CONGENITAL CARDIOLOGY TODAY

Timely News and Information for BC/BE Congenital/Structural Cardiologists and Surgeons

April 2017; Volume 15; Issue 4
International Edition

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Upcoming Medical Meetings

CSI Dubai
Apr. 20 - 22, 2017; Dubai, UAE
www.csi-congress.org/csi-dubai.php

Pediatric Academic Societies Meeting 2017
May 6-9, 2017; San Francisco, CA USA
www.pas-meeting.org

Society for Cardiovascular Angiography and Interventions
May 10-13, 2017; New Orleans, LA USA
www.scai.org/SCAI2017/

2017 Heart Rhythm Society Annual Meeting
May 10-13, 2017; Chicago, IL USA
www.hrssessions.org/#axzz3hsLSBDcN

CONGENITAL CARDIOLOGY TODAY
Editorial and Subscription Offices
16 Cove Rd, Ste. 200
Westerly, RI 02891 USA
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Official publication of the CHiP Network

Temporal Trends in Discharges of Critical Congenital Heart Diseases in United States: 1997-2012*

By Ramesh Vidavalur, MD, MBA; Nitin Wadhwa, MD

**Presented at the 2016 Pediatric Academic Societies Annual Conference, Baltimore, MD USA*

Objective

Congenital Heart Diseases (CHDs) are serious and common conditions that have a significant impact on morbidity, mortality, and healthcare costs in children. CHDs are also the most common birth defects affecting nearly 1% of live births every year in the United States, and are the leading cause of birth defect-associated morbidity and mortality among infants.[1] Fifteen percent to twenty-five percent of these infants are estimated to have Critical Congenital Heart Disease (CCHD) (a subgroup of Congenital Heart Defects that often cause severe and life-threatening symptoms and are a major cause of cardiovascular mortality in newborns, requiring specialized procedures and surgery within the first year of life.[2,3,4] With improved screening programs, early identification and advances in cardiothoracic surgery, survival rates of newborns with CCHDs have been steadily improving, and have enabled the majority of these patients to reach adulthood.

Considering current annual births of 3.9-4 million in United States, around 32,000-40,000 newborns are expected to be diagnosed with CHD and approximately 6,000-10,000 of them are estimated to have CCHDs. However, with changing demographics, diagnostic methods and screening programs, epidemiologic studies have reported an increase in birth prevalence of overall CHDs across the globe over the last five decades.[5] Although several genetic and environmental factors have been implicated in the occurrence of many CHDs, the exact etiology of most forms of CCHDs is not completely understood. In 2013, an AHA report confirmed that congenital cardiovascular defects were the most common cause of infant mortality resulting from birth defects and almost 1 in 4 infants who died of a birth defect had a heart anomaly. The same report estimated that the hospital costs in United States were ~$1.4 billion for stays related to cardiac and circulatory congenital anomalies, which was more than half of all hospital costs for all birth defects.[6]

Background

Our main aim was to determine temporal trends of hospital stays with diagnosis of CCHDs in the United States for the years 1997-2012. We also sought to evaluate the trends in mortality and hospital charges during the same years and, in addition, to understanding the patterns of hospital

> ***"Congenital Heart Diseases (CHDs) are serious and common conditions that have a significant impact on morbidity, mortality, and healthcare costs in children.[1]"***

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discharges with a principle diagnosis of the three most frequent CHDs- VSD, ASD, PDA.

Design/Methods

We performed a serial cross-sectional analysis of childhood hospitalizations during the years 1997-2012, using the Healthcare Cost and Utilization Project's (HCUP) Kids' Inpatient Database (KID), which represents a nationwide sample of inpatient pediatric admissions, compiled by the Agency for Healthcare Research and Quality.[6] With this database, we can describe national trends in rates of inpatient diagnoses, trends in hospital charges/costs, and mortality rates. Hospital discharges for patients age 0 to 17 years, who had an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code for CCHDs (Common truncus, Corrected Transposition of Great Vessels, Congenital tricuspid atresia/stenosis, Complete Transposition of the Great Vessels, Ebstein's anomaly, Double outlet right ventricle, Tetralogy of Fallot, Hypoplastic Left Heart Syndrome, Total Anomalous Pulmonary Venous connection and the three most common CHDs – ASD, VSD, PDA), were included in our analyses. We queried the ICD 9-codes in principal diagnosis and All-listed modes. The principal diagnosis denotes the first listed diagnosis that is chiefly responsible for the patient's admission to the hospital and is used to describe trends in length of stay and hospital charges for each diagnosis. All-listed diagnoses include the principle diagnosis plus additional conditions that coexist at the time of admission and this mode was used to describe trends in discharges and mortality.

We also selected another cohort from the National Inpatient Sample (NIS) database for the years 1997 through 2012 using the clinical classification software (CCS) principal diagnosis category 213, cardiac and circulatory Congenital Anomalies to evaluate trends, hospital costs and inpatient mortality.[7] Descriptive analyses were used to describe the results and Z-test was used to determine statistical significance among trends.

Results

Our analysis suggests there was a statistically significant trend in the number of discharges of Hypoplastic Left Heart Syndrome (HLHS) (p=0.00028) during the study period. Interestingly, though statistically not significant,

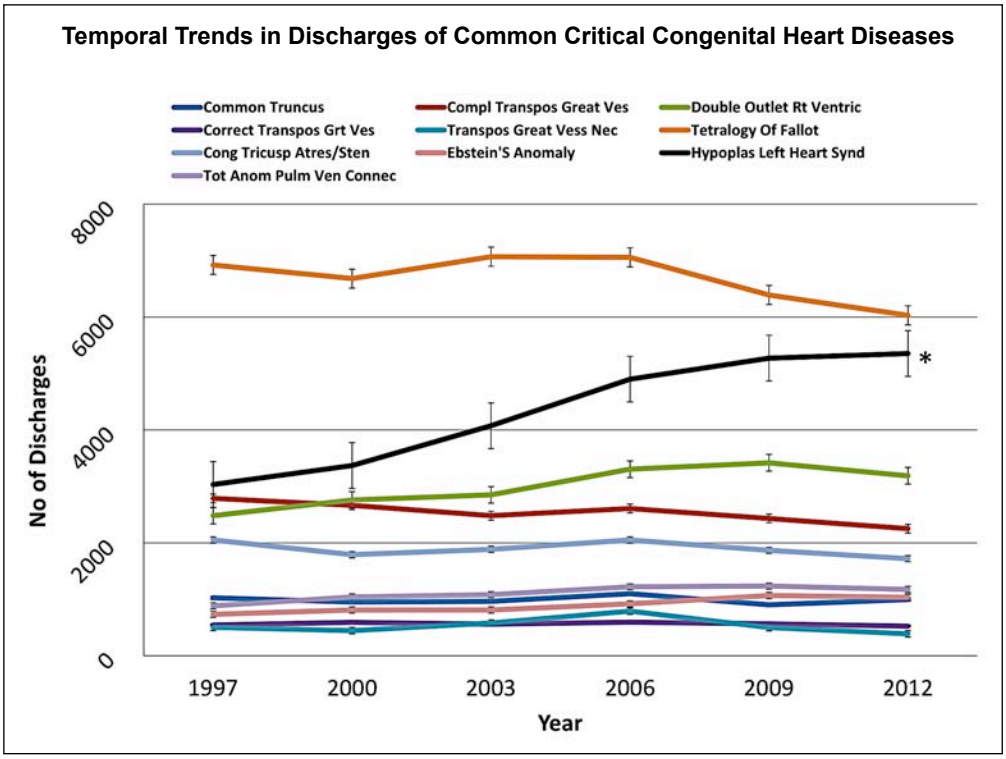

Table 1. Trends in discharges- All diagnosis- ICD-9.

