

# CONGENITAL CARDIOLOGY TODAY

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By R. Kishore Kumar, MD, FRCPC, FRACP; Arvind Shenoi, MD; Kishore Vrajananda Yerur DCH, MRCPCH; Syed Tajamul, DCH, MD; Prakash Kini, DGO, MD  
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### Medical News, Products & Information

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## Upcoming Medical Meetings

CSI Focus Innovation 2017  
Jun. 28, 2017; Frankfurt, Germany  
[www.csi-congress.org/focus-innovation.php](http://www.csi-congress.org/focus-innovation.php)

PFO 2017  
Jun. 28, 2017; Frankfurt, Germany  
[www.csi-congress.org/focus-pfo](http://www.csi-congress.org/focus-pfo)

Catheter Interventions in Congenital, Structural and Valvular Heart Disease  
Jun. 28 - Jul. 1, 2017; Frankfurt, Germany  
[www.csi-congress.org](http://www.csi-congress.org)

7th WPCPCS (World Congress of Pediatric Cardiology & Cardiac Surgery)  
Jul. 16 - 21, 2017; Barcelona, Spain  
[wpcpcs2017.org/en](http://wpcpcs2017.org/en)

CSI at UCSF - Catheter Interventions in Structural, Valvular and Congenital Heart Disease, Atrial Fibrillation and Heart Failure  
Sep. 8-9, 2017; San Francisco, CA USA  
[www.csi-congress.org/csi-ucsf.php?go=0](http://www.csi-congress.org/csi-ucsf.php?go=0)

27<sup>th</sup> International ACHD Advanced Symposium, 2017  
Sep. 14-16, 2017; Cincinnati, OH USA  
[cincinnatichildrens.org/service/a/congenital-heart/achd-annual-symposium](http://cincinnatichildrens.org/service/a/congenital-heart/achd-annual-symposium)

50<sup>th</sup> Anniversary Southeast Pediatric Cardiovascular Society (SEPCS) Conference  
Sep. 28-30, 2017; Atlanta, GA USA  
[choa.org/medical-professionals/professional-events/50th-anniversary-southeast-pediatric-cardiovascular-society-meeting](http://choa.org/medical-professionals/professional-events/50th-anniversary-southeast-pediatric-cardiovascular-society-meeting)

11<sup>th</sup> IPC Workshop  
Sep. 28-30, 2017; Milan, Italy  
[www.workshopipc.com/main.php](http://www.workshopipc.com/main.php)

## CONGENITAL CARDIOLOGY TODAY

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## Routine Pulse Oximetry Screening to Detect Critical Cyanotic Congenital Heart Disease in Neonates After Birth – A Developing Country Perspective & Experience

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### Abstract

#### Objective

Pulse Oximetry in newborns to detect the Critical Cyanotic Congenital Heart Diseases has become a standard of care in many developed countries after recent guidelines. We undertook this to see if it is feasible in Indian circumstances and also wanted to see the cost implications of the same.

#### Setting

Tertiary Maternity Hospitals in Bangalore, India.

#### Participants

All babies born above 36 weeks at the hospital and were with the mothers during the first few days – and not requiring Neonatal Intensive Care Unit (NICU) admission.

#### Main outcome measures

The economic feasibility of the results of our protocol is reviewed after 2 years.

#### Results

Screening by Pulse Oximetry was done

for a total of 22,601 neonates between June 2012 and Oct 2016 (study period). Thorough clinical examination done by the neonatologists for the 14 neonates who failed screenings revealed that three babies had a pulmonary condition requiring treatment (false positive cases) and 11 babies were investigated with an Echocardiography by a Paediatric Cardiologist. One infant had PDA with no other abnormalities, one had VSD with a small PDA, but no other abnormalities and the remaining nine infants were diagnosed with CCHD: three were found to have Transposition of Great Vessels (TGV) (3); two were found to have Total Anomalous Pulmonary Venous Drainage (TAPVD) (2); one baby was found to have Fallot's Tetralogy (TOF), one baby had VSD, ASD and Patent Foramen Ovale with pulmonary hypertension; one baby had severe pulmonary hypertension (PAH) and two babies had pulmonary stenosis (PS).

**Conclusion:** Our data shows evidence for Pulse Oximetry screening of apparently healthy newborns to become a standard of care in India like many developed countries and is very cost effective, and is affordable.

**Key Words:** Congenital Heart Disease (CHD), Critical Cyanotic Congenital Heart Disease (CCCHD), newborn, Pulse Oximetry, screening.

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# The Heart Institute at the CHILDREN'S HOSPITAL OF PITTSBURGH OF UPMC Is **EXPANDING!**

With a strategic plan for growth and expansion, the Division of Cardiology within the Heart Institute of the Children's Hospital of Pittsburgh of UPMC / University of Pittsburgh School of Medicine is recruiting five faculty positions over the next 1-3 years. All candidates must possess an MD (or equivalent) degree and be board-eligible/certified in pediatric cardiology:

## **DIRECTOR of Pediatric Electrophysiology (EP) PROGRAM**

For this leadership level position, the applicant should have expertise in the management of pediatric EP and adult congenital heart disease electrophysiology with excellent clinical, teaching and research skills. Clinical skills should include radiofrequency/cryoablation, transvenous pacemaker/AICD insertion, ventricular tachycardia ablation and complex congenital heart disease EP cases. In addition, he or she should have sufficient experience to serve as director of the EP program, working closely with division chief and hospital leadership to lead EP program development. Candidates must have completed a 4<sup>th</sup> year pediatric electrophysiology advanced fellowship. The well-established pediatric electrophysiology program is currently staffed by two experienced EP physicians and a dedicated EP RN. The EP team also works in close conjunction with the Heart-Vascular Institute of UPMC-Presbyterian adult hospital.

