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The Congenital Cardiac Catheterization Outcomes Project (C3PO)

By Lisa Bergersen, MD on behalf of the investigator group

Pediatric cardiac catheterization involves a complex patient population with variable illness severity and procedural objectives. Therefore, outcome assessment, particularly comparison of adverse event rates, must adjust for case mix differences among providers and institutions. Single institutionally derived methods may not be generalizable to the greater pediatric interventional community

(*Congenit Heart Dis* 2008;3;230-240). Therefore, we sought to create a multi-institutional data set that would allow us to prospectively develop valid outcome assessment tools for congenital cardiac catheterization. The participants of the congenital cardiac catheterization outcomes project (C3PO) are practitioners with a clinical role primarily defined by interventional catheterization, recruited from academic affiliated pediatric hospitals centers across the United States. Currently, seven sites are participating in the project, Table 1.

Table 1. C3PO Participating Interventional Cardiologists and Institutions

Children's Hospital Boston <ul style="list-style-type: none">• Lisa Bergersen, MD• Kathy Jenkins, MD, MPH• Michael Landzberg, MD• Peter Lang, MD• James Lock, MD• Audrey Marshall, MD• Doff McElhinney, MD	Nationwide Children's Hospital <ul style="list-style-type: none">• John Cheatham, MD• Ralf Holzer, MD• Curt Daniels, MD• Timothy Hoffman, MD
Cincinnati Children's Hospital Medical Center <ul style="list-style-type: none">• Robert Beekman, III, M.D.• Russel Hirsch, MD• Robert Spicer, MD	St. Louis Children's Hospital <ul style="list-style-type: none">• David Balzer, MD• Susan Foerster, MD• Ramzi Nicolas, MD• Joshua Murphy, MD
Morgan Stanley Children's Hospital of New York Presbyterian <ul style="list-style-type: none">• William Hellenbrand, MD• Julie Vincent, MD• Christine Donnelly, M.D.• Alejandro Torres, MD	Rady Children's Hospital – San Diego <ul style="list-style-type: none">• John Moore, MD, MPH• Howaida El-Said, MD
	Pittsburgh Children's Hospital <ul style="list-style-type: none">• Jacqueline Kreutzer, MD• Lee Beerman, MD• Brian Feingold, MD• Susan Miller, MD



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“Pediatric cardiac catheterization involves a complex patient population with variable illness severity and procedural objectives.”

In February 2007, sites began prospectively recording patient and procedural characteristics, as well as the occurrence of adverse events, on all diagnostic and interventional cases performed at the institution. Data are entered using a web-based data entry tool developed for the project with support from the Children's Heart Foundation, Figure 1 and 2. Ongoing project expenses are supported by the *American Heart Association Physician's Round Table Award* and the *Keane Operating Fund at Children's Hospital Boston*. Participating institutions provide non-compensated time and personnel resources for data entry. This is an example of the participant's commitment to the objectives of the project.

As of April 1st, 2009, data have been entered on 9,794 cases including the record of 1,787 adverse events, with nearly 600 classified as “high severity,” and 900 “preventable or possibly preventable.” Data accuracy and validation is achieved through monthly exception reports and an independent audit of 10% of the cases by an on-site review of source documentation. Complete case capture is assured by institutional coordinators comparing cases in the database to institutional records. All adverse events are reviewed by two designated interventionalists in the group for proper application of severity and preventability definitions, Table 2.

At the *American College of Cardiology Conference (ACC) Scientific Sessions in March 2009*, the group presented descriptive outcome data on the occurrence of adverse events in diagnostic, interventional, biopsy, as well as hybrid cases (Abstract). Working groups are currently developing analytical plans to assess both safety and efficacy outcomes for specific procedure types such as: PDA closure, pulmonary valvotomy, aortic valvotomy, ASD closure, and coarctation intervention. Also a better understanding of arrhythmia events, access-related events, and events related to sedation will be explored in detail. We hope to provide important information on these topics as they relate to safety and in some cases efficacy outcomes.

In the midst of this activity, we remain focused on our primary objective which is to develop a risk-

