December 29, 2016

VIA EMAIL AND COURIER

Ms. Kimberly Martone
Director of Operations
Office of Health Care Access (OHCA)
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Re: Yale-New Haven Hospital
Replacement of SPECT Imaging Equipment

Dear Ms. Martone:

Please find enclosed one (1) original hardcopy of a Certificate of Need application from Yale New Haven Hospital to replace two (2) SPECT cameras with two (2) SPECT/CT cameras. Also enclosed is the application fee and a USB with an electronic version of the Certificate of Need application and financial attachments.

Sincerely,

Nancy Rosenthal
VP, Strategy and Regulatory Planning

Strategy and Regulatory
2 Howe Street
New Haven, CT 06510
Phone: 203-688-5721
Email: nancy.rosenthal@ynhh.org

ynhh.org

YALE NEW HAVEN HOSPITAL

REPLACEMENT OF TWO SPECT CAMERAS

WITH

TWO SPECT CT CAMERAS

CERTIFICATE OF NEED APPLICATION

16-32124-CON

December 2016

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 a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.

☒ (**New**). A completed supplemental application specific to the proposal type can be found on OHCA's website at "OHCA Forms." A list of supplemental forms can be found on page 2.

☒ 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.

☒ 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 completed Financial Attachment

☒ Submission includes one (1) original hardcopy in a 3-ring binder and a USB flash drive containing:

1. A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.
2. An electronic copy of the applicant's responses in MS Word (the applications) and MS Excel (the financial attachment).

For OHCA Use Only:

Docket No.: 16-32124-CON **Check No.:** 1019293975
OHCA Verified by: LMG/KR **Date:** 12/29/16

TABLE OF CONTENTS

YALE NEW HAVEN HOSPITAL REPLACEMENT OF TWO SPECT CAMERAS WITH TWO SPECT CT CAMERAS - CON 16-32124-CON

DECEMBER 2016

TABLE OF CONTENTS

ATTACHMENT 1

CON PUBLIC NOTICE

HOW TO PLACE A CLASSIFIED AD:

CALL ▸ 1.800.922.7066 (Toll Free)

EMAIL ▸ classifiedads@nhregister.com
WEBSITE ▸ www.nhregister.com
FAX ▸ 1-888.243.0060

Classified is open Monday through Friday from 8am to 5pm.

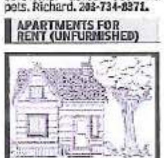
The ad deadline is 5pm for publication the following day (Friday @ 5pm for publication Sunday or Monday).

Please check your ad on the first day it is published to make sure it is correct. If you find an error, please report it IMMEDIATELY. Call 1.800.922.7066. The New Haven Register will be responsible for only ONE incorrect insertion.

APARTMENTS FOR RENT (FURNISHED)

NEW HAVEN 2BR, Woodbridge Crossing. 2nd fl. Stove, refrig, gas/hot wtr. base-board heat. $1050/mo. Lease. Sec. No pets. Richard. 203-734-8371.

APARTMENTS FOR RENT (UNFURNISHED)



#1 Rental Company in NEW HAVEN

Apartments for Rent, starting at $575 and Up! 1, 2, 3, 4, 5 & 6 Bedroom Apartments for Rent. High Rises, Multi-Family Houses, Single Family. Commercial Rentals. Free Parking (some include Free Heat/Hot water, Free Parking) and much more!

203-773-9710

LOOK!

ANSONIA
1 & 2 BR townhouse units available at Beaver Brook Apts. Located in wooded setting yet 10 minutes to New Haven and Bridgeport with no traffic lights! Prices from 1 BR, $875-$1025; 2 BR $975-$1175; incl. heat & hot water. Fall Special: 1/2 off 1 month's rent. Call for your appointment today.
203-734-5117

New Haven - 2 BR Sherman $900/mo. 4 BR 1 BA, 2nd & 3rd floor, Lilac St. $1400/mo. No Pets. 203-314-8567 for info.

NEW HAVEN 1 & 2 BR
Starting at $790. FREE HEAT & HOT WTR. Fridge, Range. On-site laundry/more.
(866)-490-2528
17013@newhome1.com

New Haven 1 Rm. Effic. Apt. 1623 Chapel St. 3rd flr walk-up, $675/mo. + $1,000 sec. All utils. incl. Avail. immed. Call (203) 257-6550

West Haven & Orange Dogwood Rd. Apts
1 & 2 Bdrms & Efficiencies. Carpeted & Laundry Rooms Starting at $685 When Avail. 203-795-3748

RENT NOW!

WEST HAVEN
1 BR, $850-$995; w/heat, HW included. Avail now! For appt 203-931-7700

HOUSES FOR RENT (UNFURNISHED)

East Haven: 3 bdrm, 2nd floor, 2 balconies, no pets $1300 + 1 mo dep. 203-640-1189

ROOMS FOR RENT

Hamden, Furnished room Share house, Kitchen, Cable TV, Internet, Wash/Dryer, On bus. $195/wk. 203-214-4343

HELP WANTED GENERAL

LICENSED P-2 PLUMBER
For commercial and residential work. Salary based on exp. Please call to schedule an interview **203-222-1111**

DRIVERS

DRIVER - Shoreline Fuel Co. Oil truck driving exp. req'd. CDL, Hazmat, Twic & Medical card req'd. Full & Part-Time. Call 203-488-2669, 8am-4pm.

NURSING

RN'S to work in schools, clinics, etc. Short & long term. Start now. 203-891-8243 www.lifelinenursing.net

SKILLED LABOR

ELECTRICIAN, E-2 - FT Permanent opportunity with large Stamford based Co. Must be committed, self-motivated, self-disciplined, 5 plus yrs' experience. Bnft's Inc. Medical/Dental/ 401k. Call 203-327-1120 Or email resume to: info@camsaninc.com

LEGAL NOTICES

LEGAL NOTICE
REQUEST FOR PROPOSALS – One Stop Services Provider South Central WIOA Region

Workforce Alliance (WA) is issuing a Request for Proposals for a One Stop services provider for the South Central region of Connecticut. Funds are available under the federal Workforce Innovation and Opportunity Act and other state and federal sources. Workforce Alliance reserves the unilateral right to extend this contract.

The RFP will be available the WA website, www.workforcealliance.biz Tuesday, Nov. 22, 2016. A Bidders' Conference will be held on Wednesday, November 30, 2016, at 1:30 PM at Workforce Alliance, 560 Ella Grasso Boulevard, New Haven. Proposal respondents must submit a letter of intent to Workforce Alliance by 3:00 PM, Thursday, Dec. 15, 2016. Proposals due 12:00 noon, on Tuesday, January 24, 2017. No late proposals will be accepted. WA reserves the right to accept or reject any or all portions of a proposal. EEO/AA.

LEGAL NOTICES

LEGAL NOTICE

The Superior Court has found that the persons listed below own property seized in connection with a drug offense. Pursuant to General Statutes § 54-36h, the State of Connecticut has petitioned for forfeiture of the property. The State hereby gives notice that unless the owners appear to contest the forfeiture, the State will move the Court to enter a default and judgment, resulting in forfeiture of the property.

The Court has ordered a hearing on the State's Petition for **December 2nd, at 10:00 a.m., the Superior Court, G.A. 23, Courtroom "A", 121 Elm Street, New Haven, CT 06510.**

The following is a list of the pending cases:
CV16-15577: State v. $3,255.00 in U.S. Currency [Alexis Viera]
CV16-15581: State v. $344.00 in U.S. Currency [Miguel Lewis]

By: SEAN MCGUINNESS
Assistant State's Attorney
Judicial District of New Haven, G.A. #23
121 Elm Street
New Haven, CT 06510
Tel.# (203) 789-7455

LEGAL NOTICES

LIQUOR PERMIT

Notice of Application

This is to give notice that I,
EMI NAGATA
18 CAVRAY RD
NORWALK, CT 06855-2231

Have filed an application placarded 11/11/2016 with the Department of Consumer Protection for a RESTAURANT LIQUOR PERMIT for the sale of alcoholic liquor on the premises at
754 STATE ST
NEW HAVEN, CT 06511-3920

The business will be owned by: JADE HOSPITALITY LLC
Entertainment will consist of: None

Objections must be filed by: 12/22/2016

EMI NAGATA

LEGAL NOTICES

NEW HAVEN CITY PLAN COMMISSION
NOTICE OF DECISIONS
11/16/16

Approved with conditions:
3 CLIFTON STREET. Site Plan and Coastal Site Plan Review for construction of 10 residential units in a BA zone. (Owner/Applicant: Erik Styluk of Oryx Investments)
34 FULTON STREET. Certificate of Approval of Location (CAL) for Used Car Dealer in an IH zone. (Owner: Pasquale Somma of JLS, LLC; Applicant: Richard Murphy for R.J. Shore Collision, LLC)
50 TOWER PARKWAY AND 400 YORK STREET. Site Plan Review for improvements and renovations to Baker Hall in an RH-2 zone. (Owner/Applicant: John Bollier for Yale University)
1219/1223 TOWNSEND, 490 FORBES AVENUE, AND 17 ASHLAND PLACE. Site Plan Review for new commercial building and related parking in BA and RM-1 zones. (Owner/Applicant: 1219 Townsend Associates LLC)
59 AND 65 DIXWELL AVENUE. Site Plan Review for conversion and addition for residential use in an RM-2 zone. (Owner/Applicant: Fatma Catalbasoglu)

NOTICE OF PUBLIC SALE

TO BE HELD AT:
THE LOCK UP SELF STORAGE
1950 Dixwell Avenue
Hamden, CT 06514
DATE:
November 29, 2016
BEGINS AT: 11:00 AM

CONDITIONS: All units will be sold to the highest bidder. Bids taken only for each unit in its entirety. Payment must be made by cash, credit card, or certified funds. No personal checks accepted. All goods must be removed from the unit within 24 hours. Payment due immediately upon acceptance of bid. Unit availability subject to prior settlement of account.

Unit 1128 Kimberly Gallagher
furniture, boxes

Unit 2054 Joshua Lainey
furniture, fan, boxes

Unit 2139 Clyde Toles
bike, tv, ac unit, boxes, bags

Unit 2213 John Pisano
Bed frame, mattress, furniture, TV, books

Unit 2260 NuQun Davis
Clothes, weight bench

Unit 2545 Chantel Davis
Bins, clothes, chair, musical instruments

Unit 2550 John Brailsford
furniture, boxes, mattress, stroller, bike

LEGAL NOTICES

Public Notice

Pursuant to section 19a-638 of the Connecticut General Statutes, Yale New Haven Hospital will submit the following Certificate of Need application:
Applicant(s):
Yale New Haven Hospital
Address:
1450 Chapel Street, New Haven, CT 06511
111 Goose Lane, Guilford, CT 06437
Proposal:
Replacement of 2 SPECT Cameras with 2 SPECT/CT Cameras
Estimated Total Project Cost/Expenditure:
$1,000,000

REQUEST FOR QUALIFICATIONS (RFQ)
FOR BUILDING CUSTODIAL SERVICES & HARD SURFACE FLOOR CARE

The South Central Connecticut Regional Water Authority is seeking qualified prospective bidders for custodial services and hard surface floor care at the offices of the Regional Water Authority.

Responses to the RFQ will be evaluated against a variety of criteria, with the top 3 qualifiers being invited to bid for Building Custodial Services & Hard Service Floor Care.

A copy of the RFP may be obtained at the Purchasing Department at the office of the Regional Water Authority at the above address between 9 am and 4 pm, Monday through Friday.
Vendors may also register on our website to obtain specifications. Go to:
www.rwater.com
Click on "Opportunities with RWA" then "Doing Business with the RWA" then "Register to do business with......"

The RFQ response must be submitted at the Purchasing Department of the Authority no later than:
December 5, 2016
at 4:00 p.m.

South Central Connecticut Regional Water Authority
90 Sargent Drive
New Haven, CT 06511
Peter Bocciarelli
Purchasing Manager
November 21, 2016

NEW TODAY
Our newest Classified ads are right here!

MISCELLANEOUS

WANTED ALL MILITARY ITEMS - West Haven Veterans Museum is looking for donation of area related military items - swords, medals, uniforms, etc. Volunteers also welcome. Call Ed, 203-915-4821

MUSICAL INSTRUMENTS

USED STEINWAY, Baldwin, Yamaha Grand & Vertical pianos. Mint condition. Private sales. Priced below retail. **203-260-0191**

APARTMENTS FOR RENT (UNFURNISHED)

New Haven 1 Rm. Effic. Apt. 1623 Chapel St. 3rd flr walk-up, $675/mo. + $1,000 sec. All utils. incl. Avail. immed. Call (203) 257-6550

ROOMS FOR RENT

Hamden, Furnished room Share house, Kitchen, Cable TV, Internet, Wash/Dryer, On bus. $195/wk. 203-214-4343

AUTOS WANTED

NICHOLS Salvage - Will buy your scrap steel, cars, trucks, alum., trailers, copper, batteries, heavy equip. 46 Meadow Rd. Clinton CT. 860-669-2808

BRICK, BLOCK & STONE

KC MASONRY
Stonewalls-brickwalls-bluestone-steps-fireplaces-chimneys-patios-sidewalks.
We can also do all masonry repairs.
Reliable, quality Workmanship
Free Estimates-Lic. 0606514
KEN 203-558-4951
20 yrs experience

Monday, November 21, 2016

GOREN BRIDGE

WITH BOB JONES
©2016 Tribune Content Agency, LLC

WEEKLY BRIDGE QUIZ ANSWERS

Q 1 - Neither vulnerable, as South, you hold:

♠ K J 5 ♡ A 7 4 ◇ A 9 4 ♣ J 9 7 4

SOUTH	WEST	NORTH	EAST
1♣	1♡	1♠	Pass
?			

What call would you make?

A - Partner has promised at least five spades — he would have made a negative double with only four. Despite the completely balanced nature of your hand, bid two spades.

Q 2 - North-South vulnerable, as South, you hold:

♠ K Q 9 7 6 4 3 ♡ A ◇ K J 9 ♣ 6 3

SOUTH	WEST	NORTH	EAST
1♠	Pass	1NT	Pass
?			

What call would you make?

A - There are only 13 high-card points, but this hand is well worth a jump rebid. Bid three spades. We know some wild men who would bid four spades.

Q 3 - East-West vulnerable, as South, you hold:

♠ Q J 6 5 ♡ A 2 ◇ Q 9 6 ♣ K 8 5 2

SOUTH	WEST	NORTH	EAST
1♣	1♡	Dbl*	2♡
?			

*Negative, values with no clear bid
What call would you make?

A - This is a command performance. After the negative double, you must compete to two spades whenever you have four of them, even with a dead minimum. Bid two spades.

Q 4 - Both vulnerable, as South, you hold:

♠ J 10 8 ♡ K J 9 7 4 2 ◇ 10 9 4 ♣ 10

Partner passes and so does right-hand opponent. What call would you make?

A - Partner is a passed hand and you have only five points. The opponents are almost surely cold for game. Do your best to get in their way. Bid two hearts.

Q 5 - North-South vulnerable, as South, you hold:

♠ A K 10 8 ♡ 8 7 6 5 2 ◇ 4 2 ♣ A 9

Partner passes and so does right-hand opponent. What call would you make?

A - Partner may be quite weak and it's possible that the opponents will outbid you on this hand. Open one spade. You don't want a heart lead if partner ends up on lead.

Q 6 - Both vulnerable, as South, you hold:

♠ A Q 9 8 6 2 ♡ A Q J 10 ◇ 10 ♣ A 4

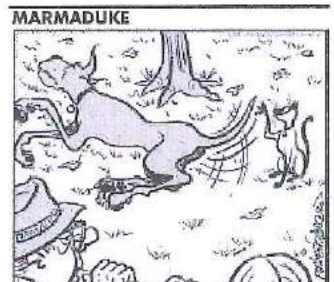
SOUTH	WEST	NORTH	EAST
1♠	Pass	1NT	Pass
?			

What call would you make?

A - This is an excellent hand, but it is not quite worth a jump to three hearts. Bid two hearts.

(Bob Jones welcomes readers' e-mails at tcaeditors@tribpub.com.)

MARMADUKE



"Just another two seconds and the show starts."

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HAMDEN 5 rm, 2 br, 1st or 2nd flr, newly remodeled, no pets/smoking, good credit/ref. $1100 + util. (203) 671-9644

New Haven - 2 BR Sherman $900/mo. 4 BR 1 BA, 2nd & 3rd floor, Lilac St. $1400/mo. No Pets. 203-314-8567 for info.

NEW HAVEN 1 & 2 BR Starting at $790. FREE HEAT & HOT WTR. Fridge, Range. On-site laundry/more. (866)-490-2528 17013@newhome1.com

West Haven & Orange Dogwood Rd. Apts 1 & 2 Bdrms & Efficiencies. Carpeted & Laundry Rooms Starting at $685 When Avail. 203-795-3748

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20 yrs experience

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LEGAL NOTICES

LEGAL NOTICE
CITY OF ANSONIA
NOTICE OF DECISIONS

At the meeting of the Ansonia Zoning Board of Appeals held on November 14, 2016 the Board voted the following:

DENIED: 49 Myrtle Ave. – AAF Developers, LLC – request to subdivide an existing building lot into two non-conforming lots.

ANSONIA ZONING BOARD OF APPEALS
Claudia Degnan,
Chairman
Dated at Ansonia, CT
This 22nd day of
November 2016

Notice of Decision
Woodbridge Inland Wetlands Agency

At its regular meeting on November 16, 2016, the Inland Wetlands Agency of the Town of Woodbridge acted to approve the following application with special conditions:
Geraldine Giering: 91 Forest Glen Drive
Application for residential site development of lot
Robert Blythe, Chairman

THE CLASSIFIEDS ... they go where you can't ... into thousands of homes. Andy they do all in one day!

LEGAL NOTICES

LEGAL NOTICE
CONNECTICUT LOTTERY CORPORATION
NOTICE OF END OF INSTANT GAME

The Connecticut Lottery Corporation hereby gives notice that sales of the scratch game "5X The Money 5th Edition" (Game #1325) ended on 11/17/2016.
All winning tickets, including top prizes, for this game must be validated no later than 5/16/17.
The Official Procedures for All Scratch Games apply to this game. These Official Procedures, as well as end of game and unclaimed prize information, are available at ctlottery.org and from CT Lottery Games Dept., 777 Brook St., Rocky Hill, CT 06067.

Public Notice

Pursuant to section 19a-638 of the Connecticut General Statutes, Yale New Haven Hospital will submit the following Certificate of Need application:
Applicant(s):
Yale New Haven Hospital
Address:
1450 Chapel Street, New Haven, CT 06511
111 Goose Lane, Guilford, CT 06437
Proposal:
Replacement of 2 SPECT Cameras with 2 SPECT/CT Cameras
Estimated Total Project Cost/Expenditure:
$1,000,000

The Planning & Zoning Commission, Town of Hamden, held a Public Hearing & Regular Meeting on Tuesday, November 15, 2016 with the following results
1)Special Permit & Site Plan 16-1289, *Approved with conditions* 2)Proposed Amendment to the Zoning Regulations 16-959, *Approved with an effective date of 11/30/16; 3)C.G.S. 8-24 16-393, Favorable review; For additional information regarding the Applications go to www.hamden.com,* Planning & Zoning Commission Submitted: Stacy Shellard, Commission Clerk

CLEANING OUT YOUR ATTIC OR GARAGE?
CALL 1-800-922-7066
TO ADVERTISE YOUR ARTICLES FOR SALE

LEGAL NOTICES

Notice of Permit Application
Town: Guilford

Notice is hereby given that Michael Dewar & Kimberly Howland (the "applicant") of 137 West Lane, Guilford, CT has submitted to the Department of Energy & Environmental Protection an application under Sections 22a-361 of the Connecticut General Statutes (CGS) for a permit to conduct work in tidal, coastal or navigable waters of the State.

Specifically, the applicant has requested authorization to install a fixed pier and steps within Connecticut waters. The proposed activity will take place at 137 West Lane, Guilford. The proposed activity will potentially affect coastal resources.

Interested persons may obtain copies of the application from Coastline Consulting & Development, LLC, 57-B East Industrial Road, Branford, CT 06405, telephone (203) 433-4485, e-mail david@coastlineconsulting-ct.com.

The application is available for inspection at the Office of the Department of Energy & Environmental Protection, Office of Long Island Sound Programs, 79 Elm Street, Hartford, CT 06106-5127, telephone (860) 424-3034 from 8:30 to 4:30 Monday through Friday.

The Zoning Board of Appeals, Town of Hamden, held a Public Hearing & Regular Meeting on Thursday, November 17, 2016 with the following results
1) 16-6605 5 Corporate Ridge, Granted; 2) 16-6607 380 Mather Street, *Granted; For additional information regarding the variance requests go to www.hamden.com,Zoning Board of Appeals;* Submitted: Stacy Shellard, Commission Clerk

CARPENTERS! PAINTERS! LANDSCAPERS!
Place your ad in our Business Card Section or our Service Directory. Our readers will call you! They trust our advertisers to do the job right!
Call 203-850-6628

LEGAL NOTICES

REPRESENTATIVE TOWN MEETING
BRANFORD, CONNECTICUT
SPECIAL MEETING
LEGAL NOTICE AND CALL

The RTM will be convened for a special meeting on Wednesday, November 30, 2016 at 8:00 p.m. at Branford Fire Headquarters, 45 North Main Street, to consider and act upon the following matters:

1. Roll Call
2. To hear a presentation from the First Selectman, selected staff, and Quisenberry Arcari Architects, LLC on the planned Community Center and Senior Center addition and renovation.
3. Adjourn.

Dated this 21st day of November, 2016
Dennis T. Flanigan
Moderator
Branford RTM

STATE OF CONN
Superior Court
Juvenile Matters
NOTICE TO
Harry Carter
Of Parts Unknown

A petition has been filed seeking commitment of minor child of the above named or vesting of custody and care of said child of the above named in a lawful, private or public agency or a suitable and worthy person. The petition, whereby the court's decision can affect your parental rights, if any, regarding minor child(ren) will be heard on 11/29/2016 at 11 a.m. at 239 Whalley Ave. New Haven, CT 06511.
Therefore, ORDERED, that notice of the hearing of this petition be given by publishing this Order of Notice once, immediately upon receipt, in the New Haven Register, a newspaper having a circulation in the city of New Haven, CT.
Hon. B Conway
Judge
M. Laudun
Clerk
11/17/16
Right to Counsel: Upon proof of inability to pay for a lawyer, the court will provide one for you at court expense. Any such request should be made immediately at the court office where your hearing is to be held.

[Your Ad Here.]

Call to place your Classified ad:
1.800.922.7066
Mon–Fri • 8:00am–5:00pm

Ads can also be placed through our website newhavenregister.com or by emailing classifiedads@nhregister.com

NEW HAVEN REGISTER

PROBATE NOTICES

NOTICE TO CREDITORS
ESTATE OF:
Jacqueline D. Green, AKA Jacqueline Labounty

The Hon. Beverly K. Streit-Kefalas, Judge of the Court of Probate, District of Milford-Orange Probate Court, by decree dated October 7, 2016, ordered that all claims must be presented to the fiduciary at the address below. Failure to promptly present any such claim may result in the loss of rights to recover on such claim.

Karen Adams,
Assistant Clerk

The fiduciary is:

Michline Fiordelisi c/o David C. Slepian Esq., Garson & Slepian, 72 Ruane St, Fairfield, CT 06854

NOTICE TO CREDITORS

NOTICE TO CREDITORS
ESTATE OF:
Sallie R. Brooker

The Hon. John A. Keyes, Judge of the Court of Probate, District of New Haven Probate Court, by decree dated October 13, 2016, ordered that all claims must be presented to the fiduciary at the address below. Failure to promptly present any such claim may result in the loss of rights to recover on such claim.

Edward Cleary,
Assistant Clerk

The fiduciary is:

Georgia B. Sturgis, 256 Betsy Branch Drive, Thomson, GA 30824

LOST & FOUND

Farley has been missing since about October 23rd from his home on Roosevelt Street Extension next to Bishop Woods Bird Sanctuary in New Haven near the East Haven and North Haven town lines. He may have been scared through the Woods and come out on another side. He is a big neutered male with no collar, medium gray and white with lighter wide stripes on his sides and tail. He is very skittish and doesn't like people or other animals.
If seen: 203-457-8891

IMPOUNDED By East Haven ACO: 4 mo. old brown terrier mix, female 203-468-3249

IMPOUNDED by Hamden ACO. #63, male husky, brown & white, Helen St. and Pine Rock area.
To reclaim: 203-230-4080

IMPOUNDED BY NORTH HAVEN ACO. Female DSH Cat Torti, Valley Service Rd. Call to redeem. 203-239-5321 x250

CALL TOLL-FREE
1-800-922-7066
TO PLACE YOUR CLASSIFIED AD

Tuesday, November 22, 2016

GOREN BRIDGE

WITH BOB JONES
©2016 Tribune Content Agency, LLC

ELEGANT END-PLAY

East-West vulnerable, North deals.

NORTH
♠ K J 8
♡ Q 10 8
◇ A 10
♣ A K 10 9 8

WEST
♠ A 10 9 5
♡ 6 3
◇ Q 9 5 2
♣ Q 5 2

EAST
♠ Q 3
♡ A 9 4
◇ J 7 4 3
♣ J 7 6 4

SOUTH
♠ 7 6 4 2
♡ K J 7 5 2
◇ K 8 6
♣ 3

The bidding:

NORTH	EAST	SOUTH	WEST
1♣	Pass	1♡	Pass
2NT	Pass	3◇*	Pass
3♡	Pass	4♡	All pass

*Checkback Stayman

Opening lead: Two of ◇

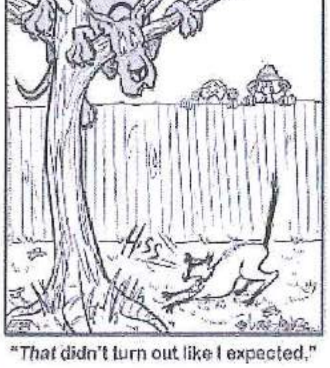
North treated his hand as being too good for a one no trump opening. No good player would disagree with his evaluation. The excellent five-card suit and the rich intermediate cards make this hand easily worth more than 17 points. South used Checkback Stayman over North's two no trump rebid. This bid of the "new minor" asked North if he held either four spades or three-card heart support.

South rose with dummy's ace of diamonds at trick one and led the queen of hearts. When this was allowed to hold the trick, declarer led a diamond to his king and ruffed his last diamond in dummy. Dummy's last heart was led, this time won by East, who continued with a fourth round of diamonds. South ruffed this in his hand and drew the last trump with the jack of hearts. What next?

Declarer could try tackling the spades by leading low to the jack, and later low to the king, but he was running out of entries to his hand. He had only one trump remaining, so a bad guess in spades would put the contract in some jeopardy. Rather than leading spades, South found the elegant play of leading a low club to dummy's 10! East was known to have no red cards remaining, so he was forced to lead a black suit into dummy. East did the best and he could and led a spade to West's ace as South claimed the rest. Note that this line of play would have succeeded even if East held the ace-queen-10 of spades.

(Bob Jones welcomes readers' responses sent in care of this newspaper or to Tribune Content Agency, LLC., 16650 Westgrove Dr., Suite 175, Addison, TX 75001.)

MARMADUKE



"That didn't turn out like I expected."

LEGAL NOTICES

NOTICE OF MOTOR VEHICLE AUCTION

The City of New Haven, through the Tax Collector's office (in accordance with C.G.S. 12-155) and Crown Auto Center hereby give notice that a Motor Vehicle auction has been scheduled, through it's agent, State Marshal H. Mark DeAngelis, (203) 215-7857.

DATE: (SATURDAY)12/3/16 TIME: 8:30 A.M. viewing 9:00 A.M. Auction starts PLACE: CROWN AUTO CENTER 388 Crown Street, New Haven, CT.

VEHICLES

3FAHP0JA5BR158588
1N4BA41E24C804600
1FMZU72K74UA98649
4S4BRBCC9B3432834
5NPEU46F36H101414
2HKYF18175H564873
WVWDK73C17P076311
4F4YR16U6WTM19114
JM1BL1S55A1342179
WBAD143441GX21622
1N4BA41E74C901383
JTDBT923174001723
1FMZU74K84UA31541
19UUA66266A054563
KNDJC733035056036
1N4BA41EX7C801413
JTDAT123X30275047
KNAFU6A26A5295575
1FMZU72K24UB08973
1GNEK13T31R156888

The Property being auctioned pursuant to this notice is being sold "as is" and "where is"

NOTICE OF PUBLIC SALE: The following self-storage unit contents containing household and other goods will be sold for cash by CubeSmart 171 Cedar Street Branford, CT 06405 to satisfy a lien on December 7th, 2016 at approx. 12:30 PM at www.storagetreasures.com. The Ads should be ran for 11/23/2016 11/25/2016

Nicole G Dostie- Falcone, Unit B 48

Ronald J Messina, Unit C60

Andrew Sharpe, Unit D119/120

Meghan L Miller, Unit E187A

Jason William Wojciechowski, Unit E183A

Christien M Corso, Unit D131

Eric W Pierce, Unit B10

Allison L Deuza, unit N412 and unit J367

Lisa R Landow, Unit D105/D106

Gina M Rodriguez, Unit C73

Lin Yong Yan, Unit M403/407

Public Notice

Pursuant to section 19a-638 of the Connecticut General Statutes, Yale New Haven Hospital will submit the following Certificate of Need application:
Applicant(s): Yale New Haven Hospital
Address: 1450 Chapel Street, New Haven, CT 06511
111 Goose Lane, Guilford, CT 06437
Proposal: Replacement of 2 SPECT Cameras with 2 SPECT/CT Cameras
Estimated Total Project Cost/Expenditure: $1,600,000

The Glendower Group, Inc

Request for Proposals

Master Planner for the Redevelopment of Westville Manor and Surrounding Area

The Glendower Group, Inc an affiliate of Housing Authority City of New Haven d/b/a Elm city Communities is currently seeking Proposals for Master Planner for the Redevelopment of Westville Manor and Surrounding Area. A complete copy of the requirement may be obtained from Elm City's Vendor Collaboration Portal https://newhavenhousing.cobblestonesystems.com/gateway beginning on Thursday, November 17, 2016 @ 9:00 AM.

LEGAL NOTICES

The West Haven Zoning Board of Appeals held a Regular Meeting following the Public Hearing on WEDNESDAY, November 16, 2016, in the Harriet North Room, Second Floor, City Hall, 355 Main Street, West Haven, at 7:15 P.M. and made the following decisions.

APPROVED WITH CONDITIONS
29 Crest Avenue – Paul Gradoia

John Clifford
Chairman

Town of East Haven Bid # 16-10 Sand for Snow & Ice Control

Sealed Bids may be submitted to the Finance Office at Town Hall 250 Main Street, East Haven, CT 06512 until 10:00 a.m., local time on Tuesday, December 06, 2016 at which time they will be opened.

One original and two copies of the Bid are to be submitted along with a Five Hundred Dollar ($ 500.00) Bid Bond.

Bids Specifications are available at Town Hall on November 23, 2016 or on the Town Website: www.townofeasthavenct.org

The Director of Finance reserves the right to reject any and all Bids or to waive defects in same if it be deemed in the best interest of The Town of East Haven to do so.

The Town of East Haven is an Affirmative Action Equal Opportunity Employer.

Paul S. Rizza
Director of Finance

FORECLOSURES

LEGAL NOTICE FORECLOSURE AUCTION SALE

Docket No. NNH-CV-15-6056105-S
Case Name: Ocwen Loan Servicing, LLC
v.
Scott E. Zakos, et al
Property Address: 920 Ocean Avenue, Unit 2C West Haven, CT
Property Type: Condominium
Date of Sale: December 3, 2016
Committee Name: Earle Giovanniello, Esq.
Committee
Phone Number: (203) 777-4003

See Foreclosure Sales at www.jud.ct.gov for more detailed information

LEGAL NOTICE FORECLOSURE AUCTION SALE

Docket No: NNH-CV-14-6050526-S
Case Name: NRZ Pass-Through Trust IV, US Bank National Association, Trustee
vs.
Karla Miller, A/K/A Karla T. Miller, Et Al
Property Address: 151 Curtis Drive New Haven, CT
Property Type: Residential
Date of Sale: December 3, 2016 at 12:00 Noon
Committee Name: Alfred J. Onorato, Esq.
Committee
Phone Number: 203-787-5797

See Foreclosure Sales at www.jud.ct.gov for more detailed information.

FORECLOSURES

LEGAL NOTICE FORECLOSURE AUCTION SALE

Docket No.: NNH-CV-16-6061851 S
Case Name: Wells Fargo Bank, National Association as Trustee
v.
Mighty, Chester A., AKA Mighty, Chester, et al
Property Address: 147 Colony Street Hamden, CT 06518
Property Type: Residential
Date /Time of Sale: December 3, 2016 at 12:00 p.m.
Committee Name: Alison L. Broad Committee
Phone Number: 203.281.2700

See Foreclosure Sales at www.jud.ct.gov for more detailed information

LEGAL NOTICE FORECLOSURE AUCTION SALE

Docket No. NNH CV 16 6062300 S
Case Name: JPMorgan Chase Bank, National Association
vs.
Sandra Arnold, et al
Property Address: 43 Circle Drive Wallingford, Connecticut
Property Type: Residential - Single Family
Date of Sale: Saturday, December 3, 2016, 12:00 noon, on the premises.
Committee Name: Chris Dellaselva, Esq. Committee
Phone Number: (203) 641-3323

See Foreclosure Sales at www.jud.ct.gov for more detailed information

LEGAL NOTICE FORECLOSURE AUCTION SALE

Docket No.: NNH CV-16-6061530 S
Case Name: HSBC Bank USA, N.A.
VS.
Matthew A. Pasqualoni, Executor of the Estate of Diane V. Pasqualoni, Et Al
Property Address: 4 Field Drive, Wallingford, CT
Property Type: Residential
Date of Sale: December 3, 2016
Committee Name: Susan I. Epstein Committee
Phone Number: (203) 281-4451

See Foreclosure Sales at www.jud.ct.gov for more detailed information

LEGAL NOTICE FORECLOSURE AUCTION SALE

Docket No.: NNH CV 15-6059093 S
Case Name: City of New Haven
v.
Richard Ware, Et Al
Property Address: 671 Quinnipiac Avenue Unit 13 New Haven, Connecticut
Property Type: Residential
Date of Sale: Saturday December 3, 2016 at 12:00 Noon on the Premises
Committee Name: Richard M. Franchi Committee
Phone Number: (203) 495-1000

See Foreclosure Sales at www.jud.ct.gov for more detailed information

AN ORDINANCE APPROPRIATING $2,540,400 FOR THE PLANNING, DESIGN, CONSTRUCTION, EQUIPPING AND FURNISHING OF ALICE PECK SCHOOL AND RELATED COSTS AND AUTHORIZING THE ISSUANCE OF $2,540,400 BONDS OF THE TOWN TO MEET SAID APPROPRIATION AND PENDING THE ISSUANCE THEREOF THE MAKING OF TEMPORARY BORROWINGS FOR SUCH PURPOSE

BE IT ORDAINED BY THE LEGISLATIVE COUNCIL OF THE TOWN OF HAMDEN:
Section 1. The sum of $2,540,400 is hereby appropriated by the Town of Hamden, Connecticut (the "Town") for the planning, design, construction, equipping and furnishing of Alice Peck School and related costs, including, but not limited to, infrastructure improvements, including boiler replacement, roof replacement, hazardous material abatement in building tunnels as well as several pre-K program improvements, and related legal, consulting, licensing, advisory, administrative, governmental fees and expenses and costs of issuance related thereto, said appropriation being inclusive of any and all State and Federal grants-in-aid thereof (the "Project"). The total cost of the Project is expected to be financed by State grants. **Section 2.** To meet said appropriation, $2,540,400 bonds of the Town or so much thereof as shall be necessary for such purpose, shall be issued, maturing not later than the maximum maturity permitted by the General Statutes of Connecticut, Revision of 1958, as amended from time to time (the "Connecticut General Statutes"). Said bonds may be issued in one or more series as determined by the Director of Finance, in the amount necessary to meet the Town's share of the cost of the Project determined after considering the estimated amount and timing of State and Federal grants-in-aid of the Project, provided that the total amount of bonds to be issued shall not be less than an amount which will provide funds sufficient with other funds available for such purpose to pay the principal of and the interest on all temporary borrowings in anticipation of the receipt of the proceeds of said bonds outstanding at the time of the issuance thereof, and to pay for the costs of issuance of such bonds. The bonds shall be issued in fully registered form, be executed in the name and on behalf of the Town by the facsimile or manual signatures of the Mayor, President of the Legislative Council and the Director of Finance, or any two of them, bear the Town seal or a facsimile thereof, be certified by a bank or trust company, which bank or trust company may be designated the registrar and transfer agent, be payable at a bank or trust company, and be approved as to their legality by Robinson & Cole LLP, Attorneys-at-Law, of Hartford, Connecticut. The bonds shall be general obligations of the Town and each of the bonds shall recite that every requirement of law relating to its issue has been duly complied with, that such bond is within every debt and other limit prescribed by law, and that the full faith and credit of the Town are pledged to the payment of the principal thereof and interest thereon. The aggregate principal amount of the bonds of each series to be issued, the annual installments of principal, redemption provisions, if any, the certifying, registrar and transfer agent and paying agent, the date, time of issue and sale and other terms, details and particulars of such bonds, including the approval of the rate or rates of interest, shall be determined by the Mayor and the Director of Finance in accordance with the Connecticut General Statutes. **Section 3.** Said bonds shall be sold by the Mayor and the Director of Finance in a competitive offering or by negotiation, in their discretion. If sold in a competitive offering, the bonds shall be sold at not less than par and accrued interest on the basis of the lowest net or true interest cost to the Town. A notice of sale or a summary thereof describing the bonds and setting forth the terms and conditions of the sale shall be published at least five days in advance of the sale in a recognized publication carrying municipal bond notices and devoted primarily to financial news and the subject of state and municipal bonds. If the bonds are sold by negotiation, provisions of the purchase agreement shall be subject to the approval of the Mayor and the Director of Finance. **Section 4.** The Director of Finance is authorized to make temporary borrowings in anticipation of the receipt of the proceeds of said bonds. Notes evidencing such borrowings shall be signed by the Mayor and the Director of Finance, have the seal of the Town affixed, be payable at a bank or trust company designated by the Director of Finance be approved as to their legality by Robinson & Cole LLP, Attorneys-at-Law, of Hartford, Connecticut, and be certified by a bank or trust company designated by the Director of Finance pursuant to Section 7-373 of the Connecticut General Statutes. The notes shall be issued with maturity dates which comply with the provisions of the Connecticut General Statutes governing the issuance of such notes, as the same may be amended from time to time. The notes shall be general obligations of the Town and each of the notes shall recite that every requirement of law relating to its issue has been duly complied with, that such note is within every debt and other limit prescribed by law, and that the full faith and credit of the Town are pledged to the payment of the principal thereof and the interest thereon. The net interest cost on such notes, including renewals thereof, and the expense of preparing, issuing and marketing, to the extent paid from the proceeds of such renewals or said bonds, shall be included as a cost of the Project. Upon the sale of the bonds, the proceeds thereof, to the extent required, shall be applied forthwith to the payment of the principal of and the interest on any such notes then outstanding or shall be deposited with a bank or trust company in trust for such purpose. **Section 5.** The Director of Finance is authorized to make temporary borrowings in anticipation of the receipt of the proceeds of State grants-in-aid of eligible school building projects pursuant to Section 7-405a of the Connecticut General Statutes ("grant anticipation notes"). Notes evidencing such borrowings shall be signed by the Mayor and the Director of Finance, have the seal of the Town affixed, be payable at a bank or trust company designated by the Director of Finance be approved as to their legality by Robinson & Cole LLP, Attorneys-at-Law, of Hartford, Connecticut, and be certified by a bank or trust company designated by the Director of Finance pursuant to Section 7-373 of the Connecticut General Statutes. The notes shall be issued with maturity dates which comply with the provisions of the Connecticut General Statutes governing the issuance of grant anticipation notes, as the same may be amended from time to time. The notes shall be general obligations of the Town and each of the notes shall recite that every requirement of law relating to its issue has been duly complied with, that such note is within every debt and other limit prescribed by law, and that the full faith and credit of the Town are pledged to the payment of the principal thereof and the interest thereon. The net interest cost on such notes, including renewals thereof, and the expense of preparing, issuing and marketing, to the extent paid from the proceeds of such renewals or said bonds, shall be included as a cost of the Project. Upon the sale of the bonds, the proceeds thereof, to the extent required, shall be applied forthwith to the payment of the principal of and the interest on any such notes then outstanding or shall be deposited with a bank or trust company in trust for such purpose. The Mayor and the Director of Finance are authorized to entered into credit facilities, including loan agreements, bond purchase agreements, commercial paper facilities and similar agreements to provide for the issuance of grant anticipation notes. The Mayor and the Director of Finance are authorized to select a lender, remarketing agent and any other professionals necessary or desirable to provide for the issuance of grant anticipation notes. **Section 6.** The Town hereby expresses its official intent pursuant to Section 1.150-2 of the Federal Income Tax Regulations, Title 26 (the "Regulations"), to reimburse expenditures paid sixty days prior to and anytime after the date of passage of this ordinance in the maximum amount and for the Project with the proceeds of bonds, notes, or other obligations ("Tax-Exempt Obligations") authorized to be issued by the Town. The Tax-Exempt Obligations shall be issued to reimburse such expenditures not later than 18 months after the later of the date of the expenditure or the substantial completion of the Project, or such later date the Regulations may authorize. The Town hereby certifies that the intention to reimburse as expressed herein is based upon its reasonable expectations as of this date. The Director of Finance or his designee is authorized to pay Project expenses in accordance herewith pending the issuance of the Tax-Exempt Obligations, and to amend this declaration. **Section 7.** The Mayor and the Director of Finance are hereby authorized, on behalf of the Town, to enter into agreements or otherwise covenant for the benefit of bondholders to provide information on an annual or other periodic basis to the Municipal Securities Rulemaking Board (the "MSRB") and to provide notices to the MSRB of material events as enumerated in Securities and Exchange Commission Exchange Act Rule 15c2-12, as amended, as may be necessary, appropriate or desirable to effect the sale of the bonds and notes authorized by this ordinance. Any agreements or representations to provide information to the MSRB made prior hereto are hereby confirmed, ratified and approved. **Section 8.** The Mayor and the Director of Finance, or either of them, are hereby authorized, on behalf of the Town, to enter into any other agreements, instruments, documents and certificates, including tax and investment agreements, for the consummation of the transactions contemplated by this ordinance. The Mayor and the Director of Finance, or either of them, are hereby authorized, on behalf of the Town, to apply for and accept any and all Federal and State loans and or grants-in-aid for any Project, to expend said funds in accordance with the terms hereof, and in connection therewith to contract in the name of the Town with engineers, contractors and others. **Section 9.** The balance of any appropriation or the proceeds of any bonds not needed to meet the cost of the Project authorized hereby may be transferred by the Mayor, upon approval of the Legislative Council, to meet the actual cost of any other capital project of the Town (including capital projects authorized by prior or future bond ordinances) for which an appropriation and bond authorization has been adopted; provided that the aggregate amount of bonds authorized pursuant to such transfer shall not be increased. **Section 10.** It is hereby found and determined by the Legislative Council that the maximum amount of debt service due in any fiscal year from the date hereof and hereafter, on outstanding, authorized but unissued, and proposed bonds of the Town, including the bonds proposed to be authorized by this ordinance, does not exceed ten percent (10%) of the current year's budget and as such, submission of this ordinance to binding referendum is not required pursuant to Section 10-9 of the Charter. For purposes of this section, the debt service on the aggregate principal amount of authorized but unissued bonds and proposed bonds of the Town, including the bonds proposed to be authorized by this ordinance, which totals $21,000,608, has been estimated assuming that the aggregate principal amount of all such bonds, reduced by expected grants to be received for the projects financed by such bonds, are issued on or about August 15, 2017 (the "Issue Date"), amortize in twenty equal installments over twenty years beginning on the one year anniversary of the Issue Date and bear interest at 2.98% (based on Bond Buyer 20-Bond GO Index), and when added to the debt service on the Town's outstanding bonds in each fiscal year, results in maximum annual debt service of the Town of approximately $19,968,131, which is less than ten percent (10%) of the Town's current budget of $211,420,681, or $22,142,068, and is expected to be less than ten percent (10%) of the Town's future budgets. Such assumptions are based on current market conditions for, and past practice in structuring, the Town's bonds.
Adopted by the Legislative Council at its meeting held November 21, 2016.

APPROVED — TOWN OF HAMDEN, CONNECTICUT

ATTEST:

Curt Leng, Mayor — James Pascarella, President of Legislative Council

Date: 11/22/16 — Kim Renta, Clerk of Legislative Council

Ordinance No.: 684 Published: November 23, 2016
Newspaper: New Haven Register Effective: December 14, 2016

ATTACHMENT 2
AFFIDAVIT

Affidavit

Applicant: Yale-New Haven Hospital

Project Title: Replacement of 2 SPECT Cameras with 2 SPECT/CT Cameras

I, Vincent Tammaro, CFO
(Name) (Position – CEO or CFO)

of Yale New Haven Health System being duly sworn, depose and state that the (Facility Name) said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

Vincent Tammaro 12/28/2016
Signature Date

Subscribed and sworn to before me on 12/28/2016

Rose Arminio

Notary Public/Commissioner of Superior Court

My commission expires: ROSE ARMINIO
NOTARY PUBLIC
State of Connecticut
My Commission Expires
February 28, 2018

ATTACHMENT 3

CON FILING FEE

Bank of America — **Cashier's Check** — No. 1019293975

Void Over 90 Days

Bank of America, N.A.
San Antonio, Texas
Deposit Services
318-0005594 T D

30-1/1140

DATE
12/27/2016 10:21:53 AM

PAY BANK OF AMERICA 510 00 FIVE ONE ZERO CTS CTS *********$510.00

To The Order Of: Treasurer State of Connecticut

[redacted]

Purchaser: YALE NEW HAVEN HOSPITAL

Void Over $ 510.00

AUTHORIZED SIGNATURE

THE ORIGINAL DOCUMENT HAS A REFLECTIVE WATERMARK ON THE BACK. HOLD AT AN ANGLE TO VIEW WHEN CHECKING THE ENDORSEMENTS.

CON APPLICATION & SUPPLEMENT

State of Connecticut
Department of Public Health
Office of Health Care Access

Certificate of Need Application
Main Form

Required for all CON applications

Contents:

- Checklist
- List of Supplemental Forms
- Proposal Information
- Affidavit
- Executive Summary
- Project Description
- Public Need and Access to Health Care
- Financial Information
- Utilization

Supplemental Forms

In addition to completing this **Main Form** and **Financial Worksheet (A, B or C)**, the applicant(s) must complete the appropriate **Supplemental Form** listed below. Check the box of the **Supplemental Form** to be submitted with the application, below. If unsure which form to select, please call the OHCA main number (860-418-7001) for assistance. All CON forms can be found on OHCA's website at OHCA Forms.

Check form included	Conn. Gen. Stat. Section 19a-638(a)	Supplemental Form
☐	(1)	**Establishment of a new health care facility (mental health and/or substance abuse)** - *see note below**
☐	(2)	**Transfer of ownership of a health care facility** (excludes transfer of ownership/sale of hospital – see "Other" below)
☐	(3)	**Transfer of ownership of a group practice**
☐	(4)	**Establishment of a freestanding emergency department**
☐	(5) (7) (8) (15)	**Termination of a service:** - inpatient or outpatient services offered by a hospital - surgical services by an outpatient surgical facility** - emergency department by a short-term acute care general hospital - inpatient or outpatient services offered by a hospital or other facility or institution operated by the state that provides services that are eligible for reimbursement under Title XVIII or XIX of the federal Social Security Act, 42 USC 301, as amended
☐	(6)	**Establishment of an outpatient surgical facility**
☐	(9)	**Establishment of cardiac services**
☒	(10) (11)	**Acquisition of equipment:** - acquisition of computed tomography scanners, magnetic resonance imaging scanners, positron emission tomography scanners or positron emission tomography-computed tomography scanners - acquisition of nonhospital based linear accelerators
☐	(12)	**Increase in licensed bed capacity** of a health care facility
☐	(13)	**Acquisition of equipment utilizing [new] technology** that has not previously been used in the state
☐	(14)	**Increase of two or more operating rooms** within any three-year period by an outpatient surgical facility or short-term acute care general hospital
☐	Other	**Transfer of Ownership / Sale of Hospital**

*This supplemental form should be included with all applications requesting authorization for the establishment of a **mental health and/or substance abuse treatment facility**. For the establishment of other "health care facilities," as defined by Conn. Gen. Stat § 19a-630(11) - hospitals licensed by DPH under chapter 386v, specialty hospitals, or a central service facility - complete *the Main Form* only.

**If termination is due to insufficient patient volume, or it is a subspecialty being terminated, a CON is not required.

Proposal Information

Select the appropriate proposal type from the dropdown below. If unsure which item to select, please call the OHCA main number (860-418-7001) for assistance.

Proposal Type (select from dropdown)	Acquisition of imaging equipment
Brief Description	Replace 2 existing SPECT cameras with 2 SPECT/CT cameras
Proposal Address	1450 Chapel Street (St. Raphael Campus), New Haven, CT 111 Goose Lane, Guilford, CT
Capital Expenditure	$ 927,862

Is this Application the result of a Determination indicating a CON application must be filed?

☐ No

☒ Yes, Docket Number: 16-32124-DTR

Applicant(s) Information

	Applicant One
Applicant Name & Address	Yale-New Haven Hospital 789 Howard Avenue New Haven, CT
Parent Corporation Name & Address (if applicable)	Yale-New Haven Health Services Corporation 789 Howard Avenue New Haven, CT
Contact Person Name	Nancy Rosenthal
Title	VP
Email Address	Nancy.rosenthal@ynhh.org
Phone	203-688-5721
Fax Number	N/A
Tax Status (check one box)	☐ For Profit ☒ Not-for-Profit

**For more than two Applicants, attach a separate sheet with the above information*

FOR OFFICE USE ONLY	
Docket #:	Staff Assigned :
Date Received:	

Executive Summary

The purpose of the Executive Summary is to give the reviewer a conceptual understanding of the proposal. In the space below, provide a succinct overview of your proposal (this may be done in bullet format). Summarize the key elements of the proposed project. Details should be provided in the appropriate sections of the application that follow.

Yale-New Haven Hospital (YNHH) proposes to replace two (2) of its existing SPECT cameras with two (2) SPECT/CT cameras. One of these cameras has reached the end of its useful life due to age and quality issues, and the other camera and is not able to produce the superior images offered by SPECT/CT.

- **YNHH purchased a GE MyoSite SPECT camera in 2005 and this equipment is located at 111 Goose Lane in Guilford. YNHH intends to replace this camera with a GE Optima 640 SPECT/CT at the same location.**
- **YNHH purchased a Siemens Symbia SPECT camera in 2014 and this equipment is located at 1450 Chapel Street (St. Raphael Campus) in New Haven. YNHH intends to replace this camera with a GE Optima 640 SPECT/CT at the same location.**

The new replacement SPECT/CT cameras will produce a higher quality image than the existing SPECT cameras due to the attenuation correction offered by the CT component, which the current SPECT cameras lack. There are certain limitations of a SPECT scan due in part to variation in the density of tissues within the body. Overlying breast tissue and/or adipose tissue can create shadows or artifacts, which cloud the image and may appear in a similar manner as true coronary defects. This can make interpretation of a nuclear medicine scan challenging. To resolve these issues, a CT component can be applied immediately after the SPECT scan, offering attenuation correction to remove these shadows and artifacts. The result is a high quality nuclear cardiology scan that can be interpreted by a physician with greater confidence.

YNHH proposes to continue offering high-quality cardiovascular imaging services for its patients by replacing existing equipment with more advanced and clear SPECT/CT systems.

Pursuant to Section 19a-639 of the Connecticut General Statutes, the Office of Health Care Access is required to consider specific criteria and principles when reviewing a Certificate of Need application. Text marked with a "§" indicates it is actual text from the statute and may be helpful when responding to prompts.

Project Description

1. Provide a detailed narrative describing the proposal. Explain how the Applicant(s) determined the necessity for the proposal and discuss the benefits for each Applicant separately (if multiple Applicants). Include all key elements, including the parties involved, what the proposal will entail, the equipment/service location(s), the geographic area the proposal will serve, the implementation timeline and why the proposal is needed in the community.

<u>Response:</u>
Yale-New Haven Hospital (YNHH) is a 1,541 bed (including bassinets) teaching hospital with two integrated campuses located in New Haven. It is affiliated with the Yale University School of Medicine, and includes the Yale-New Haven Children's Hospital, the Yale-New Haven Psychiatric Hospital, and the Smilow Cancer Hospital. YNHH provides primary, secondary, tertiary and many quaternary acute care services.

YNHH Heart and Vascular Center (HVC) treats the most heart and vascular patients of any facility in Connecticut, and is consistently ranked one of the nation's top providers of heart and vascular services in the nation. It offers every type of advanced cardiac imaging technology, including echocardiography, ultrasound, molecular nuclear medicine imaging, cardiac magnetic resonance imaging, positron emission topography, and computed tomography at various locations throughout Connecticut. Using a broad range of imaging tests, physicians at the YNHH HVC are able to evaluate a variety of cardiac issues such as chest paint, congestive heart failure, and valve disease.

YNHH HVC proposes to replace two (2) of its existing SPECT cameras with two (2) SPECT/CT cameras to continue its tradition of providing the highest quality cardiac imaging services. This existing equipment is not able to produce the significantly superior images offered by SPECT/CT.

YNHH filed a Determination Request with the Office of Health Care Access (OHCA) on September 28, 2016, seeking confirmation as to whether Certificate of Need approval was required for the replacement of a SPECT camera with a SPECT/CT. A copy of the Determination Report from OHCA is attached in <u>Exhibit A</u>. The Determination Request noted five (5) SPECT cameras in line for replacement, but due to various reasons, including the efficient allocation of capital resources, YNHH HVC proposes to replace only two (2) of these existing SPECT cameras with SPECT/CT equipment at this time.

<u>End of Useful Life</u>. YNHH HVC intends to replace two (2) nuclear cameras, one of which is at the end of its useful life due to age.

The GE MyoSite SPECT camera was purchased in 2005 and is located at 111 Goose Lane in Guilford. This camera is 11 years old, is nearing the end of its useful life, and does not offer the same high-quality imaging available on a SPECT/CT. YNHH HVC intends to replace this camera with a GE Optima 640 SPECT/CT at this location.

The Siemens Symbia SPECT camera was purchased in 2014 and is located at 1450 Chapel Street (St. Raphael Campus) in New Haven. Although it is not as old as the SPECT camera in Guilford, it has limitations in its scan quality. YNHH HVC intends to replace this camera with a GE Optima 640 SPECT/CT at the same location.

As noted previously, both of these nuclear cameras have certain limitations in scan quality, and the replacement SPECT/CT equipment represents a significant improvement in image quality, as explained below.

Higher Quality. Specifically, the new replacement SPECT/CT cameras will produce a higher quality image than the existing SPECT cameras due to the attenuation correction offered by the CT component, which the current SPECT cameras lack.

In the diagnosis and treatment of heart and vascular disease, patients often receive a test called myocardial perfusion to see how well blood flows through the heart muscle. A radioactive tracer is injected into the patient and a nuclear camera (such as a SPECT or SPECT/CT) is then used to capture images of the heart immediately after exercise, rest, or both to show areas of the heart with blocked arteries or injured by heart tissue.

There are certain limitations of this type of scan due in part to variation in the density of tissues within the body. Overlying breast tissue and/or adipose tissue can create shadows or artifacts, which cloud the image and may appear in a similar manner as true coronary defects. This can make interpretation of a nuclear medicine scan challenging. To resolve these issues, a CT component can be applied immediately after the SPECT scan, offering attenuation correction to remove these shadows and artifacts. The result is a high quality nuclear cardiology scan that can be interpreted by a physician with greater confidence, eliminating unnecessary follow-up testing, and decreasing the risk of false positive exams.

By replacing two (2) SPECT cameras with two (2) SPECT/CT cameras, YNHH HVC intends to offer the best available technology to assist in the treatment of its heart and vascular patients. It should also be noted that the new replacement cameras are faster, offer low-dose technology which is safer for patients, and are able to serve a more diverse population, including obese patients due to the attenuation correction feature which eliminates artifacts caused by adipose tissue.

YNHH HVC intends to replace this equipment within the next two (2) years after receiving approval of OHCA. The same patient population currently served will continue to be served at the same locations. This proposal is necessary because the existing SPECT cameras are nearing the end of their useful lives due to age and/or limited quality of the scan produced, and YNHH HVC intends to continue providing the highest quality nuclear imaging services to its heart and vascular patients.

2. Provide the history and timeline of the proposal (i.e., When did discussions begin internally or between Applicant(s)? What have the Applicant(s) accomplished so far?).

Response:

YNHH HVC continuously monitors and evaluates the age and effectiveness of its imaging technology, and as part of this review identified the need to replace these cameras due in

part to the age of one of the cameras and the limitation in imaging quality of both, as well as the availability of superior technology via the SPECT/CT.

3. Provide the following information:

   a. utilizing **OHCA Table 1**, list all services to be added, terminated or modified, their physical location (street address, town and zip code), the population to be served and the existing/proposed days/hours of operation;

Response:
See OHCA Table 1.

   b. identify in **OHCA Table 2** the service area towns and the reason for their inclusion (e.g., provider availability, increased/decreased patient demand for service, market share);

Response:
See OHCA Table 2.

4. List the health care facility license(s) that will be needed to implement the proposal;

Response:
No additional facility licenses are needed to implement the proposal.

5. Submit the following information as attachments to the application:

   a. a copy of all State of Connecticut, Department of Public Health license(s) currently held by the Applicant(s);

Response:
See Exhibit B.

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

Response:
See Exhibit C, which includes the Curriculum Vitae of the following professional, administrative, and clinical personnel:

- **Keith Churchwell, MD; Senior Vice President of Operations and Executive Director Heart and Vascular Center and Transplantation Center, YNHH/YNHHS**
- **Edward Miller, MD, PhD; Assistant Professor of Medicine and Radiology at Yale University; Director, Nuclear Cardiology.**
- **Francine LoRusso; Executive Director YNHH HVC**

   c. copies of any scholarly articles, studies or reports that support the need to establish the proposed service, along with a brief explanation regarding the relevance of the selected articles;

Response:
See Exhibit D.