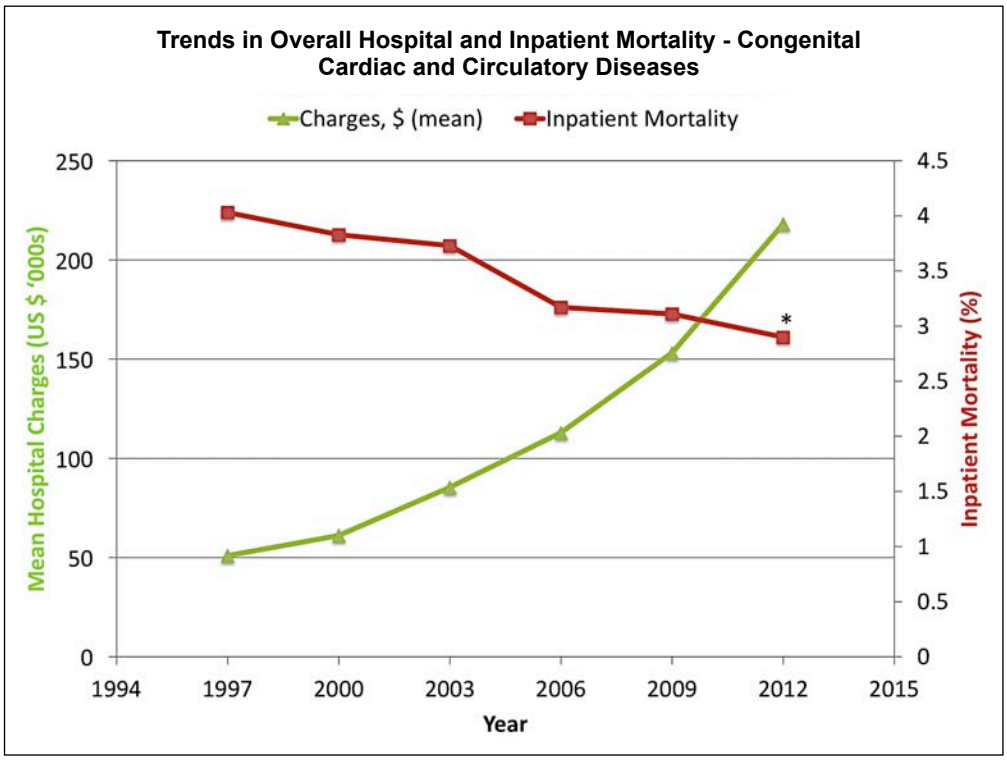

Table 2. Trends in average hospital charges and inpatient mortality- CCS.

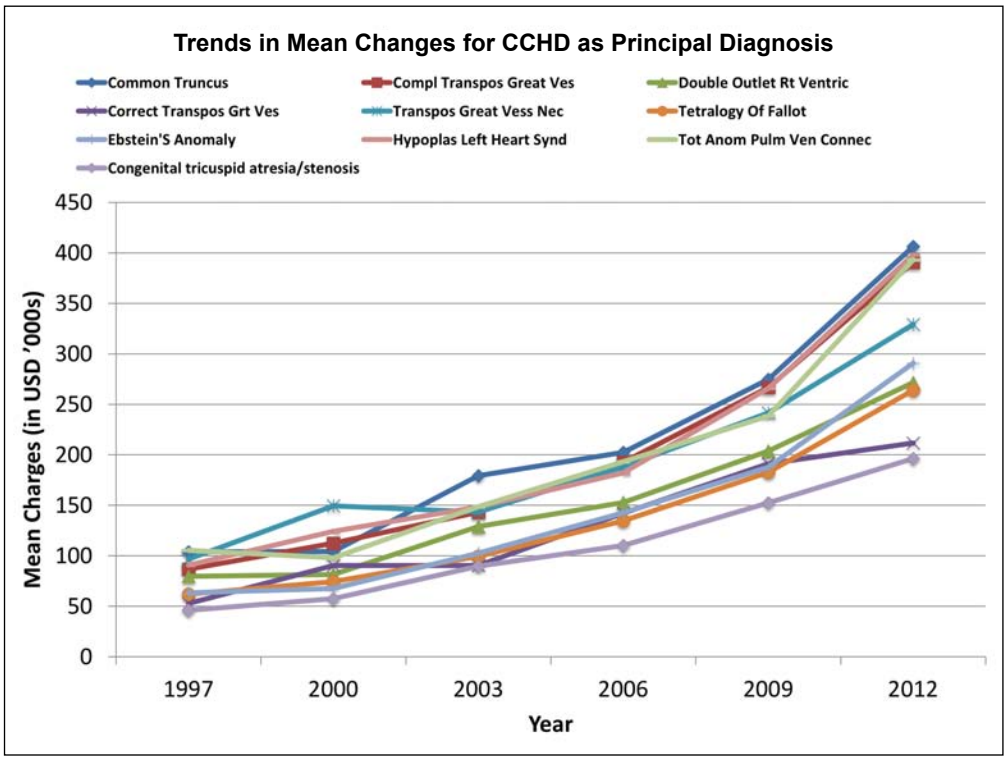

Table 3. Trends in mean charges for each CCHD as principal diagnosis.

there was a downward trend in discharges of Tetralogy of Fallot and significant in discharges of Double Outlet Right Ventricle (DORV) were noted between years 1997-2012 (Table 1). Significant reduction in inpatient mortality (4% vs. 2.9% p=0.001) (Table 2) and estimated total number of discharges (33,124 vs. 28,000; p=0.21) from congenital cardiac and circulatory anomalies were seen during the study period while mean total hospital charges (Table 2) and mean hospital charges for each diagnosis (Table 3) increased exponentially. There was a consistent increase in average length of stay for each principal diagnosis of CCHD (Table 4). We also noted that there was an upward trend increase in hospital discharges with all listed diagnoses of ASD and PDA during the last 15 years (Table 5).

Conclusions

During the last decade, there was a significant increase in the number of patients (3034 ±389 vs. 5355 ±506) cared for with a diagnosis of HLHS and inpatient mortality from congenital cardiac and circulatory anomalies has decreased by 40% in U.S. hospitals. Mean hospital charges for treatment of CCHDs increased four-fold; overall charges of treatments increased from $1.6 billion to 6.1 billion, along with increased length-of-stay for all CCHDs. Increasing numbers of children (0-17 years) with diagnosis of ASD and PDA were cared for in hospitals during study period.

Overall, we noted that hospital discharges and survival of few patients with CCHDs like HLHS and DORV are increasing in number, while others are trending down or remained stable. Robust state/ federal surveillance programs are needed to measure the active and accurate birth prevalence rates of CCHDs to plan for adequate resource allocation, care quality and monitoring. The ongoing interest in finding precise biomarkers and genetic sequencing may provide some additional insights into the causal associations of CCHDs. We hypothesize that survival rates among these infants are improving as a result of advancement in science and technology, with better antenatal ultrasound surveillance, early identification, better understanding of pathophysiology, improved surgical techniques, superior cardiac critical care and focused approach to manage the associated disabilities.

