



February 17, 2017

William Agostinucci
Director Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
Phone: 860-837-5752
Fax: 860-545-9793
wagosti@connecticutchildrens.org

VIA HAND DELIVERY:

Kimberly R. Martone
Director of Operations
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13 HCA
Hartford, CT 06134-0308

Re: **Connecticut Children's Medical Center CoN Application**

Dear Ms. Martone:

Please find a Certificate of Need application for the acquisition of a 3T MRI scanner at Connecticut Children's Medical Center included in the provided documents.

Original documents are included in the binder as well as a USB flash drive containing a scanned copy of the main form application and the supplemental document required. The documents are also saved in Word and Excel formats as requested.

Finally, a check for \$500.00 is included as the filing fee.

Please contact me at 860-837-5752 if there are any questions.

Sincerely,

William Agostinucci



Payee ID: 204913-124

Payee Name: TREASURER STATE OF CONNECTICUT

03119406

REQUEST DATE	REQUEST NUMBER	GROSS	DISCOUNT	WITHHOLDING	NET
2/17/2017	CON-APPLICATION 1-05	500.00	0.00		500.00
			TOTAL	*****500.00	

Memo:

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Connecticut Children's Medical Center
Attn: Accounting/Finance Dept
282 Washington Street
Hartford, CT 06106

BANK OF AMERICA
Hartford, CT 06115

51-57
119

No. 03119406

Date: 2/21/2017

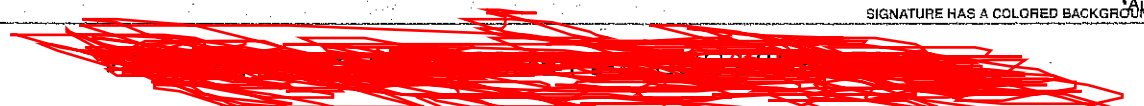
Pay Five Hundred And 00/100 US Dollars

AMOUNT OF CHECK
\$*****500.00

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TREASURER STATE OF CONNECTICUT
PO BOX 1080
HARTFORD, CT 06143-1080

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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.:

OHCA Verified by:

CWD

Check No.:

03119406

Date:

2/21/17

Checklist

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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.
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For OHCA Use Only:

Docket No.: _____ Check No.: _____
OHCA Verified by: _____ Date: _____

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
<input type="checkbox"/>	(1)	Establishment of a new health care facility (mental health and/or substance abuse) - see note below*
<input type="checkbox"/>	(2)	Transfer of ownership of a health care facility (excludes transfer of ownership/sale of hospital – see “Other” below)
<input type="checkbox"/>	(3)	Transfer of ownership of a group practice
<input type="checkbox"/>	(4)	Establishment of a freestanding emergency department
<input type="checkbox"/>	(5) (7) (8) (15)	Termination of a service: <ul style="list-style-type: none"> - 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
<input type="checkbox"/>	(6)	Establishment of an outpatient surgical facility
<input type="checkbox"/>	(9)	Establishment of cardiac services
<input checked="" type="checkbox"/>	(10) (11)	Acquisition of equipment: <ul style="list-style-type: none"> - 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
<input type="checkbox"/>	(12)	Increase in licensed bed capacity of a health care facility
<input type="checkbox"/>	(13)	Acquisition of equipment utilizing [new] technology that has not previously been used in the state
<input type="checkbox"/>	(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
<input type="checkbox"/>	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	Connecticut Children's Medical Center is applying for a Certificate of need to add a 3T MRI scanner.
Proposal Address	282 Washington Street, Hartford, CT 06106
Capital Expenditure	\$ 3,960,846.00
Is this Application the result of a Determination indicating a CON application must be filed? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, Docket Number: Click here to enter text.	

Applicant(s) Information

	Applicant One	Applicant Two* (if applicable)
Applicant Name & Address	Connecticut Children's Medical Center 282 Washington Street Hartford, CT 06106	
Parent Corporation Name & Address (if applicable)		
Contact Person Name	William Agostinucci	
Title	Senior Director, Clinical Support	
Email Address	wagosti@connecticutchildrens.org	
Phone	860-837-5752	
Fax Number	860-545-9793	
Tax Status (check one box)	<input type="checkbox"/> For Profit <input checked="" type="checkbox"/> Not-for-Profit	<input type="checkbox"/> For Profit <input type="checkbox"/> 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:	



Payee ID: 204913-109

Payee Name: STATE OF CONNECTICUT

Copy

03118248

REQUEST DATE	REQUEST NUMBER	GROSS	DISCOUNT	WITHHOLDING	NET
1/5/2017	CON APPLICATION	500.00	0.00		500.00
Memo:			TOTAL	*****500.00	

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Connecticut Children's
Medical Center
Attn: Accounting/Finance Dept
282 Washington Street
Hartford, CT 06106

BANK OF AMERICA
Hartford, CT 06115

51-57
119

No. 03118248

Date: 1/11/2017

Pay Five Hundred And 00/100 US Dollars

AMOUNT OF CHECK
\$*****500.00

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STATE OF CONNECTICUT
DEPT OF PUBLIC HEALTH
PO BOX1080
HARTFORD, CT 06143-1080

Patricia [Signature]

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Affidavit

Applicant: Connecticut Children's Medical Center

Project Title: Acquisition of a 3T MRI Scanner

I, James E. Shmerling , President & CEO
(Name) (Position – CEO or CFO)

of Connecticut Children's Medical Center being duly sworn, depose and state that the (Connecticut Children's Medical Center) 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.

James E. Shmerling
Signature

2/14/2017
Date

Subscribed and sworn to before me on Feb 14, 2017

[Signature]

Notary Public/Commissioner of Superior Court

My commission expires: _____

REBECCA J. PHILLIPS
NOTARY PUBLIC
State of Connecticut
My Commission Expires
October 31, 2021



The Hartford Courant.

A TRIBUNE PUBLISHING COMPANY

Affidavit of Publication

State of Connecticut

Thursday, December 28, 2016

County of Hartford

I, Janet Tarasuk, do solemnly swear that I am Sales Assistant of the Hartford Courant, printed and published daily, in the state of Connecticut and that from my own personal knowledge and reference to the files of said publication the advertisement of Public Notice was inserted in the regular edition.

On the following dates: 12/23/2016, 12/24/2016, 12/25/2016

In the amount of \$600.00

CT Children's: CU00577725

Full Run

Janet Tarasuk

Sales Assistant
Janet Tarasuk

Subscribed and sworn to before me December 28, 2016

Renee Janes

Notary Public

RENEE N. JANES 4673556
NOTARY PUBLIC
MY COMMISSION EXPIRES MAR. 31, 2018

Shopping

Continued from Page D1
 Walmart, Kohl's, JCPenney, Macy's, Stop & Shop and Big Y stores are all open until 6 p.m. Ocean State Job Lot stores will close at 7 p.m., and Whole Foods will be open until 8 p.m. Target and Kmart stores will be open until 10 p.m. (a few Targets will be open until 11 p.m.; a few Kmart stores will be open until 2 a.m.)
 Some Walgreens locations will be open until midnight; various Rite Aid stores will close at 5 or at 7 p.m.

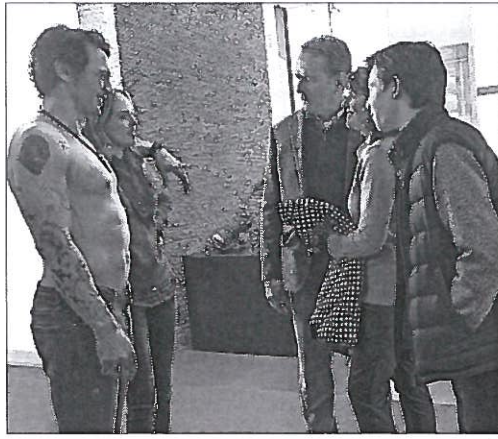
When the countdown sign reads "Shopping Days Until Christmas," your options get more limited. Some Connecticut Family Dollar stores will be open on Sunday, as will select chain drug and grocery store locations.
 For 7-Eleven stores, open 365 days a year, Christmas Day is business as usual and locations stock an assortment of gift cards, toys and small gifts. Cumberland Farms stores are also open on Christmas Day — and giving out free cups of coffee to shoppers who stop by.
 Many restaurants and movie theaters are open on holidays, so you can pick up gift certificates or movie passes.

Huntress

Continued from Page D1

Aisholpan Nurgai, an ebullient, open-faced charmer of many interests but one in particular soaring high above the others. Over the course of 87 tightly packed but gorgeously spacious minutes, shot with a variety of ground-level and drone cameras crisscrossing the northwest Mongolian steppes, the film follows Aisholpan's ambition to become the first female in 12 generations of her family to earn the title of eagle huntress. She spends most days in a typical week going to school in the nearest village, living in a dormitory with her two siblings. Aisholpan has designs on a medical career. But first things first.
 She trains at the side of her father, Nurgai. Particulars of the family's nomadic life aren't plentiful, but what's there on screen registers vividly. Nurgai herds cattle and goats and is himself an accomplished eagle hunter, having twice won the ceremonial Golden Eagle Festival in the village of Olgi. Aisholpan's fierce determination breaks tradition. "Women are weaker and more fragile," scoffs one veteran eagle hunter on camera. The irony is purely visual: The man himself looks frail enough to be knocked

over with an eagle feather. Narrated by "Star Wars" breakout star Daisy Ridley, "The Eagle Huntress" relays just enough information to keep track of how an eaglet is caught (at the age of 3 months, snatched from its nest) and what a training montage looks like in this forbidding context. Using a dead rabbit tied to a rope, the hunters train the bird to catch its prey. For fervent competition purposes, the eagle in training leaves the upraised arm of one hunter, high on a hill, and the bird swoops down, hopefully at a competitive, foot-catching speed, onto the arm of another hunter.
 The eaglet captured by Aisholpan and her father, to mix metaphors, has the eye of the tiger. "This will be a best-catching bird," Aisholpan's grandfather says, offering his blessing. "Let it grow old with you."
 With its screw-tightening editing and ESPN use of GoPro clip-on cameras, director Bell's technique is slick enough to skirt the edges of cliché. Some of the musical stings and swells are pure dreck and come straight out of reality television; there's too much slow-motion, intended to draw out the suspense of the later sequences. But as "The Eagle Huntress" proceeds from the safe confines of the annual festival competition to the harsher, 40-below-degree hunting expedition completing this young woman's training, an absorbing portrait becomes a genuinely exciting one. For a while there, I completely forgot about the foxes' bad luck.



LAIRD (James Franco, left) meets his girlfriend Stephanie's (Zoey Deutch) family: Ned (Bryan Cranston), Barb (Megan Mullally) and Scotty (Griffin Gluck).

'Why Him?'

Continued from Page D1

video-chat screen at dad Ned's (Bryan Cranston) birthday celebration. And when the Flemings land in the Bay Area, they're in for a cultural odyssey they could never have expected.
 "Why Him?" is probably the best setup of contemporary California tech culture to date. There's the yoga, the fancy food (Laird practices "dawn-to-dawn" cuisine with the help of "Top Chef" Richard Blais), the pretentious art (a moose suspended in its own urine), the celebrity, the wealth, the tank tops, for crying out loud. When we see these cultures clash, it's clear that #Calexit has already happened — it might as well be a foreign country for all the toilet mishaps and communication misunderstandings that take place.
 There's fun to be had in watching the Flemings go Cali, as mom Barb (Megan Mullally) learns about vaping and twerking, and tween son Scotty (Griffin Gluck) takes up code and a slouchy beanie. Cranston, ever the fuddy-duddy crank, as Ned, is more resistant. Threatened by Laird's off-putting lack of filter and peculiar ways, he staunchly refuses to give his blessing.
 Franco is quite funny in his uniquely laid-back way as the computer nerd who never quite figured out how to interact with a family. While

his initial forthrightness tends toward the TMI, he's refreshingly honest and endearingly vulnerable. His tribe is made up of Gustav (Keegan-Michael Key), his combination concierge, trainer and best friend, whose German accent wavers into Jamaican territory at times. He's also hired Kaley Cuoco — "the girl from 'Big Bang Theory'" he exclaims — to voice Justice, the all-seeing, all-knowing smart house entity whose helpfulness verges on the intrusive.
 In that vein, there are opportunities to explore how technology goes wrong, but "Why Him?" is far more about how the culture of tech is wacky in this world, tech is good, tech has the power and money to save Middle American manufacturing companies and keep jobs right here in the U.S. of A. If a little privatized surveillance comes along with it, so be it.
 The biggest problem with "Why Him?" though, isn't him, it's her. Stephanie is so underwritten that though these men are competing ruthlessly over her, she drops out of the story completely. She's the center of attention, but she's a void. That's not the fault of the winsome Deutch. It's that the writers haven't fleshed out her character, and she only has two modes, either bratty or exasperated, in which to work. It's difficult to empathize with her, so we latch on to the kooky Laird and stern Ned, whose rivalry the film revolves around. In true Hollywood fashion, they get him right, but not her.

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A.O. Sues, THE NEW YORK TIMES

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Public Notice Filing for Connecticut Children's Medical Center Acquisition of a 3T MRI Scanner

Statutory Reference: 19a-638

Applicant: Connecticut Children's Medical Center

Project Address: 282 Washington Street, Hartford, CT 06108

Proposal: The Applicant intends to file a Certificate of Need application with the State of Connecticut Office of Health Care Access for approval to acquire a 3T MRI scanner.

Capital Expenditure: \$3,960,846.00

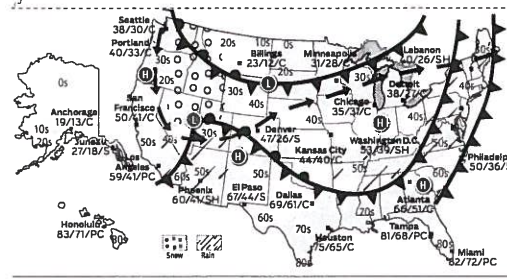
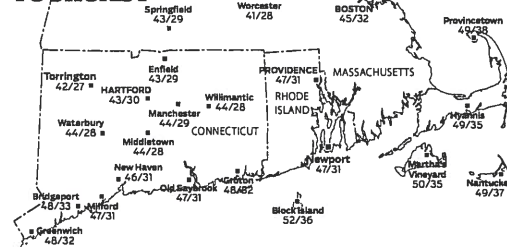
SATURDAY	SUNDAY	MONDAY	TUESDAY	WEDNESDAY
Cloudy, periods of rain, ending during the afternoon. Starts as a wintry mix in the hills. HIGH 43 LOW 30	Mostly sunny and cool. HIGH 44 LOW 21	Increasing cloudiness, chance for some scattered late day and evening showers. HIGH 45 LOW 34	Partly sunny, breezy and seasonably mild. HIGH 48 LOW 27	Partly sunny and colder. HIGH 37 LOW 21

Joe Furey Chief meteorologist
Rachel Frank FOX 61 meteorologist
Matt Scott FOX 61 meteorologist

Dan Amaranta
FOX 61 meteorologist

FOX 61 WEATHER

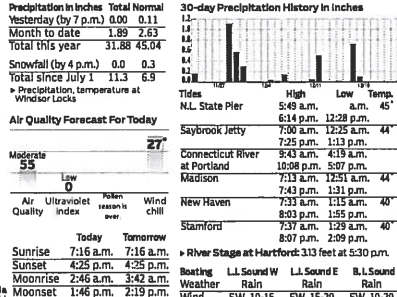
YOURCAST



OUTLOOK

Rain is here Saturday morning, and we'll be watching temperatures closely, especially in higher elevations. As numbers inland get close to freezing, we may see some of this moisture freeze, making it slippery. This won't last as temperatures moderate to the mid 40s. The rain, which will be moderate at times, leaves quickly in the early afternoon, so plans for the first night of Hanukkah, Christmas Eve and Christmas Day are fine.

ALMANAC



AROUND THE WORLD

Today's forecast in cities not included in the maps above:

NEW ENGLAND	Bangor 37 25 SH	Baltimore 48 33 SH	Birmingham 68 54	Boston 41 25 SF	Buffalo 42 28 SH	Cambridge 42 30 SH	Charleston 71 51 C	Cincinnati 47 40 C	Cleveland 41 31 SH	Columbus 42 36 SH	Dallas 67/44/5	Dallas 67/44/5	Dallas 67/44/5	Dallas 67/44/5
NATION	Albany 43 31 SH	Albuquerque 52 31 C	Albany 43 31 SH	Albuquerque 52 31 C	Albany 43 31 SH	Albuquerque 52 31 C	Albany 43 31 SH	Albuquerque 52 31 C	Albany 43 31 SH	Albuquerque 52 31 C	Albany 43 31 SH	Albuquerque 52 31 C	Albany 43 31 SH	Albuquerque 52 31 C

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 MegaMillions: 21, 39, 60, 69;
 MegaBall: 15
 Megaplier: 5
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 Tonight's estimated Powerball jackpot: \$50 million

Hartford Courant media group

Publication Date: 12/24/2016

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Capital Expenditure: \$3,960,846.00

Jeff Jacobs
 a COURANT Exclusive

Hartford Courant

WORLD & NATION



GRAHAM HUGHES/THE CANADIAN PRESS

In Montreal: A boy with a Santa stocking hat skis along a street in the Canadian city.

POPE PLEADS FOR WORLD'S CHILDREN

Christians around the world marked Christmas Eve on Saturday in ways including prayer and song.

At the Vatican, Pope Francis urged Christians to celebrate the birth of Jesus by thinking about the plight of today's children, including those who must escape bombs. Francis celebrated a somber Mass in a packed St. Peter's Basilica, processing to the altar behind cardinals draped in golden vestments as the Sistine Chapel choir sang "Gloria" and the church bells rang out across Rome.

Meanwhile, in the biblical town of Bethlehem, thousands of pilgrims and tourists from around the world gathered to celebrate in the traditional birthplace of Jesus.

—Associated Press



KHALIL HAMRA/AFAP

In Gaza City: A Palestinian Christian girl attends prayers with her family at Gaza Strip's Holy Family Catholic Church.



WU HONG/CPA

In Beijing: Members of a choir attend Christmas Eve Mass in the state-approved Xuanwumen Catholic Church.



ALESSANDRA TABARIN/NOVA/AFAP

In Vatican City: Pope Francis kisses a statue of the baby Jesus as he celebrates Mass in St. Peter's Basilica.

Europe

Continued from Page A1

followers to plan and carry out independent strikes against Europe bodies ill for efforts to stem the violence, officials and analysts say, given the practical barriers to constantly monitoring a large pool of potential attackers.

The change in terror tactics suggests that counterterrorism authorities may be successfully disrupting larger attacks, analysts say, offering a positive spin to the grim reality that small-scale violence may be inevitable.

"We see how the terrorism networks have much more difficulty in planning operations on a large scale," said Mohammad-Mahmoud Quid Mohamed, deputy director of the Geneva Center for Security Policy. The Berlin attack "is not necessarily an intelligence failure, because unless you start surveilling everyone, then these cases can happen everywhere."

Assaults like the one in Berlin require little advance planning or logistical support, starving authorities of chances to snag perpetrators in advance, even when they have been flagged on suspicion of terrorist activity. German authorities monitored the Berlin attacker, 24-year-old Tunisian Amri, before the incident but abandoned their chase after concluding they had no evidence to press terror-related charges. Amri's connections to the Islamic State remain unclear, although a video of him pledging allegiance to the group released Friday suggests at least some level of contact before he commandeered a truck and plunged it into the market stands.

Europe's open borders — a cherished centerpiece of the European Union — also make potential attackers more mobile than security authorities, a fact underlined by Amri's apparently suc-

cessful escape by train from Germany after the attack, making it more than 500 miles despite being Europe's most-wanted man before his death in a shootout in Milan early Friday. Some European countries have temporarily closed their borders this year because of migration and terrorism, only to quickly reopen them because of the economic and logistical demands involved.

Top security authorities have increasingly taken to warning citizens that Europe will never be fully without the risk of terrorism. "We can't ignore the risk that exists. There can never be 'zero risk,'" Julian King, the top EU official in charge of security matters, told reporters last week as he unveiled a package of measures intended to stymie terrorist financing. "We can and must continue to reduce the risk of attacks as far as we possibly can."

The painful regularity of the attacks has fueled support for far-right politicians who want to reinstate national borders and restrict the flow of migrants to Europe — steps that would challenge the basic future of the European Union. Critics say the proposals could further inflame tensions and spur radicalization.

At the same time, analysts point to a list of missed connections that may have helped Amri evade authorities' oversight. European information about security threats is fragmented into several databases, making it difficult to piece together a full picture of suspects. Italy expelled Amri from its territory last year with little thought of the consequences. And Germany's law enforcement agencies are scattered across the nation's regions in a post-World War II attempt to make it difficult for an authoritarian leader to grab power in the capital.

The dangers may be increasing as Islamic State leaders shift tactics, calling for followers to attack U.S.

TERROR, A6

HOME DECOR 50% OFF
Categories Listed
Does not include Seasonal Decorations

- Candle Holders
- Knobs, Drawer Pulls & Handles
- Glass Decor
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- Decorative Bottles
- Metal Decor
- Decorative Luminaires, Birdcages & Terrariums
- Framed & Canvas Art
- Wicker, Decorative Boxes & Storage
- Decorative Mirror Boards, Chalkboards & Corkboards
- Men's Metal & Wood Decor

Valentine's Day Items and Items labeled The Spring Shop™ are not included in Home Decor sale.

CHRISTMAS 66% OFF
Remaining CHRISTMAS 66% OFF
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- Bead Design Co.™, in Bloom™ and Treasures Studio™
- Fairy Tale™
- Blank Sticks
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Public Notice Filing for Connecticut Children's Medical Center Acquisition of a 3T MRI Scanner

Statutory Reference: §19a-63B
Applicant: Connecticut Children's Medical Center
Project Address: 282 Washington Street, Hartford, CT 06106
Proposal: The Applicant intends to file a Certificate of Need application with the State of Connecticut Office of Health Care Access for approval to acquire a 3T MRI scanner.
Capital Expenditure: \$3,960,846.00

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.

Connecticut Children's Medical Center ("CT Children's") is applying for a Certificate of Need to meet the unique needs of our pediatric population by adding 3T MRI scanning capability to be located at our hospital campus at 282 Washington Street in Hartford, CT. This will allow us to better serve our inpatient and outpatient (including Emergency Department) populations requiring advanced imaging in neurologic, cardiac, orthopedic and other sub-specialty diagnostics.

This CON helps achieve the following goals:

1. To improve access to high quality care by enhancing our technological imaging capability as 3T imaging has become more widespread and a capability of most freestanding children's hospitals in the country.
2. To improve patient safety due to decreased length of time under sedation and decreased exposure to radiation, proven to be a risk to children.
3. To reduce anesthesia and sedation MRI exam wait times of up to 15 days.

We completed approximately 4,400 exams in FY16 on our 1.5T scanner. This represents an increase in both inpatient and outpatient exams and we are at capacity for this unit. Many of our patients require sedation and/or anesthesia which requires additional time and adds to the potential delays in our schedule; therefore, reducing the number of exams we can perform and creating a backlog and waiting list. The addition of the 3T scanner, to be located adjacent to the existing scanner, will allow us to increase capacity for general anesthesia cases, reduce wait time for procedures, and provide advanced imaging for our patients. Estimated time to be clinically operational would be approximately 8 months after Certificate of Need approval, estimated to be by January 2018.

The total estimated cost of the project, including major and minor equipment plus construction would be \$3,960,846.00.

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.

RESPONSE

General Background

- CT Children’s is a nationally recognized, 187-bed not-for-profit children’s hospital serving as the primary teaching hospital for the Department of Pediatrics at the University of Connecticut School of Medicine. The facility has a medical staff of 1,100 practicing in more than 30 specialties.
- Our facility is currently serviced by one 1.5 Tesla (T) Magnetic Resonance Imaging (MRI) scanner performing 4,400+ studies annually, many of which require sedation or general anesthesia due to the length of time needed to perform the exam in our unique patient population. Wait times for non-emergent sedated studies have averaged 10-15 days over the last several years. The current scanner is located at the main campus at 282 Washington Street, Hartford. We are at capacity for scanning on this unit based on increasing volume, the extended timeframes required for pediatric imaging using sedation and anesthesia as well as limits to times we can schedule pediatric patients, typically during day shift hours due to the need to fast before the procedure.
- Higher strength magnetic field scanners (3.0 T and above) are the current standard of care for diagnostic imaging in the United States for many conditions such as orthopedic, neurologic, cardiac, GI and urologic conditions.
 - o Two-thirds of free standing children’s hospitals in the US currently have this technology based on data obtained from the Children’s Hospital Association.
- We are seeking Certificate of Need authorization to acquire a new 3.0 Tesla MRI scanner to be located at our main campus in addition to our existing 1.5 Tesla MRI scanner. This will increase both our capacity and technical capabilities in line with our goals to make Connecticut’s children the healthiest in the nation and serve more complex cases that require this imaging.

- CT Children's determined a second MRI scanner was necessary when wait times started increasing. Although our patients have been finding other facilities to schedule non-sedated outpatient follow up MRI exams, we pride ourselves on the fact that CT Children's providers are dedicated to the care of only children. We provide both non-sedated and sedation/anesthesia services which results in a unique care environment for patients and families. Our imaging center is a safe and comfortable environment for patients and their families that is unmatched by other facilities in our service area.

Furthermore, we understand the need for a high quality care team being present for our pediatric patients, especially because many of these exams require sedation or anesthesia in order to keep the patient motionless. MRI requires that a patient remain still while images are obtained. Study lengths vary from as little as 10 minutes to well over an hour. In our experience, children under the age of 10 and/or developmentally delayed children may have difficulty remaining still for these studies, and often require sedation/anesthesia for the studies to be completed,

Sedated/anesthesia studies require a coordinated group of individuals/providers to ensure that:

- a. The child's sedation is accomplished safely;
- b. The child and family's anxiety surrounding the procedure are addressed;
- c. Imaging is completed effectively and with little to no movement, so that the required diagnostic information is obtained and does not need to be repeated.

The sedation team includes a Pediatric Anesthesiologist, Sedation Nurse, Child Life Specialist, MRI Technologist and Pediatric Radiologist - all working together to provide safe, family-centered care to the child and parent during the encounter.

Service Area

- The new 3T MRI scanner will serve the same pediatric population currently served by the 1.5T scanner. Because we serve as the state's only freestanding children's hospital, our service area is relatively broad (nearly statewide) and cannot be narrowly defined as compared to general acute care hospitals in CT. The OHCA Table 2 below shows the towns with the larger numbers of patients receiving an MRI exam. Even when we select those towns with the highest number of exams (see Table), the percent of total scans (43%, 44%, and 44% respectively for FY14, FY 15, and FY16) remains below what OHCA would traditionally consider a primary service area.

OHCA TABLE #2

CT Towns	CCMC MRI Exam Volume by Town, Inpatient & Outpatient Combined		
	FY 2014	FY 2015	FY 2016
Bristol	157	166	179
East Hartford	140	156	151
Glastonbury	81	125	110
Hartford	477	488	474
Manchester	144	149	133
Meriden	79	105	100
Middletown	78	78	75
New Britain	180	239	205
Southington	91	69	103
Torrington	59	54	76
Waterbury	147	165	210
West Hartford	148	135	162
SUBTOTAL	1,781	1,929	1,978
GRAND TOTAL	4,165	4,374	4,490
Percent of Total	43%	44%	44%

In light of the foregoing, we consider our service area for the proposed 3T MRI scanner to be the same as our existing MRI scanner as it will be located at the hospital campus serving our existing patient base which is exclusively for children.

Timeline

Once CoN approval has been completed, the timeline forward would be approximately 8 months to purchase, design, construct and cite the new scanner to be clinically operational.

Improved Safety

- Decreased length of sedation: Scanners employing 3T magnets decrease the amount of time required to acquire images resulting in decreased length of sedation and decreased risk to patients receiving sedation or anesthesia for imaging (1)
- Decreased radiation exposure: Availability of two scanners on campus would result in increased utilization of 'fast' MRI scans for the evaluation of urgent/emergent conditions, such as ventriculo-peritoneal shunt malfunction (2), that are currently evaluated with computed tomography (CT). Radiation exposure from head CT in children is estimated to result in one head and neck cancer per 500 scans over the course of a lifetime (3).

Improved capability

- Increased spatial resolution: Scanners employing 3T magnets provide increased spatial resolution and improved diagnostic capability to a diverse group of patients to include neurologic, cardiovascular, and musculoskeletal disease (4).
- Improved post-imaging processing: Combining state of the art coil and scanner technology with post-imaging processing provides enhanced capability in cardiovascular and neuroscience imaging to include cardiac MRI (5), MR tractography (6), and functional MRI (7). These techniques and sequences are essential for a facility to offer advanced neurosurgical and cardiac surgical services

Improved access

- Access will be improved for CT Children's pediatric patients including inpatient, Emergency Department and outpatient visits. Because our single MRI scanner is currently scheduled at capacity, our patients are waiting longer to receive their exams. Additionally, because of emergencies and inpatient exams, those patients who can be served on an outpatient basis may have their appointments disrupted and sometimes choose to go to other MRI providers in the community.
- Seeking approval for a 3.0T MRI will provide access to improved quality of care as providers will be able to provide state-of-the-art pediatric diagnosis.
- Providers will be able to provide improved pediatric care to all patients whether inpatient, outpatient or Emergency Department visits regardless of their ability to pay. Our payer mix consists of 46% Medicaid and 53% commercial coverage.

Summary

- Connecticut Children's Medical Center has a mission to provide state-of-the-art care to the children we serve. The addition of a 3.0T MRI scanner will improve the safety of care we render, as well as increase imaging capacity, capability, and access to the children of CT and greater region

(1) Chavhan GB et al. MR Imaging at 3.0 T in Children: Technical Differences, Safety Issues, and Initial Experience. Radiographics 2009; 29: 1451-1466.

(2) Thompson et al. Results of a North American survey of rapid-sequence MRI utilization to evaluate cerebral ventricles in children. JNS Pediatrics 2014; 13: 636-640.

(3) <https://www.cancer.gov/about-cancer/causes.../risk/radiation/pediatric-ct-scans>

(4) Bhargava R et al. Contrast-Enhanced Magnetic Resonance Imaging in Pediatric Patients: Review and Recommendations for Current Practice. Magnetic Resonance Insights 2013; 6: 95-111.

(5) Ntsinjana HN et al. Journal of Cardiovascular Magnetic Resonance 2011; 13: 51

(6) Okada T et al. Diffusion-Tensor Fiber Tractography: Intraindividual Comparison of 3.0-T and 1.5-T MR Imaging. Radiology 2006; 2: 668-678.

(7) Voss HU et al. Functional MR Imaging at 3.0 versus 1.5 T: A Practical Review. Neuroimag Clin N Am 2006; 16: 285-297.

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:

Initial discussions for the addition of a 3T scanner began in 2015. An Imaging Committee of sub-specialty physicians convened a group to discuss future needs for imaging within the hospital. The decision was that 3T MRI imaging was becoming the standard of care for specific diagnoses and advanced imaging should be a part of our current services. A full financial analysis was performed and proposed to the Finance Committee of the CT Children’s Board of Directors in September 2016. The Board approved the request to proceed with application for a 3T MRI scanner.

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:

The addition of 3.0T MRI services is proposed to be added.

See OHCA Table 1 Page # 31

- 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:

CT Children’s Medical Center serves as the state’s only freestanding children’s hospital and has a very broad service area. Service area towns were determined by towns with the higher scan volumes (>75) as we attempted to identify those towns that represent a majority of percent of total volume.

See OHCA Table 2 below and page # 31

Service Area Towns	CCMC MRI Exam Volume by Town, Inpatient & Outpatient Combined			Reason for Inclusion
	FY 2014	FY 2015	FY 2016	
Bristol	157	166	179	Demand for service
East Hartford	140	156	151	
Glastonbury	81	125	110	
Hartford	477	488	474	
Manchester	144	149	133	
Meriden	79	105	100	
Middletown	78	78	75	
New Britain	180	239	205	
Southington	91	69	103	
Torrington	59	54	76	
Waterbury	147	165	210	
West Hartford	148	135	162	
SUBTOTAL	1,781	1,929	1,978	
GRAND TOTAL	4,165	4,374	4,490	
Percent of Total	43%	44%	44%	

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

RESPONSE:

The existing hospital license is all that is required and can be found in **Exhibit 1**

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 1

- 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:

Patrick J. Garvey, CPA, CHFP, Senior Vice President & Chief Financial Officer
Jonathan Martin MD, FAANS, Chief, Division of Neurosurgery
R. Timothy Brown MD, Medical Director, Department of Radiology
Michael Thomas O'Loughlin, Director of CT and MRI, Jefferson Radiology Group

See Exhibit 2 for Curriculum Vitae's

- 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:

- 1) **"MR Imaging at 3.0 T in Children: Technical Differences, Safety Issues, and Initial Experience"** - Chavhan et al: Article highlights shorter acquisition times required for 3.0T field magnets, resulting in reduced requirements for sedation and improved patient safety. Provides additional technical information regarding imaging with stronger field magnets in children.
- 2) **"Results of a North American Survey of Rapid-Sequence MRI Utilization to Evaluate Cerebral Ventricles in Children"** - Thompson et al: Provides results of a 9-question survey provided to all US/Canadian institutions with a board-certified pediatric neurosurgeon on staff, highlighting the wide utilization of rapid-sequence MRI techniques in the evaluation of potential shunt malfunction to minimize radiation exposure in this patient population
- 3) **"Radiation Risks and Pediatric Computed Tomography (CT): A guide for Healthcare Providers"** - National Cancer Institute- Radiation risks in pediatric CT: Summary webpage discussing heightened risks of radiation exposure in children from diagnostic imaging
- 4) **"Contrast-Enhanced Magnetic Resonance Imaging in Pediatric Patients: Review and Recommendations for Current Practice"** - Bhargava et al: Article summarizes the wide range of applications of MRI in pediatric imaging to include cardiovascular, musculoskeletal, neurologic, and other gastrointestinal imaging.

- 5) **“The Role of Cardiovascular Magnetic Resonance in Pediatric Congenital Heart Disease” - Ntsinjana et al:** Article discusses use of MRI in performing non-invasive diagnostic imaging in pediatric congenital heart disease
- 6) **“Diffusion-Tensor Fiber Tractography: Intraindividual Comparison of 3.0-T and 1.5-T MR Imaging” - Okada et al:** Article comparing the quality of higher field (3.0T) MRI to lower field (1.5T) MRI in the specific application of diffusion-tensor fiber tractography, an imaging technique that provides improved visualization of brain pathways, increasing the safety of surgical resection in neuro-oncology
- 7) **“Functional MR Imaging at 3.0 T versus 1.5 T: A Practical Review” - Voss et al:** Technical article regarding improved results with functional imaging BOLD sequences in high field (3.0T) versus low field (1.5T) MRI. Allows for improved visualization of functional brain tissue for planning of respective procedures in neurosurgery when pathology involves eloquent cortex.
See Exhibit 3 for actual articles.
- d. letters of support for the proposal;
RESPONSE:
See Exhibit 4
- 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
Guidelines will be the same as current and follow ACR standards.
<https://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/MRI>
- 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
Purchase order for the 3T scanner is found in **Exhibit 5**

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:
The proposed project complies and follows the application process for Certificate of Need adopted by the Department of Public Health regulations as set forth in Conn Gen Stat 19a-639 (a)(1). The proposal is to enhance clinical care utilizing advanced MRI imaging supporting the clinical services provided by Connecticut Children’s Medical Center.

§ "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 proposal aligns with the Statewide Health Care Facilities plan as it will improve access to vulnerable populations (including children with developmental disabilities) and Medicaid patients, provide better continuity of care as services can be obtained in one location, and improve the quality and timeliness of diagnosis in all pediatric patients. This new technology is considered a standard of care for specific clinical needs and is found in a majority of pediatric and adult hospital settings currently.

§ "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 is the pediatric population serviced by CT Children's

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

RESPONSE:

Currently the one 1.5T magnet at the hospital is servicing our population.

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

RESPONSE:

CT Children's has documented the need for an additional MRI scanner based on a full schedule and extended wait times for patients to receive the necessary diagnostic imaging for their care. Because CT Children's serves inpatients, outpatients and the immediate needs of emergency care, our patients may decide to receive their MRI exams at other outpatient facilities. We understand the need for a high quality care team being present for our pediatric patients. Many of these exams require sedation in order to keep the patient motionless. MRI requires that a patient remain still while images are obtained. In our experience, children under the age of 10 and/or developmentally delayed children may have difficulty remaining still for these studies, and often require sedation/anesthesia for the studies to be completed. The sedation team includes a Pediatric Anesthesiologist, Sedation Nurse, Child Life Specialist, MRI Technologist, and Pediatric Radiologist- all working together to provide safe, family centered care to the child and parent during the encounter.

CT Children's would also like to note the decision of OHCA to approve a 3T MRI scanner for Yale Children's Hospital in 2013, Docket Number 12-31810, attached for your convenience at the end of the CoN. OHCA concluded a clear public need based on

- anticipated needs in pediatric imaging
- 3T advanced imaging capabilities
- Pediatrics is a unique environment
- The provision of pediatric anesthesia and sedation services is limited within the state

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

RESPONSE:

The location was chosen to be at the main campus to provide an additional advanced level of imaging to both inpatient and outpatients simultaneously as well as the availability of sedation and anesthesia services.

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

RESPONSE:

CT Children's provides a significant number of sedated and general anesthesia cases annually, approximately 50% of our current volume. Wait times for this service over the last two years have been between 10-15 days on average. Due to the volume of studies and additional time needed for these procedures in pediatrics, we have encountered continuing competition for the current magnet between inpatient emergencies and outpatient imaging. We also service a very large Medicaid population (approximately 46%) and access to this level of imaging would be enhanced. The additional scanner would be located within Hartford and allow easy access to services and our highly trained team.

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

RESPONSE:

Increasing the capacity of MRI imaging will reduce wait times for all pediatric patients.

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

RESPONSE

This proposal does not represent a change of service, but an enhancement to our existing services. Offering 3T MRI services enables our specially trained team the ability to provide state-of-the-art care and improve their ability to diagnose complex care issues.

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

RESPONSE

Access and timeliness to MRI scanning will improve as a result of increased capacity to this type of imaging.

- i. discuss any alternative proposals that were considered.

RESPONSE:

Other alternatives that have been discussed but do not improve patient care:

- 1) continue current service level and use CT scanner versus MRI scanner which would increase exposure to radiation in pediatric patients.
- 2) Choose an off-site location for the new scanner. This would not meet an immediate need for advanced 3T imaging in our inpatient population.

The option of adding a 3T scanner at our main campus is the best for patient care.

§ *“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;

RESPONSE:

Advanced 3T imaging availability will improve the quality of diagnoses for critical cases within the hospital as described in the project description. Care can be better coordinated within the hospital for cases requiring this type of imaging. As the hospital advances the care of pediatric patients and grows our service lines this imaging supports that clinical care. Furthermore, quality is improved by decreasing the amount of radiation exposure that can occur from CT scanning in some cases, and furthermore the 3T MRI will conduct exams more efficiently than the 1.5T reducing the amount of time the pediatric patient must be sedated.

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

RESPONSE

Increased capacity for MRI imaging will allow for pediatric patients to receive care in a pediatric environment.

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

RESPONSE:

The availability of 3T imaging will allow for patients that may require this type of imaging to stay within the hospital's service area and reduce the overall cost by not transporting a patient to another facility.

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:

Through following the procedures linked to the Language and Communication Policy at CT Children's, patients and families are regularly assessed for their language and communication needs, with appropriate services allocated. These services include the use of qualified interpreters, translation services, and assistive devices. Through our Patient Rights and Responsibilities and our partnership with families to deliver family-centered care, the essential practice of assessing, acknowledging and accommodating cultural needs is maintained. The multi-disciplinary team is responsible for assuring adherence to the National Standards on Culturally and Linguistically Appropriate Services, and adherence is monitored by following hospital protocols. Through Human Resources, strong talent is recruited to assure representative leadership and a workforce well trained in providing excellent and unbiased care, helping to advance health equity and improving health care quality.

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:

Care coordination is improved as we will be able to provide state-of-the-art MRI imaging and not consider more invasive testing or testing with higher inherent risks (such as CT). In addition, there are inherent risks in transferring a patient to another facility and these risks can be avoided. Also, when the MRI exam is conducted by CT Children's, the electronic image and results are easily maintained within that patient's electronic medical record and the images are immediately available when the study is completed. Access to the reading is available to all providers within the CT Children's EHR system.

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

RESPONSE:

The location of the scanner in Hartford and the increased capacity of MRI services will improve timely access to this type of imaging and reduce wait times to improve the efficiency of diagnosis for all our patients, including the 46% of Medicaid patients and those patients not able to pay for their care.

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

RESPONSE:

See Exhibit 6

§ "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.

RESPONSE:

The proposed addition of an MRI scanner will not fail to provide or reduce access to services for any patient population.

§ "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.

RESPONSE:

There will be no changes to the pricing structure as a result of this acquisition.

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:

Fiscal year is 10/01 to 09/30.

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:

The purchase and installation of the new 3T scanner will be funded out of operating cash and no loan or lease will be developed.

18. Provide a final version of all capital expenditure/costs for the proposal using [OHCA Table 3](#).

RESPONSE:

See OHCA Table 3 on Page # 32 and Exhibit 7 for construction details and timeline.

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:

The scanner will be funded from operating cash.

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 8

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 9

21. Complete [OHCA Table 4](#) utilizing the information reported in the attached Financial Worksheet.

RESPONSE:

See OHCA Table 4 on Page # 32

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

RESPONSE:

Assumptions:

A review of MRI ordering from our electronic health record showed that many studies were being referred outside annually due to access and wait times. Inpatient ordering has grown significantly from 2015 to 2016 (approximately 30%) and is expected to be flat over the next 3-4 years as we do not anticipate a significant growth in inpatient days, therefore no inpatient increased testing was factored in to the projections. Projected volume increases were based on capturing more of the outside referrals in the first year. Successive years will see slower volume growth per year. Growth will come from our service line advances, additional complex cases in sub-specialty care, rotation away from CT imaging to avoid radiation exposure in children and the increased need for more sedation and anesthesia related cases as well as reducing our back-log of patients waiting for exams.

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

RESPONSE:

Based on our financial analysis and the lack of a loan or lease provision, we do not anticipate a loss from operations for the addition of a 3T MRI scanner.

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

RESPONSE:

MRI scans per year to break-even.

FY18 = 722

FY19 = 1304

FY20 = 1330

FY21 = 1314

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 Table 6 on page # 33

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:

A review of MRI ordering from our electronic health record showed that many studies were being referred outside annually due to access and wait times. Inpatient ordering has grown significantly from 2015 to 2016 (approximately 30%) and is expected to be flat over the next 3-4 years as we do not anticipate a significant growth in inpatient days, therefore no inpatient increased testing was factored in to the projections. Projected volume increases were based on capturing more of the outside referrals in the first year. Successive years will see slower volume growth per year. Growth will come from our service line advances, additional complex cases in sub-specialty care, rotation away from CT imaging to avoid radiation exposure in children and the increased need for more sedation and anesthesia related cases as well as reducing our back-log of patients waiting for exams.

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 on page # 34

§ *“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 will be a pediatric age group, between 0-21 years of age and comprise the current mix of gender currently seen by the hospital. Sub-specialty areas such as Neuro-Surgery, Neurology, Cardiac and Orthopedics will benefit from the advanced imaging as described in our clinical summary.

The need is demonstrated by our inability to schedule pediatric MRI exams to meet the patient demand. Our patients scheduled for outpatient testing are sometimes waiting for care to be delivered to our emergency cases and our inpatients. Furthermore, we are driven to provide the best care to our patients and advances available with the use of 3T MRI procedures for specific pediatric diagnoses.

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 Tables below and Exhibit 10

The tables that follow show the towns where approximately 58% of our volume exists in FY16 and shows this has been steady over the last three years. As we are a specialized pediatric provider, we have patients from many towns in the state. As can be seen in the exhibit, we are providing data on all scans by all towns for your information for the last three years. The data is broken out by inpatients and outpatients. ED patients are considered outpatients.

OHCA Table #8 CCMC INPATIENT MRI PROCEDURES BY TOWN BY YEAR

	CCMC Inpatient MRI Procedures		
	FY 2014	FY 2015	FY 2016
MRI Exams by Town			
Avon	1	3	16
Bloomfield	7	7	11
Bristol	25	16	37
Coventry	6	23	2
Danbury	6	4	33
East Hartford	28	20	32
Ellington	3	3	22
Farmington	11	6	8
Glastonbury	15	25	17
Hartford	75	78	66
Manchester	8	25	34
Meriden	12	22	22
Middletown	10	17	6
New Britain	35	40	23
Newington	5	6	11
Plainville	6	7	2
Rocky Hill	7	11	5
South Windsor	11	17	9
Southington	6	5	15
Torrington	6	7	10
Wallingford	1	3	0
Waterbury	24	38	41
Wethersfield	2	7	7
West Hartford	19	11	6
Windsor	8	5	7
MRI Exams by Town SUBTOTAL	337	406	442
MRI Exams by Town Percent of Total	63%	65%	64%
All Other Towns SUBTOTAL	196	221	250
All Other Towns Percent of Total	37%	35%	36%
GRAND TOTAL	533	627	692

OHCA TABLE #8 CCMC OUTPATIENT MRI PROCEDURES BY TOWN BY YEAR

	CCMC Outpatient MRI Procedures		
	FY 2014	FY 2015	FY 2016
MRI Exams by Town			
Avon	56	48	51
Bloomfield	33	28	35
Bristol	132	150	142
Coventry	34	34	43
Danbury	11	33	27
East Hartford	112	136	119
Ellington	34	19	24
Farmington	36	35	36
Glastonbury	66	100	93
Hartford	402	410	408
Manchester	136	124	99
Meriden	67	83	78
Middletown	68	61	69
New Britain	145	199	182
Newington	78	60	56
Plainville	26	34	36
Rocky Hill	37	30	27
South Windsor	53	62	55
Southington	85	64	88
Torrington	53	47	66
Wallingford	14	9	18
Waterbury	123	127	169
Wethersfield	51	70	45
West Hartford	129	125	156
Windsor	54	72	48
MRI Exams by Town SUBTOTAL	2,035	2,160	2,170
MRI Exams by Town Percent of Total	56%	58%	57%
All Other Towns SUBTOTAL	1,597	1,587	1,628
All Other Towns Percent of Total	44%	42%	43%
GRAND TOTAL	3,632	3,747	3,798

**OHCA TABLE #8 CCMC INPATIENT & OUTPATIENT MRI PROCEDURES COMBINED
BY TOWN BY YEAR**

	CCMC MRI Procedures Inpatient & Outpatient Combined		
	FY 2014	FY 2015	FY 2016
MRI Exams by Town			
Avon	57	51	67
Bloomfield	40	35	46
Bristol	157	166	179
Coventry	40	57	45
Danbury	17	37	60
East Hartford	140	156	151
Ellington	37	22	46
Farmington	47	41	44
Glastonbury	81	125	110
Hartford	477	488	474
Manchester	144	149	133
Meriden	79	105	100
Middletown	78	78	75
New Britain	180	239	205
Newington	83	66	67
Plainville	32	41	38
Rocky Hill	44	41	32
South Windsor	64	79	64
Southington	91	69	103
Torrington	59	54	76
Wallingford	15	12	18
Waterbury	147	165	210
Wethersfield	53	77	52
West Hartford	148	135	162
Windsor	62	77	55
MRI Exams by Town SUBTOTAL	2,372	2,565	2,612
MRI Exams by Town Percent of Total	57%	59%	58%
All Other Towns SUBTOTAL	1,793	1,809	1,878
All Other Towns Percent of Total	43%	41%	42%
GRAND TOTAL	4,165	4,374	4,490

§ "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:

The majority of our pediatric MRI scans require sedation and therefore are routinely performed within a hospital setting. We therefore included other existing hospital providers in the table. The service area hospitals can perform such MRI procedures in the event they have a child in need of such services, however, we believe we provide the majority of these services currently in our service area. CT Children's service area is very broad and includes many towns through the state since we are the only freestanding children's hospital in CT.

See OHCA Table 9 on Page # 35

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

RESPONSE:

There would be minimal to no effect on existing providers as our volume is spread over a large portion of the state, therefore, no one provider of services currently should be adversely effected. CT Children's provides sedation and anesthesia services that are not routinely available by most providers.

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

RESPONSE:

Existing referrals predominantly come from our Connecticut Children's Specialty Group physicians and other outside referral sources associated with the hospital, specific to pediatrics.

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

RESPONSE:

CT Children's current in-coming referrals will not be changed significantly with the additional scanner; however, with a reduction in wait times we will retain more of our existing outpatient business that currently leaves CT Children's for another pediatric MRI provider. Because we are adding more advanced technology, 3T MRI, CT Children's expects to see an increase in outside providers referring their pediatric patients to receive this level of care.

§ *“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:

Based upon our current referral patterns, wait times and the need for advanced imaging within the hospital will allow for more pediatric patients to receive care within a pediatric environment. Services will be better coordinated under the same instance of care and there would be no duplication of services.

§ *“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.

RESPONSE:

This proposal will positively impact patient and family choice to receive services in a pediatric facility dedicated to children. CT Children’s provides the right environment for patients and families utilizing techniques and services specific to pediatrics. This does enhance the patient and family experience and reduces anxiety of the procedure.

Tables

**TABLE 1
APPLICANT'S SERVICES AND SERVICE LOCATIONS**

Service	Street Address, Town	Population Served	Days/Hours of Operation	New Service or Proposed Termination
Siemens 1.5T	282 Washington Street Hartford, CT	CCMC current pediatric patients	M-F 730am-11pm Sat 730am- 4pm	Existing
Philips 3.0T	282 Washington Street Hartford, CT	CCMC current pediatric patients	M-F 730am-11pm Sat 730am-4pm	Proposed

[\[back to question\]](#)

**TABLE 2
SERVICE AREA TOWNS**

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

Town*	Reason for Inclusion
	Current demand for services
Bristol	"
East Hartford	"
Glastonbury	"
Hartford	"
Manchester	"
Meriden	"
Middletown	"
New Britain	"
Southington	"
Torrington	"
Waterbury	"
West Hartford	"

* Village or place names are not acceptable.

[\[back to question\]](#)

**TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$3,138,920
Land/Building Purchase*	
Construction/Renovation**	\$821,926
Other (specify)	
Total Capital Expenditure (TCE)	\$3,960,846
Lease (Medical, Non-medical, Imaging)***	
Total Lease Cost (TLC)	
Total Project Cost (TCE+TLC)	\$3,960,846

- * 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.

[\[back to question\]](#)

**TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2018*	FY 2019*	FY 2020*	FY 2021*
Revenue from Operations	\$736,896	\$1,452,957	\$2,171,920	\$2,788,745
Total Operating Expenses	\$709,435	\$1,306,373	\$1,359,073	\$1,369,477
Gain/Loss from Operations	\$27,461	\$146,584	\$812,847	\$1,419,268

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

[\[back to question\]](#)

**TABLE 5
HISTORICAL UTILIZATION BY SERVICE**

Service**	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY 2014	FY 2015	FY 2016	FY 2017 (10/1/2017- 11/30/2017)
MRI - Inpatient	533	627	692	106
MRI – Outpatient/ED	3,632	3,747	3,798	600
Total	4,165	4,374	4,490	706

* 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**

Service*	Projected Volume			FY 2021
	FY 2018**	FY 2019**	FY 2020**	
MRI	5,240	5,940	6,615	7,165
Total	5,240	5,940	6,615	7,165

* Identify each service type by location and add lines as necessary. Provide the number of visits/discharges as appropriate for each service listed.

** 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. 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 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX**

Payer	Most Recently Completed				2 Months		Projected							
	FY 2015		FY 2016		FY 2017		FY 2018		FY 2019		FY 2020		FY 2021	
	Volume	%	Volume	%	Volume	%	Volume	%	Volume	%	Volume	%	Volume	%
Medicare*	7	0.2%	12	0.3%	2	0.3%	15	0.3%	17	0.3%	19	0.3%	20	0.3%
Medicaid*	2,013	45.9%	2,060	45.9%	324	45.9%	2,404	45.9%	2,726	45.9%	3,035	45.9%	3,289	45.9%
CHAMPUS & TriCare	47	1.1%	34	0.8%	6	0.8%	45	0.9%	50	0.8%	56	0.8%	61	0.9%
Total Government	2,067	47.2%	2,106	47.0%	332	47.0%	2,464	47.1%	2,793	47.0%	3,110	47.0%	3,370	47.1%
Commercial Insurers	2,289	52.3%	2,369	52.8%	372	52.7%	2,761	52.7%	3,130	52.7%	3,486	52.7%	3,775	52.7%
Uninsured Workers Compensation	18	0.4%	15	0.3%	2	0.3%	15	0.3%	17	0.3%	19	0.3%	20	0.3%
		0.0%		0.0%	-	0.0%	-	0.0%	-	0.0%	-	0.0%	-	0.0%
Total Non-Government	2,307	52.7%	2,384	53.1%	374	53.0%	2,776	53.0%	3,147	53.0%	3,505	53.0%	3,795	53.0%
Total Payer Mix	4,374	99.9%	4,490	100.1%	706	100.0%	5,240	100.1%	5,940	100.0%	6,615	100.0%	7,165	100.1%

* 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.

[\[back to question\]](#)

**TABLE 8
UTILIZATION BY TOWN**

Town	Utilization FY 2016_**
SEE EXHIBT <u>10</u>	

* 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**

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current ** Utilization Totals
Bristol Hospital	Adult & Pediatrics		41 Brewster Road Bristol CT 06010		3060
Charlotte Hungerford Hospital	Adult & Pediatrics		540 Litchfield Street Torrington, CT 06790		1483
Hartford Hospital	Adult & Pediatrics		80 Seymour Street Hartford CT 06106		10,684
Hospital of Central CT	Adult & Pediatrics		100 Grand Street New Britain, CT 06052		8069
Manchester Memorial Hospital	Adult & Pediatrics		71 Haynes Street Manchester, CT 06040		3114
Middlesex Hospital	Adult & Pediatrics		28 Crescent Street Middletown, CT 06457		12,560
Midstate Medical Center	Adult & Pediatric		435 Lewis Avenue Meriden, CT 06450		5751
Saint Francis Hospital and Medical Center	Adult & Pediatrics		114 Woodland Street Hartford, CT 06105		14,265
Saint Mary's Hospital	Adult & Pediatrics		56 Franklin Street Waterbury, CT 06706		3611
Waterbury Hospital	Adult & Pediatrics		68 Robbins Street Waterbury, CT 06708		1074

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

**Data Obtained from the Patient Census Report, Connecticut Hospital Association

[\[back to question\]](#)



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

August 1, 2013

IN THE MATTER OF:

An Application for a Certificate of Need filed
Pursuant to Section 19a-638, C.G.S. by:

Notice of Final Decision
Office of Health Care Access
Docket Number: 12-31810-CON

Yale-New Haven Hospital

Acquisition of a 3.0 Tesla Magnetic
Resonance Imaging Scanner for the
Yale-New Haven Children's Hospital

To: Ms. Nancy Rosenthal
Senior Vice President, Health Systems Development
Department of Planning & Business Development
Yale-New Haven Hospital
2 Howe Street
New Haven, CT 06511

Dear Ms. Rosenthal:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-638, C.G.S. On August 1, 2013, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

A handwritten signature in black ink, appearing to read "Kimberly R. Martone".

Kimberly R. Martone
Director of Operations

Enclosure

KRM:lkg

An Equal Opportunity Provider

(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)

410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Fax: (860) 418-7053 Email: OHCA@ct.gov

0036. 2/17/17



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital
20 York Street, New Haven, CT 06504

Docket Number: 12-31810-CON

Project Title: Acquisition of a Dedicated 3.0 Tesla Magnetic Resonance
Imaging Scanner for the Yale-New Haven Children's Hospital

Project Description: Yale-New Haven Hospital ("Applicant" or "YNHH") is proposing the acquisition of a 3.0 Tesla Magnetic Resonance Imaging ("MRI") Scanner dedicated for use at the Yale-New Haven Children's Hospital.

Nature of Proceedings: The Applicant published notice of its intent to file the Certificate of Need ("CON") application in *The New Haven Register* on November 14, 15 and 16, 2012. On December 14, 2012, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project. On March 15, 2013, OHCA deemed the CON application complete.

On March 22, 2013, the Applicant was notified of the date, time and place of the hearing. On March 23, 2013, a notice to the public announcing the hearing was published in *The New Haven Register*. Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a, a public hearing regarding the CON application was held on April 10, 2013.

Commissioner Jewel Mullen designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a(f). The public hearing record was closed on April 26, 2013.

Findings of Fact

1. YNHH is a not-for-profit 1,470-bed acute care general hospital located at 20 York Street, New Haven, Connecticut and a health care facility or institution as defined by Conn. Gen. Stat. § 19a-639. Ex. A, p. 273
2. YNHH is proposing the acquisition of a 3.0 Tesla Siemens Magnetom Skyra MRI Scanner, to be dedicated for use in the Children's Hospital located in the West Pavilion of its New Haven campus, with the following special features:
 - Undockable table, which in the event of an adverse reaction to anesthesia or other emergency during the scan, the staff can detach and remove the patient quickly, enhancing patient safety;
 - Short, wide bore design to reduce episodes of claustrophobia;
 - Advanced cardiac software for pediatrics which allows imaging of children with congenital cardiac disease;
 - Tim® 4G and DOT Engine Technology¹ for high resolution imaging and faster acquisition and exam time and patient personalization for the patient's condition or clinical questions, which ensures more consistent imaging on follow-up exams that monitor the progression of disease or growth of pathology;
 - Spectroscopy package to examine metabolic changes in the brain; and
 - Patient supervision package with special video camera for monitoring patients during an exam.

Ex. A, pp. 2, 75, 276; Ex. C, p. 306; Ex. I, p. 368, Prefiled Testimony of Dr. Thomas Robin Goodman, Interim Chair/Chief of Diagnostic Radiology at YNHH and the Chief of Pediatric Radiology at Yale University School of Medicine.
3. YNHH will centralize its pediatric MRI exams into a single location specifically designed for children; using dedicated staff and child life support; and with no exposure to adult patients.

Ex. A, p. 15; Ex. I, p. 368, Prefiled Testimony of Dr. Goodman.
4. YNHH proposes operating the dedicated pediatric MRI scanner 7 a.m. to 9 p.m. Monday through Friday and 7 a.m. to 5 p.m. on Saturday. Children are not scanned any later than 9 p.m. Ex. C, p. 302

¹ Total imaging matrix ("Tim®") and Day optimizing throughput ("DOT").

5. YNHH currently operates eleven (11) MRI Scanners at the following locations:

Table 1: YNHH's Existing MRI Scanners by Location

Name and Location	Location and Scanner No.	Type and Tesla Strength	Purpose
MRI Center New Haven Campus 20 York St., New Haven	MRI Center 1	Closed 3.0T	Orthopedic, large patients, brain & prostate imaging
	MRI Center 2	Closed 1.5T	Bariatric & routine imaging
	MRI Center 3	Closed 1.5T	Cardiac & liver transplant program imaging
Smilow Cancer Center New Haven Campus 20 York St., New Haven	MRI Smilow 1	Closed 3.0T	Breast imaging only
	MRI Smilow 2	Closed 3.0T	Inpatient, outpatient & emergency department
	MRI Smilow 3	Closed 1.5T	Inpatient, outpatient & emergency department
	MRI Smilow 4	Closed 3.0T	Inpatient, outpatient & emergency department
	Operating Room	Intraoperative MRI *	Operating room only
Temple Radiology Shoreline Medical Center 111 Goose La., Guilford		Closed 1.5T	Outpatient and satellite emergency department
Temple Radiology 60 Temple St. New Haven		Closed 1.5T **	Physician offices patients
North Haven Medical Center 6 Devine St. North Haven		3.0T ***	Outpatients, patients with multiple sclerosis and patients of Smilow's satellite cancer center

* 3.0 T MRI for operating room use only was authorized under CON Application 08-31289-CON.

** Until July 2012, a second scanner, a stand-up 0.6T, was also operating at this location. The scanner was replaced with a temporary mobile MRI and located in Hamden.

***The scanner became operational on March 18, 2013, replacing the mobile scanner operating in Hamden.

Ex. A, pp. 15, 16; Ex. C, pp. 294-299; Ex. L, p. 413

6. In addition to the MRI Scanners listed in Table 1, YNHH is a joint venture partner in the Saint Raphael Magnetic Resonance Center² which operates a 1.5T and a 3.0T scanner on the Saint Raphael Campus at 330 Orchard St., New Haven. The two scanners are not appropriate for pediatric use as there are no pediatric anesthesiology services on the Saint Raphael Campus. Ex. A, pp. 16,19

² YNHH submitted a CON application to OHCA on January 25, 2013, requesting authorization from OHCA to end the joint venture and become the sole owner of the Saint Raphael Magnetic Resonance Center.

7. In Fiscal Year (“FY”) 2012, 97% of inpatients discharged from YNHG originated from Connecticut.³ Three-quarters of these inpatient discharges were from the following Connecticut towns: New Haven, West Haven, Hamden, East Haven, Branford, Bridgeport, Milford, North Haven, Guilford, Wallingford, Madison, North Branford, Waterbury, Meriden, Cheshire, Groton, Stratford, Clinton, Shelton, and Orange (“Service Area”).
CT DPH, Office of Health Care Access Acute Care Discharge Database
8. A dedicated MRI Scanner for the Children’s Hospital will enable pediatric MRI service centralization; create a pediatric friendly environment; and increase the efficiency of staff since:
- MRI is the preferred imaging modality for children because it does not involve exposure to radiation;
 - Pediatric patients are currently served on various MRI Scanners located in multiple buildings designed for and primarily serving adult inpatients, outpatients, emergency department and trauma patients, exposing the children to a variety of ill adults and potentially increasing their anxiety about the procedure;
 - It will eliminate having to continuously move specialized pediatric staff to the different MRI locations to provide sedation and anesthesia for children that need it to receive their scans.
- Ex. A, pp. 4-6; Ex. C. pp. 302-306
9. The current MRI procedure requires that children receiving an MRI scan be:
- Transported to an adult area away from other pediatric services;
 - Exposed to ill adults, including oncology, trauma and surgical patients; and
 - Required to use physical facilities that do not offer any child-sized furniture or equipment or child-oriented décor which help to reduce fear and anxiety.
- Ex. A, pp. 20, 22
10. Dr. Thomas Robert Goodman, Interim Chair/Chief of Diagnostic Radiology at YNHG and the Chief of Pediatric Radiology at Yale University School of Medicine, testified that “The majority of pediatric MRI scans are performed on the MRI Scanners in the Smilow Cancer Hospital.” Ex. A, p. 18; Ex. I, pp. 367-368, Prefiled Testimony of Dr. Goodman
11. The proposed MRI Scanner, to be operated in a child-friendly and clinically appropriate environment, will:
- Accommodate the growth of MRI scanning as a preferred imaging modality for children;
 - Improve the delivery of pediatric MRI services; and
 - “provide a much improved environment for pediatric patients undergoing an MRI exam.”
- Ex. A, pp. 14, 16; Ex. I, p. 368, Prefiled Testimony of Dr. Goodman

³ The remaining 3% were from other states and countries.

12. Pediatric MRI scanning at YNHH grew 24% between 2009 and 2012. The following table reports the actual volumes by fiscal year and type of patient.

Table 2: Actual Pediatric MRI Scan Volume by Fiscal Year and Type

Type	2009	2010	2011	2012
Inpatient	760	1,034	939	1,077
Outpatient	2,937	3,246	3,388	3,370
Emergency	47	57	130	194
Total	3,744	4,337	4,457	4,641
Year to Year Increase	-	15.8%	2.8%	4.1%
Increase from 2009-2012				24%

Ex. A, p. 26

13. MRI scans are increasingly being preferred over computed tomography as an imaging modality for children since they do not involve exposure to radiation. In addressing the increased risks to children, Dr. Goodman stated, "Specifically, their bodies and tissues are more sensitive and too much radiation can increase the risk of developing a radiation-related cancer." Ex. A, pp. 14, 48; Ex. I, p. 368, Prefiled Testimony of Dr. Goodman
14. Recent developments in MRI technology, such as specialized pediatric coils and monitors, rapid pulse sequences, functional and metabolic imaging and novel contrast agents have led to an increase in MRI scanning of the body, brain, spine and bones. MRI is used by YNHH to assess pediatric heart function, metastatic screening, multifocal osteomyelitis, avascular necrosis and vascular anomalies. MRI also precludes expensive invasive procedures in pediatric patients, such as liver biopsies. Ex. I, pp. 370, 371, Prefiled Testimony of Dr. Goodman
15. YNHH's Y Access Transfer Line, which coordinates the transfer and admission of acutely ill patients to the hospital from referring physicians, is leading to significant increases in the number of acutely ill children transferred to the children's hospital, driving up the demand for pediatric MRI services, particularly those requiring anesthesia. Pediatric MRI transfers from non-YNHH physicians grew from 431 in FY 2010 to 1,018 in FY 2012, a 136 % increase. Ex. A, pp. 7-8; Ex. C, p. 307
16. Many children receiving an MRI scan frequently require sedation or general anesthesia since it is difficult for them to remain still during an hour-long scan. Therefore, pediatric MRI scans must be performed where pediatric anesthesia and sedation services can be provided. The percentage of children requiring anesthesia or sedation grew from 9% to 28% of annual pediatric MRI scan volumes between FY 2009 and FY 2012. Ex. A, pp. 14, 15; Ex. C. p. 409
17. Pediatric MRI scans that require anesthesia or sedation must have a pediatric anesthesiologist or nurse anesthetist present. "The Smilow Cancer Hospital is currently the only area where anesthesia or sedation services can be safely administered for pediatric patients." Ex. I, p. 369, Prefiled Testimony of Dr. Goodman

18. According to YNHH, none of the providers in its Service Area provide pediatric anesthesiology and pediatric MRI services. Ex. A, p. 25
19. As there are a limited number of facilities in the state that provide pediatric anesthesiology and MRI services, most pediatric MRI cases are referred to YNHH and Connecticut Children's Medical Center. Referral patterns are not expected to change as a result of the acquisition of the proposed MRI Scanner. Ex. A, p. 17
20. The proposed MRI Scanner, scan room and support spaces will facilitate the administration of sedation or anesthesia, reduce patient anxiety and improve the throughput of pediatric MRI patients. "Centralizing efforts into one area has added advantages, as well, in that [YNHH] is able to perform sedation and anesthesia far more easily and, therefore reduce the waiting time for children to have these types of examination." Ex. A, p. 33, Tr. Testimony of Dr. Goodman, p.7
21. Dr. Goodman testified that:
- A children's hospital without a pediatric MRI scanner is extremely unusual;
 - MRI is a vital component for pediatric imaging with an ever-growing list of indications for pediatric MRI use, including bowel pediatric enterography, urography, and cardiac work;
 - Children are susceptible to the carcinogenic effects of ionizing radiation that can damage a child's cells;
 - A dedicated pediatric MRI environment includes staff trained to deal with children, including nurses, child life specialists, pediatric anesthesiologists, and the pediatric radiologists;
 - Provision of pediatric MRI services on a dedicated scanner becomes easier for sedation and anesthesia cases and reduces the waiting time for children in general; and
 - Moving children out of adult scanners into a dedicated pediatric scanner provides space for other adult indications for MRI.
- Tr. Testimony of Dr. Goodman, pp.6-8
22. YNHH expects to initiate the use of the pediatric MRI Scanner at the start of FY 2014. The projected utilization of the pediatric MRI Scanner for inpatients and outpatients is reported in the following table, and reflects a projected 1% annual increase.

Table 3: Projected Utilization of the Proposed Pediatric MRI Scanner

	FY 2014	FY 2015	FY 2016
Projected Pediatric MRI Scans	4,261	4,304	4,346

Ex. A, pp. 18, 31; Ex. C, p. 313

23. YNHH assumes that 10% of the pediatric volume, mostly older children who do not require sedation, will receive their MRI scans on one of the scanners at the MRI Center. Ex. A, p 26; Ex. C, pp. 294, 296, 297
24. The total estimated capital expenditure for the acquisition of the MRI Scanner is \$5,875,828, including the imaging equipment purchase for \$2,392,690 and \$3,483,138 for

the required construction and renovations. YNHH will finance the project with operating funds (20%) and funded depreciation (80%). Ex. A, pp. 20-21

25. YNHH projects the following incremental gain from operations for the project:

Table 4: YNHH Incremental Gain from Operations Description

	FY 2014	FY 2015	FY 2016
Incremental Revenue from Operations	\$3,655,000	\$3,803,000	\$3,956,000
Incremental Operating Expense*	1,627,000	2,021,000	2,060,000
Incremental Gain from Operations	\$2,028,000	\$1,782,000	\$1,896,000

* Includes salaries, fringe benefits, professional and contracted services, supplies and drugs and depreciation.
Ex. A, p. 285

26. The minimum number of MRI scans required to show an incremental gain from operations for each of the next three fiscal years is between 803 and 969 scans.

Table 5: YNHH Minimum Number Required to Show Incremental Gain

Description	FY 2014	FY 2015	FY 2017
Total Incremental Operating Expenses	\$1,627,123	\$2,020,902	\$2,060,199
Average Revenue per Scan	\$2,025	\$2,086	\$2,149
Scans Needed to Show Incremental Gain from Operations	803	969	959

Ex. A, p. 33

27. YNHH expects the payer mix with the proposal to remain constant at FY 2013 distribution since the project will serve YNHH's existing patient population which is 36% government and 64% non-government:

Table 6: Current and Projected Patient Population Payer Mix

Primary Payer	Current FY 2013	Year 1 FY 2014	Year 2 FY 2015	Year 3 FY 2016
Medicare	0%	0%	0%	0%
Medicaid	35%	35%	35%	35%
CHAMPUS/TriCare	1%	1%	1%	1%
Total Government	36%	36%	36%	36%
Commercial	61%	61%	61%	61%
Uninsured	2%	2%	2%	2%
Workers Compensation	0%	0%	0%	0%
Total Non-Government	64%	64%	64%	64%
Total Payer Mix	100%	100%	100%	100%

Ex. A, pp. 21-22.

28. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))
29. This CON application is consistent with the overall goals of the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
30. YNHH has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
31. YNHH has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
32. YNHH has satisfactorily demonstrated that its proposal would improve the accessibility of health care delivery in the region and it has satisfactorily demonstrated a potential improvement in quality and cost effectiveness. (Conn. Gen. Stat. § 19a-639(a)(5))
33. YNHH has shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))
34. YNHH has satisfactorily identified the population to be served by its proposal and has satisfactorily demonstrated that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))
35. YNHH's historical MRI scanner utilization in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
36. YNHH has satisfactorily demonstrated that its proposal would not result in an unnecessary duplication of existing MRI scanning services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in § 19a-639(a) of the Statutes. The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008).

Yale New Haven Hospital (“YNHH” or “Applicant”) is a not-for-profit 1,470-bed acute care general hospital located at 20 York Street, New Haven, Connecticut. Finding of Fact (“FF”) 1 YNHH is proposing the acquisition of a 3.0 Tesla Magnetic Resonance (“MRI”) Scanner to be dedicated for use in the Children’s Hospital located in the West Pavilion of its New Haven campus. YNHH will centralize its pediatric MRI exams into the single location specifically designed for children; using dedicated staff and child life support; ensuring pediatric patients have no exposure to adult patients. The proposed MRI Scanner will be designed for the safety of the children; include an undockable table; a short, wide bore design to reduce episodes of claustrophobia; and patient supervision package to monitor patients during scanning. The proposed MRI Scanner will also have advanced cardiac software; spectroscopy package; and technology for patient personalization. *FF 2&3.*

YNHH currently operates eleven MRI Scanners. On the main campus in New Haven there are three scanners in the MRI Center and five in the Smilow Cancer Center, including an intraoperative MRI Scanner that is used solely for patients having surgery. The Shoreline Medical Center in Guilford, Temple Radiology in New Haven, and the North Haven Medical Center each has one scanner. *FF 5.* There are two additional scanners on YNHH’s Saint Raphael campus that are not appropriate for pediatric use since there are no pediatric anesthesiology services available. *FF 6.*

MRI scans are increasingly being preferred over computed tomography as an imaging modality for children, as children are susceptible to the carcinogenic effects of ionizing radiation that can damage a child’s cells. *FF 13.* Moreover, there is an ever-growing list of indications for pediatric MRI use, including bowel pediatric enterography, urography, and cardiac work. *FF 14&21.* Additionally, the number of acutely ill pediatric patients transferred and admitted to YNHH through its Y Access Transfer Line is driving up the demand for pediatric MRI services. *FF 15.* Between 2009 and 2012, YNHH’s volume of pediatric MRI scans has grown 24%. *FF 12.*

As many as 28% of the children receiving MRI scans require sedation or general anesthesia since it is difficult for them to remain still during an hour-long scan. Currently, the Smilow Cancer Hospital is the only area where anesthesia or sedation services can be safely administered to pediatric patients, but transporting them to Smilow exposes them to oncology, trauma and surgical patients, which may induce fear and anxiety. A dedicated pediatric MRI Scanner in the children’s hospital will eliminate the need to move specialized pediatric staff to different MRI locations to administer sedation and anesthesia to children. *FF 8, 10, 16, 17 & 20.*

Based on the anticipated increase in the use of pediatric MRI scans; the proposed MRI Scanner's advanced imaging capabilities; and the unique environment in which the proposed MRI Scanner will be located, OHCA concludes that YNHH has demonstrated a clear public need for its proposal. Additionally, none of the other MRI scan providers in YNHH's Service Area provide pediatric anesthesiology and pediatric MRI services. *FF 18*. Therefore, OHCA concludes that there will not be an unnecessary duplication of existing MRI scanning services.

The total estimated capital expenditure for the acquisition of the proposed MRI Scanner and the construction and renovations needed to accommodate the MRI Scanner is \$5,875,828, to be financed through YNHH's funded depreciation and operating funds. *FF 24*. YNHH projects incremental gains from operations associated with the proposal for the first three full fiscal years of operation. *FF 25*. Therefore, OHCA concludes that the proposal is financially feasible.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Yale-New Haven Hospital for the acquisition of a 3.0 Tesla Magnetic Resonance Imaging Scanner to be located at 20 York St., New Haven, Connecticut, and dedicated to pediatrics, is hereby **APPROVED**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

Date

8/1/13


Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner

EXHIBIT

1

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 2-CH

Children's Hospital

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

Connecticut Children's Medical Center of Hartford, CT d/b/a Connecticut Children's Medical Center is hereby licensed to maintain and operate a Children's Hospital.

Connecticut Children's Medical Center is located at 282 Washington Street, Hartford, CT 06106-3322.

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

72 Bassinets
115 General Hospital Beds

This license expires **December 31, 2017** and may be revoked for cause at any time.

Dated at Hartford, Connecticut, January 1, 2016. RENEWAL.

Satellites:

Neo-Natal Intensive Care Unit, North Building, Hartford Hospital
CCMC/Waterbury Unit/Sacred Heart Bldg./St. Mary's Hospital, 56 Franklin Street, Waterbury
Neo-Natal Intensive Care Unit, John Dempsey Hospital, 263 Farmington Avenue, Farmington
CCMC Ambulatory Surgery Center, 505 Farmington Avenue, Farmington



Handwritten signature of Jewel Mullen in black ink.

Jewel Mullen, MD, MPH, MPA
Commissioner

EXHIBIT

2

PATRICK J GARVEY, CPA, CHFP
25 Birch Rd
West Hartford, CT 06119
(860) 545-8557 (W), (203) 641-5645 (C), pgarvey@connecticutchildrens.org

SUMMARY OF QUALIFICATIONS

Financial Administrator with 20+ years of increasing financial reporting and accounting responsibilities and supervision. Experienced in all areas of financial statement preparation and analysis, financial planning, budgeting, and financial reporting. From 2004 through the present, held various financial positions in healthcare, with the overall goal of developing a standardized and consistent financial reporting package to senior management and boards of directors as well as streamlining the close and reporting processes. Has served as Chief Financial Officer for the past 3+ years.

PROFESSIONAL EXPERIENCE

Connecticut Children's Medical Center (a 187 bed Freestanding Children's Hospital)

Senior Vice President and Chief Financial Officer – April 2014 – Present

Interim CFO March 2013 – March 2014

Sr. Director & Corporate Controller- November 2009 – March 2013

Responsibilities include:

- Responsible for the guidance of the entire financial operation of the organization. This includes the accounting operation, taxes, treasury, budgeting and the revenue cycle. Scope of influence for a staff of approximately 90 people.
- Completed executive level training in Lean Management and performing leader standard work rounding in units and influencing the lean activities. Combined with safety rounding to ensure that both safety and efficiency are top of mind for all line level staff in the institution. Currently engaging with our Lean consultants on an overarching implementation of Lean principles in the Revenue Cycle.
- Finance lead for Connecticut Children's Huron engagement which yielded revenue improvements and expense savings of approximately \$25 million. Led the Revenue Cycle project which included the implementation of Huron's workflow tools and establishing productivity measures for revenue cycle staff. Responsible for the validation and verification of the savings experienced during the engagement.
- Responsible for the analysis and implementation of insurance programs including professional malpractice, property, business interruption, general liability as well as significant umbrella policies. Working regularly with Risk Management staff and external advisors, we determine the appropriate levels of coverage and manage all the risks surrounding the operations of the hospital. In 2017, established a wholly owned captive insurance company to insure all the professional liability and umbrella policies for Connecticut Children's Medical Center. Working with predecessor insurer to novate all outstanding claims to the new captive insurer.
- Presentation of monthly consolidated financial reporting package to the Finance Committee and the Board of Directors as well as the organization's internal leadership group comprised of Executive Management, directors, managers and supervisors to inform them about the operating results of the organization.
- Overseeing the implementation of a new Enterprise Resource Planning system (Lawson) and the transition from our existing software currently shared with Hartford Hospital. Working with both Connecticut Children's and Hartford Hospital leadership to ensure a smooth transition for both organizations.

- Responsible for all aspects of debt reporting on a monthly, quarterly and annual basis, including completing officer's certifications of compliance with debt covenants and relevant financial reports to bondholders. Led the refinance of approximately \$40 million of outstanding debt into a direct placement of variable rate bonds, utilizing an interest rate swap to synthetically fix the interest at significant savings to Connecticut Children's.
- Working with appropriate parties on new strategic initiatives and projecting their financial impact to ensure that proposals are sensible for both short term and long term objectives and organizational health. Evaluating the capital needs of these strategic initiatives and determining if additional debt issuance is required.
- Working closely with Executive Management Team members, on the evaluation, analysis and financing of an Electronic Medical Record adoption.
- Working with the Director of Budget, overseeing the creation, analysis and reporting of the annual operating and capital budgets and presenting the proposals to the Finance Committee, Board of Directors and the departmental end users.
- Responsible for ensuring that financial policies are adequate, controls are in place, and that a regular review of policies and procedures is completed to ensure continued compliance with existing policies.

**Hospital for Special Care (a 228 bed Long-Term Acute Care Hospital)
Corporate Manager of Accounting and Budget- September 2008- November 2009**

Responsibilities include:

- Responsible for overseeing all aspects of the Fiscal Department's operations. Guiding a staff of five through the month end close process, consolidation of financial statements, year end audit, internal audits, budgeting and all reporting requirements. Additionally, served as support for clinical staff in the analysis and review of results and assist in the preparation of budgets for the individual units.
- Responsible for projecting the financial impact of proposed business opportunities to ensure that proposals are sensible for both short term and long term objectives and organizational health.
- Reporting requirements includes internal management reports, Form 990, payroll tax returns, reporting to CHEFA, US Bank (trustee) and Radian (bond insurer) on interim results and reporting on the organizations meeting of bond covenants as well as miscellaneous other reports on an ad hoc basis.

**Yale-New haven Health System (a \$1.5 billion healthcare organization)
Manager of Revenue Reporting and Analysis- December 2007- September 2008
Manager of Financial Reporting- June 2006- December 2007
Senior Financial Accountant/Analyst- January 2004- June 2006**

Responsibilities include:

- Oversight and reporting on monthly revenue close and results. Analysis of key revenue drivers, including surgical implants to ensure that claims are paid appropriately. Analysis of service mix by physician to identify opportunities to maximize contribution margins.
- Manage a staff of five professionals with the goal of ensuring that the reporting function for the organization is efficient, accurate and flexible. Publication of Board of Finance packages, including detailed analysis, projections, budgets and special proposals to members of the board.
- Oversee the preparation of annual audited financial statements and footnotes as well as directing the year end audit.

Connecticut Container Corporation (a manufacturer of corrugated cardboard products)

Senior Accountant (2001-2004)

- Oversight of A/P, A/R, billing and collections of the division. Responsible for completion of a timely and accurate month end close process, financial statement analysis and financial reporting to CFO and CEO. Instrumental in the company's implementation of a new financial software program

Sirocco Systems/ Sycamore Networks (Telecommunications equipment manufacturers)

Senior Accountant (2000-2001)

- Responsible for the financial function, from invoice entry to financial statement preparation and audit support. Lone financial staff member, reporting to CFO. Duties included daily data entry to special analysis for CFO and CEO of the company, budgeting, projections, monthly close and financial reporting. Also instrumental in the integration of Sirocco Systems financial data into Sycamore Networks financial systems after Sycamore Networks' \$2.9 billion purchase of Sirocco Systems. Post merger, I was responsible for the monthly analytic review of the Sirocco division.

Connecticut Pikaart, Viconti & Associates (a quality local CPA Firm)

Staff Accountant (1996-2000)

- Preparation of income tax returns, compilation of client financial statements and completion of audit field work.

EDUCATION

Southern Connecticut State University, New Haven, Connecticut

Bachelor of Science, Magna Cum Laude, December 1995

Major: Accounting

Inducted into the Delta Mu Delta Business Honor Society, 1995

Certified Public Accountant, 2000

Certified Healthcare Financial Professional, 2011

BOARD EXPERIENCE

Regular reporting of financial results and recommendations to Connecticut Children's Medical Center Finance Committee of the Board of Directors, December 2010 - present

Appointed to the Winding Trails, Inc. Finance Committee, Jan. 2014 – present, Chair 2015

Appointed to the Winding Trails, Inc. Board of Directors, Jan. 2015 – Present

Appointed as Treasurer for Winding Trails, Inc. Jan. 2016 - Present

Appointed to the Prudence Crandall Center's Board of Directors, October 2011 – July 2015

Member of the Prudence Crandall Center's Finance Committee, November 2011 – July 2015

Secretary of the Board of Directors, November 2012 – December 2014

Elected to the Board of Directors of the Connecticut Chapter of Healthcare Financial Management Association May 2012 – February 2015

CURRICULUM VITAE

Jonathan Martin, MD, FAANS

Personal Information:

Birthdate: January 2, 1971

Mailing Address: Department of Pediatric Neurosurgery
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
(860) 545-8373
(860) 545-8233 (fax)
jmartin03@ceemekids.org

Home Address: 22 Drumlin Road
West Simsbury, CT 06092
(860) 299-3500

Medical License(s):

Active

Connecticut #046724
Massachusetts #261522

Inactive:

Hawaii #13175
Oregon #21270
Wyoming #TL674

National Provider: 1275512980
Identification

Education:

Medical: University of Vermont College of Medicine
Burlington, VT
MD, awarded June 1997

Undergraduate: Bowdoin College
Brunswick, ME
BA, awarded May 1992

Post-Graduate Training:

Fellowship: Pediatric Neurosurgery
Children's National Medical Center
Washington, DC
July 2003-March 2004
Chairman: Robert Keating, MD

Residency National Capital Region Consortium
Neurosurgery Residency Program
Washington, DC
January 2000-March 2004
Chairman: James Ecklund, MD

Oregon Health Sciences University
~~Neurosurgery Residency Program~~
Portland, OR
July 1998-June 1999
Chairman: Kim Burchiel, MD

Internship Walter Reed Army Medical Center
General Surgery Internship
Washington, DC
July 1997-June 1998
Chairman: David Jacques, MD

Faculty Appointments:

January 2016-present Chief, Division of Neurosurgery
Connecticut Children's Medical Center
Hartford, CT

September 2015-present Associate Professor, Dept of Surgery
University of CT School of Medicine
Farmington, CT

February 2009-May 2015 Assistant Professor, Dept of Surgery
University of CT School of Medicine
Farmington, CT

April 2007-September 2007 Attending Physician, Neurosurgery
332nd Medical Operations Squadron
Balad, Iraq

May 2005-January 2007 Chief, Division of Neurosurgery
Tripler Army Medical Center

Honolulu, HI

April 2004-September 2008 Attending Physician, Neurosurgery
Tripler Army Medical Center
Honolulu, HI

July 2003-September 2008 Clinical Instructor, Surgery
Uniformed Services University of the Health Sciences
Bethesda, MD

July 1999-December 1999 2nd Brigade Surgeon, 3rd Infantry Division
Fort Stewart
Hinesville, GA

Hospital Privileges:

July 2015 – present Baystate Children’s Medical Center
Springfield, MA

October 2008-present Connecticut Children’s Medical Center
Hartford, CT

October 2008-present Hartford Hospital
Hartford, CT

March 2006-October 2006 Wyoming Medical Center
Casper, WY

April 2004-September 2008 Tripler Army Medical Center
Honolulu, HI

July 1999-December 1999 Winn Army Community Hospital
Hinesville GA

Board Certification:

December 2014 Diplomate, American Board of Pediatric Neurosurgery
Certificate Number: #14-0314

November 2007 Diplomate, American Board of Neurological Surgery
Certificate Number: #27116

May 1998 Diplomate, American Board of Medical Examiners

Other Certification:

Aug 2016- present Disaster Management and Emergency Preparedness,
Instructor

Jun 2007-present Advanced Trauma Life Support, Instructor

Professional Societies:

Oct 2016-present American College of Surgeons

February 2016-present American Society of Pediatric Neurosurgery

February 2014-present Children's Oncology Group

March 2010-present Pediatric-Craniocervical Society

January 2009-present American Association of Neurological Surgeons

January 2009-present Trauma Section
American Association of Neurological Surgeons

January 2009-present Pediatric Section
American Association of Neurological Surgeons

Honors and Awards:

July 2016 Didactic Teaching Award
University of Connecticut School of Medicine
Pediatric Residency Program
Farmington, CT

June 2016 McNeill Teaching Award
University of Connecticut School of Medicine
Pediatric Residency Program
Farmington, CT

May 2016 2015 Vitals Patient's Choice Award

May 2016 2015 Vitals Compassionate Doctor Award

April 2016 Voted to *Top Doc 2016*- Pediatric Neurosurgery
Connecticut Magazine, Hartford, CT

April 2015 Voted to *Top Doc 2015*- Pediatric Neurosurgery
Connecticut Magazine, Hartford, CT

October 2014 2014 Vitals Patient's Choice Award

July 2014	2014 Top Ten Doctor, Hartford CT
January 2014	2013 Compassionate Doctor Award
December 2013	Continuing Education Award in Neurosurgery American Association of Neurological Surgeons
September 2013	2013 Patient's Choice Award
February 2013	2012 Compassionate Doctor Award
January 2013	2012 Patient's Choice Award
January 2012	2011 Patients' Choice Award
December 2010	Continuing Education Award in Neurosurgery American Association of Neurological Surgeons
December 2008	McNeill Teaching Award University of Connecticut School of Medicine Pediatric Residency Program Farmington, CT
May 2008	Meritorious Service Medal US Army
December 2007	Continuing Education Award in Neurosurgery American Association of Neurological Surgeons
September 2007	Bronze Star Medal US Army
July 2007	Combat Action Badge US Army
June 2007	Purple Heart Medal US Army
June 2003	Department of Neurology Resident Instructor of the Year Uniformed Services University of Health Sciences Bethesda, MD
May 2003	Army Commendation Medal US Army

June 2002	Department of Neurology Resident Instructor of the Year Uniformed Services University of Health Sciences Bethesda, MD
February 2000	Army Commendation Medal US Army
August 1992	Maine Army National Guard Adjutant General Award
May 1992	Departmental Honors, Biochemistry Thesis: "Discovery of a Phosphite-dependent pyrophosphate synthetase in a marine bacterium" Bowdoin College Brunswick, ME

May 1991	Merck Summer Research Fellowship Bowdoin College Brunswick, ME
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Committees and Clinical Programs:

Sept 2016	Chief, Urology Search Committee
Jan 2016- present	Chief, Division of Neurosurgery Connecticut Children's Medical Center
Sep 2014-Jan 2016	Assistant Chief, Division of Neurosurgery Connecticut Children's Medical Center
Sep 2014-present	Associate Director for Trauma Connecticut Children's Medical Center
Dec 2013-Aug 2016	Co-Chairman, Compliance Committee Connecticut Children's Medical Center
Mar 2010-present	Active Member, Trauma Committee Connecticut Children's Medical Center
June 2009-Jan 2016	Ethics Committee Connecticut Children's Medical Center
May 2009-Aug 2016	Active Member, Compliance Committee Connecticut Children's Medical Center

Volunteer International Neurosurgical Activities:

June 2010-present Medical Advisor
Afghan Care Today

May 2005-May 2008 Operation Smile/World Healing Institute
Tripler Army Medical Center

Undergraduate Student Clinical and Research Internships:

Ryan Geelan, Trinity College Senior, January 2014-June 2014
“An Evaluation of Methods Used to Improve Pediatric Craniocervical Measurement Fidelity”

Nicole Albino, Trinity College Senior, January 2010-June 2010
“Measured Outcomes of Neurosurgeries During the Iraq War”

Publications:

Peer-Reviewed Journal Articles:

1. **Martin JE***, Teff RJ, Spinella PC. Care of pediatric neurosurgical patients in Iraq, 2007: clinical and ethical experience of a field hospital. *J Neurosurg Pediatr.* 2010;6(3):250-56.
2. Bowen DK, Mitchell LA, Burnett MW, Rooks VJ, **Martin JE***. Spinal epidural abscess secondary to tropical pyomyositis in immunocompetent adolescents: case series and review of the literature. *J Neurosurg Pediatr.* 2010;6(1):33-37.
3. Ragel BT, Klimo P Jr, **Martin JE**, Teff RJ, Bakken H, Armonda RA, Wartime decompressive craniectomy: technique and lessons learned. *Neurosurg Focus.* 2010;28(5):E2.
4. Mitchell LA, Rooks VJ, **Martin JE**, Burgos RM. Paraspinal tropical pyomyositis and epidural abscesses presenting as low back pain. *Radiol Case Rep*, online. 2009;4(3):epub.
5. **Martin J***, Neal C, Moores L, Ecklund J. Use of a nitrogen arm-stabilized endoscopic microdriver in neuroendoscopic surgery. *Minim Invasive Neurosurg.* 2005;48:63-65.
6. Rushing EJ, Bouffard JP, Neal CJ, Koeller K, **Martin J**, Ozdemerli M, Mena H, Ecklund J. Erdheim-Chester Disease mimicking a primary brain tumor: a case report. *J Neurosurg.* 2004;100:1115-18.