- **Clinical Applications of SPECT/CT: New Hybrid Nuclear Medicine Imaging System. This article provides a comprehensive summary of SPECT/CT technology, including, but not limited to, the general architecture of the device, scan protocols, staff training, advantages of SPECT/CT, and clinical applications such as thyroid cancer, adrenal tumor, neuroendocrine tumors, lymphoma, bone scintigraphy, cerebral masses, and various cardiac images.**

- **American Society of Nuclear Cardiology and Society of Nuclear Medicine Joint Position Statement: Attenuation Correction of Myocardial Perfusion SPECT Scintigraphy. This statement notes that "incorporation of attenuation correction in addition to ECG gating with SPECT myocardial perfusion images will improve image quality, interpretive certainty, and diagnostic accuracy. These combined results are anticipated to have a substantial impact on improving the effectiveness of care and lowering health care costs."**

d. letters of support for the proposal;

Response:
See Exhibit E.

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

Response:
YNHH HVC is accredited by the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories and the American College of Radiology, and will continue to maintain such accreditation.

f. copies of agreements (e.g., memorandum of understanding, transfer agreement, operating agreement) related to the proposal. If a final signed version is not available, provide a draft with an estimated date by which the final agreement will be available.

Response:
Not applicable.

Public Need and Access to Care

> § *"Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Department of Public Health;" (Conn.Gen.Stat. § 19a-639(a)(1))*

6. Describe how the proposed project is consistent with any applicable policies and standards in regulations adopted by the Connecticut Department of Public Health.

Response:
This proposal is consistent with the Connecticut Department of Public Health policies and standards as it will expand access to high quality health services. The new imaging is more advanced than the current service which is beneficial to patients because it enables more accurate diagnosis of cardiovascular disease.

> § *"The relationship of the proposed project to the statewide health care facilities and services plan;" (Conn.Gen.Stat. § 19a-639(a)(2))*

7. Describe how the proposed project aligns with the Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan, available on OHCA's website.

Response:
The Statewide Health Care Facilities and Services Plan notes that hospitals serve as critical safety net providers to many Connecticut residents, treating a substantial number of patients who are uninsured or have limited ability to pay. It also shows that heart disease is the second leading cause of hospitalizations in the state, and that the percent of adults diagnosed with high blood pressure or diabetes is highest among the African American community. This proposal will enable YNHH to better serve all patient populations. YNHH is a non-profit hospital that serves a significantly large proportion of the state's Medicaid and indigent population, and the diverse City of New Haven. By replacing aging and less advanced equipment, this proposal will enable YNHH to better care for all patients, including those in need of a safety net providers, by accurately diagnosing and treating the growing number of residents in need of cardiovascular care.

> § *"Whether there is a clear public need for the health care facility or services proposed by the applicant;" (Conn.Gen.Stat. § 19a-639(a)(3))*

8. With respect to the proposal, provide evidence and documentation to support clear public need:

   a. identify the target patient population to be served;

Response:
The target population to be served includes those patients in the service area in need of diagnostic imaging for cardiovascular disease. See OHCA Table 2 for a list of service area towns. These same towns and patient population will continue to be served by the replacement of this existing imaging equipment.

b. discuss how the target patient population is currently being served;

Response:
The target patient population is currently served with the existing SPECT equipment owned and operated by YNHH HVC. This purchase will simply replace two (2) machines with new equipment that offers better imaging and more accurate diagnostics.

c. document the need for the equipment and/or service in the community;

Response:
One of the current SPECT cameras that YNHH HVC intends to replace is nearing the end of its useful life due to age, and both do not offer the same high-quality diagnostic features available with the new SPECT/CT equipment. This demonstrates a need to replace this equipment to serve the current patient population utilizing these services.

d. explain why the location of the facility or service was chosen;

Response:
YNHH HVC will replace two (2) machines with new equipment that offers better imaging technology and more accurate diagnostics. The location of the new equipment is the same as the equipment to be replaced.

e. provide incidence, prevalence or other demographic data that demonstrates community need;

Response:
As noted in response to Question 7, the State Health Care Facilities and Service Plan notes that heart disease is the second leading cause of hospitalizations in the state, and that the percent of adults diagnosed with high blood pressure or diabetes is highest among the African American community. YNHH is based in New Haven where a large share of the overall population lives below the poverty line, and is home to a large African American population compared to the State of Connecticut. This proposal seeks to enhance access to cardiovascular imaging services in the region to serve this need.

f. discuss how low income persons, racial and ethnic minorities, disabled persons and other underserved groups will benefit from this proposal;

Response:
See response to 8e. YNHH provides services to all regardless of race, ethnicity, religion, income or ability to pay for services. This will not change as result of this proposal. YNHH HVC will simply replace two (2) machines at the same sites with better imaging technology and more accurate diagnostics for all patients, including low income persons, racial and ethnic minorities, disabled persons and other underserved groups.

g. list any changes to the clinical services offered by the Applicant(s) and explain why the change was necessary;

Response:
Not applicable.

h. explain how access to care will be affected; and

<u>Response:</u>
YNHH HVC will replace two (2) machines with new equipment that offers better imaging and more accurate diagnostics for all patients, which will improve access to better diagnostic technology.

i. discuss any alternative proposals that were considered.

<u>Response:</u>
Not applicable. The new SPECT/CT cameras are more accurate and better technology, and are in need of replacement.

> § *"Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, (A) provision of or any change in the access to services for Medicaid recipients and indigent persons; (Conn.Gen.Stat. § 19a-639(a)(5))*

9. Describe how the proposal will:

a. improve the quality of health care in the region;

<u>Response:</u>
The new SPECT/CT cameras will replace existing SPECT equipment with technology that offers higher quality imaging. As noted previously, the CT component of the SPECT/CT provides attenuation correction to eliminate the shadows or artifacts that appear in an image due to overlying breast or adipose tissue. This results in higher quality cardiac imaging and myocardial perfusion studies which decreases false positive results and can eliminate unnecessary follow-up testing.

b. improve accessibility of health care in the region; and

<u>Response:</u>
YNHH is a non-profit hospital that treats all patients regardless of ability to pay. This replacement technology will be accessible by any and all patients in need of cardiovascular imaging studies in the region, and will offer enhanced access to the higher quality testing available with a SPECT/CT compared to the older SPECT cameras.

c. improve the cost effectiveness of health care delivery in the region.

<u>Response:</u>
Diagnostic imaging performed on the replacement SPECT/CT cameras will have the same cost to the patient as imaging on the older equipment. As noted previously, the quality of the image produced with a SPECT/CT camera is much better and more accurate than the older SPECT cameras which may decrease false positive results and may eliminate follow-up testing which is cost-effective to the health care delivery system.

10. How will the Applicant(s) ensure that future health care services provided will adhere to the National Standards on culturally and Linguistically Appropriate Services (CLAS) to advance

health equity, improve quality and help eliminate health care disparities in the projected service area. (More details on CLAS standards can be found at http://minorityhealth.hhs.gov/).

Response:
YNHH is committed to providing patient care services that adhere to the National CLAS standards. YNHH offers comprehensive language interpretation services to all patients who require it. Yale-New Haven Health System employs a Chief Diversity Officer who is charged with ensuring our care is delivered in a culturally competent manner. YNHH trains and conducts regular diversity and inclusion training for all of its staff (including new employee orientation).

11. How will this proposal help improve the coordination of patient care (explain in detail regardless of whether your answer is in the negative or affirmative)?

Response:
As noted previously, the new SPECT/CT equipment will produce a superior image compared to the SPECT cameras which may decrease false positive results and may eliminate follow-up testing. This is beneficial to patients because it could eliminate the need to coordinate follow-up visits and is beneficial to physicians because it will help coordinate diagnosis and treatment planning. Otherwise, this is a simple replacement of existing equipment due to better technology.

12. Describe how this proposal will impact access to care for Medicaid recipients and indigent persons.

Response:
YNHH is a non-profit hospital that treats all patients regardless of ability to pay. The new SPECT/CT cameras will increase access for Medicaid recipients and indigent persons to the best quality cardiovascular imaging services.

13. Provide a copy of the Applicant's charity care policy and sliding fee scale applicable to the proposal.

Response:
See Exhibit F.

> *§ "Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;" (Conn.Gen.Stat. § 19a-639(a)(10))*

14. If the proposal fails to provide or reduces access to services by Medicaid recipients or indigent persons, provide explanation of good cause for doing so.

<u>Response:</u>

Not applicable. This proposal does not reduce access to services by Medicaid recipients or indigent persons. It will replace existing equipment in place with new equipment that is able to provide higher quality imaging services.

> *§ "Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care." (Conn.Gen.Stat. § 19a-639(a)(12))*

15. Will the proposal adversely affect patient health care costs in any way? Quantify and provide the rationale for any changes in price structure that will result from this proposal, including, but not limited to, the addition of any imposed facility fees.

<u>Response:</u>

Not applicable. This proposal will not adversely affect patient health care costs. Patients will receive enhanced quality diagnostic services.

Financial Information

> § *"Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant;" (Conn.Gen.Stat. § 19a-639(a)(4))*

16. Provide the Applicant's fiscal year: start date (mm/dd) and end date (mm/dd).

Response:
Start date: 10/1
End date: 9/30

17. Describe the impact of this proposal on the financial strength of the state's health care system or demonstrate that the proposal is financially feasible for the applicant.

Response:
YNHH has the capital available to fund this purchase and install the equipment. The new replacement equipment will offer a higher quality service which will enhance the accuracy of cardiovascular imaging that may result in fewer false positives and eliminate the need for duplicative testing.

18. Provide a final version of all capital expenditure/costs for the proposal using **OHCA Table 3**.

Response:
See OHCA Table 3.

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

Response:
YNHH will fully fund through cash on hand, no debt will be incurred.

20. Include as an attachment:

   a. audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, provide other financial documentation (e.g., unaudited balance sheet, statement of operations, tax return, or other set of books). Connecticut hospitals required to submit annual audited financial statements may reference that filing, if current;

Response:
See Exhibit G.

   b. completed **Financial Worksheet A (non-profit entity), B (for-profit entity) or C (§19a-486a sale)**, available on OHCA's website under OHCA Forms, providing a summary of revenue, expense, and volume statistics, "without the CON project," "incremental to the CON project," and "with the CON project." **Note: the actual results reported in the**

Financial Worksheet must match the audited financial statement that was submitted or referenced.

Response:
See Exhibit H.

21. Complete **OHCA Table 4** utilizing the information reported in the attached Financial Worksheet.

Response:
See OHCA Table 4.

22. Explain all assumptions used in developing the financial projections reported in the Financial Worksheet.

Response:
See Exhibit H.

23. Explain any projected incremental losses from operations resulting from the implementation of the CON proposal.

Response:
Not applicable, no losses from operations resulting from implementation.

24. Indicate the minimum number of units required to show an incremental gain from operations for each projected fiscal year.

Response:
Not applicable, replacement of existing equipment.

TABLE 5
HISTORICAL UTILIZATION BY SERVICE

Scan Volume by Machine	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY 2014***	FY 2015***	FY 2016***	FY 2017 (Oct-Nov. 2016)
GUILFORD (GE MyoSite SPECT)	816	912	887	213
SRC (Siemens Symbia SPECT)	281	233	231	35

* 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 6 months, report actual volume and identify the period covered.
** Identify each service type and level adding lines as necessary. Provide the number of visits or discharges as appropriate for each service type and level listed.
*** Fill in years. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

[back to question]

TABLE 6
PROJECTED UTILIZATION BY SERVICE

Scan Volume by Machine	Projected Volume		
	FY 2017**	FY 2018**	FY 2019**
GUILFORD (GE MyoSite SPECT) (OLD MACHINE)	887	0	0
GUILFORD (GE Optima 640 SPECT/CT) **(NEW)**	0	887	887
SRC (Siemens Symbia SPECT) (OLD MACHINE)	231	0	0
SRC (GE Optima 640 SPECT/CT) **(NEW)**	0	231	231

* Identify each service type by location and add lines as necessary. Provide the number of visits/discharges as appropriate for each service listed.
** FY17, 18, 19, projected flat based on most recent completed year volume in FY16.

[back to question]

TABLE 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX

GUILFORD SPECT

Payer	FY 2016**		Projected					
			FY 2017**		FY 2018**		FY 2019**	
	Scans	%	Scans	%	Scans	%	Scans	%
Medicare*	414	46.7	414	46.7	414	46.7	414	46.7
Medicaid*	38	4.3	38	4.3	38	4.3	38	4.3
CHAMPUS & TriCare	1	0.1	1	0.1	1	0.1	1	0.1
Total Government	**453**	**51.1**	**453**	**51.1**	**453**	**51.1**	**453**	**51.1**
Commercial Insurers	429	48.4	429	48.4	429	48.4	429	48.4
Uninsured/Self Pay	2	0.2	2	0.2	2	0.2	2	0.2
Workers Compensation	3	0.3	3	0.3	3	0.3	3	0.3
Total Non-Government	**434**	**48.9**	**434**	**48.9**	**434**	**48.9**	**434**	**48.9**
Total Payer Mix	**887**	**100**	**887**	**100**	**887**	**100**	**887**	**100**

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

[back to question]

SRC SPECT

Payer	FY 2016**		Projected					
			FY 2017**		FY 2018**		FY 2019**	
	Scans	%	Scans	%	Scans	%	Scans	%
Medicare*	84	36.4	84	36.4	84	36.4	84	36.4
Medicaid*	52	22.3	52	22.3	52	22.3	52	22.3
CHAMPUS & TriCare	0	0.1	0	0.1	0	0.1	0	0.1
Total Government	**136**	**58.9**	**136**	**58.9**	**136**	**58.9**	**136**	**58.9**
Commercial Insurers	93	40.4	93	40.4	93	40.4	93	40.4
Uninsured/Self Pay	2	0.7	2	0.7	2	0.7	2	0.7
Workers Compensation	0	0.0	0	0.0	0	0.0	0	0.0
Total Non-Government	**95**	**41.1**	**95**	**41.1**	**95**	**41.1**	**95**	**41.1**
Total Payer Mix	**231**	**100**	**231**	**100**	**231**	**100**	**231**	**100**

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

Utilization

> § *"The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;" (Conn.Gen.Stat. § 19a-639(a)(6))*

25. Complete **OHCA Table 5** and **OHCA Table 6** 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/or proposed services. Report the units by service, service type or service level.

Response:
See OHCA Table 5 and OHCA Table 6.

26. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected service volume; explain any increases and/or decreases in volume reported in OHCA Table 5 and 6.

Response:
Volumes are conservatively projected flat in the near future in OHCA Table 5 and 6.

27. Provide the current and projected patient population mix (number and percentage of patients by payer) for the proposal using **OHCA Table 7** and provide all assumptions. **Note: payer mix should be calculated from patient volumes, not patient revenues.**

Response:
See OHCA Table 7.

> § *"Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;" (Conn.Gen.Stat. § 19a-639(a)(7))*

28. Describe the population (as identified in question 8(a)) by gender, age groups or persons with a specific condition or disorder and provide evidence (i.e., incidence, prevalence or other demographic data) that demonstrates a need for the proposed service or proposal. **Please note: if population estimates or other demographic data are submitted, provide only publicly available and verifiable information (e.g., U.S. Census Bureau, Department of Public Health, CT State Data Center) and document the source.**

Response:
The population served by this proposal includes all residents within the service area in need of cardiovascular imaging services. The current population served will continue to be served by the new replacement equipment.

TABLE 8

UTILIZATION BY TOWN

Guilford SPECT	
Town	Utilization FY 2016**
Branford	161
Guilford	130
Madison	118
East Haven	72
Clinton	59
Westbrook	36
Old Saybrook	26
North Branford	24
New Haven	23
Killingworth	22
Old Lyme	20
West Haven	19
Northford	16
Essex	11
Milford	9
Hamden	8
Waterford	8
New London	8
Mystic	6
Niantic	6
North Haven	5
Groton	5
Woodbridge	5
Deep River	5
Higganum	4
Durham	4
Ivoryton	4
Norwich	3
Orange	3
Middletown	3
Chester	2
Bethany	2
Haddam	2
Stratford	2
Other	56
TOTAL	**887**

* List inpatient/outpatient/ED volumes separately, if applicable
** Fill in most recently completed fiscal year.

[back to question]

TABLE 8

UTILIZATION BY TOWN

SRC SPECT	
Town	Utilization FY 2016**
New Haven	85
West Haven	32
Hamden	27
East Haven	14
North Haven	9
Branford	8
Wallingford	6
Milford	5
Guilford	5
Orange	4
Cheshire	4
Seymour	3
Woodbridge	3
North Branford	3
Clinton	2
Northford	2
Ansonia	2
Derby	1
Westbrook	1
Bethany	1
Stratford	1
Meriden	1
Bridgeport	1
Killingworth	1
Southington	1
Fairfield	1
Waterbury	1
Shelton	1
Naugatuck	1
Other	7
TOTAL	**231**

* List inpatient/outpatient/ED volumes separately, if applicable
** Fill in most recently completed fiscal year.

[back to question]

TABLE 9
SERVICES AND SERVICE LOCATIONS OF EXISTING PROVIDERS

HEART AND VASCULAR SERVICES

IN ADDITION TO THOSE IN TABLE 1

Service or Proogram Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Scan Utilization (FY16)
YNHH SPECT	Heart & Vascular	1851568828	YNHH HVC 1450 Chapel Street New Haven, CT	M-F 7am-5pm	491
YNHH SPECT	Heart & Vascular	1851568828	YNHH HVC 2 Divine Street North Haven, CT	M-F 7am-5pm	915
YNHH SPECT	Heart & Vascular	1851568828	YNHH HVC 79 Wawecus Street Norwich, CT	M-F 7am-5pm	776
YNHH SPECT/CT	Heart & Vascular	1851568828	YNHH HVC 20 York Street New Haven, CT	M-F 8am-5pm	660
YNHH SPECT	Heart & Vascular	1851568828	YNHH HVC 20 York Street New Haven, CT	M-F 8am-5pm	484
YNHH SPECT	Heart & Vascular	1851568828	YNHH HVC 20 York Street New Haven, CT	M-F 8am-5pm	193
YNHH SPECT	Gated Blood Pool Exams	1851568828	YNHH HVC 20 York Street, New Haven, CT	M-F 8am-5pm	0
YNHH SPECT	ED	1851568828	YNHH HVC 20 York Street, New Haven, CT	7 days/week 8am-8pm	984

* Provide the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.

[back to question]

Supplemental CON Application Form

Acquisition of Equipment

Conn. Gen. Stat. § 19a-638(a)(10),(11)

Applicant: Yale-New Haven Hospital

Project Name: Replace 2 existing SPECT cameras with 2 SPECT/CT cameras

1. **Project Description: Acquisition of Equipment**

    a. Provide the manufacturer, model and number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

Response:
Yale-New Haven Hospital (YNHH) intends to replace two (2) existing SPECT cameras with two (2) of the following scanners:

- **GE Optima 640 SPECT/CT**

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

Response:
YNHH offers SPECT and SPECT/CT services for its heart and vascular patients at the following sites:

- **1450 Chapel Street, New Haven, CT: SPECT (2 machines, 1 being replaced)**
- **20 York Street, New Haven, CT: SPECT (4 machines), SPECT/CT (1 machine)**
- **111 Goose Lane, Guilford, CT: SPECT (1 machine, 1 being replaced)**
- **2 Divine Street, North Haven, CT: SPECT (1 machine)**
- **79 Wawecus Street, Norwich, CT: SPECT (1 machine)**

2. **Clear Public Need**

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

Response:

YNHH offers SPECT and SPECT/CT services for its heart and vascular patients at the following sites:

TABLE A

EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Service*	Days/Hours of Operation **	Utilization (FY16)
YNHH HVC, 111 Goose Lane, Guilford, CT	SPECT	M-F, 7am-5pm	887
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	231
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	491
YNHH HVC, 2 Divine Street, North Haven, CT	SPECT	M-F, 7am-5pm	915
YNHH HVC, 79 Wawecus Street, Norwich, CT	SPECT	M-F, 7am-5pm	776
YNHH HVC, 20 York Street, New Haven, CT	SPECT/CT	M-F, 8am-5pm	660
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	484
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	193
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	0
YNHH ED, 20 York Street, New Haven, CT	SPECT	M-F, 8am-8pm	984

*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

   b. Provide the rationale for locating the proposed equipment at the proposed site;

Response:

YNHH intends to replace the equipment at existing sites of service.

3. 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).

Response:

YNHH offers SPECT and SPECT/CT services for its heart and vascular patients at the following sites:

HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY EQUIPMENT UNIT

Equipment***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume		
	FY 14	FY 15	FY 16	FY 17 (Oct-Nov 2017)	FY 17	FY 18	FY 19
YNHH HVC, 111 Goose Lane, Guilford, CT	816	912	887	213	887	0	0
YNHH HVC, 111 Goose Lane, Guilford, CT (new)	0	0	0	0	0	887	887
YNHH HVC, 1450 Chapel St. New Haven, CT	281	233	231	35	231	0	0
YNHH HVC, 1450 Chapel St. New Haven, CT (new)	0	0	0	0	0	231	231
YNHH HVC, 1450 Chapel St. New Haven, CT	597	495	491	76	491	491	491
YNHH HVC, 2 Divine Street, North Haven, CT	914	965	915	145	915	915	915
YNHH HVC, 79 Wawecus Street, Norwich, CT	889	689	776	118	776	776	776
YNHH HVC, 20 York Street, New Haven, CT	717	524	660	117	660	660	660
YNHH HVC, 20 York Street, New Haven, CT	541	608	484	59	484	484	484
YNHH HVC, 20 York Street, New Haven, CT	113	245	193	24	193	193	193
YNHH HVC, 20 York Street, New Haven, CT	0	1	0	0	0	0	0
YNHH ED, 20 York Street, New Haven, CT	983	926	984	99	984	984	984
Total	**5851**	**5598**	**5621**	**886**	**5621**	**5621**	**5621**

*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.).

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

Response:

All projected volumes are conservatively project flat in the future FYs.

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

Response:

All projected volumes are conservatively project flat in the future FYs.

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

Response:

See below for the utilization by town for the SPECT cameras to be replaced with SPECT/CT cameras at Guilford and the YNHH St. Raphael Campus in New Haven.

UTILIZATION BY TOWN

Guilford SPECT	
Town	**Utilization FY 2016****
Branford	161
Guilford	130
Madison	118
East Haven	72
Clinton	59
Westbrook	36
Old Saybrook	26
North Branford	24
New Haven	23
Killingworth	22
Old Lyme	20
West Haven	19
Northford	16
Essex	11
Milford	9
Hamden	8
Waterford	8
New London	8
Mystic	6
Niantic	6
North Haven	5
Groton	5
Woodbridge	5
Deep River	5
Higganum	4
Durham	4
Ivoryton	4
Norwich	3
Orange	3
Middletown	3
Chester	2
Bethany	2
Haddam	2
Stratford	2
Other	56
TOTAL	**887**

* List inpatient/outpatient/ED volumes separately, if applicable

** Fill in most recently completed fiscal year.

UTILIZATION BY TOWN

SRC SPECT	
Town	Utilization FY 2016**
New Haven	85
West Haven	32
Hamden	27
East Haven	14
North Haven	9
Branford	8
Wallingford	6
Milford	5
Guilford	5
Orange	4
Cheshire	4
Seymour	3
Woodbridge	3
North Branford	3
Clinton	2
Northford	2
Ansonia	2
Derby	1
Westbrook	1
Bethany	1
Stratford	1
Meriden	1
Bridgeport	1
Killingworth	1
Southington	1
Fairfield	1
Waterbury	1
Shelton	1
Naugatuck	1
Other	7
TOTAL	**231**

* List inpatient/outpatient/ED volumes separately, if applicable
** Fill in most recently completed fiscal year.

29. Using **OHCA Table 8**, provide a breakdown of utilization by town for the most recently completed fiscal year. Utilization may be reported as number of persons, visits, scans or other unit appropriate for the information being reported.

Response:
See OHCA Table 8.

> § *"The utilization of existing health care facilities and health care services in the service area of the applicant;" (Conn.Gen.Stat. § 19a-639(a)(8))*

30. Using **OHCA Table 9**, identify all existing providers in the service area and, as available, list the services provided, population served, facility ID (see table footnote), address, hours/days of operation and current utilization of the facility. Include providers in the towns served or proposed to be served by the Applicant, as well as providers in towns contiguous to the service area.

Response:
See OHCA Table 9, which includes all existing SPECT and SPECT/CT equipment owned by YNHH and utilized for heart and vascular services.

31. Describe the effect of the proposal on these existing providers.

Response:
There will be no impact on existing providers.

32. Describe the existing referral patterns in the area served by the proposal.

Response:
Patients are referred for cardiac nuclear medicine imaging by their primary care provider or specialist based on the medical need for the service.

33. Explain how current referral patterns will be affected by the proposal.

Response:
No change in referral patterns due to the proposal.

> § *"Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;" (Conn.Gen.Stat. § 19a-639(a)(9))*

34. If applicable, explain why approval of the proposal will not result in an unnecessary duplication of services.

Response:
Not applicable, replacement of existing equipment with better technology.

§ "Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region;" (Conn.Gen.Stat. § 19a-639(a)(11))

35. Explain in detail how the proposal will impact (i.e., positive, negative or no impact) the diversity of health care providers and patient choice in the geographic region.

<u>Response:</u>
The proposal will have no impact on the diversity of health care providers and patient choice in the region. This is a replacement of existing equipment.

Tables

TABLE 1
APPLICANT'S SERVICES AND SERVICE LOCATIONS TO BE REPLACED

Service	Street Address, Town	Population Served	Days/Hours of Operation	New Service or Proposed Termination
SPECT	1450 Chapel Street (St. Raphael Campus) New Haven, CT	Heart and vascular patients of greater New Haven region	M-F 7am – 5pm	Replacement
SPECT	111 Goose Lane Guilford, CT	Heart and vascular patients of greater New Haven region	M-F 7am – 5pm	Replacement

[back to question]

TABLE 2
SERVICE AREA TOWNS

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

Guilford SPECT	
Town*	**Reason for Inclusion**
Branford Guilford Madison East Haven Clinton Westbrook Old Saybrook North Branford New Haven Killingworth	Represents 75% of scan volume.

* Village or place names are not acceptable.

St. Raphael Campus SPECT	
Town*	**Reason for Inclusion**
New Haven West Haven Hamden East Haven North Haven Branford	Represents 75% of scan volume.

[back to question]

TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	453,931
Land/Building Purchase*	
Construction/Renovation**	10,000
Other (specify)	
Total Capital Expenditure (TCE)	**463,931**
Lease (Medical, Non-medical, Imaging)***	**0**
Total Lease Cost (TLC)	**0**
Total Project Cost (TCE+TLC)	**463,931**

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

The above is for 1 machine, and is doubled for 2 machines.

[back to question]

TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2017*	FY 2018*	FY 2019*
Revenue from Operations	$0	$0	$0
Total Operating Expenses	0	0	0
Gain/Loss from Operations	$0	$0	$0

* Fill in years using those reported in the Financial Worksheet attached.

[back to question]

EXHIBIT A

DETERMINATION DECISION FROM OHCA

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

October 4, 2016

VIA EMAIL ONLY

Nancy Rosenthal
VP, Strategy and Regulatory Planning
Yale New Haven Hospital
2 Howe Street
New Haven, CT 06511

RE: Certificate of Need Determination Report Number 16-32124-DTR
Replacement of Imaging Equipment

Dear Ms. Rosenthal:

On September 28, 2016, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") Determination request on behalf of Yale New Haven Hospital ("Petitioner") with respect to the replacement of five (5) single photon emission computed tomography ("SPECT") cameras with five (5) single-photon emission computed tomography/computed tomography ("SPECT-CT") cameras.

The Petitioner currently operates SPECT cameras at locations in the following towns: New Haven, CT; North Haven, CT; Guilford, CT; and Norwich, CT. Petitioner contends that its equipment has reached the end of its useful life and that the new SPECT-CT cameras will enable higher quality imaging studies than is currently possible. Petitioner requests guidance as to whether a CON is required to replace a SPECT camera with a SPECT-CT camera.

Pursuant to Conn. Gen. Stat. § 19a-638(a)(10), a certificate of need is required for the "acquisition of computed tomography scanners..." SPECT-CT cameras combine computed tomography with the technology currently utilized by the Petitioner to enhance imaging.

Therefore, the Petitioner's request to replace its SPECT cameras with SPECT-CT cameras constitutes an acquisition of imaging equipment, and a ***CON is required***.

Sincerely,

Kimberly R. Martone
Director of Operations

cc: Rose McLellan, License and Applications Supervisor, DPH, DHSR

EXHIBIT B

YNHH LICENSE

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0044

General Hospital

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

Yale-New Haven Hospital, Inc. of New Haven, CT d/b/a Yale-New Haven Hospital, Inc. is hereby licensed to maintain and operate a General Hospital.

Yale-New Haven Hospital, Inc. is located at 20 York Street, New Haven, CT 06510-3220.

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

134 Bassinets
1407 General Hospital Beds

This license expires **September 30, 2017** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, October 1, 2015. RENEWAL.

SATELLITES:
Hill Regional Career High School, 140 Legion Avenue, New Haven, CT
Branford High School Based Health Center, 185 East Main Street, Branford, CT
Walsh Middle School, 185 Damascus Road, Branford, CT
James Hillhouse High School Based Health Center, 480 Sherman Parkway, New Haven, CT
Weller Building, 425 George Street, New Haven, CT
Yale-New Haven Psychiatric Hospital, 184 Liberty Street, New Haven, CT
Yale-New Haven Shoreline Medical Center, 111 Goose Lane, Guilford, CT
Pediatric Dentistry Center, 1 Long Wharf Drive, New Haven, CT
YNHASC Temple Surgical Center, 60 Temple Street, New Haven, CT
YNHASC Women's Surgical Center, 40 Temple Street, New Haven, CT
Mauro-Sheridan School Based Health Center, 191 Fountain Street, New Haven, CT
Yale-New Haven Hospital Dental Center, 2560 Dixwell Avenue, Hamden, CT
Murphy School Based Health Center, 14 Brushy Plain Road, Branford, CT
YNHCH at Bridgeport, 267 Grant Street, 6th Floor, Bridgeport, CT
Pediatric Primary Care Center, 226 Mill Hill Avenue, Bridgeport, CT
Yale-New Haven Hospital-Saint Raphael Campus, 1450 Chapel Street, New Haven, CT
Adolescent Day Hospital, 646 George Street, New Haven, CT
Children's Psychiatric Day Hospital, 1450 Chapel Street, New Haven, CT
Elder Care Clinic/Edith Johnson Tower, 114 Bristol Street, New Haven, CT
Troup Magnet Academy School-Based Health Center, 259 Edgewood Avenue, New Haven, CT
Adult PHP, 1100 Sherman Avenue, Hamden, CT
Project MotherCare at Wheat, 674 Washington Avenue, West Haven, CT
Barnard Environmental Studies Magnet School, 170 Derby Avenue, New Haven, CT
Project Eldercare, 2080 Whitney Avenue, Suite 150, Hamden, CT
Shoreline Child and Adolescent Mental Health Services, 21 Business Park Drive, Branford, CT
Yale-New Haven Hospital Urology, Parkview Bldg., 1291 Boston Post Road, Suite 205, Madison, CT
*Psychiatric Day Hospital, 425 George Street, New Haven
*Adult Psychiatric PHP and Continuing Care, 1294 Chapel Street, New Haven, CT

License Revised to Reflect:
*Change of address for (2) Satellites effective 2/4/15
Removed (4) Satellites effective 9/19/14

Jewel Mullen, MD
Jewel Mullen, MD, MPH, MPA
Commissioner

EXHIBIT C

CVs

Keith B. Churchwell, MD, FACC, FAHA, FACP

Curriculum Vitae

Office Address:	20 York Street Tompkins Building, Room 106 Yale New Haven Hospital New Haven, Connecticut 06510-3202
Office Phone Number:	(203) 688-2610
Office Fax Number:	(203) 688-7352
Email:	keith.churchwell@ynhh.org
Date and Place of Birth:	November 12, 1961 (Nashville, TN)
Home Address:	21 Mill Road Guilford, CT 06437
Home Phone Number:	(615) 512-1232
Spouse's Name:	Married, Leslie Douglas-Churchwell, M.D.
Children:	Lauren Churchwell (February 21, 1996)
Present Position:	Senior Vice President of Operations and Executive Director Heart and Vascular Center and Transplantation Center Yale New Haven Hospital / Yale New Haven Health

Education

- Harvard University (Cambridge, MA), AB Biology, 1979-1983
- Washington University School of Medicine (St. Louis, Missouri), MD, 1983-1987

Postgraduate Training: Emory University Affiliated Hospitals (Atlanta, GA)

- Internal Medicine Internship, June 23, 1987 – June 23,1988
- Internal Medicine Residency, July 1, 1988 – June 30, 1990

- Cardiology Fellowship, July 1, 1990 – June 30, 1994
- Nuclear Cardiology Fellowship July 1, 1993 –June 30, 1994

Licensure and Certification

- Connecticut: Medical License, 1998 – 2015, License # MD 054404
- Tennessee: Medical License, 1994, 2015, License # MD 25554
- Kentucky: Medical License, 1998 – 2014, License # MD 37555
- State Board of Georgia and Composite Board of Medical Examiners Certification in Medicine and Surgery, 1988-1996, License #032531
- Diplomate, The American Board of Internal Medicine, 1990, 2001, 2011 License # 134614
- Diplomate, The American Board of Internal Medicine (Cardiovascular Disease), 1995, 2005
- Diplomate, Certification Council of Nuclear Cardiology, October 1996

Academic Appointments

- Chief Resident, Internal Medicine, Emory University Affiliated Hospitals, Grady Memorial Hospital, July 1991 – June 1992
- Assistant Clinical Professor of Medicine, Vanderbilt University Medical Center, September 1998 – April 2005
- Associate Clinical Professor of Medicine and Radiological Sciences, Vanderbilt University Medical Center, June 2005 – June 2006
- Assistant Professor of Medicine and Radiological Sciences, Vanderbilt University Medical Center, July 2006 – July 2008
- Associate Professor of Medicine and Radiological Sciences, Vanderbilt University Medical Center, July 2009 – 2014
- Adjunct Associate Professor , Vanderbilt University Medical Center, 2015 -

Hospital Appointments

- Baptist Hospital, Medical Staff, July 1994 – June 2006
- St. Thomas Hospital, Medical Staff, July 1994-June 2006
- Livingston Regional Hospital, June 1996 – 2014
- Muhlenberg Community Hospital 2000 – 2014
- University Medical Center, 2008 – 2014
- Vanderbilt University Medical Center, 1998 - 2014

Professional Organizations

- American Association of Nuclear Cardiology, Full Member
- American Society of Echocardiography, Member
- American College of Cardiology, Fellow
- American Heart Association, Fellow
- American College of Physicians, Fellow

Professional Activities

- Director, American Society of Nuclear Cardiology Working Group for Middle Tennessee 2002-2004
- Member, Quality Assurance Committee, American Society of Nuclear Cardiology, 2004-2008
- Member/Liaison, Science Advisory and Coordinating Committee, American Heart Association 2012-2017
- Member, Diversity Leadership Committee, American Heart Association, 2012-present
- Member, Hospital Accreditation Committee, American Heart Association, 2013-2015
- Member, Mission Lifeline Out of Hospital Task Force, American Heart Association, 2013
- Member, YNHHS Ambulatory Anti-Coagulation Charter, 2015
- Member, YNHH Joint Leadership Council, 2015

- Member, YNHH Medical Leadership Council, 2015
- Member, YNHH Clinical Advisory Board, 2015
- Member, YNHH Physician Advisory Board, 2015
- Member, Diversity Leadership Liaison on the Social Determinants of Health Committee of the Epidemiology & Prevention (EPI) Council, American Heart Association, 2016
- Member, Founders Affiliate, American Heart Association, 2016
- Member, YNHTC Leadership Advisory Committee, 2016

Teaching Activities

- Co-Director, the American College of Physicians, Georgia Scientific Sessions, St. Simon's Island, May 1992
- Harrison Service Clinical Attending, Cardiovascular Service 1999 - 2009
- Nuclear Cardiology Yearly lecture series (Initiated series, lectures —3 times each year 2005 - Present)
- Cardiovascular Imaging Research Conference (Initiated conference, monthly meeting, 2011-present)
- Hypertrophic Cardiomyopathy Clinical Conference (Initiated conference – monthly meeting, 2012 – present)
- Vanderbilt 28thi Annual Research Forum, Review Committee, April 22, 2010
- Originator and Course Director (with Douglas Vaughan, MD), Cardiology 2002 -2003, Vanderbilt Cardiology Symposium [Now in its 14th year]
- Presenter and Coordinator, Nuclear Cardiology Quarterly Review and Quality Assurance 2010 – Present
- Vanderbilt Cardiology Valve Symposium 2012, Course Director (with Drs. John Byrne and David Zhao)

Civic Activities

- Co-Chair, Northeast Health Equity Consortium, American Heart Association
- Member, Columbus House, 2016

- Nashville Symphony Association, Board of Directors, 2012 - Present
- Nashville Symphony Association Annual Campaign Chair, 2013
- American Heart Association, Board of Directors, 2009 -Present
- President, American Heart Association, State of Tennessee, 2010-2011
- Board of Directors, Greater Southeast Affiliate, American Heart Association, 2010-Present
- Vice President, Greater Southeast Affiliate, American Heart Association, 2011-2012
- President, Greater Southeast Affiliate, American Heart Association, 2013-2014
- Music Director Search Committee, New Haven Symphony Orchestra, 2016

Honors and Awards

- Edward Massie Award in Cardiology, Washington University School of Medicine, June 1987
- Alpha Omega Alpha, accepted Emory University, 1990
- Selection as one of the "Best Doctors in America" by Best Doctors, 2001-2013
- Selection as one of the "Top Cardiologists" by Guide to America's Top Cardiologists, 2006-2012
- Nashville Alliance Public Schools Hall of Fame Inductee, 2009
- Trumpet Award (Presented by the Trumpet Award Foundation) for Medicine, 2010
- Joshua Award "The Jericho Project" Tennessee State University, April 2011
- Selection as one of the "Best Doctors in Nashville" by *Nashville Business Journal*, 2012, 2013
- Selection as one of the "Top Doctors in Nashville" by *Nashville Lifestyles*, 2006, 2008, 2011, 2013
- AT&T Tennessee African American History Calendar (Highlighting the contributions of African-Americans across the state), 2013

Institutional Service

- Medical Director, The Page Campbell Vanderbilt Heart Institute, July 2000-April 2004
- Interviewer, Vanderbilt University School of Medicine Medical School Applicants 2004-Present

- Interviewer, Vanderbilt University Medical Center Internal Residency Applicants, 2006 - Present
- Associate Medical Director, Vanderbilt Heart Institute 2006- March 2008
- Medical Director, Cardiac Imaging, Vanderbilt Heart and Vascular Institute March 2008-Present
- Executive Medical Director, Vanderbilt and Heart Vascular Institute March 2008-June 2009
- Director, Anticoagulation Advisory Committee, November 2008-2010
- Executive Director/Chief Medical Officer, Vanderbilt Heart and Vascular Institute July 2009-Present
- Co-Clinical Director, Nuclear Cardiology, Vanderbilt Heart and Vascular Institute 2009 - Present

Invited Lectures

- Medical Grand Rounds, "Cardiac PET Imaging," University of Tennessee, Knoxville, October 1998.
- Physician Liaison Program, "Non-Invasive Strategies for the evaluation of Ischemic Heart Disease — Is There a Right Approach?" Bedford County Medical Center, April 2001.
- University of Mississippi — Cardiology Grand Rounds, Jackson, Mississippi, May 10, 2001.
- American College of Cardiology — Strategies for Success, "EMR Adaptation into Physician Culture — An Impossible Task?" Bermuda, June 27, 2001.
- ASNC Symposium and Scientific Session — 6th Annual Read with the Experts, "Focus on CAD," Boston, Massachusetts, September 2001.
- Redmond Regional Medical Center — Fall Medical Symposium," Cardiovascular Disease in Women: Why, How and with What," Rome, Georgia, September 26, 2001.
- "Women and Heart Disease," Parkway East Center, Oak Ridge, Tennessee, November 13, 2001.
- Vanderbilt School of Nursing, "Long Term Medical/Surgical Therapy After MI," Nashville, Tennessee, May 24, 2002.
- Facilitating the Advancement of Rural Medicine, "Risk Stratification," Madison, Tennessee, June 24, 2002.
- "Patient Selection for CV Imaging," Pensacola, Florida, June 27, 2002.
- Facilitating the Advancement of Rural Medicine, "Risk Stratification," Lenoir City, Tennessee, September 10, 2002.

- Cardiolite Imaging Meeting, "Risk Stratification," Jackson, Tennessee, December 4, 2002.
- Society of Nuclear Medicine, Southeastern Conference, "Myocardial Imaging Techniques," Nashville, Tennessee, October 2004.
- Cardiology Grand Rounds, Vanderbilt University Medical Center, March 21, 2007, "Myocardial PET Imaging".
- Medical Grand Rounds, Vanderbilt University Medical Center, "Myocardial Viability" August 20, 2009 "Myocardial Viability".
- Vanderbilt Valve Symposium, "Mitral Valve Case Studies", October 30, 2009.
- Vanderbilt Symposium 2010 "Athletes and Heart Disease", February 26, 2010.
- Vanderbilt Critical Skills Summit, "Utility of TEE in the ICU", May 23, 2010.
- Vanderbilt Heart and Vascular Institute, Middle Tennessee Cardiovascular Disease Update Conference, "What is the Appropriate Screening for Athletes?" August 27, 2011.
- American College of Cardiology Annual Meeting 2012, " The Development of the Academic Cardiovascular Institute".
- Vanderbilt Valve Symposium, October 2012, "Financial Implication of TAVR".
- ACC Cardiovascular Summit, January 2013, "Academic Cardiovascular Service Lines".

Publications and Presentations

Original Investigations

Patterson RE, Pilcher WC, **Churchwell KB**, Goodman MM, Garcia EV, Eisner RL. Positron Emission Tomographic Imaging of the Cardiovascular System: an emerging clinical tool. Heart Disease and Stroke 1994 Nov-Dec; 3(6): 330-7

Patterson RE, **Churchwell KB**, Eisner RL. Diagnosis of coronary artery disease in women: roles of three-dimensional imaging with magnetic resonance or positron emission tomography. American Journal of Cardiac Imaging 1996 January 10 (1): 78-88

Darbar D, Yang T, **Churchwell K**, Wilde AAM, Roden DM. Unmasking of Brugada syndrome by lithium. *Circulation*. 2005 Sept 13; 112(11): 1527–1531

Stankewicz MA, Mansour CS, Eisner RL, **Churchwell KB**, Williams BR, Sigman SR, Streeter J, Patterson RE. Myocardial viability assessment by PET: (82)Rb defect washout does not predict the results of metabolic-perfusion mismatch. *J Nucl Med.* 2005 Oct; 46(10): 1602-9.

Fong PP, Jackson EB, **Churchwell KB**, Steaban R, Starmer JM, Johnson DC, McNeil JD, Klint Z, Scalf SL, Parsons CM, Cortez S, Christensen D, French T, McPherson JA. Acute coronary syndrome pathways: alignment with a bundled care reimbursement model. *Critical Pathways in Cardiology: A Journal of Evidence-Based Medicine*. March 2011; 10(1): 1-8.

Brittain, EL, Goyal SK, Sample M, Leacche M, Absi T, Papa F, **Churchwell K**, Ball S, Byrne, J, Maltais, S, Petracek M, Mendes L. Minimally invasive fibrillating mitral valve replacement for patients with advanced cardiomyopathy: A safe and effective approach. *Journal of Thoracic and Cardiovascular Surgery* (IN PRESS)

Book Chapters

Patterson RE, Cloninger K, **Churchwell KB**, Shonkoff DW, Sullivan KW, Williams BR, Eisner RL. Special problems with cardiovascular imaging to assess coronary artery disease in women. *Women & Heart Disease.* 91-117, 1993.

Reviews, Case Reports, Letters, Editorials:

Hansen CL, Goldstein RA, Berman DS, **Churchwell KB**, Cooke CD, Corbett JR, Cullom SJ, Dahlberg ST, Galt JR, Garg RK, Heller GV, Hyun MC, Johnson LL, Mann A, McCallister BD Jr, Taillefer R, Ward RP, Mahmarian JJ; Quality Assurance Committee of the American Society of Nuclear Cardiology. Myocardial perfusion and function single photon emission computed tomography. *J Nucl Cardiol.* 2006 Nov; 13(6):e97-120.

Hansen CL, Goldstein RA, Akinboboye OO, Berman DS, Botvinick EH, **Churchwell KB**, Cooke CD, Corbett JR, Cullom SJ, Dahlberg ST, Druz RS, Ficaro EP, Galt JR, Garg RK, Germano G, Heller GV, Henzlova MJ, Hyun MC, Johnson LL, Mann A, McCallister BD Jr, Quaife RA, Ruddy TD, Sundaram SN, Taillefer R, Ward RP, Mahmarian JJ; American Society of Nuclear Cardiology. Myocardial perfusion and function: single photon emission computed tomography.*J Nucl Cardiol.* 2007 Nov-Dec; 14(6):e39-60.

Churchwell K. State smoking ban "Issues related to second hand smoke" (published in the *Tennessean* Newspaper, Monday, October 26, 2009).

Churchwell K. "Black Lives Do Matter – Association of Hospital Physician Characteristics and Care Processes with Racial Disparities in Procedural Outcomes Among contemporary patients Undergoing Coronary Artery Bypass Grafting Surgery", American Heart Association Circulation. 2015; 020085.

Abstracts

Churchwell KB, Eisner RL, Patterson , RE, et al. Accuracy of PET Rubidium-82 Myocardial Perfusion Imaging (MPI) to Diagnose Coronary Artery Disease: New Software for Objective Quantitative Analysis. *Journal of Nuclear Medicine* Volume 35. Issue 3. 23P (abstract presented at the Society of Nuclear Medicine annual meeting, Orlando, Florida, June, 1994).

Streeter T, **Churchwell KB**, Patterson RE, et al. A Comparison of High Dose vs. Low Dose Dipyridamole Infusion for Pharmacological Stress Testing. (abstract presented at the Institute for Clinical PET Sixth Annual International Conference, October 1994).

Churchwell KB, Pilcher WC, Eisner RL, Barclay AB, Patterson RE. Quantatitative Analysis of Positron Emission Tomography: The "Women's test for Coronary Artery Disease. Journal of Nuclear Medicine

1995. Volume 36. Issue 3 41P (presented at the 42°d Society of Nuclear Medicine annual meeting, Minneapolis, Minnesota, June 1995).

Huntsinger DR, Martin W, **Churchwell K**, Delbeke D. Value of Prone Myocardial Perfusion Spect Imaging (MPI) for Patients with Chest Pain in the Emergency Department. Journal of Nuclear Cardiology 2002. Volume 9. Issue 4. S 12 (abstract presented at ASNC Annual Meeting, September 2002).

Oddis CV, Byrne D, Myers JS, Churchwell AL, **Churchwell KB**.Vanderbilt University Medical Center and The Page-Campbell Cardiology Group, Nashville, Tennessee. Effect of Patient Positioning on Left Ventricular Functional and Volumetric Measurements by Quantitative Gated Myocardial SPECT. (presented at the American Society of Nuclear Cardiology Annual Meeting, September 16, 2005).

Delbeke D, Kronenberg MW, **Churchwell K**, Mazer M, Martin WH, Brenner R, Forrester J, Patton JA; Sandler MP. Integrated rest/stress myocardial perfusion SPECT (MPS) and 64-slice coronary CT Angiography (CCTA): Impact on management in patients post-revascularization. Vanderbilt University (presented at the Society of Nuclear Medicine Annual Meeting June, 2008).

Mohamed T, Sathappan K, Theilade C, **Churchwell K**. The outcome of minimally invasive mitral valve surgery in patients with severe mitral stenosis without aortic cross clamping. (Accepted for poster presentation SCA Annual Meeting June, 2008).

Delbeke D, Kronenberg M, **Churchwell K**, Mazer M, Martin W, Brenner R, Forrester J, Patton JA, Sandler M; Vanderbilt Hospital, Nashville, TN. Integrated rest/stress myocardial perfusion SPECT (MPS) and 64-slice coronary CT Angiography (CCTA): Impact on management of patients post-revascularization. (Accepted for presentation, American Society of Nuclear Cardiology Annual Meeting, September 2008).

Brittain EL, Goyal S, Leacche M, Absi T, Balaguer JM, **Churchwell KB**, Mendes LA, Byrne JG, Ball SK, Petracek MR, Vanderbilt University Medical Center, Nashville, TN, USA, Veterans Affairs Medical Center, Nashville, TN. Mitral Regurgitation: Novel Surgical and Percutaneous Observations. (Accepted for presentation, American College of Cardiology Annual Meeting March 2012).

Brittain EL, Goyal S, Marzia Leacche M, Absi T, Byrne JG, Petracek MR, Ball SK, **Churchwell KB**, Mendes LA. Pre-operative Left Ventricular Size and Function Predict Outcome After Minimally-Invasive Mitral Valve Replacement in Patients with Advanced Heart Failure. Division of Cardiovascular Medicine[1] and Department of Cardiac Surgery[2], Vanderbilt University Medical Center, and Department of Cardiac Surgery, Veterans Affairs Medical Center[3], Nashville, TN (Accepted for presentation, Heart Valve Society of America April 2012 Scientific Sessions).

Brittain EL, Goyal S, Leacche M, Absi T, **Churchwell KB**, Mendes LA, Byrne JG, Ball SK, Petracek MR, Vanderbilt University Medical Center, Nashville, TN, USA. Minimally-Invasive Mitral Valve Replacement without Aortic Cross-Clamp is Safe in Patients with Severe Cardiomyopathy (submitted for presentation, American Heart Association 2012 Scientific Sessions November 2012).

CURRICULUM VITAE

Date of Revision: **September 30, 2016**

Name: Edward J. Miller, MD, PhD

Education:

1994	B.S.	University of Notre Dame, Notre Dame, IN; *Cum Laude*, Preprofessional Studies
1999	M.D.	Loyola Stritch School of Medicine, Maywood, IL
2008	Ph.D.	Yale Graduate School of Arts and Sciences, New Haven, CT; Investigative Medicine *with Distinction*

Career/Academic Appointments:

1999-2000	Intern, Yale-New Haven Hospital, New Haven, CT
2002-2003	Resident, Internal Medicine, Yale-New Haven Hospital, New Haven, CT
2003-2006	Research Fellow in Cardiology, Mentor Lawrence Young, MD; Yale School of Medicine, New Haven, CT
2006-2008	Clinical Fellow in Cardiology, Yale-New Haven Hospital, New Haven, CT
2008-2010	Assistant Professor of Medicine (adjunct), Uniformed Services University of the Health Sciences, Bethesda, MD
2008-2010	Staff Cardiologist, National Naval Medical Center, Bethesda, MD
2010-2015	Assistant Professor of Medicine and Radiology, Boston University School of Medicine, Boston, MA
2010-2015	Attending Cardiologist; Nuclear Cardiologist, Boston Medical Center, Boston, MA
2011-2015	Attending Cardiologist; Cardiac Sarcoidosis Clinic (founding member), Boston Medical Center Sarcoidosis Center, Boston, MA
2013-2015	Attending Cardiologist; Boston University Amyloidosis Center, Boston, MA
2015-present	Attending Cardiologist; Cardiac Sarcoidosis and Amyloidosis Clinic, Yale School of Medicine, New Haven, CT
2015-present	Assistant Professor of Medicine and Radiology, Yale University School of Medicine, New Haven, CT

Administrative Positions:

2010-2015	Director, Boston Medical Center Cardiology Fellowship Nuclear Cardiology Training program, Boston Medical Center, Boston, MA
2011-2015	Site Preceptor (Boston Medical Center), Certification Board of Nuclear Cardiology, Boston Medical Center, Boston, MA
2013-2015	Director of Nuclear Imaging (Cardiology), Boston Medical Center, Boston, MA
2013-2015	Assistant Cardiology Fellowship Program Director, Boston Medical Center, Boston, MA
2015-present	Director, Nuclear Cardiology, Yale-New Haven Hospital, Yale School of Medicine, New Haven, CT
2015-present	Director, Cardiology Fellowship Program, Yale-New Haven Hospital, Yale School of Medicine, New Haven, CT

2015-present	Site Preceptor (Yale School of Medicine), Certification Board of Nuclear Cardiology, Yale School of Medicine, New Haven, CT

Board Certification:

2000	North Carolina Medical License (#881234) – inactive
2002	Connecticut Medical License (#041697) – pending reactivation
2004	American Board of Internal Medicine (#228306)
2008	American Board of Internal Medicine – Cardiology
2008	Certification Board in Nuclear Cardiology (#6424)
2010	Commonwealth of Massachusetts Medical License (#244989) - inactive
2011-2015	Boston Medical Center – Clinical Radioisotope Use Permit/Authorized User (#M-122)
2013	Cardiac CT – Level II Certification
2015	State of Connecticut Medical License (#04167) - active

Professional Honors and Recognition:

2014	Fellow, American Society of Nuclear Cardiology (FASNC)
2010	Navy Humanitarian Service Medal
	Navy and Marine Corps Commendation Medal
	Armed Forces Service Medal
2009	American Society of Nuclear Cardiology Leadership Development Program
2008	PhD *with Distinction*, Yale University
2006	International Society for Heart Research Young Investigator Competition-Finalist, 1st Runner-Up
2005	Yale Graduate Student Assembly Conference Travel Award
	Northwestern University Feinberg School of Medicine Cardiovascular Young Investigators' Forum-3rd Prize, Fellows Basic Science
2001	Navy and Marine Corps Commendation Medal
	Navy and Marine Corps Achievement Medal
	Navy Combat Action Ribbon
1999	Alpha Omega Alpha
	President's Medallion - Loyola University Chicago
	Alpha Sigma Nu National Jesuit Honor Society
1994-1999	Navy Health Professions Scholarship Program
1994	*Cum laude* graduate, University of Notre Dame

Grant History:

Current Grants:

Agency: NIH/NHLBI
ID# K08 HL109158
Title: "The Role and Regulation of the LKB1-AMPK axis in diabetic cardiomyopathy"
P.I. Edward J. Miller, MD PhD
Percent Effort: 75%
Direct costs per year: $143040
Total costs for the project period: $643,680
Project period: 4/2011-4/2017 (transferred to Yale)

Agency: Bracco, Inc
ID# HIC #1512016912
Title: "Optimizing acquisition parameters and interpretive methods of FDG-PET/CT with Rb-82 myocardial perfusion imaging for evaluation of cardiac sarcoidosis"
P.I. Edward J. Miller, MD PhD
Percent Effort: 5%
Direct costs per year: $10000
Total costs for the project period: $20000
Project period: 10/2016-10/2018

Past Grants:

Agency: BU CTSI/DOM Pilot Grant
ID# N/A
Title: "Measurement of cardiac mitochondrial membrane potential in vivo using Tc-99m sestamibi microSPECT"
P.I. Edward J. Miller, MD PhD
Percent Effort: 2%
Direct costs per year: $15000
Total costs for the project period: $15000
Project period: 2/2012-2/2013

Agency: NNMC Intramural Award
ID# N/A
Title: "Activation and Regulation of AMP-Activated Protein Kinase in Congestive Heart Failure"
P.I. Edward J. Miller, MD PhD
Percent Effort: 2%
Direct costs per year: $8570
Total costs for the project period: $17140
Project period: 10/2008-6/2010

Past Clinical Trials

Agency: Lantheus Medical Imaging
ID# Protocol BMS747158-301
Title: "A Phase 3, Open-Label, Multicenter Study for the Assessment of Myocardial Perfusion using Positron Emission Tomography (PET) Imaging of Flurpiridaz F 18 Injection in Patients with Suspected or Known Coronary Artery Disease (CAD)"
P.I. Edward J. Miller, MD PhD (site)
Percent Effort: 2%
Direct costs per year: $23998
Total costs for the project period: $23998
Project period: 3/2012-6/2013

Invited Speaking Engagements, Presentations, Symposia & Workshops Not Affiliated With Yale:

National/International

09/2016	American Society of Nuclear Cardiology Scientific Sessions, "Optimal Imaging of Newer Less Common Nuclear Modalities (mIBG, Amyloid, PET for infection): Reporting, Clinical Use", Boca Raton, FL
09/2016	American Society of Nuclear Cardiology Scientific Sessions, "Getting out of the Silo: Intersocietal Collaboration in Cardiac Imaging" (Moderator/session organizer), Boca Raton, FL
06/2016	Society for Nuclear Medicine and Molecular Imaging Scientific Sessions, "Imaging of Reactive Oxygen Species", San Diego, CA
09/2015	American Society of Nuclear Cardiology Scientific Sessions, "Effective Use of Multimodality Imaging in Evaluation of Cardiac Sarcoidosis: Use of Imaging to Follow Treatment Response", Washington, DC
9/2014	Heart Failure Society of America, 18th Annual Scientific Meeting, "The Role of Positron Emission Tomography in Unexplained Cardiomyopathy", Las Vegas, NV
9/2014	American Society of Nuclear Cardiology Scientific Sessions 2014, "Integration of PET Imaging in Clinical Practice: Assessment of Myocardial Sarcoidosis", Boston, MA
9/2012	American Society of Nuclear Cardiology Scientific Sessions 2012, "Patient-Centered Imaging"; Baltimore, MD

Regional

12/2016	Brown University Cardiology Grand Rounds, "Emerging Concepts in Nuclear Imaging of Cardiac Amyloidosis", Providence, RI
11/2016	Society for Nuclear Medicine and Molecular Imaging Northeast Regional Meeeting, "PET and Cardiac Sarcoidosis", Stamford, CT
7/2015	Boston Medical Center, Department of Family Medicine Grand Rounds, Boston, MA; "An Update on Cardiac Stress Testing"
8/2014	East Boston Neighborhood Health Center, Boston, MA; "Stress Tests: What to order, when to order, WHY to order (and, why NOT to order)"
12/2013	Beth Israel Deaconess Cardiovascular Institute seminar, Boston, MA "AMPK, LKB1 and Metabolic Heart Disease: Hypertrophy and Mitochondrial Remodeling"
11/2013	Yale School of Medicine Cardiovascular Medicine Grand Rounds, New Haven, CT "Quantitative Imaging of FDG PET/CT in Cardiac Sarcoidosis" (NOTE: I was not affiliated with Yale at the time of this presentation)
10/2013	Brigham and Women's Hospital Cardiovascular Imaging Conference, Boston, MA; "Quantitative Imaging of FDG PET/CT in Cardiac Sarcoidosis"
9/2011	East Boston Neighborhood Health Center, Boston, MA: "Cardiac Imaging and Risk Stratification in 2011"
2/2009	NNMC Nuclear Medicine Authorized User Course, Bethesda, MD; "SPECT Physics and Instrumentation"
10/2008	Uniformed Services University of Health Sciences, Department of Medicine Research Grand Rounds, Bethesda, MD; "AMPK and the Heart"

Professional Service:

Journal Service:

Reviewer:

2007-present	Reviewer for eMedicine/WebMD, Cardiology CME case editor, Diabetologica, American Journal of Physiology, Heart and Circulatory Physiology, Journal of Thoracic Imaging, Journal of Molecular and Cellular Cardiology, PLos One, Expert Reviews of Cardiovascular Therapy, Circulation, Journal of Clinical Endocrinology and Metabolism, Circulation: Cardiovascular Imaging, European Journal of Nuclear Medicine and Molecular Imaging, JACC: Cardiovascular Imaging, Amyloid

Professional Service for Professional Organizations

Society of Nuclear Medicine and Molecular Imaging

2017	Scientific Program Committee, Sub-Chair, Cardiovascular Track
2015-2018	Society of Nuclear Medicine and Molecular Imaging (Cardiovascular Council) – Board of Directors

American Society of Nuclear Cardiology

2017	American Society of Nuclear Cardiology Scientific Sessions Program Committee – PET Program Committee
2016	American Society of Nuclear Cardiology Scientific Sessions Program Committee – Core Program Committee
2015	American Society of Nuclear Cardiology Scientific Sessions Program Committee ASNC2015 Research/Abstract Track Working Group (Chair)
2015-2017	American Society of Nuclear Cardiology Quality Steering Committee
2012	American Society of Nuclear Cardiology Scientific Sessions 2012 Faculty Session preceptor (Poster Session IV: PET, CT and Hybrid Imaging) Presenter; Patient-Centered Imaging Session
2011	American Society of Nuclear Cardiology and American Heart Association Scientific Programming Committee
2010	American Society of Nuclear Cardiology Half-Dose Imaging Task Force
2010	American Society of Nuclear Cardiology Patient Centered Imaging Task Force
2010-present	American Society of Nuclear Cardiology Travel Awards Review Committee (2010, 2011, 2012)
2010	Nuclear Cardiology Knowledge Self-Assessment Program Review Faculty
2009-2010	ASNC Leadership Development Program

American Heart Associate:

2013-2016	American Heart Association Scientific Sessions Abstract Reviewer

Certification Board of Nuclear Cardiology

2016	Certification Board of Nuclear Cardiology – Lead for Imaging and Media Working Group Exam Development Committee
2013	CCCVI Statistics Dissemination Cross Division Task Force (CBNC representative)
2013-2015	Certification Board of Nuclear Cardiology – Board of Directors, At Large Member
2013	CBNC Exam Review Committee

American College of Cardiology

2015	Connecticut Chapter of the American College of Cardiology – Education Committee Member

University Service:

Medical School Committees

2014-2015	Boston University School of Medicine Committee on Admissions (MD/PhD)
2008-2010	Scientific Review Panel/Institutional Review Board National Naval Medical Center Bethesda
2004-2007	Graduate Medical Education Advisory Committee YNHH/Yale School of Medicine

Departmental Committees

2013	Department of Internal Medicine Laboratory Space and Use Committee, Boston University School of Medicine
2011	Department of Medicine Review Committee, Graduate Program in Molecular Medicine, Boston University School of Medicine
2010-2015	Boston Medical Center Cardiology Fellowship Applicant Review Committee
2010-2011	Boston Medical Center Internal Medicine Residency Applicant Review Committee
2008-2010	Internal Medicine Residency Research Council National Naval Medical Center Bethesda
2008-2010	Interdepartmental Collaborative Bethesda Research Group (ICEBERG) NNMC Bethesda

Hospital Committees

2015-present	YNHH Radiation Safety Committee
2016-present	YNHH GME Committee

Bibliography:

Peer-Reviewed Original Research

1. Baron S, Li J, Russell RR, Neumann D, **Miller EJ**, Tuerk R, Walliman T, Hurley R, Witters LA, Young LH. Dual mechanisms regulating AMPK kinase action in the ischemic heart. Circulation Research, 2005. 96(3): p. 337-45. PMID: 15653571

2. Li J, **Miller EJ**, Ninomiya-Tsuji J, Russell RR, Young LH. AMP-activated protein kinase activates p38 mitogen-activated protein kinase by increasing recruitment of p38 MAPK to TAB1 in the ischemic heart. Circulation Research. 2005. 97(9):872-9. Epub 2005 Sep 22. PMID: 16179588

3. Li J, Coven DL, **Miller EJ**, Hu X, Young ME, Carling D, Sinusas AJ, Young LH. Activation of AMPK α- and γ- Isoform Complexes in the Intact Ischemic Rat Heart. Am J Physiol Heart Circ Physiol. Oct;291(4):H1927-34. Epub April 28, 2006. PMID: 16648175

4. **Miller EJ,** Li J, Sinusas K, Holman GD, Young LH. Infusion of a biotinylated bis-glucose photolabel: A new method to quantify cell-surface GLUT4 in the intact mouse heart. Am J Physiol Endo. 2007. June;292(6):E1922-8. Epub 2007 Mar 6. PMID: 17341550

5. **Miller EJ,** Li J, Leng L, McDonald C, Atsumi, T, Bucala R, Young LH. Macrophage migration inhibitory factor stimulates AMP-activated protein kinase in the ischemic heart. Nature. 2008. Jan 31;451(7178): 578-82. PMID: 18235500

6. Amundson D, Dadekian G, Etienne M, Gleeson T, Hicks T, Killian D, Kratovil K, Lewis C, Monsour M, Pasiuk B, Rhodes D, **Miller EJ.** Practicing Internal Medicine Onboard the USNS COMFORT in the Aftermath of the Haitian Earthquake. Ann Intern Med. 2010 Jun 1;152(11):733-7. Epub 2010 Mar 2. PMID: 20197507

7. Kim AS, **Miller EJ**, Wright TM, Li J, Qi D, Atsina K, Zaha V, Sakamoto K, Young LH. A small molecule AMPK activator protects the heart against ischemia-reperfusion injury. J Mol Cell Cardiol. 2011 Jul;51(1):24-32. PMID: 21402077

8. Qin F, Siwik DA, Luptak I, Hou X, Wang L, Higuchi A, Weisbrod RM, Ouchi N, Tu VH, Calamaras TD, **Miller EJ**, Verbeuren TJ, Walsh K, Cohen RA, Colucci WS. The Polyphenols Resveratrol and S17834 prevent the Structural and Functional Sequelae of Diet-Induced Metabolic Heart Disease in Mice. Circulation. 2012 Apr 10; 125(14):1757-64. PMID: 22388319

9. Urocortin 2 autocrine/paracrine and pharmacologic effects to activate AMP-activated protein kinase in the heart. Li J1, Qi D, Cheng H, Hu X, **Miller EJ,** Wu X, Russell KS, Mikush N, Zhang J, Xiao L, Sherwin RS, Young LH. PNAS. 2013 Oct 1;110(40):16133-8. PMID: 24043794

10. Tamminga C, Sedegah M, Maiolatesi S, Fedders C, Reyes S, Reyes A, Vasquez C, Alcorta Y, Chuang I, Spring M, Kavanaugh M, Ganeshan H, Huang J, Belmonte M, Abot E, Belmonte A, Banania J, Farooq F, Murphy J, Komisar J, Richie NO, Bennett J, Limbach K, Patterson NB, Bruder JT, Shi M, **Miller E**, Dutta S, Diggs C, Soisson LA, Hollingdale MR, Epstein JE, Richie TL. Human adenovirus 5-vectored Plasmodium falciparum NMRC-M3V-Ad-PfCA vaccine encoding CSP and AMA1 is safe, well-tolerated and immunogenic but does not protect against controlled human malaria infection. Hum Vaccin Immunother. 2013 Oct;9(10):2165-77. doi: 10.4161/hv.24941. Epub 2013 Jun 4. PMID: 23899517

11. Berman JS, Govender P, Ruberb FL, Mazzini M, **Miller EJ**. Scadding Revisited: A Proposed Staging System for Sarcoidosis Based on Advanced Imaging. Sarcoidosis Vasc Diffuse Lung Dis. 2014. Apr 18,31(1):2-5. PMID 24751447

12. Ahmadian A, Brogan A, Berman JS, Sverdlov AL, Mercier G, Mazzini M, Govender P, Ruberg RL, **Miller EJ.** Quantitative Interpretation of FDG PET/CT with Myocardial Perfusion Imaging Increases the Diagnostic Information in the Evaluation of Cardiac Sarcoidosis. J Nuc Card. 2014. May 31. PMID: 24879453

13. Dahmani R, Just PA, Delay A, Canal F, Finzi L, Prip-Buus C, Lambert M, Sujobert P, Buchet-Poyau K, **Miller E**, Cavard C, Marmier S, Terris B, Billaud M, Perret C. A novel LKB1 isoform enhances AMPK metabolic activity and displays oncogenic properties. Oncogene. 2014. Jul 7. PMID: 24998845.