References

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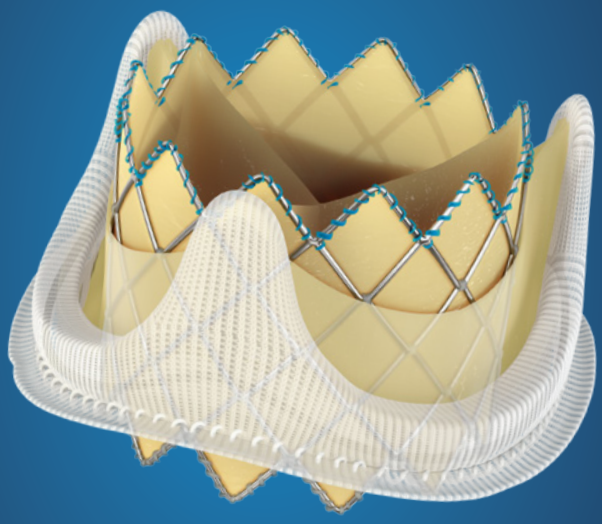

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- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture*, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions For Use provided with the product or available on http://manuals.medtronic.com.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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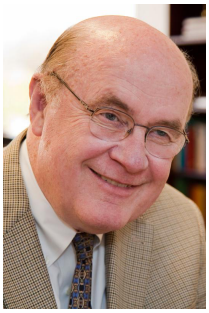

Sincerely,

Gary Webb, MD
CHiP Network
215-313-8058
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The CHIP Network, the Congenital Heart Professionals Network, is designed to provide a single global list of all CHD-interested professionals.

CONGENITAL CARDIOLOGY TODAY

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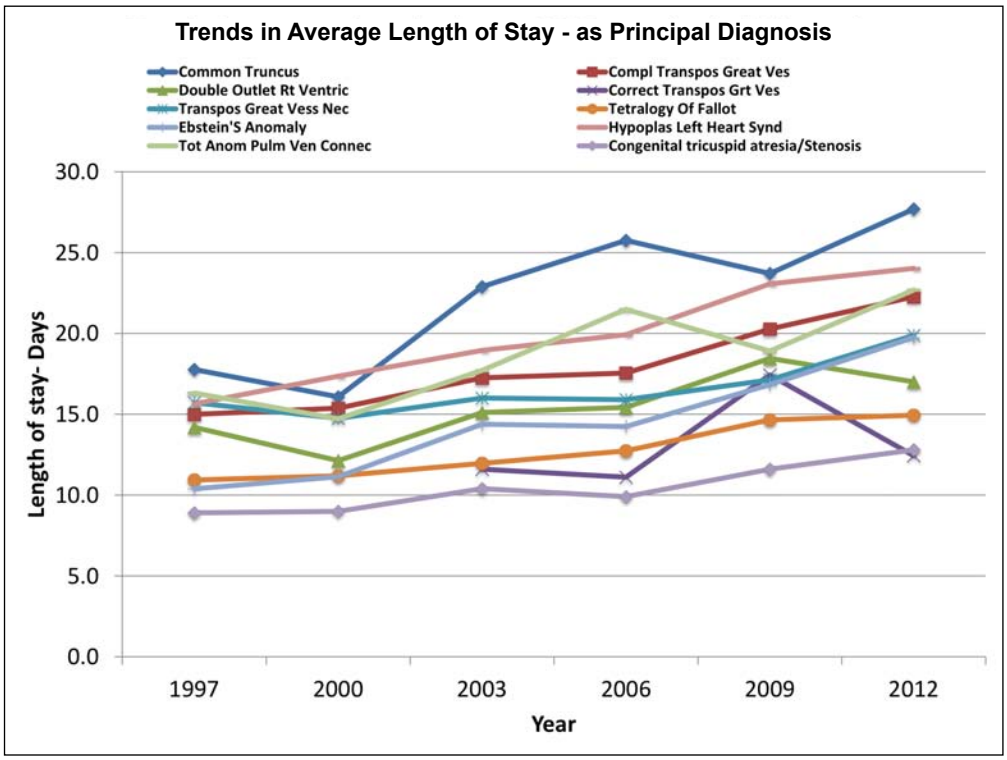

Table 4. Trends in length of stay – Principal diagnosis.

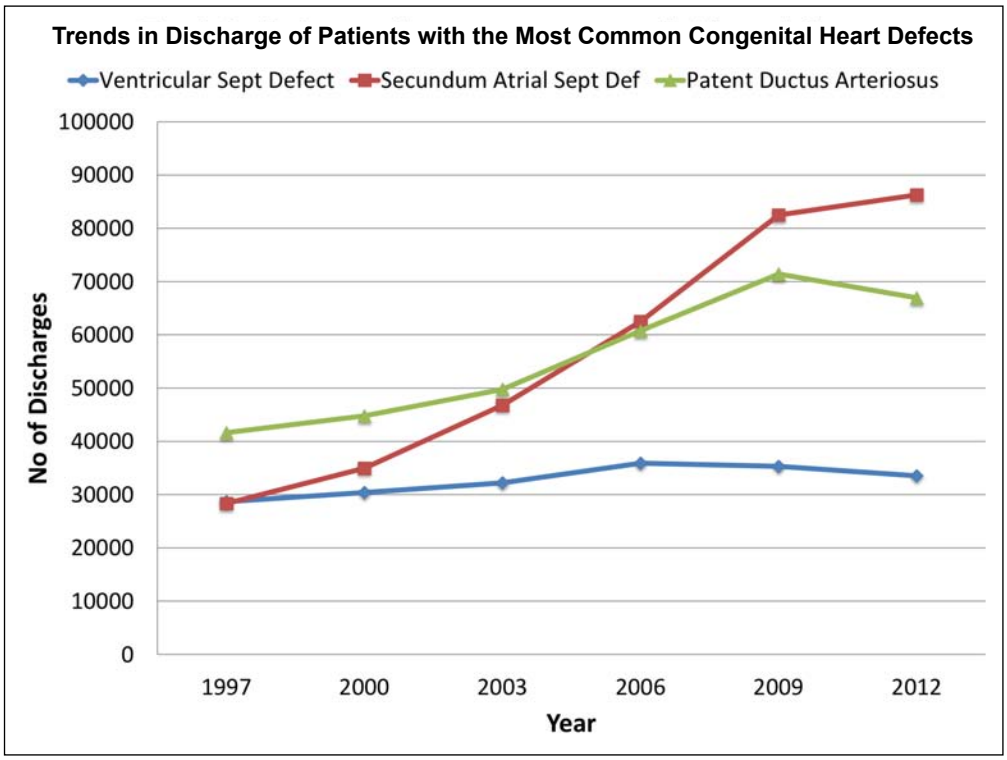

Table 5. Trends in three most common CHDs.

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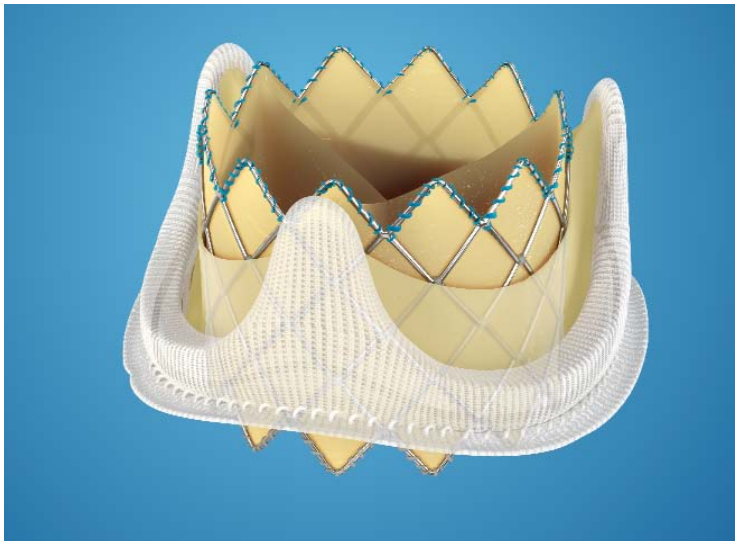
Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

Medtronic Melody Transcatheter Pulmonary Valve First of Its Kind to Receive FDA Approval for Implantation in Failed Surgical Pulmonary Heart Valves

Newly Approved Indication in U.S. Expands Treatment Options to More Patients with Congenital Heart Disease

Medtronic plc (NYSE: MDT) announced in mid-March that its Melody™)



Transcatheter Pulmonary Valve (TPV) received approval from the United States Food and Drug Administration (FDA) for implantation in patients whose surgical bioprosthetic pulmonary heart valves have failed. Designed specifically for the pulmonic position, Melody TPV (Melody-TPV.com) is the first transcatheter pulmonary valve to receive this approval in the U.S.

