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Automated Emergency Defibrillator Programs in Schools – Outcome of Individual Initiatives and Legislative Mandates in Orange County, California

By Nivedita Mohari, MD; Pamela Kahn, RN, MPH; Anjan S. Batra, MD

Introduction

The risk of Sudden Cardiac Arrest (SCA) is estimated to affect one in 200,000 high school athletes per year. Careful screening at the pre-participation sports physical and, if necessary, further diagnostic testing can identify athletes at risk. However, no single test will guarantee that sudden cardiac arrest will not occur. When a young athlete collapses without warning, prior preparation is essential to deal with it. The most important factor in determining survival following sudden cardiac arrest (SCA) is time from collapse to defibrillation. Survival benefit has been demonstrated with the use of school-based Automated External Defibrillators (AED) for both students and non-students suffering SCA.¹ In instances where early defibrillation can mean the difference between life and death, the presence of school-based AED programs are of utmost importance.

Prevention of SCA in young athletes in schools with implementation of AED programs has received intensified attention in Orange County (OC), California. As OC is the county with the

highest per capita National Collegiate Athletic Association and Olympic athletes, the athletic environment likely initiated the attention on AED programs in OC. Several individual initiatives and legislative mandates contributed to sustaining the interest and may be the major driving force for the implementation of AED programs at school district levels in OC. In this article, our aim is to report the effect of individual initiatives and the assistance from legislative mandates on the current status of AED programs in OC schools.

“The most important factor in determining survival following sudden cardiac arrest (SCA) is time from collapse to defibrillation.”

Individual Initiatives

Several initiatives, evolving over the past decade in OC, have aimed at increasing the awareness of the risk of SCA in young athletes. Their specific roles, in facilitating the

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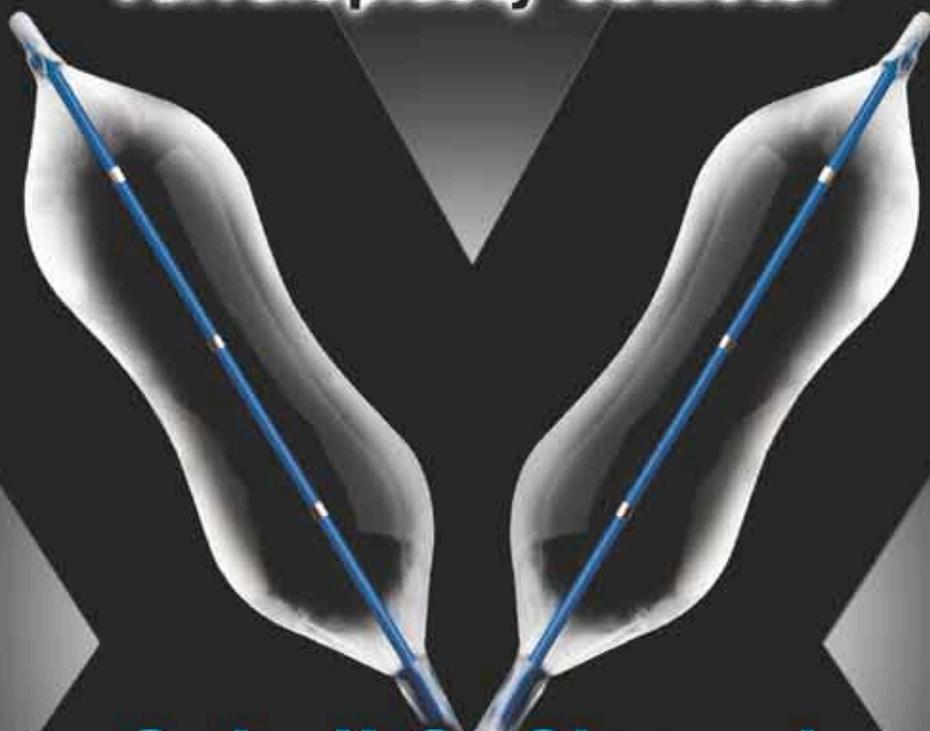
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Initiatives (Year)	Role in Implementing AED Programs
Life Threatening Events Associated with Pediatric Sports (LEAPS) (2008)	<ul style="list-style-type: none"> • Educational programs for athletic directors, high school and youth sports coaches, student athletes and parents • Recommendations regarding EKGs as part of the pre-season physical • Procedures and guidelines for adoption and implementation of AEDs in all OC • Review of life threatening events occurring at OC schools
Shauna Ann Stuewe Foundation (2006)	Placement of AEDs in schools throughout Southern California
The Dick Butkus Center for Cardiovascular Wellness (2005) Sparkling Angel Charities (2001) Heartfelt Cardiac Project (1999)	Screening echocardiograms and EKGs
The Derrick Faison Foundation (2004)	Placement of AEDs, CPR training and screening efforts

implementation of AED programs, have been varied (Table 1). Life-Threatening Events Associated with Pediatric Sports (LEAPS), an effort spearheaded by the medical community has worked on providing education, developing guidelines for implementation of AEDs, and providing feedback from review of life-threatening events. Using a hands-on approach, parents struck by the tragedy of a child with sudden death, have begun initiatives that provide AEDs in the classroom and arrange for screening echocardiograms and EKGs. The Shauna Ann Stuewe Foundation was created in memory of 14-year-old Shauna Stuewe, who died from a SCA because of Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT). The foundation has donated over 50 AEDs in 45 locations in OC since 2006.

Legislative Mandate in California

The primary goal of AED laws should be to simply and meaningfully offer qualified liability protection to all AED program constituents with the objective of encouraging more organizations to deploy AEDs² (Table 2).

California was one of the first states to pass legislature in 2005 urging public and private K-12 schools to have an AED.³ Assembly Bill 254 passed in 2005 (amended in 2006) and extended to Jan 2013 (AB 2083) incorporates most of the characteristics of the Model AED Law. This bill states that AEDs in public or private K-12 schools must be maintained and regularly tested according to the operation and maintenance guidelines set forth by the manufacturer, the American Heart Association, and the American Red Cross. In addition, the AED must be checked for readiness after each use and at least once every 30 days, if the AED has not been used in the preceding 30 days. The other aspects of the bill, assisting the use of AED in schools, pertain to activation of the

Model AED Law
1. Law that effectively reduces liability risk in order to encourage more organizations to acquire AEDs
2. Easy-to-read and understand guidelines that are uniform all over US
3. Protect all AED program participants and actions from grossly negligent, willful or wanton misconduct
4. Elimination of burdensome and complex immunity conditions, AED program design or operational requirements, as conditions of immunity

emergency medical services system, and reporting the use of the AED to the local physician and EMS agency. This legislature also states the number of persons trained and quality of training per AED acquired and having a written plan for procedures. Importantly, it also mandates notification of school employees by the principal as to the location of all AED units on the campus. Section 1714.21 of the Civil Code provides immunity to AED program participants (person using, training and acquiring AEDs). However, this legislation does not mandate schools have an AED program, nor provide state funding for AED programs.

Liability for not acquiring AED. Despite the recent legislative activity promoting AED programs in schools, a decision by a school district to not acquire AEDs for use in emergency care is unlikely to expose a school district to liability for negligence.

