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ACC 13 American College of Cardiology
Mar. 9-11, 2013; San Francisco, CA USA
accscientificsession.cardiosource.org/ACC.aspx

9th Workshop IPC International Workshop
Mar. 20, 2013; Milan Italy
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The 60th International Conference of the Israel Heart Society
Apr. 22-23, 2013; Jerusalem; Israel
www.israelheart.com

LAA Asia Pacific - How to Close the Left Atrial Appendage
May 4, 2013; Hong Kong
csi-congress.org/laa-asia-pacific-workshop.php

SCAI 2013 Scientific Sessions
May 8-11, 2013; Orlando, FL USA
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ICi 2013 - Imaging in Structural, Valvular & Congenital Interventions
Jun. 26, 2013; Frankfurt, Germany
www.ici-congress.org

International Academy of Cardiology, 18th World Congress on Heart Disease, Annual Scientific Sessions 2013
July 26-29, 2012; Vancouver, Canada
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Critical Complex Congenital Heart Disease (CCHD)

By Mitchell Goldstein, MD

Critical Complex Congenital Heart Disease (CCHD) refers to a number of congenital heart diseases that are characterized by anatomical variations capable of causing severe morbidity or mortality within the newborn period or beyond. These are a number of different conditions that characteristically require intervention during the first year of life for survival or have a chance for survival¹. Seven-nine babies per 1,000 live births have some form of Complex Congenital Heart Disease (CHD).¹⁻³ Before the advent of modern surgical techniques, there was little possibility of intervention even if the diagnosis was clear. Regardless of the time of discovery, many of these complex congenital heart diseases were deemed fatal or associated with a markedly diminished life expectancy. Along with the ability to intervene, it has become abundantly clear that late diagnosis is associated with a worse prognosis for surgical correction, as well as increased risk for complications associated with a failing circulation prior to the intervention. The interest in achieving earlier intervention is largely mediated by wanting to assure the best possible outcomes.^{1,4-6}

A number of studies focused on the strength of the physical exam in diagnosis of CCHD.⁷⁻¹¹ A suspicious murmur or a decreased femoral pulse were hallmarks of the "at risk" neonate or small child. Physical exam alone has failed to identify approximately 50% of the CHD cases.^{6,9,12-14} Fetal ultrasound and associated echocardiography could readily identify lesions that were not associated with a normal four-

"Seven to nine babies per 1,000 live births have some form of Complex Congenital Heart Disease (CHD). Before the advent of modern surgical techniques, there was little possibility of intervention even if the diagnosis was clear."

chambered heart anatomy, but a number of lesions, especially those involving extra cardiac vessels, are still difficult to detect antenatally.⁵ Distinguishing between the benign heart murmurs associated with the normal closing of the Patent Ductus Arteriosus, and that associated with the unmasking of an Aortic Coarctation was not for the faint-of-heart. Increased utilization of pediatric echocardiography could help make this determination, but frequent false positives on the physical exam made this a costly proposition.¹⁴ Moreover, many birthing centers and community hospitals did not have ready access to a pediatric cardiologist.¹⁵ Not every baby with a heart murmur could be transported for evaluation. The referral process was not standard, and many infants left the hospital undiagnosed. As

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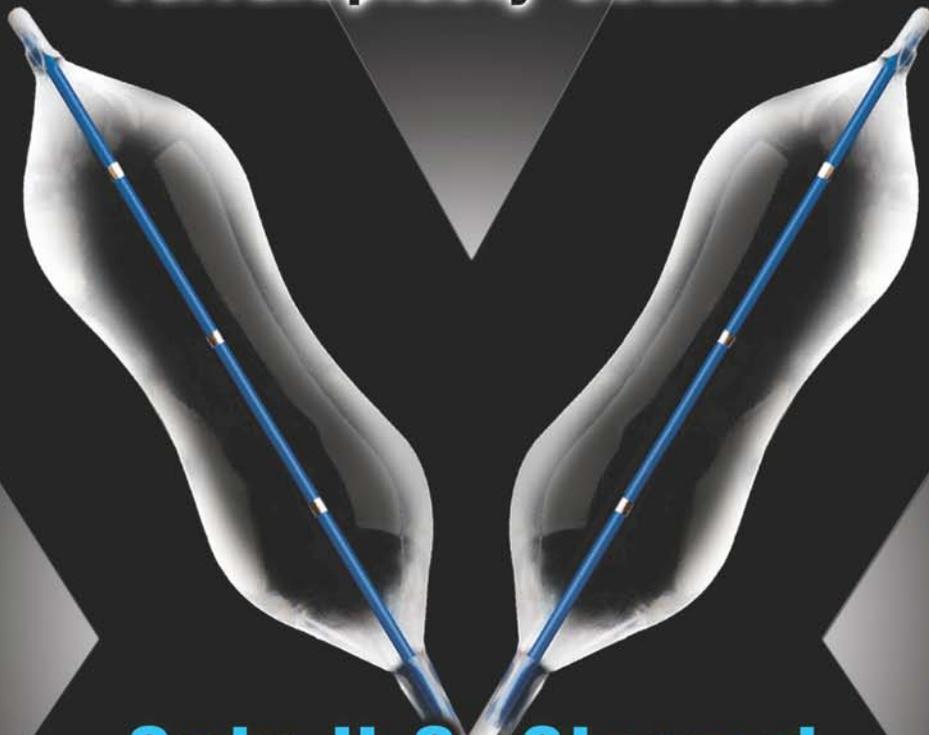
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inpatient maternity length of stay declined, many more babies with duct dependent pulmonary circulation left hospitals undetected. Of babies that died from CHD, studies have shown that up to 30% of infant deaths from CHD occurred before diagnosis.^{1,9,13,16,17}

Pulse oximetry was thought to hold promise in helping to screen for CCHD. Early pulse oximeters were not designed to read through motion and low perfusion, which are frequently present in the hours following birth. Frequent, alarming, dropping out of the signal, and freezing of the waveform were frustrating at best. Repositioning of the sensor, quieting the baby, waiting for the signal to transduce were very time-consuming.^{12,14} These devices were not designed to be used for neonates. The potential cost of using individual disposable sensors for each screen was thought not to be cost-effective.¹⁸ Although the technology to read through motion and low perfusion had been developed and validated in CCHD by the early 1990's, these devices were not readily available.¹²