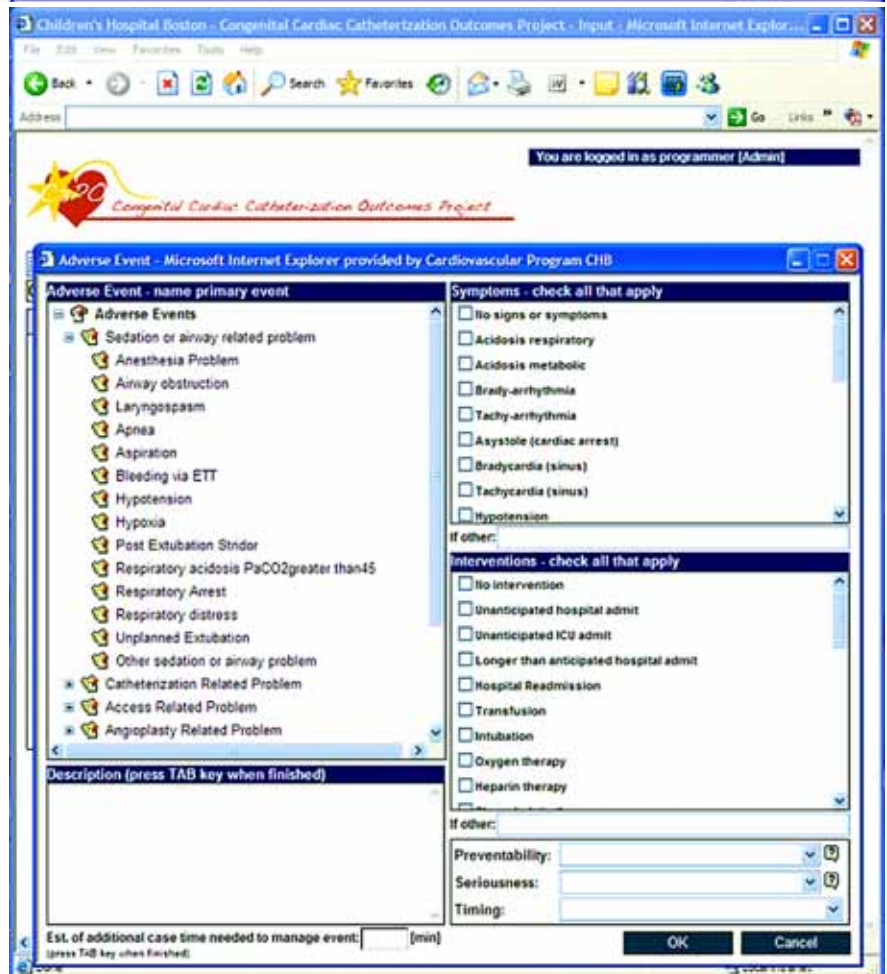
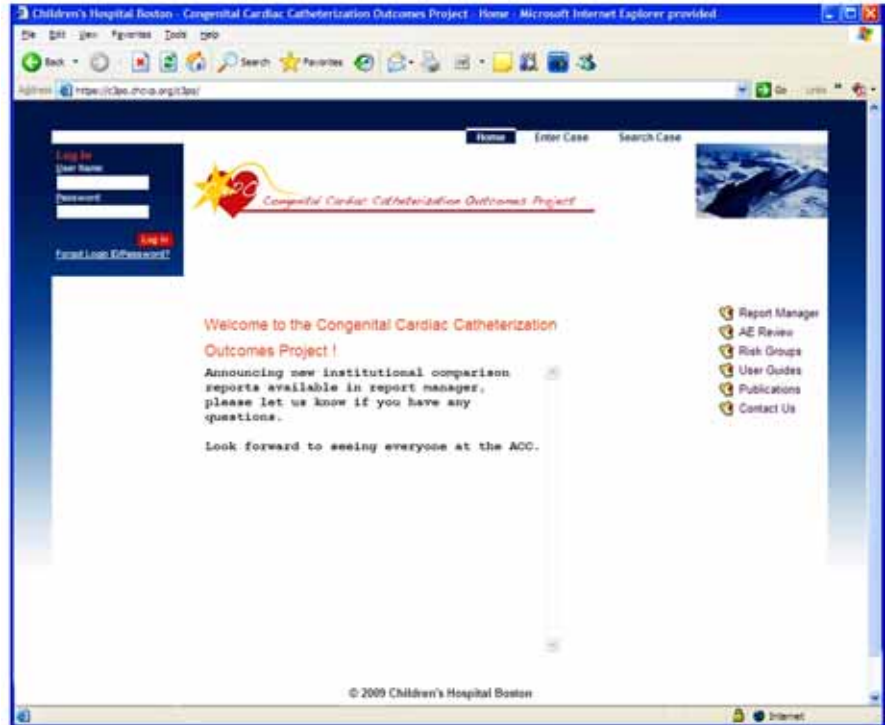


Figure 1. Home Page C3PO web site (top); Figure 2. Adverse Event Data Entry C3PO web site (bottom)

adjusted outcome assessment method to account for case mix differences. In 2006 the group classified procedure types into different risk groups based on the expertise and judgment of the participants. These results were reviewed and consensus-based groups agreed upon. Now the database has enough outcomes to analytically evaluate the performance of the consensus based risk groups. Based on previous work, once refined, we anticipate that procedure-type risk groups will be an important variable for models used to adjust for outcome risk. In the next few months we will be developing these models using the first 15 months of the data (2/07 to 4/08), followed by an assessment of the performance of our methods in the subsequent 15 month (5/08 to 8/08) data set.

After many years of work and data entry the C3PO participants have created a data set that will support our objectives and allow us to create tools and assess outcomes in congenital cardiac catheterization. The year 2009 is going to be a busy year for all the participants, as they will be actively involved in the development and execution of carefully constructed analytical plans. This project has been made possible by the transparent participation of multiple interventionalists in the pediatric cardiology community who are committed to understanding outcomes with an ultimate goal of improving outcomes in the field of congenital cardiac catheterization.

Table 2. Definitions for Adverse Event Severity and Preventability

	Severity Level	Definition
Low	1 - None	No harm, no change in condition, may have required monitoring to assess for potential change in condition with no intervention indicated.
	2 - Minor	Transient change in condition, not life threatening, condition returns to baseline, required monitoring, required minor intervention such as holding a medication, or obtaining lab test.
High	3 - Moderate	Transient change in condition may be life threatening if not treated, condition returns to baseline, required monitoring, required intervention such as reversal agent, additional medication, transfer to the intensive care unit for monitoring, or moderate trans-catheter intervention to correct condition.
	4 - Major	Change in condition, life threatening if not treated, change in condition may be permanent, may have required an intensive care unit admission or emergent readmit to hospital, may have required invasive monitoring, required interventions such as electrical cardioversion or unanticipated intubation or required major invasive procedures or trans-catheter interventions to correct condition.
	5 - Catastrophic	Any death, and emergent surgery or heart lung bypass support (ECMO) to prevent death with failure to wean from bypass support.

Abstract ACC 2009

Adverse Event Rates in Congenital Cardiac Catheterization – A Multi-center Experience

Lisa Bergersen, Audrey Marshall, Kimberlee Gauvreau, John Moore, Susan Foerster, David Balzer, Robert Beekman, Russel Hirsch, William Hellenbrand, Julie Vincent, John Cheatham, Ralf Holzer, James Lock, Kathy Jenkins

Background: Reported adverse event rates for patients with congenital heart disease undergoing cardiac catheterization vary considerably, due to non-comparable

Preventability Category	Definition
Not Preventable	Events where no obvious breach of standard technique occurred; necessary precautions were taken; no clearly known alteration in method or care exists to prevent the event.
Possibly Preventable	may not have been taken; event may have been preventable by modification of technique or care.
Preventable	Events where definite breach of standard technique was identified; necessary precautions were not taken; event was preventable by modification of technique or care.