7. **Martin JE***, Mehta R, Aarabi B, Ecklund JE, Martin AH, Ling GS. Intracranial insertion of a nasopharyngeal airway in a patient with craniofacial trauma. *Mil Med.* 2004;6:496-97.
 8. **Martin JE***, Neal CJ, Monacci WT, Eisenman DJ. Superior semicircular canal dehiscence: a new indication for middle fossa craniotomy. *J Neurosurg.* 2004;100:125-27.
 9. **Martin JE***, Keating RE, Cogen PH, Midgley F. Long-term follow-up of direct heart shunts in the management of hydrocephalus. *Pediatr Neurosurg.* 2003;38:94-97.
 10. Frank E, **Martin JE**, Hsu F. An endoscopic curved Kerrison rongeur for spinal stenosis surgery. *Minim Invas Neurosurg.* 2002;45:254-56.
-

Letters:

1. Brockmeyer DL, Oakes WJ, Rozzelle C, Johnston J, Rocque BG, Anderson RCE, Feldstein N, **Martin J**, Tuite GF, Rodriguez L, Wetjen N, Aldana P, Pincus D, Storm P, Proctor MR, Lew S. Chiari malformation Type 1 and atlantoaxial instability: a letter from the Pediatric Craniocervical Society. *Journal of Neurosurgery: Spine.* 2015; 17.

Book Chapters :

1. Spinella PC, **Martin, JE**, Azarow KS. Chapter 11: Pediatric trauma. In: Savitsky E, Eastridge B, editors. *Combat casualty care: lessons learned from OEF and OIF.* Washington, DC: United States, Department of the Army, Office of the Surgeon General, Borden Institute; 2012. p. 529-91.
2. Spinella PC, **Martin JE**, Azarow KS. Pediatric trauma. *Combat casualty care: lessons learned from OEF & OIF.* [DVD] Los Angeles, CA: Pelagique, LLC; 2010.
3. **Martin JE***, Bakken HE, Bell RS. Chapter 10: Neurosurgery. In: Fuenfer MM, Creamer KM, editors. *Pediatric surgery and medicine for hostile environments.* Washington, DC: United States, Department of the Army, Office of the Surgeon General, Borden Institute; 2010. p. 77-92.
4. Aarabi B, Eisenberg H, O'Mally BW, **Martin JE**. Surgical management of CSF leaks. In: Sekhar LL, Fessler R, editors. *Atlas of neurosurgical techniques.* New York: Thieme Medical Publishers; 2006. p. 927-37.
5. **Martin JE***, Monacci JE. Metastatic disease of the cranial cervical junction. In: Batjer HH, Loftus CM, editors. *Textbook of neurological surgery:*

principles and practice. Philadelphia: Lippincott Williams & Wilkins; 2003. p. 1808-11.

Other Journal Articles:

1. **Martin JE***, Keating RF. Review of atypical etiologies of tethered spinal cord syndrome for the general neurosurgical practitioner. *Semin Spine Surg.* 2005;17: 30-39.
 2. **Martin JE***, Armonda RA. Carotid dissection: a clinical review. *Semin Neurosurg.* 2002;13(3):265-78.
 3. Moores LE, **Martin JE**. Myelomeningocele and tethered cord: caring for an aging population. *Semin Neurosurg.* 2002;13(1):61-69.
-

Oral Presentations:

Peer-Reviewed Submissions:

1. **Martin JE***. C1 lateral mass screws in the reduction of atlanto-axial deformity: technical note. 38th Annual Meeting of the American Society of Pediatric Neurosurgery; 2015 Jan; Kohala Coast, HI.
2. Tabak B, Teff R, Armonda R, **Martin JE**. Stabbed in the brain – coordinated tri-service care of a critically injured soldier from point of injury to Echelon 5 on the modern battlefield. 30th Gary P. Wratten Surgical Symposium; 2008 Apr; Bethesda, MD.
3. **Martin JE***, Donovan DJ. Use of minimally-invasive techniques for tethered cord release: technical note. AANS/CNS Section of Pediatric Neurosurgery Annual Meeting; 2005 Dec; Orlando, FL.
4. Keating RF, **Martin JE**, Boyajian M, Posnick J, Bruce D. Delayed repair of scaphocephaly: significance of intracranial pressure. AANS/CNS Section of Pediatric Neurosurgery Annual Meeting; 2004 Dec; San Francisco, CA.
5. **Martin JE***, Ecklund JE, Keating RF. Low-frontal transventricular endoscopic approach to the pineal region. AANS/CNS Section of Pediatric Neurosurgery Annual Meeting; 2004 Dec; San Francisco, CA.
6. **Martin JE***, Bell RS, Monacci WT, Moquin RR, Ecklund JE, Ling GS. The neurosurgical experience at an Echelon 5 facility during Operation Iraqi Freedom. American Association of Neurological Surgeons; 2004 May; Orlando, FL.

7. **Martin JE***, Neal CJ, Ecklund JE, Moores LE. Use of an endoscopic microdriver in minimally invasive neurosurgery. Congress of Neurological Surgeons; 2003 Oct; Denver, CO.
 8. **Martin JE***, Moores LE. Independent learning modules for pediatric neurosurgery. AANS/CNS Section of Pediatric Neurosurgery Annual Meeting; 2002 Dec; Phoenix, AZ.
 9. Ramage A, Blanchard J, Menzies R, Crommett J, Rosner M, **Martin J**, Ecklund J, Rhee P, Fitzpatrick T, Ling G. A novel tool for predicting brain injury in the trauma patient. 30th Society of Critical Care Medicine Educational and Scientific Symposium; 2001 Feb; San Francisco, CA.
-
10. Kellogg J, Horgan M, **Martin J**, Chesnut R. Does CPP therapy really do what we think it does? Congress of Neurological Surgeons; 1999; Boston, MA.

Invited Presentations:

Professional Conferences:

1. **Martin JE***. Austere Surgical Care- Models of care delivery in the developing world. 12th Annual Trauma Symposium: Rural Trauma Care- Pushing the Golden Hour. 2016 October; Saint Francis Hospital and Medical Center, Hartford, CT.
2. **Martin JE***. Pediatric Head Injury- The first thirty minutes. Pediatric Trauma: An update for EMS Providers. 2016 January; Connecticut Children's Medical Center, Hartford, CT.
3. **Martin JE***. Neurosurgical Lessons Learned from the Battlefield and Their Implications for the Acute Care Surgeon. 17th Annual CT Trauma Conference; 2015 April; Foxwoods Resort and Conference Center, Ledyard, CT.
4. **Martin JE***. Radiographic evaluation of the pediatric neuro-oncology patient. 16th Annual Pediatric Radiology Conference; 2014 May; Connecticut Children's Medical Center, Hartford, CT.
5. **Martin JE***. The evolution of cervical spine clearance: where are we in 2014? CT Trauma 14; 2014 Mar; Foxwoods Resort and Conference Center, Ledyard, CT.

6. **Martin JE***. Faculty/moderator, Pediatric Craniocervical Society, 28th Annual Meeting AANS/CNS Section on Disorders of the Spine and Peripheral Nerves; 2012 Mar; Orlando, FL.
7. **Martin JE***. Faculty/moderator, Pediatric Craniocervical Society, 27th Annual Meeting AANS/CNS Section on Disorders of the Spine and Peripheral Nerve; 2011 Mar; Phoenix, AZ.
8. **Martin JE***. Damage control neurosurgery. CT Trauma 10: The Many Faces of Trauma Care; 2010 Apr; Foxwoods Resort and Conference Center, Ledyard, CT.
9. **Martin JE***. Management of the head injured patient at Echelon 3 and below: a critical appraisal of deployment neurosurgery. 14th Annual San Antonio Trauma Symposium; 2008 Aug; San Antonio, TX.

10. **Martin JE***. Abnormal head shape in infancy. Uniformed Services Pediatric Seminar; 2008 Mar; Honolulu, HI.
11. **Martin JE***. Neurocritical care: a conceptual overview of treatment paradigms. Fundamentals of Critical Care Support Conference; 2005 Mar; Tripler Army Medical Center, Honolulu, HI.

Scholarly Institutions:

1. **Martin JE**. Neurosurgical Lessons Learned from the Battlefield and their Implications for Emergency Care in the United States Healthcare System. Emergency Medicine Grand Rounds; 2015 October; Hartford Hospital, Hartford, CT.
2. **Martin JE***. Deployment neurosurgery: a personal experience with the 53rd Head and Neck Detachment during Operation Iraqi Freedom. Abbasy Lecture, Baystate Medical Center; 2015 March; Springfield, MA.
3. **Martin JE***. Abnormal head shape in infancy. Pediatric Grand Rounds, Baystate Medical Center; 2015 January; Springfield, MA.
4. **Martin JE***. Management of craniocervical junction instability in the pediatric patient: diagnostic and technical challenges of a select patient population. Department of Neurosurgery, Dartmouth-Hitchcock Medical Center; 2010 Oct.
5. **Martin JE***. Deployment neurosurgery: a personal experience with the 53rd Head and Neck Detachment during Operation Iraqi Freedom, April-September 2007. Division of Neurosurgery, University of Vermont College of Medicine; 2007 Nov.

Other:

1. **Martin JE***. Hydrocephalus and the primary care provider: what do I need to know? Department of Pediatrics Residency Program, Connecticut Children's Medical Center; 2016 October; Hartford, CT.
 2. **Martin JE***. Management of post-hemorrhagic hydrocephalus in the NICU. Neonatal Lunch Educational Series, Baystate Medical Center; 2016 June; Springfield, MA.
 3. **Martin JE***. Hydrocephalus and the primary care provider: what do I need to know? Department of Pediatrics Residency Program, Connecticut Children's Medical Center; 2016 May; Hartford, CT.
-
4. **Martin JE***. Incidental benign cysts on intracranial imaging. Pediatrics: Real Cases, Real Solutions, Hadley Farms Meeting House; 2016 April, Hadley, MA.
 5. **Martin JE***. Common Neurosurgical Problems Seen in Primary Care. Pediatric Evening Lecture, Connecticut Children's Medical Center Continuing Medical Education Program; 2015 November; West Hartford, CT.
 6. **Martin JE***. Hydrocephalus and Chiari Malformation. Contemporary Trends in Neuroscience, Baystate Health; 2015 October; Holyoke, MA.
 7. **Martin JE***. Pediatric Cervical Spine and Spinal Cord Injury. Department of Pediatrics Residency Program, Connecticut Children's Medical Center; 2014 January; Hartford, CT.
 8. **Martin JE***. Abnormal head shape in infancy. Pediatric Grand Rounds, Day Kimball Hospital; 2012 May; Putnam, CT.
 9. **Martin JE***. Introduction to Pediatric Neurosurgery. Guest Lecturer, "Introduction to Neurosurgery" Course, Hartford Hospital; 2012 February-present. Hartford, CT.

Poster Presentations (Peer-reviewed):

1. Beshai B, **Martin J**, Brown T, Balarezo F. Congenital Salivary Gland (Anlage) Tumor: Report of a unique tumor with intracranial extension and review of literature. College of American Pathologists Annual Meeting; 2015 Oct; Nashville, TN.

2. **Martin JE***, Garcia C, Moote D, Geelan R. Total Rotational Quality (TRQ): A novel measure of cervical radiographic quality. AANS/CNS Section of Pediatric Neurosurgery Annual Meeting; 2015 Dec; Amelia Island, FL.
3. Ragel BT, Klimo P Jr, Armonda RA, **Martin JE**, Teff RJ, Bakken H. Wartime decompressive craniectomy: the Iraq and Afghanistan experience. American Association of Neurological Surgeons Annual Meeting; 2010 May; Philadelphia. [Awarded first place, Trauma/Critical Care category]
4. Clark P, Rooks VJ, **Martin JE**. Penetrating head injury: imaging and prognosis in the pediatric population during the Iraq Conflict. Society for Pediatric Radiology 52nd Annual Meeting; 2009 Apr; Carlsbad, CA.

5. Mitchell LA, Burgos RM, **Martin JE**, Rooks VJ. Paraspinal pyomyositis and epidural abscesses: an association discovered on review of paraspinal muscle pyomyositis cases from one hospital over a seven-year period. Radiological Society of North America Annual Meeting; 2008 Dec; Chicago.
6. Huyn LT, Pulling TM, Rooks VJ, **Martin JE**. Normal and abnormal embryogenesis of the spine: radiographic findings in congenital anomalies of the spine. ASRN Annual Meeting; 2008 Jun; New Orleans.
7. **Martin JE***, Bingaman KD, Keating RF. Management of bilateral jumped facets in the thoracic spine in a pediatric patient. AANS/CNS Section of Pediatric Neurosurgery Annual Meeting; 2005 Dec; Orlando, FL.
8. Bell RS, **Martin J**, Noonan P, Ecklund J. Operation Iraqi Freedom: experience with traumatic neck and cranial vascular injury from Walter Reed Army Medical Center. American Association of Neurological Surgeons; 2004 May; Orlando, FL.

9. Geyer DG, Monacci WT, **Martin JE**. The infratemporal fossa: a collaborative approach to disorders involving a unique location. Congress of Neurological Surgeons; 2003 Oct; Denver, CO.
10. Bell RS, **Martin JE**, Noonan P, Armonda RA. Craniocervical vessel dissection and pseudoaneurysm in military patients: a five-year institutional review. Congress of Neurological Surgeons; 2003 Oct; Denver, CO.
11. **Martin JE**, Rosner MK, Neal C, Moquin RR. Use of kyphotic titanium cages in the management of multilevel thoracic corpectomy: technical note. World Spine II International Conference; 2003 Aug; Chicago, IL.

12. **Martin JE***, Gilhooly JE, Moquin RR. Surgical correction of short-segment kyphosis with thoracic corpectomy via lateral extra cavitary approach. International Meeting on Advanced Spine Techniques; 2003 Jul; Rome, Italy.
 13. **Martin JE**, Rosner MK, Neal C, Moquin RR. Use of kyphotic titanium cages in the management of multilevel thoracic corpectomy: technical note. International Meeting on Advanced Spine Techniques; 2003 Jul; Rome, Italy.
 14. **Martin JE***, Gilhooly JE, Moquin RR. Surgical correction of short-segment kyphosis with thoracic corpectomy via lateral extra cavitary approach. AANS/CNS Section on Disorders of Spine and Peripheral Nerve Annual Meeting; 2003 Mar; Orlando, FL.
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15. **Martin JE***, Monacci WT, Eisenman DJ. Superior semicircular canal dehiscence: a new indication for middle fossa craniotomy. Congress of Neurological Surgeons; 2002 Sep; Philadelphia, PA.
 16. **Martin JE***, Rosner MK, Neal C, Moquin RR. Use of kyphotic titanium cages in the management of multilevel thoracic corpectomy: technical note. Congress of Neurological Surgeons; 2002 Sep; Philadelphia, PA.



Curriculum Vitae
R. Timothy Brown, M.D.

Personal Data:

Home Address

90 Uplands Drive
West Hartford, Connecticut 06107

Date of Birth

February 25, 1955

Place of Birth

Montréal, Canada

Marital Status

Married

Children

Three

Work Address

Jefferson Radiology, P.C.
85 Seymour Street, Suite 200
Hartford, Connecticut 06106

Certification

American Board of Radiology 1986
Diagnostic Radiology *with added* 1995
Qualifications in Pediatric Radiology
Recertified: 2005

Telephone

Work 860/289-3375
Pager 860/825-6052
Home 860/561-5148

Work Experience:

Professional Employment

- ♦ Jefferson Radiology, P.C. August 22, 1994 - Present
Hartford, Connecticut

- ♦ Staff Radiologist 1/19/95 - Present
Hartford Hospital

- ♦ Staff Radiologist 5/27/99 - Present
Johnson Memorial Hospital

- ♦ Staff Radiologist 5/2/96 – Present
Medical Director, Department of Radiology 2007- Present
Connecticut Children's Medical Center

- ♦ Staff Radiologist 7/7/06 - Present
Windham Hospital

- ♦ Staff Radiologist 9/1/10 - Present
Day Kimball Hospital

- ♦ Staff Radiologist 3/31/11 - Present
Noble Hospital

- ♦ Staff Radiologist 10/25/2012 – Present
Holyoke Medical Center

- ♦ Staff Radiologist 06/16/14 – Present
Griffin Hospital

- ♦ Assistant Clinical Professor 1998 - Present
Department of Radiology
UCONN School of Medicine

- ♦ District Councillor for Western Ontario 1992 - 1994
The Canadian Association of Radiologists



Curriculum Vitae
R. Timothy Brown, M.D.

- ◆ Staff Radiologist *1987 - 1994*
Children's Hospital of Western Ontario and
Victoria Hospital, London
- ◆ Clinical Assistant Professor *1987 - 1994*
Departments of Radiology and Pediatrics, U.W.O.
- ◆ Assistant in Radiology *1985 - 1987*
Children's Hospital, Boston and Harvard Medical School

Education:

Fellowship

- ◆ The Children's Hospital of Boston/Harvard University *Pediatric Radiology*
Boston, Massachusetts *7/85 – 7/87*

Residency

- ◆ University of Western Ontario *Radiology*
London, Ontario *7/82 – 6/85*

Post Graduate Training

- ◆ University of Western Ontario *R2 Medicine*
London, Ontario *7/81 – 6/82*

Internship

- ◆ University Hospital *Straight Medicine*
London, Ontario *9/80 – 6/81*

Medical

- ◆ University of Western Ontario *9/76 – 6/80 Cum Laude*
London, Ontario *Degree: M.D.*

College

- ◆ University of Western Ontario *Natural Sciences Undergraduate Program*
London, Ontario *9/73 – 6/76*

Awards/Honors:

- ◆ McNeill Teaching Award for Excellence in resident teaching *2005,2008, 2010*
University of Connecticut Health Center School of Medicine
Pediatric Residency Program
- ◆ Pediatric House Officers Award for Excellence *1995, 1997-1999, 2001, 2008, 2010-2011*
in Teaching in an Affiliated Pediatric Field
University of Connecticut Health Center
- ◆ Clinical Teaching Award, Department of Pediatrics *1994 & 1989*
University of Western Ontario
- ◆ McLaughlin Fellow *1987 & 1986*
- ◆ M.D. (cum laude) *1980*
- ◆ Class of 1977 Award, Medical Records *1980*
- ◆ Gold Medal in Anatomy, Class of 1980 *1977*



Curriculum Vitae
R. Timothy Brown, M.D.

Memberships/Organizations:

- ♦ Northeast Pediatric Radiology Society *President 2000-2002*
- ♦ Radiological Society of North America *Member*
- ♦ Ontario Medical Association *Member*
- ♦ Society for Pediatric Radiology *Member*
- ♦ Royal College of Physicians, Canada in Diagnostic Radiology *Fellow 1985*
- ♦ Diplomate of National Board of Medical Examiners (U.S.A.) *1981*
- ♦ Alpha Omega Alpha Honour Medical Society *Member 1980*
- ♦ Medical Council of Canada *Member 1980*

Presentations:

- ♦ Hartford Hospital PQI Symposium, Evaluation of Radiation Dose and Image Quality using Direct Digital Radiography Compared to Computed Radiography: Seth, A; Brown, RT, Presented at the Hartford Hospital PQI Symposium **December 5, 2012**. Winner first place.
- ♦ Pediatric Rounds, Imaging Evaluation of Thyroid Nodules **November 27, 2012**
- ♦ Radiology Grand Rounds
University of Connecticut – Dept of Radiology
Lecture: Imaging the Neonatal Chest. Resident review session
January 9, 2012
- ♦ Danbury Hospital, 25th Annual Pediatric Update Conference “Appropriateness in Pediatric Imaging”
November 2010
- ♦ CCMC Grand Rounds “Appropriateness in Pediatric Imaging”
April 2009
- ♦ CCMC Grand Rounds “Imaging in Newborn Lung Disease”
April 2000

Publications:

- ♦ B. Banwell, J. Gillett, R. Reid, R.T. Brown. **HMPAO Scan vs. CT Scan: A Comparison in Pediatric Traumatic Brain Injury**. Submitted to *Ann. Neurology*.
- ♦ C. Romano, R.T. Brown, T.C. Frewen. **Assessment of Pediatric Near-Drowning Victims: Is There a Role for CT?** *Pediatric Radiology*, 23: 261-63, 1993
- ♦ R. Connors, T.C. Frewen, N. Kissoon, J.B. Kronick, R.T. Brown, et al. **The Relationship of Cross Brain Oxygen Extraction, Cerebral Blood Flow and Metabolic Rate to Neurologic Outcome Following Severe Pediatric Near-Drowning**. *Journal of Pediatrics*, Vol. 21, No. 6:839-844, 1992.



Curriculum Vitae
R. Timothy Brown, M.D.

- ♦ D. Chacon, N. Kissoon, R.T. Brown. **Usefulness of Comparison Radiographs in the Diagnosis of Traumatic Injuries of the Elbow.** *Annals of Emergency Medicine*, 21; 8:895-899, 1992.
- ♦ M. Gayle, T. Frewen, R.T. Brown, et al. **Jugular Venous Bulb Catheterization in Infants and Children.** *Crit. Care Med.*, 17:385-88, 1989.
- ♦ R.T. Brown, K.E. Fellow. **Cervical Collateral Arteries in Pulmonary Atresia with Ventricular Septal Defect.** *Am. J. Cardiol*, 62:1310-11; 1988.
- ♦ R.T. Brown, R.L. Lebowitz, J. Mandell. **Neonatal Hydronephrosis in the Era of Sonography.** *AJR*, 148:959-963, 1987.
- ♦ R.T. Brown, R. Wilkinson. **Chronic Recurrent Multifocal Osteomyelitis.** *Radiology*, 166:493-496, 1987.
- ♦ R.T. Brown, R.K. Coates, J.J. Gilbert. **Radiographic-Pathologic Correlation Cerebral Amyloid Angiopathy- A Review of Twelve Patients.** *Journal of the Canadian Association of Radiologists*, Vol. 36, 308-311, December 1985.
- ♦ N. Kissoon, R. Galpin, R.T. Brown. **Evaluation of the Role of Comparison Radiographs in the Diagnosis of Traumatic Elbow Injuries.** *Journal of Pediatric Orthopedics*, 15: 449-453, 1995.

Michael Thomas O'Loughlin, M.D.

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(860) 246-6589
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MTO@Jeffersonradiology.com

- OBJECTIVE** A long term career in an intellectually challenging environment with a strong, growing, and collegial radiology practice
- EDUCATION** **University of Connecticut School of Medicine**, Farmington, CT
M.D. May 1995
- Colby College**, Waterville, ME
B.A. May 1990, *cum laude*, Distinction in the Major
Bio-Chemistry Major
- PROFESSIONAL EXPERIENCE** **Jefferson Radiology Group**, Hartford, CT, 7/01 to present
Partner Radiologist, Board Member
Director of MRI
Director of CT
- Hartford Hospital Department of Radiology**, 7/01 to present
Department Vice Chair
Section Chief - MR Imaging
Radiology Residency Program Director, 7/10 to present
- University of Connecticut School of Medicine, Department of Diagnostic Imaging and Therapeutics**, Farmington, CT
Clinical Instructor, 9/02 to present
- Mayo Clinic Graduate School of Medicine**, Rochester, MN
Cross Sectional Imaging Fellowship, 7/00 to 6/01
- Hartford Hospital Diagnostic Radiology Residency Program**, Hartford, CT
Resident in Radiology, 7/96 to 6/00
Chief Resident, 1999/2000
- University of Connecticut Internal Medicine Residency Program**, Farmington, CT
Internship in Internal Medicine, 7/95 to 6/96
- HONORS** Certificate of Achievement, Academy of Radiology Leadership and Management 2013
Fred Ziter Teacher of the Year Award, Hartford Hospital Radiology Residency 2007
Fred Ziter Teacher of the Year Award, Hartford Hospital Radiology Residency 2004
Honors in Internal Medicine and Surgery Clerkships, UCONN
Deans List for Five Semesters, Colby College
Senior Scholar, Colby College
Senior Class Award in Chemistry, Colby College
Junior Class Award in Chemistry, Colby College

ACTIVITIES

Hartford Hospital	Member at Large, Hartford Hospital Medical Executive Committee, 2015 to present Graduate, Hartford Healthcare Physician Leadership Development Institute, 2015 Chairman, Professionalism in Graduate Medical Education Committee, 2013 to present Member, Genitourinary Disease Management Team Hartford Healthcare, 2013-present Member, Gynecologic Oncology Disease Management Team, Hartford Healthcare 2013-present Member, Esophageal Cancer Work Group, 2012 to present Member, Mead Fund Committee, 2012 to present Member, Hepato-Oncology Program Work Group Committee, 2011 to present Member, Hartford Hospital Multidisciplinary Care Committee, 2010 to present Member, Genital Urinary Workgroup, MDC Committee, 2010 to present Member, Gynecologic Oncology Workgroup, MDC committee, 2010 to present Member, Hartford Hospital Research Committee, 2010 to present Chief Resident, 1999/00 Member, Hospital Graduate Medical Education Committee, 1999/00 and 7/10 to present Member, Radiology Residency Education Committee, 1999/00 and 7/01 to present Member, Quality Assurance Committee 1999/00 Resident Coordinator, Visiting Professor Staff Lecture Series 1997/98 Resident Coordinator, Interdepartmental Staff Lecture Series 1996/97
UCONN	Laboratory Instructor for the General Pathology, Respiratory, Cardiovascular, and Renal-Urinary Subject Committees Member, First and Second Year Pre-Clinical Operating Committees Member, Peer Support (Stress relief/emotional support group for students) Volunteer, South Park Inn Medical Clinic (a clinic for homeless in Hartford) Volunteer, Hartford Area Habitat for Humanity Tutor, First and Second Year Medical and Dental Students
Colby	Director, Colby Emergency Response (our college based EMT service) President, Colby Outing Club
U.S.M.L.E.	Part I June 1992 82 nd percentile Part II Sept. 1994 87 th percentile Part III May 1996 91 st percentile
LICENSURE	Massachusetts 2010 to present Connecticut 1998 to present Minnesota 2000 to 2001
BOARD CERTIFICATION	American Board of Radiology, May 17, 2000 Magnetic Resonance Medical Director/Physician (MRMD), Oct. 21, 2015
PATENTS RECEIVED	Fixed Anterior Gantry CT Shielding for Dose Reduction, United States Patent 9,101,272

GRANTS
RECEIVED

Hyundai Hope on Wheels \$250,000 Research Grant 2012

“Early Onset Occult Asymptomatic Cardiotoxicity in Childhood Cancer Survivors Exposed to Anthracycline Therapy: A Cardiac Magnetic Resonance and Biomarker Imaging and Serological Biomarker Study”. Olga Salzar, Eileen Gillan, Kerry Moss, Michael O’Loughlin, Bruce Liang

Saint Baldericks Foundation \$100,000 Research Grant, 2011

“Defining Late Onset Occult Asymptomatic Cardiotoxicity in Childhood Cancer Survivors Exposed to Anthracycline Therapy: A Cardiac Magnetic Resonance and Biomarker Imaging and Serological Biomarker Study”. Olga Salzar, Eileen Gillan, Kerry Moss, Michael O’Loughlin, Bruce Liang

Medtronic \$81,000 Research Grant, 2011

“Use of a Screening Questionnaire to Decide whether a Pacing System with the Revo-MRI Pacemaker is Warranted (the “Ready MRI” trial)”. Steven Zweibel, Michael O’Loughlin, David O’Sullivan

Connecticut Breast Health Initiative \$50,000 Research Grant, 2004

Principal Investigator - “Prospective Analysis of Breast MRI Outcomes in a Large Hospital Population”, Hartford Hospital, Received 12/09/04

RESEARCH

Co-Investigator St. Jude Medical CRD 874, Hartford Hospital 2016

MRI Diagnostic Imaging Registry, Assessing the MRI compatibility of current St. Jude Pacemakers/Implants, Eric Crespo, M O’Loughlin

Sub Investigator – MSK 12-078 , Hartford Hospital 2016

A Phase I/II, Two part Multicenter Study to Evaluate the Safety and Efficacy of M402 in Combination with Nab-Paclitaxel and Gemcitabine in Patients with Metastatic Pancreatic Cancer

Site Principal Investigator – American College of Radiology Imaging Network (ACRIN), Hartford Hospital 2003

Study 6667, Site Principal Investigator for multicenter trial assessing contralateral breast disease in patients with recent diagnosis of breast cancer.

Site Principal Investigator - International Breast MRI Consortium, Hartford Hospital 2001-2002

Study 6884, Arm 1B and Arm 1C. Site Principal Investigator for multicenter trials assessing breast MRI in high risk subjects.

Post Sophomore Medical Student Fellowship in Anatomic Pathology, University of Connecticut Health Center 1992-1993

Functioned as a Junior Resident in the Department of Anatomic Pathology. Dissected surgical specimens, prepared microscopic slides, and then jointly worked of diagnoses with an attending Pathologist. Performed over thirty postmortem examinations from initial incision to signature on final dictated report. Presented cases at Radiology, Internal Medicine, and Orthopedic conferences. Participated in month long electives in Neuropathology and Renal Pathology. Attended bi-weekly brain dissections.

University of Connecticut School of Medicine Summer Research Fellowship 1991

“Lymphocyte Glucocorticoid Receptors in PTSD, Major Depression, Panic and Schizophrenia” with Dr. Earl Giller in the Department of Psychiatry

Senior Scholars Project, Colby College 1989-1990

“Two-Dimensional Gel Electrophoretic Analysis of Cellular Proteins from E. coli in the Presence of Mutated and Homologous Genes for 4.5s RNA” with Dr. David Bourgaize in the Department of Chemistry

University of Connecticut School of Medicine Summer Research Fellowship 1989

“Characterization of the B. Malayi 70 Kilodalton Heat Shock Protein Gene Family” with Dr. T.V. Rajan in the Department of Pathology

PROFESSIONAL MEMBERSHIPS

American Roentgen Ray Society 1996 to present
Radiological Society of North America 1996 to present
American College of Radiology 1996 to present
Wilderness Medical Society 1994 to 2004
European Society of Radiology 2004 to present
International Society of Magnetic Resonance in Medicine 2004 to present
Society of Cardiovascular Magnetic Resonance Imaging 2004 to present
Society of Cardiovascular Computed Tomography 2010 to present
Association of Program Directors in Radiology 2010 to present

RESIDENT LECTURES

The Radiology of Wilderness Medicine, Not Necessarily a Contradiction in Terms
May 1997
Magnetic Resonance Angiography, Understanding the Flow
May 1998
The Radiology of Renal Transplantation
March 1999

PAPERS and PRESENTATIONS

“Image Screening for Individuals with a High Risk of Pancreatic Cancer”, Presented at the HHC Cancer Institute Pancreatic Cancer Symposium. Farmington, CT 11/3/2016
“Soft Tissue Pseudotumors of the Hip”, MR Kaleel, J Czajka, M O’Loughlin, H Baweja. Presented at ECR 2016, Vienna Austria
“Introduction to Cardiac MRI”, Department of Cardiology Grand Rounds. Hartford Hospital, Sept 22, 2015.
“Radiation Doses in Modern Imaging.” M O’Loughlin. Presented at the Day Kimball Hospital Quarterly Medical Staff Meeting. Sept. 8, 2015. Putman, CT
“Comparative Assessment of Gleason Scoring of Prostate Biopsies Obtained by Standard US and MRI-TRUS at Follow-up in Active Surveillance Patients.” M Jackson, Haddock, I Staff, R Dorin, S Kesler, M O’Loughlin, A Meraney, J Wagner. Presented at the AUA Annual Meeting. New Orleans, May 2015
“Serial Lung Magnetic Resonance Imaging to Monitor Disease Progression in a Child with a Diffuse Alveolar Hemorrhage Syndrome” Kaleel M, Schramm C, Pascal M, O’Loughlin M, Collins MS. J Clin Med Res 2015 Apr; 7 (4):267-9
“The Impact of Enteric Contrast on Radiologist Confidence in Intravenously Enhanced MDCT of the Abdomen and Pelvis: A Randomized Controlled Trial”. C. Garcia, S. Boe, B. Coughlin, D. O’Sullivan, D. Moote, MT O’Loughlin, D. Jajoo, S Lee. Advances in Computed Tomography, 2014:3, 18-23
“Expected and Unexpected Findings in Diffusion Weighted Imaging MRI in Pediatric Patients with IBD.” M. Froicu, D Moote, M O’Loughlin. Presented at the Society of Abdominal Radiology SAR 2014 Meeting. Boca Raton FL, March 23, 2014
“Occult Cardiotoxicity in Childhood Survivors Exposed to Anthracycline Therapy” OH Toro-Salazar, E Gillan, M O’Loughlin, et al. Circulation Cardiovascular Imaging. 2013;6:873-880

- “Reduced Z-Axis Coverage CTA vs Standard Z-Axis Coverage CTA for Pulmonary Embolism” Kallen J, Coughlin BF, O’Loughlin MT, and Stein B. Presented at RSNA 95th Scientific Assembly and Annual Meeting 2009
- “Reduced Z-axis coverage multidetector CT Angiography for Suspected Acute Pulmonary Embolism Could Decrease Dose and Maintain Diagnostic Accuracy”. J Kallen; B F Coughlin, MT O’Loughlin, B Stein. *Emerg Radiol.* 2010 17(1) 31-35
- MRI Contrast Reactions and Nephrogenic Systemic Fibrosis”, Spring Contrast Safety Conference, Jefferson Radiology. Farmington Educational Center, April 4, 2009
- “R/O Foreign Body”: Looking for Embedded Glass Fragments with Digital Imaging” Chang J, Tubbs D, O’Loughlin MT. Presented at RSNA 94th Scientific Assembly and Annual Meeting 2008
- “Urologic MRI – Part One, Male and Gender Neutral Pathology”, University of Connecticut Urology Residency Lecture Series. August 28 2008
- “Radiation Dose Issues in Modern Imaging”, Dept. of Emergency Medicine Grand Rounds, Hartford Hospital August 21, 2008
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“Bayesian Analysis of Lumbar Spine MR Imaging” Glickstein, M., and O’Loughlin, M.
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INTERESTS Canoeing, Canoe Poling (ACA National Champion 2010), Carpentry, Traditional Archery

REFERENCES Available on Request

EXHIBIT

3

Summary of Attached Articles:

- 1) "MR Imaging at 3.0 T in Children: Technical Differences, Safety Issues, and Initial Experience" - Chavhan et al: Article highlights shorter acquisition times required for 3.0T field magnets, resulting in reduced requirements for sedation and improved patient safety. Provides additional technical information regarding imaging with stronger field magnets in children.
- 2) "Results of a North American Survey of Rapid-Sequence MRI Utilization to Evaluate Cerebral Ventricles in Children" - Thompson et al: Provides results of a 9-question survey provided to all US/Canadian institutions with a board-certified pediatric neurosurgeon on staff, highlighting the wide utilization of rapid-sequence MRI techniques in the evaluation of potential shunt malfunction to minimize radiation exposure in this patient population
- 3) "Radiation Risks and Pediatric Computed Tomography (CT): A guide for Healthcare Providers" - National Cancer Institute- Radiation risks in pediatric CT: Summary webpage discussing heightened risks of radiation exposure in children from diagnostic imaging
- 4) "Contrast-Enhanced Magnetic Resonance Imaging in Pediatric Patients: Review and Recommendations for Current Practice" - Bhargava et al: Article summarizes the wide range of applications of MRI in pediatric imaging to include cardiovascular, musculoskeletal, neurologic, and other gastrointestinal imaging.
- 5) "The Role of Cardiovascular Magnetic Resonance in Pediatric Congenital Heart Disease" - Ntsinjana et al: Article discusses use of MRI in performing non-invasive diagnostic imaging in pediatric congenital heart disease
- 6) "Diffusion-Tensor Fiber Tractography: Intraindividual Comparison of 3.0-T and 1.5-T MR Imaging" - Okada et al: Article comparing the quality of higher field (3.0T) MRI to lower field (1.5T) MRI in the specific application of diffusion-tensor fiber tractography, an imaging technique that provides improved visualization of brain pathways, increasing the safety of surgical resection in neuro-oncology
- 7) "Functional MR Imaging at 3.0 T versus 1.5 T: A Practical Review" - Voss et al: Technical article regarding improved results with functional imaging BOLD sequences in high field (3.0T) versus low field (1.5T) MRI. Allows for improved visualization of functional brain tissue for planning of respective procedures in neurosurgery when pathology involves eloquent cortex.

MR Imaging at 3.0 T in Children: Technical Differences, Safety Issues, and Initial Experience¹

ONLINE-ONLY CME

See www.rsna.org/education/lrg_cme.html

LEARNING OBJECTIVES

After reading this article and taking the test, the reader will be able to:

- List the physics differences between 1.5-T and 3.0-T MR imaging.
- Discuss the safety issues and potential advantages of 3.0-T imaging in children.
- Describe the potential benefits and challenges of 3.0-T imaging in various body regions.

TEACHING POINTS

See last page

Govind B. Chavhan, MD, DNB • Paul S. Babyn, MD • Manoj Singh, MRT (MR) • Logi Vidarsson, PhD • Manohar Shroff, MD

The high signal-to-noise ratio and contrast-to-noise ratio of 3.0-T magnetic resonance (MR) imaging can be used to obtain high-resolution thin-section images in a short acquisition time. These advantages are associated with an increased specific absorption rate (SAR) and more artifacts owing to B_1 inhomogeneity and increased susceptibility and chemical shift. Potential advantages of 3-T imaging in children include acquisition of good-quality images even with a small field of view (FOV). The shorter overall acquisition time of 3-T imaging is useful in children, who may not be able to cooperate for long. Shorter acquisition times also improve safety by reducing patient monitoring time within the enclosed bore of an MR imaging unit. SAR-related issues and dielectric artifacts are less problematic with a small FOV. Parallel imaging helps reduce SAR, susceptibility artifacts, and blurring of T2-weighted fast spin-echo (FSE) and single-shot FSE images by reducing the echo train length.

Introduction

Magnetic resonance (MR) imaging at 3.0 T was introduced for clinical imaging with the promise of high signal-to-noise ratio (SNR), spatial resolution, and temporal resolution. It also brought with it new challenges in the form of artifacts related to susceptibility and chemical shift and specific absorption rate (SAR)-related issues. Many excellent reviews have been written on 3-T imaging related to physical differences from

Abbreviations: ETL = echo train length, FLAIR = fluid-attenuated inversion-recovery, FOV = field of view, FSE = fast spin-echo, SAR = specific absorption rate, SNR = signal-to-noise ratio, SSFP = steady-state free precession, 3D = three-dimensional

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1.5-T imaging, image quality, and initial clinical experiences in various body parts (1–5). Physics differences between 1.5-T and 3-T imaging are summarized in Table 1.

Little has been written on 3-T imaging in children (6); to our knowledge, nothing has been written on actual clinical experience imaging children at 3 T. Potential advantages of imaging children at 3 T include acceptable image quality with good SNR and spatial resolution even for a small field of view (FOV). These are helpful in imaging small children and infants with varying body sizes (2). With use of a small FOV, SAR-related issues and dielectric artifacts are less problematic. Thin-section, high-resolution images can be acquired in a shorter time than in 1.5-T imaging (Fig 1). This is useful in pediatric patients, who may not stay still during long pulse sequences. Shorter overall examination time at 3-T imaging is beneficial in imaging newborns, especially premature babies, who cannot be kept long in the bore of the imaging unit (2). High-field-strength systems and parallel imaging complement each other, reducing the imaging time further.

In this article, we present our initial experience with 3-T imaging in children, discuss safety issues, and describe artifacts. We also discuss sequence-related challenges at 3 T and describe clinical applications in neurologic, body, and musculoskeletal imaging.

Initial Experience in Children

Our initial experience was based on more than 2500 MR imaging examinations performed on a 3-T system (Achieva; Philips Medical Systems, Best, the Netherlands) since its installation at our institution 1 year ago. These examinations included 1506 brain, 188 body, 296 musculoskeletal, and 362 spinal MR imaging examinations, among others. The patients ranged in age from 7 days to 18 years.

For the first 3 months after installation, no children who had implants or had undergone surgery were imaged. Gradually, children with bioclips (Bioplate, Los Angeles, Calif), port-catheter systems, and dental braces (for non-head-and-neck examinations) were imaged. Patients' body temperature was monitored with an MR imaging-compatible monitor (Veries MR vital signs monitor; Medrad, Warrendale, Pa) for the initial 6 months. No significant body heating was seen. However, a study performed elsewhere on two

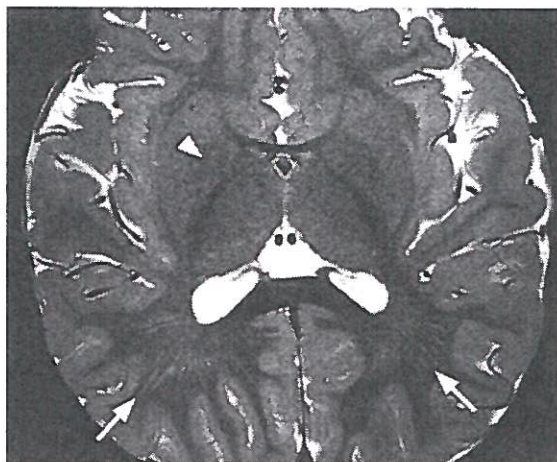


Figure 1. Superior anatomic details. Axial T2-weighted image of the brain (repetition time msec/echo time msec = 3000/80, flip angle = 90°, bandwidth = 248 Hz, voxel size = 0.5 × 0.5 × 2.0 mm, ETL = 15, FOV = 180 × 180 mm) shows good anatomic details of the basal ganglia. Virchow-Robin spaces (arrows) are more frequently seen at 3-T imaging. Arrowhead = right globus pallidus.

groups of 38 children (aged 1 month to 6 years 5 months) who underwent brain MR imaging under sedation showed a mean increase in tympanic and rectal temperature by 0.5°C at 3 T compared with 0.2°C at 1.5 T (7).

The initial experiences with sequences, image quality, and artifacts described in the following paragraphs are collective subjective experiences of radiologists and technologists. The data have not been analyzed objectively by means of a 1:1 comparison. Most of the image quality comparison discussed in this article was with images from similar sequences performed on a 1.5-T imaging system (Achieva; Philips Medical Systems).

Safety Issues

Major MR imaging safety concerns include SAR, potential harmful effects related to metal and implants in the body, and acoustic noise. SAR limits and ways to reduce it are given in Table 2. Some general safety precautions are discussed in Table 3. Acoustic noise can be minimized with headphones and earplugs, given to children and the parent inside the imaging room. Implants and devices that are able to be imaged at 1.5 T but not at 3 T at our institution are listed in Table 4. This list was prepared on the basis of information from a textbook (8), Web sites on MR imaging safety (www.mrisafety.com), phantom testing at our institution, and initial attempts that resulted in significant artifacts.

Teaching
Point

Table 1
Differences between 1.5-T and 3-T Imaging and Their Practical Implications

Parameter	Differences between 1.5-T and 3-T Imaging	Practical Implications: Advantages, Disadvantages, Solutions
Larmor frequency	63.9 MHz at 1.5 T vs 127.8 MHz at 3 T	Frequency of RF field (B_1) is doubled; wavelength is shortened with more absorption in tissues; increased SAR Short wavelength also causes B_1 inhomogeneity
T1	Increased at 3 T by ~25%–30%, depending on tissues; T1 of fluid and blood is largely unchanged	Improved contrast at time-of-flight imaging; good MR angiography Stronger effects of gadolinium enhancement; same enhancement with half dose of gadolinium contrast material as achieved at 1.5 T Reduced T1 contrast between tissues; solution is to increase TR Long imaging time for T1-weighted imaging; solution is to use T1-weighted GRE sequence
T2 and T2*	Reduction in T2 by <15% at 3 T, more reduction in T2*	FSE sequences are more blurred Solution is to use shorter TE, shorter ETL, parallel imaging
SNR	In theory, SNR is doubled at 3 T; in practice, two times SNR is not realized because of many factors, including increased susceptibility, chemical shift, and inhomogeneity along with relaxation changes; increase in SNR is approximately 1.7 times	SNR is the most important advantage of 3 T Increased SNR can be used to reduce acquisition time at a given spatial resolution or to improve spatial resolution at a given imaging time Increased conspicuity of fluid structures; improved visualization of small bile ducts
CNR	Improved CNR at 3 T from increased SNR and different T1 prolongation effects on tissues and between contrast-enhancing and nonenhancing tissues	Improved lesion conspicuity in solid organs like the liver Reduced need for intravenous contrast material Improved resolution in contrast-enhanced MR angiography
SAR	Increased fourfold at 3 T	Faster body heating and more energy deposition Sequences need to be modified to avoid exceeding limits (eg, reducing ETL and flip angle, increasing TR) Solution is to use parallel imaging, flip angle modulation methods such as VERSE, hyperechoes, and restoration of magnetization
Susceptibility	Increased at 3 T; shortened T2* from local field distortion results in more signal loss at a given TE at 3 T than at 1.5 T	Image distortion and signal loss especially in the bowels and cardiac-lung interface, increased artifacts with balanced SSFP sequence; solution is to use smaller voxel size and shortest possible TE with highest achievable receiver bandwidth, local shimming, parallel imaging to reduce ETL Improved sensitivity for BOLD-functional MR imaging, MR perfusion imaging, and detection of hemosiderin and iron
Chemical shift	Increased from 220 Hz at 1.5 T to 440 Hz at 3 T	Chemical shift artifact of first kind is increased; solution is to increase bandwidth TEs for in-phase and out-of-phase GRE images are changed: typical in-phase TEs at 3 T are 2.3 msec, 4.5 msec, 6.8 msec, etc (vs 4.5 msec, 9.5 msec, 14.5 msec, etc, for 1.5 T); typical out-of-phase TEs at 3 T are 1.1 msec, 3.4 msec, 5.7 msec, etc (vs 2.5 msec, 7.0 msec, 12 msec, etc, at 1.5 T) Improved spectral separation for spectroscopy at 3 T Improved fat suppression if field is homogeneous
Field homogeneity	Difficult to achieve homogeneous RF field (B_1) because of short wavelength, dielectric effects, and eddy currents	Inhomogeneous signals in the images Heterogeneous SAR distribution Poor fat suppression Solution is to use dielectric padding over the abdomen, new coil design, and shimming

Source.—References 1–5.

Note.—BOLD = blood oxygen level-dependent, CNR = contrast-to-noise ratio, ETL = echo train length, FSE = fast spin-echo, GRE = gradient-echo, RF = radiofrequency, SSFP = steady-state free precession, TE = echo time, TR = repetition time, VERSE = variable-rate selective excitation.

Table 2
SAR Limits and Ways to Reduce SAR

FDA limits*

- 4 W/kg for the whole body for 15 min
- 3 W/kg averaged over the head for 10 min
- 8 W/kg in any gram of tissue in the head or torso for 5 min
- 12 W/kg in any gram of tissue in the extremities for 5 min

Ways to reduce SAR

- Increase TR, decrease flip angle, decrease number of sections
- Use parallel imaging, which reduces ETL
- Intersperse gradient-echo and spin-echo sequences
- Minimize the saturation band
- Make sure the patient is changed into a loose hospital gown for better heat dissipation
- The bore fan should be on
- The room temperature should be cool

Note.—FDA = U.S. Food and Drug Administration, TR = repetition time.

*FDA limits for SAR are such that radiofrequency exposure should elevate core body temperature by $\leq 1^\circ\text{C}$.

Table 3
Some Basic Safety Precautions for MR Imaging

When the patient is placed inside the bore, the table should be moved slowly to avoid dizziness
The technologist should move the patient's head slowly, not abruptly, near the bore to avoid any dizziness

If the patient experiences dizziness or nausea before the examination, imaging at 3 T should be avoided

If the patient is dizzy after the examination, make sure that blood pressure, oxygen saturation, and other vital signs are normal

Communicate with the patient after every pulse sequence to confirm that he or she feels well

If the patient feels hot, stop the examination and inform radiologists

Headphones and earplugs should both be used to reduce noise

Patients should not be positioned with crossed arms or legs to avoid inducing a magnetic field and potential burns

If the accompanying person is wearing steel-toed shoes or high-heeled sandals, they should be removed outside the imaging room because they may flip near the magnet and cause injury

The accompanying person should be given a chair to sit on instead of a stool to avoid a potential fall due to dizziness

The accompanying person should sit at least 2 m from the magnet bore

During the first year after installation and 2500 examinations, 13 children and one parent experienced dizziness, two children experienced nausea, and one child experienced headache at a variable time after the start of the examination. All of these children had stable vital signs at physical examination. They were observed for some time before discharge from the MR imaging department. Twelve of the 13 children who experienced dizziness were girls. This female preponderance was similar to that in a previous study (9). The prevalence of dizziness was reduced when the word "dizziness" was not used by technologists in their explanation about possible effects before starting the examination. No heating or radiofrequency burns have occurred so far.

Table 4
Prosthetic Devices Imaged at 1.5 T But Not at 3 T

- Programmable ventriculoperitoneal shunt
- Patent ductus arteriosus closure clips
- Dental braces for head imaging
- Sternal wires
- Cardiac metallic stent
- Tattoos
- Aortic stents
- Inferior vena cava filters
- Harrington rods
- Orthopedic metallic implants

Artifacts

MR imaging at 3 T is much more affected by artifacts than is imaging at 1.5 T. Commonly observed artifacts include flow artifacts, movement

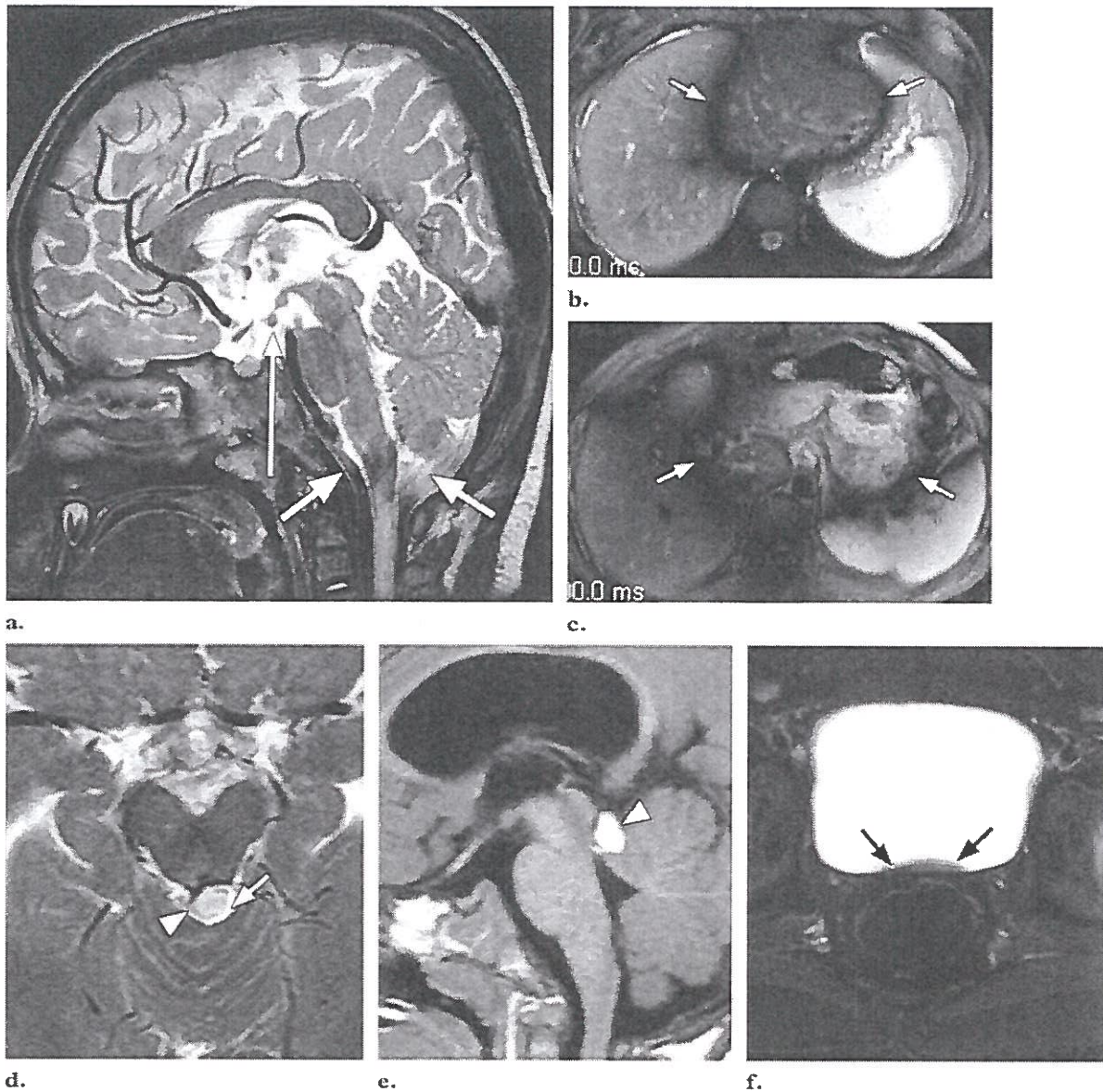


Figure 2. Artifacts. (a) Sagittal T2-weighted image (3000/80, flip angle = 90°, bandwidth = 364 Hz, voxel size = 0.6 × 0.6 × 3.0 mm, ETL = 15, FOV = 180 × 180 mm) shows flow artifacts in the posterior cranial fossa (short arrows) that obscure details of the lower brainstem and cerebellum. Long arrow = thalamic hamartoma. (b, c) Axial T2-weighted single-shot FSE images (1800/80, flip angle = 90°, bandwidth = 380 Hz, voxel size = 1.2 × 1.5 × 5.0 mm, ETL = 62, sensitivity encoding factor = 2, FOV = 384 × 480 mm), obtained through the upper (b) and lower (c) parts of the liver, show a circular area of signal loss (arrows) in the intermediate region of the FOV, a finding indicative of dielectric or inhomogeneity-related artifact. (d, e) Axial T2-weighted (3828/80, flip angle = 90°, bandwidth = 380 Hz, voxel size = 0.45 × 0.74 × 3.0 mm, ETL = 17, FOV = 220 × 220 mm) (d) and sagittal T1-weighted fluid-attenuated inversion-recovery (FLAIR) (2318/20, inversion time = 1116 msec, flip angle = 90°, bandwidth = 228 Hz, voxel size = 0.7 × 1.0 × 3.0 mm, ETL = 7, FOV = 220 × 220 mm) (e) images show a small tectal lipoma (arrowhead). Chemical shift artifact (arrow in d) is seen on the T2-weighted image. (f) Axial T2-weighted image of the pelvis (5451/100, flip angle = 90°, bandwidth = 131 Hz, voxel size = 1.0 × 1.0 × 4.0 mm, ETL = 16, FOV = 300 × 300 mm) shows susceptibility artifact in the posterior part of the urinary bladder (arrows) owing to rectal air.

artifacts, dielectric effect, chemical shift-related artifacts, and susceptibility artifact.

Flow Artifacts

Flow artifacts, seen mainly on T2-weighted images, affect the spine and posterior cranial fossa

more severely (Fig 2a). Flow artifacts may be reduced by the use of saturation bands and flow compensation techniques.

Teaching Point

Dielectric Effect

At higher magnetic field strength, the B_1 field (the radiofrequency field perpendicular to the main magnetic field) is inhomogeneous and the maximum B_1 field is reached in the center of the body. This effect is termed *field focusing* (1). Field focusing effect is increased at 3 T by short wavelength (26 cm) and dielectric effects. Standing wave or dielectric resonance occurs from reflection of radiofrequency waves at interfaces with high-conductivity gradients such as the chest or body wall. Field focusing and dielectric effect cause inhomogeneity of signal across the FOV with signal loss, particularly in the intermediate area between the center and the periphery (1) (Fig 2b, 2c).

Artifact related to dielectric effect tends to be more pronounced on FSE images and in the presence of metals, ascites, and a large ellipsoid abdomen (5). This artifact is usually less problematic in small children with smaller body sizes. It can be reduced by placing dielectric cushions that contains fluid such as ultrasonographic gel on the anterior abdominal wall and by improving the homogeneity of the magnetic field (5).

Chemical Shift Artifacts

Chemical shift artifact of the first kind, which results from mismapping of the frequency-encoded signal of fat into water voxels, is increased at 3 T (3). It is seen as a dark and white band at the margins of fatty tissue (Fig 2d, 2e). This can be reduced by increasing the receiver bandwidth; however, SNR drops as receiver bandwidth is increased. Chemical shift artifact of the second kind (India ink artifact), which results from cancellation of signal from fat and water protons within voxels at out-of-phase echo times, is not increased at 3 T (5).

Teaching Point

Susceptibility Artifact

Increased susceptibility at 3 T causes image distortion and signal loss at soft-tissue and gas interfaces, such as the bowel wall (Fig 2f) and lung bases and near paranasal sinuses. Gradient-echo images are severely affected. Susceptibility artifacts can be minimized by means of localized shimming, reduced voxel size, and shortening of echo time and ETL (3).

**Challenges at 3 T
Related to Sequences****T1-weighted Sequences**

Because of prolonged T1 relaxation, T1-weighted sequences at 3 T are longer and prone to movement artifacts. Contrast between tissues, especially

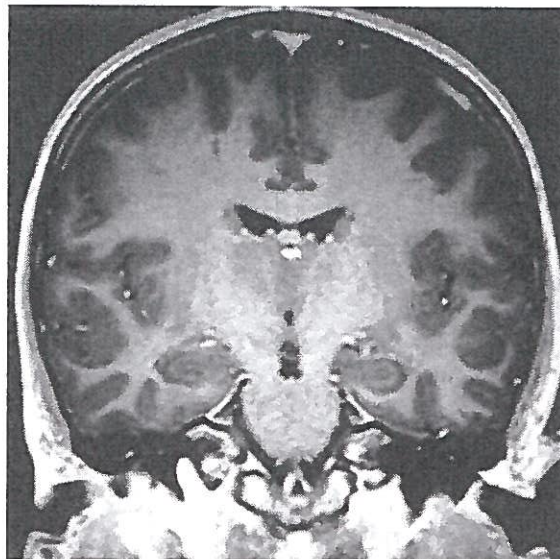


Figure 3. High-resolution 3D T1-weighted turbo field echo imaging of the brain. Coronal reformatted image from axial 3D T1-weighted turbo field echo imaging (5/2.3, flip angle = 8°, bandwidth = 393 Hz, voxel size = 1.0 × 1.0 × 1.0 mm, FOV = 220 × 220 mm), obtained after intravenous administration of gadolinium contrast material, shows excellent anatomic details and gray-white matter differentiation.

gray-white matter differentiation in the brain, is reduced on T1-weighted images at 3 T (1). Use of the FLAIR T1-weighted turbo spin-echo sequence in the brain improves gray-white matter contrast. Shorter T1-weighted gradient-echo sequences, such as T1-weighted turbo field echo imaging, can be used as an option. A T1-weighted three-dimensional (3D) turbo field echo sequence is even better and provides excellent-quality images in the brain as well as the spine in our experience (Fig 3). Recent work by Edelman et al (10) also confirms the significantly superior quality of 3D spoiled gradient-echo images in comparison with two-dimensional spoiled gradient-echo inversion-recovery and two-dimensional spin-echo images.

The T1 relaxation time of the tissue enhancing with gadolinium is not significantly different at 1.5 T and 3 T. However, because of the increased T1 of baseline tissues, stronger enhancement is seen at 3 T (Fig 4). This has led some authors to propose that a half dose of contrast material is sufficient to achieve the same degree of enhancement in brain and abdominal imaging at 3 T (11–13). Imaging with a half dose of gadolinium contrast material has not yet been used at our institution.

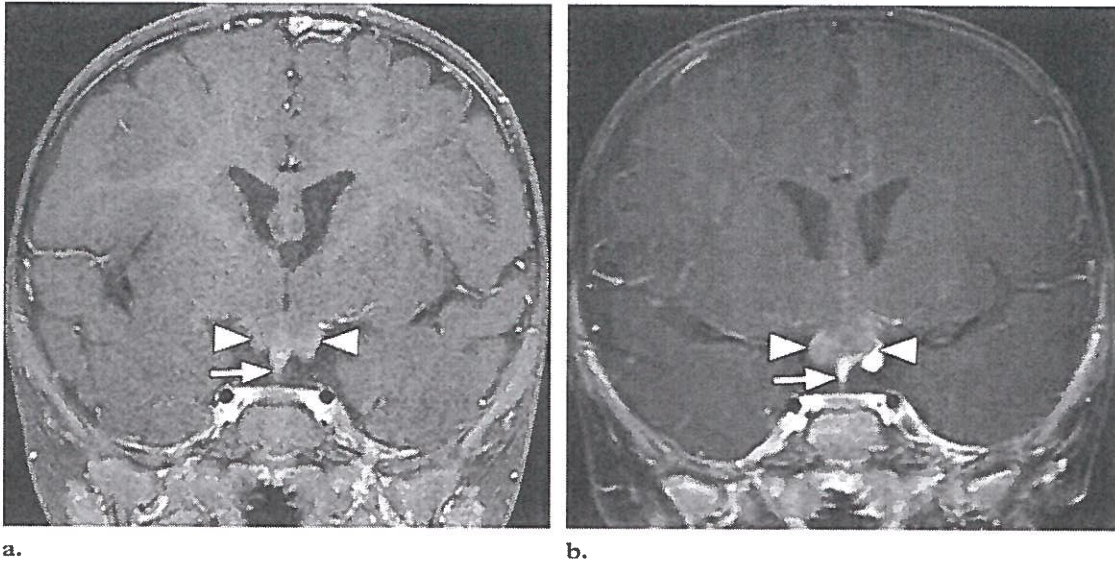


Figure 4. Gadolinium-enhanced imaging of the brain in an 8-year-old girl with neurofibromatosis type 1 and an optic pathway glioma. Coronal postcontrast T1-weighted image obtained at 1.5 T (450/15, flip angle = 90°, bandwidth = 108.6 Hz, voxel size = 0.7 × 0.65 × 3.0 mm, FOV = 160 × 160 mm) (a) and coronal post-contrast T1-weighted FSE image obtained at 3 T (674/11, flip angle = 67°, bandwidth = 200 Hz, voxel size = 0.7 × 0.9 × 3.0 mm, ETL = 3, FOV = 180 × 180 mm) (b) show an optic pathway glioma (arrowheads) in the chiasmatic region. The images were obtained 6 months apart with the same dose of gadolinium contrast material. One of the components of the glioma on the left side shows enhancement at 3 T, a finding that may be related to the change in the mass itself. Note the greater enhancement of the pituitary stalk (arrow) at 3 T than at 1.5 T. The image obtained at 1.5 T has more noise (is grainy) for almost the same voxel size compared with the image obtained at 3 T.

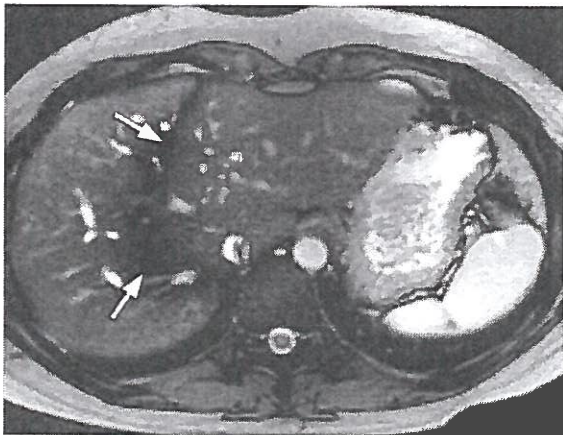


Figure 5. Axial balanced SSFP image (2.4/1.2, flip angle = 60°, bandwidth = 1705 Hz, voxel size = 1.5 × 1.8 × 7.0 mm, FOV = 340 × 280 mm) of the abdomen shows a prominent susceptibility artifact (arrows).

T2-weighted Sequences

T2-weighted images benefit most from high SNR because the longer repetition time used at 3 T allows more recovery of longitudinal magnetization (5,14). T2-weighted images are also the ones that are affected more by flow and motion artifacts, especially in the abdomen, spine, and posterior cranial fossa. T2-weighted FSE and single-shot

FSE sequences with a long ETL may show blurring because of faster T2 relaxation and are affected by the field inhomogeneity at 3 T. This situation can be improved with use of parallel imaging, which reduces ETL. Parallel imaging also reduces susceptibility artifacts and SAR.

T2-weighted sequences are used with fat saturation in body imaging. Frequency-selective fat suppression is robust at 3 T because of more separation of fat and water peaks (3). However, a homogeneous magnetic field is needed, which is difficult to achieve at 3 T. Single-shot FSE images show improvement in lesion and fluid conspicuity owing to high SNR (5). The result is good-quality MR cholangiopancreatography. In our experience, single-shot FSE sequences with reduced imaging time are useful in pediatric imaging, where cooperation is variable. The inversion time for short inversion time inversion-recovery imaging is increased at 3 T, from the typical 150 msec at 1.5 T to 210–230 msec at 3 T.

Balanced SSFP Sequences

Balanced SSFP sequences such as true fast imaging with steady-state precession, fast imaging employing steady-state acquisition, and balanced fast field echo, which are particularly sensitive to field inhomogeneity, are difficult to implement at 3 T (3). They are affected more significantly by susceptibility and banding artifacts at 3 T than at 1.5 T (Fig 5).

Teaching Point

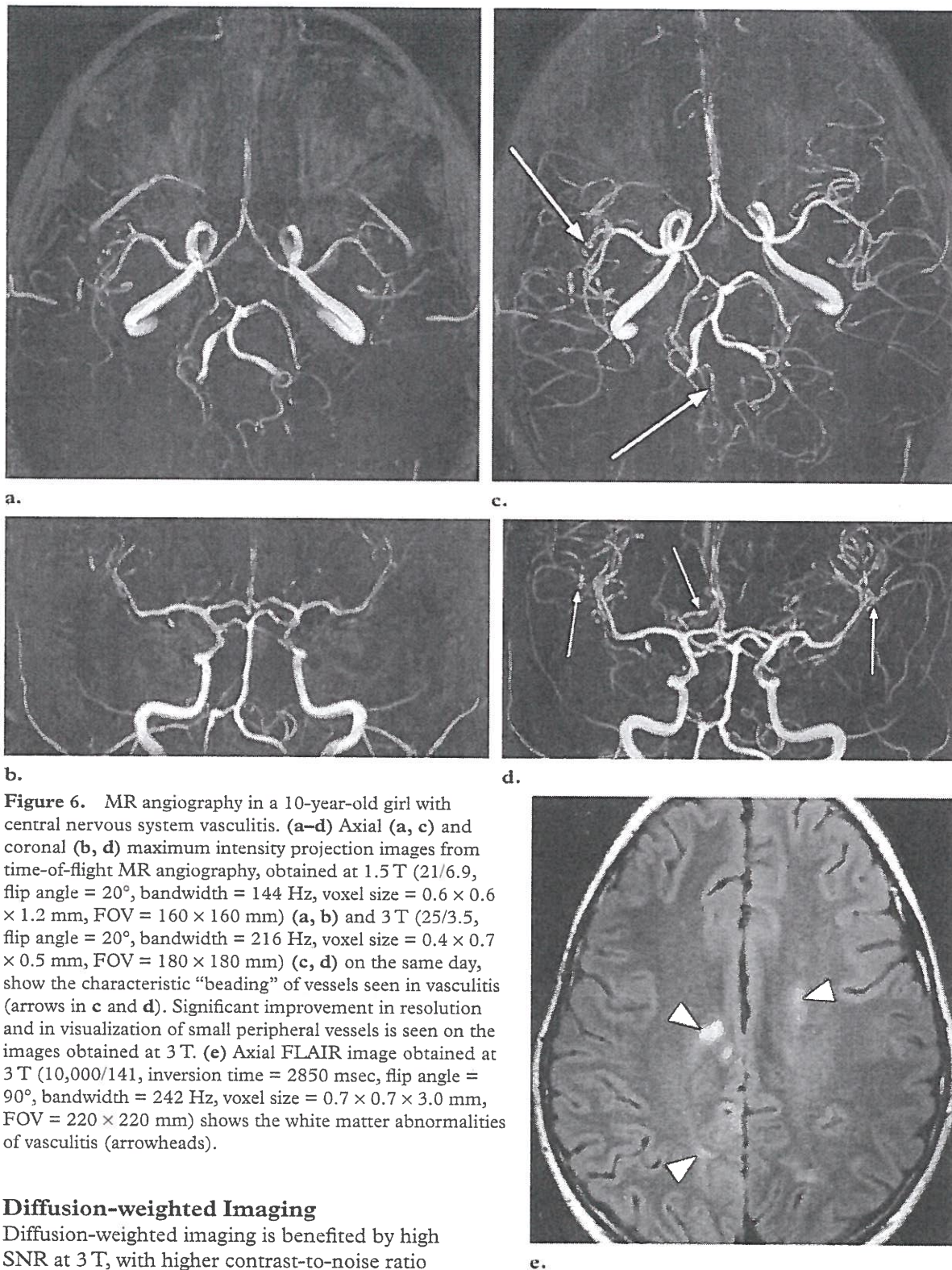


Figure 6. MR angiography in a 10-year-old girl with central nervous system vasculitis. (a–d) Axial (a, c) and coronal (b, d) maximum intensity projection images from time-of-flight MR angiography, obtained at 1.5 T (21/6.9, flip angle = 20°, bandwidth = 144 Hz, voxel size = 0.6 × 0.6 × 1.2 mm, FOV = 160 × 160 mm) (a, b) and 3 T (25/3.5, flip angle = 20°, bandwidth = 216 Hz, voxel size = 0.4 × 0.7 × 0.5 mm, FOV = 180 × 180 mm) (c, d) on the same day, show the characteristic “beading” of vessels seen in vasculitis (arrows in c and d). Significant improvement in resolution and in visualization of small peripheral vessels is seen on the images obtained at 3 T. (e) Axial FLAIR image obtained at 3 T (10,000/141, inversion time = 2850 msec, flip angle = 90°, bandwidth = 242 Hz, voxel size = 0.7 × 0.7 × 3.0 mm, FOV = 220 × 220 mm) shows the white matter abnormalities of vasculitis (arrowheads).

Diffusion-weighted Imaging

Diffusion-weighted imaging is benefited by high SNR at 3 T, with higher contrast-to-noise ratio leading to increased sensitivity for detection of areas of restricted diffusion (1,5). Susceptibility artifacts can be minimized by use of parallel imaging.

Clinical Applications at 3 T

MR Angiography

The T1 relaxation time of fluids such as blood and cerebrospinal fluid is relatively constant across different field strengths, while that of sta-

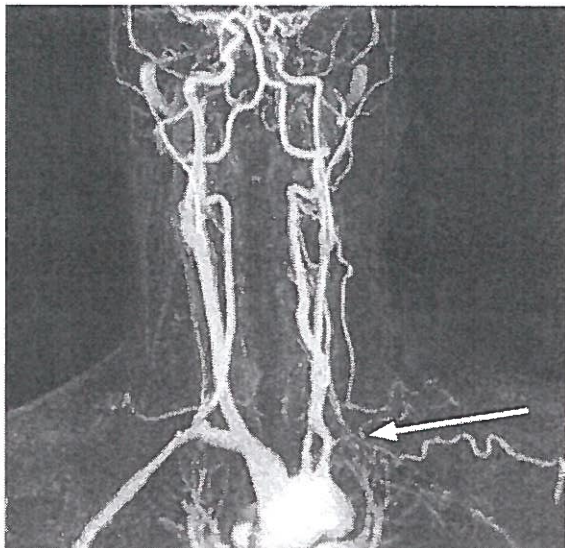


Figure 7. MR angiography in a case of Takayasu disease. Coronal maximum intensity projection image from contrast-enhanced MR angiography, obtained at 3 T (4.6/1.5, flip angle = 27°, bandwidth = 851 Hz, voxel size = 0.74 × 0.74 × 1.5 mm, FOV = 320 × 320 mm), shows occlusion of the left subclavian artery (arrow) and the resultant collateral vessels.

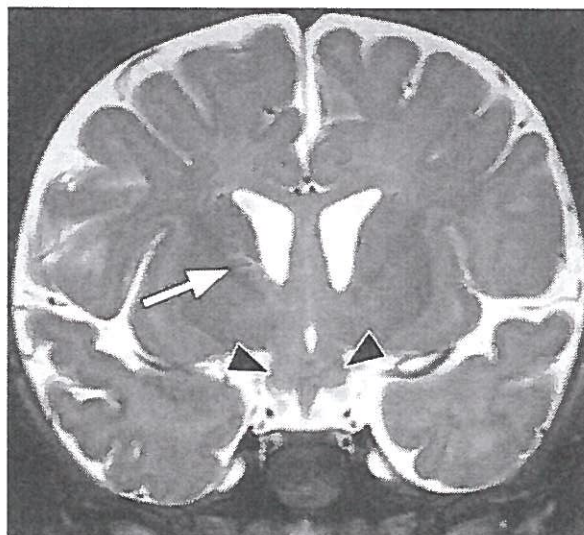
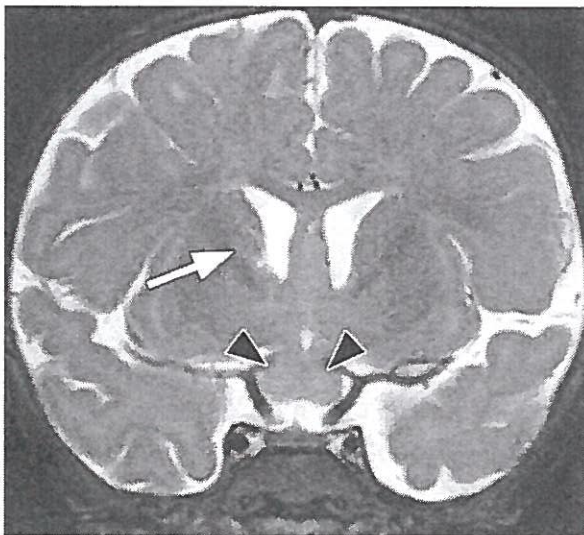


Figure 8. Superior anatomic details at 3-T imaging in an 8-year-old girl with neurofibromatosis type 1 and an optic pathway glioma (same patient as in Fig 4). Coronal T2-weighted images, obtained at 1.5 T (6245/110, flip angle = 90°, bandwidth = 224 Hz, voxel size = 0.60 × 0.66 × 3.0 mm, number of signals acquired = three, ETL = 21, FOV = 160 × 160 mm) (a) and at 3 T (3694/84, flip angle = 90°, bandwidth = 184 Hz, voxel size = 0.4 × 0.7 × 3.0 mm, number of signals acquired = two, ETL = 15, FOV = 180 × 180 mm) (b) 6 months apart, show a branching structure in the right caudate nucleus (arrow). This structure, which probably represents a perivascular space, is better demonstrated on the 3-T image than on the 1.5-T image. The 3-T image is also less grainy, an appearance suggestive of superior SNR and resolution than in the 1.5-T image. Arrowheads = optic pathway glioma.

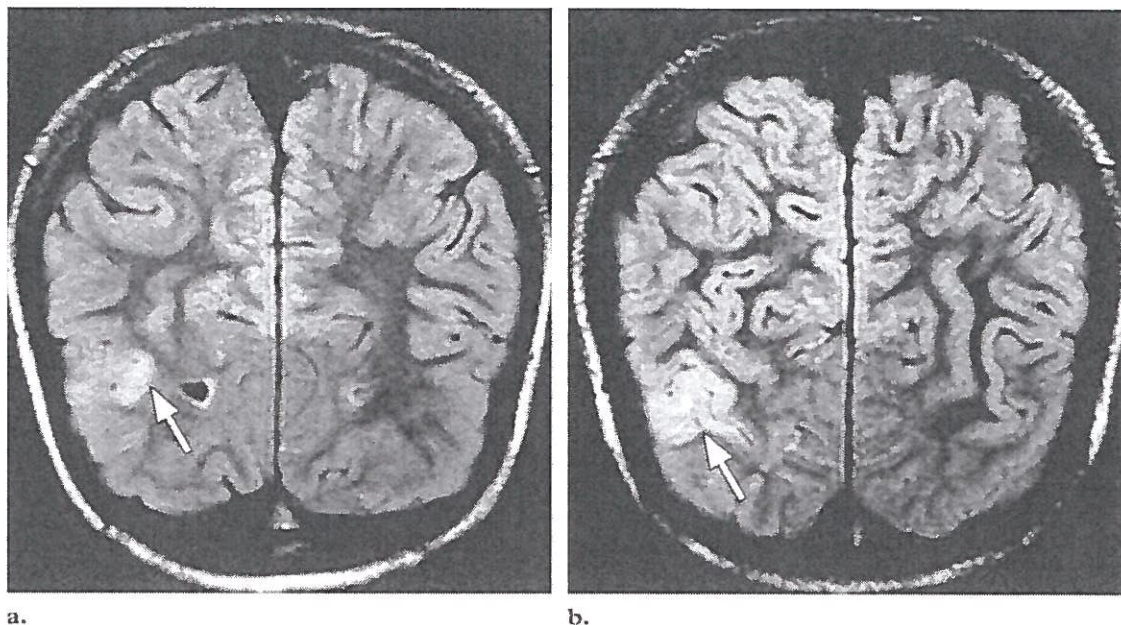
tionary tissues is increased at 3 T. This results in improved vessel-to-stationary tissue contrast for time-of-flight angiography (1) (Fig 6). In addition, high contrast-to-noise ratio at 3 T results in improved resolution for contrast-enhanced MR angiography (Fig 7). MR angiography can be performed in a shorter time at 3 T than at 1.5 T. In our experience, consistently superior quality of MR angiography with better visualization of peripheral small vessels in children is seen at 3 T.

Teaching Point

Brain Imaging

Thin-section images with high spatial resolution that are acquired in a shorter time at 3 T than at 1.5 T provide superior anatomic details in pediatric brain imaging, even with a small FOV (Fig 8). This results in better visualization of small structures such as nerves and vessels. Similar observations about superior anatomic details at 3 T have been made by Zimmerman et al (15).

Figure 9. Imaging of epilepsy. Consecutive coronal FLAIR images of the brain obtained at 3 T (10,000/141, inversion time = 2850 msec, flip angle = 90°, bandwidth = 242 Hz, voxel size = 0.7 × 0.7 × 3.0 mm, FOV = 220 × 220 mm) show an ill-defined area of increased signal intensity (arrow) in the right occipital lobe, a finding consistent with focal cortical dysplasia.



At 3 T, imaging of epilepsy benefits from better visualization of hippocampal anatomy and cortical dysplasias (Fig 9). Improved visualization of small nerves and vessels in the posterior fossa with increased clarity of cisternal nerve roots makes 3 T superior in inner ear imaging (Fig 10). At our institution, 3-T imaging is the preferred modality for MR angiography, epilepsy imaging, and inner ear imaging.

Increased chemical shift at 3 T results in improved spectral resolution and separation of metabolite peaks in MR spectroscopy (1,5). T2*-based techniques like blood oxygen level-dependent functional MR imaging and dynamic susceptibility-weighted contrast-enhanced MR perfusion imaging benefit from increased suscep-

tibility at 3 T (1). However, worsening susceptibility artifacts can limit this benefit. The actual clinical experience is still limited.

Spine Imaging

Better visualization of intrinsic spinal cord disease, such as demyelinating disease, spinal cord edema, and myelomalacia, has been observed at 3 T in adults (16). Most pediatric spine studies are performed for evaluation of thecal sac and spinal cord disease. In our experience, conspicuity of the spinal cord is reduced on T2-weighted images owing to flow artifacts (Fig 11a). Spinal cord conspicuity is also reduced on T1-weighted images owing to prolonged T1 relaxivity. As in brain imaging, a 3D T1-weighted turbo field echo sequence works well in spinal cord imaging and can be a good option for T1-weighted imaging of the cord (Fig 11b). However, there may be decreased visibility of marrow disease owing to

Figure 10. Imaging of the inner ear and posterior cranial fossa. (a) Sagittal T2-weighted image obtained at 3 T (3000/113, flip angle = 90°, bandwidth = 255 Hz, voxel size = 0.3 × 0.3 × 2.0 mm, number of signals acquired = three, ETL = 21, FOV = 90 × 90 mm) shows four nerves in the internal auditory canal (arrow). (b) Axial T2-weighted image (3000/113, flip angle = 90°, bandwidth = 255 Hz, voxel size = 0.3 × 0.3 × 1.0 mm, number of signals acquired = three, ETL = 21, FOV = 120 × 120 mm) of the posterior fossa shows cranial nerves VII and VIII (arrows) in the cerebellopontine angle cisterns.



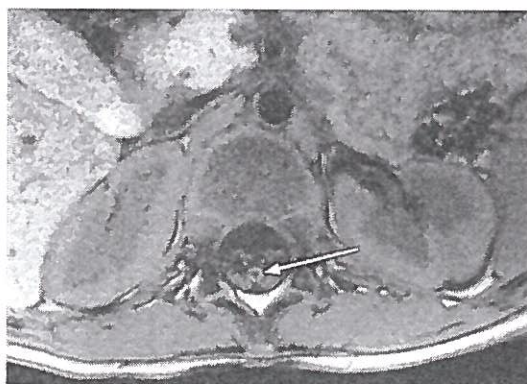
a.

b.

Figure 11. Imaging of the spine. (a) Sagittal T2-weighted image (4245/102, flip angle = 90°, bandwidth = 444 Hz, voxel size = 0.6 × 0.9 × 3.0 mm, number of signals acquired = three, ETL = 25, FOV = 300 × 292 mm, no flow compensation) of the cervicothoracic spine shows poor demonstration of the spinal cord—especially in the thoracic region—owing to flow artifacts (arrows). (b) Axial 3D T1-weighted turbo field echo image (5.7/2.8, flip angle = 8°, bandwidth = 300 Hz, voxel size = 0.7 × 0.8 × 4.0 mm, number of signals acquired = three, FOV = 200 × 200 mm) shows a nonexpansile syrinx (arrow) in the conus of the spinal cord.



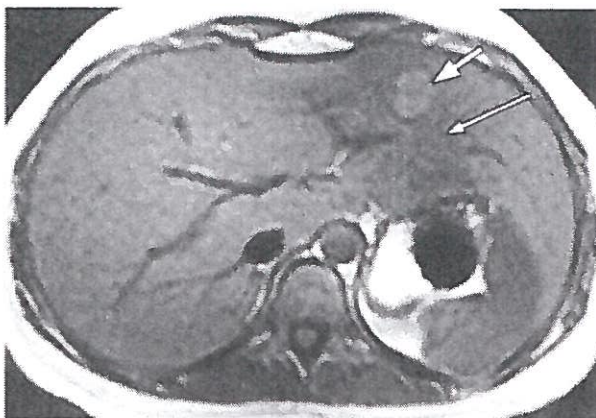
a.



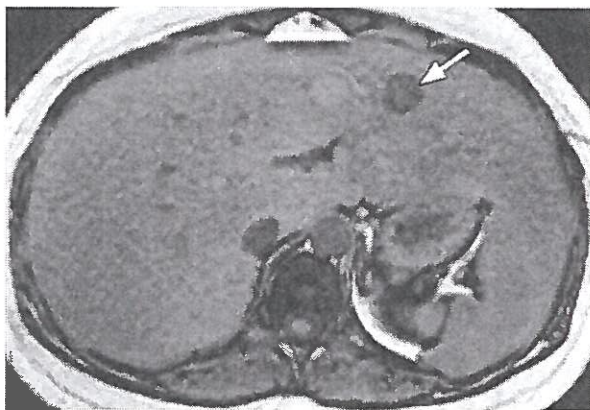
b.



a.



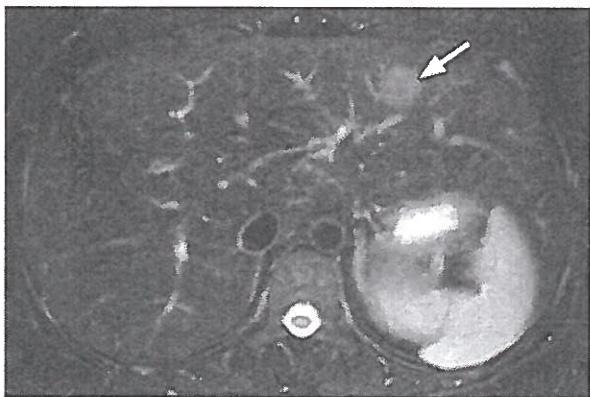
e.



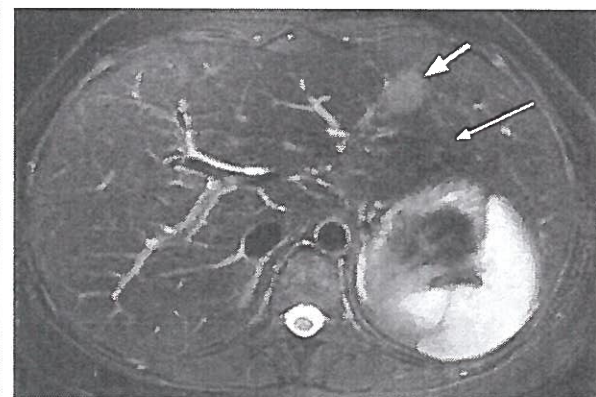
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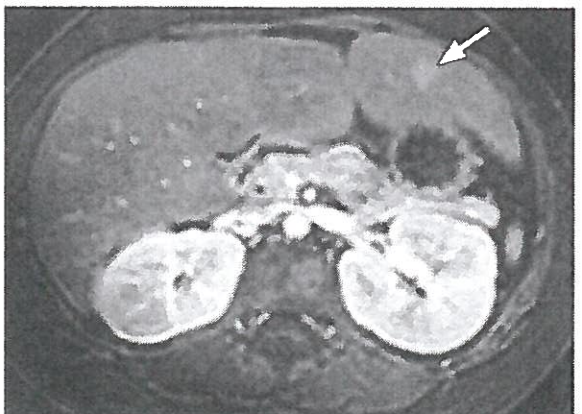
f.



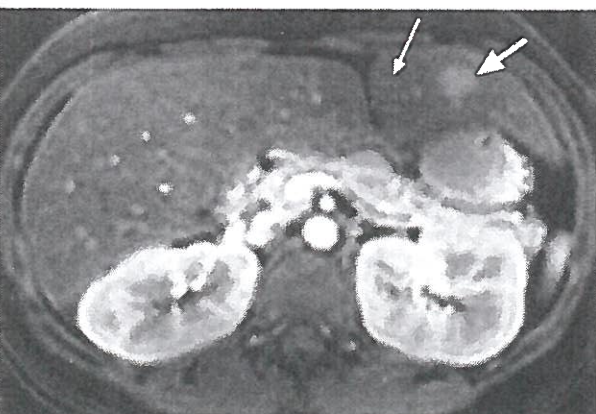
c.



g.



d.



h.

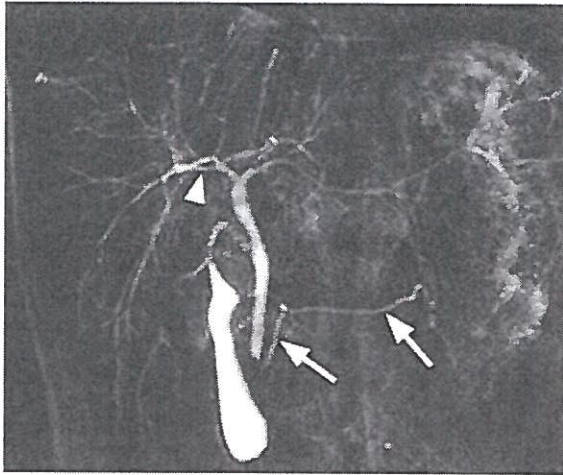


Figure 13. Early changes of primary sclerosing cholangitis in a 16-year-old boy with ulcerative colitis. Coronal thick-slab single-shot FSE image from MR cholangiopancreatography, obtained at 3 T (9449/740, flip angle = 90°, bandwidth = 408 Hz, voxel size = 0.93 × 1.2 × 40.0 mm, FOV = 300 × 300 mm), shows mild dilatation of the common bile duct and minimal caliber change of the right intrahepatic duct (arrowhead). Arrows = normal pancreatic duct.

decreased contrast between fat and focal marrow abnormalities on T1-weighted images. For these reasons, spine imaging is preferably performed at 1.5 T at our institution.

Body Imaging

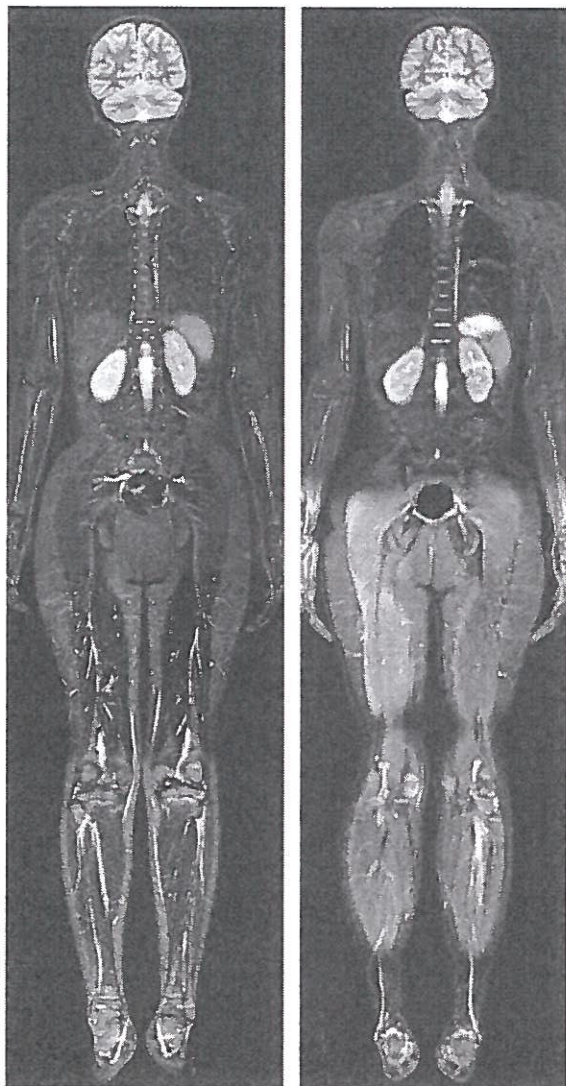
Body imaging at 3 T, in particular abdominal imaging, is limited by artifacts. It is difficult to maintain homogeneity of the magnetic field in the presence of various motions inherent to the abdomen. Dielectric effect can cause local variation in signal intensity (5). Parallel imaging and single-shot sequences are useful. Body imaging applications that potentially benefit from 3-T imaging include contrast-enhanced evaluation of solid organs (Fig 12), contrast-enhanced MR angiography, MR cholangiopancreatography, and diffusion-weighted imaging (5).

Thin-section high-resolution images can improve lesion conspicuity. Increased SNR can

be used to shorten the imaging time, which is particularly useful in children, who may not hold their breath for long. Higher SNR and contrast-to-noise ratio have been shown for MR cholangiopancreatography at 3 T in two small studies (17,18). In our experience, visualization of small peripheral intrahepatic ducts and the pancreatic duct in children is improved at 3 T in comparison with that at 1.5 T (Fig 13).

Superior anatomic details can be seen in the pelvis, which is less affected by breathing motion. This can benefit evaluation of perianal fistulas, the uterus and ovaries, and urethral anatomy in children. Good-quality whole-body MR images comparable with those from 1.5-T imaging can be obtained in a shorter time at 3 T (Fig 14).