The depth of the problems was described by Chang who looked at a series of missed diagnosis of Critical Congenital Heart Disease. In this study, close to 900 patients from the California 1989-2004 statewide registries were investigated. There were an average of 10 patients with missed CCHD diagnosis, and 20 patients with late diagnosis per year. The overall incidence of missed CCHD diagnosis was 1.7 per 100,000 live births. "Although many screening strategies have been studied, none have proved effective in detecting newborn CCHD."⁹

The sentinel study was performed by Granelli and her associates using a Swedish cohort in a very large collaborative multicenter study (n=39,821). Using a newer pulse oximetry technology capable of reading through motion and low perfusion, Granelli suggested that pulse oximetry could be cost-neutral in the short-term, but with the probable prevention of long-term neurological morbidity. The reduction in pre-operative care costs of a child presenting at extremis cost analysis could favor pulse oximetry screening. Adding pulse oximetry screening (Masimo SET) before discharge increased detection of CCHD by 28% (from 72% to 92%). No babies died from undiagnosed duct-dependent lesion in the pulse oximetry group. Five babies in the control group died during the same period of time. There was an improved rate of detection

N= 39,821 babies	Physical Exam Alone	Physical Exam + Pulse Oximetry Screening
Sensitivity	63%	83%
Specificity	98%	99.8%

of duct dependent circulation of 92% as shown in Table 1.¹⁷

Ewer (2011) performed a large accuracy study (n=20,000) in the UK studying the use of pulse oximetry in the detection of babies with CCHD. He found that pulse oximeters produce saturations that are not only accurate, but stable in active individuals with low perfusion making these instruments ideal for screening newborns in the first hours of life. The Ewer study used a saturation cutoff of less than 95% in either limb to indicate the presence of a positive screen test or a difference of more than 2% between the limb saturations versus the 3% difference used by the expert panel. The median age at testing in the Ewer study was 12.4 hours, while the expert panel and/or Granelli suggested greater than 24 hours or before discharge. In Europe, an earlier discharge is the norm.^{1,17,19}

Roberts studied the issue of cost-effectiveness in the UK. Their objective was to conduct a cost-effectiveness analysis comparing pulse oximetry as an adjunct to clinical examination or examination alone in newborn screening for congenital heart defects (CHD). In a study that involved six large maternity units in the UK, the study showed that pulse oximetry as an adjunct to current routine practice of clinical examination alone is likely to be considered a cost-effective strategy in the light of currently accepted thresholds for medical needs justification. The clinical examination alone strategy detects 91.5 additional cases of clinical significant CHD per 100,000 birth at an estimated cost of £614,100 (app. \$964,700) for the strategy. Using the intervention Strategy of Pulse Oximetry as an adjunct to Clinical Examination would detect 121.4 cases of CHD per 100,000 live births at a cost of £1,358,800 (app. \$2,133,900). An additional cost of £744,700 (app. \$1,169,900) would be required to detect approx. 30 additional cases of a timely diagnosis per 100,000 live births. The incremental cost-effectiveness ratio (ICER) which represents the additional cost per additional case of timely diagnosed case of CHD per 100,000 live births is approximately

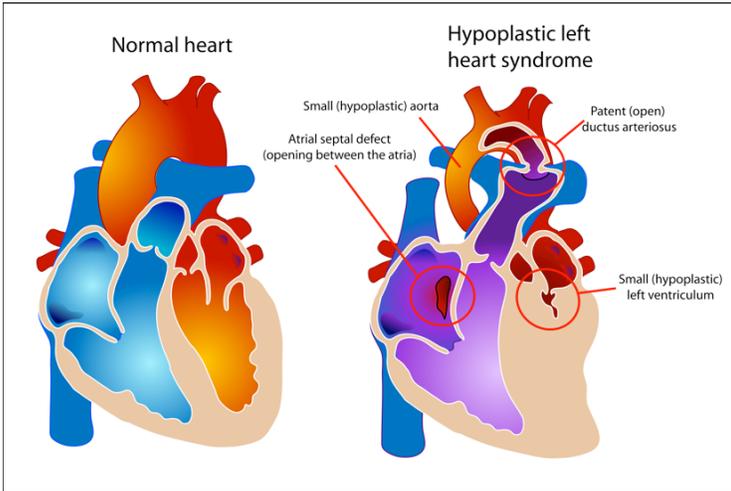
£24,900 (app. \$39,100). The cost-effectiveness acceptability curve presents the probability that a screening strategy is cost-effective with society's willingness to pay (WTP) for a timely diagnosis of a clinically significant CHD. The WTP threshold used by the National Institute for Health and Clinical Excellence (NICE) in the UK is £20,000 per quality-adjusted life year (QALY). QALY has been described as the only acceptable threshold used by decision making institutions or payer. Up to this threshold, a society is willing to pay £20,000 per QALY per annum of life in good health. For society to pay £100,000, a newborn with timely diagnosis of a CHD, and thereby good health, would need to gain five QALYs. If the majority of these children reach early adulthood in good health, at £100,000 WTP threshold proposed, the probability that 'pulse oximetry as an adjunct to clinical examination' would be cost-effective is greater than 90%.¹⁸

Kemper proposed a series of national standards based on the recommendation of a panel of pediatric and cardiac experts from the American Academy of Pediatrics (AAP), American College of Cardiology (ACC), and American Heart Association (AHA). They also defined CCHD as including, but not limited to: Hypoplastic Left Heart Syndrome, Pulmonary Atresia (PA), Tetralogy of Fallot (TOF), Total Anomalous Pulmonary Venous Return (TAPVR), Transposition of the Great Arteries (TGA), Tricuspid Atresia (TA), and Truncus Arteriosus. According to the algorithm, newborns are eligible for screening at 24-48 hours of age, or shortly before discharge if under 24 hours of age. If the screen identifies saturation less than 90% in the right hand or foot, the newborn has had a "positive" screen, and is referred for additional testing. A 90% to less than 95% screen in the right hand or foot or a greater than 3% difference between the right hand and foot is considered an equivocal screen and requires re-screening in an hour. Saturations greater than or equal to 95% in the right hand or foot of or saturation difference of 3% or less between the right hand and foot defines a negative screen. For equivocal

