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Diagnostic Utility of the EKG in Newborns with Hypoplastic Left Heart Syndrome

By Juan N. Aliaga, BS; Tabitha G. Moe, MD; Kelly M. McDonnell, DO; Rhonda A. Bitinis, DO; and Edward K. Rhee, MD

Abstract

Objective

Hypoplastic Left Heart Syndrome is Critical Congenital Heart Disease (CCHD). Early detection is essential to guide further imaging and treatment. The purpose of this study was to identify electrocardiographic markers that may aid with early diagnosis.

Design, Setting, and Patients

Electrocardiograms of thirty-two patients in an urban tertiary care hospital with known Hypoplastic Left Heart Syndrome were age and gender matched in a 2:1 ratio to normal patients. Standard intervals were recorded, including: heart rate, PR interval, QRS duration (QRSd), corrected QT interval, axis (P, QRS, T-wave), and precordial lead voltages.

Outcome Measures and Results

QRS duration, S-wave voltage in lead V1, and heart rate were found to be statistically significant in predicting patients with HLHS. QRS duration of greater than 60 msec was highly correlated with identification of Hypoplastic Left Heart Syndrome.

Conclusions

QRS duration greater than 60 milliseconds is 91% sensitive and 92% specific to separate HLHS patients from age-matched controls. Twelve-lead EKG is inexpensive, readily available, and should be added to the newborn cardiovascular screening armamentarium.

Keywords: Hypoplastic Left Heart Syndrome, Newborn Screening, EKG

Introduction

Hypoplastic Left Heart Syndrome (HLHS) is one of the Critical Congenital Heart Diseases (CCHD) currently accounting for approximately 20%-25% of infant mortality attributed to Congenital Heart Disease.¹ The current incidence rate of HLHS is 0.016 to 0.036% of all live births within the general newborn population.² Annually, it is estimated that in the United States, 2100 infants are effectively diagnosed at initial cardiac screening.¹

Typically, HLHS is characterized by underdevelopment of the left heart, including severe hypoplasia of the left ventricle, with associated atresia, stenosis and hypoplasia of the mitral and/or aortic valves, as well as the ascending aorta and aortic arch.³ The current gold standard in diagnostic testing for HLHS is a screening echocardiogram. HLHS may be identified early during fetal ultrasound; however, in many instances the prenatal and newborn examinations will fail to properly detect the lesions associated with congenital heart defects, particularly in areas with limited resources. Identifying a significant marker within a routinely available, cost-effective screening test is significant and has the potential to be useful in practice. Electrocardiographic evaluation has served as a quick, relatively inexpensive tool in the diagnosis of cardiac conditions in pediatric and adult settings at all levels of care. A 12-lead electrocardiogram (EKG) has limited specificity in diagnosing congeni-

“Annually, it is estimated that in the United States, 2100 infants are effectively diagnosed at initial cardiac screening.¹”



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tal heart disease; it can serve as an additional tool for early recognition of congenital heart defects.

Current newborn cardiac screening recommendations include auscultation, four-limb comparison oxygen saturation,⁴ and four-limb comparison sphygmomanometry. These routine screening tests guide practitioners to additional investigations if abnormalities are detected. Screening tests for CCHD can be performed by a community provider, are cost-effective, and widely available. None of these will exclude the presence of HLHS.⁵

The purpose of this case-controlled study is to evaluate the diagnostic utility of the 12-lead EKG in HLHS patients by identifying statistically significant electrocardiographic markers for HLHS. In addition, a quantitative comparison of EKG interpreting accuracy between an experienced specialist versus a novice pediatric resident was evaluated in order to develop further investigation of different factors affecting EKG evaluation in the pediatric care setting.

Methods

Between February 2005 and October 2008, 32 newborns with HLHS were evaluated at St. Joseph's Medical Center

Table 1. The Mean Values and Standard Deviation for Each Measured Variable Between the Control and HLHS Groups. Heart Rate, PR Interval, QRS Duration, QT Interval, S Wave Voltages in V1, V2, V5, V6		
	HLHS Group Mean (SD)	Control Group Mean (SD)
Heart Rate (bpm)	153.7 (17)	133.1 (17.6)
PR Interval (msec)	96.7 (46.6)	100.8 (12.8)
QRS Duration (msec)	68.3 (10.9)	54.2 (5.6)
QT Interval (msec)	258.7 (36.8)	282.6 (32.3)
S-Wave in V1 (mV)	1.2 (1.5)	4.8 (4.8)
S-Wave in V2 (mV)	6.2 (6.1)	11.8 (6.8)
S-Wave in V5 (mV)	8.6 (4.8)	5.2 (3.8)
S-Wave in V6 (mV)	6.8 (4.6)	3.3 (2.8)

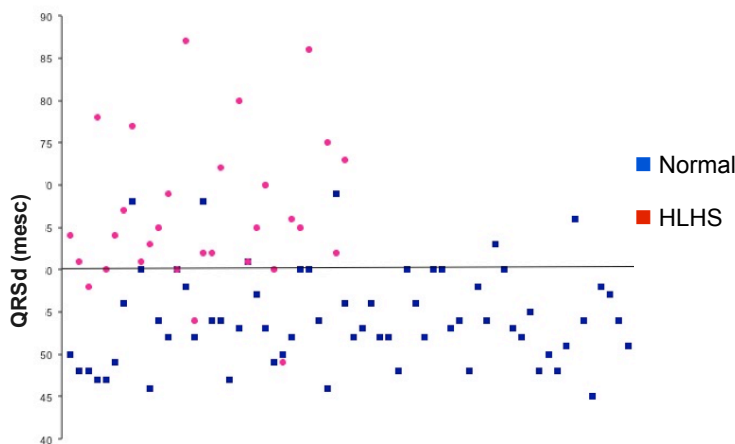


Figure 1. QRS Duration

in Phoenix, Arizona. Twelve-lead EKG tracings from known HLHS patients were matched at a ratio of 2:1 to EKGs of normal, age and gender-matched newborns (n=64). Standard intervals from HLHS and normal EKGs were recorded, including: heart rate, PR interval, QRS duration, corrected QT interval, axis (P, QRS, T-wave), and precordial lead voltages. Measurements were performed manually and then evaluated for statistical significance.

The analysis of measured and scored data was done using a two-tailed, two-sample unequal variance Student T-test. Mean, median, maximum and minimum values were calculated for each variable, as well as their respective standard deviations.

A receiver operating characteristic curve (ROC curve) was derived from our data in order to determine the accuracy of EKG-measured variables in helping to diagnose HLHS in the clinical setting.

The reader's overall impression (normal vs. abnormal) was also calculated for HLHS and normal newborns. All diag-