Figure 12. Liver imaging in a child with glycogen storage disease and a presumed hepatic adenoma. (a–d) Axial in-phase (133/4.6, flip angle = 80°, bandwidth = 523 Hz, voxel size = 1.25 × 1.5 × 6.0 mm, FOV = 320 × 320 mm) (a), out-of-phase (echo time = 2.3 msec) (b), fat-saturated T2-weighted FSE (2083/100, flip angle = 90°, bandwidth = 235 Hz, voxel size = 1.0 × 1.1 × 7.0 mm, number of signals acquired = two, FOV = 320 × 320 mm) (c), and gadolinium-enhanced T1-weighted high-resolution isovolumetric volume (4.0/2, flip angle = 10°, bandwidth = 434 Hz, voxel size = 2.0 × 2.0 × 4.0 mm, FOV = 340 × 340 mm) (d) images obtained at 1.5 T show a hepatic adenoma (arrow). (e–h) Axial in-phase (180/2.3, flip angle = 60°, bandwidth = 1132 Hz, voxel size = 1.7 × 2.0 × 7.0 mm, FOV = 320 × 320 mm) (e), out-of-phase (echo time = 3.4 msec) (f), fat-saturated T2-weighted FSE (1795/80, flip angle = 90°, bandwidth = 151 Hz, voxel size = 0.7 × 0.7 × 8.0 mm, number of signals acquired = two, ETL = 15, FOV = 300 × 300 mm) (g), and gadolinium-enhanced T1-weighted high-resolution isovolumetric volume (3.16/1.5, flip angle = 10°, bandwidth = 718 Hz, voxel size = 2.0 × 2.0 × 4.0 mm, FOV = 280 × 280 mm) (h) images, obtained at 3 T 6 months later, show the hepatic adenoma (thick arrow). There are areas of signal loss (thin arrow in e, g, and h), which represent artifacts related to dielectric effects or inhomogeneity.



a.

b.

Figure 14. Whole-body MR imaging. Coronal combined short inversion time inversion-recovery images, obtained at 1.5 T (2444/64, inversion time = 165 msec, flip angle = 90°, bandwidth = 487 Hz, voxel size = 1.0 × 1.0 × 6.0 mm, ETL = 30, FOV = 530 × 530 mm) (a) and 3 T (8067/70, inversion time = 230 msec, flip angle = 90°, bandwidth = 218 Hz, voxel size = 1.4 × 1.6 × 6.0 mm, ETL = 28, FOV = 470 × 470 mm) (b), show the whole body. The 1.5-T image shows fairly uniform signal intensity throughout the body and less signal loss in the lungs from susceptibility in comparison with the 3-T image. However, the 3-T image shows individual muscles more clearly owing to high SNR and spatial resolution.

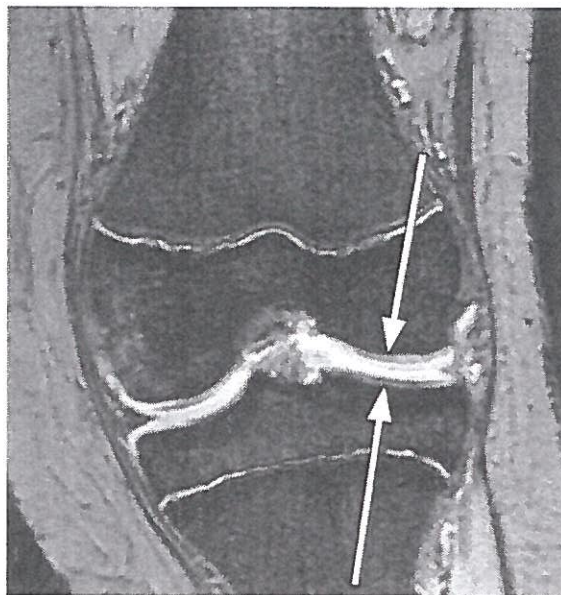


Figure 15. Articular cartilage. Coronal T2-weighted fast field echo image (681/12, flip angle = 20°, bandwidth = 217 Hz, voxel size = 0.5 × 0.5 × 3.0 mm, FOV = 165 × 165 mm) of the left knee joint shows articular cartilage as an intermediate-signal-intensity structure (arrows) that is separate from joint fluid.



Figure 16. Juvenile idiopathic arthritis involving the temporomandibular joints. Sagittal oblique proton-density-weighted image of the temporomandibular joint, obtained at 3 T (3000/30, flip angle = 90°, bandwidth = 308 Hz, voxel size = 0.43 × 0.63 × 3.0 mm, FOV = 110 × 110 mm), shows flattening of the mandibular condyle (arrow).

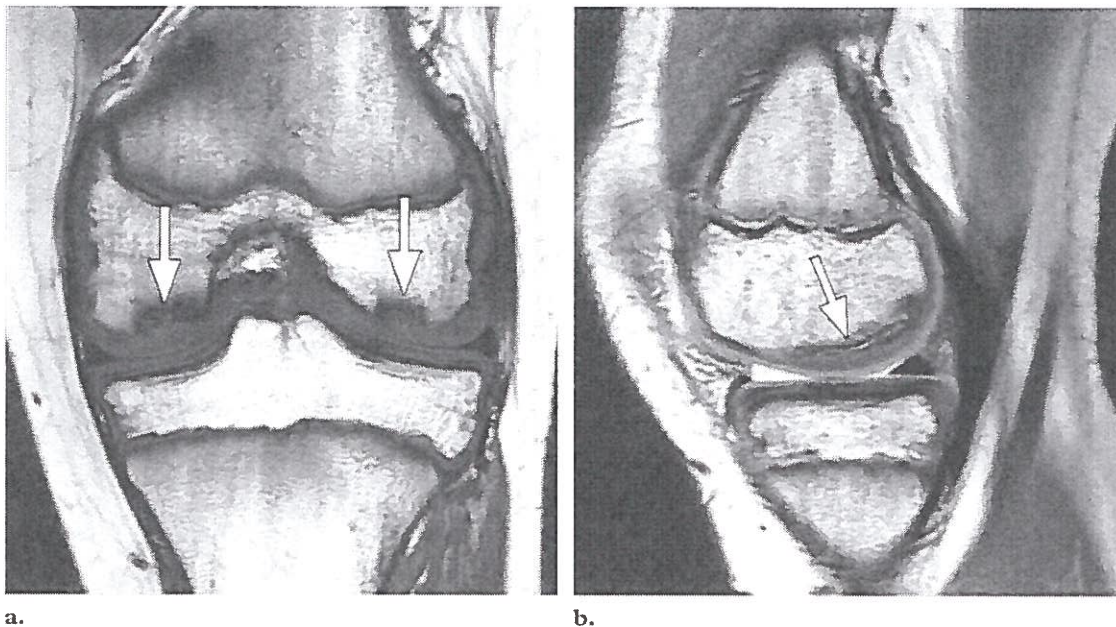


Figure 17. Osteochondritis dissecans at 3-T imaging. **(a)** Coronal T1-weighted image (577/20, flip angle = 90°, bandwidth = 290 Hz, voxel size = 0.43 × 0.63 × 3.0 mm, FOV = 165 × 165 mm) of the knee joint shows osteochondral lesions (arrows) in both femoral condyles. **(b)** Sagittal proton-density-weighted image (4000/30, flip angle = 90°, bandwidth = 290 Hz, voxel size = 0.43 × 0.63 × 3.0 mm, FOV = 165 × 165 mm) shows excellent details of one of the osteochondral lesions (arrow).

However, there are significantly more artifacts at 3 T; thus, 1.5-T imaging is the preferred modality for whole-body MR imaging at present (19).

Musculoskeletal Imaging

Musculoskeletal imaging has emerged as one of the most important clinical applications of high-field-strength MR imaging, with reduced imaging time, thin sections, and high-spatial-resolution images even for a small FOV (1). Visualization of cartilage, nerves, and ligaments and imaging of small joints are improved at 3 T (1,20,21) (Figs 15–17). In approximately 300 musculoskeletal imaging examinations performed at 3 T, we found consistently superior image quality with better visualization of cartilages and ligaments. Imaging time for musculoskeletal MR imaging examinations was reduced.

Conclusions

Clinical experience with the utility of 3-T imaging is still accumulating. Our initial experience suggests image quality improvement in epilepsy imaging, inner ear imaging, and musculoskeletal imaging at 3 T because thin-section high-resolution images are obtained in a short time even with

the small FOV used in children. Furthermore, 3-T imaging is excellent in MR angiography and MR cholangiopancreatography and should be the preferred modality for these applications wherever available. Potential benefits in spine and body imaging are limited by the presence of significantly more artifacts, which degrade image quality. The effect of the improved image quality of 3-T imaging on diagnostic ability, clinical utility, and treatment decisions is still not clear. However, 3-T imaging has the potential to increase throughput, especially in musculoskeletal imaging.

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MR Imaging at 3.0 T in Children: Technical Differences, Safety Issues, and Initial Experience

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Page 1452

Potential advantages of imaging children at 3 T include acceptable image quality with good SNR and spatial resolution even for a small field of view (FOV). These are helpful in imaging small children and infants with varying body sizes (2).

Page 1456

Field focusing and dielectric effect cause inhomogeneity of signal across the FOV with signal loss, particularly in the intermediate area between the center and the periphery (1) (Fig 2b, 2c).

Page 1456

Chemical shift artifact of the first kind, which results from mismatching of the frequency-encoded signal of fat into water voxels, is increased at 3 T (3). It is seen as a dark and white band at the margins of fatty tissue (Fig 2d, 2e).

Page 1457

T2-weighted images benefit most from high SNR because the longer repetition time used at 3 T allows more recovery of longitudinal magnetization (5,14). T2-weighted images are also the ones that are affected more by flow and motion artifacts, especially in the abdomen, spine, and posterior cranial fossa.

Page 1459

In our experience, consistently superior quality of MR angiography with better visualization of peripheral small vessels in children is seen at 3 T.

Results of a North American survey of rapid-sequence MRI utilization to evaluate cerebral ventricles in children

Clinical article

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Object. Growing concern about potential adverse effects of ionizing radiation exposure during imaging studies is particularly relevant to the pediatric population. To decrease radiation exposure, many institutions use rapid-sequence (or quick-brain) MRI to evaluate cerebral ventricle size. There are obstacles, however, to widespread implementation of this imaging modality. The purpose of this study was to define and quantify these obstacles to positively affect institutional and governmental policy.

Methods. A 9-question survey was emailed to pediatric neurosurgeons who were either members or candidate members of the American Society of Pediatric Neurosurgeons at every one of 101 institutions in the US and Canada having such a neurosurgeon on staff. Responses were compiled and descriptive statistics were performed.

Results. Fifty-six institutions completed the survey. Forty-four (79%) of the 56 institutions currently have a rapid-sequence MRI protocol to evaluate ventricle size, while 36 (64%) use it routinely. Of the 44 institutions with a rapid-sequence MRI protocol, 29 (66%) have had a rapid-sequence MRI protocol for less than 5 years while 39 (89%) have had a rapid-sequence MRI protocol for no more than 10 years. Thirty-six (88%) of 41 rapid-sequence MRI users responding to this question obtain a T2-weighted rapid-sequence MRI while 13 (32%) obtain a T1-weighted rapid-sequence MRI. Twenty-eight (64%) of 44 institutions never use sedation while an additional 12 (27%) rarely use sedation to obtain a rapid-sequence MRI (less than 5% of studies). Of the institutions with an established rapid-sequence MRI protocol, obstacles to routine use include lack of emergency access to MRI facilities in 18 (41%), lack of staffing of MRI facilities in 12 (27%), and the inability to reimburse a rapid-sequence MRI protocol in 6 (14%). In the 12 institutions without rapid-sequence MRI, obstacles to implementation include lack of emergency access to MRI facilities in 8 (67%), lack of staffing of MRI facilities in 7 (58%), the inability to reimburse in 3 (25%), and lack of administrative support in 3 (25%). To evaluate pediatric head trauma, 53 (96%) of 55 institutions responding to this question use noncontrast CT, no institution uses rapid-sequence MRI, and only 2 (4%) use standard MRI.

Conclusions. Many North American institutions have a rapid-sequence MRI protocol to evaluate ventricle size, with most developing this technique within the past 5 years. Most institutions never use sedation, and most obtain T2-weighted sequences. The greatest obstacles to the routine use of rapid-sequence MRI in institutions with and in those without a rapid-sequence MRI protocol are the lack of emergency access and staffing of the MRI facility during nights and weekends.

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KEY WORDS • rapid sequence MRI • radiation • hydrocephalus • ventricles • technique

THE deleterious effects of radiation exposure in children from CT are now well defined.^{3,4} The risk of developing a radiation-induced malignancy is relative to a patient's cumulative radiation exposure and increases with exposure at younger ages.³ Radiation exposure in children with shunted hydrocephalus is particularly concerning given their lifetime exposure to numerous head CT scans for shunt evaluation. Reported high failure rates after primary shunt insertion⁵ is one factor contributing to an increased likelihood of CT exposure in younger populations.

Gaskill and Marlin found that children with myelomeningocele receive on average 3.6 head CT scans dur-

ing their lifetime, and an average of 6.38 rad/year (range 0.79–37.81 rad/year) from radiography and CT.⁷ Another report found that children with complex hydrocephalus received an average of 13.4 head CT scans (range 1–94 scans) during a 5-year period.¹³ This exposure to radiation is more than the annual limit of 5 rad for occupational doses¹⁴ and 0.1 rad for the general public as specified by the US Nuclear Regulatory Commission.¹⁵

To reduce the amount of lifetime radiation exposure in children with shunts, some institutions use rapid-sequence, “fast-brain,” or “vent-check” MRI^{1,2,8–12,16} that takes approximately the same amount of imaging time as a head CT scan but eliminates exposure to radiation or sedation risks. This technology is relatively new and its use in North America is unknown. The purpose of this study was to evaluate the use of rapid-sequence MRI in North

Abbreviation used in this paper: TBI = traumatic brain injury.

Rapid-sequence MRI use in North America

America, to determine the primary obstacles for expanding use of this safer imaging technique, and to provide data for institutions without this resource to subsequently positively affect institutional and governmental policy.

Methods

A 9-question survey (Table 1) was emailed to pediatric neurosurgeons who were either members or candidate members of the American Society of Pediatric Neurosurgeons at every one of 101 institutions in the US and Canada having such a neurosurgeon on staff. Only 1 individual per institution was surveyed to eliminate duplicate institutional responses. Response data were collected using Survey Monkey (<https://www.surveymonkey.com>). Stata (version 10.1, StataCorp LP) and Microsoft Excel were used to tabulate the results.

Results

Fifty-six of 101 institutions completed the survey (55% response rate). Forty-four (79%) of 56 institutions have a rapid-sequence MRI protocol to evaluate ventricle size, and 36 (82%) of those 44 institutions use it routinely. The majority of institutions have used rapid-sequence MRI for less than 5 years (29/44, 66%), obtain at least T2-weighted sequences (36/41, 88%), and never use sedation (28/44, 64%; Fig. 1). Of the 44 institutions with a rapid-sequence MRI protocol, obstacles to routine use include lack of emergency access to MRI facilities in 18 (41%), lack of staffing for MRI facilities in 12 (27%), and inability to reimburse a rapid-sequence MRI protocol from third-party payers in 6 (14%). Of those who noted the inability to reimburse a rapid-sequence MRI protocol, 3 (50%) indicated that they had made an effort to appropriately reimburse rapid-sequence MRI, while 3 (50%) were unsure if an effort had been made.

In the 12 institutions without rapid-sequence MRI, obstacles to implementation included lack of emergency access to MRI facilities in 8 (67%), lack of staffing for MRI facilities in 7 (58%), inability to reimburse a rapid-sequence MRI protocol from third-party payers in 3 (25%), and lack of administrative support in 3 (25%). Of those with reimbursement difficulties, 1 had not made an effort to reimburse rapid-sequence MRI, 1 had made an effort, and 1 was unsure if any effort had been made.

To evaluate nonpenetrating traumatic brain injury (TBI), 53 (96%) of 55 institutions responding to this question use noncontrast head CT while 2 (4%) use standard MRI. Forty-nine (89%) of the 55 institutions have a radiation reduction protocol for CT head imaging in children while 3 (5%) do not and 3 (5%) were unsure.

Discussion

Based on the results of this survey, a large number of institutions in the US and Canada have a rapid-sequence MRI protocol to evaluate ventricle size in pediatric patients. Only 81% of these institutions, however, routinely use this technology. The most commonly cited obstacles for the routine use of rapid-sequence MRI were similar among

those institutions with a rapid-sequence MRI protocol and those without a protocol: lack of emergency access to MRI facilities, lack of staffing for MRI facilities during nights and weekends, and inability to obtain reimbursement from third-party payers for rapid-sequence MRI.

Based on survey responses, the availability of rapid-sequence MRI protocols is relatively new in many institutions and rapid-sequence MRI use is rapidly increasing. Sixty-six percent of institutions have used a rapid-sequence MRI protocol for less than 5 years and 89% have had a rapid-sequence MRI protocol for less than 10 years. Ideally, within another 5 years, all institutions caring for pediatric neurosurgical patients will use rapid-sequence MRI in lieu of CT for cerebral ventricle evaluation.

Study Limitations

The present study is limited by a 55% survey response rate, and further does not reflect the practices at pediatric neurosurgical services and hospitals not staffed by members or candidate members of the American Society of Pediatric Neurosurgeons. Conceivably, the nonreturned surveys (45%) could be from sites that do not use rapid-sequence MRI, and thus the reported results could be skewed. Responses received were not validated directly with the respondents' institutions to assure accuracy. Questions regarding barriers to rapid-sequence MRI were subjective in nature, and the survey instrument has not been previously validated.

Clinical Rapid-Sequence MRI

Most reports of clinical rapid-sequence MRI use have focused on the evaluation of hydrocephalus.^{1,8-10,12,16} However, other pathologies may be successfully screened, evaluated, and/or followed using rapid-sequence MRI, including tumors, inflammatory/demyelinating lesions, hemorrhage in children and adults, macrocephaly, intracranial cysts, Chiari malformations, congenital abnormalities, and traumas.^{2,11} For trauma patients, rapid-sequence MRI has been used primarily for follow-up imaging.¹¹ Additionally, in 1 study 13 of 64 patients with minor TBI underwent initial evaluation with rapid-sequence MRI and none were subsequently noted to have a missed lesion.¹¹

Traumatic brain injury is a potential area for expanded rapid-sequence MRI use. The present survey demonstrated that more than 96% of institutions continue to rely on noncontrast head CT scanning in the evaluation of nonpenetrating TBI in children. The sensitivity and specificity of rapid-sequence MRI for various findings that influence the medical and surgical management of cranial trauma have yet to be firmly established. One clearly established disadvantage of MRI in comparison with CT for the evaluation of cranial trauma, however, is insensitivity to nondisplaced skull fractures, which do not typically alter clinical management. Conversely, rapid-sequence MRI is effective in demonstrating many clinically relevant findings, such as parenchymal or extraaxial hemorrhage and mass effect,¹¹ and in our experience, sinus opacification sometimes associated with skull base fractures.

Other potential drawbacks of using rapid-sequence MRI include the need for a parent or health care profes-

TABLE 1: Survey questions

Does your institution have a "quick brain/vent check" MR imaging protocol to evaluate the ventricle size in pediatric patients?

- yes
- no
- unsure

How long has your institution utilized "quick brain/vent check" MR imaging?

- < 5 years
- 5–10 years
- > 10 years
- unsure

At your institution, what are the primary sequence(s) obtained for the "quick brain/vent check" MR imaging protocol? (e.g., T2 axial, T1, DWI)

Is sedation used to obtain "quick brain/vent check" protocol MR imaging?

- never
- rarely (< 5% of studies)
- occasionally (5–49% of studies)
- frequently (50–99% of studies)
- always (100% of studies)
- unsure

If you have encountered obstacles to implementation of "quick brain/vent check" MR imaging what are/were they (check all that apply)?

- unable to reimburse "quick brain/vent check" study
- lack of emergency access to MR imaging facilities
- lack of staffing for MR imaging facilities
- lack of administrative support
- have not attempted to implement
- unsure
- other
- if other (please specify)

If "quick brain/vent check" is not reimbursed, has an effort been made by your institution to change reimbursement policy?

- not applicable
- yes
- no
- unsure
- if yes (please specify)

At your institution, what is the preferred method of evaluating ventricle size in patients with an existing ventriculoperitoneal shunt?

- CT
- quick brain/vent check MRI
- standard MRI
- other
- if other (please specify)

At your institution, what is the preferred method of evaluating the brain in patients with a GCS of 14 or 15 with non-penetrating traumatic brain injury?

- CT
- quick brain/vent check MRI
- standard MRI
- other
- if other (please specify)

At your institution, does a CT brain imaging protocol exist to reduce radiation exposure in pediatric patients?

- yes
- no
- unsure

Rapid-sequence MRI use in North America

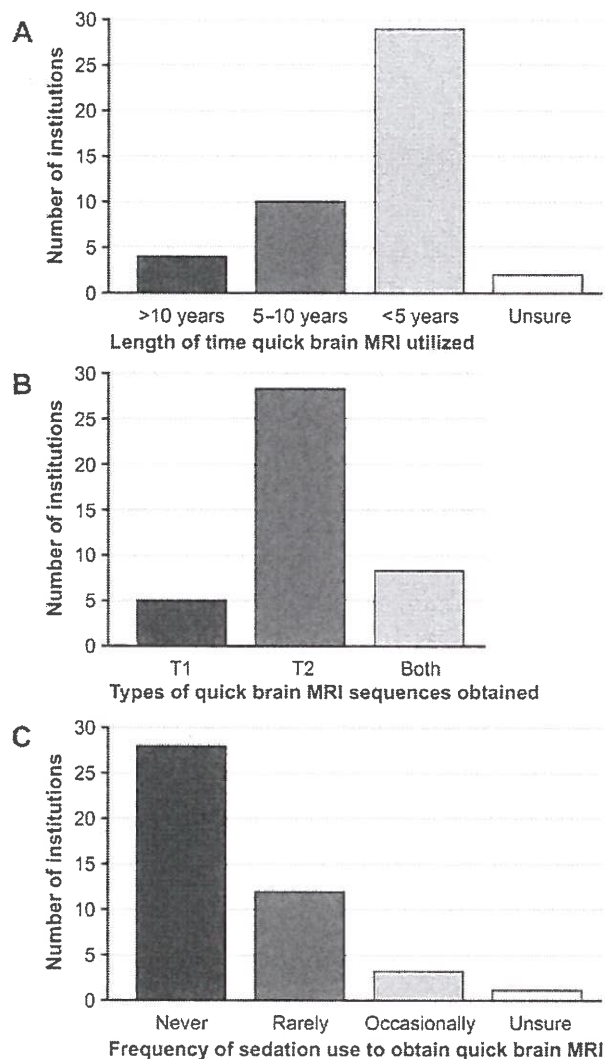


Fig. 1. Graphs of rapid-sequence MRI use characteristics of institutions with a quick-brain MRI protocol. The graphs show responses to the following survey questions: "How long has your institution utilized 'quick brain/vent check' MR imaging?" (A); "At your institution, what are the primary sequence(s) obtained for the 'quick brain/vent check' MR imaging protocol? (e.g. T2 axial, T1, DWI)" (B); and "Is sedation used to obtain 'quick brain/vent check' protocol MR imaging?" (C). Note that no institution reported the use of diffusion weighted imaging as part of their rapid-sequence MRI protocol.

sional to accompany the patient into the MRI machine to aid with quality image acquisition, concerns with medical device and implant incompatibility, and inadvertent reprogramming of some programmable shunts. Notably, the Medtronic SynchroMed II intrathecal infusion pump is reported to be safe at field strengths $\leq 3T$, and the Cyberonics Vagus Nerve Stimulator Therapy System is reported to be safe at field strengths $\leq 3T$ as long as a head or local transmit/receive coil is used.

Recently, a quick-spine MRI non-sedation imaging protocol has been investigated for its potential to replace cervical CT or sedated diagnostic MRI in patients with

suspected cervical trauma.⁶ In the future, it is possible that MRI-based urgent evaluation of nonpenetrating craniocervical trauma in children could substantially reduce radiation exposure in this patient population.

Conclusions

Adoption and utilization of rapid-sequence MRI protocols in the US and Canada are increasing. Key obstacles to widespread utilization of rapid-sequence MRI are lack of emergency or off-hour MRI availability, lack of available MRI technicians to perform these studies, and barriers to study reimbursement. Quantification of rapid-sequence MRI use in the US and Canada and objective identification of barriers to adoption and routine use are important to influence institutional and governmental policies regarding this important imaging technique. Expanded use of MRI offers the potential of minimizing the adverse effects of radiation exposure in children.

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Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers

The use of pediatric CT, which is a valuable imaging tool, has been increasing rapidly. However, because of the potential for increased radiation exposure to children undergoing these scans, pediatric CT is a public health concern. This page discusses the value of CT and the importance of minimizing the radiation dose, especially in children. It will address the following issues:

- CT as a diagnostic tool
- Unique considerations for radiation exposure in children
- Radiation risks from CT in children
- Immediate strategies to minimize CT radiation exposure to children

CT as a Diagnostic Tool

CT can be a life saving tool for diagnosing illness and injury in children. For an individual child, the risks of CT are small and the individual risk-benefit balance favors the benefit when used appropriately.

Approximately 5 to 9 million CT examinations are performed annually on children in the United States. The use of CT in adults and children has increased about eightfold since 1980, with annual growth estimated at about 10 percent per year. Much of this increase is due to its utility in common diseases, as well as to technical improvements.

Despite the many benefits of CT, a disadvantage is the inevitable radiation exposure. Although CT scans comprise up to about 12 percent of diagnostic radiological procedures in large U.S. hospitals, it is estimated that they account for approximately 49 percent of the U.S. population's collective radiation dose from all medical x-ray examinations. CT is the largest contributor to medical radiation exposure among the U.S. population.

Unique Considerations for Radiation Exposure in Children

Radiation exposure is a concern in both adults and children. However, there are three unique considerations in children.

- Children are considerably more sensitive to radiation than adults, as demonstrated in epidemiologic studies of exposed populations.
- Children have a longer life expectancy than adults, resulting in a larger window of opportunity for expressing radiation damage.
- Children may receive a higher radiation dose than necessary if CT settings are not adjusted for their smaller body size.

As a result, the risk for developing a radiation-related cancer can be several times higher for a young child compared with an adult exposed to an identical CT scan.

In the last decade improvements in CT equipment have allowed for better images at lower doses. The use of appropriate settings has also become much more widespread, resulting in reductions in doses for children. There is no need for higher doses in children, and appropriate settings should always be used.

Regardless of the lower doses, multiple scans to an individual patient present a particular concern. In addition, the use of more than one scan (that is, more than one contrast "phase") during a single examination will further increase the radiation dose. In the vast majority of cases, a single scan should be sufficient during pediatric CT.

Radiation Risks from CT in Children

Major national and international organizations responsible for evaluating radiation risks agree that there probably is no low-dose radiation "threshold" for inducing cancers. In other words, no amount of radiation should be considered absolutely safe.

The first study to assess directly the risk of cancer after CT scans in childhood found a clear dose-response relationship for both leukemia and brain tumors: risk increased with increasing cumulative radiation dose. For a cumulative dose of between 50 and 60 milligray or mGy (mGy is a unit of estimated absorbed dose of ionizing radiation) to the head, the investigators reported a threefold increase in the risk of brain tumors; the same dose to bone marrow (the part of the body responsible for generating blood cells) resulted in a threefold increase in the risk of leukemia. For both findings, the comparison group consisted of individuals who had cumulative doses of less than 5 mGy to the relevant regions of the body.

The number of CT scans required to give a cumulative dose of 50-60mGy depends on the type of CT scan, the age of the patient and the scanner settings. If typical current scanner settings are used for head CT in children, then two to three head CT scans would result in a dose of 50-60mGy to the brain. The same dose to re. bone marrow would be produced by five to 10 head CT scans, using current scanner settings for children under age 15.

Previously, the potential cancer risk from CT use has been estimated using risk projection models derived primarily from studies of survivors of the atomic bomb explosions in Japan. The risks observed in the study described above were consistent with those previous estimates.

It is important to stress that the absolute cancer risks associated with CT scans are small. The lifetime risks of cancer due to CT scans, which have been estimated in the literature using projection models based on atomic bomb survivors, are about 1 case of cancer for every 1,000 people who are scanned, with a maximum incidence of about 1 case of cancer for every 500 people who are scanned.

The benefits of properly performed and clinically justified CT examinations should always outweigh the risks for an individual child; unnecessary exposure is associated with unnecessary risk. Minimizing radiation exposure from pediatric CT, whenever possible, will reduce the projected number of CT-related cancers.

Immediate Measures to Minimize CT Radiation Exposure in Children

Physicians, other pediatric health care providers, CT technologists, CT manufacturers, and various medical and governmental organizations share the responsibility to minimize CT radiation doses to children. Several immediate steps can be taken to reduce the amount of radiation that children receive from CT examinations:

- *Perform only necessary CT examinations.* Communication between pediatric health care providers and radiologists can determine the need for CT and the technique to be used. There are standard indications for CT in children, and radiologist should review reasons prior to every pediatric scan and be available for consultation when indications are uncertain. When appropriate, other modalities such as ultrasound or magnetic resonance imaging (MRI), which do not use ionizing radiation, should be considered.
- *Adjust exposure parameters for pediatric CT based on*
 - Child size: guidelines based on individual size / weight parameters should be used.
 - Region scanned: the region of the body scanned should be limited to the smallest necessary area.
 - Organ systems scanned: lower mA and/or kVp settings should be considered for skeletal, lung imaging, and some C angiographic and follow up examinations.
- *Scan resolution:* the highest quality images (i.e., those that require the most radiation) are not always required to make diagnoses. In many cases, lower-resolution scans are diagnostic. Providers should be familiar with the dose descriptors available on CT scanners and minimize the use of CT examinations that use multiple scans obtained during different phases of contrast enhancement (multiphase examinations). These multiphase examinations result in a considerable increase in dose and are rarely necessary, especially in body (chest and abdomen) imaging.

Questions from parents:

Parents may have concerns about the amount of radiation their children receive while undergoing CT examination. It's helpful for healthcare providers to address questions such as:

- *Is CT the best examination to diagnose this condition in the child?*
- *Is there an alternative test that does not involve radiation?*
- *Will the results change the treatment decisions?*
- *Will the CT examination be adjusted based on the size of the child?*
- *Will the examination be performed at an accredited facility and by a radiologist and radiology team familiar with pediatric CT?*

It should be noted that there have been studies in which parents were given information regarding the risks and benefits of CT, and this did not result in reduced compliance, but did result in parents asking more informed questions of the care providers.

If the test is clinically justified, then the parents can be reassured that the benefits will outweigh the small long-term cancer risks.

Long-Term Strategies to Minimize CT Radiation

In addition to the immediate measures to reduce CT radiation exposure in children, long-term strategies are also needed.

- Encourage the development and adoption of pediatric CT protocols.
- Encourage the use of selective strategies for pediatric imaging, such as for the pre-surgical evaluation of appendicitis.
- Educate through journal publications and conferences within and outside radiology specialties to optimize exposure settings and assess the need for CT in an individual patient. Disseminate information through associations, organizations, or societies involved in health care of children, including the American Academy of Pediatrics, the American Academy of Family Physicians, , and the American College of Emergency Physicians. Provide readily available information sources, such as the Alliance for Radiation Safety in Pediatric Imaging.
- Conduct further research to determine the relationship between CT quality and dose, to customize CT scanning for individual children, and to further clarify the relationship between CT radiation and cancer risk.

Conclusion

Although CT remains a crucial tool for pediatric diagnosis, it is important for the health care community to work together to minimize the radiation dose to children. Radiologists should continually think about reducing exposure as low as reasonably achievable by using exposure settings customized for children. All physicians who prescribe pediatric CT should continually assess its use on a case-by-case basis. Used prudently and optimally, CT is one of the most valuable imaging modalities for both children and adults.

Related Resources

Society for Pediatric Radiology
1891 Preston White Drive
Reston, Virginia 20191
<http://www.pedrad.org>

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Contrast-Enhanced Magnetic Resonance Imaging in Pediatric Patients: Review and Recommendations for Current Practice

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ABSTRACT: Magnetic resonance imaging (MRI), frequently with contrast enhancement, is the preferred imaging modality for many indications in children. Practice varies widely between centers, reflecting the rapid pace of change and the need for further research. Guideline changes, for example on contrast-medium choice, require continued practice reappraisal. This article reviews recent developments in pediatric contrast-enhanced MRI and offers recommendations on current best practice. Nine leading pediatric radiologists from internationally recognized radiology centers convened at a consensus meeting in Bordeaux, France, to discuss applications of contrast-enhanced MRI across a range of indications in children. Review of the literature indicated that few published data provide guidance on best practice in pediatric MRI. Discussion among the experts concluded that MRI is preferred over ionizing-radiation modalities for many indications, with advantages in safety and efficacy. Awareness of age-specific adaptations in MRI technique can optimize image quality. Gadolinium-based contrast media are recommended for enhancing imaging quality. The choice of most appropriate contrast medium should be based on criteria of safety, tolerability, and efficacy, characterized in age-specific clinical trials and personal experience.

KEYWORDS: magnetic resonance imaging, contrast-enhanced, pediatrics, gadolinium, gadobutrol, expert consensus

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Introduction

Magnetic resonance imaging (MRI) is an important modality for diagnosing and monitoring a wide range of childhood diseases. Gadolinium-based contrast media enhance the efficacy of MRI for many applications. Until recently,

evidence to direct best practice in pediatric MRI was based largely on adult studies, but pediatric-specific data are now increasingly available. However, a number of open issues remain, indicated by the large variations in practice between centers.



This review article reports current perceptions on the practice of MRI in children, based on discussions and consensus statements developed at an international expert meeting, attended by nine pediatric radiologists from internationally recognized radiology centers in Canada, Germany, Italy, South Korea, Spain, Sweden, and the UK, combined with follow-up collegiate revisions during manuscript development. The review is not intended to be comprehensive, but focuses on areas of topical interest while noting areas for further investigation. Reflecting recent clinical trial activity, the role of gadolinium-based contrast media in pediatric MRI receives particular attention.

The recommendations expressed in this review are intended solely as general guidance on best practice in pediatric MRI. Clinical decision-making must be based on the requirements of each patient, guided by the latest sources of information available, including local guidelines and newly published trial data.

Advantages of MRI in pediatric radiology. Imaging modalities available in children may be classified as invasive (eg, intra-arterial digital subtraction angiography and endoscopy) and noninvasive (eg, ultrasound, X-ray, computed tomography [CT], nuclear medicine, positron emission tomography, and MRI). In practice, all these techniques are routinely employed, since no single modality can fully replace another. The preference for particular methods depends on the local availability of each modality and on the clinical scenario, taking into account the degree of invasiveness and potential associated morbidities, including those from exposure to ionizing radiation.

CT has developed rapidly as an imaging modality. This is explained by the increasing availability of multidetector CT scanners and the ability of the technique to provide rapid, high-quality image acquisition. However, the radiation associated with CT represents a major concern, particularly for children, who are more sensitive to the effects of ionizing radiation than adults.^{1,2} The risk of cancer due to radiation exposure is two to three times higher in children than in adults.^{1,2} While specific protocols have been developed for CT with scanning parameters specifically designed for children, the best way to reduce the radiation dose to pediatric patients is to avoid unnecessary CT exams.³ Thus, alternative imaging modalities without ionizing radiation exposure, commonly ultrasound and MRI, are preferred for diagnosis in pediatric clinical practice.

Ultrasound is easy to perform and provides real-time imaging of dynamic processes at relatively low cost. In addition, there is no need for sedation. However, ultrasound does not always suffice to confirm or exclude pathology, characterize lesions, or display exact anatomic limits to plan patient management.

MRI has the capacity to provide high-resolution images of tissue anatomy in multiple planes, combined with quantitative functional imaging. A particular advantage of MRI

is its ability to differentiate soft tissues. The main drawbacks of MRI relevant to pediatric imaging are the potential need for sedation or anesthesia and the limited availability of MR equipment tailored to pediatric use outside specialized centers. The long sequence time utilized in conventional MRI has the potential drawback of making timed scanning difficult, for example when both an arterial and a portal venous phase scan of the liver is required. This drawback has been minimized with newer, shorter acquisition sequences designed for contrast-enhanced MRI, such as VIBE or FLASH.

Consensus statement. MRI offers the major safety advantage of a lack of ionizing radiation, combined with efficacy benefits of excellent three-dimensional anatomic representation, tissue characterization, and quantitative/functional capabilities.

Applications of MRI in pediatric radiology. MRI is an established technique for the detection, evaluation, staging, and follow-up of a range of disease processes.⁴ MRI provides data on anatomy and physiologic processes (flow, diffusion, and perfusion) with high sensitivity and specificity.

The extensive experience of MRI in adult patients is often—but not always—directly transferable to the pediatric population. Pediatric MRI presents challenges that relate primarily to: (a) anatomic differences in structures, including developmental changes, (b) different physiologic parameters, (c) characteristic diseases of this age-group, and (d) behaviors typical of this age-group that limit adequate performance of an MRI study.

Specific applications of MRI in children include anatomic imaging of the central nervous system (CNS), chest, abdomen, pelvis, and musculoskeletal tissue for disorders including congenital malformations, tumors, infections, metabolic disorders, and inflammatory diseases (Table 1).⁴ Additional, quantitative information for the characterization of disorders can be provided by techniques including diffusion-weighted MRI, MR spectroscopy (MRS), and perfusion MRI.⁵⁻⁸ Diffusion-weighted MRI has particular applications to detect early cerebral ischemia and infarction, to differentiate intracranial cysts from solid masses, to diagnose encephalopathy or encephalitis, and to identify congenital anomalies; recent applications based on technological developments extend beyond the CNS to include tissue characterization (eg distinguishing benign from malignant tissue), organ function (such as for liver and kidneys), and monitoring response to therapy in extra-neurological tumors.^{9,10} MRS combines information from MRI with nuclear magnetic resonance to provide information on tissue metabolites that can help differentiate abnormalities such as certain types of tumors. MRS has been used to evaluate neurodegenerative diseases, including early detection and monitoring of response to therapy for demyelinating diseases (where N-acetyl aspartate [NAA] and choline levels may be increased), as well as in epilepsy and trauma (where NAA levels may be decreased); a widespread role for MRS is not yet established.¹¹⁻¹³ Perfusion MRI, such as by arterial spin labeling (ASL), assesses relative cerebral blood flow and



Table 1. Applications of pediatric MRI by body region.

BODY REGION	APPLICATIONS OF MRI	ADVANTAGES OF MRI	MR PROTOCOL
Brain and spine	<ul style="list-style-type: none"> – Tumors (eg, ependymoma, medulloblastoma, cerebellar low-grade astrocytoma) – Congenital malformations – Demyelinating diseases – Neurodegenerative disease – Inflammatory diseases – Epilepsy 	Extensive experience of anatomic and functional characterization of CNS pathologies	Brain: axial T2-weighted, coronal FLAIR, and coronal and sagittal T1-weighted images Spine: sagittal, fast spin-echo T1- and T2-weighted sequences Gadolinium enhancement used in suspected inflammation, tumors/metastases, white matter disorders, neurocutaneous disorders
Chest	<ul style="list-style-type: none"> – Pulmonary diseases of alveolar infiltration or exudation patterns (eg, segmental pneumonia or bronchopneumonia, pulmonary edema) – Tumors – Interstitial pulmonary diseases, fibrotic processes – Lung malformations 	Superior visualization of interstitial processes, inflammatory disease	T2-weighted (turbo spin echo) T1-weighted spin echo or 3D-gradient echo sequence after applying gadolinium contrast (if suspicion of abscess, assessment of fibrosis activity) Combination of cardiac and ventilator gating often required (use fast imaging technique)
Cardiovascular system	<ul style="list-style-type: none"> – Congenital malformations (eg, shunts, fistulae, regurgitant valves) 	Provision of 3D anatomic and hemodynamic information, beyond echocardiography and catheterization	Breath-held, ECG-gated, balanced steady-state free precession (b-SSFP) cine image Gadolinium enhancement used in b-SSFP and MRA
Abdomen	<ul style="list-style-type: none"> – Acute abdomen – Unexplained abdominal pain – Appendicitis – Inflammatory bowel disease (Crohn's disease, ulcerative colitis) – Motility disorders – Congenital GI malformations, eg, biliary atresia, cloacal malformations – GI tumors – Pancreatitis – Ovarian pathology – Trauma 	Anatomic depiction of complete abdominal organ systems Enterography (oral contrast distention of the bowel combined with intravenous gadolinium) provides increased sensitivity for bowel wall abnormalities	Coronal T2-weighted or STIR images in combination with axial T2-weighted and/or fat suppressed (STIR) T2-weighted images Further sequences obtained according to underlying pathology Intravenous hyoscine or glucagon to reduce peristalsis Gadolinium enhancement used in suspected inflammatory bowel disease
Musculoskeletal system	<ul style="list-style-type: none"> – Skeletal, congenital, and developmental disorders (eg, hip dysplasia, Meyer's dysplasia) – Rheumatic diseases (eg, juvenile spondyloarthropathies) – Trauma (bone fracture, tendon, and muscle) – Bone tumors (benign, malignant) – Soft tissue masses (eg, vascular malformations, cysts, fibromatous tumors, neurofibromas, soft tissue malignancies) 	Versatile depiction of bone marrow, cartilage, joints, and soft tissues to identify and localize pathology	T1-weighted, T2-weighted, and proton density sequences (at least one combined with fat saturation), short tau inversion recovery sequence T1-weighted images performed with gadolinium contrast
Genitourinary tract (urography)	<ul style="list-style-type: none"> – Congenital anatomic abnormalities – Vesicoureteric reflux – Hydronephrosis – Obstructive uropathy 	Evolving technique for generating high-quality anatomic scans (kidneys, ureters, and bladder) and renal function assessments (eg, split renal function and drainage)	T2-weighted imaging (static-fluid MR urography) T1-weighted fat suppressed post-contrast imaging (excretory function urography)
Infections	CNS <ul style="list-style-type: none"> – Bacterial intracranial infection (eg, epidural and subdural empyema, meningitis, pyogenic abscess) – Spinal infection (eg, spondylodiscitis, epidural abscess) – Viral meningoencephalitis (eg, herpes simplex virus) – HIV Non-CNS <ul style="list-style-type: none"> – Musculoskeletal (eg, osteomyelitis) – Gastrointestinal (eg, cholangitis) – Vascular (eg, vasculitis) 	Sensitive and specific imaging, providing early diagnosis	T1- (pre- and post-gadolinium) and T2-weighted images Gadolinium enhancement provides additional information for differential diagnosis

(continued)



Table 1. (Continued).

BODY REGION	APPLICATIONS OF MRI	ADVANTAGES OF MRI	MR PROTOCOL
Metabolic disorders and malformations	<ul style="list-style-type: none"> –Stroke (arterial, venous, hemorrhagic) –Hypoxic–ischemic brain injury –Hereditary metabolic diseases (eg, peroxisomal disorders, lysosomal storage disorders, disorders of amino acid and organic acid metabolism) –Brain malformations –Vascular malformations 	Depiction of small/subtle pathology	<p>Axial T2-weighted turbo spin echo, an axial FLAIR, T2*-weighted gradient-echo sequences, diffusion-weighted imaging and sagittal T1-weighted acquisition</p> <p>Gadolinium-enhanced T1-weighted images for inflammatory diseases or tumors</p>
Whole body	<ul style="list-style-type: none"> –Tumors –Multifocal lesions (eg, metastases, storage disorders, soft tissue disorders, multifocal osteomyelitis) –Fever of unknown origin –Non-accidental trauma 	3D-anatomic visualization for determining location and extent of lesions; functional/quantitative capabilities	<p>STIR or fat suppressed T2 spin echo, diffusion-weighted imaging, fat suppressed T1 spin echo, 3D-spoiled gradient echo sequences in arterial or portovenous phase following gadolinium contrast, fat suppressed T1 SE (post-gadolinium)</p>

volume, and can be used to better characterize tumors and detect areas of ischemia during stroke.¹⁴ Increasingly, functional and quantitative techniques are being incorporated into standard MRI protocols.¹⁵

The majority of MRI procedures in children are for CNS disorders, most frequently congenital malformations, inflammatory diseases, epilepsy, stroke, or brain tumors; the recent availability of age-specific MRI templates for neuroimaging during pediatric development provides a reference resource for normal structural changes over time.^{16–18} Also common are abdominal MRI to identify tumors and infections, and musculoskeletal MRI to diagnose arthritis, osteomyelitis, other bone and soft tissue infections, and tumors. MRI of the cardiovascular system is being more widely used, both alone and in combination with echocardiography, as it provides exceptional visualization of three-dimensional anatomy and reliable measures of function.¹⁹ Additional emerging applications for pediatric MRI include urography, enterography (see Fig. 7), and cine airway imaging.²⁰ Whole body MRI, while technically demanding in children, can aid detection of disease through the entire body, with particular applications for locating multifocal lesions (eg, metastases, storage disorders, and multifocal osteomyelitis) and determining the extent of soft tissue disorders.^{21,22}

MRI has therefore become the modality of choice, in place of CT, in children because of the variety and types of tissue contrast it provides, combined with its non-invasiveness. Use of MRI is recommended in most clinical scenarios, particularly in follow-up to avoid repeated radiation exposure. Nonetheless, there are specific exceptions where other imaging modalities are preferred, such as the following examples:

- Lung pathology: conventional X-ray and CT are preferred
- Pathology of small bones (eg, temporal bone) and cortical bone lesions: CT is preferred in the emergency setting. MRI may misdiagnose lesions, but is useful for imaging complications as in acute mastoiditis²³

- Congenital heart disease in the newborn: CT offers greater speed in diagnosis
- Multitrauma: CT offers greater speed and, usually, no requirement for sedation.

The selection of MRI over ionizing-radiation modalities is based on the availability of high-quality and high-field MR scanners, coils, and software and reflects the expertise and experience of the operator. Despite variability between centers in the current first-choice indications for imaging techniques, MRI will likely become the modality of choice for most indications in future.

Consensus statement. MRI is the modality of choice for diagnosing a broad spectrum of clinical disorders and for evaluating abnormalities detected at ultrasound or X-ray. Alternative imaging modalities currently have advantages in specific situations. In future, MRI is likely to become the first-choice modality across most indications.

Practical issues in pediatric MRI.

Preparing the child. Aspects of the MRI procedure, such as the enclosed space and the loud noise from the scanner, can cause anxiety in children, especially those of younger age. An adult family member or guardian should be encouraged to stay with the child during the scan. Child life specialists are a resource available at many hospitals, offering expertise to assist pediatric patients and their parents/guardians to cope with the procedure and to provide educational information, as required.²⁴

Sedation or anesthesia is effective for reducing anxiety and movement in approximately 90% of cases. Sedatives/hypnotics at the lowest possible dose are preferred.²⁵ Widely used agents for sedation include:

- Propofol: administered by infusion at 2–5 mg/kg/h for sedation, with advantages of short induction (2 min) and recovery (8 min) times and a low incidence of complications.^{26,27}



- Dexmedetomidine: administered as a loading dose (2–3 $\mu\text{g}/\text{kg}$, over 10 min) and maintenance infusion (1–2 $\mu\text{g}/\text{kg}$) for sedation. Dexmedetomidine is unsuitable in patients with cardiac compromise; however, less airway support may be required for dexmedetomidine than for propofol.^{27,28}
- Pentobarbital: oral or rectal dosing at 3–6 mg/kg, with a time to onset of 15–60 min and duration of effect 60–120 min.²⁷ Pentobarbital may be associated with cardiovascular and respiratory depression.
- Chloral hydrate is not recommended at many centers, based on high incidences of nausea and vomiting, long recovery time, postoperative agitation, and high failure rates for MRI.²⁷

General anesthesia (GA) may be chosen in selected children (eg, with congenital heart defects or airway abnormalities) and particularly in patients requiring long-duration scans (eg, with staging investigations, in cases of malignancies) or with a history of failed sedation.²⁹ In small children, the predictable safety of GA may be preferred over deep sedation; sedation also has a lower success rate.^{27,30}

Sedation and GA carry risks of complications that necessitate continuous monitoring.²⁵ Adverse events (AEs) of sedation, including respiratory depression and hypoxemia, may occur in up to 20% of children. Conversely, inadequate sedation, potentially leading to failure of the MRI procedure, is reported in 13% of children.³¹ GA can impact adversely on data acquisition, such as brain chemistry assessments in MRS.³² Sedation and GA are also costly, may be impractical, and require a recovery period. For these reasons, sedation and GA are generally avoided where possible and alternative approaches are employed. The choice of the agent and technique used for sedation or GA reflects the experience of the practitioner, potential constraints imposed by the patient and procedure, the availability of appropriate monitoring equipment (including electrocardiography, pulse oximetry, blood pressure, and body temperature assessments), and the institutional policies in place.²⁷ All members of the anesthetic team should be familiar with MRI-specific safety issues and the requirements of the diagnostic procedure before induction.³³

Familiarizing the child and parent or guardian with MRI can facilitate the MR procedure. Verbal explanation supported by explanatory literature or cartoons (for very young children) represents good practice. Novel approaches to familiarizing young patients include interactive online programs and recordings of MRI scanner noise that can be played at home.³⁴ Exposing the patient to “mock MRI” using a scanner “shell” has been reported effective.^{35,36} Audio and video entertainment can be integrated into the scanner to distract the patient during the procedure.

Another approach that is especially suitable for infants is to time the scan to coincide with normal sleep patterns or following breastfeeding, or to encourage the child to remain

awake until the scan, aiming for natural sleep during the examination.³³ A feed-and-sleep technique with use of swaddling to reduce movement (“feed and swaddle” protocol) can successfully avoid the need for sedation in neonates and infants.^{37–40} Preparing the child before transfer to the scanner (eg, removing intravenous therapy equipment and monitors) can help lower anxiety. The anxiety and pain of procedure-related injections can be reduced by using anesthetic cream at the venipuncture site and, in inpatients, performing intravenous access on the ward.

Many centers offer their own recommendations on practical methods for preparing the child, including information on food intake before the scan, what to bring to the appointment, the duration of the test, and how the scan results will be communicated. Adult family members or guardians can be encouraged to become familiar with these recommendations.

Consensus statement. Staff and environment should help the patient and parent or guardian feel secure and remain calm during the MR examination. Patients can be familiarized with the procedure before the scan. Younger children may be encouraged into natural sleep during the examination. In selected cases, sedation or GA may be used, according to institutional preference.

Performing the pediatric MR examination.

Scanning times. As described elsewhere, a short scan time is a desirable objective in pediatric MRI. Hardware-based strategies to minimize scan times include high field-strength magnets and multi-channel phased-array coils for enhanced image quality. Software-based strategies include fast imaging sequences (mentioned in Table 1), parallel image processing, compressed sensing, and respiratory triggering or combined respiratory-cardiac triggering methods.^{41,42} MR applications that utilize parallel imaging with potential to reduce scan times in wider practice include contrast-enhanced dynamic imaging, volumetric (3D) T2-weighted imaging, and single shot imaging (SSFSE, HASTE).⁴² Continuing advances in hardware and software are predicted to reduce scan times further in the future.

Equipment. Knowledge of the field of view of the imaging coils available in the department dictates coil choice. The size of the imaging coil should be approximately 1.5 times the size of the body region imaged. Institutions that scan children frequently may consider obtaining a selection of dedicated coils with fields of view that fit the range of anatomy to be scanned.⁴³ Use of an array of multichannel coils permits parallel imaging, which can substantially reduce the duration of pediatric MRI, particularly of the abdomen and cardiovascular system.

The progressive introduction of 3 Tesla (T) imaging offers improved spatial resolution and signal-to-noise ratio (SNR) compared with 1.5 T.⁴⁴ 3 T imaging may be particularly beneficial for children because of their smaller body size, although specific coils are required (detailed in²¹). Low-field MRI (0.2–0.5 T) cannot be recommended in children.



Consensus statement. To achieve optimal resolution, coils should be selected according to the body region. At minimum, a 1.5 T system should be used, but a 3 T system will provide superior imaging if specific coils are available.

MRI protocol. The procedures used and their sequence in the protocol have a substantial impact on the efficacy of the MR examination. Selection of the optimal protocol for individual patients is complex, especially in children. Continued changes in technology and the relative rarity of some disorders largely preclude an evidence-based approach to protocol choice. At individual centers, factors influencing protocol choice include the equipment available, staff experience, and guidelines in place.

Fluid-attenuated inversion-recovery (FLAIR) imaging is an important component of MR examination of the brain in adults, but FLAIR sequences are not routinely recommended for patients under 1 year old, because pathology may be masked by hyperintense unmyelinated white matter. Also, GA with high content of oxygen may increase the subarachnoid signal in FLAIR imaging, which can falsely suggest bleeding.

T1- and T2-weighted sequences are recommended in all age-groups. In acute situations, in all pediatric age-groups (beginning in the newborn), diffusion-weighted imaging and gradient echo imaging are necessary for diagnosing ischemic or hemorrhagic stroke. Gradient echo imaging, by being less susceptible to motion artefacts, also has a place in bowel

imaging. Time-of-flight angiographic and venographic techniques have value in assessing vascular abnormalities. Recent studies of contrast-enhanced MR angiographic (MRA) and venographic (MRV) techniques suggest benefit in the assessment of vascular pathology.^{45,46} MRS can be used in cases of suspected metabolic disorder and for differentiating tumor and inflammation.

Additional protocol components may include inversion recovery with inversion times set to suppress fat (STIR) in CNS, abdominal, and musculoskeletal imaging; time-resolved angiography for dynamic angiographic data (TWIST, Siemens; TRICKS, GE Healthcare; 4D-TRAK, Philips; Freeze Fame, Toshiba; and TRAQ, Hitachi); and volumetric interpolated breath-hold examination for contrast-enhanced thoracic, vascular, and abdominal imaging (VIBE, Siemens; LAVA, GE Healthcare; THRIVE, Philips; and Quick 3D, Toshiba) (see Fig. 6).

Readers are referred to recent reviews and recommendations for guidance on specific protocols in neurology,¹⁵ cardiology,¹⁹ respiratory medicine,⁴⁷ gastroenterology,⁶ musculoskeletal disorders,⁵ and whole body imaging.⁴⁸

Protocol selection—experience in clinical practice. Representative case studies of MRI procedures in children for indications including CNS, circulatory, abdominal, and soft tissue disorders are shown in Figures 1 and 2.

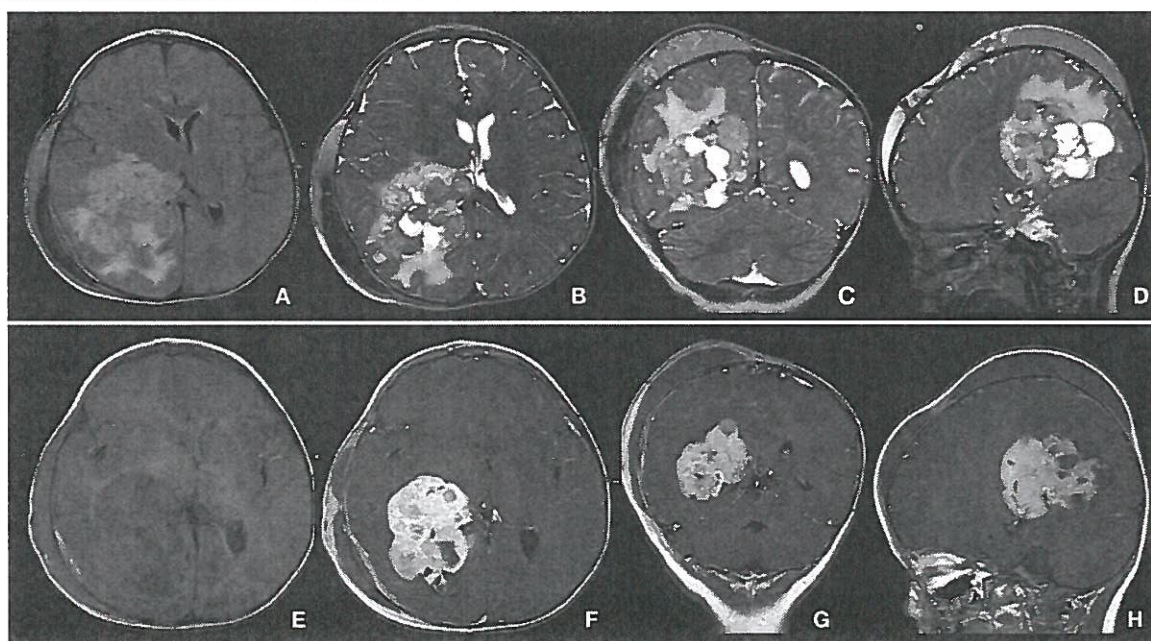


Figure 1. Choroid plexus carcinoma of right ventricle, in 2-year-old girl with Turner syndrome, polycystic kidney, nephrolithiasis, and posttraumatic skull fracture with cephalohematoma over right hemisphere. Technique: head coil, 1.5 T, gadobutrol 1 mL by manual injection. Protocol: FLAIR, T2 TSE, T1, T1 Gd. Slice thickness 3–4 mm. Findings: Pre-contrast T2-weighted (B, C, D) and FLAIR (A) images showed a brain tumor with inhomogeneous signal in right ventricle. Surrounding parenchyma of the right hemisphere showed bright signal in T2. Post-contrast (F, G, H): inhomogeneous enhancement in the tumor with cystic changes compared with pre-contrast images (E). Conclusions: MRI provided differential diagnosis of plexus carcinoma vs. plexus papilloma. Courtesy Dr G Hahn.

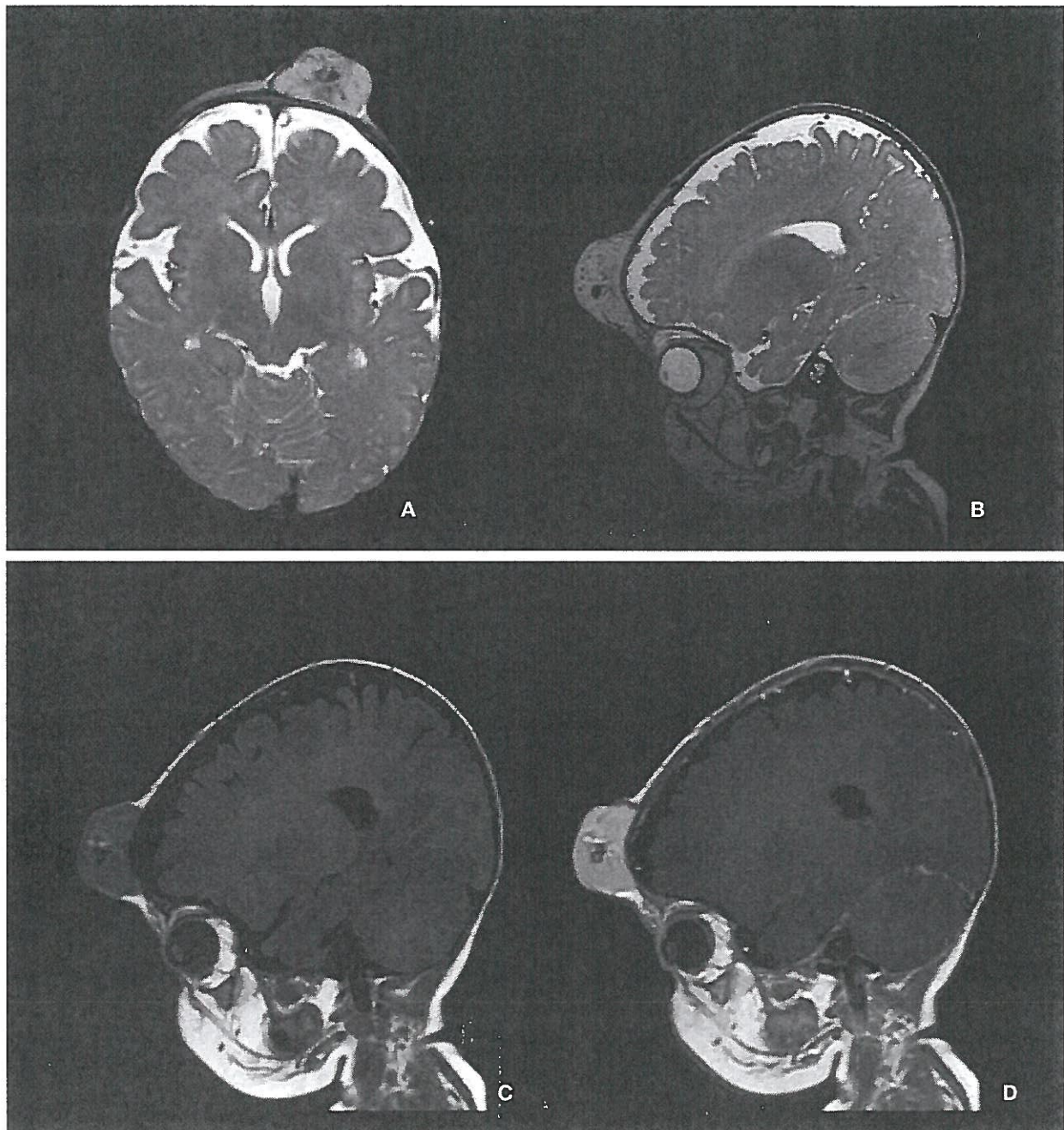


Figure 2. Hemangioma in 7-month-old girl with large soft tissue mass in forehead. Technique: head coil, 1.5 T, gadobutrol 0.6 mL by manual injection. Protocol: T2, T1, T1 Gd. Slice thickness 1.2–3.0 mm. Findings: 3 × 4 × 2 cm tumor attached to the bony calvarium on left side on T2-weighted images (A, B). Intermediate signal on T1 (C) with small spots of higher signal and small tubular hypointensities (signal voids) within the mass. After administration of gadobutrol, the tumor enhanced uniformly, except for central vascular structures (D). No obvious intracranial extension or other pathologic findings. Conclusions: MRI with gadolinium enhancement was valuable for determining the extent of disease and associated anomalies and for excluding malformations of the brain. Courtesy Dr E Stokland.



Table 2. Practical suggestions for pediatric MRI: equipment and protocol.

TECHNICAL RECOMMENDATIONS	
•	Select protocol sequences and parameters on a patient-by-patient basis
•	Use the smallest coil possible to maximize SNR
•	Minimize the examination time
•	Perform the most critical sequences first
•	Key sequences: T1/T2, fast spin echo, gradient echo, FLAIR/STIR/diffusion
•	Slice thickness: <ul style="list-style-type: none"> • Brain: <1-year-old: 3–4 mm, school-age children: 4–5 mm • Orbits: 2–3 mm • Spine: 3 mm • Pituitary: 2–3 mm • Body: 4–6 mm • Musculoskeletal system: 3–5 mm • Angiographic sequences: 1–2 mm
•	Keep voxel size large enough for adequate SNR
PATIENT CARE RECOMMENDATIONS	
•	Use ear plugs or headphones to protect the patient's ears
•	Apply anesthetic cream to reduce pain at venipuncture site
•	Encourage natural sleep to reduce anxiety and movement
•	Sedation/GA, if required, should follow local guidelines
•	An adult family member should accompany the child during the scan

Abbreviations: FLAIR, fluid-attenuated inversion-recovery; GA, general anesthesia; MRI, magnetic resonance imaging; SNR, signal-to-noise ratio; STIR, short inversion-time inversion recovery; T, Tesla.

Practical suggestions for performing MRI in children, based on expert discussions, are summarized in Table 2.

Consensus statement. MRI protocols should be selected on an individual basis, adjusting parameters appropriately to the patient's size and condition.

Applications of contrast-enhanced MRI in pediatric radiology.

Criteria for use of contrast enhancement. In many indications, gadolinium-based contrast media provide additional, clinically relevant information when compared with native MRI. Discussion of contrast enhancement in pediatric MRI can be divided into CNS (brain and spine) and non-CNS applications.

Contrast-enhanced brain and spine MRI. At many centers, gadolinium-based contrast enhancement represents the clinical standard for imaging CNS disorders, providing additional information on the location, type, and stage of lesions for diagnosis and treatment planning.^{49,50} Contrast-enhanced MRI improves the accuracy of differential diagnosis between CNS tumors and alternative diseases, such as demyelinating disorders (multiple sclerosis and acute disseminated encephalomyelitis) and abscesses.⁷ Evaluation

of tumors is improved with contrast enhancement not only by looking at enhancement patterns but also for detecting metastasis indicating the malignant nature of CNS masses. Besides its role in imaging tumors, contrast-enhanced MRI is a valuable tool in characterizing CNS infections; vascular anomalies and disorders⁵¹; neurological pathologies (including demyelinating diseases and neurodegenerative disease); and neurocutaneous syndromes (such as neurofibromatosis). For bacterial infections such as meningitis and meningoencephalitis, contrast-enhanced MRI assists in monitoring the response to therapy and the development of complications such as ischemic lesions, abscess, or empyema.^{4,52,53} Contrast-enhanced MRI also has an important role in the diagnosis of intracranial tuberculosis and bacterial spondylodiscitis, and in detecting and monitoring viral infection and immune-mediated inflammation. Inflammatory disorders such as Guillain-Barré syndrome are better identified with contrast than on non-enhanced studies with identification of enhancing nerve roots.^{54,55}

In addition to providing conventional images based on anatomy, MRI can characterize functional and metabolic features of cerebral tissue. Functional imaging techniques (eg, dynamic susceptibility contrast, DSC) can provide information on the relative cerebral blood volume (rCBV), which may assist in identifying the neovascularization associated with tumor growth and help to guide biopsy by localizing the most capillary-dense portion of a tumor. DSC is the current MR imaging-based technique of choice for in-vivo quantification of perfusion parameters in normal or tumor tissue.⁵⁶ Following treatment, contrast-enhanced MRI can detect lesion recurrence before symptoms develop, increasing the likelihood of an improved outcome.

Contrast-enhanced non-CNS MRI. Gadolinium-based contrast-enhanced MRI is widely used for characterizing infections; inflammatory processes; neurocutaneous syndromes (eg, neurofibromatosis); abdominal, musculoskeletal, and soft tissue disorders, including tumors; cardiovascular disease and malformations; and metabolic disease. Contrast enhancement can be especially helpful for defining small or subtle lesions or foci of inflammation that are unclear on native scans.⁵⁷

MR urography with contrast enhancement has become an accepted substitute for intravenous urography and scintigraphy, with the capability to combine in a single study the assessment of morphology and function, including the concentrating and excretory functions of each kidney.⁵⁸ Furosemide is administered at the beginning of the study to enhance dilation of the urinary tract and aid in the distribution and dilution of gadolinium-based contrast medium. A typical protocol includes pre-contrast T1 and T2 images through the kidneys, ureters, and bladder, followed by gadolinium-based contrast medium administration for contrast enhancement and dynamic contrast-enhanced T1 imaging of the urinary tract. MR urography is particularly



useful for investigation of hydronephrosis and malformations of the ureteropelvic unit.^{59,60}

Contrast-enhanced MRA is as effective as digital subtraction angiography for the evaluation of vascular diseases.^{51,61} Pediatric applications of contrast-enhanced MRA include the characterization of congenital cardiovascular abnormalities of the chest, abdomen, and extremities, with superiority over cine angiography or echocardiography.^{62–65}

Typically, local and national guidelines are in place to advise on use of contrast enhancement in different indications. While contrast enhancement offers additional information relative to unenhanced MRI in the great majority of indications, contrast media are not routinely employed for certain metabolic and musculoskeletal (eg, suspected herniated disk, bone fracture) MR imaging procedures. In children with severely impaired renal function or on dialysis, or in very young children, contrast medium use should be subjected to careful risk/benefit assessment, because of the low risk for nephrogenic systemic fibrosis (NSF, discussed below). For these groups, unenhanced MRI or other imaging techniques should be considered; for example, studies show that diffusion-weighted MRI has potential applications for the characterization of kidney function and pathology in patients with renal insufficiency.⁶⁶ Guidelines should ideally allow flexibility in the use of contrast media to reflect the complexities of clinical practice. The injection method, speed, timing, and flush should all be decided on an individual patient basis.

Consensus statement. Gadolinium-based contrast media provide reliable enhancement on T1-weighted images and represent the clinical standard in many pediatric MRI protocols. Gadolinium-based contrast media improve the localization, characterization, and staging of tumors/lesions, the differentiation of inflammatory and infective disorders, and the performance of MRA.

Considerations in contrast medium choice. Readers are referred to local guidelines and prescribing information for details on the contrast media approved for use in different age-groups. Table 3 summarizes selected properties of gadolinium-containing contrast media.

Readers are referred to recent reviews for a discussion of the potential role of organ-specific contrast media, such as gadoxetate disodium for hepatobiliary imaging, in pediatric patients.⁶⁷

Clinical Trials in Pediatric MRI

Until recently, few well-controlled clinical trials were available to guide contrast medium choice in pediatric MRI, in contrast to the extensive experience in adults. The trials that were available typically included low numbers of pediatric patients in limited indications.^{68–71}

Studies to characterize contrast agent use specifically in pediatric MRI include pharmacokinetic and safety investigations of the 0.5 molar gadolinium-based contrast media^{72–74} and the 1 molar agent, gadobutrol.^{75,76}

Factors Influencing Contrast Medium Choice

Safety. Safety is the primary determinant in the choice of contrast medium. Safety considerations for each contrast medium include the stability of the molecule, AEs, and the pharmacologic profile.

Chelate stability. Gadolinium-based MRI contrast media can be classified by their molecular structure into linear and macrocyclic groups. Agents with a linear structure have a polyamino-carboxylic acid “backbone” that wraps around, but does not fully enclose, the gadolinium ion, whereas macrocyclic compounds (gadobutrol, gadoterate meglumine, and gadoteridol) possess a tetra-aza “cage” that surrounds the ion.

In-vitro experiments under physiologic conditions show that macrocyclic agents are more stable and less prone to release gadolinium ions than linear compounds (Fig. 3).⁷⁷ Gadolinium-containing contrast media have been linked to the condition of NSF in patients with renal impairment.^{78,79} The stability of the chelate appears to have a role in the development of NSF.

Recently, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) released guidelines on the risk of NSF associated with gadolinium-based contrast media, placing macrocyclic compounds in the low-risk category (Table 4).⁸⁰ In similar initiatives, the U.S. Food and Drug Administration and the European Society of Urogenital Radiology (ESUR) also placed macrocyclic agents in the lowest-risk group for development of NSF.^{81,82}

Growing awareness of NSF has been accompanied by a decline in the number of reported cases. For children, in particular, incidences of NSF appear to be very rare.^{83,84}

Adverse events/adverse drug reactions. The safety margin for diagnostic drugs should be high, particularly for those used in pediatric patients. The published literature, reflecting primarily adult MRI experience, reports that adverse reactions occur at low rates and are qualitatively similar for current gadolinium-based contrast media, regardless of molecular structure.^{85–88} Common adverse drug reactions (ADRs) include nausea, vomiting, and hives.

Assessments of AEs and ADRs in pediatric MRI are more problematic, reflecting the low number of age-specific studies when compared with adult MRI. In the absence of extensive clinical study data, perceptions on the safety and tolerability of contrast media in pediatric MRI may be informed by personal experience. AEs have been reported to occur at low rates in individual studies of gadodiamide, gadobutrol, gadobenate dimeglumine, gadopentetate, and gadoversetamide in pediatric patients of different ages, while a retrospective chart review reported that allergic-like reactions to gadolinium-containing contrast media were rare.^{72,89–92} A recent safety study of gadobutrol in 130 patients aged 2 to 17 years⁷⁵ reported a tolerability profile that was comparable with adult experience,⁸⁸ with low rates of AEs that were mostly mild to moderate in intensity.



Table 3. Properties and approval status of extracellular gadolinium-based contrast agents.^a

CHEMICAL NAME	TRADE NAME	MANUFACTURER	CHARGE AND CHEMICAL STRUCTURE	CONCENTRATION (mol/l)	KINETIC STABILITY ^b	RELAXIVITY (β T IN PLASMA, 37°C) [L/mmol ⁻¹ s ⁻¹]	T1 SHORTENING TIME (MS) IN BLOOD FOR 1 mL/L AGENT	VISCOSITY [mPa·s]	OSMOLALITY [mOsm/kg H ₂ O]	EXCRETION	RECOMMENDED DOSES FOR IMAGING (mmol/kg)	APPROVED DOSES FOR CHILDREN (mmol/kg)
Gadodiamide	Omniscan	GE Healthcare	Nonionic linear	0.5	35 s	4.0	880.85	1.4	790	Renal	Body 0.1 CNS 0.1 Kidney 0.05 Intrathoracic, intra-abdominal, pelvic 0.1	From 2 years: 0.1
Gadopenetate dimeglumine	Magnevist	Bayer	Ionic linear	0.5	10 min	3.7	864.80	2.9	1960	Renal	CNS 0.1 Extracranial/extraspinal 0.1 Body 0.1	From 2 years: 0.1
Gadobenate dimeglumine	MultiHance	Bracco	Ionic linear	0.5	N/A	5.5	960.96	5.3	1970	Renal, 4–5% hepatobiliary	CNS 0.1 MRA 0.1	From 2 years: 0.1
Gadoversetamide	OptiMARK	Tyco	Nonionic linear	0.5	N/A	4.5	N/A	2.0	1110	Renal	CNS 0.1 Liver 0.1	Not approved <18 years
Gadoterate meglumine	Dotarem	Guerbet	Ionic cyclic	0.5	>1 month	3.5	859.0	2.0	1350	Renal	CNS 0.1 Extracranial/extraspinal 0.1 Body 0.1	Infants and children: 0.1
Gadoteridol	ProHance	Bracco	Nonionic cyclic	0.5	3 h	3.7	870.33	1.3	630	Renal	CNS 0.1 Extracranial/extraspinal 0.1	From 2 years: 0.1
Gadobutrol	Gadovist, Gadavist	Bayer	Nonionic cyclic	1.0	24 h	5.0	1036.96	4.96	1390	Renal	CNS 0.1 Liver 0.1 Kidney 0.1 MRA 0.1 Whole body (EU) 0.1	From 2 years: 0.1
Gadoxetic acid	Primovist	Bayer	Ionic linear	0.5	N/A	6.2	N/A	1.19	668	50% renal, 50% hepatobiliary	Liver 0.025	Not approved <18 years

^aPlease consult your local prescribing information for the latest information on approved indications and dosing.

^bKinetic stability; dissociation half-life at pH 1.0.

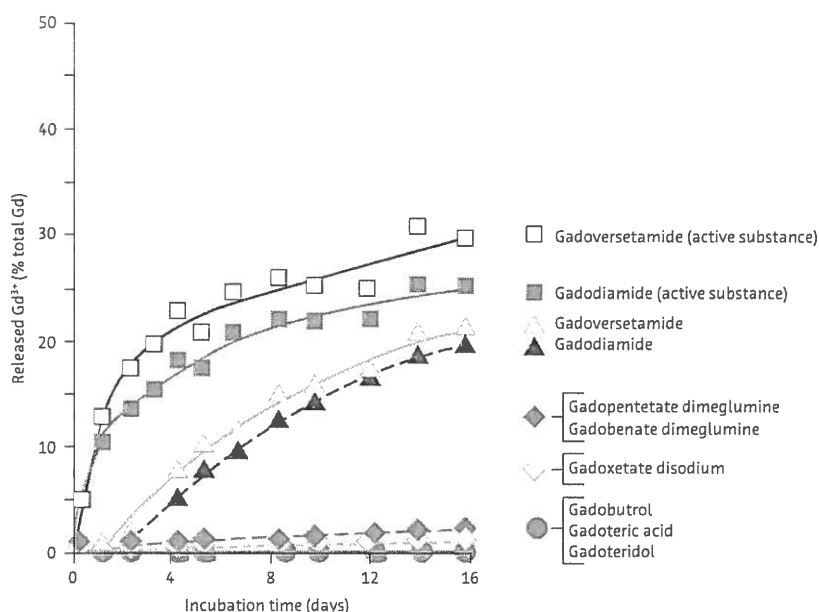


Figure 3. Comparative rates of gadolinium ion release for 1 molar solutions of gadolinium-based contrast media in serum from healthy volunteers at 37°C. Reproduced from Thomas Frenzel, Philipp Lengsfeld, Heiko Schirmer, Joachim Hütter, Hanns-Joachim Weinmann, Stability of Gadolinium-Based Magnetic Resonance Imaging Contrast Agents in Human Serum at 37°C, *Invest Radiol*, 2008;43:817–828 with permission from Wolters Kluwer Health.

Pharmacologic profile. The currently available gadolinium-based contrast media display similar pharmacokinetic profiles in adults.⁹³ Pharmacokinetic studies in children aged 2 and older have included the 0.5 molar agent, gadoversetamide,^{72,74} and the 1 molar agent, gadobutrol.⁷⁵ These studies concluded that individual differences in pharmacokinetics (total body clearance and central volume of distribution) were attributable to body weight, with no additional effect from age (Fig. 4). Dosage based on body weight—as in adults—is therefore appropriate in children aged 2 and older, and no age-dependent dose adjustment is required. Experience of gadobutrol use in children under 2 years indicates that standard weight-adjusted dosing is feasible also with gadobutrol in this age-group.⁷⁶

In summary, safety considerations are a priority when selecting a gadolinium-based contrast medium for contrast-enhanced MRI. From this perspective, macrocyclic contrast

agents (gadobutrol, gadoterate meglumine, or gadoteridol) are preferred for pediatric use, particularly in relation to the potential risk of NSF, even if theoretical in most patients.

Efficacy. The efficacy of a contrast medium—ie, its capacity to enhance image quality—represents an important consideration. Individual contrast media have demonstrated differences in efficacy in adult studies.

The characteristics of an MRI contrast medium that determine its efficacy include its effect on shortening the T1 relaxation time. In dynamic examinations, the T1 relaxation time is also related to the gadolinium concentration of the solution. Gadolinium-containing contrast media with high T1 relaxivity (gadobenate dimeglumine and gadobutrol) demonstrate excellent image quality in adult studies.^{94–97} The majority of gadolinium-based contrast media are available as 0.5 molar formulations, while gadobutrol is a new-generation contrast medium available as a 1 molar formulation. An additional advantage of a higher gadolinium concentration is that a smaller injection volume may be used, which enables a more compact bolus geometry that is favorable for dynamic MRI procedures such as perfusion examinations and MRA.^{98–100}

Data on the comparative efficacy of contrast media are available from preclinical studies and clinical studies in adults.^{95,99,101–108} In intraindividual trials, gadobenate dimeglumine demonstrated superior lesion enhancement and diagnostic information relative to gadopentetate or gadodiamide,^{106,107,109} which is explainable by the higher relaxivity of gadobenate. In similarly designed trials, gadobutrol demonstrated superior

Table 4. Gadolinium-based contrast media classified according to CHMP categorization of NSF risk (CHMP 2009).⁸⁰

- **High risk:** gadoversetamide, gadodiamide, gadopentetate dimeglumine
- **Medium risk:** gadofosveset trisodium, gadoxetate disodium, gadobenate dimeglumine
- **Low risk:** gadoterate meglumine, gadoteridol, gadobutrol

Abbreviations: CHMP, Committee for Medicinal Products for Human Use; NSF, nephrogenic systemic fibrosis.

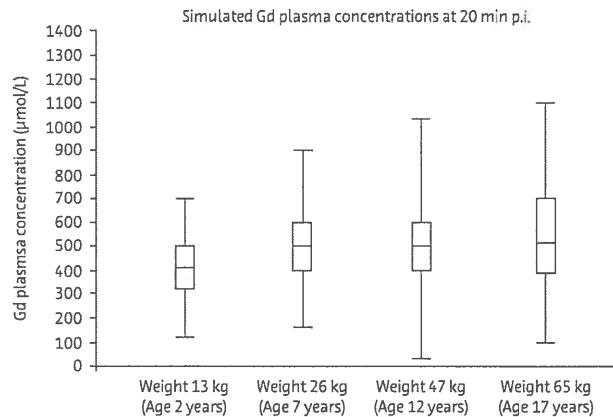


Figure 4. Simulated gadolinium concentrations in plasma 20 minutes after injection of 0.1 mmol/kg body weight gadobutrol in four subjects of different ages represented by typical body weight. Boxes represent interquartile range, with the center horizontal line at median. Whiskers extend to data nearest to a distance of at most 1.5 times the interquartile range. Reproduced from Gabriele Hahn, Ina Sorge, Bernd Gruhn, Katja Glutig, Wolfgang Hirsch, Ravi Bhargava, Julia Furtner, Mark Born, Cronelia Schroder, Hakan Ahlstrom, Sylvie Kaiser, Jorg Detlev Moritz, Christian Wilhelm Kunze, Manohar Shroff, Eira Stokland, Zuzana Jirakova Trnkova, Marcus Schultze-Mosgau, Stefanie Reif, Claudia Bacher-Stier, Hans-Joachim Mentzel, Pharmacokinetics and Safety of Gadobutrol-Enhanced Magnetic Resonance Imaging in Pediatric Patients, *Invest Radiol*, 2009;44:776-783 with permission from Wolters Kluwer Health.

performance, including enhanced lesion detection and conspicuity, compared with the 0.5 molar agents gadopentetate and gadoterate meglumine, again attributable to the higher relaxivity of gadobutrol.^{96,101,110}

Current guidelines indicate that efficacy results for contrast media in adult studies can be extrapolated to pediatric populations with the same indications.¹¹¹ In support, a study of pediatric subjects aged 2 to 17 years confirmed the comparable efficacy of 1 molar gadobutrol in this population as in adults.⁷⁵ The same may apply when comparing younger and older pediatric patients with similar disease processes.¹¹¹

One study has directly compared contrast media for imaging brain and spine tumors in children, reporting significant superiority for gadobenate dimeglumine over gadopentetate in lesion visualization.¹¹² Additional studies comparing the efficacy of contrast media in pediatric patients will aid practice in future. Experience in clinical practice supports the trial evidence of differences in efficacy between contrast media (see case study in Fig. 5).

Practical suggestions for the use of contrast media in pediatric MRI are summarized in Table 5.

Consensus statements.

Formulation. Gadolinium-containing contrast media are available at 0.5 molar concentrations, with the exception of the 1 molar agent, gadobutrol.

Safety. Safety is the primary consideration when selecting a contrast medium in pediatric MRI. Macrocyclic compounds (gadobutrol, gadoterate meglumine, and gadoteridol) are the most stable class of contrast media and are associated with lowest risk of NSF. Trial evidence on safety is available for a limited number of contrast media in pediatric MRI, but clinical experience indicates a similarity to adult profiles.

Efficacy. Signal enhancement in contrast-enhanced MRI is associated in adult studies to the T1 shortening effect, which is a function of relaxivity and, in dynamic scans, gadolinium concentration. Gadobutrol demonstrates superior lesion detection and conspicuity compared with 0.5 molar agents with a lower relaxivity in adult studies. The relationship between relaxivity and efficacy may also apply in pediatric imaging. Optimal SNR for dynamic MRI procedures may be provided by a high-concentration, tight bolus injection of contrast medium.

Conclusions

MRI, frequently with contrast enhancement, offers definitive diagnostic imaging, treatment guidance, and monitoring for a wide range of conditions, at low risk to the pediatric patient. Pediatric radiologists should assess the needs of patients individually, drawing on the available literature, personal experience, and the opinions of colleagues. To guide practice in the future, there is a need for more evidence-based decision making, founded on well-performed, pediatric-specific trials. The continued introduction of novel technologies and protocols, and the optimized use of contrast enhancement, are predicted to further increase applications of MRI in children.

Summary of expert meeting recommendations.

Advantages of MRI in pediatric radiology.

- MRI has advantages over ionizing-radiation modalities in safety and efficacy for a range of indications and organ systems.
- MRI provides high-resolution images of tissue anatomy in multiple planes, with the capability to perform quantitative functional imaging.

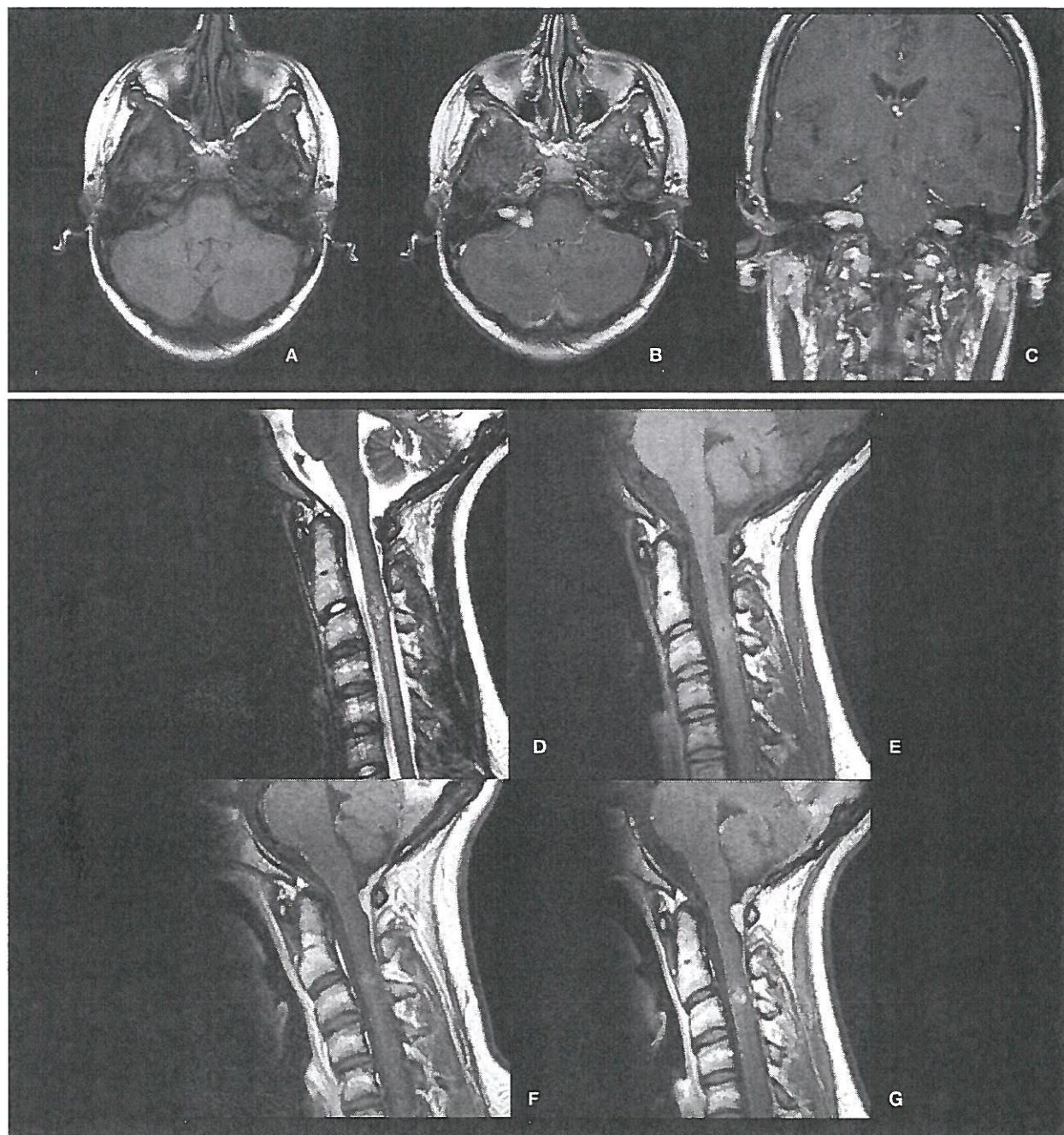


Figure 5. Neurofibromatosis type II diagnosed in 15-year-old girl with multiple cutaneous tumors and meningeal tumors. Technique: head coil, 1.5 T, Gd (gadopentetate dimeglumine or gadobutrol) by manual injection. Protocol: T2 TSE, T1, T1 Gd. Slice thickness 3–5 mm. Transverse (A, T1; B, T1 Gd), coronal (C, T1 Gd), and sagittal views (D, T2; E, T1; F and G, T1 Gd with gadopentetate dimeglumine and gadobutrol, respectively). Findings: Strong contrast enhancement in internal auditory canal. A high relaxivity agent (gadobutrol, 5 ml) showed strong enhancement in the cervical myelon (G vs. F). Conclusions: MRI assisted to diagnose schwannoma of the vestibular nerve at both hemispheres and also intraspinal neurofibroma. Notably, gadobutrol provided greater imaging efficacy than gadopentetate dimeglumine. Courtesy Professor H-J Mentzel.



Table 5. Practical suggestions for pediatric MRI: contrast medium use.

- Use of gadolinium-containing contrast media should not be a problem in patients with normal renal function according to age
- Base dose on the child's weight, not age
 - Weight should be measured, not estimated
- Syringes should allow precise dosing, eg, 1 mL insulin syringes are recommended for young infants
- Injection technique (manual vs. automated) is age-dependent
- Contrast injection uses a 22 or 24 gauge needle
- Prior to injection of contrast, the intravenous line is flushed with saline to clear the line. Contrast of 0.1 mL/kg is injected at a rate of 0.5 mL/sec
- A saline flush of sufficient volume to clear the intravenous line post-contrast administration should be injected at a rate of 0.5 mL/sec
- Bolus timing is affected by heart rate, cardiac output, and injection site and is therefore unpredictable. Bolus monitoring is recommended
- Renal function (ie, estimated glomerular filtration rate) should be determined in patients at risk, such as:
 - Children with known renal disease
 - Children on medication toxic to the kidneys, eg, oncology patients on treatment
 - Children with dehydration
 - Children with complex diseases also affecting the kidneys
 - Children who received iodinated contrast media in the last 24 hours
- In children with severely reduced renal function, MRI without intravenous contrast or an alternative method should be considered
- Safety concerns regarding risk/benefit assessment remain the responsibility of the treating clinician and local label indications should be observed

Abbreviation: MRI, magnetic resonance imaging.

Practical issues in pediatric MRI.

Preparation.

- Prior to the scan, the patient (with parent or guardian) should be familiarized with the examination to alleviate anxiety and reduce movement during the examination.
- Younger children may be encouraged into natural sleep during the examination.
- Decisions to use sedation or general anesthesia should be made on an individual patient basis, taking into account the benefits and risks.

Equipment and protocol.

- For optimized imaging, coil sizes should be selected according to the area of interest.
- The scanner should be 1.5 T at minimum, and preferably 3 T.
- Protocols should be individualized according to the patient's age and imaging indication.

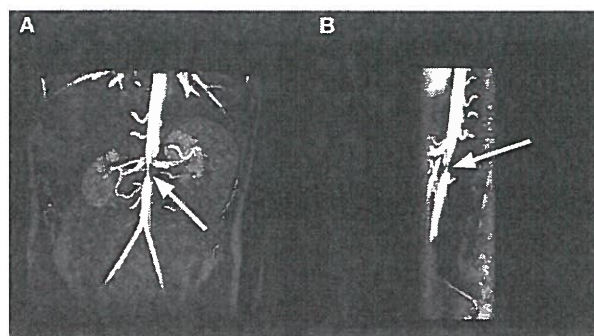


Figure 6. 15 year old with aortic and superior mesenteric artery stenosis secondary to neurofibromatosis. Maximal intensity projections of the subtracted contrast-enhanced VIBE sequences show focal narrowing of the abdominal aorta (arrow) at the level of the renal arteries in coronal (A) and sagittal (B) projections. The sagittal image also shows focal narrowing of the origin of the superior mesenteric artery, just caudal to the normal-sized celiac axis and cranial to the aortic narrowing. Courtesy Professor R Bhargava.

Criteria for use of contrast enhancement in pediatric MRI.

- Gadolinium-based contrast media: (1) aid the localization, characterization, and staging of lesions/tumors, (2) help differentiate inflammatory and infective disorders, and (3) allow MRA.
- Contrast media are increasing the diagnostic value of the MR examination in many situations. In children with severely impaired renal function or on dialysis, or in very young children, contrast medium use should be subjected to careful risk/benefit assessment. For these groups, unenhanced MRI or other imaging techniques should be considered.

Considerations in choice of contrast medium.