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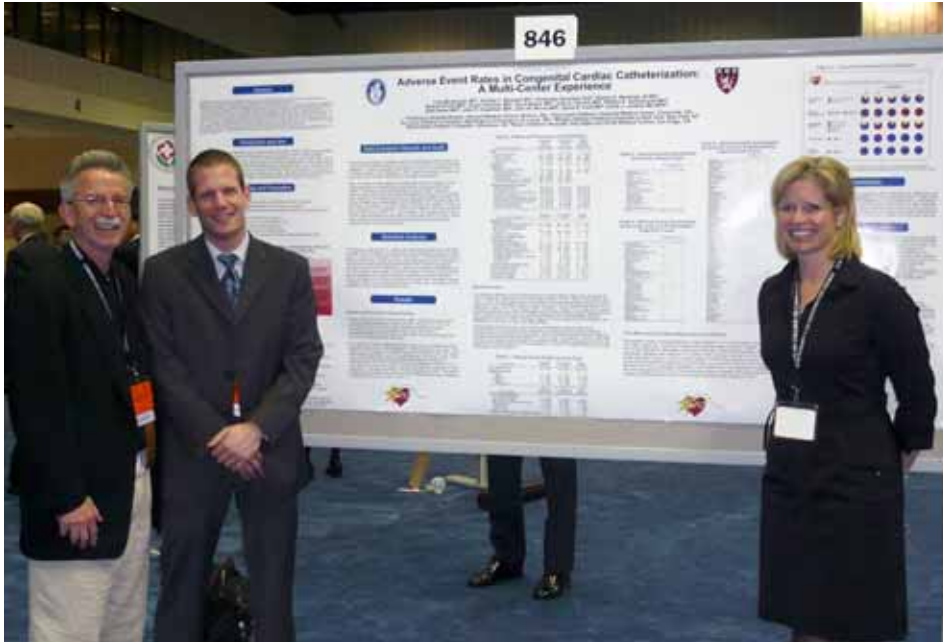
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From left to right - Drs. John Cheatham, Ralf Holzer of Nationwide Children's Hospital, and Lisa Bergersen of The Children's Hospital Boston - photo taken at the ACC 2009.

standards of data inclusion, and highly variable case mix.

Methods and Results: The Congenital Cardiac Catheterization Outcomes Project (C3PO) has been capturing case characteristics and adverse events (AE) for all cardiac catheterizations performed at six pediatric institutions. Validity and completeness of data were independently audited. Between 2/1/07 and 4/30/08, 3855 cases (670 biopsy, 1037 diagnostic, and 2148 interventional) were recorded, median number of cases per site 480 (308 to 1526). General anesthesia was used in 70% of cases (28 to 99%), and 22% of cases (15 to 26%) were non-electively or emergently performed. Three institutions performed a higher proportion of interventions during a case, 72 to 77% compared to 56 to 58%. The median rate of AE reported per institution was 16%, ranging from 5 to 18%. For interventional cases the median rate of AE reported per institution was 19% (7 to 25%) compared to 10% for diagnostic cases (6 to 16%). The incidence of AE was significantly higher for

interventional compared to diagnostic cases (20% vs 10%, $p < 0.001$), as was the incidence of higher severity AE (9% vs 5%, $p < 0.001$). Adverse events in biopsy cases were uncommon.

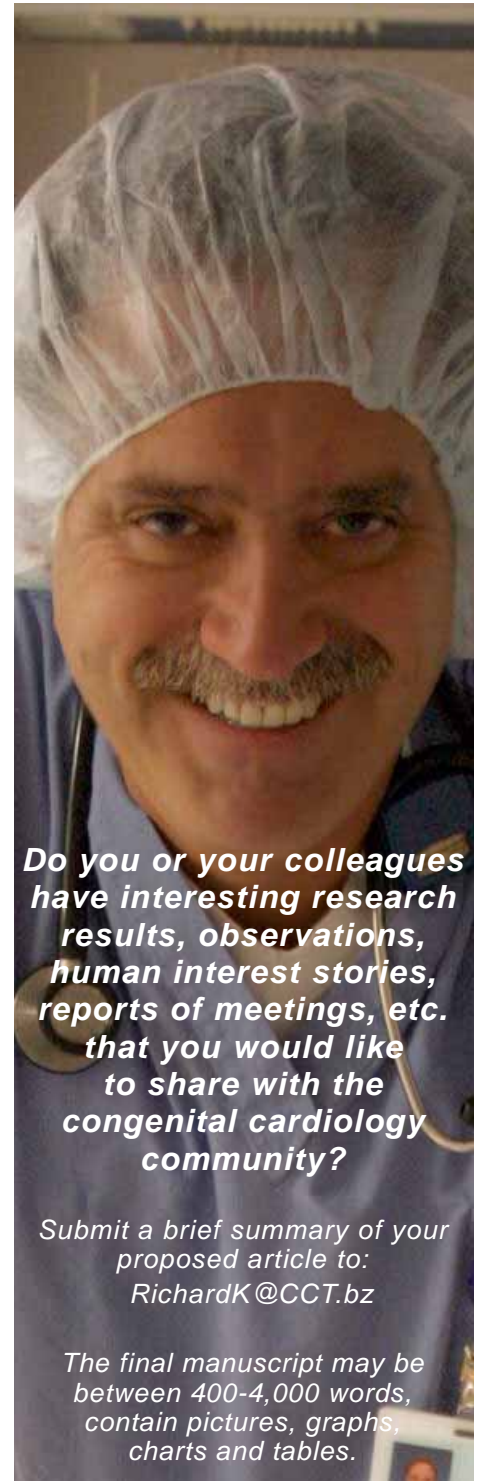
Conclusions: In this multi-institutional cohort, the incidence of AE is higher among interventional compared to diagnostic cases, and is very low among biopsy cases. Equitable comparisons among institutions will require the development and application of risk adjustment methods.

CCT

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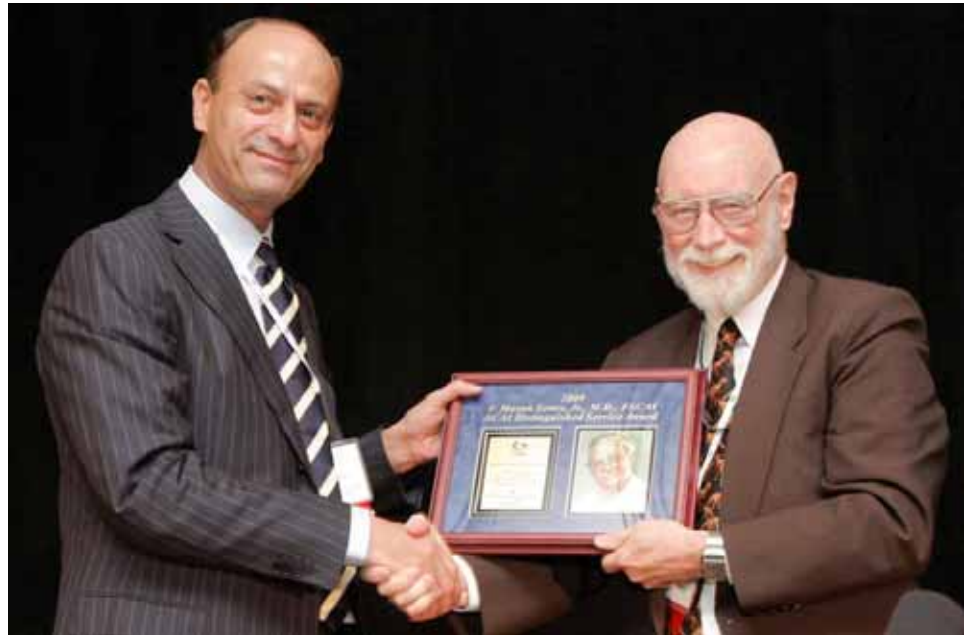
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The Chuck Mullins Annual Congenital/Pediatric Lecture