When a surgical valve degenerates over time, patients may require another valve replacement, which would involve undergoing another open-heart surgery. Intended to prolong the time between open-heart surgeries for patients with a dysfunctional right ventricular outflow tract (RVOT) conduit caused by CHD, the Melody TPV may now provide these patients with a minimally invasive treatment option.

"As the first commercially available transcatheter heart valve, the Melody TPV brought a breakthrough non-surgical option to treat failing pulmonary valve conduits," Jeremy Asnes, MD, Associate Professor of Pediatric Cardiology and Director of the Congenital Cardiac Catheterization Laboratory at the Yale School of Medicine in New Haven, Conn. "Thousands of congenital patients globally have benefited from this therapy in the past decade. With this expanded indication, we can further reduce the need for obtrusive open-heart surgery and allow even more patients to benefit from this minimally invasive treatment option."

During the procedure, the Melody TPV is placed inside a failing pulmonic surgical heart valve through the recently launched Ensemble™ II Delivery System, a low-profile, delivery catheter, specifically designed to deliver the Melody TPV.

The first transcatheter heart valve available anywhere in the world, and now implanted in more than 10,500 patients worldwide, the Melody TPV first received CE Mark in September 2006 for the treatment of failing pulmonary valve conduits. It was introduced in the U.S. in 2010 following FDA approval. Over the last 10 years, clinical evidence from three Medtronic clinical studies has demonstrated the valve's effectiveness in delaying the need for open-heart reoperation.

"Unlike other transcatheter valves currently on the market, Melody TPV is uniquely designed for use in the pulmonic position and is thus well suited for implantation in failed surgical pulmonary heart valves," said Rhonda Robb, VP and General Manager of the Heart Valve Therapies business, which is part of the Cardiac and Vascular Group at Medtronic. "This approval further demonstrates our commitment to improving treatment options for congenital heart disease and we look forward to bringing this proven non-surgical option to congenital patients."

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries.

Radiology Professionals Connect at RSNA 2016

OAK BROOK, Ill. (Jan. 17, 2017) – *The Radiological Society of North America's 102nd Scientific Assembly and Annual Meeting (RSNA 2016)*, held in Chicago's McCormick Place from November 27th to December 2nd, highlighted RSNA's ongoing commitment to improve patient care through radiology education, research and technological innovation.

"The 2016 theme was 'Beyond Imaging,'" said RSNA Executive Director, Mark Watson. "The meeting offered attendees a wealth of opportunities to broaden their perspectives on both the current state of radiology, and the challenges and opportunities the future holds."

RSNA 2016 featured a number of hot topics in radiology including machine learning and 3-D printing for medical applications.

Advances in machine learning and artificial intelligence offer an exciting suite of technologies that are now being applied to medical imaging with compelling results. *RSNA 2016* provided a variety of events related to machine learning, including scientific and education sessions, a hands-on workshop and the "Eyes of Watson" interactive demonstration of IBM's Watson technology platform.

To showcase the increasing clinical significance of 3-D printing and its connection to medical imaging, in addition to many hands-on courses, the Learning Center included presentations on 3-D printing along with demonstrations throughout the week.

Another popular feature of the meeting was the National Cancer Institute (NCI) Perception Lab, where researchers supported by NCI conducted studies on radiologic image perception in an open lab environment. RSNA meeting attendees had the opportunity to participate as volunteers.

Throughout the week at McCormick Place, professional attendees could choose from an abundance of scientific presentations, education courses, plenary sessions, education exhibits and scientific posters, as well as special presentations and performances at the Discovery Theater, part of the new RSNA Connections Center.

"A highly visible new feature for 2016 was the Connections Center," Watson said. "The RSNA Services area was completely redesigned to enhance the attendee experience. The Connections Center provided not only important RSNA services, but also entertainment, networking functions, expanded lounge seating and digital support."

The technical exhibition was 412,000 square feet and housed 663 exhibits, including 104 first-time exhibitors.

The *RSNA 2016 Virtual Meeting* offered attendees on-demand access to more than 90 sessions from *RSNA 2016*, as well as Cases of the Day, digital education exhibits and scientific posters. The virtual meeting attracted 5,645 attendees from 98 countries.

Official registration figures for RSNA 2016 reported total registrant numbers at 54,037, including 26,988 professional registrants of which 1,813 were virtual-meeting only.

RSNA 2016's economic impact on the City of Chicago is estimated at $131 million.

RSNA 2017, RSNA's 103rd Scientific Assembly and Annual Meeting, will take place November 26th to December 1st in Chicago. The meeting's theme is "Explore. Invent. Transform."

RSNA (RSNA.org) is an association of 54,000 radiologists, radiation oncologists, medical physicists and related scientists, promoting excellence in patient care and health care delivery through education, research and technologic innovation.

Women with High-Risk Congenital Heart Disease Can Have Successful Pregnancies

New recommendations from the American Heart Association provide guidance to women with complex congenital heart defects and their healthcare providers about managing successful pregnancies, childbirth and post-natal care.

"Women with Complex Congenital Heart Disease were previously advised to not get pregnant because of the risk to their lifes," said Mary M. Canobbio, RN, MN, Chair of the Writing Committee for the new scientific statement published in the American Heart Association journal *Circulation.*

"Now scientific research demonstrates that with proper management in the hands of experienced cardiologists and obstetricians, these women can have successful pregnancies," said Canobbio, who is also a lecturer at UCLA School of Nursing in Los Angeles, California.

Complex Congenital Heart Defects (CCHD) are serious abnormalities of the heart's structure that are present at birth. People born with these conditions need immediate medical care soon after birth that continues throughout their lives. While most female children born with Congenital Heart Disease will reach childbearing age and will do well, their pregnancy in women with CCHD carries a moderate to high risk for both the mother and her child.

Pre-pregnancy counseling is essential for women with complex congenital heart defects so that they have a clear understanding of how their heart abnormalities could affect both their own health and the health of their child during a pregnancy.

Once pregnant, a delivery plan is also essential, Canobbio said, so the medical team can anticipate problems that could happen during and following delivery and be prepared. The authors recommend that pregnant women deliver their babies at medical centers that have a cardiologist experienced in managing complex congenital heart disease, obstetricians trained in high-risk maternal-fetal medicine, cardiac anesthesia, and a cardiac surgical team.

After delivery, monitoring of the mother needs to continue, because the effects of pregnancy can linger with the woman for six weeks and as long as six months.

