169	24.1
Medicaid*	0	0	219	36.5	248	36.5	255	36.5
CHAMPUS & TriCare	0	0	4	0.6	4	0.6	5	0.6
Total Government	0	0	**368**	**61.2**	**416**	**61.2**	**429**	**61.2**

Commercial Insurers	0	0	192	32.0	218	32.0	224	32.0
Uninsured	0	0	30	5.1	34	5.1	35	5.1
Workers Compensation	0	0	10	1.7	12	1.7	12	1.7
Total Non-Government	0	0	**232**	**38.8**	**264**	**38.8**	**271**	**38.8**
Total Payer Mix	0	0	**600**	**100**	**679**	**100**	**700**	**100**

*Includes managed care activity.
**Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.
Note: The patient population mix should be based on patient volumes, not patient revenues.

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

The above is based on current Winsted Emergency Department Payer Mix. We are not anticipating any change in payer mix. The payer mix of patients who would now be able to be definitively treated in the Winsted Facility because of the project would mirror the current population being served in the ED at the HEMC.

c. For the Medicaid population only, provide the assumptions and actual calculation used to determine the projected patient volume.

Not Applicable, we are not expecting a change in patient mix or demographics.

d. If the proposal fails to provide or reduces access to services by Medicaid recipients or indigent persons, provide explanation for good cause for doing so. *Note: good cause shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers.*

Not Applicable.

- **Financial Attachment I**

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.
See Attachment I

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

See Attachment Ib

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

The breakeven point is 469 exams per year

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

Not applicable

e. Describe how this proposal is cost effective.

We feel that the proposed service is cost effective for the following purposes:

- **We will use existing space in our center.**
- **We will use existing radiology staff and train them in CT Imaging.**
- **We will avoid intra agency transfers for CT services, for which today we must pay a private service to perform.**

ATTACHMENT A

State of Connecticut
GENERAL ASSEMBLY
STATE CAPITOL
HARTFORD, CONNECTICUT 06106-1591

October 15, 2014

Mr. Daniel J. McIntyre, President & Executive Director
Charlotte Hungerford Hospital
540 Litchfield Street
Torrington, CT 06790

Dear Mr. McIntyre,

We are writing in strong support of Charlotte Hungerford Hospital's application to the Department of Public Health for a Certificate of Need to perform CT Scanning on patients at the Hungerford Emergency & Medical Care located at 115 Spencer Street in Winsted.

CT Scanning provides numerous benefits to staff in accurately diagnose medical conditions and to patients to quickly treat them using the information. With the agreement reached earlier this year with the Winsted Health Center Foundation on a long-term lease this health care facility will provide a vital service to Winsted and surrounding communities. Currently patients have to be transported to Torrington via ambulance while being treated at Hungerford Emergency & Medical Care for CT Scanning. Having another location to perform CT Scanning will decrease travel time for ambulances and allow more emergency personnel to be available to respond to calls.

Best of luck with your application. Please let us know if we can be of further assistance.

Kindly,

Jay Case, 63rd District
State Representative
Winchester, Colebrook, Goshen, Torrington

Clark J. Chapin
State Senator, 30th District

Connecticut Office of Rural Health

Health care branching out to rural communities

c/o Northwestern Connecticut Community College
Park Place East, Winsted, CT 06098-1798
Phone: (860) 738-6378
Fax: (860) 738-6443

October 14, 2014

Daniel J. McIntyre, President & Executive Director
Charlotte Hungerford Hospital
540 Litchfield Street
Torrington, CT 06790

Dear Mr. McIntyre:

The Connecticut Office of Rural Health (CT-ORH) fully supports Charlotte Hungerford's proposal to the Connecticut Office of Health Care Access for a CT Scanner to use in the Emergency Department at the Emergency & Medical Center in Winsted.

The addition of a CT Scanner in this rural health care facility will provide timely definitive diagnosis and assist in determining the proper care and treatment for many life-threatening medical conditions. This imaging tool is cost-effective, noninvasive, accurate and provides a wealth of clear and specific information.

Charlotte Hungerford Hospital's Emergency Department and Medical Center in Winsted is a crucial resource for thousands of individuals living in rural northwest Connecticut. This vital equipment will greatly increase access to timely quality health care for the residents in this area of the state. The CT-ORH is in full support of this proposal.

Sincerely,

Mary Winar

Mary Winar
Program Manager

Heather Cappabianca

Heather Cappabianca
Director

Winsted Health Center

October 14, 2014

To Whom It May Concern,

The purpose of this letter is to show our support for the Charlotte Hungerford Emergency Department located on Spencer Street in Winsted to obtain a CT Scan machine. We believe that it would greatly improve emergency care for Winsted and the surrounding towns.

Thank you.

Regards,

Christopher Battista
Board President

115 Spencer Street, PO Box 888
Winsted, CT 06098-0888
p: 860.379.0888 | f: 860.379.1476

Hungerford
Emergency and
Medical Care
at the Winsted Health Center

115 Spencer Street
Winsted, CT 06098

November 21, 2014

To whom it may concern:

My name is Gregg Grinspan, MD, and I have been the Medical Director of the Hungerford Emergency Department in Winsted since 1997 when it was opened. I would ask that you consider positively the Charlotte Hungerford application for the CON for a CT Scanner to be placed in the ED in Winsted. Among the cases for which dispatch and early discharge would be possible if a CT were on site would be:

1. Head injuries with cognitive or minimal (but present) neurological changes which shouldn't be discharged without a head CT.
2. Abdominal pain, whether localizing in the RLQ, LLQ, or generalized in appropriate patients, in which an imaging diagnosis most times can lead to discharge but in other cases obviously might lead to the surgical suite.
3. Neck injuries in patients with disconcerting mechanism of injury in whom plain films may not provide the comfort in diagnosing bony integrity.
4. The many flank pain patients in whom the location and size of their kidney stone will help determine therapy going forward and who could be processed before being discharged.

At present these patients require transfer from our facility to the Charlotte Hungerford Hospital ED in Torrington. They then require another registration, another medical team assessment, and then a wait for the CT imaging that we might have already taken, seen, and acted upon were there a CT in house in Winsted.

Many thanks for your consideration. If I can answer any further questions, please call me at 860-965-0776 any time after 10am weekdays.

Gregg Grinspan, MD
Medical Director, Hungerford Emergency Department in Winsted

ATTACHMENT B

Connecticut Department of Public Health

Healthy Connecticut 2020

2 State Health Improvement Plan

BRIEF REPORT

Availability and Quality of Computed Tomography and Magnetic Resonance Imaging Equipment in U.S. Emergency Departments

Adit A. Ginde, MD, MPH, Anthony Foianini, BS, Daniel M. Renner, BE, Morgan Valley, MS, Carlos A. Camargo, Jr MD, DrPH

Abstract

Objectives: The objective was to determine the availability and quality of computed tomography (CT) and magnetic resonance imaging (MRI) equipment in U.S. emergency departments (EDs). The authors hypothesized that smaller, rural EDs have less availability and lower-quality equipment.

Methods: This was a random selection of 262 (5%) U.S. EDs from the 2005 National Emergency Department Inventories (NEDI)-USA (http://www.emnet-usa.org/). The authors telephoned radiology technicians about the presence of CT and MRI equipment, availability for ED imaging, and number of slices for the available CT scanners. The analysis was stratified by site characteristics.

Results: The authors collected data from 260 institutions (99% response). In this random sample of EDs, the median annual patient visit volume was 19,872 (interquartile range = 6,788 to 35,757), 28% (95% confidence interval [CI] = 22% to 33%) were rural, and 27% (95% CI = 21% to 32%) participated in the Critical Access Hospital program. CT scanners were present in 249 (96%) institutions, and of these, 235 (94%) had 24/7 access for ED patients. CT scanner resolution varied: 28% had 1–4 slice, 33% had 5–16 slice, and 39% had a more than 16 slice. On-site MRI was available for 171 (66%) institutions, and mobile MRI for 53 (20%). Smaller, rural, and critical access hospitals had lower CT and MRI availability and less access to higher-resolution CT scanners.

Conclusions: Although access to CT imaging was high (>90%), CT resolution and access to MRI were variable. Based on observed differences, the availability and quality of imaging equipment may vary by ED size and location.

ACADEMIC EMERGENCY MEDICINE 2008; 15:780–783 © 2008 by the Society for Academic Emergency Medicine

Keywords: **imaging, access to care, emergency medicine, rural, healthcare quality**

The emergency department (ED) provides acute medical care 24 hours per day for an estimated 115 million patients in the United States each year.[1] Characterization of the distribution and quality of emergency services has gained greater attention as public health officials have sought to understand and reduce geographic disparities in access to high-quality emergency care. For instance, we recently created the first national inventory of U.S. EDs, a project that allowed us to describe the number, distribution, and basic characteristics of EDs.[2]

Increasingly, cross-sectional imaging has become an important component of the diagnostic evaluation for many ED patients. Indeed, ED utilization of computed tomography (CT) or magnetic resonance imaging (MRI) has increased from 2.4% of all ED visits in 1992 to 11.2% in 2005.[1,3] National stroke and trauma guidelines recommend 24-hour availability of CT imaging and interpretation.[4,5] Clinical pathways for abdominal pain and pulmonary embolism emphasize the role of CT in timely diagnosis.[6,7] Additionally, multislice CT scanners have been touted for their increased quality and speed,[8] but their availability for ED patients is unknown. Although not as widely utilized as CT, emergent MRI is

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Received March 31, 2008; revision received May 13, 2008; accepted June 2, 2008.

Presented at the Society for Academic Emergency Medicine Annual Meeting, Washington, DC, May 30, 2008.

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ISSN 1069-6563
PII ISSN 1069-6563583

doi: 10.1111/j.1553-2712.2008.00192.x

increasingly utilized for stroke care and spinal emergencies and was performed during 0.5% of all U.S. ED visits in 2005.[1]

The availability and quality of diagnostic imaging equipment in U.S. EDs are important extensions of the effort to describe access to high-quality emergency care, but has not previously been characterized on a national level. In this study, we sought to characterize the availability and quality of CT and MRI equipment in U.S. EDs, with particular attention to differences based on ED characteristics. We hypothesized that smaller and rural EDs would have less availability of on-site cross-sectional imaging and less access to higher-resolution equipment.

METHODS

Study Design and Population

We performed a multicenter, cross-sectional survey of radiology technologists at a random sample of U.S. hospitals with EDs. We obtained Institutional Review Board approval with waiver of informed consent.

We used the 2005 version of the National Emergency Department Inventories (NEDI)-USA (http://www.emnet-usa.org/nedi/nedi_usa.htm) to obtain a comprehensive list of all nonfederal US hospitals with EDs (n = 4,828). Methods for derivation of this database have been previously described.[2] Briefly, NEDI-USA combines data from three sources: Verispan Marketing Group's Hospital Market Profiling Solution Database, the American Hospital Association Annual Survey of Hospitals, and information collected independently by Emergency Medicine Network (Boston, MA) staff. EDs were defined as emergency care facilities that are open 24 hours per day, 7 days per week, and available for use by the general public; "urgent care" facilities known to be closed at certain hours or days were excluded.

We obtained a random sample of 262 (5%) hospitals from the 2005 NEDI-USA database, using a random number generator. Site characteristics obtained from the database included: U.S. region, urban status, annual ED visit volume, critical access hospital status (receive federal reimbursement for importance in access to care in remote areas), and academic hospital status (per Association of American Medical Colleges Council of Teaching Hospital designation). Additionally, we used data from the Joint Commission (http://www.jointcommission.org/) and the American College of Surgeons (http://www.facs.org/) to obtain site designations as primary stroke centers and trauma centers, respectively.

Survey Content and Administration

The survey asked whether the hospital had CT and MRI equipment available for imaging ED patients. Affirmative responses were recorded for "mobile" MRI units, if they were available for ED patients when on site. For hospitals with access to equipment, we asked about hours of availability for ED patients, including hours that technologists were at the hospital or on-call from home. Finally, we asked about the resolutions (in slices) of CT scanners.

Three study investigators (AF, DMR, MV) attempted to contact CT and MRI technologists by telephone during usual business hours. These investigators were unaware of the primary hypothesis at the time of data collection. If referred, responses from radiology department supervisors or physician radiologists were accepted. After verbal consent was obtained, we administered the <5-minute survey (see Data Supplement S1, available online at http://www.blackwell-synergy.com/doi/suppl/10.1111/j.1553-2712.2008.00192.x/suppl_file/acem_192_sm_DataSupplementS1.pdf) by telephone and collected responses using a standardized data abstraction form. Additionally, a second study investigator, blinded to the responses from the initial survey, repeated the survey for a random 10% subsample to evaluate interrater agreement.

Data Analysis

Our primary hypotheses were based on descriptive outcomes (i.e., availability and quality of imaging equipment). Thus, we based our estimated sample size requirements on the stability of 95% confidence intervals (CIs) around the prevalence of characteristics at increasing sample sizes. We calculated that an overall sample size of approximately 250 would yield two-tailed 95% CIs that span ≤15%, which we deemed adequate precision for this study.

We performed statistical analyses using Stata 9.0 (StataCorp, College Station, TX) and summarized data using descriptive statistics. We calculated the kappa statistic to evaluate interrater agreement for the subgroup of surveys administered by two investigators. We evaluated the magnitude and statistical significance of associations between site characteristics and imaging availability and quality by calculating 95% CIs for the difference in proportions.

RESULTS

We collected responses from 260 (99%) of the 262 hospitals, which represent a 5% random sample of all U.S. EDs. Interobserver agreement for survey responses was high (kappa = 0.77 to 1.00).

Site characteristics, compared to the overall NEDI-USA database, are presented in Table 1. Sample characteristics were similar to the overall population. In our sample, 56% of critical access hospitals had volumes under 5,000 visits per year, all had more than 20,000 visits per year, and 76% were rural. Additionally, all teaching hospitals, trauma centers, and 93% of stroke centers had visit volumes ≥20,000 per year; none of these designations were present in rural areas.

Survey responses on availability and quality of imaging equipment are presented in Table 2. Lack of CT capability was more common in EDs with fewer than 10,000 annual patient visits (difference = 13%; 95% CI = 7 to 21), rural hospitals (difference = 8%; 95% CI = 2 to 17), and critical access hospitals (difference = 8%; 95% CI = 2 to 17). Low-resolution CT (≤4 slices) was more common in EDs with <10,000 annual patient visits (difference = 46%; 95% CI = 33 to 57), rural hospitals (difference = 40%; 95% CI = 26 to 52), critical access hospitals (difference = 41%; 95% CI = 27

Table 1
Site Characteristics of Representative Sample of U.S. Hospitals with EDs

	Representative Sample		NEDI-USA Database,
	n	% (95% CI)	*n* (%)
Total	260	100%	4,828 (100%)
ED annual visit volume			
<5,000	48	18% (14, 23)	883 (18%)
5,000–9,999	46	15% (11, 20)	657 (14%)
10,000–19,999	42	16% (12, 21)	1,052 (21%)
20,000–29,999	41	16% (11, 20)	762 (16%)
30,000–39,999	41	16% (11, 20)	579 (12%)
≥40,000	48	18% (14, 23)	895 (19%)
U.S. region			
Northeast	50	19% (15, 24)	667 (14%)
Midwest	81	31% (25, 37)	1,410 (29%)
South	95	36% (30, 42)	1,844 (38%)
West	36	14% (10, 19)	907 (19%)
MSA			
Urban	140	53% (48, 60)	2,785 (58%)
Suburban	48	18% (14, 23)	846 (18%)
Rural	72	28% (22, 33)	1,197 (25%)
Critical access hospital	70	27% (21, 32)	1,267 (26%)
Teaching hospital	17	7% (4, 10)	289 (6%)
Primary stroke center	29	11% (8, 16)	NA
Trauma center	14	5% (3, 9)	NA

CI = confidence interval; ED = emergency department; MSA = metropolitan statistical area; NA = not available; NEDI = National Emergency Department Inventories.

Table 2
Access to Imaging Equipment among a Representative Sample of U.S. Hospitals with EDs

	n	% (95% CI)
CT available (*n* = 260)	249	96% (93, 98)
CT hours (*n* = 249)		
24/7 (on-site technologist)	235	94% (91, 97)
24/7 (on-call technologist)	12	5% (3, 8)
7 days/week (<24 hours/day)	2	1% (0, 3)
CT resolution, slices (*n* = 246)		
1	35	14% (10, 19)
2–4	33	13% (9, 18)
5–16	81	33% (27, 39)
>16	97	39% (33, 46)
MRI available (*n* = 260)		
On-site	171	66% (60, 72)
Mobile	52	20% (15, 25)
MRI hours (*n* = 223)		
24/7 (on-site technologist)	29	13% (9, 17)
24/7 (on-call technologist)	59	26% (21, 32)
6–7 days/week (<24 hours/day)	30	13% (9, 18)
5 days/week	50	22% (17, 28)
<5 days/week	55	25% (19, 30)

CI = confidence interval; CT = computed tomography; ED = emergency department; MRI = magnetic resonance imaging.

to 53), nonteaching hospitals (difference = 23%; 95% CI = 2 to 31), and nonstroke centers (difference = 23%; 95% CI = 7 to 31).

Lack of on-site MRI capability was more common in EDs with fewer than 10,000 annual patient visits (difference = 72%; 95% CI = 61 to 80), rural hospitals (difference = 60%; 95% CI = 48 to 70), critical access hospitals (difference = 70%; 95% CI = 59 to 78), nonteaching hospitals (difference = 37%; 95% CI = 17 to 43), nonstroke centers (difference = 38%; 95% CI = 25 to 45), and nontrauma centers (difference = 36%; 95% CI = 14 to 42).

DISCUSSION

We found that while ED access to CT imaging was nearly universal for patients in U.S. EDs, the resolution of this CT imaging and access to MRI were quite variable. Basic characteristics of the EDs (e.g., visit volume, location) were associated with important differences in the availability and quality of imaging.

Given the increased utilization of MRI in U.S. EDs, particularly for stroke care,[1] access to MRI equipment has become increasingly important. Moreover, the resolution of CT imaging can affect the speed and quality of imaging and disparities in distribution of this technology may indicate a modifiable barrier to the provision of higher-quality emergency care. These differences must, however, be balanced in the context of competing concerns, such as increased utilization and cumulative radiation exposure that may result from greater availability of imaging equipment.

While the theoretical risks of increased exposure to diagnostic radiation have garnered recent attention,[9] multislice CT scanners offer the opportunity to more accurately and rapidly diagnose a variety of serious medical conditions, such as pulmonary embolism, appendicitis, and traumatic injuries.[6–8] New applications, such as evaluation of possible acute coronary syndrome, may enhance their importance in emergency care.[10] The added value of routine ED use of higher-resolution equipment is not known and merits further investigation.

In the initial report of NEDI-USA,[2] we found significant variation in distribution and use of U.S. EDs, which suggested potential variation in the quality and availability of services, particularly in smaller, rural EDs. Indeed, these EDs had less access to CT, especially higher-slice scanners, and MRI. Increasing availability of higher technology imaging equipment in these EDs must be balanced with the cost-benefit of this decision versus regionalized referral care. However, disparities in imaging availability and quality for critical access hospitals are of particular concern. These institutions are, by definition, more than 35 miles away from the nearest hospital and, therefore, transfer to another facility, let alone a referral center, is more challenging. While EDs of critical access hospitals are of low volume, they typically serve as the only source of acute care for their large catchment area and are designated to provide higher levels of service than would be expected based on their size.

LIMITATIONS

The NEDI-USA database is limited by the quality of information available from data sources, as previously described.[2] Selection of a 5% sample may have created bias, but random sampling and the similar characteristics of our sample compared to the overall database support the generalizability of our estimates. Data on availability and quality of imaging equipment are limited by reliance on self-report. However, the selected respondents were knowledgeable on imaging equipment at their institutions, and high interobserver agreement indicates reproducibility of data collected by independent observers, on different days, and usually from different respondents. We assumed that on-site and higher-resolution imaging equipment is a quality marker, but the accuracy of this assumption and the ideal distribution of imaging resources are unknown. Associations between site characteristics and imaging availability and quality of imaging equipment are not causal and probably are confounded or modified by other factors. However, disparities in availability of imaging suggest important variability in potential quality of care based on site characteristics.

CONCLUSIONS

Although access to CT imaging was high, CT resolution and access to MRI were quite variable in this nationwide study. Smaller, rural EDs have more limited availability and quality of imaging equipment. Further evaluation of the impact of these differences on the efficiency and quality of emergency care for common conditions, such as stroke, is warranted.

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Supporting Information

The following supporting information is available in the online version of this paper:

Data Supplement S1. Appendix: survey of hospital radiology technologists (PDF file).

Please note: Wiley Periodicals, Inc. are not responsible for the content or functionality of any supporting information supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.

AHA Scientific Statement

Recommendations for Imaging of Acute Ischemic Stroke

A Scientific Statement From the American Heart Association

Richard E. Latchaw, MD, Chair; Mark J. Alberts, MD, FAHA; Michael H. Lev, MD, FAHA; John J. Connors, MD; Robert E. Harbaugh, MD, FAHA; Randall T. Higashida, MD, FAHA; Robert Hobson, MD, FAHA†; Chelsea S. Kidwell, MD, FAHA; Walter J. Koroshetz, MD; Vincent Mathews, MD; Pablo Villablanca, MD; Steven Warach, MD, PhD; Beverly Walters, MD; on behalf of the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, and the Interdisciplinary Council on Peripheral Vascular Disease

Stroke is a common and serious disorder, with an incidence of ≈795 000 each year in the United States alone. Worldwide, stroke is a leading cause of death and disability. Recombinant tissue plasminogen activator (rtPA) was approved a decade ago for the treatment of acute ischemic stroke. The guidelines for its use include stroke onset within 3 hours of intravenous drug administration, preceded by a computed tomographic (CT) scan to exclude the presence of hemorrhage, which is a contraindication to the use of the drug. Although randomized, controlled studies in Europe and North America demonstrated the efficacy of this treatment, it also was associated with an incidence of intracranial hemorrhage of 6.4%,[1,2] which was shown on subsequent studies to be even greater if there was not strict adherence to the administration protocol.[3] The goal of these controlled studies was to evaluate patient outcome. There was no attempt to determine the site, or even the actual presence, of a vascular occlusion, the degree of tissue injury, or the amount of tissue at risk for further injury that might be salvageable.

More than a decade later, progress for treating acute ischemic stroke has been slow,[4,5] yet the goals for treating this common disease have expanded. First, there is the need to extend the therapeutic window from 3 to ≥6 hours. Even with the rapid communication and transportation in our societies today, very few patients present for treatment within 3 hours.[6] Second, there is the desire to improve the efficacy of treatment. It had been shown even before the randomized, controlled studies that intravenous rtPA works better in small peripheral vessels than in the large vessels at the skull base.[7] Third, there is a need to decrease the complication rate, especially if patients are to be treated later in the course of the ischemic process.

How are these goals to be achieved? First, new therapies are being developed. The efficacy of new intravenously administered thrombolytic drugs may be better than rtPA, while associated with fewer complications.[8] The intra-arterial administration of a thrombolytic agent is not a new technique,[9] but no agent has yet been approved for intra-arterial delivery to treat acute stroke. A number of devices have either been approved[10] or are under evaluation for the performance of intra-arterial mechanical thrombectomy. The hope is that these devices will partially or totally remove an occluding thrombus without requiring any, or as much, of the drugs associated with hemorrhage. Such an approach (starting with an intra-arterial therapy instead of the administration of an intravenous drug) requires that vascular imaging be performed during the initial imaging assessment of the patient.

Second, the patient may be triaged for appropriate management with improved imaging techniques beyond a simple CT scan.[4,5] To extend the therapeutic window, improve efficacy, and limit complications, imaging should address 4 essential issues: (1) the presence of hemorrhage; (2) the presence of an intravascular thrombus that can be treated with thrombolysis or thrombectomy; (3) the presence and size of a core of irreversibly infarcted tissue; and (4) the presence of

†Deceased.

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on June 1, 2009. A copy of the statement is available at http://www.americanheart.org/presenter.jhtml?identifier=3003999 by selecting either the "topic list" link or the "chronological list" link (No. LS-2098). To purchase additional reprints, call 843-216-2533 or e-mail kelle.ramsay@wolterskluwer.com.

The American Heart Association requests that this document be cited as follows: Latchaw RE, Alberts MJ, Lev MH, Connors JJ, Harbaugh RE, Higashida RT, Hobson R, Kidwell CS, Koroshetz WJ, Matthews V, Villablanca P, Warach S, Walters B; on behalf of the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, and Interdisciplinary Council on Peripheral Vascular Disease. Recommendations for imaging of acute ischemic stroke: a scientific statement from the American Heart Association. *Stroke*. 2009;40:3646–3678.

Expert peer review of AHA Scientific Statements is conducted at the AHA National Center. For more on AHA statements and guidelines development, visit http://www.americanheart.org/presenter.jhtml?identifier=3023366.

(*Stroke*. 2009;40:3646-3678.)

Stroke is available at http://stroke.ahajournals.org

DOI: 10.1161/STROKEAHA.108.192616

hypoperfused tissue at risk for subsequent infarction unless adequate perfusion is restored.[11–13] There are now a myriad of imaging tests for evaluation of these 4 issues, with the number of new and improved magnetic resonance (MR) and CT techniques virtually exploding during the past decade. MR diffusion-weighted imaging (DWI) is the most sensitive and specific technique available for demonstrating acute infarction within minutes after its occurrence,[14] and this can be combined with MR perfusion (MRP) to differentiate viable from probably nonviable hypoperfused tissue.[15–17] In the same examination, MR angiography (MRA) can demonstrate the vascular occlusion, whereas a gradient-recalled echo (GRE) sequence excludes intracerebral hemorrhage (ICH).[18] The fluid-attenuated inversion recovery (FLAIR) sequence is now routine and is the best method for showing abnormal accumulations of fluid. Such a combination of MR sequences can be performed in 10 minutes.[19] With multidetector scanners, nonenhanced CT (NECT) scanning of the head can be performed in a matter of seconds to evaluate hemorrhage and other insults to the brain; CT angiography (CTA) from the aorta to the top of the head can be performed in less than a minute; and the source images from that CTA (CTA-SI) can provide a qualitative cerebral blood volume (CBV) map that detects the core of infarction and improves the demonstration of the tissue at risk for infarction compared with NECT.[20–22] Quantitative (dynamic) CT perfusion (CTP) can be focused on the tissue at risk during the same imaging session to differentiate infarcted from oligemic but probably viable tissue.[23] Imaging at a single point in time presents only a portion of the desired information, with the evolution of tissue perfusion and viability the ultimate goal. The decision to treat acute stroke with a variety of chemical agents and devices requires that essential information be obtained rapidly, however; the treating physician does not have the luxury of acquiring multiple data points over time. Thus, the newest imaging methodologies should be viewed as excellent methods for patient triage.

Which of these many techniques should be used by the medical team, made up of imaging specialists and clinicians? There are many factors to consider, such as the differential diagnosis, availability and reliability of the technique, time for performance, expertise required for performance and interpretation, cost, and both patient monitoring and comfort. A recent symposium attended by imagers and clinicians from many subspecialties within the neurosciences produced by consensus a roadmap for the use of a variety of imaging techniques.[24] The goals of this ongoing research group will be to determine the accuracy of the various modalities, their ability to triage a patient for therapy, and their role in assessing patient prognosis and outcome; however, that group did not undertake an in-depth review of the literature regarding their current status. Thus, it is appropriate that a review of the literature be undertaken to determine the current state of various imaging techniques and procedures in terms of what they offer relative to what we need to know to provide proper medical management. This imaging analysis can be divided into 3 components: Imaging of the cerebral parenchyma, imaging of the blood vessels, and perfusion imaging to assess tissue viability. The review has been confined to the English literature and includes all relevant articles but focuses on the literature from 2000 to 2006, with some more recent. The quality of each article has been assessed for its level of evidence (LOE), per Table 1. From this analysis, guidelines and recommendations have been proposed, with the class (strength) of each recommendation based on the LOEs (Table 2). The definitions for the LOEs and classes of recommendations conform to the American Heart Association's practice guidelines classification scheme. When the LOEs are weak and a firm guideline or recommendation cannot be established, trends are discussed and suggestions made for further studies.

Table 1. Levels of Evidence

A	Data derived from multiple randomized clinical trials or meta-analyses
B	Data derived from a single randomized trial or nonrandomized studies
C	Only consensus opinion of experts, case studies, or standard-of-care

Imaging the Cerebral Parenchyma

CT and MR imaging (MRI) are used for imaging of the density and intensity, respectively, of the cerebral parenchyma and its anatomic structure. The 3 roles of these imaging modalities in assessing the status of brain tissue in the acute stroke patient are the same: the exclusion of hemorrhage, the detection of the ischemic tissue, and the exclusion of conditions that mimic acute cerebral ischemia. The ability of each modality to determine the amount of salvageable versus nonviable tissue depends on the perfusion techniques that each can perform, which will be discussed below.

Evaluation of the literature must be done with the recognition that the ability of each modality to accomplish these 3 goals has improved progressively over the past decade, which makes comparative evaluation more difficult. The perfection of multidetector technology has enabled a CT scan of the head to be obtained with submillimeter slice thickness in a few seconds and with superior tissue differentiation (contrast resolution) to the past. The speed of MR image acquisition and reconstruction has decreased markedly, the quality of the images has improved, and the diversity of the pulsing sequences has increased significantly. The latter is exemplified by the development of DWI to detect ischemic tissue within minutes of its occurrence, the perfection of the FLAIR sequence that permits the detection of subtle intraparenchymal and subarachnoid fluid collections far better than other sequences, and the common use of gradient-echo (magnetic

Table 2. Classification of Recommendations

Class I	Conditions for which there is evidence for and/or general agreement that a procedure or treatment is beneficial, useful, and effective
Class II	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment
Class IIa	Weight of evidence/opinion is in favor of usefulness/efficacy
Class IIb	Usefulness/efficacy is less well established by evidence/opinion
Class III	Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful

susceptibility) imaging to detect acute parenchymal hemorrhage and thrombus formation.

Exclusion of Hemorrhage

Intracerebral Hemorrhage

It is usually assumed that CT is the gold standard for the detection of ICH. In fact, there are no level A studies, which use a true gold standard such as immediate surgery or autopsy, to determine the sensitivity and specificity of CT in detecting acute ICH. Most imagers and clinicians have long assumed the high accuracy of CT in demonstrating parenchymal blood on the basis of a few level C studies with early CT scanners[25,26] and practical experience. Two prospective and randomized level A studies used CT in the evaluation of intravenous tissue plasminogen activator (tPA) for the treatment of cerebral ischemia within 3 hours of onset, in which the exclusion of intracranial hemorrhage was mandatory for the administration of the thrombolytic agent.[1,2] However, the accuracy of CT was not being evaluated, and the participants in these studies assumed the high sensitivity of CT for this detection.

The appearance of ICH on MRI is dependent on both the age of the blood and the pulsing sequences used.[18,27–33] Magnetic susceptibility imaging is based on the ability of a T2*-weighted MR sequence to detect very small amounts of deoxyhemoglobin, in addition to other compounds such as those that contain iron or calcium. During the past few years, numerous authors have described anecdotal series in which these gradient-echo techniques have demonstrated cerebral hemorrhage.[34] In a 2004 study, gradient-echo MRI was performed followed by NECT in 200 patients presenting with stroke symptoms of ≤6 hours. Although the gold standard was the consensus of 4 blinded readers, they found that MRI and CT were equivalent in detecting acute hemorrhage (96% concordance). In 4 patients, MRI demonstrated hemorrhagic transformation of areas of ischemia that the CT did not detect. In another 49 patients, deposits of chronic hemorrhage (microbleeds) were visualized on MRI but not on CT. The conclusion was that the MR GRE sequence appeared to be at least as accurate as CT for the detection of acute ICH.[18] Does the presence of tiny amounts of hemorrhage seen on MR but not CT contraindicate the use of a thrombolytic agent? Recent evidence (level B) suggests that although the presence of old microbleeds may predict recurrent disabling and fatal strokes, there was no statistically significant increase in the risk of symptomatic ICH when patients with a small number of microhemorrhages (<5) on MR were treated with intravenous thrombolysis.[35] The risk in patients with multiple microbleeds (>5) is underdetermined.

Subarachnoid Hemorrhage

Although the clinical presentation of subarachnoid hemorrhage (SAH) is sufficiently different from the presentations of either acute ICH or cerebral ischemia in most cases, it is important to exclude the presence of SAH if the administration of a thrombolytic agent is considered, as well as to determine the cause of the SAH once detected (eg, aneurysmal rupture). Studies comparing CT and lumbar puncture are numerous and have demonstrated the high sensitivity of CT in detecting SAH.[36–39] In fact, it is this proven ability of CT to detect small amounts of SAH that has led to the assumption that CT has a high sensitivity for the detection of any acute intracranial hemorrhage.

FLAIR, an MRI sequence, nulls the signal from cerebrospinal fluid, which enables the detection of tiny amounts of hyperintense fluid, be it blood or an inflammatory exudate, within the subarachnoid spaces. Level C studies have demonstrated the ability of FLAIR to detect SAH, proven with subsequent CT and lumbar puncture[40]; however, prospective randomized studies have not been performed. In addition, cerebrospinal fluid turbulence within prepontine and other basilar cisterns produces increased signal, which simulates subarachnoid blood/exudate as a false-positive sign on the FLAIR sequence.

Detection of Cerebral Ischemia and Exclusion of Mimics

The dual roles of detecting the ischemic tissue to ensure the diagnosis while excluding mimics such as tumor or subdural hematoma are heavily dependent on the contrast resolution of the imaging system. Although MRI greatly exceeds NECT in such resolution, NECT traditionally has been used to assess the acute stroke patient because of its speed and availability.

Findings on NECT

A significant early CT sign of cerebral ischemia within the first few hours after symptom onset is loss of gray-white differentiation, because there is an increase in the relative water concentration within the ischemic tissues.[39–43] This sign includes loss of distinction among the nuclei of the basal ganglia and a blending of the densities of the cortex and underlying white matter in the insula and over the convexities. The subsequent swelling of the gyri produces sulcal effacement, which may lead to ventricular compression. The sooner these signs become evident, the more profound is the degree of ischemia. However, the ability of observers to detect these signs on NECT is quite variable, depending on the size of the infarct, the time between symptom onset and imaging, and the methodology of the trial itself; the detection rate appears to be ≤67% in cases imaged within 3 hours.[44–48] In a post hoc analysis of the National Institute of Neurological Disorders and Stroke rt-PA Stroke Study, Patel et al[49] found 31% sensitivity for these early infarct signs. The rate of detection increases to 82% at 6 hours, which is outside the therapeutic window for intravenous rtPA.[50] Such detection may increase with the use of scoring systems such as the Alberta Stroke Program Early CT Score (ASPECTS),[51,52] as well as with the use of better CT windowing and leveling to differentiate the normal and abnormal tissues.[53]

The significance of these early CT signs has been debated. In the European Cooperative Acute Stroke Studies (ECASS), patients with large infarcts with early swelling had an increased incidence of hemorrhage and poor outcome with the use of rtPA, and so it was considered essential to detect them.[43,50] Conversely, Patel et al[49] demonstrated that in the National Institute of Neurological Disorders and Stroke rt-PA Stroke Study, such extensive early CT signs of infarction were associated with stroke severity but not with adverse outcome after rtPA treatment. They concluded that such early CT signs should not be used to exclude patients from receiving thrombolytic treatment within 3 hours.[49] However,

Schellinger et al[54] have argued that Patel et al[49] did not evaluate whether the outcome might have been better if rtPA had not been given to those with such extensive early signs and that such extensive signs are typically found in patients presenting in the 3- to 6-hour time window. Thus, the NECT criteria of Schellinger et al for withholding rtPA in the 0- to 3-hour time window are hemorrhage or definite signs of ischemia that exceeds one third of the middle cerebral artery (MCA) territory.[54]

Another significant CT sign is that of increased density within the occluded vessel, which represents the thrombus. When this is the MCA, it is called the hyperdense MCA sign, and it is seen in one third to one half of all cases of angiographically proven thrombosis.[55,56] Hence, it is an appropriate indicator of thrombus when present, but its absence does not exclude thrombus. Attempts have been made to determine the composition of a thrombus with CT, which might aid in the decision to use intra-arterial rtPA or thrombectomy if a hard white clot is present.[57] Unfortunately, the apparent density of a small but occluding thrombus can be altered by partial volume averaging with adjacent calcium, cerebrospinal fluid, fatty atheromatous material, and other tissues, and thus, determination of its composition is not accurate.