14. Ayalon N, Gopal DM, Mooney DM, Simonetti JS, Grossman JR, Dwivedi A, Donohue C, Perez AJ, Downing J, Gokce N, **Miller EJ**, Liang CS, Apovian CM, Colucci WS, Ho JE. Preclinical

Left Ventricular Diastolic Dysfunction in Metabolic Syndrome. Am J Cardiol. 2014; Jul 1. PMID: 25084691

15. Sverdlov AL, Elezaby A, Behring JB, Bachschmid MM, Luptak I, Tu VH, Siwik DA, **Miller EJ**, Liesa M, Shirihai OS, Pimentel DR, Cohen RA, Colucci WS. High fat, high sucrose diet causes cardiac mitochondrial dysfunction due in part to oxidative post-translational modification of mitochondrial complex II. J Mol Cell Cardiol 2015 Jan; 78:165-73. PMID: 25109264

16. Elezaby A, Sverdlov AL, Tu VH, Soni K, Luptak I, Qin F, Liesa M, Shirihai OS, Rimer J, Schaffer JE, Colucci WS, **Miller EJ.** Mitochondrial Remodeling in Mice with Cardiomyocyte-Specific Lipid Overload. J Mol Cell Cardiol 2014; *Dec 9 Epub.* PMID: 25497302

17. Sung MM, Zordoky BN, Bujak AL, Lally JS, Fung D, Young ME, Horman S, **Miller EJ**, Light PE, Kemp BE, Steinberg GR, Dyck JR. AMPK deficiency in cardiac muscle results in dilated cardiomyopathy in the absence of changes in energy metabolism. Cardiovasc Res. 2015 Jul 15; 107(2):235-45. PMID 26023060

18. **Miller EJ**, Calamaras T, Elezaby A, Sverdlov A, Qin F, Luptak I, Wang K, Su X, Vijay A, Croteau D, Bachschmid M, Cohen RA, Walsh K, Colucci WC. Partial LKB1 Deficiency Promotes Diastolic Dysfunction, *de novo* Systolic Dysfunction, Apoptosis and Mitochondrial Dysfunction with Dietary Metabolic Challenge. JAHA. 2015. Dec 31;5(1) PMID: 26722122

19. Sverdlov A, Elezaby A, Qin F, Behring J, Luptak I, Calamaras T, Siwik D, **Miller EJ**, Liesa M, Shirihai O, Pimental D, Cohen RA, Bachschmid M, Colucci WC. Mitochondrial reactive oxygen species mediate cardiac structural, functional and mitochondrial consequences of diet-induced metabolic heart disease. J Am Heart Assoc. 2016 Jan 11;5(1). PMID: 26755553

20. Patchett ND, Pawar S, **Miller EJ.** Visual identification of coronary calcifications on attenuation correction CT improves diagnostic accuracy of SPECT/CT myocardial perfusion imaging. J Nucl Card. 2016. Feb 5 (epub ahead of print). PMID: 26850031

21. Harb SC, Haq M, Flood K, Guerrieri A, Passerell W, Jaber WA, **Miller EJ**. National patterns in imaging utilization for diagnosis of cardiac amyloidosis: A focus on Tc99m-pyrophosphate scintigraphy. J Nucl Cardiol. 2016 Mar 25. [Epub ahead of print]. PMID: 27016106

22. Gillmore JD, Maurer MS, Falk RH, Merlini G, Damy T, Dispenzieri A, Wechalekar AD, Berk JL, Quarta CC, Grogan M, Lachmann HJ, Bokhari S, Castano A, Dorbala S, Johnson GB, Glaudemans AW, Rezk T, Fontana M, Palladini G, Milani P, Guidalotti PL, Flatman K, Lane T, Vonberg FW, Whelan CJ, Moon JC, Ruberg FL, **Miller EJ**, Hutt DF, Hazenberg BP, Rapezzi C, Hawkins PN. Nonbiopsy Diagnosis of Cardiac Transthyretin Amyloidosis. Circulation. 2016 Jun 14;133(24):2404-12. PMID: 27143678

23. Haq M, Pawar S, Berk JL, **Miller EJ,** Ruberg FL. Can 99m-Tc-Pyrophosphate Aid in Early Detection of Cardiac Involvement in Asymptomatic Variant TTR Amyloidosis?. *J Am Coll Cardiol Img.* 2016;():. doi:10.1016/j.jcmg.2016.06.003.

24. Castano A, Haq M, Narotsky DL, Goldsmith J, Weinberg RL, Morgenstern R, Pozniakoff T, Ruberg FL, **Miller EJ**, Berk JL, Dispenzieri A, Grogan M, Johnson G, Bokhari S, Maurer MS. Multicenter Study of Planar Technetium 99m Pyrophosphate Cardiac Imaging: Predicting

Survival for Patients With ATTR Cardiac Amyloidosis. JAMA Cardiol. 2016 Aug 24. doi: 10.1001/jamacardio.2016.2839. [Epub ahead of print] PMID: 27557400

25. Ahmadian A, Pawar S, Govender P, Berman J, Ruberg FL, **Miller EJ**. The response of FDG uptake to immunosuppressive treatment on FDG PET/CT imaging for cardiac sarcoidosis. J Nucl Cardiol. 2016 Jul 25. [Epub ahead of print]. PMID: 27457527

26. Salinaro F, Meier-Ewert HK, **Miller EJ,** Pandey S, Sanchorawala V, Berk JL, Seldin DC, Ruberg FL. Longitudinal systolic strain, cardiac function improvement, and survival following treatment of light-chain (AL) cardiac amyloidosis. Eur Heart J – CV Imaging. *In press.*

Chapters, Books, and Reviews

1. Louie EK, **Miller EJ**, "Hypertrophic Cardiomyopathy: Pathophysiology, Principles, Diagnosis and Therapy" in Advances and Challenges in Today's Cardiology from *The Third International Review Course on Cardiology*, October 1997. Griffith Publishing, Caldwell, Idaho, pp. 225-232.

2. **Miller EJ,** Russell RR. *Physics and Instrumentation of Cardiac SPECT.* Ho and Reddy: Imaging of the Cardiovascular System. Chapter 20. (edited by). Ho V, Reddy G. Elsevier. 2011. *p. 270-280*

3. **Miller EJ**, Qi D, Li J, Young LH. *Macrophage Migration Inhibitory Factor in Cardiovascular Disease.* The MIF Handbook. (edited by) Richard Bucala. World Scientific Publishing Company. 2012. *p.* 347-358

4. **Miller EJ** *Chapter 1: Evaluation of Chest Pain.* The Evidence-Based Cardiology Consult. (edited by) Kathleen Stergiopoulos and David Brown. Springer. 2013. *p. 3-14.*

5. Blankstein R, **Miller EJ.** *Multimodality Imaging of Cardiac Sarcoidosis: How to choose which test at what time and what they all mean.* Cardiac Sarcoidosis: Key Concepts in Pathogenesis, Disease Management, and Interesting Cases. (edited by) Andrew Freeman and Howard Weinberger. 2015.

Peer-Reviewed Educational Materials

1. Dorbala S, Bokhari S, **Miller EJ,** Palmer R, Soman P, Thompson. ASNC Practice Points: ^{99m}Technetium-Pyrophosphate Imaging for Transthyretin Cardiac Amyloidosis. American Society of Nuclear Cardiology. 2016. http://www.asnc.org/content.asp?admin=Y&contentid=182

Invited Editorials and Commentaries

1. **Miller EJ**, Russell RR, Li J, Young LH. AMPK-a pivotal rheostat in the control of cardiac metabolism. Drug Discovery Today: Disease Mechanisms, 2005. 2(1): p. 93-100.

2. Kim A, **Miller EJ,** Young LH. AMPK, a Core Signaling Pathway in the Heart. Acta Physiol (Oxf). 2009 May;196(1):37-53. Epub 2009 Feb 23. PMID: 19239414

3. Russell RR, Abbott BG, Arrighi JA, Blankstein R, Cohen MC, Faber TL, Mahmarian JJ, **Miller EJ**, Shaw L, Soman P, Travin MI. Highlights of the 2010 Scientific Session of the American Society of Nuclear Cardiology. Philadelphia, Pennsylvania, September 23-26, 2010. J Nucl Cardiol. 2011;18:177-84

4. Russell RR, Abbott BG, Arrighi JA, Blankstein R, Faber TL, Mahmarian JJ, **Miller EJ**, Miller TD, Shaw LJ, Soman P, Travin MI. Highlights of the 2011 Scientific Session of the American Society of Nuclear Cardiology: Denver, Colorado, September 8-11, 2011. J Nucl Cardiol. 2012 Feb;19(1):158-64. PMID: 22071955

5. Ruberg, FL, & **Miller, EJ** (2013). Nuclear Tracers for Transthyretin Cardiac Amyloidosis: Time to Bone Up? Circ Cardiovasc Imaging, 6(2), 162–164. PMID: 23512778

6. Blankstein, R, & **Miller, EJ.** Quantifying FDG uptake to diagnose cardiac device infections: When and how should we do it? J Nucl Cardiol. 2015.

Practice Guidelines, Standards and Consensus Statements

1. Depuey EG, Mahmarian JJ, Miller TD, Einstein AJ, Hansen CL, Holly TA, **Miller EJ**, Polk DM, Samuel Wann L. Patient-Centered Imaging. J Nucl Cardiol. 2012 Apr;19(2): 185-215. PMID: 22328324

Case Reports, Technical Notes, Letters

1. Ozcan C, **Miller EJ**, Russell KS, Dewar ML, Rosenfeld LE. An unusual case of nonbacterial thrombotic (marantic) endocarditis. J Thorac Cardiovasc Surg. 2009 Jan;137(1):239-41. Epub 2008 May 2. PMID: 19154931

Scholarship In Press

1. Hyafil F, Hacker M, Gheysens O, Glaudemans A, Rouzet F, Signore A, Donal E, Gimelli A, Lanselotti P, Plein S, Dorbala S, Blankstein R, Schwartz R, Russell R Jaber W, **Miller EJ**, Slart R. Imaging in cardiac sarcoidosis: a joint position statement by the European Association of Nuclear Medicine (EANM), the European Association of Cardiovascular Imaging (EACVI). Eur Heart J – CV Imaging. 2016. *In press*

2. Chareonthaitawee P, Beanlands R, Birnie D, Borges-Neto S, Chen E, Chen W, Cooper L, Di Carli M, Dorbala S, Gropler R, **Miller EJ**, Murthy V, Ruddy T, Schindler T, Tung R, White E, Blankstein R. The Role of PET/CT in cardiac sarcoid detection and monitoring therapy: Position Paper of the Cardiovascular Council of the Society of Nuclear Medicine and Molecular Imaging. Jour Nucl Med. 2016. *In press*

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Summary of Qualifications

- Strategic leader with progressive Healthcare experience supporting major acquisitions and high impact initiatives. Excellent reputation for building effective relationships and producing results through a blend of strategic, operational and customer focus.
- Over 34 years as a critical care nurse with 9 years as direct caregiver ICU nurse, 15 years spent as a Patient Services Manager, 7 years as Director of Patient Services and approximately 3 years as Service Line Executive Director.
- Experienced executive leader responsible for two distinct service lines: Heart and Vascular Center (HVC) and Transplantation Center.
- Accomplished leader responsible for over 900 FTEs with annual budgets over $148 million.

Professional Experience

Executive Director, Heart and Vascular Center and Transplantation Center
Yale New Haven Hospital, New Haven Conn.
December 2013 – Present

- Responsible for executive leadership, as well as clinical and financial oversight for one of the largest and most comprehensive heart and vascular programs in New England. The Heart and Vascular service line encompasses two distinct campuses; YSC and SRC. It includes 2 ICUs (38 beds) and 151 inpatient beds (including 17 step down beds); 21 interventional laboratories (Cardiac, Interventional Radiology, Electrophysiology, Neuro intervention); Imaging services, inclusive of ECHO services and Cardiac Nuclear Medicine; Cardiac Rehab services, Clinical Research department (with 100+ active studies) and 12 ambulatory satellites. Budget responsibility encompasses over $149 million.

- Responsible for the executive leadership, as well as clinical and financial oversight of solid organ transplantation center. Center encompasses 4 transplantation programs of liver, kidney, pancreas, and heart. Budget oversight includes $5.5 million for inpatient programs and 14.5 million for broad transplant services with a total annual budget of over $20 million. Includes a 36 bed Transplant inpatient unit; 3 outpatient transplant and infusion clinics.

Director Patient Services, Heart and Vascular Center
Yale New Haven Hospital, New Haven Conn.
June 2008- 2013

- Responsible for executive leadership and clinical and financial oversight of 15 diverse HVC cost centers within the 1000 bed York street hospital campus. Areas include two ICUs, cardiac and cardiothoracic; two stepdown units, cardiac medicine and cardio-vascular surgical; one cardiac telemetry unit; one 26 bed observation unit; five cardiac cath labs and three electrophysiology labs; six vascular and neuro interventional labs; nuclear cardiology areas; cardiac exercise lab; ECHO labs; HVC recovery area ,PICC service; HVC procedural nursing ; HVC Clinical Research department; and Yale Cardiology practice at Shoreline and Branford, as well as Yale cardiac rehab in Branford .

- Responsible for full oversight and clinical integration of Heart and Vascular services at St. Raphael's campus with the 511 bed hospital acquisition on September 12, 2012. HVC areas include two cardiac cath labs and two electrophysiology labs; two interventional radiology labs; cardiac diagnostic imaging unit; radiology procedural nursing; Take Heart cardiac rehab in New Haven and Cardiac outpatient practices in West Haven and Hamden.

- Accountable for attaining high performance in all elements of four business pillars: Quality/ safety, Provider of Choice; Employer of Choice; Financial

Director Patient Services, Medicine
Yale New Haven Hospital, New Haven Conn.
September 2006- June 2008

- Responsible for executive leadership and clinical and financial oversight of 13 cost centers. Areas include one cardiac ICU, two medical ICUs, one cardiac telemetry floor, one cardiac stepdown floor, one pulmonary stepdown floor, 5 general medicine floors, PICC Service, ICU resource unit and diagnostic radiology / cardiac nursing.
- Accountable for attaining high performance in all elements of four business pillars: Quality/ safety, Provider of Choice; Employer of Choice; Financial

Patient Services Manager of PICC Service
Yale New Haven Hospital, New Haven Conn.
June 1999- September 2006

- Created bedside PICC insertion service. Service developed to meet both adult and pediatric patient population needs. Coverage provided 7 days; operating 12 hour days Monday-Friday, and 4 hours on-call weekends and holidays.

- Responsible for consulting on approximately 2400 cases a year.

Patient Services Manager of DI Recovery Area
Yale New Haven Hospital, New Haven, Conn.
December 1998-September 2006

- Oversaw site location and creation of 13 bed outpatient recovery area for Diagnostic Imaging and Heart Center procedural patients.
- Patient population includes cardiac cath, EPS, and cardiac biopsy patients.
- Interventional radiology population includes oncology, renal, and vascular.
- Neuro interventional patients are also cared for in this setting.

Patient Services Manager of Diagnostic Imaging
Yale New Haven Hospital, New Haven, Conn.
May 1995-September 2006

- 24 hour accountability for nursing practice and nursing staff in Diagnostic Imaging
- Patient populations include inpatients and outpatients of varying acuity levels and with multiple diagnoses.
- General nursing oversight of 10 principal interventional labs, including 4 cardiac cath labs, 5 peripheral vascular/ neuro interventional labs, 1 electrophysiology lab.
- Primary nursing coverage for 5 MRI scanners with flexible staffing provided for CT biopsies, bronchoscopies, ultrasound, and x-ray.
- Accountable for personnel management, staffing, scheduling, clinical practice, fiscal planning, quality improvement, environmental management, education, orientation, and patient satisfaction.

Patient Services Manager Cardiac ICU
Yale New Haven Hospital, New Haven, Conn.
July 1991-September 2006

- 24 hour responsibility for the clinical, fiscal, and environmental management of a 14 bed cardiac intensive care unit.
- Patient population includes patients with medical diagnosis of cardiogenic shock; end stage cardiomyopathy; acute coronary syndrome; as well as patients with unstable cardiac arrhythmias.
- Accountable for interviewing, selecting, and professional development of approximately 90 staff.

Staff Nurse Cardiac ICU
Yale New Haven Hospital, New Haven, Conn.
July 1982-1991

- Primary nurse responsible for coordinating and implementing care of critically ill patients.
- Preceptor Coordinator
- One of first Clinical Nurse IV recognitions and advancements.

Recent Committee Memberships

- HVC Executive Operations Committee
- Senior Clinical Leadership Group
- HVC Ambulatory Strategy Team
- YNHHS system HVC Non-labor reduction   Chair
- Executive Cost & Value Non-Labor steering committee
- Y-NH Transplantation Center QA/PI Executive Committee
- Senior Operations Group
- Advanced Heart Failure Multidisciplinary Committee
- Transplant Operations Council
- CT Operations Council
- IR Operations Council
- CV Operations Council
- Off-shift team of Nurse Leaders and Executives   Nursing liaison
- Recognition and Clinical Advancement Program   Administrative liaison
- Chest Pain Center Steering committee
- HVC and Transplant Patient Experience Forum   Co-chair
- HVC Quality/Safety Committee
- Transplant Quality & Performance Improvement Committee
- Joint Leadership Committee
- Nurse Collaborative Governance: HVC cluster   Administrative liaison
- Nursing Executive Committee
- Nursing Cabinet
- Innovation Operating Steering Committee

Recent Special Projects

- Selected to participate in first Strategic Agility and Innovation Course, IFE and YSM -2016
- Restructuring of outpatient site locations (opening/closings) for optimum coverage and best patient access 2016
- Planning and oversight for an HVC integrated Cardiovascular Imaging system (CVIS) initiated July 2014
- Yale-New Haven Transplantation Center strategic plan development 2014
- Development of Old Saybrook vascular procedure suite planned for January 2015
- Acquisition of Norwich Cardiology Associates September 2014
- Integration of 4 site Cardiology Associates of New Haven (CANH) physician practice sites 2013
- Acquisition of HVC operations on St.Rapheal's campus September 12, 2012
- Oversight of Transitional Care Center on YPB2
- Opened HVC joint venture Clinical Research department 2012
- Opened 26 bed Observation Unit May 2011
- Successful Oversight of Chest Pain Center accreditation process
- Successful Oversight of TJC VAD Destination Therapy Accreditation
- One of several authors on ST-Map ECG software research poster/ article
- CON process, design and opening of a multitude of HVC procedural labs
- Replacement and implementation of new EKG Tracemaster View System
- Cardiac Nuclear design, construction and relocation to 2EP .
- Provided operations support for shared services model of Guilford / Branford programs

Professional Organizations/ Certifications

- 2014-present Certified Nurse Executive (CENP)
- 1987-present Certified Critical Care Nurse (CCRN)
- 1985- present American Association of Critical Care Nurses (AACN)
- 1992- present American Association of Critical Care Nurses/ South Central Connecticut Chapter (AACN / SCCC)
- American Heart Association – Council of Cardiovascular Nursing
- 2006 –present American Organization Nurse Executives (AONE)
- 2006-present Organization of Nurse Executives, Conn. Chapter (ONE-CT)

Education

- 2002 Quinnipiac University, Hamden, Conn.
  Masters in Health Administration with Distinction
- 1997 Quinnipiac University, Hamden, Conn.
  Bachelors of Science in Nursing, Magna cum Laude
- 1982 Quinnipiac University, Hamden, Conn.
  Associate Degree in Nursing, Cum Laude

Publications

Creating a 24/7 Model for Patient–Family-Centered Care. Nurse Leader Volume 13, Issue 4, August 2015, Pages 56–60, 73 Copyright 2015 by Elsevier Inc.

EXHIBIT D

ARTICLES REGARDING SPECT/CT

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY AND SOCIETY OF NUCLEAR MEDICINE JOINT POSITION STATEMENT

Despite advancements in technologies, non-uniform soft tissue attenuation still affects the diagnostic accuracy of single photon emission computed tomography (SPECT) myocardial perfusion imaging. A variety of indirect measures have been used to reduce the impact of attenuation, most notably electrocardiography-gated SPECT imaging. However, all available techniques have limitations, making interpretation in the presence of attenuation difficult. The ultimate solution, similar to positron emission tomography imaging, is to use hardware/software algorithms to eliminate attenuation and provide images that are more uniform and easier to interpret. Several attenuation correction solutions are currently available and more will be available soon. The value of these solutions has been varied, particularly with clinical applications. Guidelines and standards clearly are necessary.

In recognition of the importance of this issue, the American Society of Nuclear Cardiology and the Society of Nuclear Medicine convened a joint task force to develop a position statement on attenuation correction. It is being published concurrently in the *Journal of Nuclear Cardiology* and *The Journal of Nuclear Medicine*, a first for these societies.

The purpose of this position statement is to clarify the role of attenuation correction in SPECT procedures, to provide guidelines for its clinical use, and to provide a basis for the evaluation of published validation. It is hoped that this position statement will provide an important and useful road map to the widespread adoption of attenuation correction into clinical practice.

Gary V. Heller, MD, PhD
President, American Society of Nuclear Cardiology

The value and practice of attenuation correction for myocardial perfusion SPECT imaging: A joint position statement from the American Society of Nuclear Cardiology and the Society of Nuclear Medicine

Robert C. Hendel, MD, James R. Corbett, MD, S. James Cullom, PhD, E. Gordon DePuey, MD, Ernest V. Garcia, PhD, and Timothy M. Bateman, MD

PREAMBLE

The diagnostic accuracy of single photon emission computed tomography (SPECT) myocardial perfusion imaging is profoundly influenced by the presence of tissue attenuation. Although interpretative education, experience, and the application of gated SPECT imaging have had a favorable impact on the clinical value of radionuclide perfusion imaging, the nuclear cardiology community has long-awaited correction techniques for photon attenuation. The purposes of this statement are to review the recent developments in the field of attenuation correction, to define its clinical utility, and to delineate contemporary recommendations regarding attenuation correction techniques.

BACKGROUND

Soft tissue attenuation, Compton scatter, and depth-dependent reduction of spatial resolution degrade myocardial perfusion SPECT image quality, thereby decreasing test sensitivity in the detection of coronary artery disease. In addition, localized soft tissue attenuation by the breasts, lateral chest wall, abdomen, and left hemidiaphragm may create artifacts that mimic true perfusion abnormalities and thereby decrease test specificity.

Conventional SPECT imaging has used a variety of techniques to minimize the impact of attenuation, includ-

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1071-3581/2002/$35.00 + 0 **43/1/120680**
doi:10.1067/mnc.2002.120680

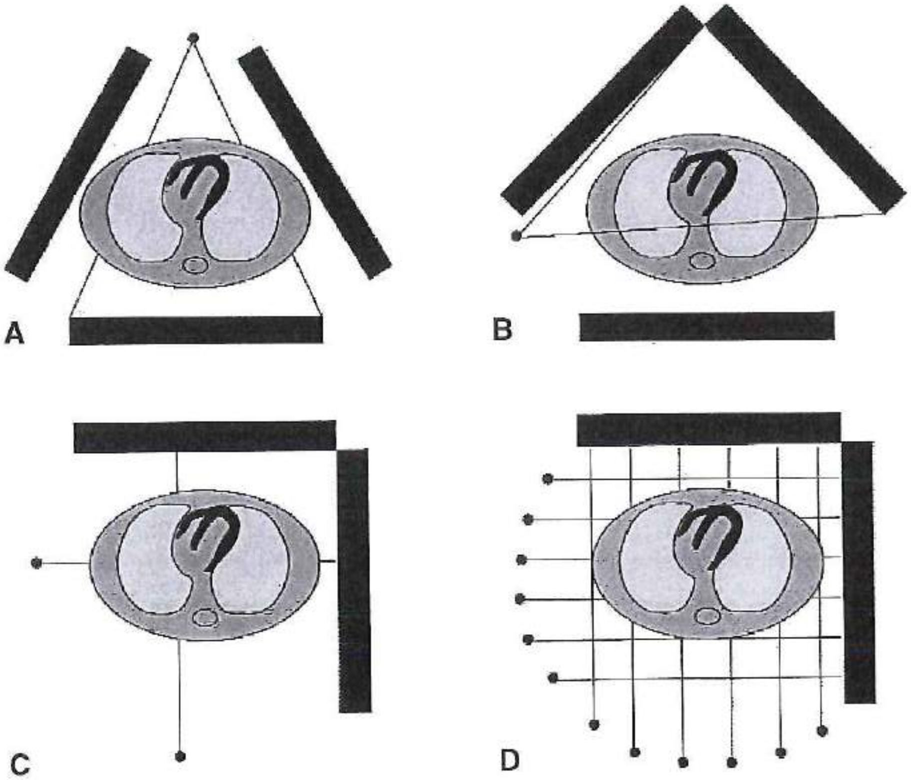


Figure 1. Commercial configurations for SPECT-based transmission imaging for cardiac attenuation-corrected myocardial perfusion imaging: fan-beam **(A)**, off-axis **(B)**, scanning line source **(C)**, and source array **(D)**.

ing breast binding, prone imaging, and electrocardiography-gated SPECT imaging. However, each technique is an indirect solution and possesses specific limitations. For example, normal regional wall motion on a gated SPECT study after stress is not helpful in distinguishing artifact from ischemia in the presence of a reversible perfusion defect. Therefore gated SPECT and other methods fail to provide a universal solution for attenuation artifacts.

The diagnostic accuracy of conventional SPECT is also compromised by artifacts associated with localized subdiaphragmatic tracer concentration in the abdominal viscera, including the liver, stomach, and bowel. Such visceral activity that approximates the heart may scatter into the adjacent left ventricular walls, resulting in artifactually increased associated count densities. Alternatively, intense visceral tracer concentration may result in a ramp filter (negative lobe) artifact, which results in decreased count densities adjacent to "hot" objects.

TECHNIQUES

Several types of systems with transmission hardware modifications and external sources have emerged for clinical implementation. They predominantly use gadolinium 153 (100 keV) as the external source but may use cobalt 57 (122 keV), barium 133 (360 keV), americium 241 (60 keV), and technetium 99m (140 keV). The main configurations (Figure 1) are (1) fixed line source with convergent collimation on a triple-detector system, (2) scanning line sources with parallel-hole collimation on dual 90° systems, (3) the multiple line source array approach with parallel-hole collimation on 90° dual-detector systems, (4) scanning point sources on dual- and triple-detector systems, and (5) rotating x-ray tube–based technology on dual-detector systems. Each system has unique attributes and limitations. The fixed line source with convergent geometry provides highly efficient transmission image acquisition that allows the use of comparatively low source strength. The limited field of view of convergent collimation can cause regions of the body to be outside of the field of view for some projection images, leading to truncation artifacts that may limit the accuracy of attenuation correction, unless highly sophisticated iterative reconstruction algorithms are used to minimize these effects.

The most widely implemented configuration for commercial transmission acquisition is the scanning line

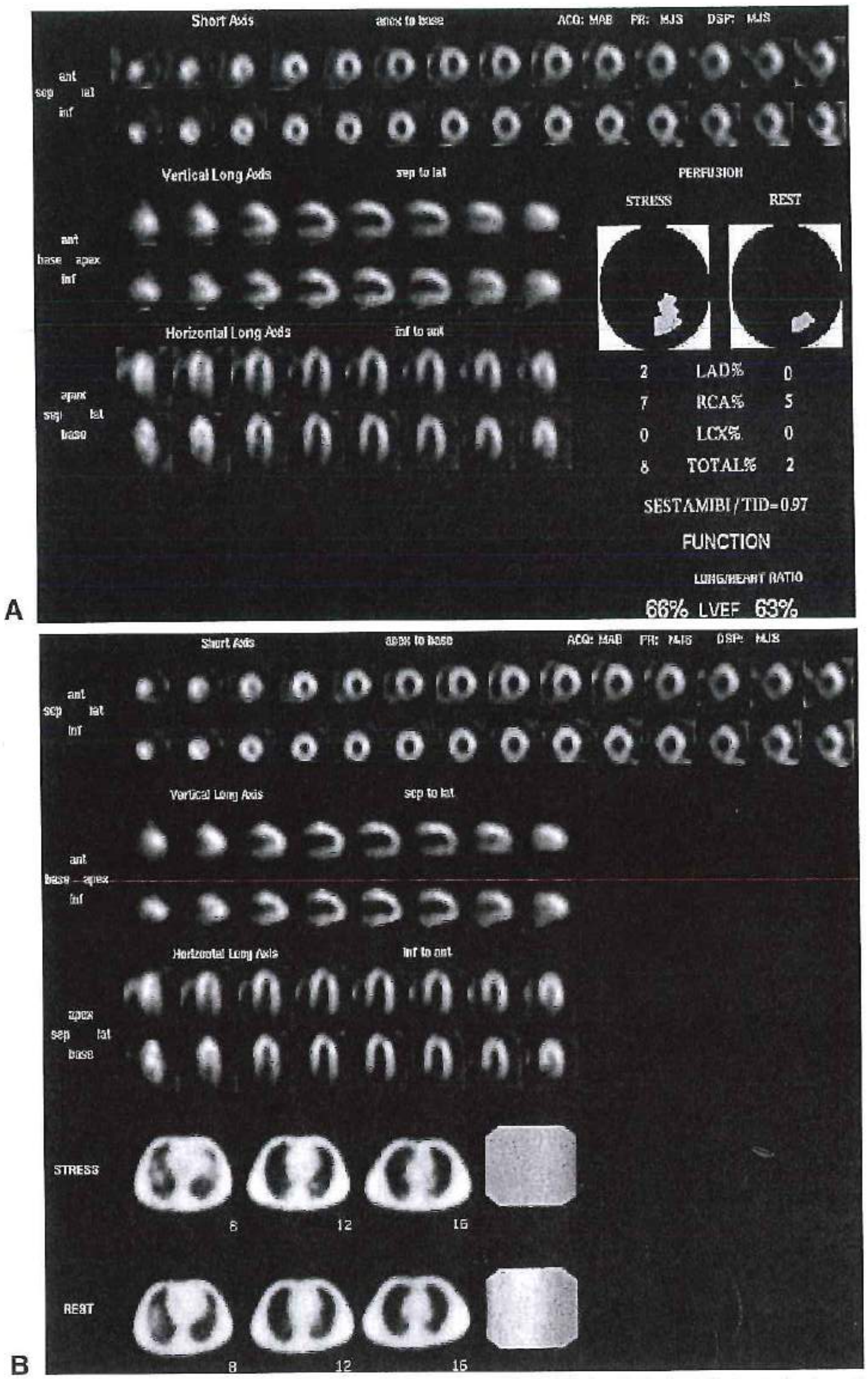
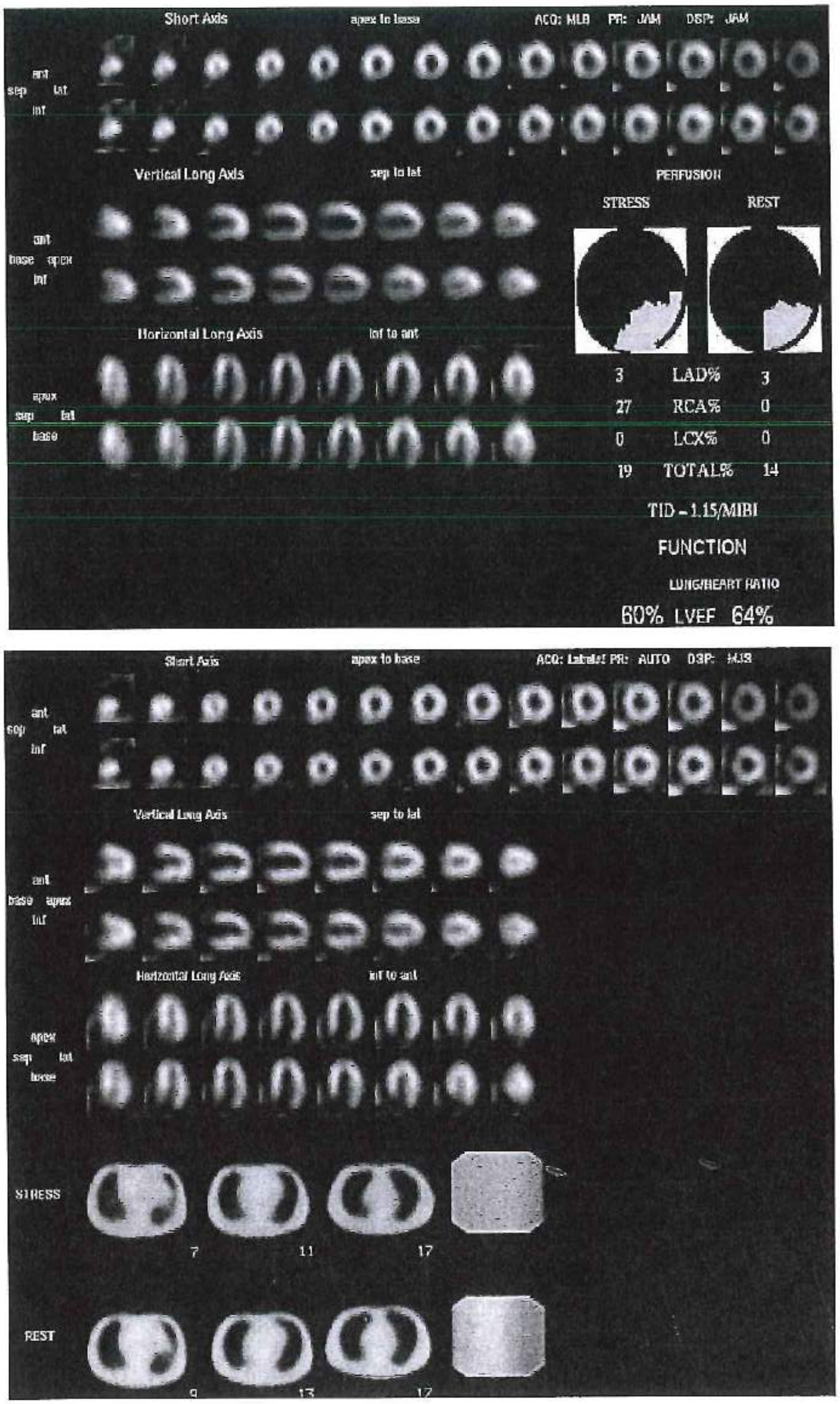


Figure 2. A, Exercise-rest Tc-99m sestamibi SPECT study, suggestive of ischemia in the inferior, inferolateral, and inferoseptal regions but confounded by the presence of possible subdiaphragmatic attenuation. **B,** After attenuation correction, the SPECT study demonstrates definite ischemia in the distribution of the right coronary artery. Attenuation map samples and daily reference scans are shown for quality control.

A



B

Figure 3. A, Exercise-rest Tc-99m sestamibi SPECT study in a large man depicting a persistent reduction of activity in the inferior and inferolateral regions of the left ventricle, suggestive of a prior infarction. B, Attenuation-corrected images reveal normal perfusion in all regions. Attenuation map samples and daily reference scans are shown for quality control.

Table 1. Diagnostic value of attenuation correction systems

Author	System	n	Sensitivity (%)		Specificity (%)		Normalcy (%)	
			NC	AC	NC	AC	NC	AC
Ficaro	U Mich	119	78	84	48	82	88	98
Hendel	ADAC	200	76	78	44	50	86	96
Links*	SMV	112	84	88	69	92	69	92
Gerson†	Picker	113	85	90	NA	NA	72	70
Gallowitsch	Elscint	49	89	94	69	84	NA	NA
Lenzo†	Siemens	171	93	93	84	88	78	85
Composite		764	81	85	64	81	80	89

NC, Non-attenuation-corrected SPECT; *AC*, attenuation-corrected SPECT; *NA*, not available.
*Includes motion correction and depth-dependent blur correction.
†Includes scatter correction.

source geometry on 90° dual-detector SPECT systems. This approach has collimated line sources that scan mechanically across the field of view at each angle and project onto the opposing detector, where an electronic window moves opposite the source to accept transmission photons. These systems have a maximum field of view, thereby minimizing the likelihood of patient truncation. The electronic window provides maximal separation of the emission and transmission images. Scanning hardware requires careful monitoring because some systems are prone to mechanical instability.

The multiple line source array approach uses groups of collimated line sources mounted on the gantry opposite the detectors for transmission image acquisition. This method provides highly efficient measurement geometry without the need for additional mechanical motion. The photon flux from the collimated source arrays spans the field of view of each opposing detector. The continuous incidence of the transmission source photons over the fields of view for both detectors with this geometry can cause significant crosstalk from downscatter with thallium 201 imaging requiring interleaved or sequential emission-transmission imaging.

A system that uses a conventional x-ray tube and detector mounted on a large–field-of-view SPECT gantry has recently been introduced. The photon flux is very high with this approach, yielding high-quality attenuation maps. This system was developed largely for anatomic registration with emission images for oncology studies but should have application in attenuation correction of cardiac images. A system that uses scanning point sources of Ba-133 (360 keV) has recently become available. The point sources are collimated, but the holes of the detectors are not aligned with the focal point of each source. The high-energy emissions from these sources penetrate the low-energy collimators' septa, forming the transmission projections from which the attenuation map is reconstructed.

CLINICAL TRIALS

One of the most encouraging methods was used by Ficaro and colleagues, who reported the results of attenuation correction in phantoms and patient cohorts using a 3-detector system equipped with 2 parallel-hole collimators for collection of emission data and a third detector with a fan-beam collimator to acquire the transmission data from an Am-241 line source. They demonstrated significant improvement in diagnostic accuracy in 60 patients with Tc-99m sestamibi SPECT imaging, with a marked improvement in specificity (from 48% to 82%) (Table 1). Similarly, in a group of 59 patients with a low likelihood of coronary artery disease, an increase in the normalcy rate from 88% to 98% was demonstrated. Although the increase in test sensitivity was not statistically significant, there were significant increases in sensitivity for individual vessels overall (63% vs 78%) and in 2 of 3 vascular territories.

The method used in the above trial was subsequently compared in 171 patients with the commercially available technique that uses the multiple line source array method for acquiring the transmission maps (Profile, Siemens). Profile attenuation correction demonstrated improved diagnostic specificity by patient, as well as sensitivity and accuracy for individual coronary arteries. Attenuation correction also demonstrated statistically significant increases in normalcy rates. The overall sensitivity by patient was similar with both the corrected and uncorrected images.

The first prospective multicenter trial was performed by Hendel et al using a commercially available 90° dual-

Table 2. Clinical value of attenuation correction

Confirmed	Potential
Improved artifact recognition	Increased sensitivity
Higher specificity	Improved recognition of MVD and LM
Higher normalcy rates	Enhanced prognostic value
Increased reader confidence	Stress-only imaging
Acute-use applications	Absolute flow quantitation

MVD, Multivessel coronary disease; *LM*, left main coronary disease.

detector system with a scanning Gd-153 line source (Vantage, ADAC Laboratories). The diagnostic sensitivity (n = 96) for the detection of 50% or greater stenoses was similar with the use of uncorrected perfusion data or attenuation- and scatter-corrected data. The normalcy rate (n = 88), however, was significantly improved (86% vs 96%, respectively), and false-positive perfusion images were reduced by more than 4-fold (from 14% to 4%). Furthermore, observer confidence for the presence or absence of image normalcy was increased, as reflected in the visual diagnostic scores. Regional differences were noted with reduced sensitivity but improved specificity for right coronary lesions through use of attenuation-scatter correction methods. However, the ability to detect multivessel disease was reduced with attenuation-scatter correction, which may have important prognostic implications.

Gallowitsch et al studied 107 patients with known or suspected coronary artery disease with Tl-201 imaging using another dual-detector system equipped with a scanning Gd-153 line source and an iterative Chang reconstruction algorithm (Transact, Elscint). There were no significant improvements in diagnostic accuracy noted in this trial, although specificity was somewhat improved with attenuation correction, from 69% for non–attenuation-corrected SPECT to 84% for attenuation-corrected SPECT (P = not significant).

Another multicenter trial was recently completed by Links et al using a similar system (TAC/Restore, SMV), in which the transmission data were acquired with a scanning Gd-153 source for Tc-99m emissions and a Tc-99m transmission source for Tl-201 emission imaging. The imaging algorithm incorporated a motion correction algorithm along with attenuation correction and depth-dependent resolution compensation. These investigators demonstrated significant gains in overall specificity (from 69% to 92%; $P = .002$) and in all 3 coronary territories. In addition, normalcy increased from 74% to 91% ($P = .04$) with combined attenuation, motion, and blur correction, and test sensitivity demonstrated a slight but insignificant increase from 84% to 88% (P = not significant).

Table 3. Quality control methods for attenuation correction

Ensure adequate count density
Recognition of truncation
Appropriate gating
Correct photopeak windowing
Recognition of patient motion
Transmission scan uniformity

Additional clinical trials are under way that are using second-generation systems (Vantage Pro, ADAC Laboratories), as well as new approaches for transmission map generation including the translucent collimator with high-energy photons (Ba-133) (Beacon, Marconi) described earlier. Hybrid systems, such as those that use x-ray computed tomography–generated transmission maps, may provide high-quality transmission maps as a result of the high count density and spatial resolution that these systems provide (Hawkeye, GE Medical Systems).

The impact of attenuation correction on the detection of coronary artery disease within a specific vascular territory is variable (Figures 2 and 3). Several studies have shown a substantial improvement in specificity for right coronary artery disease, but occasionally with a loss of sensitivity in either right coronary artery or left anterior descending coronary artery distribution. The promise of enhanced sensitivity is yet to be realized clinically, although a recent phantom study demonstrated that defect detection is improved with attenuation correction. In addition, some trials have demonstrated that attenuation correction enables improved recognition of multivessel and left main disease. Complete and accurate correction for attenuation and scatter would be a major step toward the long-held promise of absolute perfusion quantification and the enhanced diagnostic accuracy it would afford, especially in the setting of "balanced" 3-vessel disease.

Quantitative analysis programs specific for each camera system and radiopharmaceutical are limited but are under active development. It is anticipated that quantitative reference (normal) databases will be available for each manufacturer's system. Ideally, these databases obtained from healthy subjects should be gender-independent, assuming total correction for attenuation.

Attenuation correction may have substantial value for specific applications beyond the detection of coronary artery disease (Table 2). Preliminary data reveal superior diagnostic performance in the triage of emergency department patients with chest pain. Attenuation-corrected

SPECT images have demonstrated the ability to better detect areas of viable myocardium, correlate better with positron emission tomography imaging, and provide improved prediction of functional recovery after revascularization. Attenuation correction also possesses the potential to further improve the prognostic value of myocardial perfusion imaging, as patients with soft tissue attenuation artifacts may be more accurately categorized as being at low risk for cardiac events. The use of attenuation and scatter correction techniques may be especially valuable for less-experienced interpreters of myocardial perfusion studies, with improvements in both sensitivity and overall diagnostic accuracy demonstrated in some studies for this group of interpreters.

QUALITY CONTROL

Experience with SPECT myocardial perfusion data processed with filtered backprojection has led to widespread appreciation of the importance of quality control measures. Attenuation correction introduces a number of additional quality issues that, if not addressed systematically and satisfactorily, will translate into suboptimal and in some cases clinically misleading image data (Table 3). Over the past several years, it has become increasingly apparent that accurate attenuation correction is dependent upon high-quality transmission images, and to ensure accuracy, appropriate quality control measures have been developed. In particular, count densities must be sufficient to overcome the intrinsic inconsistencies of scans with poor signal-to-noise ratios. Other important quality control issues related to the creation of transmission maps include body truncation, patient motion, scaling of attenuation coefficients to the correct tissue densities, accurate registration of attenuation maps and emission data, and gating artifacts unique to attenuation correction processing, especially with scanning transmission source systems. Objective measurements of these technical factors are crucial to the accuracy of attenuation correction. Automated quality control procedures should be provided by each vendor and routinely used.

Correct windowing of relevant photopeaks for attenuation-corrected SPECT imaging is also essential. Besides the energy window of the main emission photon, additional windows are required for transmission data and for scatter and crosstalk measurements; scatter and crosstalk between transmission and emission photopeaks significantly degrade the quality of the attenuation map.

Reference transmission scans should be performed daily to ensure optimal equipment performance and should include quantitative analysis. In addition, each manufacturer should provide automatic safeguards to ensure that the transmission and emission data are reconstructed properly. Finally, education of technologists, physicists, and interpreting physicians is an essential component of the quality assurance process.

Therefore quality control should include each of the following for the performance of attenuation correction: criteria for uniformity, variability, and temporal drift of the reference transmission scan; consistency of hardware performance; pre-scanning methods to ensure sufficient transmission scan counts; and algorithms that assist the operator and interpreting physician in assessing the sufficiency of the data. Although these tools are essential to all commercial methods of attenuation correction, implementation of many of the aforementioned quality control techniques has not been incorporated in the current releases of all available attenuation correction protocols. Furthermore, quality control of transmission data and attenuation-corrected reconstructed images should be performed for each patient.

SCATTER CORRECTION AND DEPTH-DEPENDENT RESOLUTION

Attenuation-corrected images, although usually of higher diagnostic quality than uncorrected images, need to be corrected for scattered photons coming from activity in structures near the heart, such as the liver and intestines. These scatter photons may result in regional overcorrection following attenuation correction techniques. The planar transmission images also must be corrected for scatter into the energy window of the transmission source because failure to perform scatter correction may result in undercorrection for attenuation.

Simultaneous emission-transmission acquisition methods must address crosstalk from downscattering of photons from the emission or transmission photopeaks (whichever is higher). Crosstalk minimization is accomplished through the geometric design of the transmission sources and detectors and consideration of the position of the patient and possible scattering angles. Software methods applied after image acquisition may be used to correct for crosstalk with data collected in additional energy windows. In order to perform attenuation, scatter, and crosstalk correction, 3 or 4 independent energy windows for data must be collected: one window for the emission information (perfusion photopeak energy); a second window for transmission data (photopeak of transmission source); a third window for scatter, positioned between the other windows; and in some systems, a fourth window, slightly above the emission window, used in conjunction with the third window to estimate scatter.

In addition to correcting for attenuation, some methods correct for photopeak scatter and the variable distance-dependent spatial resolution from the collimator.

These are primarily software implementations that use additional "scatter" information acquired simultaneously with the emission data, models of the distance-dependent collimator effects, and knowledge of the orbital position of the detectors. Scatter compensation may be performed by mapping photons back to their point of origin; although promoting less noise propagation, this approach may require substantial computation time.

Image degradation is related to increasing cross-sectional area detected by each collimator hole with distance (depth) from a radioactive source, thereby creating a loss of resolution with increasing object distance away from the collimator. The use of iterative correction algorithms may be applied for Compton scatter, photon attenuation, and depth-dependent resolution to achieve higher contrast between perfusion defects and more uniformly distributed counts within normal myocardium. One commonly employed method for such compensation is the use of collimator- and energy-dependent pre-processing filters.

CONCLUSION

Attenuation correction SPECT techniques represent a significant advance in myocardial perfusion imaging and hold great promise for improved assessment of cardiac patients. Substantial technical advances have been made in the past several years, including the recognition of the importance of effective quality control and the continued development of scatter correction and resolution compensation. Advanced SPECT perfusion imaging systems, including features such as attenuation correction, must undergo complete system characterization, development of normal activity distribution profiles, and definition of differences among various manufacturers' solutions. Finally, quantitative analysis programs adapted for each camera system and radiopharmaceutical are limited but are under active development. Ideally, reference databases from healthy subjects should be gender-independent after total correction for attenuation.

Clinical validation has been performed for several but not all commercially available systems, although "complete" correction still does not occur in all patients. The true value of these methods to improve diagnostic accuracy compared with other techniques has yet to be fully defined. Attenuation correction methods offer the potential for improved diagnostic accuracy but require a modified approach to image interpretation accounting for the effects of these methods on the resultant images. Technologist and physician education in the details of these advanced imaging techniques, along with effective quantitative tools and improved processing algorithms, will continue to advance the value and acceptance of attenuation-corrected SPECT imaging.

RECOMMENDATIONS

On the basis of the available clinical evidence and the rapid development of attenuation correction technology, it is recommended that providers (institutions and practitioners) consider the addition of hardware and software that have undergone clinical validation and include appropriate quality control tools to perform non-uniform attenuation correction. Currently, it is suggested that both noncorrected and corrected image sets be reviewed and integrated into the final report. However, as the reader gains the appropriate experience and confidence in correction methodology, only the corrected images may be necessary, as is the standard in positron emission tomography. On the basis of current information and the rate of technology improvement, the Society of Nuclear Medicine and the American Society of Nuclear Cardiology believe that attenuation correction should be regarded as a rapidly evolving standard for SPECT myocardial perfusion imaging. Therefore it is our recommendation that the adjunctive technique of attenuation correction has become a method for which the weight of evidence and opinion is in favor of its usefulness.

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The authors have indicated they have no financial conflicts of interest, unless stated otherwise in the Appendix.

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APPENDIX

The Boards of Directors of the American Society of Nuclear Cardiology and the Society of Nuclear Medicine have reviewed and approved this position statement with the belief that it provides balanced and objective information on the value of attenuation correction for myocardial perfusion SPECT imaging. However, to ensure that the most recent information and diverse perspectives on attenuation correction were included in this statement, individuals with potential conflicts of interest participated in the development of this document. The following contributing authors have provided declarations of potential conflicts of interest as listed and have excluded themselves from the final position statement review and approval process: Timothy M. Bateman, MD, stock ownership (Cardiovascular Consultants Imaging Technologies, Inc) and research grants (ADAC Laboratories, Inc, and Dupont Pharmaceuticals), and S. James Cullom, PhD, and Ernest V. Garcia, PhD, royalties from the sale of ExSPECT II software (ADAC Laboratories, Inc).

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Clinical Applications of SPECT/CT: New Hybrid Nuclear Medicine Imaging System

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FOREWORD

Interest in multimodality imaging shows no sign of subsiding. New tracers are spreading out the spectrum of clinical applications and innovative technological solutions are preparing the way for yet more modality marriages: hybrid imaging.

Single photon emission computed tomography (SPECT) has enabled the evaluation of disease processes based on functional and metabolic information of organs and cells. Integration of X ray computed tomography (CT) into SPECT has recently emerged as a brilliant diagnostic tool in medical imaging, where anatomical details may delineate functional and metabolic information.