Complex Congenital Heart Defects include:

- Single Ventricle, in which a patient is born with only one of the two chambers that pump blood
- Transposition of the Great Arteries, in which the position of the two main arteries leaving the heart are reversed;
- pulmonary hypertension, a type of high blood pressure that affects the arteries in the lungs
- Eisenmenger Syndrome, a condition in which a hole exists between the heart's two chambers, causing blood to flow from the left side of the heart to the right, leading to high blood pressure in the lungs (pulmonary hypertension); and
- severe aortic stenosis, a critical narrowing of one of the valves on the left side of the heart.

"This scientific statement outlines the specific management for these high-risk patients: what we know about the risks for these patients; what the potential complications are; what cardiologists; advanced practice nurses and other cardiac health providers should discuss in counseling these women, and once pregnant, recommendations in terms of the things we should be looking out for when caring for these women," said Canobbio said.

Co-authors are: Co-Chair Carole A. Warnes, MD; Jamil Aboulhosn, MD; Heidi M. Connolly, MD; Amber Khanna, MD; Brian J. Koos, MD, D.Phil.; Seema Mital, MD; Carl Rose, MD; Candice Silversides, MD; and Karen Stout, MD; on behalf of the American Heart Association Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; Council on Cardiovascular Disease in the Young; Council on Functional Genomics and Translational Biology; and Council on Quality of Care and Outcomes Research. Author disclosures are on the manuscript.

Soft Robots Hug the Heart to Help Pump Blood

An implantable soft-robotic device could help failing hearts pump blood by giving the organ gentle squeezes, mimicking the natural motion of the cardiac muscle, a new study reveals. The silicon-based device, which stiffens or relaxes when inflated with pressurized air, could prove to be a promising strategy for the development of assistive devices for heart failure – a serious condition afflicting 41 million people worldwide and over five million in the U.S., costing the nation an estimated $32 billion each year.

While Ventricular Assist Devices (VADs) are currently used as a life-prolonging therapy, they are in constant contact with the blood – increasing a patient's risk for infection, coagulation and stroke, and requiring the use of long-term blood-thinning medications. VADs also interfere with the normal curvature of the

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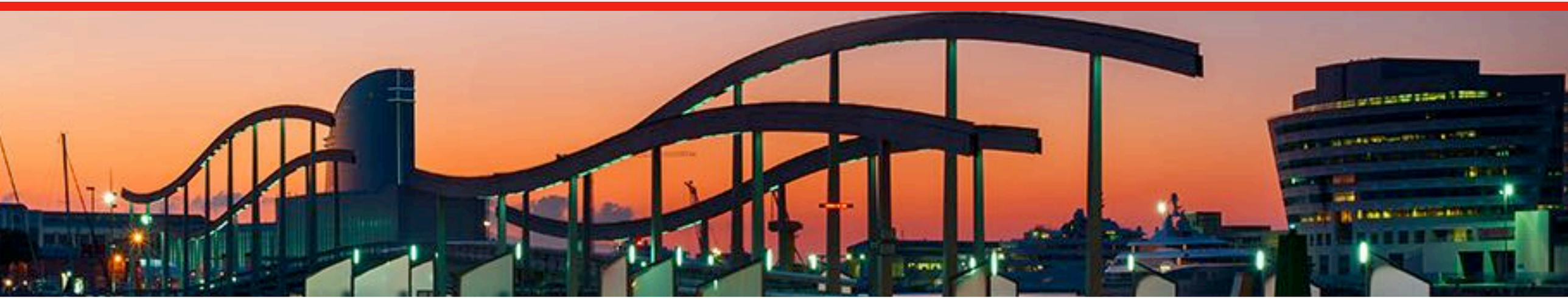

Dear Colleagues,

The Organizing Committee is pleased to announce the **7th World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS)**, which will take place on July 16 - 21, 2017, in the Centre Convencions Internacional de Barcelona (CCIB), Barcelona, Spain.
The aim of WCPCCS is to bring together all professionals involved in the care of children's heart disease and congenital heart disease of all ages, from the fetus to the aged. The Congress will provide a unique opportunity to meet the leaders of specialties worldwide; to learn about the latest innovations and the results of procedures; and to contribute to the discussions, debates and plenary sessions with renowned speakers.

The central philosophy of the Congress is "bridging together" all major specialties in the field. Accordingly, the scientific program is carefully planned to address all interests and expertise with concentration streams on pediatric cardiology, pediatric cardiac surgery, adult congenital heart diseases, anesthesia, intensive care and nursing.

We are excited to offer the scientific and cultural feast of a lifetime to one of the most refined crowd in the profession, in one the most welcoming, inimitably exciting venues of the world. Come to Barcelona in July 2017 and join us in forging this unforgettable experience.

Let's meet in Barcelona in July 2017!

Cordial Regards,
Prof. Sertaç Çiçek Congress Chairman, WCPCCS 2017 Prof. Levent Saltık, Congress Co-Chairman, WCPCCS 2017

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heart and its contraction mechanics. Seeking to pioneer a more effective device, Ellen Roche and colleagues developed a novel apparatus designed to augment cardiac function by closely replicating normal heart muscle behavior, instead of disrupting it. In ex vivo experiments, the device successfully conformed to porcine heart surfaces, synchronizing with native heart motion. It also restored normal blood flow after acute cardiac arrest in six living pigs. The researchers were able to "fine tune" the device by selectively twisting and compressing either the right or left ventricle of explanted pig hearts – a key finding, as chronic heart-failure often only affects a portion of the organ. With further investigation, the device could be tailored for individual patient needs, to better target cardiac rehabilitation or recovery. Additional work is needed to make this technology suitable for longer-term implantation in the body, the authors say.

Article #3: "Soft robotic sleeve supports heart function," by E.T. Roche; M.A. Horvath; A. Alazmani; S.-E. Song; W. Whyte; C.J. Payne; D.J. Mooney; C.J. Walsh at Harvard University in Cambridge, MA; E.T. Roche; M.A. Horvath; A. Alazmani; S.-E. Song; W. Whyte; C.J. Payne; J. Weaver; D.J. Mooney; C.J. Walsh at Wyss Institute for Biologically Inspired Engineering in Boston, MA; E.T. Roche at National University of Ireland Galway in Galway, Ireland; M.A. Horvath at Technische Universität München in Garching, Germany; I. Wamala; A. Alazmani; S.-E. Song; Z. Machaidze; J. Kuebler; N.V. Vasilyev; F.A. Pigula at Boston Children's Hospital in Boston, MA; A. Alazmani at University of Leeds in Leeds, UK; S.-E. Song at University of Central Florida in Orlando, FL; W. Whyte at Royal College of Surgeons in Ireland in Dublin, Ireland; W. Whyte at Trinity College Dublin in Dublin, Ireland. For a complete list of authors, please see the manuscript.

This paper's abstract is located at: http://stm.sciencemag.org/lookup/doi/10.1126/scitranslmed.aaf3925

Parents of Children Born with Heart Defects Crave Disease Stats, Surgeon Info - New Survey Shows Parents Want Accessible and Easily Understood Public Reporting

Newswise — Survival statistics, surgeon-specific experience, and complication rates are the types of information most wanted by parents of children with Congenital Heart Ddisease, according to a survey released at the *53rd Annual Meeting of The Society of Thoracic Surgeons (STS).*

STS launched public reporting of outcomes from its Congenital Heart Surgery Database (CHSD) in early 2015, as a continuation of its commitment to increase public awareness and understanding of cardiothoracic surgery procedures. Public reporting of outcomes from the STS Adult Cardiac Surgery Database (www.sts.org/national-database/database-managers/congenital-heart-surgery-databas) began in 2010.