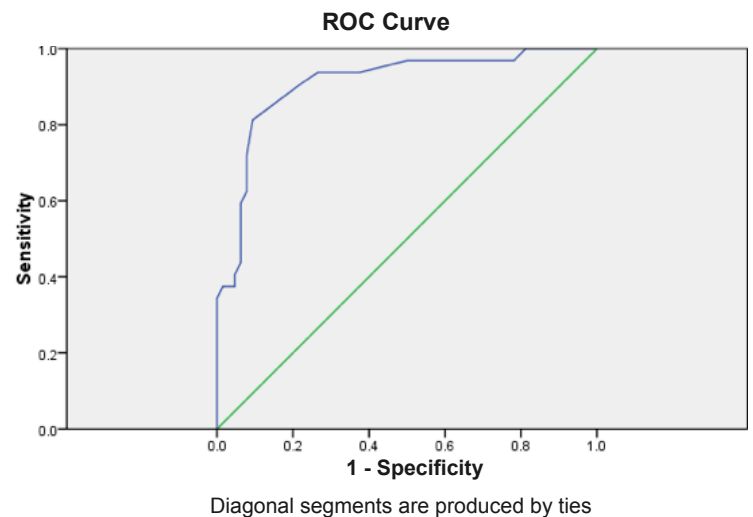


Figure 2. QRS Duration

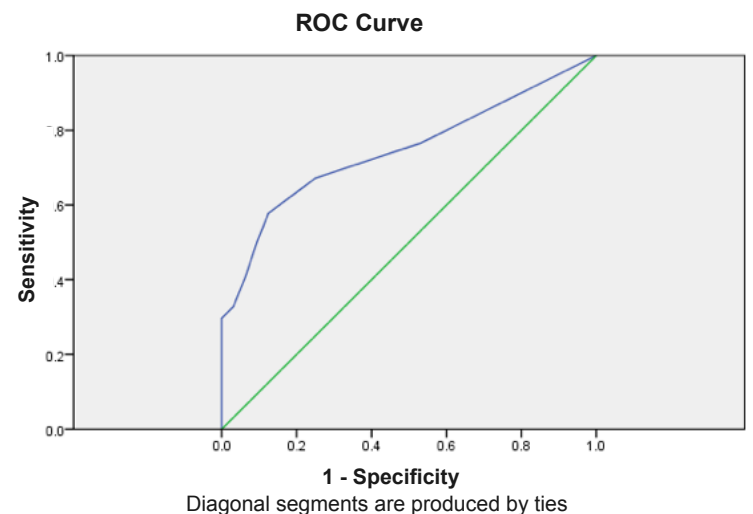


Figure 3. S-Wave in V1

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR	+PV	-PV
>=45	100.00	89.0 - 100.0	0.00	0.0 - 5.7	1.00		33.3	
>48	100.00	89.0 - 100.0	18.75	10.1 - 30.5	1.23	0.00	38.1	100.0
>49	96.87	83.7 - 99.5	21.87	12.5 - 34.0	1.24	0.14	38.3	93.3
>53	96.87	83.7 - 99.5	50.00	37.2 - 62.8	1.94	0.062	49.2	97.0
>54	93.75	79.2 - 99.1	62.50	49.5 - 74.3	2.50	0.10	55.6	95.2
>60 *	81.25	63.6 - 92.7	90.62	80.7 - 96.5	8.67	0.21	81.2	90.6
>65	43.75	26.4 - 62.3	93.75	84.7 - 98.2	7.00	0.60	77.8	76.9
>69	34.38	18.6 - 53.2	100.00	94.3 - 100.0		0.66	100.0	75.3
>95	0.00	0.0 - 11.0	100.00	94.3 - 100.0		1.00		66.7

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR	+PV	-PV
< 0	0.00	0.0 - 11.0	100.00	94.3 - 100.0		1.00		66.7
<=0	46.88	29.1 - 65.2	76.56	64.3 - 86.2	2.00	0.69	50.0	74.2
<=1	75.00	56.6 - 88.5	67.19	54.3 - 78.4	2.29	0.37	53.3	84.3
<=2 *	87.50	71.0 - 96.4	57.81	44.8 - 70.1	2.07	0.22	50.9	90.2
<=3	90.62	75.0 - 97.9	50.00	37.2 - 62.8	1.81	0.19	47.5	91.4
<=4	93.75	79.2 - 99.1	40.63	28.5 - 53.6	1.58	0.15	44.1	92.9
<=5	96.87	83.7 - 99.5	32.81	21.6 - 45.7	1.44	0.095	41.9	95.5
<=6	100.00	89.0 - 100.0	29.69	18.9 - 42.4	1.42	0.00	41.6	100.0
<=19	100.00	89.0 - 100.0	0.00	0.0 - 5.7	1.00		33.3	

nostic evaluations were performed by experienced (pediatric cardiologist) and novice (second-year pediatric resident) EKG readers for comparison purposes.

Results

QRS duration, S-wave voltage in lead V1, and heart rate were found to be statistically significant in predicting patients with HLHS. QRS duration was the most statistically significant variable with a significantly longer duration in HLHS patients than the control group (68.3 +/-10.9 vs. 54.2 +/-5.6 msec) $p = <0.001$, followed by S-wave voltage in V1 (1.2 +/-1.5 vs. 4.8 +/-4.8 mV) $p = <0.001$, and faster heart rate (153.7 +/- 17 vs. 133.1 +/-17.6 bpm) $p = <0.001$ (Table 1). Plotting of the raw data showed a clear and well-defined separation in the values of QRS duration between the control group and the HLHS group (Figure 1). Constructed ROC curves (Figures 2 and 3) show the theoretical

optimal cutoff values derived for each of the significant variables with value of 60 msec for QRS duration (sensitivity 81.3%, specificity 90.6%, negative predictive value 90.6%) and an optimal cutoff voltage value of 2 mV (sensitivity 57.8%, specificity 87.5%, negative predictive value 90.2%) for S wave amplitude in lead V1 (Tables 2 and 3). The area under the ROC curve evaluating the usefulness of QRS duration in predicting HLHS patients was 0.909 (95% CI 0.843 – 0.974). The area under the ROC curve evaluating the usefulness of S-wave amplitude in V1 in predicting HLHS patients was 0.746 (95% CI 0.650 – 0.843). Calculated values for sensitivity and specificity are 91% and 92% respectively when using QRSD values to separate HLHS patients from normal.

The evaluation of diagnostic ability between an experienced specialist versus a novice resident was found to be significant, with the experienced specialist having more specificity and

“The evaluation of diagnostic ability between an experienced specialist versus a novice resident was found to be significant with the experienced specialist having more specificity and the pediatric resident more sensitivity in regard to their interpretation of the 12-lead EKGs in the study.”

the pediatric resident more sensitivity in regard to their interpretation of the 12-lead EKGs in the study. The experienced EKG reader identified 72% of EKGs from HLHS patients; however, 13% of normal patients had abnormal EKG readings. Novice EKG reader identified 75% of EKGs from HLHS patients; however the novice reader identified 20% of EKGs from normal patients as abnormal.

Discussion

There are some EKG findings that are typically seen with HLHS, such as right ventricular hypertrophy (RVH) and paucity of left ventricular forces;⁶ however, these findings can be typical in newborns. QRS duration has now been identified as a significant marker in differentiating HLHS from normal; as a result, the evaluation of QRSD values in a 12-lead EKG can complement the rest of the clinical findings during assessment. It is reasonable to utilize these measured variables as an effective way to screen or evaluate suspected HLHS patients in instances where the availability of echocardiography is limited or delayed.

Considering that the mortality rate of HLHS is the highest among all congenital heart defects and that in many instances, up to 14% of cases can go undiagnosed before death,⁷ identifying a low-cost, efficient, screening test is of great importance. Electrocardio-

graphic characteristics can contribute to the diagnosis of HLHS and guide further diagnostic work-up to determine degree of hypoplasia and associated mitral and aortic valve atresia, which will guide therapeutic interventions.⁸

Another aspect of the diagnostic process that was investigated in this project was the comparison of diagnostic ability between experienced and novice readers. The findings conclude that the experienced reader can evaluate EKGs with more specificity and the novice reader with more sensitivity. This suggests that novice readers may be able to evaluate EKGs efficiently enough to at least prompt further investigation and evaluation by subspecialized, expert staff. In the future, it would be of interest to evaluate how the reading efficiency of novice EKG evaluators rate on a large, generalized scale (general pediatricians, family practitioners, emergency department physicians, etc.).

Overall, the 12-lead EKG has a high sensitivity and specificity for assisting in the diagnosis of HLHS. Its use could be implemented as a low-cost, easily accessible screening tool in areas or instances where echocardiography is not readily available and where a moderately trained healthcare professional can evaluate QRSd and determine whether an EKG as a normal or abnormal tracing with an assessed high risk for HLHS.

Conclusion

Early identification of patients with CCHD is essential to improving outcomes and directing care. Clinical features, combined with electrocardiographic findings can guide further work-up. A 12-lead EKG is the standard of care in evaluating patients with suspected cardiovascular disease and is easily obtained. The utilization of QRSd to standard EKG evaluation can add to early identification and is a readily accessible test.

No Conflicts of Interest

Disclosures: none

Contributions

- Edward K Rhee- Study Design, methods

- Juan Aliaga - Statistics
- T. Moe – Manuscript drafting, editing, and submission
- K. McDonnell – Manuscript drafting
- R. Bitinis – Residency coordination and interpretation of EKG's, data collection

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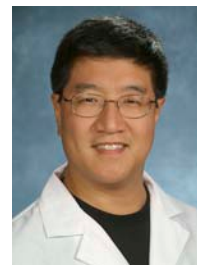


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NT Column: National Perinatal Association, 2015

By Raylene M. Phillips, MD

The NPA will be writing a regular column in *Neonatology Today*. Dr. Phillips and others from the association will share important news about and from the organization.