Liability for use of AED. The AED will make the correct 'shock' decisions more than 95 of 100 times and a correct 'no shock indicated' decision in more than 98 of 100 times. Thus, liability for use of an AED, when available, is more likely to arise based on the more procedural requirements for immunity – e.g. notices to employees, failure to test the device as specified – rather than injuries resulting from "gross negligence" in using an AED. A related question is whether the failure of a trained employee to use an AED, when use was appropriate in an emergency situation, would subject a district to liability. Similarly, there is the issue of whether there would be liability if, in the midst of an otherwise compliant AED program, a trained individual is not on the scene at the time of the cardiac arrest. In the absence of an appellate decision addressing the failure of a public employee to use an AED, it is difficult to predict how a trier of fact would rule in such a case. The approach recommended by the legal service at Orange County Office of Education is to ensure that AEDs, if acquired, are used when appropriate.

The decision whether to implement an AED program is difficult, and at times requires an uncomfortable balance between the safety of students and staff on the one hand, and the potential liability associated with a good faith but ultimately non-compliant AED program on the other. That is a choice that is ultimately one for individual districts, based on a specific analysis and review of the feasibility, cost, and necessity of an AED program at some or all of its schools.

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School Districts, Schools and Students in Orange County

According to the 2012 Orange County *Education At A Glance* brochure, there are a total of 27 school districts with 12 unified, 12 elementary and 3 high school districts. There are 592 public schools with 392 elementary schools, 83 junior high/intermediate/middle schools, 68 senior high schools, 38 continuation/alternative/special education schools, 11 charter schools and 290 private schools in the county. The total enrollment in schools is over 500,000 students, an average of 628 per school.

Status of AED Programs in OC, California

For assessing the status of AED programs in OC schools, an electronic survey was sent to all the 27 school districts in November, 2010. The personnel who responded on behalf of the school districts included: athletic directors, coordinators of health services/nurses, assistant superintendents, facility directors and administrative assistants. Questions covered various topics including the presence of an AED program, challenges of implementing an AED program, source of funding, number of AEDs, and placement, supervision and training for use of AEDs.

As of November 2012, all of the 3 high school districts, 7 of the 12 unified school districts and 2 of the 12 elementary school districts have an AED program. Among the school districts which have an AED program, 67 % (n=8) have had their program in place for more than 4 years and 33% (n=4) started their program within the last four years. High schools are the major locations of AEDs (84%), and 55% of the school districts mandate traveling with an AED during athletic competitions. The districts with an AED program have 3-4 AEDs in high schools, 1-2 in middle schools and 1 in each elementary school.

Challenges Preventing School Districts from Implementing an AED Program (Figure 1)

Funding. The most common challenge to fulfilling an AED program was funding (84.2%), with non-availability of staff cited as the next major hurdle (74%). Outside organizations or foundations initially funded the purchase of AEDs for the majority of the schools (69.2%). However, district funded the maintenance of AEDs and ongoing training (69.2%). Ninety percent responded that having more AED grants might support the AED program at their site. Information about AED budgets (42%) was also reported as a service that might support AED policy and program.

Liability. A significant proportion of the respondents of the survey (68%) stated that concern for liability after acquiring an AED was a major obstacle in implementing the program. The respondents also emphasized that services such as advocacy tools and resources and information about sample AED policies from Orange County Office of Education would help overcome this concern.

Need Assessment. The need for implementing an AED program is based on the probability of a SCA event within 5 years and an EMS call-to-shock interval of more than 5 minutes. Less than 20% of the respondents reported the lack of need for an AED as the reason for not implementing an AED program. As there is no SCA registry in Orange County, California, it is challenging to accurately determine the need or benefit of an AED program in various school districts.



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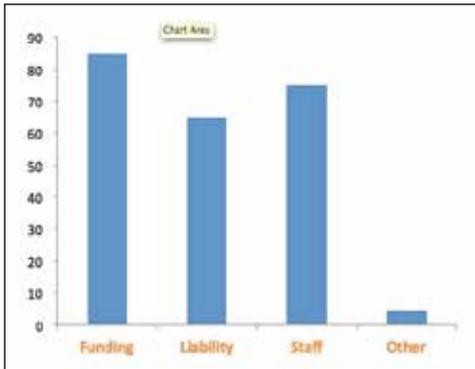


Figure 1. Challenges preventing districts from implementing an AED program.

Conclusion

With the initiatives and legislative mandates, there has been a significant increase in the number of school-based AED programs in Orange County, California. However, the concern for funding and liability, are the major barriers to the expansion of the implementation of AED programs to all the school districts. Individual initiatives and district funding are important sources and complement each other in funding the AED programs in schools. The legislative mandates have been modified to encourage more widespread use of AED in schools. AED grants, advocacy tools and legal resources would be helpful in planning and implementation of AED programs. The existence of a SCA registry would be helpful to track the benefit from implementation of AED programs. We are in the process of implementing such a registry in Orange County that would help us better determine the benefits of the AED programs in our schools.

There is an upcoming symposium on the current controversies surrounding sudden cardiac arrest in children & adolescents to be held at Disney's Grand Californian Hotel & Spa on Friday & Saturday, January 25-26, 2013. Keynote speakers will include: Dr. Barry Maron, Minneapolis Heart Institute Foundation, and Frank Marcos, University of Arizona Health Sciences Center. This two-day conference will present current controversies on topics related to the diagnosis, therapy and prevention of cardiac arrest in children and adolescents.

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Nivedita Mohari, MD
Fellow, Pediatric Critical Care Medicine
Children's Hospital of Orange County
Harbor-University of California, Los Angeles
nmohari@choc.org

Pamela Kahn, RN, MPH
Coordinator, Health and Wellness
Orange County Department of Education
pKahn@ocde.us

Corresponding Author:



Anjan S. Batra, MD, FHRS
Director of Electrophysiology
Children's Hospital of Orange County
Associate Professor of Clinical Pediatrics
University of California, Irvine
Irvine, CA USA
Phone: (714) 456-5338
abatra@uci.edu

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An Adult with Cor Triatriatum: A Case Report

By Gagandeep Singh, MD; Keshwar Ramkissoon, MD; Anatoliy Tsirlin, MD; Sanjay Kumar, MD; Jason Lazar, MD

A 73-year-old woman with hypertension for 30 years, type 2 diabetes for 25 years and cerebrovascular accident in 2007 with residual left sided weakness, presented to the hospital with complaints of worsening weakness and pain in her left leg started six hours ago. She did not experience dysphagia, dysarthria, diplopia, bowel or bladder incontinence. She did not report any prior surgery or tobacco, alcohol and illicit drug use.

On examination, the patient was alert and oriented to person, place and time. Her temperature was 99.3°F; her blood pressure was 159/89 mmHg, her pulse was 104 beats per minute, the respiratory rate was 18 breaths per minute, and oxygen saturation was 100% on room air. Cardiac exam revealed a normal S1 and S2, regular rhythm with no murmurs, rubs, or gallops. Jugular venous pulsation was normal. Lungs were clear to auscultation. On neurological exam, she had a very slight left facial weakness. Motor strength in her left arm was 2/5 proximally, left hand was contracted with 0/5 strength, her left leg had 0/5 strength, knee flexion was 2/5, and left foot dorsiflexion was 1/5 strength. Reflexes were decreased in all extremities, but sensation was intact. The electrocardiogram revealed normal sinus rhythm at 96 beats per minute, with normal p waves, and normal QRS complexes. Chest x-ray showed an enlarged cardiac silhouette, but no effusion or consolidation. CT head without contrast showed a hypodensity in the right internal capsule and lenticular nucleus consistent with old infarcts, but no evidence of acute intracranial hemorrhage. There was also a hypodensity in the right frontal cortex, for which chronicity could not be determined.