By Ziyad M. Hijazi, MD

The Society for Cardiovascular Angiography and Interventions (SCAI) has announced the naming of the first Congenital/Pediatric Annual Lecture to be "The Chuck Mullins Annual Congenital/Pediatric Lecture." The intent of this designation is to honor Dr. Charles E. Mullins for his contributions to this field over the last 40 years. Not only has Dr. Mullins been a true pioneer in the field of angiography and interventions throughout his career, he continues to work after his retirement to advance the causes of the Society and patient care! He has written hundreds of papers in peer-reviewed medical journals, and published a book in 2006 on cardiac catheterization. The lecture designation took place during the recent SCAI Scientific Sessions held in Las Vegas, NV, May 6-9, 2009.

The President of the Society, Dr. Ziyad M. Hijazi, announced this honor, and presented Dr. Mullins with a plaque of the first lecture. Dr. Frank Ing, Director of the Cath Lab at Texas Children's Hospital, and a trainee of Dr. Mullins, then proceeded to recite a very entertaining rap about Dr. Mullins. Of note, Dr. Bob Vincent, who was the chair of the Congenital/Pediatric sessions at the meeting, invited Dr. Mullins to give this talk. Both Drs. Hijazi and Vincent worked hard to keep the honor a surprise, and were successful in their attempt. This annual lecture will be the 3rd such named lecture that the Society has created in honoring the pioneers of the specialty. The Society's first named lecture was the Founder's Lecture, and the second lecture was the Hildner Lecture. This is great recognition from the Society for the role of congenital/pediatric cardiologists and what they do



Dr. Hijazi (left) presenting the F. Mason Sones SCAI Distinguished Service Award to Dr. Mullins (right).

to advance patient care, education, research and advocacy efforts.

Further, as the outgoing President of the Society, Dr. Hijazi presented Dr. Mullins with the *F. Mason Sones Distinguished Service Award*, the highest award the Society has for all that he has done to advance the causes of the Congenital/Pediatric Heart Diseases Committee since its inception in the early 1990's. Dr. Mullins and Dr. Carlos Ruiz are the only two congenital cardiologists that have ever received this award.

Dr. Chuck Mullins was surprised and pleased by this recognition, and expressed appreciation for the honor bestowed on him by the society. Bob Mullins, Chuck's eldest son, was in the

audience during his dad's reception for these two awards.

Congratulations Chuck, well deserved!

CCT

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Materials from Children's Cardiomyopathy Foundation Designed to Meet Different Patient Education Needs

By Kella Boyer, Patient Outreach & Support Manager, Children's Cardiomyopathy Foundation

Research has found that there are many benefits to patient education including enhanced patient participation in health-care decision-making, improved commitment to treatment, increased patient satisfaction, better ability to cope with illness, greater quality of life in patients and their families, and decreased anxiety (Yoon et al, 2006). The Children's Cardiomyopathy Foundation (CCF), a national non-profit focused on pediatric cardiomyopathy, understands the importance of patient education following a diagnosis of pediatric cardiomyopathy, a chronic heart condition that affects an estimated 30,000 children. CCF believes strongly that educating patients and their caregivers on the basics of their disease can empower them to more proactively manage their or their loved ones' health and well-being. In order to educate newly diagnosed children and their families, CCF has developed a variety of resources to cover the full range of patient needs. All materials have been

carefully reviewed by CCF's medical advisors and in most cases are offered free of charge.

Cardiomyopathy is a complex disease with many variations in presentation, outcome and cause. The most detailed of CCF's literature, "*Understanding Pediatric Cardiomyopathy*" is a 14-page overview booklet with accompanying inserts on dilated, hypertrophic, and restrictive cardiomyopathy. The easy-to-understand booklet covers common questions of parents and caregivers by addressing topics such as diagnosis, causes, symptoms, treatment options, family screening, effect on daily life, and coping with a chronic disease.

A second resource is a 29-page booklet, titled, "*Cardiowhat? A Kids' Guide to Cardiomyopathy*", which was developed by CCF and the National Society of Genetic Counselors to help children better understand their own and/or their family member's diagnosis of cardiomyopathy. When an ill child lacks disease understanding, the child may wrongfully think the disease or being hospitalized is a punishment (Walker, et. al., 2006). Developed after it was discovered that many parents found it

"Research has found that there are many benefits to patient education including enhanced patient participation in health-care decision-making..."

difficult to explain the concept of cardiomyopathy to their children, "*Cardiowhat?*" uses simple language, colorful illustrations, and fun activities to teach children the basics of the disease.

Information in audio or video format can help some people learn about a disease more effectively (Roberts, 2008). CCF's third resource, "*Secrets of the Heart - Living with Pediatric Cardiomyopathy*" is a 38-minute DVD that profiles three families with different forms of cardiomyopathy. Their personal stories are interspersed with factual information on the disease contributed by the physicians that care for them. For someone who prefers visual or auditory learning, the DVD is an optimum way to increase knowledge of pediatric cardiomyopathy and learn how other families have successfully handled the challenges of living with this heart disease.

Studies show that patients only remember about half of what they are told during a visit to the doctor (Ley, 1972). Physicians can pass out CCF's materials as a take-home resource to reinforce information about pediatric cardiomyopathy not absorbed during the



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visit. In addition to printed resources, CCF has also collaborated with the National Organization for Rare Disorders and the American Heart Association to offer web-based educational materials on pediatric cardiomyopathy.