## **Two IMAGING FACULTY WITH EXPERTISE IN CARDIAC MRI or FETAL ECHOCARDIOGRAPHY**

We are recruiting for two imagers with a focus on FETAL echocardiography or cardiac MRI. Completion of a 4th year imaging fellowship plus skill and independence in transesophageal echocardiography is a requirement. Faculty will join an outstanding imaging team: Including twelve echocardiographers, 10 pediatric sonographers in a highly productive echo lab – with over 18,000 echocardiograms, including over 1200 fetal echo's and 550 TEE's.

Echocardiography program covers Children's Hospital, Magee Womens hospital and multiple outreach sites and a robust tele-echo program.

The cMR pediatric cardiology position is to join a partnership between cardiology and radiology. CHP has a state-of-the-art MRI facility with a new 3D lab and plans for growth adding an additional cardiac MRI scanner. Further collaboration with the adult cardiology program for ACHD cMR program is anticipated.

## **INPATIENT CARDIOLOGY – HOSPITALIST**

The division of cardiology is seeking a pediatric cardiologist with interest in inpatient cardiology – to join our pediatric cardiology hospitalist program, currently staffed by two hospitalists. Interest in clinical pathways, quality outcomes and cost-analysis research is preferred. Educational skill and passion are a must.

## **OUTPATIENT PREVENTATIVE CARDIOLOGY**

The division of cardiology is seeking a pediatric cardiologist with interest/expertise in outpatient and preventative cardiology. This position will require interest in lipidology, hypertension and work in conjunction with nephrology, endocrinology, weight management and the diabetes center. Interest and expertise in exercise physiology is preferred.

The Heart Institute provides comprehensive pediatric and adult congenital cardiovascular services to the tri-state region and consists of 23 pediatric cardiologists, 4 pediatric cardiothoracic surgeons, 5 pediatric cardiac intensivists and 8 cardiology fellows along with 12 physician extenders and a staff of over 100. The Heart institute is currently ranked 14<sup>th</sup> in the US News and World report ranking for pediatric cardiac programs. The Cardiac surgical program is one of the top in the country, with a 3-star rating from Society of Thoracic Surgery (STS) in the most recent survey.

Children's Hospital of Pittsburgh of UPMC has been named to *U.S. News & World Report's* 2015-16 Honor Roll of Best Children's Hospitals, one of only 10 hospitals in the nation to earn this distinction. Consistently voted one of America's most livable cities, Pittsburgh is a great place for young adults and families alike.

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### **What is Already Know on this Topic:**

1. Pulse Oximetry screening has been shown to improve the prognosis of early-diagnosed Critical Congenital Cyanotic Heart Disease in newborn babies.
2. Barriers to implementation include concerns about increased workload on echocardiography services.
3. Screening programs are being implemented in most developed countries.

### **What this Paper Adds:**

1. Pulse Oximetry screening does improve early diagnosis of CHD with minimal increase in cost and the burden on echocardiography services.
2. It is equally effective in improving early diagnosis of other, mainly respiratory, pathologies.
3. There is enough evidence to suggest a national recommendation for Pulse Oximetry screening in India.

Congenital Heart Disease is an important cause of death and morbidity in early childhood with a prevalence of 5-10 per 1000 live births worldwide.<sup>1</sup> One-fourth of these have major CHD (defined as requiring surgery or catheter intervention in the first year of life). In India, heart disease in young children accounts for more than 10% of all childhood deaths due to late presentation or diagnosis.<sup>2,3</sup>

Early diagnosis can prevent progression to cardiac failure, cardiovascular collapse, neurological sequelae and death.<sup>2,3</sup> Currently, screening for CHD relies on antenatal ultrasonography in the mid-trimester and post-natal clinical examination. Antenatal scans have a diagnosis rate of up to 44%, while newborn examination diagnoses less than 50% of CHD and have a false positive rate of 1.90%.<sup>4,5</sup> Pulse Oximetry screening of newborns has been shown to be a non-invasive test that increases the ability to identify infants with major CHD before clinical presentation with collapse, which may result in long-term complications.<sup>2,5</sup>

In 2012, a chain of tertiary maternity hospitals in India reviewed the published evidence of the benefit and decided to implement this practice into routine care, especially after one of their parents was upset and they alleged that we had 'missed' diagnosing their baby with CCCHD at birth. These parents were quite upset when they learned that a simple non-invasive test could have helped their baby to be diagnosed at birth instead of at the age of 2 ½ months when the baby was diagnosed because of a murmur. We present our Indian experience.