Findings on MRI

The ability of MRI to detect cerebral ischemia is dependent on the sequence used, and these sequences have evolved over time. The most important of these is DWI, based on the demonstration of restricted diffusion as extracellular water moves into the intracellular environment during ischemia, accompanied by swelling of cells and narrowing of the extracellular spaces. The isotropic DWI map makes abnormal areas of ischemia readily visible. However, because the diffusion sequence is T2-based, shine-through of high T2 abnormalities, such as vasogenic edema, may be misinterpreted. Thus, correlation with the apparent diffusion coefficient map, which demonstrates restricted diffusion as low intensity, greatly increases the specificity of the technique. Alternatively, the calculated isotropic diffusion value of each pixel on the DWI map may be divided by the T2 value of each pixel to derive an exponential image that eliminates the T2 shine-through, again greatly increasing specificity for true restricted diffusion. A series of level A and B studies have demonstrated convincingly that DWI is significantly better than FLAIR and T2-weighted MRI, and much better than CT, for detecting an ischemic focus within 6 hours of ictus.[58–61] Gonzalez et al[62] demonstrated the very high sensitivity and specificity of DWI for the diagnosis of acute ischemia using the final clinical and imaging diagnoses as gold standards. Barber et al[63] demonstrated 100% sensitivity to ischemia with DWI versus 75% with CT within 6 hours. Because there was a time delay between the CT and MR studies in that project, Fiebach et al[14] undertook a randomized crossover comparison of DWI and CT within 6 hours of symptom onset, which demonstrated a sensitivity/specificity for DWI of 91%/95% versus 61%/65% for CT. Thus, DWI has emerged as the most sensitive and specific imaging technique for acute ischemia, far beyond NECT or any of the other MRI sequences. In addition, additional MR sequences provide the ability to detect other types of lesions that may mimic acute ischemic stroke.

There are a few anecdotal papers describing negative DWI studies when cerebral perfusion is decreased enough to produce infarction,[64,65] as well as the reversal, partial or complete, of DWI abnormalities with restoration of perfusion.[66] Thus, DWI is not a simple indicator of irreversible infarction but a complex variable that requires more study. In addition, other conditions can produce restricted diffusion, such as infection (eg, abscesses, aggressive viral infections) and other inflammatory conditions (eg, aggressive demyelination), and certain tumors with either little cytoplasm (eg, lymphoma, meningioma) or with a complex internal architecture (epidermoid, some metastases).

The MCA clot sign can be seen on MRI and CT. A direct comparison of CT and MRI in patients with occlusion of the proximal MCA found that 54% of patients demonstrated this sign on CT, whereas 82% of the same patients had a clot demonstrated on MRI with a GRE sequence.[56] Sheikh et al[67] have recently presented their data that indicate that CTA is better than GRE for a proximal arterial thrombus, but GRE is superior to CTA for a more distal clot. Hyperintensity of an intravascular thrombus is also seen on the FLAIR sequence. One group has recently found that the sensitivity for detection of a thrombus on GRE is actually less than that for FLAIR but exceeds that of NECT.[68] Other, more subtle signs include the loss of a flow void within a fast-flowing large artery at the skull base on T2-weighted studies, whereas more peripheral cortical vessels demonstrate contrast enhancement due to stasis.[69] As with CT, thrombus characterization with MR has proved difficult because of the small size of the clot and the relative values of tissue-intensity measurements with MR.[70]

Findings on CTA-SI

The source images of the brain during CTA acquisition, which reflect blood volume, make a focus of hypoperfusion much more detectable than does the NECT. Lev et al[20] demonstrated the very close correlation between the size of the infarct on CTA-SI and that which was demonstrated on follow-up CT studies. This same study also demonstrated that those patients with large infarcts (>100 mL, equivalent to more than one third of the MCA distribution) had significantly poorer outcomes after intra-arterial recanalization than did those with small infarcts as demonstrated with CTA-SI. CTA/CTA-SI was compared with NECT plus history in 40 patients in a blinded study that demonstrated marked improvement in localization of both the infarct and the occluded vessel(s) with the use of CTA/CTA-SI.[71] Direct comparisons of CTA-SI and DWI have demonstrated the extremely close sensitivity of the 2 techniques in detecting ischemic regions, with DWI better at demonstrating smaller infarcts and those in the brain stem and posterior fossa.[72,73] The overall LOE for CTA-SI is a strong B. Analogous to the improved detection with CTA-SI, dynamic quantitative CTP has recently been shown in level B studies (addressed more fully elsewhere herein) to dramatically increase the sensitivity for detection of an ischemic focus from 46% to 58% by NECT to 79% to 90% by CTP.[74]

Study Acquisition Time

The acquisition time for NECT with a multidetector scanner is 1 to 2 minutes. The addition of CTA/CTA-SI and dynamic CTP to NECT recently has been shown to increase the time of the total examination from 2 to 10 minutes.[74] One of the major arguments against the routine use of MRI for the evaluation of the acute stroke patient is the time required to perform the numerous pulsing sequences. Schellinger et al[19] have been leaders in demonstrating that a diagnostic examination that consists of DWI, FLAIR, GRE, MRP, and intracranial MRA can be performed in 10 minutes, thus making it competitive with CT, especially if CTA and CTA-SI are added to equal the diagnostic yield of the MR examination. To date, there have been no randomized series to compare these techniques and their time requirements directly. Although the total time for imaging must include such things as transferring the patient to the scan table, positioning the patient, data entry, and the placement of an intravenous line, both of the studies noted above, 1 of which used CT and another MR, took into account all of these variables in acute stroke patients who came to the scanner with an intravenous line in place. The major problem with MR as an imaging technique to triage the acute stroke patient to appropriate therapy is access to the scanner, which is really a function of the ability of an institution to provide this resource on an emergency basis. If MRI/MRA is proven to be indispensable to the diagnosis and triage of the acute stroke patient, and if reliable therapies are developed, adequate MR resources will be demanded, and access will improve.

Summary

1. It is important to remember that the US Food and Drug Administration did not require an NECT scan, only that ICH be excluded within 45 minutes for performance and interpretation of any study before the administration of intravenous tPA. The use of MRI and contrast-enhanced CT studies (CTA, CTA-SI) is therefore justifiable, but their acquisition cannot unduly delay the administration of intravenous tPA within the 3-hour time window (LOE: A).
2. MRI appears to be at least equal in efficacy to CT for detection of ICH in the hyperacute stroke patient, and both appear to have very high sensitivity and specificity (LOE: B). MRI is superior to CT for demonstration of subacute and chronic hemorrhage and hemorrhagic transformation of an acute ischemic stroke (LOE: B).
3. The gradient-echo MR sequence can detect microhemorrhage, both old and new, better than CT, indicating the presence of amyloid angiopathy, hypertension, small vascular malformations, and other vascular diseases (LOE: strong B). The presence of a small number of these microhemorrhages (<5) does not contraindicate intravenous thrombolysis (LOE: B).
4. DWI is far superior to NECT and other routine MRI sequences in the detection of acute ischemia, with very high sensitivity and specificity (LOE: A).
5. CTA-SI appears to be as good as DWI at detecting acute ischemia, with the exception of small foci and those in the posterior fossa (LOE: B).
6. NECT is excellent at detecting SAH (LOE: A). Although the FLAIR sequence is also very effective at such detection (LOE: C), the lack of randomized trials makes direct comparison impossible at this time.
7. Both GRE and FLAIR exceed the sensitivity of NECT for the detection of thrombus within the vasculature in the acute stroke patient (LOE: B).
8. Within the 3-hour window from the onset of symptoms, the use of intravenous tPA is the US Food and Drug Administration–approved therapy. NECT has been used as the imaging modality to exclude hemorrhage because it is usually more accessible than MRI. However, the ideal would be to use the more sensitive and specific imaging modality, MRI, to detect hemorrhage and ischemic tissue, if this examination does not unduly delay the administration of intravenous tPA. Similarly, it would be ideal to obtain vascular imaging studies such as CTA and MRA if they do not unduly delay the administration of intravenous tPA and if an endovascular team is available to potentially use the data to triage the patient to intra-arterial therapies (see "Imaging the Cerebral Vasculature"; LOE: B).

Recommendations

1. For a patient within a 3-hour time period from onset of symptoms, either NECT or MRI is recommended before intravenous tPA administration to exclude ICH (absolute contraindication) and to determine whether CT hypodensity or MRI hyperintensity of ischemia is present. Frank hypointensity on CT, particularly if it involves more than one third of an MCA territory, is a strong contraindication to treatment. Early signs of infarct on CT, regardless of their extent, are not a contraindication to treatment. (Class I, LOE: A).
2. For a patient within 3 hours of onset of symptoms, there is a suboptimal detection rate of ischemic changes with NECT alone, and a more definitive diagnosis will be obtained with MR-DWI or CTA-SI as detailed below if this does not unduly delay the administration of intravenous tPA:
   a. MR-DWI surpasses NECT and other MR sequences for the detection of acute ischemia. The MR sequences accompanying DWI are more effective than CT for excluding some mimics of acute cerebral ischemia, and thus, MRI can be used if it does not unduly delay the timely administration of intravenous tPA. (Class IIa, LOE: B).
   b. CTA-SI exceeds NECT and may approach DWI for the detection of large ischemic regions, and although it is less effective for demonstrating small lesions or those in the posterior fossa, it is reasonable to use (Class IIa, LOE: B).
   c. A vascular study is probably indicated during the initial imaging evaluation of the acute stroke patient, even if within 3 hours from ictus, to further determine the diagnosis of acute stroke, if such a study does not unduly delay the administration of intravenous tPA and if an endovascular team is available (see "Imaging the Cerebral Vasculature"; Class IIa, LOE: B).
3. For patients beyond 3 hours from onset of symptoms, either MR-DWI or CTA-SI should be performed along with vascular imaging and perfusion studies, particularly if mechanical thrombectomy or intra-arterial thrombolytic therapy is contemplated (Class I, LOE: A).
4. Although a gradient-echo MR sequence can be useful during initial evaluation, the presence of MRI-detected

cerebral microbleeds, in the absence of unenhanced CT-detected hemorrhage, is not a contraindication to intravenous tPA within 3 hours of stroke onset in patients with a small number of microbleeds (Class IIa, LOE: B); the risk in patients with multiple microbleeds (>5) is uncertain (Class IIb, LOE: B).

5. a. CT is recommended for the detection of SAH (Class I, LOE: A).
   b. However, if MR is being used to image the patient, the FLAIR sequence can also be used, although there may be some artifacts at the skull base (Class IIa, LOE: B).
6. The MR GRE and FLAIR sequences can be useful instead of CT if intravascular thrombus detection is desired without the use of vascular imaging techniques (Class IIa, LOE: B).

Imaging the Cerebral Vasculature

An important aspect of the workup of patients with stroke, transient ischemic attack (TIA), or suspected cerebrovascular disease is the imaging of the extracranial and intracranial vasculature. The majority of strokes and TIAs are due to disease in ≥1 of these vessels. For the acute stroke patient, vascular imaging greatly improves the localization of the site of vascular occlusion.[71] Given that intravenous thrombolysis appears more efficacious for distal than for proximal thrombus[7] and that intra-arterial thrombolysis and mechanical thrombectomy may be more efficacious for treatment of a proximal large-vessel occlusion than intravenous thrombolysis, the detection of the site of the arterial disease may be crucial to determining the type of acute therapy to institute. It is also essential to establish as soon as possible the mechanism of ischemia to prevent subsequent episodes. For chronic cerebrovascular disease, determination of the vessels that are diseased is paramount for patient management, which may require carotid endarterectomy (CEA) or angioplasty and stenting. These same procedures are occasionally performed in the acute setting of cerebral ischemia. A variety of imaging modalities are widely available, relatively safe and reliable, and each technique has particular strengths and weaknesses. Given all of these roles for vascular imaging, it is appropriate to consider them all, even if some are used more frequently for chronic cerebrovascular disease. The technical aspects and clinical evidence for each modality will be reviewed, with the understanding that imagers and clinicians will use their clinical judgment in each case to provide the best possible care.

Carotid Ultrasound

Introduction and Methods

Ultrasound techniques have been described in numerous texts. Pulse-wave Doppler ultrasound can identify significant luminal narrowing based on increased velocity of blood flow across a stenotic lesion. High-resolution B-mode ultrasound scanning uses linear-array transducers (7 to 12 MHz) to display morphological features of the arterial wall. Duplex sonography combines integrated pulse-wave Doppler spectrum analysis and B-mode sonography.[75] The B-mode image offers information about morphology in addition to serving as a template for accurate pulse-wave Doppler velocity measurement.[76] Color Doppler flow imaging based on the direction of flow superimposes color-coded blood flow patterns over the B-mode template. Power Doppler imaging color-codes blood flow according to the amplitude of the Doppler signal.[77,78] These latter modalities afford greater sensitivity to blood flow detection, which allows improved detection of near-occlusive stenoses, tortuosity, and other morphological abnormalities in the arterial wall.[79,80]

Table 3. Representative Criteria for the Classification of ICA Stenosis by Doppler Velocity Criteria

Velocity Criteria, cm/s	ICA Stenosis, %
PSV 110	0–29
PSV 111–130	30–49
PSV >130, EDV 100	50–69
PSV >130, EDV >100	70–99

EDV indicates end-diastolic velocity.

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Quantification of Carotid Stenosis

Catheter-based cerebral angiography (digital subtraction angiography [DSA]) is the standard against which all noninvasive assessments of carotid luminal narrowing are commonly compared. Although several methodologies have been proposed for the angiographic quantification of stenosis, the Committee on Standards for Noninvasive Vascular Testing of the Joint Council of the Vascular Societies has recommended that percent diameter reduction should be determined relative to the distal uninvolved internal carotid artery (ICA).[81] Doppler measures that have been correlated with angiographic stenosis include ICA peak systolic velocity (PSV) and end-diastolic velocity, as well as ratios of ICA PSV and common carotid artery PSV.[82]

Using receiver operator characteristic curves to compare sensitivity, specificity, positive predictive value, and negative predictive value for criteria to define degrees of stenosis relevant to clinical management, Faught et al[83] concluded that the combination of a PSV >130 cm/s and an end-diastolic velocity >100 cm/s defined a stenosis of 70% to 99% (Table 3). Using a similar approach, Moneta et al[84] concluded that an ICA PSV/common carotid artery PSV ratio >4.0 provided optimal accuracy for the diagnosis of a stenosis of 70% to 99%. A third set of criteria for the same degree of stenosis were proposed by Carpenter et al[85] that indicated that a combination of PSV >210 cm/s, end-diastolic velocity >70 cm/s, ICA PSV/common carotid artery PSV ratio >3.0, and ICA end-diastolic velocity/common carotid artery end-diastolic velocity ratio >3.3 was most accurate.

Recent publications demonstrate that Doppler test results and diagnostic criteria are influenced by several factors, such as the equipment, the specific laboratory, and the technologist performing the test.[86–88] In addition, factors such as contralateral occlusive disease have been associated with increased carotid volume flow that results in an overestimation of the severity of stenosis.[89,90] For these reasons, it is recommended that each laboratory validate its own Doppler criteria for clinically relevant stenosis.[91,92] One such methodology is to have the vascular laboratory undergo a certification process by an independent auditing organization such as the Intersocietal Commission for Accreditation of Vascular Laboratories Essentials and Standards for Accreditation in Noninvasive Vascular Testing. Studies comparing the accuracy of duplex

ultrasound examinations have noted consistently superior results from accredited versus nonaccredited laboratories.[93]

Ultrasound Assessment of Arterial Wall Morphology

Certain atherosclerotic patterns may be associated with a higher occurrence rate of cerebrovascular thromboembolic events. Histological analyses of atherosclerotic plaques have demonstrated that they originate from fatty streaks (type I) and progress through organized plaques (type IV) to complicated plaques (type VI).[94,95] Regional compositional and architectural changes within the plaque in the form of hemorrhage, lipid core expansion, lipid core proximity to flow lumen, and fibrous cap thinning may predispose to rupture and atheroembolic neurological complications.[94–97] Asymptomatic patients harboring carotid plaques with such features may be at increased risk for developing thromboembolic strokes or TIAs.[98–104] Reilly et al[105] first noted that echo patterns in B-mode images of carotid plaques could be related to tissue composition. They qualitatively defined plaque echogenicity as the degree of acoustic brightness. Goes and colleagues[106] subsequently proposed that echogenicity of plaques increased when fibrous tissue or calcium content increased. Gray-Weale et al[107] reported that predominantly hypoechoic plaques were associated with neurological symptoms. Using digital image processing to objectively measure pixel intensity (brightness) of B-mode ultrasound images, el-Barghouty et al[108] quantified the grayscale intensity of the entire plaque (grayscale median). Low grayscale median values may be associated with a higher incidence of neurological symptoms.[108–111] Digital image segmentation protocols have been proposed to accurately detect regional variations in the composition and architecture of plaques.[112] Further development of such image-analysis techniques may allow identification of tissue signatures of unstable carotid plaques with a high risk for producing ischemic events.

Accuracy of Carotid Ultrasound and CEA

There is continuing debate about the optimal imaging technique for determining the severity of carotid artery stenosis. Imaging modalities such as MRA and CTA are being used with increasing frequency to determine the degree of carotid artery stenosis. These techniques are discussed in more detail below. One study found high concordance rates among CTA, contrast-enhanced MRA (CE-MRA), and ultrasound for patients with asymptomatic carotid stenosis.[113] Another study comparing ultrasound with DSA for severe carotid artery stenosis found a sensitivity of 87.5% and a specificity of 76%.[114] When ultrasound is compared with DSA, the sensitivity for detecting surgical lesions has been as low as 65%, with specificities of 95%.[115] Other studies report sensitivities of 83% to 86% and specificities of 87% to 99% for detecting lesions with >70% stenosis.[116,117] One meta-analysis found that in most reports, all of the ultrasound studies had sensitivities of >80% and specificities of >90%.[118] Other studies comparing ultrasound and MRA to DSA for evaluation of patients for possible CEA found that ultrasound alone would have misassigned 28% of patients to the surgical group, whereas ultrasound combined with CE-MRA reduced the misassignment rate to 17%.[119,120] However, even a misclassification rate of only 15% means that almost 1 of every 6 patients evaluated may undergo an unneeded operation or may not have a needed surgery.

Table 4. Accuracy of Transcranial Doppler for Various Types of Cerebrovascular Disease

Indication	Sensitivity, %	Specificity, %	Comparator
Intracranial stenotic/ occlusive disease			
Anterior circulation	70–90	90–95	DSA
Posterior circulation	50–80	80–96	DSA
Vasospasm after SAH			
MCA	39–94	70–100	DSA
ACA	13–71	65–100	DSA
Posterior circulation	44–100	42–88	DSA

ACA indicates anterior cerebral artery.

Adapted from Nederkoorn et al,[114] with permission from Lippincott Williams & Wilkins. Copyright 2002, American Heart Association.

In summary, although carotid ultrasound/Doppler imaging is a safe and inexpensive technique, its sensitivity and specificity appear less than that of other modalities (overall LOE: A). In addition, carotid ultrasound only images a small region of the carotid and vertebral arteries in the neck. Although level A evidence indicates that it remains useful as a screening tool, level B studies indicate that carotid ultrasound should not be used as the sole methodology for the definitive diagnosis of carotid or vertebral artery disease (Class I recommendation; see below).

Transcranial Doppler

Transcranial Doppler (TCD) uses energy of 2 to 4 MHz to insonate cerebral vessels, typically through several bony windows in the skull. This technique can detect intracranial flow velocities, the direction of flow, vessel occlusion, the presence of emboli, and vascular reactivity. The arteries best evaluated are those at the base of the brain (MCA, anterior cerebral artery, carotid siphon, vertebral artery, and basilar artery) and the ophthalmic artery. The primary applications of TCD are to detect and quantify intracranial vessel stenosis, occlusion, collateral flow, embolic events, and cerebral vasospasm (particularly after SAH).[121,122] TCD is also useful for monitoring patients with sickle cell disease who might benefit from transfusion therapy.[123,124]

For the detection of intracranial stenoses in the anterior circulation, the sensitivity and specificity of TCD range from 70% to 90% and from 90% to 95%, respectively.[125–129] These numbers are slightly reduced when vessels in the posterior circulation are studied (Table 4). In these studies, cerebral angiography was generally used as the comparator. TCD was equally effective for the detection of MCA occlusion (Table 5). The ability of TCD to detect occlusion of the ICA, vertebral artery, or basilar artery was somewhat less, with sensitivities in the 55% to 80% range and specificities up to 95%.[125,130,131] These results can be improved with the use of contrast material such as saline with bubbles.[132–134] A number of underlying conditions, such as carotid stenosis, prosthetic heart valves, atrial fibrillation, patent foramen ovale, plaque in the aortic arch, and cardiopulmonary bypass, have been associated with the occurrence of microembolic signals in the cerebral circulation. TCD is capable of detecting microem-

Table 5. Sensitivity and Specificity of Contrast-Enhanced MRA Versus DSA for Patients With Extracranial Carotid Stenosis

Reference	Comparator	Sensitivity, %	Specificity, %	Threshold Stenosis	Comment
148	DSA	90	77	Unclear	PCC=0.94
149	DSA	94	??	70%	
150	DSA	86	91	Surgically significant	SCC=0.90
151	DSA	97	82	Degree of stenosis	κ=0.87
109	DSA	92	62	Need for CEA	κ=0.72
152	DSA	93	85	70%	
153	DSA+U/S	94	85	70%	
154	DSA	90–99	90–99	Surgically significant	Meta-analysis

PCC indicates Pearson correlation coefficient; SCC, Spearman correlation coefficient; and U/S, ultrasound.

bolic signals in such cases, thereby giving an indication of the relative risk of the underlying condition. The typical TCD finding is a high-intensity transient signal, which is due to the reflective differences between the flowing blood and the embolic material.[135,136] Some studies have shown an association between increased microembolic signals/high-intensity transient signals during CEA and new brain ischemic lesions postoperatively.[137–141]

Cerebral vasospasm is a common and deadly complication after an SAH. TCD is a useful and noninvasive technique for serial assessment of the development of vasospasm after SAH.[142,143] Flow velocities >200 cm/s, elevated Lindegaard ratios, and a rapid increase in flow velocities all predict a high likelihood of vasospasm.[143,144] The sensitivity and specificity of TCD for the diagnosis of vasospasm vary depending on the vessel being evaluated. The highest detection rates are in the MCA, with sensitivities of up to 90% and specificities ranging from 90% to 100%. Detection of vasospasm in the posterior circulation is less reliable (Table 4).[125,145,146]

TCD has been used to monitor the response of cerebral vessels to thrombolytic therapy, as well as to augment such therapy using ultrasonic energy to enhance clot lysis.[147–149] In general, recanalization and restoration of flow are associated with improved neurological outcomes.[150,151] A recent study reported enhanced clot lysis and improved neurological outcomes when TCD was combined with intravenous tPA therapy.[152]

Sickle cell disease is associated with an increased risk of ischemic stroke in children. TCD has been shown to be extremely useful in monitoring velocities in the intracranial ICA and MCA, where mean maximum velocities of ≥200 cm/s are associated with an increased risk of ischemic stroke.[123,153–156]

In summary, TCD is a safe and noninvasive technique for imaging the intracranial vasculature for some types of cerebrovascular disease, particularly vasospasm and sickle cell disease (LOE: A). Its accuracy is less than that of CTA and MRA for steno-occlusive disease (LOE: A). It is also used for the detection of emboli from a variety of sources. Its usefulness is limited in patients with poor bony windows, and its overall accuracy is dependent on the experience of the technician and interpreter, as well as the patient's vascular anatomy.

Magnetic Resonance Angiography

Introduction and Methods

MRA is performed in combination with brain MRI in the setting of acute stroke to guide therapeutic decision making.[19] There are several different MRA techniques that are used for imaging cerebral vessels. They include 2-dimensional time-of-flight (TOF), 3-dimensional TOF, multiple overlapping thin-slab acquisition (MOTSA), and CE-MRA. A review of the technical aspects of each of these techniques can be found in prior statements and publications.[157]

Accuracy of MRA

A key clinical issue is the comparative sensitivity and specificity of MRA compared with conventional angiography or carotid ultrasound in the detection of high-grade atherosclerotic or atherothrombotic lesions in the neck and head. MRA is also helpful for detecting other, less common causes of ischemic stroke or TIAs, such as arterial dissection, fibromuscular dysplasia, venous thrombosis, and some cases of vasculitis.[158] For hemorrhagic stroke, MRA may be used to detect intracranial aneurysms and arteriovenous malformations. These are reviewed in more detail below.

A review of prospective studies of nonenhanced MRA used for the detection of extracranial carotid disease (threshold stenosis typically 70%) showed a mean sensitivity of 93% and a mean specificity of 88% with 2-dimensional or 3-dimensional TOF sequences.[157] MRA with gadolinium contrast is rapidly replacing TOF techniques for detecting extracranial carotid stenosis. Recent studies of CE-MRA compared with DSA (with or without carotid ultrasound) have shown specificities and sensitivities of 86% to 97% and 62% to 91%, respectively (Table 5).[159–165] The general consensus is that CE-MRA provides more accurate imaging of extracranial vessel morphology and the degree of stenosis than nonenhanced TOF techniques (LOE: A). CE-MRA is now being performed routinely in some centers to detect arterial occlusive disease, sometimes in the setting of acute ischemic stroke (overall LOE: A).[158,166–169] However, other authors have questioned whether enhanced TOF really offers more than unenhanced imaging to detect stenoses >70%.[170]

Intracranial MRA with nonenhanced TOF techniques has a sensitivity that ranges from 60% to 85% for stenoses and from 80% to 90% for occlusions compared with CTA and/or DSA (sensitivity=100%).[171] Some studies[172] have reported sensitivities and specificities of 90% or more for MRA in detecting stenoses >50% (LOE: B). The diagnostic sensitivity and specificity of intracranial CE-MRA compared with TOF techniques and DSA for intracranial atherosclerotic disease are under active investigation in the Stroke Outcomes and Neuroimaging of Intracranial Atherosclerosis (SONIA)

study, which is a currently unpublished substudy of the recently stopped Warfarin versus Aspirin for Intracranial Disease (WASID) trial.[173]

MRA is also used for the diagnosis and serial imaging of cerebral aneurysms, particularly the 3-dimensional TOF technique. Although not a cause of acute cerebral ischemia, and although the clinical presentation of a ruptured aneurysm is usually different from that of acute ischemic stroke, the ability of the various MRA techniques to demonstrate an aneurysm is a reflection of their spatial resolution. In general, MRA can reliably detect up to 90% of intracranial aneurysms.[174] Specifically, MRA can detect up to 99% of aneurysms >3 mm; this declines to 38% sensitivity for those <3 mm.[174]

Craniocervical arterial dissections of the carotid and vertebral arteries can often be detected with MRA.[175–178] CE-MRA may improve the detection of arterial dissections,[158] although there are few large, prospective studies to prove its accuracy versus catheter angiography. Nonenhanced T1-weighted MRI with fat-saturation techniques frequently can depict a subacute hematoma within the wall of an artery, which is highly suggestive of a recent dissection.[179,180] However, an acute intramural hematoma may not be well visualized on fat-saturated T1-weighted MRI until the blood is metabolized to methemoglobin, which may not occur until a few days after ictus.

Overall, CE-MRA has greater sensitivity and specificity than Doppler ultrasound for detecting most types of extracranial cerebrovascular lesions (overall LOE: A). It can also noninvasively detect most significant intracranial vaso-occlusive lesions (LOE: B). CE-MRA is useful for detecting intracranial aneurysms (LOE: A) and extracranial arterial dissections (LOE: B); however, it cannot be used in patients with pacemakers, some metallic implants, and those with allergies to MR contrast agents, and its use is limited in patients with severe claustrophobia.

CT Angiography

Introduction and Methods

The evolution of CT scanners over the past decade from a single row of detectors to multidetector imaging (4, transiently 8, then 16, and now 64 rows of detectors), which results in an ever-increasing speed of acquisition and spatial resolution, is likely the single most important factor accounting for the differences in performance of this technique among published studies.[181–183] A number of authors have addressed the appropriate scanning parameters to optimize the technique.[184–186] In general, CTA has twice the spatial resolution of MRA but only half that of DSA.[187] However, as the number of rows of detectors increases, assuming the use of x-ray tube focal spot sizes of ≤0.5 mm, the spatial resolution of CTA will continue to approach that of DSA.[183,187–189] The postprocessing time of CTA images is similar to that of MRA. Because both CTA and MRA produce static images of vascular anatomy, both techniques suffer relative to DSA for the demonstration of flow rates and direction and collateral input into tissues at risk for hypoperfusion.

Accuracy of CTA

CTA is commonly used for the evaluation of extracranial carotid artery stenosis. A large meta-analysis found it to have a sensitivity >80% and specificity >90% for detecting significant lesions compared with DSA.[118] One study found CTA to have equal sensitivity and specificity (100%) compared with DSA for diagnosing severe carotid stenosis.[190] Another study found that CTA had a sensitivity of 89%, specificity of 91%, and accuracy of 90% compared with DSA for diagnosing carotid lesions of >50% stenosis.[191] A study by Berg et al[192] found that CTA was comparable to DSA for diagnosing significant carotid disease. Leclerc et al[193] compared CTA with DSA and found that CTA correctly determined the degree of stenosis in 88% to 90% of cases with carotid stenosis. The differentiation of a very-high-grade stenosis (*string sign*) from a total occlusion is of importance, because a vessel with a high-grade stenosis can be opened with either surgery or angioplasty plus stenting, whereas a total occlusion, unless hyperacute, cannot. CTA has been found to be highly accurate for detecting such a lumen, although not always as good as DSA.[194] However, in some cases, CTA was more accurate than DSA for determining the degree of carotid stenosis, especially the very-high-grade type.[195] CTA is clearly superior to carotid ultrasound for differentiating a carotid occlusion from a very-high-grade stenosis.[196] In terms of identifying plaque morphology, CTA has only 60% sensitivity for detecting significant plaque ulcerations.[197]

Several studies have found CTA to be very reliable for the detection of intracranial occlusions, with sensitivities ranging between 92% and 100%, specificity ranging between 82% and 100%, and a positive predictive value of 91% to 100%.[20,21,172,198] Specifically for the acute stroke patient, Lev et al[20] have demonstrated that the accuracy of CTA for defining the acute intra-arterial thrombus is close to that of DSA. The published sensitivities of CTA for intracranial stenoses are slightly lower than those for occlusion, ranging between 78% and 100%, with specificities of 82% to 100% and a positive predictive value of 93%.[20,171,172,198]

CTA is superior to TCD in the detection of stenoses and occlusions. Suwanwela et al[199] and Graf et al[200] performed prospective studies of 70 and 103 patients, respectively, and found CTA to be clearly superior to TCD for the detection of intracranial stenotic or occlusive disease, with a high false-negative rate for Doppler ultrasound.[199] Suwanwela et al[199] found that CTA was able to detect MCA stenosis in 81% of patients compared with only 41% studied by TCD, whereas distal M1 or M2 disease was detected in 53% of patients with CTA versus 24% of patients with TCD.

Recent literature suggests that CTA not only has sensitivity and specificity for the detection of intracranial stenosis and occlusion that are nearly equal to DSA in the anterior circulation, but it also has a higher sensitivity and positive predictive value than 3-dimensional TOF MRA for both intracranial stenosis and occlusion, including the petrous and cavernous segments of the ICA. CTA appears superior to 3-dimensional TOF MRA, with a higher sensitivity and positive predictive value than MRA for both intracranial stenosis (MRA=70% and 65%) and occlusion (MRA=87% and 59%).[171] Some studies suggest that CTA may be more accurate than MRA for the detection of stenoses in the posterior circulation when slow flow states are present.[195] In addition, Bash et al,[171] using unblinded consensus readings, found 7 (6%) of 115 false-positive occlusions for DSA in the

posterior circulation arteries and noted that CTA was superior to both MRA and DSA in the detection of posterior circulation stenoses when slow or balanced flow states were present. Hirai et al[172] reported a 13% false-positive rate for occlusion when heavy atheromatous calcifications were present. Skutta et al[198] found that CTA was least accurate for stenosis quantification when extensive atheromatous calcifications were present. In contrast, Bash et al[171] noted the sensitivity and specificity of CTA for stenosis quantification were not compromised by the presence of atheromatous calcifications when appropriate window and level adjustments were made to account for the blooming artifacts that are frequently associated with heavy calcific plaque. The study by Bash et al[171] suggests that it may be beneficial to perform low-pitch or delayed CTA whenever DSA shows a posterior circulation vessel to be occluded. They postulated that this advantage of CTA over DSA was due to the longer scan times necessary to perform the CTA study, which allowed for an estimated 9 to 12 intracranial circulation times per CTA (when single-detector systems were in use) as opposed to the single intracranial circulation time (5 to 7 seconds) encountered during routine DSA. This additional scan time allows more contrast to pass through a critical stenosis to opacify the artery distally.

Recent studies show that CTA may be as sensitive and specific as DSA for the detection and characterization of intracranial aneurysms.[201] Most recent studies comparing CTA and DSA have reported sensitivities and specificities for CTA of >90% to 95% for the detection of aneurysms.[202–206] In some cases, a CTA can detect an aneurysm missed by DSA.[207,208] This ability to detect aneurysms almost as well as or even better than DSA demonstrates the significantly greater spatial resolution of CTA over MRA.

In summary, the available data support the fact that CTA is a safe and accurate technique for imaging most extracranial and intracranial vessels for stenoses/occlusions (LOE: A) and for the detection of many intracranial aneurysms (LOE: A). In general, the accuracy of CTA is equal to or superior to that of MRA in most circumstances, and in some cases, its overall accuracy approaches or exceeds that of DSA (LOE: A). New CT scanners with even more detectors may further enhance the accuracy of this technique in the future. Because CTA requires the use of substantial amounts of intravenous contrast material, its application may be limited in patients with contrast allergies and renal dysfunction.