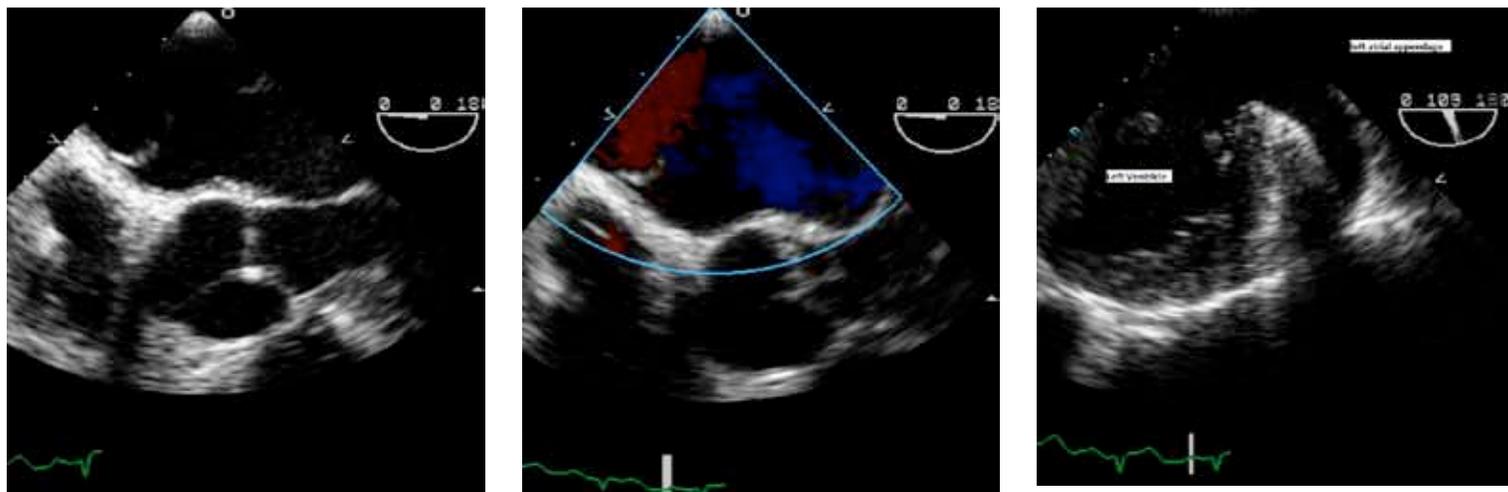
Magnetic resonance imaging (MRI) of the brain without contrast demonstrated no definite focus of restricted diffusion, but did show a focal area of encephalomalacia in right basal ganglia/corona radiata with

associated volume loss suggestive of old infarcts. Carotid ultrasound revealed tortuous arteries without any other pathologic findings. A transesophageal echocardiogram (TEE) showed a Left Ventricular Ejection Fraction of 60-65%, with normal left ventricular size, mildly dilated left atrium (LA) with a membrane diagnostic of cor triatriatum. There was fenestration in the membrane and wide communication between the proximal and distal parts. The membrane was upstream to the atrial appendage, differentiating it from the mitral membrane. There was no intra-cardiac thrombus. Clopidogrel was added to her medication regimen of aspirin, enalapril and metformin, and she was discharged in stable condition. At the six months follow-up visit she did not demonstrate clinic signs of worsening CVA or heart failure symptoms.

Discussion

Cor triatriatum or cotriatriatum sinister is a rare congenital heart defect in which the LA is subdivided by a thin fibromuscular membrane, resulting in proximal and distal chambers. The proximal chamber communicates with the pulmonary veins and the distal chamber communicates with the mitral valve and left atrial appendage. The incidence of cor triatriatum has been reported as 0.1% to 0.4% of all congenital cardiac malformations worldwide (Chen, et al.). There are 3 main theories that have been put forward as possible embryologic explanations of cor triatriatum. In the malseptation theory, the fibromuscular membrane is believed to be an abnormal growth of the septum primum. The entrapment theory suggests that the pulmonary vein is entrapped by the sinus venosus, preventing the pulmonary vein from reaching the left atrium. Finally, the mal-incorporation hypothesis, proposes that cor triatriatum results from incomplete incorporation of the pulmonary vein into the left atrium (Chen et al.).

There have been many classification schemes for cor triatriatum. One of the first was suggested by Loeffler, who classified cor triatriatum into three groups based on the number and size of the openings in the



Left: Semi-short axis view of aortic valve and anterior mitral leaflet. There is a membrane in the LA dividing it into postero-superior chamber and antero-inferior chamber. **Middle:** Color Doppler across the membrane does not show any turbulence. **Right:** Mid-esophageal two-chamber view showing location of LAA distal to membrane.



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membrane (Loeffler E). The first group having no opening, the second group with one or more small openings and the third having a wide opening as seen in our case.

The most common symptoms present in adults with cor triatriatum are dyspnea, orthopnea and hemoptysis (Mcguire et al.). However, it is important to remember that cor triatriatum can be asymptomatic. The most significant physical exam finding is a cardiac murmur, most commonly a holosystolic murmur heard best at the apex. The most frequent cardiovascular abnormalities associated with cor triatriatum include: mitral regurgitation, supraventricular annulus, persistent left superior vena cava draining in the coronary sinus, and atrial septal defect (Hamden et al.). Our patient was asymptomatic (no dyspnea, orthopnea, or hemoptysis) and did not have a cardiac murmur on physical exam. The only significant finding was trace mitral regurgitation reported on the transesophageal echocardiogram.

Our patient presented with lower extremity weakness, left greater than right, which was likely an embolic stroke in the distribution of the right anterior cerebral artery. Park and colleagues reported a case similar to this one, where the first manifestation was an embolic stroke (Park, et al.). They reviewed previous literature on embolic events in adults with cor triatriatum and found the mean age of cor triatriatum diagnosis was 49 years with a median age of 55 years, and a female:male ratio of 3:2. Spengos and colleagues suggest a direct association between stroke and cor triatriatum as a result of the obstructive effect of the membrane that reduces blood flow between the two chambers of the subdivided left atrium (Spengos, et al.).

The most commonly used imaging modality for diagnosis of cor triatriatum is echocardiography (Park, et al.). Although the diagnosis can be made by transthoracic echocardiography, transesophageal echocardiography is used to precisely define the anatomy of the membrane. Surgical resection of the membrane is indicated in symptomatic patients. Cor triatriatum repair is a relatively simple procedure, with an excellent postoperative course, as well as long-term results (Rodefeld, et al.). Early diagnosis plays a major role in reducing mortality. In their study, Rodefeld and colleagues found that of the 11 patients who underwent surgical repair of cor triatriatum, 9 survived, with a 17% surgical mortality rate (Rodefeld, et al.).