Patient education is an important part of healthcare that all health care workers should take seriously (Bellamy, 2004). It is CCF's hope that patient education will help improve quality of life and enhance healthcare participation for families affected by pediatric cardiomyopathy. For more information on CCF's other patient services or to receive any of the materials described in this article please contact the Children's Cardiomyopathy Foundation at kboyer@childrenscardiomyopathy.org or visit the website at www.childrenscardiomyopathy.org.

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NMT Medical Receives PMA Approval for STARFlex® as a Ventricular Septal Defect Repair Implant

BOSTON, MA, April 9, 2009 – NMT Medical, Inc. (NASDAQ: NMTI), an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat structural heart disease through minimally invasive, catheter-based procedures, today announced that it received Pre-Market Approval (PMA) from the US Food and Drug Administration (FDA) enabling commercial sale of the company's STARFlex® cardiac septal repair implant in the United States for patients with ventricular septal defects (VSD). The STARFlex® implant can be placed in the heart to close the VSD using a catheter during a minimally invasive procedure, avoiding the need for the alternative treatment of open-heart surgery, which is considered a high-risk, invasive procedure.

Commenting on the FDA approval, Frank Martin, NMT's President and Chief Executive Officer said, "The approval of STARFlex® for VSD is welcome news for NMT and our customers, along with their patients, as we can now offer this next generation implant. STARFlex® will replace our CardioSEAL® implant, which had previously received FDA approval for VSD treatment. STARFlex® features the addition of a unique self-centering mechanism, which accommodates easier implantation as well as the treatment of larger defects."

"It will be rewarding to provide this innovative treatment option to these VSD patients, and we are excited about its commercial introduction in the United States. STARFlex® has been used in our CLOSURE I patent foramen ovale (PFO)/stroke and transient ischemic attack pivotal study and has been widely used in Europe for several years," Martin continued. "Over the next several weeks, we will be finalizing our plans for launching the product in the US market."

VSD is an opening between the right and left ventricle in the lower chambers of the heart and is the most common type of congenital heart defect. When there is a large opening between these ventricles, a large amount of oxygen-rich (red) blood from the heart's left side is forced through the defect into the right side. It is then pumped back to the lungs, even though it has already been filtered and refreshed with oxygen. This is inefficient, because oxygenated blood displaces blood that needs oxygen, which means the heart must pump more blood and may enlarge from the added work. In addition, high blood pressure may occur in the lungs' blood vessels. Over time, this increased pulmonary hypertension may permanently damage the blood vessel walls and could lead to heart failure.

NMT Medical is an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat structural heart disease through minimally invasive, catheter-based procedures. NMT is currently investigating the potential connection between a common heart defect that allows a right-to-left shunt or flow of blood through a defect like a patent foramen ovale (PFO) and brain attacks such as embolic stroke, transient ischemic attacks (TIAs) and migraine headaches. More than 30,000 PFOs have been treated globally with NMT's minimally invasive, catheter-based implant technology.

For more information about NMT Medical, please visit www.nmtmedical.com.

Chemical Found in Medical Devices Impairs Heart Function

Researchers at the Johns Hopkins University School of Medicine have found that a chemical commonly used in the production of such medical plastic devices as intravenous (IV) bags and catheters can impair heart function in rats. Appearing online this week in the *American Journal of Physiology*, these new findings suggest a possible new reason for some of the common side effects - loss of taste, short term memory loss - of medical procedures that require blood to be circulated through plastic tubing outside the body, such as heart bypass surgery or kidney dialysis. These findings also have strong implications for the future of medical plastics manufacturing.

In addition to loss of taste and memory, coronary bypass patients often complain of swelling and fatigue. These side effects usually resolve within a few months after surgery, but they are troubling and sometimes hinder recovery.

His personal experience with coronary bypass surgery propelled his search for a root cause for the loss of taste phenomenon, reports principal investigator Artin Shoukas, PhD, Professor of Biomedical Engineering, Physiology and Anesthesiology and Critical Care medicine at Johns Hopkins. "I'm a chocoholic, and after my bypass surgery everything tasted awful, and chocolate tasted like charcoal for months."

Shoukas and Caitlin Thompson-Torgerson, PhD, a postdoctoral fellow in anesthesiology and critical care medicine suspected that the trigger for these side effects might be a chemical compound of some kind.

To test their theory, Shoukas and his team of researchers took liquid samples from IV bags and bypass machines before they were used on patients. The team analyzed the fluids in another



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machine that can identify unknown chemicals and found the liquid to contain a chemical compound called cyclohexanone. The researchers thought that the cyclohexanone in the fluid samples might have leached from the plastic. Although the amount of cyclohexanone leaching from these devices varied greatly, all fluid samples contained at least some detectable level of the chemical.

The researchers then injected rats with either a salt solution or a salt solution containing cyclohexanone and measured heart function. Rats that got only salt solution pumped approximately 200 microliters of blood per heartbeat and had an average heart rate of 358 beats per minute, while rats injected with cyclohexanone pumped only about 150 microliters of blood per heartbeat with an average heart rate of 287 beats per minute.

In addition to pumping less blood more slowly, rats injected with cyclohexanone had weaker heart contractions. The team calculated that cyclohexanone caused a 50% reduction in the strength of each heart contraction. They also found that the reflex that helps control and maintain blood pressure is much less sensitive after cyclohexanone exposure. Finally, the team observed increased fluid retention and swelling in the rats after cyclohexanone injections.

According to Thompson-Torgerson and Shoukas, they would like to figure out how these side effects - decreased heart function and swelling - occur, and to what degree cyclohexanone is involved. Despite the findings in this study, they emphasize that patients should listen carefully to the advice of their physicians. "We would never recommend that patients decline this type of treatment if they need it," says Shoukas. "On the contrary, such technologies are life-saving medical advances, and their benefits still far outweigh the risks of the associated side effects. As scientists, we are simply trying to understand how the side effects are triggered, and what the best method will be to mitigate, and ultimately remedy, these morbidities."

This study was funded by the Bernard A. & Rebecca S. Bernard Foundation, the American Heart Association, the W.W. Smith Foundation, the National Institutes of Health, the Pulmonary Vascular Research Institute, the American College of Cardiology, the Shin Chun-Wang Young Investigator Award, the American Physiological Society, the Joyce Koons Family Cardiac Endowment Fund, and funds from Dr. Shoukas.

Authors on the paper are Caitlin S. Thompson-Torgerson, Hunter C. Champion, Lakshmi Santhanam, Z. Leah Harris and Artin A. Shoukas, all of Johns Hopkins University School of Medicine.