SPECT/CT has proven to be valuable in oncology. For example, in the case of a patient with metastatic thyroid cancer, neither SPECT nor CT alone could identify the site of malignancy. SPECT/CT, a hybrid image, precisely identified where the surgeon should operate.

However SPECT/CT is not just advantageous in oncology. It may also be used as a one-stop-shop for various diseases.

Clinical applications with SPECT/CT have started and expanded in developed countries. It has been reported that moving from SPECT alone to SPECT/CT could change diagnoses in 30% of cases. Large numbers of people could therefore benefit from this shift all over the world.

This report presents an overview of clinical applications of SPECT/CT and a relevant source of information for nuclear medicine physicians, radiologists and clinical practitioners. This information may also be useful for decision making when allocating resources dedicated to the health care system, a critical issue that is especially important for the development of nuclear medicine in developing countries. In this regard, the IAEA may be heavily involved in the promotion of programmes aimed at the IAEA's coordinated research projects and Technical Cooperation projects.

The IAEA wishes to express its thanks to all experts who have contributed to this publication. The IAEA officer responsible for this publication was N. Watanabe of the Division of Human Health.

EDITORIAL NOTE

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CONTENTS

1. INTRODUCTION

During the past several years there has been growing utilization of PET/CT, based on the fact that functional and morphologic correlative images produced by this methodology improve diagnostic accuracy. Similar progress is now being reported for SPECT/CT, a modality which is rapidly evolving from a somewhat under-utilized technical option to gain an acknowledged status for optimizing the diagnostic capabilities of single photon imaging, with potential impact on patient management.

SPECT and CT are tomographic imaging procedures, each one with separately proven good diagnostic performance. SPECT produces computer-generated images of local radiotracer uptake, while CT produces 3-D anatomic images of X ray density of the human body. Combined SPECT/CT imaging provides sequentially functional information from SPECT and the anatomic information from CT, obtained during a single examination. CT data are also used for rapid and optimal attenuation correction of the single photon emission data.

By precisely localizing areas of abnormal and/or physiological tracer uptake, SPECT/CT improves sensitivity and specificity, but can also aid in achieving accurate dosimetric estimates as well as in guiding interventional procedures or in better defining the target volume for external beam radiation therapy.

Gamma camera imaging with single photon emitting radiotracers represents the majority of procedures in a routine nuclear medicine practice. Many of these examinations are tumour or cardiac imaging studies. The development of better instruments, newer computer based procedures for image analysis and display, new ^{99m}Tc labelled agents for visualizing biologically significant events (such as cellular growth, hypoxia, angiogenesis, apoptosis) may enhance the future value of SPECT/CT in terms of both clinical impact on patient care and cost effectiveness, as compared to PET/CT.

Diagnosis and characterization of disease by CT imaging is based on morphologic criteria such as size, texture and tissue attenuation. CT provides information regarding changes in organ size and tissue density, as well as their precise spatial localization and topographic landmarks. However, structural data do not necessarily correlate with the metabolic status of disease. On the other hand, nuclear medicine imaging is based on the bio-distribution of a radioactive agent over time and space, thus visualizing dynamic physiological and pathophysiological processes that define the functional characteristics of disease. Furthermore, whole body assessment is possible with a single radiation exposure, as the ionizing agent is administered to patients rather than being delivered from an external source to each region of the body to be evaluated, as performed with radiologic imaging (e.g. conventional X ray or CT). However, scintigraphic images lack accurate anatomic landmarks for precise localization and characterization of findings, in spite of the fact that specific radiopharmaceuticals are used for assessment and diagnosis of specific disease processes. The above mentioned considerations explain why morphologic and functional imaging modalities are complementary and not competing techniques, especially if precise image registration is made possible by using a single imaging unit combining the emission based data (SPECT) with the transmission based data (CT, which also serve to correct the emission data for tissue attenuation). Image registration is the process of determining the geometric relationship between multimodality imaging studies, in order to use information provided by one test in the context of the other modality.

2. OVERVIEW OF SPECT/CT TECHNOLOGY

2.1. Update on SPECT/CT installations worldwide

While image fusion techniques have been in clinical use for many years, the first commercial SPECT/CT system was only introduced in 1999. This system combined a low-power X ray tube with separate gamma and X ray detectors mounted on the same slip ring gantry. The X ray system operated at 140 kV with a tube current of only 2.5 mA. This resulted in a significantly lower patient dose than that received during a conventional CT imaging procedure (by a factor of 4–5), but the quality of the CT images was inferior to state of the art CT. Nevertheless, the fan beam formed by the X ray tube on the detectors allowed the measurement of patient attenuation along discrete paths providing significantly higher quality attenuation maps than those available with conventional ^{153}Gd scanning lines sources [1, 2].

This system has recently been equipped with a 4 slice low-dose CT scanner yielding an axial slice thickness of 5 mm with each rotation instead of one 10 mm slice. This tool retains the very compact design of the previous system, delivers a low radiation dose to the patient and requires minimal room shielding [2, 3]. Over the last 2–3 years there has been a large expansion of SPECT/CT technology worldwide and, as at June 2007, there are approximately 600 of these installations around the world and over 200 across the United States. The relatively large distribution of these SPECT/CT systems equipped with a low definition CT tube versus those equipped with high definition, standard diagnostic CT tubes (see below) can be explained by two main factors: 1) this is the first SPECT/CT system made commercially available, and 2) the overall cost of these tomographs (equipped with a low definition CT component) is considerably lower than that of tomographs equipped with a CT component having full diagnostic capabilities.

In this regard, following the commercial success of PET/CT systems that employ multi-slice CT scanners, there has been growing interest in the development of comparable SPECT/CT systems. Thus, in an effort to further improve imaging quality and reduce acquisition time, new hybrid systems employing state of the art spiral CT scanners have been developed. These systems combine dual-head gamma cameras with full diagnostic, up to 16 slice CT scanners that allow variation of CT slice thickness from 0.6 mm up to 10 mm, yielding diagnostic quality CT images with a scan speed shorter than 30 s for a 40 cm axial field of view [2, 3]. However, because of the addition of a separate CT gantry, these systems are considerably larger than conventional SPECT systems and have very different setting and shielding requirements compared with the system equipped with the low definition CT tube. Since their introduction in the market, over 210 such units have been installed worldwide.

Access to hybrid systems is limited in several countries due to their high cost, SPECT/CT systems based on combining a 'gantry-free' commercial SPECT system with a single- or multiple-slice CT scanner have recently been developed [4, 5]. In the future, further cost reduction and technological improvement are desirable in order to encourage a larger diffusion of such devices worldwide.

2.2. General architecture of SPECT/CT devices

SPECT/CT systems have the same SPECT component as conventional nuclear medicine systems, the dual-head gamma cameras are generally used for planar and tomographic imaging of single photon emitting radiotracers. As mentioned above, the CT component of the first-generation hybrid devices used a low resolution CT detector while recently developed, second-generation SPECT/CT systems incorporate a variety of multi-slice CT scanners. SPECT/CT systems include separate CT and gamma camera devices using common or adjacent mechanical gantries, and sharing the same scanning table. Integration of SPECT and X ray imaging data is performed by a process that is similar to that of PET/CT.

X ray scatter can reach and possibly damage the SPECT detectors designed for radionuclide low count rate imaging. Therefore, in a hybrid system the SPECT detectors are off-set in the axial direction from the plane of the X ray source and detector. In a hybrid system both detectors have to be able to rotate and position accurately for tomographic imaging. In this regard, accuracy of translation and angular motion differs from one imaging system to another. While CT requires the highest accuracy, SPECT (with a lower spatial resolution) can perform clinical images with a motion accuracy of slightly less than one millimetre.

SPECT/CT systems using a low-dose single- or multi-slice CT have both the SPECT and the CT detectors mounted on the same rotating platform. Imaging is performed while the detectors are rotating sequentially around the patient. While this concept has the advantage of using the gantry of a conventional gamma camera for both imaging modalities, it limits the rotational speed of the SPECT/CT option to approximately 20 seconds per rotation. In SPECT/CT systems incorporating diagnostic CT scanners, the gamma camera detectors are mounted on a different platform, separated from the high speed rotating CT device (0.25 to 0.5 s per revolution). This design increases the performance of the CT subsystem, but it also increases the complexity of the gantry and the cost of the technology.

Dual modality imaging requires longer stretchers than single modality imaging devices. While built to support patients weighing up to 500 pounds, these scanning tables, extended to accommodate the needs of both components (SPECT and CT), deflect to some degree while loaded with normal adult patients. The extension and degree of deflection of the table can introduce a patient-dependent mis-registration between CT and SPECT data. One solution to this problem is the design of a table supported on its base at the front of the scanner as well as at the far end of the X ray system, thus minimizing the table deflection. Another solution is to use a table fixed on a base, moving on the floor to introduce the patient into the scanner.

The workstation of the SPECT/CT device is responsible for system control, data acquisition, image reconstruction and display, as well as data processing and analysis. CT data are calibrated in order to obtain attenuation correction maps for the SPECT images. SPECT and CT images are displayed on the same screen in addition to the fused images, which represent the overlay of a coloured SPECT over a grey-scale CT image. A 3-D display with triangulation options allows to locate lesions and sites of interest on the CT image and to redisplay them on the registered SPECT and fused SPECT/CT images.

2.3. SPECT/CT acquisition protocols

Acquisition on SPECT/CT systems is performed in a sequential mode. With devices that have a low-dose CT component, data are typically acquired by rotating the X ray detector 220° around the patient, with the X ray tube operated at 140 kV and 2.5 mA. The CT images obtained have an in-plane spatial resolution of 2.5 mm, and of 10 mm in the axial direction. Scan time is approximately 16 s per slice, for a total study duration of 10 min for the CT. SPECT/CT systems using a diagnostic CT component are characterized by higher spatial resolution and faster scanning time (approximately 30 s for the whole field of view), associated however with higher radiation doses. An attenuation map is created at the end of the CT acquisition time.

The SPECT component is represented by a rotating, dual-head, variable angle sodium-iodide scintillation camera. The detectors can be placed either in a 180° or a 90° position. Regardless of the type of SPECT/CT that is used, SPECT acquisition currently requires a routine scanning time of approximately 20–30 min, depending on the radiotracer, as for stand-alone SPECT acquisition protocols. SPECT is reconstructed using iterative methods incorporating photon attenuation correction based on the X ray transmission map and scatter correction.

Since X ray and radionuclide data are not acquired simultaneously, SPECT images are not contaminated by scatter radiation generated during the X ray image acquisition. Also, since the patient is not removed from the table, both imaging components are acquired with a consistent and identical patient position, allowing accurate image registration if we assume that the patient has not moved during the entire duration of the SPECT/CT study. CT is usually acquired in matrices of 512 × 512 with the newest CT scanners, or 256 × 256 in older scanners, and has to be resized into slices with the same pixel format and slice width as SPECT. Spatial registration of the CT and SPECT acquisitions is important since misalignment of the attenuation map relative to corresponding radionuclide images can cause 'edge artefacts', bright and dark 'rims' across edges of these regions.

SPECT/CT image mis-registration or blurring may occur, mainly due to patient movement as well as respiration, cardiac motion, and peristalsis. Differences in urinary bladder filling can lead to erroneous co-registration between SPECT and CT acquisitions. With SPECT/CT devices equipped with low-dose X ray tubes, CT is performed during shallow breathing to facilitate image registration. However, the longer acquisition time increases the chances for patient motion. With hybrid devices equipped with multi-slice CT, anatomic imaging is acquired following breath-hold, during tidal breathing, or during a short part of the respiratory cycle, whereas SPECT data are acquired over several minutes. This again can lead to mis-registration. In addition to faulty localization, non-registered attenuation maps can lead to under- or overestimation of radionuclide uptake.

The presence of contrast media in the CT images acquired as part of the SPECT/CT study complicates the attenuation correction process. Also, high concentrations of intra-venous contrast material captured during the CT acquisition may have redistributed by the time the SPECT acquisition is performed. Image segmentation techniques separating different areas inside the images may solve this problem, or alternatively, a very low powered non-contrast CT can be performed prior to the SPECT for attenuation correction, followed by the contrast CT study as the last step.

2.4. Technical staffing for SPECT/CT

A major asset for proper implementation of novel SPECT/CT procedures is the technologist. It is important to take the time to train and educate the technologists so that they can deliver an end product of the highest quality. While it is preferable for technologists to have their work product directly checked by the interpreting physician before the patient leaves the department, in some outpatient settings technologists must make their own decision, and therefore they need to be well trained and using robust and reproducible protocols. The new generation technologists therefore have to be trained in nuclear medicine and CT, to have experience in reviewing scans and to be able to identify artefacts occurring during acquisition of studies. Instructing the technologists about pertinent history questions and designing a template to be filled out for each patient will ensure that all of the clinical information to further assist in the reading of the images is available. Training requirements for CT and SPECT technologists differ in various countries. Under ideal circumstances a technologist should be fully trained, experienced and certified in both nuclear and X ray/CT technologies.

3. GENERAL NUCLEAR MEDICINE SPECT/CT PROCEDURES

The SPECT component of the SPECT/CT procedure is performed using the acquisition protocols routinely employed for the dual-head gamma camera. This device is equipped with collimators adequate for the specific radioisotope in use, such as low energy, high resolution parallel hole collimators for ^{99m}Tc, or medium energy collimators for ^{67}Ga, ^{111}In or ^{131}I. Imaging is typically performed with the detectors facing each other at 180°, typically acquiring 120 projections over a 360° orbit and using a time per projection of 40–50 s. A 64 × 64 matrix is commonly employed for the low count isotopes, while the higher resolution 128 × 128 matrix can be applied for the higher count rates typically generated by ^{99m}Tc.

CT images are obtained immediately following the SPECT acquisition. For the low-dose CT devices the acquisition parameters include settings at 140 kV, 1–2.5 mA, 13 s/slice, 256 × 256 image matrix, 5 mm slice thickness and slice spacing. For diagnostic CT acquisitions the settings are 140 kV, 80 mA, 1 s/slice, 512 × 512 image matrix, 48 cm reconstruction diameter, 5 mm slice thickness and slice spacing. Skeletal CTs of diagnostic quality can be performed at lower mAs products to reduce the radiation exposure of the patient. A variety of other settings are possible depending on the specific diagnostic question asked of the CT scanner. These include, in particular, protocols to perform low powered CT with the multi-detector scanners, e.g. when a CT of diagnostic quality is already available or high powered CT is not deemed necessary for the particular question under study. Some strategies restrict the CT field of view to the regions exhibiting SPECT abnormalities, thus reducing the radiation dose delivered to the patient even further [6]. Data are reconstructed using filtered back-projection software and filters provided by the manufacturer.

Co-registered CT and SPECT are acquired by translating the patient from one detector to the other while the patient remains lying on the same table. This allows the CT and radionuclide images to be acquired with a consistent scanner geometry and body habitus, and with a minimal delay between the two acquisitions.

3.1. ^{131}I-Iodide SPECT/CT in thyroid cancer

Well differentiated thyroid cancer has an incidence of approximately 1:10 000 [7]. Its standard treatment includes total thyroidectomy and therapy with ^{131}I-iodide [8, 9]. With this combined approach, overall 5 year survival rates exceed 95%. However, the long term prognosis is worse for patients who present with locally advanced tumours or distant metastases at diagnosis, as well as in case of dedifferentiated neoplasms (because of their reduced iodine-trapping property) [10]. This subgroup accounts for approximately 20% of patients with well differentiated thyroid carcinomas and deserves special attention on follow-up.

The therapeutic effect of ^{131}I is provided by its beta-emission. In addition, this isotope of iodine emits 364 keV gamma rays that can be detected by gamma cameras. Therefore, ^{131}I is also used as a diagnostic agent since most, but not all metastases of thyroid carcinoma have retained the normal thyroid parenchyma's ability to accumulate iodine. The bio-distribution of ^{131}I is usually sufficiently defined by planar scintigraphy. SPECT is only rarely used for this purpose, as the image quality of ^{131}I-SPECT is hampered by the high energy of the gamma radiation emitted by this radionuclide.

^{131}I is only poorly concentrated by most extrathyroidal tissues. The salivary glands, stomach, intestines, and urinary bladder are the most notable exception to this rule. Thus, gamma camera images of ^{131}I distribution in the human body lack anatomical detail, because no clear reference landmarks can be recognized. This renders localization of radioiodine foci difficult, if not impossible at times, and may constitute a problem in those patients in whom surgical removal of metastases is indicated.

Iodine-avid metastases can be small. Furthermore, they may occur in regions exhibiting distorted anatomy due to previous surgery. Their localization using CT or MRI may therefore also not be possible. SPECT/CT co-registration certainly is an elegant method of localization (Fig. 1), although the evidence to this effect is still scarce. Papillary and, albeit to a lesser extent, follicular thyroid carcinomas metastasize frequently to the cervical and mediastinal lymph nodes. Therefore, dissection of the central cervical lymph nodes is, in many cases, part of the initial surgical procedure [11]. Despite a theoretically total thyroidectomy, a variable amount of normal thyroid parenchyma persists within the patient. This provides the rationale for postoperative radioiodine therapy for ablation of thyroid remnants. On the post-therapeutic radioiodine scans, the high activity contained in this parenchymal residue may hamper cervical N staging in many cases. With SPECT/CT, this problem may be overcome (Fig. 2). Preliminary data using SPECT/CT indicate that approximately one fourth of patients may actually harbour cervical lymph node metastases at the time of radioiodine ablation, the majority of which elude detection by planar imaging [12]. Clearly, further longitudinal studies are needed to define the possible clinical impact of this previously unavailable early information on cervical lymph node involvement.

(A) (B)

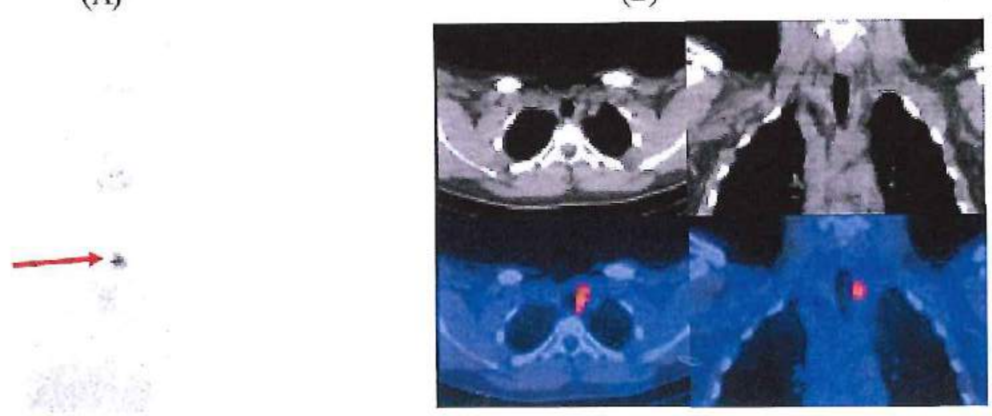


FIG. 1. (A) The planar ^{131}I-iodide scan in a 16 year old patient with thyroid cancer discloses an iodine-avid focus (arrow). The patient had had three surgical procedures (including total thyroidectomy) and 37 GBq of ^{131}I, so that this focus indicates the presence of a further lymph node metastasis. Considering scarring from prior surgeries, exact localization of this lesion is an essential requisite for its surgical resection. This anatomic information can only be achieved by SPECT/CT (B).

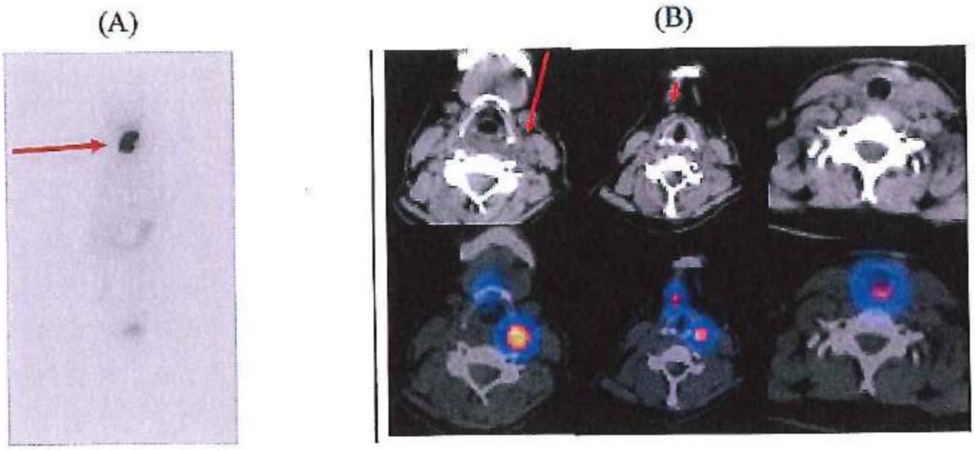


FIG. 2. (A) The planar scan post-radioiodine ablation of thyroid remnants shows radioiodine-avid tissue in the neck of a patient after total thyroidectomy, without the possibility of discriminating ^{131}I uptake in remnant normal thyroid parenchyma from possible lymph node metastasis. (B) SPECT/CT demonstrates two cervical lymph nodes in this patient (arrows) that cannot be differentiated from benign remnant tissue in the planar scan.

Although ^{131}I uptake is quite specific for tissue originating from the thyroid gland, the list of false–positive findings on planar whole body scans is quite long [13]. Only in rare instances, false–positive findings are accounted for by ^{131}I uptake in cancers of non-thyroid origin, such as small-cell bronchial carcinomas. Persisting thymic tissue has been described to concentrate radioiodine and may be the benign correlate of mediastinal ^{131}I accumulation frequently seen in children and young adults. In addition, many false–positive scans are caused by structural abnormalities of organs physiologically excreting radioiodine, or by contaminations of the skin. All such false–positive findings reduce specificity of the scan.

Clearly, ^{131}I uptake in metastases may be mistaken for physiological uptake if it is seen in regions where this usually occurs, thus lowering the sensitivity of ^{131}I scintigraphy. However, probably due to the lack of a reliable gold standard, evidence on sensitivity and specificity of radioiodine scanning is scarce. Furthermore, the recent introduction of ultra-sensitive assays for serum thyroglobulin (a marker of persistent/recurrent disease after surgery and radioiodine ablation of thyroid remnants) is somewhat changing the approach to the follow-up of these patients, especially in the low-risk group [14–18]. Nevertheless, by offering the possibility to precisely localize ^{131}I uptake, SPECT/CT is expected to improve the diagnostic accuracy of radioiodine scanning and therefore to have a significant effect on patient management. As yet two publications have dealt with this issue [12, 19]. Tharp and colleagues retrospectively studied the diagnostic impact of ^{131}I-SPECT/CT imaging in a heterogeneous group of 71 patients with thyroid cancer [12]. In 61 of these, SPECT/CT was used to evaluate the neck, allowing a precise characterization of equivocal lesions on planar imaging in 14/17 patients and changing the assessment of the lesion localization in five patients as compared with planar studies. Thirty-six patients of that group had SPECT/CT for foci of uptake distant from the neck. In this subgroup, SPECT/CT identified equivocal lesions as definitely benign in nine patients. Furthermore, it helped to precisely localize malignant lesions in seventeen patients. The incremental diagnostic value of SPECT/CT was reported to be 57% in the whole group. Ruf et al. investigated the benefit of SPECT/CT hybrid imaging in 25 patients with thyroid carcinoma exhibiting 41 foci of ^{131}I uptake considered inconclusive on planar imaging

[19]. Of these foci, 95% were correctly classified as benign or malignant by hybrid imaging, the gold standard for final classification being represented by clinical follow-up and/or additional ultrasound, CT, or MRI. In the patient based analysis, SPECT/CT was found to change the therapeutic procedure in 25% of the subjects studied.

These pilot studies suggest that diagnostic improvements brought about by SPECT/CT in patients with thyroid carcinoma are considerable. However, considering the variable clinical presentations of differentiated thyroid cancer, validity of the above conclusion should be based on large-scale multi-centre prospective studies enabling stratification of patients into statistically meaningful homogeneous subgroups.

3.2. Neural crest and adrenal tumours

Pheochromocytomas and paragangliomas are chromaffin cell tumours originating from the adrenal medulla and from the paraganglia, respectively. Sympathetic-derived paragangliomas are most frequently located in the retroperitoneum and thorax, while parasympathetic paragangliomas are located near the aortic arch, neck and skull base. These tumours are said to follow in general the 10% rule: approximately 10% are malignant, 10% familial, 10% extra-adrenal, 10% bilateral, and 10% occur in children [20, 21].

Early diagnosis, accurate pre-treatment staging and adequate follow-up are crucial as to the possibility of curing such tumours. Although multi-detector row CT and high-field MRI are reliable for accurate evaluation of these tumours and are usually employed for initial imaging, they are inadequate for whole body assessment (especially MRI).

Radioiodinated metaiodobenzylguanidine (MIBG), an analogue of norepinephrine and guanethidine, was the first radiopharmaceutical capable of specifically depicting and localizing catecholamine-secreting tumours, including pheochromocytomas and paragangliomas. Nowadays, MIBG scintigraphy (generally performed with the ^{123}I labelled radiopharmaceutical) is still regarded as one of the first-choice imaging techniques for diagnosis and follow-up, as it depicts primary and residual or recurrent tumours, as well as metastatic lesions, with an overall accuracy of about 90% [22]. Moreover, in patients with malignant disease, MIBG scintigraphy is an essential step to select patients for ^{131}I-MIBG therapy.

However, the clinical utility of MIBG scintigraphy is often impaired by a lack of accurate anatomical information, in particular with regard to lesion localisation. Nevertheless, the combination of anatomical maps and scintigraphic imaging, as provided by the SPECT/CT hybrid systems, has allowed a significant improvement in localizing MIBG-avid foci (Fig. 3), mainly by more precisely defining the tumoural extension and by increasing specificity (as it permits to exclude disease in foci of tracer uptake identified as sites of physiological accumulation). In this respect, major benefits have been observed in case of tumours located near organs with high physiological tracer uptake, such as liver and myocardium, and when characterizing areas of normal MIBG bio-distribution or excretion, thus avoiding the need for delayed imaging [23, 24].

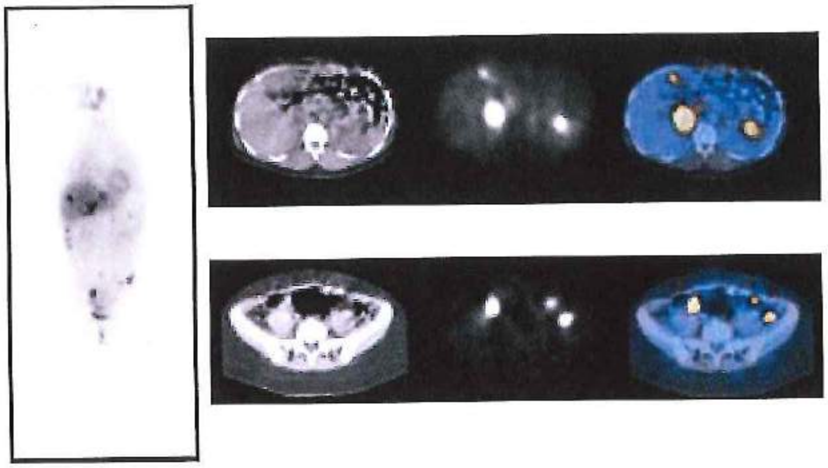


FIG. 3. ^{123}I-MIBG scintigraphy in a 26 year old woman who had undergone laparoscopic left adrenalectomy 5 years earlier because of pheochromocytoma. Despite histological appearance of benign pheochromocytoma, symptoms and biochemical markers of disease recurred, leading to the diagnostic scan. The whole body planar scan (left panel) shows multiple foci of tracer uptake in the abdominal area, most notably in the liver and in other areas suggesting possible lymph node metastases. However, SPECT/CT images (upper and lower right panels) show that such foci represent peritoneal implants rather than visceral or lymph node metastases, possibly secondary to intra-surgical dissemination of benign pheochromocytoma cells.

Ozer et al. have explored the role of fused SPECT/CT imaging for MIBG scintigraphy in a series of 31 patients with suspected pheochromocytoma [25]. In 81% of the cases, fused images correctly characterized the focal tracer uptake detected on planar ^{123}I-MIBG scan as physiological intestinal, renal or hepatic accumulation. Furthermore, SPECT/CT correctly localized focal accumulation in the adrenal glands of four patients and differentiated bone metastases from a local recurrence of pheochromocytoma in two patients. SPECT/CT also discriminated MIBG uptake in a retroperitoneal recurrence from adrenal hyperplasia consequent to contralateral adrenalectomy [26].

Neuroblastomas and ganglioneuroblastomas are poorly differentiated tumours arising from precursors of the sympathetic nervous system that typically occur in infants and young children. Neuroblastoma is the most common extracranial solid tumour of childhood. It may arise anywhere along the sympathetic chain, but most commonly occurs in the adrenal gland, with metastases present in 50–60% of patients at the time of diagnosis. Prognosis is affected by age, site of the primary tumour, and surgical resectability. Ganglioneuroblastomas are transitional tumours of sympathetic cell origin that contain elements of both malignant neuroblastoma and benign ganglioneuroma [21]. The most common tumour sites are the adrenal medulla (35%), retroperitoneum (30–35%), posterior mediastinum (20%), neck (1–5%), and pelvis (2–3%).

MIBG scintigraphy is useful not only for identifying the primary tumours, but also to monitor the pattern of metastatic spread (with an overall 92% sensitivity and 96% specificity) and response to treatment [22]. However, fused SPECT/CT images are expected to further improve its diagnostic accuracy, especially if performed in selected cases, i.e. in patients with inconclusive planar or SPECT imaging with respect to the exact anatomic localization of the lesions detected on the scintigraphy. In particular, given the relatively high frequency of skeletal metastases in neuroblastomas, SPECT/CT can differentiate between bone and bone marrow involvement. Moreover, hybrid imaging helps to characterize tumour recurrence in close vicinity to the heart or liver, organs with high physiological MIBG uptake. On the other hand, in paediatric patients SPECT/CT may help to clarify the diffuse physiologic tracer uptake in the right heart sometimes misinterpreted as malignant mediastinal, sternal or vertebral sites of tumour involvement [23, 26].

SPECT/CT provides therefore a clinically useful option for localizing sites of abnormal MIBG uptake and for characterizing their benign or malignant nature. In addition to increasing specificity of staging and providing useful anatomic information on surgical resectability, the procedure also has an impact on the selection of patients to be treated with ^{131}I-MIBG.

3.3. ^{111}In-octreotide SPECT/CT for assessing neuroendocrine tumours

^{111}In-octreotide scintigraphy is widely employed to image somatostatin–receptor-positive neuroendocrine tumours. Over the last decades, lesion detection and overall clinical accuracy have improved due to optimized imaging techniques. The currently injected dose of 6 mCi of ^{111}In-octreotide (^{111}In-DTPA-pentetreotide) has doubled as compared to the 3 mCi dose administered in the initial studies. SPECT imaging is now routinely performed.

Neuroendocrine (NE) tumours of the gastrointestinal tract include carcinoid and islet-cell tumours, and surgery is the treatment of choice. Detection of all tumour sites is critical for referring patients to surgery and for its optimal planning. Localization of lesions may be difficult, due to their small diameter and lack of anatomical delineation [27]. The sensitivity of conventional imaging modalities, mainly CT and ultrasound, ranges between 13% and 85%, depending on the type, site and size of the tumour and on the imaging protocol [28].

Many neuroendocrine tumours show an increased expression of somatostatin receptors. A variety of analogues with high binding affinity to somatostatin receptors have been synthesized. One of these is octreotide, an eight amino acid cyclic peptide, with a biologic half-life measured in hours, which is used as an injectable therapeutic agent to inhibit excess secretions from neuroendocrine tumours. Somatostatin receptor scintigraphy is based on the use of octreotide as a carrier of radionuclides for diagnostic imaging or targeting therapy. A tyrosyl moiety in position 3 of the cyclic amino acid ring, the tyrosyl^{3}-octreotide has been substituted initially with ^{123}I [29]. Since ^{123}I is an expensive and short lived radioisotope, the use of ^{111}In bound to the octreotide molecule, ^{111}In-DTPA-pentetreotide, has been further developed, with the original octreotide eight amino acid molecule covalently bound to DTPA that, in turn, serves to link the radiometal [30].

Diagnosis, staging and follow-up of neuroendocrine tumours have advanced considerably with the advent of ^{111}In labelled pentetreotide scintigraphy. This modality has a reported sensitivity of 82–95%, and can successfully detect previously unknown sites of disease, undetected by conventional imaging techniques, in 30–50% of various NE tumours [31, 32]. Octreotide scintigraphy improves the localization and staging of primary tumours and enables early detection of recurrence [33]. In addition, octreotide scintigraphy facilitates the detection of receptor-dense microscopic foci during radio-guided surgery and is being used to determine if the whole tumour has been resected. Scintigraphy is also being used to define the receptor-status of metastases for octreotide treatment [34–36] or for targeted receptor-mediated radiotherapy [37–39]. It has been previously demonstrated that octreotide scintigraphy induced a change in classification in 24% and in surgical strategy in 25% of patients with gastro-entero-pancreatic tumours [40], and changed the patient management in 47% of patients with gastrinomas [41].

Despite the valuable contribution of planar and/or SPECT ^{111}In-octreotide scintigraphy to the diagnosis and management of patients with known or suspected neuroendocrine tumours or other processes characterized by the increased expression of somatostatin receptors, the patterns of distribution of ^{111}In-octreotide have raised the need for correlating scintigraphic findings with anatomic imaging results. The overall specificity of scintigraphy may be affected by tracer uptake in physiological sites or in benign conditions. False–positive interpretations may be caused by the high receptor status of normal organs, such as the pituitary gland, thyroid, liver and spleen, or by physiological excretion of the tracer via the kidneys or the bowel. Hepatobiliary excretion, accounting for clearance of 2% of the administered dose, may lead to occasional visualization of the gallbladder which may potentially be misinterpreted as hepatic metastasis [42]. Guidelines for octreotide scintigraphy therefore recommend performing delayed studies that demonstrate changes in tracer kinetics and thus provide the differential diagnosis between benign, physiologic and malignant sites of radiotracer uptake. Neuroendocrine tumours are often localized in the abdomen and it can be difficult to precisely localize a suspicious lesion, or to differentiate whether a focus of abnormal uptake is in the pancreas, small bowel, liver or bone without anatomic correlation. In the region of the liver, it is difficult to distinguish between physiologic gallbladder accumulation versus a lesion in the head of the pancreas, in the right adrenal or in the small bowel.

Octreotide scintigraphy, although highly sensitive, is limited by the lack of precise anatomic localization, and requires correlation with high resolution anatomic imaging modalities in a large number of cases [40, 43]. Side by side interpretation of the two image sets (SPECT and CT) acquired separately, as well as co-registration of separately acquired anatomic (usually CT) and SPECT ^{111}In-octreotide imaging data have been developed. These techniques work quite well for fusion of studies of the brain, as there is no shift of the intra-cranial content from one study to another. In the thorax, there are differences in organ and lesion position depending on respiratory dynamics. Central mediastinal structures have limited excursion so that satisfactory co-registration, although very cumbersome and time-consuming, can be achieved. In the abdomen and the pelvis, there is the potential for significant shift of lesions depending upon patient positioning and variations in stomach, bowel or bladder distension. This represents a challenge for co-registration of separately performed SPECT and CT examinations, even when they are obtained within a close temporal interval, leading to possible mis-alignment of suspicious foci. A software package has been used to fuse helical CT and SPECT images of 28 lesions identified in 10 patients, using either external fiducial markers or internal anatomic landmarks (spleen and kidney contour) [44], and a shift of a few mm in organ location between SPECT and CT has been demonstrated. The use of image co-registration in the preoperative staging of patients with gastro-entero-pancreatic neuroendocrine tumours following ^{111}In-octreotide administration has also been evaluated in 38 patients with 87 lesions [45]. The accuracy of successfully assigning the anatomical location by two independent readers increased from 57% and 61% to 91% and 93%, respectively, using co-registration. Diagnosis and localization of liver metastases to a specific segment improved from 45% and 58% to 98% and 100%, respectively, with relevant information for further therapeutic decisions in 19% of the patients [45]. Nevertheless, the approach of co-registering separately performed octreotide-SPECT and CT studies cannot be considered as the optimal approach for assessment of function and anatomy of neuroendocrine tumours.

SPECT/CT may localize foci of increased tracer activity to normal organs with known physiological activity, without the need for performing delayed scans on additional days. SPECT/CT may also improve image interpretation when the foci of increased tracer uptake can be precisely localized to octreotide-avid benign processes, such as recent surgery or colostomy, increased thyroid uptake in Graves' disease, accessory spleen, parapelvic cyst, benign breast lesions and granulomatous lung disease (e.g. sarcoidosis) [34, 46]. When active malignant disease is diagnosed, SPECT/CT can precisely define the organ involved and determine the presence or absence of invasion into surrounding tissues. Following the diagnosis and localization of neuroendocrine tumours, SPECT/CT may also help in determining the extent of disease, defining it as localized or disseminated, and thus influence the choice of the most appropriate treatment modality [47–49]. When disease is confined to a single organ, a localized mode of organ-specific therapy is suggested, such as surgery or chemoembolization (Figs 4, 5). When a soft-tissue tumour has invaded the adjacent bone, surgery is inadvisable. In extensive, unresectable disease, systemic therapy is required.

Initial studies have shown that SPECT/CT had an impact on patient management in 5 out of 10 patients with neuroendocrine tumours [50]. Further studies have indicated that octreotide SPECT/CT has a specificity of 86% and a positive predictive value of 85% for diagnosis of neuroendocrine tumours, and resulted in a change in management in 3–14% of patients [46, 49]. Pfannenberg et al., in an analysis of 43 patients with neuroendocrine tumours, compared SPECT/CT results to those of SPECT and to high-end CT stand-alone images, histopathology or clinical and imaging follow-up representing the diagnostic standard. Separate SPECT and CT interpretations were in agreement for 56 of 114 lesions overall (49% concordance). For the remaining 58 lesions (51%), consensus readings of the fused SPECT/CT images resulted in a change from the original interpretation of 39 CT and 19 SPECT examinations. Overall, SPECT/CT outperformed significantly both SPECT and high-end CT. The greatest accuracy involved the use of SPECT/CT with side by side availability of high-end CT. In fact, in this report SPECT and side by side high-end CT performed slightly better than SPECT/CT [51]. A preliminary report of ^{111}In-octreotide SPECT/CT in 27 patients with suspected or known neuroendocrine tumours, primarily of the gastro-entero-pancreatic type, indicated that fused images improved the overall diagnostic confidence in 15 of 27 cases [52].

In a large series including 72 patients with neuroendocrine tumours, Krausz et al. evaluated the impact of SPECT/CT on the diagnostic accuracy of octreotide scintigraphy and on further clinical patient management [47]. SPECT/CT improved the study interpretation in 32% of the total study population (52% of the positive studies). SPECT/CT allowed for the precise localization of foci of increased ^{111}In-octreotide activity thereby defining the whole extent of disease in 17 patients, it diagnosed previously unsuspected bone metastases in 3 patients and defined suspicious lesions as sites of physiologic activity, unrelated to cancer, in 3 additional patients. SPECT/CT altered the subsequent management of 10 patients (14%). Results of fused images modified the previously planned surgical approach in 6 patients, spared unnecessary surgery in 2 patients with newly diagnosed involvement of the skeleton, and led to referral of one patient each to liver transplant and to chemoembolization, rather than to systemic therapy.

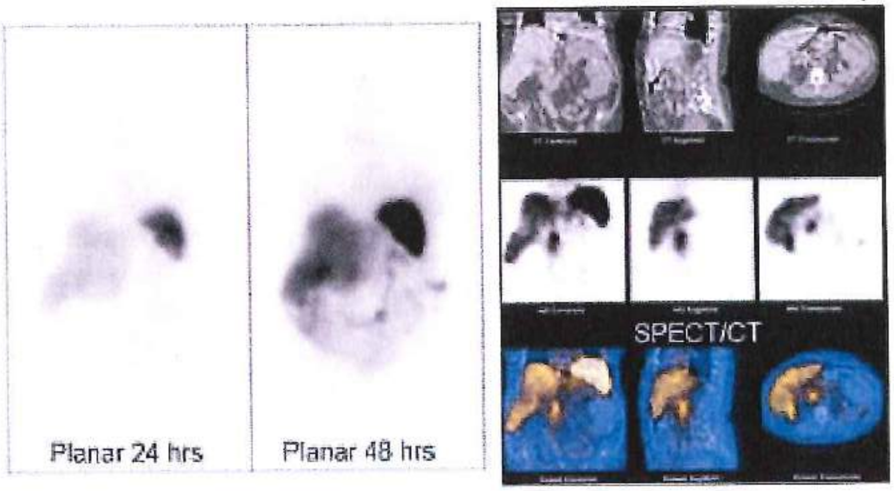


FIG. 4. [111]In-octreotide SPECT/CT in duodenal carcinoid. A 56 year old woman with duodenal carcinoid diagnosed following biopsy of a duodenal ulcer was referred for defining extent of disease prior to treatment planning. Whole body planar scans performed at 24 and 48 h after tracer injection are normal. SPECT demonstrates a small focus of abnormal tracer activity in the right mid-abdomen, localized by SPECT/CT fused images to the duodenum, consistent with the known primary tumour. No additional sites of abnormal tracer activity are seen. The patient was referred for surgery.

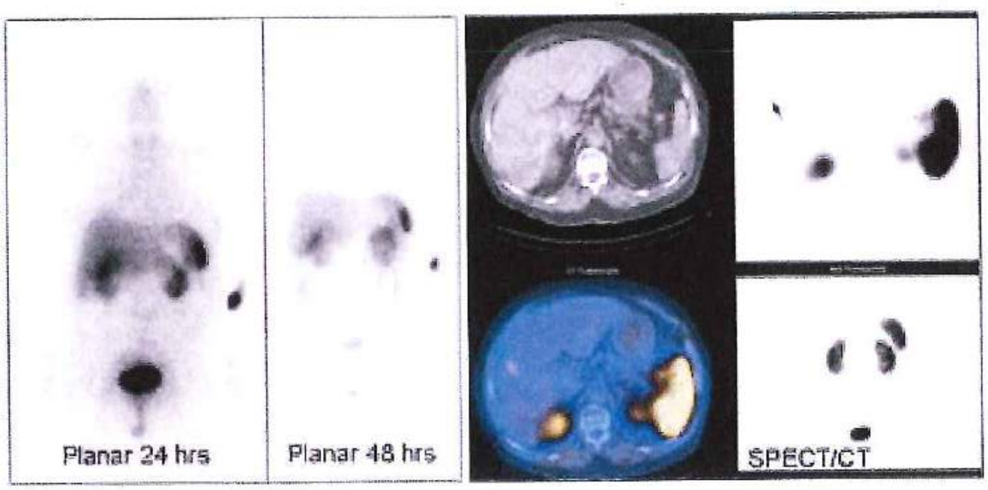


FIG. 5. [111]In-octreotide SPECT/CT in pancreatic insulinoma. A 68 year old woman was hospitalized because of severe hypoglycemia. CT indicated a suspicious lesion in the tail of the pancreas. Whole body planar scans performed at 24 and 48 h after tracer injection are normal. SPECT demonstrates a small focus of abnormal tracer activity in the left upper abdomen, in close proximity to the high [111]In-octreotide uptake in the spleen. This suspicious lesion is localized by SPECT/CT fused images to the small lesion seen on CT in the tail of the pancreas, consistent with a pancreatic insulinoma. No additional sites of abnormal tracer activity are seen. The patient was referred for surgery.

Octreotide-SPECT/CT provides information regarding the functional status of the tumour, its precise localization and the whole extent of disease. Fused images are therefore useful tools to choose the optimal treatment strategy, mainly in patients with advanced disease. When scintigraphy is negative, SPECT/CT is of no additional value except for verification of receptor density in a tumour visualized on CT. SPECT/CT provides greater accuracy in localization of findings than functional SPECT imaging alone and greater specificity than anatomic CT as a stand-alone procedure.

In summary, despite the favourable impact that ^{111}In-octreotide scintigraphy, particularly SPECT, has had on the diagnosis and management of patients with neuroendocrine tumours, these features improve even further when correlated with anatomic imaging data acquired sequentially during a single imaging session. Criteria for improvement include higher diagnostic sensitivity and specificity, as well as impact on patient management. Thus, it can be concluded that near simultaneous acquisition of both CT and SPECT image sets (hybrid SPECT/CT) represents the state of the art for diagnostic ^{111}In-octreotide imaging of neuroendocrine tumours.

3.4. ^{67}Ga-citrate SPECT/CT in lymphoma

^{67}Ga-citrate scintigraphy has long been shown to be useful for evaluating patients with lymphoma, and SPECT/CT has further improved its diagnostic sensitivity as well as localization of areas with abnormal tracer uptake [53]. In particular, SPECT/CT proved to be very helpful for distinguishing spinal lesions from adjacent nodal involvement. It was also able to clarify the tracer uptake at the edges of the lower chest, projecting over the hepatic dome, ribs or sternum. Furthermore, SPECT/CT imaging has been shown to provide additional information or diagnosis from CT-detected abnormalities leading to significant change in patient's management [54].

3.5. Lymphoscintigraphy

Accurate lymph node staging is essential for the treatment and prognosis in patients with cancer. The sentinel lymph node is the first node to which lymphatic drainage and metastasis from the primary tumour occur. Procedures for sentinel lymph node detection and biopsy have already been implemented into clinical practice [55, 56]. Precise anatomic localization of the sentinel lymph node is critical for minimally invasive surgery and to avoid incomplete removal of the sentinel node, especially in the regions of the head and neck, the chest and the pelvis.

In the head and neck the lymphatic drainage is in the levels I through VII. A node in level I-A is in the subdigastric muscle area, and a node in level I-B is in the submandibular area. A node in level II-A is anterior to the sternocleidomastoid (SCM) muscle, and a node in level II-B is adjacent to the SCM muscle. Nodes in level II are above the hyoid bone. A node in level III is adjacent to the SCM muscle, between the hyoid bone and the cricoid cartilage. A node in level IV is adjacent to the SCM muscle below the cricoid cartilage. A node in level V-A is behind the SCM muscle above the cricoid cartilage, and a node in level V-B is behind the SCM muscle below the cricoid cartilage. A node in level VI is in the anterior middle neck between bilateral SCM muscles, and a node in level VII is in the superior mediastinum.

Axillary lymph node levels are level I (low) lateral to the pectoralis minor (PM) muscle, level II (mid) behind the PM muscle, and level III (high) medial to the PM muscle.

The resection of external iliac *versus* inguinal lymph nodes requires significantly different surgical approaches, and thus precise preoperative localization is crucial for optimal surgical approach. A node above the level of the inferior epigastric artery which is anterior and lateral to the bladder base is an external iliac node, and the nodes below the inferior epigastric artery are inguinal nodes, further subdivided into superficial and deep ones by the sapheno-femoral venous junction.

Only SPECT/CT imaging can precisely locate the sentinel lymph node since CT images provide critical anatomical landmarks such as the hyoid bone, cricoid cartilage, SCM and PM muscles, inferior epigastric artery and sapheno-femoral venous junction.

SPECT/CT increases the sensitivity and specificity of lymphoscintigraphy, and also provides the additional diagnostic information from the CT images [57–62]. A standard dose of 0.5 mCi ^{99m}Tc labelled colloid (5–80 nm) is injected intradermally around the melanoma lesion, interstitially around the breast cancer lesion and subcutaneously around other tumours. SPECT/CT is usually obtained immediately after identifying drainage of the activity on serial planar images (Fig. 6).

(A) (B)

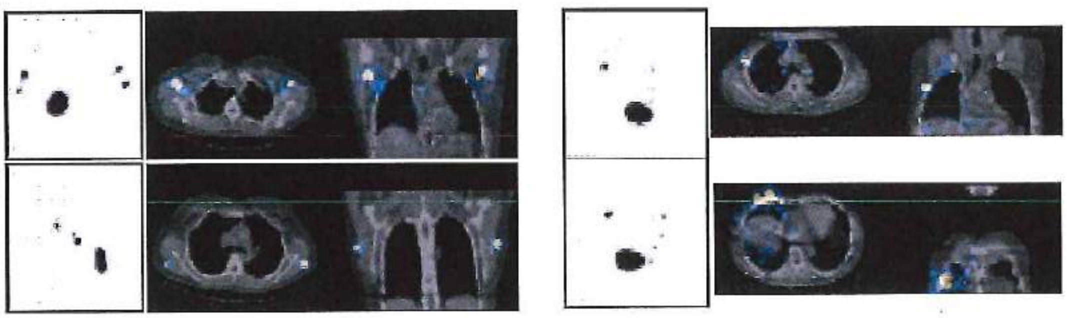


FIG. 6. Additional information over planar scintigraphy provided by SPECT/CT in two patients with malignant cutaneous melanoma submitted to lymphoscintigraphy with ^{99m}Tc-albumin nanocolloid before radioguided sentinel lymph node biopsy. (A) Left panels show the planar posterior (top) and left lateral (bottom) views in a patient with melanoma located on her back: multiple bilateral lymph nodes can be detected, without however clear reference to precise anatomic structures. Right panels show SPECT/CT tomographic sections at different levels, demonstrating bilateral lymphatic draining to both axillary (top) and subscapular (bottom) lymph nodes. (B) Left panels show the planar right oblique (top) and anterior (bottom) views in a patient with melanoma located on his anterior right chest: multiple lymph nodes can be detected, without however clear reference to precise anatomic structures. Right panels show SPECT/CT tomographic sections at different levels, demonstrating lymphatic draining to both axillary and internal mammary chain lymph nodes

3.6. Skeletal scintigraphy for staging malignant disease

Scintigraphic imaging of bone metabolism is a cost efficient way to prove or exclude skeletal metastases in patients with tumours prone to metastasize to the skeleton, such as breast, prostate, or lung carcinomas [63]. Therefore, bone scintigraphy is included in the majority of guidelines addressing management of these neoplastic conditions in many countries and is one of the most frequently performed radionuclide imaging procedures performed worldwide.

In a recent study comparing the diagnostic accuracy of ^{99m}Tc-phosphonate skeletal scintigraphy to that of [^{18}F]FDG-PET in patients with thyroid carcinoma [64], sensitivity of the conventional procedure was not significantly different from that of [^{18}F]FDG-PET. However, its specificity was significantly worse. This result can be considered representative also of other tumours and is not at all unexpected, since there are several highly prevalent benign conditions leading to focally increased uptake of the radiolabelled phosphonates in the skeleton. Most of these conditions reflect degenerative processes of the joints increasing in frequency with age, such as spondylarthrosis or coxarthrosis. Additional benign causes of enhanced uptake are rheumatic disease or benign bone tumours.

Since most of these benign conditions are readily identifiable on CT, SPECT/CT is expected to improve specificity of skeletal scintigraphy without reducing its sensitivity. Besides single case reports illustrating this assumption, several prospective studies have investigated this issue.

In 2004, Horger et al. demonstrated significantly increased specificity when using SPECT/low-dose non-spiral-CT for classifying 104 lesions in 47 subjects exhibiting indeterminate findings on conventional planar imaging [65]. This study is particularly valuable considering that the reference gold standard for final classification of lesions was either histological confirmation or extended clinical follow-up, and thus independent from the results obtained by SPECT/CT.

Römer et al. employed a SPECT/CT camera equipped with a two slice spiral-CT for classifying 52 lesions in 44 patients, defined as indeterminate on SPECT imaging [6]. These authors reported that SPECT/CT enabled correct classification of the scintigraphic abnormalities in 92% of the subjects studied.

Utsunomiya et al. used a hardware set-up comparable to that of a hybrid SPECT/CT camera, by transferring the patient positioned on the same table in an identical position from a stand-alone SPECT camera to a gantry of an 8 slice CT [66]. By studying 45 patients and based on receiver-operation curve (ROC) analysis, they confirmed the significant increase in diagnostic accuracy brought about by co-registration of these two modalities. Furthermore, they also showed that co-registration performs significantly better than side by side viewing of the two sets of images (SPECT and CT, respectively) on the same workstation.

Considering the evidence summarized above, one cannot but conclude that skeletal SPECT/CT is the new imaging gold standard when searching for osseous metastases and that for this purpose conventional scintigraphy becomes obsolete (Fig. 7). Unsettled issues include the quality of the CT integrated into the hybrid system needed for this purpose, as well as the relative diagnostic accuracy of this approach compared to whole body MRI and PET using [^{18}F]FDG or ^{18}F-fluoride. Although these options appear attractive, a cost effectiveness analysis might strengthen the role of SPECT/CT in this context.

Pt #1

Pt #2

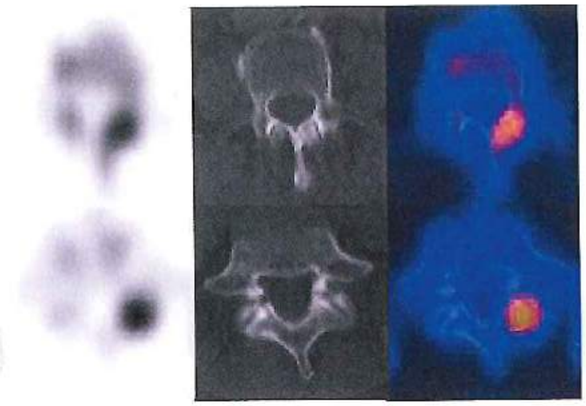


FIG. 7. The upper row shows SPECT, CT, and fused images of a lumbar vertebra in a patient with breast cancer (Pt #1). In this patient, increased uptake of ^{99m}Tc-MDP is due to arthrosis of the facet joint. The lower row depicts similar images in another breast cancer patient (Pt #2). Although the SPECT appearance of the lesion is quite similar to that in Pt #1, the CT overlay proves it to be a small osteolysis.

3.7. Skeletal SPECT/CT in orthopaedics

Up until approximately 20 years ago, planar X ray and skeletal scintigraphy were the imaging procedures of choice in patients with benign orthopaedic disease. Although MRI has brought a dramatic change to the predominance of radionuclide imaging in this field, skeletal scintigraphy still holds the promise of sensitively depicting functional alterations of bone. However, difficulties in precisely localizing abnormalities of bone metabolism relative to the complex anatomy of the skeleton have greatly weakened its clinical role, despite its much lower costs than MRI.

In principle, SPECT/CT would be suited to overcome these problems as demonstrated in several case reports (Fig. 8) [67]. However, so far only one study has systematically studied the clinical benefit of SPECT/CT in orthopaedic disease [68]. Using a SPECT/multi-slice non-spiral CT, Even-Sapir et al. analysed skeletal image data from 89 consecutively studied, non-oncological patients. These patients had non-specific lesions on planar skeletal scintigraphy for which correlation with morphological imaging was considered necessary. The indications for radionuclide bone imaging were pain in 61, prior trauma in 7, suspected infection or inflammation in 6, and fever of unknown origin in the remaining 2 patients. Gold standard for final classification was consensus opinion among the readers, and this represents a possible limitation of the study since it was not independent from SPECT/CT itself. Hybrid imaging enabled a definite diagnosis to be reached in 59% of the patients studied, obviating the need to perform additional imaging. In another 30% of patients, SPECT/CT provided information relevant for their further diagnostic workup. The authors therefore concluded that SPECT/CT is a clinically relevant component of the diagnostic process in patients with non-oncological disease referred for bone scintigraphy.

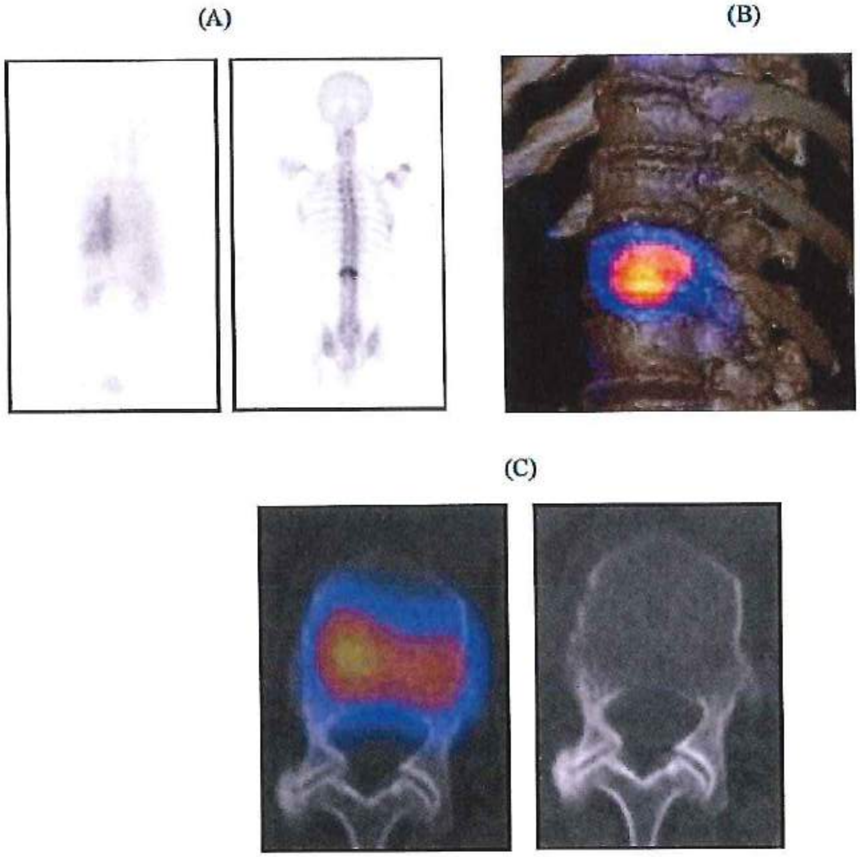


FIG. 8. (A) Early (left panel) and late (right panel) posterior planar skeletal scintigrams of a 74 year old patient after recent trauma, showing enhanced uptake of ^{99m}Tc-MDP in a vertebral body of the lower thoracic spine. 3-D-volume rendering of the SPECT/CT fusion (B) shows that the lesion is in the twelfth vertebral body. The inspection of the fused tomograms (C) proves it to be a fracture; moreover, the one-stop shop examination discloses it to be unstable since the posterior corticalis is involved, thus motivating immediate surgery.

3.8. ^{201}Tl-chloride in cerebral masses

The diagnosis of a postoperative residual brain tumour is a challenging clinical problem, since both contrast-enhanced CT and T1-weighted MRI after surgery are difficult to interpret while precise diagnosis is needed for planning radiation therapy. Likewise, in HIV infected patients, the differential diagnosis between primary lymphoma and cerebral toxoplasmosis is often problematic.