This paper describes a post-implementation review of the first 52 months of Pulse Oximetry screening of well newborns at these hospitals. The aim is to describe the implementation of the screening programme and review whether the outcomes were consistent with those described in the literature in our setting & the cost implications for doing that.

### **Methods**

The study population included all babies born at the four tertiary maternity hospitals between June 2012 and October 2016. A group of tertiary maternity hospitals (four of which are located in Bangalore (one each at Old Airport Road, Malleshwaram and

two in Jayanagar)), delivering over 5,000 babies a year, provide maternal fetal medicine service, including screening for high-risk births & cardiac screening.

### **Pulse Oximetry Screening**

Screening was initiated in June 2012, in all the 4 hospitals after deliberations of the evidence available so far in the literature and discussions among peers as to its feasibility. Pulse Oximetry screening was conducted according to the Royal College of Paediatrics and Child Health (RCPCH) recommendations by placing the pulse oximeter sensor initially on one foot, obtaining a post-ductal oxygen saturation reading, and then immediately moving the sensor to the right hand to obtain a pre-ductal oxygen saturation reading.<sup>6,7</sup> Then the other two limb saturations were also measured to increase accuracy.

### **Screening was Considered Positive If:**

1. Oxygen saturation measure is <90% (in the initial screen or in repeat screens);
2. Oxygen saturation is <95% in the right hand and foot on three measures, each separated by one hour; or
3. >3% absolute difference exists in oxygen saturation between the right hand and foot on three measures, each separated by one hour.

A neonate was categorized as having passed the screening if SaO<sub>2</sub> was more than 95% in all limbs and if the difference in SaO<sub>2</sub> was less than 3%. Screening was performed by specially trained nurses between 24 – 48 hours of age or at the time of discharge, which is usually after 48 hours. When screening was positive, the neonate underwent a thorough physical examination by a neonatologist and, if indicated, a chest radiograph and an electrocardiogram was done. If no pulmonary condition was found, the neonate was immediately referred for a complete echocardiogram by a pediatric cardiologist, as applicable.

### **Data Collection and Analysis**

The results of screening were entered into the HIS (Hospital Information System) database and stored. For this study we derived descriptive statistics for the number of babies screened, their demographics, the results of the screening, and the associated variables.

### **Ethics and IRB Approval**

The parents or guardians of each child were informed about the screening using a printed brochure prior to the screening. Ethical committee approval for retrospectively analyzing the stored screening data was obtained.

This screening was done between 24 and 48 hours of life. For babies going home on early discharge (discharge before 24 hours), the oximetry was performed prior to discharge and then repeated within the first 3-5 days by the home care team.

AGE saturation monitor with Masimo probe was fixed to the portable trolley of examination equipment, which was used for newborn examination. At the start of the examination, a reusable probe was attached to one foot of the baby with disposable tape (one-inch

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self-adherent wrap manufactured by 3M); the oximeter was switched on and oxygen saturation documented when the reading stabilized with a strong plethysmographic signal. This typically took between 2 and 4 min. This post-ductal saturation was entered into the hospital clinical records, and also was recorded in the parent-held baby booklet – a personal health record given by the hospital. The probe was cleaned between babies with 70% isopropyl alcohol wipes.

The screening protocol is shown in Figure 1. If the post-ductal saturation was 95% or more, the result was assigned as a pass. Readings between 90% and 95% lead to a repeat saturation measurement in the next 2 to 6 hours. If the post-ductal saturation remained below 95% on repeat testing, the baby was reviewed by a senior neonatologist without waiting for a repeat test.

The hospital electronic, clinical database was searched for all saturation readings performed since commencement of the screening programme. Medical records were searched if further information was needed. Information was collected on the oxygen saturation, the subsequent management, review by senior neonatologist, further management and need for echocardiography. We calculated the sensitivity, specificity, positive and negative predictive values, and a false positive rate.

## Results

There were a total of 22,821 babies born after 36 weeks in the study period. Of these, 22,601 babies had saturation screening performed. Of the 220 babies not screened, 207 had been admitted to the nursery and did not qualify for screening, as per our criteria. Screening was missed in a further 12 babies {not performed because of non-consent by parents (11), performed but not recorded (1)}. Of the 22,601 babies screened, 22,579 (99.9%) passed the test, and 22 babies (0.1%) were referred. These were babies who had failed the screening protocol, as their initial saturations were difficult to obtain for whatever reason or was <90% or 90-95% on two occasions. Of the 22 cases who were referred, repeat saturation monitoring after a few hours was normal in eight babies and abnormal in 14 babies. Of the 14 babies with abnormal saturations, an examination by a neonatologist found that three had low saturations secondary to a previously unrecognized pulmonary cause, which was diagnosed following review - these included persistent pulmonary hypertension of the newborn in one, Transient tachypnea of newborn in one and congenital pneumonia with sepsis in the other.