“The most commonly used imaging modality for diagnosis of cor triatriatum is echocardiography (Park, et al.). Although the diagnosis can be made by transthoracic echocardiography, transesophageal echocardiography is used to precisely define the anatomy of the membrane..”

The patient described in this case report was asymptomatic, did not have atrial fibrillation, or any other anomaly associated with cor triatriatum. She did not have changes on MRI suggestive of an acute infarct or hemorrhage. The fact that the patient was asymptomatic is likely the reason for the late discovery. Given the advanced age, lack of disabling findings, absence of arrhythmia or concomitant serious cardiac anomalies, the patient was treated conservatively (without surgical removal of the membrane). She received physical therapy for her weakness, and at a six-month follow-up, she had no orthopnea, or evidence of recurrent stroke.

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Corresponding Author:

Keshwar Ramkissoon, MD
Department of Medicine, State University of New York, Downstate Medical Center
Brooklyn, NY 11203

115-48-114th Place
South Ozone Park, NY, 11420 USA
Phone: 347. 730.9248
Keshwar.Ramkissoon@downstate.edu

Gagandeep Singh, MD
Department of Medicine, State University of New York, Downstate Medical Center
Brooklyn, NY 11203

Anatoliy Tsirlin, MD
Department of Medicine, State University of New York, Downstate Medical Center
Brooklyn, NY 11203

Sanjay Kumar, MD
Department of Medicine, State University of New York, Downstate Medical Center
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Beirut International Congress of Pediatric and Congenital Cardiology Briefing - October 18th-20th, 2012

By Samer I. Masri, MD; Fadi Bitar, MD; Karim Diab, MD

Named 'one of the top places to visit' by *New York Times*, and one of the 'ten liveliest cities in the world' by *Lonely Planet*, Beirut with its unique blend of East and West, hosted an international congress of pediatric and congenital cardiology under the umbrella of the Pan-Arab Congenital Heart Disease Association (PACHDA) at the Children's Heart Center at the American University of Beirut (AUB). More than 35 speakers and 200 guests participated in the conference. This congress was distinguished for its rich scientific program and hosted participants from the Arab world and various countries such as South Korea, Malaysia, Pakistan, Iran, Turkey, Germany, United Kingdom, Greece, Italy and the United States of America. The congress provided the opportunity to exchange expertise with speakers who came from around the world and covered various aspects of congenital cardiology, and spanned a full day and two half-days.

A major highlight of the meeting was a pre-congress workshop focusing on fetal echocardiography. With the increasing focus on the need for prenatal detection of Congenital Heart Disease (CHD), it was inevitable to have a session focusing on this topic. Following a welcome address by the Congress President and Director of the Children's Heart Center at AUB, Dr. F. Bitar, the fetal echocardiography workshop, directed by Dr. K. Diab, covered various topics pertaining to general fetal cardiology, as well as specific topics related to the Arab World. Dr. F. El-Kak, President of the Lebanese Society of Obstetrics and Gynecology, presented an overview of maternal conditions affecting the fetal heart, Dr. Rima Bader

from King Abdul Aziz University Hospital in Jeddah, KSA lectured on the Indications for Fetal Echocardiogram and mentioned the common indications encountered for fetal echo referrals in KSA; she also lectured on 3D Fetal echocardiography and its clinical application. Dr. Emmerio Alboliras, Director of Fetal Cardiology at Phoenix Children's Hospital, USA, discussed the technique of fetal echocardiography and the anomalies of the outflow tract session. Dr. K. Diab then lectured on the abnormalities of septation and inflow. The workshop was concluded with a brief overview by Dr. Badr on the status of fetal cardiology in the Arab World, stressing the need for improvement in prenatal counseling.

The second day continued with sessions that focused on imaging, right-sided lesions for uni-ventricular track, VSD closure devices, and hot debates.

In the first session focusing on imaging in congenital heart disease (CHD), Dr. E. Alboliras stressed the importance of intraoperative echocardiographic assessment of congenital heart disease in furnishing excellent surgical outcomes. Dr. A. Kouatli from King Faisal Specialist Hospital & Research Center in Jeddah, KSA lectured on the pre-operative echocardiographic assessment of uni-ventricular repair. Then Dr. J. Vettukattil from Southampton University in the UK discussed the various applications of 3D-echocardiography in congenital heart disease ranging from the diagnosis of several valve-related pathologies to implications of 3D in interventional procedures such as device closure of septal defects. Dr. Vettukattil stressed the significance of 3D-echocardiography in revolutionizing our clinical management of complex congenital heart defects, as well as the need for accurate interpretation and training.

Dr. Malek El Yaman from West Virginia University, USA lectured on the application of MRI and CT angiography in congenital heart disease and on when to use either modality and for what complex lesions. The final imaging session was given by Dr. E. Alboliras who elucidated echocardiographic assessment techniques of coronary artery anomalies and on the importance of imaging for these abnormalities in order to prevent any disastrous complications during congenital heart disease surgery.

Following a coffee break during which the guests roamed around the scientific and industry posters, breakout sessions on right sided lesions for uni-ventricular track commenced with Dr. M. Alwi, Chairman of the Department of Pediatric Cardiology at Institute Jantung Negara in Malaysia, who reviewed the indications for single ventricle vs. 11/2 ventricle repair in newborns with PA/IVS. In the second session, Dr. H. Najm, head of cardiac surgery at King Abdulaziz Cardiac Center reviewed the single ventricle vs. two ventricle repair in newborns with severe Ebstein anomaly. Dr. A. El Sisi from University of Cairo, Egypt then went over the controversies of leaving the forward flow following Glenn operations vs. disconnecting it.

This was followed by an update on the surgical management of patients with single ventricle by Dr. E. Bacha from Morgan Stanley Children's Hospital of New York who went over an update on diagnostics, interventional cardiology, surgery, intensive care, long-term care and transplantation in single ventricle patients. He stressed the importance of a vigilant partnership between the surgeon and the cardiologist with special attention on the status of the branch PAs and AV valves, ventricular function, and development of aortopulmonary collaterals and pulmonary arteriovenous malformations.



Dr. B. Mora from Cleveland Clinic concluded the session with a discussion on the vexing problems and challenges of heart transplantation for congenital heart disease.

This was followed by a session with hot debates that tackled various controversial topics including: stenting the ductus vs. BT Shunts in ductal-dependent lesions (Pro: Dr. M. Alwi; Con: Dr. H. Najm); surgery vs. balloon angioplasty in neonatal coarctation (Pro: Dr. C. Zein; Con: Dr. M. Omar Gall), and on ablation in asymptomatic WPW (Pro: Dr. Bernard Abi Saleh; Con: Dr. Maurice Khouri). The session was concluded with Dr. Emile Bacha who had a pro debate favoring primary complete surgical repair in neonatal TOF rather than shunts as the primary operation.

Thereafter, an extensive session was held on VSD closure and devices. Dr. T. Apostolos from St. Luke's Hospital in Greece reviewed the early experience with the new Amplatzer Membranous VSD Occluder 2. Dr. S. Ho Kim from South Korea demonstrated the use of Amplatzer Ductal Occluder for transcatheter closure of perimembranous VSD with a lower incidence of complete heart block than the Amplatzer Perimembranous VSD Occluder. Then Dr. T. Phi Le from Hamburg, Germany introduced a number of newer closure devices for left to right shunts.