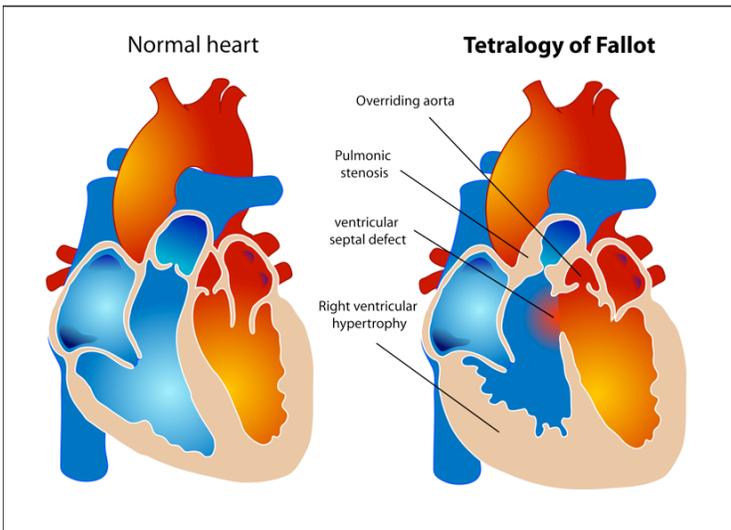
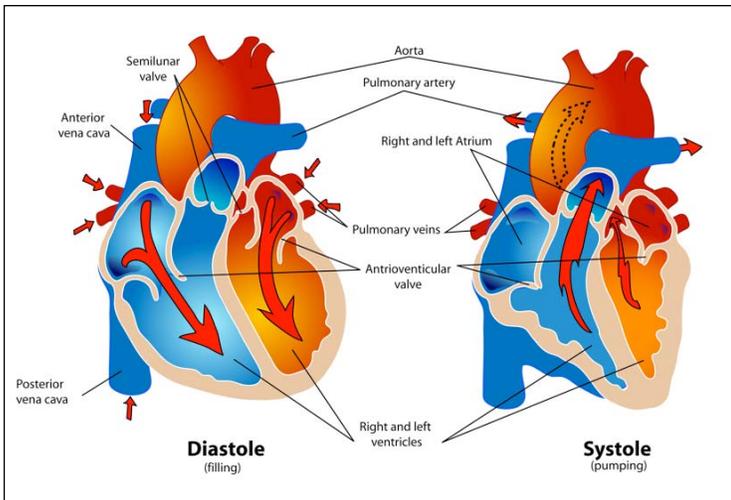
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screens, the three-prong decision tree is repeated for a second iteration in one hour as shown in the diagram. For equivocal screens, re-screening occurs again after an hour. If the screen is equivocal a third time, it is considered a positive screen. It is essential that those newborns who have what is considered a positive screen have a

complete work-up for congenital heart disease prior to discharge home. Although ready access to a pediatric cardiologist may not be available, it is mandatory to at least document a negative echocardiogram prior to discharge given the high sensitivity and specificity of the screen. Other recommendations were made as well. Chief among these were the use of disposable or reusable probes and probes with close coupling to skin (i.e., taped rather than clamped), which can improve oximetry monitoring in newborns. Because of minor differences in the calibration of the LED signals, third party sensors should not be used. Although this seems trivial on the surface, hospital buying practices can often times focus on the lowest cost, as opposed to quality of the signal. The work group noted that performing a typical physical examination alone for CCHD led to almost 10 times more false-positive results compared with using similar screening protocols in Sweden and the United Kingdom. Further, the group suggested a 5-point implementation strategy and follow-up procedures including screening, diagnostic confirmation, electronic results reporting, primary care follow-up, as well as surveillance and tracking.^{1,3,5,7,8,17,19,20}

An earlier Granelli study published in 2007 looked at 10,000 normal Swedish infants along with 9 confirmed with CCHD. Another parameter, the perfusion index (PI), was described. The PI is the infrared component of the pulse oximetry signal. In neonates, they established reference values for PI using the right hand and foot in normal infants between 1 and 120 hours of age. Values lower than 0.70 may indicate illness. PI may indicate abnormal blood flow from the heart in babies with CCHD. In all of the babies with a confirmed left heart obstructive disease CCHD, newborns had either pre or post ductal PI values below the interquartile cut-off value of 1.18 and five of the nine had a value below the recommended cut off of 0.70. PI is not included in the Kemper recommendation, but it is reported in all stand-alone pulse oximeters that have been validated by the FDA to read through motion and low perfusion and may be beneficial to consider in evaluation for CCHD.²¹ In 2010, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children recommended adding Critical Congenital Heart Disease to the Recommended Uniform Screening Panel. In 2011, Health and Human Services Secretary Kathleen Sebelius agreed with the Committee and recommended that Health and Human Services agencies "proceed expeditiously" with the implementation of newborn screening for critical congenital heart disease. In a letter dated September 21, 2011, she outlined the decision to adopt expert panel recommendations for universal CCHD screening by pulse oximetry for all newborns into federal Recommended Uniform Screening Panel (RUSP) Guidelines—the national newborn screening system standards and policies.²²

State Laws have been passed to incorporate the federal mandate. Although HHS has defined the expectation that newborn CCHD screening be incorporated into state newborn screening as soon as possible, the implementation process has been left to each individual state, along the lines of the original newborn screening.^{2,22}

New Jersey passed legislation requiring each birthing facility licensed by its Department of Health and Senior Services to perform a pulse oximetry screening for CHDs on every newborn in the state that is at least 24 hours old (P.L. 2011, Chapter 74, Assembly No. 3744). The act went into effect August 31st, 2011. New Jersey was the first state in the nation to enact legislation.²³

Maryland passed legislation (Chapter 553, HB 714), in May 2011. This required the state Department of Health and Mental Hygiene to adopt the federal screening recommendations if the HHS secretary issues recommendations on critical heart disease screening of newborn.²⁴