"Public reporting for congenital heart surgery is definitely a work in progress, with the diversity of the field and wide spectrum of congenital heart defects being some of the greatest challenges. Each hospital's case mix is unique, as are the specific defects treated at the individual institutions. This makes the comparison of outcomes across many different hospitals difficult," explained Mallory L. Irons, MD, MBE, from the Hospital of the University of Pennsylvania, in Philadelphia, PA. "Our research emphasized that parents have valuable opinions about the content and format of the information that should be provided. How data are presented may be more important than the data itself, with the type of visual display employed affecting the degree to which parents correctly interpret the data presented."

Dr. Irons, along with members of the cardiothoracic surgical team at Children's Hospital of Philadelphia (CHOP) and three parent advocacy groups (Mended Little Hearts, the Pediatric Congenital Heart Association, and Sisters by Heart), developed a 43-question survey to assess parent attitudes regarding the format and content of an "optimal" public reporting scheme. Survey questions evaluated demographic and socioeconomic information, as well as the parents' perspectives about the importance of various potential surgical outcome measures and the preferred graphical format of displaying outcomes data.

Parents were solicited for participation via member lists from the three parent advocacy groups and from a cohort of parents whose children had undergone surgical correction for an STS benchmark procedure at CHOP after January 1, 2007. Of the 1,862 survey responses collected, 1,281 (69%) provided complete data for analysis. Nearly all (92%) of the participants were mothers of children with congenital heart disease (CHD).

What Parents Want to Know About Congenital Heart Surgeries

In their responses, parents identified survival statistics, surgeon-specific experience, and complication rates as the most important congenital heart surgery outcome measures to publicly report. Additionally, when presented with three display formats for hospital--specific mortality rates, most parents (89%) preferred a numerical, procedure--based approach as the best format, and more than half (60%) thought the hospital star rating system was the least desirable format to display mortality data.

Researchers hypothesized that parents preferred the numerical, procedure--based format because it allows them to see mortality data for a specific procedure. But for procedures that are performed less frequently, the numbers may be too small for surgeon-specific outcomes to be meaningful enough for families faced with a choice. Consequently, as public reporting of congenital heart surgery outcomes continues to evolve, Dr. Irons said, the optimal reporting scheme may be a hybrid of the numerical, procedure--based format and star rating system, providing overall rankings along with procedure-specific data.

While the American Heart Association (AHA) identifies at least 18 distinct categories of congenital heart defects, with many additional anatomic variations, the STS CHSD actually contains data pertaining to almost 200 unique diagnoses and more than 150 different types of surgical procedures. Congenital heart defects are the leading cause of all infant deaths in the United States, with approximately 40,000 babies born with at least one congenital heart defect in the US each year, according to the US Centers for Disease Control and Prevention.

Achieving adequate risk adjustment also presents problems in the public reporting of outcomes in congenital heart surgery. Risk adjustment is a way to measure surgical results by taking into consideration how sick the patients were before treatment. “Many factors, such as preterm birth, genetic anomalies, and extra-cardiac anomalies may significantly alter the procedural risk for an individual patient, but current risk models still do not include many factors that may increase the risk of death,” said Dr. Irons.

“Efforts for public reporting like those developed by STS are very important,” said Dr. Irons. “The organization strives to report results that are based on accurate data, robust outcomes, and risk adjustment, and are presented in an easily understood format. In promoting transparency in the reporting of outcomes, not only do we help patients and their families make decisions about where and from whom to receive care, but we also strive to improve outcomes across all centers.”

According to the research group, future efforts in public reporting for congenital heart surgery outcomes must include more robust risk adjustment, long-term outcomes, and better methods for presenting the data in a valid, easily interpreted format that meets the unique needs of parents and other stakeholders. “Moving forward, the challenge will be to find ways to meet the goals of all stakeholders, without compromising the quality of data,” Dr. Irons said.

“This study has helped clarify what types of information parents want; however, just because parents want certain data does not mean that we can provide this in a meaningful way,” concluded Dr. Irons. “Our ultimate goals with this project were to improve patient care and understand how the public reporting effort can help attain this goal.”

The CHSD—a component of the STS National Database—is the largest clinical database in the world dealing with congenital cardiac malformations. The CHSD contains more than 400,000 congenital heart surgery procedure records and currently has more than 800 participating physicians, including surgeons and anesthesiologists, representing more than 95% of all congenital heart surgery hospitals in the United States and Canada. STS also has available a CHSD mortality risk model that calculates the operative mortality rate of hospitals performing pediatric and congenital heart surgery, adjusting for procedural and patient-level factors.

STS voluntary reporting of hospital-level outcomes from pediatric and congenital heart surgery currently includes both star ratings (as used in all STS National Database public reporting) and actual numerical data for observed and risk-adjusted rates of operative mortality (provided as point estimates with confidence intervals), with these data reported both for all operations and for risk stratified groups of operations.

The other authors of the study were: J. William Gaynor, MD, Thomas L. Spray, MD, and Chris Feudtner, MD, PhD.

Shock from Heart Device Often Triggers Further Health Care Needs

A shock from an implantable cardioverter defibrillator (ICD) may trigger an increase in health care needs for many people, regardless whether the shock was medically necessary, according to a new study published in *Circulation: Cardiovascular Quality and Outcomes,* an American Heart Association journal.

ICDs save people from sudden cardiac death by delivering a shock to restore a normal rhythm when the lower chambers of their heart, or ventricles, beat erratically. Inappropriate shocks occur with ICDs, most often when the device mistakes a different heart rhythm problem for ventricular arrhythmia--abnormal heart rhythms that originate in the lower chambers of the heart.

"ICDs cannot assess patients the way a doctor can," said lead study author Mintu Turakhia, MD, MAS, Cardiac Electrophysiologist and Senior Director of Research and Innovation at the Center for Digital Health at Stanford University in California. "The device doesn't know, for instance, if the patient is unconscious or has a pulse. We wanted to see what happens after a shock, in terms of care and cost, to help define the potential benefit of smarter ways to program these devices."

The authors analyzed the experience of 10,266 patients implanted with an ICD in the U.S. between 2008 and 2010 by linking data transmitted to the device manufacturer with the patients' healthcare records. During that time, 963 patients, average age 61, experienced 1,885 shocks. Thirty-eight percent of those shocks were determined to be inappropriate.

Researchers also found:

- Nearly half of all patients (46%) who experienced a shock received health care related to the shock.
- One in three patients received emergency room or outpatient care only.
- One in seven patients was admitted to the hospital.
- Invasive cardiovascular procedures, including electrophysiology studies, cardiac catheterization and cardia ablation, were commonly performed following both appropriate and inappropriate shock.
- The average cost of health care following a shock was $5,592 for an appropriate shock and $4,470 for an inappropriate shock.

"Obviously, shocks that save people's lives are a good thing, but they are also very painful, can be traumatic and often lead to more health care procedures and expenses," Turakhia said. "This is why strategies to make these ICDs more selective, so that they deliver fewer inappropriate shocks is especially important. Fortunately, the industry has made many advancements in this area."

Turakhia added that newer programming strategies reduce the number of inappropriate shocks, even among older-generation ICDs. The devices can be programmed by clinicians to deliver fewer inappropriate shocks by waiting briefly to see if the ventricular arrhythmia resolves itself and by cautiously avoiding triggering shocks for heart rhythms with moderately fast rates.

"The quality of care is no longer just an issue of whether an ICD was implanted in appropriate patients but also whether it was programmed in the best way possible," he said. "We have the technology to do that today."

The findings may be limited as all patients had an ICD from the same manufacturer (Medtronic) and information about factors that may have biased results, including patient behavior and health status, was not available.