Heart Procedure? Bring Your iPod Along, Review Suggests

The right mix of Portuguese instrumentals calms Philadelphia researcher Joke Bradt. That's what she'd want to hear during a serious medical procedure — that or classical music.

She points out quickly that this is her musical preference. She knows the right music can help her and, as a music therapist, she uses it to help others as well. "If you can relax patients, if you can calm them down a bit, that is only going to be beneficial," says Bradt, who is assistant director of the Arts and Quality of Life Research Center at Temple University.

Bradt and Cheryl Dileo, another Temple researcher, conducted a review of 23 studies that focused on the use of music with 1,461 patients with coronary heart disease. They found that listening to music reduced heart rate, respiratory rate and blood pressure. However, Bradt cautioned that the quality of evidence was not strong and the clinical significance unclear.

The review appears in the latest issue of *The Cochrane Library*, a publication of The Cochrane Collaboration, an international organization that evaluates medical research. Systematic reviews draw evidence-based conclusions about medical practice after considering the content and quality of existing medical trials.

Alleviating stress is important, said Robert Bonow, Professor of Medicine and Chief of Cardiology at Northwestern University and a past president of the American Heart Association, although he adds that this review shows there is "no conclusive evidence that this relaxation therapy actually reduces the stress, let alone reducing the outcome of the stress."

Stress and its influence can be a cloudy issue for researchers. "Is it the stress that causes heart attacks?" he asked. Often, people who are under stress are also smoking or eating the wrong things and their blood pressure goes up, he said.

"Exercise is beneficial because it reduces stress, but it also lowers blood pressure," he said, adding that data on the benefits of exercise are irrefutable. This review presents a meticulous study of music therapy, he said, yet it does not make absolute conclusions that it is beneficial.

The reviewers found that if patients chose their music, the effects were greater; however, studies using researcher-selected music had results that were more consistent. Listening to patient-selected music lowered pulse rates by more beats per minute than listening to researcher-selected music. Several studies only offered classical music. Other trials allowed patients to choose from a selection of genres, such as "Fresh Aire" by Mannheim Steamroller or country-western instrumentals.

It did not surprise Bradt that patient-selected music produced a more calming effect than music chosen by a nurse or doctor. "There is a lot of classical music I like or don't like," she said. "So we do know from clinical experience that if people select music they like and the music has sedative qualities such as slow tempo, predictable harmonies and absence of sudden changes, they will be better able to relax to the music."



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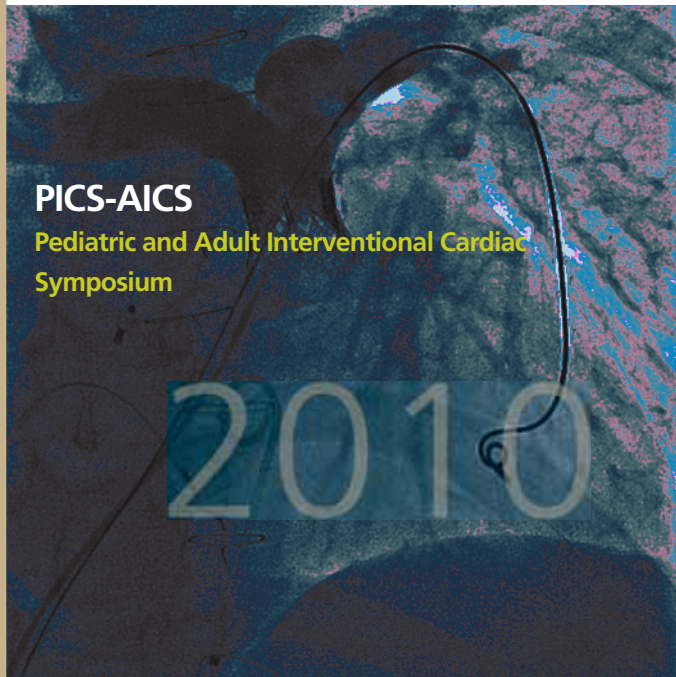
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Patients in the comparison groups had no music and researchers might have asked them to rest quietly, Bradt said. "Researchers would have made sure the patient didn't get interrupted."

In reviewing the studies, she lacked data to determine which music genre — country-western, classical, New Age — helped patients most. "None of the studies ran an analysis on whether one music style was more efficient than another," Bradt says.

Some studies looked at music offered during a cardiac procedure or within 48 hours of hospitalization. Others included three or more sessions during consecutive days. Most of the studies did not use music therapists — trained professionals like Bradt. That's important, she said: Although researchers in these studies knew it was important to use slow music, music therapists are trained specifically to use music interventions that meet the individual's needs.

Music therapists avoid using music that might evoke strong emotional reactions. If a patient likes music, but it reminds him of his belated mother, for example, it could bring about sadness. "We're not going to use it because it has too much emotional impact," she said. Music should have a steady, even tempo, kept between 60 and 80 beats per minute.

When she had an MRI not long ago, the technician played classical music. This should have worked for Bradt. The problem was that the MRI was so loud that she could not hear it. The result, she said, was counterproductive. "It annoyed me more than anything else."

Bradt said if she needed a coronary procedure, she would come prepared. "I would make sure I brought an iPod with music I love that had relaxing qualities. Preferably, I would like to have a music therapist in the room."

The Cochrane Collaboration is an international nonprofit, independent organization that produces and disseminates systematic reviews of health care interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. Visit www.cochrane.org for more information.

Effects of Maternal Exercise on Fetal Breathing Movements

Newswise — Exercise has many benefits for adults, teens, and youngsters. It is less clear what benefit, if any, exercise may have during fetal growth during gestation. Now that scientists have determined that, generally speaking, maternal exercise poses no significant risk to a fetus, studies are underway to examine the mother/fetus/exercise/health connection.

One important study is now complete. Entitled *The Effects of Maternal Exercise on Fetal Breathing Movements*, it was



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Symptoms: Cardiomyopathy, Neutropenia, Muscle Weakness, Exercise Intolerance, Growth Retardation

conducted by Stephanie Million and Linda E. May, Kansas City University of Medicine and Biosciences (KCUMB), Kansas City, MO; and Kathleen M. Gustafson, University of Kansas Medical Center (KUMC), Kansas City, KS. The researchers discussed their findings at the 122nd Annual Meeting of the American Physiological Society, which is part of the Experimental Biology 2009 scientific conference. The meeting was held April 18-22, 2009 in New Orleans.