- Gadolinium-containing contrast media are available at a 0.5 molar concentration, with the exception of the 1 molar agent, gadobutrol.
- Safety is the primary consideration when selecting a contrast medium, preferably based on trial evidence. Macrocyclic agents (gadobutrol, gadoterate meglumine, and gadoteridol) have the highest chelate stability, associated with reduced gadolinium ion release.
- Efficacy (image quality) that is confirmed in comparative trials is desirable. The signal intensity of a contrast medium is shown in adult studies to depend on its effect on T1 relaxivity.
- Gadobutrol is the gadolinium-containing contrast medium with the highest relaxivity among the macrocyclic agents.

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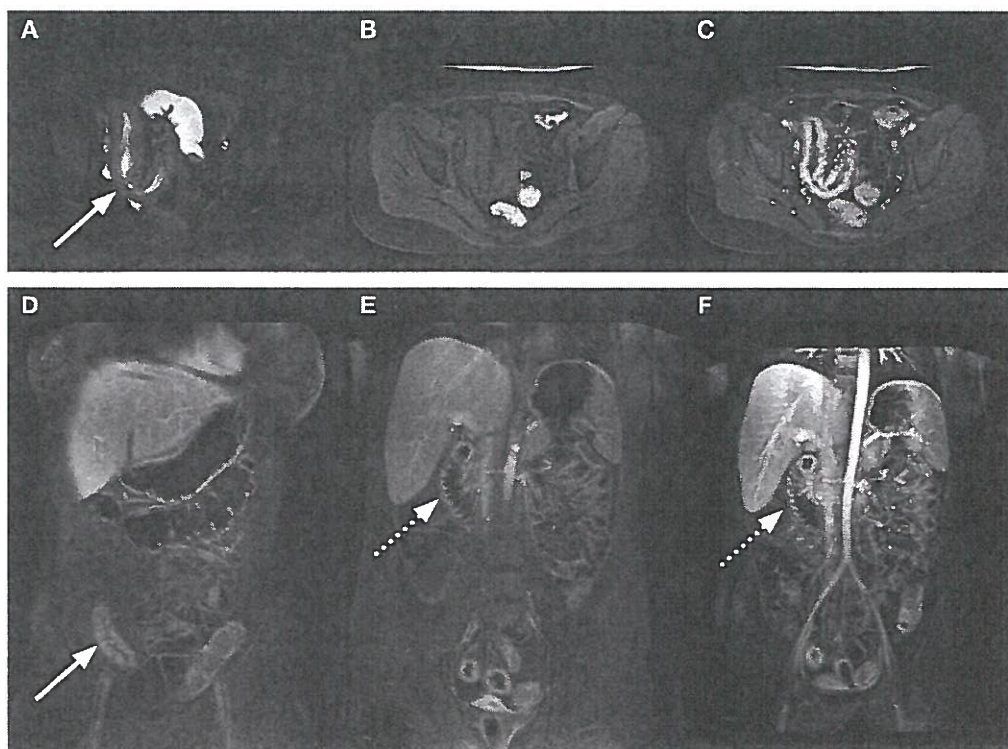


Figure 7. Child with Crohn's disease with inflamed terminal ileum and inflamed duodenum demonstrated by MR contrast-enhanced enterography. HASTE (A) axial images show thickening of the wall of the distal ileum (arrow) that is slightly brighter than muscle. The T1 transverse images pre- (B) and post-contrast (C) show diffuse enhancement of the thickened wall along with prominence of the vascularity in the adjacent mesentery. This is also seen in the coronal T1 contrast-enhanced images with fat saturation (arrow, D and E), along with similar abnormal enhancement of the thickened duodenal wall (dashed arrow, E and F). Courtesy Professor R Bhargava.

Author Contributions

All authors contributed to the manuscript concept, review of data, writing, and critical review of the draft. All authors approved the final version of the text.

DISCLOSURES AND ETHICS

As a requirement of publication the authors have provided signed confirmation of their compliance with ethical and legal obligations including but not limited to compliance with ICMJE authorship and competing interests guidelines, that the article is neither under consideration for publication nor published elsewhere, of their compliance with legal and ethical guidelines concerning human and animal research participants (if applicable), and that permission has been obtained for reproduction of any copyrighted material. This article was subject to blind, independent, expert peer review. The reviewers reported no competing interests.

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REVIEW

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The Role of Cardiovascular Magnetic Resonance in Pediatric Congenital Heart Disease

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Abstract

Cardiovascular magnetic resonance (CMR) has expanded its role in the diagnosis and management of congenital heart disease (CHD) and acquired heart disease in pediatric patients. Ongoing technological advancements in both data acquisition and data presentation have enabled CMR to be integrated into clinical practice with increasing understanding of the advantages and limitations of the technique by pediatric cardiologists and congenital heart surgeons. Importantly, the combination of exquisite 3D anatomy with physiological data enables CMR to provide a unique perspective for the management of many patients with CHD. Imaging small children with CHD is challenging, and in this article we will review the technical adjustments, imaging protocols and application of CMR in the pediatric population.

1. Introduction

Congenital heart disease (CHD) has an incidence of 6-8 per 1000 at birth [1,2]. The survival of CHD patients has also increased because of improvements in early diagnosis (including fetal echocardiography) and treatment, which have led to more patients surviving into adulthood [1-3]. Furthermore, there is an increasing number of children with acquired heart disease, in particular related to anthracycline cardiotoxicity, following treatment of oncological disease in early childhood.

Imaging is fundamental to the diagnosis of CHD and is required at all stages of patient care. From the fetal stage onwards, imaging outlines anatomy and physiology, helps to refine management, evaluates the consequences of interventions and helps guide prognosis. However, no single available imaging modality fulfills these roles for all patients and diseases. ***Therefore, assessment for CHD must involve a variety of modalities that can be used in a complementary fashion, and that together are sensitive, accurate, reproducible, and cost effective, whilst minimizing harm.***

Echocardiography remains the first-line imaging investigation for pediatric patients, as it is portable, non-invasive and provides immediate, high-resolution anatomical and physiological information [4,5]. For co-operative patients with good acoustic windows, echocardiography

alone can define diagnosis and guide management and prognosis. However, echocardiography fails when acoustic windows are poor, particularly for the assessment of extra-cardiac vascular structures.

Where cardiac catheterization was traditionally used to provide hemodynamic information and visualize extracardiac great vessels, [6] cardiovascular MR (CMR) is progressively fulfilling this role [7]. The burgeoning availability of MR scanners and physicians' rapid uptake of CMR is escalating the prominence of this modality in the management of pediatric congenital heart disease.

CMR provides a powerful tool, giving anatomical and physiological information that echocardiography and catheterization alone cannot provide [8,9]. Extra-cardiac anatomy, including the great arteries, systemic and pulmonary veins, can be delineated with high spatial resolution. Vascular and valvular flow can be assessed, [10] shunts can be quantified, [11] and myocardial function can be measured accurately with high reproducibility, regardless of ventricular morphology [12]. Finally, CMR surpasses both catheterization and echocardiography in providing high-resolution, isotropic, three-dimensional datasets [13]. This allows for reconstruction of data in any imaging plane, giving complete visualization of complex cardiac anomalies, without the use of ionizing radiation [14]. ***In the pediatric population, CMR could be justified for any patient in whom clinical or echocardiographic data is insufficient for monitoring, decision-making or surgical planning.***

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Despite its widespread use CMR still has some technical limitations that have to be overcome in order to perform successful pediatric CMR. These technical difficulties involve the high spatial resolution required for imaging small anatomical structures, and the patients' inability to consistently follow breath-holding commands, due to young age or developmental delay. This review will aim to provide guidance on the indications for CMR in pediatric CHD, provide potential protocols and describe imaging techniques for the main conditions referred for CMR.

2. Indications

The decision to perform CMR depends on the information required, the local facilities and resources available for scanning, the clinical state of the patient, and the risks to the patient of carrying out the examination. Without the use of sedation or contrast, a comprehensive CMR examination in a willing patient carries minimal risk. However, the need for sedation, general anesthesia or gadolinium contrast changes the balance of risk in some patients. Furthermore, CMR is a resource-high investigation. In addition to the costs of purchasing, running and maintaining the MR scanner, significant expertise and training is required for all staff involved in acquiring and interpreting the images.

The technical and diagnostic complexity of pediatric CMR is significant. The patients' body size is small and heart rates are rapid. Imaging these patients requires a radiographer trained to expedite image planning and optimize pulse sequences in this context, and a CMR physician with expertise in the anatomical and physiological changes of CHD. In addition, because general anesthesia is often necessary for the youngest children, an anesthetic team is required, and this team must be trained to care for cardiac patients with hemodynamic compromise.

2.1. CMR with general anesthesia

Because of the potential increased risks involved in pediatric patients with congenital heart disease, in our institution, the decision for a child to undergo CMR under general anesthesia is made in the setting of a multidisciplinary clinical planning meeting. The decision-making involves careful analysis of potential risks and benefits. Our unit policy is that a senior cardiac anesthesiologist always carries out the anesthetic procedure. Prior to each case there is detailed discussion between the anesthetic and cardiac imaging teams, regarding the specific hemodynamic and imaging issues pertaining to the case. With these considerations, our unit and others, have a very good safety profile for imaging these complex patients [15,16].

Generally, children less than seven years of age will have CMR performed under a general anesthetic. This practice varies in different centers, depending on local anesthetic and sedation policy. Some institutions use various degrees of sedation, with or without the need for an anesthetist to monitor the patient. General anesthesia ensures prolonged cooperation and enables reliable breath holding.

Potential indications for children undergoing CMR under general anesthesia are outlined in Additional file 1, Table S1. The set-up of a typical CMR control room containing anesthetic equipment is shown in Figure 1. Other procedures can be carried out while the patient is under anesthetic. For example, in those patients with a functionally uni-ventricular heart and a cavo-pulmonary shunt, the jugular venous pressure can be measured via needle transducer, prior to surgical completion of the total cavo-pulmonary circulation. This gives an estimation of pulmonary artery pressure at the same time that image data gives pulmonary artery morphology, flow volume, ventricular and valvular function. Diagnostic catheterization can be avoided in many patients who have traditionally required catheter angiography [17,18].

2.2 CMR without anesthesia

The older pediatric patient groups for whom CMR is indicated are listed in Additional file 2, Table S2. For many of these patients CMR is often a single, focused study prior to intervention. For others the benefit of CMR lies in serial imaging leading up to, or following intervention. While avoiding ionizing radiation, CMR can give accurate and reproducible quantification aortic arch dimensions [19,20], ventricular volumes, and valvular function [21]. This guides the management team with regards to the appropriate timing for, [22] or the effect of any intervention [23,24].

2.3 Prior to transfer to adult services

An important indication for CMR in our pediatric centre is the stage of transfer of the patient to an adult institution for ongoing care. Prior to transfer, CMR gives a comprehensive summary of the anatomical and physiological status of the patient, for all types of post-surgical situations.

2.4 Decision making

When there are local facilities and expertise in all the modalities: CMR, cardiovascular CT and cardiac catheterization, the imaging strategy for complex patients can be discussed in a forum comprising cardiologists, cardiac imaging specialists, interventionists and surgeons.

For many patients the imaging choice is obvious. For example, for a cooperative 10 year old with clinical signs of recurrent aortic coarctation, following repair in

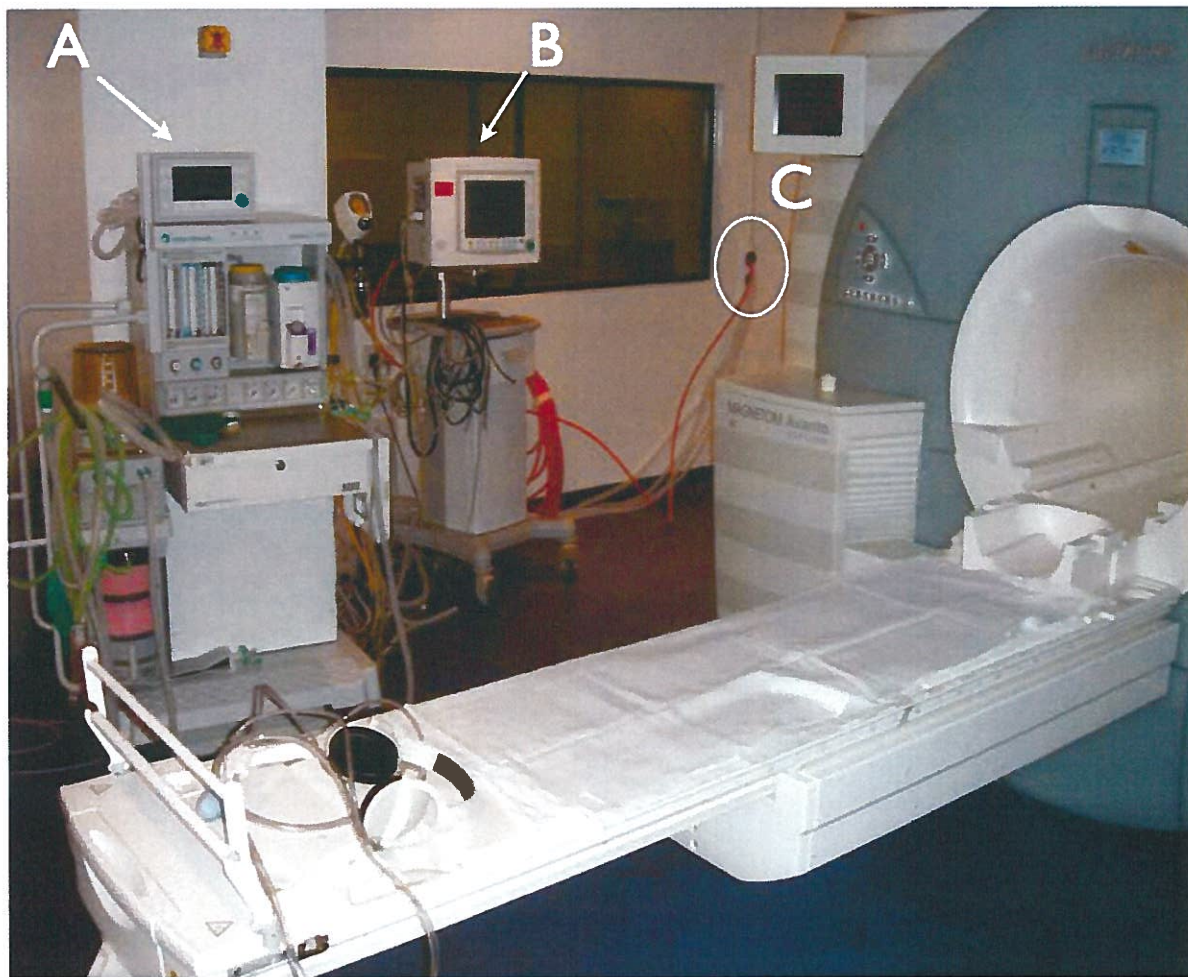


Figure 1 CMR set-up for paediatric general anaesthetic cases. View of the MR scanner room showing the anaesthetic machine (A) and monitoring equipment (B). Ventilation tubing and leads from both pieces of equipment pass through a small opening in the wall (C) into the control room, so that the anaesthetist can control breath-holding and monitor the patient from within the control room.

infancy, CMR would yield high-resolution images of the aortic arch morphology and give the flow profile through the arch. At the same time, the CMR would portray and quantify aortic valve function and left ventricular myocardial structure, mass and systolic function. This data could be acquired within 40 minutes of scanning time, with no need for sedation, anaesthetic or irradiation.

One could argue that for this patient, cardiac catheterization could provide data on the arch morphology and give an opportunity for arch intervention. However, the best mode and timing of intervention is not always clear for many patients. Imaging, with a subsequent temporal pause or “discussion window” for consideration of all management options would most frequently yield the optimal outcome.

At the other end of the risk-benefit spectrum for comprehensive imaging is an infant with hypoplastic left heart syndrome (HLHS), clinically deteriorating soon after the first stage of surgical palliation. With poor acoustic windows, urgent further imaging of the branch pulmonary arteries and aortic arch is necessary. In this context, general anaesthetic may carry a high risk, and CT imaging of the chest would usually be performed, using a non-sedated “feed and wrap” technique. The CT images would then be used to refine the decision-making, regarding whether intervention appears justified, which intervention would be optimal (surgical revision or balloon angioplasty) and the specific method of intervention. Our perceived advantage of non-invasive imaging, in this way, rather than initial hemodynamic investigation in the catheterization laboratory, is that we

achieve an, often crucial, “window” for discussion and procedure planning.

The potential vascular complications of catheterization [25,26], and the dangers of exposure to radiation [27] mean that for many centers, cardiac catheterization is reserved for patients in whom hemodynamic data is essential (e.g. high risk Fontan, pulmonary hypertension), or in whom it is known that interventional procedures are highly likely and necessary.

Finally, some patients benefit from a combined approach using a hybrid CMR/cardiac catheterization laboratory, in which patients can be transferred, under the same general anesthetic, from imaging to interventional procedures and vice versa. This guides the intervention procedure, and gives potential to immediately assess the hemodynamic results of intervention with assessment of flow and ventricular function [28,29] (see section 6).

3. Scanning environment, sequences and protocols

3.1. Scanning environment for general anesthetic cases (Figure 1)

Performing general anesthesia (GA) in a magnetic resonance environment is challenging for many reasons: [30] There is limited access to the child and ventilation equipment during the CMR scan; care is required for staff and patient safety with regards to ferromagnetic equipment; and there is a potential for RF interference with monitoring. It is therefore very important to have an appropriately trained anesthetic team (the cardiothoracic operative team in our institution), with excellent monitoring equipment. Several technical factors specific to MR in infants and small children must be taken into consideration. Prolonged, multiple breath holds are required, thus adequate pauses for ventilation control between breath holds are required, to ensure that hypoxia and hypercapnoea are avoided. Reliable monitoring of the electrocardiogram, pulse oximetry and expired gas concentrations is necessary. Additionally, patient temperature must be closely monitored. The low ambient temperature in MR scanning room produces a risk of hypothermia, particularly for small infants.

3.2 Sequences

Additional file 3, Table S3 describes the sequences that can be used for assessing patients with CHD. In Additional file 4, Table S4 suggestions are given for which sequences are most useful for a range of clinical indications.

Although time consuming, a full scanning protocol, including 3D data acquisition, is necessary for most patients because their complexity brings a high likelihood of previously undiagnosed or unexpected

morphological or physiological findings. Acquiring a complete image data set gives the opportunity for full delineation of the sequential segmental anatomy in every patient.

3.2.1. 3D imaging

The 3D capabilities of CMR play a key role for pediatric CHD. There are two conventional methods of acquiring 3D data. One uses angiographic techniques with gadolinium-based contrast agents that can be injected via any peripheral vein [31]. The other uses a 3D balanced-SSFP sequence, which is respiratory and cardiac gated, but does not require contrast [32,33]. Both data sets are acquired in such a way to give isotropic voxels, so that the images can be viewed with the same spatial resolution in any anatomical plane. These data can be used during the scan to plan image planes for further scanning, as well as during the reporting phase to assess 3D relationships between structures, quantify vessel size and view morphology. The high-signal, isotropic 3D images that are achieved using gadolinium-contrast angiography allow complex modeling of structures so that interventional techniques can be optimized [34].

3.2.2. Cine imaging

Cine imaging using balanced-steady state free precession or fast gradient echo sequences, gives multiphase data that shows myocardial or valvular motion over the entire cardiac cycle. These cines have up to 40 frames per cardiac cycle, a temporal resolution adequate for accurate physiological representation. Cines can be performed in any plane to assess the dynamic function of any structure, including the outflow tracts, valves and great arteries. Furthermore, short-axis cine images, acquired in equal-width slices, perpendicular to the long-axis of the heart from base to apex (short axis imaging), or similar long-axis imaging in an axial plane, can be used to accurately assess cardiac function and measure the ventricular volumes.

The post-processing of cine images to calculate ventricular volumes and function is performed off-line, using commercially available software. The segmentation of the blood pool and myocardial border can be performed manually, or by using automated signal thresholding techniques. There is currently a wide range of software available, and a wide variation in segmenting practice and procedures. A fundamental issue, particularly for pediatric patients and those with congenital disease, is that of inclusion or non-inclusion of the trabeculae in the blood pool. If a simple endocardial contour is drawn and the trabeculae ignored and included in the blood pool, the manual segmentation process is more efficient and more reproducible [35]. However, this leads to erroneously large volume estimates for the ventricles, and prohibits internal validation of stroke volumes using great arterial flow volumes. Additionally, this could lead

to the miscalculation of atrio-ventricular valve regurgitation.

3.2.3. Flow assessment

Accurate quantification of flow volume is crucial in patients with known or suspected CHD. For volume quantification, we favor a free-breathing, velocity encoded, phase-contrast sequence with a temporal resolution of at least 30 frames per cardiac cycle. Slice positioning and velocity encoding must be optimized [36]. If these parameters are rigorously controlled, flow can be assessed in large and small arteries, systemic and pulmonary veins [10,37]. Aortic and pulmonary valve regurgitant fractions can be calculated. Phase contrast flow sequences also enable the profiling of flow acceleration jets, with velocity estimation. More importantly, with appropriate combinations of arterial and venous flow volume assessment, the technique allows accurate assessment of inter-atrial, inter-ventricular, arterial and venous shunt volumes. In the context of atrio-ventricular valve regurgitation, knowledge of the ventricular stroke volume, combined with knowledge of the forward arterial flow volume from that ventricle allows for calculation of mitral or tricuspid valve regurgitant fraction. For every patient in whom ventricular function is quantified, the practice of our unit is to undertake great arterial flow volume assessment to guide the volumetric analysis. This greatly enhances the accuracy and reproducibility of our reporting procedure [38].

3.2.4 Black-blood Imaging

Spin echo pulse sequences can still play a role in imaging CHD. These sequences are effective for the assessment of the 2D morphology of the blood vessels and cardiac chambers, [39,40]. This is particularly useful when turbulent flow at the site of stenosis reduces the accuracy of balanced-SSFP or MRA images. Black blood imaging is also useful for elucidating the relationship between airway and blood vessels. This helps in identifying airway abnormality associated with various airway diseases, or in airway problems occurring as a complication of CHD [41]. Black-blood imaging is also useful when tissue characterization is necessary, in particular when fat infiltration of the myocardium is suspected. Though black-blood imaging has been suggested as a good method for assessing stents, we believe that this can give false re-assurance about stent patency (non-visualization of the stent interior) and hence we recommend other MR techniques to define stent morphology using CMR. These include using high-flip-angle gradient echo cine images, to assess the stent in longitudinal and cross-sectional planes [42].

3.2.5. Late-gadolinium enhancement (LGE)

LGE-CMR has become an integral part of imaging both congenital and acquired cardiovascular diseases. This is achieved through the use of gadolinium-based agent and

specific MR pulse sequences that help to differentiate between the normal and the diseased myocardium. The role of LGE-CMR in adults with ischemic cardiomyopathy has long been established [43], and its impact in the imaging work-up in pediatric population is growing. For patients with previously repaired tetralogy of Fallot, LGE has been associated with RV dilatation and worsening hemodynamics [44,45]. LGE has also been shown to be a good indicator of systemic RV failure in patients following atrial switch repair of transposition of great arteries [46]. Late after Fontan operation it has also been shown that LGE is associated with dilated and hypertrophied systemic ventricles, systolic dysfunction, regional dyskinesis and ventricular arrhythmias [47]. Areas of myocardial fibrosis following coronary artery re-implantation during repair of congenital heart diseases are also detected with LGE-CMR [48]. Moreover, the extent of late enhancement is associated with increased risk of arrhythmias and sudden death in adult patients with hypertrophic cardiomyopathy [49]. LGE-CMR has been shown to have a high diagnostic accuracy in patients with acute myocarditis [50].

3.2.6. Stress perfusion CMR - adenosine and dobutamine

Myocardial perfusion CMR can be performed at rest and during stress with coronary vasodilatation induced by adenosine. This defines myocardial viability and the stress/rest adenosine perfusion deficit, while a bolus of gadolinium contrast agent is being administered. Indications for pharmacological perfusion CMR in the pediatric age group include suspected ischemia secondary to acquired coronary artery disease, such as Kawasaki's, or suspected ischemia following surgical transfer of coronary arteries during repair of CHD. The clinical value of adenosine perfusion CMR is similar to that of myocardial scintigraphy, with an advantage that adenosine perfusion is performed over a single 45-minute session, with no radiation exposure, as compared to two long sessions of scintigraphy. The high specificity and sensitivity of adenosine perfusion studies have been validated in adult patients with coronary artery disease [51,52].

There is very little data regarding the use of dobutamine stress CMR in pediatric patients with congenital disease. Currently our unit does not use this methodology, but many centres are gathering experience. The feasibility has been shown in one small study [53]. Some centres are utilizing dobutamine stress methodology for additional decision support in the decisions regarding timing for intervention, for example in the population of patients with repaired tetralogy of Fallot [54,55].

3.2.7. Sequence optimization

Pediatric CMR poses various technical challenges that need to be considered in order to obtain optimal images to answer the clinical question being investigated. These include: fast heart rate in neonates and infants (100-150

beats per minute) requiring a high temporal resolution for accurate ventricular volume and flow measurements; small-sized heart and blood vessels requiring greater spatial resolution; [56,57] and potential arrhythmias as complications surgical procedure or the congenital anomaly itself. These will render CMR difficult, and will require adjustments to normal CMR imaging protocols.

To meet the needs of successful pediatric CMR, some adjustments are as follows. Due to small size of the heart and blood vessels, slice thickness is reduced to 3-5 mm. The field of view is also reduced, but this is at the expense of signal:noise ratio (SNR). Sometimes, smaller size, pediatric radiofrequency coils or the application of multiple signal averages can help to maintain the SNR at high spatial-resolution for these small hearts. To avoid image blurring due to fast heart rate in newborns and infants, it is necessary to improve the temporal resolution. Reducing the number of views to be acquired per segment in the segmented k-space and minimizing repetition time (TR) during each cardiac cycle in retrospective sequences such as balanced SSFP cine, will help improve the temporal resolution. In prospectively gated sequences such as turbo spin echo (TSE) every other heart beat techniques can be applied [57-59]. In patients with arrhythmias, real time imaging can be used [60,61]. In patients having difficulty with breath-holding, or with respiratory motion artifacts, averaging techniques or a respiratory navigator can be applied.

3.2.8. A note on normal values in children

The rapid uptake of CMR and exponential rise in use for pediatric cardiology accentuates the paucity of CMR data giving normal reference values for pediatric patients. Normal data for ventricular volumes, function and other structural measurements has been published [19,62,63] and multicentre data is now being accumulated. It is crucial that these data incorporate, or at least attempt to unify, the multitude of different imaging and post-processing conventions that have evolved in the international centers developing pediatric CMR.

4. Clinical applications

4.1. Cardiovascular shunts

The suspicion of significant systemic to pulmonary shunt at any level; intrapulmonary, atrial, ventricular or systemic arterial, can be an indication for CMR, with the aim to assess the anatomy, quantify the shunt, and measure the effect of any volume loading on the atrial and ventricular chambers.

Conventionally, the most common methods of evaluation of these shunts have been invasive oximetry or thermal dilution, non-invasive first-pass radionuclide angiography or color Doppler echocardiography. All of these techniques have significant limitations [64]. CMR techniques have been shown to correlate well with

oximetry and Doppler echocardiography in quantification of the shunt volume [65-67].

Importantly, CMR also gives morphological information to guide intervention and management. Gaps in septal signal in dark-blood acquisitions may suggest the presence of defects, but this may be due to partial volume effects and possible signal drop out [65]. Suspected defects should be investigated further by appropriately aligned cine and velocity map acquisitions [68]. Signal artefact caused by flow turbulence through the defect can be visualized during different phases of the cardiac cycle by white-blood cine imaging techniques such as SSFP, orientated perpendicular to the adjacent septum, and acquired in stacks of relatively thin slices, without gaps. This can be followed by a through-plane or in-plane flow velocity acquisition, transecting the jet emerging through the defect [69], prior to flow velocity mapping within the great vessels [70] to quantify the shunt volume.

Quantification of the left to right shunt is traditionally based on Flick's principle, which looks at the ratio of pulmonary (Q_p) to systemic (Q_s) flow. The feasibility of CMR to quantify intra-cardiac shunt has been shown to correlate well with the other methods. Quantification of blood flow is done using velocity encoded cine CMR (VENC-CMR), carefully optimized for spatial and temporal resolution, and planned in a plane perpendicular to the direction of flow in the relevant great vessels. At the simplest level, by measuring the flow volume in both the main pulmonary artery and the proximal ascending aorta, a Q_p/Q_s ratio is obtained [11,70-74]. Correlating this data with ventricular stroke volumes, can give the level of the shunt.

4.2. Diseases of the aorta

4.2.1. Coarctation of the aorta (CoA) is a congenital narrowing of the aorta, usually at the site of ductal insertion (aortic isthmus) [75]. The treatment of choice in infancy is surgery, though in older subjects balloon angioplasty or stent implantation can give effective relief of arch stenosis.

CMR is the first line assessment in the follow-up of CoA (Figure 2), and can identify the arch geometry and morphology (residual stenosis or aneurysm formation), as well as assess aortic valvular morphology, and left ventricular systolic function and hypertrophy. A "gothic" arch is associated with high risk of resting hypertension despite successful repair [76]. CMR can characterise coarctation stents, using black blood and gradient echo cine sequences. Stent-associated stenosis can also be diagnosed with phase contrast flow mapping and angiography, or high-flip angle gradient echo cine images [42]. However, often cardiovascular CT may also help to assess internal stent morphology and adjacent complications.

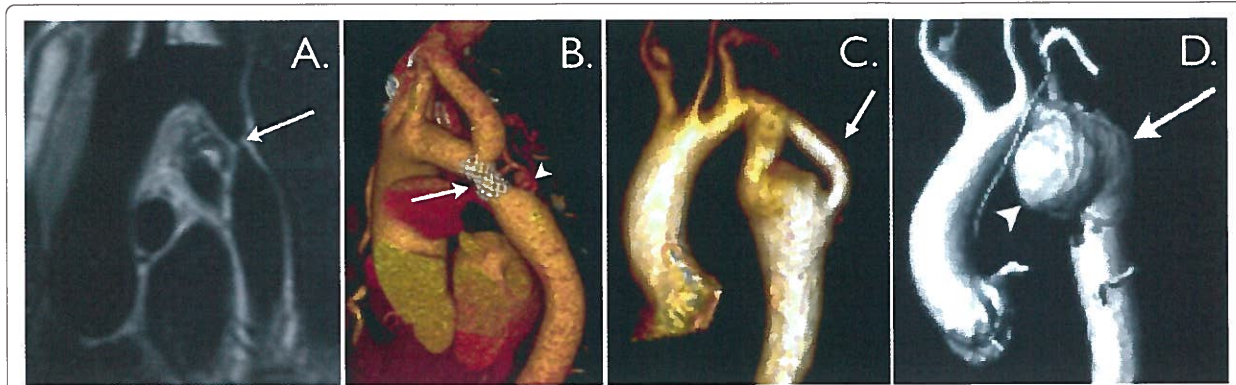


Figure 2 Aortic coarctation. **A.** 'Black-blood' oblique sagittal view showing discrete, tight coarctation at the aortic isthmus (arrow). **B.** 3D, contrast-enhanced CT angiogram showing mildly narrowed bare metal stent (arrow) that partially overlies the left subclavian artery origin. The arrowhead shows a subtle pseudo-aneurysm at the distal end of the stent. **C.** 3D, contrast-enhanced MR angiogram showing aortic arch hypoplasia and coarctation with a 'jump' by-pass graft posteriorly (arrow). **D.** 3D, contrast-enhanced MR angiogram showing large pseudo-aneurysm (arrowhead) after previous patch angioplasty repair. The true lumen is shown posteriorly (arrow).

4.2.2. Interrupted aortic arch (IAA) is rarely imaged pre-operatively in the neonate with CMR, as echocardiography can usually define the arch anatomy and associated intracardiac anomalies [77]. Post-operative CMR imaging has the same advantages as for simple coarctation aorta, and the imaging protocols used generally correlate.

4.2.3. Anomalies of the aortic arch are due to failure of fusion and regression of the brachial arches in a usual manner during the embryologic development of the aortic arch, pulmonary arteries and ductus arteriosus [78,79]. The diagnosis of these abnormalities using CMR can be achieved by contrast enhanced (CE-MRA) and non-contrast enhanced 3D SSFP sequences, which delineate the anatomy very well, [80] and can often depict associated airway anomalies.

4.3. Disease that predominantly affect the right ventricle

4.3.1. Tetralogy of Fallot is the most common cyanotic congenital heart disease accounting for 420 per million live births [1]. CMR has become a prominent diagnostic and monitoring tool for both pre- and post-operative assessment of tetralogy of Fallot [81-83].

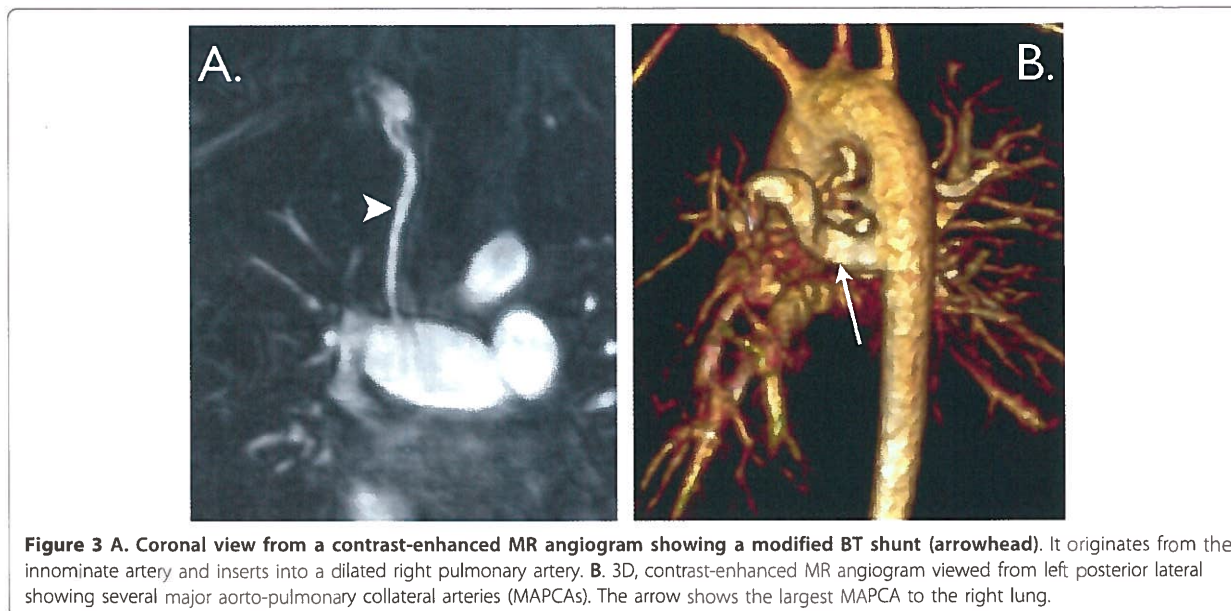
Echocardiography is usually sufficient to define anatomy prior to surgery in most patients during infancy, however those with complex pulmonary stenosis or atresia can be effectively assessed with CMR [84], with the aim of identifying the presence and the size of the native pulmonary arteries and the source of pulmonary blood supply (Figure 3). CMR defines the degree of RVOT obstruction [40,85,86], and with the use of 3D SSFP sequences, can define the coronary anatomy, to exclude the presence of a large coronary artery branch crossing the RV outflow tract.

The degree of RV dilatation secondary to chronic volume load, as a result of pulmonary regurgitation, has a deleterious impact on biventricular systolic function and functional efficiency [87-89] (Figure 4). Currently the main treatment of severe pulmonary regurgitation in this population is the replacement of the pulmonary valve. This can be achieved surgically or trans-catheter percutaneous pulmonary valve implantation (PPVI). CMR provides a basis for deciding which route to employ in replacing the pulmonary valve and has demonstrated significant physiological improvement following PPVI [90,91].

Pulmonary stenosis following Tetralogy repair can be well characterised by CMR, using cine imaging and flow mapping. PC-MRI is the best modality in demonstrating the relative volume of blood flow to each lung after the repair of Tetralogy of Fallot [92]. CMR has been shown to be sensitive and specific in detecting branch pulmonary artery stenosis following Tetralogy repair especially 3-D MRA [93-95]. RV diastolic function can be assessed with tricuspid valve inflow volumetric curves using PC-MRI [96].

4.3.2. Transposition of the great arteries (TGA) comprises 3% of all congenital heart disease [1]. CMR is seldom required for pre-operative assessment of simple TGA, as echocardiography usually provides adequate diagnostic information [97]. The main indication for CMR in TGA is the evaluation of post-operative complications.

Surgical therapy for this condition was revolutionized in the 1960's with the introduction of the Senning and the Mustard procedures (atrial switch operations), which involved the diversion of systemic venous return to the left ventricle and pulmonary venous return to the right



ventricle. This creates a physiological correction of the problem with a very abnormal anatomy.

Post-atrial switch assessment involves cine and 3D imaging of the venous pathways for baffle leaks or obstruction, and assessing systemic RV systolic function and tricuspid valve function (Figure 5). Late gadolinium enhancement of the ventricular myocardium after atrial switch operation has been found to correlate with outcome [98,99].

In the current era, the surgical procedure of choice for neonates diagnosed with TGA is the arterial switch operation [100,101]. This produces both physiological and anatomical correction.

Although the arterial switch operation (ASO) has excellent long-term outcomes, there can be serious complications concerns related to this surgical procedure. The main complications of ASO are main pulmonary artery or branch pulmonary artery stenosis, related to the LeCompte maneuver [102] (Figure 6). Additionally, dilatation of the neo-aortic root and regurgitation of the neo-aortic valve can cause hemodynamic complications in the long term. Assessment of these post operative complications involve CMR techniques previously described in this review; stenosis, valve function and baffle leaks are assessed using PC-MRI and anatomical and physiological assessment employs the use of spin echo, gradient echo and 3-D MRA [103,104].

Proximal coronary artery geometry can be assessed by MRA or MDCT and the presence of reversible damage caused by the stenosis is assessed by pharmacologically induced myocardial perfusion stress using adenosine or dobutamine [48,51,105].

4.3.3. Double outlet right ventricle (DORV) is a rare cyanotic congenital heart malformation in which both great arteries arise predominantly from the right ventricle. There is almost always a VSD that acts as an outlet from the left ventricle. DORV is classified according to the relationship (commitment) of the VSD to each of the great vessel's valve and the most common sub-groups are:

- Sub-aortic VSD (Fallot physiology) has pulmonary stenosis and if there is no associated pulmonary stenosis it presents with VSD physiology. This is the most common type of DORV.
- Sub-pulmonic VSD with transposition of the great vessels (Taussig-Bing type) DORV [86].
- Double committed: where the VSD is committed to both great arteries.
- Non-committed VSD

The ultimate goal of management of these patients is to align LV with systemic outflow tract and RV with the pulmonary outflow tract. The LV can be hypoplastic, and these are the groups that pose challenges to the surgeon. Detailed imaging is therefore mandatory to assess the anatomical relations and ventricular physiology before deciding surgical strategy for a biventricular or single ventricular repair. CMR has replaced invasive cardiac catheterization for this cause and has been shown to correlate very well with surgical findings in investigating the exact position of great arteries and their relationship to the VSD [106,107]. The 3-D isotropic CMR is ideal for assessing this complex type of anatomy.

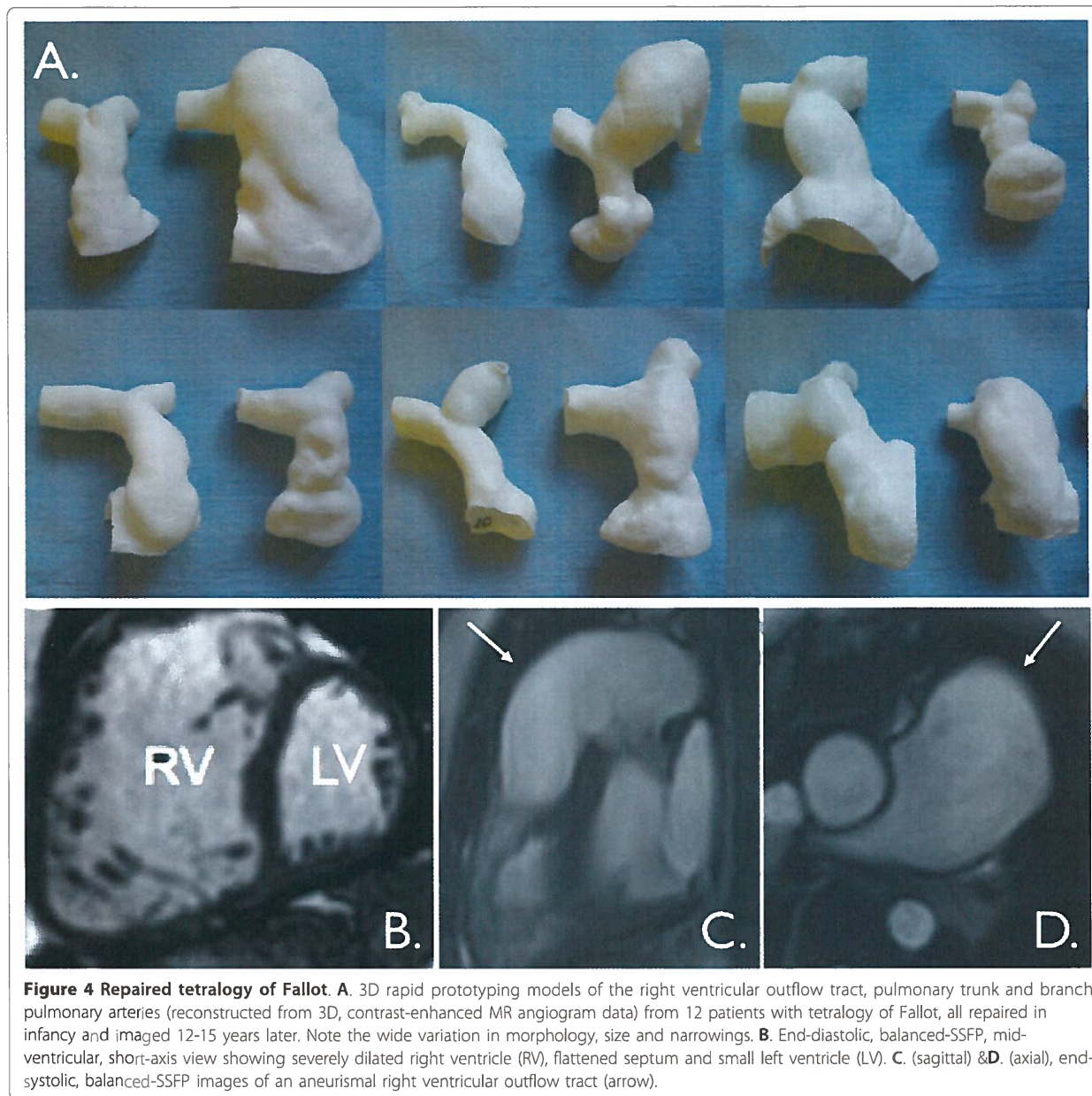


Figure 4 Repaired tetralogy of Fallot. **A.** 3D rapid prototyping models of the right ventricular outflow tract, pulmonary trunk and branch pulmonary arteries (reconstructed from 3D, contrast-enhanced MR angiogram data) from 12 patients with tetralogy of Fallot, all repaired in infancy and imaged 12-15 years later. Note the wide variation in morphology, size and narrowings. **B.** End-diastolic, balanced-SSFP, mid-ventricular, short-axis view showing severely dilated right ventricle (RV), flattened septum and small left ventricle (LV). **C.** (sagittal) & **D.** (axial), end-systolic, balanced-SSFP images of an aneurismal right ventricular outflow tract (arrow).

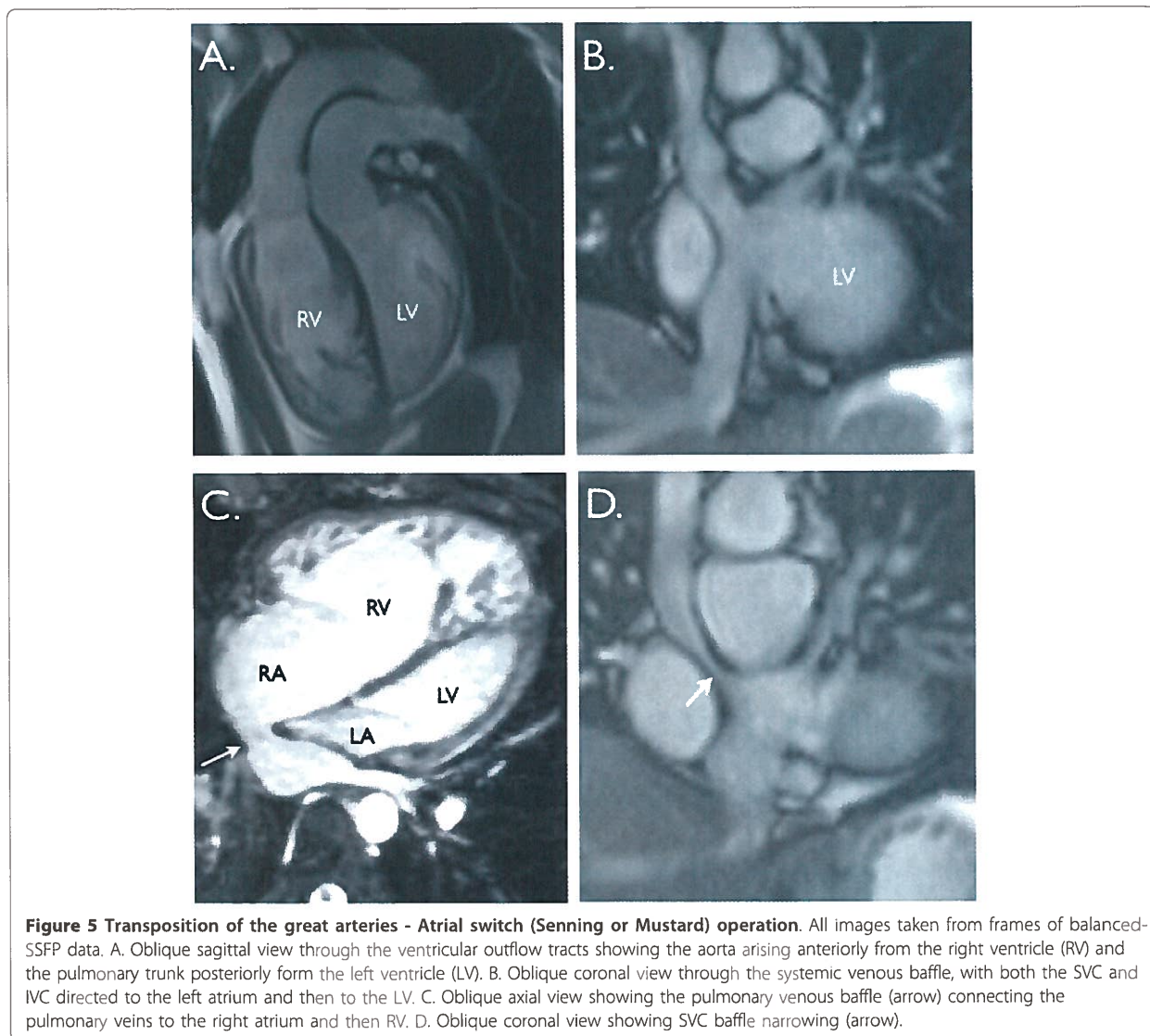
Post-operative complications are usually imaged using a combination of black-blood images, balanced-SSFP, PC-CMR and 3-D MRA. With the tetralogy physiology complications are similar to those experienced with tetralogy of Fallot, and with the Taussig-Bing type complications are similar to those experienced in TGA (see previous sections).

4.4. Complex congenital heart disease

4.4.1 The single ventricle heart is a complex entity that encompasses varying degrees of anatomic and physiologic states in which only one ventricle supports

the circulation. Specific anatomical examples include hypoplastic left heart syndrome (HLHS), which is characterized by the underdevelopment of the left-sided heart structures, and tricuspid atresia (hypoplastic right heart).

For simplicity we will use HLHS as our reference point to illustrate imaging issues of the uni-ventricular heart. Management of a single ventricle involves a series of staged palliative procedures. CMR can valuably contribute intervention planning before and after each stage of the palliative surgical process, and keeps radiation exposure at a minimum (Figure 7). CMR has been



shown to be superior to both x-ray angiography and echocardiography in this group of patients [17,108-110].

Prior to any procedure, a number of centres are using CMR methodology to give decision support for patients with “borderline size” ventricles. For those within the spectrum of hypoplasia of the left ventricle, LGE techniques can often identify significant endocardial fibroelastosis [111]. Long-term outcome data for patients studied and classified with these techniques remains under investigation.

After the first stage of surgery, CMR, using black-blood sequences or gadolinium-enhanced angiography can delineate the aortic arch and branch pulmonary artery anatomy, and visualize the aorto-pulmonary shunt. The second surgical stage is most frequently the bidirectional superior cavopulmonary connection

(BCPC) at age 4-6 months. There are various aspects of the haemodynamics that need to be considered when assessing a patient post-BCPC and before the final stage of palliation - formation of the total cavopulmonary circulation. These include the ventricular function, the aortic arch for obstruction, the caliber and patency of the branch pulmonary arteries, shunting through the collateral vessels, and adequacy of inter-atrial communication [112]. The BCPC is a low flow velocity circuit and its CMR is achieved using cine, contrast enhanced and PC-CMR sequences. Assessment of a BCPC circuit non-invasively for collaterals using the PC-CMR is reliable [113].

The final stage of a single ventricular repair is the creation of a Fontan-type circuit in which the SVC and IVC blood is directed into the pulmonary arteries and

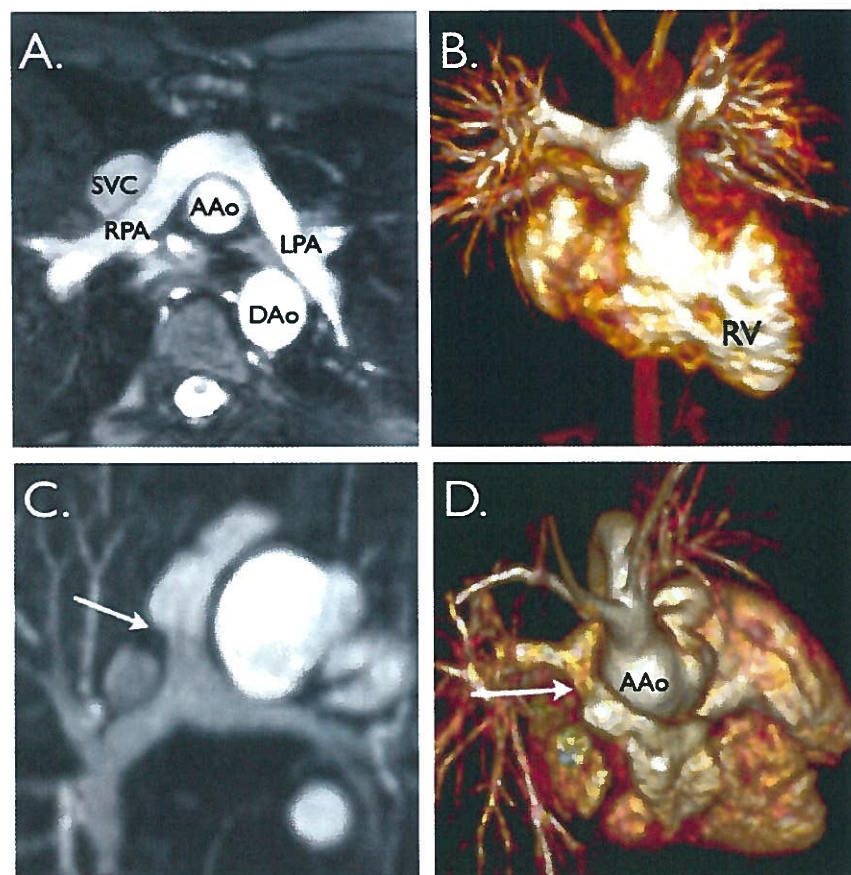


Figure 6 Transposition of the great arteries - Arterial switch operation. **A.** Axial reformat from contrast-enhanced MR angiogram & **B.** 3D, contrast-enhanced MR angiogram. Both **A** and **B** show Leconte maneuver with the pulmonary artery anterior to the ascending aorta (AAo) with the right (RPA) and left pulmonary arteries passing either side of the aorta, note descending aorta (DAo). **C.** (axial reformat from contrast-enhanced MR angiogram) & **D.** (3D, contrast-enhanced MR angiogram) Showing alternative arterial switch operation, with the main pulmonary artery (arrow) seen to pass on the right side, between the superior vena cava (SVC), and aorta.

completely bypasses the heart to enter the lungs. CMR presents valuable 3D morphological and functional information regarding the Fontan circulation, as well as the possibility to sensitively assess for thrombus.

4.4.2. Defining atrial morphology and associated findings: Abnormal atrial situs is often associated with complex cardiac malformations and abnormal abdominal and thoracic anatomy [86]. 3D balanced-SSFP images are valuable for determining the atrial situs. Isomerism of the right atrial appendages is associated with bilateral right bronchi and tri-lobed lungs, bilateral right atrial appendages, asplenia and midline liver. The left atrial isomerism is associated with bilateral left bronchi; bi-lobed lung, bilateral left atrial appendages, polysplenia and interrupted IVC [114,115].

4.5. Assessment of coronary artery problems

Congenital coronary artery anomalies are rare, affecting 0.3-0.8% of the population [116]. CMR is a valuable

adjunct for the assessment of anomalous coronary arteries [117,118]. 3D mapping of the coronary morphology using respiratory and cardiac-gated balanced SSFP imaging can reveal the proximal course of the coronary arteries and delineate aneurismal dilatation. The definition of the proximal course of the coronary arteries is becoming increasingly important in the assessment of patients who are undergoing interventions to cardiac structures in close proximity to the coronary arteries for example percutaneous pulmonary valve implantation into the pulmonary trunk [119], or stenting of the branch pulmonary arteries in ASO.

Multi slice CT coronary angiography has been shown to have sensitivity, specificity and negative predictive value of almost 100% in assessing coronary artery problems following ASO for TGA [120].

Though CMR does not portray lumen patency well, CMR myocardial stress perfusion and late gadolinium studies are the gold standard for assessment of end-

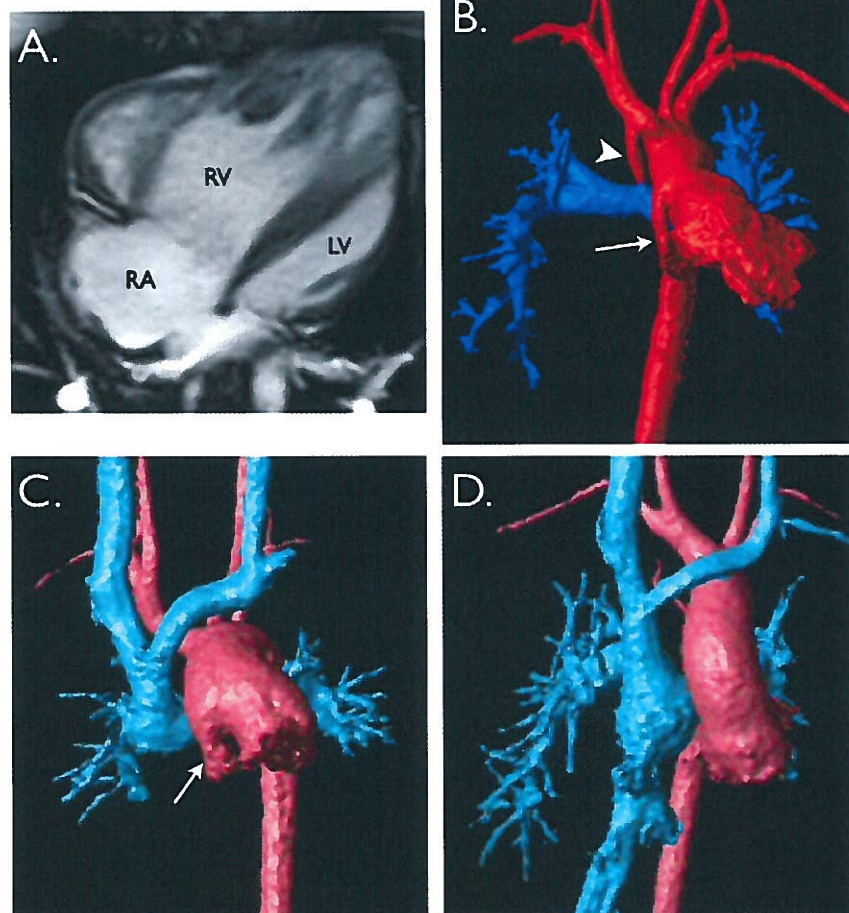


Figure 7 Hypoplastic left heart syndrome. **A.** End-diastolic, balanced SSFP, 4 chamber-view showing hypoplastic left ventricle (LV). Pulmonary venous return passes from left atrium to the right atrium, via a large atrial septostomy. **B.** 3D, contrast-enhanced MR angiogram after Stage 1, Norward operation, with a modified BT shunt (arrowhead) supplying the pulmonary arteries [153]. Note the hypoplastic native ascending aorta (arrow). **C.** 3D, contrast-enhanced MR angiogram after Stage 2 bi-directional cavo-pulmonary connection operation. This connects the SVC to the branch pulmonary arteries (pale blue). Again arrow shows hypoplastic native ascending aorta. **D.** 3D, contrast-enhanced MR angiogram after Stage 3, total cavo-pulmonary connection operation. This further connects the IVC into the pulmonary circulation (pale blue).

organ function in adults: characterizing myocardial ischemia, scarring and viability respectively [44,46,121]. There are many pediatric and adolescent populations with congenital heart disease (post arterial switch operation [48], post Kawasaki's disease, post coronary re-positioning surgery) who may benefit from assessment of coronary adequacy. Many centers are exploring this, and finding success in pediatric patients [53,122].

5. Emerging indications

There are other patient groups in which the benefits of and indications for CMR are well validated in the adult population, but where there is currently a paucity of data pertaining to patients in the pediatric age range. Many factors limit the comparability of adult and

pediatric populations, however the potential for pediatric CMR in these fields is rapidly being realized.

5.1. Cardiomyopathy assessment

CMR is showing great potential in the pediatric population for the diagnostic assessment and therapeutic monitoring of patients with all types of cardiomyopathies [123,124] (Figure 8). CMR has the capacity to acquire images without acoustic limitations, in 3-dimensions, with tissue contrast and myocardial border definition that is often superior to echocardiography. This gives great advantage for pre-clinical diagnosis or family screening [125,126]. CMR has the advantage of accurate quantification of segmental function, ventricular volume and systolic shortening, while sensitively imaging

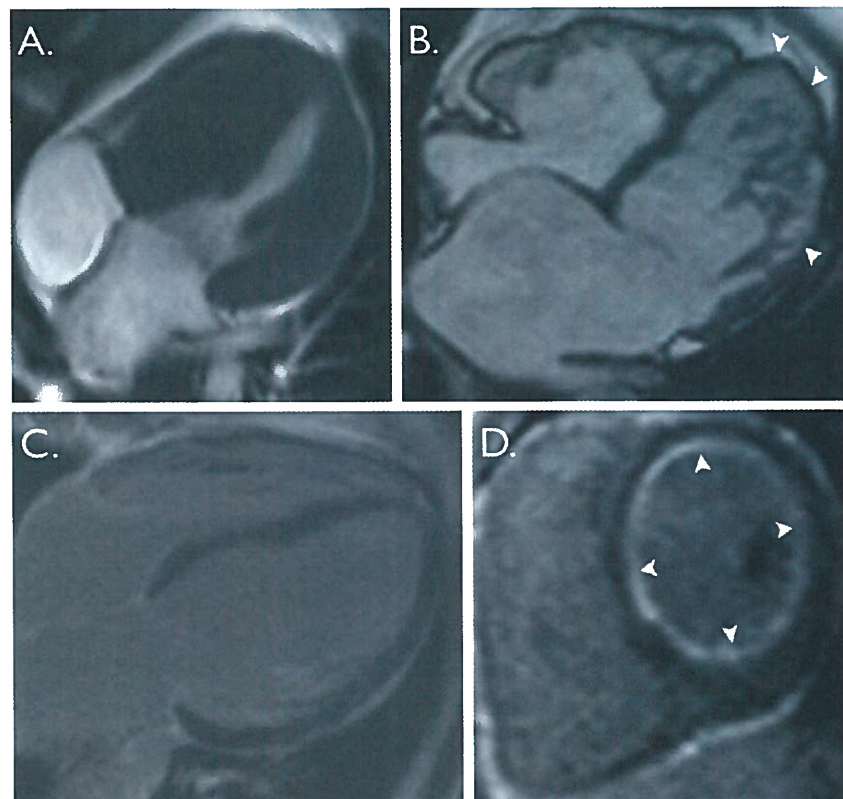


Figure 8 Examples of cardiomyopathies. **A.** 4-chamber, balanced-SSFP view in hypertrophic cardiomyopathy. Note the marked thickening of the septum with compression of the RV cavity. **B.** 4-chamber, balanced-SSFP view in left ventricular non-compaction. Note the arrowheads show areas of thin compacted myocardium. **C.** 4-chamber, late gadolinium enhancement (LGE) image in idiopathic dilated cardiomyopathy. Note no LGE. **D.** Short-axis, LGE image in a patient with critical aortic stenosis, restrictive cardiomyopathy secondary to global, sub-endocardial fibrosis.

myocardial architecture. The extent of LGE in patients with HCM has been independently associated with adverse outcome and worsening clinical symptoms, suggesting its link to prognosis and its ability to be used as an independent risk factor in these patients [127,128]. This comprehensive assessment also enlightens clinical and pharmacological management in the many types of dilated cardiomyopathies and skeletal myopathies with cardiac involvement [129].

5.2. Iron loading

Cardiac T2* assessments for myocardial iron loading [130] are an increasing referral source for CMR assessment. Pediatric patients with thalassemia major, or other chronic anemias requiring multiple transfusions are at risk of myocardial iron deposition, progressive fibrosis and systolic impairment. The optimal timing for screening of these young patients by CMR is under debate. Some evidence suggests that initiation of assessment should be determined according to the patient's age and transfusional burden [131]. When the appropriate chelation therapy has been administered since birth, CMR can be postponed

until 8 years of age, so that anesthesia is not required for the scan. Patients with suboptimal chelation or with increased transfusional requirements should be tested sooner. However, as with many other pediatric pathologies, the CMR T2* technique for iron assessment has only been validated in adults. No validation or range of normal values exists for the infant and pediatric population.

6. Role of the hybrid CMR/catheter laboratory

The hybrid MR/X-ray catheter suite (XMR) is emerging as a useful diagnostic and interventional tool for cardiovascular diseases in both children and adults (Figure 9). There are many attractive attributes to these hybrid suites as compared to purely X-ray techniques, which have been the gold standard imaging modalities in cardiovascular medicine.

XMR reduces the amount of radiation exposure to both patients and medical staff due to the lack of ionizing radiation of the MR imaging component [132,133]. This is mainly important for children who are prone to DNA and chromosomal damage by radiation exposure leading to development of malignancies [134,135].



Figure 9 Hybrid CMR/cardiac catheterization laboratory. Fish-eye view of a hybrid CMR/cardiac catheterization lab - The bi-plane catheter lab (left) is connected to the MR scanner room (right), via a set of sliding doors (open). The pedestal of the catheter table slides toward the MR scanning room to join with the MR scanner table. The patient then slides across between the two tabletops, using Miyabi table technology (Siemens AG).

CMR provides a detailed anatomy, which is useful in pre-procedural planning for electrophysiological studies and cardiac interventional procedures. In electrophysiology, CMR helps to identify the scar tissue acting as the focus for the abnormal electrical impulse and it also gives a detailed anatomy of adjacent structures to prevent ablation therapy related complications [132,136,137]. Various studies have shown the feasibility of CMR guided intervention due to its superior soft tissue quality and having an XMR means the X-ray can be used as a bail out if need arise [138-142].

CMR use in physiological studies such as pulmonary vascular resistance (PVR) and left and right heart catheterization seems to be coming out of its shell. In an XMR suite both invasive pressure data and flow data can be acquired. This is particularly good in PVR studies and in quantification of collateral flow in cavo-pulmonary connection patients including ventricular function assessment [17,29,133,143,144].

7. Role of cardiovascular CT

CT imaging also plays an important role in the management of pediatric CHD. This modality provides very high-resolution 3D data sets with an extremely short acquisition period and therefore can usually be performed in infants and small children without general anesthetic. The expense of this imaging is the exposure of patients to potentially large doses of ionizing radiation, particularly for ECG-gated studies, though this continues to fall. Its use for serial evaluations is therefore very limited. CT imaging is useful for patients who are unable to co-operate with CMR or who are too clinically unstable to undergo general anesthetic. Additionally, when CMR provides inadequate images for

clinical decision-making, CT angiography is the modality of choice in:

- Patients with vascular rings, where it is important to visualize the airway anatomy.
- Patients in whom we are investigating pulmonary venous anatomy (in our experience MR imaging of the pulmonary veins can be problematic).
- Patients in whom we are assessing pulmonary atresia with major aorta pulmonary collateral arteries (MAPCAs) - our protocol for assessing these patients is to perform a CT scan prior to cardiac catheterization. The CT scan will identify the number of large aorta pulmonary collaterals and the presence of any central pulmonary arteries, and this information can be used to guide cardiac catheterization. The main purpose of the cardiac catheterization is to identify the temporal distribution of blood flow and define which areas of the lungs the pulmonary arteries, the MAPCAs, or both supply. This significantly aids the surgeons in unifocalisation in these patients.
- Patients who have metallic implants - e.g. routine CT following aortic coarctation stenting at 3 months to exclude pseudo-aneurysm formation at the distal ends of the stent.
- Patients in whom there is contraindication to CMR (e.g. permanent pacemaker).

8. Future directions and conclusions

8.1. Real-time imaging

This technique employs continuous imaging of dynamic cardiovascular processes in real time using (SENSE, SMASH and their variants). Data acquisition is

accelerated for any CMR pulse sequence with the use of parallel imaging. Importantly, there is no need of cardiac gating and breath holding, which is an added advantage for an uncooperative and poor breath-holder pediatric patient [145,146]. The fact that it is real-time means that it is very useful in interventional CMR with endovascular devices and in CMR guided catheterization where position of catheters or devices can be tracked in real-time.

8.2. 4D flow

Time resolved 3D (4D) phase contrast flow velocity acquisition allows the reconstruction of multidirectional flow velocities; measurements for each phase of the cycle being effectively averaged over many heart cycles. Such acquisitions typically take 10 minutes or more, so beat-to-beat variations related to respiration or flow instabilities are not represented. Besides the visualization of principal multidirectional flow paths, this offers the potential to retrospectively quantify flow through selected planes in the volume covered [147]. Reported applications include the depiction of large-scale flow patterns in the aortas of patients with bicuspid aortic valves and the retrospective measurements of flow in

the presence of more than one shunt [148,149]. Moreover, this method has also been used in the evaluation of Fontan pathway dynamics [150,151].

8.3. Exercise

Progressive worsening of the symptoms related to cardiovascular disease can be masked at rest and only brought out through pharmacological stress or physical exercise. Physiological response seems to differ between pharmacological and exercise induced stress, with exercise more superior to pharmacological stress [152]. Real time biventricular volumetric assessment has been validated and found to be feasible and reproducible [145]. This helps to ensure that the physiological CMR changes secondary to exercise are acquired simultaneously, with the use of an MR compatible ergometer (Figure 10).

8.4. Conclusion

CMR is now a major imaging tool in pediatric congenital heart disease. It is made attractive by its non-invasiveness and lack of ionizing radiation. The technological advancements, with improved image resolution and ultra-short imaging time, have allowed real-

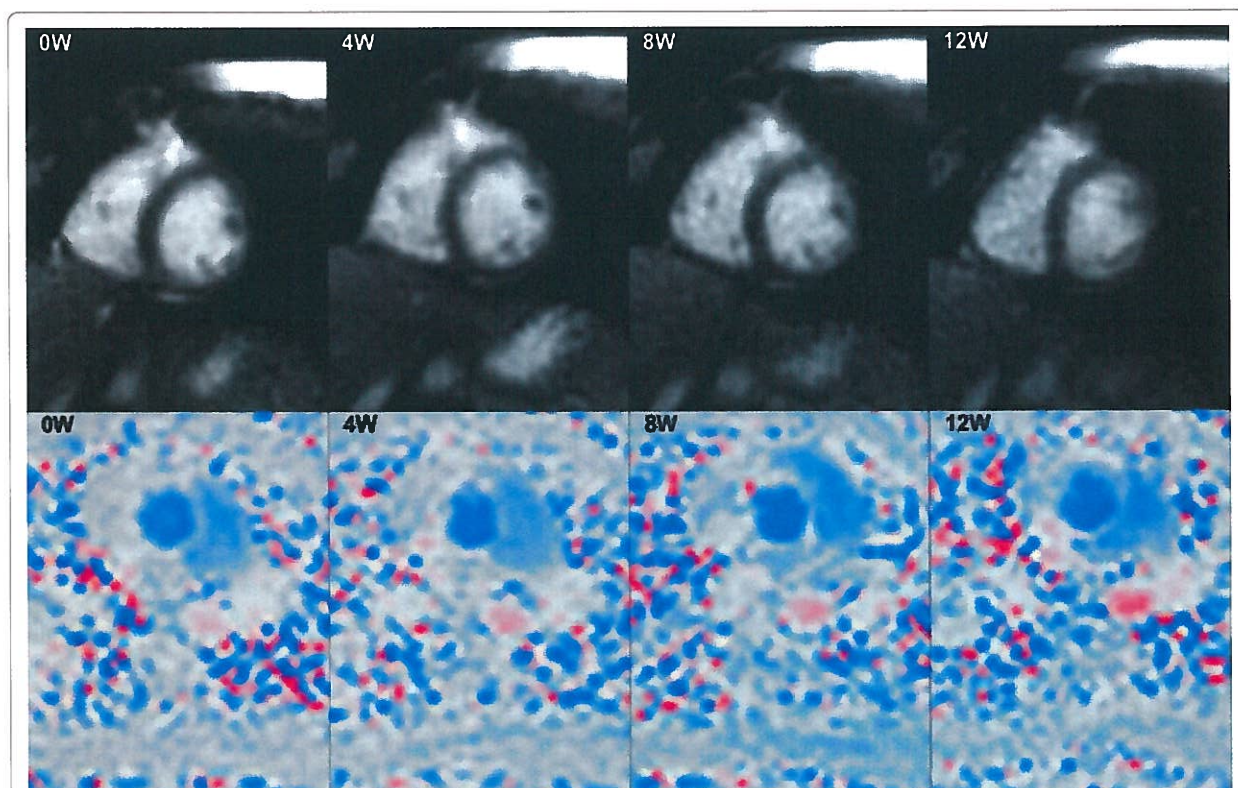


Figure 10 Real time data. Short-axis ventricular volumes (top) and flow data (bottom) acquired during increasing exercise within the MR scanner (0, 4, 8, 12W). Because the data is acquired in real-time, there is no need for the patient to attempt breath-holding during peak exercise, which is often difficult to achieve.

time imaging to come to the fore. This lends towards the added advantage of CMR-guided catheterization and interventions. Promising studies done in this and the many other areas described in this review show that CMR will revolutionise pediatric cardiology practice due to the radiation-free environment it provides [153].

Conflict of interests

The authors declare that they have no competing interests.

Additional material

Additional file 1: Table S1. Common indications for pediatric CMR under general anesthetic.

Additional file 2: Table S2. Common indications for pediatric CMR without anesthetic (usually, children greater than 7 years age).

Additional file 3: Table S3. Example of the standard sequences and views of a usual pediatric congenital cardiac scan, in the order of workflow.

Additional file 4: Table S4. Sequences that are useful in various clinical conditions.

Authors' contributions

HNN: Drafted the manuscript, reviewed literature, prepared the manuscript and approved the final version of this manuscript; MLH: Drafted the manuscript, reviewed literature, prepared the manuscript and approved the final version of this manuscript; AMT: Drafted the manuscript, reviewed literature, prepared the manuscript and approved the final version of this manuscript.

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Diffusion-Tensor Fiber Tractography: Intraindividual Comparison of 3.0-T and 1.5-T MR Imaging¹

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Purpose:

To prospectively evaluate the depiction of brain fiber tracts at 3.0- versus 1.5-T diffusion-tensor (DT) fiber tractography performed with parallel imaging.

Materials and Methods:

Institutional review board approval was obtained, and each subject provided written informed consent. Subjects were 30 healthy volunteers (15 men, 15 women; mean age, 28 years; age range, 21–46 years). Single-shot spin-echo echo-planar magnetic resonance (MR) sequences with parallel imaging were applied. Four fiber tracts were reconstructed: corticospinal tract (CST), superior longitudinal fasciculus (SLF), corpus callosum (CC), and fornix. Two neuroradiologists compared 3.0- and 1.5-T tractography in terms of fiber tract depiction by using five depiction scores (scores 0–4) and numbers of reconstructed tract fibers and in terms of lateral asymmetry in the CST by using numbers of reconstructed fibers. The Wilcoxon signed rank test was applied for statistical analysis.

Results:

Visual scores for both CST hemispheres ($P < .001$), the right SLF ($P = .005$), the CC ($P = .01$), and the right fornix ($P = .04$) were higher at 3.0-T DT tractography. Larger numbers of CST (right, $P = .008$; left, $P < .001$), SLF (right, $P = .001$; left, $P = .02$), and fornix (bilaterally, $P = .02$) tract fibers were depicted at 3.0 T. The asymmetry index for the CST was lower ($P < .001$) at 3.0 T. Visual scores for the left SLF and the left fornix and numbers of CC tract fibers were not significantly different.

Conclusion:

Depiction of most fiber tracts was improved at 3.0-T DT tractography compared with depiction at 1.5-T tractography.

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Diffusion-tensor (DT) imaging is a magnetic resonance (MR) imaging technique that is sensitive to the orientation of mobility in intravoxel water molecules (1,2). DT imaging reveals two specific characteristics: diffusion anisotropy and the directional distribution of water diffusivity. When water diffusion in a tissue is almost the same in all directions, the diffusion is considered to be isotropic and have lower anisotropy. Conversely, when water diffusion is restricted along a specific direction, the diffusion is considered to be anisotropic and have higher anisotropy. Brain white matter has high diffusion anisotropy because diffusion is faster when it is parallel to the fiber direction than when it is the same in all other directions (3,4).

DT images of the human brain can be reconstructed for visualization of the macroscopic three-dimensional fiber tract architecture by using a process known as fiber tractography, or the fiber-tracking technique (5–10). DT imaging and fiber tractography are powerful tools for studying cerebral white matter and have been applied clinically to assess brain tumors (11,12), diffuse axonal injury (13), pediatric brain development (14), and cerebral infarcts (15).

With recent advances in actively shielded 3.0-T magnets, the use of high-field-strength MR imaging in clinical settings has become practical (16,17). Parallel imaging techniques, such as simultaneous acquisition of spatial harmonics, or SMASH (18); sensitivity encoding (19); and auto-SMASH-based generalized autocalibrating partially parallel acquisition (20), also have improved with recent advances in MR imaging hardware. Owing to shortened echo train lengths and echo times, parallel imaging techniques can be used to reduce artifacts related to spin-echo echo-planar imaging. Some reports have described the performance of parallel imaging in spin-echo echo-planar DT imaging and fiber tractography at 1.5 or 3.0 T (9,10,21–24). However, to our knowledge, in no reports have the differences between 3.0- and 1.5-T spin-echo echo-planar DT fiber tractography with parallel

imaging been compared. Thus, the purpose of our study was to prospectively evaluate the depiction of brain fiber tracts at 3.0-T versus 1.5-T DT fiber tractography performed with parallel imaging.

Materials and Methods

Study Subjects

The study population comprised 30 healthy volunteers (15 men, 15 women; mean age, 28 years; age range, 21–46 years) with no history of neurologic injury or psychiatric disease. All subjects were examined by one of the authors (T.H., with 14 years of experience as a neurologist), and no subjects had abnormal neurologic signs or symptoms. Institutional review board approval was obtained for this study, and each subject provided written informed consent.

Data Acquisition

All subjects underwent 3.0- and 1.5-T DT imaging, which was performed by using a whole-body 3.0-T MR unit (Trio; Siemens, Erlangen, Germany) with a 40 mT/m gradient and a 1.5-T MR unit (Symphony; Siemens) with a 30 mT/m gradient, on the same day. MR imaging at 3.0 T was performed by one author (T.O.), and MR imaging at 1.5 T was performed by another author (Y.F.), both of whom had 8 years of experience as neuroradiologists and 2 years of experience in DT imaging. The time delay between 3.0- and 1.5-T MR imaging was less than 1 hour for all subjects. Both MR units were equipped with integrated parallel acquisition capability and a receive-only eight-channel phased-array head coil. Both the 3.0-T and the 1.5-T DT imaging examinations involved the use of single-shot spin-echo echo-planar sequences and nearly identical parameters: 5200/79 (repetition time msec/echo time msec), a 220-mm field of view, a 128 × 128 matrix, 3-mm section thickness without intersection gaps (matrix size, 1.7 × 1.7 × 3.0 mm), and four repetitions.

The generalized autocalibrating partially parallel acquisition algorithm was applied for parallel imaging with use of a

reduction factor of two, 24 additional autocalibrating phase-encoding steps in the center of k-space, and a 75% partial Fourier technique in the phase-encoding direction. Only the bandwidths differed: A bandwidth of 1502 Hz per pixel was used for 3.0-T imaging, and a bandwidth of 1056 Hz per pixel was used for 1.5-T imaging. Motion-probing gradients were applied along 12 noncolinear directions with a *b* factor of 700 sec/mm² after one non-diffusion-weighted image (*b* = 0 sec/mm²) was obtained. A total of 40 sections encompassed the entire cerebral hemisphere and the brainstem. The imaging times for 3.0- and 1.5-T DT imaging were almost the same—about 7.5 minutes.

Data Processing

DT imaging data sets were transferred, in Digital Imaging and Communications in Medicine format, to a Windows personal computer (IBM, New York, NY) workstation. DtiStudio, version 1.02, software (H. Jiang, S. Mori, Department of Radiology, Johns Hopkins University, Baltimore, Md) was used for tensor calculations (6,10). All source images from the DT imaging data sets were visually inspected by one author (T.O.), and images with visually apparent artifacts due to bulk motion were removed. In our DT imaging data set, there was low eddy current-related

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Abbreviations:

DT = diffusion tensor
ROI = region of interest

Author contributions:

Guarantors of integrity of entire study, T.O., Y.M., K.T.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, T.O., Y.M., Y.F., H.F., M.H., K.T.; clinical studies, T.O., Y.M., Y.F., T.H., M.K., A.Y., S.U., K.T.; statistical analysis, T.O., Y.M., M.K., A.Y., M.H., K.T.; and manuscript editing, all authors

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geometric distortion between images obtained in each motion-probing gradient direction (23,25), so postprocessing distortion correction was not applied for this data set. After calculating the six independent elements of the 3×3 tensor and diagonalization, three eigenvalues and three eigenvectors were obtained (1,3–5). The eigenvector associated with the largest eigenvalue was assumed to represent the intravoxel fiber orientation. The fractional anisotropy map and directional color-coded map were synthesized (Fig 1). Fiber orientations were assigned specific colors on the color-coded map, as follows: Red represented the right-to-left orientation; green, the anterior-to-posterior orientation; and blue, the superior-to-inferior orientation (26).

Fiber Tractography

The DtiStudio software was used to also perform fiber tractography on the basis of the fiber assignments derived by means of the continuous tracking method (6,9,10). With this software, tracking from all the pixels inside the brain (ie, with the brute force approach) was performed, and tracking results that penetrated the two manually segmented regions of interest (ROIs) on the basis of the known anatomic distributions of tracts were assigned to specific tracts (ie, with the two-ROI approach). Propagation in each fiber tract was terminated if a voxel with a fractional anisotropy value of less than 0.2 was reached or if the inner product of two consecutive vectors was greater than 0.75. These conditions prohibited the turning of angles larger than 41° during tracking (10).

Four fiber bundles—the corticospinal tract, the superior longitudinal fasciculus, the corticocortical connection fibers through the corpus callosum, and the limbic fibers through the fornix—were reconstructed by drawing specific ROIs according to the anatomic distributions of each fiber tract. ROI manipulations were performed by one neuroradiologist (A.Y.) with 3 years of experience performing tractography and 10 years of experience as a neuroradiologist. This author was blinded as to

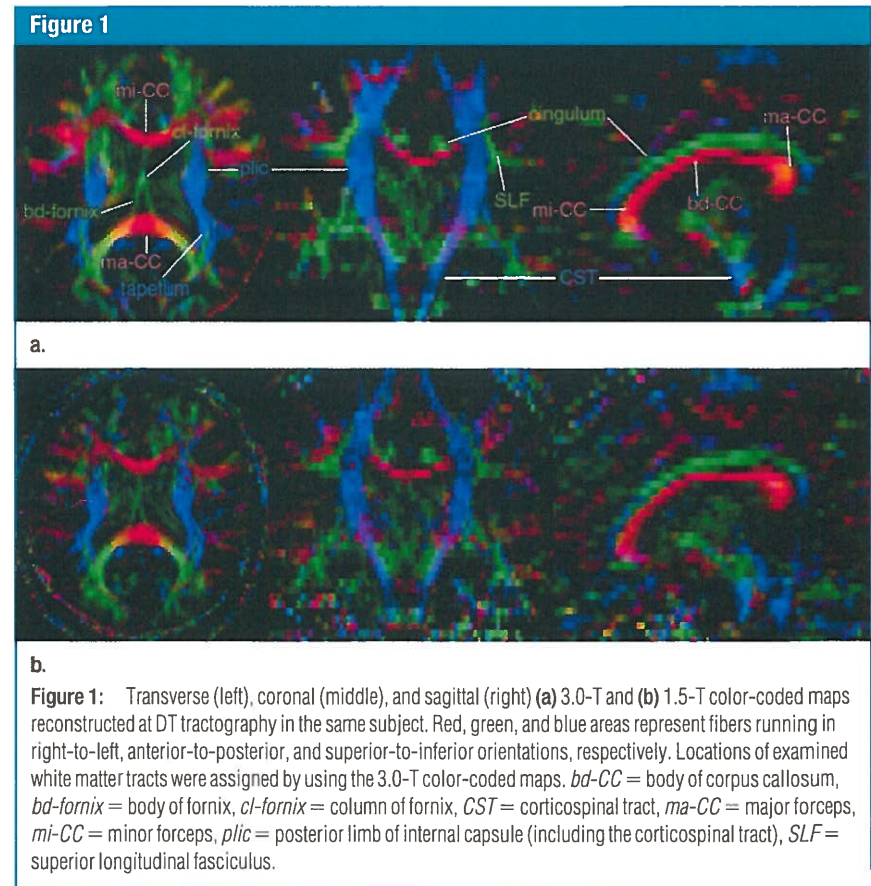
whether the images had been obtained by using 3.0 T or 1.5 T when he performed each ROI segmentation.

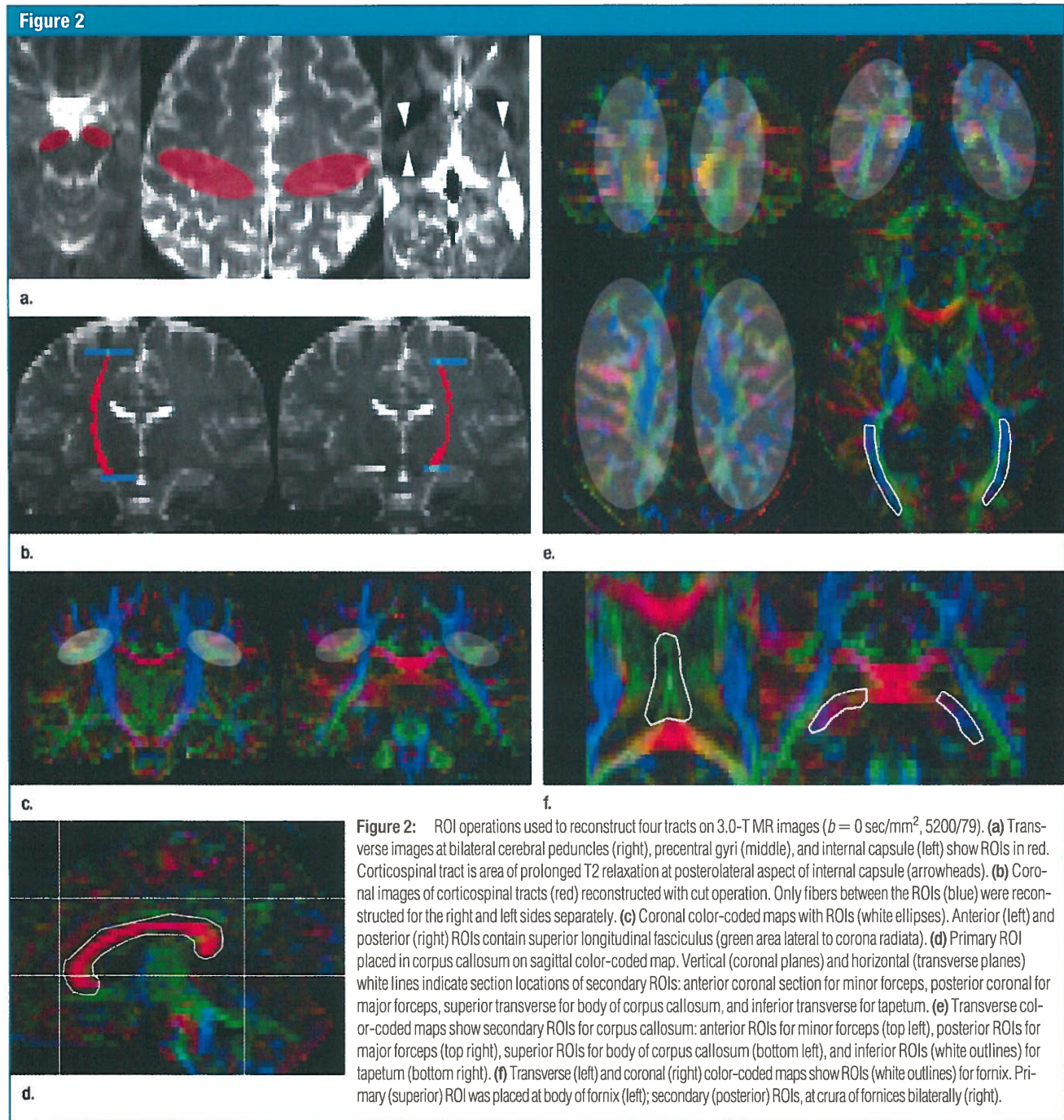
For corticospinal tract tractography, two ROIs were placed on transverse non-diffusion-weighted ($b = 0 \text{ sec/mm}^2$) images (10,12,15) according to established anatomic landmarks: The first ROI was placed in the cerebral peduncle bilaterally, and the second ROI was placed in the precentral gyrus bilaterally (27) (Fig 2a).

The superior longitudinal fasciculus was reconstructed at tractography by placing two ROIs in the cerebral deep white matter on a coronal directional color-coded map. The superior longitudinal fasciculus was identified on the coronal color-coded map as a region where the fiber orientation was anterior to posterior (green), lateral to the corona radiata (26,28). An anterior ROI was placed in the plane passing through the reconstructed corticospinal tract,

and a posterior ROI was placed in the plane passing through the rostral surface of the splenium of the corpus callosum, with both ROIs covering the green area representing the superior longitudinal fasciculus (Fig 2c). Some “noise” fibers that were apparently tracing the error course were then removed (10).

Corpus callosum tractography was performed by imaging the combination of four different callosal fiber bundles. The primary ROI was placed in the corpus callosum in the midsagittal plane (Fig 2d). To visualize different parts of the callosal fibers, secondary ROIs were placed in four regions: two ROIs on the coronal color-coded map and two ROIs on the transverse color-coded map (Fig 2e). Anterior callosal fibers, referred to as minor forceps, were reconstructed by placing the ROI covering the deep white matter in the coronal plane anterior to the genu of the corpus callosum. For reconstruction of the posterior cal-



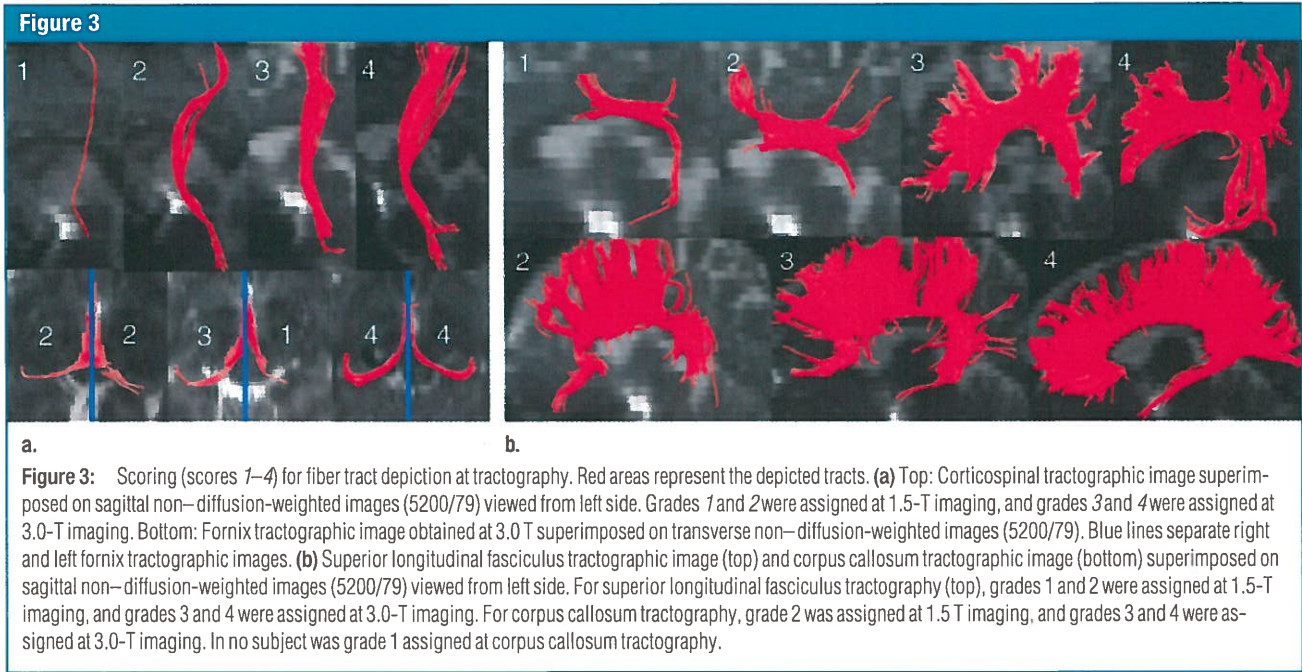


losal fibers, referred to as major forceps, the ROI was placed posterior to the splenium of the corpus callosum. Callosal body fibers were reconstructed by placing the ROI at the centrum semi-ovale in the transverse plane superior to the body of the corpus callosum. For

reconstruction of the temporal inter-hemispheric connection fibers, referred to as tapetum, ROIs were placed bilaterally in the temporal deep white matter, lateral to the trigon of the lateral ventricles. These four fibers (ie, minor forceps, major forceps, callosal body fi-

bers, and tapetum) were combined to delineate the entire corpus callosum.