Cerebral Angiography

DSA remains the gold standard for the detection of many types of cerebrovascular lesions and diseases. Indeed, many of the studies cited above used DSA as the comparator for other imaging modalities. Excellent reviews by Barr and by Culebras et al have summarized many of the technical and clinical issues related to DSA.[209,210] For most types of cerebrovascular disease, the resolution, sensitivity, and specificity of DSA equal or exceed that of the noninvasive techniques.[209–214] This is true for many cases of arterial narrowing, dissection, small arteriovenous malformations, vasculopathies/vasculitides, and determination of collateral flow patterns. One exception is intracranial aneurysms, in which case CTA is equal to or better than DSA for large aneurysms and may in some cases detect small aneurysms missed by DSA, because of its multiprojectional capabilities.[201–208]

DSA is an invasive test and can cause serious complications such as stroke and death. Most large series have reported permanent deficits or death in <1% of DSA procedures.[215,216] The largest series of cases to date reported permanent neurological deficit or death in <0.2%.[217] The use of DSA in patients with a contrast allergy or renal dysfunction is complicated, but DSA can be used with proper medical precautions.

Importance of Vascular Imaging in the Acute Stroke Patient

Progress in the treatment of the acute stroke patient has been very slow, and it is apparent that the use of a simple NECT scan of the brain is insufficient to properly select the best patients for treatment.[4,5] For example, patients with the hyperdense MCA sign, which is indicative of a hard thrombus within the MCA, do not respond well to intravenous tPA and may respond better to intra-arterial therapy.[52,218–220] A similar poor response to the drug and poor outcomes have been found when a proximal occlusion is seen on TCD[221] or CTA.[222] The recent randomized trial of intra-arterial urokinase from Japan (MELT: MCA Embolism Local Fibrinolytic Intervention Trial) demonstrated that the outcome after intra-arterial therapy was influenced by the location of the thrombus.[223,224] A retrospective comparison of intravenous versus intra-arterial tPA in patients with the hyperdense MCA sign demonstrated an improvement in outcome when the intra-arterial technique was used, even though it was started later in most cases (<3 hours for the intravenous group versus <6 hours for the intra-arterial group).[220] Thus, there is very strong justification for vascular imaging of the acute stroke patient at the time of the initial brain imaging study, to triage the patient to the best therapy and to determine prognosis, even if that patient presents within the 3-hour window. This has been the routine practice at a number of institutions, such as the Sims group, for years.[222] The Acute Stroke Imaging Research Group has made such a recommendation,[24] as has the American College of Chest Physicians.[225] However, such a practice, especially in the <3-hour window, requires that there be no undue delay in the administration of intravenous tPA, if that is the therapy of choice, and that there be an endovascular team at the institution to undertake intra-arterial therapy, if that is selected.

Summary

Extracranial Vascular Evaluation

1. It is important to evaluate the extracranial vasculature soon after the onset of acute cerebral ischemia to aid in the determination of the mechanism of the stroke, and thus potentially prevent a recurrence. In addition, CEA or angioplasty/stenting is occasionally performed acutely, which requires appropriate imaging (LOE: B).
2. The major extracranial cerebral vessels can be imaged by several noninvasive techniques such as ultrasound, CE-MRA, CTA, and DSA. Although each technique has certain advantages in specific clinical situations, the noninvasive techniques show general agreement with DSA in 85% to 90% of cases (overall LOE: A).

3. Carotid ultrasound is a good screening technique for imaging the carotid bifurcation and measuring blood velocities, but it has limited ability to image the extracranial vasculature proximal or distal to the bifurcation (LOE: A). The use of carotid ultrasound as the sole test may lead to erroneous determination of the degree of stenosis, which may have implications in terms of medical and surgical therapy (LOE: A). The addition of CE-MRA to the ultrasound evaluation still results in a misassignment to the surgical group in 17% of cases (LOE: B).
4. CE-MRA and CTA appear to be more sensitive and specific, and more accurate, than Doppler ultrasound alone for imaging the extracranial vasculature (LOE: A).
5. DSA remains the optimal technique for imaging the cerebral vasculature, particularly when making decisions about invasive therapies (LOE: A). In addition to providing specific information about a vascular lesion, DSA can provide valuable information about collateral flow, perfusion status, and other occult vascular lesions that may affect patient management. However, DSA is associated with a risk, albeit small (<1%), of serious complications such as stroke or death.

Intracranial Vascular Evaluation

1. Imaging of the intracranial circulation in the patient with acute ischemia in the 3-hour window after ictus is extremely important and may aid in the decision to administer a thrombolytic agent intravenously or have the patient undergo intra-arterial thrombolysis with or without mechanical thrombolysis (LOE: B). However, such imaging cannot unduly delay the administration of the intravenous thrombolytic agent, if that is the therapy of choice. In addition, such early imaging presupposes that an endovascular team is available to initiate intra-arterial therapy.
2. Vascular imaging of the acute stroke patient who is seen >3 hours after ictus is an absolute necessity if intra-arterial therapy is contemplated, to determine whether a thrombus amenable to such therapy is present (LOE: A).
3. Imaging of the acute stroke patient can be accomplished quickly and noninvasively with CTA and MRA. For occlusions of the major vessels at the skull base, these modalities are almost as accurate as DSA (LOE: A).
4. Imaging of chronic stenoses and occlusions can best be accomplished by CE-MRA, CTA, and DSA. CTA and DSA have a higher accuracy in determining the degree of stenosis, with DSA being superior to CTA (LOE: A).
5. Imaging of the intracranial vessels for aneurysms can best be accomplished by CE-MRA, CTA, or DSA. CTA and DSA have a higher accuracy rate than MRA (LOE: A).
6. TCD is useful for monitoring the development of vasospasm in large vessels at the base of the brain (LOE: A) and for determining major occlusive disease in those arteries, although CTA, MRA, and DSA are more accurate for occlusive/stenotic lesions (LOE: A). TCD is also useful for monitoring large brain vessels in patients with sickle cell disease (LOE: A).
7. DSA is still the optimal technique for imaging most types of intracranial vascular lesions, as well as determining patterns of collateral flow (LOE: A).

Recommendations

I. Intracranial Vascular Evaluation
   A. Circle of Willis
      1. Acute large-vessel intracranial thrombus is very accurately detected by CTA, DSA, and MRA. Each of these modalities far surpasses the sensitivity of nonvascular studies such as NECT, FLAIR, or gradient-echo MRI, and they are all recommended (Class I, LOE: A).
      2. A vascular study is probably indicated during the initial imaging evaluation of the acute stroke patient within 3 hours of ictus, if such an evaluation does not unduly delay the administration of intravenous tPA, and only if an endovascular team is available to undertake intra-arterial therapy if that is contemplated on the basis of the findings (Class IIa, LOE: B).
      3. A vascular study is strongly recommended during the initial imaging evaluation of the acute stroke patient who presents >3 hours after ictus, especially if either intra-arterial thrombolysis or mechanical thrombectomy is contemplated for management (Class I, LOE: A).
      4. For the detection of vascular stenoses and aneurysms, CTA and DSA are recommended (Class I, LOE: A), whereas MRA is less accurate but can be useful (Class IIa, LOE: A).
      5. Although TCD can be used as a noninvasive technique to detect vasospasm or stenoses due to sickle cell and other arterial diseases (Class IIa, LOE: A), CTA and DSA are more accurate in determining the degree of stenosis and should be used for definitive diagnosis (Class I, LOE: A). MRA is less accurate for such assessment than CTA and DSA but can be useful (Class IIa, LOE: A).
   B. Distal intracranial vessels

For the demonstration of more distal acute branch occlusions, or for evaluation of subacute to chronic stenoses, vasospasm, and vasculitis, DSA surpasses CTA and MRA and should be used (Class I, LOE: A).

II. Extracranial Vascular Evaluation
   A. Evaluation of the extracranial vasculature by ultrasound alone should not be done for assessment of occlusive disease if surgical (CEA) or endovascular (arterial angioplasty and stenting) therapy is contemplated (Class III, LOE: A).
   B. For evaluation of the degree of stenosis and for determination of patient eligibility for CEA or carotid angioplasty and stenting:
      1. DSA is the recommended imaging modality to determine the degree of stenosis (Class I, LOE: A).
      2. Two noninvasive techniques (among ultrasound, CTA, and MRA) can be used, although with less accuracy with regard to the degree of stenosis than DSA alone, which thus may increase the chance of inappropriate therapy (Class IIa, LOE: B).
   C. Although CTA (in the absence of heavy calcifications) and MRA are highly accurate for detecting dissection (CTA likely greater than MRA), DSA remains the gold standard and should be used for definitive diagnosis (Class I, LOE: A).

D. A very-high-grade stenosis (string sign) is most accurately detected by DSA, followed closely by CTA. Either can be useful (Class IIa, LOE: B).

Imaging of Cerebral Perfusion

Prior publications have both compared the technical aspects of various brain perfusion imaging techniques[226] and offered guidelines and recommendations for their clinical application in the evaluation of cerebral ischemia.[227] In this section, we survey and expand on those guidelines in the context of current clinical practice and therapeutic trials, using more recently developed definitions for LOEs (Table 1) and strength of recommendations (Table 2). We focus on a time window greater than 3 hours after ictus, because there is an approved therapy for use within the first 3 hours after an acute ischemic stroke (intravenous tPA) that requires only a plain CT scan, although the use of other parenchymal and vascular imaging tests has also been suggested for a more definitive diagnosis, as needed. However, the potential use of intra-arterial thrombolysis or mechanical thrombectomy after 3 hours requires more sophisticated imaging to select the proper patient population to treat with an acceptable risk-benefit ratio.

Possible Roles for Perfusion Imaging of Acute Stroke

Potential utility for perfusion imaging in acute stroke includes the following: (1) Identification of brain regions with extremely low cerebral blood flow (CBF), which represent the *core* (tissue likely to be irreversibly infarcted despite reperfusion) that is at increased risk of hemorrhage with thrombolysis; (2) identification of patients with at-risk brain regions (analogous to the physiological penumbra, the acutely ischemic but viable tissue at risk for infarction in the absence of reperfusion) that may be salvageable with successful intra-arterial thrombolysis beyond the standard 3-hour window for intravenous drug administration; (3) triage of patients with at-risk brain regions to other available therapies, such as induced hypertension or mechanical clot retrieval; (4) disposition decisions regarding intensive monitoring of patients with large abnormally perfused brain regions; and (5) biologically based management of patients who awaken with a stroke for which the precise time of onset is unknown.[228] Perfusion imaging may additionally be of value in clinical trial enrollment. Promising neuroprotective agents in animal models have performed poorly in humans to date.[229] However, there is a growing literature positing that ischemic, potentially salvageable penumbral tissue is an ideal target for neuroprotective agents, which requires proper patient selection.[230–232]

The potential value of perfusion imaging in determining patient management was well illustrated in the recently published DIAS (Desmoteplase in Acute Ischemic Stroke–phase II) trial. In that study, which used the degree of MR diffusion/perfusion mismatch as an entry criterion to receive an intravenously administered thrombolytic compound based on vampire bat venom, a highly significant difference in good outcome was demonstrated between treated and untreated patients up to 9 hours postictus with a sample size in the tens of patients (LOE: B).[8] By contrast, in the original trial (National Institute of Neurological Disorders and Stroke rt-PA Stroke Study), hundreds of patients were required to demonstrate a smaller benefit of treatment with a 3-hour time window.[2] Although this difference may reflect the inherent efficacy of the drug, it may just as well demonstrate the effect of proper patient selection with sophisticated imaging. Further trials will be necessary to separate these 2 variables.

Additional level B evidence for the beneficial role of mismatch in extending the time window for intravenous thrombolysis beyond 3 hours was published recently with both the DEDAS (Dose Escalation of Desmoteplase for Acute Ischemic Stroke) trial[233] and the German Multicenter Study.[234] As the results of other similar in-progress, prospective, randomized trials become available, including the Echoplanar Imaging Thrombolysis Evaluation Trial (EPITHET), DWI Evolution For Understanding Stroke Etiology (DEFUSE), MR and Recanalization of Stroke Clots Using Embolectomy (MR RESCUE), and DIAS phase III, the indications for perfusion imaging of the acute stroke patient, whether with MRI or CT, will likely continue to increase. Indeed, the results of the 7-center DEFUSE study suggest that intravenous tPA can be administered safely and effectively up to 6 hours after stroke onset when MR diffusion/perfusion mismatch is present.[235]

Determining the Penumbra and the Core

The anatomic estimate of the penumbra is clearly dependent on the modality with which it is measured[232,235,236] and how rigorously it is defined. Thus, the penumbra determined by flumazenil positron emission tomography (PET) is unlikely to correspond with that determined by DWI/MRP mismatch.[237,238] Even within a given modality, different parameters will lead to different estimates of the penumbra. For example, multiple studies have found that CBF abnormalities are more useful than mean transit time (MTT) measurements in distinguishing different portions of the penumbra that live or die. This is consistent with the fact that MTT is a measure of circulatory dysfunction. All levels of decreased perfusion do not cause ischemia, because ischemia is the metabolic consequence of the decreased delivery of energy-producing metabolites relative to local metabolic demand.[15,239–242] Animal studies have demonstrated that specific thresholds of decreased CBF are predictive of tissue outcome in stroke. The identification of these thresholds in patients is essential to operationally define the penumbra.[243] With MRI, the presence of a larger perfusion abnormality than the DWI lesion is a qualitative marker for potential infarct expansion, although as currently used, it is not a predictor of how much expansion actually occurs.[244] However, the difficulty in truly quantifying MRP severely restricts its ability to define thresholds that accurately differentiate the core from the penumbra within the zone of abnormally perfused tissue. MRP remains extremely sensitive in identifying regions of abnormal perfusion, which makes it useful as a triage technique for patient management, but its specificity in accurately predicting tissue outcome is poor, and in most cases, but not all, MRP overestimates the final infarct volume (FIV).[245–247] Thus, a number of recent publications have highlighted the need for quantitative determination of the penumbra to predict infarct

growth,[248–250] which may require techniques other than MRP to achieve, as will be discussed.

Some centers rely on the qualitative mismatch between the apparent core and the penumbra for management decisions beyond the 3-hour, and especially the 6-hour, time windows for thrombolysis.[16] Although phase II of the DIAS trial was encouraging, the mismatch concept has yet to be validated in large clinical trials providing level A evidence. Indeed, while awaiting the results of trials such as EPITHET and DIAS-phase III, which were designed to assess the role of core/penumbra mismatch in extending the time window for intravenous thrombolysis, some authors have already cautiously proposed the use of either advanced MR or CT for making treatment decisions in patients not in a clinical trial.[55,251] These authors point to the growing evidence of a relevant volume of salvageable tissue present in the 3- to 6-hour time frame in >80% of stroke patients.[252,253] In fact, salvageable tissue may be present so commonly in patients <3 hours postictus that the value of perfusion imaging may be minimal at these early time points.[252,253] Numerous authors have suggested that MR perfusion/diffusion mismatch is present in at least 50% of patients up to 24 hours after stroke onset.[254–256]

The goal is to determine whether perfusion technology in general provides information that aids in patient management decisions and improves patient outcomes. If so, will this be a qualitative or a quantitative approach? There are a number of perfusion technologies, and it must be determined which modality provides the essential information most consistently and accurately. A systematic evaluation of the literature regarding these modalities is presented.

Techniques of Perfusion Imaging

There are 2 major groups of perfusion methodologies. The older group includes those that use a diffusible tracer, whereas the newer group includes those that use an injected contrast agent that, assuming no break in the blood-brain barrier, is a nondiffusible tracer. The former group is exemplified by single-photon emission CT (SPECT) and xenon-enhanced CT (XeCT) scanning, whereas CTP and MRP are examples of the latter group.

Single-Photon Emission CT

Rationale of Technique

SPECT imaging utilizes an intravenously injected radioisotope, typically technitium-99m (^{99m}Tc), attached to some delivery compound capable of traversing the intact blood–brain barrier and being metabolized by neurons and glia. The radiolabeled compounds are taken up during first passage in proportion to CBF at the time of passage.[257] Imaging is performed during the next few hours after injection.

Method of Performance

The delivery compounds to which the radioisotope, ^{99m}Tc, is attached are hexamethylpropyleneamine oxime (HMPAO) or ethyl cysteinate dimer (ECD). ^{99m}Tc and HMPAO may be combined in-house with commercially available kits in approximately 20 to 30 minutes.[258]

After injection, the compound circulates to and localizes within the brain tissues within 1 minute. Scanning of the brain is performed within a few hours of injection[257] with 2- or 3-headed SPECT imaging systems. Data acquisition begins 5 to 10 minutes after injection and is completed in approximately 5 minutes. Image reconstruction is performed with standard filtered back-projection techniques.

Quantification, Accuracy, and Reliability

Even though absolute quantification is possible, semiquantitative techniques are usually performed by comparing counts of radioactivity in a specific region with counts in a comparable, usually homologous region of the opposite normal hemisphere or in a control area, such as the cerebellum. The assumption that the CBF in the opposite, unaffected hemisphere is normal may be incorrect, particularly in patients with chronic cerebrovascular disease or vasospasm. In addition, in the setting of acute stroke, there may be alterations of CBF in distant territories in the ischemic and nonischemic hemispheres that can produce errors in the calculation of such ratios.[259,260] The accuracy and reliability of SPECT CBF have been evaluated through comparisons with other techniques. The relative CBF (rCBF) measured by ECD-SPECT is linearly related to the rCBF measured with perfusion MRI, which in turn is linearly related to absolute CBF as measured by PET. The volumes of hypoperfused brain measured by HMPAO-SPECT correlated significantly with volumes demonstrated by perfusion MRI (LOE: B).[261–263]

Compared with MR and CT, SPECT is a relatively low-resolution technique. Because of high radioactivity counts, large amounts of data can be acquired rapidly, which makes SPECT relatively insensitive to minor head motion.

Applications in Acute Stroke

Patients With No Thrombolytic Treatment

A number of studies have documented the ability of HMPAO-^{99m}Tc SPECT imaging to demonstrate hypoperfusion associated with acute stroke symptoms.[262–280] The sensitivity of this technique to perfusion abnormalities in acute stroke ranged from 61% to 74% and the specificity ranged from 88% to 98% in 2 blinded, prospective, controlled trials (LOE: A).[276] Imaging findings have correlated with infarct size, severity of neurological deficit, and clinical outcome in patients without treatment and with evidence of spontaneous recanalization (LOE: A, B).[263,267–272,279–282] SPECT predicted infarct size, which correlated significantly with infarct size measured by CT.[272] Severe hypoperfusion in the first 6 to 12 hours after symptom onset highly predicted poor neurological outcome (LOE: A).[267–271,282,283] When performed within 72 hours of onset of symptoms, SPECT imaging better predicted short-term outcome than clinical neurological deficit score; if performed later than this, the improved flow due to spontaneous recanalization caused false-negative results.[267] In the first 6 hours after symptom onset, an rCBF threshold of 0.52 on SPECT imaging was found to discriminate between eventual infarction and viability without thrombolysis (LOE: B).[263] Improvement in perfusion caused by spontaneous recanalization correlated with improved clinical outcome (LOE: B).[263,284]

Several studies have included a minority of patients who received thrombolytic treatment. In 1 such study in which most patients were not treated but a minority received streptokinase, SPECT in the first 48 hours of stroke had a

sensitivity of 79% and a specificity of 95% in locating the infarct site as determined by CT at 7 to 10 days after the stroke.[285] In another series of patients, the majority (>60%) of whom received only heparin therapy, semiquantitative SPECT within 6 hours of stroke had a sensitivity of 82% and a specificity of 99% for eventual fatal ischemic edema when an activity deficit of the entire MCA territory was used as the predictor. By comparison, baseline CT sensitivity was 36% and specificity was 100% with hypoattenuation of the entire MCA territory, and the sensitivity and specificity of various clinical predictors ranged from 36% to 73% and from 45% to 88%, respectively.[286] Similarly, count densities above and below 70% of normal distinguished TIA and stroke, respectively, in the first 6 hours after symptom onset with ECD-SPECT in a group of patients, in which 14 of 82 were enrolled in an intravenous tPA trial[285] (overall LOE of these studies: B).

Patients Treated With Thrombolytic Drugs

In patients treated with intra-arterial thrombolysis, the rCBF threshold for reversibility of ischemia was 0.55, whereas the threshold for the development of hemorrhage after treatment was 0.35.[287] These parameters predicted treatment outcome regardless of the duration of the ischemia, the site of vascular occlusion, patient gender, or thrombolytic drug dosage (LOE: B).[287]

Combined HMPAO- and ECD-SPECT have been used within 3 hours after treatment with intra-arterial thrombolysis. Recanalization resulted in normal or increased activity in a previously hypoperfused area with HMPAO-SPECT. Normal activity on ECD-SPECT was seen in patients who recovered neurologically. Decreased activity with ECD was seen in patients with irreversible neurological injury. When decreased activity with ECD was present along with increased activity with HMPAO, patients developed hemorrhage and severe edema (LOE: B).[288] These observations were explained by the theory that HMPAO uptake reflects tissue perfusion only, whereas ECD uptake reflects both perfusion and cellular metabolism[289] (overall LOE: B).

rCBF measured by SPECT also has correlated with clinical outcome in patients treated with intravenous tPA.[265,279] These studies provide evidence for the critical role of collateral circulation to maintain neuronal viability until treatment is initiated. They support the importance of determining the level of perfusion to ischemic tissue in treatment decision making, rather than merely using the time between onset of symptoms and treatment. Demonstration of the extent of tissue viability could permit prediction of treatment response without regard to time from symptom onset. The level of pretreatment perfusion can predict hemorrhagic potential after thrombolytic treatment, guiding the decision to accept the risk of medical recanalization (LOE: A).[265,266,279,288] Comparisons of pretreatment and immediate posttreatment SPECT may also predict long-term clinical outcome. For example, patients who showed perfusion recovery on ECD-SPECT were significantly more likely to be neurologically unimpaired at 3 months after stroke and to have smaller infarcts on CT than patients without perfusion recovery.[289]

Summary

The advantages of SPECT imaging are that it is easy and quick to perform, requiring only an intravenous injection, and it is available in most radiology departments. Widely available software provides CBF images in 3 orthogonal views. Its semiquantitative measurements are simple and can be performed rapidly. Numerous studies have demonstrated that perfusion measured with SPECT correlates with clinical outcome (LOE: A, B).

The disadvantages of SPECT include difficulty in acquiring the kit to prepare the labeled compound on short notice. The data are physiological and not anatomic, such that correlation with either CT or MR acquired at another time must be performed. Overlaying the SPECT on an anatomic CT or MR substrate may be a time-consuming procedure. Compared with CT and MR, SPECT has low spatial resolution. Because arterial concentration of the radioisotope is difficult to obtain, only semiquantitative analysis, such as radioactivity count comparison in analogous regions, is usually possible. Comparison with activity in another area assumes that CBF in the comparison region is normal, which may be inaccurate. Comparison of studies of different patients, performed on different days, or between different institutions requires the use of assumptions that may lead to errors.

Xenon-Enhanced CT

Rationale of Technique and Method of Performance

Xenon is a biologically inert molecule that is used as an inhaled diffusible tracer during CT scanning to provide a measure of brain perfusion. As the patient inhales a 28% to 33% mixture of inert xenon gas, a steady state of xenon is achieved in the brain parenchyma. The CT density changes within the tissues after xenon gas inhalation are used to calculate quantitative CBF values for each voxel at 6 brain levels by use of the Kety-Schmidt equation. A detailed description of the technique has been reported previously.[290]

Quantification, Accuracy, and Reliability

Both animal and human studies have been performed that have demonstrated a strong correlation between normal CBF values acquired with XeCT and other perfusion techniques, including ^{133}Xe and microsphere embolization.[291–294] Studies in animal models and humans with acute cerebral ischemia indicate that XeCT provides accurate CBF values with mild to severe levels of ischemia.[259,293,295]

Applications in Acute Stroke

Identification of Ischemia in Acute Stroke

Firlik and colleagues[295] retrospectively explored the sensitivity of XeCT in the diagnosis of ischemic stroke in 20 patients with MCA territory occlusions who presented within 6 hours of onset and correlated XeCT abnormalities with angiographic findings. In this select population of patients, noncontrast CT scans were abnormal in 55% of patients, and XeCT scans were abnormal in 100% of patients. In the 15 patients who underwent angiography, a mean CBF in the affected vascular territory <20 mL $\cdot$ 100 g^{-1} $\cdot$ min^{-1} was 91% sensitive and 100% specific for an M1 occlusion.

Rubin and colleagues[296] documented transhemispheric diaschisis in the setting of acute cerebral ischemia. They retrospectively analyzed XeCT CBF values in 23 patients studied within 8 hours of symptom onset. The mean CBF in the unaffected hemisphere was 35% less than the normal

mean value and was also significantly decreased in the ipsilateral cerebellum.

Prediction of Prognosis and Clinical Outcome

Rubin et al[297] retrospectively analyzed XeCT findings obtained within 8 hours of symptom onset in 50 patients with hemispheric stroke. CBF values in the symptomatic vascular territory were compared with the contralateral homologous region and correlated with discharge National Institutes of Health Stroke Scale (NIHSS) scores. They found that mild CBF asymmetry (≤20%) correlated with good neurological outcome, whereas severe asymmetry (≥60%) correlated with poor outcome. Outcomes in patients with CBF asymmetries in the range of 20% to 60% were variable.

In the previously cited study by Firlik et al of acute MCA territory strokes imaged within 6 hours of symptom onset with XeCT,[295] they found that a mean CBF of 15 mL · 100 $g^{-1} \cdot min^{-1}$ or lower was significantly associated with the development of severe brain edema and herniation. Sensitivity and specificity of this threshold were 89% and 63%, respectively, for severe edema and 100% and 50%, respectively, for herniation.

In another retrospective analysis, Firlik and colleagues[298] explored whether XeCT CBF measurements could distinguish patients with transient deficits from patients with evolving strokes. They studied 51 patients with acute hemispheric stroke symptoms who underwent XeCT within 8 hours of symptom onset. All 8 of the patients whose deficits resolved without thrombolytic therapy had normal CBF values compared with 42 of 44 patients whose deficits did not resolve and who had abnormal CBF values.

Kilpatrick and colleagues[299] subsequently explored whether XeCT alone or in combination can be used to predict new infarction and functional outcome. They retrospectively identified 51 patients with hemispheric stroke symptoms who underwent CT, CTA, and XeCT within 24 hours of symptom onset at their institution. They found that patients with no infarction on initial CT and normal XeCT CBF had significantly fewer new infarctions and were more likely to be discharged home than those with compromised CBF.

Prediction of Irreversible Ischemia and FIV

Kaufmann et al[300] explored whether CBF thresholds could be identified that predict FIV. They retrospectively analyzed XeCT images from 20 stroke patients with MCA occlusions imaged within 6 hours of symptom onset. In the 12 patients with follow-up CT scans available (obtained between 2 and 41 days after onset), a significant correlation was found between the extent of severe ischemia with CBF ≤6 mL · 100 $g^{-1} \cdot min^{-1}$ and the area of final infarction (Pearson correlation coefficient=0.866). Of note, some patients were treated with intra-arterial thrombolytic therapy.

Rubin and colleagues[301] retrospectively analyzed XeCT findings in 10 patients undergoing thrombolytic (either intravenous or intra-arterial) therapy for acute hemispheric ischemic stroke within 6 hours of symptom onset. In the 9 patients with partial or complete recanalization at angiography after thrombolysis, the follow-up XeCT showed reperfusion of the ischemic brain areas. However, regions with CBF of 0 mL · 100 $g^{-1} \cdot min^{-1}$ at baseline demonstrated infarction on follow-up imaging despite reperfusion.

Jovin et al[302] retrospectively studied XeCT values in 36 patients with MCA stem occlusions imaged within 6 hours of symptom onset; 11 patients were treated with thrombolytic therapy. Using CBF thresholds identified from prior studies, they found marked variability in the percentage of core tissue present but a relatively consistent percentage of penumbra present. However, only the percentage of core present was significantly associated with clinical outcome.

Use of XeCT to Guide Acute Stroke Treatment

The above studies suggest that XeCT has the potential to predict both tissue and clinical outcome in acute stroke, particularly in the subset of patients with large-vessel anterior circulation occlusions. Although it has been proposed that this information, particularly in combination with data from noncontrast CT and CTA, could be useful in therapeutic decision making, no prospective study has been performed to date to test this hypothesis.

Summary

There is a paucity of primary research articles related to XeCT imaging in acute stroke in the literature. The majority of reports have been generated from a single center, with overlap of patients across studies. Most reports were retrospective analyses, generally without a control group available. Additional limitations include small sample size and the use of select patient populations. The LOE across all studies ranges from level C to level B. Current data support the diagnostic accuracy of XeCT for determining quantitative CBF values in acute stroke. Although retrospective case series support the use of XeCT to improve efficacy in diagnosis and therapeutic management, prospective validation studies are needed to demonstrate this. No data exist to date that address the role of XeCT to improve patient outcome or to show its cost-benefit ratio in treatment. An important task for future research will be to compare the clinical utility of XeCT in combination with NECT and CTA with multimodal MR and multimodal CT approaches.

CT Perfusion

Rationale of Technique

In the emergency assessment of acute ischemic stroke, the complete CTP examination has 3 components: (1) NECT, (2) vertex-to-arch CTA, and (3) dynamic first-pass cine CTP, performed over 1 or 2 slabs of tissue.[20,21] Importantly, the source images from the whole-brain CTA vascular acquisition (CTA-SI) provide clinically relevant data concerning tissue-level perfusion. Assuming an approximately steady state level of contrast in the intracranial arteries and capillaries, CTA-SI is predominantly CBV weighted rather than CBF weighted.[303–305] Although the CTA-SI images can be viewed qualitatively, coregistration and subtraction of the conventional NECT brain images from the CTA-SI images results in quantitative blood-volume maps of the entire brain.[305–307] The subsequent dynamic CTP examination with cine acquisition measuring the first pass of a contrast agent in 1 or 2 regions of interest (tissue slabs) produces quantitative CBF, MTT, and CBV maps.

Method of Performance

Data Acquisition

CTA with CTP is fast,[20] increasingly available,[306] safe,[308] and affordable.[309] It typically adds no more than 5 minutes to the time required to perform a head NECT and does not delay intravenous thrombolysis, which can be administered, with appropriate monitoring, directly at the CT scanner after completion of the NECT.[20,21,71,306,308,310–334] Immediate interpretation of the vascular anatomy is aided by reformatting the images in thick (2 cm) axial, coronal, and sagittal sections.

The following is a typical sample protocol: An 18- or 20-gauge cannula is positioned in an antecubital vein; patients are monitored during scanning, which enables intravenous thrombolysis to be started on the CT table after the NECT is completed through a separate intravenous catheter (which is important to avoid inadvertent rtPA administration). CTA is acquired immediately after NECT, from the vertex to aortic arch, with semiautomated threshold-based triggering of the administration of 105 mL of low-osmolar, nonionic contrast agent, infused at 4 mL/s with a saline push power injector. Dynamic CTP is performed next, which requires an additional 45 to 60 seconds of scanning time, as well as an additional 40 to 50 mL of contrast per slab over what is needed for CTA. This small contrast bolus is administered at 4 to 7 mL/s during continuous cine imaging over a single brain region that is started 5 seconds after the start of the infusion. With most scanners, 2 to 4 cm of coverage per bolus is obtained (5- or 10-mm-thick slices).[310,313,322] Some centers routinely obtain 2 slabs, which requires an additional bolus of 40 mL of contrast, to double the coverage, as advocated by Wintermark et al.[333] Although CTP can be performed on even early-generation multidetector CT scanners, the newer 16- and 64-slice machines provide faster, more complete coverage. Imaging parameters are 80 kilovolts (peak) [kVp], 200 mA, and 1-second rotation time. At least 1 imaged slice must include a major intracranial artery for CTP map construction. The scan plane is angled along the superior orbital roof. CTA-SI data are available immediately before the CTP acquisition, to locate the region of abnormal perfusion and to guide the choice of imaging plane through that region.

Contrast Safety and Radiation Dose Considerations

Unlike DWI/MRP, CTA/CTP requires ionizing radiation and iodinated contrast. The safety issues involved are no different from those of any patient group receiving contrast-enhanced head CT scanning.[307,310,335] The recommended scanning parameters for CTP (specifically, 80 kVp and approximately 200 mA) have been optimized to provide maximal perfusion signal with minimal radiation dose.[310] It has been estimated that a 2-slab CTP deposits only a slightly greater radiation dose than a routine unenhanced head CT, or approximately 3.3 mSv.[310,336] Hardware and software innovations have the potential to further reduce this dose to as low as 0.85 to 1.85 mSv with currently available scanners and postprocessing tools.[337]

Modern iodinated CT contrast agents have been shown not to worsen stroke outcome.[338–340] Most centers performing stroke CTA/CTP call for the use of low or iso-osmolar contrast to minimize the risk of contrast-induced nephropathy. It has been suggested that iso-osmolar contrast agents (≈300 mOsm) have an improved safety profile over that of high-osmolar contrast agents, even for high-risk diabetic patients with baseline creatinine of ≈1.9 mg/dL (range 1.5 to 3.5 mg/dL) who are undergoing high-dose procedures such as aortofemoral angiography.[341] It has additionally been suggested that low-osmolar contrast agents (<600 to 800 mOsm) have a similar safety profile.[342] The mainstay of contrast-induced nephropathy prevention is adequate preprocedure and postprocedure hydration, up to 12 hours before and after contrast administration, if possible, especially given that mannitol and diuretics have not proved beneficial in the prevention of contrast-induced nephropathy.[343]

Reconstruction and Postprocessing

Although postprocessing of CTA and CTP images is more labor intensive than that of MRA and MRP, with training and quality control, 3-dimensional reconstructions of CTA data sets, as well as quantitative CTP maps, can be constructed rapidly and reliably.[344–346] Indeed, newer-generation CTP reconstruction software holds the promise of being truly turn-key (M.H. Lev, written communication, December 2005). Moreover, because CTA-SI maps consist only of the raw data from the CTA acquisition, no postprocessing is involved.[20,72,73,347]

The first-pass CTP cine source images are transferred to a freestanding workstation and analyzed with commercially available deconvolution-based software to create quantitative maps of CBF, CBV, and MTT. The deconvolution-based software requires the user to select multiple input variables. In 1 small study, major variations of either arterial region-of-interest placement or arterial and venous region-of-interest size had no significant effect on the mean CBF, CBV, and MTT values at the infarct core ($P<0.05$). Even minor variations, however, in the choice of venous region of interest placement or in preenhancement and postenhancement cutoff values significantly altered the quantitative values for each of the CTP maps by as much as 3-fold.[346] Awareness of these results by clinical imagers may be important in the creation of quantitatively accurate CTP maps.