The National Perinatal Association is unique among national organizations focused on the perinatal period. While there are multiple national professional organizations dedicated to improving the care of mothers and babies, each of these organizations directs its efforts towards the particular profession it serves. For example, the American Academy of Pediatrics (AAP) Section on Perinatal Pediatrics supports primarily neonatal-perinatal medical providers while the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and the National Association of Neonatal Nurses (NANN) support nurses involved in perinatal care. The National Association of Perinatal Social Work (NAPSW) and National Association of Neonatal Therapists (NANT) support perinatal social workers and NICU therapists respectively.

In contrast, since 1977 the NPA has had the unique mission of providing a forum for all of these organizations to communicate with each other and with parents and families of new babies. As such, it is a multidisciplinary organization, comprised of healthcare providers, parents and caregivers, educators and service providers, all driven by their desire to give voice to and support babies and families at risk across the country. We do this by con-

vening, educating, advocating, and integrating.

We Convene

We bring together people who are interested in perinatal care to share, listen and learn from each other, so that collectively we can make the greatest positive impact on perinatal care in the United States.

We Educate

We provide educational opportunities through conferences, summits, webinars, position statements, guidelines, newsletters, publications and learning resources in order to increase knowledge about evidence-based practices in perinatal care.

We Advocate

We advocate for those in need of support in order to promote best practices, improve perinatal outcomes, and ensure justice for pregnant women, infant and families at risk.

We Integrate

Rather than replicating the work of other organizations and individuals, the NPA facilitates the collaboration of all disciplines as we work together to improve perinatal care.

Over the next few months, I will be sharing with you some of the ways the NPA has been working to fulfill our mission. This month the focus will be on "We Convene" illustrated by two upcoming events.

The first event is a Symposium to be held October 2nd-3rd, 2015, in Nashville, TN at Nashville Marriott at Vanderbilt. The Symposium is entitled "*Pregnant Women, Drug Use, and Neonatal Abstinence Syndrome: Experts Share Science and Strategies That Help Women, Babies, and Families,*" and will be provided in partnership with National Advocates for Pregnant Women. Professionals who care for women with substance use during pregnancy and the babies born to them, as well as women and families with direct involvement in this area, will share their experiences and challenges, as well as ways to help.

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Save the Dates for These NPA Meetings

2015 Symposium - National Perinatal Association & National Advocates for Pregnant Women "Pregnant Women, Drug Use, and NAS: Experts Share Science & Strategies That Help Women, Babies, and Families"
October 2-3, 2015
Nashville Marriott at Vanderbilt
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2016 Annual Conference - National Perinatal Association: "Decision Making in Perinatal Care"
April 28-29, 2016
Texas Children's Pavilion for Women
Houston, TX USA

The second event is the *NPA Annual Conference* in Houston, TX to be held April 28-29, 2016 at Texas Children's Pavilion for Women, hosted by Baylor College of Medicine, Department of OBGYN. The Conference is entitled "*Decision Making in Perinatal Care*" and will deal with the multitude of choices families face from prenatal care, labor management and delivery to postpartum care. We will learn from each other as parents and professionals share their perspectives about a wide range of perinatal choices.

At NPA, we focus on the impacts and effects of perinatal care and policy on families and the healthcare providers that care for them – ensuring their voices are heard. That includes your voice. We want to hear from you!

We invite you to join us in an interdisciplinary dialogue with all those

"At NPA, we focus on the impacts and effects of perinatal care and policy on families and the healthcare providers that care for them – ensuring their voices are heard. That includes your voice. We want to hear from you!"

involved in perinatal care. No matter how you are involved across the spectrum of care for mothers, babies and families, the NPA provides programs, services and opportunities to learn and engage.

If you would like to be involved, you can find more information on our website at www.nationalperinatal.org or contact our Director of Operations at 888-971-3295.

NT

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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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Preview of the International Cardiology Neonatology Symposium to be held October 8th-10th, 2015 at the InterContinental Hotel – Miami, Florida, USA

By Mitchell Cohen, MD; Alan Spitzer, MD

October in Miami is perfect! This coming October, neonatologists and cardiologists will gather for a three-day innovative, collaborative scientific meeting, *International Cardiology Neonatology Symposium*. As neonatal care becomes increasingly complex, optimal outcomes will be obtained as neonatologists and cardiologists depart from traditional silos and work together as a team. This conference pairs over 30 internationally-recognized leaders in the field of Pediatric Cardiology and Neonatology along with pediatric cardiothoracic surgeons, anesthesiologists, pediatric cardiac intensivists, and bedside and clinical nurses to discuss and debate the challenges and dilemmas that face the neonate with Congenital Heart Disease (CHD). This conference is designed to present the most up-to-date clinically relevant information on topics related to the diagnosis, management and outcomes of neonates with cardiovascular disease. We will present the daily chal-

lenges faced in the management of neonates with congenital heart disease, an isolated patent ductus arteriosus, pulmonary hypertension and arrhythmias. We will also explore the secondary effects of cardiovascular disease on the neonatal lung, brain and kidney. It is the focus of the organizing committee and all the speakers to provide valuable information for all of our attendees to take back to their respective neonatal and cardiac intensive care units. The meeting begins with a fantastic optional pre-conference, followed by 12 plenary sessions over the three days. The meeting departs from smaller breakout sessions so that all attendees can be part of the entire larger symposium. There are numerous discussion periods so that the audience can ask pertinent and relevant questions. By having physicians, advanced nurse practitioners and clinical bedside nurses all within the same plenary sessions, the content, interaction and discussion will be relevant for the entire team caring for babies with congenital heart disease.

“As neonatal care becomes increasingly complex, optimal outcomes will be obtained as neonatologists and cardiologists depart from traditional silos and work together as a team.”

The optional pre-conference, surely not to be missed, begins Thursday morning with a primer dedicated to Critical Congenital Heart Disease in the neonate. Dr. Paul Weinberg, Children’s Hospital of Philadelphia, is one of the preeminent cardiac anatomists in the world and will be showing anatomic specimens with D-transposition of the great arteries, total anomalous pulmonary venous return, Hypoplastic Left Heart Syndrome, Ebstein’s anomaly, pulmonary atresia with intact septum as well as with Tetralogy of Fallot. After each specimen is reviewed, a cardiologist will review the pertinent echocardiographic findings and discuss the pathophysiology of the lesion and what to expect in the NICU or CVICU. The specimen session will conclude with a cardiothoracic surgeon reviewing the surgical approach and, in some cases, intra-operative videos will be used. By the end of the pre-conference the attendee should have an excellent refresher in the anatomy, pathophysiology, and medical and surgical approaches to over 10 congenital heart substrates.

The main conference starts Thursday afternoon, October 8th, 2015 and runs through Saturday evening, October 10th. *The Cardiology Neonatology Symposium* is arranged thematically around either a specific organ system related to CHD or to the concepts of infrastructure and team building. The opening plenary session features key





lectures by some of the best-known cardiologists in the country. Dr. Gil Wernovsky, Director of Family-Centered Care at Miami Children's Hospital, will introduce the concepts of refining neonatal CHD along a paradigm of teamwork. Dr. Jack Rychik, Director of the Cardiac Fetal Program at The Children's Hospital of Philadelphia, will bridge the gap between fetus and neonate, and discuss ways to categorize CHD based upon complexity and expected postnatal course. The plenary will continue with discussions from neonatology, cardiology, surgery and nursing on managing the neonate with CHD and what each discipline brings to the team and how to continue to strive to be better. The plenary ends with a remarkable guest speaker, Tiffany Christensen, a patient advocate at Duke University, author of "Sick Girl Speaks," and who is the recipient of two lung transplants for cystic fibrosis (CF). Ms. Christensen will discuss CF as a chronic condition, much akin to CHD, and the decisions parents make for their children and how those decisions can impact their lives. This opening session promises to be an extraordinary and special one that will set the tone for the meeting and should not be missed.

The second day, October 9th, begins with a review of the Patent Ductus Arteriosus (PDA). While the PDA in the neonate seems so simple, it continues to generate discussion and controversy about how to best approach this remnant of the distal portion of the left 6th embryonic aortic arch. This session will feature two excellent debates. The first debate will feature two well-known neonatologists: Ron Clyman, MD,

UCSF, and Alan Groves, MD, New York-Presbyterian Hospital. These physicians will discuss closure of the PDA in the preterm infant. As echocardiography becomes more universal, discussion has arisen regarding neonatologists performing echocardiograms after an initial study ruled-out CHD. We will have two world-renowned echocardiographers, Dr. Meryl Cohen, Children's Hospital of Philadelphia, and Dr. Leo Lopez, Miami Children's Hospital, debate this question.