Limbic fibers through the fornix were reconstructed by placing one primary ROI and two secondary ROIs. The primary ROI was placed in the body of the fornix, and the secondary ROIs



were placed in the crura of the right and left fornices anterolateral to the splenium of the corpus callosum (Fig 2f).

Evaluation of Tractography

The tractographic depiction of fiber tracts was graded on three-dimensional volume views and in three orthogonal two-dimensional planes by two neuroradiologists (T.O., with 2 years of experience performing tractography; Y.M., with 3 years of experience performing tractography and 19 years of experience as a neuroradiologist). Grading was performed on the basis of the following three criteria: the fiber tract volume, the anatomic distribution of the tract, and the presence or absence of the tract at the expected location. The readers were blinded to the magnetic field strength used (1.5 or 3.0 T). After performing independent interpretations, the two readers resolved any score discrepancies by consensus to establish final scores.

One score was derived from one tractographic examination—not from the pair of ROIs used to perform reconstructing tractography. The scores assigned at fiber tractography were as follows: 4 meant excellent—that is, the depicted fiber tract accurately matched

the known anatomic distribution, and there was a sufficient volume of fibers; 3 meant adequate for diagnosis—that is, imaging errors such as image distortion and tract propagation error were minor, so the image was still adequate for use as a diagnostic tool; 2 meant fair—that is, moderate imaging errors or moderate tract volume loss markedly reduced imaging quality; 1 meant poor—that is, there were major imaging errors and/or tract volume loss, and the readers were unable to interpret the course or shape of the tract; and 0 meant no tract visualization.

At corticospinal tract tractography, anatomically accurately depicted tracts were defined as those passing through the lateral segment of the cerebral peduncle, the posterior limb of the internal capsule, and the precentral gyrus. At superior longitudinal fasciculus tractography, fibers connecting the frontal and parietal lobes (ie, long association fibers) and fibers connecting the frontal and temporal lobes (ie, arcuate fibers) were considered. Anatomically accurate results for the superior longitudinal fasciculus were defined as good visualization of both the long association fibers and the arcuate fibers. At corpus callosum tractography, anatomically ac-

curate results were defined as good visualization of the four different subsegments. At limbic tractography, the depiction of fibers connecting the column, body, and crus of the fornix was considered to represent anatomically accurate results. At tractography, the depicted superior longitudinal fasciculus, corpus callosum, and fornix are each composed of several subsegments of fiber bundles, and all subsegments were integrated to establish a single final score for each tractographic examination. The scoring of tractographic images is illustrated in Figure 3.

Tractographic depictions of the corticospinal tract, superior longitudinal fasciculus, and fornix on the right and left sides were assessed independently. At corpus callosum tractography, the right and left sides were assessed together, because callosal fiber connects the right and left hemispheres.

Reconstructed tract fibers were counted by using the DtiStudio software. The numbers of fibers depicted at tractography of the corticospinal tract and the superior longitudinal fasciculus in the right and left hemispheres were counted separately. The right and left fibers were not counted separately at tractography of the corpus callosum and

the fornix, because right- and left-hemisphere limbic fibers were difficult to differentiate at the column of the fornix, which was visualized as a single fiber bundle.

Although the diffusion characteristics of the normal brain are somewhat asymmetric, corticospinal tract tractography in healthy subjects reportedly reveals minimal asymmetry (17,29). To assess the reliability of corticospinal tract tractography in healthy subjects, lateral asymmetry was evaluated on the basis of the numbers of right- and left-hemisphere fibers at tractography of the corticospinal tract. For this purpose, the “cut” operation was performed by using DtiStudio software. With the cut operation, only the fiber coordinates between the two ROIs are reconstructed (Fig 2b). The conventional two-ROI ap-

proach involves the use of three corticospinal tract regions at tractography: the areas below the cerebral peduncle, between the two ROIs, and above the precentral gyrus. These three regions have very different properties. In the region between the two ROIs, tracking results do not branch and are more robust against noise. This approach is particularly useful for quantitative analysis.

The index of asymmetry (AI) between the right (*R*) and left (*L*) corticospinal tracts in each subject at tractography was calculated as the absolute difference in fiber numbers between the two sides, divided by the mean of the two sides, as modified from a previously described method (14): $AI = |L - R| / [(L + R)/2]$. Lateral asymmetry analysis of superior longitudinal fasciculus tractography was not performed, because

the superior longitudinal fasciculus comprises numerous long and short connecting fibers and lateral asymmetry is commonly observed in healthy subjects (6,29).

Statistical Analyses

Differences between 3.0- and 1.5-T DT imaging were calculated in terms of the following features: (a) depiction scores for right and left corticospinal tract tractography, right and left superior longitudinal fasciculus tractography, corpus callosum tractography, and right and left fornix tractography; (b) numbers of fibers depicted at right and left tractography of the corticospinal tract, right and left tractography of the superior longitudinal fasciculus, corpus callosum tractography, and fornix tractography; and (c) asymmetry index at corticospinal tract tractography. Statistical

Figure 4

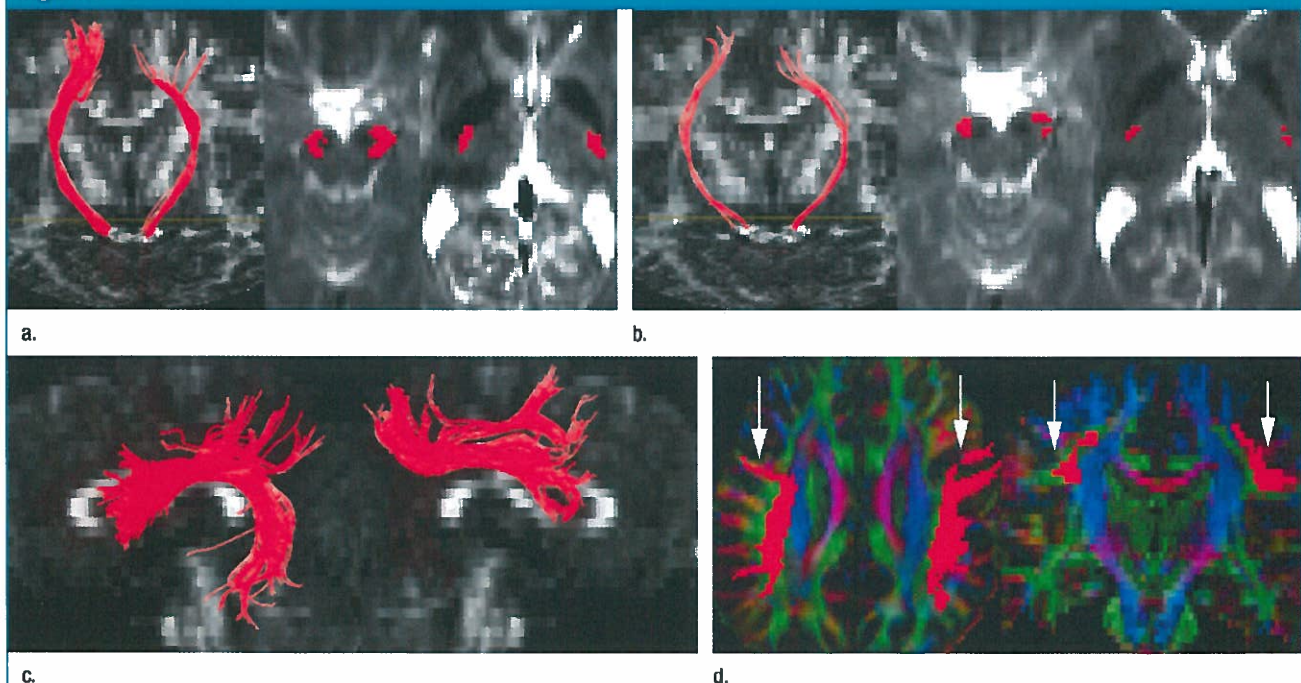


Figure 4: Fiber tractographic results. (a, b) Left: Three-dimensional reconstruction of corticospinal tract (red) in the same subject at (a) 3.0-T and (b) 1.5-T tractography, with use of transverse and coronal fractional anisotropy images. Middle and right: Transverse non-diffusion-weighted images with two-dimensional overlays of tractographic images at the sections of the cerebral peduncles (middle) and internal capsule (right) bilaterally. The voxels where the depicted corticospinal tract penetrates the transverse planes are shaded red. At 1.5-T corticospinal tract tractography (b), although the proper anatomic distribution is depicted, the tract volume is lower than that at 3.0 T. (c) Three-dimensional reconstruction of superior longitudinal fasciculus (red) on sagittal fractional anisotropy map at 3.0-T tractography in a different subject. At tractography in this subject, the shapes and distributions of the right and left superior longitudinal fasciculi differed. Although tractography of the left superior longitudinal fasciculus depicted arcuate fibers toward the temporal lobe, tractography of the right superior longitudinal fasciculus depicted no arcuate fibers. The cortico-cortical long connection fibers between the frontal and parietal lobes, however, were thicker on the right side than on the left side. (d) Tractographic image of superior longitudinal fasciculus (red, arrows) overlaid on 3.0-T transverse (left) and coronal (right) color-coded maps obtained in the subject described in c (Fig 4 continues).

analysis was based on the consensus scores for each tract in each subject derived by the two neuroradiologists. The Wilcoxon signed rank test was applied by using JMP, version 5.1, software (SAS Institute, Cary, NC). For all statistical analyses, $P < .05$ was considered to be indicative of a significant difference.

Results

Fiber Tract Visualization

DT imaging at both 3.0 and 1.5 T was successfully performed in all 30 subjects. The corticospinal tract was visualized at 3.0 and 1.5 T (Fig 4a, 4b) in all subjects. At superior longitudinal fasciculus tractography, long association fibers were visualized in all subjects at 3.0 and 1.5 T. Right arcuate fibers were visualized in 22 subjects (73%) at 3.0 T

and in 20 subjects (67%) at 1.5 T, whereas left arcuate fibers were identified in 29 subjects (97%) at 3.0 and 1.5 T (Fig 4c, 4d).

All four subsegments of the corpus callosum were successfully visualized at 3.0 and 1.5 T (Fig 4e) in every subject. The body and column of the fornix were visualized at 3.0 and 1.5 T in every subject. The right crus of the fornix was visualized in 21 subjects (70%) at 3.0 T and in 18 subjects (60%) at 1.5 T. The left crus of the fornix was visualized in 27 subjects (90%) at 3.0 T and in 25 subjects (83%) at 1.5 T (Fig 4f). One subject was incidentally found to have cavum septum pellucidum and cavum vergae. The right and left columns of the fornix were visualized separately in this subject (Fig 4g).

All tractographic results were included in the analysis of tract depiction scores and numbers of depicted tract

fibers. All tractographic results for the corticospinal tract were included for asymmetry analysis. With regard to the 420 depiction scores (30 subjects times seven tracts times two readers), there were discrepancies between the two independent readers regarding 152 scores (36%). The two readers discussed the discrepancy and established a final consensus score in each case. The depicted fiber tracts and the depiction scores are listed in Table 1.

Statistical Analyses

For tractography of the corticospinal tract, both right- and left-hemisphere depiction scores ($P < .001$) and numbers of tract fibers (right, $P = .008$; left, $P < .001$) were significantly higher at 3.0 T than at 1.5 T. The asymmetry index at corticospinal tract tractography was significantly lower at 3 T ($P < .001$). For tractography of the right su-

Figure 4

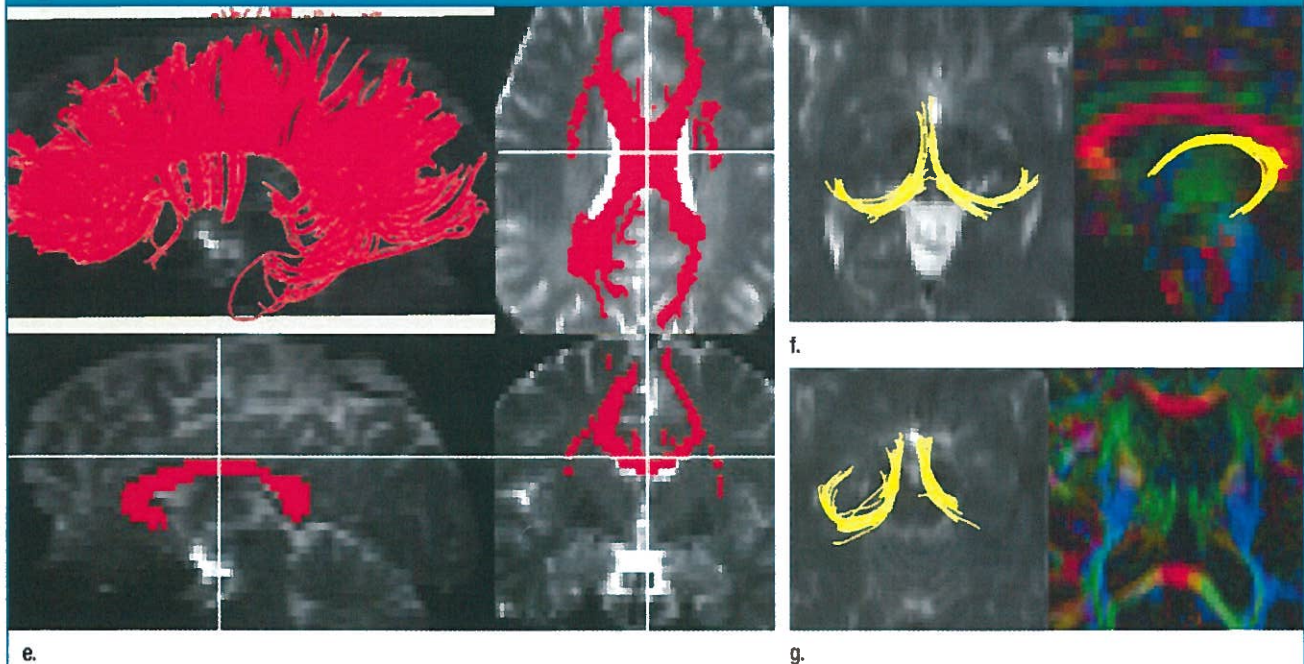


Figure 4 (continued): (e) Three-dimensional 3.0-T tractographic reconstruction of corpus callosum (red) on sagittal non-diffusion-weighted image (5200/79) (top left) and on overlay in three orthogonal planes (top right, bottom left, and bottom right). Various kinds of transcallosal connection fibers are depicted. The center indicated by the intersecting of the vertical and horizontal lines on the three orthogonal images (top right, bottom left, and bottom right) indicate the same location. (f) Three-dimensional 3.0-T tractographic reconstruction of fornix (yellow) on transverse non-diffusion-weighted image (5200/79) (left) and sagittal color-coded map viewed from left (right). (g) Three-dimensional 3.0-T tractographic reconstruction of fornix (yellow) on transverse non-diffusion-weighted image (5200/79) (left) and transverse color-coded map (right) obtained in a subject with cavum septum pellucidum and cavum vergae. The bodies and columns of the fornices on the right and left sides were visualized separately.

perior longitudinal fasciculus, depiction scores ($P = .005$) and numbers of tract fibers ($P = .001$) were significantly higher at 3.0 T than at 1.5 T. Depiction scores for tractography of the left superior longitudinal fasciculus did not differ significantly between 3.0- and 1.5-T DT

imaging. For tractography of the left superior longitudinal fasciculus, the numbers of tract fibers were significantly higher at 3.0 T than at 1.5 T ($P = .02$). For corpus callosum tractography, depiction scores were significantly higher at 3.0 T than at 1.5 T ($P = .01$), al-

though the numbers of tract fibers did not differ significantly. Scores for depiction of the right fornix ($P = .04$) and numbers of fornix tract fibers bilaterally ($P = .02$) were significantly higher at 3.0 T than at 1.5 T, although scores for depiction of the left fornix were not significantly different. These results are summarized in Table 2.

Table 1

Depiction Scores Assigned at Fiber Tractography

Tract and Score	3.0-T Tractography	1.5-T Tractography
Right corticospinal tract		
0	0	0
1	0	2
2	1	8
3	6	13
4	23	7
Left corticospinal tract		
0	0	0
1	0	6
2	1	9
3	6	10
4	23	5
Right superior longitudinal fasciculus		
0	0	0
1	1	3
2	10	11
3	6	9
4	13	7
Left superior longitudinal fasciculus		
0	0	0
1	1	0
2	3	3
3	14	17
4	12	10
Corpus callosum		
0	0	0
1	0	0
2	2	6
3	9	14
4	19	10
Right fornix		
0	0	0
1	10	11
2	8	16
3	11	3
4	1	0
Left fornix		
0	0	0
1	3	4
2	14	17
3	12	9
4	1	0

Note.—Data are numbers of subjects with the given depiction score. Scores were determined in consensus between two readers.

Discussion

In recent studies, investigators have reported on intraindividual comparisons between 3.0- and 1.5-T DT imaging performed for functional MR imaging based on blood oxygen level-dependent contrast (30), intracranial time-of-flight MR angiography (31), supraortic contrast material-enhanced MR angiography (32), and high-spatial-resolution inner ear imaging (33). These studies revealed the clinical feasibility of and the better visualization that is achievable at 3.0-T imaging compared with these features at 1.5-T imaging. DT imaging also reportedly yields a higher signal-to-noise ratio at 3.0 T, suggesting the possibility that it renders higher spatial resolution without enhanced noise-related errors (22,34).

Parallel imaging techniques involve the use of multiple receiver coil elements for spatial information encoding and gradient encoding and, owing to shortened echo train lengths, have been shown to markedly reduce the number of echo-planar imaging-related artifacts. The potential of parallel imaging for DT imaging has been demonstrated at both 1.5 and 3.0 T (21,22). Naganawa et al (23) challenged the optimization of 3.0-T DT fiber tractography performed with parallel imaging and found that DT imaging data on brain fiber tracking in healthy subjects can be acquired within a very short imaging time (<2 minutes). Nagae-Poetscher et al (24) performed high-spatial-resolution DT imaging of the brainstem at 3.0 T with parallel imaging and visualized various brainstem structures, including deep cerebellar nuclei, some cranial nerves, and white matter tracts.

To our knowledge, our study is the first in which the findings of 3.0- and

1.5-T DT fiber tractography, both performed with parallel imaging, were compared in a relatively large number of subjects. Improved image quality was observed at 3.0-T tractography of the corticospinal tract.

More complex results were observed at tractography of the superior longitudinal fasciculus. Although the right superior longitudinal fasciculus was visualized significantly better at 3.0 T, the depiction score for left superior longitudinal fasciculus tractography did not differ significantly between 3.0 and 1.5 T. The numbers of tract fibers depicted at 3.0 T were significantly higher than the numbers of fibers depicted at 1.0 T. We speculated that the reason for this was as follows: According to fiber dissection study findings, the corticospinal tract is a long projection fiber bundle with a well-established anatomic distribution (35). Most fibers in the corticospinal tract run parallel through the posterior limb of the internal capsule, without sharp turning angles or directional diversity.

Conversely, both the superior longitudinal fasciculus and the corpus callosum consist of groups of fiber bundles that comprise association or commissural fibers of varying lengths and directions. The superior longitudinal fasciculus contains arcuate fibers that turn sharply toward the temporal lobe. This sharp turning angle may surpass the tracking terminate threshold, and tracking does not extend to reach the temporal lobe. Temporal fibers are susceptible to image distortion at the middle cranial fossa and temporal bone, where the air-tissue interface induces magnet susceptibility artifacts. Thus, we propose that temporal arcuate fibers are more affected by image distortion than are long association fibers. In the present study, left arcuate fibers were visualized in a larger number of subjects than were right arcuate fibers at both 3.0 and 1.5 T. Such asymmetry of the arcuate fibers at tractography may be due to image distortion or the known lateral asymmetry of temporal fibers (36), and, thus, differences between 3.0- and 1.5-T DT imaging may be underestimated on the left side.

Table 2

Analyses of Tract Depiction Scores and Numbers of Tract Fibers

Tract	Difference in Depiction Score*		Difference in No. of Tract Fibers*	
	Score*	P Value [†]	Fibers*	P Value [‡]
Right corticospinal tract [§]	0.87 ± 0.15	<.001	27 ± 12	.008
Left corticospinal tract	1.32 ± 0.21	<.001	70 ± 9.2	<.001
Right superior longitudinal fasciculus	0.52 ± 0.16	.005	192 ± 57	.001
Left superior longitudinal fasciculus	0.03 ± 0.14	NS	65 ± 34	.02
Corpus callosum	0.34 ± 0.12	.01	220 ± 149	NS
Right fornix	0.35 ± 0.16	.04
Left fornix	0.19 ± 0.15	NS
Left and right fornices	14 ± 5.5	.02

Note.—NS = not significant.

* Data are mean difference values ± standard deviations.

[†] P values for difference in depiction scores at 1.5- versus 3.0-T tractography.

[‡] P values for difference in numbers of tract fibers at 1.5- versus 3.0-T tractography.

[§] The mean asymmetry index for the corticospinal tract was 0.47 ± 0.11 (standard deviation), and the difference in corticospinal tract asymmetry index at 1.5- versus 3.0-T tractography was significant ($P < .001$).

For corpus callosum tractography, tract depiction scores were better at 3.0 T than at 1.5 T but the numbers of tract fibers did not differ significantly. At corpus callosum tractography, the crossing-fiber problem of unidirectional tracking models (37) may contribute to the discrepancies observed between depiction scores and tract fiber numbers. Corpus callosum tractography is susceptible to the crossing-fiber problem at the centrum semiovale. In this area, a small number of callosal fibers intersect a large number of corticospinal tract fibers. Thus, corpus callosum tractography might reveal a smaller number of fibers than the appropriate fiber trajectory owing to limitations related to the crossing-fiber problem, and differences between 3.0- and 1.5-T imaging may be underestimated.

The statistical methods used may have been responsible for the differences in results obtained at analyses of the depiction scores and the numbers of tract fibers. Although mean differences in the numbers of depicted fibers between 3.0- and 1.5-T imaging were as large as 220, no significant difference was noted. This was probably because of the relatively large numbers of depicted fibers (mean numbers: 3784 at 3.0 T and 3565 at 1.5 T). Low statistical power also may have contributed to this lack of a significant difference.

Depiction scores for right fornix tractography were significantly better at 3.0 T than at 1.5 T, but no significant differences were noted for the left fornix. The numbers of tract fibers depicted at 3.0-T fornix tractography were significantly higher than the numbers depicted at 1.5-T tractography. This result was probably due to the relatively lower volume of limbic fibers compared with the volumes of other fiber bundles. Our DT imaging voxel size was 1.7 × 1.7 × 3.0 mm. The body and crus of the fornix are composed of narrow fiber bundles—they are smaller in diameter than a single voxel—so partial volume-averaging artifacts would have had a greater effect in this region than in the other fiber tracts.

The present study had some limitations. First, the imaging parameters for 3.0-T imaging were not optimized to achieve the best DT image quality. For the most part, we used identical imaging parameters to perform 3.0- and 1.5-T imaging for comparisons so that features other than magnetic field strength would be equivalent. However, differences in T1 and T2* interfere with the equal conditions between 3.0- and 1.5-T imaging. A DT imaging sequence optimized for 1.5-T imaging is not the optimal sequence for 3.0-T imaging. The differences in bandwidth between 3.0- and 1.5-T imaging also may have biased

our results. We tried to keep other acquisition parameters equivalent between 3.0- and 1.5-T imaging, but the bandwidth was higher at 3.0 T. Higher bandwidth results in a reduced signal-to-noise ratio and reduced image distortion. DT imaging at 3.0 T yields a higher signal-to-noise ratio and causes greater magnet susceptibility artifacts owing to the higher static magnetic field strength. We adjusted parameters so that we could use a bandwidth of 1502 Hz per pixel for 3.0-T imaging, which is up to 50% higher than the bandwidth used for 1.5-T imaging. Further optimization of 3.0-T imaging to improve the quality of DT images may be required in the future.

Second, the development of imaging methods to reduce the effects of the crossing-fiber problem, such as high angular DT imaging with high *b* values (38) and diffusion-spectrum imaging (36), is progressing. Other fiber-tracking methods, such as probabilistic tractography to estimate the probability of fiber connections through the data field (39), also are advancing. These advanced methods will affect the results of both 3.0-T and 1.5-T tractography.

In conclusion, DT tractography at 3.0 T enables improved visualization of the corticospinal tract compared with DT tractography at 1.5 T, and 3.0-T tractography of the superior longitudinal fasciculus, corpus callosum, and fornix has some advantages over 1.5-T tractography. Advances in efficient MR sequences are needed to improve the image quality and reliability of 3.0-T DT tractography.

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Functional MR Imaging at 3.0 T versus 1.5 T: A Practical Review

Henning U. Voss, PhD^{a,*}, Jason D. Zevin, PhD^b,
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|--|--|
| <ul style="list-style-type: none"> ■ Signal-to-noise and contrast-to-noise ratio
<i>Signal-to-noise ratio</i>
<i>Contrast-to-noise ratio</i> ■ Field tests: direct comparisons of 1.5 T and higher fields for functional imaging
<i>Greater extent and strength of activation</i>
<i>Success stories of high-field MR imaging</i> ■ Potential gains and tradeoffs of high-field imaging | <ul style="list-style-type: none"> <i>Susceptibility artifacts</i>
<i>Imaging time</i>
<i>Acoustic noise</i>
<i>Specific absorption ratio</i>
<i>Statistical analysis and modeling</i> ■ Clinical functional imaging ■ Summary and discussion ■ References |
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Since 1999, when 3.0 T MR imaging scanners were approved by the US Food and Drug Administration (FDA) for imaging studies of humans, the numbers of available devices has been rising steadily [1]. The main interest in higher magnetic fields stems from the fact that signal-to-noise ratio (SNR) increases with the field strength, allowing greater sensitivity to contrasts of interest, including functional blood oxygen level dependent (BOLD) contrasts, and higher spatial resolution. Although the availability of higher field scanners has driven new progress in functional neuroimaging, most studies are still performed on more widely available 1.5 T machines. A PubMed search in June 2005 revealed a ratio of 180 to 970 functional MR imaging studies conducted on 3.0 T and 1.5 T, respectively. This article reviews recent comparisons of research and clinical functional imaging for 1.5 T and 3.0 T, emphasizing advantages and disadvantages

of the two field strengths. The article also details technical issues associated with the field strength, including how theoretically anticipated improvements associated with high field strength can be offset by practical considerations.

The main physical reason for going to higher field strength in anatomical MR imaging is the increased SNR, which can be beneficial in itself or traded against decreased imaging time or voxel size. As more experience is gained in functional MR imaging at 3.0 T and higher, however, it turns out that there are also rather complex physiological dependencies that are much less obvious and cannot be assessed easily by physical laws. The dynamic contrast-to-noise ratio (CNR) of the BOLD effect, which is from a statistical point of view more important than SNR in functional magnetic resonance imaging (fMRI) experiments, may depend on the part of the brain imaged, the functional paradigm,

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the local tissue microstructure, the local magnetic field distortions, the local and surrounding blood vessel distribution, scanner noise, chemical shifts, and other influences that each have the potential to interact with field strength. In surveying the literature of direct comparisons of 1.5 T with 3.0 T and higher fields, the authors found that it is virtually impossible to clearly separate out the effects of field strength alone. The fact that scanner hardware and pulse sequences have improved over time and that 3.0 T scanners have on average more advanced hardware than 1.5 T scanners contribute to the complexity of this topic. Yet, from many carefully conducted fMRI experiments, there are an increasing number of experimental findings that can be attributed mainly to effects of field strength.

The purpose of this article is to review some of the main results and, rather than provide definite answers, to give the neuroscientist a feel for how functional MRI depends on magnetic field strength. It concentrates on 1.5 T and 3.0 T fields, but also includes some important results obtained on 4.0 T magnets. Since MRI techniques, as well as FDA and International Electrotechnical Commission (IEC) standards, differ profoundly for higher fields, fields larger than 4.0 T are not covered. Before reviewing some field studies, the authors describe the concepts of SNR and CNR with focus on BOLD-dependent fMRI. Then, potential gains and trade-offs of imaging at high fields are discussed, and, finally, the emerging application of clinical functional imaging is reviewed.

Signal-to-noise and contrast-to-noise ratio

Greater SNR and CNR are the main motivations for scanning at higher field strengths. Whereas SNR is only slightly tissue-dependent, CNR depends on the tissue properties and is the more important quantity with respect to detecting functional activations in the brain. For these reasons, each quantity is described separately.

Signal-to-noise ratio

The SNR typically is used to compare imaging hardware and data acquisition methods. Roughly, it is defined as the mean signal divided by the standard deviation of the noise. Sometimes correction factors are used to account for the fact that the noise distribution is non-Gaussian. Signal and noise usually are measured by comparing signal from different regions of interest, for example mean tissue signal versus the standard deviation of the background signal in areas that are not affected by ghosting. Another way to measure SNR is to acquire two consecutive images and subtract the intensities afterwards. The SNR then can be

computed from a single region of interest and applied to one of the images and the difference image. An overview about the different ways to measure SNR is given by McRobbie and colleagues [2].

The noise components are background noise, generated by the scanner, coil noise, motion-related noise, physiologic noise, partial volume effects, flow artifacts, and physical errors caused, for example, by a nonequilibrium average spin state at the beginning of an fMRI sequence. Central to fMRI, however, is the SNR of the time series data of single voxels and the stability of the signal over time.

fMRI is more susceptible to noise than many other neuroscience methodologies, because the random variation of the BOLD activation can reach or exceed the level of the signal even in a blocked design [3]. In high-field MR imaging, the physical equipment and coil noise become less important relative to physiological noise, the latter one depending on signal strength itself. Furthermore, in fMRI one is interested in the BOLD signal and contrast, which are not accessible by phantom studies. Therefore, many phantom studies provide only limited information about fMRI relevant noise [3]. Parrish and colleagues [4] provide a recipe to compute the necessary minimum SNR to detect functional activations in dependence of given relative signal change, significance (t value or correlation coefficient), and power of the test. As an example, for a typical blocked design paradigm with 5% error probability and 95% detection rate or power, and expected 2% BOLD signal change, the required minimum SNR is about 34.

The dependence of SNR on magnetic field strength has two physical contributions, the signal from the receiver coil and the signal from the nuclear spin system. When only noise generated by the coil is considered, the dependence on the field strength B_0 is $\text{SNR} \sim B_0^{7/4}$ [5,6]. This contribution is not dominant in high-field imaging, however, because the patient resistance is much greater than the coil resistance. In high fields, the following consideration dominates the coil noise contribution. The signal intensity is both proportional to the number of excited spins and the voltage induced by each spin. For imaging at body temperature, both the number of excited spins and the induced voltage are proportional to the magnetic field. This results in a quadratic signal intensity dependency on the magnetic field. When all noise comes from a phantom sample, noise is proportional to the magnetic field. From this it follows that a doubling of field strength causes a doubling of SNR [7,8].

On the other hand, BOLD-fMRI is based on susceptibility effects of deoxygenized hemoglobin, which are also more prominent in higher fields

and may cause a larger expected signal change [9]. Taking this into account, one would expect an even more increased SNR if the relaxation times T_1 , T_2 , and T_2^* are assumed to be constant.

In practice, however, the relaxation times change. T_1 increases, and T_2 and T_2^* decrease with field strength. For example, T_1 increases with field strength about 30% for 3.0 T versus 1.5 T, and for spin echo experiments, the relaxation rate $1/T_2$ depends in a quadratic way on the field strength [10]. Krüger and colleagues [11] gave a recent overview about these dependencies and performed a thorough quantitative comparison between 1.5 T and 3.0 T fMRI of the brain. For this kind of quantitative comparison, it is important that echo time (TE) is adjusted to the corresponding T_2^* values in gray matter at 1.5 T and 3.0 T, or, if other values are preferable to maximize the signal, that the ratios of TE to T_2^* for both field strengths are kept equal. Also, the Ernst angle is affected, and thus the optimal flip angle should be scaled accordingly [11–14]. Typical values in cortical gray matter are [11] $T_2^* = 65$ milliseconds and 49 milliseconds for 1.5 T and 3.0 T, respectively, suggesting imaging parameters of TE = 40 milliseconds and 30 milliseconds, and $\alpha = 67^\circ$ and 64° , respectively. For BOLD imaging, one should adjust the imaging parameters to the values for gray matter only. Fera and colleagues [15] present a thorough study in which TE was varied over a broad range in functional imaging experiments, confirming a decreased optimum TE at 3.0 T.

Contrast-to-noise ratio

In functional MR imaging, CNR usually refers to time series properties of voxel intensities rather than to the comparison of intensity in different regions of interest as in anatomical MR imaging. To make a clear distinction, it is sometimes called functional or dynamical CNR, or even functional SNR. An overview about functional CNR, including the design of studies to optimize it, is given by Huettel and colleagues [16]. Because there are few comparative studies of functional imaging using cerebral blood flow changes or diffusion, this article only focuses on the most widely used BOLD effect. The BOLD contrast relies on the interplay between cerebral blood flow, cerebral metabolic rate of oxygen, and blood volume, among other parameters [9,17–22].

A useful quantity is the maximal functional CNR for fully relaxed BOLD imaging [8], $\Delta S/N$. It can be computed from measurements of the apparent transverse relaxation rates of the baseline and the activated states. The BOLD contrast $\Delta S/N$ depends on the strength of the main magnetic field. This is because the bulk magnetic susceptibility difference

between blood containing paramagnetic deoxyhemoglobin and surrounding diamagnetic tissue increases with the main magnetic field strength, creating larger MR signal changes between baseline and activated states. There are many physiological factors that may influence the functional CNR, and the optimal field strength for performing fMRI experiments has been a matter of some debate [23,24].

Numerous studies have reported a higher CNR in fMRI studies performed at higher field strengths [11,15,25–27]. For example, in optimized gradient echo imaging experiments at 0.5 T, 1.5 T, and 4.0 T, Gati and colleagues [8] found that on the one hand the SNR increased linearly with field strength, whereas there was a complex relationship of functional CNR with tissue structure [17]. The maximally calculated BOLD contrast increased less than linearly in voxels containing vessels larger than the voxel itself and greater than linearly in voxels containing a mixture of capillaries and draining veins or venules with a diameter less than that of the voxel. The latter is the more relevant contrast for fMRI, given the desirability of tissue BOLD response for an accurate localization of brain function. Similarly, Ugurbil and colleagues [28,29] found, by comparing human brain scans at 1.5 T and 4.0 T, that the higher field provides increased contribution from the venules and the capillaries, which again favors fMRI at higher fields. This result is also in agreement with early studies from Menon and colleagues [30] at 4.0 T.

Krüger and colleagues [11] also found a tissue dependence of the gain in CNR, again for the benefit of functional imaging. CNR in venous vessels increased sublinearly with field strength, but CNR in activated areas increased 2.2-fold, again outperforming the theoretical results obtained under pure physical considerations. Looking alone at functional CNR and extrapolating these results, one could conclude that for the highest spatial or temporal resolution, one should operate at the highest available magnetic field strength. In one of the earliest of these studies by Turner and colleagues [25], it was found that in and primary visual cortex, image contrast over time was 7% at 1.5 T and 28% at 4.0 T during photic stimulation. It was concluded that this superproportional increase is because of an increased importance of susceptibility differences between deoxygenated and oxygenated blood. This result was later questioned by Krüger and colleagues [11] who related it partly to using coils with different spatial sensitivities. This points toward a general difficulty in direct comparisons of CNR and SNR. There are few studies where all imaging and technical parameters besides the field strength are kept constant. Nevertheless, it is worth

examining direct comparisons of functional activations at different field strength, which is covered in the next section.

Field tests: direct comparisons of 1.5 T and higher fields for functional imaging

Numerous groups have studied the relative benefits of functional imaging at different field strengths by directly comparing the results from typical experiments on two different MR systems. These studies provide the most straightforward data regarding the relative benefits of different field strengths for functional neuroimaging, and suggest real advantages for higher field strengths in terms of the extent and strength of activation observed, and the spatial resolution that can be achieved.

Greater extent and strength of activation

Two measures of the relative sensitivity of a functional mapping experiment are the voxel-wise significance of activation and mean cluster size of activated voxels during tasks that engage specific brain regions. In such experiments, activity throughout the brain specifically associated with stimulation in a particular sensory modality (eg, seeing patterns or listening to sounds) or engaging in a particular motor or cognitive task (eg, finger tapping or rehearsing strings of digits) is determined by inferential statistical tests. When the site of neural activity is established by existing research (eg, activity in primary motor cortex should be related to finger tapping), the strength and extent of activation reflect the sensitivity of the instrument to this neural activity.

If greater SNR at higher fields is traded for greater spatial resolution, it seems odd to state that a larger extent of activation is indicative of greater sensitivity. However, one also must consider the influence of local autocorrelation. Activity observed in fMRI tends to reflect responses in relatively large regions, and there is a tendency for adjacent neurons to have correlated firing patterns. Thus, to some degree, extent and strength of activation as measured by the value of inferential tests necessarily are related. A more sensitive instrument will give higher values for a statistical test for the same real correlation. Thus, peak activations will have higher values, but lower levels of activity in surrounding tissue that may be subthreshold at one field strength will cross statistical thresholds at higher field strength.

The results of direct comparisons at different field strengths generally have shown increased sensitivity at higher field strengths. For example, in a simple finger tapping task, Yang and colleagues [26] found that average cluster size of activated voxels was

70% larger, and average t score was 20% greater in a 4.0 T experiment as compared with 1.5 T experiment. Fera and colleagues [15] found, again in a finger tapping task, that the number of pixels and t score values were 59% and 18% higher, respectively, at 3.0 T than at 1.5 T, an improvement that was much lower than the observed 100% to 110% increase in SNR at 3.0 T. What makes this study unique is that the authors varied TE over a broad range. They also varied the receiver bandwidth and found that it affected the BOLD sensitivity only marginally. This result is interesting, because the receiver bandwidth directly determines the expected image SNR.

The main advantage of the finger tapping task is the reliability and strength of activity in motor cortex associated with finger movements. In the Yang and colleagues study, extent and strength of activation were determined by examining the BOLD response within a predefined anatomical region. Most cognitive neuroscience research involves less neatly circumscribed anatomical regions, however, and a more relevant measure of sensitivity is the extent and strength of typical activations in whole-brain analyses.

To this end, Krüger and colleagues [11] examined responses to a simple visual stimulation paradigm and a timed finger tapping task using whole-brain analysis techniques more typical of cognitive neuroscience research. They found an increase in the number of activated voxels between comparable 1.5 T and 3.0 T systems of 36 to 44% in the primary motor and visual cortices, respectively. More specifically, they discovered that the gain in functional SNR depends on whether the images are acquired in a fully relaxed way or, as more realistic for functional imaging, with a shorter repetition time (TR). Between 1.5 T and 3.0 T the average gain in the brain was only 1.7 in the fully relaxed condition but 2.2 in images with a realistic TR of 1.5 seconds. They explain this finding with the fact that the physiological noise depends on signal strength and becomes a larger fraction of the total noise at 3.0 T. The ratio of physiological noise against thermal plus systematic noise is about 0.67 in 1.5 T and 1.14 in 3.0 T. To deal with this, the signal strength and the fraction of physiological noise on the total image noise can be manipulated by varying the flip angle. Generally, T1 increases in higher fields, and saturation effects in functional sequences counteract the gain in SNR for sequences with TR much smaller than T1.

Krasnow and colleagues [31] used a suite of tasks involving visual processing, working memory, and emotional processing. In the visual task, which consisted of flashing checkerboards, they found an increase in the number of active voxels in striate

and extrastriate regions of visual cortex. Okada and colleagues [32] showed similar results in an anatomically defined region of interest in calcarine sulcus. As these regions are known from numerous neuroimaging and neurophysiological studies to be engaged by a wide range of visual stimuli, the increased extent of activation at higher field strength is taken to be evidence of a more accurate representation of functional activity. In the working memory task, greater extent and higher Z scores were observed throughout a broad network of regions known from previous neuroimaging research to play a role in working memory, including frontal, parietal, and cerebellar cortices. Results for the emotion processing task did not differ between the two field strengths.

Hoenig and colleagues [27] compared activity in a series of tasks typical of cognitive neuroscience research at 1.5 T and 3.0 T. They focused on the motor decision component of three disparate tasks: lexical decision, semantic decision, and letter identification. Their tasks were designed so that half of all responses would be made with the left and right hands. Common areas of activation across tasks requiring a motor decision (relative to a verbal fluency baseline) and between field strengths were SFG and M1. They found that the overall mean cluster size in motor decision paradigms was 60% to 80% higher, and t scores for peak activations were 30% higher at 3.0 T [11]. Some novel regions of activity also were observed at higher field strength.

There are few studies directly addressing the payoff of sensitivity and specificity, for example by looking at receiver operating characteristic (ROC) curves. In a preliminary multi-institutional study of the reproducibility of fMRI, Zou and colleagues [33] found that field strengths of both 3.0 T and 4.0 T were better than 1.5 T, yielding more activation and less variability in terms of sensitivity and specificity. Sensitivity was defined as the true activation fraction of activated voxels, whereas specificity was defined as the true nonactivation fraction of nonactivated voxels. For example, at 3.0 T, the mean sensitivity per subject ranged 0.58 to 0.76, while the mean specificity ranged 0.99 to 1.00. At 1.5 T, however, the mean sensitivity only ranged from 0.42 to 0.69, while the mean specificity ranged from 0.95 to 1.00. In other words, at 1.5 T, one not only detects less activation, but the activation that is detected is less reliable. These differences may look small, but for hypothesis testing and in view of type I errors, a specificity of 0.95 is much worse than a specificity of 0.99. The ROC curves demonstrated moderate to high classification accuracy, which was generally higher at 3.0 T and 4.0 T than at 1.5 T.

A discussion of statistical aspects would be incomplete without mentioning experiments concerning the reproducibility of activations. In a comparative study of visual activations, Miki and colleagues [34] found that activation of the visual cortex was observed in all subjects, and activation of lateral geniculate nucleus also was detected in four of the five subjects. The ratio of overlapping activated voxels in the first and second acquisition was 0.81. The authors concluded that reproducibility of visual activation using fMRI at 4.0 T is acceptable, and the results from 4.0 T scanners show reliability similar to those at 1.5 T. A similar reproducibility study, using a finger opposition task, has been performed by Tegeler and colleagues [35].

Success stories of high-field MR imaging

Thus far studies have been considered in which high field strength enhanced the ability to observe activity readily observable at lower field strengths. A main consequence of an increased SNR and CNR at higher fields is that the image resolution can also be increased. SNR of a single voxel is proportional to its volume; thus, a doubled SNR means that the voxel volume can be half as large without losing sensitivity. The partial volume effect, meaning that the signal in a voxel constitutes a mixture of signals from different tissue types, like gray and white matter or different cortical columns, is decreasing accordingly.

The increased sensitivity, and particularly the spatial resolution available with higher field strengths, enables researchers to observe novel phenomena [22]. For example, in their battery of motor decision tasks, Hoenig and colleagues [27] found several areas activated only in 3.0 T but not in 1.5 T. Specifically, activity in supplementary motor area (SMA), which seems to play a role in motor-related decision making was found only at higher field strength. In addition to its greater sensitivity, the higher spatial resolution possible at high fields opens up the possibility of observing functional activity at the level of hyper-columns or potentially single columns of neurons, providing the possibility of observing activity of functional units on a scale more compatible with how the brain is thought to be organized.

Maldjian and colleagues [36] could identify the sensory somatotopic organization of individual digits using sensory stimulated fMRI at 4.0 T. They took advantage of the increased SNR at 4.0 T; previous attempts to recover the well-known fact of a somatosensory organization at 1.5 T showed only limited success.

Numerous groups have reported functional imaging of human ocular dominance columns at 4.0 T

[37,38]. Cheng and colleagues [37] used a combination of a 4.0 T scanner and small surface coil to obtain very high (less than 0.5 mm) resolution, and they were able to resolve the differential responses to left or right eye stimulation in the V1 area, which agreed with postmortem cytochrome oxidase studies.

These seminal papers were the first to show the feasibility of fMRI at the cortical columnar resolution, and it seems that this is only possible at high fields. Liu and colleagues [39] were able to identify patches of V1 preferentially sensitive to one or the other eye on 1.5 T, albeit on a much lower resolution than what would be necessary for resolving cortical columns. The high spatial resolution available at higher fields also has enabled investigation of the lateral geniculate nucleus, in thalamus, from its topographic organization [40] to its specific response properties and modulation by attention [41,42]. Further accomplishments of fMRI at higher fields, like single-trial fMRI, which avoids averaging of signals with its associated information loss, are given by Ugurbil and colleagues [22].

The studies reviewed here lead to a strong conclusion. Both the number of activated voxels and the sensitivity increase consistently with the field strength, and hard-to-detect functional parcellations of the cortex can be detected more easily in higher fields. The following section explores the physical and technical considerations that pose limits on the relative benefit of higher-field scanning, and considers some new techniques that may allow practitioners to take fuller advantage of the potential gains.

Potential gains and tradeoffs of high-field imaging

There are further aspects that should be considered when comparing fMRI at different field strengths. Some of them like imaging time can be traded against each other or against SNR, whereas others like acoustic noise, cannot.

Susceptibility artifacts

Susceptibility artifacts result from abrupt changes in magnetic susceptibility that occur across tissue–air and tissue–bone interfaces, for example the air-filled sinuses and the brain parenchyma [43]. These artifacts give rise to geometric and intensity distortions, and intravoxel signal dephasing, and therefore, signal dropout. In higher fields, the effected brain regions spread out and suffer from stronger intravoxel dephasing or even a total signal loss, in particular for long TE [11]. Signal dropout is more serious for gradient echo planar

imaging (EPI), as used for fMRI, than for spin echo EPI.

There is one study so far that compares the extent of these artifacts in a region of strong signal dropout onto fMRI sensitivity at 1.5 T and 3.0 T [31], concentrating on the amygdala. It was found that susceptibility induced signal dropout was slightly larger at 3.0 T (12%) versus 1.5 T (9%).

There are different methods to overcome high-field intravoxel decoherence in EPI imaging. Some require new pulse sequences or come at the cost of increased scan time, like z shimming [44–47], spiral sequences [48], and radiofrequency (RF) pulse excitation with nonlinear phase responses [49–52]. Others are based on simply optimizing prescription parameters. Sorensen [53] reports very good results by simply decreasing the slice thickness to decrease the voxel size. Chen and colleagues [3] optimize signal by using optimal voxel sizes and slice orientations for 1.5 T and 3.0 T. Slice orientation can be optimized by first measuring the dominant susceptibility field gradient in the region of interest (eg, the amygdala) and then by choosing the frequency encoding direction parallel to the field gradient measured from each subject.

Spiral-in/out data acquisitions [48] showed superior performance with respect to signal dropout in a recent comparison for 1.5 T and 3.0 T imaging [54]. The spiral-in/out sequence acquires one image before the echo time and a second image after the echo time. Weighted averaging of the two images then provides a time series with reduced susceptibility dropout in frontal and medial temporal regions and increased SNR in regions of uniform cortex. Another way to reduce these artifacts is multi-shot EPI. As was found by Menon and colleagues [55], multi-shot EPI improves BOLD fMRI at high magnetic field strengths.

Geometric distortions can be reduced by multi-shot EPI, by field map approaches [56–59], or by reversed gradient methods [60–65] for signal acquisition. In the reversed gradient method, phase encoding gradients are applied twice, at the second time with reversed polarity. In functional imaging, by alternating gradients in each repetition, this can be accomplished without elongating the sampling interval. Fig. 1 demonstrates the latter approach.

The performance of many of the methods, however, depend on the specific region of the brain to which they were optimized, and the full potential of these methods for fMRI in the whole brain has not been explored and represents an active field of research [67].

Imaging time

One theoretical advantage of higher field strength is that acquisition times can be shorter in 3.0 T com-

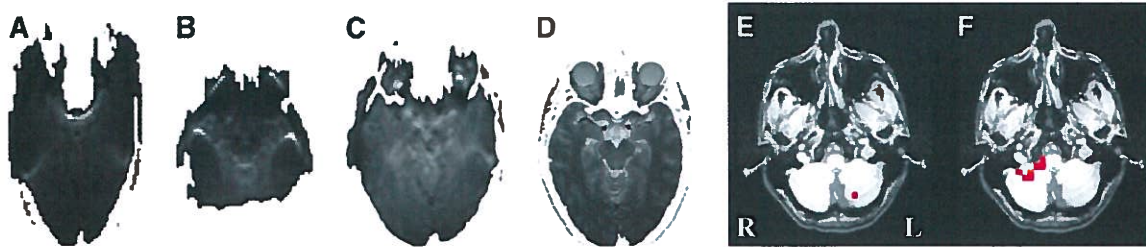


Fig. 1. Reversed gradients to reduce geometric distortions at 3.0 T. Application of the reversed gradient method to reduce susceptibility induced geometric distortions at 3.0 T to EPI images of the brain (A–D). (A) An EPI image with parameters set to enhance distortion for demonstration purposes. (B) Same with reversed gradients. (C) The combined image. (D) Anatomical control image. Application of the reversed gradient method to reduce susceptibility induced distortions at 3.0 T to EPI images of the brain in a preliminary study of a functional sequence [66] without and with alternating gradients (E, F, respectively). For this slice, only in the reversed gradient method imaging sequence were ipsilateral right-hand- finger-tapping task activations detected in the cerebellum (F).

pared with 1.5 T. Theoretically, as Takahashi and colleagues [68,69] argue, because SNR doubles in the higher field and increases with the square root of the number of averaged images, the imaging time to get the same SNR at 3.0 T should be only a quarter of the time needed at 1.5 T. One could ask whether acquiring a larger number of images to increase the SNR and CNR in 1.5 T would provide an advantage equivalent to doubling field strength. However, turning this argument around, one can see that this is not a feasible strategy.

In practice, imaging time is determined primarily by the longitudinal relaxation time T_1 of the tissue (which increases in 3.0 T, as mentioned before), because in many applications, a single acquisition is sufficient. For example, DUEWELL and colleagues [70] compared T_1 and T_2 values in anatomical scans of the knee at 1.5 T and 4.0 T, and found that, depending on tissue, the T_1 values increased up to 56%. T_2 values were 10% to 20% shorter in all tissues, but did not affect image contrast. The longer T_1 relaxation time at higher fields should be accounted for by using a longer TR to achieve the same CNR [27]. This would impair the temporal resolution during data acquisition, however. If TR is kept fixed, the repetition time becomes relatively shorter (as compared with T_1), penalizing the BOLD sensitivity at 3.0 T. In fMRI, the repetition rate is determined mostly by T_1 (and the flip angle), diminishing these advantages in scan time. Thus, the theoretical value of a quarter scan time is not achieved, and in practice the gain in SNR often is used to get a better resolution and only slightly reduced scan time [71].

Acoustic noise

The acoustic noise generated by Lorentz forces on the gradient coils because of rapid gradient switching increases with magnetic field strength. This problem is most severe for EPI-based imaging as

used in fMRI. Ravicz and colleagues [72] performed acoustic noise measurements at 1.5 T and 3.0 T for EPI sequences, and found that the high-field scanner produces significantly louder noise (an increase in 15 dB), mainly attributable to the EPI readout gradients. This can hamper imaging with auditory stimuli considerably, as the authors' own experience with experiments on speech perception shows. Using a clustered spiral sequence in a study of eight subjects, the authors found only weak activation of Heschl's gyrus (A1) for a simple speech versus silence contrast [Fig. 2]. These results agree with data from Gaab and colleagues (submitted for publication), who only observed activity in primary auditory cortex when a very sparse imaging protocol with one volume every 12 seconds was used. In a continuous scanning condition, no activity was observed in this region, although other auditory areas did show activity relative to silent baseline for complex sounds.

Aside from passive noise attenuation, there are other means to reduce the influence of scanner noise. In a study of attentional modulation of the human auditory cortex at 1.5 T, Petkov and colleagues [73] had success with masking the scanner noise with white noise at a sound pressure level that subjectively matched the scanner noise. It is believed that in this way the frequency scatter of loud sounds can be attenuated.

Another way is to reduce the noise at the source before it is produced. There are currently two main approaches now: the design of silent gradients and the switching off of EPI gradients. For the former, there have been numerous reports demonstrating the use of smoothed gradient waveforms to eliminate higher harmonics that are produced by trapezoid waveforms (eg, the SIMEX pulse sequence [74]). In the latter possibility, called ISSS (interleaved silent steady state), the EPI readout gradients are switched off during the silent period, but the

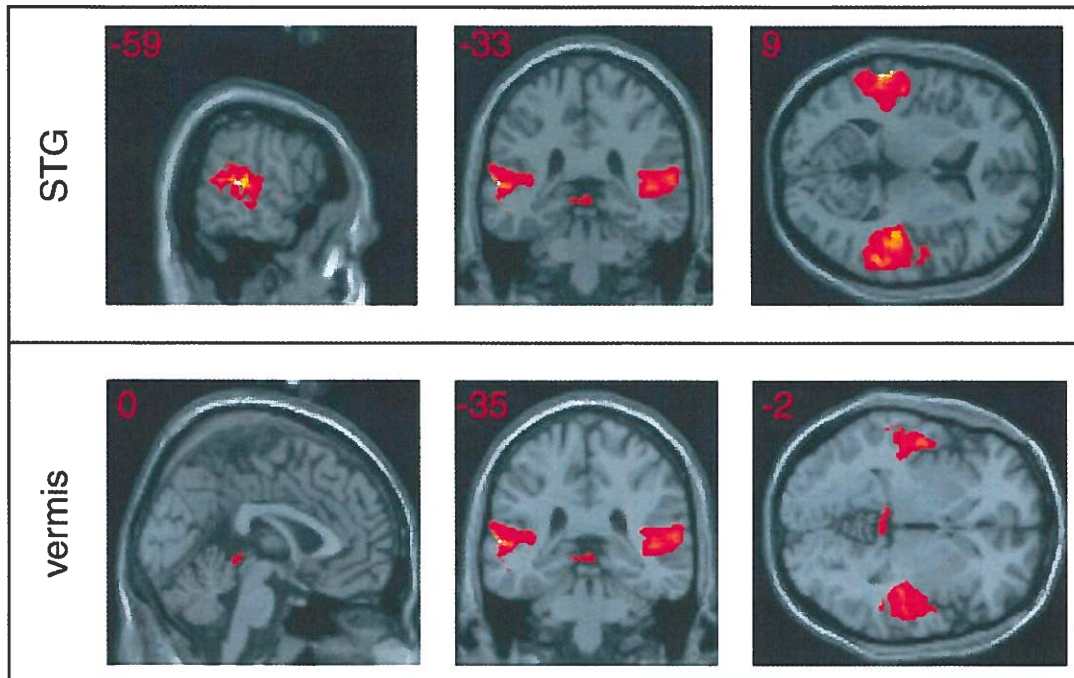


Fig. 2. Speech—silence activations. Areas of greater activation for speech than silence, measured for eight subjects at 3.0 T. Note the lack of activity in Heschl's gyrus (top), likely the result of stimulation by the acoustic noise of the scanner. *Abbreviation:* STG, superior temporal gyrus. (From Zevin JD, McCandliss BD. Dishabituation of the BOLD response to speech sounds. *Behav Brain Funct* 2005;1(1):4; with permission.)

silent RF excitation pulses are kept unchanged to maintain longitudinal magnetization equilibrium [75]. This method was found to be a promising alternative to sparse imaging, in which data acquisition is preceded by a silent interval without EPI readout trains or RF pulses, during which the auditory stimuli are presented, and there are neither EPI readout trains nor RF pulses [76].

Specific absorption ratio

Because the specific absorption ratio (SAR) of the RF field scales with the square of field strength, RF deposition is more limiting at higher fields [77]. With advanced scanner technology and pulse sequence design, however, SAR limits place only minor restrictions on, for example, the number of sections that can be acquired in one scan. The higher SAR, however, may limit the straightforward applicability of sequences designed for 1.5 T, and there is a learning curve one needs to navigate [78]. Overall, SAR considerations do not impose much of a practical constraint on fMRI, because EPI has inherently low SAR compared with spin echo sequences.

Statistical analysis and modeling

Although not directly field dependent, the statistical processing of functional MR imaging data

becomes more and more refined, and one may believe that improved statistical tools may compensate somewhat for imaging at lower field strengths. The general trend is to take more prior knowledge about the signal to be expected into account, thus increasing the sensitivity of statistical tests for BOLD activation. An improved statistical analysis may be able to overcome the limitations of a lower magnetic field to some degree. One prominent approach is the general linear model [79–81], which takes account, for example, of a known hemodynamic response function and time delays, and can integrate other nuisance factors, such as the influence of breathing, in a quite flexible way.

The general linear model can be refined by using other concepts like an improved smoothing of the signal for a more accurate estimation of cluster shape [82,83] (Tabelow and colleagues, submitted for publication, 2006), or unknown hemodynamic delays [84]. BOLD modeling, and, therefore, statistical significance of activation may be improving by a better understanding of the BOLD effect and other effects related to neuronal activity. For example, a phenomenon called the initial dip was used to increase spatial resolution of functional activation effectively [85]; this was used in monkey studies at 4.7 T [86]. The reason for the failure to detect the initial dip in some studies with field

strengths of 1.5 T or lower may be that low-field measurements are not sufficiently sensitive to deoxyhemoglobin concentration changes in cortical capillaries [87].

No matter how much statistical processing and modeling of the BOLD effect improves, however, the limitations in SNR and CNR in lower magnetic fields are unlikely to be completely overcome. Because any averaging of signal causes a loss of information, and neuroscientists are striving for an ever higher resolution, the authors believe that imaging at higher fields will open new possibilities. This process may not end before the smallest length scales of capillary blood flow are reached, if not even new markers of neuronal activity emerge.

Clinical functional imaging

fMRI is becoming a routine tool in clinical applications like presurgical planning [88] or neuropsychologic evaluation. Presurgical fMRI can be used to localize motor, sensory, and language-control areas [89], and it has been used to study cerebral reorganization in tumor patients [90]. In presurgical planning of tumor resection [91–93], it is important to have a high test power to avoid false-positive (in particular in the lesion) and false-negative (in particular outside the lesion) activations. False-negative activations (ie, there is no activation visible at locations where it should be) are of particular concern in brain tumor resection.

Because of the clinical circumstances, usually simple-to-understand and strong activation paradigms are used, such as finger tapping, word rhyming, or picture naming. Motion, fatigue, and degree of cooperation may play a more significant role in patients than in normal volunteers participating in well-controlled neuroscience studies. These circumstances sometimes even render the detection of activated areas in simple and strong activation paradigms difficult. This is even more serious as the sensitivity of fMRI measurement directly affects the detectability and reproducibility of the activation area, which will affect clinical decisions strongly. Nakai and colleagues [94] performed a comparative study between 1.5 T and 3.0 T using a sequential finger tapping paradigm in healthy volunteers. They found that the detectability of the premotor area, the supplementary motor area, and the ipsilateral sensorimotor area showed significant improvement at 3.0 T, whereas detectability of the contralateral sensorimotor area was about equal. The authors, however, point out the adverse effect of susceptibility distortions, in particular at 3.0 T. Nevertheless, they conclude that fMRI at 3.0 T has greater potential for detecting neuronal activation as a functional network, and emphasize

that the difference in detectability between different motor areas, which is dependent on the field strength, must be taken into account when considering the application of fMRI for surgical planning or evaluation of neurological symptoms.

The evaluation of functional activations relies on the overlay onto anatomical images and can be only as good as the anatomical images. For this reason, decisions about scanning patients at 1.5 or 3.0 T cannot be considered on the basis of functional imaging quality alone. Magnetic field inhomogeneity induced distortions are greater for higher fields, rendering a coregistration of EPI-based functional images to the anatomy more difficult or imprecise. There is another drawback of high-field imaging; it has been observed frequently that the white/gray matter contrast in 3.0 T is diminished considerably compared with 1.5 T. The reason is because at 3.0 T, the relaxation rates of gray and white matter become more similar. This is a non-negligible drawback, in particular for neuroscience studies that involve quantification of the anatomy as well, for example, volumetric studies where automated segmentations of brain compartments are performed. Another point to consider is the chemical shift artifact. At 3.0 T, it doubles in size and needs to be corrected by means that can considerably decrease SNR. Shapiro and colleagues [71], however, mention that in practice and with advanced technology, this issue is only of minor importance.

On the other hand, pathologic abnormalities often can be detected better at higher fields. For example, Keiper and colleagues [95] conducted a detailed comparison of the detection of white matter abnormalities in multiple sclerosis and found a clear superiority in the detection rate at 4.0 T versus 1.5 T. Nobauer and colleagues [96] report a significant increase of contrast between brain tumors and surrounding tissue in 3.0 T compared with 1.5 T, for two different anatomical sequences [1].

To summarize, in clinical fMRI there are certain drawbacks and pitfalls that arise, in particular in anatomical imaging. Many of these drawbacks have been overcome recently by a better design of pulse sequences and hardware [77]. Taking this aspect into account, one can conclude that clinical fMRI at 3.0 T is advantageous over scanning at 1.5 T.

Summary and discussion

Functional BOLD imaging depends in a complex way on the main magnetic field strength. Neither the signal intensity nor the signal extent depend in a direct way on the field strength. Rather, many issues affecting experiments at different field

Table 1: Summary of advantages and disadvantages of functional MR imaging at 1.5 and 3.0 T

Property	1.5 T	3.0 T
SNR	-	+
Dynamical CNR	-	+
White/gray matter CNR	+	-
Extent of activation	-	+
Strength of activation	-	+
Resolution	-	+
Imaging time	-	+
Susceptibility artifacts	+	-
Chemical shift artifact	+	-
Specific absorption ratio	+	-
Acoustic noise	+	-

The table should not be read in a too dogmatic way, because some disadvantages at 3.0 T can or could be overcome in the future or already are compensated for by technical improvements, such as stronger gradient systems in 3.0 T magnets.

+ = advantageous.

- = disadvantageous.

strengths have to be taken into account. There are direct factors, like signal-to-noise and BOLD contrast-to-noise ratios, and more indirect factors like altered relaxation rates and artifacts, and very indirect factors, like the effects of acoustic noise on an auditory experiment, or the generally more advanced technology available for newer 3.0 T scanners. Table 1 summarizes the main results as obtained by various authors.

There is, however, one general advantage of higher fields dominating the consideration: the increased signal-to-noise and functional contrast-to-noise ratios. At higher field strength, the BOLD effect is more pronounced in capillary tissue, closer to the expected true functional activity, and relatively more suppressed in venous tissue. This fact favors 3.0 T fMRI beyond what is expected based on purely physical considerations. As MR imaging techniques develop, other problems may be solved in the future like the correction for susceptibility induced artifacts and the acoustic noise problem. Another rather pragmatic point is that few MR imaging devices are used solely for functional imaging, meaning that their purchase often has to be justified by clinical usage. In addition to the clear advantages for functional imaging, there are some clinical anatomical advantages as well, such as rendering some tumor and white matter abnormalities. Taking everything together, the authors believe it can only be beneficial to concentrate future research activities on functional imaging at 3.0 T or higher fields.

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EXHIBIT

4

January 5, 2017

James E. Shmerling
President and CEO
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106

Dear Jim,

This letter is in support of the Connecticut Children's Medical Center application to acquire a 3T MRI scanner to be located at the main campus across from Hartford Hospital.

Advance imaging using a 3T MRI scanner has become a standard of practice for specific diagnoses and supports establishing the best plan of care. As a stand-alone pediatric institution, Connecticut Children's will be able to accept more complex pediatric cases and treat children in a pediatric environment. In addition, this modality will support our joint Trauma Program allowing children to be directly admitted to the hospital. Having the scanner at the main campus will avoid the need to transfer a patient to another facility and better coordinate care in one location, especially for difficult Neurology, Neuro-Surgery, Cardiac and Orthopedic care.

The addition of a 3T scanner will not have a negative impact on Hartford Hospital. I strongly support Connecticut Children's application for the acquisition of a 3T MRI scanner.

Sincerely,



Elliot Joseph
Chief Executive Officer

0171. 2/17/17

OFFICES

JEFFERSON RADIOLOGY

January 4, 2017

This letter is in support of the Connecticut Children's Medical Center proposal to purchase a new 3 Tesla MRI to be placed in the Connecticut Children's Medical Center in Hartford Connecticut.

I am currently the Director of MRI and CT at Jefferson Radiology as well as the Section Chief of MRI at Hartford Hospital. I strongly support obtaining this new MRI scanner as described in their CON proposal. The proposed MRI scanner will provide a much needed increase in MRI imaging capabilities for the Connecticut Children's Medical Center patients, as well as providing a better patient experience for their outpatients that require MRI exams.

The proposed 3 Tesla MRI will be able to provide additional benefits to this special population of patients. Although there are many benefits, the two most important in my mind are related to the newer technology and increased strength of the 3 Tesla magnet over the current 1.5 Tesla magnet. MRI is typically a "signal starved" examination and imaging smaller patients can be very challenging. The added strength of the 3 Tesla MRI machine will allow for:

1. Shorter exam times. This increase speed can hopefully allow more of the exams to be performed without the need for anesthesia.
2. Better image quality for smaller patients. The increased signal will allow for higher resolution pictures and details to be obtained, especially in their smaller pediatric patients.

It is essential that the Connecticut Children's Medical Center be able to acquire the 3T MRI to provide state of the art imaging and proper care for this population of patients.

Sincerely,



Michael T. O'Loughlin, M.D.

Director of CT and MRI,
Jefferson Radiology Group
85 Seymour St, Suite 200
Hartford, CT 06106

Radiology Residency Program Director,
Vice Chair Department of Radiology
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EXHIBIT

5

PHILIPS HEALTHCARE
 A division of Philips Electronics North America Corporation
 22100 Bothell Everett Highway
 P.O. Box 3003
 Bothell, Washington 98041-3003



Quotation #: 1-1JIFD6U	Rev: 7	Effective From: 03-Jan-17	To: 30-Jun-17
Presented To: CONNECTICUT CHILDRENS MEDICAL CTR 282 WASHINGTON ST HARTFORD, CT 06106-3322 Tel: Alternate Address:		Presented By: Eugene Prendergast <i>Account Manager</i> Joseph Longo <i>Regional Manager</i> Tel: (914) 806-2268 Fax: (425) 458-0390 Tel: (845) 216-9288 Fax: (845) 216-9288	
Date Printed: 03-Jan-17			
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IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Quote Solution Summary

<u>Line #</u>	<u>Product</u>	<u>Qty</u>	<u>Price</u>
	100333 Ingenia 3.0T Omega	1	\$2,736,599.20
	100963 Ambient Experience for MR	1	\$88,500.00
Equipment Total:			\$2,825,099.20

Solution Summary Detail

<u>Product</u>	<u>Qty</u>	<u>Each</u>	<u>Monthly</u>	<u>Price</u>
100333 Ingenia 3.0T Omega	1	\$2,736,599.20		\$2,736,599.20

Buying Group: GNYHA

Contract #: GNYHA-IM-016

Add'l Terms: Refer to Contract# noted above for applicable discounts, fees and terms and conditions (Terms), as well as the Terms of Sale printed with this solution to the extent not in express conflict with such Contract Terms.

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice

100963 Ambient Experience for MR	1	\$88,500.00	\$88,500.00
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Buying Group: GNYHA

Contract #:

Add'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice

Quote Summary

100333 Ingenia 3.0T Omega

Qty	Product
1	NNAF992 Ingenia 3.0T Omega HP Q4 2016
1	NNAF994 Ingenia 3T Premium IQ VP Q4 2016
1	NMRB229 T/R Interface 3.0T
1	NMRB214 dS Torso 3.0T
1	NMRB249 dS Knee 16ch 3.0T
1	NMRB255 dS Shoulder 8ch 3.0T
1	NMRB252 dS Wrist 8ch3.0T
1	NMRB253 dS FootAnkle 8ch 3.0T
1	NMRB375 dS Head 32ch 3.0T
1	NMRB411 dS Ped NeuroSpine 8ch 3.0T
1	NMRB412 dS Ped Torso 8ch 3.0T
1	NMRB496 Expansion to Premium
1	NMRB462 mDIXON Body Fat Quant Spec
1	NMRB461 ASL Neuro Specialist
1	NMRB484 Bold Specialist
1	NMRB486 FiberTrak Specialist
1	NMRB492 Coronary Acquisition
1	NMRB616 NeuroScience Specialist
1	NMRB618 Cardiac Expert Spec
1	NMRB808 Cardiac Quant
1	NMRB194 FlexCaddy
1	NMRB584 Head and Arm Support
1	NMRB032 Pediatric support mattress
1	FMR0340 FlexTilt
1	FMR0326 Anterior Coil Frame
2	989801256069 MR Full Travel Package OffSite
1	989801270041 Spectris Solaris EP Injector
1	NNAF952 MR Chiller
1	NNAF891 Enhanced Warranty Terms
1	SP007 Rigging Charges

Quote Summary

100333 Ingenia 3.0T Omega

Options

Qty	Product
1	NMRB346 Expansion to dS WholeBody 3.0T
1	NMRB254 dS T/R Head 3.0T
1	FMR0274 HA FlexTrak
1	NMRB676 dS Pediatric positioning pack
1	NMRB371 Acoustic Hood Ingenia
1	989801256382 MRI Baseline Safety Audit OnSite

Quote Summary

100963 Ambient Experience for MR

Qty	Product
1	NAEA108 Ingenia
1	NAEA161 Ambient Lighting and In-bore Solution

100333 Ingenia 3.0T Omega

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms: Refer to Contract# noted above for applicable discounts, fees and terms and conditions (Terms), as well as the Terms of Sale printed with this solution to the extent not in express conflict with such Contract Terms.

Line #	Part #	Description	Qty
1	**NNAF992	Ingenia 3.0T Omega HP Q4 2016	1

Ingenia 3.0T Omega HP

Ingenia with dStream architecture provides flexible and intelligent tools for faster exams and more consistent scanning, as well as excellent clinical performance for a variety of applications – all while increasing patient comfort. Designed for today and tomorrow, it is a safe investment that will serve your needs well into the future.

The R5 system software supports a new generation of clinical options for head, neck, spine, MSK and body imaging. In addition, R5 brings important improvements to the scanner GUI for better control and usability throughout the MR exam, including:

- Smart conflict management for improved workflow
- Selective archiving for better control of archiving & export
- Combined accession numbers for improved scan efficiency during procedure based billing
- AutoSPAIR, software controlled SPAIR delay time for consistent fat suppression
- Increased patient database image bulk storage capacity to >= 250GB
- Patient specific safety protocols with SAR/PNS management

At the heart of the Ingenia is the new dStream architecture. dStream comprises:

- DirectDigital RF receive technology, which samples the MR signal directly in the RF coil on the patient.
- FlexStream workflow, which increases system versatility and throughput
- EasyExpand, which enables plug and play expansion of clinical capabilities without major upgrades

Philips Ingenia significantly improves MR image clarity, speed and expandability.

- Clarity: By digitizing the signal directly on the patient, dStream captures image data where the signal is at its purest.
- Speed: Patient and coil handling have never been easier: flexible exam setup to meet each patient's unique situation, simplified coil changeover and optimal quality for any exam.
- Expandability: The number of channels is determined by the coil, rather than limited by the system. This makes the MRI system forward-compatible to easily access emerging applications like body and cardiac and new enhancements for established applications like neuro and musculoskeletal imaging.

dStream architecture

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		Unique digital broadband MR architecture capturing the purest MR signal combined with enhanced workflow and ease of use to provide increased SNR and greater efficiency in your daily operations. In addition the number of channels is no longer determined by the MR system. <ul style="list-style-type: none">• Up to 40% greater signal-to-noise ratio (DirectDigital)• As much as 30% improvement in throughput (FlexStream)• Easy expandability of clinical capabilities without the need for major system upgrades (EasyExpand)	

Xtend design

System design optimized not only to provide a 70cm wide bore, but also to provide optimum quality and performance for imaging even the largest patients. Industry-leading magnet, gradient and system body coil designs provide the largest field-of-view for a 70cm system. Xtend offers the best combination of magnet homogeneity and gradient performance over a 55 cm FOV.

- Image eyes-to-thighs in as few as 2 stations
- Excellent large FOV and off-center imaging, ideal even for large patients
- Increased image accuracy for large FOV and multi-station exams

Magnet system

- Xtend ultra-large up to 55 cm field-of-view combined with a 70cm bore system, enabling uncompromised coverage and imaging of large patients.
- Actively shielded, lightweight design (<4940 kg) and compact fringe field (3.1 x 5.0) footprint facilitate easy siting
- Ultra compact patient-friendly magnet design - only 1.62m in length
- Best-in-class magnet homogeneity (1.8 ppm / 50 x 50 x 45 cm V-RMS) for excellent image quality, off-center imaging and fat suppression.
- Superconducting screening coils to reduce magnetic field susceptibility caused by moving external ferrous objects.
- HeliumSave zero boil-off technology for zero helium consumption (0 l/hr) under regular scanning conditions.
- Side turret design for easy installations even with low ceiling and difficult access

Gradient system

Omega HP Gradients

High-performance gradients specifically designed for a wide bore magnet. Omega HP provides a high linearity and maximum peak and slew rate over the entire imaging field of view.

- Peak amplitude up to 45 mT/m (78 mT/m effective), peak slew rate up to 200 mT/m/ms (346 mT/m/ms effective). All specifications are on axis (x, y and z).
- Superb linearity (< 1.4% over 50 cm FOV) to improve geometric and diffusion accuracy, and to maximize resolution, even at the edges of the field-of-view.
- High order shimming capabilities: first (x, y, z) and second order (x²-y², z², xy, xz, yz) for improved patient-specific shimming.
- State-of-the-art water-cooled gradient coil and solid-state amplifier for high fidelity and 100% duty cycle.
- Non-resonant gradient design allows flexible generation of any type of gradient waveform.

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">• The integrated force-balanced design of the gradient coil and magnet reduces vibrations and ensures acoustic noise is minimized.• Extremely low eddy currents for short echo times• AutoSofTone further reduces gradient acoustic noise by up to 30 dB (an 86 % reduction in patient-perceived acoustic noise).	

RF receive: DirectDigital and EasyExpand

DirectDigital: Unique Philips technology that samples the MR signal directly in the RF coil on the patient. The fiber-optic transmission of digital broadband data from the coil to the image reconstructor removes potential noise influences typical with analog pathways.

- Capturing the purest MR signal with up to 40% greater signal-to-noise, enabling higher speed/resolution
- Increased dynamic range (max 187 dB)

DirectDigital technology additionally includes:

- Sub-millisecond TRs and ultra-short TEs
- Real-time imaging control for clinical motion correction:
 - navigator-corrections required for free-breathing cardiac techniques
 - high-resolution diffusion (i.e., PhaseTrak) with profile updates within 1 ms.
- Real-time control of RF transmission, gradient switching, data acquisition and triggering.

EasyExpand: Inherent design of the dStream architecture, where channels are determined by the coils rather than the system. The MR system becomes channel independent, which means a removal of the number of channels as a system specification. This enables plug-and-play expansion of clinical capabilities.

- Expansion does not require major system upgrades, resulting in lower life cycle costs.

dS-SENSE

Next generation parallel imaging for the dStream (dS) architecture, which simplifies and speeds up scan setup and enables higher parallel imaging factors for more speed or resolution.

- Includes quick, fully integrated reference scans which are planned automatically.

RF Transmit: MultiTransmit 4D

Unique RF transmit design using multiple RF sources. MultiTransmit parallel RF transmission enhances signal and image contrast uniformity, speed and consistency at 3.0T for all applications.

- Patient-adaptive RF matches the RF field to the anatomy of each and every patient.
- Up to 40% more speed compared to single transmit RF systems.
- New MultiTransmit 4D enables the RF field to be optimized even during real-time cardiac applications.

- Parallel RF transmission and reception (2 x 2 channels) using two independent RF sources, amplifiers and receivers enabling patient-adaptive RF shimming: Adjustment of individual RF sources to provide uniform, consistent RF distribution and lower local RF deposition in each individual patient.
- The independent RF amplifiers feed into the individual ports of the MultiTransmit dS T/R System Body coil

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">• Patient-adaptive RF shimming adapts the RF (power, amplitude, phase, waveform) to each patient and each anatomy to maximize RF uniformity, contrast and consistency• 2 x 18kW high-performance solid-state RF power amplifiers allow short, complex RF pulses, even on large patients.• Digital control loops for each individual (TX) transmit channel digitize the transmit signals close to the System Body coil. These feedback loops ensure outstanding image quality by delivering optimal amplitude, phase and waveform of the RF pulses.• RF-SMART technology enables SAR to be effectively managed through balanced system design, and maximizes scanner performance in combination with the application of Philips-unique imaging capabilities such as SENSE, SPAIR, Flip Angle Sweep and RF amplitude control.	

Standard RF receive coils

dS T/R System Body coil 3.0T

The integrated dS T/R System Body coil is a transmit/receive system coil which is typically used for RF excitation, but can also be used for imaging various (large) body parts.

- MultiTransmit solid-state phased-array Transmit/Receive system body coil for improved SAR control and a high signal-to-noise ratio
- DirectDigital sampling in the coil where the MR signal is at its purest.
- Channels: 2x2 (Transmit x Receive)
- Excellent homogeneity
- 70 cm aperture

dS coil solutions

dStream (dS) coil solutions provide a full range of clinical solutions with two types of coils:

- Integrated coils combine to provide solutions for multiple applications
- Dedicated coils optimize imaging for a single application

dS coil solutions have been optimized for 3 important characteristics:

- Intrinsic signal-to-noise ratio (DirectDigital)
- Imaging coverage
- Parallel imaging performance

dStream Interface

Allows the connection and digitization of the signal from traditional RF coils* at the table. The digital signal from the interface is transferred via an optical connection to the reconstructor.

- Connector interface designed for easy connection and automatic release of coil
- Connects traditional coils up to 16 channels

*Note: Achieva coils are not compatible with dStream interface

Workflow / throughput: FlexStream

FlexStream is hinged upon the unique FlexCoverage Posterior coil that provides neck-to-toe coverage without the need for any manual coil removal or patient repositioning. The FlexCoverage

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<p>Posterior coil simply combines with other unique dS coils to enable imaging with fewer coils and reduce concerns for coil positioning and patient setup. The optional FlexTrak patient transport system enables easy patient preparation and more efficient use of the MR scanner. FlexTrak solutions can instantly convert your MR system from general purpose use to dedicated advanced clinical use, such as breast imaging, intervention or therapy applications, while ensuring high throughput.</p> <ul style="list-style-type: none">• As much as 30% improvement in throughput• Easy coil handling through lightweight patient conforming coil design• Large coverage coils for easier positioning• Flexible combinations of coils• Efficient coil usage – more applications with fewer coils• Unique design allows up to 70% of routine applications without additional coil connections.• FlexConnect easy to use, single-handed coil connections.	

FlexCoverage Posterior coil

Posterior coil, used routinely in 60% of all applications, is an integrated coil below the thin table top providing neck-to-toe coverage. This coil does not need to be carried, positioned, connected nor exchanged, thereby enhancing workflow. It is always there when you need it.

- Head-to-toe coverage up to 200 cm* in combination with the base coil

FlexConnect coil connection / connectors:

Single-handed coil connection for fast and easy plugging and unplugging of coils, and for auto-eject with FlexTrak undocking in emergency cases.

The small FlexConnect connectors use advanced fiber-optic connections for carrying digital broadband MR signals.

- Enhanced reliability by eliminating delicate RF pin connections.

FlexTrak table top

Ultra-thin table top that maximizes bore space. Includes coil connections directly on the table top for fast and easy setup.

- Ultra-thin design ensures minimal distance between patient and FlexCoverage Posterior coil for optimal SNR
- Ultra-strong design supports patients up to 250 kg (550 lbs)
- Wide table for enhanced patient space and comfort
- Easily removed for patient transport using the optional FlexTrak patient transport system

Workflow / throughput: SmartAssist

Next generation, easy-to-use SmartExam and ExamCards software that helps the user reduce the number of manual tasks.

- Simplifies workflow by making ExamCards more efficient
- Can reduce repetitive tasks by half

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
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- Increases efficiency, reproducibility and consistency

ExamCards

A grouping of individual sequences and operations that define a clinical protocol. An ExamCard can include both the imaging sequences and any of the SmartAssist functionalities. ExamCards makes even the most complex exams simple.

- A set of Philips defined ExamCards is standard
- User-defined ExamCards can be created and stored
- Can be exported to memory stick or portable device
- Can be locked with a password to prevent unintended changes
- Can be shared among any of your scanners
- Philips Netforum provides an online community that allows ExamCards to be shared and downloaded
- Supports user-editable tips and processing/viewing/networking steps
- Supports single mouse-click scanner operation

SmartStart

One button action that automatically moves the table to isocenter and starts the ExamCard while the operator walks back to the console reducing the setup time.

SmartSelect coil and element selection

Automatically detects and selects the right coil and coil elements to maximize the SNR matching the area to be scanned.

- Simplifies patient positioning and coil placement
- No need for manual coil or element selection
- Optimal SNR
- Facilitates higher throughput

SmartExam planning (optional)

Assists the operator in planning the MR exam. SmartExam uses sophisticated algorithms to recognize the anatomy. Then, using previously run exams as input, SmartExam automatically positions slices on the target anatomy, and uses ExamCards to conduct the study, reducing operator input to as little as a single mouse click.

- Targeted for 100% reproducibility and consistency in outcome

SmartExam optional packages include:

- SmartExam Brain
- SmartExam Spine
- SmartExam Shoulder
- SmartExam Knee
- SmartExam Breast

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Line #	Part #	Description	Qty
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SmartLink geometry linking

SmartLink (geolink) is a tool for simplifying the planning, viewing and processing of multi-sequence multi-station exams, treating multi-station exams as one volume.

- Allows a single table sweep for multi-sequence (e.g. T1, T2, STIR) multi-station exams. All sequences are run at each station before the table is moved to the next station minimizing the number of table movements for increased patient comfort.
- Provides the flexibility to perform one sequence at all stations before starting the next sequence.
- Labels and sorts images regardless of the order in which they are acquired for subsequent viewing and processing as a single volume.
- BolusTrak (fluoroscopic scans) can be interleaved at any point during a multi-station exam.

SmartLine processing

Smart, automated and intelligent processing of image data. SmartLine processing steps can be run simultaneously and in parallel with image acquisition. Defined in the ExamCard, the same processing settings are used every time for consistent results.

- Progress of each processing step is clearly displayed to the user alongside the scanning progress.

The following packages are included:

- **SmartLine** VolumeView Real-time MIP, MPR and 3D surface rendering (standard or user defined volumes of interest enable elimination of unwanted signals regions)
- **SmartLine** ImageAlgebra (including addition, subtraction, relative subtraction, cumulation, ratios, MTC, ASL calculation)
- **SmartLine** PicturePlus for user-defined image filtering (smoothing and/or edge enhancement)
- **SmartLine** T1 / T2 / rho map calculation
- **SmartLine** Delayed Reconstruction enables various retrospective image reconstructions from raw data (e.g. reconstruction of various flow directions from a 3D phase-contrast MRA dataset)

Scantools dependent options:

- **SmartLine** Diffusion registration
- **SmartLine** Diffusion (ADC, eADC, etc.)
- **SmartLine** IViewBold real-time fMRI analysis

Viewing, filming and export

The MR viewing environment supports fast and flexible viewing, processing and film generation

- Window width/level, zoom, pan, rotate, mirror
- Image annotation (text, arrows and lines)
- Simultaneous visualization of up to four independent series for comparison.
- Cine movie display in various formats
- Drag & drop functionality to enable the creation of films containing random image selections
- Single mouse click film generation of image series using a range of predefined formats

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">Images and movies can be exported to Windows PC formats as visible on screen	

Patient environment and patient handling

The Ingenia was designed with the patient in mind, no matter the age, size or physical condition. The Ingenia's patient environment and patient handling features enhance patient comfort and facilitate exams.

Important features:

- Lightweight, patient-conforming coils
- 70 cm bore and extra large FOV imaging space
- Digital coil management workflow
- DirectDigital RF technology digitizes the signal in the RF coil on the patient
- SmartAssist efficiency enhancing software
- MultiTransmit RF transmit

Benefits include:

- More comfortable exams
- Decreased need for coil positioning
- Fewer retakes
- Faster exams

Patient Comfort

- 70 cm aperture for enhanced patient comfort, patient fit and reduced anxiety
- Choice of feet-first or head-first imaging for most applications
- FlexCoverage Posterior coil: Never worry about the position of the patient to this coil. No cables, no connections. This invisible, patient-friendly coil is always there when you need it.
- Lightweight, conforming coils for enhanced patient comfort and operator handling
- Ambient Ring circular light to enhance the visual openness of the system.
- Adjustable fresh air supply in 6 increments
- Adjustable variable in-bore lighting in 3 increments
- In-bore microphone and ceiling-mounted loudspeakers support two-way patient-operator communication and music.
- Hand-held technologist call button.
- Patient headset with built-in two-way communication reduces acoustic noise by up to 25 dB.
- Look-out mirror with adjustable angulation

Patient support

- Patient support enables patients weighing up to 250 kg (550 lbs) to be comfortably positioned and lifted.
- Wide table top for improved patient comfort and accommodation of larger patients
- Patient table height can be quickly lowered, providing access for compromised or non-ambulatory patients.
- Detachable tabletop can be combined with one or more FlexTrak patient transport systems for efficient patient management and rapid egress. Supported by manual mode table release.
- Up to 200 cm* scan range

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">• Horizontal travel of 275 cm (9 ft 1 in.) with +/- 0.5 mm (0.02 inch) accuracy• Horizontal table speeds of up to 325 mm/s to enable fast, easy patient positioning and rapid multi-station examinations• Ergonomically designed control units on both sides of the bore to increase operating flexibility.	

Whole Body Specialist

Whole Body Specialist enables automated multi-station head-to-toe coverage. Extended table stroke for Ingenia and table-top extender for Achieva to increase total table travel, allowing whole-body multi-station feet-first imaging studies. Single table motion by combining all imaging sequences per station. Scanalign guarantees user defined overlap between stations. Whole Body Specialist extends DWIBS to whole body coverage.

Physiology measurement and gating

Wireless physiological hardware to provide synchronization for sequence triggering and gating. Wireless physiological signals can be observed on the operator's console monitor or on the optional Interventional Monitor.

- Wireless Physiology consisting of wireless Basic Triggering Unit (wBTU) and respiratory module hardware
- Physiological synchronization for sequence triggering and gating through
 - Wireless VCG
 - Wireless Respiratory
 - Wireless PPU (requires optional PPU Sensors)

Patient accessories

Comprehensive set of patient accessories, including

- Table mattress set
- Head/leg support
- Knee support
- Positioning wedges
- Small foam wedges
- Set of sandbags
- Set of patient fixation straps

Computer specifications (may be supplied on one or two computers)

Host

- >= 32 GB host memory
- >= 100GB system disk
- >= 250 GB main image database disk (Approx. >= 300,000 images – 256 x 256 image resolution)
- >= 23-inch LCD wide-screen format monitor enabling large overview
- LCD wide screen resolution: 1920 x 1200
- MicroSoft Windows® OS 64 bits
- External storage via USB port
- 10BaseT, 100BaseT or 1000BaseT connections.

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
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Recon

- Fast reconstruction of demanding imaging techniques (interactive real-time, dS-SENSE, high resolution and high coil receiver count).
- >= 6000 images per second (256 x 256 reconstructions)
- >= 13000 recons/sec (256 FFT, 100% FOV)
- >= 32 GB reconstruction memory (RAM)

Connectivity / interoperability

The MR environment fits seamlessly into local network environments. Communication is performed via DICOM protocols. The system can be configured for safe storage of MR images and other patient data in departmental information systems and PACS. The MR workspace conforms to the new Enhanced (multi-frame) MR DICOM standard, which improves the performance of data transfer of large data sets and fully supports information associated with diffusion and spectroscopy.

The system can be configured (per node) to support standard DICOM MR image transfer or DICOM Enhanced MR Image Transfer. If a receiving node does not support DICOM Enhanced MR, standard DICOM MR Images will be transferred.

- DICOM Workflow Management:
 - DICOM Modality Worklist
 - DICOM Modality Performed Procedure Steps
 - DICOM Storage Commitment
- DICOM Send/Receive:
 - DICOM Enhanced MR:
 - Export / Import of DICOM Enhanced MR Images
 - Export / Import of DICOM MR Spectroscopy
 - Export / Import of DICOM Raw
 - DICOM MR:
 - Export / Import of DICOM MR Images
 - Export / Import of Philips Private MR Series Data
 - Export / Import of Philips Private MR Spectrum Data
 - Export / Import of Philips Private MR ExamCards Data
 - DICOM SC:
 - Export / Import of SC (color) Image Data
 - DICOM Grayscale Softcopy Presentation State:
 - Export / Import of Grayscale Softcopy Presentation State
- DICOM Query / Retrieve of Philips MR data, all the exported image types
- DICOM Print
 - Grayscale Softcopy Presentation State with preset window settings as on the console
 - Basic Grayscale Print
- DICOM Media
 - MR Studies on DVD (Read / Write)
- IHE Integration Profiles
 - Scheduled Workflow
 - Patient Information Reconciliation
 - Consistent Presentation of Images
 - Basic Security

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Line #	Part #	Description	Qty
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- Consistent Time

Full information on compliance with DICOM standards and available functionality is contained in Philips' DICOM Conformance Statement.

Installation: EasySite and PowerSave

EasySite

System design for rapid installation times, compact siting footprint and low ceiling heights.

- Installation times as short as 7 days, based on prepared site conditions.
- Industry's lightest wide-bore magnet enables siting on upper floors.
- Siting (exam/technical/control room) as little as 30 m²
- Low ceiling height
- Low transport height for easy facility access
- System / building vibration transfer is minimized by special vibration pads that require no facility adaptations.

PowerSave

Unique, efficient design combined with smart power management of the high power sub-systems (gradient amplifiers, RF amplifiers, etc.) enable reduction in power consumption by up to 50% without affecting overall performance.

ScanTools Pro

Scantools Pro provides the following generic workflow features for all clinical anatomies:

- ExamCards for automated scanning and processing of patient studies.
- SENSE parallel imaging methods for fast scan times, high resolution or to reduce susceptibility artifacts.
- CLEAR for signal uniformity correction based on coil-sensitivity and on patient loading.
- PicturePlus to improve appearance of images through edge enhancement and smoothing. Provides full control over all enhancement parameters, which can be applied automatically post-acquisition or as a post-processing option.
- High-resolution acquisitions and reconstruction (1024 matrix)

In addition, ScanTools Pro contains fast, high resolution imaging methods for the assessment of morphology of all anatomical areas including brain and spine, MSK, body and breast, cardiac, and various blood vessels with or without contrast agents. Specific features per clinical area are listed below.