Quantification, Accuracy, and Reliability

CTP Image Review

Eastwood et al[334] showed good κ-Pearson correlation between readers for extent of CBF abnormality (0.94, $P=0.001$); intraobserver variation was 8.9% for CBF abnormalities. In another study, raw data derived from dynamic CTP examinations performed in 20 subjects were postprocessed 7 times by 3 experienced CT technologists.[344] The authors concluded that although there was a high degree of correlation between parenchymal regions of interest derived from CTP maps generated from the same dynamic source data postprocessed by different operators, the level of agreement may not be sufficient to incorporate quantitative values into clinical decision making. It is likely, however, that with optimization of postprocessing parameter selection, the degree of variability may be reduced substantially.[344] There have been continued efforts toward the development of practical automated and semiautomated imaging tools for interpretation of CTP images.[347] CTP software is being distributed with new CT scanners, and is being used as part of

the phase III DIAS trial in which mismatch between CTP and the noncontrast CT abnormality is a selection criterion.

CTP Validation and Penumbral Measurement

The creation of accurate, quantitative CTP maps by the deconvolution method has been validated in a number of studies.[313,321-323,332,348-351] Specifically, validation has been accomplished by comparison with XeCT,[332,352] PET,[353] and MRP,[69,354-357] both in humans and with microspheres in animals.[313,321,323] However, 1 study found the correlation between MRP and PET perfusion values to be less reliable than expected.[358] CTP has greater spatial resolution than MRP and more readily lends itself to quantification. MRP may also be more sensitive to contamination by large vascular structures. These factors may contribute to the possibility that visual assessment of core/penumbra mismatch is more reliable with CTP than with MRP.[359,360] Of note, if vascular pixels are excluded from the calculation of CT-CBF, quantification of mean CBF is highly accurate compared with values obtained with $H_2{}^{15}O$ PET.[361]

Applications in Acute Stroke

Tissue Outcome

CTA-SI

It has been hypothesized that CTA-SI, like DWI and CBV, can specifically detect infarct core (ischemic regions likely to be irreversibly infarcted despite recanalization) and can therefore be used to define a worst-case lower limit to final infarct size.[21,72,311] Also, like DWI, a time-dependent threshold for these blood volume changes has been observed, and reversal can and does occur in the setting of early complete recanalization.[65,362,363] CTA-SI is important for the CT evaluation of stroke, because as opposed to quantitative CTP, it is a series of images of the whole brain and hence may be useful in extrapolating regional tissue CTP models to the entire brain.

In a study of 22 consecutive patients with MCA stem occlusion who underwent intra-arterial thrombolysis within 6 hours of stroke onset, it was found that with early complete recanalization, CTA-SI lesion volume approximated that of the follow-up scan, whereas in the absence of recanalization, there was significant lesion growth. Moreover, an admission CTA-SI lesion volume of <100 mL (coincidentally, approximately one third the volume of the MCA territory) reflected the break point between patients expected to have a good or fair outcome on follow-up modified Rankin score (depending on degree of recanalization) versus poor outcome despite complete recanalization (those with a volume >100 mL). The strength of the association between CTA-SI lesion volume and outcome was stronger than that between NIHSS score and outcome.[21]

A more recent study of 37 consecutive anterior circulation stroke patients imaged <6 hours after ictus has confirmed and expanded on these results. In patients with major reperfusion, mean CTP-CBV and CTP-SI infarct size closely predicted final infarct size; review of the CTP source images was more accurate at identifying the extent of reversible and irreversible ischemia and at predicting final clinical outcome than review of the unenhanced CT or CTA-SI.[347]

CT Perfusion

A recent study sought to determine whether CTP-CBF thresholds for distinguishing benign oligemia from nonviable penumbra could be established.[247] The authors studied a homogeneous population of 14 intra-arterial lysis patients within 8 hours of stroke onset, performing separate region-of-interest analyses for gray versus white matter, and reported both relative and absolute threshold results. They concluded that normalized or relative CTP-CBF (rCBF) is the most robust parameter for distinguishing benign oligemia from nonviable penumbra (assuming that the normalization accounts for the variable gray-to-white matter ratio within the ischemic region of interest, because gray and white matter have different baseline CBF values, a conclusion that has recently been underscored in the MRI literature as well[364]). When the recanalization versus no-recanalization groups were compared, ischemic regions with >66% reduction in CTP-CBF, normalized to contralateral mean values, had >95% positive predictive value for infarction (95% specificity), despite the presence of robust recanalization, and ischemic regions with <50% reduction in CTP-CBF had >90% positive predictive value for survival (95% sensitivity), despite the absence of robust recanalization.[247]

These preliminary thresholds—>66% reduction in CBF for nonviable penumbra and <50% reduction in CBF for benign oligemia—may predict the upper and lower limits of final infarct size in a more precise manner than is currently possible with DWI/MR-MTT mismatch. Additionally, the authors found that the visual threshold for identification of the CTP-CBV core corresponded to a 75% reduction in CTP-CBF.[247] The visually evident CTP-CBV lesion (along with the CTA-SI lesion) is therefore likely to infarct, because it is associated with CTP-CBF reductions below the threshold for nonviable penumbra. Another recent study has suggested a quantitative threshold of CBV <2 mL/100 g as being highly accurate for determination of infarct core, and a relative CTP-MTT increase of >150% as being accurate for defining the at-risk penumbra.[365]

Clinical Outcome: CTA/CTP

The penumbra is dynamic, and several factors influence its fate, including time since stroke, residual and collateral blood flow, admission glucose, temperature, hematocrit, systolic blood pressure, and treatment, including normobaric hyperoxia.[366] It is technically challenging to measure the penumbra. Despite this, a number of consistent messages emerge from a review of the literature regarding outcome prediction in acute ischemic stroke with various imaging parameters. One such message is that a determination of the volume of the core is critical. In cases of successful recanalization, multiple studies have found that clinical outcome is strongly correlated with admission core lesion volume, be it measured by DWI, CTP-CBV, CTA-SI, XeCT-CBF, or unenhanced CT.[302,367-371]

A second is that bolus-tracking techniques, such as dynamic MRP, sensitively identify the region at risk for infarction, correlate better than core with admission NIHSS, but in general overestimate the final infarct and lack specificity.[248-250] In a recent study, the correlation between the degree of MR diffusion/perfusion mismatch volume and DWI expansion was not found to be statistically significant.[244] Like DWI/MRP imaging,

CTA-SI/CTP has the potential to serve as a surrogate marker of stroke severity, possibly exceeding the NIHSS or ASPECTS scores as a predictor of outcome.[44,45,51,230,311,372–375] A report suggested that multimodal CT evaluation improves detection rate and prediction of the final size of infarction compared with NECT, CTA, and CTP alone.[376] Nabavi et al,[377] using a very simple approach, were able to create a surprisingly accurate CTA-SI/CTP–based stroke scale score predictive of NIHSS, called the MOSAIC (Multimodal Stroke Assessment Using Computed Tomography) score. The MOSAIC score, a number ranging from 0 to 8 that reflects the sum of the scores for these components, was a stronger predictor of final clinical outcome at 3 months (modified Rankin score and Barthel Index) than were any of the individual components alone, or the NIHSS score.

Evidence Supporting the Use of CTP in Acute Stroke Imaging

Many of the studies cited in this section reflect level C evidence, with some of the larger prospective trials being of B level.

Summary

Compared with MRP, CTP has advantages of speed, low cost, and most importantly, widespread availability. CTP parameters of CBV, CBF, and MTT can be more easily quantified than their MRP counterparts, owing in part to the linear relationship between iodinated CT contrast concentration and resulting CT image density (expressed in Hounsfield units), a relationship that does not hold for gadolinium concentration versus MRI signal intensity. However, as with other bolus-tracking techniques, quantification is dependent on the deconvolution method to calculate CBF based on a comparison of the tissue curve with the arterial input function. Because of its availability, simpler methodology, and greater degree of quantification, CTP has the potential to increase patient access to new treatments and imaged-based clinical trials. Pilot studies have suggested that the mismatch between ischemic lesion size on admission CTP-CBV (or CTA-SI) and CBF maps can be used much like MR DWI/MRP mismatch to operationally identify salvageable brain tissue in the acute stroke setting. CTA also has the potential to rapidly and accurately localize the vascular source of stroke to identify appropriate candidates for recanalization. In addition, hypodense regions on the source images from the CTA (CTA-SI) reflect reduced CBV that denotes tissue that is difficult to salvage with reperfusion (core). These CTA-SIs cover the entire brain volume, require no postprocessing, and are available immediately at scan completion.

A current disadvantage of CTP is limited coverage, typically a 2- to 4-cm-thick slab per contrast bolus depending on the manufacturer and the generation of multidetector CT scanner used. The many contraindications to MRP in acute stroke patients, such as difficulty scanning patients on monitors or ventilators, presence of pacemakers or implantable defibrillators, aspiration with long periods supine, and inability to obtain a history to rule out metallic implants, do not exist with CT.

The ultimate goal of acute stroke treatment is to minimize neurological deficit and maximize functional outcome. Because of the superior quantitative capability of CT, as opposed to MRP imaging, application of specific CTP CBF and CBV thresholds to predict tissue survival or infarction appears promising. Because smaller studies have suggested that the calculated volume salvaged by reperfusion is correlated with improvement in NIHSS, it is essential that these thresholds be validated in larger patient cohorts for which reperfusion status is known.

MR Perfusion

Rationale of Technique

Preliminary studies exploring the use of perfusion-weighted MRI (PWI, or MRP, which has been used throughout the present statement) in acute ischemic stroke have suggested its utility in predicting lesion growth and clinical outcome. Baird et al[378] demonstrated that most patients with a perfusion/diffusion mismatch (hypoperfusion volume greater than DWI ischemic lesion volume) have a significant increase in infarct volume over time if no increased perfusion occurs, whereas patients without a mismatch have no subsequent growth in infarct size. Without recanalization, baseline volumes of hypoperfusion were found to have better correlation with the size of the final infarct than baseline lesion volumes on DWI.[379,380] Particularly in the hyperacute setting, an ischemic region on MRP may be present even in the absence of an acute lesion on DWI, which further emphasizes the potential utility of MRP in identifying tissue at risk.[379] Baseline volumes of hypoperfusion by MRP have also been shown to correlate better with clinical scales at baseline or outcome than do lesions on baseline DWI.[379–381] Investigations of the best MRP analytical method focus on identifying the highest correlation of ischemic volume with acute clinical deficits (symptomatic hypoperfusion) or with the volume of the infarct that becomes defined over time (tissue at risk).

Method of Performance

Magnetic susceptibility effects, as defined by the MR parameter T2*, are due to metals, blood products, air, and other substances that produce local magnetic field variations or gradients, which lead to proton dephasing and intravoxel signal loss. After a contrast agent containing a heavy metal, such as gadolinium or dysprosium from the lanthanide group, is injected into the bloodstream, it passes rapidly through the microvasculature to produce local signal loss equal to the size of the blood vessel and usually an additional capillary radius beyond that vessel. Gradient-echo imaging is particularly effective at detecting T2* effects, and a high-speed, multislice gradient-echo technique that uses a single radiofrequency input or shot, such as echoplanar imaging, is capable of obtaining thin imaging slices through the entire brain every second that are T2* sensitive.[382,383]

Typically, images are obtained every 1 to 2 seconds. Baseline images without contrast are acquired over approximately 40 seconds before the injected contrast agent arrives, followed by sequential imaging over the next minute as the contrast moves rapidly through the vasculature. Signal intensity–versus-time curves can be determined for each voxel. Theoretically, the area under the curve closely approximates CBV, whereas the full width of the curve at one half of its maximum value (FWHM) is proportional to MTT. The ratio of the 2 yields CBF. These are all relative values, because the signal intensity is not linearly related to the volume of contrast in the vasculature (in CTP, there is a linear

relationship to the density measured by the CT scanner and the volume of the iodinated contrast agent in the vasculature). For more accurate quantification, an arterial input function is a necessary component, but this is not an easy parameter to measure with MR. Direct determination of the concentration of the paramagnetic contrast agent in a small vessel such as an MCA is not trivial, and it is difficult to measure the signals from a large vessel such as the ICA that may be outside the scanning volume. However, there are mathematical models that allow the arterial input function to be deconvolved from the tissue concentration–versus-time curve to estimate the arterial input function and produce multiparametric perfusion maps, similar to the methods used for CTP.[54,382,383]

As with CTP, the echoplanar imaging data are transferred to a separate workstation on which the perfusion maps are produced. Data derived from the diffusion-weighted sequence are used to construct apparent diffusion coefficient maps. These diffusion and perfusion maps are then compared to produce a perfusion/diffusion map, to look for a mismatch that might indicate the presence of ischemic but salvageable tissue.

The major advantages of MRP over CTP include whole brain coverage, speed of acquisition of many data points per voxel, and its inclusion in a package of imaging sequences that effectively evaluate many aspects of the parenchyma, including the presence of ischemia with DWI. The vasculature can also be evaluated with MRA. The disadvantage is the lack of linearity between signal intensity and contrast concentration, which makes quantification very difficult, and thus, no absolute value of perfusion is available for clinical decision making. Instead, regions of interest on relative maps must be compared as surrogates for absolute data.[54,382,383]

Relative Quantification, Accuracy, and Reliability

Preliminary Studies Evaluating MRP Thresholds

To achieve the goal of predicting infarct evolution and clinical outcome, different thresholds of MRP parameters have been proposed to identify tissue at risk of infarction. Acute hypoperfusion volumes derived from a variety of analytical approaches have been found to be predictive of tissue outcome. Schlaug et al[243] found that a reduction in initial relative CBV (rCBV) to 47% of the contralateral control region and a reduction in rCBF to 37% of the contralateral control region characterized the ischemic penumbra, which they operationally defined as the region between the initial diffusion abnormality (core) and its extension as seen on the 24- to 72-hour follow-up DWI study. A more severe reduction in these perfusion parameters was proposed as the threshold that fit the ischemic core. Other groups have proposed different MRP thresholds to differentiate ischemic penumbra from benign oligemia or ischemic penumbra from core. Neumann-Haefelin et al[254] found that a time to peak (TTP) delay of ≥6 seconds was predictive of lesion enlargement at 6 to 10 days after stroke, whereas Parsons et al[384] and Thijs et al[385] found that MTT delays between 4.3 and 6.1 seconds and >4 and <6 seconds, respectively, predicted tissue that progressed to infarction. Shih et al[386] instead sought to differentiate irreversibly infarcted core tissue from penumbral tissue despite early recanalization by thrombolysis. Using an adjusted TTP of the residue function (T_{max}), they found that T_{max} ≥6 and ≤8 seconds correlated best with FIV at day 7.

Which MRP Method Is the Most Accurate?

Further investigations of perfusion MR in larger series of patients have continued to demonstrate that these different MRP methods are, on the whole, predictive of FIV and clinical outcome, variably defined; however, they have not resulted in a consensus as to which perfusion parameter is the most accurate predictor of tissue fate and clinical outcome. Individual centers have prospectively accumulated their own case series and retrospectively analyzed the imaging data with different perfusion postprocessing techniques. Thus, CBF, MTT, TTP, and CBV parameters may not be directly comparable between studies because different analytic models have been used to derive nominally the same parameter, and different image-acquisition techniques (eg, spin echo versus gradient echo) have been used. Furthermore, patients studied have varied both within and between reports with respect to vessel status, ie, recanalization versus persistent occlusion, or thrombolytic treatment, factors that could affect stroke evolution and thus the evaluation of MRP as a predictor of stroke outcome. All of these variations have made it difficult to compare the relative accuracy of the methods, and direct comparisons of different methods on the same sample of patients are lacking. Notwithstanding the lack of a validated best method, a variety of perfusion MRI techniques (eg, CBF, CBV, and MTT) reveal volumes of hypoperfused brain that correlate variably with clinical severity and outcomes. The following review includes studies with sample sizes of >30 patients to summarize the current state of knowledge of the utility of perfusion MR in acute stroke.

1. MRP Volumes as Predictors of FIV and Outcome. Schellinger et al,[387] in studying 51 acute stroke patients with MRI within 6 hours of symptom onset, almost half of whom received thrombolytics, found only a small correlation between acute diffusion and perfusion lesion volumes and both acute and day 90 NIHSS scores. For DWI, these correlations were better in the subgroup of patients who had recanalized by day 2 than in those who had not, whereas the opposite was true for MRP. In that study, MTT perfusion maps were calculated as the normalized first moment of the concentration/time curve. On the basis of their findings, they concluded that hyperacute DWI and MRP may not represent the true baseline or severity of clinical outcome but instead the potential best-case (and worst-case) scenarios, depending in part on early recanalization.

However, many other groups have found a strong correlation between acute MRP values and clinical outcome, as well as FIV, although imaging was often performed up to 24 to 48 hours after symptom onset in patients who did not receive thrombolytics. Karonen et al[261] compared MRP rCBF maps, correlated to SPECT as the reference standard of measuring CBF, and FIV, defined as DWI lesion volume at 1 week, in patients who did not receive thrombolytics. In 46 patients, half of whom also underwent SPECT, they found that acute MRP volumes of hypoperfusion had a statistically significant correlation with FIV and with acute SPECT

hypoperfusion volumes performed on the same day as the MRP. In a subsequent study,[280] they compared different MRP parameters (rCBV, rCBF, and MTT) with the FIV in 49 patients, none of whom had received thrombolytics. All of the MRP maps correlated significantly with the FIV. The best correlation was found with the initial rCBV volume, whereas the rCBF and MTT maps tended to overestimate the final infarct. Schaefer et al[388] and Kluytsmans et al[389] also found rCBV to be the best predictor of FIV when comparing different MRP parameters in patients who had not received thrombolytics. The presence of an rCBV-DWI mismatch was also the best predictor of lesion growth compared with an rCBF-DWI or MTT-DWI mismatch.[278,388,389] Furthermore, rCBV correlated better with clinical outcome, measured by 4-month NIHSS, modified Rankin scale, and Barthel index, than did MTT.[389] The presence or absence of spontaneous recanalization was not assessed in these studies.

2. Is There an MRP Threshold Value That Is Most Predictive of Lesion Growth and FIV? Different groups have used different perfusion mapping techniques in an attempt to retrospectively identify a perfusion threshold that best predicts final infarct size on follow-up T2-weighted imaging, although again, there is no consensus on which threshold to use. In evaluating different thresholds of perfusion delay on TTP maps of 50 stroke patients within 24 hours of symptom onset, Wittsack et al[390] found through volumetric analysis that a TTP delay >6 seconds best correlated with final infarct size as measured on days 6 to 11 and was particularly useful <4 hours after symptom onset, when DWI was less reliable in demonstrating the full extent of the ischemic territory. Although other perfusion maps were calculated, they were not included in the volumetric analysis. Butcher et al[17] explored potential thresholds for infarcted versus salvageable tissue on MTT, rCBF, and rCBV maps in 35 patients, half of whom were treated with intravenous thrombolysis. Evidence of reperfusion was also assessed. They found a difference in relative MTT and rCBF values, but not rCBV, in infarcted versus salvaged tissue, although there was significant overlap. Furthermore, early reperfusion allowed more severely hypoperfused tissue to be salvaged. Therefore, an absolute perfusion threshold could not be demonstrated with any of the techniques studied, because the perfusion thresholds for infarction depended on time to reperfusion.

Thomalla et al[234,391] chose to use a TTP delay of >4 seconds ($TTP_{>+4s}$) to retrospectively identify a perfusion volume threshold within 6 hours of symptom onset that could predict the development of malignant MCA infarction. A $TTP_{>+4s}$ >162 mL had 83% sensitivity and 75% specificity for predicting malignant MCA infarction. Fiehler et al[392] chose instead to evaluate a CBF threshold of $\leq 12\ mL \cdot 100\ g^{-1} \cdot min^{-1}$ (CBF_{12}), derived from the PET literature, and found that a relative CBF_{12} tissue volume ≥50 mL within 6 hours of symptom onset was predictive of further lesion enlargement.

Although different absolute perfusion thresholds and perfusion volume thresholds have been correlated with FIV and lesion growth, the best method has yet to be identified. However, time to reperfusion will be an important factor to take into consideration when this determination is being made.

Applications to Acute Stroke Therapy

Because MRP provides important pathophysiological information in acute stroke, MRP in concert with DWI has the potential to guide patient selection for acute stroke treatment and serve as a potential imaging surrogate end point in clinical trials. It is understood that although they are based on physiology, these imaging techniques provide an operational methodology at a given point in time for patient selection to a management protocol. For this purpose, the simplest model of the tissue at risk, the qualitative diffusion/perfusion mismatch, which is highly predictive of lesion growth, may be adequate.[256,378]

Through their retrospective analysis, Derex et al[393] suggested the use of MRP and DWI along with site of vessel occlusion to guide treatment. They obtained MRIs in 49 patients within 6 hours of symptom onset before intravenous thrombolysis; 47 of these patients had an intracranial large-vessel occlusion by MRA, and patients with extracranial ICA stenosis were excluded. TTP maps were used to measure perfusion lesion volumes. Patients with intracranial ICA occlusion had significantly larger pretreatment perfusion defects and perfusion/diffusion mismatch volumes. Differences in rCBF and peak height values between the ischemic focus and an analogous region in the contralateral hemisphere were also significantly higher in patients with intracranial ICA occlusions than in those with more distal occlusions, whereas MTT, TTP, and CBV difference values did not distinguish among the sites of arterial occlusions. Patients with intracranial ICA occlusions also had a lower recanalization rate after thrombolysis than those with more distal occlusions, and they had worse clinical outcomes. The hemodynamic information gained from acute MRI, including perfusion and site of vessel occlusion, could be used to identify patients in whom intra-arterial therapy alone or combined intravenous and intra-arterial therapy may be necessary to achieve recanalization. Sunshine et al[238] applied this use of multimodal MRI prospectively for treatment selection in 35 patients within 6 hours of symptom onset. Patient management was guided primarily by evidence of large-vessel occlusion; in addition, the treatment of 2 patients was determined by the demonstration of hyperperfusion on MRP, and these patients were managed conservatively.

In addition to having the potential to identify appropriate patients for treatment, MRP along with DWI has been used as a surrogate marker of outcome in phase II trials to signal efficacy. With the use of serial MRIs, including MTT maps with a threshold delay >4 seconds, Barber et al[394] demonstrated in 49 acute ischemic stroke patients that major reperfusion and infarct expansion are associated with clinically significant changes in outcome. On the basis of their results, they calculated theoretical sample sizes that would be necessary for phase II stroke therapy trials to demonstrate proof-of-concept to determine whether a larger phase III trial should be pursued.

An early reperfusion response on MTT has been found to be predictive of clinical recovery with standard intravenous tPA therapy. Chalela et al[395] found that the strongest independent predictor of excellent outcome in multivariate logistic regression analysis was improved brain perfusion 2 hours after treatment,

assessed as a decrease of >30% in the volume of hypoperfusion on MTT maps. This criterion of early reperfusion was a stronger predictor of clinical outcome than patient age or baseline clinical severity measured by the NIHSS, 2 clinical variables that are highly predictive of outcome. Thus, with the administration of a clinically effective thrombolytic therapy, early reperfusion by MRP predicted clinical recovery.

This use of perfusion with diffusion MR as a selection variable and as a surrogate outcome measure was applied in the DIAS phase II trial.[8] It was the first prospective, randomized, placebo-controlled thrombolytic stroke trial to use MRI both to determine patient eligibility and as a primary efficacy end point. A diffusion/perfusion mismatch by visual inspection was an inclusion criterion for this trial, which involved 104 patients within 3 to 9 hours of symptom onset. A primary efficacy end point was the rate of reperfusion on MRI after 4 to 8 hours, defined as either ≥30% reduction of MTT lesion volume or ≥2 points of improvement on the adapted Thrombolysis In Myocardial Infarction (TIMI) grading scheme with MRA. This trial demonstrated that intravenous desmoteplase was associated with a higher rate of early reperfusion and better 90-day clinical outcome in the patients selected for treatment than in the placebo group.

Summary

Although widely accepted and used in practice, the diagnostic and clinical utility of perfusion MRI has not been proven in controlled, adequately powered studies. Descriptive case series and studies of the relationship of MRP parameters to other clinical, imaging, and therapeutic variables have shaped the concepts and hypotheses about its potential utility (LOE: B, C). The identification and response to treatment of the ischemic penumbra pattern when defined as a simple diffusion/perfusion mismatch may be the most useful application of perfusion MR, both for patient selection and as an outcome measure in clinical trials. Individual centers have demonstrated that different MRP parameters are generally predictive of tissue fate and clinical outcome; however, despite these different methods already being applied, there has been no determination of which technique is most accurate. Contributing to the lack of consensus is the variability in definitions of what represents ischemic core, penumbra, final infarct size, and clinical outcome on which the measures of accuracy are based. Furthermore, time to reperfusion affects these parameters and is an integral component in the evaluation of all MRP methods, yet it often is not taken into account. To progress toward a consensus on the optimal perfusion MR technique to use in the diagnosis and management of acute ischemic stroke, it is imperative that multicenter, prospective, systematic trials be conducted to fully evaluate this promising tool.

Summary of Perfusion Imaging Techniques

1. SPECT: In terms of making decisions as to whether to perform thrombolysis, and in terms of patient outcome, perfusion from collaterals to the ischemic region may be as important a variable as time from ictus (LOE: A).
2. XeCT: Quantification appears to be important in predicting patient outcome. CBF thresholds and volume of infarction determined by these thresholds correlate with outcome (LOE: B).
3. Although CTP is more easily quantified than MRP, the accuracy of that quantitation is still being debated (LOE: B).
4. Normalized quantitative thresholds as determined by CTP, which differentiate potentially viable and nonviable ischemia within the penumbra, are similar to the relative threshold values found with SPECT (LOE: B).
5. The core of initial infarction is determined similarly with DWI, CTP-CBV, CTA-SI, and XeCT CBF <12 mL · 100 g^{-1} · min^{-1} (LOE: B).
6. With successful recanalization, outcome strongly correlates with the volume of the initial core of infarction. The threshold of 100 mL, as found in CTP studies, is approximately one third of the MCA territory, as found in older tPA clinical studies. Patients with infarctions equal to or greater than that size tend to have poor outcomes (LOE: A).
7. A combination of values derived from dynamic CT studies, reflecting size of initial core and volume of salvageable tissue, may predict clinical outcome with successful recanalization better than clinical parameters (eg, NIHSS) alone (LOE: B).
8. MRP is difficult to quantify because of a lack of a linear relationship between contrast agent concentration and signal intensity (LOE: B).
9. There are a variety of MRP maps; which one best predicts tissue fate and clinical outcome is still being debated (LOE: B).
10. A combination of MRA, DWI, and multiple MRP parametric maps can be used operationally to select patients for acute therapy (intravenous versus intra-arterial thrombolysis versus mechanical thrombectomy versus conservative management; LOE: B).
11. Diffusion/perfusion mismatch (the specific perfusion map in debate) may be used to select the appropriate patient for thrombolysis, especially within the patient group that is >3 hours after ictus (LOE: B).
12. Changes in MRP (specific map still in debate) may serve both as a surrogate marker of treatment efficacy and a predictor of clinical outcome. Changes in dynamic CTP data may serve the same functions (LOE: B).

Recommendations

Perfusion-Derived Values

Quantitative thresholds of tissue that is dead or destined to die versus tissue that is still living and may be salvageable are the goal of all perfusion techniques. Although the performance of such studies may be considered to identify and differentiate the ischemic penumbra and infarct core, their accuracy and usefulness have not been well established (Class IIb, LOE: B).

Clinical Role of Perfusion Imaging

1. The admission volumes of infarct core and ischemic penumbra may be significant predictors of clinical outcome, possibly exceeding the prognostic value of admission NIHSS score (Class IIb, LOE: B).
2. There is increasing but as yet indirect evidence that even relatively imprecise measures of core/penumbra mismatch may be used to select patients for treatment beyond a strict 3-hour time window for intravenous thrombolysis. Together with vascular imaging, these approaches may determine suitability for other therapies such as mechanical clot retrieval and intra-arterial thrombolysis, as well as provide a surrogate marker for treatment efficacy (Class IIb, LOE: B).

Disclosures

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Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Ownership Interest	Consultant/Advisory Board	Other
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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Deceased.

‡Significant.

Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
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KEY WORDS: AHA Scientific Statements ■ stroke ■ tissue plasminogen activator ■ computed tomography ■ magnetic resonance imaging ■ stroke, acute ■ stroke, ischemic ■ ultrasonography

Stroke
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Recommendations for Imaging of Acute Ischemic Stroke: A Scientific Statement From the American Heart Association

Richard E. Latchaw, Mark J. Alberts, Michael H. Lev, John J. Connors, Robert E. Harbaugh, Randall T. Higashida, Robert Hobson, Chelsea S. Kidwell, Walter J. Koroshetz, Vincent Mathews, Pablo Villablanca, Steven Warach and Beverly Walters
on behalf of the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, and the Interdisciplinary Council on Peripheral Vascular Disease

Stroke. 2009;40:3646-3678; originally published online September 24, 2009;
doi: 10.1161/STROKEAHA.108.192616
Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0039-2499. Online ISSN: 1524-4628

JEMS
JOURNAL OF EMERGENCY MEDICAL SERVICES

'Time Is Brain' in Prehospital Stroke Treatment

Monday, June 4, 2012
W. Ann "Winnie" Maggiore, JD, NREMT-P

You're called to the home of a 55-year-old female because of a fall. On arrival, you find her sitting up in a chair in her living room, which smells strongly of cigarette smoke. She stares at you blankly when you attempt to question her about what happened. Her husband tells you he was in another room when he heard a thump and that he found her on the living room floor. He says he was able to move her into a chair, but says she has been unable to tell him what happened.

The patient's blood pressure is 200/110; her pulse is 88, strong at the radial but irregularly irregular. You administer oxygen and start an IV. Her husband tells you she takes a "blood pressure pill," but her medications are nowhere to be found. She's able to follow your commands, but now when she tries to speak, her words are garbled. You suspect she's suffered a stroke.

Types of Strokes

Stroke, or cardiovascular accident (CVA), represents a serious medical condition in which

the blood supply to areas of the brain is interrupted, resulting in ischemia. There are two basic types of strokes: ischemic and hemorrhagic. The majority of CVAs (87%) are ischemic.

In ischemic stroke, a blood vessel is blocked. The tissue distal to the blockage becomes ischemic and will eventually die if blood flow isn't restored. Reperfusion therapy is the goal of treatment for ischemic stroke. The extent and severity of the stroke will be dictated by the location of the blockage. An ischemic CVA in the brainstem is a life-threatening condition.
In contrast, the other 13% of strokes are caused when a blood vessel in the brain ruptures, causing bleeding into the surrounding tissue. Fibrinolytic therapy is contraindicated.

Hemorrhagic stroke tends to worsen over time due to bleeding within the cranium. The bleeding increases intracranial pressure (ICP) and leads to brainstem herniation. One hallmark of a hemorrhagic CVA is a patient who complains of "the worst headache of my life."

Incidence & Risk Factors
Each year, about 795,000 Americans have either a new or recurrent stroke. Every 40 seconds, someone in this country suffers a stroke. Stroke kills more than 137,000 people each year; every four minutes someone in the U.S. dies from a stroke.

It's the fourth leading cause of death and the leading cause of disability in adults in the U.S. Approximately 40% of stroke deaths occur in males and 60% in females. Although men have more CVAs, women die of them more often.

Stroke falls under a larger classification of cardiovascular disease. The American Stroke Association (ASA), a division of the American Heart Association, is now heavily focused on stroke prevention and has identified numerous risk factors for stroke, including hypertension, age, elevated serum cholesterol, smoking, diabetes and most notably, elevated body mass index (BMI) and the "obesity epidemic."

Race can also be a risk factor, with 2010 statistics showing that an estimated 2.5% of Caucasians had a stroke; 3.9% of African Americans; 2.6% of Hispanics and Asians; 5.9% of Native Americans; and 10.6% of Hawaiians and Pacific Islanders. Family history may also indicate a risk factor for stroke, particularly if family members had strokes while they were young.

Atherosclerosis—a systemic disease process in which fatty deposits, inflammation and scar tissue build up within the walls of arteries—is the underlying cause of most cardiovascular disease and stroke. Individuals who develop atherosclerosis tend to develop it in a number of different arteries, both large and small. This is especially true in those arteries that feed the brain, heart, lungs, kidneys and extremities, although the patient may have much more disease in some places than others.

Time Is Brain
Although the call may come in as a stroke, it also may come in as a fall, a seizure, an unconscious person, a person with "difficulty speaking" or any one of several other categorizations.

Every minute of delay to treatment is said to cost a patient 1.9 million brain cells. EMS dispatchers using priority dispatch systems are trained to place stroke symptoms as high-priority calls for which minutes matter. Because they do.

When EMS arrives, patients presenting with stroke can exhibit a variety of signs and symptoms, including paralysis. This numbness or weakness can appear in the face, arms or legs. It is usually on the side of the body opposite the side of the brain damaged by the stroke. It's called hemiplegia if it involves complete inability to move and hemiparesis if it involves weakness.

Patients may have difficulty swallowing, called dysphagia. Cerebellar strokes can cause ataxia.
Other symptoms include sudden onset of confusion, difficulty speaking or understanding due to aphasia, trouble seeing in one or both eyes, dizziness, or loss of balance or difficulty walking due to ataxia. Some patients will complain of the sudden onset of a severe headache.

As with all patients in the prehospital setting, assessment of the airway, breathing and circulatory status of stroke patients is essential. Administer oxygen if appropriate and obtain a set of vital signs. Gather patient history and medications, paying particular attention to whether the patient is being treated with anticoagulants or antiplatelet drugs. Try to find out the time of onset of symptoms because this is the "start time" from which the three-hour window for fibrinolytic therapy will be calculated. Obtain IV access and a glucometry reading because hypoglycemia can mimic stroke but it's much simpler to treat in the prehospital setting.

Stroke assessment tools, such as the Cincinnati Prehospital Stroke Scale (see Table 1) or the Los Angeles Prehospital Stroke Screen, were created to increase the accuracy of field evaluations of potential stroke patients.

Use of a stroke assessment tool improves prehospital triage in stroke patients. These evaluations can be performed in less than one minute. With standard training in stroke recognition, paramedics have demonstrated a sensitivity of 61–66% for identifying patients with stroke; however, paramedic sensitivity for identifying stroke patients rose to 86–97% after receiving training in use of a stroke assessment tool. EMS personnel should follow their local service protocols with respect to evaluation tools for stroke and triage in suspected stroke patients to the hospital best able to care for them.

Evaluation of the three factors of facial droop, arm drift and abnormal speech can assist EMS in rapidly identifying potential stroke patients. To evaluate facial paralysis, ask the patient to smile and show their teeth so that you can see whether both sides of the mouth elevate the same way. To evaluate for hemiparesis, ask the patient to hold out both arms palms up and close their eyes for 10 seconds to see if one arm drifts downward or doesn't move.

To evaluate speech, ask the patient to repeat a common phrase, such as "You can't teach an old dog new tricks."

If the left side of the brain is affected, patients often present with right-sided hemiparesis and such language effects as aphasia, dysphasia and apraxia, as well as facial droop and ataxia. Sudden blindness can also be a symptom of stroke.

Patients may experience such changes in level of consciousness as decreasing level of consciousness, cognitive impairment, seizures and even coma. Hypertension may be present. Patients with right-sided strokes may present with left-sided hemiplegia.

Obtain a 12-lead ECG. Although no arrhythmias are specific to stroke, the ECG can identify recent acute myocardial infarction or atrial fibrillation as a potential cause for embolic stroke. In general, the ECG of a stroke patient will be monitored in the hospital for 24 hours to detect potentially life-threatening arrhythmias.