The third plenary will review issues of brain development and maturation in neonates with CHD. Over the last 15 years, much has been learned about associative cerebral structural abnormalities in neonates with CHD as well as pre-operative and post-operative strategies to improve neurologic outcomes. Many heart centers have developed proactive neurodevelopmental clinics to track and follow children following complex neonatal heart surgery. This session will look back at the accomplishments of the last 15 years, but also focus on the challenges and dilemmas moving forward. Recently, there has been a tremendous focus on growing the fetal brain and new information will be presented at this meeting regarding this particular strategy. This session features three preeminent cardiologists, a cardiac neurologist, surgeon and cardiac intensivist. Given the tremendous interest in this particular topic we have a lengthy discussion period built in to encourage audience participation.

The afternoon fourth plenary will probe the issues surrounding feeding neonates with CHD and how to manage caloric needs in the setting of ductal dependent systemic circulation. How should feeds be introduced and maintained? What should the neonatal nurse be monitoring during feeds? When is it time to stop the feeds and move to surgery? This will undoubtedly be a hot topic for all attendees and will likely generate many questions during the panel discussion. Friday afternoon will continue with a plenary dedicated to neonates with arrhythmias with interactive rhythm strips and electrocardiograms. This is a must for the neonatologist, nurse practitioner and bedside nurse.

The last decade has seen a major shift in the number of neonatal interventional cardiac procedures that previously could only be done with a sternotomy or thoracotomy. We will review the current state-of-the-art of interventional catheterization in the neonate with CHD, as well as probe the issue of when to refer to the cath lab and what to watch for when returning from the cath lab to the NICU or CICU. Friday evening will conclude with a session on the kidney and congenital heart disease. We will review the current understanding of neonatal GFR maturation in the first month of life and balance the needs of the neonate against the risk of fluid overload in some forms of complex CHD. Dr. Michael Zappitelli, MD, MSc, Director of the Dialysis and Aphaeresis Program at Montreal Children's Hospital, is a world expert in acute kidney injury and will review how we best identify AKI and manage it once it is identified.

Saturday morning, October 10th, the meeting will resume with a plenary on resuscitation, ECMO and neonatal CHD. The speakers will review issues on preparing for a cardiac arrest, use of VV ECMO in CHD, ECPR in the

"The last decade has seen a major shift in the number of neonatal interventional cardiac procedures that previously could only be done with a sternotomy or thoracotomy. We will review the current state-of-the-art of interventional catheterization in the neonate with CHD, as well as probe the issue of when to refer to the cath lab and what to watch for when returning from the cath lab to the NICU or CICU."

NICU, and where the future of mechanical circulatory support in the neonate with heart disease is headed. The ninth plenary will open with a discussion on the issues of family support as well as a frank discussion about the advantages and disadvantages of social media. Amy Basken, President of the Pediatric Congenital Heart Association, will discuss family support from the parent's perspective; this will be followed by a remarkable talk by Kathy Mussatto, RN, PhD, on the view of family support from a nurse's vantage.

The noon lecture promises to be one of the highlights of the meeting. Dr. Andrew Redington, Executive Co-Director, Heart Institute; Professor and Chief of Pediatric Cardiology at Cincinnati Children's Hospital will give the first Annual Roger Medel Lecture, titled, "Understanding Myocardial Function and Failure in the Neonate." Dr. Redington is one of the most remarkable speakers who captivates an audience and, no doubt, this will prove to be an insightful talk.

The organizing committee encourages all attending physicians, neonatologists, cardiologists, advanced practice nurses, clinical nurses, and neonatal and cardiology fellows to submit an abstract. The abstracts should be relevant to the field of neonatal cardiology and the top five abstracts chosen by the scientific organizing committee will be presented in an oral fashion at the main plenary. The abstracts will be presented in poster fashion at multiple times throughout the meeting and will allow the presenter to meet with neonatologists, cardiologists and nurses to discuss their research. This is a great opportunity for young investigators to have one-on-one dialogue with clinicians from around the world.

The tenth plenary will focus on the premature infant with CHD. In every NICU these are the most troubling and difficult patients to manage. Dr. Ganaga Krishnaumrthy, a leading neonatologist from Presbyterian-New York Hospital, will discuss low birth weight neonates with CHD and present outcomes data. While discussions will focus on the best place to care for such a complex neonate, the

"The organizing committee encourages all attending physicians, neonatologists, cardiologists, advanced practice nurses, clinical nurses, and neonatal and cardiology fellows to submit an abstract. The abstracts should be relevant to the field of neonatal cardiology and the top five abstracts chosen by the scientific organizing committee will be chosen and presented in an oral fashion at the main plenary."

better question may be how we, as a team, should care for our most difficult patients, location aside. The eleventh plenary will be a didactic review on understanding BPD, pulmonary hypertension and PVR. What can the neonatologist learn from the cardiologist and what can the cardiologist learn from the neonatologist? The meeting will conclude Saturday evening with a look to future. What will be the future state of imaging babies with CHD? Will MRI replace the echocardiogram in certain diagnosis? Dr. Groves will also review how a neonatologist can better use the ECHO to assess circulatory function. Much information is available on the echocardiogram. Is all that information being shared and how as a team do we take the bedside information and put it together with the echocardiogram so as to best care for the baby? We promise you a remarkable journey through neonatal cardiology. Of course there will also be great food at the meeting and the Miami atmosphere is second to none.

The meeting promises to be as good as the views from the InterContinental Hotel looking out at Biscayne Bay, the

giant cruise ships and South Beach a few miles away. The InterContinental Hotel is located in the heart of downtown Miami with excellent restaurants, shopping, night-life and a short ride to South Beach. If you choose to stay at the hotel there is an excellent mySpa with 10 treatment rooms and a fitness center on site. We look forward to seeing you at the first *International Cardiology Neonatology Symposium*.

For more information, go to: www.neocardisymposium.com.

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Applications for a Mobile Life in the Office: Part 2 of 3 - Social and Mobile Media for the Neonatologist

By Clara H. Song, MD

“Social & Mobile Media for the Neonatologist” by Dr. Song, is a column in *Neonatology Today*. Dr. Song created and moderates the social media outlets for the American Academy of Pediatrics, Section on Perinatal Pediatrics, as well as the NICU at the Children’s Hospital at OU Medical Center. She holds workshops and speaks regionally and nationally on the topic of social communication for the healthcare professional, including: the AAP Perinatal Section Spring meeting, yearly, and the 2011 *NEO: The Conference for Neonatology*.

When we clinicians aren’t at the bedside of our patients, we are in the office. However, “office” work doesn’t always take place just in the office. Most take the work with us and make our office wherever we are. Smartphones and apps may not be essential for this transformation, but sure make it a whole lot easier.

Here are some particularly helpful mobile apps that may help us stay on the go and keep us productive.

GLIDE: Glide is an app that allows for video messaging. The messages are sent in the same manner and speed as texting. Also, like texting, the video messages can be watched immediately, later deleted, saved and set up as single or group chats. Obviously, the visual component of this app is what gives it the edge. This app is ideal for those moments when you don’t have the time to text, would rather say it than type it, or need to ‘show’ your message. Available at the iTunes Apple Store and Google Play Store without cost.

WHATSAPP: This is currently the most widely used messaging app. It uses the web to send texts, photos, video, and audio media without incurring SMS costs. This comes in handy, particularly when traveling internationally. Available at the iTunes Apple Store, Google Play Store and the WhatsApp website for all smartphones for a small subscription fee.

HANGOUTS: This app from Google allows for instant text, audio and video messaging with up to ten participants. Hangouts can occur on mobile devices or on your desktop. This app is great for video conference calls especially when multiple players and presentations are involved. Available at the iTunes Apple Store and Google Play Store without cost.

CAMSCANNER: This app is a mobile scanner and PDF creator. The basic version is available at no cost, and is a no-

frills, convenient way to store and organize any document. For example, snap a photo and quickly scan business cards. You’ll never lose another one again. Available at the iTunes Apple Store and Google Play Store without cost for the Basic account (subscription fee for Premium account).

GOODREADER: This is one of the first PDF readers and still remains one of the most highly recommended. Available at the iTunes Apple Store for a fee.

POCKET: Another hugely popular app, Pocket allows you to save web content- namely articles- and ‘pocket’ them to read later. The web articles are saved on a user-friendly platform that can be accessed later offline. This is a great app when traveling. Available at the iTunes Apple Store and Google Play Store without cost.