The second day was concluded with a St. Jude/AGA industry sponsored symposium featuring challenging PDA cases using the Amplatzer Ductal Occluder II additional sizes, as well as challenging ASD cases and the TV FX new delivery system.

The 3rd day of the congress commenced with interesting updates in interventional cardiology. Dr. A. Erdem from Istanbul, Turkey went over a variety of modified implantation methods and assisting techniques to close difficult ASDs and to stent complex aortic coarctation. Dr. S. Ho Kim from South Korea

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demonstrated the “treat-and-repair approach” in patients with large PDA and pulmonary hypertension concluding that pulmonary vasodilators widen the operability criteria in patients with congenital heart disease and pulmonary hypertension. Dr. Kim also touched on the technical issues for transcatheter closure of PDAs larger than 10 mm using the Amplatzer Muscular VSD Occluder or the Amplatzer Septal Occluder. Dr. E. Bacha gave an update on a number of hybrid procedures in congenital heart disease including: Hybrid stage I for HLHS, periventricular closure of muscular VSDs, intraoperative ballooning and stenting of pulmonary arteries, intraoperative ballooning of pulmonary valve during primary TOF repair, intraoperative ballooning of pulmonary veins and the intraoperative use of fluoroscopy.

Following a coffee break, an Occlutech industry sponsored symposium exhibited an update on ASD Flex II devices, Occlutech PDA devices, and the role of 3D echo in

device closures. This was followed by oral abstract presentations that involved topics from genetics to telemedicine.

Some research and innovative techniques were presented including research done at the CHC at AUB discussing the discovery of the “NFATC1” gene which causes defects in heart valves and a case that is a first of its kind in the world, which described closure of an ascending aortic pseudoaneurysm with a septal occluder device in a child utilizing a novel percutaneous femoral arterial-thoracic approach.

The concluding session was on congenital heart disease in the Arab World. The session included presentations on the status of pediatric cardiology in a number of Arab countries and a PACHDA registries and database presentation by the PACHDA President, Dr. R. Abu-Sulaiman. Two special lectures were provided by Dr. R. Abdullah from Rush University, USA on “What is needed to get your research published?” and by Dr. R. Sulayman from Advocate Hope Children's Hospital, USA on “Collaboration: Regional and International and opportunity for physicians and fellows.” Following the distribution of tokens of appreciations to the speakers by the organizing committee, Dr. F. Bitar brought down the curtains on a scientifically fruitful meeting with the hope to keep the PACHDA meetings held in the Arab World on a yearly basis.

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*Samer Masri, MD
Children's Heart Center- American
University of Beirut
Beirut, Lebanon*

*Fadi Bitar, MD
Children's Heart Center- American
University of Beirut
Beirut, Lebanon*

Corresponding Author:

*Karim Assaad Diab, MD, FACC, FASE
Children's Heart Center- American
University of Beirut
Beirut, Lebanon*

*Phoenix Children's Hospital
Cardiology Dept.
1919 East Thomas Rd.
Phoenix, AZ 85016 USA
Phone: 603.933.3336
Fax: 603.933.4161*

karim.diab2@aub.edu.lb



Medical News, Products and Information

Is Declining Medical Imaging Use Driving Up Hospital Stays and Medical Costs?

Newswise — A new report by the Harvey L. Neiman Health Policy Institute shows that the length of the average hospital stay in the United States has increased at the same time as use of medical imaging scans has declined. It is unclear if the trends are related, but potentially important, as hospital admissions are among the largest, and fastest growing, health care costs. More research is needed to assess the potential negative impact of government and private insurer imaging reductions on overall medical costs and patient safety.

“Lawmakers, regulators and medical professionals are making medical imaging policy decisions without fully understanding or examining their downstream effects — which may include an increase in hospital stays, associated costs and other adverse events. We need to examine imaging, as it relates to a patient’s overall continuum of care, to ensure that decision makers don’t create imaging cost reduction policies which paradoxically raise overall costs, create barriers to care, and ultimately harm patients,” said Richard Duszak, MD, CEO and Senior Research Fellow of the Harvey L. Neiman Health Policy Institute.

Much of a building body of research regarding medical imaging focuses on declining costs and utilization of imaging. There is relatively little research focused on imaging as a component of overall patient care. For many serious indications, imaging scans have been shown to reduce the number of invasive surgeries, unnecessary hospital admissions and length of hospital stays. Rarer still is data on the effect of \$6 billion in funding reductions for imaging diagnosis and treatment planning since 2006. The information that is available is not necessarily positive in terms of patient safety and access to care.

This is the first policy brief produced by the Neiman Institute, which conducts and supports research regarding medical imaging use, quality and safety metrics, and human resources as medicine moves toward non-traditional, value-based payment and delivery. The data gleaned from these efforts will serve as the basis for true, evidence-based medical imaging policy.

“We need to take a hard look at the cost, access and quality and safety issues related to present government and private insurer medical imaging policies and find ways to maximize the value, role and efficiency of radiology as health care systems evolve. The Neiman Institute will provide much needed information to ensure that future imaging policies benefit patients and make efficient, effective use of health care resources,” said Duszak.

Cincinnati Children’s Announces Major Advancement In Treatment of Duchenne Muscular Dystrophy

In what may be the biggest breakthrough in muscular dystrophy in years, a patient at Cincinnati Children’s Hospital Medical Center is believed to be the first in the nation with Duchenne Muscular Dystrophy (DMD) to have a device implanted to help his heart pump blood to the body long-term.

Because 80% of boys and men with Duchenne muscular dystrophy, ultimately die of heart failure, the implanted Left-Ventricular Assist Device (LVAD), could add years or even decades to the lives of patients with DMD.

“This is a major milestone in the care of Duchenne muscular dystrophy,” says John Lynn Jefferies, MD, Director of the Heart Failure and Ventricular Assist Device Programs at the Cincinnati Children’s Heart

Institute. “This treatment offers the possibility of changing the outcome and the lives of these young men in a significant way that has never been realized up until now.”

Due to their severe muscle disease, patients with DMD are not typically candidates for heart transplant and some other treatment options that exist for patients with other muscular dystrophies. Patients with Becker Muscular Dystrophy, for example, a less severe form of muscular dystrophy caused by the same gene as DMD, have a larger range of treatment options, including transplant and LVADs, which have been successfully implanted in this population. DMD patients often die at a much younger age than patients with Becker muscular dystrophy due to heart failure.

Surgeons at Cincinnati Children’s, led by David Morales, MD, Chief of Cardiovascular Surgery and Executive Co-Director of the Heart Institute, demonstrated the feasibility of using LVADs as an option for Duchenne patients by implanting a Thoratec HeartMate II LVAD into the chest of Jason Williams, 29, a DMD patient from Peebles, Ohio. Williams is hoping not only for an improved quality of life for himself but to be a pioneer in helping all patients with DMD.

“I wanted to live longer with a better quality of life, and help other people — those with Duchenne facing heart failure and death,” says Williams. “I hope that doctors and surgeons can learn from my surgery and my recovery and be able to offer this treatment to other men and boys with Duchenne.”

“Our team is honored to be a part of such a significant event and feels a great sense of gratitude toward Jason and his family for their desire to open new doors to all those with Duchenne,” adds Dr. Jefferies.