The primary aim of the pilot project was to test the theory that maternal exercise imparts a cardiovascular benefit to the fetus. The secondary aim was to determine if exercise-exposed fetuses have increased breathing movements compared to non-exercise exposed fetuses. Fetal breathing movements are a marker of fetal well-being and reflect functional development of the respiratory system and central nervous system control.

The researchers used a non-invasive, dedicated fetal biomagnetometer to measure maternal and fetal magnetocardiograms (MCG) along with fetal movements (breathing, body movements, hiccups and non-nutritive suck). Unlike an ultrasound, which takes static measurements of anatomy, MCG records the physiology of the developing fetus.

The investigators looked at the results from pregnant women between 20 and 35 years of age. The mothers were classified as exercisers if they performed moderate intensity aerobic exercise at least 30 minutes three times per week (moderate to vigorous walking, stationary bicycling and running). Mothers in the control category did not partake in a regular exercise routine. The MCG was measured between 24-36 weeks gestational age.

Between 36-38 weeks gestational age, breathing movements were identified using specific criterion. Measures of fetal heart rate and autonomic control were analyzed during episodes of fetal breathing and non-breathing movements. Although there was no difference in the number of breathing episodes, differences were noted between the groups.

The researchers found:

- Fetal HR was significantly lower in the exercise group during both breathing and non-breathing movement periods.
- Fetal short-term and overall heart rate variability were higher in the exercise group during breathing movements.
- Three independent measures of vagal control were higher in the exercise-exposed fetuses during breathing movements.
- During periods of fetal non-breathing, there were no significant differences in measures of vagal control between groups. There were no group or breathing period differences in sympathetic heart rate control.

According to Drs. May and Gustafson, "These findings suggest a potential benefit of maternal exercise on fetal development because of the link between fetal breathing movements and the developing autonomic nervous system." Their next step is to use

exercise as a potential intervention to improve short and long-term outcomes in children born to women at risk for gestational diabetes.

Physiology is the study of how molecules, cells, tissues and organs function to create health or disease. The American Physiological Society has been an integral part of this discovery process since it was established in 1887.

New Sites Choose Digisonics for its Web-based Image Interpretation and Reporting Capabilities.

Houston, TX (April 17, 2009) – Pediatric Cardiology Associates of Southwest Louisiana in Lake Charles has chosen the #1 KLAS ranked DigiView Image Management and Reporting System to satisfy their clinical reporting needs. The unique DigiNet Pro component will provide users with fully functional image analysis and reporting via the web.

St. Clare Health Center in Fenton, MO has recently selected Digisonics OB-View Net System for web-based interpretation, viewing and reporting of their OB ultrasound studies online. Additional HL7 interfaces will enable St. Clare to integrate the Digisonics system with their McKesson and EPIC systems for a streamlined electronic workflow.

Digisonics image management & reporting systems combine high-performance image analysis, professional reporting, an integrated clinical database, a powerful PACS image archive and exceptional solutions for remote connectivity into one system. Digisonics solutions maximize efficiency by integrating and automating the entire complex workflow resulting in maximum productivity. For further information, please visit www.digison.net.

New Potential Therapeutic Target Discovered for Genetic Disorder – Barth Syndrome

Newswise — Researchers at NYU Langone Medical Center may have discovered a new targeted intervention for Barth Syndrome (BTHS). BTHS, a sometimes fatal disease, is a serious genetic disorder occurring predominantly in males that leads to infection or heart failure in childhood. The new study entitled, "Role of calcium-independent phospholipase A2 in the pathogenesis of Barth Syndrome", was recently published in the Proceedings of National Academy of Sciences, shows the benefits of targeted intervention with an iPLA2-VIA inhibitor that prevents a major symptom of the disease- cardiolipin deficiency.

"Our research has established a causal role of cardiolipin deficiency in the pathogenesis of Barth Syndrome and identified an important enzyme in cardiolipin degradation called iPLA2-VIA as a potential target for therapeutic intervention of the



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A handwritten signature in blue ink, appearing to read "Alan J. Tower". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Alan J. Tower
Chief Executive Officer

disease,” said Mindong Ren, PhD, lead investigator of the study and Assistant Professor of Cell Biology at NYU Langone Medical Center.

BTHS is an X-linked genetic cardioskeletal muscle disease resulting in muscle weakness and fatigue in patients. The debilitating disorder is caused by a mutation in the genetic coding of tafazzin, an enzyme of the cardiolipin pathway. Cardiolipin is an essential lipid in the inner membrane of mitochondria responsible for normal cell structure and energy production. BTHS patients exhibit defects in cardiolipin metabolism which help fight infections. The various symptoms of BTHS, in addition to cardiolipin deficiency, include: cardiomyopathy (weakness in heart muscle), neutropenia (a reduction in neutrophils or white blood cells that fight bacterial infections), muscle weakness & fatigue (caused by cellular deficiency), growth delay, and increase of organic acids in urine.

In a previous study, NYU researchers documented the characteristics of a tafazzin-deficiency in a *Drosophila* (fruit fly) model of the disease, showing low and abnormal cardiolipin concentration, abnormal mitochondria, and poor motor function. In this new study, researchers documented that tafazzin or cardiolipin deficiency in *Drosophila* disrupts the final stage of spermatogenesis causing male sterility. Using this fly model, the study showed that this trait of cardiolipin deficiency can be genetically suppressed by inactivating calcium-independent phospholipase A2, which prevents the degradation of cardiolipin. This method keeps cardiolipin levels normal. Researchers were also able to show that treatment of BTHS patients' lymphoblasts within a tissue culture with the iPLA2-VIA inhibitor BEL partially restored the tissue cultures cardiolipin homeostasis.

“Taken together, our two findings establish a causal role of cardiolipin deficiency in the pathogenesis of Barth Syndrome and identify iPLA2-VIA as a very important enzyme,” said Michael Schlame, MD, Associate Professor of Anesthesiology and Cell Biology, NYU Langone Medical Center. “This is good news for patients since this enzyme is now a potential target for therapeutic intervention.”

According to researchers, although this has not been tested in humans, the successful restoration of these mutated cells with BEL shows promise for continued BTHS research, patients and their families. There are no treatments for Barth Syndrome at this time.