Neuro Pro

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Line #	Part #	Description	Qty
		<ul style="list-style-type: none"> • Sequences include SE, FFE and EPI based methods, with fat suppression methods including STIR, SPIR, ProSet and SPAIR. • FLAIR for CSF suppression. • Snapshot imaging, intended for uncooperative patients, eliminates the effects of patient and physiological motion through the combination of rapid TSE sequences and SENSE. Individual Snapshot images can be acquired in any orientation in approximately 250ms to 300ms. Asymmetric TSE makes Snapshot compatible with T1-, T2- and diffusion-weighted imaging. • Single, Dual and Triple IR sequences for evaluation of gray and white matter differentiation. • 2D TSE with Flip Angle Sweep technology for SAR and Magnetization Transfer reduction, improving gray/white matter contrast in both T2 and FLAIR acquisitions. • 3D based anatomical sequences including: <ul style="list-style-type: none"> • VISTA, isotropic 3D TSE for volumetric acquisitions with reconstruction in any plane. • 3D T1-TFE sequences for volumetric acquisition and reconstruction of the original dataset in any orientation. • 3D TFE for isotropic coverage of the entire head in short scantimes using SENSE. A single data set can be reformatted into alternate planes both pre- and post-contrast, eliminating the need for additional scans. • DRIVE for T2-weighted 2D and 3D TSE acquisitions enabling short TRs while maintaining contrast-to-noise and SNR. Used to improve fluid visualization (IAC), for short scan times and to increase resolution. • Balanced FFE/TFE for high-resolution high contrast (IAC and Spine applications). • ProSet water and fat excitation for spinal nerve root imaging. Combines the characteristics of the high-resolution volume acquisitions with ProSet water or fat only selection. • Multiple radial projection myelography both with 2D and 3D sequences. • MultiVane to correct motion for multi-shot TSE examinations with radial encoding. MultiVane delivers high resolution diagnostic images even in case of patient motion for T2, IR-real & FLAIR TSE imaging as well as gradient-echo examinations. • Dynamic multi-slice T2*-weighted sequences based on single- or multi-shot FFE-EPI methods for perfusion and fMRI sequences. • Single-shot EPI diffusion-weighted imaging (DWI) with three diffusion directions and up to 16 b-values, robust against motion and generating isotropic DWI images. • BolusTrak enables accurate synchronization of high-resolution CE-MRA acquisitions. BolusTrak uses a real-time fluoroscopic display of bolus arrival in the area of interest and manual start of the target acquisition. BolusTrak in combination with CENTRA minimizes venous contamination and produces optimal arterial vessel contrast and resolution. • TRACS enables accelerated time-resolved contrast-enhanced vascular imaging. TRACS uses SENSE for image acceleration and CENTRA phase-encode ordering for optimized contrast. • m-FFE provides unique image contrast - ranging from 2D or 3D gradient-echo sequences to the combination of echoes. • Venous BOLD provides T2*-weighted 3D sequences compatible with SENSE. These sequences are useful for evaluating various brain anomalies associated with venous blood. • Phase contrast (PC) sensitive imaging for the visualization of moving fluids. • MobiFlex and MobiView, compatible with all sequences, for easy Total Spine imaging. • T2* perfusion analysis. • Diffusion imaging processing with automatic generation of the ADC maps. • Perfusion tools package, enabling: <ul style="list-style-type: none"> • Dynamic multi-slice T2*-weighted sequences based on single- or multi-shot FFE or FFE EPI methods, including the PRESTO technique. 	

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">• Processing and calculation of T1 and T2* hemodynamic maps including Mean Transit Time (MTT), Time to Peak (TTP), Time of Arrival (T0), Negative Integral (NI), Index or upslope. All post-processing can be included as an in-line step within Examcard• Prospective Motion Correction: accounts for subject motion by real time monitoring of motion during acquisition and adjustment of acquisition parameters accordingly. PMC enables overall improvements in image registration.• 3D PRESTO<ul style="list-style-type: none">• Whole brain coverage and high temporal-resolution T2*-weighted imaging for perfusion-weighted and BOLD imaging studies.• Higher temporal resolution and coverage compared to traditional multi-slice techniques.• Reduce sensitivity to susceptibility and flow artifacts associated with EPI techniques, enabling imaging throughout the brain and into the skull base.	

MSK Pro

- SE, TSE, and FFE sequences, with fat suppression provided by STIR, ProSet, SPIR and adjustable fat suppression with the SPAIR method.
- Balanced acquisitions (bFFE) for high-resolution morphology scans.
- DRIVE combined with TSE to increase sensitivity to fluids (with good T2 weighting), even with short TRs.
- Turbo-STIR for fat-suppressed evaluation of bone bruises.
- TSE with asymmetric profile ordering for proton density weighted imaging of joints with higher spatial resolution or faster scan times.
- Mixed Mode (interleaved IR/SE for combined T1 & T2 map calculation).
- Multi-Echo T2 measurements (up to 32 echoes) for T2 mapping.
- 3D FFE with ProSet for water-only (selective excitation) sequences. Optimizes cartilage and/or fluid imaging with high-resolution in all directions.
- e-THRIVE for 3D high-resolution fat-suppressed imaging for MR arthrograms and evaluation of soft tissue lesions as well as rheumatoid arthritis.
- MobiFlex for simple visualization of total spine imaging and multiple-station long bone studies.
- Dynamic imaging sequences for TMJ or other joint studies.
- Includes protocols for imaging in the presence of prostheses, with improved susceptibility using SENSE, modifications of water-fat shift and user-specified bandwidth.
- Up to 1024 acquisition resolution and flexible reconstruction resolution via interpolation.

Body Pro

- TSE sequences with respiratory triggering (in combination with breath hold or free breathing).
- MultiVane motion correction for T2w TSE diagnostic images, even in case of severe patient motion.
- In and out of phase FFE/TFE sequences .
- SPAIR for high uniformity fat saturation.
- e-THRIVE volumetric imaging with fat suppression, in short breath-hold times Keyhole for high temporal dynamic imaging.
- Diffusion-weighted sequences with automated creation of Apparent Diffusion Coefficient (ADC) maps.

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">• MRCP sequences, (radial) single shot and 3D acquisitions.• High-resolution pelvic imaging.• VISTA: isotropic 3D TSE pelvic imaging allowing volumetric acquisitions to be reconstructed in any plane.• MobiView and MobiFlex for automatic composition of data sets from multi-station acquisitions into full FOV images.• Dynamic scan techniques for monitoring and evaluation of contrast uptake viewing.• High Resolution Diffusion / DWIBS package enables single or multi-station high resolution diffusion weighted imaging with background suppression. Patient and physiological motion is controlled by navigator-based motion correction.• MotionTrak Body includes a real-time respiratory navigator to synchronize data acquisition to the respiratory cycle of the patient. Options include: gating, tracking, gating & tracking, triggering, triggering & tracking. Tracking improves slice accuracy position over multiple breath hold sequences. Designed for all Body applications, including diffusion and DWIBS.	

Breast Pro

- SPAIR for high uniformity fat saturation.
- e-THRIVE for volumetric coverage with uniform fat suppression.
- BLISS, two bilateral sagittal volumes within a single acquisition.
- Diffusion-weighted sequences with automated creation of Apparent Diffusion Coefficient (ADC) maps.
- Silicone-Only sequences optimized for breast implants.

Cardiac Pro

- Black blood prepulses to suppress blood signal for optimized myocardial and lumen visualization.
- Multi Slice / Multi Phase for function studies.
- Retrospective triggering with real-time prospective updating for full R-to-R coverage of function studies.
- Temporal profile sharing for playback frame rates higher than acquisition frame rates.
- VCG gating for robust ECG gating and triggering (includes a four-lead cable set).
- ECG-triggered STIR (inversion recovery TSE) including black blood imaging (triple IR)
- ECG-triggered Inversion Recovery (including PSIR) for myocardial tissue characterization.
- Non-invasive quantitative flow measurements of blood, including overlaid color-encoded flow maps on the console.

MRA Pro

- 3D FFE sequences for contrast-enhanced MRA, including assessment of carotids, peripherals and renal arteries.
- Quantitative flow with variable VENC values for non-invasive measurements of blood flow in three directions.
- 2D/3D Balanced TFE/FFE for fast, high-resolution non-contrast enhanced vascular imaging.
- Phase-Contrast Angio for imaging of brain vasculature.
- TRANCE for 3D high contrast TSE acquisitions without vascular contrast agents.
- Time-of-flight (inflow) sequences with TONE to improve contrast and MTC to reduce peri-orbital fat signal.

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none">CENTRA for 3D high-resolution contrast enhanced imaging to allow an increase in spatial resolution without venous contamination.Keyhole imaging to improve temporal resolution in dynamic studies.BolusTrak for synchronization of high-resolution CE-MRA acquisitions with a real-time fluoroscopic display of bolus arrival in the area of interest.MobiView for automated composition of multi-station acquisitions (e.g. MRA runoffs) into single images.MobiFlex for setup and acquisition of complex multi-station exams, combining different FOVs, resolution, geometries and SENSE acceleration factors.VCG gating for robust ECG gating and triggering (includes a four-lead cable set).	

3D SpineView

3D SpineVIEW delivers high resolution isotropic 3D TSE acquisitions in short scan times by employing high 3D dS SENSE factors. Isotropic acquisition allows reformats in arbitrary planes.

3D PelvisView

3D PelvisVIEW delivers high resolution isotropic 3D TSE acquisitions in the pelvis area with short scan times by employing high 3D dS SENSE factors. Isotropic acquisition allows reformats in arbitrary planes.

3D BreastView

3D BreastVIEW delivers high resolution isotropic 3D TSE breast acquisitions with short scan times by employing high 3D dS SENSE factors. Isotropic acquisition allows reformats in arbitrary planes.

dS TotalSpine 3.0T

An integrated coil solution for total spine related imaging. It includes the FlexCoverage Posterior and the Base coil with 90 cm coverage, using 44 channels maximum. Posterior coil, used routinely in 60% of all applications, is an integrated coil below the thin table top providing neck-to- toe coverage. This coil does not need to be carried, positioned, connected nor exchanged, thereby enhancing workflow. It is always there when you need it.

- Coverage: 90 cm
- Maximum nr. of channels: 44
- Main applications: Total spine, C-Spine, T-Spine, L-Spine
- Coil type: Integrated
- DirectDigital sampling in the coil where the MR signal is at its purest, without loss in the RF chain, enabling:
 - Enhanced SNR
 - dS-SENSE enhanced parallel imaging performance
 - Single FlexConnect coil connection and cable for fast and easy setup

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		The Base coil can stay on the table for most examinations without exchanging coils and additional dS Base is ideal to improve workflow by preparing the patient outside the magnet room.	

dS HeadNeck 3.0T

An integrated coil solution for head, neck and total neuro related imaging. It includes the HeadNeck coil.

Combined with the FlexCoverage Posterior coil and Base it enables:

- 45 cm coverage, using 20 channels maximum (Head-Neck)
- 90 cm coverage, using 52 channels maximum (Total Neuro)
- Coverage: 45 cm (HeadNeck) and 90 cm (Total Neuro)
- Maximum nr. of channels: 20 (HeadNeck) and 52 (Total Neuro)
- Main applications: NeuroVascular, Head, Brain, Pediatric, Total Neuro, Total spine, C-Spine, T-Spine, L-Spine
- Coil type: Integrated
- Lightweight coil(s)
- DirectDigital sampling in the coil for the purest MR signal without loss in the RF chain, enabling:
 - Enhanced SNR
 - dS-SENSE enhanced parallel imaging performance
 - dS-SENSE capable in AP, LR and FH directions
- Cable-less connection of top coil

When used with an Ingenia, the head section can be tilted to provide optimal positioning and comfort for challenging patients such as Kyphosis patients. Note: this feature is only available with an Ingenia 70cm bore system.

dS Head 3.0T

An integrated coil solution for head and total neuro related imaging. It includes the Head coil.

Combined with the FlexCoverage Posterior coil and Base it enables:

- 30 cm coverage, using 15 channels maximum (Head)
- 90 cm coverage, using 51 channels maximum (Total Neuro)

When used with an Ingenia, the head section can be tilted to provide optimal positioning and comfort for challenging patients such as Kyphosis patients. Note: this feature is only available with an Ingenia Omega or Ingenia Omega HP.

- Coverage: 30 cm (Head) and 90 cm (Total Neuro)
- Maximum nr. of channels: 15 (Head) and 51 (Total Neuro)
- Main application: Head, Brain, Total Neuro, Total spine, C-Spine, T-Spine, L-Spine
- Coil type: Integrated
- Lightweight coil(s)
- DirectDigital sampling in the coil where the MR signal is at its purest, without loss in the RF chain, enabling:

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
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- Enhanced SNR
- dS-SENSE enhanced parallel imaging performance
- dS-SENSE capable in AP, LR and FH directions
- Cable-less connection of top coil

dS Small Extremity 8ch 3.0T

Semi-flexible coil designed for imaging of elbows, hands and small knees. The coil has an inner diameter of 20 cm to match the size of the small extremities. It has a flexible wrap-around design for easy positioning and good fit. A mattress that supports both patient and coil is provided to increase patient comfort and avoid motion.

- Coverage: 20 cm
- Maximum nr. of channels: 8
- Main applications: Elbow, Arm, Extremities
- Coil type: Dedicated
- dS-SENSE enhanced parallel imaging performance

dS Flex M 3.0T

An integrated coil solution for general-purpose imaging. It includes two medium-sized flexible general-purpose coils. Combined with the FlexCoverage Posterior coil they enable 15 cm coverage, with a maximum of 6 channels.

The shape and size of the flexible coil elements enable a wide variety of applications, including imaging of medium sized anatomies. The coil can be used to locally enhance resolution of images acquired over a larger FOV, for example in pediatric applications.

- Coverage: 15 cm
- Maximum nr. of channels: 6
- Main applications: Shoulder, Foot, Ankle, Knee, Pediatric
- Coil type: Integrated
- dS-SENSE enhanced parallel imaging performance

ComforTone is a scan technique that brings noise reduction. ComforTone ExamCards will be available for routine exams (Brain, Spine, MSK) including the reference scans.

With **AutoVoice** the patient is guided through the MR examination with voice audio information to the patient on length of scan, breath hold and table movement. Multiple languages can be selected. Includes a recording option for specific commands or languages.

PPU for wireless physiology

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		The PPU for wireless physiology package contains a peripheral pulse sensor with the following 4 different sizes: neonate, infant, pediatric and adult. This option is required to use the peripheral pulse as a means to do physiological synchronization for sequence triggering and gating . The sensor can be positioned on finger, toe or foot, and is compatible with the Ingenia, Multiva, HFO and Achieva platforms. This package is ONLY compatible with Ingenia, Achieva, Multiva, and/or Panorama systems with wireless physiology.	

Arm support

The arm support is designed to work in conjunction with the existing MR tabletop to provide additional support for a patients arm when injections are required. The support easily slides under the patient.

Features:

- Transparent arm support contoured to match the MR table-top
- Positioning on either side of table

HA console table

Standard office table for MR-operator

- Table surface 160x100 cm
- Adjustable Height

DVD-PC

Local media storage option intended for burning and reading DICOM data on medical grade DVD's. This option enables the operator to burn DVD's directly or prepare multiple DVD's for burning later.

- Includes DICOM viewer on every DVD created
- Create multiple DVD's for exchange with off-line stations
- Burn DVD's independently of other scanner functions.
- Dimensions (hwxwd): 10x34x38cm

Clinical Education Package for Ingenia Release 5:

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<p>Customer Applications Training _Introduction to Philips MR Release 5 - Learning Path 1: This online pre-learning material will introduce the User Interface and clinical handling of the MR scanner to prepare the technologist for on-site training. Learning Path 1 will guide the technologist through specific workflow steps, this self-paced learning module is highly recommended for all Ingenia users and should be completed prior to Essentials OffSite or Handover Onsite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips.</p> <p>Release 5 Essentials OffSite Education: The MR Release 5 Essential course is a prerequisite to attending the MR Release 5 Advanced Concepts course. Philips will provide up to two (2) technologists, as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the magnetic resonance imaging system. This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation, and trainee should have prior knowledge of basic MR theory. CEU credits may be available for each participant that meets the guidelines provided by Philips.</p> <p>Handover OnSite Education: Philips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, as selected by customer. Students should attend all 28 hours, and must include the two OffSite education attendees. This course does not cover Cardiac or Spectroscopy. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready, including all inspections approved, all accessory equipment installed and functioning (injectors, hard copy units, film processors and physiologic monitors), and all supplies stocked. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.</p> <p>FollowUp OnSiteEducation: Philips Education Specialists will provide twenty-eight (28) hours of Follow-Up Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Customer must have operated the system for at least 30 days. CEU credits may be available for each participant that meets the guidelines provided by Philips. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.</p> <p>PLEASE NOTE for all OnSite Education: It is recommended to purchase additional training, 16 or 24 hours, for customers purchasing specialist packages and requiring dedicated training for Breast Imaging, BOLD fMRI, Cardiac or Spectroscopy.</p> <p>Project and Workflow Evaluation: Philips Education representative(s) conduct an eight (8) hour onsite customer MR Site/Clinical assessment; to include site demographics, workflow, identifying key contact personnel and decision makers. This process includes direct observation of customer's MR department workflow. Additionally, a copy of the Customer's MR protocol list is requested to be made available to Philips Education representative. Customer information provided during this process is the first building block for planning educational support and Clinical Exam Card configuration.</p> <p>Implementation Support: Philips Clinical Education Representative supports the overall implementation of all customer training phases of the MR system handover and continued educational support. A Philips Education Representative works with the customer to design a</p>	

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
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customized MR education program and coordinate the customer training/education implementation. Implementation support includes all onsite and offsite customer training events.

Clinical Exam Card Configuration: Exam Card (MR scan protocol) Configuration process is to ensure the Philips MR system is producing acceptable image quality according to customer preferences. Philips Clinical Education Specialist will provide sixteen (16) hours offline customized MR exam card configuration prior to onsite exam card IQ confirmation. Philips Clinical Education Specialist also conducts sixteen (16) hours onsite MR exam card configuration and image quality confirmation. This process includes Image quality acceptance made by the Customer's designated physician representative. Philips Clinical Education Specialist, working with the Customer Lead Technologist will make requisite adjustments to the exam card database in order to meet the customer's initial image quality expectations. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

PLEASE NOTE: For all OffSite Education listed above: CEU credits may be available for each participant that meets the Guidelines provided by Philips. Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292093 (MR Full Travel Pkg OffSite) is purchased with all OffSite courses. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. OffSite training is scheduled based on your equipment configuration and availability.

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 62616026614615622762286229-20150615

2	**NNAF994	Ingenia 3T Premium IQ VP Q4 2016	1
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Ingenia 3T Premium IQ VP Q4 2016

mDIXON XD FFE Specialist brings the next generation mDIXON algorithms for enhanced fat-free performance with a 2-point mDIXON method with flexible echo times and a 7-peak fat spectrum algorithm. mDIXON XD FFE Specialist provides fat-free FFE imaging with large FOV and sub-millimeter resolution, extending its use to challenging anatomies, including head, neck and spine, with access to new imaging methods such as subtractionless MRA.

mDIXON XD TSE Specialist brings the next generation mDIXON algorithms for enhanced fat-free performance. Our fast, 2-point mDIXON method brings flexible echo times and high sharpness, while a new 7-peak fat spectrum algorithm enhances accuracy. mDIXON XD TSE Specialist can be combined with Multivane XD in the head for simultaneous fat- and motion free imaging.

The **SWI Specialist** package enables a SWIp sequence offering:

- 3D high resolution and high contrast susceptibility weighted imaging of the brain
- High SNR thanks to a multi-echo technology
- Enhanced contrast between tissues presenting susceptibility differences such as venous blood products or mineral deposits (e.g. iron or calcium) thanks to the utilization of MR phase information
- Visualization of phase maps to further help diagnosis.

MultiVane XD is an enhanced Multivane technique for Multi-slice TSE and for Multi-slice FFE techniques, suitable for all anatomies. It provides an enhanced Multivane motion control algorithm

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		especially suited for gross motion. Combinable with SENSE parallel imaging in any direction allowing for short scantimes	
		O-MAR XD Specialist O-MAR XD improves soft tissue visualization in the vicinity of MR conditional orthopedic implants. Suitable for use on patients cleared for MR exams, it uses the latest acquisition and reconstruction techniques to help reduce susceptibility artifacts caused by metal. It employs MARS (Metal Artefact Reduction Sequences) high bandwidth TSE methods, VAT (View Angle Tilting) technology and SEMAC to reduce metal-induced distortions both in-plane and through-plane. For use with MR conditional orthopedic implants only. Contact the implant manufacturer in order to obtain the latest safety information to ensure patient safety relative to the use of an MR procedure.	
		Full SmartExam Pack The Full SmartExam Pack enables automatic planning of brain, knee, shoulder, spine and breast examinations for consistent studies with optimized scan quality, independent of patient, patient positioning or operator.	
3	**NMRB229	T/R Interface 3.0T	1
		T/R Interface with connector on gantry to enable connection of Transmit/Receive coils or Multinuclear coils.	
4	**NMRB214	dS Torso 3.0T	1
		An integrated coil solution for body and peripheral vascular related imaging. It includes the FlexCoverage Anterior coil. Combined with the FlexCoverage Posterior coil it enables 60 cm coverage, with a maximum of 32 channels. The flexible, lightweight easy-to-position FlexCoverage Anterior coil is designed to conform both in right-left and foot-head directions for almost any patient. This enables large coverage and comfortable strap-free operation.	
		<ul style="list-style-type: none"> • Coverage: 60 cm • Maximum nr. of channels: 32 • Main applications: Torso, Chest, Pelvis, Heart, Peripheral-vascular • Coil type: Integrated • Lightweight coil(s) • DirectDigital sampling in the coil where the MR signal is at its purest, without loss in the RF chain, enabling: <ul style="list-style-type: none"> • Enhanced SNR • dS-SENSE enhanced parallel imaging performance • dS-SENSE capable in AP, LR and FH directions • Single FlexConnect coil connection and cable for fast and easy setup 	
5	**NMRB249	dS Knee 16ch 3.0T	1
		Coil designed for ultra-high SNR imaging over an extended field of view of the knee and other extremities. The T/R design gives lower RF deposition and shorter RF pulses for increased speed and SNR. Two overlapping rings of eight elements extend the coverage area and minimize the need for precise positioning. dS-SENSE enhanced parallel imaging can be selected in all directions. The dS Knee 16ch has a split design for easy patient setup and an ergonomically ramped insert for patient comfort.	

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		<ul style="list-style-type: none"> Coverage: 20 cm Maximum nr. of channels: 16 Main applications: Knee, extremities Coil type: Dedicated, Transmit/Receive dS-SENSE enhanced parallel imaging performance 	
6	**NMRB255	dS Shoulder 8ch 3.0T	1
		<p>Coil designed for high uniformity throughout the shoulder joint, with excellent penetration into the labrum. The coil consists of a base plate and an adjustable shoulder cup which can be raised and pivoted for comfortable positioning. Adjustable design for a comfortable fit for either left or right shoulder.</p> <ul style="list-style-type: none"> Coverage: 12 cm LR Maximum nr. of channels: 8 Main application: Shoulder Coil type: Dedicated DirectDigital sampling in the coil where the MR signal is at its purest, without loss in the RF chain, enabling: <ul style="list-style-type: none"> Enhanced SNR dS-SENSE enhanced parallel imaging performance Single FlexConnect coil connection for fast and easy setup 	
7	**NMRB252	dS Wrist 8ch3.0T	1
		<p>Coil that closely fits the left or right wrist for high SNR. This design provides the high SNR needed to acquire images with a small FOV. It has a one piece, ovoid, hinged design for easy patient set up. Good quality imaging can be obtained with the coil at the patient's side. The coil attaches to a rigid base plate for fixation to reduce patient motion artifacts.</p> <ul style="list-style-type: none"> Coverage: 8 cm Maximum nr. of channels: 8 Main application: Wrist Coil type: Dedicated dS-SENSE enhanced parallel imaging performance 	
8	**NMRB253	dS FootAnkle 8ch 3.0T	1
		<p>Ski-boot shaped coil for optimum coverage of the ankle and entire foot up to the toes. The coil design and element layout allow for either large FOV imaging of the whole foot or small FOV high resolution imaging for ankle joints. The coil is easy to set up and can be used with the patient's foot vertical or up to 15 degrees plantar flexed.</p> <ul style="list-style-type: none"> Coverage: 30 cm Maximum nr. of channels: 8 Main applications: Foot, Ankle, Toes Coil type: Dedicated dS-SENSE enhanced parallel imaging performance 	
9	**NMRB375	dS Head 32ch 3.0T	1

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		The dS Head 32ch 3.0T is a 32-channel coil designed for advanced neuro applications including fMRI, Spectroscopy, Angiography. It is also designed to facilitate EEG studies. The coil includes both front and rear facing mirrors for visual stimuli and movie projection.	

Features:

- Complete high resolution coverage of the brain
- Parallel imaging with SENSE in all directions
- Compatible with the Ingenia 3.0T platform

Note - This option requires R4.1.3. Customers will be brought to the required software and hardware level.

10	**NMRB411	dS Ped NeuroSpine 8ch 3.0T	1
		The Pediatric SENSE Neuro/Spine coil is an 8 element coil for high resolution pediatric Neuro imaging. The coil is optimized for neonates, but will accommodate pediatric patients up to 10kg. This coil is cradle shaped, and specifically designed for excellent care of the youngest pediatric patients. For a more efficient patient handling, the open, one piece design enables the operator to position and prepare the patient outside the examination room. Neuro examinations of brain and spine can be performed on one coil without having to move the patient.	

Features:

- Maximum SENSE factor of 4
- Outside coil dimensions 260x300x720 mm

11	**NMRB412	dS Ped Torso 8ch 3.0T	1
		The SENSE Pediatric Torso Cardiac coil is an 8-element coil designed for body and cardiac applications in pediatric patients weighing up to 33lbs/15kg. The coil has a split top design for easy positioning and patient access. The coil is compatible with the patient cradle (sold separately) for positioning and transporting.	

Features:

- Internal dimension 23cm x 17.5cm
- Maximum SENSE factors of 6
- Outside coil dimensions: 260x300x260 mm

12	**NMRB496	Expansion to Premium	1
		The extension from ScanTools Pro to ScanTools Premium provides exciting new innovations:	

- k-t BLAST
- 4D-THRIVE and 4D-BLISS
- 4D-TRAK
- 2k Imaging

These powerful techniques provide benefits in cardiac, angio and general imaging.

k-t BLAST

Philips' k-t BLAST offers a new dimension in temporal resolution in dynamic (multi-frame) MRI,

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Line #	Part #	Description	Qty
		<p>maintaining resolution and increasing the number of slices acquired in a single breath hold. k-t BLAST optimizes each acquisition by distinguishing between dynamic and static anatomy, then adapting the acquisition accordingly. This technique provides scanning speeds that are five times higher than conventional methods. k-t BLAST's speed is perfectly suited for imaging cardiac, uncooperative, claustrophobic, elderly and pediatric patients, by providing high spatial resolution and image quality, unsurpassed frame rates and higher throughput potential, with unprecedented scan times. K-t BLAST is particularly well suited for single breath hold and multi-slice cardiac function studies. k-t BLAST can be combined with any other method. Applications include: Fast Imaging, Real time imaging, Cardiac imaging.</p> <p>4D THRIVE / BLISS: With 4D imaging technique (4D-THRIVE, 4D-BLISS and 4D-TRAK) provides a 4D time-resolved technique that combines a keyhole method with CENTRA and SENSE techniques to drastically accelerate acquisition speeds, resulting in acceleration factors as much as 60 times faster than traditional scanning. 4D-THRIVE and BLISS offers this unique combination of methods affords both unprecedented spatial resolution and superb temporal resolution for a variety of abdominal (liver) and breast applications, including evaluation of breast, liver and other abdominal areas</p> <p>4D-TRAK: 4D-TRAK offers this unique combination of methods affords both unprecedented spatial resolution and superb temporal resolution for a variety of CE-MRA applications, including evaluation of brain AVM, congenital heart disease, cardiac function and hemodialysis shunts and diabetes patients with short arterio-venous transit time in lower legs/feet</p> <p>2k imaging: 2K imaging offers a scan matrix of 2048 x 2048, providing the highest resolution even with larger FOVs. 2K imaging also allows lower resolution scans to be reconstructed with a 2048 matrix. This method is compatible with all imaging methods, multi-channel coils and SENSE. Features include: Scan and reconstruction resolutions up to 2048 (in steps of 16), compatible with all imaging methods and multi-channel and SENSE coils</p>	
13	**NMRB462	mDIXON Body Fat Quant Spec	1
		<p>mDIXON Body Fat Quant specialist produces quantitative fat fraction maps in a single breath-hold, covering the whole liver. It is based on a 3D mDIXON sequence with multiple echoes , correcting for T2* decay and employing a multi-peak fat model. Next to the fat fraction maps, water, fat, In-phase, out-phase and T2*/R2* relaxation maps can be produced. Fat fraction maps and T2* relaxation maps can be visualized in color with quantification bar, in the MR console viewing environment or on Intellispace Portal. Note: requires mDIXON Body Specialist as a pre-requisite.</p>	
14	**NMRB461	ASL Neuro Specialist	1
		<p>ASL Neuro Specialist enables:</p> <ul style="list-style-type: none"> • Non-contrast brain perfusion imaging • A sensitive pseudo-continuous labeling technique (pCASL) providing high SNR and contrast • Whole brain coverage with isotropic resolution • Multi-phase ASL for dynamic perfusion assessment and selection of optimal labeling delays. • In-line post-processing within Examcard • Color coded ASL maps with relative quantification bar 	
15	**NMRB484	Bold Specialist	1

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		The BOLD Specialist package provides: <ul style="list-style-type: none"> • High temporal resolution dynamic single slice, multi-slice FFE or FFE-EPI sequences. • Protocol-controlled trigger interface for integrated BOLD analysis environment. • Acquisition of up to 16,000 images. • iView BOLD analysis package providing real-time processing of functional BOLD MR data sets into functional activation maps. 	
16	**NMRB486	FiberTrak Specialist	1
		The FiberTrak Specialist package provides advanced imaging and processing methods for assessment of white matter fiber tracts in the brain. Functionalities include: <ul style="list-style-type: none"> • Diffusion Tensor Imaging (DTI) (up to 32 directions and 16 b-values). • Automatic calculation of Fractional Anisotropy (FA) maps. • Visualization of the white matter tracts using fiber tracking. <p>Fibertracking key features:</p> <ul style="list-style-type: none"> • Advanced 3D visualization of (multiple) white matter fiber tracts. • Overlays of anatomical and Bold Analysis datasets. • 3D display movies of the entire white matter fiber structures. • 2D cross sections of anatomical and Bold Analysis datasets. • 2D color cross sections with fiber tracts. • Multiple ROI fiber tracking. • Statistics on voxels fibers and ROIs. 	
17	**NMRB492	Coronary Acquisition	1
		Enables non-invasive imaging of coronary arteries. Deploys 3D sequences combined with MotionTrak respiratory navigators for real-time motion correction and T2-preparation for good contrast between myocardium and vessels.	
18	**NMRB616	NeuroScience Specialist	1
		Neuroscience Specialist provides functionalities for neuroscience research and neurofunctional imaging, to help e.g. explore structural brain connectivity. Functionality includes: <ul style="list-style-type: none"> • Export functions (NIFTI, XML, SPAR/SDAT are part of basic software) • Extended data size (64k) • B0 mapping • Extended DTI acquisition capabilities with up to 128 b-directions, up to 32 b-values, multi-shell and user defined schemes 	
19	**NMRB618	Cardiac Expert Spec	1

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		Cardiac Expert Specialist adds the following cardiac MR functionality:	
		<ul style="list-style-type: none"> • Acquisition of multi-slice, dynamic tissue studies with saturation prepulse (for T1 weighting). • WET saturation pulses (B1 insensitive) for uniform tissue suppression on 3.0T • Look Locker methods for determination of optimal inversion delay time. • Myocardial tagging with REST grids for regional wall motion studies. • Real-time interactive imaging. 	
20	**NMRB808	Cardiac Quant	1
		Cardiac Quant performs a pixel-wise analysis of myocardial tissue based on T1, T2/R2 and T2*/R2* maps. T1 mapping uses an optimized MODified Look-Locker Inversion recovery (MOLLI) acquisition. On-the-fly parametric maps are overlaid for assessment of myocardial condition with confidence maps for diagnostic quality. Two robust MOLLI schemes (5s(3s)3s and 4s(1s)3s(1s)2s) are provided. T2* mapping is based on single breathhold, multi-echo, ECG-triggered acquisitions to provide T2* and R2* relaxation maps in addition to T2 and R2 maps for assessment of myocardial tissue characteristics.	
21	**NMRB194	FlexCaddy	1
		Coil storage cart which stores dStream coils and accessories to enhance workflow for a large range of clinical applications. Includes:	
		<ul style="list-style-type: none"> • IV pole • Storage for <ul style="list-style-type: none"> • 2x Anterior coils • 1x Head Top / other coil • 1x HeadNeck Top / other coil • 1x Base coil • Accessories 	
22	**NMRB584	Head and Arm Support	1
		Dedicated Head and Arms support enabling enhanced image quality with improved patient comfort through high dS-SENSE acceleration in Body imaging. This device provides comfortable patient positioning and can be used with Head first or Feet First patient positioning. The use of high dS-SENSE acceleration in Body imaging is enabled by the design of the dS Torso coil, allowing dS SENSE factors up to 6 in RL direction. Benefits of this approach are:	
		<ul style="list-style-type: none"> • Improved image sharpness • Reduced image distortion • Less # Breath Holds • Shorter Breath Hold times 	
23	**NMRB032	Pediatric support mattress	1
		This convenient support mattress fits around the pediatric neuro/spine coil, and delivers additional support for the arms and feet of larger babies, up to ~10kg. Will also fit the HFO SENSE head coil, with the use of two additional inserts.	
24	**FMR0340	FlexTilt	1

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		The FlexTilt is an easy to use device which allows the dS Base in combination with the dS Head and dS HeadNeck coils to be tilted. The coils can be tilted up to 18 degrees in incremental steps of 2 degrees.	
25	**FMR0326	Anterior Coil Frame	1
		The Anterior coil frame creates a distance between the coil and the patient thereby avoiding direct contact (e.g. for peripheral vascular disease, pediatric patients).	
26	**989801256069	MR Full Travel Package OffSite	2
		Includes one (1) participant's airfare from North American customer location to Cleveland, Ohio with lodging, ground transportation, and meal expenses. Breakfast/dinner provided by the hotel, and lunch/breaks are catered by Philips. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process. Note: Cancellation/rescheduling policy strictly enforced. Education expires one (1) year from equipment installation date (or purchase date if sold separately).	
27	**989801270041	Spectris Solaris EP Injector	1
		The MEDRAD Spectris Solaris EP MR injection system offers Enhanced Performance capabilities designed for use with scanners up to and including 3T with uncompromised ease of use and more flexibility than ever before. The injector delivers precisely timed injections for performing contrast enhanced MR exams to include, MRA, Dynamic and functional procedures with consistent and reproducible results. Key features include: <ul style="list-style-type: none">• 3T compatibility• Enhance performance battery with increased injections per fully charge battery• Optional integrated Continuous Battery Charger (iCBC) increases operator efficiency by not having to change out the battery• Fiber optic cable enables direct, reliable communication.• Six user- programmable phases for added programming flexibility• Hold or Pause phases for programming delay type and time.• Keep- Vein- Open (KVO)- Function maintains line patency. KVO function operates independently from the injection profile.• Large 115 ml syringe holds sufficient saline for longer KVO and multiple injections.• Continuous status display on optimized color touch screen.• Disposable syringe set SSQK 65/115vs.• One- year warranty.• Installation included in purchase of injection system.• Applications Training included with purchase of injections system. Control room unit <ul style="list-style-type: none">• Dimensions (H x W x D):• 279 mm x 305 mm x 267 mm •• (screen in up position) Integrated Continues Battery Charger (iCBC) <ul style="list-style-type: none">• iCBC provides maximize operator flexibility by not having to change battery• Flexible installation, in-room or out-of-room	

100333 Ingenia 3.0T Omega

Line #	Part #	Description	Qty
		Battery charger	
		<ul style="list-style-type: none"> • Dimensions (H x W x D): • 40 mm x 77 mm x 129 mm 	
		Scan room unit	
		<ul style="list-style-type: none"> • Dimensions (H x W): 1327 mm x 489 mm x 546 mm • Volume Syringe A: 0.5 ml to max. syringe volume in 0.1 ml increments between 0.5 and 31 ml, 1 ml increments for 31 ml and above • Volume Syringe B: 1 ml to max. syringe volume in 1 ml increments • Flow rates: 0.01 to 10 ml/s in 0.01 ml/s increments between 0.01 and 3.1 ml/s, 0.1 ml/s increments for 3.1 ml/s and above • Pressure limitation: 325 psi 	
28	**NNAF952	MR Chiller	1
		Chiller and associated hardware designed in accordance with cooling requirements necessary for selected MR scanner with appropriate ambient and seismic options. Bundle includes chiller, remote display, interface panel and start-up kit. Installation cost is not included.	
29	**NNAF891	Enhanced Warranty Terms	1
		<u>Enhanced Warranty</u>	
		The Philips Ingenia MR System will receive the following service coverage for a period of twelve (12) months after completion of installation or availability for patient use, whichever occurs first.	
		<ul style="list-style-type: none"> • Extended service coverage hours from Monday to Friday, 8am to 9pm • Flexible Planned Maintenance scheduling from Monday to Friday, 7am to 12am and Saturday 8am to 5pm • Onsite labor response of 2 hours • Expedited parts delivery on same day 	
30	SP007	Rigging Charges	1
		Rigging allotment	

100333 Ingenia 3.0T Omega

NET PRICE

\$2,736,599.20

Buying Group: GNYHA

Contract #: GNYHA-IM-016

Add'l Terms: Refer to Contract# noted above for applicable discounts, fees and terms and conditions (Terms), as well as the Terms of Sale printed with this solution to the extent not in express conflict with such Contract Terms.

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is:_____.

If you do not issue formal purchase orders indicate by initialing here_____.

Tax Status:

Taxable_____ Tax Exempt_____

If Exempt, please indicate the Exemption Certification Number:_____, and attach a copy of the certificate.

Delivery/Installation Address:

Invoice Address:

Contact Phone #:

Contact Phone #:

Purchaser approval as quoted:

Date:

Title:

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

100333 Ingenia 3.0T Omega

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
1	**NMRB346	Expansion to dS WholeBody 3.0T	1	\$67,051.41	\$67,051.41	_____

In combination with the dS Torso 3.0T coil solution this expansion provides an integrated coil solution for whole body and peripheral vascular related imaging. It includes an additional FlexCoverage Anterior coil. Combined with the FlexCoverage Posterior, HeadNeck and Base it enables 200 cm coverage, with a maximum of 108 channels.

The flexible, lightweight easy-to-position FlexCoverage Anterior coil is designed to conform both in right-left and foot-head directions for almost any patient. This enables large coverage and comfortable strap-free operation.

- Coverage: 200 cm*
- Maximum nr. of channels: 108
- Main applications: Whole body, Peripheral-vascular, Torso, Chest, Pelvis, Heart
- Coil type: Integrated
- Lightweight coil(s)
- DirectDigital sampling in the coil where the MR signal is at its purest, without loss in the RF chain, enabling:
 - Enhanced SNR
 - dS-SENSE enhanced parallel imaging performance
 - dS-SENSE capable in AP, LR and FH directions
- Only 3 FlexConnect coil connections and cables for fast and easy setup

* WholeBody Specialist required

2	**NMRB254	dS T/R Head 3.0T	1	\$18,950.26	\$18,950.26	_____
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Transmit/receive coil, consisting of a base, sliding coil and head support, that provides excellent spectroscopy results due to its higher B1 field. In addition, it enables imaging of patients with stereotactic frames. The open design reduces claustrophobia, while ensuring good homogeneity.

- Single channel transmit
- Single channel receive
- Main applications: Head, Brain, Spectroscopy, Extremities, Patients with stereotactic frames.

3	**FMR0274	HA FlexTrak	1	\$16,035.79	\$16,035.79	_____
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Dockable patient transport system for simplified patient preparation, handling and transportation from preparation room to the MR scanner, without repositioning the patient.

- HA: Height-adjustable to facilitate easy patient transfer
- Lightweight, easy to maneuver FlexTrak dockable patient transport system docks and undocks quickly and easily with patient support and table top. Docking is possible from both sides.
- Patient and coils can be prepared outside the MR room. No need to remove coils or to reposition patients.
- Integrated coil connections on table and FlexConnect connectors for efficient patient management and rapid evacuation.

100333 Ingenia 3.0T Omega

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
		<ul style="list-style-type: none"> • Easy to use foot pedal locks wheel direction during transport or brakes the FlexTrak while standing still. • When the FlexTrak is positioned and locked against a wall, an adjustable side-rail can be used to prevent a patient from falling. • Optional second FlexTrak offers economical solution to allow improved throughput. • 250 kg / 550 lb capacity 				
4	**NMRB676	dS Pediatric positioning pack	1	\$8,743.41	\$8,743.41	_____
		A comprehensive set of pediatric accessories for dStream systems, including: <ul style="list-style-type: none"> • Baby Support Mattress for small infants that can be used in combination with the dS HeadNeckSpine solution; • The Anterior Coil Frame to create a distance between the coil and the patient thereby avoiding direct contact; • A dedicated Soft Mattress for positioning a 1-5 year old child in the isocenter of the system; • The Comfort pads can be used to create distance between the patient and e.g. the RF coils or the bore of the magnet. They are soft and flexible for easy positioning with a smooth surface for extra comfort. • A Knee Support that allows for comfortable positioning of the patient to reduce patient motion • A set of patient fixation straps 				
5	**NMRB371	Acoustic Hood Ingenia	1	\$4,371.71	\$4,371.71	_____
		The acoustic hood acts as an additional sound absorber to reduce gradient noise levels for the very sensitive ears of babies. Recommended for neonates under sedation, this unit decreases the sound level around the head of the patient by up to 10 dBA.				
6	**989801256382	MRI Baseline Safety Audit OnSite	1	\$13,200.00	\$13,200.00	_____
		MRI Baseline Safety Audit OnSite (Single Site up to 2 magnets): Philips Education representative(s) will conduct a comprehensive MRI Safety assessment in three phases on up to two (2) magnets. Phase One: The Discovery phase will include phone discussions with the customer, exchange of needed information, preparation of a statement of work, review of all shared documents and materials and scheduling/planning Phase Two. Phase Two: The Observation phase consists of the Philips Safety Education representative(s) traveling to the customer site, initial discussions and the tour of the facility. Education representative will observe and photograph all aspects of MRI operations, interview key staff and deliver an MRI Safety lecture if requested. Phase Three: The Reporting phase is where the Philips Education representative(s) review observation data, photographs, and interview notes and creates and electronically submits a detailed report of findings. Note: To have Education representative present findings at customer site, part 989801256385 MRI Safety Audit Follow-Up Visit must be purchased.				

100333 Ingenia 3.0T Omega

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
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For each additional magnet at the same site it is required that part 989801256383 MRI Safety Audit Additional Magnet is purchased. For additional magnets located at a separate location it is required that part 989801256384 MRI Safety Audit Additional Site is purchased for each location.

Education expires one (1) year from equipment installation date (or purchase date if sold separately).

100963 Ambient Experience for MR

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.

Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.

Additional Terms:

Line #	Part #	Description	Qty
1	**NAEA108	Ingenia	1
2	**NAEA161	Ambient Lighting and In-bore Solution	1

This AE promo provides the benefits of Ambient Lighting and the patient in-bore solution. This commercially attractive promo is available for the Ingenia 1.5T, 3T and Ingenia S products. It is not currently available for the Ingenia CX or Achieva dstream, but will be for installs in 2016Q4 forward.

Ambient Experience provides a unique approach to the MR clinical environment. Insights into how people feel, work and interact with each other and with technology are reflected in a purposefully designed environment that combines design strategies and enabling technologies to make patients less anxious, staff more comfortable and hospitals nicer places to be. The solution begins with site-specific recommendations to optimize the clinical area in terms of workflow and storage, including opportunities to minimize clutter for a more soothing environment. These recommendations are incorporated into the equipment Site Plans. A proprietary Control System integrates, dynamic lighting, audio elements and optional video projection to provide both positive distractions for the patient and an opportunity to personalize an otherwise intimidating environment.

The Ambient Experience for MR solution includes:

- Design recommendations to minimize clutter and improve workflow incorporated in Site Plans
- Oversight by Philips Project Manager
- Coordinate communication, resources and implementation logistics, interface with construction contractor and/or architect Control System hardware and cabling
- Outlet/jack for connection to MR audio system
- Patient-selectable theme-controlled color "wall-washing" LED light system
- One touch screen with desk mount and wall mount fixtures
- Ambient Experience functionality such as volume and light intensity control as well as theme or color selection is accessed with a touch screen interface.
- 10 selectable video themes and a palette of selectable colors for LED-created wall wash A breath-hold animation may be initiated from the touch screen, to help familiarize patients with the process of lying still and holding their breath.

Instructions for Use

IMPORTANT: Many of the Ambient Experience architectural requirements are interdependent with the RF shield in the examination room. The selected RF cage vendor must be certified for installation of AE suites.

100963 Ambient Experience for MR

Line #	Part #	Description	Qty
		Note: the lighting component provides decorative lighting only. It is not intended as, nor replaces' functional lighting.	

Patient in-bore solution

The patient in-bore solution is designed to help patients relax and hold still during the MRI examination. Head-first patients get an immersive viewing experience when they are moving into the scanner (patients' highest anxiety moment) and during the examination. Engaging visuals are displayed on the back wall and can be seen via a mirror on the head coil, while patients can listen to music or sound through the Headphone.

Note:

Please take into account the following requirements are met:

1. the magnetic field at the back wall is less than the maximum allowed magnetic field of 10mT AND
2. there is no passive shielding behind the back wall.

Please contact site planning or AE contact person if you have any questions, or need additional support.

Available for Philips Ingenia S only.

100963 Ambient Experience for MR

NET PRICE

\$88,500.00

Buying Group: GNYHA

Contract #:

Add'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is: _____.

If you do not issue formal purchase orders indicate by initialing here _____.

Tax Status:

Taxable _____ Tax Exempt _____

If Exempt, please indicate the Exemption Certification Number: _____, and attach a copy of the certificate.

Delivery/Installation Address:

Invoice Address:

Contact Phone #:

Contact Phone #:

Purchaser approval as quoted:

Date:

Title:

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

Philips Standard Terms and Conditions of Sale

The products and services listed in the quotation are offered by Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") only under the terms and conditions described below (the "Terms and Conditions of Sale").

1. Price: Taxes.

The purchase price stated in the quotation does not include applicable sales, excise, use, or other taxes in effect or later levied. Customer shall provide Philips with an appropriate exemption certificate reasonably in advance of the date the product is available for delivery, otherwise, Philips shall invoice Customer for those taxes, and Customer shall pay those taxes in accordance with the terms of the invoice. Customer is defined as a legal entity, its affiliates and or subsidiaries who purchase product(s), and take title of the purchased product(s) from Philips.

2. Cancellation.

Philips' cancellation policies are set forth in the applicable Product Specific Schedule attached to these Terms and Conditions of Sale.

3. Payment Terms.

3.1 Unless otherwise specified in the quotation, Philips will invoice Customer, and Customer will immediately pay such invoice based on the date of invoice for each product in accordance with the payment terms set forth in the applicable Product Specific Schedule attached to these Terms and Conditions of Sale:

3.2 Orders are subject to Philips' on-going credit review and approval.

3.3 Philips may make partial or early shipments and Customer will immediately pay such invoice based on the date of invoice for each product in accordance with the payment terms set forth in the quotation.

3.4 Customer shall pay interest on any amount not paid when due at the annual rate of twelve percent (12%) or at the maximum rate permitted by applicable law, whichever is lower. If Customer fails to pay any amount when due, in addition to any other rights or remedies available to Philips at law or in equity, Philips may discontinue the performance of services, discontinue the delivery of the product, or deduct the unpaid amount from any amounts otherwise owed to Customer by Philips under any agreement with Customer. In any action initiated to enforce the terms of the quotation following a Customer default or product cancellation under an order arising from the quotation, Philips shall be entitled to recover as part of its damages all costs and expenses, including reasonable attorneys' fees, in connection with such action.

3.5 Credit Card. Philips, at its discretion, will accept a credit card for payment on orders with a net value of \$50,000 or less.

4. Trade - In.

If Customer will be trading-in any equipment ("Trade-In"), then:

4.1 Customer represents and warrants that Customer has good and marketable title to such Trade-In;

4.2 Title to the Trade-In shall pass from Customer to Philips upon Philips making the new equipment available to Customer for first patient use. Removal of the Trade-In from Customer's site shall occur no later than the date Philips makes the new product available for first patient use, unless otherwise agreed in writing between Philips and the Customer;

4.3 Notwithstanding anything to the contrary in any Business Associate Addendum ("BAA"), Customer represents and warrants that Customer has removed or de-identified all Protected Health Information ("PHI") from the Trade-In equipment as of the date the equipment is removed and will otherwise comply with all applicable privacy laws. To the extent Customer has not done so, Customer agrees to reimburse Philips for any out-of-pocket costs Philips incurs to remove or de-identify PHI from the Trade-In.

4.4 Customer will ensure that the Trade-In is clean and sanitized and that all potentially infected materials and biological fluids are removed prior to its de-installation and removal.

4.5 If (a) the condition of the Trade-In is not substantially the same when Philips removes the Trade-In (ordinary wear and tear excepted) as it was when Philips quoted the Trade-In value; or (b) Customer delays the removal of the Trade-In, then Philips may reduce the price quoted for such Trade-In or cancel the Trade-In and Customer will pay the adjustment amount within thirty (30) days of receipt of invoice.

4.6 If Philips does not receive timely possession of the Trade-In, Philips will, at its option, either charge Customer the amount of the Trade-in allowance and cancel the trade-in, re-value the trade-in allowance accordingly, and/or charge Customer a rental fee of 10% of the trade-in allowance per month or partial month until the trade-in is available for removal. Customer will pay any invoiced allowance adjustment or rental fee within thirty (30) days from the invoice date.

4.7 Evidence that Customer intends to trade in an asset as part of the purchase or lease of any product(s) shall be in the form of, but not limited to: (a) receiving a trade in quote and/or authorization from Philips on the value of the asset to be traded in; (b) providing Philips with serial numbers of assets to be traded in; and/or, (c) providing Philips with a de-installation date to remove an existing asset in order to install Philips quoted equipment.

5. Leases. If Customer desires to convert the purchase of any product to a lease, Customer will arrange for the lease agreement and all other related documentation to be reviewed and approved by Philips not later than ninety (90) days prior to the date of the availability for delivery of major components of the product. The Customer is responsible for converting the transaction to a lease, and is required to secure the leasing company's approval of all of these Terms and Conditions of Sale. No product will be delivered to the Customer until Philips has received copies of the fully executed lease documents and has approved the same.

6. Security Interest. By signing the quotation or issuing a purchase order for the products described, Customer hereby grants to Philips a purchase money security interest in the products until all payments have been made. Philips may file a financing statement for such security interest and Customer shall sign any financing statements or other documents necessary to perfect Philips' security interests in the products. Where permitted by applicable law, Customer's signature on the quotation or on a purchase order issued as a result of the quotation gives Philips the right to sign on Customer's behalf and file any financing statement or other documents to perfect Philips' security interest in the product.

7. Shipment and Risk of Loss.

7.1 Delivery terms are stated in the applicable Product Specific Schedule attached to these Terms and Conditions of Sale.

7.2 Except as otherwise stated in the applicable Product Specific Schedule, title to any product (excluding software), and risk of loss or damage shall pass to the Customer F.O.B. destination. Customer shall obtain and pay for insurance covering such risks at destination.

8. Site Preparation and Installation.

8.1 **Site Access.** Customer shall provide Philips full and free access to the installation site and a suitable safe space for the storage of the products before installation. Customer shall ensure, at no charge to Philips, that there are no obstacles preventing Philips from moving the product from the entrance of the Customer's premises to the installation site.

8.2 Site Preparation and Installation.

(a) Customer Responsibility. Customer shall be responsible, at its expense, for rigging, the removal of partitions or other obstacles, installation of safety switch or breaker, and restoration work. The products will be installed during normal working hours. Except where Philips has agreed in writing to provide construction services for a fee pursuant to a construction agreement and scope of work signed by Customer, Customer shall be responsible, at its expense, for the preparation of the installation site where the product will be installed including any required structural alterations. Customer shall provide any and all plumbing, carpentry work, conduit, wiring including communications and/or computer wiring, network equipment, power supply, surge suppression and power conditioning (except to the extent they are expressly included in the quotation), fire protection and environmental controls, ground fault and isolation system, and other fixtures and utilities required to properly attach, install, and use the product. Site preparation shall be in compliance with all applicable laws, including all safety, electrical, and building codes relevant to the product and its installation and use. The sufficiency of any installation site plans shall be the responsibility of Customer. Customer, at its expense, shall obtain all permits and licenses required by federal, state, or local authorities in connection with the installation and operation of the product, including any certificate of need and zoning variances.

(b) Unless otherwise stated by Philips, Customer shall advise Philips of site conditions at or near the location where equipment is installed five (5) days prior to the mutually agreed upon delivery date. The update shall include but not limited to the following:

(i) Hazardous Materials. Asbestos and other hazardous materials that could adversely affect the installation or pose a health or safety risk to Philips' personnel, and Customer shall ensure that those conditions are corrected and hazardous materials removed, and that the site is fully prepared and available to Philips before installation work begins. Customer represents and warrants that an asbestos survey of the facility has been performed to determine the presence, location, quantity and condition of asbestos containing materials (ACM) or presumed asbestos containing materials (PACM) at the facility; and the facility and/or work area does not contain any ACM or PACM or the facility and/or work area contains ACM or PACM, such material has been encapsulated or enclosed and the work will not disturb any such materials.

(ii) Construction. All construction work in technical and operator room(s) is finished including but not limited to the responsibilities identified in 8.2 (a).

(c) Delays. If site preparation is not on schedule five (5) days prior to the mutually agreed upon delivery date or as otherwise specified by Philips, Philips and Customer will conduct an evaluation of the site and establish a revised installation schedule. In the event that installation is delayed by Customer within five (5) days prior to the mutually agreed upon delivery date or after the start of installation, Customer will be responsible for: (i) storage and fees for the preservation and life support of the equipment to ensure high quality and long life of system(s); and, (ii) Costs associated with rescheduling and coordination for all resources and third party providers, including travel costs for split delivery and installation directly related to the delay in installation. If during installation Philips discovers hazardous materials (i.e. asbestos, etc.) all installation activities will stop and Customer will remove and dispose of the hazardous materials. Once the issue giving rise to the delay has been rectified and the site meets the criteria set forth in this Section 8, Philips and Customer will conduct an evaluation of the site and establish a new installation schedule.

(d) Philips Responsibility. Unless additional professional services are purchased separately (including turnkey) and/or professional services are set forth in a statement of work or project implementation plan under the agreement for the product purchased hereunder, Philips role upon delivery will solely be to unpack the product, construct applicable pads (if required for certain products), and connect the product to a safety switch or breaker to be installed by the Customer, and calibrate and test the product.

8.3 PHILIPS MAKES NO WARRANTY AND ASSUMES NO LIABILITY FOR THE FITNESS OR ADEQUACY OF THE SITE IN WHICH THE PRODUCT IS TO BE INSTALLED OR USED. EXCEPT OTHERWISE PROHIBITED BY STATE LAW OR STATE CONSTITUTION CUSTOMER SHALL INDEMNIFY, DEFEND, AND HOLD HARMLESS PHILIPS AND ITS AFFILIATES AGAINST ANY LIABILITIES, COSTS, LOSSES, EXPENSES, PHYSICAL PROPERTY DAMAGES, AND/OR THIRD PARTY CLAIMS, INCLUDING SUBROGATION CLAIMS, COLLECTIVELY ALL THE FOREGOING ARISING FROM OR RELATING TO CUSTOMER'S SITE PREPARATION RESPONSIBILITIES.

8.4 **Local Labor.** If local labor conditions, including but not limited to a requirement to utilize union labor, require the use of non-Philips employees to participate in the installation of the product, then such participation of non-Philips employees shall be at Customer's expense. In such case, Philips will provide engineering supervision during the installation.

8.5 **Remote Services Network ("RSN").** Customer will (a) provide Philips with a secure location at Customer's premises to store one Philips remote services network router and provide full and free access to this router, (or a Customer-owned router acceptable to Philips) for connection to the equipment and to Customer's network; or (c) provide Philips with outbound internet access over SSL; at all times during the warranty period provide full and free access to the equipment and Customer network for Philips' use in remote servicing of the product, remote assistance to personnel that operate the products, updating the products software, transmitting automated status notifications from the product and regular uploading of products data files (such as but not limited to error logs and utilization data for improvement of Philips products and services and aggregation into services). Customer's failure to provide such access will constitute Customer's waiver of the scheduled planned maintenance service and will void support or warranty coverage of product malfunctions until such time as planned maintenance service is completed or RSN access is provided. Customer agrees to pay Philips at the prevailing demand service rates for all time spent by Philips service personnel waiting for access to the products.

9. Product Warranty.

9.1 (a) If a separate product warranty prints as part of the quotation, that product warranty applies to your purchase and is incorporated herein; otherwise Section 9.2-9.7 shall apply unless the product is identified under 9.1 (b). (b) For Patient Care and Monitoring Solutions Portfolio (PCMS), Emergency Care & Resuscitation Portfolio, (ECR) and Medical Supplies Portfolio (MS) Products, the product warranty document can be found at: <http://www.usa.philips.com/healthcare/about/terms-conditions>, or can be provided upon request.

9.2 **Hardware/Systems.** Philips warrants to Customer that the Philips equipment (including its operating software) will perform in substantial compliance with its performance specifications, in the documentation accompanying the products, for a period of 12 months beginning upon availability for first patient use.

9.3 **Stand-alone Licensed Software.** For a period of ninety (90) days from the date Philips makes Stand-alone Licensed Software available for first patient use, such Stand-alone Licensed Software shall substantially conform to the technical user manual that ships with the Stand-alone Licensed Software. "Stand-alone Licensed Software" means sales of Licensed Software without a contemporaneous purchase of a server for the Licensed Software. If Philips is not the installer of the Stand-alone Licensed Software, the foregoing warranty

period shall commence upon shipment.

9.4 If the start of the installation is delayed for any reason beyond the control of Philips for more than thirty (30) days following the date that Philips notifies Customer that the major components of the product are available for delivery, the warranty period begins on the thirty-first (31st) day following that date.

9.5 Philips' sole obligations and Customer's exclusive remedy under any product warranty are limited, at Philips' option, to the repair or the replacement of the product or a portion thereof within thirty (30) days after receipt of written notice of such material breach from Customer ("Product Warranty Cure Period") or, upon expiration of the Product Warranty Cure Period, to a refund of a portion of the purchase price paid by the Customer, upon Customer's request. Any refund will be paid, to the Customer when the product is returned to Philips. Warranty service outside of normal working hours (i.e. 8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips' observed holidays), will be subject to payment by Customer at Philips' standard service rates.

9.6 This warranty is subject to the following conditions: the product: (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips); (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips' written instructions and for the purpose for which the products were intended; and, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the product and Customer is to notify Philips immediately if the product at any time fails to meet its printed performance specifications. Philips' obligations under any product warranty do not apply to any product defects resulting from improper or inadequate maintenance or calibration by the Customer or its agents; Customer or third party supplied interfaces, supplies, or software including without limitation loading of operating system patches to the Licensed Software and/or upgrades to anti-virus software running in connection with the Licensed Software without prior approval by Philips; use or operation of the product other than in accordance with Philips' applicable product specifications and written instructions; abuse, negligence, accident, loss, or damage in transit; improper site preparation; unauthorized maintenance or modifications to the product; or viruses or similar software interference resulting from connection of the product to a network. Philips does not provide a warranty for any third party products furnished to Customer by Philips under the quotation; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described herein and in the applicable product-specific warranty document are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a product warranty.

9.7 THE WARRANTIES SET FORTH HEREIN AND IN PHILIPS' WARRANTY DOCUMENT WITH RESPECT TO A PRODUCT (INCLUDING THE SOFTWARE PROVIDED WITH THE PRODUCT) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE PRODUCT, THE SOFTWARE, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Philips may use refurbished parts in the manufacture of the products, which are subject to the same quality control procedures and warranties as for new products.

10. Philips Proprietary Service Materials.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the products or to assist Philips and its authorized agents to maintain and to service the products under warranty or a separate support agreement with Customer. Customer agrees to restrict access to such software and documentation to Philips' employees and those of Philips' authorized agents only and to permit Philips to remove its Proprietary Service Materials upon request.

11. Patent Infringement Claims.

11.1 Philips shall indemnify, defend, and hold harmless Customer against any new claim that a Philips product provided in the quotation infringes, misappropriates, or violates any third party intellectual property right, whether patent, copyright, trademark, or trade secret, provided that Customer: (a) provides Philips prompt written notice of the claim, (b) grants Philips full and complete information and assistance necessary for Philips to defend, settle, or avoid the claim, and (c) gives Philips sole control of the defense or settlement of the claim.

11.2 The provisions of this section shall not apply if the product is sold or transferred.

11.3 If (a) a Philips product is found or believed by Philips to infringe a valid patent or copyright; or, (b) Customer has been enjoined from using the Philips product pursuant to an injunction issued by a court of competent jurisdiction, Philips may, at its option; (i) procure the right for Customer to use the product; (ii) replace or modify the product to avoid infringement; or, (iii) refund to Customer a portion of the product purchase price upon the return of the original product. Philips shall have no obligation for any claim of infringement arising from: Philips' compliance with Customer's designs, specifications, or instructions; Philips' use of technical information or technology supplied by Customer; modifications to the product by Customer or its agents; use of the product other than in accordance with the product specifications or applicable written product instructions; use of the product with any other product not sold by Philips to Customer and the Philips product in and of itself is not infringing; if infringement would have been avoided by the use of a current unaltered release of the products; or use of the Philips Product after Philips has advised Customer, in writing, to stop use of the Philips Product in view of the claimed infringement. The terms in this section state Philips' entire obligation and liability for claims of infringement, and Customer's sole remedy in the event of a claim of infringement.

12. Limitation of Liability.

THE TOTAL LIABILITY, IF ANY, OF PHILIPS AND ITS AFFILIATES FOR ALL DAMAGES AND BASED ON ALL CLAIMS, WHETHER ARISING FROM OR RELATING TO BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING FROM A PRODUCT, LICENSED SOFTWARE, AND/OR SERVICE IS LIMITED TO THE PRICE PAID HEREUNDER FOR THE PRODUCT, LICENSED SOFTWARE, OR SERVICE GIVING RISE TO THE LIABILITY.

THIS LIMITATION SHALL NOT APPLY TO:

(a) THIRD PARTY CLAIMS FOR DIRECT DAMAGES FOR BODILY INJURY OR DEATH TO THE EXTENT CAUSED BY PHILIP'S NEGLIGENCE OR PROVEN PRODUCT DEFECT;

(b) CLAIMS OF TANGIBLE PROPERTY DAMAGE REPRESENTING THE ACTUAL COST TO REPAIR OR REPLACE PHYSICAL PROPERTY TO THE EXTENT CAUSED BY PHILIPS NEGLIGENCE OR PROVEN PRODUCT DEFECT.

(c) OUT OF POCKET COSTS INCURRED BY CUSTOMER TO PROVIDE PATIENT NOTIFICATIONS, REQUIRED BY LAW, TO THE EXTENT SUCH NOTICES ARE CAUSED BY PHILIPS UNAUTHORIZED DISCLOSURE OF PHI; and,

(d) FINES/PENALTIES LEVIED AGAINST CUSTOMER BY GOVERNMENT AGENCIES CITING PHILIPS UNAUTHORIZED

DISCLOSURE OF PHI AS THE BASIS OF THE FINE/PENALTY, ANY SUCH FINES OR PENALTIES SHALL CONSTITUTE DIRECT DAMAGES.

13. DISCLAIMER.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, BUSINESS INTERRUPTION, LOSS OF DATA, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT.

14. Confidentiality.

Each party shall maintain as confidential any information furnished or disclosed to one party by the other party, whether disclosed in writing or disclosed orally, relating to the business of the disclosing party, its customers, employees, and/or its patients, and the quotation and its terms, including the pricing terms under which Customer has agreed to purchase the products. Each party shall use the same degree of care to protect the confidentiality of the disclosed information as that party uses to protect the confidentiality of its own information, but in no event less than a reasonable amount of care. Each party shall disclose such confidential information only to its employees having a need to know such information to perform the transactions contemplated by the quotation. The disclosing party maintains exclusive ownership of the confidential information which it discloses to the receiving party, and a receiving party shall be responsible for the breach of these confidentiality terms by any of its representatives or other person to whom it may disclose the confidential information. The obligation to maintain the confidentiality of such information shall not extend to information that (a) is or becomes generally available to the public without violation of these Terms and Conditions of Sale or any other obligation of confidentiality or (b) is lawfully obtained by the receiving Party from a third party without any breach of confidentiality or violation of law. Notwithstanding the foregoing, in the event that the receiving party is required by law to disclose any confidential information to a court, government department/agency or regulatory body, the receiving party may so disclose, provided that it shall, to the extent permitted by applicable law, first inform the disclosing party of the request or requirement for disclosure to allow an opportunity for the disclosing party to apply for an order to prohibit or restrict such disclosure. Moreover, nothing set forth herein shall prohibit Customer from disclosing confidential information required by state or federal open records laws, to the extent disclosed in compliance with the rules and procedures applicable thereto, including notifying Philips and providing Philips an opportunity to argue certain information may be exempt as a trade secret, if applicable thereunder

15. Compliance with Laws & Privacy.

15.1 Each party shall comply with all laws, rules, and regulations applicable to the party in connection with the performance of its obligations in connection with the transactions contemplated by the quotation including, but not limited to, those relating to affirmative action, fair employment practices, FDA, Medicare fraud and abuse, and the Health Information Portability and Accountability Act of 1996 ("HIPPA"). Health care providers are reminded that if the purchase includes a discount or loan, they must fully and accurately report such discount or loan on cost reports or other applicable claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, as required by federal law (see 42 CFR 1001.952[h]).

15.2 In the course of providing project implementation related services and/or warranty services to Customer, hereunder, it may be necessary for Philips to have access to, view and/or download computer files from the products that might contain Personal Data. "Personal Data" means information about an identifiable individual, and includes any information that is "personal information" or "personal health information" within the meaning of any applicable privacy laws relating. Personal Data can include both personal health information (i.e., images, heart monitor data, and medical record number) and non-health information (i.e., date of birth, gender). Philips will process Personal Data only to the extent necessary to perform and/or fulfill its project implementation related service, warranty service and/or warranty obligations hereunder. Customer further acknowledges and agrees that all telephone conversations between Philips and Customer may, in Philips discretion, be recorded.

15.3 It is Customer's responsibility to notify Philips if any portion of the order is funded under the American Reinvestment and Recovery Act ("ARRA"). To ensure compliance with the ARRA regulation, Customer shall include a clause stating that the order is funded under ARRA on its purchase order or other document issued by Customer.

15.4 Product Safety and Other Complaints. Customer will report immediately to Philips any event of which Customer becomes aware that suggests that any services or products provided by Philips, for any reason: (a) may have caused or contributed to a death or serious injury, or (b) have malfunctioned where and such malfunctions would be likely to cause or contribute to a death or serious injury if the malfunction were to occur again. Additionally, Customer will also report to Philips complaints it receives from its personnel and patients or any other person regarding the identity, quality, performance, reliability, safety, effectiveness, labels or instructions for use of the services or products provided by Philips. Philips shall be solely responsible for submitting any filings or reports to any government authorities with respect to the Philips products and services provided by Philips hereunder, unless otherwise required by law.

16. Excluded Provider.

As of the date of the sale of this product, Philips represents and warrants that Philips, its employees and subcontractors, are not debarred, excluded, suspended or otherwise ineligible to participate in a federal or state health care program, nor have they been convicted of any health care related crime for the products and services provided under these Terms and Conditions of Sale (an "Excluded Provider"). Philips shall promptly notify Customer if it becomes aware that Philips or any of its employees or subcontractors providing services hereunder have become an Excluded Provider under a federal or state healthcare program, whereupon Customer shall provide Philips with a reasonable opportunity to discuss and attempt to resolve in good faith with Customer any Customer related concerns in relation thereto, and/or will give Philips a reasonable opportunity to dispute its, or its employee's or subcontractor's, designation as an Excluded Provider. In the event that the Parties are unable to resolve any such Customer concerns to the reasonable satisfaction of Customer within sixty (60) days of the applicable party's designation as an Excluded Provider, the Customer may terminate this order by express written notice for products and services not yet shipped or rendered prior to a date of exclusion.

17. (Omnibus Reconciliation Act (OMNI) Social Security (PL96-499, Public Law)

Philips and Customer shall comply with the Omnibus Reconciliation Act of 1980 (P.L. 96-499) and its implementing regulations (42 CFR, Part 420). Philips agrees that until the expiration of four (4) years after furnishing services or products pursuant to these Terms and Conditions of Sale, Philips shall make available, upon written request of the Secretary of the Department of Health and Human Services, or upon request of the Comptroller General, or any of their duly authorized representatives, these Terms and Conditions of Sale and the books, documents and records of Philips that are necessary to verify the nature and extent of the costs charged to Customer hereunder.

Philips further agrees that if Philips carries out any of the duties of these Terms and Conditions of Sale through a subcontract with a value or cost of ten-thousand U.S. dollars (\$10,000.00) or more over a twelve (12) month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four (4) years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request to the Secretary, or upon request to the Comptroller General, or any of their duly authorized representatives the subcontract, and books and documents and records of such organization that are necessary to verify the nature and extent of such costs. This paragraph relating to the retention and production of documents is included because of possible application of Section 1861(v) (1) (1) of the Social Security Act (42 U.S.C. 1395x (v) (1) (I) (1989)), as amended from time to time to these Terms and Conditions of Sale. If Section 1861(v) (1) (1) should be found to be inapplicable, then this paragraph shall be deemed inoperative and without force and effect.

18. General Terms.

The following additional terms shall be applicable to the purchase of a product:

18.1 Force Majeure. Each party shall be excused from performing its obligations (except for payment obligations) arising from any delay or default caused by events beyond its reasonable control including, but not limited to, acts of God, acts of third parties, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or mandatory direction, request, shortage of labor, materials or manufacturing facilities. For clarity, Customer requests shall not be considered 'government' requests under this section 17.1.

18.2 Bankruptcy. If Customer becomes insolvent, is unable to pay its debts when due, files for bankruptcy, is the subject of involuntary bankruptcy, has a receiver appointed, or has its assets assigned, Philips may cancel any unfulfilled obligations, or suspend performance; however, Customer's financial obligations to Philips shall remain in effect.

18.3 Assignment. Customer may not assign any rights or obligations in connection with the transactions contemplated by the quotation without the prior written consent of Philips, which consent shall not be unreasonably withheld, and any attempted assignment without such consent shall be of no force or effect.

18.4 Export Controls. Customer shall assume sole responsibility for obtaining any required export authorizations in connection with Customer's export of the products from the country of delivery.

18.5 Governing Law. All transactions contemplated by the quotation shall be governed by the laws of the province where the equipment will be installed, without regard to that province's choice of law principles. EACH PARTY, KNOWINGLY AND AFTER CONSULTATION WITH COUNSEL, FOR ITSELF, ITS SUCCESSORS' AND ASSIGNS, WAIVES ALL RIGHT TO TRIAL BY JURY OF ANY CLAIM ARISING WITH RESPECT TO THIS AGREEMENT OR ANY MATTER RELATED IN ANY WAY THERETO.

18.6 Entire Agreement. These Terms and Conditions of Sale, the terms and conditions set forth in the quotation and the applicable Philips' product-specific warranty constitute the entire understanding and agreement by and between the parties with respect to the transactions contemplated by the quotation, and supersede any previous understandings or agreements between the parties, whether written or oral, regarding the transactions contemplated by the quotation. The pricing in the quotation is based upon the terms and conditions in the quotation. No additional terms, conditions, consents, waivers, alterations, or modifications shall be binding unless in writing and signed by the parties. Customer's additional or different terms and conditions, whether stated in a purchase order or other document issued by Customer, are specifically rejected and shall not apply to the transactions contemplated by the quotation.

18.7 Headings. The headings in the quotation are intended for convenience only and shall not be used to interpret the quotation.

18.8 Severability. If any provision of the quotation is deemed to be illegal, unenforceable, or invalid, in whole or in part, the validity and enforceability of the remaining provisions shall not be affected or impaired, and shall continue in full force and effect.

18.9 Notices. Notices or other communications shall be in writing, and shall be deemed served if delivered personally, or if sent by facsimile transmission, by overnight mail or courier, or by certified mail, return receipt requested and addressed to the party at the address set forth in the quotation.

18.10 Performance. The failure of Customer or of Philips at any time to require the performance of any obligation will not affect the right to require such performance at any time thereafter. Course of dealing, course of performance, course of conduct, prior dealings, usage of trade, community standards, industry standards, and customary standards and customary practice or interpretation in matters involving the sale, delivery, installation, use, or service of similar or dissimilar products or services shall not serve as references in interpreting the terms and conditions of the quotation. **18.11 Obligations.** Customer's obligations are independent of any other obligations the Customer may have under any other agreement, contract, or account with Philips. Customer will not exercise any right of offset in connection with the terms and conditions in the quotation or in connection with any other agreement, contract, or account with Philips. **18.12 Additional Terms.** The Product specific schedules listed below are incorporated herein as they apply to the equipment listed on the quotation and their additional terms shall apply solely to Customer's purchase of the products specified therein. If any terms set forth in a schedule conflict with terms set forth in these Terms and Conditions of Sale, the terms set forth in the schedule shall govern. (a) Schedule 1: Imaging Systems Portfolio (IS).

18.11 Obligations. Customer's obligations are independent of any other obligations the Customer may have under any other agreement, contract, or account with Philips. Customer will not exercise any right of offset in connection with the terms and conditions in the quotation or in connection with any other agreement, contract, or account with Philips.

18.12 Additional Terms. The Product Specific Schedules listed below are incorporated herein as they apply to the equipment listed on the quotation and their additional terms shall apply solely to Customer's purchase of the products specified therein. If any terms set forth in a Product Specific Schedule conflict with terms set forth in these Terms and Conditions of Sale, the terms set forth in the schedule shall govern.

(a) Schedule 1: Imaging Systems Portfolio (IS) ("Product Specific Schedules").

LICENSED SOFTWARE

1. License Grant

1.1 Subject to any usage limitations for the Licensed Software set forth on the product description of the quotation, Philips grants to Customer a nonexclusive and non-transferable right and license to use the computer software package ("Licensed Software") in accordance with the terms of the quotation and these Terms and Conditions of Sale. The License shall continue for as long as Customer continues to own the product, except that Philips may terminate the License if Customer is in breach or default of these Terms and Conditions of Sale and/or the quotation. Customer shall return the Licensed Software and any authorized copies thereof to Philips immediately upon expiration or termination of this License.

1.2 The License does not include any right to use the Licensed Software for purposes other than the operation of the product. Customer may make one copy of the Licensed Software in machine-readable form solely for backup purposes. Philips reserves the right to charge for backup copies created by Philips. Except as otherwise provided under section 1.6, Customer may not copy, reproduce, sell, assign, transfer, or sublicense the Licensed Software for any purpose without the prior written consent of Philips. Customer shall reproduce Philips' copyright notice or other identifying legends on such copies or reproductions. Customer will not (and will not allow any third party to) decompile, disassemble, or otherwise reverse engineer or attempt to reconstruct or discover the product or Licensed Software by any means whatsoever.

1.3 The License shall not affect the exclusive ownership by Philips of the Licensed Software or of any trademarks, copyrights, patents, trade secrets, or other intellectual property rights of Philips (or any of Philips' suppliers) relating to the Licensed Software.

1.4 Customer agrees that only authorized officers, employees, and agents of Customer will use the Licensed Software or have access to the Licensed Software (or to any part thereof), and that none of Customer's officers, employees, or agents will disclose the Licensed Software, or any portion thereof, or permit the Licensed Software, or any portion thereof, to be used by any person or entity other than those entities identified on the quotation. Customer acknowledges that certain of Philips' rights may be derived from license agreements with third parties, and Customer agrees to preserve the confidentiality of information provided by Philips under such third party license agreements.

1.5 The Licensed Software shall be used only on the product(s) referenced in the quotation.

1.6 Customer may transfer the Licensed Software in connection with sale of the product to a healthcare provider who accepts all of the terms and conditions of this License; provided that Customer is not in breach or default of this License, the Terms and Conditions of Sale, or any payment obligation to Philips.

2. Modifications.

2.1 If Customer modifies the Licensed Software in any manner, all warranties associated with the Licensed Software and the products shall become null and void. If Customer or any of its officers, employees, or agents should devise any revisions, enhancements, additions, modifications, or improvements in the Licensed Software, Customer shall disclose them to Philips, and Philips shall have a non-exclusive royalty-free license to use and to sub-license them.

2.2 The Licensed Software is licensed to Customer on the basis that (i) Customer shall maintain the configuration of the products as they were originally designed and manufactured and (ii) the product includes only those subsystems and components certified by Philips. The Licensed Software may not perform as intended on systems modified by other than Philips or its authorized agents, or on systems which include subsystems or components not certified by Philips. Philips does not assume any responsibility or liability with respect to unauthorized modification or substitution of subsystems or components.

Philips Std Terms and Conditions of Sale_Rev. M.09.2016

Imaging Systems Portfolio (IS)
Schedule 1

Interventional X-Ray (iXR), IntelliSpace Portal (ISP), Digital Radiography (DR), Mobile Radiography (MDR), Radiography and Fluoroscopy (RF), C-Arms (surg), Women's Healthcare (WHC) Mammography Products, Computed Tomography (CT), Magnetic Resonance (MR), Invivo, Positron Emission Tomography (PET/CT), Advanced Molecular Imaging (SPECT & SPECT/CT) and Radiation Oncology (PROS)

1. Payment Terms.

Unless otherwise specified in the quotation, Philips will invoice Customer, and Customer will pay such invoice on receipt, as follows:

1.1 For Imaging Systems Portfolio

(a) 10% of the purchase price shall be due with Customer's submission of its purchase order.

(b) 70% of the purchase price shall be due on delivery of the major components of the product. Product installation will not begin until Customer has paid this portion of the purchase price.

(c) 20% of the purchase price shall be due net thirty (30) days from the date the product is available for first patient use. Available for first patient use means the product has been installed and substantially meets Philips' published specifications.

1.2 If the start of the installation is delayed for any reason beyond the control of Philips for more than thirty (30) days following the date that Philips notifies customer that the major components of the product are available for delivery, the unpaid portion of the purchase price shall be due on the thirty-first (31st) day following such date.

2. Cancellation. The quotation is subject to change or withdrawal prior to written acceptance by Customer. All purchase orders issued by Customer are subject to acceptance by Philips. If Customer cancels an order prior to product shipment, Customer shall pay a cancellation charge of fifteen percent (15%) of the net order price. Orders are non-cancellable for Products shipped.

3. Delivery.

3.1 Philips will use reasonable efforts to ship the Product to the Customer by: (a) by the mutually agreed upon shipment date; or (b) by the date stated in the quotation; or (c) as otherwise agreed in writing. Philips will ship the Product according to Philips' standard commercial practices. Philips will deliver the equipment during normal working hours, 8:00 - 5:00 PM, in the time zone where the Customer is located. Philips may make partial shipments. Philips will pay shipping costs associated with Product shipment.

3.2 Prior to the shipment of any Product, Philips may change the construction or the design of the product without notice to the Customer so long as the function, footprint, and performance of the Product are not substantially altered.

3.3 If Customer requests a delay in the date major components of the Product are available for delivery, then Philips will place the Product in storage and the unpaid portion of the purchase price shall be due. Customer will reimburse Philips for all storage fees, transportation expenses, and related costs incurred by Philips upon receipt of invoice.

4. Additional Customer Installation Obligations for Magnetic Resonance.

4.1 Customer shall provide any and all site preparation and shall be in compliance with all RF or magnetic shielding and acoustical suppression and building codes relevant to the Product and its installation and use.

4.2 Customer's contractor or Customer's architect is required to provide detailed information on the proposed Helium Exhaust Pipe for their MRI system prior to installation to ensure safety specifications are being met.

Required Details include:

(a) Architectural drawing or sketch with complete dimensions including lengths, bending radii, bending angles, and pipe diameters for entire Helium Exhaust Pipe run from RF enclosure to discharge location.

(b) Completed Helium Exhaust Pipe Verification Checklist (Provided by Local Philips Project Manager)

(c) Picture showing the area where the Helium Exhaust Pipe will discharge.

4.3 Magnets will not be released for delivery unless and until Helium Exhaust Pipe details are provided for verification and have been confirmed to meet all life safety specifications.

4.4 Costs of equipment preservation, to ensure a high quality system, will be passed to the Customer if the installation site is not ready due to delays not caused by Philips. Additionally, climate control costs during and after equipment installation are also the responsibility of the Customer. Preservation of equipment is required to prevent exposing equipment to the negative effects of a non-climate controlled construction environment, where there is dust or high humidity. Climate control could include costs associated with ensuring a climate controlled environment. Activates and expenses required for preservation may include time, materials, and transportation to package and seal, and transport the equipment to a controlled environment to prevent dust from entering the equipment. For MR this includes the consumption of Helium for life support.

5. Additional Terms Related to Sales of the IntelliSpace Breast Solution, including the MammoDiagnost VU.

5.1 **Installation.** Philips will install the IntelliSpace Breast Solution and perform installation tests on the application running with the hardware provided as part of the solution, including the MammoDiagnost VU. Philips will also configure and provides interfaces to the equipment and information systems set forth in a statement of work signed by Philips and the Customer. Interfaces as set forth in Subsection 5.2 below are Customer's responsibility and are not part of Parts installation deliverables.

5.2 **Customer's Interface Obligations for Third Party RIS and MIS Applications.** Customer is responsible to develop and implement interfaces from the Licensed Software running on the client workstation to any third party Radiology Information System ("RIS") or Mammography Information System ("MIS") or to contract with the RIS and/or MIS vendor to have them perform these interface obligations on Customer's behalf. Interfacing the solution from the solutions server is not permitted. Philips shall provide Customer an API toolkit for the Licensed Software to aide Customer to perform such interface tasks. The successful and reasonably timely completion of these projects takes good faith efforts on the part of both Philips and Customer, especially when Customer has third party interfaces to develop and implement. A project implementation plan will be developed by Philips and the Customer based on completion dates mutually agreed by the parties that should be reflective of the obligations of both parties. These dates will be entered into the project implementation plan for this solution (the "Project Implementation Plan"). In the event Customer has not fulfilled its interface obligations by the dates set forth in the Project Implementation Plan, Customer will sign Philips' acceptance (MDIR) document for the Philips deliverables sold and pay the final payment described in Subsection 1.1(c), provided that Philips has installed the Philips deliverables and provided the interfaces Philips is responsible for pursuant to Subsection 5.1, and that the Philips deliverables substantially meet

Philips' published specifications.

5.3 Prior Validation of Operating System Updates and/or Upgrades. Patches introduced by operating system original equipment manufacturers (an "OEM") or upgrades to anti-virus software can impact the performance and functionality of the applications that run on them and affect patient safety. Philips shall perform validation testing of certain Microsoft operating systems and McAfee anti-virus software during the warranty period. Philips shall have no obligation to validate any other third party operating system or anti-virus software. Customer shall not install or use (a) operating system patches, updates or upgrades; (b) anti-virus updates (except to the DAT files, i.e., virus definitions); or, (c) upgrades to anti-virus search engines, collectively (a)-(b) prior to validation testing and approval by Philips ("Unauthorized Updates"). Philips shall have no liability, including, without limitation, for warranty claims, arising from use of the Licensed Software with Unauthorized Updates. In the event Philips discovers that Customer is using an Unauthorized Update with the Licensed Software, Philips shall have the right to require Customer to roll back to the most recently validated versions of operating systems and anti-virus, prior to performing any support.

5.4 Customer's Network Connectivity Obligations. Customer must have network connectivity between the IntelliSpace Breast solution server, the client workstation, and the optional DynaCAD server of not less than 1GB/s, and all three systems must be on the same subnet. A connection of no less than 100 MB/s is required between the IntelliSpace Breast solution and the hospital network. However for optimal performance a 1GB/s network between the IntelliSpace Breast and the hospital network is recommended.

5.5 RSN Warranty Condition Requirement. As a condition to receiving warranty service on this solution, Customer agrees it shall use Philips Remote Service Network ("RSN") service to enable Philips to access the system to perform its support obligations.

PHILIPS PRODUCT WARRANTY

MAGNETIC RESONANCE (MR) SYSTEMS

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

TWELVE-MONTH SYSTEM WARRANTY

Philips warrants to Customer that the MR System (the System) as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months after completion of installation or first patient use, whichever occurs first. If coils, chiller unit, power conditioner unit, or injector unit are purchased from Philips, they will be covered by the special warranty set forth below.

MAGNET MAINTENANCE SERVICE

During the warranty period, Philips' service personnel shall provide magnet maintenance service. The liquid helium (cryogen) levels are monitored and the boil off rate is calculated remotely and maintained within Philips Remote Services. When necessary, cryogen is transferred from Dewars (shipping containers) to the System magnet. If cryogen supplies are required, they will be provided to maintain the magnet at operating temperature after delivery and initial cool down.

PLANNED MAINTENANCE

During the warranty period, Philips' service personnel will schedule planned maintenance visits in advance at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M., excluding Philips observed holidays.

SYSTEM OPTIONS

Any commercially available options or accessories for the System which are delivered and/or installed by Philips hereafter on the System shall be subject to the same warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire: a) upon termination of the initial twelve (12) month warranty period for the System on which the option or accessory is installed, b) after ninety (90) days for parts only from the date of installation, or c) on the annual renewal date of any current service agreement on the System.

SYSTEM UPGRADES

Any commercially available upgrade to the System which is hereafter installed by Philips shall be subject to the warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire: a) upon termination of the initial twelve (12) month warranty period for the System on which the upgrade is installed, b) after ninety (90) days for parts only from the date of installation, or c) on the annual renewal date of any current service agreement on the system.

RF SURFACE COILS

The System can be purchased with optional RF surface coils ("coils"). If coils are purchased with the System, Philips will include the coils under the System warranty. Third party coils will not be covered under this warranty.

CHILLER UNIT, POWER CONDITIONER UNIT OR INJECTOR UNIT

The System can be purchased with an optional Chiller Unit, Power Conditioner Unit or Injector Unit. If any of these Units are purchased with the System, Philips will include these Units under the twelve (12) month System warranty as an OEM warranty pass through. Authorized representatives of the Original Equipment Manufacturer will perform warranty service on each of these units.

SYSTEM SOFTWARE AND SOFTWARE UPDATES

The software provided with the System will be the latest version of the standard software available for that System as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product, and/or located at Customer's premises, is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS

Philips' obligations under the System warranty are limited, at Philips' option, to the repair or the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund or credit will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as all other components in the System. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents, Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or, to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Repairs or replacement parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN PHILIPS' WARRANTY DOCUMENT WITH RESPECT TO THIS SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, THE SOFTWARE, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ACCESS TO SYSTEM

Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

WARRANTY SERVICE

In the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Philips normal working hours, Customer agrees to pay for such services at Philips standard service rates in effect. Maintenance Agreements are available for extended coverage.

TRANSFER OF SYSTEM

In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation. Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this warranty.

CONDITIONS

This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, (d) Customer is to notify Philips immediately in the event the System at any time fails to meet its printed performance specifications, and (e) only Philips personnel acting under the direct supervision of Philips service management are to perform all maintenance of the cryogen subsystem (including replenishment of cryogen).

LIMITATIONS OF LIABILITY AND DISCLAIMERS

Quotation #: 1-1JIFD6U

Rev.: 7

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The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT. PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

FORCE MAJEURE

Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03237 999

Non Disclosure Agreement for Philips Confidential Pricing Information

The parties specified below agree to the following terms:

A. Philips

Name	Philips Healthcare, a division of Philips Electronics North America Corporation
Address	22100 Bothell-Everett Highway, Bothell, WA 98021 United States of America

B. Company

Name	CONNECTICUT CHILDRENS MEDICAL CTR
Address	282 WASHINGTON ST HARTFORD, CT 06106-3322

C. Confidential Information

Authorized Purpose	To evaluate Philips' confidential information relating to pricing for imaging equipment ("Pricing") in connection with the potential purchase of such imaging equipment.
Period	Begins on the date Pricing is first disclosed and continues for 5 years from date Pricing is last disclosed.

D. Philips Contact

Name	Eugene Prendergast
Title	
Telephone	(914) 806-2268
Fax	(425) 458-0390
e-mail	
Signature	

Company Contact


Name	
Title	
Telephone	
Fax	
e-mail	
Signature	

1. The following terms and conditions (the "Agreement") apply to Pricing disclosed by Philips and its Affiliates ("Philips") to Company and its Affiliates ("Company"), in connection with the Authorized Purpose.
 - (a) Subject to Philips' prior written consent, Company may disclose, or request that Philips disclose, Pricing to Company's Affiliates that need to know the Pricing for carrying out the Authorized Purpose, provided they are advised of and agree to be bound by this Agreement. Company is responsible for any breach of this Agreement by its Affiliates.
 - (b) An Affiliate is any corporation, company, or other entity, that: (i) is under the Control of a party hereto; or (ii) has Control of a party hereto; or (iii) is under common Control with a party hereto. For this purpose "Control" means that more than fifty percent (50%) of the controlled entity's shares or ownership interest representing the right to make decisions for such are owned or controlled, directly or indirectly, by the controlling entity.
2. Philips may disclose Pricing to Company with respect to the Authorized Purpose in writing, orally, or otherwise. All information is assumed to be Pricing, and confidential, if the confidential or proprietary nature is reasonable under the circumstances.
3. All Pricing disclosed by Philips shall remain Philips' the property. Company does not, by implication, estoppel, or otherwise, acquire any intellectual property right, title, or ownership, nor a license to any such intellectual property right, with respect to any Pricing disclosed by Philips hereunder.
 ALL PRICING IS PROVIDED ON AN "AS IS" BASIS, WITHOUT ANY WARRANTY WHATSOEVER. PHILIPS SHALL HAVE NO LIABILITY WHATSOEVER RESULTING FROM THE USE OF THE INFORMATION PROVIDED.
4. Company shall:
 - (a) not use the Pricing for any purpose other than the Authorized Purpose;
 - (b) not disclose the Pricing to any third party;
 - (c) protect the Pricing against disclosure in the same manner and with the same degree of care with which Company protects its own confidential information but not less than a reasonable degree of care; and
 - (d) limit circulation of the Pricing to Company's employees as have a need to know in connection with the Authorized Purpose.
 These obligations shall survive the termination of this Agreement. Philips may terminate this Agreement at any time by means of a written notice to Company. Company shall return to Philips, or certify destruction of, all Pricing, immediately upon termination or expiration of this Agreement.
5. Information disclosed by Philips to Company pursuant to this Agreement shall not be confidential to the extent that the information:
 - (a) is or becomes part of the public domain without violation of this Agreement or any other obligation of confidentiality;
 - (b) is known by Company prior to disclosure by Philips;
 - (c) is lawfully obtained by Company from a third party without any breach of confidentiality or violation of law; or
 - (d) is developed by Company completely independently of any such disclosure by Philips.
6. If Company is required, pursuant to administrative or judicial action or subpoena, to disclose the Pricing, Company shall use its best efforts to maintain the confidentiality of the Pricing, e.g. by asserting in such action any applicable privileges. Immediately after gaining knowledge or receiving notice of such action or subpoena, Company shall notify Philips and give Philips the opportunity to seek any other legal remedies so as to maintain such Pricing in confidence, including a reasonable protective order.
7. Company may not transfer or assign any or all of its rights and/or obligations or delegate the performance of any or all of its obligations under this Agreement, directly or indirectly, through acquisition, merger or otherwise, without the prior written consent of Philips. Any transfer, assignment or delegation in contravention of the foregoing shall be void.
8. Company shall not disclose, export or release the Pricing in contravention of any applicable laws or regulations.
9. This Agreement shall be governed and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws provisions.
10. This Agreement contains the entire understanding of the parties and supersedes any previous understandings or agreements with respect to the subject matter hereof. This Agreement may be amended only in writing signed by authorized representatives of each party.

