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Pulse Oximetry in Screening for Congenital Heart Disease in Asymptomatic Newborns in the First 6 Hours After Birth

By M. Prabhu, MD; Arvind Shenoi, MD; BC Sathish, MD; Murali Mohan Voona, MD; Mohit Singhal, MD

Abstract

Objective: To evaluate the use of pulse oximetry within six hours after birth to screen newborns for early detection of life threatening congenital heart disease.

Design: Prospective observational study.

Setting: A study at tertiary level maternity and neonatal hospital from April 2012 to July 2012

Participants and Interventions

The study period was between April 2012 and July 2012. All asymptomatic neonates beyond 35 weeks of gestation were included and those needing oxygen or any support were excluded from the study. The doctor and a study nurse attending the delivery performed the test. Initially, the preductal saturations recorded from 2 minutes of age until the saturations reached 95%, and then the postductal saturations were recorded and observed until the saturations reached 95% or up to 20 minutes of age or whichever was earlier. Those newborns who failed the test at birth underwent repeat test at 3-6 hours of age. If saturation levels were less than 95%, then an echocardiogram was performed. In case the neonate showed signs of congenital heart disease, an echocardiogram was performed on these infants irrespective of the screening test.

Results

A total of 128 newborns were screened, of which 127 neonates were included in the study. Out of the 127 babies screened, one neonate had Congenital Heart Disease (CHD). One neonate had major cyanotic CHD (Pulmonary Atresia with VSD) and had passed the pulse oximetry screen. At Day 2 of life, the newborn found to have a systolic murmur and an echocardiogram confirmed CHD.

Conclusions

From our study, pulse oximetry test done within six hours of birth to rule out CCHD may not be sensitive, as a neonate with major CCHD was missed. Perhaps the earliest time to do pulse oximetry screening is beyond 24-hrs of age.

Key Words: Cyanotic Congenital Heart Disease (CCHD), newborn, pulse oximetry, screening

Introduction

Congenital Heart Defects (CHDs) are the most common group of congenital malformations and one of the leading causes of infant death in the developed world, accounting for more deaths than any other type of malformation.[1,2] Current routine screening for CHDs includes a mid-trimester anomaly ultrasound scan and a postnatal clinical examination. Both have a relatively low

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detection rate, and a number of babies are discharged from hospital and may die before a CHD is diagnosed.[4] The prevalence of CHD diagnosed in the first 12 months is estimated at 6-8 per 1000 live births.[3] About 25% of CHDs are life-threatening, and may manifest before the first routine clinical examination.[3] Failure to identify these critical lesions immediately after birth leads to delay in referral and increased mortality and morbidity.[4] Several studies have documented the lack of sensitivity of routine neonatal examination in detecting CHD.[5,6] Recent studies have reported a high sensitivity and specificity for pulse oximetry for early detection of CHD in newborn babies done after 24 hours of age.[7,8] It is more practical to do the screening test in the first few hours of birth, particularly in large maternity hospitals who practise early discharge from hospital. This study explores the option of early pulse oximetry screening for detection of Critical Cyanotic Congenital Heart Disease (CCHD).

Technology for CCHD Screening with Pulse Oximetry

Masimo SET pulse oximetry is a new and fundamentally distinct method of acquiring, processing and reporting arterial oxygen saturation and pulse rate. Masimo SET technology utilizes parallel processing engines, and enables the power of adaptive filters to be applied to real-time physiologic monitoring utilizing proprietary techniques, enabling direct calculation of arterial oxygen saturation and pulse rate.[9] Because it is not bound by a conventional "red over infrared" ratio approach, the Masimo SET system substantially eliminates the problems of motion artefact, low peripheral perfusion and most low signal-to-noise situations. This greatly expands the utility of SpO_2 in high motion, low signal and noise intensive environments.

Methods

This was a prospective hospital-based study (April 2012 – July 2012) conducted in a tertiary care perinatal hospital (Cloudnine Hospitals) in Bangalore. All consecutive newborns between April 2012 and July 2012 were prospectively screened for CCHD within six hours of birth. Babies born after 35 completed weeks and healthy at birth were included in the study. Neonates needing oxygen, symptomatic due to any other illness, or poor APGAR scores were excluded from the study. The doctor and the study nurse performed clinical screening in our study using a Masimo SET Pulse oximeter.

Once the baby was stabilised post-resuscitation, the baby was enrolled into the study within 6 hours of birth, after verbal informed consent from the parent. After initial assessment of baby, a study nurse fixed the saturation probe on right wrist (Preductal) for all babies. Serial saturation levels were documented by our study nurse at various intervals until the saturation levels reached 95% or more

"Recent studies have reported a high sensitivity and specificity for pulse oximetry for early detection of CHD in newborn babies done after 24 hours of age.[7,8] It is more practical to do the screening test in the first few hours of birth particularly in large maternity hospitals who practise early discharge from hospital. This study explores the option of early pulse oximetry screening for detection of critical cyanotic congenital heart disease (CCHD)."

consistently. Once we recorded a consistent preductal saturation level of 95% and above, the saturation probe was connected to right dorsal aspect of foot to record the postductal saturation. The time taken for the saturation reading to touch 95% and above was recorded. If the baby's SpO_2 (SAO_2) remained less than 95% or the difference between pre and post ductal SaO_2 was more than 3%, then the baby was said to have failed the primary test. A repeat test was performed within 6 hours of age. If the baby failed both the tests, then the neonate was subjected to echocardiogram by Paediatric Cardiologist.