Muscular dystrophy is a group of inherited diseases in which the muscles progressively weaken. DMD affects mostly males, appearing between the ages of 2 and 6. Disease progression varies, but many people with Duchenne need a wheelchair before the age of 12, which was the case with Williams.

Later stages of the disease are characterized by severe difficulty breathing and heart problems. Those with DMD usually die in their late teens or early 20s.

“For these patients, a long-term solution for heart failure would be groundbreaking,” says Jeffrey Towbin, MD, Executive Co-Director of the Heart Institute and Chief of Pediatric Cardiology at Cincinnati Children’s.

“We could perhaps change the natural history of this disease,” says Dr. Morales. “This operation gives Jason the most important thing: hope for a future. He has a lot going for him. In Cincinnati Children’s, he has a broad and deep heart team; a backbone of basic, translational and clinical research working for him; international thought leaders in muscle disease to help manage his care; and institutional leadership that makes advances such as this possible. Most importantly, he has a tremendously dedicated family to support him.”

The Comprehensive Neuromuscular Center at Cincinnati Children’s is dedicated to helping children, adolescents and adults with neuromuscular disorders live better, fuller lives. Directed by Brenda Wong, MD, the Center cares for more than 1,100 children from around the world with a range of neuromuscular diseases. The staff of experts includes such disciplines as pulmonary medicine, cardiology, pediatric rehabilitation, genetics, physical therapy, gastroenterology, nutrition therapy, social services, psychology, neuropsychology, endocrinology, ophthalmology, and orthopaedics.



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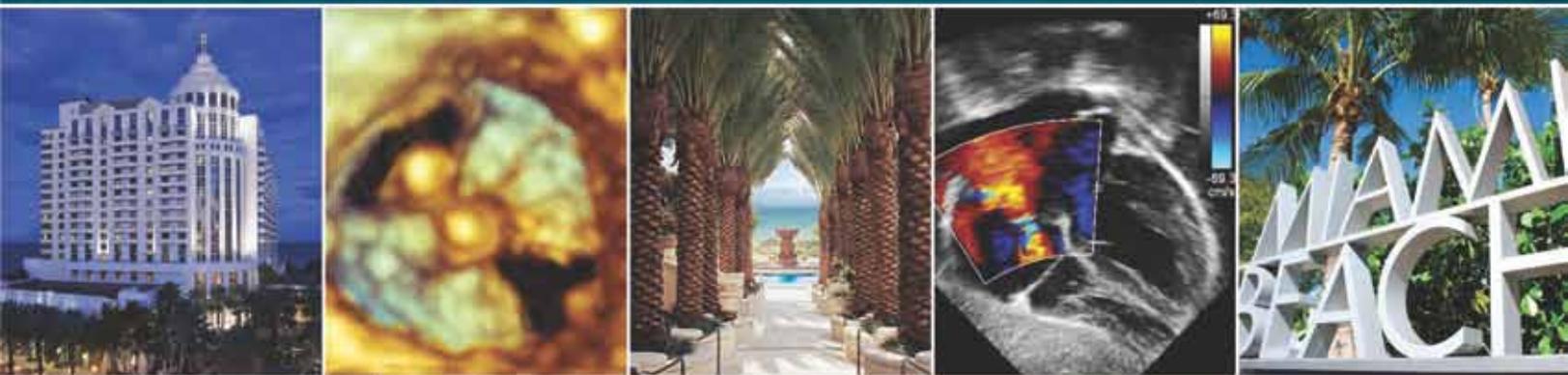
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Despite years of research into DMD and other forms of muscular dystrophy, medical advances have been limited. Perhaps the biggest impact came more than a decade ago, when steroid therapy began to be used extensively to prolong skeletal muscle. Then, in 2005, Drs. Jefferies and Towbin published a study predicting when patients would develop cardiac disease, allowing earlier intervention to occur.

Approximately 2,500 individuals are born around the world each year with DMD. By the age of 21, 100% of patients with DMD have dilated cardiomyopathy, a disease of the heart muscle.

Ventricular assist devices are mechanical pumps implanted in the chest to help a weakened heart pump blood to the body. They are often used as a bridge to transplant, delaying the need for transplant until a suitable heart can be located. Although patients with Duchenne are not candidates for heart transplant, this doesn't mean that assist devices can't be seen as bridges to more advanced care.

Current research is looking at whether stem cell therapy might be used to increase the heart's ability to squeeze and better pump blood. Researchers are examining whether bone marrow cells can be injected into the heart and replace cells that are not working properly. Researchers are hoping that VADs can be used until stem cell therapy becomes a reality.

Additional information can be found at www.cincinnatichildrens.org.

New Weill Cornell Study Provides Compelling Evidence that Commercially Available Electronic Health Records Are Associated with Better Physician Performance

Newswise — A new study by Weill Cornell Medical College researchers, published in the *Journal of General Internal Medicine*, provides compelling evidence that electronic health records (EHRs) enhance the quality of patient care in a community-based setting with multiple payers, which is representative of how medicine is generally practiced across the United States.

The use of EHRs is on the rise, in part because the federal government has invested up to \$29 billion in incentives promoting the meaningful use of these systems, with the aim of tracking and improving patient outcomes. Previous studies have provided conflicting evidence about the impact of EHRs, and until now it had been not clear whether they improved the quality of patient care, particularly in typical communities that use commercially available systems.

"The previous studies on the effects of electronic health records in the outpatient setting have been mixed," says the study's lead investigator, Dr. Lisa M. Kern, Associate Professor of Public Health and Medicine at Weill Cornell Medical College. "This is one of the first studies to find a positive association between the use of EHRs and quality of care in a typical community-based setting, using an off-the-shelf electronic health record that has not been extensively tailored and refined. This increases the generalizability of these findings."

"This study starts to grow the evidence that the use of these systems can systematically improve the quality of care, although their maximum value likely lies in their ability to support new health care delivery models," says the study's senior investigator Dr. Rainu Kaushal, Director

of the Center for Healthcare Informatics and Policy and the Frances and John L. Loeb Professor of Medical Informatics at Weill Cornell Medical College. "The findings of this study lend support to the very significant investments in health information technology that are being made by the federal government, states, and health care providers."

This study was conducted with the Health Information Technology Evaluation Collaborative (HITEC)—a multi-institutional effort directed by Drs. Kaushal and Kern and funded by New York State, in order to evaluate and assess the impact of New York's health information technology strategy. In 2008, the researchers collected data about the quality of patient care across nine measures from nearly 500 physicians and 75,000 patients in ambulatory practices in the Hudson Valley region of New York, where there has been a concerted effort to implement EHRs. They gathered data from five different health plans, including two national commercial plans, two regional commercial plans and one regional Medicaid health maintenance organization.

"This study reflects data from five different health plans, which is another strength of the study and which is critical for understanding the experiences of patients in the community," says Dr. Kern. "If you only have one health plan, then you will not be seeing the whole picture."

The team found that the 56% of physicians who used commercially available EHRs provided significantly better quality of care than physicians using paper records for four measures, including hemoglobin A1c testing in diabetes, breast cancer screening, chlamydia screening and colorectal cancer screening. EHRs typically provide reminders about these clinical tests. Moreover, the combined score across all nine measures indicated that EHRs led to better patient care than paper records.