Thallium is a metallic monovalent cationic element in group III-A of the periodic table of elements. ^{201}Tl is cyclotron-generated and is administered in the form of thallous chloride. The cellular uptake of ^{201}Tl after i.v. administration depends on both blood flow and the cellular extraction fraction, which mainly occurs via the Na^+/K^+-ATPase active transport membrane pump in viable cells. A minor fraction of ^{201}Tl uptake is also related to co-transport system, calcium ion channel system, vascular immaturity with 'leakage', and increased cell membrane permeability. Tumour cells have shown greater ^{201}Tl uptake than normal connective tissue or inflammatory cells. In primary brain tumours alterations in the blood-brain barrier play a key role in ^{201}Tl accumulation [69].

In normal subjects little ^{201}Tl activity is seen in the cerebral substance, since ^{201}Tl cannot pass the blood-brain barrier and diffuse into the brain tissue. Conversely, high radioactivity is seen in the orbits, the base of the skull and nasopharyngeal region, and around the scalp. There are no significant differences between early (10 minutes) and delayed (3 hours) images. In case of brain haematoma, ^{201}Tl uptake seen in early images significantly decreases on delayed scans [70].

Postoperative ^{201}Tl SPECT demonstrated a significantly better accuracy than contrast-enhanced CT in detecting residual tumour in 33 patients [71]. Actually, disruption of the blood-brain barrier during the postoperative period often leads to uncertainty in CT interpretation. Co-registration and fusion of ^{201}Tl SPECT with CT could thus optimize postoperative radiation therapy planning through a truly anatomo-metabolic image.

^{201}Tl SPECT has also been seen to be useful for differentiating brain tumour recurrence from radiation necrosis or gliosis after radiotherapy, with more reliable information than CT and MRI in identifying progression, improvement or no change in brain tumours in follow-up studies [72, 73].

Because ^{201}Tl does not accumulate in normal brain parenchyma, anatomical localization of increased tracer uptake is difficult. Registration and fusion with anatomical images facilitates this task during the clinical workup of patients with brain tumours [74]. Appropriate attenuation correction based on the CT transmission data could also help in the reconstruction of ^{201}Tl SPECT images, which will further improve image contrast and detectability of areas of increased uptake, leading to a higher sensitivity of ^{201}Tl imaging, particularly for infratentorial and small size tumours. Until now, physicians have relied mainly on their spatial sense to mentally reorient and overlap ^{201}Tl images with the anatomic data. This approach is inconsistent and highly subjective and can yield suboptimal results because it does not take full advantage of all the available information [74]. Image fusion allows accurate determination of the anatomic sites of normal and abnormal uptake (Fig. 9). The precise localization of ^{201}Tl accumulation is essential to guide the choice of biopsy site (conventional or stereotactic), in an effort to decrease the potential for tissue sampling error in the pathologic specimen, or for planning radiosurgery [75]. Moreover, the accurate assessment of ^{201}Tl uptake can be of significant value after surgical and/or radiotherapy treatment in planning further therapeutic strategies, such as additional surgery or radiotherapy, because CT and MRI are often unable to distinguish residual tumour from post-therapy changes. Fused images can also help in optimizing the treatment specifically to the viable malignant tissue and in the early diagnosis of recurrence during follow-up.

3.9. ^{99m}Tc-depreotide in solitary pulmonary nodules

The characterization of solitary pulmonary nodules (SPNs) represents an important clinical problem because, although they may be caused by many benign conditions, bronchogenic carcinoma is being increasingly identified as one of the main etiologies, especially in the elderly. Survival rate at 5 years may be ≥80% in patients with resected malignant SPN, while it is <5% for patients with advanced malignant disease. Ideally, diagnostic approaches to SPN would permit definitive resection when possible and avoid resection in patients with benign disease [76].

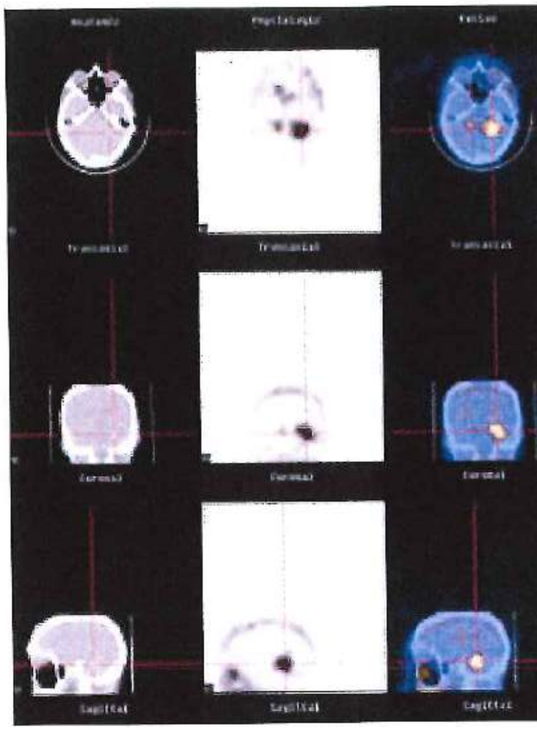


FIG. 9. SPECT/CT performed after administration of ^{201}Tl-chloride in an HIV infected patient referred for differential diagnosis between primary lymphoma and cerebral toxoplasmosis. ^{201}Tl accumulation in the left hemi-cerebellum supports the diagnosis of primary lymphoma.

Depreotide is a synthetic cyclic peptide, an analog of somatostatin, that binds with high affinity to somatostatin receptors 2, 3, and 5. Radiolabelled with ^{99m}Tc, this agent has successfully been used for SPN imaging [77]. In fact, ^{99m}Tc-depreotide has been approved by the US Food and Drug Administration for the noninvasive differentiation of SPN, and it represents a cost effective alternative to [^{18}F]FDG-PET in this application [78]. ^{99m}Tc-depreotide SPECT and [^{18}F]FDG-PET have demonstrated the same specificity (86%) for small (up to 1.5 cm), and equal sensitivity (92%) for large (more than 1.5 cm) SPNs [79]. The role of ^{99m}Tc-depreotide in staging patients with non-small cell lung cancer is still under investigation, although an elevated number of false–positive results have been reported in the hilar/mediastinal regions due to nonspecific tracer uptake [80, 81]. SPECT/CT may help image interpretation by improving specificity at diagnosis and staging and by differentiating physiologic activity (parahilar mediastinal region, bone marrow uptake in the spine, ribs and sternum) from malignant uptake in the primary tumour or into metastatic lymph nodes (Fig. 10). Additionally, the improvement in image quality by the use of X ray based attenuation-correction could increase the detection rate of smaller nodules.

3.10. ProstaScintigraphy

Functional or molecular imaging of prostate cancer presents a challenging problem because of the deep anatomical location of the prostate gland in the pelvis, which causes significant attenuation and scattering problems. Patient's movement, changes of the prostate volume, as well as changes in the shapes and contents of the rectum or bladder during imaging can further exacerbate the problem in image-fusion multimodality imaging visualization of the prostate.

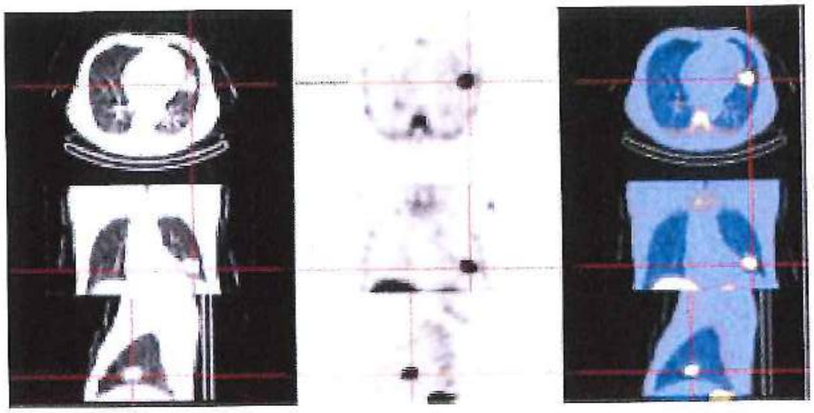


FIG. 10. Transaxial, coronal, and sagittal tomograms of SPECT/CT imaging obtained after injection of ^{99m}Tc-depreotide in a patient with a solitary pulmonary mass occasionally discovered on chest X ray. Intense tracer uptake indicates malignancy, while the fused SPECT/CT images suggest that, while there is no extension of the tumour to infiltrate the chest wall, there is possible involvement of the pericardium.

The overall diagnostic accuracy of imaging using 5 mCi ^{111}In-ProstaScint (monoclonal antibody against the prostate-specific membrane antigen) has been reported to be 76%, with 44% sensitivity and 86% specificity relative to histologic findings [82, 83]. Increased accuracy of the ProstaScint scan for diagnosis of prostate cancer has been reported when fusing SPECT images with either CT or MRI [84, 85]. In addition, ProstaScint imaging can be applied to guide brachytherapy or intensity-modulated external-beam radiation therapy [86], as well as radioimmunotherapy using ^{90}Y-capromab pendetide for recurrent prostate cancer [87].

3.11. SPECT/CT in the preoperative localization of parathyroid adenomas

Parathyroid scintigraphy with ^{99m}Tc-sestamibi (employed either as a single-tracer, dual-phase protocol or in combination with other tracers with exclusive uptake in the thyroid for subtraction imaging) is critical for preoperative localization of parathyroid adenomas, especially in the perspective of applying mini-invasive parathyroid surgery [88–90]. Even before the introduction of hybrid SPECT/CT instrumentation into clinical routine, stand-alone SPECT procedures had already demonstrated clear superiority to planar ^{99m}Tc-sestamibi scintigraphy for imaging and localizing parathyroid adenomas, especially when planning the best surgical approach to ectopic adenomas, mainly located in the mediastinum [91–98].

However, because of the paucity of anatomic landmarks in pure SPECT images, some form of multimodality co-registration often turned out to be useful for better localization of adenomas relative to critical anatomic structures, such as those available through side by side viewing with, e.g. CT images or by post-acquisition image fusion. Useful complementary information as to location of ectopic parathyroid adenomas can also be derived by sequential acquisition, after ^{99m}Tc-sestamibi scintigraphy, of scintigraphic images obtained by injecting a second tracer, e.g. an intravascular indicator such as radiolabelled albumin or red blood cells, to identify the topographic relationships of adenomas with the principal vascular structures [88].

The recent growing-scale implementation of hybrid SPECT/CT equipments has dramatically improved this scenario, by enabling simultaneous acquisition and accurate single hardware co-registration of functional images (derived from ^{99m}Tc-sestamibi scintigraphy) and of the corresponding morphologic images (derived from CT). Thus, it can be concluded that, at present, SPECT/CT represents the state of the art in preoperative localization of parathyroid adenomas, especially in cases of ectopic location and in the presence of concomitant multinodular goiter (Fig. 11). In all these conditions the localizing performance of SPECT/CT is clearly superior to both planar scintigraphy and stand-alone SPECT.

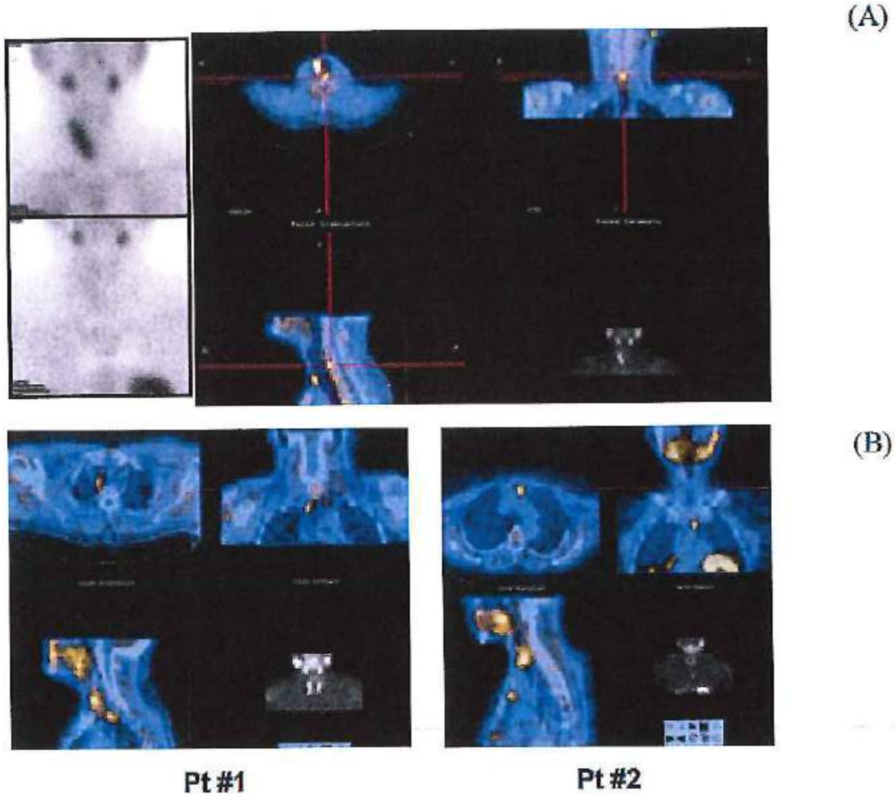


FIG. 11. Patients with parathyroid adenomas in whom hybrid SPECT/CT imaging turned out to be crucial for accurate preoperative localization and for planning the most adequate surgical approach. (A) Early (top left) and delayed (bottom left) planar ^{99m}Tc-sestamibi scans in a patient who had undergone unsuccessful parathyroid surgery during which the left thyroid lobe was also resected because of concomitant nodular goiter (persistent primary hyperparathyroidism despite removal of an enlarged parathyroid gland ectopically located in the anterior mediastinum that had been identified on a planar ^{99m}Tc-sestamibi scan). While both scans (left panels) are negative for parathyroid adenoma, SPECT/CT imaging (right panel) enabled to identify abnormal tracer uptake located posteriorly to the trachea. (B) Two patients in whom SPECT/CT imaging with ^{99m}Tc-sestamibi localized hyperfunctioning parathyroid adenomas and led to plan the optimal surgical approach for their successful resection. In Pt #1 the adenoma was located adjacent to the right wall of the trachea, while in Pt #2 the adenoma was located in the anterior mediastinum.

An early report by Gayed et al. suggested that SPECT/CT had a significant impact on surgical management of patients in only a limited fraction of patients (5 out of 48 cases in their experience), and considered therefore that the added value of CT (with the related radiation exposure) did not justify the routine application of the procedure, except perhaps in patients with ectopically located adenomas [99]. However, more recent reports emphasize the impact of SPECT/CT compared to planar and/or SPECT scintigraphy (either as a stand-alone imaging or as side by side viewing with the corresponding CT images) on surgical management of patients. This conclusion has been reached by Krausz et al. who report a change in the surgical approach in 10/33 ectopic and 4/23 orthotopic parathyroid adenomas [100].

Similarly, Serra et al. have shown that SPECT/CT improves preoperative localization of parathyroid adenomas, with significant surgical impact in 39% of the cases [101]. In their patients, SPECT alone correctly localized 14/23 parathyroid adenomas (61%), while SPECT/CT correctly localized all 23 lesions (100%, 14 of which were ectopically located). Furthermore, SPECT/CT was crucial in demonstrating the retrotracheal location of an adenoma in three patients. Better performance of SPECT/CT versus planar or stand-alone SPECT has also been reported by Lavely et al. [102], while Ruf et al. have emphasized in particular the role of SPECT/CT for attenuation correction of the SPECT data based on the CT transmission data [103].

In conclusion, image fusion as obtained by hybrid SPECT/CT imaging with ^{99m}Tc-sestamibi is of value for surgical planning in both primary and secondary hyperthyroidism [104]. Concerning in particular secondary hyperparathyroidism, it is crucial that all parathyroid tissue showing ^{99m}Tc-sestamibi uptake is removed, because these parathyroid glands are those responsible for the increased production of parathyroid hormone. When relying only on visual inspection of the surgical field, in the absence of functional information some simply hyperplastic (but not hyperfunctioning) parathyroid glands might be removed unnecessarily. Wider clinical expertise using the hybrid SPECT/CT technology will certainly have a relevant impact in this field.

3.12. SPECT/CT for diagnosing infection and inflammation

Infection and inflammation can represent a major diagnostic challenge for physicians. Diagnosis and precise delineation of infectious foci may be critical in certain clinical scenarios and render decisions concerning further patient management problematic [105, 106].

Both morphologic and functional imaging modalities have been extensively employed for diagnosing and monitoring infections. CT and MR images provide high-quality anatomic details. However, the structural abnormalities underlying the infectious process are, in some cases, non-specific or appreciable only in a subacute or late phase of the disease. Nuclear medicine has gained a crucial role in the evaluation of patients suspected of harbouring infection, especially because of its capability of demonstrating physiologic processes and metabolic changes that often precede anatomic changes by several days or even weeks [106–123].

Although a variety of new radiopharmaceuticals have been explored as to their ability to detect and localize infectious and inflammatory processes, ^{67}Ga-citrate scintigraphy and scintigraphy with ^{111}In- or ^{99m}Tc-HMPAO labelled autologous white blood cell (WBC) remain the functional imaging techniques of choice for diagnostic work-up of infection [105].

However, both ^{67}Ga-scintigraphy and WBC-scintigraphy suffer from poor spatial resolution and somewhat low specificity because of the absence or paucity of anatomic landmarks. These limitations make precise localization and characterization of areas with focal abnormal tracer uptake problematic, even when employing SPECT imaging. At least part of these difficulties can be overcome when contemporary CT images are available, by either side by side viewing and, even better, by software based image fusion analysis [124, 125]. However, similar as with other scintigraphic applications, the introduction into clinical routine of integrated SPECT/CT scanners for combined anatomic and functional imaging has offered new opportunities for infection imaging, especially for facilitating precise anatomic localization and accurate characterization of infectious foci [2].

Recent reports have explored the contribution of SPECT/CT to a more accurate interpretation of WBC-scintigraphy for an array of clinical indications in different regions of the body, by distinguishing normal physiologic distribution of labelled WBCs from accumulation due to underlying infection. Major advantages have been observed for infectious processes with thoracic or abdominal localization, because of the potential difficulty of characterizing foci of WBC accumulation near the major vessels. In such cases, the hybrid technology helps in discriminating blood-pool activity from infectious sites, with substantial benefits for the evaluation of suspected vascular graft infection and fever of unknown origin [126].

Moreover, SPECT/CT with ^{99m}Tc-HMPAO-WBC can be very useful to image bone and joint infections, by allowing accurate localization of labelled WBC accumulation. In particular, in some cases of bone infection with adjacent soft-tissue involvement, while planar images alone are not able to distinguish soft tissue from bone, hybrid imaging is able to localize additional sites of leukocyte uptake in neighbouring soft tissue and to precisely define the extent of infection, thus modifying clinical patient management and therapeutic approaches in several cases.

After traumatic injury, skeletal changes can often be observed in morphologic imaging (i.e. CT or radiography). Although fusion imaging with a hybrid camera can improve the diagnostic accuracy of SPECT, it cannot be a substitute for conventional high resolution CT, which maintains its diagnostic role in most clinical situations. However, with regard to bone imaging, reports show that even the low-dose CT of the hybrid device may provide sufficient diagnostic anatomic information.

In this regard, Filippi and Schillaci have recently evaluated the usefulness of SPECT/CT for interpreting ^{99m}Tc-HMPAO-WBC scintigraphy in 15 patients with suspected osteomyelitis and 13 patients with suspected infection of orthopaedic prosthesis [127]. SPECT/CT fusion correctly characterized and localized the site of labelled WBC uptake in all patients with osteomyelitis, discriminating soft tissue from bone and having a substantial impact on the clinical management. Moreover, among patients with suspected infection of orthopaedic implants, SPECT/CT offered a more accurate anatomic localization of the site of infection than SPECT alone allowing differentiation between prosthesis and soft-tissue uptake. The authors concluded that hybrid imaging provided additional anatomic information on all patients with positive scan results (64.2%) leading to a more accurate definition of the extent of infection with significant impact in decisions therapeutics. In particular, major benefits were achieved for the diagnosis of relapsing osteomyelitis in patients with structural bone abnormalities after trauma.

Although ^{67}Ga-citrate has been used for scintigraphic imaging of infection and inflammation for many decades, its bio-distribution (with high accumulation in the gastrointestinal tract) and its sub-optimal physical emission characteristics result in a relatively poor imaging quality, making interpretation of abdominal imaging quite problematic. In an attempt to improve the quality of ^{67}Ga-citrate imaging, Bar-Shalom et al. have explored the added value provided by hybrid SPECT/CT imaging as an adjunct to ^{67}Ga-scintigraphy (in 47 patients) and to ^{99m}Tc-HMPAO-WBC scintigraphy (in 31 patients) [126]. The contribution of SPECT/CT was analysed on a patient- and site-basis and was compared for the two tracers and for various clinical indications. SPECT/CT provided an additional contribution for diagnosis and localization of infection in 48% of the patients and in 47% of the sites. Although SPECT/CT, because of its capability to localize abdominal uptake within the bowel, enabled the correct exclusion of infection in four patients undergoing ^{67}Ga-scintigraphy, the investigators found that the clinical added value of SPECT/CT was significantly higher for WBC-scintigraphy than for ^{67}Ga scanning (63% versus 36% of patients). This data can be explained by the high specificity of WBC, with low background activity and therefore limited anatomic information.

New agents such as radiolabelled anti-granulocyte monoclonal antibodies, radiolabelled ciprofloxacin, radiolabelled biotin, may benefit from hybrid imaging, as reported in some preliminary studies. Biotin (or vitamin H) is utilized by growing bacteria at the site of infection according to the rate of their metabolism. This feature is the basis for the successful utilization of ^{111}In-biotin for imaging infection, especially in difficult to interpret conditions such as the spondylo-discitis. However, since Biotin does not appreciably accumulate in normal bone and/or bone marrow, the exact identification of the vertebral body harbouring infection can be problematic. Therefore, in order to improve diagnostic accuracy and to differentiate between vertebral and soft tissue paravertebral infection, SPECT/CT acquisitions may be performed. In a preliminary study, Lazzeri et al. have investigated the role of ^{111}In-biotin SPECT/CT in 70 patients with suspected spinal infection [128], and have thus confirmed the high diagnostic potential of one-step ^{111}In-biotin hybrid imaging. Moreover, these authors demonstrated that SPECT/CT imaging allows accurate evaluation of spinal infection differentiating between vertebral and soft tissue paravertebral involvement.

Other radiopharmaceuticals, such as ^{99m}Tc labelled anti-granulocyte antibodies (AGA), are known to be highly sensitive and specific for diagnosing infectious disease, but image analysis and exact anatomical definition of the infectious foci is often difficult. In a series of 27 patients with suspected chronic post-traumatic osteomyelitis, Horger et al. have evaluated the value of fused SPECT/CT imaging after injection of ^{99m}Tc-AGA [129]. All patients underwent planar and SPECT/CT imaging studies 4 h and 24 h after injection. The authors found high sensitivity (100%) for both planar and SPECT/CT imaging, associated however with different results in terms of specificity (78% for planar versus 89% for SPECT/CT). SPECT/CT correctly localized all abnormal foci of tracer uptake detected on planar and SPECT images, and also enabled accurate discrimination between soft-tissue infection, septic arthritis, and osteomyelitis.

Although the potential of fused SPECT/CT imaging in infectious and inflammatory disease has not yet been fully elucidated and further validation is required, hybrid imaging provides precise anatomic localization with significantly improved diagnostic accuracy over planar or SPECT alone (Figs 12–14). These new techniques, in conjunction with the use of highly specific radiotracers for detection of inflammatory disease, are creating a whole new and powerful armamentarium for diagnosing infectious foci.

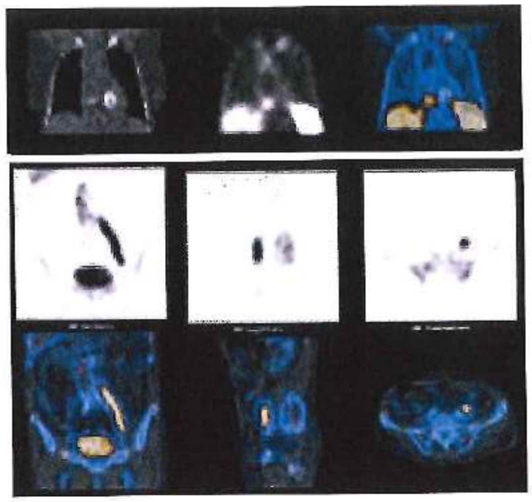


FIG. 12. Patients with cardiovascular infection imaged with autologous ^{99m}Tc-HMPAO-leukocytes and SPECT/CT. Although the most likely site of endocardial infection in Pt # 1 was expected to be a mitral valve implant (visible on the CT component of the examination), SPECT/CT correctly identified the tricuspidal valve as the actual site of infection (top panel). In Pt #2 (previously submitted to implant of aorto-bis-iliac vascular prosthesis), SPECT/CT defined the extent of infection as involving only the left side of the vascular graft (bottom panel).

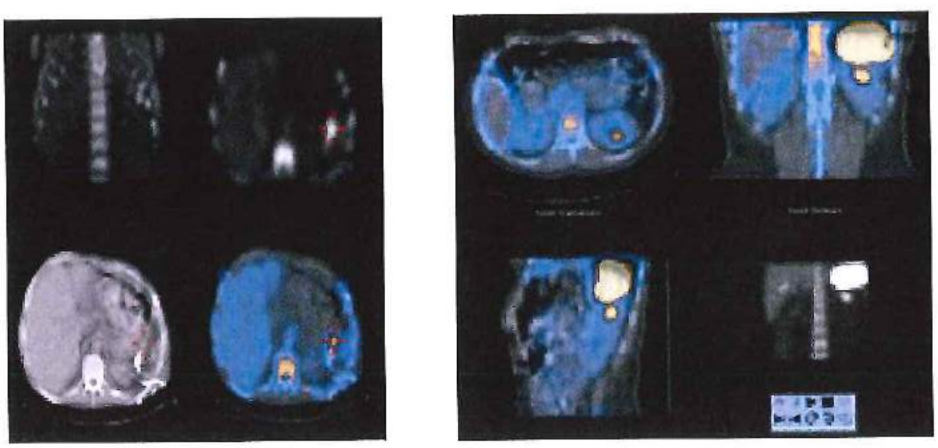
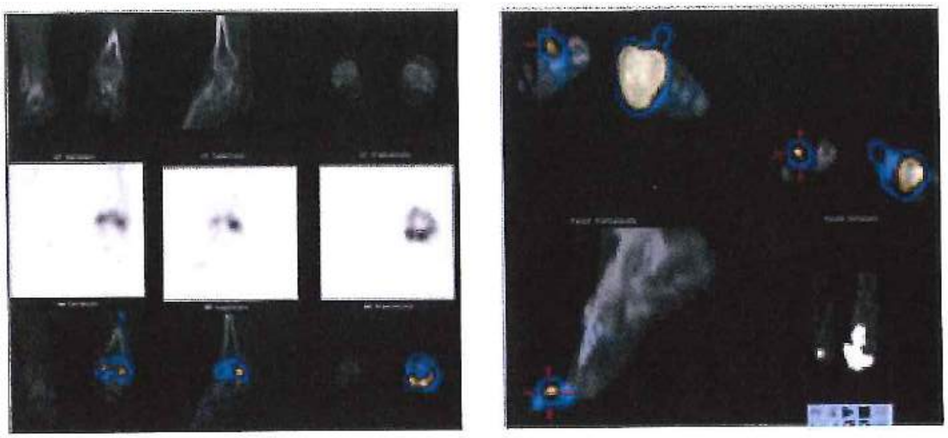


FIG. 13. Patients with infectious foci in the abdominal area. Pt # 1 (left panel) developed persistent fever resistant to antibiotic treatment shortly after combined pancreasectomy and splenectomy, performed because of a pancreatic adenocarcinoma of the tail infiltrating the splenic hilus. SPECT/CT performed as part of autologous ^{99m}Tc-HMPAO-leukocyte scintigraphy reveals a sub-diaphragmatic abscess at the tip of the draining catheter that had been placed during surgery. Pt #2 (right panel) had instead fever of unknown origin. During autologous ^{99m}Tc-HMPAO-leukocyte scintigraphy, it is only SPECT/CT that reveals location of an abscess at the upper pole of the left kidney, which on planar scan could only be generically located below the lower pole of the spleen.



Pt #1 Pt #2

FIG. 14. Patients with different forms of osteomyelitis, with accurate definition of the extent of infection by SPECT/CT. Post-traumatic osteomyelits of the left ankle in Pt #1 (left panel), imaged after injection of ^{99m}Tc-anti-granulocyte antibody. In Pt #2 (right panel) SPECT/CT performed during autologous ^{99m}Tc-HMPAO-leukocyte scintigraphy demonstrates that infection arising in a diabetic foot involves not only the soft tissue but also bone structures. Such accurate localization of the disease process was problematic not only on planar scintigraphy but also on stand-alone SPECT.

3.13. Cardiac SPECT/CT procedures

3.13.1. Myocardial perfusion imaging — CT based attenuation correction

Myocardial perfusion imaging (MPI), using ^{201}Tl and ^{99m}Tc labelled radiopharmaceuticals for stress/rest SPECT studies is at present the main non-invasive modality for evaluation of coronary artery disease [130]. Its accuracy is, however, limited by image artefacts that can cause false–positive perfusion defects and therefore reduce the test specificity. Although the initial validation of MPI-SPECT performed in luminary sites reported a specificity of greater than 90%, further large-scale clinical use of the technique has been associated with specificity in the range of 60% or lower [131, 132]. One of the most common image artefacts is caused by non-uniform reduction of photon activity from attenuation by soft tissue. This can be recognized, or at least suspected by experienced readers, because of the typical location and shape relative to the heart. Attenuation artefacts usually occur in the anterior wall in women with large breasts and in the inferior wall in obese men [133–135]. Although the true prevalence of soft tissue artefacts is unknown, estimates range between 20% and 50% of patients [136, 137].

Several approaches have been used to address the issue of spurious false positive results in MPI due to photon attenuation including, among other options, awareness of their potential occurrence and location, routine assessment of raw imaging data, comparative assessment of studies performed following a change in the patient's position (prone versus supine) and gated imaging which assesses wall motion. These approaches improve artefact recognition but they all have limitations. Although guidelines of the American Society of Nuclear Cardiology recommend that attenuation correction should be performed in all patients, there are clearly some patient populations that benefit more from this procedure, generally the largest-size patients. Depending on equipment availability and daily workload, the rest SPECT study is used in some centres as the criterion for triage decisions for performing attenuation correction acquisition.

In order to determine the true radiotracer distribution in the myocardium, several techniques have been developed with the goal of generating patient-specific attenuation maps. Attenuation maps generated by transmission sources at the time of the scan have, until the last decade, been the most commonly used method of correction. Various transmission geometries have been adopted, including sheet, multiple lines, or scanning line sources, a fixed source positioned at the focal line of a fan-beam collimator, or a moving point source [138]. Commercial systems use mainly Gadolinium-153 (^{153}Gd, 100 keV) with a 100-day half-life, supplied at a maximum of 400–500 mCi/source. With decay of the source, a degradation in the attenuation map leads to a central underestimation of the true attenuation coefficients.

An additional approach has attempted to use anatomic images imported from CT, but has been limited by difficulties in correct matching of the morphologic and scintigraphic data sets since images are acquired on different systems, at different time points, with the patients lying on different stretchers. These limitations are, at least in part, overcome by near-simultaneous acquisition of MPI and CT on a single imaging device. Historically, SPECT/CT systems have been initially developed with the specific goal of achieving optimal CT based attenuation of myocardial perfusion scintigraphy.

Cardiac SPECT is performed using a dual-head gamma camera equipped with low energy, high resolution parallel hole collimators, and with the detectors at 90° to each other. The acquisition is performed over a 180° orbit during a period of 12–20 minutes. Dual isotopes acquisition uses ^{201}Tl for rest and ^{99m}Tc-sestamibi or ^{99m}Tc-tetrofosmin for stress, while single isotope acquisition uses the same isotope, ^{99m}Tc-sestamibi or ^{99m}Tc-tetrofosmin for both rest and stress. For ^{201}Tl, imaging energy windows of 30% and 20% for the 70 keV and 167 keV peaks, respectively, are used, while the energy window width for ^{99m}Tc is 20% for the 149 keV peak. Both the rest and stress SPECT studies are followed by a low-dose CT (20–30 mAs, 140 keV for the diagnostic CT, or 2.5 mA, 140 keV for a camera-mounted CT), which is used for photon attenuation correction of the scintigraphic data. The CT-attenuation correction study is performed only over the area of the heart, as defined by the operator. The patient is asked not to move during study progression, in order to obtain good co-registration between the emission and the transmission scans [139].

CT based attenuation correction has been shown to provide the most reliable and accurate high quality cardiac SPECT images through high resolution, high count-rate and low noise attenuation maps resulting in predictable uniform tracer activity in patients with a low likelihood of haemodynamically significant coronary artery disease. The CT based attenuation correction method can be successfully implemented with all clinical cardiac SPECT protocols, including same-day or 2-days rest-stress, single and dual isotope rest-stress procedures.

3.13.2. Cardiac SPECT/CTA for assessing the significance of coronary artery lesions

Stress/rest MPI is the established imaging modality for non-invasive diagnosis of presence, severity and extent of coronary artery disease (CAD), with high sensitivity and specificity. MPI determines the physiologic significance of angiographically borderline stenosis, and defines the presence of viable but dysfunctional, hypoperfused myocardium. MPI cannot, however, diagnose early atherosclerosis and often underestimates the extent of coronary artery disease. In addition, MPI does not provide accurate anatomical information, essential prior to coronary revascularization procedures. The recently developed multi-detector CT (MDCT) technology characterized by high spatial, contrast and temporal resolution enables non-invasive CT coronary angiography (CTCA) and provides also accurate information regarding the structure and motion of the heart chambers. CT, however, does not predict the benefit of revascularization [140–142].

Cardiac SPECT/CT is a novel hybrid imaging technique that combines detailed anatomical information of coronary vessels (provided by CTCA) with physiologic information of myocardial perfusion and function (provided by MPI), through accurate spatial alignment of both data sets. This evolving modality has the potential to become the future imaging test of choice for non-invasive assessment of CAD [140–142].

While co-registration of separately performed CT and MPI may provide a very similar type of data, this process is difficult to implement beyond research purposes in dedicated centres, due to its logistical limitations. Single devices combining SPECT/CTCA data are characterized by ease of use and simple logistic set-ups, and have the potential of making cardiac hybrid imaging user-friendly and easy to plan, major factors in their future routine clinical use. SPECT/CT can provide accurate non-invasive diagnosis of the culprit coronary lesion, including its location and morphology, in conjunction with assessment of the physiologic significance of this lesion on myocardial function. SPECT/CT images precisely localize regions of impaired perfusion to the corresponding vascular territory. Cardiac SPECT/CTCA may prove of significance in a series of potential indications, which will however need to be proven by large, multi-centre studies. By allowing visualization of stenoses, the addition of CTCA to MPI can potentially eliminate one of the major reasons for false negative MPI results in patients with advanced 3-vessel disease, showing a balanced reduction of blood flow in all myocardial segments. On the other hand, by assessing the functional consequences of stenosis through its stress/rest MPI component, it may improve the performance of CTCA in patients with dense coronary plaques. CTCA results are often insufficient to guide patient management. A need for functional information will arise in many patients demonstrating anatomic coronary abnormalities on CT.

In summary, reliable attenuation correction of MPI-SPECT enhances significantly the clinical decision making process; decreases morbidity related to invasive procedures and also saves costs related to additional work-up induced by equivocal reports. High speed multislice coronary CT has a growing impact on assessment of patients with known or suspected coronary artery disease. Combined data regarding myocardial perfusion, calcium scoring and the presence or absence of coronary stenosis may, in future, enable better stratification of patients with or without ischemic heart disease. Referral algorithms will have to define patient groups that will benefit from hybrid SPECT/CTCA imaging of both myocardial perfusion and the anatomy of the coronary tree.

3.14. Added values of CT in patients with coronary artery disease

3.14.1. Coronary artery calcium

Calcium accumulates in the coronary arteries as a result of the body's response to contain and stabilize inflamed coronary plaques. Calcified plaque assessment correlates with pathologic assessment of the total amount of calcified plus noncalcified plaques [143]. The burden of coronary artery calcium (CAC) generally reflects an advanced stage of plaque development, and CAC serves as an indirect but proportional marker for global atherosclerotic burden. The CT based method of quantifying CAC was initially developed using electron-beam tomography (EBT), but multi-slice CT provides measurements of CAC comparable to those derived from EBT [144].

The CAC score is derived using highly reproducible semiautomatic computer methods based on the product of calcified plaque area by the coefficient of its density. The score is calculated as the product of the CAC area by the peak Hounsfield unit (1 for 131–199 HU, 2 for 200–299 HU, 3 for 300–399 HU, and 4 for >400 HU). Visually, coronary calcification can be categorized into mild (minimal), moderate, and marked (extensive) degrees of severity.

Accumulation of CAC is common in adults and increases with age. The presence of CAC is often associated with only insignificant (<50% luminal narrowing) coronary stenosis. However, there is a graded relationship between the extent of CAC and the annual risk of coronary heart disease. Patients with extensive CAC are likely to have marked non-calcified plaques that may be rupture-prone. Plaque erosions are infrequently calcified and associated with acute coronary syndromes [145].

3.14.2. Coronary computed tomography angiography

Coronary computed tomography angiography (CTA) visualizes not only the coronary vessel lumen but also the wall, allowing the non-invasive assessment of the presence and, potentially, the size of non-calcified coronary plaque. Furthermore, the assessment of ventricular function is possible from a single first-pass acquisition of the chest CT data, which may be of value in the emergency department setting, along with the potential to provide assessment of pulmonary embolism, acute coronary syndrome, and aortic dissection in a single study.

The relative roles of myocardial perfusion SPECT and CTA have not yet been defined. In patients with intermediate likelihood of CAD, coronary CTA may be the initial test to perform, attending to the apparently superior sensitivity over SPECT imaging. When a coronary CTA is entirely normal, no further testing would be required. In case of proximal and critical coronary stenoses, invasive coronary angiography would be indicated for possible revascularization therapy. When CTA detects coronary lesions of uncertain significance, SPECT imaging would be appropriate for further diagnostic assessment.

In patients with known disease (or likely having extensive coronary calcium) in whom risk-stratification is needed, SPECT imaging would remain the initial test.

If SPECT imaging has been performed as the initial test, further testing by CTA would be indicated whenever discordant results are obtained. This includes patients with a strong clinical suggestion of CAD after a normal or equivocal SPECT; patients with marked discordance between SPECT and clinical or stress ECG; or patients with SPECT and stress ECG results suggestive of left main or triple-vessel CAD (e.g. transient ischaemic dilation, post-stress LV dysfunction, exercise hypotension with normal SPECT), with balanced reduction of coronary flow in the LV. Coronary CTA can also be of use in patients with suspected nonischaemic cardiomyopathy, patients with coronary anomalies, and young patients undergoing valvular surgery.

Since rest/stress SPECT studies can be performed as routine in conjunction with coronary CTA, SPECT/CT systems provide data about coronary calcium, coronary stenosis and functional significance in one clinical setting, thus allowing more appropriate selection of patients who may benefit from revascularization procedures [146]. A recent study with an experimental SPECT/CT scanner (16-MSCT) showed that integrated functional and anatomic results improved specificity and positive predictive value to detect haemodynamically significant CAD in patients with angina pectoris [141]. The sensitivity, specificity, positive predictive value, and negative predictive value of CTA were 96%, 63%, 31%, and 99%, respectively, as compared with 96%, 95%, 77%, and 99%, respectively, for SPECT/CT. Patients and arterial segments excluded from the analysis raised to 21% and 23%, respectively. Another investigation described the incremental diagnostic value of integrating SPECT/CT (64-MSCT) data through three-dimensional (3-D) image fusion on the functional relevance of coronary artery lesions [140]. 3-D volume-rendered fused SPECT/CT images were generated from patients with at least one perfusion defect on SPECT imaging, and compared with the findings from the side by side analysis with regard to coronary lesion interpretation by assigning the perfusion defects to their corresponding coronary lesion. In addition to being intuitively convincing, 3-D SPECT/CT fusion images added significant information on pathophysiological lesion severity in 22% of coronary stenoses of 29% of patients. Among equivocal lesions on side by side analysis, the fused interpretation confirmed haemodynamic significance in 35% of lesions and excluded functional relevance in 25% of lesions. In 7.5% of lesions, assignment of perfusion defect and coronary lesion appeared to be reliable on side by side analysis but proved to be inaccurate on fused interpretation. Added diagnostic information by SPECT/CT was more commonly found in patients with stenoses of small vessels and involvement of diagonal branches.

3.15. Pulmonary artery imaging in pulmonary embolism

Pulmonary embolism (PE) is one of the greatest diagnostic challenges in emergency medicine. It should be suspected in any patient with unexplained dyspnea, tachypnea, or chest pain. A negative D-dimer assay reliably excludes PE in low-risk patients. Otherwise, pulmonary CT angiography is now considered by several authors to be the initial imaging study of choice for stable patients. Nevertheless, ventilation/perfusion (V/Q) scans or even perfusion scintigraphy alone (as in the PISA-PED approach [147–152]) still retain a considerable diagnostic accuracy and are valid alternatives to pulmonary CT angiography, in particular when CT is not available, or in patients with contraindications to CT scanning or intravenous contrast.

The results of the Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) study established the diagnostic criteria of V/Q scanning for the diagnosis of PE, as compared with pulmonary angiography [153]. The interpretation ranges from normal to high probability, each with its own diagnostic characteristics. However, more than 60% of patients fell into the low and intermediate probability (or non-diagnostic category), and there was a 4% incidence of PE when the scan was read as normal. Similarly troubling, high probability scans were associated with a 12% false positive rate [153]. Therefore, it is recommended to consider patients with low-to-moderate pretest probability and a normal V/Q scan as not having a significant PE. Nevertheless, if the same patients have a non-diagnostic V/Q scan, the recommendation is that, in order to exclude significant PE without going to pulmonary angiogram, the patient must have a negative whole blood D-dimer, negative bilateral ultrasound in low probability group, or negative serial bilateral ultrasound for the moderate probability group. In patients with high pretest probability a normal V/Q scan can only rule out PE if the patient has a normal chest X ray and no baseline cardiopulmonary disease. Otherwise, the patient must go on to CT angiography.

Because of the high number of indeterminate studies using V/Q scanning [153], pulmonary CT angiography (PCTA) is becoming the initial diagnostic test for PE for stable patients with no signs and symptoms of deep venous thrombosis. PCTA with 100 ml of iodinated contrast medium and dedicated imaging procedures and protocols can directly visualize thromboembolic filling defects as well as pleural effusions, vascular remodelling, and oligoemia, any of which may be present with PE [154]. In addition, PCTA may reveal alternative diagnoses, such as pneumonia, aortic dissection, tumour or pneumothorax that in the absence of PE may yield a previously unsuspected reason for symptoms mimicking PE [155]. Current multi-slice CT scanners can image the entire pulmonary vasculature in one breath-hold, allowing 1 mm to sub-millimeter resolution, and the data can be transformed into 2-D and 3-D reconstructed images. Such procedure can significantly increase the detection of 'clinically significant' subsegmental thrombi and evaluate pulmonary vasculature down to 6^{th} order branches [156–158].

The PIOPED II study [159] recently reported the high accuracy of multi-slice CT scanners for the diagnosis of PE, with 83% sensitivity, 96% specificity, 95%, 89% and 60% negative predictive values, as well as 96%, 92% and 58% positive predictive values, respectively for high, intermediate, and low clinical probability groups. These data support the use of PCTA for suspected PE as a stand-alone imaging technique in most patients. However, the false negative rate of 17% should be noted. The most likely explanation for this is that multi-slice CT scanners (mainly 4 slice) still miss small, peripheral subsegmental clots that are better detected by V/P scanning or by classic pulmonary angiography. Therefore, clinicians should be cautious with results that are discordant with their clinical judgment, particularly in front of a normal PCTA in a patient with a high clinical probability of PE [160].

While the clinical significance and treatment requirements of small, peripheral subsegmental thrombi are controversial [161], image fusion of SPECT V/Q and PCTA has demonstrated to be feasible. A recent investigation in 30 consecutive patients who underwent both imaging studies during their admission for investigation of potential PE reported good accuracy of co-registered images as determined subjectively by correlation of the anatomical boundaries and co-existent pleuro-parenchymal abnormalities [160]. Nine patients who had positive PCTA performed as an initial investigation had co-localized perfusion defects on the subsequent fused PCTA/SPECT images. Three of the 11 V/Q scans initially reported as intermediate probability could be reinterpreted as low probability owing to co-localization of defects with parenchymal or pleural pathology [162]. Therefore, the introduction of SPECT/CT hybrid systems will probably provide a single diagnostic tool that will overcome limitations of each imaging modality separately.

4. ADVANTAGES OF UTILIZING SPECT/CT

4.1. Anatomical accuracy of image registration in SPECT/CT hybrid imaging

Image registration is defined as the transfer of two image data sets into one common coordinate system. It may be mono or bimodal, i.e. between images acquired by one single modality or by two different modalities. Depending on the nature of the transformations used, rigid or non-rigid approaches can be used for this purpose, the former allowing for non-linear, 'plastic' deformation of the image data sets. A further distinction can be made between software based registration of data sets acquired independently one from each other by two different imaging devices and hardware based registration where the two data sets are obtained by hybrid equipment in a single imaging session.

In the past decade, the clinical impact of interactive software based registration between SPECT and CT data has received some attention in the literature [163, 164]. In particular, it has been repeatedly demonstrated that patient management may benefit significantly from the integration of functional and morphological data.

One major drawback of software based image fusion is logistic in nature: in the daily clinical routine of many institutions, image data sets from different modalities can be exchanged between different departments only with some difficulty. Although the implementation of hospital-embracing picture-archiving systems should overcome these difficulties, software based registration suffers from anatomical inaccuracies stemming from different positioning of the patient in the two separate imaging devices as well as by difficulties in identifying landmarks common to both data sets to be registered. In addition, the more specific a radiopharmaceutical is for a certain tissue, the poorer images of its distribution are with regard to anatomical detail, and the more difficult software based registration becomes.

These limitations are greatly reduced in hardware based registration that should therefore offer a higher anatomical accuracy of image fusion, as it obviously emerges when reviewing articles investigating the quality of alignment between [^{18}F]FDG-PET and CT. In these studies, anatomical accuracy of fusion is usually quantified by determining the average distance between landmarks or lesions identifiable on both images. This distance ranges between 4 and 12 mm for software based fusion of PET and CT images [165–169], but is reduced 3–5 mm for PET/CT hybrid scanning [168, 169], thus confirming the assumption of a higher anatomical accuracy for hybrid imaging.

Nevertheless, similar data for registration between SPECT and CT images are scarce. Förster et al. studied the accuracy of software based fusion between ^{111}In-octreotide SPECT and multi-row CT in a small group of patients [44]. They reported anatomical inaccuracies in the range of 7 mm, similar to those determined for fusion between PET and CT. Nömayr et al. reported a much higher accuracy of image fusion for SPECT/CT hybrid imaging of the lower lumbar spine [170]. In their study, misalignment ranged between 0.7–1.8 mm, smaller than pixel width in the SPECT images. Notably, software based registration performed on the data sets acquired by SPECT/CT could still significantly improve these results and bring misalignment down to values averaging 1 mm. However, their results cannot be extrapolated to regions of the human body involved in respiratory movements affecting SPECT and CT images to a different degree.

The development of hybrid imaging devices witnessed in the last decade marks a new trend in medical imaging involving the registration and fusion of all image data sets of one individual patient using the same computer platform. Current available data has already proven a major clinical impact of this approach, which is also expected to increase cost effectiveness. The field will be driven by the development of new hybrid imaging devices, but also by significant improvements of software based image fusion. Future medical imaging departments will offer a multimodal environment integrating both hybrid imaging and software based image fusion into the daily clinical routine.

4.2. The effects of CT based attenuation correction of SPECT image data sets and potential future applications

Attenuation artefacts considerably degrade the quality of SPECT images, and also hamper accurate quantification of tracer accumulation in specific volumes of interest. Various methods of attenuation correction have been proposed [171, 172], to be further subdivided into those with and those without transmission measurements. The latter calculate tissue attenuation coefficients on the basis of an assumption of their distribution in the body segment examined, using various methods to determine the body outline. This approach is widely used in studies of brain perfusion, since it is generally assumed that attenuation is homogeneous within the skull.

This assumption does not hold valid for the abdomen or the chest, since these body segments contain tissues with variable attenuation coefficients. Radionuclide transmission scanning has been used to derive maps of abdominal and thoracic attenuation coefficients. However, it has been repeatedly shown that this approach can introduce artefacts that may be difficult to identify [173]. Another major problem inherent to this approach is the low activity of the radioactive sources used for this purpose, leading either to long acquisition times or to attenuation maps with poor quality due to low counting statistics.

This problem is overcome by employing CT data to correct SPECT data for tissue attenuation. A study investigating the visualization of radioactivity in a heart phantom has indeed shown that this variable is homogenized by CT based attenuation correction [174]. Recently, Fricke et al. have demonstrated that the concordance between PET and SPECT studies of myocardial perfusion was improved after using CT based attenuation correction for the SPECT data [175]. Similar results have been reported for skeletal SPECT [176].

Nevertheless, the clinical impact of CT based attenuation correction for SPECT imaging is currently unclear. In a multi-centre trial, Masood et al. demonstrated a moderate, but statistically significant increase in the accuracy of diagnosis of coronary artery disease for myocardial perfusion SPECT [174]. Shiraishi et al. reported a significantly higher accuracy for attenuation-corrected ^{201}Tl-SPECT in staging lung cancer compared to the non-attenuation studies [177]. Likewise, improved identification of sentinel lymph nodes has been shown with the use of attenuation correction [60].

When using CT based attenuation correction for SPECT data, one should be aware of possible artefacts caused by misalignment between SPECT and CT data sets (see above). Figure 15 demonstrates such an artefact in a phantom simulation. In myocardial perfusion SPECT, a 7 mm misalignment between emission and transmission data, corresponding to the width of one pixel in that study, was shown to produce a 15% change in relative regional activity [178]. Similar data have been published for CT based attenuation correction in myocardial SPECT [179] and a method for automated control for misalignment between CT and SPECT has been proposed [180]. In skeletal SPECT, misalignment of the CT by 1 cm was shown to change even the visualization of symmetry of uptake [176]. Therefore, the anatomical accuracy of fusion should be carefully checked before applying CT based attenuation correction.

Attenuation correction of SPECT data constitutes an important step in the development of truly quantitative SPECT, which may improve dosimetric estimates of molecular radiotherapy. More sophisticated phantom studies are needed to better understand variability related to different photon energies. However, for accurate SPECT, quantitation issues related to scatter and partial volume artefacts need to be overcome. In particular, the correction of the latter could also capitalize on the use of CT images aligned to SPECT. Therefore, the new hybrid systems will stimulate research work also along that avenue.

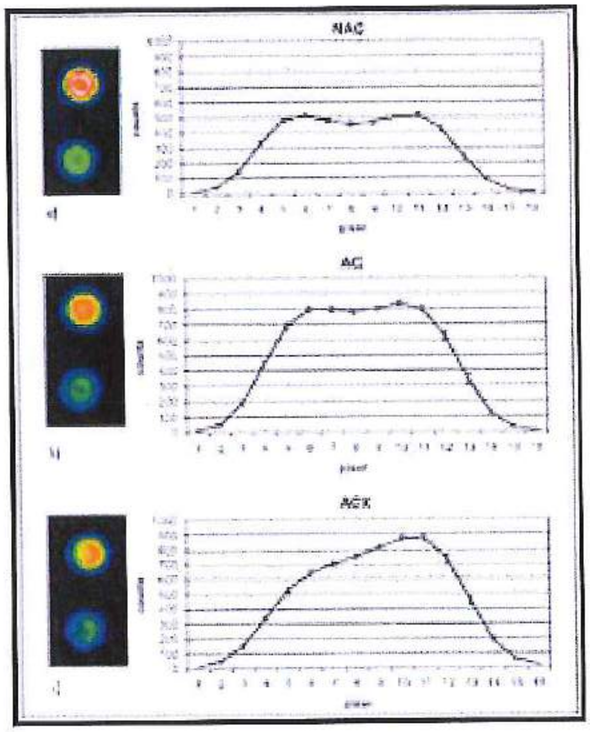


FIG. 15. Transversal SPECT images of two rods in a phantom filled with ^{99m}Tc (a) without (NAC) and (b) with attenuation correction (AC): attenuation correction homogenizes the visualization of activity in the homogeneously filled rods; (c) a CT misalignment by 1 cm in X-direction (ACX) produces a significant artefact in the visualization of activity. The curves are profiles from left to right for the rod filled with the lower activity concentration in NAC, AC, and ACX (from TKL31; with permission).

4.3. Additional information or diagnosis from CT

With continuous higher-speed and thinner sliced CT, small lung lesions (less than 1 cm in diameter) showing interval increase in size may often be detected. Small non-specific lymph nodes, low-density hepatic or renal lesion, and osteolytic or osteoblastic lesion with interval increase in size are also incidentally identified. These lesions are generally beyond the resolution of our current SPECT or PET system and may require further short term follow-up studies to confirm/exclude the diagnosis of new metastases.

4.4. Use of SPECT/CT data for estimating internal radiation dosimetry

As will be better detailed in the next section, the radiation dose is energy absorbed per unit of mass. Accurate dosimetric estimates are extremely critical in radiometabolic therapy, both for calculating radiation dose to the target organ/tissue (generally tumour, but also non-tumour lesions such as hyperfunctioning thyroid parenchyma) and for defining dose-limiting toxicities to normal organs/tissues with high physiologic accumulation of radioactivity (e.g. bone marrow, kidneys). It is well known that internal dosimetry estimates are burdened by a significant degree of estimation regarding absolute concentration of radioactivity in a given organ/tissue, and represent therefore only rough approximations with variabilities that can be as high as 50% or even 100%. Part of this variability is due to the fact that bio-distribution data are usually derived from planar imaging (such as conjugated-view whole body scans), and a-priori models and assumptions on the organ shapes/sizes are employed for the radiodosimetric analysis. Also stand-alone SPECT entails some unwarranted assumptions, since standard factors are usually applied for attenuation correction. In this regard, SPECT/CT certainly holds the promise for developing more accurate approaches to internal radiation dosimetry estimates, since the CT component of the study enables correct attenuation of the emission map specifically in each single patient.

Few reports have been published on this important application of SPECT/CT. Boucek and Turner employed SPECT/CT data to estimate bone marrow dosimetry following the administration of ^{131}I labelled anti-CD20-monoclonal antibody (rituximab) in patients with non-Hodgkin's lymphoma. These patients are usually heavily pretreated with chemotherapy, and myelosuppression is the dose-limiting toxicity. The authors demonstrated a statistically significant correlation ($p = 0.001$) between whole body effective half-life of the radiolabelled antibody and effective marrow half-life. They also found that bone marrow activity concentration was proportional to administered activity per unit weight, height or body surface area ($p < 0.001$). In their experience, SPECT/CT enabled accurate quantification of activity accumulations and thus validated patient-specific prospective dosimetric estimates methods [181].

SPECT/CT has also been advocated for the quantification of radiation doses delivered during radiometabolic therapy with ^{131}I-MIBG, using CT based tumour volume-of-interest [23]. Although based on a single patient, Song et al. have demonstrated that patient-specific 3-D dosimetry based on SPECT/CT is feasible and important in the dosimetry of thyroid cancer patients with radioiodine-avid lung metastases and prolonged retention in the lungs. In their opinion, this procedure could constitute the breakthrough for rationally planning radionuclide therapy in patients with thyroid cancer [182].

A preliminary report from the Pisa group described a novel SPECT/CT based approach to calculate attenuation- and scatter-corrected dosimetry to the bone marrow and to tumour lesions following the administration of ^{153}Sm-EDTMP for palliation of bone pain in patients with hormone-refractory metastatic prostate cancer [183]. The system was phantom-calibrated for tissue densities, and the CT images were utilized to identify bone structures. Dedicated software was developed for automatic edge recognition of skeletal uptake, which was corrected for attenuation and scatter. An S-value matrix was then derived from the attenuation map voxel-by-voxel for each individual patient (rather than pixel-by-pixel as in conventional evaluations) (Fig. 16). It was found that the conventional approach based on planar imaging and standard-factor corrections overestimated dose to bone marrow by an average 67% versus the SPECT/CT method. The new SPECT/CT based method therefore opens the perspective of calculating radiation dose to the bone marrow and to skeletal lesions (or other sites), and therefore to correlate dosimetry to lesions with efficacy of therapy (bone palliation, or true anti-tumour effect [184]).

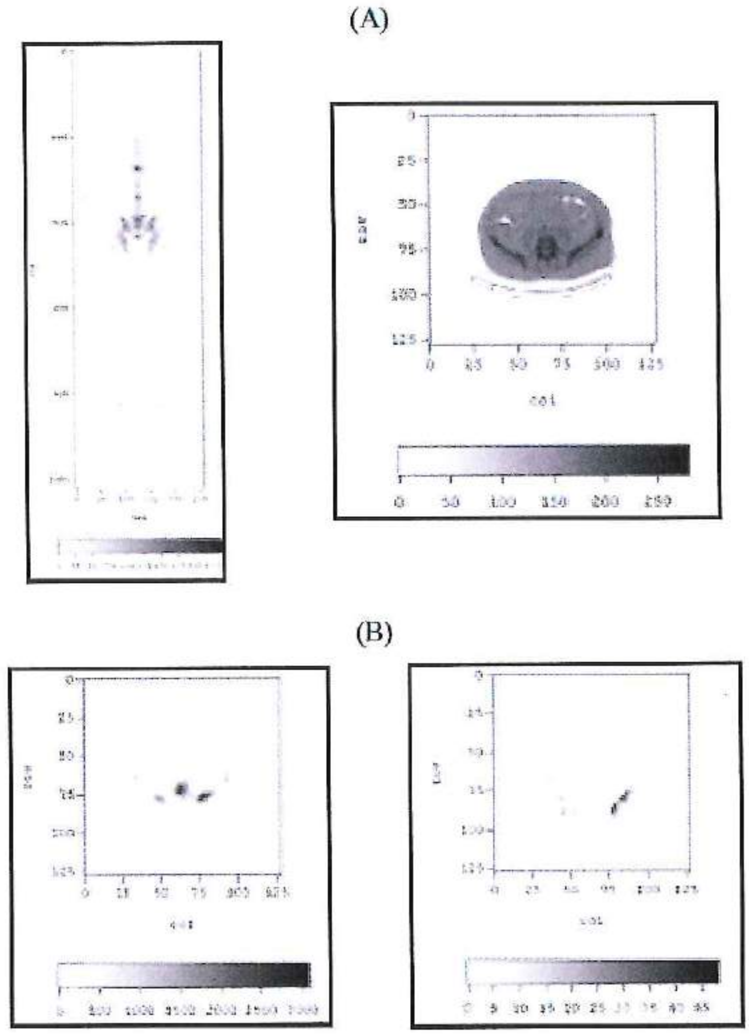


FIG. 16. Sequential steps in the elaboration of the SPECT/CT images obtained after administration of 153Sm-EDTMP given for bone pain palliation purposes in a patient with hormone-refractory prostate cancer. (A) Outline of skeletal uptake of the bone-seeking radiopharmaceutical as derived from an automatic edge-recognition software applied on the planar 24 h whole body scan (left panel). The right panel shows the CT density-reconstructed map acquired at the pelvis. (B) Reconstructed SPECT map (left panel) and tomography of the 3-D dosimetry map in Gy (right panel).