Prehospital Treatment

The goal of stroke care is to minimize brain injury and maximize the patient's recovery. The Stroke Chain of Survival described by the ASA is similar to the chain of survival for sudden cardiac arrest, linking actions to be taken by patients, family members, and healthcare providers to maximize stroke recovery.

The links are 1) rapid recognition and reaction to stroke warning signs; 2) rapid EMS dispatch; 3) rapid EMS system transport and pre-arrival notification to the receiving facility; and 4) rapid diagnosis and treatment in the hospital.

Target times and goals are recommended by the National Institute of Neurological Disorders and Stroke (NINDS,) which has recommended measurable goals for the evaluation of stroke patients. The hope is to meet these goals in 80% of the patients presenting with acute stroke.

Ischemic stroke patients may be eligible for treatment with fibrinolytics, but the time elapsed between onset of symptoms and initiation of treatment must be within a three-hour window. Selected patients may have slightly more time—up to 4.5 hours. This is why it's critically important to identify potential stroke patients and promptly transport them to an appropriate facility to avoid loss of the chance of an improved outcome with fibrinolytic therapy.

For EMS, destination decisions are critical, and stroke patients should be directed to an accredited stroke center if one is available. An early alert to the stroke center by EMS can get the stroke team activated while you're en route, and they can be waiting for your patient when you arrive.

In-Hospital Care

As of Jan. 1, 2011, more than 800 primary stroke centers (PSC) are certified by the Joint Commission in 49 states. The Joint Commission launched the primary stroke center certification program in 2003 in collaboration with the ASA, following the successful model of designated trauma centers. PSCs must have the capability to administer fibrinolytic drugs, written protocols for the administration of these drugs within three hours of symptom onset, a multidisciplinary team, as well as lab and neuroimaging available 24 hours a day, seven days a week.

The Joint Commission has also developed an advanced certification for comprehensive stroke centers, incorporating all the elements of PSC with additional requirements for volume of stroke patients, number of stroke-related procedures performed, research capability, availability of neurosurgery 24 hours a day, seven days a week, availability of advanced neuroimaging studies and interventional procedures, and dedicated neuro-intensive care units for complex stroke patients.

The prevalence of stroke centers has lowered morbidity and mortality from stroke. Studies have documented improvement in one-year survival rates, functional outcomes and quality of life when patients hospitalized for acute stroke receive care in a dedicated unit with a specialized team.

Patients with suspected stroke should be admitted to a stroke unit when one with a multidisciplinary team is available within a reasonable transport time, which is usually defined as one hour. Receiving hospitals should make their stroke care capability known to the community and to EMS providers in particular, and should not hesitate to divert or transfer suspected stroke patients to facilities with dedicated stroke units.

Critical time goals also exist for in-hospital stroke care. The NINDS has recommended immediate general assessment by the stroke team, emergency physician or another expert within 10 minutes of arrival, with an urgent order for a computed tomography (CT) scan without contrast. If CT isn't available, the patient should be stabilized and rapidly transported to a facility with CT capability. Within 25 minutes of arrival, the stroke team or designee should complete a neurological assessment, and the CT scan should be performed.

The CT scan should be interpreted within 45 minutes of arrival in the emergency department. Patients without contraindication should receive fibrinolytic therapy within one hour of hospital arrival and within three hours of onset of symptoms. The total door-to-admission time should be no more than three hours.

CT imaging will determine the type and location of the stroke. A critical decision point in the hospital assessment of suspected stroke patients is the performance and interpretation of the CT scan. The CT scan may also identify other structural abnormalities in the brain that may be responsible for stroke-like symptoms or that represent contraindications to fibrinolytic therapy. Patients with hemorrhagic stroke shouldn't receive thrombolytics, aspirin or heparin.
Not all patients with embolic stroke will qualify for fibrinolytic therapy; those with mild symptoms, who are outside of the three-hour window or who do not meet other criteria may not be candidates.

Exclusion criteria include patients with head trauma or stroke within the past three months, symptoms suggestive of subarachnoid hemorrhage, history of previous intracranial hemorrhage, elevated blood pressure, current use of anticoagulants, history of diabetes and previous prior ischemic stroke or demonstration of multilobular infarctions on CT.

Children less than 18 and adults more than 80 years of age generally aren't candidates. As with all drugs, fibrinolytic drugs have potential adverse effects, including intracranial hemorrhage and other bleeding complications, and the stroke team will perform a risk-to-benefit analysis before administration of these drugs.

Additional imaging studies, such as CT angiography or MRI, may be indicated for some patients. These studies should be rapidly interpreted by physicians with experience in diagnostic neuroradiology. In eligible patients, the performance of these studies shouldn't delay the administration of fibrinolytic therapy.

Currently, some hospitals don't have the resources to safely administer fibrinolytics, and this should be made known to the community so patients can be routed to facilities with this capability.

The NINDS trials have reported excellent outcomes in both community and tertiary care hospitals when the hospitals have, and follow, written protocols for stroke care. Institutions with commitment to comprehensive stroke care and rehabilitation have better outcomes.

Patent Foramen Ovale & Stroke

Recent research has identified a relationship between patent foramen ovale (PFO) and stroke. The existence of PFO has been cited as a stroke risk factor. PFO is a defect in the atrial septum that, under certain circumstances, may allow venous blood to pass directly from the right atrium to the left atrium without traveling first to the lungs (right-to-left shunt). This situation is called a paradoxical embolism.

For patients whose cause of stroke is unidentified (cryptogenic stroke), the presence of PFO may be investigated by transesophageal echocardiogram and "bubble study." This may determine whether the defect exists, as well as its size and whether right-to-left shunting is present. Patients are asked to cough or perform a modified Valsalva maneuver to increase the pressure and cause the PFO to open during the study.

Potential mechanisms of stroke in patients with atrial septal abnormalities include paradoxical embolus from a venous source, direct embolization from thrombi formed within an atrial septal aneurism and the formation of thrombus as a result of atrial arrhythmias.

PFO exists in about 25% of the population; in patients with cryptogenic stroke, the incidence has been found to be approximately 40%.

At present, repair of patent foramen ovale is controversial; numerous devices, such as plugs and patches, have been developed for percutaneous PFO repair by interventional cardiologists. However, the procedure still carries a number of serious risks and the risk-to -benefit ratio of PFO repair remains in controversy.

After the Stroke

About half of all stroke survivors are left with some disability. With an aging population in the U.S., the number of people disabled from stroke is on the rise. The economic burden of stroke requires increasing attention from health officials for more effective healthcare planning and allocation of resources. Informal care is important to maintain stroke survivors within the community and allow them to function up to the highest level of their ability.

Morbidity and rehabilitation: It's estimated that .27% of gross domestic product is spent on stroke by national health systems. Stroke care accounts for approximately 3% of total healthcare expenditures. In the U.S., it's estimated that $65.5 billion was spent on stroke in 2008. This figure includes the cost of physicians and other healthcare professionals, acute and long-term care, medications and durable medical equipment, and lost productivity of stroke survivors.

Early and aggressive rehabilitation efforts are essential to ensure stroke survivors can recover as much functionality as possible, and to increase the likelihood of being able to

return to being productive members of the community. Post-stroke rehabilitation starts during the inpatient phase and may involve physicians, rehabilitation nurses, physical therapists, occupational therapists, speech/language pathologists and vocational therapists. Outpatient facilities often continue rehabilitation efforts once the patient is released from inpatient status.

The type and degree of disability following stroke depends on the area of the brain that's damaged and the extent of the damage. In general, stroke causes five types of disability: paralysis or problems controlling movement; sensory disturbances, including pain; problems using or understanding language; problems with thinking and memory; and emotional disturbances.

Sensory disturbance and pain: Stroke survivors may lose their sense of touch, pain, temperature or position, or may experience pain, numbness or paresthesias. They may also initially become incontinent, although permanent incontinence is uncommon. Neuropathic pain may be present due to nervous system damage, and patients with weakened or paralyzed arm muscles often experience moderate to severe pain radiating from the shoulder, often resulting from lack of movement in a joint causing tendons and ligaments to become fixed in one position.

Language problems: At least one-fourth of stroke survivors experience language impairments. The dominant language centers are located on the left side of the brain, known as Broca's area. Damage to this area causes expressive aphasia which is characterized as difficulty with speaking and writing.

Damage to a language center in the rear of the brain known as the Wernecke's area results in receptive aphasia, which is characterized as difficulty understanding spoken language and reading. Global aphasia, a more severe form of aphasia, is caused by damage to several areas of the brain involved in language function; these patients are significantly impaired by inability to communicate or understand language.

Thinking and memory problems: Stroke survivors may have dramatically shortened attention spans, short-term memory deficits, or they may lose the ability to perform complex mental tasks. Patients with apraxia find themselves unable to plan the steps involved in a complex task and carry them out in the proper sequence. The extent of brain damage will dictate how well these patients will be able to function independently. Cognitive rehabilitation efforts using computer programs with increasingly difficult tasks have proven helpful in regaining some function.

Emotional disturbances: Stroke survivors often feel fear, anxiety, frustration, anger and a sense of grief for their physical and cognitive losses. Some emotional disturbances are caused by the structural effects of brain damage.

Clinical depression, a sense of hopelessness that disrupts an individual's ability to function, is commonly experienced by stroke survivors. Signs of clinical depression include sleep disturbances, lethargy, social withdrawal, irritability, fatigue and suicidal thoughts. Treatment may involve counseling and antidepressant medications, although exercise has also been shown to be helpful.

Conclusion

There's a large role for EMS in community education, stroke awareness and prevention

activities. The National Stroke Association's Act FAST (face, arms, speech and time) program teaches community members to be aware of the signs of stroke, and to act quickly in summoning EMS personnel to the scene for rapid evaluation and transport to an appropriate facility.

EMS personnel can become involved in community awareness programs, teaching the community how to recognize the signs of a stroke and encouraging an immediate 9-1-1 call for help. When 9-1-1 responds to the potential stroke patient, it's critical to remember that time is brain, and to quickly assess and transport the patient to optimize their chance for the best possible outcome.

Stroke is a costly disease from human, family and societal perspectives. It's a global epidemic that isn't limited to a particular socioeconomic group. Thus, reduction of the frequency and severity of stroke by preventive measures is essential to avoid the natural trend of increasing the human, economic and social burden of stroke. JEMS

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This article originally appeared in June 2012 JEMS as "Stroke of the Clock: 'Time is brain' when treating stroke patients."

Patient Care Medical Emergencies Features hemorrhagic stroke ischemic stroke stroke patients time is brain

An outcome study of the use of computed tomography for the diagnosis of appendicitis in a community-based emergency department.

Objectives: Previous studies evaluating the use of CT in the diagnosis of appendicitis have taken place at university-based institutions where surgical bedside consultation seems prudent before radiological study. In the private hospital setting, the emergency department (ED) physician is responsible for diagnosis. We attempt to assess if this process is detrimental to patient care.

Methods: Retrospective review of 150 patient's records admitted through the ED was performed with the discharge diagnosis of appendicitis between March 1998 and May 2000. Data was stratified for analysis based on age (< 15, 15-50, > 50) and gender. Using Graph Pad Prism software the groups were compared for complications based on whether or not CT was obtained. Chi-square, number needed to treat (NNT), absolute risk reduction (ARR), relative risk reduction (RRR) and respective confidence intervals were calculated for each group.

Results: No significant differences overall were obtained between CT and no CT groups at $P < 0.05$. A significant benefit is demonstrated at $P = 0.017$ in females of childbearing age while a detrimental trend is found for those over the age of 50 years.

Conclusions: Contrary to our initial hypothesis, no increased incidence of appendiceal perforation or abscess was demonstrated based on the ED physician's decision to perform CT without surgical consultation.

Key Words: appendicitis, CT scan, gynecological misdiagnosis

In the past decade, much research has been dedicated to the radiological evaluation of patients presenting to emergency departments with abdominal pain where acute appendicitis is a major focus of the differential diagnosis. There exists an argument as to the proper use of computed tomography in the diagnostic paradigm. The majority of this debate has taken place at radiology and surgery programs at large university-based hospitals where surgical teams are readily available for bedside patient care and observation. A different scenario exists in community-based hospitals where surgeons rely on emergency department evaluation and diagnosis.

Importance

With the evolving technology of CT, including high-resolution spiral CT, the abdomen and pelvis can be visualized in a relatively short period of time. For a suspected diagnosis of appendicitis, radiological studies have documented sensitivities of 90 to 100%, specificities of 91 to 99%, positive predictive values of 95 to 97%, and accuracies of 94 to 100%. (1-7) A study of patients presenting with atypical symptoms in 1998 yielded impressive results for CT scanning, which appeared to change the ED management for abdominal pain patients. (2,8-9) Considering the negative aspects of patient morbidity and mortality and the malpractice implications of misdiagnosis and delay in treatment, the decision to perform CT examination in patients presenting with abdominal pain has become prioritized in the emergency department setting. Proponents of routine use of CT examination in patients with suspected appendicitis cite its ability to decrease the negative appendectomy rate, diminish patient cost factors, and provide a surgical guide for intervention in complicated cases. (6-8,10-13) Furthermore, it can provide alternative diagnoses in patients found to be negative for the disease. This is of particular importance in women of childbearing age. Others argue that the procedure does not diminish perforation rates, may delay diagnosis, and should only be ordered after surgical consultation and evaluation. (9,15-23)

Goals Of This Investigation

In a community hospital emergency department setting, the on-call general surgeon is not always physically able to evaluate all patients presenting with symptoms suggestive of appendicitis. The diagnosis thus becomes the responsibility of the emergency department physician. To evaluate the role of contrast-enhanced CT in this process at our facility, we retrospectively analyzed patient outcomes during a period of increased diagnostic use in the emergency department. We hypothesized that the delay required for CT evaluation before surgical intervention would result in increased patient complications.

Materials and Methods

Setting

Our not-for-profit hospital is a community-based, tax-supported hospital serving a small urban population. The stable population of the area is approximately 300,000. Single coverage surgical call is provided by 12 general surgeons from a private group practice, an HMO-based group, and 2 single practitioners. Twenty four hour response is required regardless of the surgeon's private patient responsibilities or scheduled surgery. CT is available 24 hours a day utilizing a double contrast protocol. Patients are required to ingest oral contrast over an approximate 2 hour period before imaging. IV contrast is then administered and 5 mm sequential views are created through the abdomen and pelvis.

Selection of participants

Approval was received from the hospital institutional review board for this retrospective chart review. All records of patient charts from the institution with a diagnosis code of appendicitis from March 1998 to May 2000 were examined. This time period was selected based on a review of the literature regarding appendicitis management. Published surgical and radiology articles were beginning to support the diagnostic role of CT in appendicitis. (1-3, 6-8) It was our aim to gather data before this accepted standard of care to objectively inspect the outcome trends related to the use of CT in the diagnosis of appendicitis.

Only those patients who were admitted through the emergency department were utilized and direct admissions were excluded. Patients less than 3 years of age and greater than 80 years were not included in the sample of patients. Exclusion criteria also included charts with incomplete details of event time recordings. This criterion was essential to compare durations of procedures and possible links to complications between those patients who underwent CT evaluation and those who did not. Of 150 charts, 7 were excluded from the chart review for not meeting this criterion. The final sample (n = 143) consisted of 87 males and 56 females. The average age was 33.2 years with a range of 7 to 78 years.

Data collection and processing

Patient charts were examined for age, sex, date, and time of admission from the ED. The time of initial ED physician examination was recorded and used to evaluate elapsed time to the following pertinent events: order time of CT, time to operation, time of first antibiotic dose, and date and time of discharge from the hospital. Times were rounded to the nearest 15 minutes. Any complication was also noted (ie, perforation, abscess, rupture) though not characterized with regards to severity.

Outcome values were entered into a spreadsheet and the data was analyzed after separating subjects into groups based on whether or not a CT scan was performed. Of the 143 total patient sample, 87 received the procedure. The average age was 33.1 ([+ or -] 18.9) years and 33.3 ([+ or -] 15.9) years for the CT and no CT (NCT) groups respectively. As previously stated, the initial time of ED physician examination was used as the central data point from which all other measures were compared. This helped to eliminate deviations in time due to factors beyond the control of hospital staff. To minimize other possible confounding factors, all patient interventions were assessed with respect to the times annotated on the charts by the ordering physicians.

Stratification of the data was further performed specific to those less than 15 years of age, all patients greater than 15 years of age, sex and age between 15 and 50 years, and those patients greater than 50 years of age. Females between 15 and 50 years of age have been recognized in previous studies (12,14-15) to be of childbearing age and are associated with more complicated differential diagnoses when considering pelvic pathology. Males and females between these ages were subsequently compared based on whether or not a CT was performed and if an adverse event was encountered.

Results

Table 1 demonstrates absolute values for stratified groups including number and percent of complications. Using Graph Pad Prism software (San Diego, CA) the pertinent times for patient interventions (timing of antibiotics, time of operation, and time to discharge) were compared using an unpaired t test. No significant differences were discovered between the CT and NCT groups (Table 2). To evaluate the incidence of complications between all patients who received CT versus the NCT group, a [chi square] test was used and revealed no differences (P = 0.124).

When comparing complications between CT and NCT groups in the stratified data a significant difference (P = 0.017) was found for females 15 to 50 years age. Only 9.1% of the CT group encountered complications compared with 46.7% of the NCT group. This equated to an absolute risk reduction (ARR) of 37.6% with confidence interval (CI) of 9.62%-65.53% at 95%. This indicates that 33.3% [number needed to treat (NNT) = 3, 95% CI = 1.5-10.4] of females aged 15 to 50 years benefited from receiving a CT scan. An identical comparison of males in this age range yielded P = 0.20 and nothing significant with respect to NNT and ARR.

In patients older than 50 years, a trend toward increased risk of complications is demonstrated for those who underwent CT compared with those who did not. The chi-square analysis for this group was not significant at P = 0.70, however 40.0% of patients who underwent CT evaluation suffered complications, versus 30.0% of those who did not have CT evaluation. Ten percent of patients in this age group are therefore potentially harmed by the procedure. All statistical results are delineated in Table 3.

Discussion

The sensitivities and specificities for the CT diagnosis of appendicitis in both the university-based hospital (1-2,7,11-14) and community hospital settings (3,5) have been well documented. To our knowledge, no studies in community ED environments have evaluated patient outcomes in the adult population. Ours is the first to examine this perspective. We analyzed the consequences of using CT as a diagnostic aid in patients with acute appendicitis in the private hospital sector. This is important as many emergency department physicians practice in an isolated environment without immediate surgical input. In the university-based setting, the preferred practice is to consult the surgical on-call service for bedside evaluation and determination of the need for radiological study before laparotomy. (15-17,21-22) The implications of our results may impact community ED practice behavior.

Contrary to our initial hypothesis, no increased incidence of perforation or abscess was found in patients with the discharge diagnosis of appendicitis who underwent CT as a diagnostic aid in comparison to those patients who did not undergo the procedure. Furthermore, no significant delays were demonstrated for times to antibiotic administration, operating room arrival, and time of discharge from the hospital in patients undergoing the procedure. The largest absolute risk reduction for perforation was found for women considered to be of menstruating, childbearing age. Since only patients with appendicitis were analyzed, the assumption can be made that CT evaluation in this group of patients avoided gynecological misdiagnoses inherent without the benefit of CT scanning. This result comes as no surprise and substantiates previous studies evaluating the value of CT in women of this age group. (11-12,25-26) Increased risk for perforation was found for those over the age of 50 who underwent CT versus those who did not. Overall data supports no increased complications for those who undergo CT evaluation for appendicitis. Other explanations are more plausible for the results in this age group. Vague history and subjective symptoms, late presentations, and equivocal physical examinations are perhaps causative. A combination of these factors is suspected and deserves further separate investigation.

The retrospective nature of this study reveals inherent limitations that are unavoidable. These revolve around human errors of reliance on chart data documentation and collection with a possible inability to decipher decision-making after care is given. A bias of retrospective examination that must be considered is that patients who appeared more ill might have been taken to the OR without CT examination, resulting in a higher complication rate in the NCT group. A factor not established was whether a surgeon was involved in the decision to order CT evaluation. Individual cases may have had surgical input that was not evident retrospectively. This is not the normal situation at our institution given the office and operating responsibilities of any staff physician. In addition, in the private sector, on-call physicians are often reluctant to respond until a definitive diagnosis has been made in the emergency department.

Conclusion

The diagnosis of appendicitis is relatively straightforward in those patients presenting with the classic symptoms of abdominal pain of short duration, migration to the right lower quadrant, and anorexia. Atypical presentations, however, occur in approximately 30% of patients, (6,24) often at the extremes of age and the female gender. We hypothesized that the increased use of CT for the diagnosis of appendicitis in the emergency department setting would result in increased complications from a patient outcome standpoint. On the contrary we found that its use does not negatively impact patient outcome in a community-based hospital setting where diagnosis is most frequently in the hands of the emergency department physician.

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Robert D. Mathis, MD, Andrea B. Chiumento, MD, MS, Benson Yeh, MD, and Nita Dolleslager, RN

From the Department of Emergency Services, Halifax Medical Center, Daytona Beach, FL and the Department of Emergency Medicine, The Brooklyn Hospital Center, Brooklyn, NY.

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Accepted August 25, 2005.

RELATED ARTICLE: Key Points

* In the community hospital setting, bedside surgical consultation is not always available and the decision to utilize CT evaluation for the diagnosis of appendicitis becomes the responsibility of the ED physician.

* CT evaluation of the patient presenting emergently with abdominal pain has its greatest utility for those with atypical symptoms, age of presentation, and female gender.

* Perceived delays in the diagnosis of appendicitis utilizing CT imaging are not detrimental to patients presenting emergently in the community hospital-based setting.

Table 1. Stratified groups including number and percent of complications (a)

	CT - cx	NCT + cx
	CT [n (%)]	NCT [n (%)]
All (n = 143)	87 18 (20.7)	56 18 (32.1)
All > 50 years (n = 30)	20 8 (40.0)	10 3 (30.0)
All [greater than or equal to] 70 12 (17.1)	44 14 (31.8)	
15 years (n = 114)		
All < 15 years (n = 29)	17 6 (35.3)	12 4 (33.3)
F 15-50 years (n = 37)	22 2 (9.1)	15 7 (46.7)
M 15-50 years (n = 47)	28 2 (7.1)	19 4 (21.1)

(a) cx, complications; NCT, no CT; F, female; M, male.

Table 2. Comparison of intervention times (a)

	CT (n = 87)	NCT (n = 56)
Age (yrs.)	33.1	33.3
Time to CT (hr:min)	1:55	n/a
Time to OR (hr:min)	14:52	16:35
Time to Abx (hr:min)	5:31	2:19
Hospital stay (hr:min)	56:45	67:15
Complications 20.7% (n=18)	32.1% (n=18)	

(a) NCT, no CT; Abx, antibiotics.

Table 3. Statistical results (a)

P value NNT 95% CI (%)			
All (n = 143) 0.124 12 NS			
All > 50 years (n = 30) 0.702 (10) (b) NS			
All [greater than or equal to] 15 years 0.107 7 NS (n = 124)			
All < 15 years (n = 29) 1.00 51 NS			
F 15-50 years (n = 37) 0.017 3 1.5 to 10.4			
M 15-50 years (n = 47) 0.204 8 NS			

ARR (%) 95% CI (%)	
All (n = 143) 8.96 -5.92 to 23.80	
All > 50 years (n = 30) (10.00) (b) -25.60 to 45.60	
All [greater than or equal to] 15 years 14.68 -1.68 to 31.03 (n = 114)	
All < 15 years (n = 29) 1.96 -33.07 to 37.00	
F 15-50 years (n = 37) 27.58 9.62 to 65.53	
M 15-50 years (n = 47) 13.91 -6.76 to 34.57	

(a) NNT, number needed to treat; ARR, absolute risk reduction; NS, no significance [as a 95% CI for NNT cannot be calculated when the 95% CI for ARR extends from a negative (harmful result) to a positive (beneficial result).] F, female; M, male.
(b) Represents NNT for a harmful event and an absolute risk increase for this group.

Article Details

Title Annotation: Original Article
Author: Dolliesiager, Nita
Publication: Southern Medical Journal
Geographic Code: 1USA
Date: Dec 1, 2005
Words: 3345
Previous Article: The threat of malaria for US travelers
Next Article: Effectiveness of a school-based intervention to increase health knowledge of cardiovascular disease risk factors among rural Mississippi middle...
Topics: Appendicitis
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Pinch-an-inch test for appendicitis.

Intestinal ascariasis: CT findings and diagnosis.

ACEP

Rapid Growth in CT Scanning in ERs Associated with Decline in Hospital Admissions

For Immediate Release
August 10, 2011

Contact: **Julie Lloyd**
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Annals of Emergency Medicine RSS feeds:
http://www.acep.org/xmlfeeds/rss.aspx?cid=8

Computed tomography (CT) scans performed in the emergency department, which increased 330 percent between 1996 and 2007, may be reducing the frequency of hospitalization or transfer for emergency patients, according to a study published online yesterday in Annals of Emergency Medicine. The accompanying editorial notes that the reduction in hospitalizations is a beneficial result for both patients and the healthcare system ("National Trends in Use of Computed Tomography in the Emergency Department" and "The Hunting of the Snark").

"Almost one-quarter of CT scans performed in the U.S are performed in ERs, in part because primary care and other physicians refer their patients there for these studies and also because we are increasingly being asked to do all the initial tests for patients in the ER before a patient is admitted to the hospital," said lead study author Keith Kocher, MD, MPH, of the University of Michigan in Ann Arbor. "We saw a more dramatic rise in CT use among older patients. But we also saw an associated decline in post-CT hospitalizations."

Assessing emergency department visits from 1996 to 2007, researchers found an increase of CT use from 3.2 percent of patient visits to 13.9 percent. Rates of growth were highest for abdominal pain, flank pain, chest pain and shortness of breath, all of which can be symptoms of life-threatening emergencies.

In 1996, the rate of hospitalization following CT scan was 26 percent. By the end of the study period, 2007, that rate had dropped by more than half to 12.1 percent. Researchers found a similar pattern of declining risk of admission or transfer to intensive care units during the period.

In an editorial accompanying the study, Dr. Robert Wears, MD, MS of the University of Florida Health Science Center offered "the desire for greater certainty" among emergency physicians as one reason for the increase, particularly in light of the high-risk environment of the emergency department and the potential for litigation by patients with bad outcomes.

"The occasional 'near miss,' where one manages a patient without imaging, only to discover later that they had CT-detectable pathology of some sort that could have been detected sooner reinforces the desire for greater certainty," said Dr. Wears.

CT scans are powerful and provide a lot of information quickly that can be especially useful in the emergency department where patients are often very sick and time is critical. CT scans

allow doctors to arrive at a diagnosis quickly.

A 2010 study showed that patients with abdominal pain express more confidence in their medical treatment if it includes a CT scan. Dr. Kocher suggests that patients and families ask if a CT scan is necessary, given some of the risks related to radiation exposure from these tests:

"Patients or their family members sometimes want – or even expect – these advanced tests to be done, so emergency physicians may be more likely to order them," said Dr. Kocher. "I encourage patients and their families to ask the provider if they think the scan is really necessary. This allows open discussion about the necessity of the test and the patient's or family's expectations, and allows patients to be more involved in decision-making around their care."

Annals of Emergency Medicine is the peer-reviewed scientific journal for the American College of Emergency Physicians, a national medical society. ACEP is committed to advancing emergency care through continuing education, research, and public education. Headquartered in Dallas, Texas, ACEP has 53 chapters representing each state, as well as Puerto Rico and the District of Columbia. A Government Services Chapter represents emergency physicians employed by military branches and other government agencies. For more information visit www.acep.org.

Diagnostic Procedures (Ultrasound, CT, MRI, etc.)

- Focus On: Ultrasound for Thoracentesis
- Focus On: Ultrasound-Guided Paracentesis
- Focus On: Bedside Ultrasound Assessment of Left Ventricular Function
- Focus On: Pediatric Hip Ultrasound
- Focus On: Ultrasound for Appendicitis

Related Links

Annals of Emergency Medicine

- Drug Used to Deworm Animals Contaminates Cocaine, Sends Users to the ER
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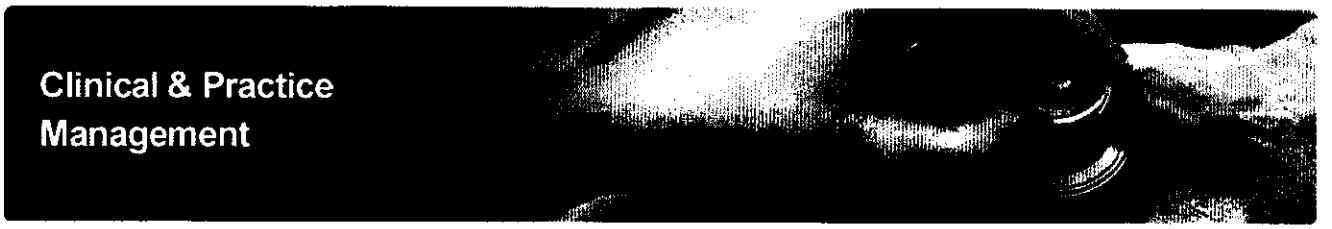

CT Beat X-Rays for High-Risk Cervical Spine Injuries

ACEP News

March 2007

By Michele G. Sullivan

Elsevier Global Medical News

RIVIERA MAYA, MEXICO - For patients with low-risk injuries, three plain-film x-rays are probably sufficient to diagnose clinically significant cervical spine injuries--but for patients with higher-risk injuries or multiple blunt traumas, a computed axial tomographic scan is indicated.

CTs are "vastly superior" to plain radiographs in identifying cervical injuries, Dr. John Marx said at a meeting on medical negligence and risk management. "While most missed injuries are stable, it only takes one missed unstable injury" to set the stage for a serious problem, he said.

Several key studies have confirmed the usefulness of CT in this setting. One of the best was a subanalysis of the National Emerger Radiography Utilization Study, which included 818 patients with cervical spine injuries. About 36% of these patients, all of whom underwent radiographic studies, had a least one additional finding on the cervical spine CT, and 27% of those were not contiguou the index injury, Dr. Marx said. Plain film also missed 33% of the cervical spine injuries that CT picked up; 74% of those missed i were clinically significant (Ann. Emerg. Med. 2006;47:129-33).

A 2005 study confirmed CT's usefulness in 437 unconscious, intubated blunt trauma patients, including 61 with cervical spine injuries. CT scanning had a sensitivity of 98%, a specificity of 99%, and a negative predictive value of 99.7%. There were no missed unstable injuries. In contrast, adequate lateral cervical spine films detected only 24 injuries (14 unstable), with a sensitivity of 53.3% (J. Trauma 2005;58:897-901).

Although CT is not an inexpensive study, it can easily prove its worth not only in cervical spine, but also in thoracolumbar injuries, said Dr. Marx, chair of emergency medicine at the Carolinas Medical Center in Charlotte, N.C.

"We have also gotten into the habit of pan-scanning the neck, head, chest, and pelvis of our very sick patients who are going to need a lot of studies. This isn't cheap--it costs about $15,000--but it's a wonderful study and seems to make sense for these patients," he said at the meeting sponsored by Boston University.

Related Links

ACEP News

- Dr. Klauer Message...ACEP News in 2014
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Feedback

RadiologyInfo.org

The radiology information resource for patients

Patient Safety:

What are the benefits of CT scans?

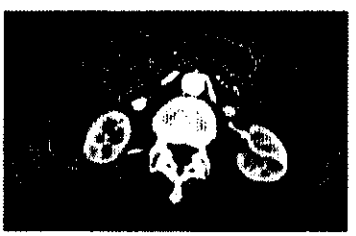
Computed tomography (CT or CAT scan) ranks as one of the top five medical developments in the last 40 years, according to most medical surveys. CT has proven so valuable as a medical diagnostic tool that the 1979 Nobel Prize in Medicine was awarded to the inventors.

How it works

Both CT and conventional x-rays take pictures of internal body structures. In conventional x-rays, the structures overlap. For example, the ribs overlay the lung and heart. In an x-ray, structures of medical concern are often obscured by other organs or bones, making diagnosis difficult.

X-ray image showing internal body structures

In a CT image, overlapping structures are eliminated, making the internal anatomy more apparent.



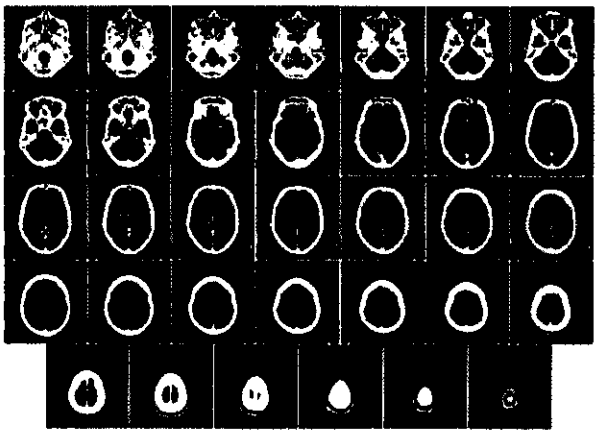
CT image showing internal body structures

During CT imaging, an x-ray tube rotates around the patient so that multiple images are collected from many angles. These images are stored in a computer that analyzes them to create a new image with the overlying structures removed.

CT images allow radiologists and other physicians to identify internal structures and see their shape, size, density and texture. This detailed information can be used to determine if there is a medical problem as well as the extent and exact location of the problem, and other important details. The images can also show if no abnormality is present.

A CT scan that shows no abnormality still provides useful data. The information aids a diagnostician by focusing attention away from unnecessary medical concerns.

Modern CT scanners acquire this information in seconds - sometimes in fractions of a second - depending on the examination.



Benefits

Benefits of CT include more effective medical management by:

- determining when surgeries are necessary
- reducing the need for exploratory surgeries
- improving cancer diagnosis and treatment
- reducing the length of hospitalizations
- guiding treatment of common conditions such as injury, cardiac disease and stroke
- improving patient placement into appropriate areas of care, such as intensive care units

In an emergency room, patients can be scanned quickly so doctors can rapidly assess their condition. Emergency surgery might be necessary to stop internal bleeding. CT images show the surgeons exactly where to operate. Without this information, the success of surgery is greatly compromised. The risk of radiation exposure from CT is very small compared to the benefits of a well-planned surgery.

CT scanning provides medical information that is different from other imaging examinations, such as ultrasound, MRI, SPECT, PET or nuclear medicine. Each imaging technique has advantages and limitations. The principal advantages of CT are:

1. Rapid acquisition of images
2. A wealth of clear and specific information
3. A view of a large portion of the body

No other imaging procedure combines these advantages into a single session.

This page was reviewed on August 19, 2011

ATTACHMENT C

MAURICE E. DEFINA, MD

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CURRENT POSITION

Full-time ED staff physician Deaconess Waltham Hospital, Waltham, MA — 1998-pres.