Indiana passed legislation (SB 552) requiring pulse oximetry screening of newborns for low oxygen levels beginning January 1st, 2012. This requires the Indiana State Department of Health (ISDH) to: (1) develop procedures and protocols for the testing and (2) report to the Indiana legislative council, by October 31st, 2011, certain information on the screening (SB 552).²⁵



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New York passed Assembly Bill 7941 of the 2011 New York Legislature. The bill requires the commissioner of the state health department to establish a newborn screening program using pulse oximetry screening to detect CHDs. Since May 22nd, 2012, the bill has been held for consideration in the health committee.²⁶

Pennsylvania introduced legislation which was introduced in the Pennsylvania General Assembly on July 25th, 2011. The bill amended the state's Newborn Child Testing Act by adding a requirement that each health care provider that provides birthing and newborn care services perform a pulse oximetry screening a minimum of 24 hours after the birth of every newborn in its care (SB 1202).²⁷

New Hampshire introduced Senate Bill 348-FN. Section 132:10-aa Newborn Screening; Pulse Oximetry Test Required. The physician, hospital, nurse midwife, midwife, or other health care provider attending a newborn child shall perform a pulse oximetry screening, according to the recommendations of the American Academy of Pediatrics, on every newborn child. This act was to take effect 60 days after its passage.²⁸

Missouri introduced House Bill No. 1058 – Newborn Screening. This bill establishes Chloe's Law which requires, subject to appropriations, the Department of Health and Senior Services to expand by January 1st, 2013, the newborn screening requirements to include a pulse oximetry screening prior to the newborn being discharged from a health care facility.²⁹

Georgia introduced House Bill No. 745. The Department of Public Health was to undertake a study to determine whether pulse oximetry screening should be implemented as a standard test for newborn infants in this state to aid in detecting congenital heart defects. The code section shall stand repealed on January 31st, 2013.³⁰

Florida introduced House Bill No. 829. By October 1st, 2012, congenital heart disease screening must be conducted on all newborns in hospitals in this state on birth admission. When a newborn is delivered in a facility other than a hospital, the parents must be instructed on the importance of having the screening performed and must be given information to assist them in having the screening performed within 10 days after the child's birth.³¹

Virginia introduced House Bill No. 399. Congenital cyanotic heart disease, critical; Virginia Department of Health to implement program for screening infants. The bill was to require the Department of Health to convene a work group to develop a plan for implementation of a program for screening infants for critical congenital cyanotic heart disease. The bill passed both state house and senate assembly but was vetoed on 4/09/12 by the Governor because Virginia had already implemented a work group.³²

West Virginia introduced House Bill No. 4327. A Bill to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-44-1 and §16-44-2, all relating to requiring pulse oximetry testing for newborns. The purpose of this bill was to require each birthing facility licensed by the Department of Health and Human Resources to perform a pulse oximetry screening for congenital birth defects on every newborn in its care, a minimum of 24 hours after birth.³³

Tennessee proposed legislation requiring the state's genetic advisory committee to develop a program to screen newborns for critical CHD

“Pulse oximetry is a noninvasive, simple test that measures the functional percentage of hemoglobin in blood that is saturated with oxygen. When performed on a newborn after birth, pulse oximetry screening is often more effective at detecting critical, life-threatening congenital heart defects than other screening methods.”

using pulse oximetry. House Bill 373 and Senate Bill 65 were signed into law by the governor in April, 2012.³⁴

Connecticut passed an Act Concerning Pulse Oximetry Screening for Newborn Infants, revising Section 1. Subsection (b) of section 19a-55 of the 2012 supplement to the general statutes (repealed) and the following was substituted in lieu thereof (effective October 1st, 2012). This act established testing requirements, and directed the administrative officer or other person in charge of each institution caring for newborn infants shall have cause to administer to every such infant in its care a screening test for cystic fibrosis, a pulse oximetry screening test and a screening test for severe combined immunodeficiency disease. Such screening tests shall be administered as soon after birth as is medically appropriate.³⁵

Minnesota introduced H.F. No. 3008, in the - 87th Legislative Session (2011-2012) Posted on Apr 20, 2012. This section was to be effective the day following final enactment. Screening shall take effect 180 days following final enactment or by December 31st, 2012, whichever was sooner. This screening must be done no sooner than 24 hours after birth, unless earlier. According to the provisions, screening is deemed clinically appropriate, but always prior to discharge from the nursery. If discharge or transport of the newborn occurs prior to 24 hours after birth, screening must occur as close as possible to the time of discharge or transport. For premature infants who are less than 36 weeks of gestation and newborns admitted to a higher level nursery, such as special care or intensive care, screening must be performed when medically appropriate prior to discharge. Any newborn that fails the screening must be referred to a licensed physician who shall arrange follow-up diagnostic testing and medically appropriate treatment prior to discharge from the hospital.³⁶

California identified a clear need for congenital heart screening prior to HHS involvement. Many hospitals were screening using Kemper's or related study as paradigm for screening prior to 2012.¹ AB 1731 was introduced by Marty Block and amended Sections 124977 and 125001 of the Health and Safety Code, relating to public health. This modified the newborn screen to include CCHD screening. AB 1731 required the California Department of Public Health to expand statewide screening of newborns to include pulse oximetry screening for critical congenital heart disease in addition to metabolic and hearing screens. “The department shall expand statewide screening of newborns as soon as



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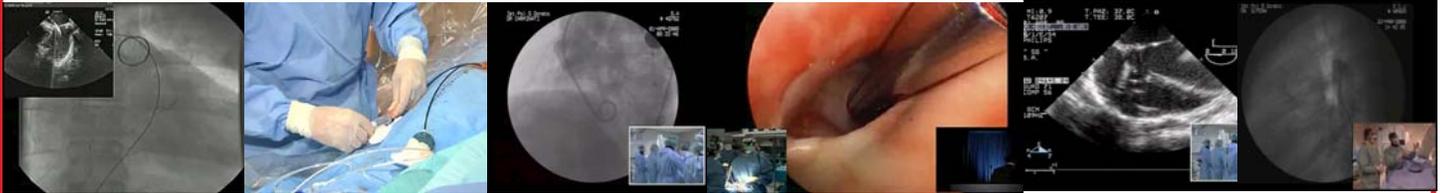
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www.chimsupport.com

HOW WE OPERATE

The team involved at C.H.I.M.S. is largely a volunteering group of physicians nurses and technicians who are involved in caring for children with congenital heart disease.