“When we clinicians aren’t at the bedside of our patients, we are in the office. However, “office” work doesn’t always take place just in the office. Most take the work with us and make our office wherever we are. Smartphones and apps may not be essential for this transformation, but sure make it a whole lot easier. ”

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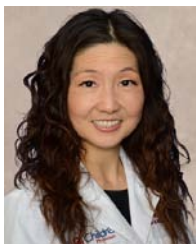
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About The Meeting: A comprehensive review of the field of fetal cardiology, providing up-to-date reference. It will be presented by well-known international leaders in the field. The course provides detailed information on the evaluation of the normal fetal heart from an anatomic and functional approach. Detailed information on the use of 3D ultrasound in fetal echocardiography and cardiac imaging in the early gestation will also be presented.

The course also provides comprehensive evaluation of various cardiac malformations, involving abnormalities of the cardiac chambers and the outflow tracts. Congenital Heart Disease (CHD) is the most common congenital malformation with a significant impact on neonatal morbidity and mortality.

Prenatal diagnosis and management of CHD is a collaborative effort between maternal-fetal medicine specialists and pediatric cardiologists. The faculty represents the specialties of those involved in caring for pregnancies complicated with fetal cardiac abnormalities.

Educational Objectives:

- Understand indications for fetal echocardiography, review existing guidelines and the approach to patient counseling.
- Understand how to optimize ultrasound equipment for the use of 2D, 3D and Doppler in fetal echocardiography.
- Review the normal fetal cardiac anatomy.
- Understand the abnormalities of the venous system of the fetal heart.
- Detailed discussion on the anomalies of the cardiac chambers to include septal defects and anomalies of the right and left ventricle.
- Review in detail anomalies of the outflow tracts to include: transposition of great arteries, Tetralogy of Fallot, complex and aortic arch abnormalities.

Program Director: Alfred Abuhamad, MD; Professor and Chairman, Department of Obstetrics and Gynecology, Associate Dean for Clinical Affairs, Eastern Virginia Medical School, Norfolk, VA USA

International Faculty Includes: Alfred Abuhamad, MD; Joshua A. Copel, MD; Bettina F. Cueno, MD; Edgar Jaeggi, MD, FRCP (C); Jack Rychik, MD; Elena Sinkovskaya, MD, PhD; Dennis C. Wood, Jr., BA, RDMS, RDCS, RCPT.

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Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

The Newborn Screening Saves Lives Reauthorization Act of 2014

On December 18, 2014 the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240), an extension of the Newborn Screening Saves Lives Act of 2008 was signed into law. The bill includes an amendment addressing research uses of newborn dried blood spots, requiring immediate new interpretations of the HHS regulations for the protections of human subjects effective 90 days from the enactment of the law (see below). The amendment also requires HHS to promulgate proposed revisions to Federal Policy for the Protection of Human Subjects within six months and final regulations within two years.

The law includes two significant changes to the human subjects regulations as they apply to research with newborn dried blood spots. First, the law requires that all research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research regardless of whether the specimens are identifiable. Second, the law eliminates the ability of the IRB to waive informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots.

Note that this law applies only to HHS-funded research, and not to research funded by other entities that is conducted at institutions that have extended their FWA to cover all research, regardless of funding (institutions that have "checked the box.")

This law went into effect Monday, March 16th, 2015. Note that this law applies only to HHS funded research that specifically involves the use of newborn dried blood spots. OHRP advises that stakeholders initially consult the relevant funding agencies for advice regarding implementation of this law. OHRP may be contacted with further questions.

TEXT OF SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH:

- (a) IN GENERAL—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of Title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

- (b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act.
- (c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations.

Babies Exposed to Narcotic Pain Relievers More Likely to Experience Withdrawal

Neonatal Abstinence Syndrome (NAS), a drug withdrawal syndrome in infants following birth, has historically been associated with illicit drug use among pregnant women.

A study by a team at Vanderbilt University Medical Center shows that pregnant women are commonly being prescribed opioids -- narcotic pain relievers such as hydrocodone -- which results in an increased likelihood of NAS. In addition, the study found that opioid type and duration of exposure combined with tobacco use or selective serotonin reuptake inhibitor use (for treating depression and anxiety) augmented risks for NAS.

The study, "Prescription Opioid Epidemic and Infant Outcomes," looked at three years of data from TennCare, Tennessee's Medicaid program, and assessed records for 112,029 pregnant mothers. An estimated 28% of the women, or 31,354, were prescribed and filled at least one opioid pain reliever. Of the babies with NAS, 65% had mothers that legally filled prescriptions for opioid pain relievers. Results were published in the April 13th issue of the journal *Pediatrics*.

"We found that babies exposed to opioids pain relievers were more likely to be born preterm, have complicated births, low birth weight and have complications such as Meconium Aspiration Syndrome (a sign of infant distress at birth) and respiratory distress," said lead author Stephen Patrick, MD, MPH, Assistant Professor of Pediatrics and Health Policy in the Division of Neonatology with the Monroe Carell Jr. Children's Hospital at Vanderbilt.

"Not all babies exposed to opioids have drug withdrawal after birth for reasons that aren't entirely clear. Our study found that several things increased an infant's risk, including the duration of opioid use, the type of prescription

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opioid, how many cigarettes a woman smoked and if they used a common antidepressant medicine called selective serotonin reuptake inhibitors."

The study shows that compared to women with no opioid exposure, the pregnant women who took opioid pain relievers were more likely to be white, have anxiety or depression, suffer from headache or migraine and have Musculoskeletal Disease. A majority of the women prescribed opioids, 96%, were prescribed short-acting medications, while 2% received maintenance doses and less than 1% received long-acting opioids.

"Historically, drug withdrawal for newborns has been described among illicit drug use such as heroin or women treated for previous opioid abuse, but this is really one of the first studies to look at legal prescriptions for pregnant women. And it draws attention to what is going on in our nation," Patrick said.

Nationwide, the amount of prescriptions for opioid drug use has quadrupled. In 2012, an estimated 259 million prescriptions were written for opioid pain relievers in the United States. That's enough for one prescription for every adult in the U.S., Patrick said.

The financial impact is substantial. As a population, every \$1 spent on short-acting opioid pain relievers was associated with \$50 spent caring for infants with drug withdrawal. National health care expenditures for treating babies with NAS are estimated to be about \$720 million a year, according to previous work done by the same researchers.

Tennessee began taking action against overprescribing and doctor shopping for opioids in 2006 when it created a prescription monitoring database, though it was an optional resource for providers and pharmacists. The state strengthened laws in 2013, mandating that providers and pharmacists use the system. Currently 49 states have similar drug monitoring programs. Missouri is the only state without one.

"All in all, we hope the study garners the attention of state and federal policy makers to highlight that the prescription opioid epidemic is having a tangible impact on both mothers and infants," Patrick said.

Funding for the study was provided by the Tennessee State Department of Health as well as the National Institutes of Health (NIH), grant Nos. KL2TR000446, UL1 RR024975-01, and R01AG04347-01A1.

Many Things Can Be Read in a Newborn's Gaze

Experienced nannies and doctors have always known how much the visual contact with a newborn can convey. A recent Finnish study provides scientific evidence for this everyday belief.

A study performed in the University of Helsinki and the Children's Hospital within Helsinki University Central Hospital shows that the visual abilities of the newborn predict childhood development of visual processing.

The study also showed that the newborn ability to fixate on objects is related to the level of maturation at the microscopic level studied by magnetic resonance imaging. An abnormal newborn fixation associates with widespread changes in the white matter tracts.

These findings support the idea that key cognitive abilities are already present in a newborn infant, and later neurocognitive development proceeds as a cascade that builds on these early cognitive building blocks.

Poor visual cognitive abilities are the most common lifelong compromise in children born very prematurely or with oxygen deprivation at birth, says Dr. Sampsa Vanhatalo, the leader of this study, and Adjunct Professor in Clinical Neurophysiology. Learning the early development of visual abilities will, hopefully, open new pathways to early recognition of cognitive problems, and, consequently, we will learn how to help the infant and prevent development of visual cognitive disabilities, says child neurologist Dr. Aulikki Lano, the head of neurological examinations in the project.

Vanhatalo points out another key conclusion of their study: A well-done clinical examination may be as informative of a child's future as many of the technologically advanced research methods currently popular.