EDUCATION

M.D. University of Connecticut School of Medicine, Farmington, Connecticut — 1991-1995

B.S./Biology, University of Connecticut, Storrs, Connecticut — 1986-1990
Honors:
- Magna Cum Laude Graduate - 1990
- Golden Key National Honor Society - 1990
- Phi Beta Kappa - 1990
- Deans List (1986 - 1990: 8 semesters)

POST-GRADUATE TRAINING

Integrated Residency in Emergency Medicine — 1995-1998
University of Connecticut / Hartford Hospital, Hartford, CT
additional training: Lifestar Helicopter Transport

LICENSURE and CERTIFICATIONS

ABEM Board Certification	1999
Massachusetts State Medical License	1998
Connecticut State Medical License	1997
Pediatric Advanced Life Support	1996
Advanced Cardiac Life Support	1995
Advanced Trauma Life Support	1995

PROFESSIONAL SOCIETY MEMBERSHIPS

American College of Emergency Physicians
Massachusetts College of Emergency Physicians
Massachusetts Medical Society

PUBLICATIONS

DeFina, M., Powers, R., "Sporotrichosis". Chapter for The Five Minute Emergency Medicine Consult, Williams and Wilkins, Philadelphia (1999)

HOBBIES/ INTERESTS

New England Travel, Golf, Skiing, Biking, Running, and Sports Medicine

REFERENCES

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   Director, Department of Emergency Medicine
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   Waltham, MA 02254
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2. Alam Virk, MD
   Asst. Director, Department of Emergency Medicine
   Deaconess Waltham Hospital
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   Waltham, MA 02254
   (781) 647-6325

3. Susan Dufel, MD
   Director, Emergency Medicine Residency Program
   University of Connecticut School of Medicine
   Hartford Hospital
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Brian Murphy R.T. (R)(T)(CT)(ARRT)

Current State of CT. licensed

Objective

Dedicated Healthcare professional.

Experience

1998 to present Charlotte Hungerford Hospital Torrington, CT

Lead Cat Scan Technologist

- Responsible for the day to day activities relating to CAT scan department.
- CT point person for the up grade to a multi slice scanner.
- Intravenous access certified and IV trainer at Charlotte Hungerford Hospital.
- CPR certification – current.

2006 to present Radiology Associates of Hartford Avon, CT

Cat Scan Technologist

- Staff CAT SCAN Technologist.

1998–1999 Charlotte Hungerford Hospital Torrington, CT

Radiation Therapist

- Staff radiation therapist.
- Treatment planning and simulation.

1994–1998 Putnam Hospital Center Carmel, NY

Radiological Technologist

- Staff Radiological Technologist.
- CAT Scan Responsibilities including call.
- Per diem Technologist.

1992-1994 Greenwich Hospital Greenwich, CT

Radiation Therapist

- Staff Radiation Therapist.

Equipment

Toshiba Aquilion 64, Siemens 16 slice, GE VCT .
DR Pacs and MediTech.

Education

1990–1991 Danbury Hospital School Of Radiation Therapy. Danbury, CT
1988- 1990 Danbury Hospital School Of Radiology Danbury, CT

Home: 209 Jackson Street
Thomaston, CT 06787
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Winsted, CT 06098
Phone 860-738-6610
Cell 860-485-4124
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Michele D. Rainville RN

Licensure

Current CT License, E51245

Professional Experience

2006-Present Hungerford Emergency & Medical Care, Winsted, CT

Clinical Manager

- Manage satellite Emergency Department, Laboratory, Radiology, Registration & Facility support staff
- Maintain compliance with The Joint Commission, CT Department of Public Health, The Centers for Medicare & Medicaid Services, & all State & Federal regulations
- Oversee Facility maintenance & safety compliance
- Plan & implement quality improvement initiatives
- Plan & implement patient satisfaction initiatives
- Plan & implement biomedical & information technology initiatives
- Plan & implement emergency & disaster preparedness
- Plan & implement budgets, manage & maximize revenue
- Process accurate & timely accounts payable, receivable & payroll
- Implement staff orientation, education & competency
- Manage human resources issues

1988-2006 Charlotte Hungerford Hospital, Torrington & Winsted, CT

Staff Nurse

- Employed as staff nurse in Emergency Department, including Charge Nurse role, at Charlotte Hungerford Hospital and Hungerford Emergency & Medical Care sites.

Special Projects

- 2012: Designed, created, and implemented web based Triage Education and competency program at Charlotte Hungerford Hospital, utilizing national standards.

Education

Baccalaureate Degree in Nursing

2007-Present Western Connecticut State University, Danbury, CT

- G.P.A. 4.0
- Expected graduation: 2014
- Alpha Sigma Lambda, Pi Zeta Chapter
- Sigma Theta Tau, Kappa Alpha Chapter

Diploma in Nursing

1988 St. Mary's Hospital School of Nursing Waterbury, CT

- Valedictorian

Associate Degree in Science

1988 Mattatuck Community College, Waterbury, CT

Professional Memberships

- Emergency Nurses Association

Professional & Community Activities

- Town of Winsted, CT: Local Emergency Planning Committee
- Winchester Youth Service Bureau Advisory Board Member
- Rotary International, Torrington Winsted Area Club, Board of Directors 2013-2014
- Health topic speaker for schools & civic groups
- Health fairs & community outreach events

Certifications

- BLS (Basic Life Support, CPR), American Heart Association
- ACLS (Advanced Cardiac Life Support), American Heart Association
- PALS (Pediatric Advanced Life Support), American Heart Association
- TNCC (Trauma Nursing Core Course)
- ENPC (Emergency Nursing Pediatric Course)

Achievements

- Celebrating Excellence Award: Charlotte Hungerford Hospital, 2005
- Northwestern Connecticut YMCA Spirit Award, 2013

CURRICULUM VITAE

NAME:	NEAL MANDELL		
ADDRESS:	Home:	55 Mountainbrook Drive Cheshire, CT 06410	(203) 272-7902
	Office:	Department of Radiology Section of Neuroradiology NF2-123 333 Cedar Street New Haven, CT 06510	(203) 785-5102
DATE OF BIRTH:	December 9, 1951		
SOCIAL SECURITY:	043-42-4213		
CERTIFICATION:	Diplomate, American Board of Radiology, 1991		
	Diplomate, National Board of Medical Examiners, 1987		
LICENSURE:	Connecticut, 1991 New York, 1990		
EDUCATION:	Boston University School of Medicine, Boston, MA M.D., 1986 AWARDS: Radiology Award, 1986 Jacob Swartz Award, 1986		
	Columbia University, New York, NY Pre-Medical Curriculum, 1980-1		
	University of Connecticut, Storrs, CT Bachelor of Fine Arts, 1975		
INTERNSHIP:	Internal Medicine, 7-86 to 6-87 Long Island Jewish Medical Center New Hyde Park, NY		
RESIDENCY:	Diagnostic Radiology, 7-87 to 6-91 Long Island Jewish Medical Center New Hyde Park, NY		
	Chief Resident		
FELLOWSHIP:	Neuroradiology, 7-91 to 6-93 Yale-New Haven Medical Center New Haven, CT		

PROFESSIONAL MEMBERSHIP:

American College of Radiology

Radiololgic Society of North America

American Medical Association

RESEARCH EXPERIENCE:

Harvard Medical School, Boston, MA
Department of Biophysics
Dr. Arthur Solomon, Director
Assisted Dr. Lenny Dawidowitz in studying an aspect of the hepatic microsomal enzyme system in rats.
Summer, 1983

Rockefeller University, New York, NY
Dept. of Cell Biology and Immunology
Dr. Zanvil Cohen, Director
Assisted Dr. Joan Mills in studying macrophages and their synthesis of prostaglandins.
Spring, 1982

SEMINARS:

Grand Rounds, L.I.J.M.C.:

MRI and Flow February 1990

MRI and Cerebral Hemorrhage January 1989

The Knee: MRI vs Arthrography November 1987

PREVIOUS EDUCATION AND EMPLOYMENT:

Neighborhood Playhouse School of the Theater, NYC, NY
1973-74

Actor
Various roles in professional theater and television.
1975-80

GREGG H. GRINSPAN, MD

47 Sunset Terrace
Collinsville, CT 06019

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Email: gregggrinspan@

PROFILE

- Over thirty years of experience as a physician with expertise in family medicine, internal medicine and emergency r
- Executive/Medical Director
- Founder of entrepreneurial healthcare enterprises.

QUALIFICATIONS

- Genuine care and compassion for the physical and emotional well being of patients.
- Significant clinical diagnostic experience.
- Strong advocate of patient-focused relationships with an evidence based approach to diagnoses and treatment p
- Highly effective coach, mentor, and teacher with a passion for imparting knowledge.

EDUCATION

BOSTON UNIVERSITY SCHOOL OF MEDICINE, Boston, MA
Medical Doctor, 1979

HARTFORD HOSPITAL
Residency in Internal Medicine, 1982

CERTIFICATIONS

Board Certified in Internal Medicine, ABIM—— Recertified in 2006
Board Certified in Emergency Medicine, BCEM—— Recertified in 2009

WORK EXPERIENCE

HUNGERFORD EMERGENCY DEPARTMENT, Winsted, CT 8/9'

MEDICAL DIRECTOR

- Hungerford ED in Winsted is a State Licensed, EMTALA compliant, low acuity/level 3 emergency departmen mostly lower socioeconomic class community with a solo physician on duty with on-site helicopter pad.
- Oversee all facets of emergency department with a focus on staff development, accurate and timely diagnose emergent and non-emergent interventions, and a positive patient experience.
- Oversee physician scheduling and staffing, as well as compliance mandates and business-related functions to profitable practice with a loyal patient following.
- **Direct patient care 36 hours a week (8/97 - 12/11).**
- **Direct patient care 26 hours a week (2012 - Present).**

NWCT EMERGENCY PHYSICIANS, PC, Torrington, CT 1!

PARTNER/PHYSICIAN

- Emergency Department Physician.
- **Direct patient care 40 hours a week.**

IMMEDIATE MEDICAL CARE CENTER (IMCC) & CONNECTICUT PHYSICAL THERAPY (CPT), HARTFORD HOSPITAL, Hartford, CT 1!

MEDICAL DIRECTOR, STAFF PHYSICIAN & BOARD MEMBER

- Retained to direct all operations as Medial Director and Board Member by Hartford Hospital from 1987 to 1995
- **Direct patient care 45 hours a week.**

Résumé (Continued)

WORK EXPERIENCE: *(Continued)*

IMMEDIATE MEDICAL CARE CENTER (IMCC) & CONNECTICUT PHYSICAL THERAPY BUSINESS UNITS (CPT)

FOUNDER, PRESIDENT & CEO, PRIMARY CARE PHYSICIAN

- Founder and Owner of IMCC (seven ambulatory care centers) and CPT (seven PT/OT units).
- Planned and implemented all business start-up strategies including financing, site selection, design of all c plans, recruitment and hiring of all initial core administrative staff, set-up of office operations, marketing of and CPTs, etc.
- Hired all physicians for Hartford area centers maintaining a culture of exceptionalism in physician recruitment. Top residents in IM from Hartford Hospital, St. Francis Hospital, Yale, Tufts, S.U.N.Y. Downstate, Michael Bellevue.
- Hired Chief Resident in Medicine from the Norwalk Hospital to run Norwalk office.
- Hired Chairman of the Emergency Department of the St. Vincent's Medical Center to run Bridgeport office.
- Required all potential new physicians to work 13-hour days with Dr. Winchester or me as a final step requir Along with Dr. Winchester exhibited standard of care expected by all physicians and ancillary staff.
- Established internal monthly CME for all physicians.
- Grew CPT to become occupational physicians for over 800 companies, including Colt Firearms, business unit Technologies, Department of Motor Vehicles, Department of Corrections, and multiple municipalities.
- Personally negotiated the sale of all businesses to major medical centers in 1987. In Hartford to the Hartford Hospital and in Bridgeport to the St. Vincent Medical Center.
- **Direct patient care 45 hours a week (1983, 1985-1987).**

NEW BRITAIN GENERAL HOSPITAL, New Britain, CT

EMERGENCY DEPARTMENT PHYSICIAN

- **Direct patient care 36 hours a week.**

CAREER HIGHLIGHTS

- Founder, President, Majority Stockholder, Immediate Medical Care Center (IMCC)/Connecticut Physical Ther now Hartford Healthcare Medical Group and Hartford Hospital Rehabilitation Network, October 1982.
- Created partnership in IMCC with Gene Winchester, MD, Chief Resident in Medicine, Hartford Hospital, Oct First physician hired in February 1983, Kent Stahl, MD, President of House Staff, Hartford Hospital, now CEC Healthcare Medical Group.
- All IMCC and CPT units opened and seeing patients in 27 months between May 1983-August 1985.
- Core Hartford area IMCC centers are now Hartford Healthcare Medical Group and have grown to 250 medical in over 50 locations.
- Core CPT units are now Hartford Hospital Rehabilitation Network.
- Bridgeport IMCC was initial ambulatory care center in what is now a group of four St. Vincent Medical Cen Care Centers.
- **Have gone from room to room caring for patients, making diagnoses, and designing treatments since 1 only two years off when developing medical care delivery system.**

DIRECT PATIENT CARE

- **Emergency medicine (1982) - 36 hours a week.**
- **Acute ambulatory care medicine (1983, 1985-1995) 45 hours a week.**
- **Emergency medicine (1995 - 2011) 36 hours a week.**
- **Emergency medicine (2011 - Present) 26 hours a week.**

ATTACHMENT D

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0042

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

The Charlotte Hungerford Hospital of Torrington, CT d/b/a The Charlotte Hungerford Hospital is hereby licensed to maintain and operate a General Hospital.

The Charlotte Hungerford Hospital is located at 540 Litchfield Street, Torrington, CT 06790.

The maximum number of beds shall not exceed at any time:

13 Bassinets
109 General Hospital Beds

This license expires **September 30, 2015** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, October 1, 2013. RENEWAL.

Satellites:

The Charlotte Hungerford Hospital Cancer Center, 200 Kennedy Drive, Torrington, CT
The Charlotte Hungerford Northwest Connecticut Medical Walk In, East Main Street, Torrington, CT
Winsted Health Center, 115 Spencer Street, Winsted, CT
The Charlotte Hungerford Psychiatric Outpatient Clinic-Peck Road, 294 Main Street, Winsted, CT
The Charlotte Hungerford Hospital Wound Care, 7 Felicity Lane, Torrington, CT

Jewel Mullen, MD, MPH, MPA
Commissioner

ATTACHMENT E

Winsted Cat Scan Renovation

Estimated Time to Complete Work: 60 Days

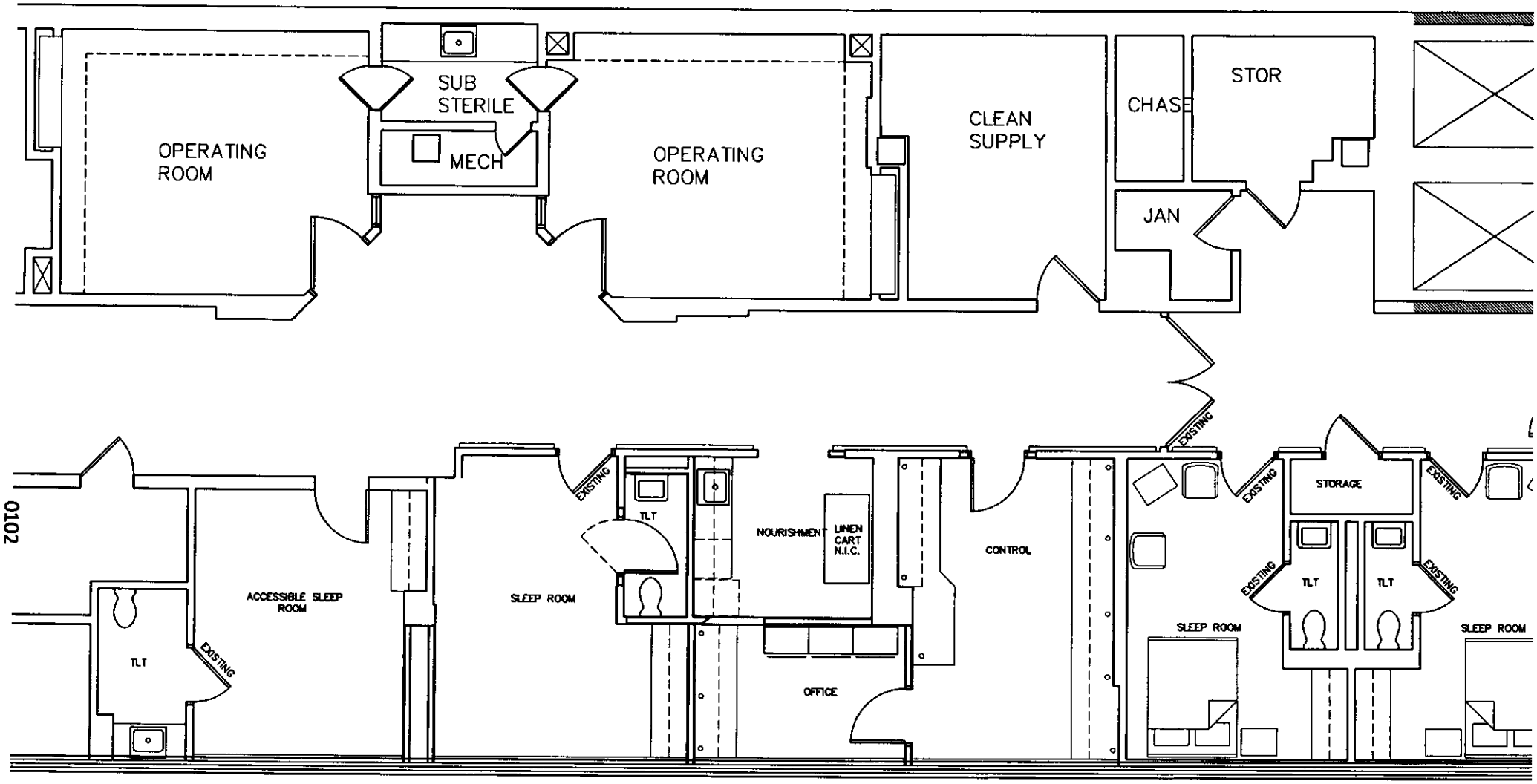
Gross Square Footage: 640

Renovation Start Date: August 1, 2015

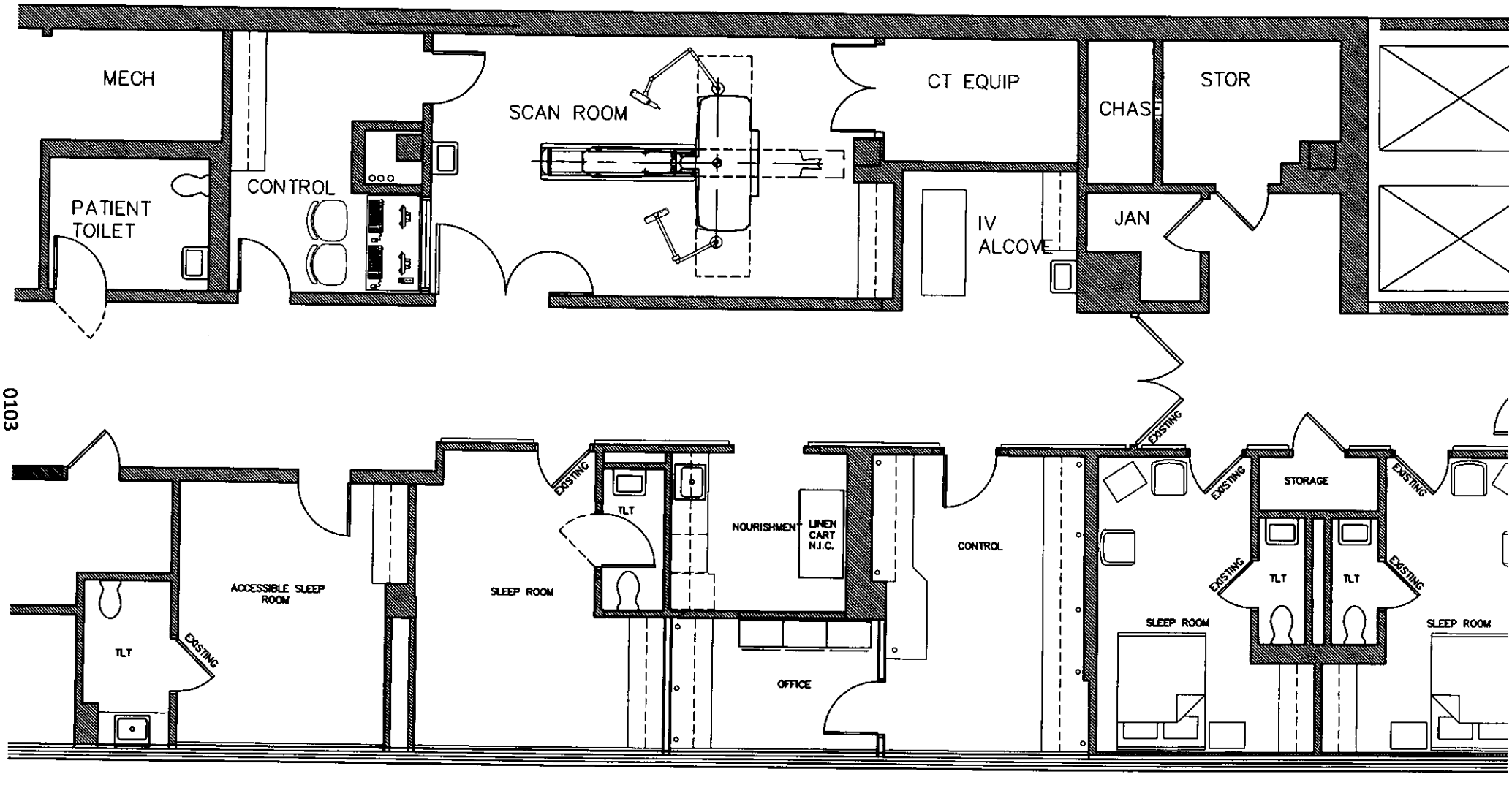
Description of work to be performed:

The work consists of removal of existing construction including walls, doors and frames, ceilings and finishes along with associated MEP system components. The new work consists of new walls with the appropriate shielding, new doors and frames, new ceilings and flooring, miscellaneous millwork, installation of supplemental cooling and modifications to the existing ventilation system. Also included will be upgraded electrical systems to serve the new equipment, new lighting, modifications to the existing fire sprinkler system and minor plumbing work.

Commencement of Operations: October 1, 2015



EXISTING FLOOR PLAN


MECH
PATIENT TOILET
CONTROL
SCAN ROOM
CT EQUIP
CHASE
STOR
IV ALCOVE
JAN
0103
EXISTING
TLT
NOURISHMENT
LINEN CART N.I.C.
CONTROL
STORAGE
ACCESSIBLE SLEEP ROOM
SLEEP ROOM
OFFICE
SLEEP ROOM
SLEEP ROOM

FLOOR PLAN

ATTACHMENT I

ATTCAHMENT I

ATTCAHMENT I

7 a. 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 14 Actual Results	FY 15 Projected W/out CON	FY 15 Projected Incremental	FY 15 Projected With CON	FY 16 Projected W/out CON	FY 16 Projected Incremental	FY 16 Projected With CON	FY 17 Projected W/out CON	FY 17 Projected Incremental	FY 17 Projected With CON
NET PATIENT REVENUE										
Non-Government	$49,040,409	$49,477,067	87,503.37	$49,564,570	$50,961,379	92,881.71	$51,054,261	$52,490,220	98,504.00	$52,588,724
Medicare	$49,157,731	$49,595,433	45,960.51	$49,641,394	$50,091,388	47,826.79	$50,139,214	$50,592,301	49,725.79	$50,642,027
Medicaid and Other Medical Assistance	$18,654,127	$18,820,224	32,641.22	$18,852,865	$18,820,224	33,630.35	$18,853,854	$18,820,224	34,619.48	$18,854,844
Other Government	$469,286	$473,465	$0	$473,465	$478,199	$0	$478,199	$482,981	$0	$482,981
Total Net Patient Patient Revenue	$117,321,553	$118,366,189	$166,105	$118,532,294	$120,351,190	$174,339	$120,525,529	$122,385,727	$182,849	$122,568,577
Other Operating Revenue	$7,533,927	$6,556,523	$0	$6,556,523	$6,687,653		$6,687,653	$6,821,407		$6,821,407
Revenue from Operations	$124,855,480	$124,922,712	$166,105	$125,088,817	$127,038,843	$174,339	$127,213,182	$129,207,134	$182,849	$129,389,983
OPERATING EXPENSES										
Salaries and Fringe Benefits	$73,040,987	$73,154,967	$0	$73,154,967	$74,618,066	$0	$74,618,066	$76,110,428	$0	$76,110,428
Professional / Contracted Services	$20,697,318	$21,393,533	$2,150	$21,395,683	$21,928,371	$1,900	$21,930,271	$22,476,581	$1,900	$22,478,481
Supplies and Drugs	$16,269,014	$15,279,267	$9,500	$15,288,767	$15,890,438	$11,000	$15,901,438	$16,526,055	$12,200	$16,538,255
Bad Debts	$2,699,503	$3,105,000	$14,145	$3,119,145	$2,407,024	$15,011	$2,422,035	$2,447,715	$15,916	$2,463,630
Other Operating Expense	$4,226,310	$4,526,528	$5,000	$4,531,528	$4,617,059	$7,000	$4,624,059	$4,709,400	$10,000	$4,719,400
Subtotal	$116,933,132	$117,459,295	$30,795	$117,490,090	$119,460,958	$34,911	$119,495,868	$122,270,178	$40,016	$122,310,194
Depreciation/Amortization	$5,899,420	$6,171,625	$99,000	$6,270,625	$6,202,483	$99,000	$6,301,483	$6,233,496	$99,000	$6,332,496
Interest Expense	$15,651	$0	$0	$0	$0	$0	$0	$0	$0	$0
Lease Expense	$1,850,131	$1,235,373	$0	$1,235,373	$1,253,904	$0	$1,253,904	$1,272,712	$0	$1,272,712
Total Operating Expense	$124,698,334	$124,866,293	$129,795	$124,996,088	$126,917,344	$133,911	$127,051,255	$129,776,385	$139,016	$129,915,401
Gain/(Loss) from Operations	$157,146	$56,419	$36,310	$92,729	$121,499	$40,428	$161,927	($569,252)	$43,833	($525,418)
Plus: Non-Operating Revenue	$2,865,900	$1,890,000		$1,890,000	$1,984,500		$1,984,500	$2,083,725		$2,083,725
Revenue Over/(Under) Expense	$3,023,046	$1,946,419	$36,310	$1,982,729	$2,105,999	$40,428	$2,146,427	$1,514,473	$43,833	$1,558,307
FTEs							0			0
*Volume Statistics: new statistics CT Exams Outpatient		660			680			700		

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.

0105

ATTACHMENT I b

Assumptions

I. Incremental to the Project

Volume

1. ED CT Scans - 400
2. Outpatient Ct Scans - 260

Volume based on:
1. review of ambulance run sheets to determine # of patients who would benefit from CT during the hours of 9 am and 9 pm from Winsted and the towns contigious to Winsted.
2. Outpatient volume based on discussion with Primary Care Physicians in the Winsted area.
3. Volume inflated 3% per year.

Revenue

Revenue is base on current CHH contracted rates.
CT Payer mix assumed to be same payer Mix as current Winsted ED payer mix.
Price Increase of 3% per year

Expenses

Exepenses based on current FY 2014 cost for CHH to operate CT scanner at the Hospitals main campus inflated by 3% per year.

Bad Debt calculated as 1.8% of Gross Revenue

Depreciation based on quote for refurbished Toshiba 16 Slice CT and renovation esitmate based on schematic design.

	Cost Estimate	Usefull life	Annual Depreciation
CT Scanner	370,000.000	5	74,000.000
Renovation	275,000.000	11	25,000.000
			99,000.000

Current Staff will operate the unit with addiotional training.

II. Assumptions Without CON

FY 2014 Audited Financial Statements were used as the starting point.

Volume

Volumes Year 1 based upon FY 2105 budget, assumed to be flat, no increase for Years 2 and 3.

Revenue

Revenue Year 1 was based on FY 2015 Price Increase inflated 3 % for Years 2 and 3.

Gross: 3% Price increase

Net:
- Non-Government - 3%
- Medicare - 1% Net
- other Government - 1%
- Other Operating - 2%
- Medicaid - no increase

Expenses

Exepenses based on current FY 2014 cost inflated for Year 1 based on FY 2015 budget and then increased as follows:

- Salaries and Fringe Benefits - 2%
- Professional/Contracted Services - 2.5%
- Supplies and Drugs - 4%
- Bad Debt - 2%
- Depreciation/Amoritization 0.5%
- Interest Expense - 0
- Lease Expense 1.5%
- other Operating - 2%

Non-Operating Revenue

5% Increase per year based on historical averages

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

May 5, 2015

VIA FAX ONLY

Mr. John Capobianco
Vice President for Operations
Charlotte Hungerford Hospital
540 Litchfield Street,
Torrington, CT 06790

RE: Certificate of Need Application, Docket Number 15-31989-CON
Acquisition of a Computed Tomography ("CT") scanner for the Hungerford Emergency and Medical Care Center in Winsted.

Dear Mr. Capobianco:

On April 8, 2015, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application filing on behalf of Charlotte Hungerford Hospital ("CHH" or "Applicant") proposing to acquire a CT scanner for use at the Hungerford Emergency and Medical Care Center ("HEMC") in Winsted, with an associated capital expenditure of $645,000.

OHCA has reviewed the CON application pursuant to Connecticut General Statutes §19a-639a(c) and requests the following additional information:

1. Please provide the CHH service area utilizing the following table:

TABLE 1
SERVICE AREA TOWNS

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion

* Village or place names are not acceptable.

2. Page nine of the application states that the distance from HEMC to CHH is twelve miles. What is the average transport time via ambulance? Once the patient has arrived at CHH, how long, on average, before the patient actually receives the CT scan?

3. Please provide the historical and projected overall volumes for HEMC using the following tables:

TABLE 2
HISTORICAL UTILIZATION AT HEMC

	Actual Volume			CFY Volume
Service	**FY 2012**	**FY 2013**	**FY 2014**	**FY 2015**
ED Visits				
Total				

TABLE 3
PROJECTED UTILIZATION AT HEMC

	Projected Volume		
Service	**FY 2016**	**FY 2017**	**FY 2018**
ED Visits			
Total			

4. What will the hours of operation be for the proposed CT scanner at HEMC?

5. Has CHH considered extending the HEMC hours of operation to 24 hours per day, 7 days per week? Please elaborate on why this is or is not a consideration.

6. Utilizing the table below, provide the historical payer mix at **HEMC**:

TABLE 4
HISTORICAL PAYER MIX AT HEMC

Payer	Projected					
	FY 2012		FY 2013		FY 2014	
	Visits	%	Visits	%	Visits	%
Medicare*						
Medicaid*						
CHAMPUS & TriCare						
Total Government						
Commercial Insurers						
Uninsured						
Workers Compensation						
Total Non-Government						
Total Payer Mix						

*Includes managed care activity.

7. Provide a detailed description on how the projected CT volumes for HEMC were determined and provide the supporting evidence (ambulance run sheets or a summary of these sheets) used to calculate these estimates.

8. Explain in further detail why CHH "assumes a 3% increase in CT volume per year" as stated on page 9 of the application.

9. Please confirm that the volumes in table 4A and 4B on pages 14-16 of the application represent scans.

10. HRS report 450 (Hungerford hospital 12 month filing), lists volumes for "Other Non-Hospital Providers' Scans" for FY12-FY14. Please revise the table on page 10 to include all missing imaging modalities for your service locations (e.g., add Advanced Medical Imaging of Northwest CT, LLC – CT imaging).

11. Provide the number of CT scans performed at the Advanced Medical Imaging of Northwest CT, LLC service location for fiscal years (FY) 2012-2014 using the table below:

TABLE 5
CT UTILIZATION AT ADVANCED MEDICAL IMAGING OF NORWEST CT, LLC

	Projected Volume		
Equipment	**FY 2012**	**FY 2013**	**FY 2014**
CT Scans			
Total			

12. Provide a breakdown of the scan volume (provided in response to question 11, above) for the area of the body examined (similar to Table 4B, pages 15-16 of the application).

13. Table 5 on page 17 shows the breakdown of volume by town for the most recently completed year. Please revise the table to include labels that explain what the "volumes" represent (scans, visits, etc.) and the service location (e.g., Charlotte Hungerford ED). Explain any variance from data reported in the Hospital Reporting System (HRS).

14. For the proposed CT scanner, please attach a vendor quote or invoice, schedule of depreciation, estimate of useful life of the equipment and anticipated residual value at the end of the lease or loan term.

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 108** and reference "**Docket Number: 15-31989-CON.**" Submit one (1) original and three (3) 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 copied to the CD.

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than **July 4, 2015**, otherwise your application will be automatically considered withdrawn.

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7014 or Alla Veyberman at (860) 418-7007.

Sincerely,

Brian A. Carney
Associate Research Analyst

* * * COMMUNICATION RESULT REPORT (MAY. 5. 2015 11:19AM) * * *

FAX HEADER:

TRANSMITTED/STORED : MAY. 5. 2015 11:18AM

FILE MODE	OPTION	ADDRESS	RESULT	PAGE
038 MEMORY TX		98604828627	OK	5/5

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JOHN CAPOBIANCO

FAX: (860) 482-8627

AGENCY: CHARLOTTE HUNGERFORD HOSPITAL

FROM: OHCA

DATE: 5/5/15 **Time:**

NUMBER OF PAGES: 5
(including transmittal sheet

Comments:
Completeness Letter for Docket Number: 15-31989

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS

Phone: (860) 418-7001 ***Fax: (860) 418-7053***

410 Capitol Ave., MS#13HCA
P.O.Box 340308
Hartford, CT 06134

Charlotte Hungerford Hospital
540 LITCHFIELD STREET, PO BOX 988, TORRINGTON, CT 06790-0988 (860)496-6666

June 30, 2015

Mr. Brian Carney
Associate Research Analyst
Office of Health Care Access
410 Capital Avenue
MS # 13HCA
P.O. Box 340308
Hartford, CT 06106

RE: Charlotte Hungerford Hospital
Certificate of Need Application
Acquisition of a CT Scanner for the
Hungerford Emergency and Medical
Care Center in Winsted – Additional
Information Requested

Dear Brian,

Enclosed please find the original and three (3) hard copies, as well as an electronic copy on CD of the additional information needed by Charlotte Hungerford Hospital for the Acquisition of a CT Scanner for our Winsted Emergency Facility.

Please do not hesitate to contact me with any additional questions or concerns.

Thank you for your time.

Sincerely,

John J. Capobianco
Vice President of Operations
The Charlotte Hungerford Hospital

Enclosures

1. Please provide the CHH service area utilizing the following table:

TABLE 1
SERVICE AREA TOWNS

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
	Each town represent the top 85% of all visits to the HEMC Emergency Department
FY 15 TO DATE	
Winsted	61.73
Torrington	8.57
Barkhamsted	5.71
Norfolk	4.97
New Hartford	4.55
	85.53
FY 14	
Winsted	57.77
Torrington	8.61
Barkhamsted	5.99
Norfolk	4.71
New Hartford	4.51
Colebrook	2.54
Riverton	1.54
	85.67

*Village or place names are not acceptable.