The other 11 babies who failed oxygen saturation screening underwent a detailed

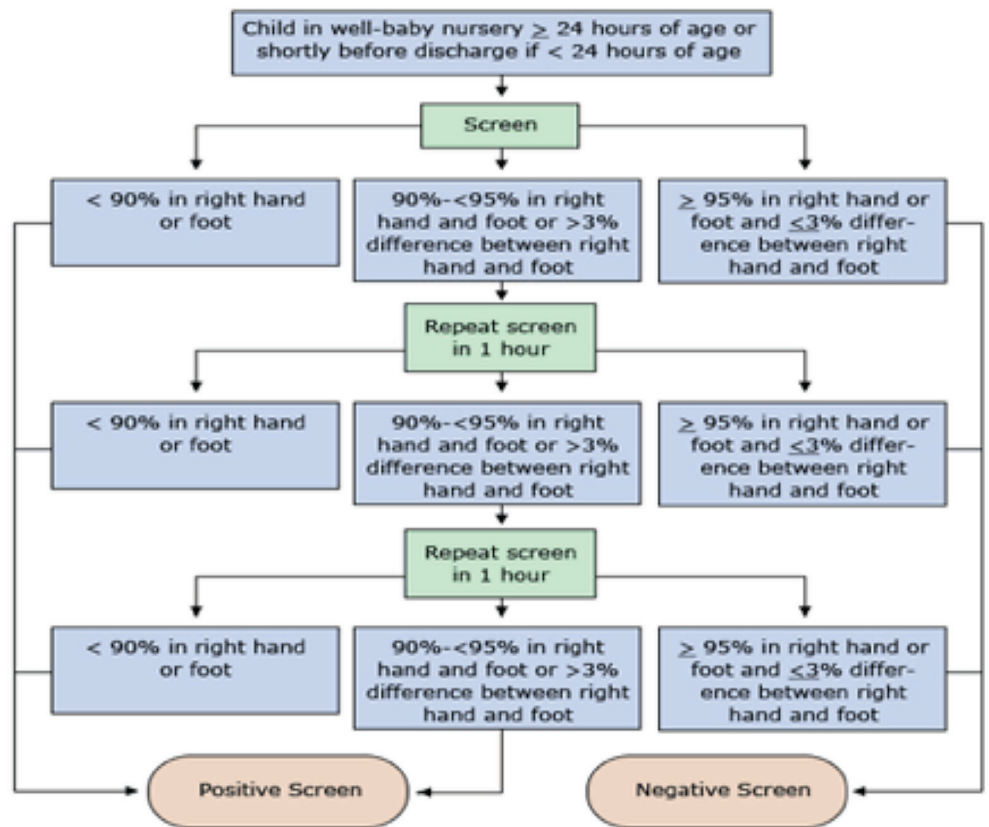


Figure 1: Screening protocol.

echocardiography by the Paediatric Cardiologist and one infant had PDA with no other abnormalities, one had VSD with a small PDA, but no other abnormalities and the remaining nine infants were diagnosed with CCHD, three were found to have Transposition of Great Vessels (TGV) (3), two were found to have Total Anomalous Pulmonary Venous Drainage (TAPVD) (2), one baby was found to have Tetralogy of Fallot's (TOF), one baby had a VSD, a ASD, and Patent Foramen Ovale with Pulmonary Hypertension, one baby had severe pulmonary hypertension (PAH) and two babies had pulmonary stenosis (PS).

Among these 11 infants, five had been picked up by antenatal scans by our Foetal Medicine specialists in the anomaly scans. All the infants were followed up by the Paediatric Cardiologist and five were referred for emergency cardiac surgery. Three underwent surgery on the 3<sup>rd</sup> Day of Life (DoL), and are currently alive and thriving. One underwent surgery on Day 7, and is currently doing well. The other underwent surgery on the 9<sup>th</sup> DoL, but unfortunately, died from post-surgical sepsis.

Analyzing the accuracy of Pulse Oximetry screening in the detection of major CHD, the sensitivity was 89%; specificity was 99.8%; positive predictive value was 0.6% and a negative predictive value

was 99.9%. The false positive rate was 0.13%. The routine use of Pulse Oximetry screening in a maternity hospital with over 5,000 deliveries per annum resulted in three extra ultrasounds of structurally normal hearts over the first 52 months.

## Discussion

This is the first Pulse Oximetry screening series from India and included 22,601 neonates. Pulse Oximetry screening of healthy newborns provided early alerts to diagnose - life-threatening conditions, both cardiac and respiratory. Successful Pulse Oximetry screening needs appropriate equipment and training. Our study showed similar accuracy to those reported in the recent meta-analysis of 13 studies, which showed a sensitivity of 76.5%, specificity of 99.5% and a low false positive rate of 0.14%.

The 11 cases with major CHD who were identified by Pulse Oximetry were all identified prior to discharge from our service with the clinical alert in all being triggered by the saturation reading, and though our foetal medicine experts had picked up five cases antenatally. All 11 cases would probably have been discharged without a diagnosis, had this been in a rural setting without foetal medicine specialists. The timely management of these cardiac conditions was vital in optimizing the prognosis for these babies.

We took a pragmatic approach at implementation into the current practice of Pulse Oximetry as one more test in normal newborn examination. The programme did involve employing one extra nurse, and the average procedure time estimated was 8-12 minutes. The main financial costs were the salary for the nurse at Rs. 15,000 per month and the purchase of GE pulse oximeters with Masimo probes at an approximate cost of Rs. 50,000 each (though as per new NRP guidelines all maternity hospitals need to have this as part of their NRP guidelines).