Most adults with experience in babysitting or other child care have always paid attention to the eye contact of the child. It is somewhere deep in the back of our minds to note when a newborn has abnormal eye contact, yet its significance has not been shown in scientific studies. Our new study provides evidence as to the scientific relevance of this intuitive experience; however, it also opens new possibilities for developing research and care in pediatric neurology.

These results have convinced us of the necessity to develop objective and quantitative measures of eye contact in the newborn. They could help us recognize children with developmental risks right after birth. Such a method would open unprecedented vistas in developing new therapeutic interventions that could start from the first months of life, which is even years before the problems become apparent using current approaches, says Dr. Marjo Metsäranta, Adjunct Professor in Neonatology.

The study was done in the Children's Hospital, Helsinki University Central Hospital, and it analyzed two different cohorts of neonates. The first cohort included 57 babies recruited in 2006 - 2007, and it included 42 extremely preterm infants. At term age, the children were tested for their visual abilities, and scanned with advanced magnetic resonance imaging, followed by neuropsychological assessment at two years of age. The second cohort consisted of 1,410 newborns recruited 1985-86 as a part of a very large, population-based follow-up study (called "Arvo Ylppö Longitudinal Study"). Altogether 948 of these infants had been hospitalized for various reasons, and about one-fifth of them were born preterm. These children were reassessed for general reasoning and visual-motor abilities at five years of age.

Gene Leads to Malformation of the Urinary Tract Researchers at the University of Bonn Discover a New Hereditary Factor Associated with a Rare Disease

An interdisciplinary team of researchers under the direction of the University of Bonn Hospital have discovered a gene which is associated with a rare congenital anomaly of the urinary tract called classic bladder exstrophy. It increases the likelihood that the urinary tract will not form properly during embryonic development. The finding is an important step for understanding the development of urinary tract malformations in general and for developing prophylactic measures. The results are published in the current online edition of the journal *PloS Genetics*.

The kidneys and urinary tract are the sites affected most frequently by congenital malformations. Approximately 1 out of every 200 children suffers from such a malformation. "These diseases make up about 20% to 30% of all congenital malformations," says Associate Professor Dr. Heiko Reutter from the Institute of Human Genetics and the Department of Neonatology and Pediatric Intensive Care Medicine of the University of Bonn.

For many years, the pediatrician has investigated the genetic causes of classic bladder exstrophy comprising malformations ranging from the bladder to the entire urinary tract. These malformations frequently result in urinary tract infections, incontinence, renal damage and sexual dysfunction. Approximately one out of 20,000 newborns is affected by this rare disease which is considered to be one of the most severe forms of malformations on this spectrum. "Congenital classic bladder exstrophy thus represents an enormous challenge in the medical care of patients affected and their families," says Dr. Reutter.

Focus at the Center for Rare Diseases

To date, the genetic causes of this rare disease have been basically unknown. In the past ten years, with the bladder exstrophy/epispadias self-help group and leading pediatric urologists and pediatric surgeons in Germany - including from the Barmherzigen Brüder Pediatric Hospital in Regensburg as well as the universities of Mainz and Ulm - researchers at the University of Bonn hospital have been able to gather the largest group of patients in the world. The researchers in Bonn received additional support for the current study from researchers at the Max Planck Institute for Molecular Genetics in Berlin. Assistance was also provided by the Center for Rare Diseases at the University of Bonn Hospital (ZSEB). The researchers focus on rare uro-rectal malformations there.

Using blood samples from a total of 210 patients, the scientists isolated the genetic information and compared it with a control group of healthy persons. The researchers used automated analysis methods to record more than 700,000 genetic markers in each case which are evenly distributed throughout the DNA. The evaluation using biostatistical methods revealed a clear connection with an altered gene: ISL1, which is located on chromosome five. "In this way, a gene in connection with this disease was identified for the very first time," says Prof. Dr. Michael Ludwig from the Insti-

tute of Clinical Chemistry and Clinical Pharmacology of the University of Bonn Hospital.

The Search for Other Genes

This has been a breakthrough for science. "With the discovery of this gene, it now becomes possible to clarify the biological foundations of this disease," says Prof. Dr. Markus Nöthen from the Institute of Human Genetics from the University of Bonn. Beyond the genetic causes of classic exstrophy, the objective is to now identify risk factors during pregnancy and to develop preventive approaches from this for the unborn child. Further investigations are intended to demonstrate which yet undiscovered genes play an additional role in the development of the disease. The scientists are still looking for affected to continue the studies. Anyone interested may email Dr. Reutter directly: reutter@uni-bonn.de.

Publication: Genome-wide association study and meta-analysis identify ISL1 as genome-wide significant susceptibility gene for bladder exstrophy, *PLOS Genetics*, DOI: 10.1371/journal.pgen.1005024.

Standardization and Simplification is Key to Helping NICU Babies Feed and Grow

A new standardized approach for feeding infants in the Neonatal Intensive Care Unit (NICU) helps babies attain full oral feeds sooner, improves their growth and sends them home sooner. The guidelines, developed by clinician-scientists at Nationwide Children's Hospital and published in the *Journal of Parenteral and Enteral Nutrition*, also reduces the cost of care for these babies by shortening their stays in the NICU by as much as two weeks.

Feeding is a complex process that involves the integration of functional connectivity between the brain, airway and foregut. For babies in the NICU, achieving full oral feeds -- milk by mouth without tubes or limitations -- is a critical step for growth and the journey to discharge. Because many infants have complicated feeding difficulties and changes in clinical caregivers throughout their hospital stay, Sudarshan R. Jadcherla, MD, Director of the Neonatal and Infant Feeding Disorders Program and principal investigator in the Innovative Feeding Disorders Research Program at Nationwide Children's, hypothesized that a standardized approach to feeding could eliminate variability and simplify the transitions from enteral feeding to full oral feeding.

The team collected baseline data from 92 infants before initiating their quality improvement study with another 92 infants they enrolled in their SIMPLE (simplified, individualized, milestone-targeted, pragmatic, longitudinal and educational) Program.

"Our SIMPLE feeding approach resulted in improved growth, eventually leading to more time at home with parents," Dr. Jadcherla says. "The emphasis of our program was on implementation of guidelines that can still be tailored to the infant's and parent's individual needs."

This specific program involved analyzing critical aspects of institutional processes, building consensus, developing educational workshops, monitoring compliance and accountability and providing constant feed-forward information.

"Simply removing the variability from feeding practices, cutting wastage of resources and optimizing staff training with regards to feeding and nutrition has helped us attain feeding success," Dr. Jadcherla says. "It also has helped us give babies more time at home and reduce costs."

Babies on the SIMPLE feeding program spent significantly less time on trophic feeds, which stimulate the gut but do not provide sufficient nutrients for growth, and less time being tube-fed. They were also able to tolerate the introduction of oral feeds and exclusive oral feeding earlier than babies prior to the guideline implementation. The team credits this improved feeding trajectory with the greater daily weight gains achieved by babies on the SIMPLE plan, which in turn led to stays of about 15 days shorter duration.

"The standardization and development of pragmatic feeding guidelines has resulted in acceleration of feeding milestones. These infants also had fewer days on mechanical breathing machines," says Dr. Jadcherla, who also is a principal investigator in the Center for Perinatal Research in The Research Institute and a Professor of Pediatrics at The Ohio State University College of Medicine. "Importantly, the length of stay was reduced while balancing measures and co-morbidities such as necrotizing enterocolitis, chronic lung disease, mortality and readmission rates remained similar or trended downward."

There are no accepted benchmarks for feeding babies in an all-referral NICU, where admission requirements and sickness levels can be heterogeneous. Dr. Jadcherla founded the concept of the SIMPLE feeding program, developed the core group, trained feeding providers and led a multi-disciplinary team of NICU caregivers in this quality improvement endeavor. They gradually refined their approaches until all providers were educated and familiar with the guidelines and the recommendations reflected a wide range of clinical circumstances.

"We saw an opportunity to create a standardized approach to our feeding management strategies that would be monitored through multi-disciplinary feeding rounds," Dr. Jadcherla says. The researchers hope the program's success at Nationwide Children's will be obtainable by other hospitals, as well.

"The guidelines were designed with an understanding of infant development, aerodigestive reflexes and individual clinical needs that will be adaptable to any NICU population," Dr. Jadcherla explains. "The SIMPLE feeding program also provides a forum for regular collaboration in regards to feeding management, which will help other institutions easily incorporate it into their care efforts."