"EHRs may improve the quality of care by making information more accessible to physicians, providing medical decision-making support in real time and allowing patients and providers to communicate regularly and securely," says Dr. Kaushal. "However, the real value of these systems is their ability to organize data and to allow transformative models of health care delivery, such as the patient-centered medical home, to be layered on top."

To follow up on this study, the researchers plan to determine how the effects of EHRs on patient care vary over time and across different locations in New York, to examine the effects EHRs on the cost of patient care and to work on improving ways to measure the quality of patient care.

This work was supported by the Commonwealth Fund, the Taconic Independent Practice Association, and the New York State Department of Health (contract #C023699).

Co-authors of the study include: Yolanda Barrón, Rina V. Dhopeswarkar, and Alison Edwards of Weill Cornell Medical College, as well as the HITEC investigators.

For more information, visit weill.cornell.edu.

In Vitro Fertilization Linked to Increase Risk for Birth Defects

In Vitro Fertilization (IVF) may significantly increase the risk of birth defects, particularly those of the eye, heart, reproductive organs and



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urinary systems, according to new research presented, Oct. 20th, at the American Academy of Pediatrics (AAP) National Conference & Exhibition in New Orleans.

According to the study, despite increasing use of IVF in the United States, associations between birth defects and IVF are poorly understood. Management of birth defects comprises a large part of pediatric surgical care and demands significant health care resources.

According to the Centers for Disease Control, California has the highest rate of IVF usage in the United States. In the abstract, "Congenital Malformations Associated with Assisted Reproductive Technology: A California Statewide Analysis," researchers examined infants born in California from 2006-2007 after IVF and other treatments such as fertility-enhancing drugs or artificial insemination. Researchers examined maternal age, race, the number of times the mother had given birth, infant gender, year of birth and presence of major birth defects.

"Our findings included a significant association between the use of assisted reproductive technology, such as certain types of in vitro fertilization, and an increased risk of birth defects," said study author Lorraine Kelley-Quon, MD, a general surgery resident at Ronald Reagan UCLA Medical Center, who conducted the research at Mattel Children's Hospital UCLA.

Overall, 3,463 infants with major birth defects were identified among 4,795 infants born after IVF and 46,025 naturally conceived infants with similar maternal demographics. Birth defects were significantly increased for infants born after IVF – 9% versus 6.6% for naturally conceived infants, even after controlling for maternal factors. Specifically, malformations of the eye (0.3% versus 0.2%), heart (5% versus 3%), and genitourinary system (1.5% versus 1%) were greater in IVF infants. Overall, an IVF infant's odds of birth defects were 1.25 times greater than that of a naturally conceived infant with similar maternal characteristics. Risk of birth defects after other fertility treatments such as artificial insemination or ovulation induction alone were not significant.

"For parents considering in vitro fertilization or other forms of assisted reproductive technology, it is important that they understand and discuss with their doctor the potential risks of the procedure before making a decision," said Kelley-Quon.

Preventive Screening for Sudden Cardiac Death in Young Athletes Debated

While ensuring the safety of high school and college athletes is hardly controversial, the method and associated costs of doing so are hotly debated. Conducting electrocardiographic (ECG) screenings of all young competitive athletes in the United States would cost up to \$69 billion over 20 years and save about 4,813 lives, making the cost per life saved over \$10 million, according to a study published online today in the *Journal of the American College of Cardiology*.

A corresponding editorial suggests that this number is inflated and "misleading," and blames the high costs on cultural attitudes and medical policies on preventative medicine in the United States. The issue has been widely debated among experts currently in sports cardiology, a growing field of medicine in the United States. The European Society of Cardiology recommends mandatory ECG screening of all competitive athletes, but the American Heart Association recommends a physical exam and family history questionnaire as a first-line screening, with further examination based on the results of those initial steps.

"While this research focuses on the monetary costs of mandatory ECG screening, it is important to consider the human costs of false positives, which can result in additional potentially unnecessary tests and removal from play of athletes who are not actually at risk," said ACC President William Zoghbi, MD, FACC. "Most in this discussion agree that

physicals, thorough family histories, targeted testing with ECG and other modalities when needed, widespread training in CPR, and availability of automated external defibrillators save lives from sudden cardiac arrest."

A 2006 Italian observational study found that mandatory ECG-based screening of athletes implemented by Italian law led, over a 20-year period, to a 89 percent relative risk reduction in sudden cardiac death; however, the absolute risk reduction, the cost and the economic ramifications have not been addressed in this study.

Researchers in the current study established a cost-projection model based on the Italian study to estimate the number of athletes who would need to undergo screening if it were required in the U.S., compute the costs and determine the number of lives that could be saved. The number of screening-eligible athletes was estimated from data provided by the National Collegiate Athletic Association and the National Federation of State High School Associations and diagnostic test costs were determined from Medicare reimbursement rates.

Based on this data, researchers determined that 8.5 million athletes would undergo annual ECG screening over 20 years, with 2% ultimately disqualified as a result of follow-up screenings each year. That equates to 170 million screening tests and 3.4 million disqualifications over two decades.

The number of athletes disqualified for heart conditions would cause the sudden cardiac death rate to decrease from 4 to 0.43 per 100,000, but the costs would be in the billions. Researchers estimate that 20 years of testing would cost between \$51 billion and \$69 billion and save about 4,813 lives, which averages to between \$10.6 million and \$14.4 million per life saved.

Antonio Pelliccia, MD, of the Institute of Sport Medicine and Science in Rome, disagrees with the conclusions of the study. He argues the study overestimates costs because the screenings are part of a preventative program that targets young people who are for the most part healthy, is conducted outside of hospitals and is performed by team physicians, not cardiologists. Screenings would be packaged as a unique medical procedure instead of priced as individual diagnostic tests.

He acknowledges that reimbursement of pre-participation screenings as a preventative medicine program does not currently exist in the Medicare system and this "represents a major obstacle" in implementing ECG-based pre-participation screening.

According to Dr. Pelliccia, in Italy where ECG screening is mandatory for athletes, the cost is about \$60 per athlete, including history, physical and 12-lead ECG, which is a price based on an agreement between the Board of Sport Physicians and the Italian government. The National Health System also refunds this fee for low income individuals.

He said the obstacles in the United States are not economic but cultural and "will require a change in the cultural attitude and current medical policy in the United States, where preventative medicine programs are unlikely to be federally supported."

Other obstacles he lists are concern for the legal consequences related to misinterpreting an ECG and the lack of knowledge around the sports cardiology profession. He said ECG-based pre-participation screening does not routinely require the expertise of cardiologists and advises more training for team physicians on reading ECGs to better distinguish normal from abnormal.

The full study was published in the Dec. 4th JACC print edition.

International Children's Heart Foundation Babyheart Medical Mission returns to Benghazi, Libya

A team of pediatric cardiac specialists from Memphis and countries all over the world returned to Benghazi, Libya (November 24th-December 8th) to operate on children with heart defects. The International Children's Heart Foundation (ICHF) is aware of the recent terrorist attacks on the US consulate in Benghazi that occurred on September 11th, 2012 that resulted in the tragic death of four Americans, including ambassador Christopher Stevens. As the United States is resolute in the face of senseless terror, so is the medical staff of ICHF who volunteer their time for this two-week Babyheart Medical Mission where they will be providing heart surgeries and medical care free of charge to children in need. Without ICHF, many of these children will be forced to wait for surgery and continue to suffer, or simply die.