Pricing NDA ver1 – 8/9/07

EXHIBIT

6

	CCMC Corporation		
	<input checked="" type="checkbox"/> Connecticut Children's Medical Center	<input type="checkbox"/> CCMC Affiliates, Inc.	
	<input checked="" type="checkbox"/> Connecticut Children's Specialty Group, Inc.	<input type="checkbox"/> Connecticut Children's Medical Center Foundation, Inc.	
	Fiscal	Date Effective:	October 1, 2016
	Policy: Patient Financial Assistance, Billing, Credit, and Collections	Date of Origin:	March 1, 2002
Approved By: Finance Administration, Administrative Policy Council	Date Approved:	September 26, 2016	

Patient Financial Assistance

I. Purpose

Connecticut Children's Medical Center and Connecticut Children's Specialty Group, Inc. (collectively "CT Children's") are dedicated to improving the physical and emotional health of children through family-centered care, research, education and advocacy. We embrace discovery, teamwork, integrity and excellence in all that we do.

Accordingly, CT Children's is committed to providing financial assistance to families who have healthcare needs and are uninsured, underinsured, ineligible for other government assistance, or are otherwise unable to pay for emergent or other medically necessary care based on their individual financial situations. The purpose of this policy is to outline eligibility criteria, parameters, and the process for providing fair and consistent financial assistance to our patients and families.


Financial assistance is only available for emergency or other medically necessary healthcare services. Not all services provided within a Connecticut Children's Medical Center hospital facility are covered under this Financial Assistance Policy ("FAP"). Please refer to Appendix A for a list of providers that provide emergency or other medically necessary healthcare services within a Connecticut Children's Medical Center hospital facility. This appendix specifies which providers are covered under this FAP and which are not. The provider listing will be reviewed quarterly and updated; if necessary.

II. Policy

It is the policy CT Children's to recognize and acknowledge the financial needs of patients and/or their families who are unable to afford the charges associated with their emergency or medically necessary healthcare services.

CT Children's will make every effort to be flexible and responsive to individual circumstances. In return, it is expected that patients and/or their families will honor their financial obligations to the extent they have the financial ability to pay for their medical services. Patients are expected to cooperate with CT Children's policies and procedures so that CT Children's remains able to provide care for those patients and/or their families whose circumstances in life are less fortunate.

It is the policy of CT Children's to provide, without discrimination, care for all emergency medical conditions to individuals regardless of their financial assistance eligibility or ability to pay. It is the policy of CT Children's to comply with the standards of the Federal Emergency Medical Treatment and Active Labor Transport Act of 1986 ("EMTALA") and the EMTALA regulations in providing a medical screening examination and such further treatment as may be necessary to stabilize an emergency medical condition for any individual coming to the emergency department seeking treatment. Additionally, CT Children's prohibits any actions that would discourage patients from seeking emergency medical care.

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	Fiscal	Date Effective:	October 1, 2016
	Policy: Patient Financial Assistance, Billing, Credit, and Collections	Date of Origin:	March 1, 2002
Approved By: Finance Administration, Administrative Policy Council	Date Approved:	September 26, 2016	

III. Definitions

Amounts Generally Billed (AGB): Pursuant to Internal Revenue Code ("IRC") §501(r)(5), in the case of emergency or other medically necessary care, the amounts generally billed for emergency or other medically necessary care to individuals who have insurance covering such care.

Amounts Generally Billed Percentage: A percentage of gross charges that a hospital facility uses to determine the AGB for any emergency or other medically necessary care it provides to an individual who is eligible for assistance under this FAP.

Application Period: The time period in which an individual may apply for financial assistance. To satisfy the criteria outlined in IRC §501(r)(6), CT Children's allows individuals up to one (1) year from the date the individual is provided with the first post-discharge billing statement to apply for financial assistance. Applications outside of the one year window will be reviewed and considered on an individual basis with approval by management.

Eligibility Criteria: The criteria set forth in this FAP (and supported by procedure) used to determine whether or not a patient qualifies for financial assistance.

Emergency medical conditions: Defined within the meaning of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

Extraordinary Collection Actions ("ECAs"): Includes any of the following actions taken by CT Children's against an individual related to obtaining payment of a bill for care covered under this FAP. ECAs include, but are not limited to, actions that require a legal or judicial process, reporting adverse information to consumer credit reporting agencies or credit bureaus, placing of a lien and/or foreclosing on real property, attaching or seizing a bank account or garnishment of wages, and deferring, denying or requiring payment prior to providing non-emergency medical care due to nonpayment of debt for previously provided care covered under the Policy.


Family: Using the Census Bureau definition, a group of two or more people who reside together and who are related by birth, marriage, civil union or adoption.

Family Income: Family Income is determined using the Census Bureau definition, which uses the following income when computing poverty guidelines:

- Income earnings, unemployment compensation, worker's compensation, Social Security, Supplemental Security Income, public assistance, veterans' payments, survivor benefits, pension or retirement income, interest, dividends, rents, royalties, income from estates, trusts, educational assistance, alimony, child support, assistance from outside the household, and other miscellaneous resources.

Family Size: The total number of family members living in the same household, who meet at least one of the following characteristics:

- Parent/Guardian (including step-parent regardless of guardianship status);
- Each child up to the age of 18;

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- A family member between the ages of 18 and 25, who is enrolled as a full-time high school, college or trade-school student;
- An elderly (over the age of 65) or disabled and not a minor (as defined by Medicaid or State welfare guidelines) family member, who is not collecting Social Security benefits.

FAP-eligible: Individuals who are eligible for full or partial financial assistance under this policy.

Federal Poverty Level Guidelines: The federal poverty level guidelines ("FPL") are established by the United States Department of Health and Human Services on an annual basis and are used within this FAP for determining financial eligibility.

Financial Assistance: Free or discounted healthcare services offered to individuals who are unable to pay for all or a portion of their medical services.

Free Bed Funds: Funds or assets donated to Connecticut Children's, Hartford Hospital, or John Dempsey Hospital (the pediatric services of which have been moved to Connecticut Children's) for pediatric patients who meet the guidelines set by the donor.

Gross Charges: The full established price for medical care that is consistently and uniformly charged to patients before applying any contractual allowances, discounts or deductions.

Medically necessary services: Health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with the generally accepted standards of medical practice; (b) clinically appropriate; and (c) not primarily for the convenience of the patient.

Plain Language Summary ("PLS"): A written statement which notifies an individual that CT Children's offers financial assistance under this FAP and provides additional information in a clear, concise and easy to understand manner.


Underinsured: An individual who has some level of insurance or third party coverage, but still has out-of-pocket healthcare costs that exceed their financial abilities. Underinsurance includes, but is not limited to, deductibles, coinsurance, co-payments, exhausted benefits and lifetime benefit limits.

Uninsured: An individual who has no level of insurance or third party coverage, including Medicare, Medicaid, Champus, or any other government or commercial insurance program, to help pay for healthcare services.

Non-covered services: Services that are not covered under the patient's benefits / insurance plan and therefore will not be paid by the patient's insurance plan.

IV. Financial Assistance Eligibility Criteria

Eligibility for financial assistance will be considered for individuals who are uninsured, underinsured, ineligible for any government healthcare benefit program, and who are unable to pay for their care, based

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upon determination of financial need in accordance with this FAP. The granting of financial assistance shall be based on an individualized determination of financial need, and shall not take into account age, gender, race, social or immigrant status, sexual orientation or religious affiliation.

Eligibility for financial assistance is based on FPL, which is dependent upon family size and family income.

Please note, per CT Children's internal policies financial assistance eligibility will be determined in the following manner:

- Household income (patient + family members) will determine financial assistance eligibility if services rendered while the patient was a minor;
- The patients income and/or letter or support will determine financial assistance eligibility if services were rendered while the patient was over 17 years old;
- Household income will determine financial assistance eligibility if the patient is disabled and over 17 years old.

Eligibility determination is automated through Experian. If Experian is unable to process an application or there is a discrepancy in the results of an application, further information may be needed from the guarantor in order to complete the application process. Please refer to Section VI, Applying for Financial Assistance, for additional information.

Full Financial Assistance (Free Care)

Patients with family income at or below 250% of FPL are eligible for full financial assistance. These patients may qualify for a 100% discount of billed charges for emergency and medically necessary healthcare services or insurance cost shares (co-pays, coinsurance and deductibles).


Partial Financial Assistance (Discounted Care)

Patients with family income over 250% but less than or equal to 500% of FPL are eligible for partial financial assistance. These patients may qualify for a 45% discount of billed charges for emergency and medically necessary healthcare services or insurance cost shares (co-pays, coinsurance and deductibles).

Patients who qualify for a 45% discount will be asked to establish a payment plan at the time of the application's approval. The financial counselor will collect the first payment at the time of establishing the payment plan.

V. Basis for Calculating Amounts Charged

In accordance with IRC §501(r)(5) CT Children's utilizes the Look-Back Method to calculate the AGB. The AGB % is calculated annually and is based on all claims allowed by Medicare Fee-for-Service + all Private Health Insures over a 12-month period, divided by the gross charges associated with those claims. The applicable AGB % will be applied to gross charges to determine the AGB. The AGB percentages for Connecticut Children's Medical Center and Connecticut Children's Specialty group are as follows:

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Connecticut Children's Medical Center: 59%

Connecticut Children's Specialty Group: 77%

Any individual determined to be eligible for financial assistance under this FAP will not be charged more than AGB for any emergency or other medically necessary healthcare services. Any FAP-eligible individual will always be charged the lesser of AGB or any discount available under this policy.

VI. Applying for Financial Assistance

Financial Counselors are available to assist families who are uninsured, underinsured, or may need financial assistance or to set up payment arrangements. Financial Counselors will assist with applying for different government programs and advise on how to proceed. Individuals are encouraged to contact CT Children's financial counselors when your child is scheduled for a procedure or surgery, scheduled to be admitted, is currently hospitalized or has recently visited our emergency department or been discharged from our care.

If your family does not qualify for any type of government programs, our counselors will review your financial status to see if you meet guidelines for special programs, Patient Financial Assistance, or hospital Free Bed Funds.

Patients who meet the eligibility criteria and wish to apply for the financial assistance offered under this FAP can obtain a Connecticut Children's Financial Assistance Application ("Application") at: <http://www.connecticutchildrens.org/patients-and-families/billing-and-finances>

Applications may be requested by calling the Financial Counseling office at (860) 545-8086.

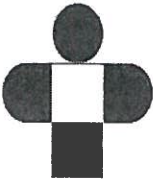
Paper copies of the Application are also available at The Cashier's Office, The Financial Counseling Office, The Emergency Department, or the Admitting Office which are located at:

Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106

Counselors are on-site to assist you Monday - Friday from 8:00 am – 7:30 pm and Saturday and Sunday from 10:00am – 6:00pm. Our offices are located at the main campus in Area 2D (behind the cashier and 1M (next to the security desk on the 1st floor entrance).

Application Process & Required Documentation:

In order to be considered for financial assistance an individual must complete an Application with a Financial Counselor or submit a completed Application to a financial counselor for processing. The patient or the patient's guarantor are required to cooperate and supply personal, financial and other information and documentation relevant to making a determination of financial need.

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All completed Applications may be faxed to (860) 845 – 8006 or mailed to:

Financial Counselor
 Connecticut Children's Medical Center
 282 Washington Street, Suite 2D
 Hartford, CT 06106

Once your Application is received Financial Counselors will process the Application. Additional information may be necessary in certain circumstances. Below are examples of documents our Financial Counselors may request from you, if required:

- Federal tax return;
- Paycheck stubs;
- Income verification from employer;
- Notice of "termination" from employer ;
- Unemployment compensation; and
- Letter of financial support.


Financial Counselors are available to work with patients to review the documentation provided and determine eligibility. They may also assist patients in completing any required Applications for financial assistance. Financial Counselors will make every effort to determine financial assistance eligibility upon submission.

Process for Incomplete Applications:

Financial assistance determinations shall be made as soon as possible, but no later than thirty (30) working days from the date of the Application submission. If sufficient paperwork is not provided, the request will be deemed to be an incomplete Application.

In the event that an immediate determination of FAP-eligibility cannot be made, the Financial Counselor will request additional information from the applicant. CT Children's will provide the applicant with both verbal and written notice which describes the additional information/documentation needed to make a FAP-eligibility determination and provide the patient with a reasonable amount of time (45 days) to provide the requested documentation. During this time CT Children's, or any third parties acting on CT Children's behalf, will suspend any ECA's previously taken to obtain payment until a FAP-eligibility determination is made.

The Application will be deemed incomplete if the information needed is not received within forty five (45) calendar days of the Counselor request. The Application will then be considered null and void and patients will have to reapply for financial assistance within in the Application Period in order to be considered eligible for financial assistance.

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Process for Completed Applications

Once a completed Application is received, CT Children's will:

- Suspend any ECAs against the individual (any third parties acting on CT Children's behalf will also suspend ECAs undertaken);
- Make and document a FAP-eligibility determination in a timely manner; and
- Notify the responsible party or individual in writing of the determination and basis for determination.

An individual deemed eligible for financial assistance will be notified in writing of a favorable determination. In accordance with IRC §501(r) CT Children's will also:

- Provide a billing statement indicating the amount the FAP-eligible individual owes, how that amount was determined and how information pertaining to AGB may be obtained, if applicable;
- Refund any excess payments made by the individual; and
- Work with third parties acting on CT Children's behalf to take all reasonable available measures to reverse any ECAs previously taken against the patient to collect the debt.

Approved initial Applications can cover healthcare services up to twelve (12) months looking back from the date of the Application. Although, at the discretion of Management, the retrospective period for an approved Application can extend beyond the previous twelve (12) months and will be reviewed on a case by case basis. An approved Application is good for twelve (12) months from the date of the Application. A patient may reapply at the end of twelve (12) months. Despite a change of circumstances new Applications will not be accepted or reviewed during an active Application Period. Any consecutive Applications (Application submitted subsequent to your initial Application) will be good for one (1) year forward from the date of the Application and will not be applied retrospectively.


VII. Widely Publicizing

CT Children's FAP, Application and PLS are available in English and in the primary language of populations with limited proficiency in English ("LEP") that constitutes the lesser of 1,000 individuals or 5% of the community served within CT Children's primary service area.

The FAP, Application and PLS are all available on-line at the following website:

<http://www.connecticutchildrens.org/patients-and-families/billing-and-finances>

Paper copies of the FAP, Application and the PLS are available upon request without charge by mail and are available within various areas throughout CT Children's facilities. This includes, but is not limited to, emergency rooms, patient registration check-in areas and the Patient Access Department.

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All patients of Connection Children's Medical Center will be offered a copy of the PLS as part of the intake/discharge process. Copies of the PLS will be made available at all Connecticut Children's Specialty Group office locations.

Signs or displays informing patient about the availability of financial assistance will be conspicuously posted in public locations including the emergency department, patient registration check-in areas and the Patient Access Department.

CT Children's will also make reasonable efforts to inform members of the community about the availability of financial assistance.

Billing, Credit and Collections

I. Purpose

To ensure that CT Children's billing, credit and collection practices comply with all Federal and State laws, regulations guidelines and policies. To follow practices outlined in IRC §501(r)(6), Centers for Medicare & Medicaid and commercial insurance manuals. To meet guidance issued by the Office of the Inspector General by following the billing compliance standards outlined below.

II. Policy

CT Children's is committed to providing the available healthcare, along with convenient billing services, payment options and financial assistance. CT Children's will make every effort to communicate CT Children's patient financial assistance, billing, credit and collection processes to the patient and/or their family.

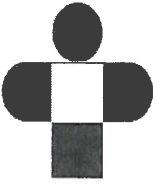
Patients and their families are responsible to provide timely and accurate information such as, but not limited to, demographic, insurance, and income to CT Children's to facilitate the patient financial assistance, billing, credit and collection processes. It is the responsibility of the patients and their families to know, understand, and comply with their insurance coverage, coinsurance, copays, deductibles, and benefit/coverage limitations. We ask our patients' families to remember that an insurance policy is a contract between them and the insurance company, and that they have the final responsibility for payment of their hospital bill.

CT Children's provides patient financial services to help families navigate the process of billing and medical insurance. In addition, customer service representatives are available to provide copies of itemized patient bills, explain particular bills, set up payment arrangements or review what costs insurance has paid and what payments are due.

A customer service representative can be reached by phone (860) 837-6170 or fax (860) 837-6169.

III. Procedures

As a courtesy to our patients, CT Children's submits bills to their insurance companies and makes every effort to advance their claim. However, it may become necessary for a policy holder to contact their

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insurance provider or supply additional information required for claims processing purposes or to expedite payment.

We request bills be paid in full within thirty (30) days. The guarantor is responsible to obtain the necessary funds from any source, such as obtaining a loan through their bank and/or credit union. If the guarantor is unable to pay by obtaining a loan or use of a credit card, payment arrangements may be made with Counselors. Monthly payments are required.

The following are CT Children's recommended guidelines for establishing payment plans:

Guarantor Balance	Maximum Payment Plan Terms
\$0.00 to \$2,499.99	12 months
\$2,500.00 to \$4,999.99	24 months
\$5,000.00 to \$9,999.99	36 months
\$10,000.00 to \$14,999.99	48 months
\$15,000.00 and above	60 months

Requests for establishing payment plans that extend past the above recommended terms greater than 12 months must be reviewed and approved by management. In addition, any requests for establishing payment plans that extend past a 60 month term must be reviewed and approved by Management.

As outlined in Section V of this FAP, any individual determined to be eligible for financial assistance under this FAP will not be charged more than AGB for any emergency or other medically necessary healthcare services. Any FAP-eligible individual will always be charged the lesser of AGB or any discount available under this policy.

IV. Compliance with IRC §501(r)(6)

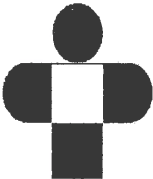
CT Children's does not engage in any ECAs (defined above) prior to the expiration of the "Notification Period". The Notification Period is defined as a 120-day period, which begins on the date of the 1st post-discharge billing statement, in which no ECAs may be initiated against the patient.

Subsequent to the Notification Period CT Children's, or any third parties acting on its behalf, may initiate the following ECAs against a patient for an unpaid balance if a FAP-eligibility determination has not been made or if an individual is ineligible for financial assistance.

- Reporting adverse information about the individual to consumer credit reporting agencies or credit bureaus; or
- Deferring, denying or requiring payment before providing medically necessary care because of an individual's nonpayment for previously provided care.

CT Children's may authorize third parties to initiate ECAs on delinquent patient accounts after the Notification Period. They will ensure reasonable efforts have been taken to determine whether or not an individual is eligible for financial assistance under this FAP and will take the following actions at least 30 days prior to initiating any ECA:

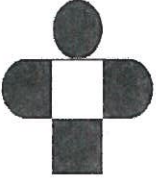
1. The patient will be provided with written notice which:

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- (a) Indicates that financial assistance is available for eligible patients;
- (b) Identifies the ECA(s) that CT Children's intends to initiate to obtain payment for the care; and
- (c) States a deadline after which such ECAs may be initiated.

2. The patient has received a copy of the PLS with this written notification; and
3. Reasonable efforts have been made to orally notify the individual about the FAP and how the individual may obtain assistance with the financial assistance Application process.

CT Children's will accept and process all Applications for financial assistance available under this policy submitted during the application period.

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**Appendix A:
CT Children's Provider Listing**

The CT Children's Financial Assistance Policy applies to Connecticut Children's Medical Center and Connecticut Children's Specialty Group, Inc. Physicians and other healthcare providers delivering services within a CT Children's hospital facility are not otherwise required to follow this Financial Assistance Policy.

The following is list of providers, by group, that provide emergency or other medically necessary healthcare services within a Connecticut Children's Medical Center hospital facility.

List of Providers who are covered under this Financial Assistance Policy:

- Connecticut Children's Specialty Group, Inc.

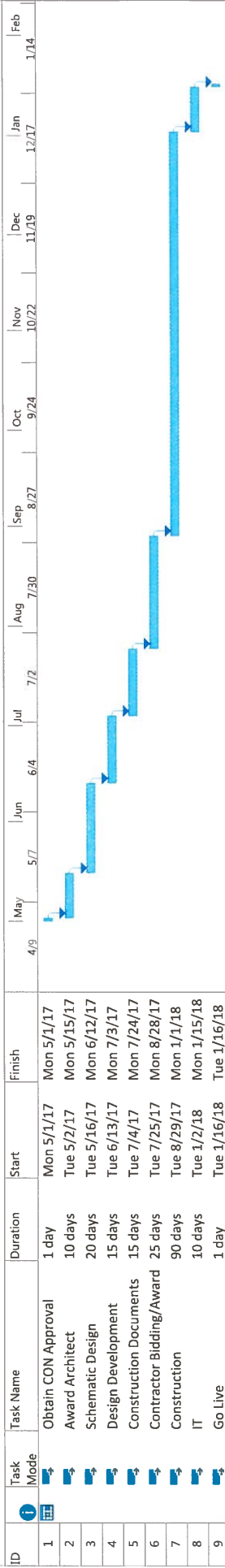
List of Providers who are not covered under this Financial Assistance Policy:

- Jefferson Radiology Group;
- Hartford Anesthesiology Associates;
- Hartford Pathology Associates;
- Institute of Living Psychologists/Clinicians; and
- Clinical Lab Partners.

EXHIBIT

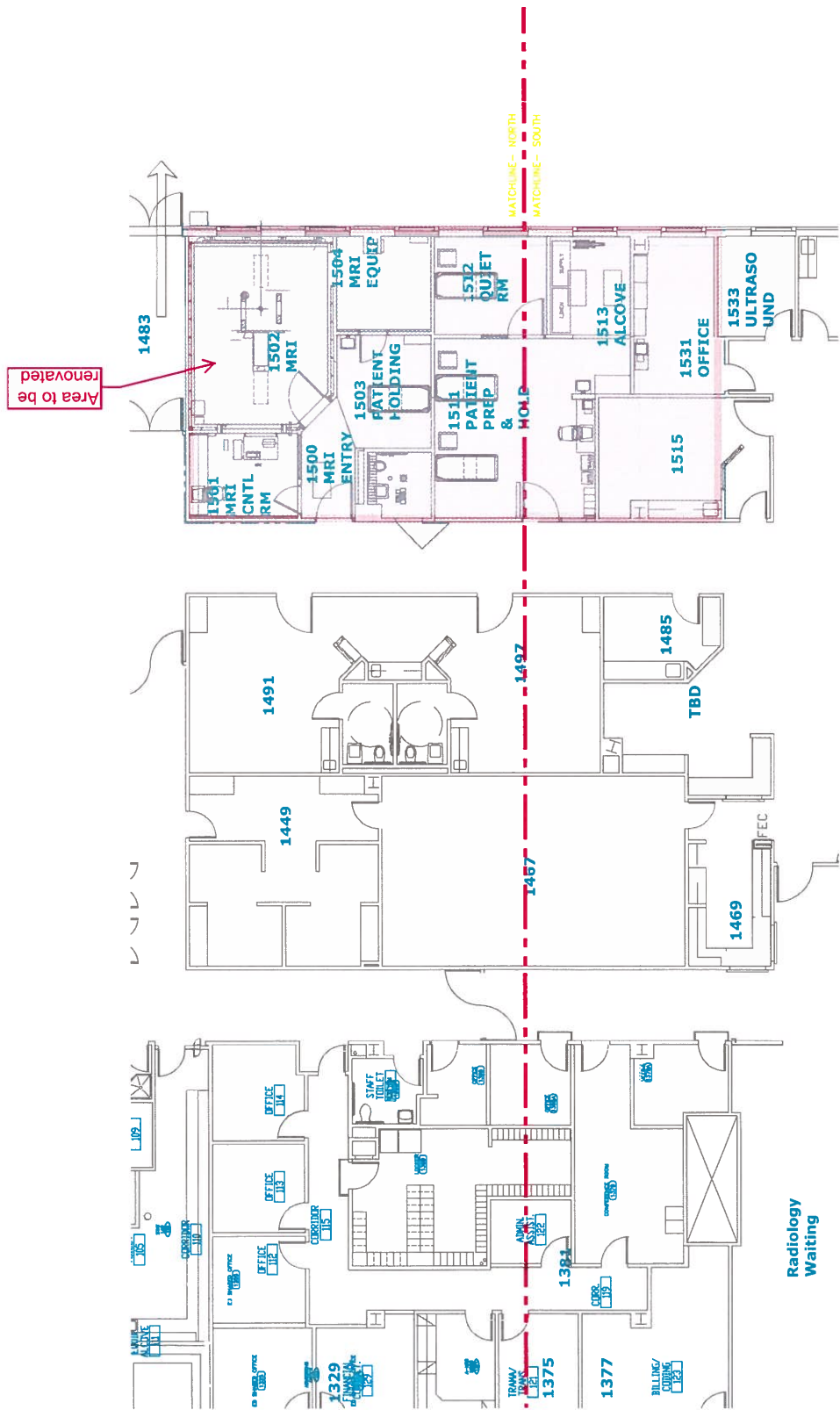
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Add 3T MRI Unit
282 Washington Street
Connecticut Children's Medical Center

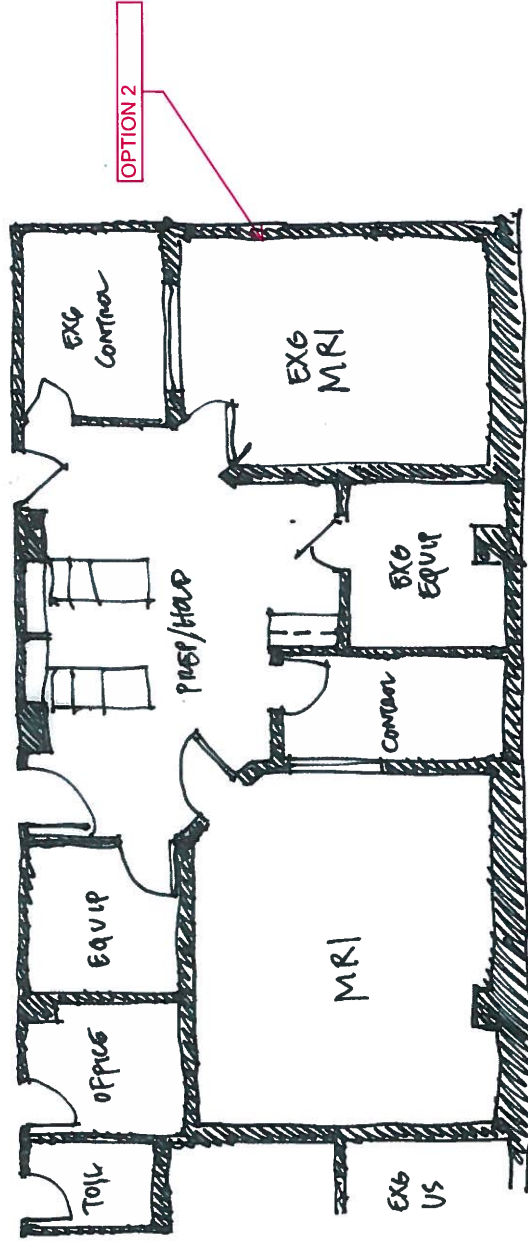
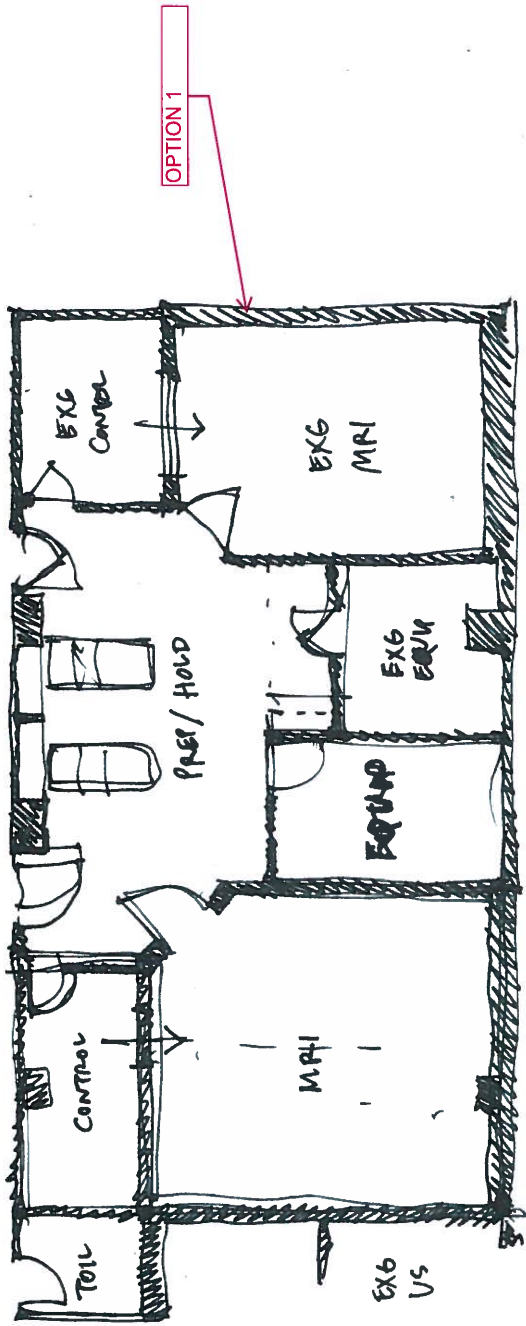


0238. 2/17/17

Project: Preliminary Schedule 1
Date: Wed 1/4/17



Proposed Renovation Options
 12/19/2016
 Connecticut Childrens Medical Center
 282 Washington Street
 1st Floor



EXHIBIT

8

**Connecticut Children's Medical Center
and Subsidiaries**

Consolidated Financial Statements and
Supplementary Information

September 30, 2016 and 2015



BAKER TILLY

Candor. Insight. Results.

0242. 2/17/17

Connecticut Children's Medical Center and Subsidiaries

Table of Contents
September 30, 2016 and 2015

	<u>Page</u>
Independent Auditors' Report	1
Financial Statements	
Consolidated Balance Sheet	3
Consolidated Statement of Operations and Changes in Net Assets	4
Consolidated Statement of Cash Flows	6
Notes to Consolidated Financial Statements	7
Supplementary Information	
Consolidating Balance Sheet	38
Consolidating Statement of Operations and Changes in Net Assets	40



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Independent Auditors' Report

Board of Directors
Connecticut Children's Medical Center and Subsidiaries

Report on the Consolidated Financial Statements

We have audited the accompanying consolidated financial statements of Connecticut Children's Medical Center and Subsidiaries, which comprise the consolidated balance sheet as of September 30, 2016 and 2015, and the related consolidated statements of operations and changes in net assets and cash flows for the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in conformity with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated 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 consolidated financial statements based on our audits. We did not audit the financial statements of The Children's Fund of Connecticut, Inc., a wholly-owned subsidiary, which statements reflect total assets constituting 8 percent of consolidating total assets at September 30, 2016 and 2015, and 1 percent of consolidated total revenues for the years then ended. Those statements were audited by other auditors, whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for The Children's Fund of Connecticut, Inc., is based solely on the report of the other auditors. We conducted our audits in conformity with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated 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 auditor's 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 consolidated 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, based on our audit and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Connecticut Children's Medical Center and Subsidiaries as of September 30, 2016 and 2015, and the changes in their net assets and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Report on Supplementary Information

Our audit was performed for the purpose of forming an opinion on the consolidated financial statements as a whole. The supplementary information is presented for purposes of additional analysis rather than to present the financial position, results of operations, and cash flows of the individual entities and is 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 conformity 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 statements as a whole.

Baker Tilly Viechow Krause, LLP
New York, New York
January 23, 2017

Connecticut Children's Medical Center and Subsidiaries

Consolidated Balance Sheet
September 30, 2016 and 2015

	2016	2015	2016	2015
Assets				
Current Assets				
Cash and cash equivalents	\$ 5,665,941	\$ 10,245,260	\$ 1,500,000	\$ 1,415,000
Funds held by trustee under revenue bond agreement	-	435,186	6,048,195	5,918,464
Patient accounts receivable, less allowance for doubtful accounts of approximately \$3,225,000 in 2016 and \$4,727,000 in 2015	35,095,688	35,293,659	41,577,973	40,501,685
Due from affiliated entities	380,743	1,040,023	17,502,917	21,616,615
Inventories	2,407,715	1,443,429	4,501,119	3,784,662
Other current assets	13,222,668	11,485,755	15,090,804	17,465,304
Total current assets	56,772,755	59,943,312	125,432	58,357
Assets Whose Use is Limited				
Funds held in trust by others	80,740,462	75,285,353	86,346,440	90,760,087
Investments	32,094,138	31,951,929	33,769,625	35,269,625
Interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	108,498,436	100,379,776	10,955,057	16,920,593
Total assets whose use is limited	221,333,036	207,617,058	24,478,050	19,397,464
Property, Plant and Equipment				
Buildings	152,171,288	144,535,354	13,193,518	16,584,377
Furniture and equipment	128,979,348	113,305,291	28,493,925	36,277,323
Construction in progress	2,160,582	13,845,701	197,236,615	215,209,469
Less accumulated depreciation	283,311,218	271,686,346	110,365,058	96,011,925
	(155,521,667)	(138,009,171)	27,079,719	29,432,838
Total property, plant and equipment	127,789,551	133,677,175	236,905,150	218,566,686
Other Assets				
Bond issuance costs	615,889	627,071		
Ground lease	2,299,514	2,328,806		
Other	25,331,020	29,582,733		
Total other assets	28,246,423	32,538,610		
Total assets	\$ 434,141,765	\$ 433,776,155	\$ 434,141,765	\$ 433,776,155
Liabilities and Net Assets				
Current Liabilities				
Current portion of bonds payable			\$ 1,500,000	\$ 1,415,000
Current portion of notes payable			6,048,195	5,918,464
Accounts payable and accrued expenses			41,577,973	40,501,685
Accrued wages			17,502,917	21,616,615
Due to third parties			4,501,119	3,784,662
Due to affiliated entities			15,090,804	17,465,304
Accrued interest payable and other current liabilities			125,432	58,357
Total current liabilities			86,346,440	90,760,087
Bonds Payable, Less Current Portion				
			33,769,625	35,269,625
Notes Payable, Less Current Portion				
			10,955,057	16,920,593
Accrued Pension Liability				
			24,478,050	19,397,464
Due to Third Parties				
			13,193,518	16,584,377
Other Long Term Liabilities				
			28,493,925	36,277,323
Total liabilities			197,236,615	215,209,469
Net Assets				
Unrestricted			110,365,058	96,011,925
Temporarily restricted			27,079,719	29,432,838
Permanently restricted			99,460,373	93,121,923
Total net assets			236,905,150	218,566,686
Total liabilities and net assets	\$ 434,141,765	\$ 433,776,155	\$ 434,141,765	\$ 433,776,155

Connecticut Children's Medical Center and SubsidiariesConsolidated Statement of Operations and Changes in Net Assets
Years Ended September 30, 2016 and 2015

	<u>2016</u>	<u>2015</u>
Revenues		
Patient service revenue	\$ 361,410,913	\$ 343,770,471
Provision for bad debts	(3,189,687)	(2,520,081)
Patient service revenue, less provision for bad debts	358,221,226	341,250,390
Other revenues	13,366,066	12,738,591
Net assets released from restrictions for operations	16,534,883	15,612,408
Total revenues	<u>388,122,175</u>	<u>369,601,389</u>
Expenses		
Salaries	182,708,421	170,680,248
Benefits	39,253,841	41,717,189
Supplies and other	139,250,186	133,500,477
Depreciation and amortization	21,489,481	18,831,846
Interest	1,141,051	1,234,420
Total expenses	<u>383,842,980</u>	<u>365,964,180</u>
Income from operations	<u>4,279,195</u>	<u>3,637,209</u>
Other Income		
Investment return, net	622,954	2,077,941
Income from trusts held by others	3,025,303	3,326,528
Change in interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	4,708,191	2,197,421
Total other income	<u>8,356,448</u>	<u>7,601,890</u>
Excess of revenues over expenses	<u>12,635,643</u>	<u>11,239,099</u>

See notes to consolidated financial statements

Connecticut Children's Medical Center and SubsidiariesConsolidated Statement of Operations and Changes in Net Assets
Years Ended September 30, 2016 and 2015

	<u>2016</u>	<u>2015</u>
Unrestricted Net Assets (continued)		
Excess of revenues over expenses (from previous page)	\$ 12,635,643	\$ 11,239,099
Transfer to affiliated organizations, net	(880,000)	(909,390)
Unrealized gains (losses) on investments	1,419,888	(3,852,126)
Net assets released from restrictions for capital	3,905,113	719,323
Change in funded status of pension and post-retirement plans	(4,937,060)	(6,921,768)
Change in interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	<u>2,209,549</u>	<u>(6,601,171)</u>
Change in unrestricted net assets	<u>14,353,133</u>	<u>(6,326,033)</u>
Temporarily Restricted Net Assets		
Transfer from affiliated organization	7,661,054	7,849,025
Net assets released from restrictions for operations	(16,534,883)	(15,612,408)
Net assets released from restrictions for capital	(3,905,113)	(719,323)
Bequests, gifts and grants	10,108,244	11,849,856
Change in interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	<u>317,579</u>	<u>(125,653)</u>
Change in temporarily restricted net assets	<u>(2,353,119)</u>	<u>3,241,497</u>
Permanently Restricted Net Assets		
Change in funds held in trust by others	5,455,109	(7,600,518)
Change in interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	<u>883,341</u>	<u>498,716</u>
Change in permanently restricted net assets	<u>6,338,450</u>	<u>(7,101,802)</u>
Change in net assets	18,338,464	(10,186,338)
Net Assets at Beginning of Year	<u>218,566,686</u>	<u>228,753,024</u>
Net Assets at End of Year	<u>\$ 236,905,150</u>	<u>\$ 218,566,686</u>

Connecticut Children's Medical Center and Subsidiaries

Consolidated Statement of Cash Flows
Years Ended September 30, 2016 and 2015

	2016	2015
Cash Flows from Operating Activities		
Change in net assets	\$ 18,338,464	\$ (10,186,338)
Adjustments to reconcile change in net assets to net cash (used in) provided by operating activities:		
Noncash items:		
Provision for bad debts	3,189,687	2,520,081
Depreciation and amortization	21,489,481	18,831,846
Realized and unrealized (gains) losses on investments	(1,637,820)	2,029,246
Change in value of funds held in trust by others	(5,455,109)	7,600,518
Change in funded status of pension and post-retirement plans	4,937,060	6,921,768
Change in interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	(8,118,660)	4,030,687
Other changes in net assets:		
Bequests, gifts and grants	(10,108,244)	(11,849,856)
Transfer from affiliated organizations	(7,661,054)	(7,849,025)
Changes in operating assets and liabilities:		
Patient accounts receivable	(2,991,716)	(2,590,468)
Due to/from affiliated entities, net	(1,715,220)	9,386,788
Inventories	(964,286)	(54,076)
Other current assets	(1,736,913)	2,055,431
Other long-term assets	4,292,187	(5,142,243)
Accounts payable and accrued expenses	1,076,288	(6,278,820)
Accrued wages	(4,113,698)	2,568,918
Accrued interest payable and other current liabilities	67,075	(5,656)
Due to third parties	(2,674,402)	(13,195,731)
Pension liability	143,526	705,600
Other long-term liabilities	(7,783,398)	1,056,790
Net cash (used in) provided by operating activities	<u>(1,426,752)</u>	<u>555,460</u>
Cash Flows from Investing Activities		
Purchase of property, plant and equipment, net	(15,766,649)	(13,692,247)
Proceeds from sale of property and equipment	250,000	-
Change in funds held by trustee under revenue bond agreement	435,186	4,586,434
Change in investments, net	1,495,611	892,623
Net cash used in investing activities	<u>(13,585,852)</u>	<u>(8,213,190)</u>
Cash Flows from Financing Activities		
Bequests, gifts and grants	10,108,244	11,849,856
Transfer from affiliates	7,661,054	7,849,025
Principal payments on bonds and notes payable	(7,336,013)	(7,866,634)
Proceeds from debt issued	-	310,500
Net cash provided by financing activities	<u>10,433,285</u>	<u>12,142,747</u>
(Decrease) increase in cash and cash equivalents	(4,579,319)	4,485,017
Cash and Cash Equivalents, Beginning	<u>10,245,260</u>	<u>5,760,243</u>
Cash and Cash Equivalents, Ending	<u>\$ 5,665,941</u>	<u>\$ 10,245,260</u>
Supplemental Schedule of Noncash Investing and Financing Activities		
Equipment acquired through capital lease agreement	<u>\$ 85,208</u>	<u>\$ -</u>

See notes to consolidated financial statements

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

1. Organization and Accounting Policies

The Connecticut Children's Medical Center (the "Medical Center") is a wholly-owned, tax-exempt subsidiary of CCMC Corporation. The Board of the Medical Center, appointed by CCMC Corporation, controls the operations of the Medical Center.

The Medical Center is the sole member of Connecticut Children's Specialty Group, Inc. ("CCSG") and The Children's Fund of Connecticut, Inc. (the "Children's Fund"). CCSG was formed to provide and promote children's health care and to support the Medical Center. The Children's Fund was formed to further the charitable mission of the Medical Center and to improve pediatric care in the Hartford Region.

Regulatory Matters

The Medical Center is required to file annual operating information with the State of Connecticut Office of Health Care Access.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets, such as estimated uncollectibles for patient accounts receivable, and liabilities, such as third party settlements, medical malpractice insurance liabilities and pension and postretirement liabilities, and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. There is at least a reasonable possibility that certain estimates will change by material amounts in the near term. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of the Medical Center and its subsidiaries. All significant intercompany accounts and transactions are eliminated in consolidation.

Cash and Cash Equivalents

Cash and cash equivalents include cash, money market funds and certificates of deposit. Restricted cash has been restricted by the donor to a specific time frame or purpose.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Investments

Investments consist of fixed income securities, equity securities (including readily tradeable stocks, exchange traded funds and mutual funds), interests in common collective/commingled trusts and investments in funds of funds. All investments, including funds held by trustee under revenue bond agreements, are measured at fair value at the balance sheet dates (see Note 16). Investment income (including realized gains and losses on investments, interest and dividends) is included in other income unless the income or loss is restricted by donor or law. The cost of securities sold is based on the specific identification method. Unrealized gains and losses on investments are excluded from excess of revenues over expenses unless the loss is considered to be other-than-temporary. Other-than-temporary losses are included in other income which is a component of excess of revenues over expenses. Based on current market conditions, as well as the Medical Center's ability and intent to hold impaired assets to recovery, no other than temporary losses were recorded.

Short-term investments represent those securities that are available for the Medical Center's operations, and can be converted to cash within one year.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market value.

Funds Held in Trust by Others

The Medical Center has an irrevocable right to receive income earned on certain trust assets established for its benefit. Distributions received by the Medical Center are unrestricted and included in income from trusts held by others in the consolidated statement of operations and changes in net assets. The Medical Center's interest in the fair value of the trust assets is included in assets whose use is limited. Changes in the market value of the trust assets are reported as increases or decreases to permanently restricted net assets.

Interest in Net Assets of Connecticut Children's Medical Center Foundation, Inc.

The interest in net assets of the Connecticut Children's Medical Center Foundation, Inc. (the "Foundation"), represents the Medical Center's interest in the net assets of the Foundation. This investment is accounted for in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 958-20, *Transfers of Assets to a Not-for-Profit Organization or Charitable Trust That Raises or Holds Contributions for Others*. In 2016 and 2015, the Medical Center did not require and did not receive any unrestricted financial support from the Foundation. The Foundation will provide support in future fiscal years as necessary.

Bond Issuance Costs

Bond issuance costs incurred to obtain financing for construction and renovation programs are being amortized using the straight-line method. The difference between the straight-line method and the effective-interest method is immaterial.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

Property, Plant, and Equipment

Property, plant and equipment are recorded on the basis of cost. The Medical Center provides for depreciation of property, plant, and equipment using the straight-line method in amounts sufficient to depreciate the cost of the assets over their estimated useful lives.

In 2016, the Medical Center incurred a loss on disposal of property, plant and equipment of approximately \$1,800,000 related to a sale of one of its practices. The loss is reported as depreciation and amortization in the consolidated statement of operations and changes in net assets.

Pension Plan

The Medical Center has a noncontributory defined benefit pension plan in effect covering all eligible employees. The Medical Center's funding policy is to contribute amounts to the plan sufficient to meet the minimum funding requirements set forth in the Employee Retirement Income Security Act of 1974.

Donor Restricted Gifts

Unconditional promises to give cash and other assets are reported at fair value at the date the promise is received. The 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 of restriction is accomplished, temporarily restricted net assets are reclassified as unrestricted net assets and reported in the statement of operations and changes in net assets as net assets released from restrictions. Donor restricted contributions whose restrictions are met within the same year as received are reported as unrestricted contributions in the accompanying consolidated financial statements.

Interest Rate Swap Agreements

The Medical Center utilizes interest rate swap agreements to reduce risks associated with changes in interest rates. The Medical Center is exposed to credit loss in the event of non-performance by the counterparties to its interest rate swap agreements. The Medical Center is also exposed to the risk that the swap receipts may not offset its variable rate debt exposure.

Temporarily and Permanently Restricted Net Assets

Temporarily restricted net assets are those where use by the Medical Center has been limited by donors to a specific time frame or purpose. Temporarily restricted net assets consist primarily of contributions restricted for certain health care and children's services. Permanently restricted net assets, which are primarily assets held in trusts by others and endowment gifts, have been restricted by donors and are to be maintained in perpetuity.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

Medical Malpractice Insurance

The Medical Center purchases malpractice coverage in which the primary level of coverage is \$4,000,000 per claim and \$12,000,000 in the aggregate. There is an additional \$6,000,000 of professional liability purchased through an external insurance company. In addition, there are four layers of excess indemnity coverage with four different insurance companies at \$10,000,000 per claim on the first three layers and \$15,000,000 per claim on the fourth layer, totaling \$45,000,000 in the aggregate. There are no deductibles. Additionally, the Medical Center purchased a loss capping policy to limit the exposure on existing claims as of September 30, 2012. Under this policy, any existing claim that settles for greater than the amount reserved for this claim is covered and paid by the insurance company, limiting the Medical Center's liability for increases in claims up to \$10,000,000 per claim and \$20,000,000 in the aggregate. Should claims settle for greater than the amount already reserved and the \$20,000,000 loss capping policy, the Medical Center is fully liable for the excess.

In 2016, CCMC Corporation created New England Pediatrics Indemnity, Ltd. ("NEPI"), a freestanding corporation through which the Medical Center and its affiliates will insure its professional liability and potentially its general liability risk. The Medical Center plans to novate outstanding and unreported claims to NEPI in fiscal 2017.

Insurance Recovery Receivable and Insurance Claims Liability

The Medical Center presents anticipated insurance recoveries separately from estimated insurance liabilities for medical malpractice claims and similar contingent liabilities on the consolidated balance sheet. The current portion of the insurance recovery receivable and related insurance claims liability totaled \$7,359,806 and \$6,460,657 at September 30, 2016 and 2015, respectively, and is included within other current assets and accounts payable and accrued expenses in the accompanying consolidated balance sheet. The non-current portion of the insurance recovery receivable and related insurance claims liability totaled \$16,147,306 and \$22,092,207 at September 30, 2016 and 2015, respectively, and is included within other assets and other long-term liabilities in the accompanying consolidated balance sheet.

Excess of Revenues over Expenses

The consolidated statement of operations and changes in net assets include excess of revenues over expenses as the performance indicator. Changes in unrestricted net assets which are excluded from excess of revenues over expenses include transfers to affiliated organizations, unrealized gains and losses on investments, net assets released from restrictions for capital, change in the equity interest in the net assets of the Foundation and changes in the funded status of the pension and post-retirement plans.

Other Income

Activities, other than in connection with providing health care services, are considered to be nonoperating and are included in other income. Other income consists primarily of income on invested funds, unrestricted gifts and bequests, realized gains and losses on sales of securities, income from funds held in trust by others, and loss on disposal of property, plant and equipment.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Advertising

The Medical Center's policy is to expense advertising costs as incurred. Total advertising expense was \$1,271,598 and \$911,134 for the years ended September 30, 2016 and 2015, respectively.

Income Taxes

The Medical Center and its subsidiaries 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.

The Medical Center accounts for uncertainty in income taxes using a recognition threshold of more-likely-than-not to be sustained upon examination by the appropriate taxing authority. Measurement of the tax uncertainty occurs if the recognition threshold has been met. Management has determined that there were no material tax uncertainties that met the recognition threshold in 2016 and 2015.

The Medical Center has net operating loss carryforwards from unrelated business activities of approximately \$586,000 which begin expiring on September 30, 2029. These net operating loss carryforwards result in a potential deferred tax asset of approximately \$234,400 which is offset by a valuation allowance of the same amount.

Recent Accounting Pronouncement – Fair Value Measurement

In May 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-07, *Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent)*. ASU No. 2015-07 removes the requirement to include investments in the fair value hierarchy for which fair value is measured using the net asset value practical expedient in Accounting Standards Codification 820. ASU No. 2015-07 requires retrospective application and is effective for fiscal years beginning after December 15, 2016 with early adoption permitted. Management has elected to early adopt the provisions of this new standard as it relates to the pension plan assets. Accordingly, the standard was retrospectively applied.

New Accounting Pronouncement – Revenue Recognition

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU No. 2014-09 supersedes the revenue recognition requirements in *Topic 605, Revenue Recognition*, and most industry-specific guidance. Under the requirements of ASU No. 2014-09, the core principle is that entities should recognize revenue to depict the transfer of promised goods or services to customers (patients) in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Medical Center will be required to retrospectively adopt the guidance in ASU No. 2014-09 for years beginning after December 15, 2017; early application is not permitted. The Medical Center has not yet determined the impact of adoption of ASU No. 2014-09 on its consolidated financial statements.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

New Accounting Pronouncement - Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU No. 2016-02 was issued to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the provisions of ASU No. 2016-02, a lessee is required to recognize a right-to-use asset and lease liability, initially measured at the present value of the lease payments, in the balance sheet. In addition, lessees are required to provide qualitative and quantitative disclosures that enable users to understand more about the nature of the leasing activities. The Medical Center will be required to retrospectively adopt the guidance in ASU No. 2016-02 for years beginning after December 15, 2019. The Medical Center has not yet determined the impact of adoption of ASU No. 2016-02 on its consolidated financial statements.

New Accounting Pronouncement – Not-for-Profit Entities

In August 2016, the FASB issued ASU No. 2016-14, *Not-for-Profit Entities (Topic 958): Presentation of Financial Statements of Not-for-Profit Entities*. The new guidance is intended to improve and simplify the current net asset classification requirements and information presented in financial statements and notes that is useful in assessing a not-for-profit's liquidity, financial performance and cash flows. ASU No. 2016-14 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. ASU No. 2016-14 is to be applied retroactively with transition provisions. The Medical Center has not yet determined the impact of this standard on its consolidated financial statements.

Subsequent Events

The Medical Center evaluates the impact of subsequent events, which are events that occur after the balance sheet date but before the consolidated financial statements are issued, for potential recognition in the consolidated financial statements as of the balance sheet date. For the year ended September 30, 2016, the Medical Center evaluated subsequent events through January 23, 2017, which is the date the consolidated financial statements were issued. No events occurred that require disclosure in or adjustment to the financial statements.

Reclassifications

Certain reclassifications have been made to the 2015 balances previously reported to conform to the current year presentation.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

2. Net Revenue from Services to Patients and Charity Care

The Medical Center provides health care services primarily to residents of the region. Revenues from the Medicaid program accounted for approximately 34% and 36% of the Medical Center's net patient service revenue for the years ended September 30, 2016 and 2015, respectively. Laws and regulations governing the Medicaid programs are complex and subject to interpretation. The Medical Center 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. While no such regulatory inquiries have been made, 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 Medicaid program. Changes in the Medicaid program and the reduction of funding levels could have an adverse impact on the Medical Center.

The following table summarizes net revenues from services to patients:

	<u>2016</u>	<u>2015</u>
Total gross revenues from patients	\$ 838,419,941	\$ 779,425,997
Less total contractual allowances	469,724,739	439,248,437
Less charity care	2,645,359	2,258,042
Less administrative and other allowances	4,638,930	4,149,047
Total allowances	<u>477,009,028</u>	<u>445,655,526</u>
DSH settlement with State of Connecticut	<u>-</u>	<u>10,000,000</u>
Patient service revenues	361,410,913	343,770,471
Less provision for bad debts	<u>3,189,687</u>	<u>2,520,081</u>
Patient service revenues, less provision for bad debts	<u>\$ 358,221,226</u>	<u>\$ 341,250,390</u>

Patient accounts receivable and revenues are recorded when patient services are performed. Amounts received from certain payors are different from established billing rates of the Medical Center, and the difference is accounted for as allowances. The Medical Center records its provision for bad debts based upon a review of all of its outstanding receivables. Write-offs of receivable balances are related primarily to its population of underinsured patients. An underinsured patient is one who has commercial insurance which leaves a significant portion of the Medical Center's reimbursement to be paid by the patient, either through large deductibles or co-pay requirements. Self-pay patients are rare in the pediatric environment, as Medicaid is readily available to children. Self-pay net revenue approximated \$4,500,000 and \$3,600,000 for the years ended September 30, 2016 and 2015, respectively.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Net patient service revenue is reported at the estimated realizable amounts from patients, third-party payors and others for services rendered. Revenue under third-party payor agreements is subject to audit and retroactive adjustments. Provisions for estimated third-party payor settlements and adjustments are estimated in the period the related services are rendered and adjusted in future periods as final settlements are determined. In 2015, the Medical Center received a \$10,000,000 settlement related to prior years that increased net patient service revenue. In 2016, net patient service revenue increased by approximately \$3,900,000 for changes in estimates related to prior year settlements.

The Medical Center has agreements with various Health Maintenance Organizations (HMOs) to provide medical services to subscribing participants. Under these agreements, the Medical Center receives per diem and fee-for-service payments for certain covered services based upon discounted fee schedules.

The Medical Center accepts all patients regardless of their ability to pay. A patient is classified as a charity patient by reference to the established policies of the Medical Center. Essentially, those policies define charity services as those services for which no payment is anticipated. In assessing a patient's inability to pay, the Medical Center utilizes the generally recognized Federal poverty guidelines.

The costs of charity care incurred were approximately \$1,107,000 and \$929,000 for the years ended September 30, 2016 and 2015, respectively. The costs of charity care are derived from both estimated and actual data. The estimated cost of charity care includes the direct and indirect cost of providing such services and is estimated utilizing the Medical Center's ratio of cost to gross charges, which is then multiplied by the gross uncompensated charges associated with providing care to charity patients.

3. Related-Party Transactions

Certain Medical Center employees render management and other services to affiliated entities for which the Medical Center is reimbursed. The amount of such reimbursement was \$881,366 and \$807,034 for the years ended September 30, 2016 and 2015, respectively.

The Foundation transferred \$7,661,054 and \$7,849,025 to the Medical Center for the years ended September 30, 2016 and 2015, respectively. These transfers related to donor-restricted contributions received by the Foundation for the benefit of the Medical Center. The Medical Center also transferred \$880,000 to CCMC Corporation for the year ended September 30, 2016.

Due to affiliated organizations, net, includes \$14,710,061 and \$16,425,281 at September 30, 2016 and 2015, respectively, which is primarily related to cash advanced from the Foundation for operating purposes. Interest is not charged and there are no fixed repayment terms on these advances.

4. Concentrations of Credit Risk

The Medical Center's financial instruments that are exposed to concentrations of credit risk primarily consist of cash and cash equivalents, short-term investments and patient accounts receivable.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

The Medical Center's cash and cash equivalents are placed with high credit quality financial institutions. The Medical Center's investment policy limits its exposure to concentrations of credit risk. In the normal course of business, the Medical Center maintains cash balances in excess of the Federal Deposit Insurance Corporation's ("FDIC") insurance limit. Cash balances exceeded FDIC limits by approximately \$6,780,000 and \$10,070,000 at September 30, 2016 and 2015, respectively.

The Medical Center provides health care services and grants credit without collateral to its patients, most of whom are Connecticut residents and are insured under third-party payor agreements. An estimated allowance for doubtful accounts as well as contractual allowances is maintained at levels considered adequate to reduce the account balances to net realizable value. The mix of receivables from patients and third-party payors at September 30 was as follows:

	<u>2016</u>	<u>2015</u>
Medicaid	34 %	35 %
Medicaid managed care	4	2
Commercial/managed care - contracted	50	51
Commercial/managed - non-contracted	4	4
Patients and other	<u>8</u>	<u>8</u>
	<u>100 %</u>	<u>100 %</u>

5. Investments

The composition of investments as of September 30, stated at fair value, is set forth in the following table:

	<u>2016</u>		<u>2015</u>	
	<u>Cost</u>	<u>Fair Value</u>	<u>Cost</u>	<u>Fair Value</u>
Short-term investments	\$ 46,760	46,760	\$ 35,653	\$ 35,653
Marketable equity securities	361,145	372,450	543,174	536,981
Fixed income securities	26,363	26,646	26,363	27,377
Institutional managed equity funds	22,720,700	23,988,217	23,772,244	23,624,360
Institutional managed bond fund	7,571,723	7,591,333	7,365,317	7,397,486
Other	<u>67,748</u>	<u>68,732</u>	<u>356,020</u>	<u>330,072</u>
	<u>\$ 30,794,439</u>	<u>\$ 32,094,138</u>	<u>\$ 32,098,771</u>	<u>\$ 31,951,929</u>

Investments consisted of mutual funds and individual securities that comprised approximately 75% equity securities and 25% fixed income investments at September 30, 2016, and 76% equity securities and 24% fixed income investments at September 30, 2015.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

The following table summarizes the unrealized losses on investments held at September 30, 2016:

	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Marketable equity securities	\$ 1,742,070	\$ 95,428	\$ 5,203,542	\$ 1,483,839	\$ 6,945,612	\$ 1,579,267
Fixed income securities	1,030,469	8,268	3,863,127	529,163	4,893,596	537,431
Institutional managed equity funds	106,116	6,531	-	-	106,116	6,531
Other	30,497	1,181	-	-	30,497	1,181
Total investments	<u>\$ 2,909,152</u>	<u>\$ 111,408</u>	<u>\$ 9,066,669</u>	<u>\$ 2,013,002</u>	<u>\$ 11,975,821</u>	<u>\$ 2,124,410</u>

The following table summarizes the unrealized losses on investments held at September 30, 2015:

	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Marketable equity securities	\$ 7,995,517	\$ 1,312,313	\$ 4,099,045	\$ 1,608,196	\$ 12,094,562	\$ 2,920,509
Fixed income securities	3,290,101	63,907	-	-	3,290,101	63,907
Institutional managed equity funds	522,612	23,753	-	-	522,612	23,753
Other	150,836	5,848	44,461	6,253	195,297	12,101
Total investments	<u>\$ 11,959,066</u>	<u>\$ 1,405,821</u>	<u>\$ 4,143,506</u>	<u>\$ 1,614,449</u>	<u>\$ 16,102,572</u>	<u>\$ 3,020,270</u>

Management continually reviews its investment portfolio and evaluates whether declines in the fair value of securities should be considered other-than-temporary. Factored into this evaluation are the general market conditions, the issuer's financial condition and near-term prospects, conditions in the issuer's industry, the recommendation of advisors, the length of time and extent to which the market value has been less than cost along with the Medical Center's intent and ability to hold the investments. During the years ended September 30, 2016 and 2015, the Medical Center has not recorded any other-than-temporary declines in the fair value of investments, as the Medical Center has the ability and intent to hold the securities to recovery.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

Investment returns for the years ended September 30 are as follows:

	<u>2016</u>	<u>2015</u>
Interest and dividend income	\$ 685,003	\$ 782,951
Realized gain	217,932	1,822,880
Net swap activity	(104,094)	(367,708)
Investment fees and other	<u>(175,887)</u>	<u>(160,182)</u>
	622,954	2,077,941
Unrealized gain (loss) on investments	<u>1,419,888</u>	<u>(3,852,126)</u>
Total	<u>\$ 2,042,842</u>	<u>\$ (1,774,185)</u>

6. Restricted Net Assets

Endowments

The endowment consists of individual donor-restricted funds established for a variety of purposes which are held and controlled by the Foundation. As required by GAAP, net assets associated with endowment funds are classified and reported based on donor-imposed restrictions. At September 30, 2016 and 2015, the Medical Center had \$22,429,597 and \$22,081,136, respectively, in endowments held at the Foundation which are recorded by the Medical Center through its interest in the Foundation.

Interpretation of Relevant Law

The Medical Center's Board and senior management have interpreted the Uniform Prudent Management of Institutional Funds Act ("UPMIFA") 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, the Medical Center classifies as permanently restricted net assets (1) the original value of gifts donated to the permanent endowment, (2) the original value of subsequent gifts to the permanent endowment, and (3) accumulations to the permanent endowment made in accordance with the direction of the applicable donor gift instrument at the time 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 the organization in a manner consistent with the standard for expenditure prescribed by UPMIFA. In accordance with UPMIFA, the Medical Center 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 the organization and the donor-restricted endowment fund

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

- (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 the organization
- (7) The investment policies of the organization

Funds with Deficiencies

From time to time, the fair value of assets associated with individual donor-restricted endowment funds may fall below the level that the donor or UPMIFA requires the Medical Center to retain as a fund of perpetual duration. In accordance with GAAP, deficiencies of this nature are reported in unrestricted net assets. There were no deficiencies at September 30, 2016 and 2015.

Return Objectives and Risk Parameters

The Medical Center has adopted investment and spending policies for endowment assets that attempt to provide a predictable stream of funding to programs supported by its endowment while seeking to maintain the purchasing power of the endowment assets. Endowment assets include those assets of donor-restricted funds that the organization must hold in perpetuity. Under this policy, the endowment assets are invested in a manner that is intended to produce results that equal or exceed relevant benchmarks. The Medical Center expects its endowment funds, over time, to provide an average rate of return of at least 5% annually. Actual returns in any given year may vary from this amount.

Strategies Employed for Achieving Objectives

To satisfy its long-term rate-of-return objectives, the Medical Center 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). The Medical Center targets a diversified asset allocation strategy that places a greater emphasis on equity-based investments to achieve its long-term return objectives within the guidelines of its investment policy and prudent risk constraints.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Endowment Net Asset Composition by Type of Fund

All endowment net assets are donor-restricted endowment funds.

Changes in endowment net assets for the years ended September 30 consisted of the following:

	2016		
	Temporarily Restricted	Permanently Restricted	Total
Endowment net assets, beginning balance	\$ 4,244,566	\$ 17,836,570	\$ 22,081,136
Contributions	-	883,341	883,341
Investment return	263,705	-	263,705
Net appreciation (realized and unrealized)	398,616	-	398,616
Appropriation of endowment assets for expenditure	(1,197,201)	-	(1,197,201)
Endowment net assets, ending balance	\$ 3,709,686	\$ 18,719,911	\$ 22,429,597
	2015		
	Temporarily Restricted	Permanently Restricted	Total
Endowment net assets, beginning balance	\$ 4,605,125	\$ 17,337,854	\$ 21,942,979
Contributions	-	498,716	498,716
Investment return	417,438	-	417,438
Net appreciation (realized and unrealized)	794,207	-	794,207
Appropriation of endowment assets for expenditure	(1,572,204)	-	(1,572,204)
Endowment net assets, ending balance	\$ 4,244,566	\$ 17,836,570	\$ 22,081,136

Income from endowment funds is considered temporarily restricted until it meets the original donor's time or purpose restriction of the donation. These funds are commingled with other temporarily restricted contributions for the same purposes (see tables below for discussion of the purpose of restrictions) and invested until such time that the funds are utilized. The Medical Center's spending policy is that any expenditure associated with the endowment is appropriated based on the donor's intention.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Temporarily Restricted

Temporarily restricted net assets are available for the following purposes as of September 30:

	<u>2016</u>	<u>2015</u>
Equipment purchases	3 %	2 %
Education	5	7
Other health care services	<u>92</u>	<u>91</u>
	<u>100 %</u>	<u>100 %</u>

Permanently Restricted

Permanently restricted net assets at September 30 are restricted to:

	<u>2016</u>	<u>2015</u>
Health care and children's services	82 %	81 %
Other health care services	14	14
Education	<u>4</u>	<u>5</u>
	<u>100 %</u>	<u>100 %</u>

7. Pension Plan and Defined Contribution Plan

Effective January 1, 1993, the State of Connecticut mandated that individuals hired by the Medical Center were no longer eligible to participate in the State of Connecticut pension plan ("State Plan"). Employees who were participants in the State Plan as of December 31, 1992 can remain participants in the State Plan so long as they continue to remain employed by the Medical Center.

Effective January 1, 1994, the Medical Center adopted a defined benefit pension plan covering substantially all of its employees. Benefits for employees who are participants in the State Plan are reduced to reflect vested benefits provided under the State Plan.

Effective January 1, 1999, the Medical Center converted its pension plan to a Cash Balance Retirement Plan (the "Plan"). Plan benefits are based on years of service and the employee's compensation. Contributions to the Plan are intended to provide for benefits attributed to services rendered to date and benefits expected to be earned in the future. Future benefits are earned and credited by participants based on a percentage of compensation (ranging from 2.5% to 12.5%) associated with years of service. Plan participants earn a return based on an interest rate established annually at the beginning of the pay year. Plan participants vest in their benefits after three years of service.

On February 26, 2009, the Board of Directors of the Medical Center adopted a resolution to freeze the Plan effective May 1, 2009.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Included in unrestricted net assets at September 30, 2016 and 2015 are unrecognized actuarial losses of \$32,059,945 and \$27,031,839, respectively. The actuarial loss included in unrestricted net assets and expected to be recognized in net periodic pension cost during the year ending September 30, 2017 is \$1,984,109.

The following table presents a reconciliation of the beginning and ending balances of the Plan's projected benefit obligation and the fair value of plan assets, as well as the funded status of the plan and accrued pension liability included in the consolidated balance sheet at year ended September 30:

	<u>2016</u>	<u>2015</u>
Change in benefit obligation:		
Benefit obligation at beginning of year	\$ 90,743,362	\$ 88,747,942
Interest cost	3,536,986	3,431,884
Actuarial loss, including the effects of any assumption changes	7,880,183	2,780,248
Benefits paid	<u>(4,468,416)</u>	<u>(4,216,712)</u>
Benefit obligation at end of year	<u>\$ 97,692,115</u>	<u>\$ 90,743,362</u>
Change in Plan assets:		
Fair value of Plan assets at beginning of year	\$ 71,345,898	\$ 76,977,846
Contributions	-	-
Actual return on Plan assets	6,336,583	(1,415,236)
Benefits paid	<u>(4,468,416)</u>	<u>(4,216,712)</u>
Fair value of Plan assets at end of year	<u>\$ 73,214,065</u>	<u>\$ 71,345,898</u>
Funded status of the Plan	<u>\$ (24,478,050)</u>	<u>\$ (19,397,464)</u>

The weighted-average assumptions used to develop the projected benefit obligation as of September 30 are as follows:

	<u>2016</u>	<u>2015</u>
Discount rate	3.27 %	4.00 %
Rate of compensation	N/A	N/A
Cash balance interest credit	5.50	5.50

Net periodic pension costs for the years ended September 30 consist of the following:

	<u>2016</u>	<u>2015</u>
Interest cost	\$ 3,536,986	\$ 3,431,884
Expected return on plan assets	(4,872,147)	(4,717,144)
Net amortization, net actuarial loss	<u>1,387,641</u>	<u>1,387,915</u>
Net periodic benefit costs	<u>\$ 52,480</u>	<u>\$ 102,655</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

The weighted-average assumptions used to determine net periodic benefit costs as of September 30 are as follows:

	<u>2016</u>	<u>2015</u>	
Discount rate	4.00 %	4.00	%
Cash balance interest credit	5.50	5.50	
Expected long-term rate of return on plan assets	6.75	6.75	
Rate of compensation	N/A	N/A	

The expected long-term rate of return on plan assets was developed through analysis of historical market returns, current market conditions and the fund's past experience. Estimates of future market returns by asset category are lower than actual long-term historical returns in order to reflect current market conditions.

The accumulated benefit obligation at September 30, 2016 and 2015 was \$97,692,115 and \$90,743,362, respectively.

Plan Assets

The Plan assets are managed by outside investment managers. The investment strategy with respect to pension assets is to maximize return while protecting principal. The investment manager has the flexibility to adjust the asset allocation and move funds to the asset class that offers the most opportunity. The investment objective for Plan assets over a full market cycle time period is to generate a return in excess of the passive portfolio benchmark for each asset class.

The asset allocations for the Plan at September 30, by asset category, are as follows:

	Percentage of Plan Assets at Year-End	
	<u>2016</u>	<u>2015</u>
Asset Category:		
Domestic equities	36 %	35 %
International equities	19	19
Debt securities	40	40
Other	<u>5</u>	<u>6</u>
	<u>100 %</u>	<u>100 %</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

The fair values of the Plan assets at September 30, 2016, by asset category, are as follows:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Money market mutual funds	\$ 620,839	\$ -	\$ -	\$ 620,839
Fixed income securities:				
U.S. government bonds	3,426,870	-	-	3,426,870
Municipal bonds	820,944	-	-	820,944
Corporate bonds	5,093,726	-	-	5,093,726
Foreign bonds	874,101	-	-	874,101
Fixed income mutual funds	3,520,735	-	-	3,520,735
Equity mutual funds	29,713,513	-	-	29,713,513
Total assets in the fair value hierarchy	<u>\$ 44,070,728</u>	<u>\$ -</u>	<u>\$ -</u>	44,070,728
Investments measured at net asset value(a)				<u>29,143,337</u>
				<u>\$ 73,214,065</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

The fair values of the Plan assets at September 30, 2015, by asset category, are as follows:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Money market mutual funds	\$ 229,131	\$ -	\$ -	\$ 229,131
Fixed income securities:				
U.S. government bonds	2,029,206	-	-	2,029,206
Municipal bonds	739,088	-	-	739,088
Corporate bonds	5,366,920	-	-	5,366,920
Foreign bonds	767,014	-	-	767,014
Fixed income mutual funds	3,715,799	-	-	3,715,799
Equity mutual funds	29,414,668	-	-	29,414,668
Total assets in the fair value hierarchy	<u>\$ 42,261,826</u>	<u>\$ -</u>	<u>\$ -</u>	42,261,826
Investments measured at net asset value(a)				<u>29,084,072</u>
Total				<u>\$ 71,345,898</u>

(a) In accordance with Subtopic 820-10, certain investments that were measured at net asset value ("NAV") per share (or its equivalent) have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the ending Plan assets disclosed.

Investments measured at net asset value are subject to various management, incentive and other fees based on net asset value, classes, capital account balances and/or capital commitments. Investments may also be subject to lock up periods.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Investments Measured Using NAV per Share Practical Expedient

The following table summarizes investments measured at fair value based on NAV per share as of September 30, 2016 and 2015, respectively.

September 30, 2016					
	Fair Value	Unfunded Commitments	Redemption Frequency (if currently eligible)	Redemption Notice Period	
Mutual fund, multi asset Limited liability companies:	\$ 9,069,100	\$ -	Daily	Upon written notice	
Intermediate bond	7,278,697	-	Monthly	Upon written notice	
Institutional loan	3,692,717	-	Daily	Upon written notice	
Limited partnership	9,103,823	-	Quarterly	Upon written notice	

September 30, 2015					
	Fair Value	Unfunded Commitments	Redemption Frequency (if currently eligible)	Redemption Notice Period	
Mutual fund, multi asset Limited liability companies:	\$ 8,753,001	\$ -	Daily	Upon written notice	
Intermediate bond	7,338,698	-	Monthly	Upon written notice	
Institutional loan	4,355,064	-	Daily	Upon written notice	
Limited partnership	8,637,309	-	Quarterly	Upon written notice	

The Medical Center does not expect to contribute to its pension plan in fiscal 2017.

The Medical Center expects to pay the following benefit payments, which reflect expected future service as appropriate:

Fiscal year:	
2017	\$ 7,357,000
2018	5,598,000
2019	5,922,000
2020	6,612,000
2021	5,358,000
Years 2022 - 2026	28,228,000

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

The Medical Center also has a defined contribution plan. The Connecticut Children's Retirement Savings Plan, (the "Savings Plan") covers all eligible employees as defined by the plan document. Eligible employees may contribute up to 100 percent of their pretax annual compensation, as defined by the plan document, up to the Internal Revenue Service limits. The Medical Center makes safe harbor matching contributions equal to 100 percent of the first 3 percent of compensation deferred by the participant, plus 50 percent of the next 2 percent of compensation deferred by the participant. In addition, the Medical Center makes an employer core contribution for eligible employees, that ranges from 1 percent to 7 percent, as determined by the Board of Directors, of a participant's annual compensation. The Medical Center expensed contributions to the Savings Plan for the years ended September 30, 2016 and 2015 of \$4,331,251 and \$5,677,473, respectively.

8. Post-Retirement Benefit Plan

The Medical Center sponsors the Connecticut Children's Medical Center Postretirement Welfare Plan (the "PRW Plan"), an unfunded plan which provides post-retirement medical benefits to retired employees who meet the specific criteria identified in the PRW Plan document. The Medical Center's contribution toward cost of medical coverage varies by years of pension credited service at retirement, ranging from 25% for employees with ten years of credited service to 100% for those employees with 25 plus years of credited service. The Medical Center's maximum fixed dollar commitment is \$2,280 per year per retiree.

Included in unrestricted net assets at September 30, 2016 and 2015 are \$2,660,882 and \$2,993,289, respectively, of net unrecognized actuarial gains that have not yet been recognized in net periodic benefit cost. There is \$191,458 of actuarial gain included in unrestricted net assets that is expected to be recognized in net periodic pension cost during the year ending September 30, 2017.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

The following table presents a reconciliation of the beginning and ending balances of the PRW Plan's projected benefit obligation and the fair value of plan assets, as well as the funded status of the plan and accrued post-retirement obligation included in the consolidated balance sheet as of September 30:

	<u>2016</u>	<u>2015</u>
Change in benefit obligation:		
Benefit obligation at beginning of year	\$ 6,071,638	\$ 6,340,898
Service cost	194,499	228,789
Interest cost	257,816	263,408
Actuarial losses (gains), including the effects of any assumption changes	117,501	(683,727)
Benefits paid	<u>(423,513)</u>	<u>(77,730)</u>
Benefit obligation at end of year	<u>\$ 6,217,941</u>	<u>\$ 6,071,638</u>
Change in PRW Plan assets:		
Fair value of PRW Plan assets at beginning of year	\$ -	\$ -
Contributions	423,513	77,730
Benefits paid	<u>(423,513)</u>	<u>(77,730)</u>
Fair value of PRW Plan assets at end of year	<u>\$ -</u>	<u>\$ -</u>
Accrued post-retirement obligation included in other long-term liabilities	<u>\$ 6,217,941</u>	<u>\$ 6,071,638</u>

The weighted-average assumptions used to develop the post-retirement benefit obligation as of September 30 are as follows:

	<u>2016</u>	<u>2015</u>
Discount rate	3.52 %	4.30 %
Healthcare cost trend rate:		
Current year	7.50	8.00
Ultimate	4.50	5.00
Year ultimate reached	2022	2021

Net periodic benefits costs for the years September 30 consist of the following:

	<u>2016</u>	<u>2015</u>
Service cost	\$ 194,499	\$ 228,789
Interest cost	257,816	263,408
Net amortization, Net actuarial gain	<u>(214,966)</u>	<u>(158,512)</u>
Net periodic benefit costs	<u>\$ 237,349</u>	<u>\$ 333,685</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

The weighted-average assumptions used to determine net periodic benefit costs are as follows for September 30:

	<u>2016</u>	<u>2015</u>
Discount rate	4.30 %	4.20 %
Health care cost trend rate		
Current year	8.00	8.50
Ultimate	5.00	5.00
Year ultimate reached	2021	2021

A one-percentage point change in assumed health care cost trend rates would have the following effect on the post-retirement benefit plan:

	<u>One-percentage Point</u>	
	<u>Increase</u>	<u>Decrease</u>
Effect on postretirement benefit obligation	\$ 81,665	\$ 72,404
Effect on total of service and interest cost	9,120	8,001

The Medical Center expects to contribute \$155,000 to its post-retirement benefit plan in fiscal 2017.

The Medical Center expects to pay the following benefit payments, which reflect expected future service as appropriate:

Fiscal year:	
2017	\$ 155,000
2018	187,000
2019	222,000
2020	241,000
2021	272,000
Years 2022 - 2026	1,678,000

9. Bonds Payable

A summary of long-term debt is as follows:

	<u>2016</u>	<u>2015</u>
Hospital revenue bonds financed with the State of Connecticut Health and Educational Facilities Authority ("CHEFA")		
Series D (4.19% effective interest rate)	\$ 35,269,625	\$ 36,684,625
Less current portion	<u>1,500,000</u>	<u>1,415,000</u>
	<u>\$ 33,769,625</u>	<u>\$ 35,269,625</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

In June 2011, the Medical Center along with the Foundation (Collectively, the "Obligated Group") refinanced their existing CHEFA hospital revenue bonds with variable rate revenue bonds (the Series D Bonds) with a principal amount of \$41,580,000. The "Series D Bonds" were issued at par and directly placed with one investor. The investor has committed to holding the bonds for a ten year period, at the end of which, the investor may put the bonds back to the Obligated Group or extend their holding period at their discretion. The bonds mature in varying amounts through 2032, with interest rates based on 65% of LIBOR plus a spread of 1.52%, ranging from 1.71% to 2.95% in the current year. In September 2016, the Obligated Group reissued the Series D Bonds to obtain a lower interest rate; the scheduled principal payments were not changed. The interest rates are now based on 67% of LIBOR plus a spread of 0.85%.

The agreement and related documents provide, among other things, that the Series D Bonds and any additional bonds will be payable from payments to be made by the Obligated Group and that it will be obligated to make such payments so long as the Series D Bonds and any additional bonds are outstanding. The Series D Bonds are collateralized by an interest in revenues of the Medical Center and a mortgage on the facilities, ground lease, easements and other certain leases that comprise the overall hospital premises owned by the Medical Center.

Pursuant to the mortgage agreement and related documents, the Obligated Group is required to meet certain covenants including a day's cash on hand, debt to capitalization and a debt service coverage ratio requirement.

The carrying value of the bonds payable approximates fair value. The Medical Center classifies bonds payable in Level 2 of the valuation hierarchy.

The Medical Center is required to make monthly interest and semi-annual principal repayments for the Series D Bonds. Interest paid for 2016 and 2015 was \$632,058 and \$618,683, respectively.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Principal payments for the next five years under the CHEFA obligations are as follows:

2017	\$ 1,500,000
2018	1,580,000
2019	1,665,000
2020	1,740,000
2021	1,830,000
Aggregate thereafter	<u>26,954,625</u>
	<u>\$ 35,269,625</u>

In November 2005, the Medical Center entered into an interest rate swap agreement (the 2005 swap) effectively converting \$23,700,000 of its then existing variable-rate debt ("Series C debt") to a fixed-rate basis of 3.704% through June 2018. The fair value of the swap (a liability of \$277,123 and \$549,134 at September 30, 2016 and 2015, respectively,) is reported in other long-term liabilities. The change in value of \$277,011 and \$326,043 is reported as a component of income from investments for the years ended September 30, 2016 and 2015, respectively. The swap, while serving as an economic hedge, does not qualify for hedge accounting.

Upon the refunding of the Series C debt in June 2011, the Medical Center applied the 2005 swap against the newly issued Series D debt and entered into a new swap agreement (the 2011 swap), which along with the 2005 swap, effectively converts all of its outstanding Series D debt to a fixed-rate basis. The interest rate on the new swap is 4.6138%. The fair value of the 2011 swap (a liability of \$553,115 as of September 30, 2015) is reported in other long-term liabilities. The change in value of \$553,115 and \$463,780 is reported as a component of income from investments for the years ended September 30, 2016 and 2015, respectively. The swap was terminated by the Medical Center in 2016 through a Termination Agreement, which required a final payment by the Medical Center of approximately \$60,000.

The following table summarizes the Medical Center's interest rate swap agreements:

Swap Type	Expiration Date	Medical Center Receives	Medical Center Pays	Notional Amount at September 30	
				2016	2015
Series C - Fixed to Floating (2005 Swap)	July 1, 2018	70% of LIBOR	3.70%	\$ 6,550,000	\$ 9,675,000
Series D - Fixed to Floating (2011 Swap)	July 1, 2032	65% LIBOR + 1.52%	4.61%	-	26,408,498
				<u>\$ 6,550,000</u>	<u>\$ 36,083,498</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

10. Notes Payable

Notes payable at September 30 consists of the following:

	<u>2016</u>	<u>2015</u>
Notes payable to a bank in monthly installments of \$128,417 through October 2018 at 1.455% interest. Secured by certain equipment.	\$ 5,620,637	\$ 7,068,428
Notes payable to a bank in monthly installments of \$114,385 through September 2019 at 2.52% interest. Secured by certain equipment.	3,962,022	5,217,573
Notes payable to a bank in monthly installments of \$147,233 through October 2018 at 2.85% interest. Secured by certain equipment.	3,569,569	5,209,211
Notes payable to a bank in monthly installments of \$59,782 through August 2019 at 4.08% interest. Secured by certain equipment.	1,969,561	2,592,756
Notes payable to a bank in monthly installments of \$55,978 through June 2018 at 1.302% interest. Secured by certain equipment.	1,161,630	1,813,638
Notes payable to a bank in monthly installments of \$9,845 through January 2021, interest free. Secured by certain equipment.	511,960	630,104
Note payable to a software company in quarterly installments of \$25,875 through September 2017.	105,250	182,946
Note payable to a software company in monthly installments of \$4,713 through September 2017.	56,786	-
Notes payable to landlord for leasehold improvements payable in monthly installments of \$1,431 through August 2019 at 6%, unsecured.	45,837	59,799
Notes payable to a health care equipment manufacturing company in monthly installments of \$18,392 through December 2015, at 4.15% interest. Secured by certain equipment.	-	51,544
Notes payable to a hospital association payable in monthly installments of \$6,529, interest free.	-	13,058
	<u>17,003,252</u>	<u>22,839,057</u>
Less current portion	<u>6,048,195</u>	<u>5,918,464</u>
Total	<u>\$ 10,955,057</u>	<u>\$ 16,920,593</u>

The carrying value of the notes payable approximates fair value. The Medical Center classifies notes payable in Level 2 of the valuation hierarchy.

Interest paid on the notes was \$508,993 and \$615,737 for the years ended September 30, 2016 and 2015, respectively.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements

September 30, 2016 and 2015

Principal payments on the notes for the next five years are as follows:

2017	\$ 6,048,195
2018	5,857,646
2019	3,791,106
2020	1,266,924
2021	<u>39,381</u>
	<u>\$ 17,003,252</u>

11. Line of Credit

The Medical Center has a line of credit agreement with Bank of America, N.A. for \$15,000,000. Amounts advanced under this line of credit are due on demand and interest is charged at the LIBOR rate plus 1.25%. There were no borrowings at September 30, 2016, and this line of credit expires on March 31, 2017.

12. Contingencies

The healthcare industry is subject to numerous laws and regulations of federal, state, and local governments. Compliance with these laws and regulations is subject to future government review and interpretation as well as regulatory actions unknown or unasserted at this time. Government activity continues to increase with respect to investigations and allegations concerning possible violations by healthcare providers of fraud and abuse statutes and regulations, which could result in the imposition of significant fines and penalties as well as significant repayments for patient services previously billed. Management is not aware of any material incidents of noncompliance; however, the possible future financial effects of this matter on the Medical Center, if any, are not presently determinable.

There have been malpractice claims that fall within the Medical Center's malpractice insurance which have been asserted against the Medical Center. In addition, there are known incidents that have occurred through September 30, 2016, that may result in the assertion of claims. Refer to Note 1.

The Medical Center is a party to various lawsuits incidental to its business. Management does not believe that the lawsuits will have a material adverse effect on the Medical Center's consolidated financial position.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

The Medical Center and CCSG record as a liability the estimate for claims-made malpractice liabilities and the estimate for incurred but not reported claims. The estimate for incurred but not reported claims, discounted at 4.00%, totaled \$3,276,331 and \$4,312,042 at September 30, 2016 and 2015, respectively, and are reported as other liabilities in the consolidated balance sheet. The Medical Center has recorded related insurance recoveries receivable in consideration for the expected insurance recoveries for the total claims-made insurance as follows:

	<u>2016</u>	<u>2015</u>
Other current assets	\$ 7,359,806	\$ 6,460,657
Other assets	<u>16,147,306</u>	<u>22,092,207</u>
	<u>\$ 23,507,112</u>	<u>\$ 28,552,864</u>

The Medical Center records as a liability an estimate of workers' compensation claims. Such liability, undiscounted, totaled approximately \$2,213,000 and \$2,201,000 at September 30, 2016 and 2015, respectively.

13. Commitments

Ground Lease

The Medical Center has a ground lease with Hartford Hospital to lease the site on which the Medical Center stands. The lease term is 99 years beginning November 1, 1993 with an optional extension for an additional 99-year term.

The Ground Lease was recorded as a prepaid asset in the original amount of \$2,900,000 and is amortized over the term of the lease. The net asset is recorded at \$2,299,514 and \$2,328,806 as of September 30, 2016 and 2015, respectively, and is included in other assets in the accompanying consolidated balance sheet. The lease includes certain covenants which restrict, among other things, the Medical Center's ability to be a party to mergers.

Parking Agreement

The Medical Center has a Parking Agreement with Hartford Hospital ("HH") for the use of 450 parking spaces on the Hartford Hospital campus. The agreement continues in full force and effect until the earlier of a written termination of the agreement by the Medical Center and HH or the termination of the ground lease.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

14. Operating Leases

Rental and lease expense amounted to \$14,227,288 and \$14,066,271 for the years ended September 30, 2016 and 2015, respectively.

The minimum lease commitments under all noncancelable operating leases with initial or remaining terms of more than one year are as follows:

Fiscal years ending September 30:	
2017	\$ 11,525,894
2018	8,133,803
2019	7,700,146
2020	7,101,438
2021	6,702,218
Thereafter	<u>36,658,594</u>
	<u>\$ 77,822,093</u>

15. Functional Expenses

The Medical Center provides health care services to residents within its geographic location including pediatric care and outpatient surgery. Expenses related to providing these services are as follows:

	<u>2016</u>	<u>2015</u>
Health care services	\$ 299,419,982	\$ 287,851,536
General and administrative	<u>84,422,998</u>	<u>78,112,644</u>
	<u>\$ 383,842,980</u>	<u>\$ 365,964,180</u>

16. Fair Value of Financial Instruments

The Medical Center calculates fair value of its financial assets and liabilities, when applicable, based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are applied based on a unit of account from the Medical Center's perspective. The unit of account determines what is being measured by reference to the level at which the asset or liability is aggregated (or disaggregated). In order to increase consistency and comparability in fair value measurements, the Medical Center utilizes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2 - Observable inputs that are based on inputs not quoted in active markets, but corroborated by market data.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

Level 3 - Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. In determining fair value, the Medical Center utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible.

The Medical Center's financial assets and liabilities carried at fair value as of September 30, 2016 are classified in the table below in one of the three categories described above:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Cash and cash equivalents	\$ 5,665,941	\$ -	\$ -	\$ 5,665,941
Fixed income securities	73,406	-	-	73,406
Mutual funds:				
Domestic	372,450	-	-	372,450
Equity:				
Domestic growth (a)	4,867,114	-	-	4,867,114
Domestic value (a)	8,858,633	-	-	8,858,633
International (a)	4,214,746	-	-	4,214,746
Domestic equity common trust fund	-	2,898,245	-	2,898,245
Fixed Income:				
International	86,049	-	-	86,049
Domestic	159,577	-	-	159,577
Intermediate term (a)	-	7,505,284	-	7,505,284
Global (a)	2,537,837	-	-	2,537,837
Inflation protected (a)	452,065	-	-	452,065
Foundation held funds and miscellaneous other investments	68,733	-	-	68,733
Funds held in trust by others	-	-	80,740,462	80,740,462
Total	<u>\$ 27,356,551</u>	<u>\$ 10,403,529</u>	<u>\$ 80,740,462</u>	<u>\$ 118,500,542</u>
Liabilities,				
Interest rate swap agreements (b)	<u>\$ -</u>	<u>\$ 277,123</u>	<u>\$ -</u>	<u>\$ 277,123</u>

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

The Medical Center's financial assets and liabilities carried at fair value as of September 30, 2015 are classified in the table below in one of the three categories described above:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Cash and cash equivalents	\$ 10,245,260	\$ -	\$ -	\$ 10,245,260
Fixed income securities	63,030	-	-	63,030
Mutual funds:				
Domestic	536,981	-	-	536,981
Equity:				
Domestic growth (a)	4,675,896	-	-	4,675,896
Domestic value (a)	4,620,275	-	-	4,620,275
International (a)	7,478,722	-	-	7,478,722
Domestic equity common trust fund	-	3,221,152	-	3,221,152
Fixed Income:				
International	112,904	-	-	112,904
Domestic	292,327	-	-	292,327
Intermediate term (a)	7,284,582	-	-	7,284,582
Global (a)	2,520,778	-	-	2,520,778
Inflation protected (a)	815,210	-	-	815,210
Foundation held funds and miscellaneous other investments	330,072	-	-	330,072
Funds held in trust by others	-	-	75,285,353	75,285,353
Total	\$ 38,976,037	\$ 3,221,152	\$ 75,285,353	\$ 117,482,542
Liabilities,				
Interest rate swap agreements (b)	\$ -	\$ 1,102,249	\$ -	\$ 1,102,249

(a) Includes investments in domestic and international equity mutual funds and exchange traded funds. Investments are broken out into the underlying funds' asset type and investment goals.

(b) The value of the Medical Center's swaps is determined by examining the present value of the future cash flows among other factors. The Medical Center utilizes an independent third party to calculate the value of the swaps based on all of the relevant factors.

Connecticut Children's Medical Center and Subsidiaries

Notes to Consolidated Financial Statements
September 30, 2016 and 2015

The following is a description of the Medical Center's valuation methodologies for assets measured at fair value. The fair value methodologies are not necessarily indicators of liquidity but are descriptive of the measures used to arrive at fair value pricing. Fair value for Level 1 is based upon quoted market prices. Fair value for Level 2 is based on quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Inputs are obtained from various sources, including market participants, dealers and brokers. The methods described above may produce a fair value that may not be indicative of net realizable value or reflective of future fair values. Furthermore, while the Medical Center believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

The changes in funds held in trust by others classified as Level 3 are as follows for the years ended September 30:

	<u>2016</u>	<u>2015</u>
Beginning balance for the year	\$ 75,285,353	\$ 82,885,871
Valuation gain (loss)	<u>5,455,109</u>	<u>(7,600,518)</u>
Ending balance for the year	<u>\$ 80,740,462</u>	<u>\$ 75,285,353</u>

The amounts reported in the tables above exclude assets invested in the Medical Center's defined benefit pension plan (Note 7).