4.5. Radiation dose of CT from SPECT/CT

The radiation absorbed dose delivered to the patient from the use of CT in SPECT/CT study is difficult to measure because of many factors involved, but the CT Dose Index (CTDI) based on scan parameters can be calculated, and represents an index of radiation dose to a standard phantom. The CT scanners generally provide an X ray tube current modulation function that makes uniform image quality and dose for various patient sizes [185]. The system will automatically increase or decrease the tube current (mA) when the user selects a reference effective mA in response to changes in diameter or tissue density of the patient. The effective mA includes the tube current, rotation speed, and pitch used for the scan. The user-selected scan parameters that affect patient dose in CT examinations are effective mA, kVp, detector collimation setting (affecting the width of the radiation beam in table-travel direction), beam-shaping filter associated with the scan type (body or head), and number of scans over the same section of the body. If the dose distribution from the centre to the edge of the phantom as well as the pitch used in the scan is taken into account, a term called CTDIvol can be used to represent the dose index to the volume of the phantom. The radiation dose is energy absorbed per unit mass. The CTDIvol associated with a single CT scan covering one SPECT bed position is the same as the CTDIvol for a CT scan covering two non-overlapped SPECT bed positions if the same CT scan parameters are used. However, there is a factor of two variation in the radiation risk to the patient between these two cases. The CTDIvol in milli-Gray (mGy) is multiplied by the length of the CT scan in cm, to yield the dose-length product (DLP). Once the DLP is determined, an effective dose can be estimated using conversion factors for the relative radiosensitivity of the organs within the range of the scan. Some CT scanners save the CDTIvol and DLP values for a specific patient scan at the end of the examination. If there are multiple CT scans of the same region of the patient, each scan adds to the radiation dose and risk.

The effective dose and CTDIvol values from typical CT scans to the chest and abdomen have been calculated [186], and they are 4 mSv and 8 mGy, respectively. The value to the head and neck are 4 mSv and 10–20 mGy, respectively. These doses are for one SPECT bed position, relating to a 39 cm CT scan length, acquired using a fixed technique at the reference mA. Doses can be scaled linearly with the actual scan effective mA for the patient study. In case of a CT for a two-bed SPECT/CT, the appropriate effective dose values are added together. A planning CT view is obtained prior to determining the scan extent and location with low (about 20) mA for the postero-anterior projection and with the beam direction such that the beam enters the table prior to passing through the patient. These measures ensure an adequate planning view with the lowest dose to the patient, which is about the same as for a single view of the chest X ray.

5. FURTHER DEVELOPMENT OF SPECT/CT WITH NEW RADIOPHARMACEUTICALS

There is a continuous interest to label biologically important drugs or agents with easily available and cheaper isotopes than PET tracers, such as ^{99m}Tc labelled tracers (Table 1) for SPECT/CT to diagnose, differentiate, and stage cancers and also to evaluate as well as to predict therapeutic responses. L,L-ethylenedicystein, the most successful example of N_2S_2 chelates, can be labelled with ^{99m}Tc with high radiochemical purity, and the preparation remains stable for several hours [187]. Reliable molecular imaging that: assesses cellular targets at low cost, treatment response more rapidly, provides a good differential diagnosis, predicts correctly therapeutic response and allows for better radiation dosimetry for internal radiotherapy, would be very valuable.

6. CT TRAINING IMAGING FOR NUCLEAR PHYSICIANS AND TECHNOLOGISTS

The Societies of Nuclear Medicine, Computed Body Tomography and Magnetic Resonance, and the American College of Radiology have recently agreed that only properly trained qualified physicians should interpret PET/CT images [189]. The issue of training nuclear physicians to interpret the CT images produced by SPECT/CT devices is similar to that for

PET/CT. In this regard, earning 100 hours of CT continuing medical education credits and interpreting 500 CT cases under the supervision of qualified diagnostic radiologists were recommended. The CT cases should include reasonable numbers of head and neck, chest, abdomen and pelvis examinations. According to these recommendations, both radiology and nuclear medicine residents are required to interpret SPECT/CT images.

TABLE 1. SPECIFIC RADIOTRACERS [187, 188]

Character of cancer cells	Compounds
Cellular growth	^{99m}Tc-deoxyglucose ^{99m}Tc-guanine
Hypoxia	^{99m}Tc-metronidazole
Angiogenesis	^{99m}Tc-endostatin ^{99m}Tc-bevacizumab (against VEGF receptor)
Apoptosis	^{99m}Tc-annexin-V
Hormones	^{99m}Tc-estradiol

SPECT/CT and PET/CT present therefore similar practical issues regarding education, training and certification of nuclear medicine technologists to become properly qualified and competent to perform the CT portion of the study. The American Registry of Radiologic Technologists has adapted its CT certification examination and has allowed certified or registered nuclear medicine technologists who have met the required prerequisites to take this examination.

Nevertheless, the choice of the optimal way to achieve adequate training for interpreting multimodality imaging examinations will differ between countries owing to differences in infrastructure and legislation. The European Association of Nuclear Medicine (EANM) and the European Society of Radiology (ESR) have agreed to work together to produce a common position paper regarding multimodality imaging systems [190, 191]. Both organizations recognize the importance of coordinating working practices for multimodality imaging and that undertaking the nuclear medicine and radiology components of imaging with hybrid systems requires different skills. Training should be properly structured and comprehensive and should be conducted in accredited training centres. It should incorporate the principles and all modalities of both specialties to allow the trainee to acquire a full understanding of the possibilities and difficulties of each technique and its medical background, and provide the basis for participating in the evolution of multimodality imaging. Refresher type courses can prepare for specific training or refresh knowledge, but cannot replace appropriate on site training. It is not acceptable for training to be focused on a single technique.

Three different training models have been proposed [190]:

- Comprehensive training in both specialties, clinical radiology and nuclear medicine, in those countries where it is possible for the individual to practice both specialties and where such dual specialty training can be obtained. Such training gives the trainee the possibility of ultimately practicing in one or both of the specialties and of billing appropriately. The duration of the entire training programme in both specialties would most likely be neither politically nor economically acceptable in many European countries.

- An adequate period of training in the other specialty in addition to full training in the primary specialty. This model would facilitate acquisition by nuclear medicine specialists or radiologists of the necessary training in the other specialty after having completed full training in their primarily chosen specialty. Such adjusted additional training programme should be defined to provide a broad foundation of knowledge in the second specialty and should not be confined to a single technique such as CT or SPECT or a single clinical application. For nuclear medicine specialists, besides relevant radioprotection issues, training will include the physical principles and practical clinical skills of CT imaging. For radiologists, besides relevant radioprotection issues, training will include knowledge of radiopharmacy and radiotracer biokinetics and the physical principles and practical skills of SPECT. Training needs not to include therapeutic interventional radiology or radionuclide therapy. The core of the additional training would be dedicated to hybrid imaging. For radiologists, part of the nuclear medicine component should be undertaken during the fourth and fifth year of training. Maintenance of radiology skills during this time would be mandatory. For nuclear medicine specialists, part of the radiology component should be undertaken during the fourth and fifth years of training. Maintenance of nuclear medicine skills during this time would be mandatory. The remaining part of the training would then be obtained with an additional year fully dedicated to the second specialty, giving a total of 6 years' training for both specialties. The exact duration of the training is subject to local regulations, which may vary from country to country. Nonetheless, the general time scale as outlined in this option should be considered as the model. Such additional training will lead to a special competency certification.

- Potential future integration of training: an incorporated training in nuclear medicine and radiology taking the form of a cross-over or integrated training programme, where both specialties agree and recognize a training curriculum which encompasses the principles of all imaging modalities of both specialties. The curricula of both specialties would be adapted to include knowledge of anatomy, cell biology, genetics and physiology as well as the normal requirements of the physical basis of all imaging modalities and patient safety.

Each country should establish a training schedule that ensures the accomplishment of appropriate education in both specialties, bearing in mind that this cannot be achieved by merely performing a certain number of studies with one or the other technique. Only thorough training will give the necessary insight into anatomical and functional aspects of the various modalities, their interpretation with respect to patient-tailored treatment and risk assessment, and finally the further development and refinement of multimodality imaging.

During the interim period while these training models are set up, the nuclear medicine specialist would manage and report the nuclear medicine component of the examination and the radiologist would manage and report the anatomical and pathological component, with consultation between the two specialists to combine the data into a final diagnosis. Each specialist would provide a report with regard to the part of the study that he/she is directly responsible for. The benefit of this strategy is that those fully trained in the specific modalities would interpret the images jointly, thus providing a high-quality result. At a practical level this concept requires careful organization, cooperation and discussion between nuclear medicine and clinical radiology specialists.

7. REFERRAL CRITERIA FOR SPECT/CT

Local logistics and availability of different medical specialties dictate how diagnostic algorithms are applied in the clinical routine when patients are referred for diagnosis and/or characterization of their disease, and in particular to SPECT/CT. These examinations should be performed with the purpose of, whenever possible, avoiding the use of invasive procedures, when surgery is contemplated as part of treatment, or prior to adopting mini-invasive approaches. Clearly, a combined imaging technique such as SPECT/CT provides all the morpho-functional information enabling the surgeon to plan the surgical approach most suited to the individual patient. Referring clinicians have learned to regard radionuclide studies as useful tests that may confirm a suspected clinical diagnosis and characterize disease processes with information that can be relevant to treatment of the disease. This review has been designed to provide a summary of a methodological radionuclide based approach, SPECT/CT, a still evolving procedure with the final goal of enhancing diagnostic information and guiding therapy. It includes the methodology, analysis and estimation of usefulness of these examinations with an emphasis on more recently published data. Based on this review and on the experience accumulated by each centre represented in this panel of experts, referral criteria for a SPECT/CT examination can briefly be summarized in the indications that follow.

Indication to perform a SPECT/CT examination can be raised on primarily clinical ground. Such indications include:

- High suspicion for active disease, or known structural pathology, as SPECT/CT may localize multiple sites and define extent of disease;

- Planning treatment (medical, surgical, or radiation therapy);

- Monitoring response to treatment.

In some other cases, indication can also originate on the basis of data from previous anatomic imaging, including situations such as:

- Abnormal structural findings of equivocal functional significance, either at diagnosis or post-treatment;

- Absence of overt structural pathology in the presence of high clinical suspicion.

It is sometimes necessary to clarify inconclusive results of prior functional imaging (usually planar scintigraphy), showing foci of increased radiotracer uptake of unclear localization and clinical significance. Inconclusive scintigraphic studies can be due to tracer-related factors (because of poor physical characteristics, high target-specificity with paucity of non-target anatomic landmarks, physiologic bio-distribution with the lesion close to excretion sites). Alternatively, inconclusive radionuclide imaging can be due to patient/disease-related factors, such as complex regional anatomy or anatomic distortion post-treatment (surgical and/or radiation therapy).

Finally, emphasis should be placed on the use of the CT component of a SPECT/CT examination for correcting, on a patient-specific basis, the single photon emission data for attenuation and scatter. This is crucial for proper estimation of radioactivity concentration in specific organs/tissues on a volumetric basis.

8. CONCLUDING REMARKS

In summary, a high quality SPECT/CT study requires a reliable, well functioning hybrid scanner which has met acceptance testing criteria and which is regularly monitored for quality of performance. The study must be designed to answer the specific question asked by the referring physician, and the patient must be appropriately educated and compliant with the preparations for the scan, including fasting if so indicated. The technical staff must be well trained to perform and monitor both components of the study according to a well defined protocol. The acquisition and processing protocols must be carefully followed. The images must be reviewed for technical and diagnostic quality before the patient leaves the department. Finally, the images must be interpreted by skilled readers who are well aware of the clinical history of the patient, using workstations that allow integrated viewing of the functional and anatomic data. In this way, a high quality study will provide useful diagnostic information for further clinical management and patient care. As the quality of SPECT/CT devices improves, it is expected that new applications will emerge.

The impact on reader confidence and increased credibility with referring clinicians is an important add-on feature for SPECT/CT. The concept of incremental confidence is difficult to quantify. It is clear that evaluating the impact of combined SPECT/CT remains a subjective process. While nuclear medicine physicians interpret a study, referring clinicians often remain in doubt because of the difficulties visualizing the location of the finding on scintigraphy alone. Correlation with CT data through precise image registration makes the interpretation of high signal-to-background functional images, combined with better anatomic information, less dependant upon individual expertise. Thus, SPECT/CT results in more meaningful communication with referring physicians, as the hybrid imaging study interpretation is more credible to the clinician who is able to see the location of the functional, tracer-avid focus.

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Consultants Meeting on Recent Advances on SPECT/CT,
Vienna, Austria, 25–27 June 2007

EXHIBIT E

LETTER OF SUPPORT

Yale SCHOOL OF MEDICINE
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December 1, 2016

RE: Letter of Support for Yale Nuclear Cardiology SPECT/CT Certificate of Need (CON) Application

To Whom It May Concern:

As the Medical Director of the Yale-New Haven Hospital (YNHH) Nuclear Cardiology Laboratory, I am writing to express my enthusiastic and unequivocal support for our laboratory's CON application for the installation of a GE NM 640 SPECT/CT system at the YNHH Saint Raphael's Campus. As background, YNHH Nuclear Cardiology is a world-leading clinical nuclear cardiology laboratory, where the field of nuclear cardiology has literally been developed and advanced from its start in the 1970's. We are a state-of-the art nuclear cardiology laboratory, with current equipment that includes traditional wide field-of-view SPECT/CT, dedicated cardiac solid-state detector SPECT/CT, and 3-D PET/CT equipment (shared with Radiology) at the York Street Campus. Since 2012, the oversight of the YNHH nuclear cardiology laboratories at the York Street Campus, Saint Raphael's Campus, and Guilford, North Haven, and Norwich outpatient locations has been consolidated.

Over the past 40 years, the YNHH Nuclear Cardiology Laboratory has been on the forefront of many advances in nuclear cardiology, including:

- One of the first laboratories in the world to be accredited for nuclear cardiology by the Intersocietal Accreditation Commission (IAC) in 1999, with 6 successful re-accreditations
- Development of the first of its kind quantitative nuclear cardiology reading software (Wackers-Liu)
- Instrumental development of many novel clinical nuclear cardiology radiotracers (Tc99m Sestabmibi, Tc99m Tetrofosmin, among others)
- Continuous clinical and translational research funding in the development of novel technologies, equipment and clinical applications, including gated SPECT, gated ERNA, and quantitative FDG imaging
- Five current or former Presidents of the American Society of Nuclear Cardiology have either trained in or lead our laboratory

Over the past decade, it has become increasingly evident that the use of CT-based attenuation correction for SPECT nuclear myocardial perfusion imaging is the state of the art imaging technique in the field. The benefits of CT attenuation correction (CTAC) for SPECT include improved specificity, higher accuracy, and the ability to better define the burden of coronary artery disease. Our laboratory has demonstrated the utility of CTAC to specifically show in published data that the addition of CTAC imaging increases reader certainty (particularly in obese patients), reduces unnecessary coronary angiography, and reduces downstream costs to patients and the health system (Patchett et al. JNC

2016). Therefore, it is our goal across the YNHH Health System to systemically replace our existing SPECT equipment used for myocardial perfusion imaging to systems that incorporate CTAC.

We will begin this move towards SPECT/CT imaging across the health system by first replacing an existing SPECT system (Siemens Symbia S) at the Saint Raphael's Campus with a GE NM 640 SPECT/CT system. The GE NM 640 has a number of benefits. First of all, the CT system **does not allow for diagnostic quality CT imaging**. This is due to the fact that the tube current on this system is limited to 30 mA. Therefore, this CT system cannot be re-purposed for diagnostic Radiology CT use. Second, this low-energy CT system does not require lead wall shielding, which means limited/no significant room renovation costs for installation. Third, despite this low-dose imaging, it does provide additive information on the presence of coronary artery disease and increased interpretive certainty (Patchett et al. JNC 2016).

Neither of our two current SPECT systems at the YNHH Saint Raphael's Campus have CT attenuation correction. This has lead to documented reduced specificity of nuclear cardiology myocardial perfusion imaging test results, leading to unnecessary invasive coronary angiography which puts patients at risk of rare, but potentially life-threatening complications. In addition, as the YNHH Saint Raphael's Campus is now the Bariatric Surgery Center for YNHH Health System, the need for pre-operative evaluation on obese patients is growing, and SPECT/CT imaging greatly benefits this population. Therefore, we feel the implementation of this SPECT/CT system solely for nuclear cardiology use at the YNHH Saint Raphael's Campus will improve the overall specificity of myocardial perfusion imaging in the New Haven Community, improve patient safety, add no cost to the test, and yet reduce unnecessary medical expenditures.

Thank you for your consideration and please contact me with any questions about this request.

Sincerely,

Edward J. Miller, MD PhD, FASNC
Director, Nuclear Cardiology

EXHIBIT F

YNHH FINANCIAL ASSISTANCE POLICY

Yale
NewHaven
Health

Financial Assistance Programs
Policies and Procedures

Service Area: Corporate Business Services	**YALE NEW HAVEN HEALTH SYSTEM POLICIES & PROCEDURES**
Title: Financial Assistance Programs Policy	
Date Approved: 09/20/2013	**Approved by:** Boards of Trustees Senior Vice President, Finance
Date Effective: 09/20/2013	**Date Reviewed/Revised:** 01/21//2015, 09/30/2016
Distribution: MCN Policy Manager	**Policy Type (I or II):** Type I
Supersedes: Yale New Haven Hospital Financial Assistance Programs for Hospital Services (NC:F-4) Bridgeport Hospital Financial Assistance Programs for Hospital Services (9-13) Greenwich Hospital Overview of Financial Assistance Programs for Hospital Services	

Purpose

Yale New Haven Health System ("YNHHS") recognizes that patients may not be able to pay for medically necessary health care without financial assistance. Consistent with its mission, YNHHS is committed to assuring that the ability to pay will be considered carefully when setting amounts due for emergency and other medically necessary hospital services.

In recognition of its role to help those in need of financial assistance, YNHHS has established the Financial Assistance Programs ("FAP") to assist with emergency and other medically necessary care. The objectives of the FAP are to:

- Specify all financial assistance available under the FAP;
- Provide clear information regarding eligibility criteria, application requirements and the method for applying for financial assistance under the FAP;
- The basis for calculating amounts charged to FAP-eligible patients for emergency or other medically necessary care; and
- The YNHHS measures to widely publicize this FAP within the communities served by YNHHS.

Applicability

This policy applies to each licensed hospital affiliated with YNHHS, including Bridgeport Hospital, Greenwich Hospital, and Yale-New Haven Hospital (each a "Hospital").

Policy

I. Scope and Provider List

A. **Emergency and Other Medically Necessary Care.** The FAP apply to emergency and other medically necessary care, including inpatient and outpatient services, billed by a Hospital. The FAP exclude: (a) private room or private duty nurses; (b) services that are not medically necessary, such as elective cosmetic surgery; (c) other elective convenience fees, such as television or telephone charges, and (d) other discounts or reductions in charges not expressly described in this Policy.

B. **Provider List.** A list of providers who provide emergency and other medically necessary care at a Hospital can be found here: https://www.ynhhs.org/patient-care/billing-insurance/financial-assistance.aspx. The list indicates if the provider is covered under the FAP. If the provider is not covered under this policy, patients should contact the provider's office to determine if the provider offers financial assistance and if so what the provider's financial assistance policy covers.

II. Financial Assistance Programs and Eligibility

Financial assistance is available to individuals who are residents of the United States of America, or citizens of the Unites States residing abroad, who complete a financial assistance application and meet the additional eligibility requirements described below.

A. **Free Care.** The Free Care program provides care at no cost to Hospital patients with gross annual family income less than or equal to 250% of the Federal Poverty Guidelines (*see* Attachment 1), and who have applied for, and been approved or receive a valid denial within the last six months, for State medical assistance.

In addition, YNHHS employs a third party screening tool to assist in identifying individuals with self-pay balances who have not applied for financial assistance, but who have incomes less than or equal to 250% of the Federal Poverty Level (*i.e.*, eligible for free care). If a patient is identified through this process outstanding hospital balances may be adjusted to charity (free) care.

B. **Discounted Care.** If a patient's gross annual family income is over 250% of the Federal Poverty Level, and the patient is uninsured, the Hospital will discount care to the Hospital's AGB (as defined in Section III below and on Attachment 1 hereto).

C. **Restricted Bed Funds.** You may be eligible to receive restricted bed funds, which are funds that have been donated to the Hospital to provide free or discounted care to individuals who meet the individual fund criteria. There are no specific income limits for receipt of restricted bed funds. Eligibility is determined on a case-by-case basis by the fund nominators based on financial hardship. All patients who fill out the YNHHS financial assistance application will automatically be considered for restricted bed funds.

D. **Other Hospital-Specific Financial Assistance programs:**

– **Yale New Haven Hospital Me & My Baby Program.** This program is available to Yale New Haven Hospital patients. It provides prenatal, labor and delivery services, and some post-partum care free of charge. You may be eligible if you live in New Haven County, do not have any type of health insurance and your family earns less than 2 ½ times the Federal Poverty Level. For more information or to request an application, see our representatives at the Yale New Haven Hospital Women's Center or call 203-688-5470.

– **Greenwich Hospital Outpatient Clinic** provides free or discounted care to individuals who apply for and are approved for clinic membership. You may be eligible for clinic membership if you do not have insurance, are not eligible for State Assistance (Medicaid), are a Greenwich resident and have family income less than 4 times the Federal Poverty Level. For more information or to obtain an application please call 203-863-3334.

III. Limitation on Charges - Amounts Billed to FAP-Eligible Patients

Where there is an award of financial assistance that does not cover 100% of YNHHS charges for the service, the amounts charged to patients eligible for financial assistance under this Policy will not be more than the amount a Hospital generally bills patients who have insurance coverage for such care ("AGB"). YNHHS calculates AGB annually by Hospital using the "look back method" and based on Medicare fee-for-service rates, including Medicare beneficiary cost-sharing amounts and all private health insurers that pay claims to each Hospital facility for the prior Fiscal Year. YNHHS may apply the percentage discount by Hospital, or may elect to use the percentage discount most favorable to YNHHS patients. AGB is set forth on Attachment I hereto.

As used herein, the "amount generally billed" and "look back method" have the meanings set forth in Internal Revenue Code §501(r)(5) and1.501(r)-5.

IV. Method of Applying for Assistance

To be eligible for financial assistance, the patient must complete an application for financial assistance ("Application"). The Application sets forth (i) FAP available programs and eligibility requirements, (ii) the documentation requirements for determinations of eligibility, and (iii) the contact information for FAP assistance. The Application also specifies (i) that the Hospital will respond to each Application in writing, (ii) that patients may re-apply for FAP at any time, and (iii) that additional free bed funds become available every year.

Hospitals may not deny financial assistance under the FAP based on failure to provide information or documents that the FAP or the Application do not require as part of the Application.

YNHHS Hospitals make reasonable efforts to determine eligibility and document any determinations of financial assistance eligibility in the applicable patient accounts. Reasonable efforts include suspending any extraordinary collection action to obtain payment for the care, making a determination as to whether the individual is FAP-eligible for the care and notifying him/her in writing of the eligibility determination, including, if applicable, the assistance for which the individual is eligible, and the basis for this determination.

Once Hospital identifies a patient is FAP-eligible, Hospital shall:

(i) Provide a billing statement indicating amount the individual owes as a FAP-eligible patient, including how the amount was determined and states, or describes how the individual can get information regarding the AGB for the care;

(ii) Refund to the individual any amount he or she has paid for the care that exceeds the amount he or she is determined to be personally responsible for paying as a FAP-eligible individual, unless such excess amount is less than $5, or such other amount set by the IRS; and

(iii) Take reasonable measures to reverse any extraordinary collection actions.

V. Non-Payment – Legal Action

A Hospital (and any collection agency or other party to which it has referred debt) shall not engage in any extraordinary collection action ("ECA") before making reasonable efforts to determine if a patient or any other individual having financial responsibility for a self-pay account (Responsible Individual(s)) eligible for financial assistance under this FAP. Any ECA must be approved by the Vice President of Corporate Business Services or his designee(s), prior to the initiation of any ECA.

The Hospital will follow its A/R billing cycle in accordance with internal operational processes and practices. As part of such processes and practices, the Hospital will, at a minimum, notify patients about its FAP from the date care is provided and throughout the A/R billing cycle (or during such period as is required by law, whichever is longer) by:

1. All patients will be offered a plain language summary and an application form for financial assistance under the FAP as part of the discharge or intake process from a Hospital.

2. At least three separate statements for collection of self-pay accounts shall be mailed or emailed to the last known address of the patient and any other Responsible Individual(s); provided, however, that no additional statements need be sent after a Responsible Individual(s) submits a complete application for financial assistance under the FAP or has paid in-full. At least 60 days shall have elapsed between the first and last of the required three mailings. It is the Responsible Individual(s) obligation to provide a correct mailing address at the time of service or upon moving. If an account does not have a valid address, the determination for "Reasonable Effort" will have been made. All single patient account statements of self-pay accounts will include but not limited to:

    a. An accurate summary of the hospital services covered by the statement;

    b. The charges for such services;

    c. The amount required to be paid by the Responsible Individual(s) (or, if such amount is not known, a good faith estimate of such amount as of the date of the initial statement); and

    d. A conspicuous written notice that notifies and informs the Responsible Individual(s) about the availability of financial assistance under the FAP including the telephone number of the department and direct website address where copies of documents may be obtained.

3. At least one of the statements mailed or emailed will include written notice that informs the Responsible Individual(s) about the ECAs that are intended to be taken if the Responsible Individual(s) does not apply for financial assistance under the FAP or pay the amount due by the billing deadline. Such statement must be provided to the Responsible Individual(s) at least 30 days before the deadline specified in the statement. A plain language summary will accompany this statement. It is the Responsible Individual(s) obligation to provide a correct mailing address at the time of service or upon moving. If an account does not have a valid address, the determination for "Reasonable Effort" will have been made.

4. Prior to initiation of any ECA, an oral attempt will be made to contact Responsible Individual(s) by telephone at the last known telephone number, if any, at least once during the series of mailed or emailed statements if the account remains unpaid. During all conversations, the patient or Responsible Individual(s) will be informed about the financial

assistance that may be available under the FAP.

5. Subject to compliance with the provisions of this policy, a YNHHS Hospital may take Extraordinary Collection Actions as set forth in Attachment I of this Policy, to obtain payment for medical services provided.

VI. Policy Availability

Contact Corporate Business Services toll free at 855- 547-4584 for information regarding eligibility or the programs that may be available to you, to request a copy of the FAP, FAP application form, or Billing and Collection Policy to be mailed to you, or if you need a copy of the FAP, plain language summary, or FAP application form translated to a language other than English. Further, patients may ask Patient Registration, Patient Financial Services and Social Work/Case Management about initiating the FAP application process.

Copies of the FAP, a plain language summary of the FAP and FAP application is available at https://www.ynhhs.org/billing-insurance.aspx.

Each Hospital makes available copies of the FAP, a plain language summary of the FAP and FAP application on request, free of charge, by mail or in the Hospital Emergency Department and at all points of registration in paper form in English and the primary language of any population with limited English proficiency that constitutes 5% or more of the population the Hospital serves. See Attachment 3 for a list of languages.

Further efforts to widely publicize the FAP include publishing notices in newspapers of general circulation; providing written notice of FAP in all billing statements; providing notice of FAP in all oral communications with patients regarding the amount due; and holding open houses and other informational sessions.

VII. Management Oversight Committee

The FAP will be overseen by a management oversight committee chaired by a Senior Vice President, YNHHS and comprised of representatives from Corporate Business Services, patient financial services, patient relations, finance, and the medical staff, as necessary. This committee will meet on a monthly basis.

References

- Internal Revenue Code 501(c)(3)
- Internal Revenue Code 501(r)
- Conn. Gen. Stat. § 19a-673 et seq.

Related Policies

- YNHHS Billing and Collections Policy (xx)
- Yale-New Haven Hospital Policy – Distribution of Free Care Funds NC:F-2
- Bridgeport Hospital Policy for Free Care Funds (9-14)

Attachment I

250% of the Federal Poverty Guidelines (FPG):

Family size:	Maximum Income:
1	$29,700
2	$40,050
3	$50,400
4	$60,750
5	$71,100
6	$81,450

Add **$10,400 for each additional family member*

Amounts Generally Billed (AGB):
Patients eligible for financial assistance under this Policy will receive assistance according to the following:

Annual Family Income	Amount of Discount % of Charges	Patient Pays % of Charges
< or = 250% FPG	100%	0
> 250% FPG	69%	31%*

**For calendar year 2016, AGB (% of charges: BH 68%, GH 68%, YNHH 67%. Financial assistance under the discounted care program across all Hospitals is 69%..*

Attachment II

Extraordinary Collection Actions:

Property Liens.

Liens on personal residences are permitted only if:

(i) The patient has had an opportunity to apply for free bed funds and has either failed to respond, refused, or been found ineligible for such funds;

(ii) The patient has not applied or qualified for other financial assistance under the Hospital's Financial Assistance Policy, to assist in the payment of his/her debt, or has qualified, in part, but has not paid his/her responsible part;

(iii) The patient has not attempted to make or agreed to a payment arrangement, or is not complying with payment arrangements that have been agreed to by the Hospital and patient;

(iv) The aggregate of account balances is over $10,000 and the property(ies) to be made subject to the lien are at least $300,000 in assessed value; and

(v) The lien will not result in a foreclosure on a personal residence.

Limited English Proficiency Languages

Albanian
Arabic
Simplified Chinese
French
French Creole (Haitian Creole)
German
Greek
Hindi
Italian
Japanese
Korean
Pashto
Persian Dari
Persian Farsi
Polish
Portuguese
Portuguese Creole (Cape Verdean)
Russian
Spanish
Swahili
Tagalog
Tigrinya
Turkish
Vietnamese

EXHIBIT G

AUDITED FINANCIALS

KPMG

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidated Financial Statements
and Supplementary Information

September 30, 2015 and 2014

(With Independent Auditors' Report Thereon)

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Table of Contents

KPMG LLP
345 Park Avenue
New York, NY 10154-0102

Independent Auditors' Report

The Board of Trustees
Yale-New Haven Hospital and Subsidiaries:

We have audited the accompanying consolidated financial statements of Yale-New Haven Hospital and Subsidiaries, which comprise the consolidated balance sheets as of September 30, 2015, and the related consolidated statements of operations and changes in net assets and cash flows for the year then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in conformity with U.S. generally accepted accounting principles; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the 2015 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Yale-New Haven Hospital and Subsidiaries as of September 30, 2015, and the consolidated results of their operations and their cash flows for the year then ended in accordance with U.S. generally accepted accounting principles.

KPMG

Other Matters

The accompanying consolidated financial statements of Yale-New Haven Hospital and Subsidiaries as of and for the year ended September 30, 2014 were audited by other auditors whose report thereon dated December 23, 2014, expressed an unmodified opinion on those consolidated financial statements.

Our audit was performed for the purpose of forming an opinion on the 2015 consolidated financial statements as a whole. The accompanying consolidating balance sheet and consolidating statement of operations and changes in net assets are presented for purposes of additional analysis and are not a required part of the consolidated financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the consolidated financial statements. The information has been subjected to the auditing procedures applied in the audit of the consolidated financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the consolidated financial statements or to the consolidated financial statements themselves and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the consolidated financial statement as a whole.

KPMG LLP

December 23, 2015

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidated Balance Sheets

September 30, 2015 and 2014

(In thousands)

Assets		2015	2014
Current assets:			
Cash and cash equivalents	$	103,628	69,250
Short-term investments		980,087	926,024
Accounts receivable for services to patients, less allowance for uncollectible accounts of approximately $196,203,000 in 2015 and $171,491,000 in 2014		293,352	264,671
Other receivables		35,074	33,771
Professional liabilities insurance recoveries receivable – current portion		19,852	18,968
Other current assets		75,554	72,597
Amounts on deposit with trustee in debt service fund		4,786	4,394
Total current assets		1,512,333	1,389,675
Assets limited as to use		96,888	124,869
Long-term investments		289,434	263,938
Deferred financing costs, less accumulated amortization		8,909	9,285
Professional liabilities insurance recoveries receivable – noncurrent		57,025	49,433
Goodwill		44,774	44,818
Other assets		169,842	172,823
Property, plant and equipment:			
Land and land improvements		50,200	42,308
Buildings and fixtures		1,158,500	1,151,698
Equipment		473,907	458,802
		1,682,607	1,652,808
Less accumulated depreciation		817,100	754,130
		865,507	898,678
Construction in progress		80,774	27,576
		946,281	926,254
Total assets	$	3,125,486	2,981,095

See accompanying notes to consolidated financial statements.

Liabilities and Net Assets		2015	2014
Current liabilities:			
Accounts payable	$	150,298	153,601
Accrued expenses		202,062	181,555
Professional liabilities – current portion		19,852	18,968
Other current liabilities		59,087	36,290
Current portion capital lease obligation		2,003	2,963
Current portion of debt		8,083	7,626
Total current liabilities		441,385	401,003
Long-term debt, net of current portion		800,348	802,124
Long-term capital lease obligation, net of current portion		46,850	50,838
Accrued pension and postretirement benefit obligations		228,810	231,477
Professional liabilities – noncurrent		96,778	115,868
Other long-term liabilities		246,389	215,877
Deferred revenue		42,720	44,378
Total liabilities		1,903,280	1,861,565
Net assets:			
Unrestricted		1,102,351	1,017,424
Temporarily restricted		70,941	64,318
Permanently restricted		46,886	35,906
Total Yale-New Haven Hospital and Subsidiaries net assets		1,220,178	1,117,648
Noncontrolling interest		2,028	1,882
Total net assets including noncontrolling interest		1,222,206	1,119,530
Commitments and contingencies			
Total liabilities and net assets	$	3,125,486	2,981,095

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidated Statements of Operations and Changes in Net Assets

Years ended September 30, 2015 and 2014

(In thousands)

		2015	2014
Operating revenue:			
Net patient service revenue	$	2,540,863	2,448,983
Less provision for bad debts, net		(50,382)	(72,829)
Net patient service revenue, less provision for bad debts, net		2,490,481	2,376,154
Other revenue		64,677	60,453
Total operating revenue		2,555,158	2,436,607
Operating expenses:			
Salaries and benefits		1,070,626	1,050,746
Supplies and other		1,214,194	1,096,590
Depreciation		120,235	124,012
Insurance		17,162	8,275
Interest		20,826	24,002
Total operating expenses		2,443,043	2,303,625
Income from operations		112,115	132,982
Nonoperating gains (losses), net:			
Income from investments, donations and other, net		23,623	79,111
Change in fair value of swap, including counterparty payments		(28,248)	(16,357)
Loss on refunding of long-term debt		—	(32,631)
Excess of revenue over expenses, before noncontrolling interest		107,490	163,105
Less income attributable to noncontrolling interest		(1,674)	(2,320)
Excess of revenue over expenses		105,816	160,785
Other changes in unrestricted net assets:			
Other changes in net assets		(516)	135
Transfer to Yale-New Haven Health Services Corporation – Mission Support		(12,516)	(14,042)
Transfer to Yale-New Haven Health Services Corporation		—	(25,000)
Net assets released from restrictions for purchases of fixed assets		4,515	1,502
Pension related changes other than net periodic benefit cost		(12,372)	(44,799)
Increase in unrestricted net assets	$	84,927	78,581

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidated Statements of Operations and Changes in Net Assets, Continued

Years ended September 30, 2015 and 2014

(In thousands)

	2015	2014
Temporarily restricted net assets:		
Income from investments	$ 298	298
Net realized gains on investments	297	583
Change in net unrealized gains and losses on investments	2,354	6,481
Bequests and contributions	17,989	7,457
Net assets released from restrictions for	—	
purchases of fixed assets	(3,123)	(1,502)
Net assets released from restrictions for free care	(596)	(613)
Net assets released from restrictions for operations	(9,854)	(3,099)
Net assets released from restrictions for clinical programs	(881)	(5,269)
Other	139	—
Increase in temporarily restricted net assets	6,623	4,336
Permanently restricted net assets:		
Bequests and contributions	13,654	3,492
Change in beneficial interest in perpetual trusts	(1,282)	5,259
Net assets released from restrictions for purchases of fixed assets	(1,392)	—
Increase in permanently restricted net assets	10,980	8,751
Noncontrolling interest:		
Income attributable to noncontrolling interest	1,674	2,320
Distributions to noncontrolling interest	(1,528)	(2,821)
	146	(501)
Increase in net assets	102,676	91,167
Net assets at beginning of year	1,119,530	1,028,363
Net assets at end of year	$ 1,222,206	1,119,530

See accompanying notes to consolidated financial statements.

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidated Statements of Cash Flows

Years ended September 30, 2015 and 2014

(In thousands)

		2015	2014
Operating activities:			
Increase in net assets	$	102,676	91,167
Adjustments to reconcile increase in net assets to net cash provided by operating activities:			
Depreciation		120,235	124,012
Net realized and change in net unrealized gains and losses on investments		(25,530)	(87,505)
Change in fair value of interest rate swap agreements		18,283	1,803
Amortization of long-term debt premium		(2,002)	(1,192)
Amortization of deferred financing costs		376	329
Provision for bad debts, net		50,382	72,829
Loss on refunding of long-term debt		—	32,631
Change in perpetual trusts		(255)	(5,258)
Transfer to Yale-New Haven Health Services Corporation		12,516	39,042
Bequests, and contributions, net of pledges		(30,557)	(10,949)
Pension related changes other than net periodic benefit cost		12,372	44,799
Changes in operating assets and liabilities:			
Accounts receivable, net		(79,063)	(98,599)
Other receivables		(1,303)	14,023
Other assets		68	(381)
Accounts payable		(3,303)	(1,884)
Accrued expenses		20,507	9,724
Professional insurance recoveries and liabilities		(26,682)	(2,086)
Other current liabilities, accrued pension and postretirement benefit obligations, other long-term liabilities, and deferred revenue		18,329	50,792
Net cash provided by operating activities		187,049	273,297
Investing activities:			
Net acquisitions of property, plant and equipment		(140,262)	(96,716)
Capitalized interest		—	190
Net purchases of investments		(135,862)	(178,622)
Net sales of investments		81,833	—
Debt service fund		(392)	2,782
Assets limited as to use		28,236	(35,516)
Transfer to Yale-New Haven Health Services Corporation		(12,516)	(39,042)
Net cash used in investing activities		(178,963)	(346,924)
Financing activities:			
Proceeds from issuance of long-term debt		—	578,670
Proceeds from notes payable		8,345	
Payments on capital lease obligations		(4,948)	(2,598)
Payments of long-term debt		(7,626)	(484,157)
Payments of notes payable		(36)	—
Cost of issuance of long-term debt		—	(6,299)
Bequests, and contributions, net of pledges		30,557	10,949
Net cash provided by financing activities		26,292	96,565
Net increase in cash and cash equivalents		34,378	22,938
Cash and cash equivalents at beginning of year		69,250	46,312
Cash and cash equivalents at end of year	$	103,628	69,250

See accompanying notes to consolidated financial statements.

(1) Organization and Significant Accounting Policies

(a) Organization

Yale-New Haven Hospital, Inc. (the Hospital or Y-NHH) is a voluntary association incorporated under the General Statutes of the State of Connecticut.

Y-NHH is the parent of the following and together form Yale-New Haven Hospital & Subsidiaries:

Yale-New Haven Care Continuum Corporation (YNHCCC), a Connecticut nonstock corporation, is a wholly owned subsidiary of the Hospital. YNHCCC provides long-term care for those unable to live independently and short-term rehabilitation for patients who have experienced elective surgery, an injury, or a traumatic major illness. Its services include respite care for family members and caregivers, recovery for victims of strokes, orthopedic recovery services, medications and diagnostic services (such as radiological services).

Yale-New Haven Ambulatory Services Corporation and Subsidiaries (ASC), a Connecticut nonstock, taxable corporation, is a wholly owned subsidiary of Y-NHH, and is 51% owner of Shoreline Surgery Center, LLC (SSC) and SSC II, LLC.

York Enterprises Inc. and Subsidiaries (York), a Connecticut corporation formed for the purpose of initiating or acquiring business entities. Currently, York has two subsidiaries: Medical Center Pharmacy and Home Care, Inc. (MCP) and Medical Center Realty, Inc. (MCR). MCP is a Connecticut stock, for-profit company, which operated a retail pharmacy with multiple locations until February 2011. MCR is a Connecticut stock, for-profit company, which owns or holds leases on YNHHSC's affiliated commercial space. York is the sole shareholder of MCP and MCR.

Caritas Insurance Company, Ltd. (Caritas) is a Vermont-domiciled, captive insurance company licensed under Chapter 141 of Title 8 of the Vermont Statutes Annotated. Caritas is a tax-exempt supporting organization having the Hospital as its sole shareholder. Caritas provides excess professional liability coverage and general liability coverage. Prior to the 2012 acquisition of the stock of Caritas by Y-NHH from the Hospital of Saint Raphael (HSR), Caritas was a wholly owned subsidiary of HSR. Caritas was dissolved on December 15, 2014 and the insurance liabilities were transferred to Medical Centre Insurance Company, Ltd (see note 9).

Lukan Indemnity Company, Ltd. (Lukan) is a Bermuda-domiciled captive insurance company that provides primary professional liability coverage. Prior to the 2012 acquisition of the stock of Lukan by Y-NHH from HSR, Lukan was a wholly owned subsidiary of HSR. Lukan was dissolved on March 31, 2015 and the insurance liabilities were transferred to Medical Centre Insurance Company, Ltd (see note 9).

Yale-New Haven Health Services Corporation (YNHHSC) is the sole member of Y-NHH. Y-NHH and subsidiaries operate with a separate Board of Trustees, management staff and medical staff; however, YNHHSC must approve the strategic plans, operating and capital budgets, and Board of Trustees appointments of the Hospital.

YNHHSC is the sole member of two similar organizations, Bridgeport Hospital (BH) and Greenwich Health Care Services, Inc. (GHCS). Each of these three tax-exempt organizations serves as the sole member/parent for its respective delivery network of regional health care providers and related entities. YNHHSC is also the sole member of Northeast Medical Group, Inc. (NEMG).

Concurrent with the issuance of the Connecticut Health and Educational Facilities Authority (CHEFA) Revenue Bonds, Yale-New Haven Health Obligated Group Issue, Series A, B, C, D and E dated May 20, 2014, six members of the Yale New Haven Health System and Subsidiaries were combined to form an Obligated Group. The Obligated Group comprises YNHHSC, YNHH, Yale-New Haven Care Continuum Corporation, Bridgeport Hospital, the Bridgeport Hospital Foundation and NEMG (the Obligated Group). YNHHSC serves as agent of the Obligated Group. The members of the Obligated Group have adopted certain governance provisions in their certificates of incorporation and by-laws pursuant to which YNHHSC retains the authority to directly take certain actions on behalf of each Obligated Group member without the approval of the Board of Trustees (the Board) of the applicable Obligated Group member, including the incurrence of indebtedness on behalf of each Obligated Group member, the management and control of the liquid assets of each, and the appointment of the president and chief executive officer of each Obligated Group member.

(b) Acquisitions

On June 1, 2014, NEMG and YNHHSC acquired certain assets of PriMed, LLC (PriMed), a physician practice for approximately $54.2 million. YNHHSC contributed the entire purchase price, of which $25 million was transferred from the Hospital to YNHHSC. PriMed is a multi-specialty group of approximately 120 providers in 36 locations across Fairfield County and New Haven County, Connecticut. PriMed also is the sole member of a gastroenterology surgery center, the Fairfield County Endoscopy Center, and offers a number of ancillary services, such as a sleep laboratory, cardiac diagnostic testing, physical therapy and nutritional counseling. Under the terms of the transaction, NEMG and YNHHSC acquired substantially all the assets of PriMed and a 40% interest in the gastroenterology surgery center.

On October 11, 2013, the Hospital purchased 100% controlling interest of Saint Raphael Magnetic Resonance Center (SRMP) for approximately $7.4 million. Prior to the purchase of this practice by the Hospital, the controlling interest in SRMP was owned through a 50/50 joint venture between ASC and Medical Imaging Associates, P.C. ASC transferred its 50% ownership to the Hospital. In connection with this transaction, the Hospital recorded goodwill in the amount of $5.9 million.

(c) Principles of Consolidation

The accompanying consolidated financial statements present the accounts and transactions of the Hospital and its wholly owned subsidiaries. All significant intercompany revenue and expenses and intercompany balance sheet accounts have been eliminated in consolidation.

(d) Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets, including estimated uncollectibles for accounts receivable for services to patients, and liabilities, including estimated net settlements with third-party payors and professional liabilities, and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the amounts of revenue and expenses reported during the reporting period. Actual results could differ from those estimates.

During the year ended September 30, 2015 the Hospital recorded a change in estimate of approximately $17.6 million related to favorable third-party payor settlements and during the year ended September 30, 2014 the Hospital recorded a change in estimate of approximately $8.9 million related to unfavorable third-party payor settlements.

(e) Temporarily and Permanently Restricted Net Assets

Temporarily restricted net assets are those whose use by the Hospital has been limited by donors to a specific time period or purpose and appreciation on permanently restricted net assets. Permanently restricted net assets have been restricted by donors to be maintained by the Hospital in perpetuity. The Hospital is a partial beneficiary to various perpetual trust agreements. Assets recorded under these agreements are recognized at fair value. The investment income generated from these trusts is unrestricted and the assets are classified as permanently restricted by the donor.

Certain restricted funds investments are pooled with certain unrestricted investments to facilitate their management. Investment income is allocated to both restricted and unrestricted funds participating in the investment pool on pro rata basis based on the market value of the fund. The Board of Trustees approves spending for certain pooled funds based on the spending policy. Realized gains and losses from the sale of securities are computed using the average cost method and the first-in, first-out method.

Contributions, including unconditional promises to give, are recognized as revenue in the period received. Conditional promises to give are not recognized until the conditions on which they depend are substantially met. Contributions receivable to be received after one year are discounted at a discount rate commensurate with the risks involved. Amortization of the discount is recognized as revenue and is classified as either unrestricted or temporarily restricted in accordance with donor-imposed restrictions, if any, on the contributions.

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

Contributions receivable, included in other receivables and other assets in the accompanying consolidated balance sheets at September 30, 2015 and 2014, are expected to be received as follows (in thousands):

	September 30	
	2015	2014
Less than one year	$ 3,182	3,979
One to five years	947	1,285
	4,129	5,264
Less unamortized discount on contributions receivable (0.1% to 4.2%)	(38)	(52)
	4,091	5,212
Allowance for uncollectible contributions	(123)	(156)
	$ 3,968	5,056

(f) Donor-Restricted Gifts

Unconditional promises to give cash and other assets are reported at fair value at the date the promise is received. All gifts are reported as either temporarily or permanently restricted support if they are received with donor stipulations that limit the use of the donated assets. When a donor restriction expires, that is, when a stipulated time restriction ends or purpose restriction is accomplished, temporarily restricted net assets are reclassified as unrestricted net assets.

(g) Cash and Cash Equivalents

Cash and cash equivalents include investments in highly liquid financial instruments with original maturities of three months or less when purchased, which are not classified as assets limited as to use and which are not maintained in the short- or long-term investment portfolios.

Cash and cash equivalents are maintained with domestic financial institutions with deposits that exceed federally insured limits. It is the Hospital's policy to monitor the financial strength of these institutions.

(h) Accounts Receivable

Patient accounts receivable result from the health care services provided by the Hospital. Additions to the allowance for doubtful accounts result from the provision for bad debts. Accounts written off as uncollectible are deducted from the allowance for doubtful accounts.

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

The amount of the allowances for doubtful accounts is based upon management's assessment of historical and expected net collections, business and economic conditions, trends in Medicare and Medicaid health care coverage, and other collection indicators. Management periodically assesses the adequacy of this allowance based upon historical collection and write-off experience by payor category. The results of these reviews are used to modify, as necessary, the provision for bad debts and to establish appropriate allowances for uncollectible patient accounts receivable. After satisfaction of amounts due from insurance, The System follows established guidelines for placing certain patient balances with collection agencies, subject to certain restrictions on collection efforts as determined by the System policy. See note 2 for additional information relative to third-party payor programs.

Net patient accounts receivable has been adjusted to the estimated amounts expected to be collected. These estimated amounts are subject to further adjustments upon review by third-party payors. Such receivables do not bear interest.

(i) ***Loan Receivable***

In September 2014, the Hospital entered into a term loan agreement as part of a transaction with a health care provider more fully described in note 10. The term-loan agreement has a term that coincides with an agreement for the Hospital to lease an Inpatient Rehabilitation Unit (IRU). The term of the IRU Lease Agreement is five years and provides the Hospital with two five year renewal options at the end of each term.

The term loan bears interest of 6.5% annually that is payable monthly. The loan is collateralized by certain property owned by a subsidiary of the health care provider.

(j) ***Investments***

The Hospital has designated its investment portfolio as trading. Investment income or loss (including realized gains and losses on investments, interest and dividends) and the change in net unrealized gains and losses are included in the excess of revenue over expenses unless the income or loss is restricted by donor or law.

Investments in equity securities with readily determinable fair values and investments in debt securities are measured at fair value (quoted market prices) in the accompanying consolidated balance sheets.

(Continued)

Certain alternative investments (nontraditional, not-readily marketable assets) are structured such that the Hospital holds limited partnership interests or pooled units and are accounted for utilizing net asset value per unit for measurement of the units' fair value. Individual investment holdings within the alternative investments may, in turn, include investments in both non-marketable and market-traded securities. Values may be based on historical cost, appraisals, or other estimates that require varying degrees of judgment. The equity method reflects net contributions to the investee and an ownership share of realized and unrealized investment income and expenses. The investments may indirectly expose the Hospital to securities lending, short sales of securities, and trading in futures and forwards contracts, options, swap contracts and other derivative products. While these financial instruments may contain varying degrees of risk, the Hospital's risk with respect to such transactions is limited to its capital balance in each investment. The financial statements of the investees are audited annually by independent auditors. Future funding commitments for alternative investments aggregated approximately $2.3 million at September 30, 2015.

The Hospital participates in the Yale New Haven Health System Investment Trust (the Trust), a unitized Delaware Investment Trust created to pool assets for investment by the Health System nonprofit entities. The Trust comprises two pools: the Long-Term Investment Pool (L-TIP) and the Intermediate-Term Investment Pool (I-TIP). Governance of the Trust is performed by the Yale New Haven Health System Investment Committee.

Under the terms of the investment management agreement with the Trust, withdrawals of the Hospital's investment in the L-TIP can be made annually by the Hospital on July 1. Amounts withdrawn are subject to a schedule that allows larger withdrawals with longer notice periods. As of September 30, 2015, the Hospital can withdraw 100% of its investment in the L-TIP on July 1, 2016. Withdrawals of the Hospital's investment in the I-TIP in any amount can be made quarterly with 30 days advance notice.

The Trust has an agreement with Yale University (the University) investment office (the Investment Management Agreement) which allows the University to manage a portion of the Trust's investments as part of the University's Endowment Pool (the Pool). The Trust transferred approximately $50.0 million and $100.0 million to the University in exchange for units in the Pool for years ended September 30, 2015 and 2014, respectively. The Trust's interest in the Pool is reported at fair value based on the net asset value per units held. The Pool invests in domestic equity, foreign equity, absolute return, private equity, real assets, fixed income and cash.

Under the terms of the investment management agreement with the University, withdrawals of the Trust's investment in the Pool can be made annually by the Trust on July 1. For withdrawals of amounts less than $150.0 million or 75% of the Trust's investment in the Pool, $100.0 million or 50% of the Trust's investment in the Pool, and $50.0 million or 25% of the Trust's investment in the Pool, the advance notice period is set to a maximum of 180 days, 90 days, and 30 days, respectively, prior to the University's fiscal year ending June 30. For withdrawals greater than $150.0 million or more than 75% of the Trust's investment in the Pool, the advance notice period is set to a maximum of 270 days prior to the University's fiscal year end of June 30.

In March 2006, the Hospital entered into an arrangement with the University whereby the University will manage certain Board-designated assets of the Hospital. These Board-designated assets are commingled in the University's endowment pool. At September 30, 2015 and 2014, the carrying value of assets managed by the University under this arrangement was approximately $10.6 million and $10.4 million, respectively. Because of the limitations on their use, the assets are separately classified from assets invested under the Investment Management Agreement.

In 2011, the investment management agreement between the Trust and the University was modified to allow the Trust to obtain a cash advance, up to a maximum of $75 million, on a monthly basis. For these advances interest of U.S. Prime rate, plus 2% will be paid by the Trust. Repayments on the advances are made by the Trust by way of redemptions of a sufficient number of Trust's units in the Endowment using the June 30 unit valuation. No advances have been requested or taken by the Trust.

Short-term investments represent those securities that are available for the Hospital's operations and can be converted to cash within one year.

(k) Inventories

Inventories are stated at the lower of cost or market. The Hospital values its inventories using the first-in, first-out method with the exception of pharmacy inventories, which are valued at average cost.

(l) Assets Limited as to Use

Assets so classified represent assets held by trustees under indenture agreements, beneficial interest in perpetual trusts and designated assets set aside by the Board for future capital improvements and other Board approved uses. The Board retains control and, at its discretion, may use for other purposes assets limited as to use for plant improvements and expansion. Amounts required to meet current liabilities are reported as current assets. These funds consist primarily of U.S. government securities, mutual funds and money market funds.

(m) Perpetual Trusts

The Hospital is the beneficiary of certain perpetual trusts held and administered by others. The present values of the estimated future cash receipts, which are measured based on the fair value of the assets held by the trust, are recognized as assets and contribution revenue at the dates the trusts are established. Beneficial interest in perpetual trusts is recorded as permanently restricted net assets and is adjusted for any changes in the fair value of the trusts. Income distributions received from the trusts are recorded as temporarily restricted contributions when received.

(n) Interest Rate Swap Agreements

The Hospital utilizes interest rate swap agreements to reduce risks associated with changes in interest rates. Interest rate swap agreements are reported at fair value. The Hospital is exposed to credit loss in the event of nonperformance by the counterparties to its interest rate swap agreements. The Hospital is also exposed to the risk that the swap receipts may not offset its variable rate debt service.

To the extent these variable rate payments do not equal variable interest payments on the bonds, there will be a net loss or net benefit to the Hospital.

(o) Benefits and Insurance

The Hospital is effectively self-insured for medical, hospitalization, dental and prescription drug benefits provided to employees and has a stop loss arrangement to limit exposure for these self-insured benefits. The Hospital makes annual contributions to the YNHHSC Voluntary Employee Beneficiary Association (VEBA) plan to fund medical, dental, hospitalization, group term life insurance and prescription drug benefits. Annually, premiums are set to reflect the estimated cost of benefits. During the years ended September 30, 2015 and 2014, the Hospital made actuarially determined contributions, net of premium adjustments, to the VEBA plan of approximately $135.3 million and $138.7 million, respectively.

The Hospital is effectively self-insured for workers' compensation claims. The Hospital has a stop loss arrangement to limit exposure for workers' compensation claims. Estimated amounts are accrued for claims, including claims incurred but not reported (IBNR) and are based on the Hospital specific experience. At September 30, 2015 and 2014, the estimated discounted liabilities for self-insured workers' compensation claims and IBNR aggregated approximately $23.5 million, discounted at 2.0%, and $21.3 million, discounted at 2.5%, respectively, and are included in accrued expenses in the accompanying balance sheets.

(p) Professional Liability Insurance

The Hospital participates in the YNHHSC coordinated professional liability program. Based on the terms of the agreement with YNHHSC, the Hospital records the actuarially determined liabilities for incurred but not reported professional and general liabilities and has recorded a deposit (asset) for liabilities transferred in the year ended September 30, 1998.

(q) Property, Plant and Equipment

Property, plant and equipment purchased are carried at cost and those acquired by gifts and bequests are carried at fair value established at the date of contribution. The carrying amounts of assets and the related accumulated depreciation are removed from the accounts when such assets are disposed of and any resulting gain or loss is included in income from operations. Depreciation of property, plant and equipment is computed by the straight-line method in amounts sufficient to depreciate the cost of the assets over their estimated useful lives ranging from 3 to 50 years. The cost of additions and improvements are capitalized and expenditures for repairs and maintenance, including the cost of replacing minor items not considered substantial enhancements, are expensed as incurred.

Leases are classified as capital leases or operating leases in accordance with the terms of the underlying lease agreements. Lease payments under operating leases are charged directly to rental expense, and are included in supplies and other expenses in the accompanying consolidated statements of operations.

(Continued)

(r) Goodwill

Goodwill is not amortized but instead tested at least annually for impairment or more frequently when events or changes in circumstances indicate that the assets might be impaired. This impairment test is performed annually at the reporting unit level. The Hospital evaluates goodwill at the entity level as management has determined that the Hospital's operation comprise a single reporting entity. Goodwill is considered to be impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit's fair value. Reporting unit fair value is estimated using both income (discounted cash flows) and market approaches.

The discounted cash flow approach requires the use of assumptions and judgments including estimates of future cash flows and the selection of discount rates. The market approach relies on comparisons to publicly traded stocks or to sales of similar companies. The Hospital has determined that no goodwill impairment exists at September 30, 2015.

(s) Deferred Revenue

Deferred revenue includes amounts which have been received that relate to future years. Amounts will be reduced as revenue is earned.

(t) Derivative Contracts

In the normal course of business, the Hospital procures fuel and has entered into forward delivery agreements and commodity contracts. Substantially all of the Hospital's contracts to procure fuel are designated as, and qualify as, normal purchases; accordingly, such contracts are not accounted for as derivative contracts.

(u) Excess of Revenue over Expenses

In the accompanying consolidated statements of operations and changes in net assets, excess of revenue over expenses is the performance indicator. Peripheral or incidental transactions are included in excess of revenue over expenses. Those gains and losses deemed by management to be closely related to ongoing operations are included in other revenue; other gains and losses are classified as nonoperating.

Contributions of, or restricted to, property, plant and equipment, transfers of assets to and from affiliates for other than goods and services, and pension related changes other than net periodic benefit cost are excluded from the performance indicator but are included in the change in net assets.