The false positive rate was extremely low in our study, which was consistent with the rest of the literature. 'False positive' is really a misnomer in the context of this test. This test is screening for hypoxaemia, which is never normal in a newborn baby. Such hypoxaemia has many causes, just one of which is CHD, and early detection of these other causes can be just as important. Overall, in a published series of 'false positive' cases (e.g. those with low saturations, but a normal heart), about 50% will have some other pathology. The study of Grenelli et al showed a low false-positive rate of 0.17% and that 31/69 'false-positives' had other pathology. Our data are consistent with this as three of 14 cases (21%) with low saturations and a normal heart that had previously unrecognised respiratory pathology, some of which was serious and in which timely management was equally important.

There was just one case of significant CHD identified that was not diagnosed prior to discharge. This was the baby with a large VSD, as this complied with our definition of CHD (need for surgery in the first year of life). Parents were upset that this was not diagnosed despite delivering in a tertiary centre and doing all the tests. We identified it as a false-negative case, but saturation screening would not be expected to detect an acyanotic congenital heart lesion at birth. It is a limitation of this study.

In the face of consistent evidence of the benefits of this test, it is reasonable to ask why implementation has been slow in India. The main barriers referred (in informal discussions) in meetings were lack of echocardiography availability, increased workload for paediatric cardiology services and paediatric registrars, cost of equipment or concerns about the validity/usefulness of screening and the low rate of positive screens. These barriers are consistent with those described in the 2012 survey of UK practice published by Singh and Ewer.<sup>8</sup> We have looked at these concerns and in the context of our experience have tried to answer them here.

- 1. Staffing and equipment cost:** This was implemented in our services with the need for one additional nursing staff – but this nurse was also involved in administering BCG vaccine to the babies and also conducting the hearing test for the newborns. There are relatively minor equipment costs as previously detailed. The total cost to be invested is around Rs. 80,000 per 2 years – and even if it is charged at Rs. 50 per baby (less than \$1 per baby) – the cost will be “recovered” with 1,600 deliveries!
- 2. Paediatric cardiology and false positive rates:** The main concern is paediatric cardiologists' availability and increased burden on echocardiography services. Notwithstanding, most 'false positive' have some other significant pathology. The false positive rate for CHD in this study, as in the rest of the literature, is extremely low.
- 3. Lack of availability of echocardiography.** A low saturation screen is not a trigger for an immediate referral for echocardiography. Rather, it should trigger a clinical review by an experienced neonatologist, appropriate investigations and possibly a period of observation. If the clinical pointers are towards CHD or no other cause can be found, then a referral for echocardiography should be requested. At our hospital, we have facilities for paediatric cardiology services with less

## Advanced Practitioner - Pediatric Interventional Cardiology – Charlotte, NC

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Named a Best Children's Hospital in cardiology and heart surgery by *US News & World Report*, Levine Children's Hospital and Sanger Heart & Vascular offer the most advanced and most complete pediatric heart care in the region. Due to growth, we are seeking an experienced Pediatric Nurse Practitioner and/or Physician Assistant to join our team!

**Position Details:** The Pediatric Nurse Practitioner/Physician Assistant in Pediatric Interventional Cardiology works in collaboration with the supervising physician and assists in performing diagnostic and interventional procedures for cardiology patients with critical acuity. The ACP will work with our two interventionalists and one transplant cardiologist and be the liaison between the Pediatric Cardiologist, patients and families and staff. Our new state of the art two Cath Lab suite opened in February 2017 right beside our CVICU. The cath lab volume has been growing at a rate of 10-15% per year, and we will be developing a 3-D printing program in the next 6 months. Active industry sponsored research is ongoing, affording many opportunities for clinical research projects.

**Responsibilities include but not limited to:**

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- Provide education and support for Pediatric Interventional Cardiology patients and their families
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**For more information, please email your interest and CV to:**

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than 4 hours notice. Also, elective referral to a Paediatric Cardiologist is better than a collapsed baby with CCCHD.

- 4. Workload:** This was a concern when we first implemented, and for this reason, we incorporated screening into the routine newborn examination and employed one dedicated paediatric nurse to do the test. Once the benefits were seen, there was quick acceptance amongst the staff & obstetricians regarding the value of this test, and this played an important role in promotion of the test.

## Director of Pediatric Electrophysiology

The Congenital Heart Center at Levine Children's Hospital (LCH) and **Sanger Heart & Vascular Institute** (SHVI), seeks to recruit a **Director of Pediatric Electrophysiology** to join their existing faculty. Responsibilities for this position will include diagnostic and therapeutic electrophysiology studies, pacemaker and defibrillator implantation, as well as *general cardiology* outpatient and inpatient care with shared night / weekend call.

- Candidates will have completed an ACGME accredited fellowship in pediatric cardiology and be BC/BE by the American Board of Pediatrics. A fourth year of additional training in pediatric electrophysiology is required.
- A Minimum of 5 years of independent experience is preferred.