Connecticut Children's Medical Center and Subsidiaries

Consolidating Balance Sheet

September 30, 2016

	Connecticut Children's Medical Center	Effect of Adoption of ASC 958-20	Total	Connecticut Children's Specialty Group	Children's Fund	Eliminations	Total Consolidated
Assets							
Current Assets							
Cash and cash equivalents	\$ 4,161,628	\$ -	\$ 4,161,628	\$ 256,063	\$ 1,248,250	\$ -	\$ 5,665,941
Patient accounts receivable, less allowance for doubtful accounts of approximately \$2,070,000 for the Medical Center and \$1,155,000 for CCSG	32,051,457	-	32,051,457	3,044,231	-	-	35,095,688
Due from affiliated entities	18,853	-	18,853	361,890	-	-	380,743
Inventories	2,407,715	-	2,407,715	-	-	-	2,407,715
Other current assets	8,281,500	-	8,281,500	3,980,297	960,871	-	13,222,668
Total current assets	46,921,153	-	46,921,153	7,642,481	2,209,121	-	56,772,755
Assets Whose Use is Limited							
Funds held in trust by others	80,740,462	-	80,740,462	-	-	-	80,740,462
Investments	-	-	-	721,978	31,372,160	-	32,094,138
Interest in net assets of Connecticut Children's Medical Center Foundation, Inc.	-	108,498,436	108,498,436	-	-	-	108,498,436
Total assets whose use is limited	80,740,462	108,498,436	189,238,898	721,978	31,372,160	-	221,333,036
Property, Plant and Equipment							
Buildings	149,753,616	-	149,753,616	2,417,672	-	-	152,171,288
Furniture and equipment	126,178,592	-	126,178,592	2,549,884	250,872	-	128,979,348
Construction in progress	2,121,842	-	2,121,842	38,740	-	-	2,160,582
Less accumulated depreciation	278,054,050	-	278,054,050	5,006,296	250,872	-	283,311,218
	(151,474,917)	-	(151,474,917)	(3,901,224)	(145,526)	-	(155,521,667)
Total property, plant and equipment	126,579,133	-	126,579,133	1,105,072	105,346	-	127,789,551
Other Assets							
Bond issuance costs	615,889	-	615,889	-	-	-	615,889
Ground lease	2,299,514	-	2,299,514	-	-	-	2,299,514
Other	19,616,829	-	19,616,829	5,708,698	5,493	-	25,331,020
Total other assets	22,532,232	-	22,532,232	5,708,698	5,493	-	28,246,423
Total assets	\$ 276,772,980	\$ 108,498,436	\$ 385,271,416	\$ 15,178,229	\$ 33,692,120	\$ -	\$ 434,141,765

Connecticut Children's Medical Center and Subsidiaries

Consolidating Balance Sheet
September 30, 2016

	Connecticut Children's Medical Center	Effect of Adoption of ASC 958-20	Total	Connecticut Children's Specialty Group	Children's Fund	Eliminations	Total Consolidated
Liabilities and Net Assets (Deficiency)							
Current Liabilities							
Current portion of bonds payable	\$ 1,500,000	\$ -	\$ 1,500,000	\$ -	\$ -	\$ -	\$ 1,500,000
Current portion of notes payable	6,033,372	-	6,033,372	14,823	-	-	6,048,195
Accounts payable and accrued expenses	36,868,927	-	36,868,927	3,886,297	822,749	-	41,577,973
Accrued wages	10,784,228	-	10,784,228	6,718,689	-	-	17,502,917
Due to third parties	3,164,295	-	3,164,295	1,336,824	-	-	4,501,119
Due to affiliated entities	15,089,703	-	15,089,703	1,101	-	-	15,090,804
Accrued interest payable and other current liabilities	53,729	-	53,729	71,703	-	-	125,432
Total current liabilities	73,494,254	-	73,494,254	12,029,437	822,749	-	86,346,440
Bonds Payable, Less Current Portion	33,769,625	-	33,769,625	-	-	-	33,769,625
Notes Payable, Less Current Portion	10,924,043	-	10,924,043	31,014	-	-	10,955,057
Accrued Pension Liability	24,478,050	-	24,478,050	-	-	-	24,478,050
Due to Third Parties	8,912,180	-	8,912,180	4,281,338	-	-	13,193,518
Other Long Term Liabilities	20,788,011	-	20,788,011	7,705,914	-	-	28,493,925
Total liabilities	172,366,163	-	172,366,163	24,047,703	822,749	-	197,236,615
Net Assets (Deficiency)							
Unrestricted	1,148,781	85,216,380	86,365,161	(8,869,474)	32,869,371	-	110,365,058
Temporarily restricted	22,517,574	4,562,145	27,079,719	-	-	-	27,079,719
Permanently restricted	80,740,462	18,719,911	99,460,373	-	-	-	99,460,373
Total net assets (deficiency)	104,406,817	108,498,436	212,905,253	(8,869,474)	32,869,371	-	236,905,150
Total liabilities and net assets (deficiency)	\$ 276,772,980	\$ 108,498,436	\$ 385,271,416	\$ 15,178,229	\$ 33,692,120	\$ -	\$ 434,141,765

Connecticut Children's Medical Center and Subsidiaries

Consolidating Statements of Operations and Changes in Net Assets
Year Ended September 30, 2016

	Connecticut Children's Medical Center	Effect of Adoption of ASC 958-20	Total	Connecticut Children's Specialty Group	Children's Fund	Eliminations	Total Consolidated
Revenues							
Patient service revenues	\$ 306,769,581	\$ -	\$ 306,769,581	\$ 54,641,332	\$ -	\$ -	\$ 361,410,913
Provision for bad debts	(1,605,446)	-	(1,605,446)	(1,584,241)	-	-	(3,189,687)
Patient service revenues, less provision for bad debts	305,164,135	-	305,164,135	53,057,091	-	-	358,221,226
Other revenues	3,849,544	-	3,849,544	5,329,171	4,797,102	(609,751)	13,366,066
Net assets released from restrictions for operations	16,467,708	-	16,467,708	64,214	2,961	-	16,534,883
Total revenues	325,481,387	-	325,481,387	58,450,476	4,800,063	(609,751)	388,122,175
Expenses							
Salaries	125,996,279	-	125,996,279	47,402,448	2,186,947	7,122,747	182,708,421
Benefits	26,196,501	-	26,196,501	10,745,889	673,220	1,638,231	39,253,841
Supplies and other	130,340,460	-	130,340,460	14,949,916	3,330,539	(9,370,729)	139,250,186
Depreciation and amortization	19,075,785	-	19,075,785	2,382,662	31,034	-	21,489,481
Interest	1,137,843	-	1,137,843	3,208	-	-	1,141,051
Total expenses	302,746,868	-	302,746,868	75,484,123	6,221,740	(609,751)	383,842,980
Income (loss) from operations	22,734,519	-	22,734,519	(17,033,647)	(1,421,677)	-	4,279,195
Other Income (Loss)							
Investment return, net	(10,799)	-	(10,799)	40,779	592,974	-	622,954
Income from trusts held by others	3,025,303	-	3,025,303	-	-	-	3,025,303
Change in equity interest in net assets of the Foundation	-	4,708,191	4,708,191	-	-	-	4,708,191
Total other income (loss)	3,014,504	4,708,191	7,722,695	40,779	592,974.00	-	8,356,448
Excess (deficiency) of revenues over expenses	25,749,023	4,708,191	30,457,214	(16,992,868)	(828,703)	-	12,635,643

Connecticut Children's Medical Center and Subsidiaries

Consolidating Statements of Operations and Changes in Net Assets
Year Ended September 30, 2016

	Connecticut Children's Medical Center	Effect of Adoption of ASC 958-20	Total	Connecticut Children's Specialty Group	Children's Fund	Eliminations	Total Consolidated
Unrestricted Net Assets (continued)							
Excess (deficiency) of revenues over expenses (from previous page)	\$ 25,749,023	\$ 4,708,191	\$ 30,457,214	\$ (16,992,868)	\$ (828,703)	\$ -	\$ 12,635,643
Transfer from affiliated organizations, net	(20,941,044)	-	(20,941,044)	20,061,044	-	-	(880,000)
Unrealized loss on investments	-	-	-	-	1,419,888	-	1,419,888
Net assets released from restrictions for capital	3,878,457	-	3,878,457	26,656	-	-	3,905,113
Change in funded status of pension and post-retirement plans	(4,937,060)	-	(4,937,060)	-	-	-	(4,937,060)
Change in equity interest in the net assets of the Foundation	-	2,209,549	2,209,549	-	-	-	2,209,549
Change in unrestricted net assets	3,749,376	6,917,740	10,667,116	3,094,832	591,185	-	14,353,133
Temporarily Restricted Net Assets							
Transfer from affiliated organization	7,661,054	-	7,661,054	-	-	-	7,661,054
Net assets released from restrictions for operations	(16,467,708)	-	(16,467,708)	(64,214)	(2,961)	-	(16,534,883)
Net assets released from restrictions for capital	(3,878,457)	-	(3,878,457)	(26,656)	-	-	(3,905,113)
Bequests, gifts and grants	10,017,374	-	10,017,374	90,870	-	-	10,108,244
Change in equity interest in the net assets of the Foundation	-	317,579	317,579	-	-	-	317,579
Change in temporarily restricted net assets	(2,667,737)	317,579	(2,350,158)	-	(2,961)	-	(2,353,119)
Permanently Restricted Net Assets							
Change in funds held in trust by others	5,455,109	-	5,455,109	-	-	-	5,455,109
Change in equity interest in the net assets of the Foundation	-	883,341	883,341	-	-	-	883,341
Change in permanently restricted net assets	5,455,109	883,341	6,338,450	-	-	-	6,338,450
Change in net assets	6,536,748	8,118,660	14,655,408	3,094,832	588,224	-	18,338,464
Net Assets (Deficiency) at Beginning of Year	97,870,069	100,379,776	198,249,845	(11,964,306)	32,281,147	-	218,566,686
Net Assets (Deficiency) at End of Year	\$ 104,406,817	\$ 108,498,436	\$ 212,905,253	\$ (8,869,474)	\$ 32,869,371	\$ -	\$ 236,905,150

EXHIBIT

9

EXHIBIT

10

Connecticut Childrens Medical Center
 Proposal for an additional 3T MRI Scanner
 2017

TABLE 8
 UTILIZATION BY TOWN

Town	Utilization FY 2016
Inpatient	
AMSTON	3
ANDOVER	5
AVON	16
BARKHAMSTED	1
BERLIN	2
BETHEL	1
BETHLEHEM	3
BLOOMFIELD	11
BOZRAH	1
BRISTOL	37
BROOKFIELD	8
BURLINGTON	2
CANTERBURY	1
CHESHIRE	3
CLINTON	1
COLCHESTER	3
COLUMBIA	8
COVENTRY	2
CROMWELL	5
DANBURY	33
Danielson	3
DAYVILLE	5
EAST HAMPTON	6
EAST HARTFORD	32
ELLINGTON	22
ENFIELD	11
FARMINGTON	8
GAYLORDSVILLE	5
GLASTONBURY	13
GOSHEN	2
GRANBY	3
GROTON	11
HADDAM	1
HARTFORD	66
HEBRON	2
HIGGANUM	8

Town	Utilization FY 2016
Inpatient	
JEWETT CITY	4
LISBON	4
MANCHESTER	34
MANSFIELD CENTER	1
MARLBOROUGH	3
MERIDEN	22
MIDDLE HADDAM	6
MIDDLEFIELD	1
MIDDLETOWN	6
MILFORD	1
MOODUS	3
MOOSUP	1
NAUGATUCK	1
NEW BRITAIN	23
NEW FAIRFIELD	3
NEW HARTFORD	1
NEW LONDON	3
NEW MILFORD	5
NEW PRESTON	1
NEWINGTON	11
NEWTOWN	3
NORFOLK	2
NORTHFIELD	1
NORWICH	6
OAKDALE	4
PLAINFIELD	2
PLAINVILLE	2
PORTLAND	3
PRESTON	1
PROSPECT	4
PUTNAM	3
ROCKY HILL	5
SALEM	1
SEYMOUR	1
SHELTON	2
SIMSBURY	3

Town	Utilization FY 2016
Inpatient	
SOUTH GLASTONBURY	4
SOUTH WINDHAM	1
SOUTH WINDSOR	9
SOUTHURY	1
SOUTHINGTON	15
SUFFIELD	2
TARIFFVILLE	1
TERRYVILLE	3
THOMASTON	9
TOLLAND	5
TORRINGTON	10
UNCASVILLE	4
UNION	2
UNIONVILLE	3
VERNON ROCKVILLE	1
VERNON	4
VOLUNTOWN	2
WATERBURY	41
WATERFORD	1
WATERTOWN	4
WEST HARTFORD	6
WEST HARTFRD	3
WEST SIMSBURY	1
WESTBROOK	1
WETHERSFIELD	7
WILLIMANTIC	6
WILLINGTON	2
WINDHAM	1
WINDSOR LOCKS	1
WINDSOR	7
WINSTED	6
WOLCOTT	4
N FRANKLIN	1
ROXBURY	2
REDDING	1
Inpatient Total	692

Connecticut Childrens Medical Center
 Proposal for an additional 3T MRI Scanner
 2017

TABLE 8
 UTILIZATION BY TOWN

Town	Utilization FY 2016
Outpatient	
AMSTON	7
ANDOVER	8
ANSONIA	3
ASHFORD	10
AVON	51
BALTIC	3
BARKHAMSTED	6
BEACON FALLS	3
BERLIN	29
BETHANY	1
BETHEL	11
BETHLEHEM	7
BLOOMFIELD	35
BOLTON	10
BOZRAH	11
BRANFORD	3
BRIDGEPORT	12
BRISTOL	142
BROAD BROOK	12
BROOKFIELD	11
BROOKLYN	8
BURLINGTON	12
CANAAN	3
CANTERBURY	5
CANTON	25
CHAPLIN	4
CHESHIRE	9
CLINTON	1
COLCHESTER	29
COLEBROOK	5
COLUMBIA	4
COVENTRY	43
CROMWELL	27
DANBURY	27

Town	Utilization FY 2016
Outpatient	
Danielson	19
DAYVILLE	8
DEEP RIVER	6
DERBY	6
DURHAM	2
EAST BERLIN	4
EAST GRANBY	16
EAST HADDAM	10
EAST HAMPTON	27
EAST HARTFORD	119
EAST HARTLAND	3
EAST HAVEN	5
EAST LYME	2
EAST WINDSOR	7
EASTON	2
ELLINGTON	24
ENFIELD	65
FAIRFIELD	10
FALLS VILLAGE	3
FARMINGTON	36
GALES FERRY	5
GAYLORDSVILLE	5
GLASTONBURY	74
GOSHEN	5
GRANBY	23
GRISWOLD	18
GROSVENOR DALE	1
GROTON	20
GUILFORD	1
HADDAM	3
HAMDEN	2
HAMPTON	1
HARTFORD	408
HARWINTON	5

Town	Utilization FY 2016
Outpatient	
HEBRON	12
HIGGANUM	14
IVORYTON	1
JEWETT CITY	19
kensington	13
KENT	1
KILLINGWORTH	2
LAKEVILLE	1
LEBANON	15
LEDYARD	6
LISBON	5
LITCHFIELD	9
MADISON	3
MANCHESTER	99
MANSFIELD CENTER	1
MARION	1
MARLBOROUGH	6
MERIDEN	78
MIDDLE HADDAM	3
MIDDLEBURY	3
MIDDLEFIELD	3
MIDDLETOWN	69
MILFORD	11
MILLDALE	1
MONROE	2
MOODUS	6
MOOSUP	7
MORRIS	3
MYSTIC	2
NAUGATUCK	30
NEW BRITAIN	182
NEW FAIRFIELD	4
NEW HARTFORD	23
NEW HAVEN	7

Connecticut Childrens Medical Center
 Proposal for an additional 3T MRI Scanner
 2017

TABLE 8
 UTILIZATION BY TOWN

Town	Utilization FY 2016	Town	Utilization FY 2016	Town	Utilization FY 2016
Outpatient		Outpatient		Outpatient	
NEW LONDON	18	SALEM	7	WATERBURY	169
NEW MILFORD	19	SANDY HOOK	5	WATERFORD	13
NEW PRESTON MARBLE	2	SEYMOUR	1	WATERTOWN	26
NEW PRESTON	1	SHELTON	4	WAUREGAN	2
NEWINGTON	56	SHERMAN	2	WEATOGUE	9
NEWTOWN	12	SIMSBURY	41	WEST GRANBY	2
NIANTIC	14	SOMERS	23	WEST HARTFORD	156
NORFOLK	1	SOUTH GLASTONBURY	17	WEST SIMSBURY	19
NORTH GRANBY	2	SOUTH WINDHAM	1	WEST SUFFIELD	8
NORTH GROSVENORDALE	3	SOUTH WINDSOR	55	WESTBROOK	4
NORTH HAVEN	9	SOUTHBURY	12	WESTPORT	7
NORTH STONINGTON	5	SOUTHINGTON	88	WETHERSFIELD	45
NORTH WINDHAM	4	STAFFORD SPGS	1	WILLIMANTIC	32
NORWALK	1	STAFFORD SPRINGS	14	WILLINGTON	7
NORWICH	44	STERLING	6	WILTON	2
OAKDALE	13	STORRS MANFLD	1	WINDHAM	13
OAKVILLE	17	STORRS MANSFIELD	7	WINDSOR LOCKS	28
OLD LYME	3	STORRS	8	WINDSOR	48
OLD SAYBROOK	2	STRATFORD	5	WINSTED	18
OXFORD	6	SUFFIELD	19	WOLCOTT	26
PAWCATUCK	8	TAFTVILLE	11	WOODBIDGE	1
PLAINFIELD	21	TARIFFVILLE	2	WOODBURY	12
PLAINVILLE	36	TERRYVILLE	29	WOODSTOCK VALLEY	2
PLANTSVILLE	4	THOMASTON	5	WOODSTOCK	4
PLYMOUTH	5	TOLLAND	26	RIVERTON	1
POMFRET CENTER	6	TORRINGTON	66	ROXBURY	1
PORTLAND	18	TRUMBULL	10	REDDING	2
PRESTON	2	UNCASVILLE	6	HADDAM NECK	1
PROSPECT	23	UNION	3	LAKESIDE	1
PUTNAM	19	UNIONVILLE	12	YANTIC	2
QUAKER HILL	4	VERNON ROCKVILLE	17	Outpatient Total	3798
RIDGEFIELD	3	VERNON	31	Grand Total	4490
ROCKFALL	2	VOLUNTOWN	3		
ROCKY HILL	27	WALLINGFORD	18		
ROGERS	1	WARREN	3		
S GLASTONBURY	2	WASHINGTON DEPOT	1		

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

**Fill in year



Supplemental CON Application Form
Acquisition of Equipment
Conn. Gen. Stat. § 19a-638(a)(10),(11)

Applicant: Connecticut Children's Medical Center

Project Name: Acquisition of a 3T MRI scanner

Affidavit

Applicant: Connecticut Children's Medical Center

Project Title: Acquisition of a 3T MRI Scanner

I, James E. Shmerling , President & CEO
(Name) (Position – CEO or CFO)

of Connecticut Children's Medical Center being duly sworn, depose and state that the (Connecticut Children's Medical Center) 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.



Signature

2/14/2017

Date

Subscribed and sworn to before me on Feb 14, 2017



Notary Public/Commissioner of Superior Court

My commission expires: _____

REBECCA J. PHILLIPS
NOTARY PUBLIC
State of Connecticut
My Commission Expires
October 31, 2021

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:

Philips Ingenia 3.0T Omega

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

RESPONSE:

282 Washington Street, Hartford
 General Diagnostics, Ultrasound, MRI, Fluoroscopy, CT

399 Farmington Ave, Farmington
 General Diagnostics, Ultrasound

310 Western Boulevard, Glastonbury
 General Diagnostics

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.

TABLE A
 EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Service*	Days/Hours of Operation **	Utilization***
Connecticut Children’s Medical Center 282 Washington Street Hartford, CT	Siemens 1.5T Closed MRI	M-F 730am – 11pm Sat 730am - 4pm	FY 16 4490

*Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)

**Days of the week unit is operational, and start and end time for each day

***Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

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

RESPONSE:

The location was chosen to be at the main campus to provide an additional advanced level of imaging to both inpatient and outpatients simultaneously as well as the availability of sedation and anesthesia services.

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). In **Table B**, report the units of service by piece of equipment, and in **Table C**, report the units of service by type of exam (e.g. if specializing in orthopedic, neurosurgery, or if there are scans that can be performed on the proposed scanner that the Applicant is unable to perform on its existing scanners).

TABLE B
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY EQUIPMENT UNIT

Equipment***	Actual Volume (Last 3 Completed FYs)			CFY Volume* FY 2017 (2 Mo)	Projected Volume (First 3 Full Operational FYs)**			
	FY 2014	FY 2015	FY 2016		FY 2018	FY 2019	FY 2020	FY 2021
Existing Siemen's 1.5T	4165	4374	4490	706	4490	4490	4490	4490
New Philips 3.0T				0	750	1450	2125	2675
Total	4165	4374	4490	706	5240	5940	6615	7165

Fiscal Year (FY) is October 1 to September 30th.

*For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

**If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.

***Identify each scanner separately and add lines as necessary. Also break out inpatient/outpatient/ED volumes if applicable.

****Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

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

Service***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY ****	FY ****	FY ****		FY ****	FY ****	FY ****
Scans by exam	SEE EXHIBIT <u>11</u>						
Total							

Fiscal year (FY) is October 1 to September 30th.

*For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

**If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.

***Identify each type of scan/exam (e.g., orthopedic, neurosurgery or if there are scans/exams that can be performed on the proposed piece of equipment that the Applicant is unable to perform on its existing equipment) and add lines as necessary.

****Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g., July 1-June 30, calendar year, etc.).

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

RESPONSE:

A review of MRI ordering from our electronic health record showed that many studies were being referred outside annually due to access and wait times. Inpatient ordering has grown significantly from 2015 to 2016 (approximately 30%) and is expected to be flat over the next 3-4 years as we do not anticipate a significant growth in inpatient days, therefore no inpatient increased testing was factored in to the projections. Projected volume increases were based on capturing more of the outside referrals in the first year. Successive years will see slower volume growth per year. Growth will come from our service line advances, additional complex cases in sub-specialty care, rotation away from CT imaging to avoid radiation exposure in children and the increased need for more sedation and anesthesia related cases as well as reducing our back-log of patients waiting for exams

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

RESPONSE:

See above response.

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

TABLE D
UTILIZATION BY TOWN

Equipment*	Town	Utilization FY XX**
See Exhibit <u>12</u>		

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

**Fill in year

EXHIBIT

11

**Connecticut Childrens Medical Center
Proposal for an additional 3T MRI Scanner
2017**

Table C
Historical, Current, and Projected Volume, by Type of scan/exam

Service*** Siemens 1.5T & Philips 3.0T	Actual Volume (Last 3 FY 2014			CFY Volume* FY 2017 (2 Mo)			Projected Volume (First 3 Full Operational FYs)**		
	FY 2014			FY 2015			FY 2016		
	FY 2014	FY 2015	FY 2016	FY 2017 (2 Mo)	FY 2018	FY 2019	FY 2020	FY 2021	
Inpatient									
MR ANGIOGRAPH NECK W/O&W DYE		6	6	6	6	6	6	6	6
MRA w/o fol w/cont, chest		2	2	2	2	2	2	2	2
MRI ABDOMEN W/DYE	1	1	1	1	1	1	1	1	1
Mri lower extremity w/dye	1								
Mri pelvis w/dye				1	1	1	1	1	1
MRA ABDOMEN W/WO CONTRAST MATERIAL	2	1	1	7	7	7	7	7	7
MRA CHEST W/O W/CONTRAST MATERIAL				2	2	2	2	2	2
MRA HEAD W/CONTRAST MATERIAL	1	1	1	1	1	1	1	1	1
MRA HEAD W/O W/CONTRAST MATERIAL	4	19	32	4	4	4	4	4	4
MRA HEAD W/O CONTRST MATERIAL	26	18	22	2	2	2	2	2	2
MRA LOWER EXTREMITY W/WO CONTRAST MATERIAL				1	1	1	1	1	1
MRA NECK W/CONTRAST MATERIAL				2	2	2	2	2	2
MRA NECK W/O CONTRST MATERIAL	1	2	4	4	4	4	4	4	4
MRA PELVIS W/WO CONTRAST MATERIAL				1	1	1	1	1	1
MRA UPPER EXTREMITY W/WO CONTRAST MATERIAL				4	4	4	4	4	4
MRI ABDOMEN W/O W/CONTRAST MATERIAL				1	1	1	1	1	1
MRI ABDOMEN W/O CONTRAST MATERIAL	21	29	31	7	7	7	7	7	7
MRI ANY JT LOWER EXTREM W/O W/CONTRAST MATRL	10	11	14	4	4	4	4	4	4
MRI ANY JT LOWER EXTREM W/O CONTRAST MATRL	12	9	14	1	1	1	1	1	1
MRI ANY JT LOWER EXTREM W/O CONTRAST MATRL	2	5	4	4	4	4	4	4	4
MRI ANY JT UPPER EXTREMITY W/O W/CONTR MATRL	4	8	5	5	5	5	5	5	5
MRI ANY JT UPPER EXTREMITY W/O CONTRAST MATRL				3	3	3	3	3	3
MRI BRAIN BRAIN STEM W/CONTRAST MATERIAL	1	2	2	2	2	2	2	2	2
MRI BRAIN BRAIN STEM W/O CONTRAST MATERIAL	102	113	108	24	24	24	24	24	24
MRI BRAIN BRAIN STEM W/O W/CONTRAST MATERIAL	120	167	200	26	26	26	26	26	26
MRI CHEST W/CONTRAST MATERIAL	1								
MRI CHEST W/O W/CONTRAST MATERIAL	2	6	4	4	4	4	4	4	4
MRI CHEST W/O CONTRAST MATERIAL	2			1	1	1	1	1	1
MRI LOWER EXTREM OTH/THN JT W/O W/CONTR MATR	16	18	46	6	6	6	6	6	6
MRI LOWER EXTREM OTH/THN JT W/O CONTR MATRL	1	4	2	1	1	1	1	1	1
MRI ORBIT FACE NECK W/O W/CONTRAST MATRL	8	9	12	1	1	1	1	1	1
MRI ORBIT FACE /NECK W/O CONTRAST	1	2	2	1	1	1	1	1	1
MRI PELVIS W/O W/CONTRAST MATERIAL	31	36	38	7	7	7	7	7	7
MRI PELVIS W/O CONTRAST MATERIAL	3	5	4	2	2	2	2	2	2
MRI SPECTROSCOPY	3	1	2	1	1	1	1	1	1
MRI SPINAL CANAL CERVICAL W/CONTRAST MATRL	2	1	3	2	2	2	2	2	2
MRI SPINAL CANAL CERVICAL W/O W/CONTR MATRL	31	29	24	1	1	1	1	1	1
MRI SPINAL CANAL CERVICAL W/O CONTRAST MATRL	11	21	14	2	2	2	2	2	2

**Connecticut Childrens Medical Center
Proposal for an additional 3T MRI Scanner
2017**

Table C
Historical, Current, and Projected Volume, by Type of scan/exam

Service***	Actual Volume (Last 3)				CFY Volume*				Projected Volume (First 3 Full Operational FYs)**																															
	FY 2014				FY 2015				FY 2016				FY 2017 (2 Mo)				FY 2018				FY 2019				FY 2020				FY 2021											
Siemens 1.5T & Philips 3.0T																																								
MRI SPINAL CANAL LUMBAR W/CONTRAST MATERIAL	3				2				3				2				3				3				3				3				3				3			
MRI SPINAL CANAL LUMBAR W/O W/CONTR MATRL	53				38				28				40				40				40				40				40				40				40			
MRI SPINAL CANAL LUMBAR W/O CONTRAST MATERIAL	9				12				12				2				11				11				11				11				11				11			
MRI SPINAL CANAL THORACIC W/CONTRAST MATRL	4				2				3				2				3				3				3				3				3				3			
MRI SPINAL CANAL THORACIC W/O W/CONTR MATRL	39				32				21				31				31				31				31				31				31				31			
MRI SPINAL CANAL THORACIC W/O CONTRAST MATRL	2				9				7				6				6				6				6				6				6				6			
MRI UPPER EXTREM OTHER THAN JT W/O W/CONTRAS	3				4				4				4				4				4				4				4				4				4			
Inpatient Total	533				627				692				106				634				634				634				634				634				634			
Outpatient																																								
MR ANGIOGRAPH NECK W/O&W DYE	4				9				2								6				7				8				8				8				8			
MRA w/o fol w/cont, chest					1				5								2				2				2				2				2				2			
Mri lower extremity w/dye	1				1				1								1				1				1				1				1				1			
MRI ORBIT/FACE/NECK W/DYE	2				3				5								4				5				6				6				6				6			
MRI UPPER EXTREMITY W/DYE					1				1								-				-				-				-				-				-			
MRA ABDOMEN W/WO CONTRAST MATERIAL	10				19				17				22				19				22				25				27				27				27			
MRA CHEST W/O W/CONTRAST MATERIAL	1				5				2								3				3				3				3				3				3			
MRA HEAD W/CONTRAST MATERIAL	5				4				2								5				6				7				8				8				8			
MRA HEAD W/O W/CONTRAST MATERIAL	22				34				28				4				35				40				45				49				49				49			
MRA HEAD W/O CONTRAST MATERIAL	51				59				74				7				76				88				99				108				108				108			
MRA LOWER EXTREMITY W/WO CONTRAST MATERIAL	1				2				3								2				2				2				2				2				2			
MRA NECK W/CONTRAST MATERIAL	1				3				3								2				2				2				2				2				2			
MRA NECK W/O CONTRAST MATERIAL	3				6				14				1				9				10				11				12				12				12			
MRA PELVIS W/WO CONTRAST MATERIAL	2				2				2								2				2				2				2				2				2			
MRA UPPER EXTREMITY W/WO CONTRAST MATERIAL	184				204				238				32				258				297				335				366				366				366			
MRI ABDOMEN W/O W/CONTRAST MATERIAL	16				17				20				3				22				25				28				31				31				31			
MRI ANY JT LOWER EXTREM W/CONTRAST MATERIAL	9				9				11								12				14				16				17				17				17			
MRI ANY JT LOWER EXTREM W/O W/CONTRAST MATRL	37				34				47				16				49				56				63				69				69				69			
MRI ANY JT LOWER EXTREM W/O CONTRAST MATRL	221				227				266				75				294				339				382				417				417				417			
MRI ANY JT UPPER EXTREMITY W/CONTRAST MATRL	3				3				3				1				4				5				6				7				7				7			
MRI ANY JT UPPER EXTREMITY W/O W/CONTR MATRL	12				10				15				5				15				17				19				21				21				21			
MRI ANY JT UPPER EXTREMITY W/O CONTRAST MATRL	32				19				29				5				33				38				43				47				47				47			
MRI BRAIN BRAIN STEM W/CONTRAST MATERIAL	3				2				21				3				11				13				15				16				16				16			
MRI BRAIN BRAIN STEM W/O CONTRAST MATERIAL	714				761				808				118				941				1,084				1,222				1,334				1,334				1,334			
MRI BRAIN BRAIN STEM W/O CONTRAST MATERIAL	857				783				771				130				994				1,145				1,291				1,410				1,410				1,410			
MRI CHEST W/CONTRAST MATERIAL	1				1				1								1				1				1				1				1				1			
MRI CHEST W/O W/CONTRAST MATERIAL	18				12				15				1				19				22				25				27				27				27			
MRI CHEST W/O CONTRAST MATERIAL	4				5				4								4				5				6				7				7				7			

**Connecticut Childrens Medical Center
Proposal for an additional 3T MRI Scanner
2017**

Table C
Historical, Current, and Projected Volume, by Type of scan/exam

Service*** Siemens 1.5T & Philips 3.0T	Actual Volume (Last 3)			CFY Volume*			Projected Volume (First 3 Full Operational FYs)**		
	FY 2014	FY 2015	FY 2016	FY 2017 (2 Mo)	FY 2018	FY 2019	FY 2020	FY 2021	
	MRI LOWER EXTREM OTH/THN JT W/O W/CONTR MATR	69	58	89	14	89	103	116	127
MRI LOWER EXTREM OTH/THN JT W/O CONTR MATRL	42	44	47	6	55	63	71	78	
MRI ORBIT FACE /NECK W/O W/CONTRAST MATRL	75	93	57	9	93	107	121	132	
MRI ORBIT FACE /NECK W/O CONTRAST	12	6	8	2	11	13	15	16	
MRI PELVIS W/O W/CONTRAST MATERIAL	175	189	233	35	246	283	319	348	
MRI PELVIS W/O CONTRAST MATERIAL	22	21	23	5	27	31	35	38	
MRI SPECTROSCOPY	5	6	1	1	5	6	7	8	
MRI SPINAL CANAL CERVICAL W/CONTRAST MATRL	10	3	5	1	7	8	9	10	
MRI SPINAL CANAL CERVICAL W/O W/CONTR MATRL	95	77	57	1	94	108	122	133	
MRI SPINAL CANAL CERVICAL W/O CONTRAST MATRL	186	248	209	31	265	305	344	376	
MRI SPINAL CANAL LUMBAR W/CONTRAST MATERIAL	8	2	5	1	6	7	8	9	
MRI SPINAL CANAL LUMBAR W/O W/CONTR MATRL	97	84	69	8	103	119	134	146	
MRI SPINAL CANAL LUMBAR W/O CONTRAST MATERIAL	311	373	330	42	418	482	543	593	
MRI SPINAL CANAL THORACIC W/CONTRAST MATRL	7	2	5	1	6	7	8	9	
MRI SPINAL CANAL THORACIC W/O W/CONTR MATRL	96	74	57	4	94	108	122	133	
MRI SPINAL CANAL THORACIC W/O CONTRAST MATRL	172	200	165	23	221	255	287	313	
MRI TEMPOROMANDIBULAR JOINT	11	15	10	5	15	17	19	21	
MRI UPPER EXTREM OTHER THAN JT W/O W/CONTRAS	17	17	15	4	20	23	26	28	
MRI UPPER EXTREMITY OTH THAN JT W/O CONTR MATRL	9	2	8	2	7	9	9	10	
Outpatient Total	3,632	3,747	3,798	600	4,606	5,306	5,981	6,531	
Total	4,165	4,374	4,490	706	5,240	5,940	6,615	7,165	

* 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.

EXHIBIT

12

Connecticut Childrens Medical Center
 Proposal for an additional 3T MRI Scanner
 2017

TABLE D
 UTILIZATION BY TOWN

Town	Utilization FY 2016
Inpatient	
AMSTON	3
ANDOVER	5
AVON	16
BARKHAMSTED	1
BERLIN	2
BETHEL	1
BETHLEHEM	3
BLOOMFIELD	11
BOZRAH	1
BRISTOL	37
BROOKFIELD	8
BURLINGTON	2
CANTERBURY	1
CHESHIRE	3
CLINTON	1
COLCHESTER	3
COLUMBIA	8
COVENTRY	2
CROMWELL	5
DANBURY	33
Danielson	3
DAYVILLE	5
EAST HAMPTON	6
EAST HARTFORD	32
ELLINGTON	22
ENFIELD	11
FARMINGTON	8
GAYLORDSVILLE	5
GLASTONBURY	13
GOSHEN	2
GRANBY	3
GROTON	11
HADDAM	1
HARTFORD	66
HEBRON	2
HIGGANUM	8

Town	Utilization FY 2016
Inpatient	
JEWETT CITY	4
LISBON	4
MANCHESTER	34
MANSFIELD CENTER	1
MARLBOROUGH	3
MERIDEN	22
MIDDLE HADDAM	6
MIDDLEFIELD	1
MIDDLETOWN	6
MILFORD	1
MOODUS	3
MOOSUP	1
NAUGATUCK	1
NEW BRITAIN	23
NEW FAIRFIELD	3
NEW HARTFORD	1
NEW LONDON	3
NEW MILFORD	5
NEW PRESTON	1
NEWINGTON	11
NEWTOWN	3
NORFOLK	2
NORTHFIELD	1
NORWICH	6
OAKDALE	4
PLAINFIELD	2
PLAINVILLE	2
PORTLAND	3
PRESTON	1
PROSPECT	4
PUTNAM	3
ROCKY HILL	5
SALEM	1
SEYMOUR	1
SHELTON	2
SIMSBURY	3

Town	Utilization FY 2016
Inpatient	
SOUTH GLASTONBURY	4
SOUTH WINDHAM	1
SOUTH WINDSOR	9
SOUTHBURY	1
SOUTHINGTON	15
SUFFIELD	2
TARIFFVILLE	1
TERRYVILLE	3
THOMASTON	9
TOLLAND	5
TORRINGTON	10
UNCASVILLE	4
UNION	2
UNIONVILLE	3
VERNON ROCKVILLE	1
VERNON	4
VOLUNTOWN	2
WATERBURY	41
WATERFORD	1
WATERTOWN	4
WEST HARTFORD	6
WEST HARTFRD	3
WEST SIMSBURY	1
WESTBROOK	1
WETHERSFIELD	7
WILLIMANTIC	6
WILLINGTON	2
WINDHAM	1
WINDSOR LOCKS	1
WINDSOR	7
WINSTED	6
WOLCOTT	4
N FRANKLIN	1
ROXBURY	2
REDDING	1
Inpatient Total	692

Connecticut Childrens Medical Center
 Proposal for an additional 3T MRI Scanner
 2017

TABLE D
 UTILIZATION BY TOWN

Town	Utilization FY 2016
Outpatient	
AMSTON	7
ANDOVER	8
ANSONIA	3
ASHFORD	10
AVON	51
BALTIC	3
BARKHAMSTED	6
BEACON FALLS	3
BERLIN	29
BETHANY	1
BETHEL	11
BETHEHEM	7
BLOOMFIELD	35
BOLTON	10
BOZRAH	11
BRANFORD	3
BRIDGEPORT	12
BRISTOL	142
BROAD BROOK	12
BROOKFIELD	11
BROOKLYN	8
BURLINGTON	12
CANAAN	3
CANTERBURY	5
CANTON	25
CHAPLIN	4
CHESHIRE	9
CLINTON	1
COLCHESTER	29
COLEBROOK	5
COLUMBIA	4
COVENTRY	43
CROMWELL	27
DANBURY	27

Town	Utilization FY 2016
Outpatient	
Danielson	19
DAYVILLE	8
DEEP RIVER	6
DERBY	6
DURHAM	2
EAST BERLIN	4
EAST GRANBY	16
EAST HADDAM	10
EAST HAMPTON	27
EAST HARTFORD	119
EAST HARTLAND	3
EAST HAVEN	5
EAST LYME	2
EAST WINDSOR	7
EASTON	2
ELLINGTON	24
ENFIELD	65
FAIRFIELD	10
FALLS VILLAGE	3
FARMINGTON	36
GALES FERRY	5
GAYLORDSVILLE	5
GLASTONBURY	74
GOSHEN	5
GRANBY	23
GRISWOLD	18
GROSVENOR DALE	1
GROTON	20
GUILFORD	1
HADDAM	3
HAMDEN	2
HAMPTON	1
HARTFORD	408
HARWINTON	5

Town	Utilization FY 2016
Outpatient	
HEBRON	12
HIGGANUM	14
IVORYTON	1
JEWETT CITY	19
kensington	13
KENT	1
KILLINGWORTH	2
LAKEVILLE	1
LEBANON	15
LEDYARD	6
LISBON	5
LITCHFIELD	9
MADISON	3
MANCHESTER	99
MANSFIELD CENTER	1
MARION	1
MARLBOROUGH	6
MERIDEN	78
MIDDLE HADDAM	3
MIDDLEBURY	3
MIDDLEFIELD	3
MIDDLETOWN	69
MILFORD	11
MILLDALE	1
MONROE	2
MOODUS	6
MOOSUP	7
MORRIS	3
MYSTIC	2
NAUGATUCK	30
NEW BRITAIN	182
NEW FAIRFIELD	4
NEW HARTFORD	23
NEW HAVEN	7

Connecticut Childrens Medical Center
 Proposal for an additional 3T MRI Scanner
 2017

TABLE D
 UTILIZATION BY TOWN

Town	Utilization FY 2016	Town	Utilization FY 2016	Town	Utilization FY 2016
Outpatient		Outpatient		Outpatient	
NEW LONDON	18	SALEM	7	WATERBURY	169
NEW MILFORD	19	SANDY HOOK	5	WATERFORD	13
NEW PRESTON MARBLE HILL	2	SEYMOUR	1	WATERTOWN	26
NEW PRESTON	1	SHELTON	4	WAUREGAN	2
NEWINGTON	56	SHERMAN	2	WEATOGUE	9
NEWTOWN	12	SIMSBURY	41	WEST GRANBY	2
NIANTIC	14	SOMERS	23	WEST HARTFORD	156
NORFOLK	1	SOUTH GLASTONBURY	17	WEST SIMSBURY	19
NORTH GRANBY	2	SOUTH WINDHAM	1	WEST SUFFIELD	8
NORTH GROSVENORDALE	3	SOUTH WINDSOR	55	WESTBROOK	4
NORTH HAVEN	9	SOUTHBURY	12	WESTPORT	7
NORTH STONINGTON	5	SOUTHINGTON	88	WETHERSFIELD	45
NORTH WINDHAM	4	STAFFORD SPGS	1	WILLIMANTIC	32
NORWALK	1	STAFFORD SPRINGS	14	WILLINGTON	7
NORWICH	44	STERLING	6	WILTON	2
OAKDALE	13	STORRS MANFLD	1	WINDHAM	13
OAKVILLE	17	STORRS MANSFIELD	7	WINDSOR LOCKS	28
OLD LYME	3	STORRS	8	WINDSOR	48
OLD SAYBROOK	2	STRATFORD	5	WINSTED	18
OXFORD	6	SUFFIELD	19	WOLCOTT	26
PAWCATUCK	8	TAFTVILLE	11	WOODBIDGE	1
PLAINFIELD	21	TARIFFVILLE	2	WOODBURY	12
PLAINVILLE	36	TERRYVILLE	29	WOODSTOCK VALLEY	2
PLANTSVILLE	4	THOMASTON	5	WOODSTOCK	4
PLYMOUTH	5	TOLLAND	26	RIVERTON	1
POMFRET CENTER	6	TORRINGTON	66	ROXBURY	1
PORTLAND	18	TRUMBULL	10	REDDING	2
PRESTON	2	UNCASVILLE	6	HADDAM NECK	1
PROSPECT	23	UNION	3	LAKESIDE	1
PUTNAM	19	UNIONVILLE	12	YANTIC	2
QUAKER HILL	4	VERNON ROCKVILLE	17	Outpatient Total	3798
RIDGEFIELD	3	VERNON	31	Grand Total	4490
ROCKFALL	2	VOLUNTOWN	3		
ROCKY HILL	27	WALLINGFORD	18		
ROGERS	1	WARREN	3		
S GLASTONBURY	2	WASHINGTON DEPOT	1		

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

**Fill in year

User, OHCA

From: Schaeffer-Helmecki, Jessica
Sent: Wednesday, March 22, 2017 1:07 PM
To: wagosti@connecticutchildrens.org
Cc: Riggott, Kaila; User, OHCA; Mitchell, Micheala
Subject: Completeness Questions: Connecticut Children's Medical Center CON application
Attachments: 32148 Connecticut Children's Medical Center.docx

Dear Mr. Agostinucci:

Attached please find completeness questions associated with docket number 17-32148-CON. Please confirm that you have received this e-mail.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA

Planning Analyst, Office of Health Care Access

Connecticut Department of Public Health

410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134

P: (860) 509-8075 | F: (860) 418-7053 | E: jessica.schaeffer-helmecki@ct.gov



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 22, 2017

Via Email Only

Mr. William Agostinucci
Director of Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
wagosti@connecticutchildrens.org

RE: Certificate of Need Application; Docket Number: 17-32148-CON
Connecticut Children's Medical Center Acquisition of a 3 Tesla MRI Scanner
Certificate of Need Completeness Letter

Dear Mr. Agostinucci:

On February 21, 2017, the Department of Public Health ("DPH"), Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Connecticut Children's Medical Center ("CT Children's") for the acquisition of a 3 Tesla MRI Scanner with a total capital expenditure of \$3,960,846. 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 both 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 using **Page 307** and reference "**Docket Number: 17-32148-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



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph
Affirmative Action/Equal Opportunity Employer

request was transmitted. Therefore, please provide your written responses to OHCA no later than May 22, 2017 **4:30 p.m.**, otherwise your application will be automatically considered withdrawn.

1. The projected volume for the use of the Phillips 3T is substantially less than the projected volume for the use of the Seimen's 1.5T in Table B on page 294 of the application. Please explain the methodology used to make those projections.
2. Update the volume for the current fiscal year in Table 5 on page 33 of the application. Additionally, the period between 10/1/2017 and 11/30/2017 is noted in the column for the *current* fiscal year of 2017. Confirm the dates used to calculate the volume for the 2017 fiscal year.
3. Define the terms "spatial resolution" and "post imaging processing" found on page 14 of the application.
4. On page 23 of the application, growth is said to be attributed, in part, to service line advancements, increased sedation and anesthesia-related cases and additional cases in sub-specialty care.
 - a. Define the term "service line advancement" and discuss why service line advancement contributes to growth.
 - b. Explain why sedation and anesthesia-related cases will increase.
 - c. List the percentage of growth projected for each of the following:
 - i. service line advances;
 - ii. complex cases in sub-specialty care;
 - iii. rotation away from CT imaging;
 - iv. increased need for more sedation and anesthesia-related cases; and
 - v. reduction in back-log of patients.
5. Enumerate the factors and explain the methodology used to derive the projected volume for fiscal years 2018, 2019, 2020 and 2021 in Table 6 on page 33 of the application.

If you have any questions concerning this letter, please feel free to contact Kaila Riggott at (860) 418-7037.

User, OHCA

From: Agostinucci, William <Wagosti@connecticutchildrens.org>
Sent: Wednesday, March 22, 2017 5:28 PM
To: Schaeffer-Helmecki, Jessica
Cc: Riggott, Kaila; User, OHCA; Mitchell, Micheala
Subject: RE: Completeness Questions: Connecticut Children's Medical Center CON application

Dear Ms. Schaeffer-Helmecki,

I am acknowledging receipt of the Completeness Questions for the Connecticut Children's Medical Center CoN application, docket number 17-32148-CON.

Thank you.

William Agostinucci, MS RPh, FACHE
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
860-837-5752

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Wednesday, March 22, 2017 1:07 PM
To: Agostinucci, William <Wagosti@connecticutchildrens.org>
Cc: Riggott, Kaila <Kaila.Riggott@ct.gov>; User, OHCA <OHCA@ct.gov>; Mitchell, Micheala <Micheala.Mitchell@ct.gov>
Subject: Completeness Questions: Connecticut Children's Medical Center CON application

Dear Mr. Agostinucci:

Attached please find completeness questions associated with docket number 17-32148-CON. Please confirm that you have received this e-mail.

Thank you,

Jessica Schaeffer-Helmecki, JD, MPA

Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075 | F: (860) 418-7053 | E: jessica.schaeffer-helmecki@ct.gov



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User, OHCA

From: Agostinucci, William <Wagosti@connecticutchildrens.org>
Sent: Wednesday, April 19, 2017 11:58 AM
To: User, OHCA; Riggott, Kaila
Subject: CCMC Completeness Questions Response - Docket Number: 17-32148-CON
Attachments: 3T MRI Completeness Questions- Docket # 17-32148-CON (00000003).docx; 3T MRI Completeness Scanned- Docket # 17-32148-CON (00000003).pdf

Dear Ms. Riggott,

Attached please find a Word and PDF scanned document of responses to the Certificate of Need Completeness Letter dated March 22, 2017, received from Ms. Jennifer Schaeffer-Helmecki, JD, MPA, regarding Connecticut Children's CON application for a 3T MRI Scanner.

Please reply that you have received this e mail.

If further information is needed please contact me at your convenience.

Sincerely,

William Agostinucci, MS RPh, FACHE
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
860-837-5752

****Connecticut Children's Confidentiality Notice****

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April 19, 2017

Ms. Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA
Hartford, CT 06134

**RE: Certificate of Need Application; Docket Number: 17-32148-CON
Connecticut Children's Medical Center Acquisition of a 3 Tesla MRI Scanner
Certificate of Need Completeness Letter.**

Dear Ms. Schaeffer-Helmecki:

Enclosed please find Connecticut Children's Medical Center's response to the Office of Health Care Access's completeness questions dated March 22, 2017.

Please do not hesitate to contact me at 860-837-5752 if you need additional information or have any further questions.

Sincerely,

A handwritten signature in blue ink that reads "William Agostinucci".

William Agostinucci
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington St.
Hartford CT 06106
(860) 837-5752
wagosti@connecticutchildrens.org

307 4/19/17

**Connecticut Children's Medical Center
Acquisition of a 3T MRI Scanner
Docket Number 17-32148-CON**

Response to the Certificate of Need Completeness Letter dated March, 22, 2017.

Question 1:

The projected volume for the use of the Philips 3T is substantially less than the projected volume for the use of the Siemen's 1.5T in Table B on page 294 of the application. Please explain the methodology used to make those projections.

The volume projections for the 3T MRI scanner were estimated as incremental volume above existing volume. The methodology used to project 3T volume was based on our estimates of being able to conduct studies for more complex cases and improved capabilities related to the pediatric cases requiring sedation and anesthesia. (see Table on page 311)

The appearance of "substantially less volume" than the 1.5T is related to the specialized case load that the 3T will be more appropriately serving. The introduction of improved quality and capability of 3T technology will provide a value to our pediatric patients in ways more related to safety and improved diagnoses. Exams that require 3T imaging will be scheduled on the 3Tscanner and will allow general anesthesia and sedation cases to be done contemporaneously.

We anticipate picking up out-migration referral volume (approximately 1,500 scans annually based on our electronic health record) as well as inherent growth. Having the capability of two scanners to conduct cases requiring sedation/anesthesia will reduce current wait times for this service and improve patient care and the overall patient and family experience. Non-anesthesia cases can then be scheduled between the two scanners and we can level out the volumes for each scanner, allowing for many exams to be done earlier in the day versus late evenings.

Question 2:

Update the volume for the current fiscal year in Table 5 on page 33 of the application. Additionally, the period between 10/1/2017 and 11/30/2017 is noted in the column for the current fiscal year of 2017. Confirm the dates used to calculate the volume for the 2017 fiscal year.

Table 5 has been amended with updated volume through 3/31/17 and the period of initial volume has been corrected. Table 5 is below.

Service***	Actual Volume (Last 3 Completed FYs)			CFY Volume*
	FY 2014	FY 2015	FY 2016	FY 2017 (10/1/2016 - 3/31/2017)
MRI - Inpatient	533	627	692	303
MRI - Outpatient/ED	3,632	3,747	3,798	1,841
Total	4,165	4,374	4,490	2,144

* 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.

Question 3:

Define the terms “spatial resolution” and “post imaging processing” found on page 14 of the application.

Spatial resolution is a term that relates to the number of pixels that make up an image. Similar to a high-resolution digital camera, more pixels of smaller size equates to a sharper image, and better diagnostic capability. 3T spatial resolution is significantly higher than 1.5 T

Post-imaging processing involves computer-based manipulation of the imaging data collected to show additional detail that is not apparent to the eye based on the anatomy alone. One example of post-imaging processing is diffusion-tensor imaging, a means of directly visualizing pathways in the brain (similar to power lines in your neighborhood) that are not apparent on conventional imaging sequences. Surgeons can use this information for surgical planning to understand where a tumor has displaced important functional pathways in the brain and avoid or minimize surgery-related deficits. Post-imaging processing requires newer software and the increased resolution available with a 3T magnet.

Questions 4:

On page 23 of the application, growth is said to be attributed, in part, to service line advancements, increased sedation and anesthesia-related cases and additional cases in sub-specialty care.

- a. Define the term “service line advancement” and discuss why service line advancement contributes to growth.**
- b. Explain why sedation and anesthesia-related cases will increase.**
- c. List the percentage of growth projected for each of the following:**
 - i. Service line advances**
 - ii. Complex cases in sub-specialty care**
 - iii. Rotation away from CT imaging**
 - iv. Increased need for more sedation and anesthesia-related cases**
 - v. Reduction in back-log of patients**

4a) A service line is a group of (condition-specific) related services defined by their integrated functions and overlapping patient need, integrated to create a coordinated patient experience. It is a patient-focused, coordinated model of care that unites Department(s), Specialty(s), settings (IP/OP), and supportive services as a single operational unit, similar to a “system of care” around specific illness or diseases.

Advancements within the (existing) service lines, as well as the development of additional service line(s), refers to the development of clinical services not currently offered within the service line. As these services are developed, many will be supported by diagnostic imaging.

Service line advancement also refers to an enhanced ability to coordinate condition-specific services, with the goal being to be able to provide those services within the walls of CT Children’s and it’s pediatric-specific system of care, reducing the need for children and their families to seek services in adult hospitals or ambulatory settings.

As service lines further develop to coordinate care, growth in the number of patients we serve is created through providers understanding the value to patients and we are attracting new providers. For instance, we are currently developing service lines for Neuro-Surgery, Neurology, Urology/Nephrology, GI and Cardiology.

4b) Sedation and anesthesia cases will increase overall as MRI technology is offering improved safety for children by decreasing radiation exposure from CT Scanning technology. The ability of having two scanners will allow us to reduce wait-times for this service, currently 3 weeks out which will improve the quality of patient care. Initial incremental volume will come from the back-log of patients as outlined in the table below.

4c) Please see the table below for a breakdown of our estimated volume growth related to *i* through *v*.

Growth Projections for the 3T MRI Scanner

ITEM	FY18 Incremental Volume	FY18%	FY19 Incremental Volume	FY19 %	FY20 Incremental Volume	FY20%	FY21 Incremental Volume	FY21%
Total Yearly Incremental Volume	750		700		675		550	
Existing Referrals and Service Lines	500	67%	500	72%	500	74%	400	73%
Complex Cases	25	3.3%	50	7%	75	11%	100	18%
Avoidance of CT	25	3.3%	50	7%	100	15%	50	9%
Anesthesia and Sedation	25	3.3%	50	7%	0	0%	0	0%
Backlog	175	23%	50	7%	0	0%	0	0%
Total Incremental Volume	750		1450		2125		2675	
Total Annual Volume	5240		5940		6615		7165	

Question 5:

Enumerate the factors and explain the methodology used to derive the projected volume for fiscal years 2018, 2019, 2020 and 2021 in Table 6 on page 33 of the application. See Table below for reference.

Growth Projections for the 3T MRI Scanner

ITEM	FY18 Incremental Volume	FY18%	FY19 Incremental Volume	FY19 %	FY20 Incremental Volume	FY20%	FY21 Incremental Volume	FY21%
Total Yearly Incremental Volume	750		700		675		550	
Existing Referrals and Service Lines	500	67%	500	72%	500	74%	400	73%
Complex Cases	25	3.3%	50	7%	75	11%	100	18%
Avoidance of CT	25	3.3%	50	7%	100	15%	50	9%
Anesthesia and Sedation	25	3.3%	50	7%	0	0%	0	0%
Backlog	175	23%	50	7%	0	0%	0	0%
Total Incremental Volume	750		1450		2125		2675	
Total Annual Volume	5240		5940		6615		7165	

The applied methodology to project MRI scan volume first used the current 4490 scans as our baseline (unit is at “capacity”). We then segmented the areas of growth to be related to the following:

- Loss of volume associated with our current back log (patients go elsewhere when no sedation is required for their child)
- The re-designing/advancements of our service lines that are coordinating the system of care for the patient is adding new providers thus increasing patient volume and associated diagnostic imaging
- The increase of complex cases with the introduction of 3T technology that will require 3T imaging
- The shift in cases from CT scanning to MRI scanning as a safety measure to reduce the radiation exposure from CT scan
- Existing out-migration of referrals

Over the course of the next four fiscal years we anticipate adding the incremental volume as shown in Table 6 of the application.

FY18 (partial year Jan -Sept) – 750	Total Scans at Connecticut Children’s	
FY19 – 1450	5240	
FY20 – 2125	5940	
FY21 – 2675	6615	
	7165	312 4/19/17

User, OHCA

From: Schaeffer-Helmecki, Jessica
Sent: Wednesday, May 17, 2017 4:52 PM
To: wagosti@connecticutchildrens.org
Cc: User, OHCA; Riggott, Kaila; Mitchell, Micheala
Subject: CON 17-32148 Second Completeness Letter
Attachments: 17-32148-CON-Connecticut Children's MRI Second Completeness 5.17.17.pdf

Dear Mr. Agostinucci:

Attached please find a second completeness letter related to CCMC's CON application to acquire an MRI Scanner (docket number 17-32148). Please confirm receipt of this message.

If you have any questions please contact Kaila Riggott at (860) 4128-7037 and have a good evening.

Sincerely,

Jessica Schaeffer-Helmecki, JD, MPA

Planning Analyst, Office of Health Care Access

Connecticut Department of Public Health

410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134

P: (860) 509-8075 | F: (860) 418-7053 | E: jessica.schaeffer-helmecki@ct.gov



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

May 17, 2017

Via Email Only

Mr. William Agostinucci
Director of Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
wagosti@connecticutchildrens.org

RE: Certificate of Need Application; Docket Number: 17-32148-CON
Connecticut Children's Medical Center Acquisition of a 3 Tesla MRI Scanner
Certificate of Need Second Completeness Letter

Dear Mr. Agostinucci:

On April 19, 2017, the Department of Public Health ("DPH"), Office of Health Care Access ("OHCA") received completeness responses on behalf of the Connecticut Children's Medical Center ("CT Children's") for the acquisition of a 3 Tesla MRI Scanner.

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 each of the following addresses:* OHCA@ct.gov and kaila.riggott@ct.gov.

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than **July 16, 2017**, otherwise your application will be automatically considered withdrawn.



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer



Repeat each question before providing your response and paginate and date your response (i.e., each page, in its entirety). Information filed after the initial CON application submission (e.g., completeness response letter, prefiled testimony, late file submissions and the like) must be numbered sequentially from the applicant’s document preceding it. Please begin your submission using **Page 313** and reference “**Docket Number: 16-32148-CON.**”

1. The total annual volume, as shown on page 311 of the application, appears to have been derived by adding the baseline of 4,490 scans performed by the existing 1.5T MRI to the “total incremental volume.” However, the total incremental volume, as calculated by the Applicant, is cumulative across all fiscal years rather than calculated for each individual year (i.e., as shown in the “total yearly incremental volume” line). Please recalculate the total annual volume. Please calculate each column separately without adding volume from the prior year.

INCREMENTAL SCAN VOLUME BY FISCAL YEAR

	FY18	FY19	FY20	FY21
Existing Referrals and Service Lines				
Complex Cases				
Avoidance of CT				
Anesthesia and Sedation				
Backlog				
Total 3T Incremental Scans				
Total 1.5T Scans				
TOTAL ANNUAL volume (total 3T incremental scans + total 1.5T scans)				

2. Page 308 of the application indicates that the Applicant’s projections are based, in part, upon an increase in volume of approximately 1,500 scans per year by recapturing out-migration referrals. Confirm that the 1,500 annual scans referenced on page 308 of the application are reflected in the table on pages 311 and 312 of the application. Additionally, indicate where this figure is reflected in the tables.
3. On page 311 of the application, the incremental volume of scans involving anesthesia and sedation for fiscal years 2020 and 2021 is 0. Verify the figures for those years and, if correct, explain why.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

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



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

If you have any questions concerning this letter, please feel free to contact Kaila Riggott at (860) 418-7037.

Sincerely,

Jessica Schaeffer-Helmecki
Planning Analyst



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, MS#13HCA
Hartford, Connecticut 06134-0308
www.ct.gov/dph

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User, OHCA

From: Agostinucci, William <Wagosti@connecticutchildrens.org>
Sent: Thursday, May 18, 2017 9:53 AM
To: Schaeffer-Helmecki, Jessica
Cc: User, OHCA; Riggott, Kaila; Mitchell, Micheala
Subject: RE: CON 17-32148 Second Completeness Letter

I acknowledge receipt of this letter.

Bill Agostinucci, MS RPh, FACHE
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
860-837-5752
(p) 860-220-2115

From: Schaeffer-Helmecki, Jessica [mailto:Jessica.Schaeffer-Helmecki@ct.gov]
Sent: Wednesday, May 17, 2017 4:52 PM
To: Agostinucci, William <Wagosti@connecticutchildrens.org>
Cc: User, OHCA <OHCA@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>; Mitchell, Micheala <Micheala.Mitchell@ct.gov>
Subject: CON 17-32148 Second Completeness Letter

Dear Mr. Agostinucci:

Attached please find a second completeness letter related to CCMC's CON application to acquire an MRI Scanner (docket number 17-32148). Please confirm receipt of this message.

If you have any questions please contact Kaila Riggott at (860) 4128-7037 and have a good evening.

Sincerely,

Jessica Schaeffer-Helmecki, JD, MPA

Planning Analyst, Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, MS #13 HCA, Hartford, Connecticut 06134
P: (860) 509-8075 | F: (860) 418-7053 | E: jessica.schaeffer-helmecki@ct.gov



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User, OHCA

From: Agostinucci, William <Wagosti@connecticutchildrens.org>
Sent: Monday, June 12, 2017 4:50 PM
To: User, OHCA; Riggott, Kaila
Subject: Connecticut Children's Second Completeness Questions Response - Docket Number: 17-32148-CON
Attachments: 3T Second Completeness Questions 6-12-17 Docket 17-32148-CON.DOCX; Scanned 3T CON Docket # 17-32148 CON - 2nd Completeness Letter 6-12-17.pdf

Dear Ms. Riggott,

Attached please find a Word and PDF scanned document of responses to the Certificate of Need Second Completeness Letter dated May 17, 2017, received from Jennifer Schaeffer-Helmecki, JD, MPA, regarding Connecticut Children's CON application for a 3T MRI Scanner.

Please contact me if you need anything further.

Sincerely,

William Agostinucci

William Agostinucci, MS RPh, FACHE
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
Phone - 860-837-5752

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June 12, 2017

Ms. Jessica Schaeffer-Helmecki, JD, MPA
Planning Analyst, Office of Health Care Access
Connecticut Departments of Public Health
410 Capital Avenue, MS #13 HCA
Hartford, CT 06134

RE: Certificate of Need Application; Docket Number: 17-32148-CON
Connecticut Children's Medical Center Acquisition of a 3 Tesla MRI Scanner
Certificate of Need Second Completeness Letter.

Dear Ms. Schaeffer-Helmecki:

Enclosed please find Connecticut Children's Medical Center's responses to the Office of Health Care Access's second completeness questions dated May 17, 2017.

Please contact me at 860-837-5752 if you need additional information or have any further questions.

Sincerely,

A handwritten signature in blue ink that reads "Will Agostinucci".

William Agostinucci
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington St.
Hartford CT 06106
(860) 837-5752
wagosti@connecticutchildrens.org

313 6/12/17

**Connecticut Children’s Medical Center
Acquisition of a 3T MRI Scanner
Docket Number 17-32148-CON**

Response to the Certificate of Need Second Completeness Letter dated May 17, 2017.

Question 1:

The total annual volume, as shown on page 311 of the application, appears to have been derived by adding the baseline of 4,490 scans performed by the existing 1.5T MRI to the “total incremental volume.” However, the total incremental volume, as calculated by the Applicant, is cumulative across all fiscal years rather than calculated for each individual year (i.e., as shown in the “total yearly incremental volume” line). Please recalculate the total annual volume. Please calculate each column separately without adding volume from the prior year.

	FY 18	FY 19	FY 20	FY 21
Existing Referrals and Service Lines	500	1000	1500	1900
Complex Cases	25	75	150	250
Avoidance of CT	25	75	175	225
Anesthesia and Sedation	25	75	75	75
Backlog	175	225	225	225
Total 3T Incremental Scans	750	1450	2125	2675
Total 1.5T Scans	4490	4490	4490	4490
TOTAL ANNUAL volume (total 3T incremental scans + total 1.5T scans)	5240	5940	6615	7165

**Connecticut Children's Medical Center
Acquisition of a 3T MRI Scanner
Docket Number 17-32148-CON**

Response to the Certificate of Need Second Completeness Letter dated May 17, 2017.

The above volume numbers are estimates by type of case. The current volume of 4490 scans is the baseline capacity for the current 1.5T. The total incremental scans for the 3T start at 750 in year one (FY18) and increase to 2675 in year four (FY21). The volume each year is the projected incremental volume above 4490 resulting in the annual volumes for both MRI scanners to be 5240, 5940, 6615 and 7165.

Question 2:

Page 308 of the application indicates that the Applicant's projections are based, in part, upon an increase in volume of approximately 1,500 scans per year by recapturing outmigration referrals. Confirm that the 1,500 annual scans referenced on page 308 of the application are reflected in the table on pages 311 and 312 of the application. Additionally, indicate where this figure is reflected in the tables.

The 1500 scans are reflected in the table on page 311 in the row titled "Existing Referrals and Service Lines." The assumption that over the course of the first three years we will achieve the annual total of 1500 scans. This is more clearly delineated in the restated table in Question 1.

Question 3:

On page 311 of the application, the incremental volume of scans involving anesthesia and sedation for fiscal years 2020 and 2021 is 0. Verify the figures for those years and, if correct, explain why.

The anesthesia and sedation volume is difficult to project in subsequent years so we chose to be conservative in our projections. In the restated table in Question 1, the anesthesia cases do not increase after FY19. We believe we are adequately estimating a stable volume of these cases in our market. However, if unforeseen marketplace conditions occur (i.e., newer technology, new procedures or an influx of pediatric cases), there may be a slight increase in cases requiring anesthesia.

User, OHCA

From: Mitchell, Micheala
Sent: Wednesday, July 12, 2017 11:49 AM
To: 'Agostinucci, William'
Cc: Schaeffer-Helmecki, Jessica; User, OHCA; Riggott, Kaila
Subject: RE: 17-32148 CON Connecticut Children's Medical Center/MRI

Mr. Agostinucci:

Thank you for speaking with us this morning. We anticipate receiving the responses to our inquiries later today unless you notify us otherwise. As we discussed, you can email them to us directly.

If you have any questions, or need additional time please contact me at 860-418-7055 or Jessica at 860-509-8075.

Micheala L. Mitchell
Staff Attorney, PHHO/OHCA
Connecticut Department of Public Health
410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134
Phone: (860) 418-7055
Email: micheala.mitchell@ct.gov



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From: Agostinucci, William [mailto:Wagosti@connecticutchildrens.org]
Sent: Tuesday, July 11, 2017 6:16 PM
To: Mitchell, Micheala <Micheala.Mitchell@ct.gov>
Cc: Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov>; User, OHCA <OHCA@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>
Subject: RE: 17-32148 CON Connecticut Children's Medical Center/MRI

Ms. Mitchell,
Thank you for the advance information. I am available at 9am tomorrow. I can call your office at that time.
Bill Agostinucci

From: Mitchell, Micheala [Micheala.Mitchell@ct.gov]
Sent: Tuesday, July 11, 2017 5:01 PM
To: Agostinucci, William

Cc: Schaeffer-Helmecki, Jessica; User, OHCA; Riggott, Kaila
Subject: FW: 17-32148 CON Connecticut Children's Medical Center/MRI

Mr. Agostinucci:

Thank you for acknowledging receipt of my email earlier this afternoon. Although we have not confirmed a time to talk tomorrow, I thought it might be proactive to share our questions with you beforehand. We are trying to avoid issuing a third completeness request for this application because we need only a few questions/clarifications regarding your June 12th responses.

First, we would like you to update the record with the current scan volume for the 1.5T, year to date, for fiscal year 2017 (see page 33 of the application).

Second, the year to year growth projections for the 3T scanner are higher than we normally see in these types of applications (see page 314 of the application). We acknowledge your assertion that increases in utilization will be derived from service line advancement, additional complex cases, rotation away from CT imaging and reductions in the backlog. However, the percentage increase in utilization is **93%** from FY 2018 to 2019. While we also note that the percentage declines to 46% from FY 2019 to 2010, and 25% from FY 2010 to 2021, we want to know if you could provide the calculation(s) and/or method(s) used to derive those projections to us.

The deadline to deem the application complete is tomorrow. Please let me know if you are available to speak at 9 a.m. If not, we can work out a mutually beneficial time to talk later in the day.

Thanks again,

Micheala L. Mitchell
Staff Attorney, PHHO/OHCA
Connecticut Department of Public Health
410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134
Phone: (860) 418-7055
Email: micheala.mitchell@ct.gov



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From: Mitchell, Micheala
Sent: Tuesday, July 11, 2017 3:02 PM
To: 'Agostinucci, William' <Wagosti@connecticutchildrens.org>
Cc: Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov>
Subject: RE: 17-32148 CON Connecticut Children's Medical Center/MRI

Sure. Are you available from 9 to 9:15?

From: Agostinucci, William [<mailto:Wagosti@connecticutchildrens.org>]
Sent: Tuesday, July 11, 2017 3:00 PM
To: Mitchell, Micheala <Micheala.Mitchell@ct.gov>
Cc: Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov>
Subject: Re: 17-32148 CON Connecticut Children's Medical Center/MRI

Good afternoon

I am at a leadership meeting this afternoon. Would tomorrow be possible?

Thank you

Bill

Sent from my iPhone

On Jul 11, 2017, at 1:39 PM, Mitchell, Micheala <Micheala.Mitchell@ct.gov> wrote:

Mr. Agostinucci:

Do you have a moment to speak with me and my colleague Jessica this afternoon? We have a few brief follow-up questions regarding the information that you provided to us in your June 12th completeness responses. We anticipate taking no more than 10 to 15 minutes of your time.

Please advise at your earliest convenience.

Thanks,

Micheala L. Mitchell

Staff Attorney, PHHO/OHCA

Connecticut Department of Public Health

410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134

Phone: (860) 418-7055

Email: micheala.mitchell@ct.gov

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User, OHCA

From: Agostinucci, William <Wagosti@connecticutchildrens.org>
Sent: Wednesday, July 12, 2017 1:33 PM
To: Mitchell, Micheala
Cc: Schaeffer-Helmecki, Jessica; User, OHCA; Riggott, Kaila
Subject: RE: 17-32148 CON Connecticut Children's Medical Center/MRI

Dear Ms. Mitchell,
Please find the responses to your questions below. Please contact me if there are any further questions.
Thank you.

Bill Agostinucci, MS RPh, FACHE
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
860-837-5752
Cell 860-306-6077

Volume Assumptions for the 3T MRI Acquisition at Connecticut Children's Medical Center

Year to date volume for the 1.5T through June 2017 is 3601.

Volume projections for the 3T scanner were based on the following factors:

- Approximately 1500 scans per year are directed outside of the hospital due to capacity issues. We project to capture those scans by a third of the total volume annually over a three year period, eventually eradicating the issue and therefore reflect 500, 1000, and 1500 scans annually in the first three years.
- In addition, the volume of complex cases will grow as a result of addition of more highly acute cases based on discussions with the Medical Staff and advancements in areas such as Oncology, Nephrology, Neurology and NeuroSurgery.
- The increases in anesthesia and sedation cases were calculated through estimates from our Radiology Medical Director and Anesthesia Director in an effort to route patients away from radiation exposure from CT. Additional growth in this area would be achieved as the backlog is reduced allowing for cases that require anesthesia or sedation to now be accommodated.

From: Mitchell, Micheala [mailto:Micheala.Mitchell@ct.gov]
Sent: Wednesday, July 12, 2017 11:49 AM
To: Agostinucci, William <Wagosti@connecticutchildrens.org>
Cc: Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov>; User, OHCA <OHCA@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>
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Mr. Agostinucci:

Thank you for speaking with us this morning. We anticipate receiving the responses to our inquiries later today unless you notify us otherwise. As we discussed, you can email them to us directly.

If you have any questions, or need additional time please contact me at 860-418-7055 or Jessica at 860-509-8075.

Micheala L. Mitchell
Staff Attorney, PHHO/OHCA
Connecticut Department of Public Health
410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134
Phone: (860) 418-7055
Email: micheala.mitchell@ct.gov



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Micheala L. Mitchell
Staff Attorney, PHHO/OHCA
Connecticut Department of Public Health
410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134
Phone: (860) 418-7055
Email: micheala.mitchell@ct.gov



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Bill

Sent from my iPhone

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Please advise at your earliest convenience.

Thanks,

Micheala L. Mitchell

Staff Attorney, PHHO/OHCA

Connecticut Department of Public Health

410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134

Phone: (860) 418-7055

Email: micheala.mitchell@ct.gov

<image001.jpg> <image002.jpg>

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User, OHCA

From: Mitchell, Micheala
Sent: Thursday, July 13, 2017 9:32 AM
To: 'Agostinucci, William'
Cc: Schaeffer-Helmecki, Jessica; Riggott, Kaila; User, OHCA
Subject: 17-32148 Connecticut Children's Medical Center
Attachments: 32148 Connecticut Children's Medical Center Deemed Complete.pdf

Good morning Mr. Agostinucci,

Attached is a letter deeming the above-referenced application complete. Please confirm receipt of this email and the attachment.

Sincerely,
Micheala L. Mitchell
Staff Attorney, PHHO/OHCA
Connecticut Department of Public Health
410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134
Phone: (860) 418-7055
Email: micheala.mitchell@ct.gov



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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

July 13, 2017

Via Email Only

William Agostinucci
Director of Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
wagosti@connecticutchildrens.org


RE: Certificate of Need Application: Docket Number: 17-32148-CON
Acquisition of a 3T MRI Scanner at Connecticut Children's Medical Center

Dear Mr. Agostinucci:

This letter is to inform you that, pursuant to Section 19a-639a (d) of the Connecticut General Statutes, the Office of Health Care Access has deemed the above-referenced application complete as of July 12, 2017.

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7055.

Sincerely,

 Digitally signed by
Micheala Mitchell
Date: 2017.07.13
09:26:21 -04'00'

Micheala L. Mitchell
Staff Attorney



Phone: (860) 418-7001 • Fax: (860) 418-7053
410 Capitol Avenue, M.S. #13HCA
P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer



User, OHCA

From: Agostinucci, William <Wagosti@connecticutchildrens.org>
Sent: Thursday, July 13, 2017 10:55 AM
To: Mitchell, Micheala
Cc: Schaeffer-Helmecki, Jessica; Riggott, Kaila; User, OHCA
Subject: RE: 17-32148 Connecticut Children's Medical Center

Ms. Mitchell,
I am confirming receipt of this e mail and the attachment.
Thank you.

Bill Agostinucci, MS RPh, FACHE
Director, Clinical Support Services
Connecticut Children's Medical Center
282 Washington Street
Hartford, CT 06106
860-837-5752

From: Mitchell, Micheala [mailto:Micheala.Mitchell@ct.gov]
Sent: Thursday, July 13, 2017 9:32 AM
To: Agostinucci, William <Wagosti@connecticutchildrens.org>
Cc: Schaeffer-Helmecki, Jessica <Jessica.Schaeffer-Helmecki@ct.gov>; Riggott, Kaila <Kaila.Riggott@ct.gov>; User, OHCA <OHCA@ct.gov>
Subject: 17-32148 Connecticut Children's Medical Center

Good morning Mr. Agostinucci,

Attached is a letter deeming the above-referenced application complete. Please confirm receipt of this email and the attachment.

Sincerely,
Micheala L. Mitchell
Staff Attorney, PHHO/OHCA
Connecticut Department of Public Health
410 Capitol Avenue, MS# 13-HCA, Hartford, CT 06134
Phone: (860) 418-7055
Email: micheala.mitchell@ct.gov



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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

Department of Public Health Final Decision

Applicant: Connecticut Children's Medical Center

Docket Number: 17-32148-CON

Project Title: Acquisition of a 3.0 Tesla Magnetic Resonance Imaging Scanner

Project Description: Connecticut Children's Medical Center (or "Applicant") seeks authorization to acquire a new 3.0 Tesla Magnetic Resonance Imaging scanner to be located at its hospital campus at 282 Washington Street in Hartford, CT.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in the *Hartford Courant* (Hartford) on December 23, December 24 and December 25, 2016. On February 21, 2017, 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 July 12, 2017. OHCA received no responses from the public concerning the Applicant's proposal and no hearing requests were received from the public pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a. Deputy Commissioner Addo considered the entire record in this matter.



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Findings of Fact and Conclusions of Law

1. Connecticut Children's Medical Center ("CCMC" or "Applicant") is a 187-bed non-profit children's hospital located at 282 Washington Street in Hartford, Connecticut. Ex. A, pp. 10-11.
2. CCMC serves as the primary teaching hospital for the Department of Pediatrics at the University of Connecticut School of Medicine. Ex. A, pp. 11-12.
3. The Applicant performs approximately 4,400 imaging studies annually using a single, 1.5 Tesla ("1.5T") Magnetic Resonance Imaging ("MRI") scanner. Ex. A, p. 11.
4. In order to increase pediatric patients' access to high quality care, improve patient safety, and to reduce anesthesia and sedation wait times, the Applicant proposes to acquire a higher strength Philips Ingenia 3.0 Tesla ("3T") Omega MRI scanner. Ex. A, pp.11, 293.
5. Higher strength magnetic scanners such as the 3T are the current standard of care for diagnostic imaging in the United States for orthopedic, neurologic, cardiac, gastrointestinal and urologic conditions. Two-thirds of free-standing children's hospitals in the United States have this technology. Ex. A, pp. 11, 16-17.
6. The acquisition of the 3T scanner is intended to:
 - a. decrease the length of sedation required to acquire images;
 - b. reduce the Applicant's reliance upon computed tomography (CT) scanners for the evaluation of urgent/emergency conditions, thereby decreasing radiation exposure;
 - c. improve access to all patients regardless of their ability to pay, and
 - d. improve spatial resolution and post imaging processing.¹ Ex. A, pp. 13-14, 81.
7. Approximately 50% of the Applicant's patients require sedated MRI studies since many children under the age of 10 and those with developmental delays require anesthesia in order to remain still throughout the procedure.² Ex. A, pp. 12, 18-19.
8. Outpatients scheduled to receive scans risk postponement of their appointments so that the Applicant can accommodate emergency scans and inpatient examinations. The Applicant's wait times for non-emergent, sedated studies currently average between 10 and 15 days. Ex. A, pp. 11, 14.

¹ The term "spatial resolution" relates to the number of pixels that make up an image; specifically, more pixels of a smaller size equate to a sharper image and better diagnostic capability. The phrase "post-image processing" refers to computer-based manipulation of the imaging data to show additional detail that is not apparent to the eye based upon anatomy alone. Ex. A, p. 309.

² When assessing the need for an MRI scanner, the 2012 Statewide Health Care Facilities and Services Plan allows for consideration of unique patient populations and the complexity of scanning procedures, including the impact on available scanner access due to lengthy procedures. These guidelines have not yet been formally adopted into regulation.

9. According to the Journal of Neurosurgical Pediatrics, “The risk of developing a radiation-induced malignancy is relative to a patient’s cumulative radiation exposure and increases with exposure at younger ages.” It recommends employing an MRI rather than a CT-scanner to eliminate exposure to radiation and minimize sedation risks.³ Ex. A p. 98.
10. Children are more sensitive to radiation than adults, have a longer life expectancy than adults with a larger window for exposure to radiation damage and may receive a higher radiation dose than necessary if CT settings are not adjusted for their smaller body size, according to the National Cancer Institute.⁴ Ex. A, p. 107.
11. In *MR Imaging at 3.0T in Children*, The Hospital for Sick Children and the University of Toronto list among the advantages of 3.T over 1.5T MRI scans the acquisition of good-quality images even with a small field of view and a shorter acquisition time, the latter of which is beneficial for children who many not be able to cooperate for long and require additional patient monitoring. As with adults, the 3T offers a doubled signal-to-noise ratio, improved spatial resolution and improved contrast-to-noise ratio, resulting in clearer images and improved diagnostics.⁵ Ex. A, p. 81.
12. The Applicant’s historical volume, as shown below, has increased since 2014, however the number of scans that can be performed on the 1.5T is constrained by the longer time required to perform pediatric scans and the limited possible scheduling hours due to the requirement that patients fast before procedures.

**TABLE 1
HISTORICAL (ACTUAL) NUMBER OF SCANS BY FISCAL YEAR**

Scanner	FY 2014	FY 2015	FY 2016	FY 2017	Change FY 2014- FY 2017
TOTAL 1.5T	4,165	4,374	4,490	4,320*	3.7%

*FY 2017 annualized based on data from 10/1/2016 through 6/30/2017.
Ex. A, p. 11; Ex. C, p. 309.

13. The Applicant estimates that the 3T scanner will be operational by January 2018. Ex. A. p. 10.

³ Eric Thompson, M.D. et al., *Results of a North American Survey of rapid-sequence MRI utilization to evaluate cerebral ventricles in children*, 13 J NEUROSURG PEDIATRICS 636-640 (June 2014).

⁴ National Cancer Institute, *Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers* (June 2012).

⁵ Govind B. Chavhan, M.D. et al., *MR Imaging at 3.0T in Children: Technical Differences, Safety Issues, and Initial Experience*, 29 RADIOGRAPHICS 1451-1466 (2009).

14. As shown in the table below, the Applicant projects an overall 37% increase in scans from FY 18 through FY 21.

**TABLE 2
PROJECTED NUMBER OF SCANS BY FISCAL YEAR**

Scanner	FY 2018	FY 2019	Change*	FY 2020	Change*	FY 2021	Change*	FY18-21 Change
Total 3T Scans	750	1,450	93%	2,125	47%	2,675	26%	257%
Total 1.5T Scans	4,490	4,490	0%	4,490	0%	4,490	0%	0%
TOTAL	5,240	5,940	13%	6,615	11%	7,165	8%	37%

* The Applicant projects declining year-over-year percent increases on the 3T as it reduces its existing backlog of patients and stabilizes the number of scans it must refer elsewhere due to 1.5T scanner capacity issues. Ex. A, pp. 23, 33; Ex. E p. 314.

15. The Applicant attributes the aforementioned projections due to:
- advancements within existing and future service lines requiring diagnostic imaging;⁶
 - additional complex cases in sub-specialty care,
 - rotation away from CT imaging to minimize radiation exposure; and
 - reductions in the back-log of patients waiting for scans. Ex. A, pp. 23; Ex. C, p. 310.
16. The Applicant anticipates that by FY21, with the addition of the 3.0T, it will be able to provide 225 MRI scans per year to children who would otherwise receive a CT-scan. Ex. E, p. 314.
17. The Applicant currently must refer approximately 1,500 patients per year elsewhere to receive their scans. Ex. C, p. 308.
18. By performing the scans in-house, coordination of care will improve by reducing invasive, high-risk testing; eliminating the risks associated with transferring patients to other facilities; and maintaining the image and results within the patient’s electronic medical record. Ex. A, p.21.
19. The Applicant has a backlog of between 175 and 225 MRI scans to perform on non-emergent patients. Ex. E, p. 314.
20. While other hospitals provide pediatric as well as adult MRI scans, CCMC is the only freestanding children’s general hospital in Connecticut. Ex. A, p. 35.
21. CCMC solely treats children and has a special team assembled for those children requiring MRIs that require sedation, consisting of a Pediatric Anesthesiologist, Sedation Nurse, Child Life Specialist, MRI Technologist, and Pediatric Radiologist. The team’s focus is trifold: to ensure

⁶ A service line is a group of condition-specific, related services, defined by their integrated functions and overlapping patient need, integrated to create a coordinated patient experience. Ex. A., p 310.

sedation is performed safely, to minimize the child and its family’s anxiety, acquire quality imaging with minimal movement to prevent the need for re-scans. Ex. A, p. 12.

22. The total capital expenditure for the purchase of the 3T MRI is \$3,960,846, approximately \$822,000 of which, the Applicant will use for construction/renovation. The Applicant will make the purchase using cash from operations. Ex. A, p. 3.
23. The Applicant anticipates operational gains associated with the acquisition and utilization of the new scanner. Ex. A, p. 23.

**TABLE 3
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2018	FY 2019	FY 2020	FY 2021
Revenue from Operations	\$736,896	\$1,452,957	\$2,171,920	\$2,788,745
Total Operating Expenses*	\$709,435	\$1,306,373	\$1,359,073	\$1,369,477
Gain/Loss from Operations	\$27,461	\$146,584	\$812,847	\$1,419,268

* Includes salaries, fringe benefits, professional and contracted services, supplies and drugs and depreciation
Ex. A, p. 32.

24. As shown in the table below, Applicant’s current payer mix consists of nearly 46% of patients covered by Medicaid and 53% covered by commercial insurers.

**TABLE 4
APPLICANT’S CURRENT & PROJECTED PAYER MIX**

Payer	FY 2015		FY2016		Projected									
					FY 2017		FY 2018		FY2019		FY2020		FY 2021	
	Vol.	%	Vol.	%	Vol.	%	Vol.	%	Vol.	%	Vol.	%	Vol.	%
Medicare*	7	0.2%	12	0.3%	2	0.3%	15	0.3%	17	0.3%	19	0.3%	20	0.3%
Medicaid*	2,013	45.9%	2,060	45.9%	324	45.9%	2,404	45.9%	2,726	45.9%	3,035	45.9%	3,289	45.9%
CHAMPUS & TriCare	47	1.1%	34	0.8%	6	0.8%	45	0.9%	50	0.8%	56	0.8%	61	0.9%
Total Government	2,067	47%	2,106	47%	332	47%	2,464	47.1%	2,793	47%	3,110	47%	3,370	47.1%
Commercial Insurers	2,289	52.3%	2,369	52.8%	372	52.7%	2,761	52.7%	3,130	52.7%	3,486	52.7%	3,775	52.7%
Uninsured/Self Pay	18	0.4%	15	0.3%	2	0.3%	15	0.3%	17	.03%	19	0.3%	20	0.3%
Workers Compensation	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Total Non-Government	2,307	52.7%	2,384	53.1%	374	53%	2,776	53%	3,147	53%	3,505	53%	3,795	53%
Total Payer Mix	4,374	99.9%	4,490	100.1%	706	100%	5,240	100%	5,940	100.1%	6,615	100%	7,165	100.1%

*FY 2017 data is based on months 10/1/2016 through 6/30/2017.
Ex. A, p. 34.

25. Due to its specialized, child-focused services, the Applicant's primary service area spans 42 towns throughout Connecticut. Ex. A, pp 29.
26. No change in access for the patient population served by this proposal is projected and, in particular, for Medicaid patients. Ex. A, pp. 21, 34.
27. The Applicant anticipates no significant change in the amount of incoming referrals received, but expects to retain more of its existing outpatient business. Ex. A, p. 29.
28. There will be no change to the Applicant's pricing structure or cost to consumers as a result of this proposal. Ex. A, p. 21.
29. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).
30. This CON application is consistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2)); Ex. A, pp. 18.
31. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3)); Ex. A, pp. 18.
32. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)); Ex. A, pp. 22-23.
33. 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)); Ex. A, pp. 17-20.
34. The Applicants have shown that there would be no significant change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients. (Conn. Gen. Stat. § 19a-639(a)(6)); Ex. A, pp. 24, 34.
35. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7)); Ex. A, pp. 24-25.
36. The utilization of existing health care facilities and health care services in the Applicant's service area supports this application. (Conn. Gen. Stat. § 19a-639(a)(8)); Ex. A, p. 35.
37. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)); Ex. A, p. 30.
38. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)); Ex. A, p. 34.

39. 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)); Ex. A, p. 30.

40. The Applicants have 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)); Ex. A, p. 21.

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).

CCMC, a 187-bed free-standing children's hospital in Hartford, currently utilizes a single 1.5T MRI scanner to conduct approximately 4,400 MRI scans annually. CCMC seeks to acquire a Phillips Ingenia 3T Omega MRI scanner for its main campus, at a cost of \$3.96 million. *FF1-FF4*, 23.

Recent studies indicate that higher strength MRI scanners, such as the 3T MRI scanner, are the current standard of care for the majority of free-standing children's hospitals in the United States. Not only will the proposed scanner produce sharper and more detailed images, the acquisition and utilization of the new scanner will reduce the length of sedation required to complete imaging, and decrease radiation exposure associated with the utilization of CT scans. *FF5-6*.

As with adults, the 3T offers a doubled signal-to-noise ratio, improved spatial resolution and improved contrast-to-noise ratio, resulting in clearer images and improved diagnostics. An added benefit to children is that, the 3T maintains good-quality images even with a small field-of-view in a shorter time. *FF12*. Limiting the acquisition time is of particular importance when scanning children as children under the age of 10 and those with special needs often have difficulty remaining still for the duration of the procedure. Approximately 50% of the Applicant's patients require sedation. *FF7*.

CT scanners are often employed for the evaluation of urgent conditions when MRI scanning is unavailable. *FF6*. MRIs eliminate the exposure to radiation resulting from CT scans. Children are more sensitive to radiation than adults and due to their longer life expectancies they have a larger window of exposure to radiation damage and may additionally receive a higher radiation dose than necessary if CT settings are not adjusted for their smaller body size, according to the National Cancer Institute. *FF10*. It is therefore recommended that MRIs be performed on children. *FF11*. The Applicant anticipates that by FY21, it will, on its second MRI, perform approximately 225 MRI scans on children that would have otherwise received CT-scans. *FF16*. As a result, image quality will be improved and childhood exposure to radiation will be minimized due to the proposal.

CCMC is the sole general children's hospital in Connecticut. It has a special team assembled for those children requiring MRIs that require sedation, consisting of a Pediatric Anesthesiologist, Sedation Nurse, Child Life Specialist, MRI Technologist, and Pediatric Radiologist. The teams' focus is trifold: to ensure sedation is performed safely, to minimize the child and its family's anxiety, acquire quality imaging with minimal movement to prevent the need for re-scans. *FF20*.

Currently, the Applicant must refer approximately 1,500 patients per year to other facilities and it has a backlog of between 175 and 225 scans to perform. *FF17*, 19. With the introduction of the second MRI, CCMC will be able to accommodate these patients in its specialty care setting. By performing the scans in-house, the risks associated with transferring patients to other facilities will be reduced, and

coordination of care will be improved due to patients' imaging results and electronic medical records remaining with CCMC. As such, the proposal will increase access to quality care.

Furthermore, the Statewide Healthcare Facilities and Services Plan takes into consideration the "unique patient populations" and "complexity of scanning procedures" when assessing a hospital's need for a new or additional MRI. As the only freestanding general children's hospital, CCMC serves a unique patient population. Due to the nature of scanning children and their specialized sedation needs and increased risk of radiation from other imaging techniques, CCMC may also be considered to provide complex scanning. *FF11, 20-21.*

The Applicant expects to retain more of its existing outpatient business as a result of increased capacity following the acquisition. Notwithstanding, the Applicant's proposal should have minimal to no effect on upon existing providers due to the size and scope of its primary service area and the specialized population it serves. As the proposed scanner will be used in the same location as the existing 1.5T MRI scanner, the Applicant will continue to serve the same patient population, including Medicaid and indigent patients. Moreover, access to care will be maintained and the proposal will not affect patient cost. All of these benefits are consistent with the Statewide Health Care Facilities and Services Plan. *FF15-FF19.*

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application requesting authorization to acquire a 3T MRI Scanner, at Connecticut Children's Hospital in Hartford, 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



9/13/2017
Date

Yvonne T. Addo, MBA
Deputy Commissioner

Olejarz, Barbara

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William Agostinucci,

Please see attached final decision for Docket Number: 17-32148-CON for the acquisition of an MRI scanner.

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