Dr. Jadcherla and his collaborators at Nationwide Children's are now working to develop methods to optimize the diagnosis and management of Gastroesophageal Reflux Disease, dysphagia and feeding intolerance in order to improve overall growth and development in premature infants while also lowering the economic burden of care.

Partners for Kids, Nationwide Children's Demonstrate Cost Savings and Quality as Pediatric ACO

A new study published in *Pediatrics* demonstrates the cost-saving and health care quality outcomes of the pediatric Accountable Care Organization (ACO) Partners for Kids (PFK). Results of this study indicate that Partners for Kids successfully improved the value of pediatric healthcare over time through cost containment, while maintaining quality of care.

Partners for Kids is a pediatric ACO serving approximately 300,000 Medicaid-eligible children in Ohio, designed to address rising costs and concerns about the quality of care delivered to low-income patients. In 1994, Nationwide Children's Hospital partnered with community pediatricians to create PFK, a physician-hospital organization with governance shared equally between Nationwide Children's and physician primary and specialty practice groups. ACOs are responsible for healthcare costs and quality across a defined population. To succeed, the ACO must improve value by reducing costs while either maintaining or improving the quality and outcomes of care.

"We believe this study is the first evaluation of a pediatric ACO. Our data demonstrate the potential for an ACO to minimize the growth in cost of care for a pediatric population, all while maintaining or improving quality of care," says lead author Kelly Kelleher, MD, MPH, VP of Community Health Services at Nationwide Children's and a member of the faculty at The Ohio State University College of Medicine.

The study assessed the value of care provided by PFK from January 2008 through December 2013. Costs of care were compared to overall reported costs of Medicaid within Ohio. Quality measures were derived from the Agency for Healthcare Research and Quality (AHRQ) Pediatric Quality Indicators, which focus on potentially preventable complications and hospitalizations and provide targets for interventions at both the provider and patient level. Four additional measures targeted specifically by PFK included: neonatal intensive care days; emergency department visits due to asthma; diabetes care management; and 3- to 6-year-old well-child checks.

Results of cost comparisons indicated that PFK had lower cost growth than Medicaid fee-for-service programs and Medicaid managed care plans. From 2008 to 2013, costs per member per month for PFK grew at a rate of \$2.40 per year. Managed care plans grew at a rate of \$6.47 per year and Medicaid fee-for-service costs grew at a rate of \$16.15 per year.

Quality metrics based on AHRQ indicators stayed consistent on most other measures, showed improvement for three measures (including two measures of overall quality of care), and declined on two measures. PFK-specific quality measures showed improvements including fewer NICU days, fewer visits to the ED for asthma and a significant increase in the number of well-child visits. A slight deterioration was seen in diabetes care management.

Overall, the results indicate the PFK model substantially reduced growth in the cost of care compared to other Ohio Medicaid plans. In addition, quality-of-care measures held steady, with some small changes in both directions.

"PFK delivered on the promise of the ACO to reduce the rate of health care cost growth while maintaining or improving the quality of care," Dr. Kelleher states.

Pediatric ACOs may prove to be efficient models of reforming healthcare, Dr. Kelleher says. The National Committee on Quality Assurance, a non-profit organization dedicated to improving health care quality, is developing an accreditation and measurement proposal for ACOs. PFK will participate in its analysis.

"While an additional 30 million Americans will have access to health coverage under the Patient Protection and Affordable Care Act, the difficult work of creating a system of better care, better health and lower cost will occur gradually, through pilot projects designed to encourage innovation, improve effectiveness and reduce costs," explains study co-author Richard Brill, MD, Chief Medical Officer at Nationwide Children's and a member of the faculty at The Ohio State University College of Medicine. "One of the primary vehicles through which the new law encourages such innovation is through provisions that establish Accountable Care Organizations in Medicare and for pediatrics, in Medicaid or CHIP."

Kelleher K, Cooper J, Deans K, Carr P, Brill RJ, Allen S, Gardner W. "Cost Saving and Quality of Care in a Pediatric Accountable Care Organization." *Pediatrics*. Feb 9, 2015 [pub ahead of print].

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About Partners for Kids

Partners for Kids is a physician hospital organization (PHO) currently composed of over 900 physicians caring for children and adolescents, including primary care physicians, pediatricians, specialty care providers and our sponsoring hospital, Nationwide Children's Hospital. More information is available at NationwideChildrens.org.

Therabron Therapeutics Names Thomas F. Miller President & COO - Company Makes Strategic Hire As It Advances a New Category of Biologic Respiratory Therapeutics



Therabron Therapeutics, Inc. (Therabron), a specialty biotechnology company focused on the advancement of respiratory therapeutics with disease-modifying potential, announced that it has named Thomas F. Miller, PhD, MBA, as the Company's President and Chief Operating Officer, effective immediately. Therabron's strategic appointment of Dr. Miller comes at a time when the company is advancing its lead product candidate through Phase

2 clinical studies and intends to advance other clinical-stage product candidates that are emerging as a result of its extensive preclinical development program. Dr. Miller will report to

Dr. Aprile Pilon, Therabron's Founder, Board Chairman, and Chief Executive Officer.

"Therabron is poised to make significant advances in the coming months and we are very pleased that Tom has agreed to join our Executive Team", commented Dr. Pilon. "His scientific training, relevant development background, and operational expertise within emerging biotechnology companies that were engaged in respiratory drug development will significantly compliment our existing team."

Prior to joining the company, Dr. Miller spent ten years with Discovery Laboratories, Inc., culminating in his role as the company's Chief Operating Officer. Prior to Discovery Labs, Dr. Miller served in commercial and clinical development roles of increasing responsibility at Johnson & Johnson, Pharmacia, Novartis and Pfizer.

Dr. Miller will oversee Therabron's operations with an initial focus on the advancement of the Company's lead development candidate, CG100, which is currently in a phase 2 clinical trial with the goal of reducing long-term respiratory complications in premature infants. He will also oversee Therabron's corporate development, finance and manufacturing operations.

"I am excited about the opportunity to support Therabron in this capacity, particularly because I believe that the Company's recombinant secretoglobin platform has transformative therapeutic potential across a wide spectrum of respiratory disorders," commented Dr. Miller. "I have a great deal of respect for the existing Executive Team and the progress they have made to date. I look forward to working with the team to advance this disruptive technology platform and contribute to building a substantial biotechnology company."

Therabron Therapeutics, Inc. is a clinical-stage biotechnology company, founded in 2007 and located in Rockville, MD. Therabron is focused on the advancement of respiratory therapeutics with disease-modifying potential. The company's product candidates aim to restore the natural immune balance in the lungs of respiratory patients through the administration of recombinant human CC10 proteins. The family of CC10 proteins, also known as secretoglobins, have the potential to change the course of acute and chronic respiratory diseases, representing large markets into which few truly novel drugs have been introduced. Therabron's product candidates have the potential to be first-in-class, disease-modifying, breakthrough biologic therapeutics. For additional information, visit www.therabron.com.

Promoting Maternal Interaction Improves Growth, Weight Gain in Premies

An intervention to teach mothers of preterm infants how to interact with their babies more effectively results in better weight gain and growth for the infants, according to a study funded in part by the National Institutes of Health (NIH).

A subsequent study showed that infants who had the benefit of a major component of this intervention more rapidly

developed the muscle control needed for feeding successfully from a bottle. The initial findings were published on line in the *Journal of Perinatology* and the subsequent study in *Advances in Neonatal Care*.

Briefly, the intervention involved teaching mothers to recognize and respond to the subtle cues their preterm infants were hungry--far less pronounced than term infants. Mothers were also taught how to provide appropriate social and physical stimulation--such as soothing talk, and gentle massages--to spur their infants' neurological development.

Infants born preterm often are not developed enough to feed on their own. Typically, the muscle control needed for infants to feed unassisted does not completely develop until the 34th week of pregnancy. Infants born before this time usually are fed through a nasogastric tube--a line passed through the nose and down the throat into the stomach. The study authors developed the intervention to help mothers stimulate their infant's alertness before feeding so that the infants would be better able to feed by mouth. The intervention also sought to spur the infants' social behaviors, such as keeping alert and looking at the mother, and neurological development, in hopes of offsetting at least some of the developmental delays often seen in preterm infants.