The concept is straightforward. We are asking all interested catheter laboratories to register and donate surplus inventory which we will ship to help support CHD mission trips to developing countries.

Watch over 300 Live Case Videos, Presentations and Workshops Online from Leading Congenital and Structural Medical Meetings from Around the World - www.CHDLiveCases.com



- Transseptal Access Workshop from Cook Medical
- Workshop: Past Present and Future of Pediatric Interventions Cardiology - St. Jude & AGA Mmedical
- Symposium on Prevention of Stroke Clinical Trials at the Heart of the Matter - WL Gore Medical
- Imaging in Congenital & Structural Cardiovascular Interventional Therapies
- Morphology of The Atrial Septum
- Morphology of The Ventricular Septum
- Pre-Selection of Patients of Pulmonic Valve Implantation and Post-Procedural Follow-up
- Echo Paravalvular Leakage (PVL)
- ICE vs TEE ASD Closure in Children - PRO & CON ICE
- 3D Rotational Angiography - Why Every Cath Lab Should Have This Modality
- PICS Doorway to the Past - Gateway to the Future
- Follow-up From PICS Live Cases 2010 Presentation
- Intended Intervention - Transcatheter TV Implantation - *Live Case*
- Intended Intervention - LAA Closure Using Amplatzer Cardiac Plug Under GA & Real Time 3D
- Provided Intervention - LPA Stenting / Implantation of a Sapien Valve
- Intended Intervention - PV Implantation
- Intended Intervention - COA Stent Using Atrium Advanta V12 Covered Stent - *Live Case*
- Intended Intervention - ASD Closure - *Live Case*
- Intended Intervention - Transcatheter VSD Device Closure - *Live Case*
- Intended Intervention - COA Stenting Using Premounted Advanta V12 Covered Sten - *Live Case*
- Stunning Revelation - The Medical System is Changing - What Can You Do To Show Patients That Your Practice Does It Right? Patient Perspective
- Percutaneous Paravalvular Leak Closure Outcomes
- Intensive Management of Critically Ill Infants Undergoing Catheterization
- Off Label Device Usage - Careful!
- Evolving Hybrid Programs Communications is the Key
- Anti-Coagulation in Pediatric Interventions - Evidence Please! Are we Flying Blind?
- Shaping Your Structural Heart Interventional Career: How Do I Get the Necessary Training and Start a Program?
- Closure of Post-Infarct VSDs Limitations & Solutions
- Percutaneous Interventions During Pregnancy
- Percutaneous PVL Closure Techniques & Outcomes
- Percutaneous Therapy for MR
- Update on Percutaneous Aortic Valve Replacement: Time to Open the Flood Gates?
- 2011 PICS/AICS Achievement Award Presented To Horst Sievert, MD.
- The Cases I Learn The Most From
- If I was Starting Now I Would... Contemplating the Question.
- 10 Tips for the Trainee
- The Perfect CV
- Why I Left The Cath Lab
- Intended Intervention Occlude Right High Flow Superior Segment PAVM
- Intended Intervention Edwards Sapien XT Transcatheter Heart Valve - 3D Guidance - *Live Case*
- Closure of the Silent PDA - Indicated or Not
- Transcatheter Tricuspid Valve Replacement
- Recommendations For Device Closure of MVSDs
- Intended Intervention Diagnostic Angio/First Intervention Occlude Left Lower Lobe - *Live Case*
- Intended Intervention PFO Closure using Gore Helix Septal Occluder Under GA and TEE Guidance - *Live Case*
- Pulmonary Valvuloplasty - Pulmonary Oedema Presentation
- Intended Intervention LAA Closure Using the Amplatzer Cardiac Plug - *Live Case*
- Transcatheter Alternatives in Sick Neonates With Coartation of the Aorta; Balloon Angioplasty vs Surgery for Native Coartation of the Aorta in Newborns
- **and many more.... Plus, live cases from other major meetings**

Presented by **CONGENITAL CARDIOLOGY TODAY**



Master Class on Congenital Cardiac Morphology Provides Comprehensive Review of Shunt Lesions and Treatments

By Vivek Allada, MD

The fifth annual *Master Class in Congenital Cardiac Morphology* provided a diverse group of attendees with a unique perspective and rich understanding of Congenital Heart Disease. Hosted by the Heart Institute at Children's Hospital of Pittsburgh of UPMC at its John G. Rangos Sr. Conference Center in Pittsburgh, Pa., the fall symposium offered three days of intensive, interactive learning for medical professionals and trainees from across the U.S. and around the world.

The program used didactic presentations, live video demonstrations, and hands-on examination of cardiac specimens to cover a range of congenital cardiac malformations. There was an emphasis on imaging and surgical correlations for each lesion, giving participants an understanding of the usefulness and practicality of the sequential segmental analytical approach to the examination of congenitally malformed hearts.

The 2012 event focused on left-to-right shunts, while helping to familiarize participants with the morphology of a full spectrum of congenital heart lesions.

Attendance at the 2012 program typified the diverse turnout of past events. Participants comprised representatives from North and South America, the Caribbean and Europe, and included cardiologists, pathology residents, cardiothoracic surgeons, cardiac intensive care specialists, cardiac interventionists, nurses and nurse practitioners, and device makers.



Bill Devine, BS explains anatomic features of a pediatric heart specimen.

While the program is always particularly beneficial for trainees and those learning cardiac anatomy, the 2012 program marked the first year a significant number of adult cardiologists took part in the program. Many of our children are now successful survivors of Congenital Heart Disease and grow up to be adults, so the adult cardiologists are quite interested in learning about congenital morphology.