This study was funded in part by grants from the Barth Syndrome Foundation, the United Mitochondrial Disease Foundation, and NIH. Link to full article published in *Proceedings of the National Academy of Sciences*:

<http://www.pnas.org/content/106/7/2337.full?sid=14754cf1-3343-490f-a418-ef589e10e510>

Guidelines For Treating Patients With Cardiovascular Disease Often Based on Weaker Evidence

An examination of clinical practice guidelines for treating cardiovascular disease finds that current recommendations are largely based on lower levels of evidence or expert opinion, according to a study in the February 25, 2009 issue of *JAMA*.

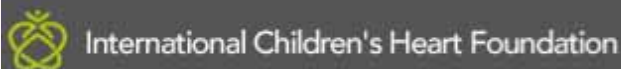
Clinical practice guidelines are developed to assist practitioners with decisions about appropriate health care for specific patients' circumstances, and are often assumed to be the standard of evidence-based medicine, according to background information in the article.

For more than 20 years, the American College of Cardiology (ACC) and the American Heart Association (AHA) have released clinical practice guidelines to provide recommendations on care of patients with cardiovascular disease. The ACC/AHA guidelines currently use a grading scheme based on level of evidence and class of recommendation. The level of evidence classification combines an objective description of the existence and the types of studies supporting the recommendation and expert consensus, and are categorized as A (higher level of evidence), B, or C [lower level of evidence).

The class of recommendation designation indicates the strength of a recommendation and requires guideline writers not only to make a judgment about the relative strengths and weaknesses of the study data but also to make a value judgment about the relative importance of the risks and benefits identified by the evidence. Classes include I (evidence that a treatment or procedure is effective), II, IIa, IIb and III (evidence that a treatment or procedure is not effective).

Whether the increase in publication of studies concerning cardiovascular disease has resulted in guideline recommendations with more certainty and supporting evidence is not known. Pierluigi Tricoci, MD, MHS, PhD, of Duke University, Durham, NC, and colleagues examined the changes in recommendations in ACC/AHA cardiovascular guidelines, and evaluated the adequacy of evidence behind current guideline recommendations. The analysis included data from ACC/AHA practice guidelines issued from 1984 to September 2008. Fifty-three guidelines on 22 topics, including a total of 7,196 recommendations, were examined.

Considering only the current guidelines with at least one revision, the total number of recommendations has increased from 1,330 to 1,973 (48% increase) from the first guideline to the current version. Overall, the guidelines shifted to more Class II recommendations and fewer Class III recommendations, while the use of class I recommendations remained fairly constant over time. The 16 current guidelines reporting levels of evidence, comprising a total of 2,711 recommendations, classify 314 recommendations as level of evidence A (median [midpoint], 11%), and 1,246 with level of evidence C (median, 48%).



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Among all 1,305 Class I recommendations of guidelines reporting level of evidence, only 245 have level of evidence A (median, 19%), with 481 (median, 36%) having a level of evidence C. Level of evidence significantly varies across categories of guidelines (disease, intervention, or diagnostic) and across individual guidelines.

"Our finding that a large proportion of recommendations in ACC/AHA guidelines are based on lower levels of evidence or expert opinion highlights deficiencies in the sources of definitive data available for the generation of cardiovascular guidelines. To remedy this problem, the medical research community needs to streamline clinical trials, focus on areas of deficient evidence, and expand funding for clinical research. In addition, the process of developing guidelines needs to be improved with information about the impact that recommendations based on lower levels of evidence has on clinical practice. Finally, clinicians need to exercise caution when considering recommendations not supported by solid evidence," the authors conclude (*JAMA*. 2009;301[8]:831-841. www.jamamedia.org).

Study Finds Virtual Doctors Visits Satisfactory for Both Patients and Clinicians

Travelers book plane tickets online, bank customers can check their accounts at any computer, and busy families can grocery shop online. Someday, even doctor visits could be among the conveniences offered via the Internet. Researchers considering the feasibility and effectiveness of virtual doctors visits report that patients and physicians found that evaluations done through videoconferencing were similar to face-to-face visits on most measures, according to a study published in the May issue of the *Journal of Telemedicine and Telecare*.

"There is growing evidence that the use of videoconferencing in the medical environment is useful for a variety of acute and chronic issues," says Ronald F. Dixon, MD, an Internist at Massachusetts General Hospital and the study's senior author. "Videoconferencing between a provider and patients allows for the evaluation of many issues that may not require an office visit and can be achieved in a shorter time."

The healthcare delivery model in the United States is under scrutiny. Reduced access to providers, rapidly increasing costs and an aging population represent major challenges for the healthcare system.

Telemedicine projects, including virtual visits (a patient-physician real-time encounters using videoconferencing technology) are being examined to evaluate their capacity to improve patient access to care and lower healthcare costs.

This study, the largest trial of virtual visits versus face-to-face visits done-to-date, randomized patients to one of two arms. In the first arm, the patients completed a visit (virtual or face-to-face) with a physician; they then completed a second visit via the other modality with another physician. In the second arm of the study, subjects had both visits face-to-face with two different physicians. All physicians and patients completed evaluation questionnaires after each visit.

Patients found virtual visits similar to face-to-face visits on most measures, including time spent with the physician, ease of interaction and personal aspects of the interaction. Physicians scored virtual visits similar to face-to-face visits on measures including history taking and medication dispensing. Though they were less satisfied on measures of clinical skill and overall satisfaction, those ratings were still in the good to excellent range.

"The tradition of medicine is to lay hands on the patients, which has always been considered paramount to patient care in the minds of physicians," says Dixon. "However, these findings suggest that virtual visits could be a viable option in circumstances where patients need to be monitored routinely for chronic conditions like diabetes, hypertension, obesity or depression, and where self-management strategies are not working. Virtual visits may also be effective for triage of acute, non-urgent issues like back pain or respiratory infections."

Among the benefits of virtual visits are reduce overhead costs for a physicians' practices by reducing the space and resource requirements. For patients, a virtual visit can minimize time taken away from work and transportation costs. The study suggests that both patients and physicians could benefit if virtual visits were used as an alternative method of accessing primary care.

The co-author of this study is James E. Stahl, MD, Internist and technology adoption researcher at Massachusetts General Hospital. The study was supported by the Center for the Innovation of Medicine and Innovative Technology (CIMIT) and the MGH Department of Medicine.

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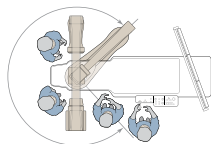
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