The Congenital Heart Center, established in 2010, has been ranked as one of the top-50 pediatric heart centers in the country by U.S. News and World Report for the last three years. Our comprehensive services include cardiac imaging, diagnostic and interventional catheterization, electrophysiology, dedicated cardiovascular intensive care staff, and regional referral programs in heart failure / transplantation, adult congenital heart disease, and fetal echocardiography. Surgical and cardiac catheterization volume have been growing at a rate of 12-15% per year over the last six years. Our new state of the art two lab cardiac catheterization and electrophysiology suite opened in February of 2017, with dedicated staffing and anesthesia teams. The interventional cardiac catheterization program is active in industry sponsored clinical research. Participation in investigator initiated and multi-center studies is ongoing within the Heart Center, with the support of an active clinical research department.

LCH and SHVI are both premier referral facilities within the Carolinas HealthCare System (CHS), one of the nation's leading and most innovative healthcare systems. CHS operates nearly 2,500 system-employed physicians, more than 60,000 employees and more than 7,460 licensed beds across the Carolinas.

For more information about this opportunity, please email your interest and CV to:

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5. **Cross-infection risk:** We adopted a pragmatic approach with re-useable probes and cleaning between patients. The cost is a fraction of what it would be to use disposable probes. There were no cross-infection issues that we are aware of during or since the period of this review.
6. **Discharge delay:** This has not been a concern in our set-up because the screening was incorporated seamlessly into our baby checks & BCG vaccination after 24 hours. This will clearly vary between services depending on the availability of nursing staff.

The optimal timing of screening remains a controversy. Earlier screening (<24h) results in more false positives, but many of these are important non-cardiac pathology. A late screening results in a lower false-positive for CHD and may be more accurate for diagnosis of obstructive left heart lesions, particularly Coarctation of the Aorta. Prudhoe et al showed that Pulse Oximetry is relatively insensitive in detection of coarctation of aorta/interrupted aortic arch (95% Confidence Interval (CI) 24-50%) and TOF (95% CI 24-58%). The AAP recommends screening at 24-48 h. We implemented this as 'late' screening for largely pragmatic reasons. Thus, since 2012, all babies have a saturation measure on the post-natal ward performed by the trained paediatric nurse after 24 hours of birth.

There is increasing evidence to justify Pulse Oximetry screening as the standard of care.<sup>9,10,11,12,13</sup> As a screening tool, Pulse Oximetry fulfills the requirements. It is inexpensive and easy to use with a low false positive rate, allows diagnosis of an important disease process (CCCHD) which has a defined natural history, a suitable confirmatory test, and is treatable. In 2011, the US Health and Human Services Secretary recommended that Pulse Oximetry screening be added to the Recommended Uniform Screening Panel. In the UK, there remains a wide variation in practice mainly due to a difference in timing of screening. We believe that apart from detecting CCCHD, Pulse Oximetry screening also picks up other important pathology which was previously categorized to be 'false positive'. In our study of the 14 babies with abnormal saturations, 11 had cardiac disease, and the three 'false-positive,' actually had unrecognised pulmonary pathology.

## Conclusions

This post-implementation review shows that Pulse Oximetry screening can be introduced into Indian practice with minimal cost and minimal extra burden to echocardiographic services. Our findings mirror those in the rest of the literature with cases of major CCCHD that might have been missed, being diagnosed prior to discharge.<sup>12</sup> The 'false-positive' rate is extremely low, but the term 'false-positive' is a misnomer in this context as over half of these babies had some other pathology. This screening practice should be seen as a test of neonatal well-being, not just for CHD, and should become a standard of care in India, especially now with new IAP NNF NRP guidelines, saturation monitoring at birth has become mandatory; there is no reason why this cannot be done.

For obstetricians this is even more important since they are concerned about the survival of the baby and both mother & baby being normal – this gives extra confidence as one cannot diagnose CCCHD otherwise at birth. This being an inexpensive test and no other new equipment is required, all obstetricians should make it mandatory for their babies to undergo this test which will go a long way to achieve our Millennium Development Goals (MDG) in reducing our infant mortality and help India achieve the goals.

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Dr. R. Kishore Kumar: conceptualized and designed the study, drafted the initial manuscript, and approved the final manuscript as submitted. Dr. Arvind Shenoi: Dr. Shenoi carried out the initial analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted. Drs. Kishore Yerur, Prakash Kini and Syed Tajamul were involved in collecting data, and approving the final manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Nationwide Children's Hospital is the primary pediatric teaching facility for The Ohio State University in Columbus, Ohio. The Heart Center, a top 10 USNWR program, embraces a culture of patient safety and quality, transparency, value-based care, public health awareness, excellence in education and engagement in translational/outcomes research. Our program is closely partnered with the Center for Cardiovascular Research at the NCH-Research Institute which provides infrastructure to support the clinical research enterprise. Along with the independent and mentored trainee clinical research expected with this position, additional research opportunities include engaging in translational research, and developing research-based quality improvement initiatives. The Heart Center is also part of the Congenital Heart Collaborative between University Hospitals Rainbow Babies & Children's Hospital (Cleveland, OH) and Nationwide Children's Hospital heart programs which provides additional opportunity for collaborative research.