2. Page nine of the application states that the distance from HEMC to CHH is twelve miles. What is the average transport time via ambulance? Once the patient has arrived at CHH, how long, on average, before the patient actually receives the CT scan?

An analysis of patient records previously submitted to illustrate the number of transfers from HEMC due to the need for CT Scanning, n=109, from November 2013 to October 2014, provided the following data.

Time from arrival at CHH to CT	Range (h:mm)	Mean (h:mm)
	0:15-4:17	1:17

Since there is only one CT Scanner at the main campus, once a patient arrives the time to scanner is variable. The major factors impacting the time to scanner are the priorities of other ED and Inpatient needs.

3. Please provide the historical and projected overall volumes for HEMC using the following tables:

Table 2
HISTORICAL UTILIZATION AT HEMC

	Actual Volume			CFY Volume
Service	FY 2012	FY 2013	FY 2014	FY 2015
ED Visits	6603	6162	6361	3765
Total				(7 months)

Table 3
PROJECTED UTILIZATION AT HEMC

	Projected Value		
Service	FY 2016	FY 2017	FY 2018
ED Visits	6500	6500	6500
Total			

4. What will the hours of operation be for the proposed CT scanner at HEMC?

   Hours of service will be 9 am to 9pm, seven days per week.

5. Has CHH considered extending the HEMC hours of operation to 24 hours per day, 7 days per week? Please elaborate on why this is or not a consideration.

No, we have not considered increasing the hours of service. We do track volume and wait times. At present we see no evidence that the extension of hours would meet a community need.

6. Utilizing the table below, provide the historical payer mix at HEMC:

Table 4
HISTORICAL PAYER MIX AT HEMC

Payer	Projected					
	FY 2012		FY 2013		FY 2014	
	Visits	%	Visits	%	Visits	%
Medicare*	1324	20.1	1412	22.9	1543	24.3
Medicaid	2159	32.7	2090	33.9	2316	36.4
CHAMPUS & Tricare	49	0.7	50	0.8	43	0.7
Total Government	3532	53.5	3552	57.6	3902	61.3
Commercial Insurers	2366	35.8	2033	33.0	2040	32.1
Uninsured	581	8.8	457	7.4	305	4.8
Worker's Compensation	124	1.9	120	1.9	114	1.8
Total Non-Government	3071	46.5	2610	42.4	2459	38.7
Total Payer Mix	6603	100	6162	100	6361	100

*Includes managed care activity, numbers are based on registered patients

7. Provide a detailed description on how the projected CT volumes for HEMC were determined and provide the supporting evidence (ambulance run sheets or a summary of these sheets) used to calculate these estimates.

We found that the common complaints that required CT scanning included: falls, abdominal pain, change in mental status, severe headache, and weakness. Of these chief complaints we reviewed ambulance run sheets which showed that 52% of the time these patients had a CT Scan as part of their work-up. We then applied this rate to the number of ambulance calls with these or similar chief complaints. We then added this number to the number of transfer to CHH for CT Scans as noted in the answer to question 4b on page 16 of the original CON document. Please see Attachment F for a summary of this data.

8. Explain in further detail why CHH "assumes a 3% increase in CT volume per year" as stated on page 9 of the application.

   We used the actual volume change from FY 2103 to FY 2104 which was 3% and applied this to subsequent years. Through 7 months (April 2015) we have a 4% increase in volume over budget. Our Winsted facility experiences seasonal volume growth especially in summer so we felt the 3% was a conservative approach.

9. Please confirm that the volumes in table 4A and 4B on pages 14-16 of the application represent scans.

   Yes they do represent scans.

10. HRS report 450 (Hungerford hospital 12 month filing), lists volumes for "Other Non-Hospital Providers' Scans" for FY 12-FY14. Please revise the table on page 10 to include all missing imaging modalities for your service locations (e.g., add Advanced Medical Imaging of Northwest CT, LLC – CT imaging).

Town	Equipment	Utilization FY 14
Charlotte Hungerford Hospital: **ED Volumes**: Torrington: 1,967 Winsted: 333 Litchfield: 196 Harwinton:124 Kent:117	**CHH:** AQ64/V-AR Toshiba Aquilion 64 slice CT Scanner **Advanced Medical Imaging of Northwest CT,LLC:**	10/1/13 to 9/30/14

Surrounding towns: 1,660 **INPATIENT Volumes:** Torrington: 1,121 Winsted: 206 Litchfield: 128 Harwinton: 77 Kent:52 Surrounding towns: 1,111 **OUTPATIENT Volumes:** Torrington: 1192 Winsted: 271 Litchfield: 127 Harwinton: 122 Kent: 85 Surrounding towns: 546 **Advanced Medical Imaging:** **Outpatient Volumes:** Torrington: 793 Winsted: 258 Litchfield: 111 Harwinton: 93 Kent: 74 Surrounding towns: 515 **Charlotte Hungerford Hospital** **Total: FY 14 9,435**	GE 16 slice	

Advanced Medical Imaging: **Total: FY 14 1,844**		

11. Provide the number of CT scans performed at the Advanced Medical Imaging of Northwest CT, LLC service location for fiscal years (FY) 2012-2014 using the table below:

Table 5
CT UTILIZATION AT ADVANCED MEDICAL IMAGING OF NORTHWEST CT, LLC

	Projected Volume		
Equipment	FY 2012	FY 2013	FY 2014
CT Scans	1848	1778	1844
Total	1848	1778	1844

12. Provide a breakdown of the scan volume (provided in response to question 11, above) for the area of the body examined (similar to Table 4B, pages 15-16 of the application).

Service* **	**Actual Volume: Advanced Medical Imaging of Northwest CT, LLC (Last 3 Completed FYs)**		
	FY 12	FY 13	FY 14
Abdomen/Pelv	648	570	578
Abdomen	67	52	65
Chest/ab/pelv	3		
Chest/thor	549	551	590
Colonoscopy	10	6	9
Abd/pelv angio	3	2	2
Chest angio	25	37	27

Head/ct angio	1	1	2
Ext lower	38	49	36
Ext upper	72	82	77
Guide needle	60	48	85
Heart	6	9	18
Head	141	119	112
Injection guid	5		2
Maxofacial	34	27	52
Orbitis	3	3	4
Pelvis	25	34	14
Cervical	24	18	28
Lumbar	74	82	62
Neck	60	62	50
Lung ca scrn		24	30
Thoracic		2	1
Total	**1848**	**1778**	**1844**

13. Table 5 on page 17 shows the breakdown of volume by town for the most recently completed year. Please revise the table to include labels that explain what the "volumes" represent (scans, visits, etc.) and the service location (e.g., Charlotte Hungerford ED). Explain any variance from data reported in the Hospital Reporting System (HRS).

TABLE 5
Utilization by Town
Service Location: **Charlotte Hungerford Hospital**

Town	Equipment	Utilization FY 14
ED Volumes:Scans		
Torrington: 1,967		
Winsted: 333		
Litchfield: 196		
Harwinton:124		
Kent:117		
Surrounding towns: 1,660		
INPATIENT Volumes: Scans		
Torrington: 1,121		
Winsted: 206		
Litchfield: 128		
Harwinton: 77		
Kent:52		
Surrounding towns: 1,111		
OUTPATIENT Volumes: Scans	AQ64/V-AR	10/1/13 to 9/30/14
Torrington: 1192	Toshiba Aquilion 64 slice CT Scanner	

Winsted: 271 Litchfield: 127 Harwinton: 122 Kent: 85 Surrounding towns: 546 **Total: FY14 9,435**		

The volume reported in the HRS reflects a variance compared to the volumes submitted in the proposed CON. The CON represents actual scans performed. The CON asked for scans volumes indicating the area of the body examined. It did not include other units such as 3d reconstruction, biopsy guide, and catheter fluid.

14. For the proposed CT scanner, please attach a vendor quote or invoice, schedule of depreciation, estimate of useful life of the equipment and anticipated residual value at the end of the lease or loan term.
    - *Please see Attachment G: for a copy of the vendor quote: Aquilion 16 Whole Body scanner.*
    - *Depreciation based on quote for refurbished Toshiba 16 Slice CT and renovation estimate based on schematic design.*

	Cost Estimate	*Usefull life*	*Annual Depreciation*
CT Scanner	*370,000.000*	*5*	*74,000.000*
Renovation	*275,000.000*	*11*	*25,000.000*
			99,000.000

ATTACHMENT F

Review of Ambulance Run Sheets
9am - 9pm

	12 Months CY 14
Abd Pain	217
Fall	190
Change in Mental Status	48
Headache	5
weakness	100
Total	560

52% conversion rate	291.2
Transfers to CHH for CT	109
Total CT Scans	400.2

ATTACHMENT G

TOSHIBA
Leading Innovation >>>

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

QUOTATION/ORDER ORDER SUMMARY

SID NO: 30026483
DATE: 10/31/2014 QUOTE NO: 62461-1

PRESENTED TO: (COMPLETE LEGAL NAME)

CHARLOTTE HUNGERFORD HOSPITAL
540 LITCHFIELD ST
TORRINGTON, CT. 06790

DELIVER TO:

CHARLOTTE HUNGERFORD HOSPITAL
540 LITCHFIELD ST
TORRINGTON, CT. 06790

EQUIPMENT SUMMARY:

AQ16/ASSURE.000

AQUILION 16 WHOLE BODY SCANNER -- REFURBISHED SYSTEM

USED CT SCANNER AQUILION 16 WITH EXTENDED COUCH

7.5 MHU CT X-RAY TUBE

ACCESSORY KIT FOR EXTENDED PATIENT COUCH

CT PHANTOM

CONSOLE DESK 65" X 36" X 30"

CHAIR WITH ADJUSTABLE ARMS AND BACK (Qty 2)

MEDIA FOR DVD-RAM DRIVE (9.4 GB) (Qty 5)

CABLE CATEGORY 5E/RJ45 5M

This quotation shall remain valid until December 19, 2014.
All prices are F.O.B. destination.
Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 30 days after shipment or upon availability for first use by purchaser, whichever comes first.

Additional terms and conditions appear at the end of this quotation. McKesson Agreement Required _____Yes _____No
Vital Software License Agreement Required _____Yes _____No
Please return signed quotation to: Toshiba America Medical Systems, 2441 Michelle Drive, Tustin, CA 92780 or fax to either number.
Fax: 714/669-4578 or 714/669-1762 Attention: Quote/Order Department.

ACCEPTED AGREED AND ORDERED:

CUSTOMER REQUESTED DELIVERY DATE: _____ _____ _____
TOSHIBA REP/CONTACT DATE

_____ _____ _____ _____
PURCHASER'S SIGNATURE/TITLE DATE ZONE SALES MANAGER DATE

QUOTATION/ORDER ORDER SUMMARY

DATE: 10/31/2014

SID NO: 30026483
QUOTE NO: 62461-1

PRESENTED TO: (COMPLETE LEGAL NAME)

CHARLOTTE HUNGERFORD HOSPITAL
540 LITCHFIELD ST
TORRINGTON, CT. 06790

EQUIPMENT SUMMARY: (continued)

CABLE CATEGORY 5E/RJ45 35M

SERVICE MODEM CABLE (Qty 2)

FLOOR LEVELING EPOXY KIT

CT SOFTWARE UPGRADE KIT (V3.5) FOR AQ16/8

PGP STUDY SPLIT FOR AQUILION 16, 32 AND 64

DICOM MODALITY WORKLIST MANAGEMENT (MWM) SERVICE CLASS USER (SCU) SYSTEM

EPROTECT AUTHENTICATION AND MALWARE PROTECTION DEVICE

EPROTECT KIT,MINI ROUTER WITH ACCESSORIES

POWER CONDITIONER/DISTRIBUTOR 125 KVA UNIVERSAL

DICOM QUERY/RETRIEVE SCU AQ/MP

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AQ16/ASSURE.000 AQUILION 16 WHOLE BODY SCANNER -- REFURBISHED SYSTEM

This Aquilion Assurance CT Scanner is a refurbished Aquilion 16 CT scanner. This Aquilion 16 CT scanner carries a one (1) year warranty beginning the date of completion of installation, and comes with a new X-ray tube.

This quotation is subject to availability of equipment and system options.

Customer will be required to execute a non-cancelable four-year Toshiba Full Service Maintenance Agreement covering the Aquilion 16 system on or before delivery of such system.

Aquilion 16 is a whole-body Computed Tomography (CT) scanner that provides uncompromised image quality and outstanding clinical performance

Its Quantum detector provides true isotropic resolution in the small field of view with 0.5 mm – the industry's thinnest slice width. This enables the user to scan in one plane and reconstruct images in another plane reducing radiation by eliminating the need for a second scan. Aquilion's Quantum detector is the only detector to provide three slice-width combinations – 16x0.5, 16x1 and 16x2 mm, and it achieves the industry's best low-contrast resolution.

The combination of a high-speed scanner and an extremely powerful, high-voltage generator meets every diagnostic requirement. Solid-state, multi-row detectors and optimal reconstruction techniques ensure high-quality images. A high-performance CPU, large color monitors, hybrid keyboard and refined Graphic User Interface (GUI) make the operating environment highly efficient.

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COMPONENTS

- Large-aperture, slip-ring gantry and extra-wide couch
- Ergonomic operator console
- High-frequency X-ray generator
- High-heat-capacity X-ray tube
- DVD disk storage
- Image data transfer link
- Patient positioning accessories
- Operator manuals and quality assurance phantoms

KEY FEATURES

Routine Fast Scanning: Using slip-ring technology, Aquilion 16 is able to perform 0.32-second partial scans and 0.5-second routine scans to meet the demands of dynamic and helical examinations.

High Image Quality: The Aquilion 16 features 896 channels in 40 rows of solid-state detectors; specialized, user-selectable, image-reconstruction algorithms; and a wide selection of slice thicknesses. The system provides outstanding low-contrast resolution of 2 mm at 0.3% and high-contrast resolution of 0.35 mm.

High-Power Generator: Robust, high-voltage circuits generate 60 kW of power and 500 mA, providing support for the 7.5 MHU X-ray tube that makes possible helical scans up to 100 seconds and scans with metal-free scan range of up to 1,800 mm.

Multiple kV Selections: 80, 100, 120 and 135 kV.

SURE**Technology:** Provides maximum productivity and best image quality. Real-time helical display, which provides instantaneous visualization of acquired images, allowing the operator to rapidly assess if additional images are needed. SUREStart bolus tracking device, provides the ability to monitor contrast media.

Easy Operation: Perform easy operations using the 19-inch LCD monitor, mouse and hybrid keyboard. Scan automatically by programming procedures with eXam Plan and vocal instructions through VoiceLink™.

NEMA XR 25 and XR 29

Aquilion 16 meets the National Electrical Manufacturers Association's (NEMA) Medical Imaging & Technology Alliance (MITA) standards XR 25 and XR 29.

- MITA XR 25 Computed Tomography Dose Check
  - Includes dose alerts and allows facilities to set dose notification values.
- MITA XR 29 Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management
  - Smart Dose standard bundles four important features to ensure that equipment produces high-quality diagnostic images while supporting patient safety:
    - DICOM Structured Reporting
    - CT Dose Check
    - Automatic Exposure Controls,
    - Pediatric and adult reference protocols.

EQUIPMENT DESCRIPTION

Aquilion 16 Gantry

The Aquilion 16 gantry uses rotate-rotate design to provide accurate alignment between beam and detector for more precise image data.

A low-voltage slip ring assures reliable, continuous power transfer.

- Digital signal transmission facilitated by innovative optical-coupling technology
- Generator is inside the gantry to conserve space

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Other features include:

- Large aperture: 72 cm
- Five scan fields of view: 18, 24, 32, 40 and 50 cm
- Gantry controls on both right and left sides
- Patient positioning lights
- Wide range of scan times provides greater flexibility for optimal image quality (0.32 partial; 0.5, 0.75, 1, 1.5, 2 and 3 seconds full)
- Gantry tilt range of ±30 degrees during axial and helical acquisitions
- Slice thickness selections of 16x0.5, 16x1 and 16x2 mm with the capability of stacking images or reconstructing images to the desired slice thickness

Couch

- 47 cm wide, metal-free couch top
- Horizontal stroke of 2,190 mm and a scanning range of 1,800 mm for tall patients
- Couch top can be lowered to 30 cm (12 inches)
- Manual control of table incrementation from both the gantry and console or programmed by an exam protocol
- Couch top supports up to 450 lbs. while maintaining accuracy of ±0.25 mm

Dual Consoles

- Consists of hybrid keyboards, mouse, monitors and Navibox
- Controls the entire system, including power
- Image display
- Scanogram control
- Remote control of couch-top movement
- Gantry tilt control
- Window level and width adjustment
- Three preset windows can be stored in the eXam Plans

- Other mouse-operated, image-processing functions
- High line-rate, 19-inch LCD monitors
- Displays images in 512x512 or 1024x1024
- CT number display ranges from -1,536 to +8,191
- 32 programmable voice commands

X-ray Tube
The Aquilion 16 is equipped with the MegaCoolTM X-ray tube. This compact, high-performance tube was designed specifically to minimize tube-cooling delays in heavy patient-load conditions using 0.5-second scan time.

Other features include:
- Dual focal spots
- Anode capacity of 7.5 MHU
- Dissipation rate of 1,386 kHU per minute maximum

Image Management
Aquilion 16 images can be stored on hard disk, DVD or transferred via gigabit Ethernet connection using DICOM 3.0 standards.

DICOM 3.0 (Storage SCU)

DICOM 3.0 (Print SCU)

Helical Scan & Functionality
MultiView: Built into protocol for fast, multi-planar reconstruction in batch mode specifically for multislice data sets. Coronal, sagittal and axial are displayed in real-time for immediate viewing.

3-D Imaging: Provides excellent image quality with surface shaded-renderings and volume-rendered 3-D images. Provides zooming and panning over the 3-D surface and performs distance measurements. Other features include:

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eXam Plan Protocols

- 684 eXam Plan protocols that can be adjusted while scanning
- Four preset reconstructions
- eXam Plan sets can be stored on optical disks and copied to other Toshiba scanners

Archiving

- Can be automated with each eXam Plan
- Raw data can be stored on and retrieved from DVD
- Raw data and image data can be protected to prevent deletion

Toshiba CT ePROTECT Authentication and Malware Protection Device

eProtect is the quickest, simplest, and most secure protection for Toshiba equipment. eProtect is a specially configured network device designed to isolate Toshiba medical products from hospital network traffic. eProtect will control and limit traffic into and out of Toshiba Products to allow DICOM services like Modality Worklist, Storage to PACS and workstations, Query & Retrieve, etc.

At the same time, eProtect restricts unnecessary network traffic from reaching the medical device. This unnecessary network traffic could be, but is not limited to viruses, malware, and malicious attacks. Toshiba has found this to be the best form of malware protection for Toshiba imaging equipment. eProtect is provided *free of charge to Toshiba warranty and service agreement customers*. This feature, a $20,000 value, is included in each Aquilion at no additional charge.

InnerVision

Remote diagnostics proactively monitor the system to minimize downtime

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APPLICATION TRAINING

Each system includes two phases of training.

Phase I: An initial thirty-two (32) hours of on-site education will be provided at the customer facility following system go-live. This training is provided for up to four (4) imaging professionals, selected by customer, to focus on maximizing scanning techniques and protocols. Training is scheduled consecutively, Monday through Friday, during standard business hours, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist.

Phase II: An additional twenty-four (24) hours of follow up on-site education, will be provided for the same four (4) imaging professionals that participated in Phase 1 training. Phase II training takes place approximately 6-8 weeks following the completion of Phase I, to optimize staff proficiency and system productivity. CE credits are earned by participants that attend both Phase I and Phase II training events in their entirety.

Note: Toshiba personnel are not responsible for scanning patients, patient safety, or any actual patient contact, or operation of equipment during education sessions. Toshiba will only demonstrate proper equipment operation.

The above training must be completed by no later than one (1) year from date of completion of installation. If not completed by such one-year period, Toshiba reserves the right to charge for any training provided after that.

Applications support is available by phone on the toll-free ASSIST line.

Additional on-site training is available for purchase.

TOSHIBA
Leading Innovation >>>

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COMPONENT SUMMARY:

USED CT SCANNER AQUILION 16 WITH EXTENDED COUCH

7.5 MHU CT X-RAY TUBE

ACCESSORY KIT FOR EXTENDED PATIENT COUCH

Includes each of the following items:

- "The Shield" Table Pad
- Rolled Edge Foot Extension Pad
- Protective Table Cover
- Wide & Medium Security Straps
- Chin Strap
- Forehead Strap with Adult Pad
- Adult Head Rests
- Tilt Wedge
- Knee Wedge
- Coronal Head Positioner
- Pediatric Lift Pad
- Rail, Detachable, 69"

CT PHANTOM

Measures image quality to ensure compliance to Toshiba standards for:

- High-contrast resolution
- Low-contrast resolution
- Slice thickness
- Noise
- Contrast scale

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DICOM MODALITY WORKLIST MANAGEMENT (MWM) SERVICE CLASS USER (SCU) SYSTEM

Allows the CT system to receive patient demographic data from an HIS/RIS system in conformance with the DICOM 3.0 standard.

Note: This option does not include a DICOM gateway for the HIS/RIS system.

EPROTECT AUTHENTICATION AND MALWARE PROTECTION DEVICE

EPROTECT KIT,MINI ROUTER WITH ACCESSORIES

PCDU-TW/U

POWER CONDITIONER/DISTRIBUTOR 125 KVA UNIVERSAL

The PCDU-CT is engineered to address the vast majority of common power problems found in the hospital environment, thus providing clean power and good grounding for optimal reliability and performance of CT systems.

This device provides most of the electrical site preparation requirements of Toshiba CT systems, including:

<u>Power Conditioning</u>
The PCDU contains a combination of a shielded, ultra-low impedance isolation transformer with matched L-R-C low-pass filters and surge suppressors. The quality of power to the Toshiba system is improved in many ways:

- The isolation transformer re-references the power line to the local ground point (with connection to local building steel), isolating the system from upstream, ground-quality problems.
- The transformer shield helps protect against ground impulses and noise (*common mode* disturbances).

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- The sine wave tracking filter protects against both high-frequency noise and fast-voltage impulses (*normal mode* disturbances), clamping spikes and filling-in notches.
- The surge suppressors protect against slower voltage impulses that have frequency below the filter cutoff.

Voltage Conversion
Wiring costs are significantly reduced since the PCDU accepts a single, 480V delta input with code minimum ground, supplying 120/208V wye to the generator and the various other parts of the system.

Distribution
The PCDU comes prepackaged with the distribution breakers needed for each system feed. Having all system breakers in one location also makes it easier for service personnel to remove power.

Control
The PCDU includes a circuit breaker on the input (primary) and a 24 VAC control signal for remote, emergency off control of the circuit breaker.

Impedance Control
The ultra-low impedance design of the isolation transformer helps ensure the power feed meets the low impedance requirement of today's CT labs as spelled out in the Toshiba Optimal Power Specifications (TOPS) manuals.

Planning
Planning is simplified by having all these components and functions delivered in a single box.

Installation
Installation is much faster, more predictable, and less expensive with a factory-assembled and tested system.

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Approvals
UL listing will reduce time and uncertainties obtaining local electrical inspection approvals.

Reduced Site Preparation Costs
The PCDU comes equipped with an input-shunt, trip-circuit breaker, eliminating, in most cases, the need for a room breaker. Only an Emergency Power Off button for remote breaker control is required.

Note: Not for use with Aquilion ONE

COT-35D **DICOM QUERY/RETRIEVE SCU AQ/MP**

The Q/R Service Class User (SCU) option allows a device to initiate a request for Patient, Study, Series and/or Image information from the Provider device in accordance with the DICOM 3.0 standard.

TOTAL QUOTE PRICE **$263,430.00**
Applicable Sales Tax Additional

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OPTIONS

UPS/TIC/VBR/64.100 **SYSTEM UPS 480 VOLT INPUT / 200 VOLT OUTPUT WITH DISTRIBUTION BREAKERS**

add **$59,500.00**

VRDU 480 V Input / 200 V Output including distribution Circuit breakers with UPS functionality -includes Battery Cabinet and Remote Alarm Status Panel

The VRDU is engineered to address the vast majority of common power problems found in the hospital environment, thus providing clean power and good grounding for optimal reliability and performance of CT systems.

Toshiba's UPS Functionality provides true on-line dual-conversion systems, providing the highest quality conditioned and uninterrupted power to critical loads and to any equipment sensitive to variations in the utility power supply. Provides 17 minutes of battery backup at full load.

The Remote Status Alarm Panel (RSAP) is used to monitor the alarm condition and state of any UPS remotely. The RSAP is wall-mounted and can be located up to 1,000 feet from the UPS. The panel shows the current input status, the output that is being used and UPS faults conditions. The RSAP also has an audible alarm to warn of UPS fault conditions.

NOTE: Frontline must make arrangements 14 days prior to installation for TIC on-site startup.

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M2-SCT-222 **MEDRAD STELLANT OCS DUAL FLOW INJECTOR**

add **$32,450.00**

Ceiling mounted Stellant D CT injector with Injector Synchronization is a full-featured, dual syringe injection system that enables clinicians to perform the most critical contrast enhanced CT exams.

Stellant D CT injector
Key features:

- Dual-syringe design for the most complicated protocols such as CTA and cardiac CT
- Effective contrast utilization
- Saline test injection for more precise control of contrast delivery
- Saline flush, following the injection, chases contrast from peripheral veins directly into the heart

Dual Flow Injection
Key features:

- Designed with CTA exams and Cardiac CT
- Effective contrast utilization
- Inject contrast and saline at a measured ratio through simultaneous plunger motion.
- This means a more uniform enhancement of both the right and left sides of the heart with reduced artifacts.

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ADDENDUM

ALL INFORMATION CONTAINED IN THIS QUOTATION IS CONFIDENTIAL AND MAY NOT BE DISCLOSED TO ANY THIRD PARTY WITHOUT TOSHIBA'S PRIOR WRITTEN CONSENT.

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PRODUCT WARRANTY AND SERVICES COVERAGE

SYSTEM WARRANTY TERMS

Toshiba America Medical Systems, Inc. (TAMS) warrants to Customer that the product(s) to be delivered hereunder will be free from defects in material, manufacturing workmanship, and title. Any product or part furnished to Customer during the warranty period (stated in the table below) to correct a warranty failure shall be warranted to the extent of the unexpired term of the warranty applicable to the repaired or replaced product or part.

The warranty period shall commence on the date the Product is delivered to Customer. However, if TAMS installs the product, the warranty period for such product shall commence on the date the installation of the product is complete. Notwithstanding the foregoing, in the event that the installation of the product is delayed for a total of thirty (30) days or more from the date of delivery for any reason or reasons for which TAMS is not responsible, the warranty period for such product may, at TAMS' option, commence on the thirtieth (30th) day from the date such product is delivered to Customer.

WARRANTY EXCLUSIONS

Warranty coverage does not include any defect which results, in whole or in part, from (1) negligent storage or handling of the product by Customer, its employees, agents, or contractors, (2) failure of Customer to prepare the site or provide power requirements or operating environmental conditions in compliance with any applicable instructions or recommendations of TAMS, (3) absence of any product, component, or accessory recommended by TAMS but omitted at Customer's direction, (4) any design, specification or instruction furnished by Customer, its employees, agents, or contractors, (5) any alteration of the product by persons other than TAMS, (6) combining TAMS' product with any product furnished by others, (7) combining incompatible products of TAMS, (8) improper use of the product, improper maintenance of the product by a party other than TAMS, or failure to comply with any applicable instructions or recommendations of TAMS, or (9) acts of God, acts of civil or military authority, fires, floods, strikes or other labor disturbances, war, riot, or other causes beyond the reasonable control of TAMS.

TAMS does not warrant any products not manufactured by Toshiba such as, without limitation, monitors, cameras, computer equipment, etc. Such items will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Toshiba.

Warranty coverage also excludes consumables, including but not limited to cassettes, magazines, imaging screens, disks, cartridges, etc.

GLASSWARE WARRANTY

Glassware, including X-ray tubes and Image Intensifiers, are provided separate warranties. Glassware included with the purchase of a new system is governed by the glassware warranty, described below, not the system warranty.

CT X-ray tubes carry a prorated warranty based on the number of rotations shown below or 12 months, whichever comes first.

Tube Type	Prorated Warranty
CXB-750/D/4A:AQ/RXL,AQ/LB-SERIES, ASSUREPLUS-V, AQ64, AQ16, AQ8	200,000 rotations*
CXB-750/E/2A:AQ/ONE/ASSURE	150,000 rotations*
CXB-750/F/2A:ONE-320-SERIES-V,ONE-640-SERIES-V, ONE-VISION-SERIES-V	100,000 rotations*
CXB-750G/2A: PRIME-SERIES	200,000 rotations*

*A rotation is any 360-degree or single rotation of the gantry with X-rays on.

The following time-based warranty terms apply to all other glassware:

Tube Type	Time-Based Warranty
Liquid Bearing Tubes (DSRX-TXXXX)	12 months, non-prorated
All Other X-ray tubes	12 months, non-prorated
Image Intensifiers	18 months, non-prorated

GLASSWARE PRORATION CALCULATION:

Credits for glassware that fails during the warranty periods stated above will be calculated as follows:

Tubes with Prorated Rotation Warranty:

$$\text{Credit} = 1 - \frac{\text{Number of Rotations Used}}{\text{Number of Rotations Warranted}}$$

Credit will be applied to the purchase of the replacement X-ray tube or Image Intensifier. Complete glassware coverage during warranty period may be purchased from the local services organization at an additional charge.

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Tubes with Non-Prorated, Time-Based Warranty:

Tubes with a non-prorated warranty will be replaced during the initial warranty period at no charge to the customer. The replacement tube carries the remainder of the original warranty. For example, a tube with a 24-month non-prorated warranty fails at month thirteen (13), the tube is replaced at no charge and carries eleven (11) months of warranty.

REMEDIES
If TAMS determines that any product fails to meet any warranty during the applicable warranty period, TAMS shall correct any such failure by either, at its option, repairing, adjusting, or replacing without charge to Customer any defective or nonconforming parts of the product. TAMS shall have the option to furnish either new or remanufactured replacement parts or assemblies. During the warranty period, Toshiba will furnish free of charge any upgrades, including software required to correct any defect in the warranted products or as required under applicable laws.

WARRANTY SERVICE
Warranty service during the applicable warranty period will be performed without charge to Customer during TAMS' normal business hours, Monday through Friday, excluding holidays. Subject to the availability of personnel, after-hours service is available upon request at an additional charge.

The remedies set forth herein are conditional upon Customer promptly notifying TAMS within the applicable warranty period of any defect or nonconformance and making the product available for correction.

DISCLAIMERS AND LIMITATIONS ON LIABILITY
TAMS' obligation to repair or replace defective parts will be Customer's sole and exclusive remedy for a breach of the warranty set forth above. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

In no event shall TAMS be liable for special, incidental or consequential damages. Toshiba does not warrant that the operation of the warranted products will be uninterrupted.

WARRANTIES BY PRODUCT LINE

	COMPUTERIZED TOMOGRAPHY	MAGNETIC RESONANCE	PACS SYSTEMS	ULTRASOUND	X-RAY VASCULAR	X-RAY R/F & RAD
SYSTEMS AND MAJOR COMPONENTS	12 Months	12 Months	12 Months	12 Months	12 Months	12 Months
ACCESSORY OPTIONS	6 Months	6 Months	6 Months	6 Months	6 Months	6 Months
REPLACEMENT & OPTIONAL PARTS	90 Days	90 Days	90 Days	90 Days	90 Days	90 Days
UPGRADE COMPONENTS	90 Days	90 Days	N/A	12 Months	6 Months	6 Months
MISC. WARRANTY ITEMS	Detectors: Solid State 12 Months	N/A	N/A	Transducers: 12 Months	N/A	N/A

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TERMS AND CONDITIONS OF SALE

1. GENERAL TERMS. Unless otherwise specified on the face of this document, this Quotation/Order ("Agreement") will remain valid only if accepted by Customer no later than 60 days from date of submission to Customer.

2. TITLE AND RISK OF LOSS. Title and risk of loss to the Equipment purchased under this Agreement will pass to Customer: (a) if Toshiba is to provide installation, upon Toshiba's completion of installation, or (b) if Toshiba will not provide installation, upon delivery by Toshiba to a common carrier at Toshiba's facility from which the Equipment is shipped.

3. TERMS OF PAYMENT. Prices stated are F.O.B. Customer's facility. All taxes which are payable by Toshiba in connection with the sale, use, or possession of the Equipment (excluding income taxes), will be paid by Customer in addition to the quoted price. Terms of payment for, C.T., M.R.I, X-Ray, and the McKesson System will be cash-10% upon execution of this Agreement, 70% upon delivery, balance due upon completion of installation and/or availability for first use, whichever is earlier. Terms of payment for Ultrasound will be cash-10% upon execution of this Agreement, 90% NET upon completion of installation and/or availability for first use, whichever is earlier. All invoices paid after due date will be assessed a late payment charge of the lesser of 1 1/2% per month or the maximum rate permitted by law.

4. DELAYS. If Customer changes the scheduled delivery date specified on the face of this document ("Scheduled Delivery Date") during the period of 120 days preceding such date, Customer will nevertheless pay the installment of the purchase price which would have been payable upon delivery, on the Scheduled Delivery Date as if delivery had been made on such date. In addition, Customer will pay all extra costs incurred by Toshiba as a result of such delay, including, without limitation, storage and transportation. Storage fees will be charged at commercially comparable rates for storage on Toshiba's site. If delivery is delayed by 12 months or more from the Scheduled Delivery Date, except through the fault of Toshiba, the price set forth in this Agreement may be increased by Toshiba to a level equal to the prevailing price in effect at the time of the revised delivery date.

5. ACCEPTANCE BY TOSHIBA. This Quotation/Order will not be binding on Toshiba even if signed by a Toshiba employee, until Customer's order for the Equipment is booked by Toshiba's Headquarter office.

6. EQUIPMENT INSTALLATION. Toshiba will install all Equipment purchased under this Agreement and connect them to existing power and/or plumbing lines at no additional charge to Customer. Customer will be responsible for electrical wiring, plumbing, carpentry, plastering, painting, or all other site preparation required prior to installation and connection of the Equipment by Toshiba. Customer will provide space at the installation site for the safe storage of Toshiba's tools, test equipment and other materials used for installation at no charge to Toshiba. Customer shall, at its cost, obtain all permits and licenses required by governmental authorities in connection with the installation and operation of the Equipment. The Equipment may contain certain components, which may have been re-manufactured. However, such components will meet the manufacturer's specifications for new components as of the date of completion of installation. Customer acknowledges that the System and Software are designed to operate within certain power, temperature, airborne contamination, and humidity ranges. Customer will be responsible for, without limitation: (i) preparing and maintaining the Customer facility in conformance with the Site Preparation Guide; (ii) maintaining its network infrastructure; (iii) providing Toshiba, McKesson or its subcontractors access to a network connection in or near the area of the System being serviced by the equipment service staff; and (iv) supplying computer grade AC power. The Equipment relies upon a stable grounded connection to the main power grid in order to function effectively. Customer acknowledges that AC power supply quality may be a problem in old facilities or in those facilities receiving poor quality utility service and that power conditioning may be necessary in such cases.