The annual program is sponsored jointly by Children's Hospital's Heart Institute and Division of Pediatric Pathology and the University of Pittsburgh School of Medicine's Center for Continuing Education in the Health Sciences. In keeping with tradition, the premier highlight of the 2012 program were lectures by one of the worlds' leading experts in cardiac morphology, Professor Robert H. Anderson, MD, FRCPath, Professorial Fellow at Newcastle University's Institute of Genetic Medicine and visiting Professor of Pediatrics, Medical University of South Carolina (MUSC).

Professor Anderson's didactic lecture on heart anatomy included a thorough review of normal heart anatomy to illustrate how to use sequential segmental analysis. His engaging review included basics, such as understanding how to properly describe and characterize a heart according to its attitudinally correct orientation, as well as a discussion of the morphological method, an explanation of how to distinguish the highly nuanced segmental features of the heart, and examination of the conduction tissues that are so vital for surgeons to understand.

Each of Professor Anderson's presentations of pathologic heart samples was complemented by correlations with multi-modality imaging. Imaging specialists Lizabeth Lanford, MD; Mark DeBrunner, MD; and Vivek Allada, MD, all of the Heart Institute at Children's Hospital, and MUSC's Anthony Hlavacek, MD, FAAP,

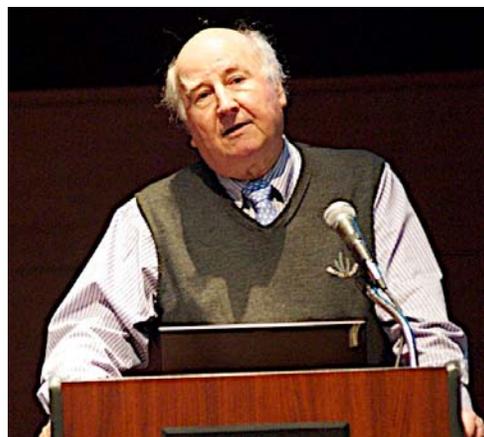


Victor Morell, MD discusses success rates of AVSD surgical procedures.

reviewed the same structures in motion and toured the heart structures using CT angiography and 3-D echocardiography.

Presenters, including Professor Anderson, built on this grounding in the structure and orientation of the heart, with additional didactic presentations and video demonstrations of interatrial communications, ventricular septal defects (VSDs), atrioventricular septal defects (AVSDs) and unbalanced AVSDs and other complex associations.

William Devine, BS, of the Department of Pediatric Pathology at Children's Hospital of Pittsburgh of UPMC and Diane Debich-Spicer, BS, PA (ASCP), curator of the Lodewyk Van Mierop Archive at the University of Florida, Gainesville, presented dozens of heart



Professor Robert Anderson, MD, FRCPath, lectures at the fifth annual Master Class in Congenital Cardiac Morphology at Children's Hospital of Pittsburgh of UPMC.



Steven A. Webber, MBChB, MRCP, Chair, Department of Pediatrics, Monroe Carell Jr. Children's Hospital at Vanderbilt, helped direct the Master Class.



In a hands-on session at the Master Class, Diane Debich-Spicer, BS (on right) points out a VSD on a pediatric heart specimen.

samples via video projection, showing each type of defect and nuanced variants. On the third day of the program, attendees were invited to examine the various specimens during an intensive hands-on workshop.

In all, more than a dozen presenters shared their considerable expertise. Leading members of the Heart Institute at Children's Hospital participated, including myself, interventionalist Jacqueline Kreutzer, MD, FACC, FSCAI, cardiothoracic surgeons Victor Morell, MD, and Peter Wearden, MD, PhD, who added important clinical perspective on management and treatment of each lesion. Helping lead the program was former chief of Children's Heart Institute, Steven A. Webber, MBChB, MRCP, who now serves as chair of the Department of Pediatrics at the Monroe Carell Jr. Children's Hospital at Vanderbilt, and who with his colleagues at Children's Hospital of Pittsburgh of UPMC founded the *Pittsburgh Master Class* series.

This *Master Class* provided an incredible opportunity for attendees to bridge pathology, imaging, and clinical management.

Dr. Kreutzer's presentation, "How Morphology Predicts Suitability for Device Closure," reviewed criteria related to secundum atrial septal defects, such as size, number of defects and characteristics of surrounding tissue to determine which type of closure device to use.

Drs. Wearden and Trucco provided the surgeon's and cardiologist's perspectives, respectively, on working with the interventionalist to determine the best approach for treating VSDs. "Like everything we do in cardiology, it's a team approach and a team outcome," Wearden emphasized to attendees before discussing rationale supporting both surgical approaches and the

use of closure devices. Complementing Dr. Wearden's presentation, Dr. Trucco reviewed studies documenting success rates, as well as complications from using closure devices in pediatric cases.

Following the presentations on VSDs, Professor Anderson provided a didactic lecture on AVSDs, followed by a review of pediatric heart specimens by Debich-Spicer and spectacular video presentations by Dr. Hlavacek using 2-D and 3-D echocardiography to show AVSDs. Dr. Morell then reviewed surgical techniques for repair of AVSDs, including the single-patch technique, the two-patch technique, and a modified single-patch technique known as the Australian method.

Additional sessions followed on unbalanced AVSD's and other complex associations, patent arterial ducts and the aortopulmonary window, including didactic presentations and video demonstrations followed by echocardiography, magnetic resonance and CT imaging and hands-on sessions.

Program participants were also invited to a Pediatric Grand Rounds presentation which preceded the second day of the program and also covered a cardiology topic. The lecture by Ferhaan Ahmad, MD, PhD, from the University of Pittsburgh School of Medicine's Division of Cardiology, addressed the "Mechanistic Insights and Clinical Implications from Genetic Studies of Hypotrophic Cardiomyopathies."

What sets the *Master Class* apart from other educational programs is its multimodal approach and the degree to which it exposes participants to pathological specimens and compares them to how hearts appear using modern imaging equipment.

2013 Master Class to Focus on Embryology

Plans are already underway for the *Sixth Annual Master Class in Congenital Cardiac Morphology* sponsored by the Heart Institute and Division of Pediatric Pathology at Children's Hospital of Pittsburgh of UPMC and the University of Pittsburgh School of Medicine's Center for Continuing Education in the Health Sciences.