Dr. William Novick, Founder and Medical Director of the International Children's Heart Foundation, and Dr. Kathleen Fenton was head up the surgical team. Dr. Ali Dodge Khatami of Hamburg, Germany was also be present to help increase the number of children who receive care. There have been two previous medical missions to Libya this year, the inaugural trip being in March, 2012 and the second in July, 2012. Each trip had 22 medical volunteers occupying all areas of a functioning pediatric cardiac unit: surgeons, scrub nurses, anesthesiologists, perfusionists, respiratory therapists, intensivists, and pediatric intensive care nurses. A combined 46 children received life-saving surgery. Dr. Novick and ICHF biomedical engineer, David Weiduwilt, performed the first site visit last year to meet with representatives of the government in Tripoli and evaluate facilities. They came to the Benghazi Medical Center and were actually quite impressed, compared to other crude facilities and other past places ICHF has operated in which there were little more than shacks. The former dictator Muammar Quaddafi had three tremendous towers built with modern design elements and beautiful marble walls and floors. Intended to be a hospital, it was little more than a front because there were no doctors or nurses or medical equipment, but rather machine guns, bullets and grenades, among other military hardware. Quaddafi used this as a weapons depot. After the fall of the regime, Dr. Novick and ICHF assisted with efforts to make this a fully functioning healthcare facility complete with a pediatric cardiac unit to operate on children with any number of heart conditions.

Former Tennessee Senator Bill Frist, an ICHF supporter, who has also been on his share of medical missions to dangerous parts of the world, said in his book, *A Heart to Serve*, "People don't usually go to war with people who helped save their children." This is at the heart of Babyheart's mission, whether in Libya or anyone of the other countries ICHF operates in such as Iraq, Ecuador, or Honduras, just to name a few.

Each year, approximately one-percent of the world's children are born with heart defects. Most of these defects are not fatal, if treated. Unfortunately, thousands of children have no access to advanced surgical procedures and medical technology. Their parents are helplessly forced to watch their withering children as they fall prey to a painfully slow, but all too early, demise. However, through the work of the International Children's Heart Foundation, these ailing children are given hope for life.

The International Children's Heart Foundation is a non-profit organization dedicated to providing lifesaving surgical care to children with congenital or acquired heart defects in developing countries around the world. Since 1993, more almost 6,000 children in 30 different countries have received surgical care and thousands of other children have benefited from the education and training provided to the in-country medical staff during these humanitarian trips.

For more information about the International Children's Heart Foundation, and how you can help support their efforts, visit www.BabyHeart.org or call 901-869-4243.

Patients with Heart Block See Strong Benefit from Cardiac Resynchronization Therapy, Clinical Trial Shows

Newswise — Heart failure patients with a condition called "heart block" derive significant benefit from Cardiac Resynchronization Therapy (CRT), according to the results of the Block HF clinical trial, presented at the November American Heart Association Scientific Sessions 2012 meeting in Los Angeles.

Anne B. Curtis, MD, Charles and Mary Bauer Professor and Chair of Medicine in the University at Buffalo School of Medicine and Biomedical Sciences and Principal Investigator of Block HF, presented results of the eight-year-long, national, multicenter, randomized clinical trial sponsored by Medtronic, Inc., which enrolled more than 900 patients. Curtis discusses the results in this video at http://youtu.be/agALz_NZDJ8.

"These findings confirm what some clinicians and researchers have hypothesized for some time -- that heart failure patients with heart block do better when both sides of the heart are resynchronized, called biventricular pacing, using a cardiac resynchronization therapy (CRT) device," she says. "The results of Block HF may lead to a reassessment of treatment guidelines for heart failure patients with heart block."

In the trial, 349 patients underwent biventricular pacing with a CRT device and 342 patients underwent the conventional right ventricular pacing. Patients who underwent biventricular pacing had a 26% reduction in the combined endpoint of mortality, heart-failure related urgent care and deterioration in heart function detected by echocardiography.

There also was a 27% relative risk reduction in the composite endpoint of heart failure urgent care and all-cause mortality.

The Block HF trial was designed to address the best way to treat Atrioventricular Block (AV block), a partial or complete block in the main "trunk" of the heart's electrical conduction system.

"AV block prevents electrical impulses from reaching the bottom chambers of the heart, which then beat very slowly or not at all," explains Curtis.

To treat AV block, many patients are implanted with a standard pacemaker with leads or pacing wires in the top chamber (right atrium) and the bottom chamber (right ventricle) of the heart.

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"But that fix can lead to other problems," Curtis says, "such as creating less synchrony between the left and right ventricles of the heart, making their heart failure symptoms even worse."

Researchers and clinicians have hypothesized that better outcomes might result from pacing both the left and right ventricles of the heart, called biventricular pacing, which involves implanting a cardiac resynchronization therapy device.

"Implanting these devices is more complicated than putting in a standard pacemaker, something clinicians don't want to put patients through without clear evidence of a benefit," says Curtis. "Today, we are announcing that Block HF does show that benefit."

Heart failure affects approximately 6 million people in the U.S. at a cost of somewhere between \$20 and \$56 billion/year. Of those, AV block affects more than 800,000 Americans, and more than a million people worldwide.

Curtis, a UB faculty member since 2010, is one of the world's leading clinical cardiac electrophysiologists and an expert in cardiac arrhythmias. Her clinical research has significantly advanced knowledge of human cardiac electrophysiology and heart rhythm abnormalities.

Her research interests include: clinical trials in implantable device therapy for prevention of sudden cardiac death and management of heart failure, as well as clinical trials in atrial fibrillation. She has been principal investigator, co-investigator, sponsor or steering committee member on 85 research studies and clinical trials and she has written more than 250 peer-reviewed manuscripts, book chapters, reviews and editorials. She also is author of a book on cardiac pacing.

Letters to the Editor

Congenital Cardiology Today welcomes and encourages Letters to the Editor. If you have comments or topics you would like to address, please send an email to: LTE@CCT.bz, and let us know if you would like your comment published or not.



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In August 2012 the first Chinese Language Edition of CCT was published in conjunction with Beijing Zenomed Scientific, Ltd. The Editorial Board is headed by Dr. Ling Han. The editorial board members are:

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Publication Headquarters:

8100 Leaward Way, Nehalem, OR 97131 USA

Mailing Address:

PO Box 444, Manzanita, OR 97130 USA
Tel: +1.301.279.2005; Fax:
+1.240.465.0692

Editorial and Subscription Offices:

16 Cove Rd, Ste. 200, Westerly, RI 02891 USA

www.CongenitalCardiologyToday.com

Publishing Management:

- Tony Carlson, Founder, President & Sr. Editor - TCarlsonmd@gmail.com
- Richard Koulbanis, Group Publisher & Editor-in-Chief - RichardK@CCT.bz
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Contact the congress secretariat or visit www.pccs2013.co.za

P.O Box 6761, Roggebaai, 8012, South Africa

Telephone: +27(0) 21 408 9796 Fax: +27(0) 21 408 9954

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