"Preterm infants who fail to gain sufficient weight are at a higher risk for delays and even impairments in cognitive ability and motor skills," said Valerie Maholmes, PhD, Chief of the Pediatric Trauma and Critical Illness Branch at the NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development, which funded the research. "We are hopeful that this intervention will prove to be an important tool in safeguarding the long-term health of an extremely vulnerable group of infants."

Additional funding for the research was provided by the National Institute of Nursing Research, also at NIH.

The study was conducted by Rosemary C. White-Traut, PhD, RN, and colleagues at the University of Illinois, Mercy Hospital and Medical Center, and Sinai Hospital Medical Center, all in Chicago. Dr. White-Traut is now at Children's Hospital of Wisconsin in Milwaukee.

During their first year, infants born preterm are at high risk for life-threatening infections, blindness, breathing problems, feeding problems, learning and developmental disabilities, and cerebral palsy. According to the U.S. Centers for Disease Control and Prevention, nearly 500,000 U.S. infants were born preterm in 2013, the most recent year for which statistics are available. Roughly 11% of births to Hispanics were preterm. The study authors write that it is common for preterm infants to grow more slowly than normal. Infants who grow at an appropriate rate have the best chances for avoiding problems in their neurological development.

"Preterm infants face increased health risks, just due to their having come into the world too early," Dr. White-Traut said. "So further complications, such as poor feeding and delayed growth, can worsen the problems they already face."

The intervention, dubbed H-HOPE, stands for Hospital to Home Transition - Optimizing Premature Infant's Environment. H-HOPE instructs mothers on how to provide behavioral, social, and physical stimulation designed to engage the baby's attention and spur brain development. Compared to a term infant, preterm infants spend much more time sleeping and much less time awake and aware of what's going on around them. They're also less able to communicate their needs than is a term infant. For this reason, the researchers devised the H-HOPE intervention to show new mothers how to provide appropriate stimulation for their new borns, and how to pick up on their frequent cues indicating that the baby is hungry.

The intervention is made up of two parts. The first part, called the Auditory, Tactile, Visual and Vestibular (ATVV) intervention, teaches mothers how to interact socially with their infants and gently stimulate their senses. The other part teaches the mothers how to interpret and respond to their infants' behavioral cues while giving the ATVV intervention and when feeding them.

The ATVV consists of a 15 minute intervention, undertaken twice daily, just before feeding. A nurse and community health worker team teaches the mother the steps involved. The mother is first taught to begin speaking to the infant in calm, soothing tones, before touching the infant. The sound of a female voice is intended to gently alert the infant that the caregiver is present. For the next ten minutes, the mother places the infant on his or her back, and gently massages the infant's head, chest, abdomen and arms, and then turns the infant over to massage the head and back. For the final five minutes, the infant is swaddled, held in the mother's arms, and rocked horizontally. Throughout the procedure, the mother is taught to make eye contact with the baby when the baby is awake. This sequence is repeated twice a day, from the time the baby reaches 31 weeks and continues after the baby is discharged from the hospital until 1 month after the approximate date the baby would have been born, had the pregnancy reached term.

The other part of the intervention teaches the mother how to recognize, interpret, and respond to her preterm infant's subtle behavioral cues. For example, a term infant will cry loudly when he is hungry, and perhaps put his hand in his mouth. In contrast, a preterm infant may not cry, may only weakly pull his hand toward his mouth to signal that he is hungry.

The researchers enrolled 183 mothers and their preterm infants, born from the 29th through the 34th week of pregnancy. Half of the mothers were Hispanic. Roughly half of the mother-infant pairs were assigned at random to the H-HOPE intervention, and roughly half to another program that provided instruction on how to care for preterm infants. The study took place at two hospitals serving impoverished neighborhoods.

"When we planned our research, we thought that preterm infants from impoverished backgrounds likely would benefit the most from this intervention," Dr. White Traut said. "Poverty is linked to poorer long-term health and infant development. And as with other negative health influences, preterm infants usually are affected more strongly than term infants."

Mothers received two visits from the nurse-community health advocate team while they were in the hospital to teach them the intervention's procedures and to monitor the mothers to make sure they carried out the steps correctly. The mothers also received two at-home visits from the nurse-community health advocate team after their infants had been discharged from the hospital.

After the infants had completed the study, those who received the H-HOPE intervention weighed more, on average, than those who did not receive it. Infants in the H-HOPE group also grew more rapidly in length, especially during the last five days of their hospital stay.

The study, published in *Advances in Neonatal Care*, found that the feeding abilities of the pre-term infants improved immediately after they received the ATVV intervention. Pre-term infants were fed with a modified bottle connected to a sensor that measured their mouth movements. Infants alternate periods of active sucking (bursts) with rest periods where they hold a nipple in their mouths but refrain from actively feeding. Among the specialized metrics the researchers cataloged were the total number of times the infant sucked on the nipple during a feeding, as well as the number of sucks "per burst." All infants were tested with the bottle and sensor just after they began oral feeding and each week while they remained in the hospital.

By all of the measurements the researchers recorded, the infants in the ATVV group outpaced the control group in the ability to perform the mouth movements needed to feed on their own.

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Cesarean Section Rates in Portugal Decline by 10%

A new study reports a significant decline in the rate of Cesarean section (C-section) births in Portugal. Findings published in *Acta Obstetrica et Gynecologica Scandinavica*, a journal of the Nordic Federation of Societies of Obstetrics and Gynecology, indicate a 10% reduction in overall C-section rates between 2009 and 2014, with a 14% reduction in state-hospitals during the same time period. Researchers believe this may be due to more information and training of healthcare staff, along with inclusion of C-section rates as part of the criteria for hospital funding.

C-section rates have been on the rise around the world, which has drawn international attention and concern, given the potential adverse effects to the health of mother and baby. Prior research shows that cesarean birth is linked to greater risk of blood clots (thromboembolism), hemorrhage, and infection in mothers. Furthermore, it increases the risk of newborn respiratory complications, obesity, diabetes, and a propensity to develop allergies in childhood.

Prof. Diogo Ayres-de-Campos at the Medical School of the University of Porto in Portugal explains, "In European countries with low cesarean birth rates, very low mortality rates in mother and child are also reported. Our study describes a concerted effort carried out in Portugal to reduce C-section rates, and evaluates its impact on obstetric indicators."

For the present study the research team used national data on births, C-sections, perinatal and maternal mortality between 2000 and 2014. Rates of instrumental vaginal delivery, Vaginal Birth After Cesarean (VBAC), hypoxia-related complications and perineal tears were also retrieved from state-owned hospitals.

From 2000 through 2009 the C-section rate in Portugal rose steadily, reaching a maximum of 36.6%. After the concerted action that started in early 2010, a significant decline to 33% was registered in the following years. During the entire period perinatal

mortality also declined, while maternal mortality remained stable. In the last few years the team also observed a significant increase in operative vaginal delivery (use of forceps or vacuum) and Vaginal Birth After Cesarean (VBAC), while newborn complications due to lack of oxygen (hypoxia) decreased.

"Our findings suggest that the intensive efforts carried out by Portuguese authorities that included sharing of information, training of healthcare professionals, and including C-section rates in the criteria for hospital funding may have been responsible for the changes observed across the country," concludes Prof. Ayres-de-Campos. "Similar efforts in countries that have high C-section rates such as the US, China, Italy, Turkey, and many others in Latin America, may prove an effective way to reduce the excessive use of this operation, and thus decrease the risks associated with delivery for both mother and child."

Full citation: "Lowered National Cesarean Section Rates After a Regional Concerted Action." Diogo Ayres-de-Campos, Joana Cruz, Claudia Medeiros-Borges, Cristina Costa-Santos and Lisa Vicente *Acta Obstetrica et Gynecologica Scandinavica*; Published online: March 2, 2015 (DOI: 10.1111/aogs.12582). URL Upon Publication: <http://doi.wiley.com/10.1111/aogs.12582>

Acta Obstetrica et Gynecologica Scandinavica is the official scientific journal of the Nordic Federation of Societies of Obstetrics and Gynecology (NFOG). It is a clinically oriented journal that covers all aspects of obstetrics, gynecology and reproductive health, including perinatology, gynecologic endocrinology, female urology and gynecologic oncology. The journal is published in English and includes: editors' messages, editorials, Acta commentaries, Acta reviews and original articles under the main categories of investigation, pregnancy, birth, fertility, infection, gynecology, gynecologic urology, oncology and surgery. The journal is published by Wiley on behalf of the NFOG. For more information, please visit <http://wileyonlinelibrary.com/journal/aogs>

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