7. EQUIPMENT OPERATION. Customer agrees that all Equipment purchased under this Agreement will be operated exclusively by duly qualified technicians and/or medical doctors in a safe and reasonable manner in accordance with Toshiba's written instructions, applicable laws and regulations, and for the purposes for which such Equipment was intended.

8. LIMITED WARRANTY AND REMEDY. **A. For the Toshiba Equipment:** For the warranty period described below by product, Toshiba, as its only obligation, will replace or repair, without charge to Customer during Toshiba's normal working hours (if Customer requests warranty service outside such hours, Customer will pay overtime premium for labor), any component of the Equipment that is defective in materials or workmanship, provided such defect is reported to Toshiba within the warranty period. Toshiba's warranty

period is as follows: (a) Systems and Major Components – one year from date of completion of installation; (b) Accessories/Options (except glassware) – six months from date of completion of installation. Components not manufactured by Toshiba will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Toshiba. During the warranty period, Toshiba will furnish free of charge any upgrades, including software required to correct any defect in the Equipment or as required under applicable laws.

B. For the McKesson System: The McKesson System ("System") will be covered by a 12-month warranty beginning the date of completion of installation of the System (the "Warranty Period"). The warranty covers repair of any defects in materials or workmanship related to the computer equipment ("Equipment") that is included in the System purchased by Customer under this Agreement. The warranty also covers correction of any McKesson software ("Software") that does not conform with its functional specifications. In order to receive services during the Warranty Period, Customer must provide McKesson and Toshiba with remote access through a VPN. During the Warranty Period, Customer is entitled to (a) all Generally Available Software Updates except for Updates that are separately priced and marketed by Toshiba or McKesson, and (b) all Generally Available Software Upgrades, except for Upgrades that are separately priced and marketed by Toshiba or McKesson. ***"Software Updates"*** means Software modifications, enhancements, corrections, improvements, and patches to the existing functionality of Customer's licensed version of the McKesson Software (e.g., version 4.1 to 4.3 to 4.5). ***"Software Upgrades"*** means new versions and future releases of the McKesson Software (e.g. version 4.x, 5.x, 6.x). Software Updates or Upgrades that provide new features not originally purchased may be separately priced and marketed. Software Updates and Software Upgrades to the McKesson Software will be delivered remotely, on-line. The warranty does not include any non-McKesson Software, the labor and travel expenses associated with on-site installation of a Software, or any hardware addition or modification.

The warranty set forth in this Section will not apply:

a. if Customer operates the Software on equipment other than Equipment purchased from Toshiba or attaches other equipment to the System not approved by Toshiba;
b. if a person or entity other than McKesson or its authorized third party suppliers modifies the Software;
c. as a result of Customer's improper use, abuse, neglect of the Equipment, including failure to maintain environmental conditions within the operating range specified by the Equipment manufacturer or accident;
d. as a result of viruses or other corruption caused by external entities; or
e. for damages resulting from a Force Majeure condition described in Section 13 below.

C. The Following Applies to Both the Toshiba Equipment and the McKesson System: Toshiba does not warrant that the operation of the Equipment of the System will be uninterrupted. All defective parts replaced by Toshiba will become the property of Toshiba. Replacement parts may be re-manufactured. However, such parts will meet the manufacturer's specifications for new components as of the date of completion of installation. TOSHIBA'S OBLIGATION TO REPAIR OR REPLACE DEFECTIVE PARTS OR SOFTWARE WILL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR A BREACH OF THE WARRANTY SET FORTH IN THIS AGREEMENT. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. The warranty set forth in this Agreement will not apply to, and Toshiba will not be liable for any defects resulting from misuse, repairs performed by unauthorized third parties, accidents, acts of God, or neglect of anyone other than Toshiba.

9. LIMITATION OF LIABILITY. NEITHER TOSHIBA NOR CUSTOMER WILL UNDER ANY CIRCUMSTANCES BE LIABLE FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR EXEMPLARY DAMAGES OR ECONOMIC LOSS ARISING OUT OF OR RELATED TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT, EVEN IF EITHER PARTY IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING. IN NO EVENT WILL EITHER PARTY'S LIABILITY TO THE OTHER (WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT, INCLUDING NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE) ARISING OUT OF OR RELATING TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT EXCEED THE AGGREGATE AMOUNT ACTUALLY PAID BY CUSTOMER TO TOSHIBA UNDER THIS AGREEMENT. THE LIMITATION OF LIABILITY SET FORTH ABOVE WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY OR PROPERTY DAMAGE CAUSED BY EQUIPMENT DEFECTS, OR TO CLAIMS FOR PATENT INFRINGEMENT.

10. SECURITY INTEREST. Toshiba hereby reserves and Customer grants to Toshiba a security interest pursuant to the Uniform Commercial Code, in and to the Equipment (and all products and proceeds of it) until full payment of the purchase price is received.

QUOTATION/ORDER
ORDER DETAIL

DATE: 10/31/2014

SID NO: 30026483
QUOTE NO: 62461-1

PRESENTED TO:

CHARLOTTE HUNGERFORD HOSPITAL
540 LITCHFIELD ST
TORRINGTON, CT. 06790

In the event that Customer finances its acquisition of the Equipment through a lease, conditional sale contract, secured loan agreement or other financing agreement (collectively, "Lease") with Toshiba, then the security interest in the Equipment (and all products and proceeds thereof) shall secure all obligations of Customer due and to become due under the Lease.

11. REMOVAL OF EQUIPMENT. Until Toshiba has received full payment of the purchase price, Customer will not remove all or any part of the Equipment from Customer's premises, nor will Customer sell, lease, transfer or otherwise part with the possession of, or permit any lien or encumbrance to be placed on all or any part of the Equipment.

12. REMEDIES OF TOSHIBA. If Customer fails to make any payment when due under this Agreement or under any other agreement between Customer and Toshiba, or becomes insolvent or makes an assignment for the benefit of creditors, or if a petition in Bankruptcy is filed by or against Customer, or if the financial responsibility of Customer becomes impaired or unsatisfactory in Toshiba's reasonable judgment, or if Customer otherwise breaches any of the terms and conditions of this Agreement, then Toshiba may, without prior notice or demand, defer shipments, cancel the balance of the order, suspend performance of any obligation (including without limitation, all obligations set forth under Limited Warranty And Remedy above), and/or take immediate possession of the Equipment delivered, until the full purchase price of the Equipment is paid by Customer or, at Toshiba's discretion, until security satisfactory to Toshiba is given by Customer. Any costs incurred by Toshiba as a result of suspending performance or repossession or collection will be payable by Customer. Toshiba may sell repossessed Equipment with proceeds to be applied to unpaid balance and expenses incurred in sale, repossession and collection. Customer will pay any remaining deficiency. Toshiba may exercise any other rights available to it by law.

13. EXCUSED PERFORMANCES. Neither party will be liable to the other for non-performance or delay in performance resulting directly or indirectly from any occurrences beyond such party's control, including without limitation, strikes or other labor troubles, acts of God, war, accidents, fires, floods, other catastrophes, inclement weather, transportation, unavailability of materials and labor, delays caused by suppliers, or laws, regulations, or acts of any governmental agency.

14. SOFTWARE. All rights and interest in any software that may be furnished under this Agreement, and any updates and enhancements to it, will remain the property of Toshiba. Such software is being furnished to Customer under a non-exclusive license. Customer will not, or allow others to decompile, modify, copy, reproduce, or transcribe the software nor allow third parties to use the same without Toshiba's prior written consent. Upon Toshiba's request, Customer will execute an End-User Software License Contract, in a form to be mutually agreed between the parties.

15. CANCELLATION. Customer may not cancel the order subject to this Agreement except with Toshiba's prior written consent. In the event of such cancellation, Toshiba will be entitled to recover any and all damages suffered by it caused by the cancellation as allowed by law, but in no event less than an amount equal to twenty percent (20%) of the purchase price for a restocking charge.

16. ASSIGNMENT. Neither party may assign any of its obligations under this Agreement without the prior written consent of the other party However, some of the obligations stated in this Agreement, such as the ones relating to installation of the McKesson System and warranty may be performed by Toshiba's contractors or suppliers.

17. EXPORT REGULATIONS. This Agreement involves products, and/or technical data that may be controlled under the U.S. Export Administration Regulations and may be subject to the approval of the U.S. Department of Commerce prior to export. Any export or re-export by Customer, directly or indirectly, in contravention of such Regulations is prohibited.

18. ATTORNEY'S FEES AND COSTS. In the event of any legal proceeding involving any party to this Agreement against the other relating to the subject matter of this Agreement, the prevailing party in such proceeding will be entitled to recover attorney's fees, expert fees, and court costs against the non-prevailing party.

19. ENTIRE AGREEMENT. This quotation as well as the attached McKesson Pass Through Terms and Conditions contains the entire agreement between the parties and supersedes all prior and contemporaneous agreements between the parties, whether oral or written, relating to its subject matter, including, without limitation, all different or additional terms and conditions which may be contained in Customer's bid documents, purchase order or any other documents furnished by Customer. The provisions of this Agreement may not be modified unless in writing and executed by both parties.

Greer, Leslie

From: Carney, Brian
Sent: Thursday, July 30, 2015 1:04 PM
To: Greer, Leslie
Subject: FW: 15-31989-CON

Leslie, can you please add this to the table of record.

Thanks,
Brian

Brian A. Carney, MBA
Office of Health Care Access

Phone: (860) 418-7014
Fax: (860) 418 7053
Email: brian.carney@ct.gov

From: John J. Capobianco [mailto:JCapobianco@hungerford.org]
Sent: Thursday, July 30, 2015 12:44 PM
To: Carney, Brian
Cc: Riggott, Kaila; Veyberman, Alla
Subject: RE: 15-31989-CON

Brian,

Thank you for your call. After we spoke I went back to the documentation which helped me better understand your question and realized my response was not as clear as it could have been. Please see below.

1. The two projections are mutually exclusive of each other meaning the 560 ambulance transfers from the Winsted Area noted on Exhibit F were transported directly to the Main Campus Hospital Emergency Department bypassing the Winsted Facility. The 109 patients were the actual number transported to CHH from the Winsted Facility. Therefore I feel we can indeed add the two numbers together to total 400.
2. The CT Scanner at the Charlotte Hungerford Hospital is located in the Radiology Department on the main campus which is adjacent to the Emergency Department. When our machine is down we at times delay scans, use an alternative modality such as MRI or transfer patients to another facility for a CT Scan.

I hope these answers are responsive to your questions. Please feel free to contact me should you have any further questions.

Thank you

John J Capobianco

Vice President of Operations
The Charlotte Hungerford Hospital
540 Litchfield Street
Torrington,CT 06790
Phone: (860)496-6611
Fax: (860) 482-8627
Email: jcapobianco@hungerford.org

From: Carney, Brian [mailto:Brian.Carney@ct.gov]
Sent: Thursday, July 30, 2015 11:26 AM
To: John J. Capobianco
Cc: Riggott, Kaila; Veyberman, Alla
Subject: 15-31989-CON

Dear Mr. Capobianco,

As per our phone conversation, we are working to determine if you application is complete. Could you please respond by the end of business today with answers to the following questions.

1. Pages 112 and 115 of the completeness responses provide the method used to determine projected ED scan volumes. In addition to a proportion of ambulance calls, 109 HEMC transfers were added to the total. Were all 109 transfers walk-in patients? If not, please explain why patients arriving via ambulance and later transferred were included in the estimate and explain why this inclusion is not duplicative. If necessary, revise the HEMC CT volume projections for FYs 2016-18.

2. Where at Charlotte Hungerford Hospital is the CT scanner located? When the machine is down, how do patients (ED, Inpatient, Outpatient) receive scans? Are the scans delayed or are patients diverted to other locations?

Sincerely,
Brian Carney

Brian A. Carney, MBA
Associate Research Analyst
Office of Health Care Access
CT Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Phone: (860) 418-7014
Fax: (860) 418 7053
Email: brian.carney@ct.gov
Web: www.ct.gov/ohca

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

VIA FAX ONLY

July 31, 2015

Mr. John Capobianco
Vice President for Operations
Charlotte Hungerford Hospital
540 Litchfield Street,
Torrington, CT 06790

RE: Certificate of Need Application, Docket Number 15-31989-CON
Charlotte Hungerford Hospital
Acquisition of a Computed Tomography ("CT") scanner for the Hungerford Emergency and Medical Care Center in Winsted

Dear Mr. Capobianco:

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 deemed the above-referenced application complete as of July 31, 2015.

If you have any questions regarding this matter, please feel free to contact me at (860) 418-7014 or Alla Veyberman at (860) 418-7007.

Sincerely,

Brian A. Carney
Associate Research Analyst

* * * COMMUNICATION RESULT REPORT (JUL. 31. 2015 2:23PM) * * *

FAX HEADER:

TRANSMITTED/STORED : JUL. 31. 2015 2:22PM

FILE	MODE	OPTION	ADDRESS	RESULT	PAGE
207	MEMORY TX		98604828627	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JOHN CAPOBIANCO

FAX: (860) 482-8627

AGENCY: CHARLOTTE HUNGERFORD HOSPITAL

FROM: OHCA

DATE: 7/31/15 **Time:**

NUMBER OF PAGES: 2
(including transmittal sheet

Comments:
Application Deemed Complete - Docket Number: 15-31989-CON

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS

Phone: (860) 418-7001 Fax: (860) 418-7053

410 Capitol Ave., MS#13HCA
P.O.Box 340308
Hartford, CT 06134

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Wednesday, September 16, 2015 11:32 AM
To: Greer, Leslie
Subject: FW: CON Application updated CFY scan volumes
Attachments: CT.CON Table 4B.docx

Hi Leslie, please add the below to Charlotte Hungerford dn 15-31989. Thank you!

From: John J. Capobianco [mailto:JCapobianco@hungerford.org]
Sent: Wednesday, September 16, 2015 10:53 AM
To: Schaeffer-Helmecki, Jessica
Subject: RE: CON Application updated CFY scan volumes

Hi Jessica

Attached please find the updated Table 4 B that reflects volumes through 8/31/15. Please feel free to contact me should you have any further questions.

Thank you
John

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Tuesday, September 15, 2015 11:26 AM
To: John J. Capobianco
Subject: CON Application updated CFY scan volumes

Hi John,

As discussed on the phone, we need the updated current fiscal year's scan volumes (as originally found on page 14 of your application), as the table now only covers through January 2015.

Please feel free to contact me with any questions you may have.

Thank you,

Jessica

Jessica Schaeffer-Helmecki
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

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TABLE 4B

HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY TYPE OF SCAN/EXAM

Service***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY 12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 18
Head	3050	2,858	2,881	2,642	184	184	187
Temporal Bones	21	23	19	0	3	4	6
Maxofacial	277	244	268	262	20	21	22
Soft Tissue neck	144	162	160	148	13	13	14
Chest Thorax	951	1,102	1,169	1,267	73	73	75
Cervical spine	731	537	426	423	33	34	35
Thoracic spine	15	11	11	13	1	2	3
Lumbar Spine	69	66	80	96	5	6	7
Pelvis	92	93	120	123	6	7	8
Upper ext	43	58	81	133	5	5	6
Lower ext	141	160	171	224	28	28	29
Abdomen	166	151	116	143	10	10	11
Abscess drain	19	15	2	0	0	0	0
Cyst Aspiration	2	6	30	0	0	0	0
Angio-abd	8	4	3	7	0	0	0
Angio-chest	435	418	426	393	1	2	2
Angio-head	4	8	6	2	33	34	35
Angio(up/low)ext	5	0	4	0	3	4	4
Angio-neck	3	1	3	4	2	3	3
Angio pelvic	4	0	1	0	1	1	1
Needle LOC	2	1	3	15	1	1	1
Inj	8	6	15	7	0	0	0
Angio-abd-pelvis	3	11	17	9	5	6	7

Paracentesis	4	1	2	0	0	0	0
CTA-Abd	0	0	5	0	0	0	0
Abd &Pelv	3,380	3,396	3,416	3,373	233	242	244
	12 months	12 months	12 months	11 months	12 months	12 months	12 months
	10/1/11 to 9/30/12	10/1/12 to 9/30/13	10/1/13 to 9/30/14	10/1/14 to 8/31/15	10/1/15 to 9/30/16	10/1/16 to 9/30/17	10/1/17 to 9/30/18
Total	**9,577**	**9,332**	**9,435**	**9,302**	**660**	**680**	**700**

*For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.
**If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
***Identify each type of scan/exam (e.g. orthopedic, neurosurgery or if there are scans/exams that can be performed on the proposed piece of equipment that the Applicant is unable to perform on its existing equipment) and add lines as necessary.
****Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Friday, September 18, 2015 11:48 AM
To: Greer, Leslie
Subject: FW: CON Application updated CFY scan volumes
Attachments: CT.CON Table 4B.docx

Hi Leslie, for Charlotte Hungerford 15-31989 thanks

From: John J. Capobianco [mailto:JCapobianco@hungerford.org]
Sent: Wednesday, September 16, 2015 10:53 AM
To: Schaeffer-Helmecki, Jessica
Subject: RE: CON Application updated CFY scan volumes

Hi Jessica

Attached please find the updated Table 4 B that reflects volumes through 8/31/15. Please feel free to contact me should you have any further questions.

Thank you
John

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Tuesday, September 15, 2015 11:26 AM
To: John J. Capobianco
Subject: CON Application updated CFY scan volumes

Hi John,

As discussed on the phone, we need the updated current fiscal year's scan volumes (as originally found on page 14 of your application), as the table now only covers through January 2015.

Please feel free to contact me with any questions you may have.

Thank you,

Jessica

Jessica Schaeffer-Helmecki
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

TABLE 4B

HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY TYPE OF SCAN/EXAM

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Lower ext	141	160	171	224	28	28	29
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Needle LOC	2	1	3	15	1	1	1
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Angio-abd-pelvis	3	11	17	9	5	6	7

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	10/1/11 to 9/30/12	10/1/12 to 9/30/13	10/1/13 to 9/30/14	10/1/14 to 8/31/15	10/1/15 to 9/30/16	10/1/16 to 9/30/17	10/1/17 to 9/30/18
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Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Friday, September 18, 2015 11:48 AM
To: Greer, Leslie
Subject: FW: CON Application updated CFY scan volumes

Another for C-H 15-31989

From: Schaeffer-Helmecki, Jessica
Sent: Wednesday, September 16, 2015 11:31 AM
To: 'John J. Capobianco'
Subject: RE: CON Application updated CFY scan volumes

Hi John,

Thank you for responding so quickly. However, the table on **page 14** that we needed updated was volume by equipment (Table 4A) not by type of scan/exam (Table B on page 15). I'm assuming that the total for CFY15 of 9,302 would be the same for both Table 4A and 4B, though.

So, to avoid having you re-submit another table, could you please just:

1. Confirm whether 9,302 is the CFY15 through 8/31 total for both Table 4A and 4B
2. Let me know how many of those 9,302 scans were inpatient and how many were outpatient?

Please let me know if I can provide any further clarification.

Thank you again,

Jessica

From: John J. Capobianco [mailto:JCapobianco@hungerford.org]
Sent: Wednesday, September 16, 2015 10:53 AM
To: Schaeffer-Helmecki, Jessica
Subject: RE: CON Application updated CFY scan volumes

Hi Jessica

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Thank you
John

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Tuesday, September 15, 2015 11:26 AM
To: John J. Capobianco
Subject: CON Application updated CFY scan volumes

Hi John,

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Thank you,

Jessica

Jessica Schaeffer-Helmecki
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Friday, September 18, 2015 11:49 AM
To: Greer, Leslie
Subject: FW: CON Application updated CFY scan volumes
Attachments: image001.jpg

And one last one (15-31989)

From: John J. Capobianco [mailto:JCapobianco@hungerford.org]
Sent: Thursday, September 17, 2015 7:41 PM
To: Schaeffer-Helmecki, Jessica
Subject: Re: CON Application updated CFY scan volumes

Jessica

Yes the volume would be the same for both Table A and Table B. The current fiscal year CT volume of 9,302 is split among Outpatient volume: 6,976. Inpatient volume: 2,326.

Sorry for the confusion on my part.

John

On Sep 16, 2015, at 11:30 AM, Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov> wrote:

> Hi John,
>
> Thank you for responding so quickly. However, the table on **page 14** that we needed updated was volume by equipment (Table 4A) not by type of scan/exam (Table B on page 15). I'm assuming that the total for CFY15 of 9,302 would be the same for both Table 4A and 4B, though.
>
> So, to avoid having you re-submit another table, could you please just:
> 1. Confirm whether 9,302 is the CFY15 through 8/31 total for both Table 4A and 4B
> 2. Let me know how many of those 9,302 scans were inpatient and how many were outpatient?
>
> Please let me know if I can provide any further clarification.
>
> Thank you again,
>
> Jessica
>
> ---
>
> **From:** John J. Capobianco [mailto:JCapobianco@hungerford.org]
> **Sent:** Wednesday, September 16, 2015 10:53 AM
> **To:** Schaeffer-Helmecki, Jessica
> **Subject:** RE: CON Application updated CFY scan volumes

Hi Jessica

Attached please find the updated Table 4 B that reflects volumes through 8/31/15. Please feel free to contact me should you have any further questions.

Thank you
John

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Tuesday, September 15, 2015 11:26 AM
To: John J. Capobianco
Subject: CON Application updated CFY scan volumes

Hi John,

As discussed on the phone, we need the updated current fiscal year's scan volumes (as originally found on page 14 of your application), as the table now only covers through January 2015.

Please feel free to contact me with any questions you may have.

Thank you,

Jessica

Jessica Schaeffer-Helmecki
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

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Greer, Leslie

From: Schaeffer-Helmecki, Jessica
Sent: Friday, September 25, 2015 3:37 PM
To: Greer, Leslie
Subject: FW: 15-31989-CON Charlotte Hungerford Final Decision
Attachments: 15-31989 Charlotte Hungerford FINAL DECISION.pdf

Leslie, please add the below communication to dn 31989. Thank you.

From: Schaeffer-Helmecki, Jessica
Sent: Friday, September 25, 2015 3:37 PM
To: 'John J. Capobianco'
Cc: Riggott, Kaila
Subject: 15-31989-CON Charlotte Hungerford Final Decision

Dear Mr. Capobianco:

Attached please find the final decision, rendered today 9/25/2015, regarding CON application 15-31989 for the acquisition of a CT-Scanner. If you have any questions please feel free to contact me.

Best Regards,

Jessica Schaeffer-Helmecki
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075|F: (860) 418-7053|E: jessica.schaeffer-helmecki@ct.gov

Department of Public Health
Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant: **Charlotte Hungerford Hospital**
540 Litchfield Street
Torrington, CT

Docket Number: **15-31989-CON**

Project Title: **Acquisition of a Computed Tomography ("CT") Scanner for the Hungerford Emergency and Medical Care Center in Winsted, Connecticut.**

Project Description: Charlotte Hungerford Hospital ("Applicant" or "Hospital") seeks authorization to acquire a Computed Tomography ("CT") Scanner with a total capital expenditure of $645,000.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in *The Register Citizen* on March 3, 4 and 5, 2015. On April 8, 2015, the Office of Health Care Access ("OHCA") received the initial CON application from the Applicant for the above-referenced project and deemed the application complete on July 31, 2015.

OHCA received no responses from the public concerning the Applicant's proposal and no hearing requests were received from the public per Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(e). Deputy Commissioner Brancifort considered the entire record in this matter.

Findings of Fact and Conclusions of Law

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

1. Charlotte Hungerford Hospital ("Applicant" or "Hospital") is a general 109-bed acute care hospital located at 540 Litchfield Street in Torrington, Connecticut. Exhibit A, pp. 4, 99.

2. The Hospital operates Hungerford Emergency and Medical Care ("HEMC"), 115 Spencer Street in Winsted, Connecticut, as an off-campus satellite Emergency Department. HEMC offers emergency medical care seven days a week from 9 a.m. to 9 p.m. Exhibit A, p. 9; Exhibit C, p. 110.

3. Currently the Applicant's sole CT-scanner is a 64-slice Toshiba Aquilion, located on its main Hospital campus. Exhibit A, p. 11.

4. The Applicant proposes the acquisition, installation and operation of a Toshiba Aquilion 16-slice whole body CT-scanner at its HEMC location. Exhibit A, p. 9.

5. The Applicant currently transports patients presenting at HEMC who require a CT-scan 12 miles via ambulance or emergency medical service to the Hospital's main campus. Exhibit A, p. 9.

6. CT-scanners have the ability to quickly and accurately provide diagnostic imaging of serious medical conditions and potentially life threatening illnesses and accidents, including stroke and other embolic events, head and spinal injury and abdominal pain and trauma. Exhibit A, pp. 11, 32

7. The National Institute of Neurological Disorders and Stroke has recommended that within 25 minutes of arriving at an urgent care facility, a CT-scan should be performed on a patient with a suspected stroke. The CT-scan should be interpreted within 45 minutes of that patient's arrival in the emergency department. W. Ann Maggiore, *'Time Is Brain' in Prehospital Stroke Treatment*, JOURNAL OF EMERGENCY MEDICAL SERVICES, June 4, 2012, at 4-5. Exhibit A, pp. 71-2.

8. For the 109 patients who were transferred from HEMC to the Hospital from November 2013 to October 2014, the mean wait-time from the point of arrival at the HEMC until a CT scan was performed at the Hospital was 1 hour 17 minutes. The range of wait-times for that same period was between 15 minutes and 4 hours 17 minutes. As there is only one CT-scanner available at the Hospital, a patient's wait time is dependent upon the priorities of other emergency department and inpatient needs. Exhibit C, p. 110.

9. The proposed CT scanner will serve as an alternate should the Hospital-based CT-scanner be temporarily inoperable, reducing the need to cancel exams, delay treatment or transfer or divert emergency department patients to other facilities for CT-scans. Exhibit A, p. 10.

10. There are no similar services, other than the Hospital-based CT-scanner, within a 25 mile radius of HEMC. Exhibit A, p. 13.

11. Smaller, rural and critical access hospitals have lower CT and MRI availability and less access to higher-resolution CT scanners. Adit A. Ginde et al., *Availability and Quality of Computed Tomography and Magnetic Resonance Imaging Equipment in U.S. Emergency Departments,* SOCIETY FOR THE ACADEMY OF EMERGENCY MEDICINE., 2008 at 780. Exhibit A, p. 30.

12. The following table lists existing emergency department or hospital-based imaging providers in the area:

TABLE 1
EXISTING HOSPITAL-BASED EQUIPMENT OPERATED BY THE APPLICANT*

Provider Name/Address	Service*	Days/Hours of Operation **	Utilization***
Charlotte Hungerford Hospital 540 Litchfield Street Torrington, CT 06790	AQ64/V-AR Toshiba Aquilion 64 slice CT Scanner	24/7 364 days per year. Routine scheduled and emergency services	Oct 1, 2014 to September 30,2014 Scans/exams: 9,435

* Excludes Advanced Medical Imaging of Northwest CT, a non-hospital based facility owned by the Applicant, which operates a GE 16-slice.

13. The Applicant's historical and projected utilization is as follows:

TABLE 2
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY NUMBER OF SCANS

Equipment***	Actual Volume (Last 3 Completed FYs*)			CFY Volume**	Projected Volume (First 3 Full Operational FYs)***		
	FY 12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 18
AQ64/V-AR Toshiba Aquilion at Hospital							
Inpatient:	2,394	2,520	2,695	2,326	2,520	2,520	2,520
Outpatient:	7,183	6,812	6,740	6,976	7,080	7,080	7,080
Proposed Winsted							
Inpatient:	n/a	n/a	n/a	n/a	0	0	0
Outpatient:	n/a	n/a	n/a	n/a	260	268	276
ED:	n/a	n/a	n/a	n/a	400	412	424
Total	**9,577**	**9,332**	**9,435**	**9,302**	**660**	**680**	**700**

* FY is Oct. 1 to Nov. 30.
** CFY is based on 11 months, from Oct. 1 through Aug. 31, 2015.
*** Assumes a 3% increase in CT volume per year.
Exhibit A, p. 14; Exhibit C, p. 112; Exhibit F.

14. From Nov. 2013 through Oct. 2014, 109 patients visiting HEMC required transfer to the Hospital to receive a CT-scan. The types of scans conducted are shown below.

TABLE 3
TYPE OF SCANS TRANSFERRED FROM HEMC TO HOSPITAL

Type of CT requiring Transfers from HEMC 11/13-10/14		
Type of CT	Number	%
Head	33	30%
Chest	12	11%
Abd/Pelvis	62	57%
Other	2	2%

Exhibit A, p. 16.

15. As shown below, patients originating from Winsted and the surrounding rural areas represented the largest percentage of visits to HEMC's emergency department.

TABLE 4
HUNGERFORD EMERGENCY AND MEDICAL CARE CENTER
PRIMARYSERVICE AREA TOWNS

Town*	**% of Visits (6/2013 – 11/2014)**
Winsted	65%
Torrington	11%
Barkhamsted	7%
Norfolk	6%
New Hartford	5%
Colebrook	3%
Riverton	2%
Canaan	1%
Total	**75.49%**

Exhibit A, p. 12.

16. The proposal's total capital expenditure is itemized below:

TABLE 5
TOTAL PROPOSAL CAPITAL EXPENDITURE

Purchase/Lease	Cost
Equipment (Medical, Non-medical Imaging)	$370,000
Construction/Renovation	$275,000
Total Capital Expenditure (TCE)	**$645,000**

Exhibit A, p. 19.

17. The Applicant's current and projected payer mix is shown below.

TABLE 6
HEMC'S PAYER MIX BY SCAN VOLUME

Payer	Projected*					
	FY16		FY17		FY18	
	Volume	%	Volume	%	Volume	%
Medicare*	145	24.1	164	24.1	169	24.1
Medicaid*	219	36.5	248	36.5	255	36.5
CHAMPUS & TriCare	4	0.6	4	0.6	5	0.6
Total Government	**368**	**61.2**	**416**	**61.2**	**429**	**61.2**
Commercial Insurers	192	32.0	218	32.0	224	32.0
Uninsured	30	5.1	34	5.1	35	5.1
Workers Compensation	10	1.7	12	1.7	12	1.7
Total Non-Government	**232**	**38.8**	**264**	**38.8**	**271**	**38.8**
Total Payer Mix	**600**	**100**	**679**	**100**	**700**	**100**

*Projected payer mix is based on the observed historical payer mix at the entire HEMC facility.
Exhibit A, pp. 20-21.

18. The Applicant projects incremental gains, as shown in Table 7, as a result of the proposal.

TABLE 7
APPLICANT'S PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2015	FY 2016	FY 2017
Revenue from Operations	$166,105	$174,339	$182,849
Total Operating Expenses	($129,795)	($133,911)	($139,016)
Gain/Loss from Operations	**$36,301**	**$40,428**	**$43,833**

Ex. A, p. 105.

19. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).

20. This CON application is consistent with the overall goals of the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2)).

21. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3)).

22. The Applicant has demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).

23. The Applicant has satisfactorily demonstrated that its proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region and that Medicaid services would not be affected. (Conn. Gen. Stat. § 19a-639(a)(5)).

24. The Applicant has shown that there will be no change in access to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6)).

25. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7)).

26. The utilization of existing health care facilities and health care services in the Applicant's service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)).

27. The Applicant has satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)).

28. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)).

29. The Applicant has satisfactorily demonstrated that the proposal will have no impact on the diversity of health care providers and patient choices in the geographical region. (Conn. Gen. Stat. § 19a-639(a)(11)).

30. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation or adversely affect health care cost or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12)).

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. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727 (2013).*

Charlotte Hungerford Hospital ("Applicant" or "Hospital") is a general 109-bed acute care hospital located at 540 Litchfield Street in Torrington, Connecticut. *FF1.* The Hospital operates Hungerford Emergency and Medical Care ("HEMC"), 115 Spencer Street, Winsted, as an off-campus satellite Emergency Department. HEMC offers emergency medical care seven days a week from 9 a.m. to 9 p.m. *FF2.*

The Applicant proposes the acquisition, installation and operation of a Toshiba Aquilion 16-slice whole body CT-scanner at its HEMC location. *FF4.* Currently the Applicant's sole CT-scanner is a 64-slice Toshiba Aquilion located on its Hospital campus and patients presenting at HEMC who require a scan must be transported via ambulance to the main campus 12 miles away. *FF3,4.*

Patients visiting HEMC are primarily from rural locations such as Winsted, Torrington and Barkhamsted and, with the exception of the Hospital, there are no comparable CT-services within a 25 mile radius from HEMC. *FF11,16.* As such, from November 2013 through October 2014, 109 patients were transported from HEMC to the Hospital to receive CT-scans. For that period, the mean wait-time from when a patient arrived at HEMC to when the patient was transported to the Hospital and a CT-scan was performed was 1 hour and 17 minutes, however patients waited up to 4 hours and 17 minutes. *FF8.*

A timely diagnosis is of particular importance in the cases of a stroke, embolic event, head or spinal injury or abdominal pain and trauma and an accurate diagnosis for these events is dependent upon imaging provided by a CT-scanner. *FF6.* The National Institute of Neurological Disorders and Stroke has recommended that CT-scans be performed on patients with a suspected stroke within 25 minutes of their arrival at an urgent care facility. *FF7.* Transporting patients from HEMC to the Hospital delays the time in which a diagnosis may be made and treatment initiated. Locating a CT-scanner on the HEMC campus will improve patients' access to more accurate and timely diagnoses, resulting in better outcomes for patients in the Winsted area. The Applicant has satisfactorily demonstrated that the quality of care for patients in the proposal's area will be improved.

The proposal will additionally improve patients' access to care. Patients at HEMC are currently transported by emergency medical services ("EMS") or ambulance to the Hospital. *FF5.* By locating the CT-scanner at HEMC, the proposal will reduce reliance on the Hospital's emergency medical services and free them to attend to other patients, preventing periods when EMS is unavailable. *FF5.* Furthermore, should the CT-scanner at the Hospital be temporarily inoperable,

the CT-scanner at HEMC may serve as a substitute, reducing the need to cancel exams, delay treatment or divert ED patients to other facilities for CT-scans. *FF9.*

The proposal will not impact Medicaid patients' access to care. The Applicant anticipates treating the same payer mix following implementation of the proposal, with 36.5% of HEMC's patients being Medicaid insured from FY16 through FY18. *FF17.*

As a result of the proposal, the Applicant projects incremental gains of $36,301 to $48,833 from FY15 through FY17 and a capital expenditure of $645,000 for the new equipment and renovations. Thus, the Applicant has demonstrated that its proposal is financially feasible. *FF16,18.*

The Applicant has shown that the addition of a CT-scan to HEMC will improve access for Winsted-area residents by enabling more timely diagnoses of patients presenting with life threatening conditions, reduce demand on ambulances and mitigate the effects of any temporary interruptions of service at the Hospital's existing CT-scanner. Moreover, the proposal is consistent with the Statewide Health Care and Facilities Plan as it reduces delays in treatment and serves rural patients, who are underrepresented in terms of access to CT-scanners and quality imaging equipment.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Charlotte Hungerford Hospital for the acquisition of a CT scanner is hereby **approved**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

September 25, 2015
Date

Janet M. Brancifort
Janet M. Brancifort, MPH RRT
Deputy Commissioner