The 2013 class will highlight anomalies of the arterial and atrioventricular valves, and coronary arteries, and will again provide a multimodality view of all aspects of the developing heart using the latest imaging technologies and hands-on demonstrations. Continuing education credits will be provided. Based on feedback from attendees, the 2013 conference will incorporate discussions about developmental embryology of each lesion. The conference is scheduled for Oct. 2 to 4, at the John G. Rangos Sr. Conference Center, located on the campus of Children's Hospital of Pittsburgh of UPMC in Pittsburgh, PA.

Complete program details will be available this summer. For more information in the meantime, contact Lynda Cocco, 412-692-3216, at the Heart Institute at Children's Hospital of Pittsburgh of UPMC, or visit www.chp.edu/masterclass.

Professor Anderson, who is known for a generation of exhaustive work in the study of heart specimens, commented on the quality of modern imaging technologies to session attendees. "What is fascinating to me, and also very rewarding, is that the morphologic concepts that we've been putting forward now for more than 30 years are now matching entirely what you see when you're treating and imaging the patients yourselves," he said. "To me, what is fortunate is that now you can see all the anatomy just as well with echocardiography, with computer tomography, and magnetic resonance imaging."

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Medical News, Products and Information

Southwest Healthcare System Selects Digisonics CVIS

California-based Southwest Healthcare System recently selected Digisonics as the Cardiovascular Information System (CVIS) Solution for Inland Valley Medical Center in Wildomar, Calif. and Rancho Springs Medical Center in Murrieta, Calif.

The Digisonics CVIS will enable clinicians at the facility to quickly create structured reports for their adult and pediatric echo studies. Users will also have fully functional remote reading capabilities through the secure web-based DigiNet Pro application for anywhere, anytime access to the complete CVIS. Southwest Healthcare will also implement the Digisonics Search Package, a comprehensive, user-configurable search engine. This powerful tool allows the facility to quickly set up search criteria to extract clinical information for use in research, compile statistics required for accreditation and generate management reports to target areas for productivity and efficiency.

HL7 interfaces for Orders In and Results Out will create a fully electronic workflow between Digisonics and the hospital's Cerner Millennium System. DICOM Modality Worklist and DataLink modules will automate transfer of patient biometry to and from the Medical Center's Philips ultrasound machines with the Digisonics CVIS, significantly reducing manual data entry time. Digisonics DigiServ, a multi-site server, will provide storage and communication management for the enterprise-wide system. As a result, Southwest Healthcare will benefit from a seamless cardiology workflow with improved efficiency, accuracy and turnaround times.

The DigiView Cardiology PACS and Structured Reporting System, ranked Best in KLAS in the 2008, 2009, 2010, 2011 and 2012 *Top 20 Best in KLAS Awards: Software & Professional Services* reports for the Cardiology market segment, combines high performance image review workstations, a powerful PACS image archive, an integrated clinical database, comprehensive measurements and calculations package, and highly configurable reporting for cardiovascular modalities. The DigiNet Pro add-on option provides users with fully functional web-based access to their cardiovascular studies from anywhere at any time. For further information, please contact: James Devlin at Digisonics, Inc. jdevlin@digison.net or visit www.digisonics.com.

BPA Linked to Potential Adverse Effects on Heart and Kidneys in Children and Adolescents

Newswise — Exposure to a chemical once used widely in plastic bottles and still found in aluminum cans appears to be associated with a biomarker for higher risk of heart and kidney disease in children and adolescents, according to an analysis of national survey data by NYU School of Medicine researchers published in the January 9, 2013, online issue of *Kidney International*, a Nature publication.

Laboratory studies suggest that even low levels of bisphenol A (BPA) like the ones identified in this national survey of children and adolescents increase oxidative stress and inflammation that promotes protein leakage into the urine, which is a biomarker for early renal impairment and future risk of developing coronary heart disease, according to

Leonardo Trasande, MD, MPP, Associate Professor of Pediatrics, Environmental Medicine, and Population Health, and co-lead author of the study.

The study adds to the growing concerns about BPA, which was recently banned by the U.S. Food and Drug Administration but is still used as an internal coating for aluminum cans. Manufacturers say the chemical provides an antiseptic function, but studies have shown the chemical disrupts multiple mechanisms of human metabolism.

"While our cross-sectional study cannot definitively confirm that BPA contributes to heart disease or kidney dysfunction in children, together with our previous study of BPA and obesity, this new data adds to already existing concerns about BPA as a contributor to cardiovascular risk in children and adolescents," says Dr. Trasande. "It further supports the call to limit exposure of BPA in this country, especially in children," he says. "Removing it from aluminum cans is probably one of the best ways we can limit exposure. There are alternatives that manufacturers can use to line aluminum cans."

Children in the United States are exposed to the chemical early in life and surveys have shown that by age six nearly 92% of children have some trace of BPA in their urine. Its use has been banned in the European Union and Canada, and in the United States for use in baby bottles and sippy cups. Last September Dr. Trasande's group published a study showing a significant association between obesity and children and adolescents with higher concentrations of BPA in their urine in the *Journal of the American Medical Association*.

In the new study Dr. Trasande, Teresa Attina, MD, PhD, MPH, and Howard Trachtman, MD, of NYU School of Medicine's Department of Pediatrics, analyzed data on 710 children and adolescents aged 6 to 19 collected in a national survey to assess the health and nutritional status of adults and children in the United States. The data was from the 2009-2010 National Health and Nutrition Examination Survey (NHANES), which contained measurements on urinary BPA, and a protein called albumin, which is not normally found in urine because the spaces in the glomerular membrane of the kidney are too small to allow protein molecules to escape. If there is membrane damage as in some kidney diseases like glomerulonephritis, albumin can leak through into the urine.

The researchers controlled for risk factors such as hypertension, insulin resistance, elevated cholesterol, exposure to tobacco smoke, race/ethnicity, caregiver education, poverty to income ratio, age, weight and gender in these children. Children with the highest amount of BPA in their urine, compared to those with the lowest amount, had a higher albumin to creatinine ratio, a potential early marker of renal impairment and future risk of developing coronary heart disease, according to the study.