#### Candidates may submit their curriculum vitae by mail or email to:

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Fellowship,  
[John.Kovalchin@nationwidechildrens.org](mailto:John.Kovalchin@nationwidechildrens.org)

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

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

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# Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

## First Implant of Harmony™ Transcatheter Pulmonary Valve in Clinical Study

Nationwide Children's Hospital today announced its first implant of the Medtronic Harmony™ Transcatheter Pulmonary Valve (TPV)—an investigational heart valve designed to help patients with Congenital Heart Disease (CHD)—as part of a new clinical study that will evaluate the valve's safety and effectiveness. The procedure was performed at Nationwide Children's by John P. Cheatham, MD, George H. Dunlap Endowed Chair in Interventional Cardiology and Co-Director of The Heart Center at Nationwide Children's.\*

Congenital Heart Disease (CHD) is the most common type of birth defect in the United States, affecting an estimated 40,000 infants each year.<sup>1,ii</sup> There are many different types of CHD, including abnormalities in the structure of the heart and pulmonary artery/valve. After surgical correction of these defects, ie. Tetralogy of Fallot, the pulmonary valve is altered or removed, resulting in severe leakiness of the valve. Severe pulmonary valve regurgitation symptoms may occur, ranging from mild to severe, from tiredness or shortness of breath to fatigue, dizziness or weakness while performing normal activities. It can also lead to irregular heartbeats, chest pain or fainting (syncope).

For CHD patients born with pulmonary artery/valve abnormalities who undergo a surgical repair early in life, the Harmony TPV is designed to provide a less invasive option to restore normal valve function later in life. Currently, the only approved option in the United States for these patients is an open heart surgical valve replacement.

The Harmony TPV therapy builds off of the Medtronic Melody TPV technology, which has been implanted in more than 10,000 patients worldwide. The Melody TPV was designed for patients with a failing right-ventricular-to-pulmonary-artery valved conduit,

which accounts for only about 23% of this patient population. The Harmony TPV Clinical Study is expected to enroll 40 patients across approximately 10 centers in the United States and Canada, and if successful, can potentially serve ~ 77% of this patient population.

"We are honored to be the first site to implant this device, both in the past Early Feasibility Study and now as part of this pivotal clinical trial," said Dr. Cheatham.

Named to the Top 10 Honor Roll on *U.S. News & World Report's* 2016-17 list of "America's Best Children's Hospitals," Nationwide Children's Hospital is one of America's largest not-for-profit freestanding pediatric healthcare systems providing wellness, preventive, diagnostic, treatment and rehabilitative care for infants, children and adolescents, as well as adult patients with congenital disease. Nationwide Children's has a staff of more than 11,000 providing state-of-the-art pediatric care during more than 1.2 million patient visits annually. As home to the Department of Pediatrics of The Ohio State University College of Medicine, Nationwide Children's physicians train the next generation of pediatricians and pediatric specialists. The Research Institute at Nationwide Children's Hospital is one of the Top 10 National Institutes of Health-funded freestanding pediatric research facilities. More information is available at [NationwideChildrens.org](http://NationwideChildrens.org).

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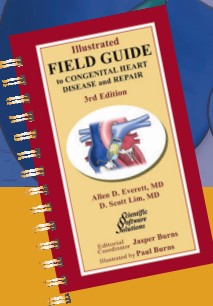
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## Coffee Shops, ATMs May Be Ideal Locations for Lifesaving AEDs

Community coffee shops and automated teller machines, or ATMs, might be ideal locations for public access to Automated

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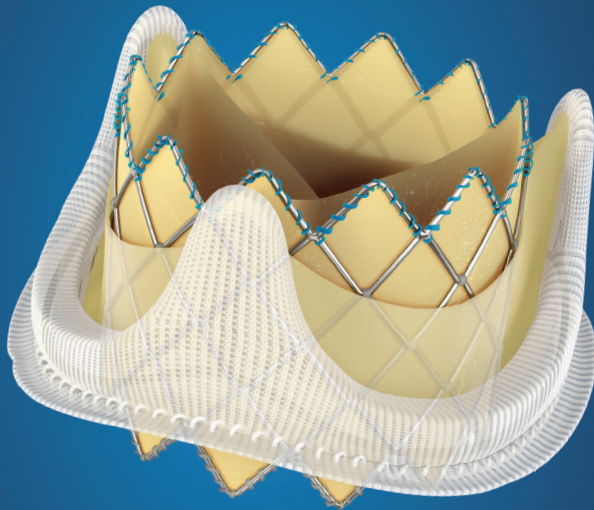
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## Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System

### Important Labeling Information for the United States

**Indications:** The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has  $\geq$  moderate regurgitation, and/or a mean RVOT gradient  $\geq$ 35 mm Hg.

**Contraindications:** None known.

### Warnings/Precautions/Side Effects:

- DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

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

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

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

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

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Not approved in Canada for use in failed surgical bioprosthetic pulmonary valves.

### Magnetic Resonance Imaging (MRI) Safety Information



Nonclinical testing and modeling has demonstrated that the Melody™ TPV is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3 T
- Maximum spatial gradient magnetic field of 2500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (Normal Operating Mode)

Based on nonclinical testing and modeling, under the scan conditions defined above, the Melody™ TPV is expected to produce a maximum in vivo temperature rise of less than 2.1°C after 15 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. In nonclinical testing, the image artifact caused by the device extends approximately 3 mm from the Melody™ TPV when imaged with a spin echo pulse sequence and 6 mm when imaged with a gradient echo pulse sequence and a 3 T MRI System. The lumen of the device was obscured.