"From this study, we cannot tell whether any patient received appropriate or inappropriate care -- only whether they received an appropriate shock or not," Turakhia said. "We can say, however, that the costs associated with both kinds of shock are substantial and that optimal device programming that reduce shock events are likely to decrease healthcare costs and improve patient health."

Co-authors are: Steven Zweibel, MD; Andrea L. Swain, MB.; Sarah A. Mollenkopf, MPH; and Matthew R. Reynolds, MD, MSc.

Author disclosures are on the manuscript. Medtronic Inc. funded the study.

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Mayo Clinic, Children's Hospital of Philadelphia Announce Rare Congenital Heart Defect Collaboration

ROCHESTER, Minn. and PHILADELPHIA — Mayo Clinic's Todd and Karen Wanek Family Program for Hypoplastic Left Heart Syndrome and Children's Hospital of Philadelphia are collaborating to delay and prevent heart failure for Hypoplastic Left Heart Syndrome (HLHS), a rare and complex form of Congenital Heart Disease (CHD) in which the left side of a child's heart is severely underdeveloped.

"We are very excited to be working with Children's Hospital of Philadelphia to explore better treatment options for patients with Hypoplastic Left Heart Syndrome," says Timothy Nelson, MD, PhD, Director, Todd and Karen Wanek Family Program for Hypoplastic Left Heart Syndrome. "By entering into this collaboration, we are making it possible for all children with Hypoplastic Left Heart Syndrome to be able to participate in cell-based treatments, no matter their location. This new Hypoplastic Left Heart Syndrome consortium significantly expands the reach of Hypoplastic Left Heart Syndrome research."

"Children's Hospital of Philadelphia has a long-standing history of caring for children with Hypoplastic Left Heart Syndrome, and this exciting collaboration with Mayo Clinic offers promising opportunities to develop new ways to give patients an even better quality of life," says Robert Shaddy, MD, Chief of Cardiology, Children's Hospital of Philadelphia. "Lifesaving palliative surgery reroutes a child's blood flow, but patients may have significant health problems, as they grow up with a unique circulation. Cell-based therapy offers us another potential option – beyond conventional medical treatments, ventricular assist devices or transplants – for a child or young adult with a failing heart."

The collaboration is part of a consortium across the nation and will allow for a decrease in the amount of time from research and discovery to the clinical application of innovative cell-based therapies.

The consortium aligns regional centers into a nationwide collaboration led by the Todd and Karen Wanek Family Program for Hypoplastic Left Heart Syndrome at Mayo Clinic (www.mayo.edu/research/centers-programs/todd-karen-wanek-family-program-hypoplastic-left-heart-syndrome/overview) to accelerate innovation on Hypoplastic Left Heart Syndrome, discovery sciences, and clinical expertise by investing local resources back into research. The program seeks to work with five to seven regional centers across the U.S. to fund the development of cell-based innovative research opportunities to transform the lives of people living with Hypoplastic Left Heart Syndrome.

Founded in 2010, the Todd and Karen Wanek Family Program for Hypoplastic Left Heart Syndrome is a collaborative network of specialists bonded by the vision of delaying or preventing heart failure for individuals affected by congenital heart defects, including Hypoplastic Left Heart Syndrome. The specialized team is addressing the various aspects of these defects by using research and clinical strategies ranging from basic science to diagnostic imaging to regenerative therapies.

Founded in 1855 as the nation's first pediatric hospital, Children's Hospital of Philadelphia (http://chop.edu) is ranked third by *U.S. News & World Report* "Best Children's Hospital for Pediatric Cardiology and Heart Surgery." Through its long-standing commitment to providing exceptional patient care, training new generations of pediatric healthcare professionals and pioneering major research initiatives, Children's Hospital has fostered many discoveries that have benefited children worldwide.

Mayo Clinic is a nonprofit organization committed to clinical practice, education and research, providing expert, whole-person care to everyone who needs healing. For more information, visit www.mayoclinic.org/about-mayo-clinic.

E-mail comments or questions on medical news to:
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Review of PICS~AICS 2017 in Miami

Karim A. Diab, MD; Damien Kenny, MD

PICS-AICS 2017 was held at the Loews Hotel in Miami, FL from January 16th-19th, 2017. This marked the 20th anniversary of the meeting and was attended by approximately 800 healthcare professionals from 52 different countries, including 20 from Brazil. The first meeting was held in Boston, MA, September 1997.

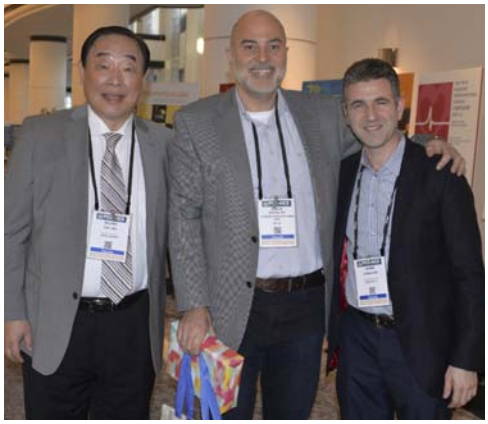
Prior to this meeting on Sunday, January 15th, 2017, an evening symposium organized by St. Jude Medical to discuss the "Role of Patent Foramen Ovale in Cryptogenic Stroke," was held. This symposium was organized in light of the recent FDA approval of the Amplatzer PFO device to close PFO in patients who sustained a cryptogenic stroke. It included a review of the long-term data from the RESPECT trial final results, patient selection and practical planning for a PFO clinic using a multi-disciplinary approach.

The *PICS* meeting was officially opened on January 16th by Dr. Ziyad M. Hijazi, Course Director and Founder of the meeting. During the four days of the course many topics were discussed.

On Monday, a keynote speech, TED-style, was given by Dr. David Nykanen. The title of the speech was "From Septostomies to Stem Cells – What the Next 50 Years Hold." This was followed by many sessions, including: 2 oral abstract sessions discussing 20 excellent abstracts, taped cases sessions presented by three institutions (Mayo Clinic, Toronto and Stanford), "Stenting in the 21st Century – How Far Have We Come…and How Far We Have Yet to Go," and the last session of the day, an FDA Town Hall and Device Development. This focused on issues such as: developing bioresorbable devices, bringing devices available outside the U.S. to the U.S. market, overcoming challenges in device development and a discussion on the process of device approval in various countries.

This last session was in honor of an engineer who was a friend of *PICS* and of all interventional pediatric cardiologists: Mr. Doug Villnave, who passed away in 2016. Doug was an engineer at NuMED Inc., a company dedicated to making products for children with Congenital Heart Disease (CHD). Monday also featured a special course to teach leadership to cath lab directors and managers, organized and given by Mr. Robert Berk, author of "Leadership between the Sheets' - Uncovering the Power of Intimacy in Business and in Life."

Also on Monday, the PICS Achievement Award was given. This is the most



prestigious award in the field of Pediatric/ Congenital Interventional Cardiology. The first PICS Achievement Award was given in 1997 to Dr. C. Mullins, and the recipient of this year's award was Dr. Thomas Jones, Director of Catheterization Laboratories at Seattle Children's Hospital.

Monday evening the exhibit was opened officially and a reception was held from 6:00-8:00 pm to thank all exhibitors.