"While we excluded children with pre-existing kidney disease from our analysis, I am concerned that BPA exposure may have even greater effects on children with kidney disease," says Dr. Trachtman, co-lead author of the study. "Because their kidneys are already working harder to compensate and have limited functional reserve, they may be more susceptible to the adverse effects of environmental toxins. We clearly need further study of BPA exposure and its effects on the kidney both

MEDICAL CONFERENCES 2013

TRENDS 2013 Catheter-based Neurohumoral Remodeling Frankfurt, Germany	LAA ASIA-PACIFIC 2013 Left Atrial Appendage Closure Hong Kong, China	iCi 2013 Imaging in Cardiovascular Interventions Frankfurt, Germany	CSI 2013 Congenital, Structural & Valvular Interventions Frankfurt, Germany	TRENDS ASIA-PACIFIC 2013 Catheter-based Neurohumoral Remodeling Hong Kong, China	LAA 2013 Left Atrial Appendage Closure Frankfurt, Germany
MARCH 1-2 www.csi-trends.org	MAY 4 www.csi-laa.org	JUNE 26 www.ici-congress.org	JUNE 27-29 www.csi-congress.org	SEPTEMBER 21 www.csi-trends.org	NOVEMBER 22-23 www.csi-laa.org

in healthy children and in children who have pre-existing kidney disease.”

The researchers concluded their analysis by emphasizing the need for further research on environmental chemicals and cardiovascular disease, noting that further study may well transform our understanding “from one that focuses on dietary risks to an approach that recognizes the role of environmental chemical factors that may independently impart the risk of ... future cardiovascular disease.”

Authors: Leonardo Trasande, MD, MPP, Associate Professor, Departments of Pediatrics, Environmental Medicine and Population Health, NYU School of Medicine, Associate Professor of Health Policy, NYU Wagner School of Public Service and associate professor of public health, NYU Steinhardt School of Culture, Education and Human Development; Teresa Attina, MD, PhD, Departments of Pediatrics, and Medicine; and Howard Trachtman, MD, Professor of Clinical Pediatrics, Department of Pediatrics.

Funding: Funding was provided by KiDS of NYU.

Most Physicians Don't Meet Quality Reporting Requirements

Newswise — Washington, DC – A new Harvey L. Neiman Health Policy Institute study shows that fewer than one-in-five healthcare providers meet Medicare Physician Quality Reporting System (PQRS) requirements. Those that meet PQRS thresholds now receive a 0.5% Medicare bonus payment. In 2015, bonuses will be replaced by penalties for providers who do not meet PQRS requirements. As it stands, more than 80% of providers nationwide would face these penalties.

Researchers analyzed 2007-2010 PQRS program data and found that nearly 24% of eligible radiologists qualified for PQRS incentives in 2010 — compared to 16% for other providers. The Neiman Institute study is published online in the *Journal of the American College of Radiology*.

“Near term improvements in documentation and reporting are necessary to avert widespread physician penalties. As it stands, in 2016, radiologists collectively may face penalties totaling more than \$100 million. Although not a specific part of this analysis, penalties for nonradiologists could total well over \$1 billion,” said Richard Duszak, MD, Chief Executive Officer and Senior Research Fellow of the Harvey L. Neiman Health Policy Institute. “Compliance with PQRS requirements has improved each year, but more physicians need to act now: their performance in 2013 will dictate penalties for 2015.”

To read the study, visit: <http://bit.ly/UmqQ3o>

Standard Written Checklists Can Improve Patient Safety During Surgical Crises

Newswise — When doctors, nurses and other hospital operating room staff follow a written safety checklist to respond when a patient experiences cardiac arrest, severe allergic reaction, bleeding followed by an irregular heart beat or other crisis during surgery, they are nearly 75% less likely to miss a critical clinical step, according to a new study funded by the US Department of Health and Human Services' Agency for Healthcare Research and Quality.

While the use of checklists is rapidly becoming a standard of surgical care, the impact of using them during a surgical crisis has been largely untested, according to the study published in the January 17th online and print issue of the *New England Journal of Medicine*.

“We know that checklists work to improve safety during routine surgery,” said AHRQ Director Carolyn M. Clancy, MD. “Now, we have compelling evidence that checklists also can help surgical teams perform better during surgical emergencies.”

Surgical crises are high-risk events that can be life threatening if clinical teams do not respond appropriately. Failure to rescue surgical patients who experience life-threatening complications has been recognized as the biggest source of variability in surgical death rates among hospitals, the study authors noted.

For this randomized controlled trial, investigators simulated multiple operating room crises and assessed the ability of 17 operating room teams from three Boston area hospitals – one teaching hospital and two community hospitals – to adhere to life-saving steps for each simulated crisis.

In half of the crisis scenarios, operating room teams were provided with evidence-based, written checklists. In the other half of crisis scenarios, the teams worked from memory alone. When a checklist was used during a surgical crisis, teams were able to reduce the chances of missing a life-saving step, such as calling for help within 1 minute of a patient experiencing abnormal heart rhythm, by nearly 75%, the researchers said.

Examples of simulated surgical emergencies used in the study were air embolism (gas bubbles in the bloodstream), severe allergic reaction, irregular heart rhythms associated with bleeding, or an unexplained drop in blood pressure.

Each surgical team consisted of anesthesia staff, operating room nurses, surgical technologists and a mock surgeon or practicing surgeon.

“For decades, we in surgery have believed that surgical crisis situations are too complex for

simple checklists to be helpful. This work shows that assumption is wrong,” said Atul Gawande, MD senior author of the paper, a surgeon at Brigham and Women's Hospital and Professor at the Harvard School of Public Health. “Four years ago, we showed that completing a routine checklist before surgery can substantially reduce the likelihood of a major complication. This new work shows that use of a set of carefully crafted checklists during an operating room crisis also has the potential to markedly improve care and safety.”

Hospital staff who participated in the study said the checklists were easy to use, helped them feel more prepared, and that they would use the checklists during actual surgical emergencies. In addition, 97% of participants said they would want checklists to be used for them if a crisis occurred during their own surgery.

The practice of using checklists is borrowed from high-risk industries such as aviation and nuclear power, where checklists have been tested in simulated settings and shown to improve performance during unpredictable crisis events.

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