(v) Income Taxes

YNHCCC and the Hospital are not-for-profit corporations as described in Section 501(c)(3) of the Internal Revenue Code (the Code), and are exempt from Federal income taxes on related income pursuant to Section 501(a) of the Code. YNHCCC and the Hospital are also exempt from state income tax.

(Continued)

There are certain transactions that could be deemed "Unrelated Business Income" and would result in a tax liability. Management reviews transactions to estimate potential tax liabilities using a threshold of more likely than not that the position will be sustainable based on the merits of the position. It is management's estimation that there are no material tax liabilities that need to be recorded.

ASC and York are subject to federal and state corporate income taxes. Deferred income taxes are provided on temporary differences between financial statement and tax reporting. The provision for income taxes and deferred taxes are not material to the consolidated financial statements.

(w) ***Operating Expenses***

The Hospital records amounts received from the University, area hospitals and other local healthcare providers for costs incurred on behalf of those organizations as reductions to expenses. These costs consist mainly of salaries and benefits. For the years ended September 30, 2015 and 2014, the Hospital recorded approximately $55.0 million and $60.5 million, respectively, as reductions to expenses.

(x) ***Deferred Financing Costs***

The Hospital capitalizes costs incurred in connection with the issuance of long-term debt and amortizes these costs over the life of the respective obligations using the effective interest method. The accumulated deferred financing cost was approximately $0.6 million and $0.2 million at September 30, 2015 and 2014, respectively.

(y) ***Impairment of Assets***

The Hospital reviews property, plant and equipment for impairment at least annually, and more frequently whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If such impairment indicators are present, the Hospital recognizes a loss on the basis of whether these amounts are fully recoverable. No impairment charge was recorded for the years ended September 30, 2015 or 2014.

(z) ***New Accounting Pronouncements***

In May 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2015-07, Fair Value Measurement (Topic 820) – *Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or its Equivalent)*, which removes the requirement to categorize within the fair value hierarchy all investments for which fair value is measured using the net asset value per share practical expedient. ASU 2015-07 also removes the requirement to make certain disclosures for all investments that are eligible to be measured at fair value using the net asset value per share practical expedient. Reporting entities will be required to disclose the amount of investments measured at net asset value (or its equivalent) using the practical expedient to reconcile total investments in the fair value hierarchy to total investments measured at fair value. ASU 2015-07 is effective for public business entities for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The effective date for all other entities is fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. Management has adopted and applied ASU 2015-07 retrospectively to all periods presented.

In April 2015, FASB issued ASU No. 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU No. 2015-03 is intended to simplify the presentation of debt issuance costs, requiring them to be presented as a direct reduction from the carrying value of the related debt liability. This guidance is effective for fiscal years beginning after December 15, 2015 and management is currently evaluating the effect of this guidance on its consolidated financial statements.

(aa) Reclassifications

Certain reclassifications have been made to the year ended September 30, 2014, balances previously reported in the consolidated financial statements in order to conform with the year ended September 30, 2015, presentation.

(2) Accounts Receivable for Services to Patients and Net Patient Service Revenue

The Hospital has agreements with third-party payors that provide for payments to the Hospital at amounts different from its established rates. The difference is accounted for as allowances. Payment arrangements include prospectively determined rates per discharge, reimbursed costs, fee-for-service, discounted charges and per diem payments. Net patient service revenue is affected by the State of Connecticut Disproportionate Share program and is reported at the estimated net realizable amounts due from patients, third-party payors and others for services rendered and includes estimated retroactive revenue adjustments due to future audits, reviews and investigations. Retroactive adjustments are considered in the recognition of revenue on an estimated basis in the period the related services are rendered and such amounts are adjusted in future periods as adjustments become known or as years are no longer subject to such audits, reviews and investigations.

Third-party payor receivables included in other receivables were $2.9 million and $0.9 million at September 30, 2015 and 2014, respectively. Third-party payor liabilities included in other current liabilities were $52.3 and $36.2 million at September 30, 2015 and 2014, respectively. Third-party payor liabilities included in other long-term liabilities were $44.1 million and $47.4 million at September 30, 2015 and 2014, respectively.

The Hospital has established estimates based on information presently available, of amounts due to or from Medicare, Medicaid and third-party payors for adjustments to current and prior year payment rates, based on Hospital specific data. Such amounts are included in the accompanying consolidated balance sheets. Additionally, certain payors' payment rates for various years have been appealed by Y-NHH. If the appeals are successful, additional income applicable to those years might be realized. In April, 2014, YNHHS began participation in the Centers for Medicare & Medicaid Services Bundled Payments for Care Improvement initiative. Under the Bundled Payments for Care Improvement initiative, YNHHS has entered into payment arrangements that include financial and performance accountability for episodes of care.

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

Revenue from Medicare and Medicaid programs accounted for approximately 30% and 11%, respectively, of Y-NHH's net patient service revenue for the year ended September 30, 2015, and approximately 33% and 11%, respectively, of Y-NHH's net patient service revenue for the year ended September 30, 2014. Inpatient discharges relating to Medicare and Medicaid programs accounted for approximately 36% and 28%, respectively for the years ended September 30, 2015, and 2014. Laws and regulations governing the Medicare and Medicaid programs are extremely complex and are subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by material amounts in the near term.

Y-NHH believes that it is in compliance with all applicable laws and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing except as disclosed in note 10. Compliance with such laws and regulations can be subject to future government review and interpretation, as well as significant regulatory action, including fines, penalties and exclusion from the Medicare and Medicaid programs. Changes in the Medicare and Medicaid programs and the reduction of funding levels could have an adverse impact on Y-NHH. Cost reports for the Hospital, which serve as the basis for final settlement with government payors, have been settled by final settlement for various years ranging through 2012 for Medicare and through 2013 for Medicaid. Other years remain open for settlement.

The significant concentrations of accounts receivable for services to patients include 37% from Medicare, 17% from Medicaid, and 46% from nongovernmental payors at September 30, 2015, and 36% from Medicare, 14% from Medicaid, and 50% from nongovernmental payors at September 30, 2014.

Net patient service revenue is comprised of the following for the years ended September 30, 2015 and 2014 (in thousands):

		2015	2014
Gross revenue from patients	$	8,833,384	8,501,209
Deductions:			
Contractual allowances		6,165,563	5,922,235
Charity and free care (at charges)		126,956	129,991
Provision for doubtful accounts		50,394	72,829
Net patient service revenue	$	2,490,471	2,376,154

Patient service revenue for the years ended September 30, 2015 and 2014, net of contractual allowances and discounts (but before the provision for bad debts), recognized from these major payor sources based on primary insurance designation, is as follows, in thousands:

		2015	2014
Third party	$	2,460,636	2,350,870
Self-pay		80,227	98,113
Total all payors	$	2,540,863	2,448,983

(Continued)

Deductibles and copayments under third-party payment programs within the third-party payor amount above are the patient's responsibility and Y-NHH considers these amounts in its determination of the provision for bad debts based on collection experience. Accounts receivable are also reduced by an allowance for doubtful accounts. In evaluating the collectability of accounts receivable, Y-NHH analyzes its past history and identifies trends for each of its major payor sources of revenue to estimate the appropriate allowance for doubtful accounts and provision for bad debts. Management regularly reviews data about these major payor sources of revenue in evaluating the sufficiency of the allowance for doubtful accounts.

Y-NHH's allowance for doubtful accounts totaled approximately $196.2 million and $171.5 million at September 30, 2015 and 2014, respectively. The allowance for doubtful accounts for self-pay patients was approximately 65.1% and 88.5% of self-pay accounts receivable as of September 30, 2015 and 2014, respectively. Substantially all write-offs are related to self-pay patients.

(3) Uncompensated Care and Community Benefit Expense

Y-NHH's commitment to community service is evidenced by services provided to the indigent and benefits provided to the broader community. Services provided to the indigent include services provided to persons who cannot afford health care because of inadequate resources and/or who are uninsured or underinsured.

Y-NHH makes available free care programs for qualifying patients. In accordance with the established policies of Y-NHH, during the registration, billing and collection process a patient's eligibility for free care funds is determined. For patients who were determined by Y-NHH to have the ability to pay but did not, the uncollected amounts are the provision for bad debts. For patients who do not avail themselves of any free care program and whose ability to pay cannot be determined by Y-NHH, care given but not paid for, is classified as charity care.

Together, charity care and the provision for bad debts represent uncompensated care. The estimated cost of total uncompensated care is approximately $114.4 million and $132.4 million for the years ended September 30, 2015 and 2014, respectively. The estimated cost of uncompensated care is based on the ratio of cost to charges, as determined by claims activity.

The estimated cost of charity care and free care provided was $82.4 million and $85.3 million for the years ended September 30, 2015 and 2014, respectively. The estimated cost of charity care is based on the ratio of cost to charges. The allocation between the provision for bad debts and charity care is determined based on management's analysis on the previous 12 months of hospital data. This analysis calculates the actual percentage of accounts written off or designated as bad debt versus charity care while taking into account the total costs incurred by the hospital for each account analyzed.

For the years ended September 30, 2015 and 2014, the provision for bad debts, at charges, was $50.4 million and $72.8 million, respectively. For the years ended September 30, 2015 and 2014, the provision for bad debts, was $32.0 million and $47.1 million, respectively. The provision for bad debts is multiplied by the ratio of cost to charges for purposes of inclusion in the total uncompensated care amount identified above.

(Continued)

The Connecticut Disproportionate Share Hospital Program (CDSHP) was established to provide funds to hospitals for the provision of uncompensated care and is funded, in part, by an assessment on hospital net patient service revenue. During the years ended September 30, 2015 and 2014, the Hospital received $9.3 million and $26.6 million, respectively, in CDSHP distributions, of which approximately $6.7 million and $17.1 million, respectively was related to charity care. Y-NHH made payments into the CDSHP of $89.3 million and $73.5 million for the years ended September 30, 2015 and 2014, respectively, for the assessment.

The State of Connecticut implemented changes to the hospital funding levels for the CDSHP in their fiscal 2016 biennium budget. As a result of these budget changes, the funding for this program was reduced effective July 1, 2015. The reduction in funding was approximately $6.8 million for the period July 1, 2015 to September 30, 2015 and the funding has been eliminated for state fiscal year 2016 in the amount of $27.2 million.

Additionally, Y-NHH provides benefits for the broader community which includes services provided to other needy populations that may not qualify as indigent but need special services and support. Benefits include the cost of health promotion and education of the general community, interns and residents, health screenings, and medical research. The benefits are provided through the community health centers, some of which service nonEnglish speaking residents, disabled children, and various community support groups. Y-NHH voluntarily assists with the direct funding of several City of New Haven programs, including an economic development program and a youth initiative program.

In addition to the quantifiable services defined above, Y-NHH provides additional benefits to the community through its advocacy of community service by employees. Y-NHH's employees serve numerous organizations through board representation, membership in associations and other related activities. Y-NHH also solicits the assistance of other healthcare professionals to provide their services at no charge through participation in various community seminars and training programs.

(Continued)

(4) Investments and Assets Limited as to Use

The composition of investments, including investments held by the Trust, amounts on deposit with trustee in debt service fund and assets limited as to use is set forth in the following table (in thousands):

	September 30 2015	September 30 2014
Money market funds	$ 50,943	$ 129,823
U.S. equity securities	70,490	59,186
U.S. equity securities – common collective trusts	—	—
International equity securities[(a)]	64,440	70,671
Fixed income:		
U.S. government	296,416	258,126
U.S. government – common collective trusts	—	—
International government[(b)]	84,944	77,706
Commodities	82	122
Hedge funds:		
Absolute return[(c)]	10,554	10,304
Real estate[(d)]	6,781	9,628
Interest in Yale University endowment pool[(e)]	768,495	685,862
Perpetual trusts[(f)]	18,050	17,797
Total	$ 1,371,195	$ 1,319,225

(a) Investments with external international equity and bond managers that are domiciled in the United States. Investment managers may invest in American or Global Depository Receipts (ADR, GDR) or in direct foreign securities.

(b) Investments with external commodities futures manager.

(c) Investment with external multi-strategy fund of funds manager investing in publicly traded equity and credit holdings which may be long or short positions.

(d) Investments with external direct real estate managers and fund of funds managers. Investment vehicles include both closed end REITs and limited partnerships.

(e) Yale University Endowment Pool maintains a diversified investment portfolio, through the use of external investment managers operating in a variety of investment vehicles, including separate accounts, limited partnerships and commingled funds. The pool combines an orientation to equity investments with an allocation to nontraditional asset classes such as an absolute return, private equity, and real assets.

(d) Investments consist of several domestic and international equity and fixed income mutual funds, REITs, commodities and money market funds. There is also an investment in a hedge fund of funds.

Y-NHH's ownership percentage of the Trust was approximately 88.6%, or $1.3 billion, and 90.5% or $1.2 billion, as of September 30, 2015 and 2014, respectively. Y-NHH's prorata portion of the Trust's investments are included above in the table.

(5) Endowment

Y-NHH's endowment includes donor-restricted endowment funds. Net assets associated with endowment funds are classified and reported based on the existence or absence of donor-imposed restrictions.

Y-NHH has interpreted the Connecticut Uniform Prudent Management of Institutional Funds Act (CUPMIFA) as requiring the preservation of the fair value of the original gift as of the gift date of the donor-restricted endowment funds absent explicit donor stipulations to the contrary. As a result of this interpretation, Y-NHH classifies as permanently restricted net assets (a) the original value of gifts donated to the permanent endowment, (b) the original value of subsequent gifts to the permanent endowment, and (c) accumulations to the permanent endowment related to Y-NHH's beneficial interest in perpetual trusts made in accordance with the direction of the applicable donor gift instrument at the time of the accumulation is added to the fund.

The remaining portion of the donor-restricted endowment fund that is not classified in permanently restricted net assets is classified as temporarily restricted net assets until those amounts are appropriated for expenditure by Y-NHH in a manner consistent with the standard of prudence prescribed by CUPMIFA. In accordance with CUPMIFA, Y-NHH considers the following factors in making a determination to appropriate or accumulate donor-restricted endowment funds: (1) the duration and preservation of the fund; (2) the purposes of Y-NHH and the donor-restricted endowment fund; (3) general economic conditions; (4) the possible effect of inflation and deflation; (5) the expected total return from income and the appreciation of investments; (6) other resources of Y-NHH; and (7) the investment and spending policies of Y-NHH.

(Continued)

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

Changes in endowment net assets for the years ended September 30, 2015, are as follows (in thousands):

		Temporarily restricted	Permanently restricted	Total
Endowment net assets, beginning of year	$	36,239	35,906	72,145
Investment return:				
Investment income		248	—	248
Net appreciation (realized and unrealized)		2,306	—	2,306
Total investment return		2,554	—	2,554
Contributions		4,976	13,654	18,630
Appropriation of endowment assets for expenditure		(5,223)	(1,392)	(6,615)
Other changes:				
Change in value of beneficial interest trusts		—	(1,282)	(1,282)
Endowment net assets, end of year	$	38,546	46,886	85,432

Changes in endowment net assets for the years ended September 30, 2014, are as follows (in thousands):

		Temporarily restricted	Permanently restricted	Total
Endowment net assets, beginning of year	$	36,106	27,155	63,261
Investment return:				
Investment income		213	—	213
Net appreciation (realized and unrealized)		5,818	—	5,818
Total investment return		6,031	—	6,031
Contributions		—	3,493	3,493
Appropriation of endowment assets for expenditure		(5,898)	—	(5,898)
Other changes:				
Change in value of beneficial interest trusts		—	5,258	5,258
Endowment net assets, end of year	$	36,239	35,906	72,145

(Continued)

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

		September 30	
		2015	2014
		(In thousands)	
The portion of perpetual endowment funds subject to a time restriction under CUPMIFA:			
Without purpose restrictions	$	8,666	8,357
With purpose restrictions		29,880	27,882
Total endowment funds classified as temporarily restricted net assets	$	38,546	36,239

(a) *Return Objectives and Risk Parameters*

Y-NHH has adopted investment and spending policies for endowed assets that attempt to provide a predictable stream of funding to programs supported by its endowment. Endowment assets include those assets of donor-restricted funds that the organization must hold in perpetuity. Under these policies, as approved by the Board, the endowment assets are invested in a manner that is intended to produce results that over time provide a rate of return that meets the spending policy objectives adjusted for inflation. Actual returns in any given year may vary from this amount.

(b) *Strategies Employed for Achieving Objectives*

To satisfy its long-term rate-of-return objectives, Y-NHH relies on a total return strategy in which investment returns are achieved through both capital appreciation (realized and unrealized) and current yield (interest and dividends). Y-NHH targets a diversified asset allocation that places a greater emphasis on equity-based investments to achieve its long-term return objectives within prudent risk constraints.

(c) *Spending Policy and How the Investment Objectives Relate to Spending Policy*

Y-NHH has a policy of appropriating for distribution each year based on a combination of the weighted average of the prior year spending adjusted for inflation and the amount that would have been spent using 5.25% of the current market value of the endowment fund. In establishing this policy, Y-NHH considered the long-term expected return on its endowment.

From time to time, the fair value of assets associated with permanently restricted endowment funds may fall below the level determined under Connecticut UPMIFA.

(Continued)

(6) Temporarily and Permanently Restricted Net Assets

Temporarily restricted net assets are available for the following purposes (in thousands):

		September 30	
		2015	**2014**
Plant improvement and expansion	$	17,712	13,005
Specific hospital operations, teaching, research, free care and training		53,229	51,313
	$	70,941	64,318

Permanently restricted net assets of approximately $46.9 million and $35.9 million at September 30, 2015 and 2014, respectively, consist of donor restricted endowment principal and beneficial interests in perpetual trusts. The income generated from permanently restricted funds is expendable for purposes designated by donors, including research, free care, health care and other services.

(7) Debt

A summary of long-term debt and capital lease obligations is as follows (in thousands):

		September 30	
		2015	**2014**
Intercompany debt with YNHHSC:			
Series N, 4.27% effective interest rate (a)	$	44,815	44,815
Series O, 2.84% effective interest rate (a)		50,000	50,000
Series A, 3.77% effective interest rate (c)		102,300	102,300
Series B, 2.30% effective interest rate (c)		168,275	168,275
Series C, 3.11% effective interest rate (d)		77,235	83,625
Series D, 3.68% effective interest rate (d)		108,275	108,275
Series E, 3.47% effective interest rate (e)		43,728	44,963
Series 2013 taxable bonds – 4.13% effective rate (b)		132,000	132,000
Series 2014 taxable bonds – 4.37% effective rate (f)		50,725	50,725
Note payable, 5.46% effective interest rate (g)		8,309	—
Capital lease obligation at an imputed interest of 6.0%, (Y-NHH) (h)		48,853	50,682
Capital lease obligations at varying rates of imputed interest rate of 6.25% collateralized by leased equipment (York)		—	3,119
		834,515	838,779
Add premium		22,769	24,772
Less current portion		(10,086)	(10,589)
	$	847,198	852,962

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

(a) In January 2013, the Hospital issued Series N and Series O revenue bonds totaling approximately $100.0 million. The Series N revenue bonds were issued as fixed rate bonds with an effective interest rate of 4.27%. The Series O revenue bonds were issued as VRDBs with an effective interest rate of 2.84%. The proceeds, including a premium of approximately $5.2 million for the Series N revenue bonds, were used to refinance a line of credit. The bond premium is being amortized as interest expense in the statement of operations and changes in net assets.

(b) In January 2013, the Hospital issued Series 2013 taxable bonds totaling approximately $132.0 million. The Series 2013 taxable bonds were issued as fixed rate bonds with an effective interest rate of 4.13%. The proceeds were used to finance and refinance the costs of certain projects and activities in furtherance of the Hospital's tax-exempt purpose, including the refinancing of certain existing indebtedness.

(c) In June 2014, the Obligated Group issued Series A revenue bonds totaling approximately $102.3 million and Series B revenue bonds totaling approximately $168.3 million. The Series A revenue bonds were issued as fixed rate bonds with an effective interest rate of 3.77%. The Series B revenue bonds were issued as floating rate notes with an effective interest rate of 2.30%. The proceeds from the Series A revenue bonds, including a premium of approximately $14.8 million, and the proceeds from the Series B revenue bonds, were used to defease certain existing indebtedness. The bond premium is being amortized as interest expense using the effective interest method in the consolidated statement of operations and changes in net assets.

(d) In June 2014, the Obligated Group issued Series C revenue bonds totaling approximately $83.6 million and Series D revenue bonds totaling approximately $108.3 million. The Series C revenue bonds were issued as VRDBs with an effective interest rate of 3.11%. The proceeds from the Series C issuance were used to refund Y-NHH's Series K revenue bonds. The Series D revenue bonds were issued as VRDBs with an effective interest rate of 3.68%. The proceeds from the Series D issuance were used to refund Y-NHH's Series L revenue bonds.

As a result of the above transactions, the Hospital incurred a loss on extinguishment of debt totaling approximately $32.6 million during the fiscal year ended September 30, 2014.

(e) In June 2014, the Obligated Group issued Series E revenue bonds totaling approximately $80.9 million. The Series E revenue bonds were issued as fixed rate bonds with an effective interest rate of 3.47%. The proceeds included a premium of approximately $10.1 million. Of the proceeds, $50 million were used to finance costs for the installation of machinery and equipment and various renovations and improvements to the Hospitals' infrastructure. The remaining proceeds were used by BH. The premium is being amortized and included in capitalized interest. Upon completion of these projects, the bond premium will be amortized as interest expense in the consolidated statement of operations and changes in net assets.

(f) In June 2014, the Obligated Group issued Series 2014 taxable bonds totaling approximately $50.7 million. The Series 2014 taxable bonds were issued as fixed rate bonds with an effective interest rate of 4.37%. The proceeds were used to finance the costs of certain projects and activities in furtherance of the System's tax-exempt purpose.

(Continued)

The Series C, Series D and Series O VRDBs are required to be supported by letter of credit facilities (LOCs) which have been executed with three financial institutions. These LOCs are scheduled to expire on December 31, 2017, June 23, 2017 and February 14, 2018, respectively.

The Hospital maintains the bank letters of credit to ensure the availability of funds to purchase any bonds tendered by bondholders that the remarketing agents are unable to remarket to new bondholders. Draws related to such tenders under the letters of credit will become Bank Bonds. As Bank Bonds, they can still be remarketed by the remarketing agents. If not remarketed successfully as Bank Bonds, the Hospital will have the opportunity to refinance them, depending upon which bond series, during a period of from 180 to 367 days from initial draw date. If the Bank Bonds are not refunded and remain outstanding exceeding such period from initial draw date, the Hospital will be required to make quarterly payments over five years. There were no draws under the letters of credit as of September 30, 2015.

The terms of the various financing arrangements between CHEFA, the Obligated Group, and the financial institutions providing the LOCs and the Obligated Group provide for financial covenants regarding the Obligated Group's debt service coverage ratio and liquidity ratio.

Sinking fund installment amounts are to be made in accordance with the Series A, B, C, D, E, N and O financing agreements. Required monthly payments on the revenue bonds by the Hospital to a trustee are in amounts sufficient to provide for the payments of principal, interest and sinking fund installments, in accordance with the terms of the agreements and certain other annual costs of CHEFA.

Arbitrage rules apply for Series E tax-exempt debt. The rules require that, in specified circumstances, earnings from the investment of tax-exempt bond proceeds which exceed the yield on the bonds must be remitted to the Federal government.

In connection with the formation of the Obligated Group the Series A, B, C, D, E, N and O tax-exempt bonds and the Series 2013 and 2014 taxable bonds became an obligation of the Obligated Group and as such are reflected as intercompany debt with YNHHSC. Under the terms of the Master Indenture all members of the Obligated Group are jointly and severally liable for debt issued by YNHHSC on behalf of the Obligated Group.

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

Scheduled principal payments on all debt, including capital lease obligations, are as follows (in thousands):

		Debt	Capital lease obligations
2016	$	8,084	4,879
2017		16,363	4,879
2018		8,493	4,879
2019		9,957	4,880
2020		10,332	5,062
Thereafter		732,433	48,988
	$	785,662	73,567
Less interest			(24,714)
Total capital lease obligations			$ 48,853

Capitalized interest at September 30, 2015 and 2014, totaled $30.9 million and $29.9 million, respectively.

YNHHSC, on behalf of the Obligated Group, has entered into interest rate swap agreements with financial institutions related to the Obligated Group's Series B, Series C and Series D debt.

The swap agreements fix the interest rate at a level viewed as desirable by the Hospital. Such agreements expose the Hospital to credit risk in the event of nonperformance by the counterparties, some of which is collateralized. At September 30, 2015 and 2014, the fair value of all swap agreements based on current interest rates was approximately $50.6 million and $32.3 million, respectively, representing a payable to the counterparties (recorded in other long-term liabilities).

The following table summarizes the interest rate swap agreements (in thousands):

Swap type	Expiration date	Hospital receives	Hospital pays		Notional amount at September 30 2015	2014
Series O – Fixed to Floating	July 1, 2053	67% of LIBOR	2.84%	$	50,000	50,000
Series B – Fixed to Floating	July 1, 2049	67% of LIBOR	2.31%		100,965	100,965
Series B – Fixed to Floating	July 1, 2049	LIBOR	2.29%		67,310	67,310
Series C – Fixed to Floating	July 1, 2025	LIBOR	3.11%		51,592	55,861
Series D – Fixed to Floating	July 1, 2036	LIBOR	3.68%		44,505	44,505
				$	314,372	318,641

For the Series O swap, there was an unfavorable change in fair value of $0.7 million and $0.6 million for the years ended September 30, 2015 and 2014, respectively, which was recorded in excess of revenue over expenses. No collateral was required under the Series O swap agreement for the years ended September 30, 2015 and 2014.

In June 2014, YNHHSC, on behalf of the Obligated Group, entered into LIBOR swap rate locks with two counter parties (the Series B swaps). For the Series B swaps, there was an unfavorable change in fair value of $13.2 million and $7.1 million for the years ended September 30, 2015 and 2014, respectively, which was recorded in excess of revenue over expenses. No collateral was required under the Series B swap agreements for the years ended September 30, 2015 and 2014.

For the Series C swap, there was a favorable change in fair value of approximately $0.5 million and $1.0 million, respectively, for the years ended September 30, 2015 and 2014, which was recorded in the excess of revenue over expenses. No collateral was required under the Series C swap agreement for the years ended September 30, 2015 and 2014.

For the Series D swap, there was an unfavorable change in fair value of approximately $4.2 million and $2.2 million for the years ended September 30, 2015 and 2014, respectively, which was recorded in the excess of revenue over expenses. No collateral was required under the Series L/D swap agreement for the years ended September 30, 2015 and 2014.

For the years ended September 30, 2015 and 2014, the Hospital paid approximately $20.3 million and $22.8 million, respectively, for interest related to long-term debt, exclusive of the swap agreements.

(h) The Hospital entered into a contract to lease space in a building adjacent to the Hospital. The Hospital's rental obligation commenced in December 2009. This capital lease has a term of twenty years from the commencement date with the option to extend the lease for four successive terms of ten years. Rental payments increase by 5% every five years. The Hospital is also subject to additional rent for its share of expenses, as defined in the contract. The Hospital has the option to purchase the property at the end of the fifth, tenth or twentieth year or at the end of each of the first three ten-year extension periods.

In January 2013, the Hospital entered into a transaction in connection with a building at 2 Howe Street, New Haven, Connecticut which was previously accounted for by the Hospital as a capital lease. Under the terms of the capital lease, the Hospital was obligated to purchase the building after an initial lease term of 3 years. In satisfaction of that obligation, the Hospital purchased the building and immediately sold the building to a third-party investor. The Hospital currently leases the building from the investor under a long-term operating lease. The Hospital owns the land on which the building is located and has entered into a prepaid long-term ground lease with the investor.

(g) In connection with the May 2015 purchase of a parcel of real estate, the Hospital assumed a note payable with an effective interest rate of 5.46%. The note payable has a term of three years and matures in May 2017.

Assets recorded under the capital lease obligations totaled $57.3 million and $70.2 million as of September 30, 2015 and 2014, respectively. Accumulated depreciation for the capital lease obligations totaled $9.7 million and $19.0 million at September 30, 2015 and 2014, respectively.

(8) Pensions and Postretirement Benefits

Y-NHH has qualified and nonqualified defined benefit pension plans covering substantially all employees and executives. The benefits provided are based on age, years of service and compensation. Y-NHH's policy is to fund the pension benefits with at least the minimum amounts required by the Employee Retirement Income Security Act of 1974.

Y-NHH also sponsors contributory 403(b) and 401(k) plans covering substantially all employees. YNHNC's contributions for the 403(b) plan are made to a matching 401(a) plan and are determined based on employee contributions and years of service. The Hospital expensed approximately $40.4 million and $32.9 million relating to the defined contribution plan for the years ended September 30, 2015 and 2014, respectively. Amounts due to the defined contribution plan amounted to $23.5 million and $16.5 million at September 30, 2015 and 2014, respectively, and is included in accrued expenses in the accompanying balance sheets. Y-NHH maintains a Section 457 nonqualified deferred compensation plan. Contributions are made on a pre-tax basis. The balances recorded at September 30, 2015 and 2014, in other assets and other long-term liabilities were $34.4 million and $32.5 million, respectively.

Y-NHH also provides certain health care and life insurance benefits upon retirement to substantially all its employees. Y-NHH's policy is to fund these annual costs as they are incurred from the general assets of Y-NHH. The estimated cost of these postretirement benefits is actuarially determined and accrued over the employees' service periods.

Included in unrestricted net assets at September 30, 2015 and 2014, are the following amounts that have not yet been recognized in net periodic pension cost: unrecognized prior service credit of $20.4 million and $22.4 million, respectively, and unrecognized actuarial losses of $172.4 million and $162.0 million, respectively. The prior service credit and actuarial loss included in unrestricted net assets and expected to be recognized in net periodic pension cost during the year ending September 30, 2016, are $2.0 million and $6.9 million, respectively.

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

The following table sets forth the change in benefit obligation, change in plan assets, and the reconciliation of underfunded status of Y-NHH's defined benefit plans as of September 30, 2015 and 2014 (in thousands):

	Defined Benefit Pension Plans		Postretirement Benefit Plans	
	2015	2014	2015	2014
Change in benefit obligation:				
Benefit obligation at prior measurement date	$ 502,711	445,908	78,136	67,904
Service cost	20,895	22,532	3,789	3,617
Interest cost	20,652	20,896	3,393	3,270
Plan amendments	—	—	—	(577)
Actuarial loss (gain)	(15,213)	37,881	(14,067)	5,413
Benefits paid	(27,013)	(24,506)	(1,670)	(1,491)
Benefit obligation at current measurement date	502,032	502,711	69,581	78,136
Change in plan assets:				
Fair value of assets at prior measurement date	347,238	313,730	—	—
Actual return on plan assets	(19,519)	19,950	—	—
Employer contributions	39,963	38,064	1,670	1,491
Benefits paid	(27,013)	(24,506)	(1,670)	(1,491)
Fair value of assets at current measurement date	340,669	347,238	—	—
Accrued benefit cost	$ 161,363	155,473	69,581	78,136

(a) Benefit Obligation and Assumptions

The actuarial loss in 2015 primarily relates to changes in the discount rate and mortality table used to measure the benefit obligation and the actuarial gain in 2014 primarily relates to changes in the discount rate.

The projected benefit obligation, accumulated benefit obligation and fair value of plan assets for the defined benefit plans were as follows (in thousands):

	2015	2014
Projected benefit obligation	$ (502,032)	(502,711)
Accumulated benefit obligation	(443,165)	(428,547)
Fair value of plan assets	340,669	347,238

(Continued)

At September 30, 2015 and 2014, the underfunded status of the qualified defined benefit pension plan was approximately $111.1 million and $107.6 million, respectively, and that of the nonqualified defined benefit pension plan was approximately $50.2 million and $47.9 million, respectively. Additionally, there are assets limited as to use of approximately $78.8 million and $77.9 million, which are available to satisfy the obligations of the nonqualified defined benefit pension plan at September 30, 2015 and 2014, respectively.

The net periodic benefit cost for the years ended September 30, 2015 and 2014, is as follows (in thousands):

	Defined Benefit Pension Plans		Postretirement Benefit Plans	
	2015	2014	2015	2014
Service cost	$ 20,895	22,532	3,789	3,617
Interest cost	20,652	20,896	3,392	3,270
Expected return on plan assets	(27,952)	(25,377)	—	—
Amortization of prior service cost	(1,951)	(2,035)	(37)	86
Recognized net actuarial loss	7,806	5,294	—	—
Net periodic benefit cost	$ 19,450	21,310	7,144	6,973

Weighted average assumptions and dates used to determine benefit obligations at September 30, 2015 and 2014 are as follows:

	Defined Benefit Pension Plans		Postretirement Benefit Plans	
	2015	2014	2015	2014
Discount rate for determining benefit obligations at year-end, qualified plan	4.30%	4.20%	4.50%	4.40%
Discount rate for determining benefit obligations at year-end, nonqualified plan	4.50%	4.40	—	—
Rate of compensation increase	4.0%–5.0%	5.00	—	—

Weighted average assumptions used to determine net periodic benefit cost for the years ended September 30, 2015 and 2014, are as follows:

	Defined Benefit Pension Plans		Postretirement Benefit Plans	
	2015	2014	2015	2014
Discount rate for determining net periodic benefit cost at year-end, qualified plan	4.20%	4.80%	4.40%	4.90%
Discount rate for determining net periodic benefit cost at year end, nonqualified plan	4.40	4.90	—	—
Expected rate of return on plan assets	7.75	7.75	—	—
Rate of compensation increase	5.00	5.00	—	—

For measurement purposes relating to the postretirement benefits plan, a 4.0% and 5.0% annual rate of increase in the per capita cost of covered health care benefits was assumed for fiscal 2015 and fiscal 2014, respectively.

Assumed health care cost trend rate assumptions have a significant effect on the amounts reported. A 1% change in the assumed healthcare cost trend rate would have the following effects (in thousands):

	1% Increase	1% Decrease
Effect on total of service and interest cost components	$ 50	(59)
Effect on postretirement benefit obligation	335	(381)

The asset allocation of Y-NHH's qualified pension plan at September 30, 2015 and 2014, was as follows:

	Target allocation	Percentage of plan assets	
Asset category	2016	2015	2014
Equity securities	42%	47%	39%
Debt securities	17	17	18
All other assets	41	36	43
Total	100%	100%	100%

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

Pension assets carried at fair value, as of September 30, 2015 and 2014, are classified in the following tables (see Footnote 14 for description) (in thousands):

	Investments measured at NAV	Investments classified in the fair value hierarchy Level 1	Total
Money market funds	$ —	$ 5,136	$ 5,136
Money market funds	—	—	—
U.S. equity securities	37,450	40,885	78,335
International equity securities	35,119	44,182	79,301
Fixed income:			
U.S. government	28,183	—	28,183
Corporate debt	—	—	—
International government	10,776	19,975	30,751
Commodities	7,951	—	7,951
Private equity	6,238		6,238
Real estate	—	—	—
Hedge funds:			
Long/short equity	—	—	—
Multi strategy/other	87,681	—	87,681
Real estate	17,093	—	17,093
Beneficial interest in remainder trusts	—	—	—
	$ 230,491	$ 110,178	$ 340,669

	Investments measured at NAV	Investments classified in the fair value hierarchy Level 1	Total
Money market funds	$ —	$ 14,528	$ 14,528
U.S. equity securities	10,673	49,322	59,995
International equity securities	11,554	62,254	73,808
Fixed income:			
U.S. government	42,800	—	42,800
International government	9,489	20,607	30,096
Commodities	23,509	—	23,509
Private equity	3,417		3,417
Hedge funds:			
Long/short equity	341	—	341
Multi strategy/other	79,300	—	79,300
Real estate	19,444	—	19,444
	$ 200,527	$ 146,711	$ 347,238

(Continued)

There are no pension investments that are measured at fair value based on Level 3 inputs at September 30, 2015 or 2014.

(b) Description of Investment Policies and Strategies

Y-NHH's investment strategy for its pension assets balances the liquidity needs of the pension plan with the long-term return goals necessary to satisfy future pension obligations. The target asset allocation seeks to capture the equity premium granted by the capital markets over the long-term, while ensuring security of principal to meet near-term expenses and obligations through the fixed income allocation. The allocation of the investment pool to various sectors of the markets is designed to reduce volatility in the portfolio. Y-NHH's pension portfolio return assumption of 7.75% is based on the targeted weighted average return of comparative market indices for the asset classes represented in the portfolio and discounted for pension expenses. The actual return on assets of the pension plan was (5.2%) and 7.4% for the years ended September 30, 2015 and 2014, respectively.

(c) Cash Flows

The future cash flows of Y-NHH relative to retirement benefits are expected to be as follows (in thousands):

		Defined benefit pension plans	Postretirement benefits plan
Estimated benefit payments related to years ending September 30:			
2016	$	26,471	2,131
2017		27,698	2,399
2018		29,624	2,606
2019		30,946	2,835
2020		33,473	3,073
2021 to 2025		190,454	20,305

Y-NHH expects to contribute approximately $34.0 million for pension benefits and $2.1 million for postretirement benefits payments in fiscal 2016.

(9) Professional Liability Insurance

In 1978, the Hospital and a number of other academic medical centers formed the Medical Centre Insurance Company, Ltd (the Captive) to insure for professional and comprehensive general liability risks. In 1997, the Captive formed MCIC Vermont, Inc. to write direct insurance for the professional and general liability risks of the shareholders. Since 1997, the Captive has acted as a reinsurer for varying levels of per claim limit exposure. MCIC Vermont, Inc. has reinsurance coverage from outside reinsurers for amounts above the per claim limits. Premiums are based on claims made coverage and are actuarially determined based on actual experience of the Hospital, the Captive and MCIC Vermont, Inc.

In fiscal 1998, the Hospital entered into a purchase and sales management agreement with YNHHSC that transferred the Hospital's participation in the Captive to YNHHSC for its book value as calculated by the

Captive. Under the terms of the agreement, the Hospital retains certain elements of control and assumes limited risk associated with the ongoing operation of the Captive. The Hospital pays insurance premiums to YNHHSC.

Additionally, because the purchase and sales management agreement entered into with YNHHSC in 1998 meet criteria for deposit accounting, the Hospital recorded an actuarially determined liability for IBNR professional and general liabilities with an offsetting deposit (asset) of an equal amount (approximately $11.8 million).

The estimate for claims-made professional liabilities and the estimate for incidents that have been incurred but not reported aggregated approximately $116.6 million and $105.2 million at September 30, 2015 and 2014, respectively for the Hospital. The undiscounted estimate for incidents that have been incurred but not reported aggregated approximately $43.5 million and $40.6 million for the Hospital at September 30, 2015 and 2014, respectively, and is included in professional insurance liabilities in the accompanying consolidated statements of financial position at the actuarially determined present value of approximately $39.9 million and $36.8 million, respectively, based on a discount rate of 2.0% and 2.5% for the years ended September 30, 2015 and 2014, respectively.

The Hospital has recorded related insurance recoveries receivable of approximately $76.9 million and $68.4 million at September 30, 2015 and 2014, respectively, in consideration of the expected insurance recoveries for the total discounted claims-made insurance. The current portion of professional liabilities and the related insurance receivable represents an estimate of expected settlements and insurance recoveries over the next 12 months.

Lukan, the Hospital sponsored professional liability program, continues to manage all incidents and claims reported to Lukan prior to the 2012 acquisition of the Saint Raphael Healthcare System Inc. (SRHS), as well as extending professional liability coverage for post acquisition risks to certain affiliated community clinicians.

Prior to the acquisition of SRHS, Caritas provided excess professional liability and general liability insurance to SRHS and their employed clinicians. Caritas continued to manage all incidents and claims reported prior to the acquisition of SRHS and are included in the amounts above.

Caritas and Lukan have recorded the undiscounted estimate for claims-made professional liabilities and the estimate for incidents that have been incurred but not reported aggregated of approximately $29.6 million at September 30, 2014, and are included in professional liabilities in the accompanying consolidated statements of financial position.

In October 2014, the Hospital disposed of its interest in Caritas and Lukan (the Captives) through a novation agreement with Medical Centre Insurance Company, Ltd (MCIC) for a total price of approximately $40.2 million. The novation agreement assigns and transfers all of the Captives' past, present and future rights, risks, liabilities and obligations, and transfers substantially all of the assets of the Captives to MCIC. The Hospital dissolved the Captives in the fiscal year ended September 30, 2015.

The estimates for professional insurance liabilities are based upon complex actuarial calculations which utilize factors such as historical claims experience for Y-NHH and related industry factors, trending models, estimates for the payment patterns of future claims and present value discount factors. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount in the near term. Revisions to estimated amounts resulting from actual experience differing from projected expectations are recorded in the period the information becomes known or when changes are anticipated.

(10) Commitments and Contingencies

(a) Leases

YNHH leases certain office, clinical and parking spaces under noncancelable operating leases that range in terms ending in 2016 through 2039. Future minimum lease payments under these leases are as follows (in thousands):

2016	$	23,387
2017		21,591
2018		19,611
2019		18,917
2020		10,424
Thereafter		110,729
	$	204,659

Y-NHH incurred net rent expense under these leases of approximately $23.5 million for the year ended September 30, 2015, and $18.7 million for the year ended 2014.

(b) Cancer Hospital

The Hospital has a shared facilities and services agreement with the University in connection with the Cancer Hospital which is recorded as deferred revenue. Deferred revenue, from this agreement, at September 30, 2015 and 2014, was $42.7 million and $44.0 million, respectively.

(c) Inpatient Rehabilitation Unit Agreement

During September 2014, the Hospital entered into an agreement with another health care provider to provide a framework for implementing programs in a manner that is consistent with the charitable mission of each organization and the communities they serve. Under the terms of the agreement the Hospital will utilize beds at the health care provider's location under a lease arrangement to provide inpatient rehabilitation services to its patients. In addition, Y-NHH will furnish an $8.0 million term loan to the health care provider.

(d) Litigation

Various lawsuits and claims arising in the normal course of operations are pending or are in progress against the Hospital. Such lawsuits and claims are either specifically covered by insurance as explained in note 9 or are deemed to be immaterial. While the outcomes of the lawsuits and claims cannot be determined at this time, management believes that any loss which may arise from these actions will not have a material adverse effect on the consolidated financial position or changes in net assets of the Hospital.

(Continued)

The Hospital has received requests for information from certain governmental agencies relating to, among other things, patient billings. These requests cover several prior years relating to compliance with certain laws and regulations. Management is cooperating with those governmental agencies in their information requests and ongoing investigations. The ultimate results of those investigations, including the impact on the Hospital, cannot be determined at this time.

(11) Functional Expenses

The Hospital provides general acute health care services to residents within its geographic area. Net expenses related to providing these services are as follows (in thousands):

		Year ended September 30	
		2015	2014
Health care services	$	1,980,819	1,796,828
General and administrative		462,224	506,797
	$	2,443,043	2,303,625

(12) Related-Party Transactions

The Hospital provided facility space and certain services to related parties as follows (in thousands):

		Year ended September 30	
		2015	2014
Recovery of expenses:			
YNHHSC:			
Facility rental	$	3,214	3,066
Shared services		—	2
	$	3,214	3,068
Bridgeport Hospital:			
Resident fees	$	2,897	2,477
Other		1,157	999
	$	4,054	3,476

YNHHSC is the sole member Bridgeport Hospital.

(Continued)

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

The Hospital purchased certain services from YNHHSC as follows (in thousands):

		Year ended September 30	
		2015	2014
Operating expenses:			
Professional and general liability insurance	$	20,470	26,887
Information systems		69,769	62,472
System business office		65,421	31,189
Other business services		74,620	99,886
	$	230,280	220,434

Amounts receivable from and payable to related organizations included in other receivables, accounts payable and other long-term liabilities, respectively, in the consolidated balance sheets are as follows (in thousands):

		Year ended September 30	
		2015	2014
Other receivables:			
YNHHSC	$	6,889	5,875
	$	6,889	5,875
Accounts payable:			
YNHHSC	$	19,236	41,038
Bridgeport Hospital		484	890
Northeast Medical Group, Inc.		7,985	2,610
Greenwich Hospital		428	85
Other long-term liabilities:			
YNHHSC		54,380	52,486
	$	82,513	97,109

The Hospital maintains certain investments for YNHHSC employees that participate in YNHH's sponsored benefit plans. The costs associated with the YNHHSC employees that participate in benefit plans are recovered by the Hospital.

The Hospital funds certain capital assets purchased by YNHHSC. Included in prepaid expenses and other assets were approximately $12.1 million and $71.8 million, respectively, at September 30, 2015, and approximately $30.3 million and $72.2 million, respectively, at September 30, 2014.

Additionally, for the year ended 2014, the Hospital funded YNHHSC approximately $2.1 million, as part of its participation in the New Clinical Program Development Corporation (NCPDC). There was no funding for the year ended September 30, 2015. The NCPDC was established for the purpose of funding

(Continued)

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

and supporting clinical research and clinical programs. The NCPDC Board approves the funding of initiatives.

Included in the consolidated statement of changes in net assets are amounts funded by the Hospital for physician related strategic mission support for NEMG of approximately $12.5 million and $14.0 million for the years ended September 30, 2015 and 2014, respectively.

(13) Other Revenue

Other revenue consisted of the following (in thousands):

		Year ended September 30	
		2015	2014
Cafeteria and vending	$	11,433	10,605
Contributions		3,406	5,495
Parking income		7,768	6,485
Net assets released from restrictions for operations		9,854	3,099
Net assets released from restrictions for free care		596	613
Net assets released from restrictions for medical research and clinical programs		881	5,269
Grants		18,175	13,574
Rental income		1,196	1,704
Electronic health records incentive payment		981	3,037
Other		10,387	10,572
	$	64,677	60,453

The American Recovery and Reinvestment Act of 2009 included provisions for implementing health information technology under the Health Information Technology for Economic and Clinical Health Act (HITECH). The provisions were designed to increase the use of electronic health record (EHR) technology and establish the requirements for a Medicare and Medicaid incentive payment program beginning in 2011 for eligible providers that adopt and meaningfully use certified EHR technology. Eligibility for annual Medicare incentive payments is dependent on providers demonstrating meaningful use of EHR technology in each period over a four-year period. Initial Medicaid incentive payments are available to providers that adopt, implement or upgrade certified EHR technology. In subsequent years, providers must demonstrate meaningful use of such technology to qualify for additional Medicaid incentive payments. Hospitals that do not successfully demonstrate meaningful use of EHR technology are subject to payment penalties or downward adjustments to their Medicare payments beginning in federal fiscal year 2015.

The Hospital uses a grant accounting model to recognize revenue for the Medicare and Medicaid EHR incentive payments. Under this accounting policy, EHR incentive payment revenue is recognized when the Hospital is reasonably assured that the EHR meaningful use criteria for the required period of time were met and that the grant revenue will be received. Medicare EHR incentive payment revenue was approximately $1.0 million and $2.0 million, respectively, for the years ended September 30, 2015 and 2014, and Medicaid EHR incentive payment revenue was approximately $1.0 million for the year ended

September 30, 2014. The Hospital did not receive any Medicaid EHR incentive payments for the year ended September 30, 2015. EHR incentive payment revenue is included in other revenue in the accompanying consolidated statement of operations and changes in net assets. Income from incentive payments is subject to retrospective adjustment upon final settlement of the applicable cost report from which payments were calculated. Additionally, the Hospital's attestation of compliance with the meaningful use criteria is subject to audit by the federal government.

(14) Nonoperating Gains (Losses)

Nonoperating gains and losses, net consisted of the following (in thousands):

		Year ended September 30	
		2015	2014
Income from investments, donations and other, net	$	4,219	3,162
Discontinued operations		(725)	—
Income attributable to noncontrolling interest		(1,674)	(2,320)
Change in unrealized gains and losses on investments		20,129	75,949
Change in fair value of swaps, including counterparty payments		(28,248)	(16,357)
Loss on refunding of long-term debt		—	(32,631)
	$	(6,299)	27,803

Contributions received consisted of the following (in thousands):

		Year ended September 30	
		2015	2014
Unrestricted	$	870	840
Temporarily restricted		17,989	12,827
Permanently restricted		13,655	3,492
Total contributions		32,514	17,159
Less fundraising expenses		(4,049)	(4,704)
Contributions, net	$	28,465	12,455

During 2015, the Attorney General approved the transfer of certain philanthropic funds to Y-NHH from the Hospital of Saint Raphael and its Foundation related to Y-NHH's acquisition of the Hospital of Saint Raphael in FY 2012. The funds approved for transfer are included as contributions to temporarily restricted net assets and permanently restricted net assets totaling $8.8 million and $11.5 million, respectively, for the year ended September 30, 2015.

(15) Fair Value Measurements

In determining fair value, the Hospital utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs. The Hospital also considers nonperformance risk in the overall assessment of fair value.

(Continued)

ASC 820-10, *Fair Value Measurements and Disclosures*, establishes a valuation hierarchy for fair value disclosure purposes. This hierarchy is based on the transparency of the inputs utilized for the valuation. The levels are defined as follows:

- Net Asset Value: Determined by the respective external investment managers, including general partners, if market values are not readily ascertainable.
- Level 1: Quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities. This established hierarchy assigns the highest priority to Level 1 assets.
- Level 2: Observable inputs that are based on data not quoted in active markets, but corroborated by market data.
- Level 3: Unobservable inputs that are used when little or no market data is available. The Level 3 inputs are assigned the lowest priority.

Financial assets carried at fair value as of September 30, 2015, are classified in the following table by level within the fair value hierarchy as described above (in thousands):

	Investments measured at NAV	Investments classified in the fair value hierarchy Level 1	Level 2	Total
Cash and cash equivalents	$ —	$ 103,628	$ —	$ 103,628
Money market funds	—	50,943	—	50,943
U.S. equity securities	13,131	57,359	—	70,490
International equity securities	18,420	46,020	—	64,440
Fixed income:				
U.S. government	247,394	49,022	—	296,416
International government	36,757	48,187	—	84,944
Commodities	82	—	—	82
Real estate	6,781	—	—	6,781
Hedge funds:				
Absolute return	10,554	—	—	10,554
Perpetual trusts	18,050	—	—	18,050
Interest in Yale University endowment pool	768,495	—	—	768,495
Total investments as of September 30, 2015	$ 1,119,664	$ 355,159	$ —	$ 1,474,823
Liabilities:				
Interest rate swap	$ —	$ —	$ (50,599)	$ (50,599)

(Continued)

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

Financial assets carried at fair value as of September 30, 2014, are classified in the following table by level within the fair value hierarchy as described above (in thousands):

	Investments measured at NAV	value hierarchy Level 1	Level 2	Total
Cash and cash equivalents	$ —	$ 69,250	$ —	$ 69,250
Money market funds	—	129,823	—	129,823
U.S. equity securities	11,274	47,912	—	59,186
International equity securities	11,397	59,274	—	70,671
Fixed income:				
U.S. government	137,425	120,701	—	258,126
Corporate debt	—	—	—	—
International government	30,873	46,833	—	77,706
Commodities	122	—	—	122
Real estate	9,628	—	—	9,628
Hedge funds:				
Absolute return	10,304	—	—	10,304
Beneficial interest in remainder trusts	17,797	—	—	17,797
Interest in Yale University endowment pool	685,862	—	—	685,862
Total investments as of September 30, 2015	$ 914,682	$ 473,793	$ —	$ 1,388,475
Liabilities:				
Interest rate swap	$ —	$ —	$ (32,316)	$ (32,316)

The fair value of debt was approximately $829.7 million and $808.5 million at September 30, 2015 and 2014, respectively. The fair value of the capital leases was approximately $51.7 million and $54.5 million at September 30, 2015 and 2014, respectively. The fair value of long-term debt is classified as Level 2 in the fair value hierarchy as it uses a combination of quoted market prices and valuation based on current market rates.

There are no assets or liabilities that are measured at fair value based on Level 3 inputs at September 30, 2015 or 2014.

The interest rate swaps listed above are classified in the accompanying balance sheets as other long-term liabilities at September 30, 2015 and 2014.

(Continued)

YALE NEW HAVEN HOSPITAL AND SUBSIDIARIES

Notes to Consolidated Financial Statements

September 30, 2015 and 2014

The following is a summary of total investments as of September 30, 2015, with restrictions to redeem the investments at the measurement date, any unfunded capital commitments and investment strategies of the investees (in thousands):

Description of investment		Carrying value	Unfunded commitment	Redemption frequency	Notice period	Funds availability
Real estate	$	6,781	2,295	N/A	N/A	N/A
Commodities		82	—	N/A	N/A	N/A

(16) Subsequent Events

Subsequent events have been evaluated through December 23, 2015, which is the date the consolidated financial statements were issued. No events, except as noted above, have occurred that require disclosure or adjustment of the consolidated financial statements.

SUPPLEMENTARY INFORMATION

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidating Balance Sheet

September 30, 2015

(In thousands)

Assets	Hospital	York	ASC	YNHCCC	Eliminations	Total
Current assets:						
Cash and cash equivalents	$ 101,130	1,256	1,196	46	—	103,628
Short-term investments	980,087	—	—	—	—	980,087
Accounts receivable for services to patients, net	286,728	3,234	1,369	2,021	—	293,352
Other receivables	33,463	893	5,442	—	(4,724)	35,074
Professional liabilities insurance recoveries receivable – current portion	19,852	—	—	—	—	19,852
Other current assets	74,322	57	1,175	—	—	75,554
Amounts on deposit with trustee in debt service fund	4,786	—	—	—	—	4,786
Total current assets	1,500,368	5,440	9,182	2,067	(4,724)	1,512,333
Assets limited as to use	96,888	—	—	—	—	96,888
Long-term investments	289,434	—	—	—	—	289,434
Deferred financing costs, less accumulated amortization	8,909	—	—	—	—	8,909
Professional liabilities insurance recoveries receivable – noncurrent portion	57,025	—	—	—	—	57,025
Goodwill	44,774	—	—	—	—	44,774
Other assets	186,745	1,078	9,663	726	(28,370)	169,842
Property, plant and equipment:						
Land and land improvements	46,283	2,337	—	1,580	—	50,200
Buildings and fixtures	1,149,033	1,962	4,641	2,864	—	1,158,500
Equipment	469,579	64	3,874	390	—	473,907
	1,664,895	4,363	8,515	4,834	—	1,682,607
Less accumulated depreciation	808,887	1,411	6,100	702	—	817,100
	856,008	2,952	2,415	4,132	—	865,507
Construction in progress	80,774	—	—	—	—	80,774
	936,782	2,952	2,415	4,132	—	946,281
Total assets	$ 3,120,925	9,470	21,260	6,925	(33,094)	3,125,486

(Continued)

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidating Balance Sheet

September 30, 2015

(In thousands)

Liabilities and Net Assets (Deficiency)	Hospital	York	ASC	YNHCCC	Eliminations	Total
Current liabilities:						
Accounts payable	$ 145,177	2,557	565	6,932	(4,933)	150,298
Accrued expenses	200,995	250	817	—	—	202,062
Professional liabilities – current portion	19,852	—	—	—	—	19,852
Other current liabilities	58,668	—	—	419	—	59,087
Current portion of capital lease obligation	2,003	—	—	—	—	2,003
Current portion of long term debt	8,083	—	—	—	—	8,083
Total current liabilities	434,778	2,807	1,382	7,351	(4,933)	441,385
Long-term debt, net of current portion	800,348	—	—	—	—	800,348
Long-term capital lease obligation, net of current portion	46,850	—	—	—	—	46,850
Accrued pension and postretirement benefit obligations	228,810	—	—	—	—	228,810
Professional liabilities - noncurrent	96,778	—	—	—	—	96,778
Other long-term liabilities	245,649	218	8,732	4,390	(12,600)	246,389
Deferred revenue	42,720	—	—	—	—	42,720
Total liabilities	1,895,933	3,025	10,114	11,741	(17,533)	1,903,280
Net assets (deficiency):						
Unrestricted	1,107,165	6,445	9,118	(4,816)	(15,561)	1,102,351
Temporarily restricted	70,941	—	—	—	—	70,941
Permanently restricted	46,886	—	—	—	—	46,886
Total Yale-New Haven Hospital & Subsidiaries net assets (deficiency)	1,224,992	6,445	9,118	(4,816)	(15,561)	1,220,178
Noncontrolling interest	—	—	2,028	—	—	2,028
Total net assets (deficiency) including noncontrolling interest	1,224,992	6,445	11,146	(4,816)	(15,561)	1,222,206
Total liabilities and net assets (deficiency)	$ 3,120,925	9,470	21,260	6,925	(33,094)	3,125,486

See accompanying independent auditors' report.