Scanning under the conditions defined above may be performed after implantation.

The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters.

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External Defibrillators (AEDs), according to new research in the American Heart Association's journal *Circulation*.

An Automated External Defibrillator (AED) is a computerized medical device that can check a person's heart rhythm, recognize a rhythm that requires a shock and advise the rescuer when a shock is needed. The AED uses voice prompts, lights and text messages to tell the rescuer the steps to take.

Placement of AEDs in communities is an ongoing effort to provide access to these lifesaving devices to bystanders, so they can help people who suffer an out-of-hospital cardiac arrest.

To determine where best to place AEDs in the community, researchers studied different businesses and municipal locations in Toronto, Canada. They ranked the businesses and other locations according to how many cardiac arrests occurred within 100 meters of the locations, and when they were open.

"We found that coffee shops and ATMs ranked highly across several related metrics, and that those rankings were stable over the years," said Timothy C.Y. Chan, PhD, study author and Canada Research Chair in Novel Optimization and Analytics in Health, University of Toronto in Canada.

### Among the Findings

There were 2,654 publicly located, non-traumatic out-of-hospital cardiac arrests in Toronto from Jan. 2007 to Dec. 2015. Coffee shops from three major chains and ATMs from the five largest Canadian banks occupied eight of the top 10 spots for out-of-hospital cardiac arrest in Toronto and its Downtown area. The rankings remained stable over time. "What this means is that health organizations, foundations and policymakers aiming to develop public access defibrillator programs could use our rankings to identify promising businesses to develop partnerships for AED deployment," Chan said. "Ultimately, we want to get AEDs in the right locations, so they are accessible when needed most."

### Children's Hospital of Pittsburgh of UPMC's 2017 Master Class to Focus on Univentricular Heart

This year's course - the tenth annual - will focus on the congenital malformations of the ventricular septum and great arteries, including sessions on VSD, transposition, TOF, DORV, and isomerism. This activity has been approved for AMA PRA. *The 2017 Master Class in Congenital Cardiac Morphology* will be held at Children's Hospital of Pittsburgh of UPMC on October 11, 12 and 13, 2017.

"We have been very lucky to have Bob Anderson return to his "roots" to co-host this course. Many may not realize that Professor Anderson did much of his seminal work in congenital cardiac morphology here at Children's Hospital of Pittsburgh. The Pittsburgh archive is one of the best in the world - it's a treasure for all of us! The Master Class has been incredibly successful over the years. We have expanded lectures to include morphology, imaging and clinical topics which really round out our understanding of the congenitally malformed heart. This conference is especially suitable for trainees and all of those interested in congenital cardiac morphology," said Vivek Allada, MD, Co-Director of Children's Heart Institute, one of the event sponsors.

Now in its tenth year, the annual event draws an international audience ranging from cardiologists, surgeons, and cardiac interventionists to nurse practitioners, medical students, device makers, and medical sonographers. Held at the John G. Rangos Sr. Conference Center, located on Children's campus, the event is co-sponsored with Children's Department of Pediatric Pathology and the University of Pittsburgh School of Medicine's Center for Continuing Education in the Health Sciences.

Featuring multiple lecturers, the event will be again moderated by Robert Anderson, MD, FRCPath, visiting Professor of Pediatrics, Medical University of South Carolina (MUSC). This year's sessions will spotlight ventricular Septal Defects, Tetralogy of Fallot, Transposition of

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I hope you will consider joining the CHiP Network and help foster a strong congenital heart care community.

Sincerely,

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



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the Great Arteries, Double Outlet Right Ventricle, and isomerism with Atrioventricular Septal Defect.

Through the program, participants will receive a multimodal look at all aspects of the developing heart using the latest imaging technologies (3D echocardiography and CT angiography) and hands-on demonstrations of pathologic specimens of each lesion. In addition, developmental embryology, clinical treatment for both cardiac catheterization and cardio-thoracic surgery will be covered in depth.

"The strength of the course is that it gives a sound fundamental basis for the understanding of Congenital Heart Disease," said Allada, adding, "The survival for congenital heart disease has vastly improved over the past decade, and much of that can be attributed to the work of people like Professor Anderson giving us a greater understanding of how the heart is malformed and how we can best treat it."

Registration details will be provided online at [www.chp.edu/MasterClassCCM](http://www.chp.edu/MasterClassCCM) in June, with enrollment limited to 75. This activity has been approved for AMA PRA Category 1 Credit™. The University of Pittsburgh is an affirmative action, equal opportunity institution.

For more information, contact Lynda Cocco, 412-692-3216, at the Heart Institute at Children's Hospital of Pittsburgh of UPMC.

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- Optionally, a picture of the author(s) may be submitted.
- No abstract should be submitted.
- The main text of the article should be written in informal style using correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts will be published within 1-3 months of receipt. Abbreviations which are commonplace in pediatric cardiology or in the lay literature may be used.
- Comprehensive references are not required. We recommend that you provide only the most important and relevant references using the standard format.
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# Congenital Cardiac Care Providers in North America at Hospitals That Offer Open Heart Surgery for Children

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