On Tuesday, January 17th, 2017, the day started at 6:00 am with the traditional 5K Run, sponsored by Siemens. Over one hundred people participated. The run aims at supporting C.H.I.M.S (Congenital Heart Intervention Mission Support), a project that was launched during *PICS 2013* to help children around the world with CHD. This organization has been very active in providing a coordinated and sustainable benefit to interventional catheterization for structural heart disease in developing countries through centralizing and consolidating pre-existing charitable mission work. For more information, visit the website at www.chimsupport.com.

This year witnessed a new winner of the race!! A pediatric cardiology fellow, Allen Ligon, from Atlanta, won the race in 17:50:2 seconds.

Live cases were transmitted live via satellite from three different international venues, including: Saudi Arabia, Santiago de Chile and Cordoba, and Argentina. Each site transmitted two excellent cases. After the end of the live cases at 1:00 pm, different breakout sessions took place, including: taped cases session from Cincinnati, Houston and Israel; a state-of-the-art ASD closure

session; a complex structural interventions session, a nursing and associated professionals session, a PICES (Pediatric Interventional Cardiology Early Career Society) session, and Advances in imaging modalities to guide interventions session.

The last session of the day was an evening symposium, "The RVOT – Volumes, Clinical Trials and the Future," which was held and was supported by the makers of the percutaneous valves: Edwards Life Sciences, Medtronic and Venus Medtech. This continues to be one of the most exciting advances in our field over the past 15 years, and updates on the ongoing clinical trials with newer valves were presented.

On Wednesday, January 18th, 2017 live cases were transmitted from New York City, Houston and Dallas. Again, each site transmitted two live cases. After the end of the live cases at 1:00 pm, different breakout sessions took place, including: taped cases sessions from Cedar Sinai, Seattle and Dublin;an intervention outside the heart session; a pushing the boundaries session, which focused on unusual interventions, including: fetal interventions, closure of the premature duct, intervention in pulmonary hypertension and advances in surgical techniques;a Left Atrial Appendage and Mitral Valve Interventions session; a measuring and reducing risk session, which was in collaboration with CCISC, and finally. a Spanish session.

In the evening, the traditional dinner party took place at the famous Nikki Beach, where all participants were treated to a great dinner and entertainment. During this event, many awards were given, including distinguished service awards to a few individuals who for the last 20 years have worked to make this meeting the best. The recipients of the awards were:

- Ms. Colene Diodati and Ms. Sally Cook, who have been managing the conference since its start in 1997,
- Ms. Michaleen Wallig, who is Dr. Hijazi's Assistant and Treasurer of the PICS Foundation, and
- Ms. Kim Ray, the PICS Coordinator since 1999. Kim works very hard with the faculty and industry to ensure a successful meeting.

Other awards given included: The Young Leadership Award, received by Jeff Zampi. (The winner of this award becomes a *PICS* faculty); the Charles S. Kleinman Scientific Award, where the *PICS* Foundation donates $5,000 towards the recipient's research; the winner of the oral abstracts; the winner of the moderated abstracts; and finally, the new Terry King Travel Award, which was created and funded by the PICS Foundation. This award helps an interventional cardiologist travel to attend the *PICS~AICS* meeting. Travel expenses, including air, hotel and registration is covered by this award.

The last day of the symposium took place on Thursday, January 19th, 2017. Live cases were transmitted from Columbus, OH; Pittsburgh, PA and Los Angeles, CA. Each site transmitted two live cases. In between the two live cases sessions, there was a didactic session: Update on Structural Heart Interventions for Congenital Interventionalists. Then, the famous session, "My Nightmare Case" took place, the winner of this year's case was a fellow from Denver Children's Hospital. Then the last scientific session of the day was, "Simplifying the Complex – My Step-by-Step Approach" with step-by-step approach to: RVOT stenting, VSD closure via retrograde approach, PDA stenting in TOF, hybrid MVR in infants, hybrid PVR, hybrid for HLHS and modalities to support large sheath advancements in RVOT interventions.

The final session of the afternoon continued with the tradition from last year - "Battle of the Continents" session, where four teams were assembled to represent: North America, South America, Asia/Africa/ROW and Europe. Again, this year North America won the contest. There were 30 questions presented to the four teams, and the North American team won by a wide margin.

At the end of the day, Dr. Hijazi selected the *PICS-AICS* Passport Winner, and closed the meeting.

During the four days of the conference, abstracts that were selected as posters were displayed in the foyer for all participants to read.

The feedback received from attendees has been very positive, and many indicated that this meeting was the best ever.

We hope to see you for *PICS-AICS 2018*, to be held at the famous MGM in Las Vegas, NV, September 5th-8th, 2018 - For more information, www.picsymposium.com.

CCT

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Physician Job Offers and Attorney Management

By Mike Hathaway

Why Read This?

Physician recruiters often hear candidates talk about the "offers" they have, especially graduating residents and fellows. What's been interesting to me over the years is how what is being called an "offer" is usually not really an offer at all. Often, the term is used synonymously with "lead," and that's all it is - they've heard about an opening somewhere but haven't actually had a meaningful conversation with anyone about it yet. Although it's becoming rarer, I've seen instances where a potential candidate will be given a "courtesy interview" even though there is no opening. This might be good interview practice for a candidate, but it should never be confused with an actual job opportunity. Too often, a candidate's hopes are dashed when the "offer" they thought they had never actually materializes into a job. So, let's look at what is an offer, what isn't, and how to deal with a real one!

What is an Offer?

To put it in the simplest terms, an offer is when you can say "yes" and have a job with a defined start date, compensation and benefits package, location, etc. Offers are also part of the negotiating process - this is where you and your potential employer will get into fine tuning one another's expectations regarding those things. An initial offer may be verbal, but you will want it written as soon as possible.

Typically, an offer is extended verbally in a phone call AFTER at least one on-site interview. Increasingly, verbal offers are reiterated by email, often to provide a record of your verbal acceptance in the phone call. Upon your acceptance of an offer, the employing entity will work on sending you a contract (sometimes simply an *Offer Letter*) that you can sign and return to solidify your position. Be patient here. Even the most efficient organizations will have an established process with several steps - it's going to take a few days to get the contract to you. Larger practice management companies may even take a few weeks to physically deliver an executable contract - this is normal, be patient. This is a good time to shop for attorneys if you feel you need one, but don't retain one just yet.

Once you have an executable contract/offer letter in hand, my advice is to sit down with some quiet time to read it carefully. Make notes of anything you have questions about. There may be some things that you will want an attorney to review, but have your notes ready before you spend the money. Plan on $300 to $500 for an attorney to review an employment contract.

Attorney Management

Attorney management is a term I use to help candidates understand the relationship that they should have with the attorney they hire to review a contract. You're smart enough to become a medical professional, so you're smart enough to understand that your attorney works for you - not the other way around. You want to clearly define for them that their role is to help you understand the contract, and what it requires of you. I've seen too many people lose great opportunities because their attorney felt compelled to rewrite the contract, often with no meaningful changes other than language or with overly onerous conditions that couldn't possibly be agreed to. Sometimes it seems that some attorneys feel that they must justify their fee by butchering your deal. Don't let that happen. You want them to clarify the implications of the contract so that you can make an intelligent decision - period! That's not to say that offered contracts are never subject to some final tweaking, they usually are - but a tweak is not a full rewrite.

You MUST specify to your attorney when you want the review to be complete. It should not take more than a week turnaround, even for a busy legal practice. There is an old saying in the recruiting business that "time kills all deals" - and that can certainly be true if it takes too long to execute a contract that's already taken a while to get out to you.

What is NOT an Offer?

This is easy. Anything that is not an opportunity to commit and have a job secured is NOT a job offer. If you cannot say "yes" and be done, then you have only just begun.

CCT

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