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidating Statement of Operations and Changes in Net Assets

September 30, 2015

(In thousands)

	Hospital	Lukan	Caritas	York	ASC	YNHCCC	Eliminations	Total
Operating revenue:								
Net patient service revenue	$ 2,507,294	—	—	4,669	16,380	12,740	(220)	2,540,863
Less provision for bad debts	(49,304)	—	—	—	(176)	(902)	—	(50,382)
Net patient service revenue, less provision for bad debts	2,457,990	—	—	4,669	16,204	11,838	(220)	2,490,481
Other revenue	68,887	—	—	5,522	731	41	(10,504)	64,677
Total operating revenue	2,526,877	—	—	10,191	16,935	11,879	(10,724)	2,555,158
Operating expenses:								
Salaries and benefits	1,053,740	—	—	1,293	5,842	9,751	—	1,070,626
Supplies and other expenses	1,202,819	—	—	4,780	6,509	3,673	(3,587)	1,214,194
Depreciation	119,157	—	—	433	393	252	—	120,235
Insurance	16,952	—	—	13	133	64	—	17,162
Interest	20,696	—	—	130	—	—	—	20,826
Total operating expenses	2,413,364	—	—	6,649	12,877	13,740	(3,587)	2,443,043
Income (loss) from operations	113,513	—	—	3,542	4,058	(1,861)	(7,137)	112,115
Nonoperating gains (losses), net:								
Income from investments, donations and other, net	24,086	—	—	(463)	(2,069)	—	2,069	23,623
Change in fair value of swap, including counterparty payments	(28,248)	—	—	—	—	—	—	(28,248)
Excess of revenue over expenses, before noncontrolling interest	109,351	—	—	3,079	1,989	(1,861)	(5,068)	107,490
Less income attributable to noncontrolling interest	—	—	—	—	(1,674)	—	—	(1,674)
Excess of revenue over expenses	109,351	—	—	3,079	315	(1,861)	(5,068)	105,816
Unrestricted net assets:								
Other changes in net assets	(516)	(10,218)	(5,065)	—	—	—	15,283	(516)
Transfer to Yale-New Haven Health Services Corporation – Mission Support	(12,516)	—	—	—	—	—	—	(12,516)
Net assets released from restrictions for purchases of fixed asset	4,515	—	—	—	—	—	—	4,515
Pension related changes other than net periodic benefit cost	(12,372)	—	—	—	—	—	—	(12,372)
Increase (decrease) in unrestricted net assets	88,462	(10,218)	(5,065)	3,079	315	(1,861)	10,215	84,927

(Continued)

YALE-NEW HAVEN HOSPITAL AND SUBSIDIARIES

Consolidating Statement of Operations and Changes in Net Assets, Continued

September 30, 2015

(In thousands)

	Hospital	Lukan	Caritas	York	ASC	YNHCCC	Eliminations	Total
Temporarily restricted net assets:								
Income from investments	$ 298	—	—	—	—	—	—	298
Net realized gains on investments	297	—	—	—	—	—	—	297
Change in net unrealized gains and losses on investments	2,354	—	—	—	—	—	—	2,354
Bequests and contributions	17,989	—	—	—	—	—	—	17,989
Net assets released from restrictions for purchases of fixed assets	(3,123)	—	—	—	—	—	—	(3,123)
Net assets released from restrictions for free care	(596)	—	—	—	—	—	—	(596)
Net assets released from restrictions for operations	(9,854)	—	—	—	—	—	—	(9,854)
Net assets released from restrictions for clinical programs	(881)	—	—	—	—	—	—	(881)
Other	139	—	—	—	—	—	—	139
Increase in temporarily restricted net assets	6,623	—	—	—	—	—	—	6,623
Permanently restricted net assets:								
Bequests, contributions, and grants	13,654	—	—	—	—	—	—	13,654
Change in beneficial interest in perpetual trusts	(1,282)	—	—	—	—	—	—	(1,282)
Net assets released from restrictions for capital	(1,392)	—	—	—	—	—	—	(1,392)
Increase in permanently restricted net assets	10,980	—	—	—	—	—	—	10,980
Noncontrolling interest:								
Income attributable to noncontrolling interest	(1,674)	—	—	—	1,674	—	1,674	1,674
Distributions to noncontrolling interest	—	—	—	—	(1,528)	—	—	(1,528)
	(1,674)	—	—	—	146	—	1,674	146
(Decrease) increase in net assets	104,391	(10,218)	(5,065)	3,079	461	(1,861)	11,889	102,676
Net assets (deficiency) at beginning of year	1,120,602	10,218	5,065	3,366	10,685	(2,955)	(27,451)	1,119,530
Net assets (deficiency) at end of year	$ 1,224,993	—	—	6,445	11,146	(4,816)	(15,562)	1,222,206

See accompanying independent auditors' report.

EXHIBIT H

FINANCIALS AND ASSUMPTIONS

NON-PROFIT

Applicant:

Financial Worksheet (A)

Please provide one year of actual results and three years of projections of Total Entity revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

LINE	Total Entity:	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
		FY15	FY16	FY16	FY16	FY17	FY17	FY17	FY18	FY18	FY18	FY19	FY19	FY19
		Actual	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
	Description	Results	W/out CON	Incremental	With CON	W/out CON	Incremental	With CON	W/out CON	Incremental	With CON	W/out CON	Incremental	With CON
A.	OPERATING REVENUE													
1	Total Gross Patient Revenue	$8,750,595,600	$11,094,372,000		$11,094,372,000	$11,204,464,000		$11,204,464,000	$11,355,046,000		$11,355,046,000	$11,510,146,000		$11,510,146,000
2	Less: Allowances	$6,209,732,400	$8,426,193,000		$8,426,193,000	$8,457,666,000		$8,457,665,000	$8,533,977,000		$8,533,977,000	$8,636,692,000		$8,636,692,000
3	Less: Charity Care				$0			$0			$0			$0
4	Less: Other Deductions				$0			$0			$0			$0
	Net Patient Service Revenue	$2,540,863,200	$2,668,179,000	$0	$2,668,179,000	$2,746,799,000	$0	$2,746,799,000	$2,821,069,000	$0	$2,821,069,000	$2,873,454,000	$0	$2,873,454,000
5	Medicare	$808,011,500	$848,498,776		$848,498,776	$873,500,462		$873,500,462	$897,118,819		$897,118,819	$913,777,600		$913,777,600
6	Medicaid	$308,108,200	$323,546,671		$323,546,671	$333,080,229		$333,080,229	$342,086,300		$342,086,300	$348,438,570		$348,438,570
7	CHAMPUS & TriCare				$0			$0			$0			$0
8	Other				$0			$0			$0			$0
	Total Government	$1,116,119,700	$1,172,045,447	$0	$1,172,045,447	$1,206,580,691	$0	$1,206,580,691	$1,239,205,120	$0	$1,239,205,120	$1,262,216,170	$0	$1,262,216,170
9	Commercial Insurers	$1,381,820,400	$1,451,059,692		$1,451,059,692	$1,493,816,311		$1,493,816,311	$1,534,207,231		$1,534,207,231	$1,562,696,235		$1,562,696,235
10	Uninsured				$0			$0			$0			$0
11	Self Pay	$42,923,100	$45,073,861		$45,073,861	$46,401,998		$46,401,998	$47,656,649		$47,656,649	$48,541,595		$48,541,595
12	Workers Compensation				$0			$0			$0			$0
13	Other				$0			$0			$0			$0
	Total Non-Government	$1,424,743,500	$1,496,133,553	$0	$1,496,133,553	$1,540,218,309	$0	$1,540,218,309	$1,581,863,880	$0	$1,581,863,880	$1,611,237,830	$0	$1,611,237,830
	Net Patient Service Revenue[a] (Government+Non-Government)	$2,540,863,200	$2,668,179,000	$0	$2,668,179,000	$2,746,799,000	$0	$2,746,799,000	$2,821,069,000	$0	$2,821,069,000	$2,873,454,000	$0	$2,873,454,000
14	Less: Provision for Bad Debts	$50,382,400	$73,453,000		$73,453,000	$74,179,000		$74,179,000	$75,170,000		$75,170,000	$76,191,000		$76,191,000
	Net Patient Service Revenue less provision for bad debts	$2,490,480,800	$2,594,726,000	$0	$2,594,726,000	$2,672,620,000	$0	$2,672,620,000	$2,745,899,000	$0	$2,745,899,000	$2,797,263,000	$0	$2,797,263,000
15	Other Operating Revenue	$64,676,500	$48,830,000		$48,830,000	$90,820,000		$90,820,000	$69,566,000		$69,566,000	$68,756,000		$68,756,000
17	Net Assets Released from Restrictions				$0			$0			$0			$0
	TOTAL OPERATING REVENUE	$2,555,157,300	$2,643,556,000	$0	$2,643,556,000	$2,763,440,000	$0	$2,763,440,000	$2,815,465,000	$0	$2,815,465,000	$2,866,019,000	$0	$2,866,019,000
B.	OPERATING EXPENSES													
1	Salaries and Wages	$831,202,100	$849,809,000		$849,809,000	$901,545,000		$901,545,000	$912,077,885		$912,077,885	$923,136,000		$923,136,000
2	Fringe Benefits	$239,423,700	$236,648,000		$236,648,000	$245,428,000		$245,428,000	$254,871,647		$254,871,647	$257,547,251		$257,547,251
3	Physicians Fees	$627,545,400	$675,960,000		$675,960,000	$695,737,000		$695,737,000	$702,563,464		$702,563,464	$709,763,691		$709,763,691
4	Supplies and Drugs	$490,320,700	$490,503,000		$490,503,000	$538,096,000		$538,096,000	$548,435,760		$548,435,760	$559,319,448		$559,319,448
5	Depreciation and Amortization	$93,281,200	$120,165,000		$120,165,000	$120,976,000		$120,976,000	$129,516,722	$66,276	$129,582,998	$136,180,830	$66,276	$136,247,106
6	Provision for Bad Debts-Other[b]				$0			$0			$0			$0
7	Interest Expense	$20,879,700	$22,196,000		$22,196,000	$22,640,000		$22,640,000	$22,643,824		$22,643,824	$27,642,154		$27,642,154
8	Malpractice Insurance Cost	$23,857,600	$23,752,052		$23,752,052	$24,181,825		$24,181,825	$24,949,383		$24,949,383	$25,850,721		$25,850,721
9	Lease Expense	$23,519,600	$23,415,547		$23,415,547	$23,839,231		$23,839,231	$24,595,915		$24,595,915	$25,484,484		$25,484,484
10	Other Operating Expenses	$93,012,900	$92,601,402		$92,601,402	$94,276,944		$94,276,944	$97,269,400		$97,269,400	$100,783,421		$100,783,421
	TOTAL OPERATING EXPENSES	$2,443,042,900	$2,535,050,000	$0	$2,535,050,000	$2,666,720,000	$0	$2,666,720,000	$2,716,924,000	$66,276	$2,716,990,276	$2,765,708,000	$66,276	$2,765,774,276
	INCOME/(LOSS) FROM OPERATIONS	$112,114,400	$108,506,000	$0	$108,506,000	$96,720,000	$0	$96,720,000	$98,541,000	($66,276)	$98,474,724	$100,311,000	($66,276)	$100,244,724
	NON-OPERATING REVENUE	($6,297,800)	$34,200,000		$34,200,000	$34,200,000		$34,200,000	$34,200,000		$34,200,000	$34,200,000		$34,200,000
	EXCESS/(DEFICIENCY) OF REVENUE OVER EXPENSES	$105,816,600	$142,706,000	$0	$142,706,000	$130,920,000	$0	$130,920,000	$132,741,000	($66,276)	$132,674,724	$134,511,000	($66,276)	$134,444,724
	Principal Payments				$0			$0			$0			$0
C.	PROFITABILITY SUMMARY													
1	Hospital Operating Margin	4.4%	4.1%	0.0%	4.1%	3.5%	0.0%	3.5%	3.5%	0.0%	3.5%	3.5%	0.0%	3.5%
2	Hospital Non Operating Margin	-0.2%	1.3%	0.0%	1.3%	1.2%	0.0%	1.2%	1.2%	0.0%	1.2%	1.2%	0.0%	1.2%
3	Hospital Total Margin	4.2%	5.3%	0.0%	5.3%	4.7%	0.0%	4.7%	4.7%	0.0%	4.7%	4.6%	0.0%	4.6%
D.	FTEs	10,432	11,235		11,235	11,323		11,323	11,345		11,345	11,367		11,367
E.	VOLUME STATISTICS[c]													
1	Inpatient Discharges	78,444	79,073		79,073	79,677		79,677	79,677		79,677	79,677		79,677
2	Outpatient Visits	1,282,539	1,331,024		1,331,024	1,347,933		1,347,933	1,388,371		1,388,371	1,430,022		1,430,022
	TOTAL VOLUME	1,360,983	1,410,097	0	1,410,097	1,427,610	0	1,427,610	1,468,048	0	1,468,048	1,509,699	0	1,509,699

[a] Total amount should equal the total amount on cell line "Net Patient Revenue" Row 14.

[b] Provide the amount of any transaction associated with Bad Debts not related to the provision of direct services to patients. For additional information, refer to FASB, No.2011-07, July 2011.

[c] 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.

YALE-NEW HAVEN HOSPITAL

Proposal for the Replacement of SPECT CT

Yale-New Haven Hospital

Assumptions

Net Revenue Rate Increases	FY 2016	FY 2017	FY 2018
1) Government	0 - 1%	0 - 1%	0 - 1%
2) Non-Government	1 - 2.2%	1 - 2.2%	1 - 2.2%

		FY 2016	FY 2017	FY 2018
	EXPENSES			
A.	Salaries and Fringe Benefits	1.0%	1.0%	1.0%
B.	Non-Salary			
	1) Medical and Surgical Supplies	1.3%	1.3%	1.3%
	2) Pharmacy and Solutions	1.3%	1.3%	1.3%
	3) Malpractice Insurance	2.3%	2.3%	2.3%
	4) Professional and Contracted Services	1.0%	1.0%	1.0%
	5) All Other Expenses	2 - 3%	2 - 3%	2 - 3%

	FY 2016	FY 2017	FY 2018
FTEs			
1) Total estimated FTEs	11,235	11,323	11,345

Note - The above increase projections reflect all changes relating to Medicare and Medicaid reimbursement regulations.

Greer, Leslie

From: Veyberman, Alla
Sent: Friday, January 27, 2017 3:04 PM
To: Fernandes, David; McKennan, Matthew (Matthew.McKennan@YNHH.ORG)
Cc: Greer, Leslie; Riggott, Kaila
Subject: Completeness letter 16-32124
Attachments: 16-32124-CON Completeness letter.docx

Good afternoon Mr. McKennan,

Please see the attached completeness letter in the matter of the proposed acquisition of two SPECT/CT cameras to replace two SPECT cameras. In responding to the completeness letter, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by March 28, 2017.

Email to OHCA@ct.gov and cc: Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letters, please contact Kaila Riggott at (860) 418-7037.

Please confirm receipt of this email.

Thank You,

Alla Veyberman, MS
CT Department of Public Health
Office of Health Care Access (OHCA)
Phone: 860.418.7007
Fax: 860.418.7053
Email: Alla.Veyberman@ct.gov

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

January 27, 2017 Via Email Only

Mr. Matthew McKennan
Assistant Counsel
Yale New-Haven Hospital
Legal & Risk Services Department
789 Howard Avenue
New Haven, CT 06510
Matthew.McKennan@YNHH.ORG

RE: Certificate of Need Application: Docket Number: 16-32124-CON
Acquisition of Two SPECT/CT cameras to replace two existing SPECT cameras

Dear Mr. McKennan:

On December 29, 2016, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") application filing on behalf of Yale-New Haven Hospital ("Applicant") proposing to acquire two Single Photon Emission Computed Tomography-Computed Tomography cameras ("SPECT/CT") to replace two existing SPECT cameras, with a total associated cost of $ 927,862.

OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). *Please "reply all" to electronically confirm receipt of this email as soon as you receive it.* Provide responses to the questions below in both a Word document and PDF format as an attachment to a responding email. *Please email your responses to all of the following email addresses:* **OHCA@ct.gov** and **kaila.riggott@ct.gov**.

Paginate and date your response (i.e., each page in its entirety). Repeat each OHCA question before providing your response. Information filed after the initial CON application submission (e.g., completeness response letter, prefiled testimony, late file submissions, etc.) must be numbered sequentially from the Applicant's preceding document. Begin your submission using **Page 219** and reference "**Docket Number: 16-32124-CON**."

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 this request was transmitted. Therefore, please provide your written responses to OHCA no later than **March 28, 2017**, otherwise your application will be automatically considered withdrawn.

1. How will Yale-New Haven Hospital dispose of the existing SPECT cameras?

2. What specific types of scans will be performed by each camera?

3. Can CT capability be added onto the existing 2014 SPECT camera located at 1450 Chapel Street?

4. Will there be a gap in services during the cameras' installation period? If yes, how will the patients be served?

5. Verify the construction cost is the same for both locations and explain why.

6. Provide a separate Capital Expenditures table for each of the proposed cameras.

7. Explain why there is no utilization reported in Table 9 on page 39 for one of the existing SPECT cameras located at 20 York Street.

8. Explain why volumes are projected to remain flat as indicated on Table 5, page 30 of the application, given historical volume fluctuation/decline.

9. Please reconcile the Projected Incremental expenses on Financial Worksheet A with Table 4 on page 34, as the figures for incremental Depreciation and Amortization do not agree.

10. Update Tables 4, 6, 7 and Financial Worksheet A to reflect the 3 projected fiscal years, 2018-2020.

11. Please update Table 5 on page 35 with year-to-date volume for the current fiscal year, 2017.

If you have any questions concerning this letter, please feel free to contact Kaila Riggott at (860) 418-7037.

Greer, Leslie

From: McKennan, Matthew <Matthew.McKennan@YNHH.ORG>
Sent: Friday, January 27, 2017 3:19 PM
To: Veyberman, Alla; Fernandes, David
Cc: Greer, Leslie; Riggott, Kaila
Subject: RE: Completeness letter 16-32124

Thank you. Have a nice weekend.

Matt

Matt McKennan
Assistant Counsel

Legal & Risk Services Department
789 Howard Avenue, CB 230
New Haven, CT 06510

Office: 203-688-7361
Cell: 203-907-9858

YaleNewHavenHealth

From: Veyberman, Alla [mailto:Alla.Veyberman@ct.gov]
Sent: Friday, January 27, 2017 3:04 PM
To: Fernandes, David; McKennan, Matthew
Cc: Greer, Leslie; Riggott, Kaila
Subject: Completeness letter 16-32124

Good afternoon Mr. McKennan,

Please see the attached completeness letter in the matter of the proposed acquisition of two SPECT/CT cameras to replace two SPECT cameras. In responding to the completeness letter, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by March 28, 2017.

Email to OHCA@ct.gov and cc: Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letters, please contact Kaila Riggott at (860) 418-7037.

Please confirm receipt of this email.

Thank You,

Alla Veyberman, MS
CT Department of Public Health
Office of Health Care Access (OHCA)
Phone: 860.418.7007
Fax: 860.418.7053
Email: Alla.Veyberman@ct.gov

User, OHCA

From: McKennan, Matthew <Matthew.McKennan@YNHH.ORG>
Sent: Wednesday, February 22, 2017 11:45 AM
To: Veyberman, Alla; Fernandes, David; User, OHCA
Cc: Greer, Leslie; Riggott, Kaila
Subject: RE: Completeness letter 16-32124
Attachments: Final Response to CQ 16-32124-CON.pdf; Final Response to Completeness Questions.docx; Updated CQ Financial Worksheet A.xlsx

All –

Please find attached the response from Yale New Haven Hospital to the completeness questions issued by OHCA on January 27 related to Docket No. 16-32124-CON.

Thank you.

Matt

Matt McKennan
Assistant Counsel

Legal & Risk Services Department
789 Howard Avenue, CB 230
New Haven, CT 06510

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YaleNewHavenHealth

RECEIVED
FEB 22 2017
Office of
HEALTHCARE ACCESS

From: Veyberman, Alla [mailto:Alla.Veyberman@ct.gov]
Sent: Friday, January 27, 2017 3:04 PM
To: Fernandes, David; McKennan, Matthew
Cc: Greer, Leslie; Riggott, Kaila
Subject: Completeness letter 16-32124

Good afternoon Mr. McKennan,

Please see the attached completeness letter in the matter of the proposed acquisition of two SPECT/CT cameras to replace two SPECT cameras. In responding to the completeness letter, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by March 28, 2017.

Email to OHCA@ct.gov and cc: Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letters, please contact Kaila Riggott at (860) 418-7037.

Please confirm receipt of this email.

Thank You,

Yale NewHaven **Health**

Yale New Haven Hospital

February 22, 2017

VIA EMAIL

Ms. Kimberly Martone
Director of Operations
Office of Health Care Access (OHCA)
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134

Re: Certificate of Need Application: Docket Number: 16-32124-CON
Acquisition of two SPECT/CT cameras to replace two existing SPECT cameras

Dear Ms. Martone:

Please find enclosed the response from Yale New Haven Hospital to the questions issued by the Office of Health Care Access on January 27, 2017, related to the replacement of two SPECT cameras with two SPECT/CT cameras under Docket No. 16-32124-CON.

Thank you for your timely attention to this matter.

Sincerely,

Matt McKennan

Matt McKennan
Assistant Counsel
Yale New Haven Health Services Corporation
Legal & Risk Services Department
789 Howard Avenue (CB230)
New Haven, CT 06510
Matthew.McKennan@YNHH.ORG

Yale New Haven Hospital

Acquisition of Two SPECT/CT Cameras to Replace
Two Existing SPECT Cameras

Docket Number: 16-32124-CON

Response to Completeness Questions

February 22, 2017

Yale-New Haven Hospital
Certificate of Need Application
Docket Number: 16-32124-CON

Acquisition of Two SPECT/CT Cameras to Replace Two Existing SPECT Cameras

Response to Completeness Questions

1. How will Yale-New Haven Hospital dispose of the existing SPECT cameras?

Response:

Yale New Haven Hospital (YNHH) intends to trade-in the existing equipment with the vendor.

2. What specific types of scans will be performed by each camera?

Response:

These cameras are part of the YNHH Heart and Vascular Center and perform myocardial perfusion studies, which are non-invasive imaging tests that shows how well blood flows through the heart muscle. A radioactive tracer is injected into the patient and a nuclear camera (SPECT or SPECT/CT) is then used to capture images of the heart after exercise, rest, or both to show areas of the heart with blocked arteries or injured by heart tissue. The benefits of the SPECT/CT include the attenuation correction offered by the CT component which eliminates shadows or artifacts in the image created by variations in the density of overlying tissues. This results in a higher quality image that can be more confidently interpreted by the patient's cardiologist.

3. Can CT capability be added onto the existing 2014 SPECT camera located at 1450 Chapel Street?

Response:

No, this camera is not designed for an add-on of the CT component.

4. Will there be a gap in services during the cameras' installation period? If yes, how will the patients be served?

Response:

There will be no gap in services. The installation period is approximately one (1) week, and during this time patients will continue to have access to myocardial perfusion testing with the second SPECT camera located on the Saint Raphael Campus, or with any of the other SPECT cameras located on the York Street Campus, and in North Haven and Norwich. Patients will be able to schedule exams at any one of these locations during the one (1) week installation period.

5. Verify the construction cost is the same for both locations and explain why.

Response:

Yes, the construction cost is the same for both locations. This cost is a conservative estimate based on the installation of a new footprint and bed for both machines; no major construction expenses are required for either site beyond these typical costs of installation.

6. Provide a separate Capital Expenditures table for each of the proposed cameras.

Response:

SPECT/CT at the YNHH Saint Raphael Campus:

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	453,931
Land/Building Purchase*	
Construction/Renovation**	10,000
Other (specify)	
Total Capital Expenditure (TCE)	**463,931**
Lease (Medical, Non-medical, Imaging)***	**0**
Total Lease Cost (TLC)	**0**
Total Project Cost (TCE+TLC)	**463,931**

SPECT/CT at the YNHH Guilford Site:

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	453,931
Land/Building Purchase*	
Construction/Renovation**	10,000
Other (specify)	
Total Capital Expenditure (TCE)	**463,931**
Lease (Medical, Non-medical, Imaging)***	**0**
Total Lease Cost (TLC)	**0**
Total Project Cost (TCE+TLC)	**463,931**

7. Explain why there is no utilization reported in Table 9 on page 39 for one of the existing SPECT cameras located at 20 York Street.

Response:

This camera is old and the technology is not the most appropriate for myocardial perfusion studies; therefore, it is rarely used for this type of scan. There is little to no volume reported for this camera because it does not typically perform myocardial perfusion studies, which are the type of exams performed by all of the other cameras in Table 9. This camera is still suitable and used for multiple gated acquisition studies ("MUGA") which are imaging tests that enable a physician to analyze blood pooling in the heart to assess its size and function. It is listed in Table 9 because it may be used once a year to perform a myocardial perfusion study if a patient is not able to lie flat or exceeds the weight limit of the table for the other cameras.

8. Explain why volumes are projected to remain flat as indicated on Table 5, page 30 of the application, given historical volume fluctuation/decline.

Response:

Volumes are conservatively projected flat because YNHH is not aware of any material factors that instruct an increase or decrease in projected volume. YNHH intends to replace existing equipment with better technology to meet current demands.

9. Please reconcile Projected Incremental expenses on Financial Worksheet A with Table 4 on page 34, as the figures for incremental Depreciation and Amortization do not agree.

Response:

TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2017	FY 2018	FY 2019	FY2020
Revenue from Operations	$0	$0	$0	$0
Total Operating Expenses	$0	$66,276	$66,276	$66,276
Gain/(Loss) from Operations	$0	($66,276)	($66,276)	($66,276)

10. Update Tables 4, 6, 7 and Financial Worksheet A to reflect fiscal years, 2018-2020.

Response:

Please see updated Table 4 below, which now includes FY2020.

TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2017	FY 2018	FY 2019	FY2020
Revenue from Operations	$0	$0	$0	$0
Total Operating Expenses	$0	$66,276	$66,276	$66,276
Gain/(Loss) from Operations	$0	($66,276)	($66,276)	($66,276)

Please see updated Table 6 below, which now includes FY2020.

TABLE 6
PROJECTED UTILIZATION BY SERVICE

Scan Volume by Machine	**Projected Volume**			
	FY 2017	**FY 2018**	**FY 2019**	**FY 2020**
GUILFORD (GE MyoSite SPECT) (OLD MACHINE)	887	0	0	0
GUILFORD (GE Optima 640 SPECT/CT) (**NEW**)	0	887	887	887
SRC (Siemens Symbia SPECT) (OLD MACHINE)	231	0	0	0
SRC (GE Optima 640 SPECT/CT) (**NEW**)	0	231	231	231

Please see updated Table 7 below, which now includes FY2020.

<u>GUILFORD SPECT</u>

Payer	FY 2016**		Projected							
			FY 2017		FY 2018		FY 2019		FY 2020	
	Scans	%	Scans	%	Scans	%	Scans	%	Scans	%
Medicare	414	46.7	414	46.7	414	46.7	414	46.7	414	46.7
Medicaid	38	4.3	38	4.3	38	4.3	38	4.3	38	4.3
CHAMPUS & TriCare	1	0.1	1	0.1	1	0.1	1	0.1	1	0.1
[redacted]										
Commercial Insurers	429	48.4	429	48.4	429	48.4	429	48.4	429	48.4
Uninsured/Self Pay	2	0.2	2	0.2	2	0.2	2	0.2	2	0.2
Workers Compensation	3	0.3	3	0.3	3	0.3	3	0.3	3	0.3
[redacted]										
Total Payer Mix	**887**	**100**	**887**	**100**	**887**	**100**	**887**	**100**	**887**	**100**

<u>SRC SPECT</u>

Payer	FY 2016**		Projected							
			FY 2017		FY 2018		FY 2019		FY 2020	
	Scans	%	Scans	%	Scans	%	Scans	%	Scans	%
Medicare	84	36.4	84	36.4	84	36.4	84	36.4	84	36.4
Medicaid	52	22.3	52	22.3	52	22.3	52	22.3	52	22.3
CHAMPUS & TriCare	0	0.1	0	0.1	0	0.1	0	0.1	0	0.1
[redacted]										
Commercial Insurers	93	40.4	93	40.4	93	40.4	93	40.4	93	40.4
Uninsured/Self Pay	2	0.7	2	0.7	2	0.7	2	0.7	2	0.7
Workers Compensation	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
[redacted]										
Total Payer Mix	**231**	**100**	**231**	**100**	**231**	**100**	**231**	**100**	**231**	**100**

Please see updated Financial Worksheet A attached as <u>Exhibit 1</u>.

11. Please update Table 5 on page 35 with year-to-date volume for current fiscal year, 2017.

<u>Response</u>:

Please see updated Table 5 below, which now includes FY2017 (October 2016 – January 2017).

TABLE 5
HISTORICAL UTILIZATION BY SERVICE

Scan Volume by Machine	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY 2014***	FY 2015***	FY 2016***	FY 2017 (Oct. 2016 – Jan. 2017)
GUILFORD (GE MyoSite SPECT)	816	912	887	381
SRC (Siemens Symbia SPECT)	281	233	231	81

226

EXHIBIT 1

Applicant:
Financial Worksheet (A)

NON-PROFIT

Please provide one year of actual results and three years of projections of Total Entity revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

LINE	Total Entity: Description	(1) FY15 Actual Results	(2) FY16 Projected W/out CON	(3) FY16 Projected Incremental	(4) FY16 Projected With CON	(5) FY17 Projected W/out CON	(6) FY17 Projected Incremental	(7) FY17 Projected With CON	(8) FY18 Projected W/out CON	(9) FY18 Projected Incremental	(10) FY18 Projected With CON	(11) FY19 Projected W/out CON	(12) FY19 Projected Incremental	(13) FY19 Projected With CON
A.	OPERATING REVENUE													
1	Total Gross Patient Revenue	$8,750,595,600	$11,094,372,000		$11,094,372,000	$11,204,464,000		$11,204,464,000	$11,355,046,000		$11,355,046,000	$11,510,146,000		$11,510,146,000
2	Less: Allowances	$6,209,732,400	$8,426,193,000		$8,426,193,000	$8,457,665,000		$8,457,665,000	$8,533,977,000		$8,533,977,000	$8,636,692,000		$8,636,692,000
3	Less: Charity Care				$0			$0			$0			$0
4	Less: Other Deductions				$0			$0			$0			$0
	Net Patient Service Revenue	$2,540,863,200	$2,668,179,000	$0	$2,668,179,000	$2,746,799,000	$0	$2,746,799,000	$2,821,069,000	$0	$2,821,069,000	$2,873,454,000	$0	$2,873,454,000
5	Medicare	$808,011,500	$848,498,776		$848,498,776	$873,500,462		$873,500,462	$897,118,819		$897,118,819	$913,777,600		$913,777,600
6	Medicaid	$308,108,200	$323,546,671		$323,546,671	$333,080,229		$333,080,229	$342,086,300		$342,086,300	$348,438,570		$348,438,570
7	CHAMPUS & TriCare				$0			$0			$0			$0
8	Other				$0			$0			$0			$0
	Total Government	$1,116,119,700	$1,172,045,447	$0	$1,172,045,447	$1,206,580,691	$0	$1,206,580,691	$1,239,205,120	$0	$1,239,205,120	$1,262,216,170	$0	$1,262,216,170
9	Commercial Insurers	$1,381,820,400	$1,451,059,692		$1,451,059,692	$1,493,816,311		$1,493,816,311	$1,534,207,231		$1,534,207,231	$1,562,696,235		$1,562,696,235
10	Uninsured				$0			$0			$0			$0
11	Self Pay	$42,923,100	$45,073,861		$45,073,861	$46,401,998		$46,401,998	$47,656,649		$47,656,649	$48,541,595		$48,541,595
12	Workers Compensation				$0			$0			$0			$0
13	Other				$0			$0			$0			$0
	Total Non-Government	$1,424,743,500	$1,496,133,553	$0	$1,496,133,553	$1,540,218,309	$0	$1,540,218,309	$1,581,863,880	$0	$1,581,863,880	$1,611,237,830	$0	$1,611,237,830
	Net Patient Service Revenue[a] (Government+Non-Government)	$2,540,863,200	$2,668,179,000	$0	$2,668,179,000	$2,746,799,000	$0	$2,746,799,000	$2,821,069,000	$0	$2,821,069,000	$2,873,454,000	$0	$2,873,454,000
14	Less: Provision for Bad Debts	$50,382,400	$73,453,000		$73,453,000	$74,179,000		$74,179,000	$75,170,000		$75,170,000	$76,191,000		$76,191,000
	Net Patient Service Revenue less provision for bad debts	$2,490,480,800	$2,594,726,000	$0	$2,594,726,000	$2,672,620,000	$0	$2,672,620,000	$2,745,899,000	$0	$2,745,899,000	$2,797,263,000	$0	$2,797,263,000
15	Other Operating Revenue	$64,676,500	$48,830,000		$48,830,000	$90,820,000		$90,820,000	$69,586,000		$69,586,000	$68,756,000		$68,756,000
17	Net Assets Released from Restrictions				$0			$0			$0			$0
	TOTAL OPERATING REVENUE	$2,555,157,300	$2,643,556,000	$0	$2,643,556,000	$2,763,440,000	$0	$2,763,440,000	$2,815,465,000	$0	$2,815,465,000	$2,866,019,000	$0	$2,866,019,000
B.	OPERATING EXPENSES													
1	Salaries and Wages	$831,202,100	$849,809,000		$849,809,000	$901,545,000		$901,545,000	$912,077,885		$912,077,885	$923,136,000		$923,136,000
2	Fringe Benefits	$239,423,700	$236,848,000		$236,848,000	$245,428,000		$245,428,000	$254,871,647		$254,871,647	$257,547,251		$257,547,251
3	Physicians Fees	$827,545,400	$875,960,000		$875,960,000	$695,737,000		$695,737,000	$702,563,484		$702,563,484	$709,763,691		$709,763,691
4	Supplies and Drugs	$490,320,700	$490,503,000		$490,503,000	$538,096,000		$538,096,000	$548,435,760		$548,435,760	$559,319,448		$559,319,448
5	Depreciation and Amortization	$93,281,200	$120,165,000		$120,165,000	$120,976,000		$120,976,000	$129,516,722	$66,276	$129,582,998	$136,180,830	$66,276	$136,247,106
6	Provision for Bad Debts-Other[b]				$0			$0			$0			$0
7	Interest Expense	$20,879,700	$22,196,000		$22,196,000	$22,640,000		$22,640,000	$22,643,824		$22,643,824	$27,642,154		$27,642,154
8	Malpractice Insurance Cost	$23,857,600	$23,752,052		$23,752,052	$24,161,825		$24,161,825	$24,949,383		$24,949,383	$25,850,721		$25,850,721
9	Lease Expense	$23,519,600	$23,415,547		$23,415,547	$23,839,231		$23,839,231	$24,595,915		$24,595,915	$25,484,484		$25,484,484
10	Other Operating Expenses	$93,012,900	$92,601,402		$92,601,402	$94,276,944		$94,276,944	$97,269,400		$97,269,400	$100,783,421		$100,783,421
	[illegible]	$2,443,042,900	$2,536,050,000	$0	$2,536,050,000	$2,666,720,000	$0	$2,666,720,000	$2,716,924,000	$66,276	$2,716,990,276	$2,765,708,000	$66,276	$2,765,774,276
	[illegible]	$112,114,400	$108,506,000	$0	$108,506,000	$96,720,000	$0	$96,720,000	$98,541,000	($66,276)	$98,474,724	$100,311,000	($66,276)	$100,244,724
	NON-OPERATING REVENUE	($6,297,800)	$34,200,000		$34,200,000	$34,200,000		$34,200,000	$34,200,000		$34,200,000	$34,200,000		$34,200,000
	[illegible]	$105,816,600	$142,706,000	$0	$142,706,000	$130,920,000	$0	$130,920,000	$132,741,000	($66,276)	$132,674,724	$134,511,000	($66,276)	$134,444,724
	Principal Payments				$0			$0			$0			$0
C.	PROFITABILITY SUMMARY													
1	Hospital Operating Margin	4.4%	4.1%	0.0%	4.1%	3.5%	0.0%	3.5%	3.5%	0.0%	3.5%	3.6%	0.0%	3.5%
2	Hospital Non Operating Margin	-0.2%	1.3%	0.0%	1.3%	1.2%	0.0%	1.2%	1.2%	0.0%	1.2%	1.2%	0.0%	1.2%
3	Hospital Total Margin	4.2%	5.3%	0.0%	5.3%	4.7%	0.0%	4.7%	4.7%	0.0%	4.7%	4.6%	0.0%	4.6%
D.	FTEs	10,432	11,235		11,235	11,323		11,323	11,345		11,345	11,367		11,367
E.	VOLUME STATISTICS[c]													
1	Inpatient Discharges	78,444	79,073		79,073	79,677		79,677	79,677		79,677	79,677		79,677
2	Outpatient Visits	1,282,539	1,331,024		1,331,024	1,347,933		1,347,933	1,388,371		1,388,371	1,430,022		1,430,022
	[illegible]	1,360,983	1,410,097	0	1,410,097	1,427,610	0	1,427,610	1,468,048	0	1,468,048	1,509,699	0	1,509,699

[a]Total amount should equal the total amount on cell line "Net Patient Revenue" Row 14.
[b]Provide the amount of any transaction associated with Bad Debts not related to the provision of direct services to patients. For additional information, refer to FASB, No.2011-07, July 2011.
[c]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.

227

NON-PROFIT

Applicant:

Financial Worksheet (A)

Please provide one year of actual results and three years of projections of **Total Entity** revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

LINE	Total Entity: Description	(1) FY15 Actual Results	(2) FY16 Projected W/out CON	(3) FY16 Projected Incremental	(4) FY16 Projected With CON	(5) FY17 Projected W/out CON	(6) FY17 Projected Incremental	(7) FY17 Projected With CON	(8) FY18 Projected W/out CON	(9) FY18 Projected Incremental	(10) FY18 Projected With CON	(11) FY19 Projected W/out CON	(12) FY19 Projected Incremental	(13) FY19 Projected With CON
A.	**OPERATING REVENUE**													
1	Total Gross Patient Revenue	$8,750,595,600	$11,094,372,000		$11,094,372,000	$11,204,464,000		$11,204,464,000	$11,355,046,000		$11,355,046,000	$11,510,146,000		$11,510,146,000
2	Less: Allowances	$6,209,732,400	$8,426,193,000		$8,426,193,000	$8,457,665,000		$8,457,665,000	$8,533,977,000		$8,533,977,000	$8,636,692,000		$8,636,692,000
3	Less: Charity Care				$0			$0			$0			$0
4	Less: Other Deductions				$0			$0			$0			$0
	Net Patient Service Revenue	$2,540,863,200	$2,668,179,000	$0	$2,668,179,000	$2,746,799,000	$0	$2,746,799,000	$2,821,069,000	$0	$2,821,069,000	$2,873,454,000	$0	$2,873,454,000
5	Medicare	$808,011,500	$848,498,776		$848,498,776	$873,500,462		$873,500,462	$897,118,819		$897,118,819	$913,777,600		$913,777,600
6	Medicaid	$308,108,200	$323,546,671		$323,546,671	$333,080,229		$333,080,229	$342,086,300		$342,086,300	$348,438,570		$348,438,570
7	CHAMPUS & TriCare				$0			$0			$0			$0
8	Other				$0			$0			$0			$0
	Total Government	$1,116,119,700	$1,172,045,447	$0	$1,172,045,447	$1,206,580,691	$0	$1,206,580,691	$1,239,205,120	$0	$1,239,205,120	$1,262,216,170	$0	$1,262,216,170
9	Commercial Insurers	$1,381,820,400	$1,451,059,692		$1,451,059,692	$1,493,816,311		$1,493,816,311	$1,534,207,231		$1,534,207,231	$1,562,696,235		$1,562,696,235
10	Uninsured				$0			$0			$0			$0
11	Self Pay	$42,923,100	$45,073,861		$45,073,861	$46,401,998		$46,401,998	$47,656,649		$47,656,649	$48,541,595		$48,541,595
12	Workers Compensation				$0			$0			$0			$0
13	Other				$0			$0			$0			$0
	Total Non-Government	$1,424,743,500	$1,496,133,553	$0	$1,496,133,553	$1,540,218,309	$0	$1,540,218,309	$1,581,863,880	$0	$1,581,863,880	$1,611,237,830	$0	$1,611,237,830
	Net Patient Service Revenue[a] (Government+Non-Government)	$2,540,863,200	$2,668,179,000	$0	$2,668,179,000	$2,746,799,000	$0	$2,746,799,000	$2,821,069,000	$0	$2,821,069,000	$2,873,454,000	$0	$2,873,454,000
14	Less: Provision for Bad Debts	$50,382,400	$73,453,000		$73,453,000	$74,179,000		$74,179,000	$75,170,000		$75,170,000	$76,191,000		$76,191,000
	Net Patient Service Revenue less provision for bad debts	$2,490,480,800	$2,594,726,000	$0	$2,594,726,000	$2,672,620,000	$0	$2,672,620,000	$2,745,899,000	$0	$2,745,899,000	$2,797,263,000	$0	$2,797,263,000
15	Other Operating Revenue	$64,676,500	$48,830,000		$48,830,000	$90,820,000		$90,820,000	$69,566,000		$69,566,000	$68,756,000		$68,756,000
17	Net Assets Released from Restrictions				$0			$0			$0			$0
	TOTAL OPERATING REVENUE	$2,555,157,300	$2,643,556,000	$0	$2,643,556,000	$2,763,440,000	$0	$2,763,440,000	$2,815,465,000	$0	$2,815,465,000	$2,866,019,000	$0	$2,866,019,000
B.	**OPERATING EXPENSES**													
1	Salaries and Wages	$831,202,100	$849,809,000		$849,809,000	$901,545,000		$901,545,000	$912,077,885		$912,077,885	$923,136,000		$923,136,000
2	Fringe Benefits	$239,423,700	$236,648,000		$236,648,000	$245,428,000		$245,428,000	$254,871,647		$254,871,647	$257,547,251		$257,547,251
3	Physicians Fees	$627,545,400	$675,960,000		$675,960,000	$695,737,000		$695,737,000	$702,563,464		$702,563,464	$709,763,691		$709,763,691
4	Supplies and Drugs	$490,320,700	$490,503,000		$490,503,000	$538,096,000		$538,096,000	$548,435,760		$548,435,760	$559,319,448		$559,319,448
5	Depreciation and Amortization	$93,281,200	$120,165,000		$120,165,000	$120,976,000		$120,976,000	$129,516,722	$66,276	$129,582,998	$136,180,830	$66,276	$136,247,106
6	Provision for Bad Debts-Other[b]				$0			$0			$0			$0
7	Interest Expense	$20,879,700	$22,196,000		$22,196,000	$22,640,000		$22,640,000	$22,643,824		$22,643,824	$27,642,154		$27,642,154
8	Malpractice Insurance Cost	$23,857,600	$23,752,052		$23,752,052	$24,181,825		$24,181,825	$24,949,383		$24,949,383	$25,850,721		$25,850,721
9	Lease Expense	$23,519,600	$23,415,547		$23,415,547	$23,839,231		$23,839,231	$24,595,915		$24,595,915	$25,484,484		$25,484,484
10	Other Operating Expenses	$93,012,900	$92,601,402		$92,601,402	$94,276,944		$94,276,944	$97,269,400		$97,269,400	$100,783,421		$100,783,421
	TOTAL OPERATING EXPENSES	$2,443,042,900	$2,535,050,000	$0	$2,535,050,000	$2,666,720,000	$0	$2,666,720,000	$2,716,924,000	$66,276	$2,716,990,276	$2,765,708,000	$66,276	$2,765,774,276
	INCOME/(LOSS) FROM OPERATIONS	$112,114,400	$108,506,000	$0	$108,506,000	$96,720,000	$0	$96,720,000	$98,541,000	($66,276)	$98,474,724	$100,311,000	($66,276)	$100,244,724
	NON-OPERATING REVENUE	($6,297,800)	$34,200,000		$34,200,000	$34,200,000		$34,200,000	$34,200,000		$34,200,000	$34,200,000		$34,200,000
	EXCESS/(DEFICIENCY) OF REVENUE OVER EXPENSES	$105,816,600	$142,706,000	$0	$142,706,000	$130,920,000	$0	$130,920,000	$132,741,000	($66,276)	$132,674,724	$134,511,000	($66,276)	$134,444,724
	Principal Payments				$0			$0			$0			$0
C.	**PROFITABILITY SUMMARY**													
1	Hospital Operating Margin	4.4%	4.1%	0.0%	4.1%	3.5%	0.0%	3.5%	3.5%	0.0%	3.5%	3.5%	0.0%	3.5%
2	Hospital Non Operating Margin	-0.2%	1.3%	0.0%	1.3%	1.2%	0.0%	1.2%	1.2%	0.0%	1.2%	1.2%	0.0%	1.2%
3	Hospital Total Margin	4.2%	5.3%	0.0%	5.3%	4.7%	0.0%	4.7%	4.7%	0.0%	4.7%	4.6%	0.0%	4.6%
D.	**FTEs**	10,432	11,235		11,235	11,323		11,323	11,345		11,345	11,367		11,367
E.	**VOLUME STATISTICS[c]**													
1	Inpatient Discharges	78,444	79,073		79,073	79,677		79,677	79,677		79,677	79,677		79,677
2	Outpatient Visits	1,282,539	1,331,024		1,331,024	1,347,933		1,347,933	1,388,371		1,388,371	1,430,022		1,430,022
	TOTAL VOLUME	1,360,983	1,410,097	0	1,410,097	1,427,610	0	1,427,610	1,468,048	0	1,468,048	1,509,699	0	1,509,699

[a] Total amount should equal the total amount on cell line "Net Patient Revenue" Row 14.

[b] Provide the amount of any transaction associated with Bad Debts not related to the provision of direct services to patients. For additional information, refer to FASB, No.2011-07, July 2011.

[c] 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.

User, OHCA

From: Fernandes, David
Sent: Monday, March 20, 2017 8:04 AM
To: matthew.mckkennan@ynhh.org
Cc: User, OHCA; Veyberman, Alla; Riggott, Kaila
Subject: CON-32124 Deemed Complete
Attachments: 16-32124-CON Notification of Application Deemed Complete.pdf

Good Morning Mr. McKennan:
Please see the attached letter deeming complete the above reference application. Please confirm receipt of this correspondence as soon as possible.

If you have any questions, do not hesitate to contact me or Alla Veyberman at alla.veyberman@ct.gov.

Thanks,

David Fernandes
Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032|F: (860) 418-7053|E: David.Fernandes@ct.gov

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Office of Health Care Access

March 20, 2017

Via Email Only

Mr. Matthew McKennan
Assistant Counsel
Yale New-Haven Hospital
Legal & Risk Services Department
789 Howard Avenue
New Haven, CT 06510
Matthew.McKennan@YNHH.ORG

RE: Certificate of Need Application: Docket Number: 16-32124-CON
Acquisition of Two SPECT/CT cameras to replace two existing SPECT cameras with a total associated cost of $ 927,862.

Dear Mr. McKennan:

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 March 17, 2017.

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

Sincerely,

A. Veyberman

Alla Veyberman
Health Care Analyst

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Certificate of Need
Final Decision

Applicant: **Yale-New Haven Hospital**

Docket Number: **16-32124-CON**

Project Title: **Acquisition of Two Single Photon Emission Computed Tomography-Computed Tomography Cameras**

Project Description: Yale-New Haven Hospital ("Hospital" or "Applicant") is seeking approval for the acquisition of two Single Photon Emission Computed Tomography-Computed Tomography ("SPECT-CT") cameras to replace two existing SPECT cameras.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in The New Haven Register on November 21, 22 and 23, 2016. On December 29, 2016, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project and deemed the application complete on March 17, 2017. OHCA received no responses from the public concerning the proposal and no hearing requests were received from the public per Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(e). In rendering the decision, Deputy Commissioner Addo considered the entire record in this matter.

Findings of Fact and Conclusions of Law

1. The Hospital is a 1,541[1] bed not-for-profit acute care teaching hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, pp. 19, 51.

2. As shown in the table below, the Hospital currently operates 10 SPECT cameras and one SPECT-CT camera.

TABLE 1
EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Service	Days/Hours of Operation	Utilization (FY16)
YNHH HVC, 111 Goose Lane, Guilford, CT	SPECT	M-F, 7am-5pm	887
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	231
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	491
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	492
YNHH HVC, 2 Divine Street, North Haven, CT	SPECT	M-F, 7am-5pm	915
YNHH HVC, 79 Wawecus Street, Norwich, CT	SPECT	M-F, 7am-5pm	776
YNHH HVC, 20 York Street, New Haven, CT	SPECT-CT	M-F, 8am-5pm	660
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	484
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	193
YNHH HVC, 20 York Street, New Haven, CT*	SPECT	M-F, 8am-5pm	0
YNHH ED, 20 York Street, New Haven, CT	SPECT	M-F, 8am-8pm	984

Exhibit A, p. 43.
* This camera is used mostly for multiple gated acquisition studies and does not perform myocardial perfusion studies. However it may be used once a year to perform a myocardial perfusion study if a patient is not able to lie flat or exceeds the weight limit of the table for the other cameras.

3. The GE MyoSite SPECT camera at 111 Goose Lane in Guilford was purchased in 2005 and is at the end of its useful life. The Siemens Symbia SPECT camera at 1450 Chapel Street (St. Raphael Campus) was purchased in 2014 and is not able to produce superior images like a SPECT-CT. The Applicant proposes replacing these two cameras with 4-slice GE Optima 640 SPECT-CT cameras. Exhibit A, pp. 18-19.

4. Under Report Number 16-32124-DTR, OHCA determined that the Hospital was required to file a CON application for the acquisition of the above-mentioned SPECT-CT cameras. OHCA CON Determination, Report Number 16-32124-DTR.

[1] Includes 134 bassinets

5. The Determination Request noted five SPECT cameras in line for replacement, but due to the need to allocate capital resources efficiently, the hospital will replace only two SPECT cameras with SPECT-CT cameras at this time. Exhibit A, p. 19

6. The new SPECT-CT cameras will be replacing one existing camera in Guilford and one of the three cameras operating at 1450 Chapel Street in New Haven. Exhibit A, pp. 19-20.

7. YNHH Heart and Vascular Center (HVC) treats heart and vascular patients and offers various cardiac imaging technology, including echocardiography, ultrasound, molecular nuclear medicine imaging, cardiac magnetic resonance imaging, positron emission topography, and computed tomography to evaluate a variety of cardiac issues such as chest pain, congestive heart failure and valve disease. Exhibit A, pp. 19-20

8. These cameras will be used to perform myocardial perfusion studies, non-invasive imaging tests showing how well blood flows through the heart muscle. A radioactive tracer is injected into a patient and a nuclear camera is used to capture images of the heart after exercise, rest, or both to show areas with either blocked arteries or injury in the heart tissue. Exhibit C, p. 220

9. There are certain limitations to this type of scan due, in part, to variation in density of various tissues within the body. Overlying breast tissue and/or adipose tissue can create shadows or artifacts especially in obese patients, which cloud the image and may result in an erroneous appearance of coronary defects. Exhibit A, p. 20

10. The SPECT-CT camera has a CT component that adds clarity to the scan via attenuation correction, which removes shadows and artifacts that frequently can appear on images as coronary defects. Exhibit A, pp. 20, 26.

11. Use of the CT component provides a higher quality of scan, improves lesion detection, eliminates the need for unnecessary follow-up testing and decreases the risk of false positives. Exhibit A, pp. 20, 26.

12. The proposed cameras will provide superior image quality within a shorter image acquisition time and less radiation exposure to patients. Exhibit A, p. 17.

13. Studies have shown the benefits of a SPECT-CT over a SPECT camera in the evaluation of coronary artery disease. Incorporation of attenuation correction in addition to ECG gating[2] with SPECT myocardial perfusion images will improve image quality, interpretive certainty and diagnostic accuracy. These combined results are anticipated to have a substantial impact on improving the effectiveness of care and lowering health care costs. *American Society of Nuclear Cardiology and Society of Nuclear Medicine Joint Position Statement: Attenuation Correction of Myocardial Perfusion SPECT Scintigraphy*. Exhibit A, pp. 22, 80-87.

[2] Gating techniques are used to improve temporal resolution and minimize imaging artifacts caused by cardiac motion.

14. Based on actual historical utilization, the Hospital has projected stable utilization volume.

TABLE 2
HISTORICAL AND PROJECTED UTILIZATION SPECT-CT CAMERAS

	Historical			Projected			
Location	**FY2014**	**FY2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**	**FY2020**
Guilford	816	912	887	887	887	887	887
New Haven	281	233	231	231	231	231	231

Exhibit A, pp. 30, 35, Exhibit C, p. 223

15. The new SPECT-CT will serve the same patient population as the existing camera including Medicaid and indigent persons. Exhibit A, pp. 20, 26-27, 30.

16. No change in the payer mix is projected by the Hospital.

TABLE 3
THE HOSPITAL'S CURRENT & PROJECTED PAYER MIX

Payer	**FY 2016**		**Projected**							
			FY 2017		**FY 2018**		**FY2019**		**FY 2020**	
	Scans	**%**	**Scans**	**%**	**Scans**	**%**	**Scans**	**%**	**Scans**	**%**
Medicare*	414	46.7	414	46.7	414	46.7	414	46.7	414	46.7
Medicaid*	38	4.3	38	4.3	38	4.3	38	4.3	38	4.3
CHAMPUS & TriCare	1	0.1	1	0.1	1	0.1	1	0.1	1	0.1
Total Government	**453**	**51.1**	**453**	**51.1**	**453**	**51.1**	**453**	**51.1**	**453**	**51.1**
Commercial Insurers	429	48.4	429	48.4	429	48.4	429	48.4	429	48.4
Uninsured/Self Pay	2	0.2	2	0.2	2	0.2	2	0.2	2	0.2
Workers Compensation	3	0.3	3	0.3	3	0.3	3	0.3	3	0.3
Total Non-Government	**434**	**48.9**	**434**	**48.9**	**434**	**48.9**	**434**	**48.9**	**434**	**48.9**
Total Payer Mix	**887**	**100**	**887**	**100**	**887**	**100**	**887**	**100**	**887**	**100**

Exhibit A, p. 36, Exhibit B, p. 224.

17. There will be no gap in services during the cameras' installation period. Installation will take one week and during that time patients will continue to have access to myocardial perfusion testing with other SPECT cameras located in New Haven, North Haven and Norwich. Exhibit C, p. 220-221

18. The construction cost is the same for both locations. This cost is based on the installation of a new footprint and bed for both machines. No major construction expenses are required for either site. The proposal's total capital expenditure is itemized as follows:

TABLE 4
TOTAL CAPITAL EXPENDITURE – GUILFORD LOCATION

Imaging Equipment (SPECT-CT Scanner)	$453,931
Construction/Renovation	$10,000
Total Capital Expenditure	**$463,931**

Exhibit A, p. 34, Exhibit C, p.221

TABLE 5
TOTAL CAPITAL EXPENDITURE – NEW HAVEN LOCATION

Imaging Equipment (SPECT-CT Scanner)	$453,931
Construction/Renovation	$10,000
Total Capital Expenditure	**$463,931**

Exhibit A, p. 34, Exhibit C, p. 221

19. This proposal will be funded through available capital.
Exhibit A, p. 28.

20. Diagnostic imaging performed on the replacement SPECT-CT cameras will have the same cost to the patient as imaging on the older equipment. Exhibit A, p. 25.

21. Incremental losses are projected in each of the next three fiscal years (FY) due to depreciation expense.

TABLE 6
YALE NEW HAVEN HOSPITAL'S PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2018	FY 2019	FY 2020
Revenue from Operations	-	-	-
Total Operating Expenses*	$66,276	$66,276	$66,276
Gain/(Loss) from Operations	($66,276)	($66,276)	($66,276)

*Operating expenses represent the change in depreciation amount, which is a non-cash expense.
Exhibit A, pp. 29, 200. Exhibit B, pp. 227

22. Despite incremental losses, the Hospital projects overall operational gains from FY2018 through FY2020 following implementation of the proposal.

TABLE 7
YALE NEW HAVEN HOSPITAL'S PROJECTED REVENUES & EXPENDITURES WITH CON

	FY 2018	FY 2019	FY 2020
Revenue from Operations	$2,815,465	$2,866,019	$2,922,450
Total Operating Expenses	$2,715,990	$2,765,774	$2,820,230
Gain/(Loss) from Operations	**$99,475**	**$100,245**	**$102,219**

Note: figures are in thousands.
Exhibit A, pp. 29, 200.

23. 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)).

24. The proposal is consistent with the Statewide Health Care Facilities and Service Plan. (Conn. Gen. Stat. § 19a-639(a)(2)).

25. The Applicant has established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3)).

26. The Applicant has demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).

27. The Applicant has satisfactorily demonstrated that the proposal will improve quality, and maintain accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat.§ 19a-639(a)(5)).

28. The Applicant has shown that there would be no change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6)).

29. The Applicant has satisfactorily identified the population affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7)).

30. The Applicant's historical provision of services in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)).

31. 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)).

32. The Applicant has demonstrated that there will be no reduction in access to services by Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)).

33. The Applicant has demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the region. (Conn. Gen. Stat. § 19a-639(a)(11)).

34. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or access 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).*

Yale-New Haven Hospital, a 1,541 bed not-for-profit acute care teaching hospital in New Haven, is seeking authorization to replace two of its ten existing SPECT cameras with SPECT-CT cameras. The new SPECT-CT cameras, which will be located in Guilford and New Haven, will be used to evaluate and diagnose a variety of cardiac and vascular issues such as chest pain, congestive heart failure and valve disease. The quality of scans produced by SPECT-CT cameras is significantly superior to the SPECT camera as its CT component delivers attenuation correction for myocardial perfusion imaging studies, improving diagnostic accuracy. The SPECT-CT provides better image quality in less time with a lower chance of false positive results, reducing the need for follow-up testing and additional radiation exposure. *FF1-13*

As both SPECT-CT cameras will be replacing existing equipment, the Applicant will be serving the same patient population, including Medicaid and indigent patients, and no change to the payer mix is projected. Access to care will be maintained and the proposal will not affect the cost to patients. All these benefits are consistent with the Statewide Health Care Facilities and Services Plan. *FF15, 16.*

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application requesting authorization to acquire two SPECT-CT cameras at the Yale-New Haven Hospital, Connecticut, 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

6/7/2017
Date

Yvonne T. Addo, MBA
Deputy Commissioner

Olejarz, Barbara

From: Olejarz, Barbara
Sent: Wednesday, June 07, 2017 12:34 PM
To: 'Matthew.McKennan@YNHH.ORG'
Subject: Final Decision
Attachments: Certificate of Need Final Decision 16_32124.pdf

Tracking:

Recipient	Delivery	Read
'Matthew.McKennan@YNHH.ORG'		
OHCA-DL All OHCA Users		
Foreman, Rebecca	Delivered: 6/7/2017 12:35 PM	
Jensen, Dana	Delivered: 6/7/2017 12:35 PM	
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Bruno, Anthony M.	Delivered: 6/7/2017 12:35 PM	
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Shauna.Walker@ct.gov	Delivered: 6/7/2017 12:35 PM	
Chalikonda, Srinivasa		Read: 6/7/2017 12:35 PM

Recipient	Delivery	Read
Roberts, Karen		Read: 6/7/2017 12:36 PM

6/7/17

Please see attached Final Decision for Yale New Haven Hospital Acquisition of Two Single Photon Emission Computed
Tomography-Computed Tomography Cameras

Thank you

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov

Olejarz, Barbara

From: Microsoft Outlook
To: Matthew.McKennan@YNHH.ORG
Sent: Wednesday, June 07, 2017 12:35 PM
Subject: Relayed: Final Decision

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Matthew.McKennan@YNHH.ORG (Matthew.McKennan@YNHH.ORG)

Subject: Final Decision

From: Mckennan, Matthew <Matthew.McKennan@YNHH.ORG>
Sent: Wednesday, June 07, 2017 12:44 PM
To: Olejarz, Barbara
Subject: RE: Final Decision

Thank you Barbara. Good news!

Have a nice week.

Matt

Matt McKennan
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Legal & Risk Services Department
Yale New Haven Health System
Office: 203-688-7361
Cell: 203-907-9858
matthew.mckennan@ynhh.org

From: Olejarz, Barbara [mailto:Barbara.Olejarz@ct.gov]
Sent: Wednesday, June 07, 2017 12:35 PM
To: Mckennan, Matthew <Matthew.McKennan@YNHH.ORG>
Subject: Final Decision

6/7/17

Please see attached Final Decision for Yale New Haven Hospital Acquisition of Two Single Photon Emission Computed
Tomography-Computed Tomography Cameras

Thank you

Barbara K. Olejarz
Administrative Assistant to Kimberly Martone
Office of Health Care Access
Department of Public Health
Phone: (860) 418-7005
Email: Barbara.Olejarz@ct.gov