Results

A total of 128 babies were included in the study. Of these one baby got admitted in NICU for reason other than CCHD and was excluded from the study. The demographic characteristics of the neonates included in our study are given in Table 1. The mean time taken to display the saturation and heart rate with good waveforms after applying the probe was 12 seconds. Ninety-seven percent of the babies reached the target preductal saturation at 12 96% the post ductal saturation reached its target at 17 mins. Twelve neonates failed the primary test, but all of them passed the re-test.

Out of 127 babies in our study, two had CHD. Major CHD was detected in one baby who was falsely negative for the test, but on routine clinical examination on Day 2 of life diagnosed to have an murmur, and an ECHO done showed Pulmonary Atresia with VSD. Antenatal scan done elsewhere was reported normal. One more baby had Muscular VSD, and was picked-up on routine postnatal follow-up. Both these babies had passed the primary test, and did not require a repeat screening.

Discussion

Most of the CHD that has been included as major (critical, serious) will have life threatening effect if not diagnosed promptly. Among infants in need of cardiac surgery before 2 months of age, Millender and Sunnegårdh[13] found that 4% with CHDs with ductus-dependent pulmonary circulation and 30% with CHDs with ductus-dependent systemic circulation were missed and had to be readmitted. An even higher percentage (38%) of ductus-independent severe CHDs was not detected before the infants were discharged. Reinhardt and Wren reported that as many as one third of babies with a potentially life-threatening CHD may leave the hospital with it undiagnosed.[14] Among these are CHDs with critical obstruction for blood flow to the lungs (eg: atresia of the pulmonary or tricuspid valves) or systemic circulation (eg, Hypoplastic Left Heart Syndrome, severe aortic stenosis, coarctation of the aorta, or interrupted aortic arch).

In a metanalyses of 8 studies, most with a SpO_2 cut-off 95%, Thangaratinam et al[15] found pulse oximetry to be a highly specific tool in detecting critical CHDs, with very low false-positive rates. The mean summary estimates of sensitivity and specificity rates were 63% and 99.8%, respectively, yielding a false-positive rate of 0.2%. However, in half the studies in the metanalyses, the infants were screened 24 hours after birth or just before discharge.

Presence of abnormal clinical signs like murmur should warrant a prompt cardiac evaluation, however, the clinical dilemma is that a majority of the CCHDs are clinically silent. Even if the initial screening is normal, it is mandatory to have a follow-up clinical evaluation prior to discharge and at first follow up

Table 1. Demographics Characteristics of the Neonate

Mode of Delivery	Caesarean section - 88 (69.3%)	Normal Delivery - 39 (30.7%)
Sex	Male - 61 (48%)	Female - 66 (52%)
Gestation	35 - 36+6 weeks - 35 (27.5%)	37 & more - 92 (72.5%) (Mean -38 weeks)

visit. A comprehensive approach consisting of improved awareness, refining of clinical skills and training of personnel in newer diagnostic techniques (pulse oximetry and echocardiography) is required to ensure that major CHDs do not go undetected in the newborn before discharge from hospital.

Because newborns with CCHD may have clinical deterioration in the first 48 hours of life, one would ideally use oximetry screening soon after delivery. However, arterial oxygen saturation varies considerably in the first 24 hours, with many healthy newborns having arterial saturations of less than 95%. As such, oximetry screening before 24 hours of life can result in a significant number of false positive results. A study from the United Kingdom reported that the false-positive rate was as high as 5% when oximetry screening was performed in the first 24 hours compared with 1% at the time of hospital discharge. Therefore, to achieve an acceptable specificity, testing 24 hours after birth would appear to be the most reasonable strategy. This screening strategy assumes that the majority of newborns will not be discharged on the first day of life.

The results obtained from our study involving 127 newborns failed to detect one case of major CCHD by pulse oximetry screening done within 6 hours of life. Based on this study, like other studies, pulse oximetry done before 24 hours of age has low sensitivity in detecting CCHD.[16] Large studies are needed for determining whether CCHDs can be reliably diagnosed prior to 6 hours of life with pulse oximetry or any other non-invasive tool.

Conclusion

Pulse oximetry immediately within 6 hours of birth cannot reliably rule out CCHD, and has low sensitivity. Larger studies are required to determine whether pulse oximetry can be used as a screening tool for CCHDs between 6-24 hours of birth. Hence, currently screening after 24 hours age should continue until such a study is done.

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"Pulse oximetry immediately within 6 hours of birth cannot reliably rule out CCHD, and has low sensitivity. Larger studies are required to determine whether pulse oximetry can be used as a screening tool for CCHDs between 6-24 hours of birth."

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Ronald McDonald House Charities® (RMHC®): An Organization Worth Knowing for the Neonatologist Community

By Muhammad Subhani, MD, MBA

Ronald McDonald House Charities® (www.rmhc.com), as it is known today, was initially started as Ronald McDonald House®, a single building in 1974, by combined efforts of Dr. Audrey, an oncologist who treated the daughter of Fred Hill, a Philadelphia Eagles tight end (TE), who was suffering from Leukemia, and local owner/operator of McDonald's in Philadelphia. Hill and his wife never left Kim's hospital bedside, sleeping on hospital chairs and benches, and eating food from vending machines. The Hills witnessed other parents doing the same, and learned that many families had traveled great distances to bring their sick children to the medical facility, burdened with the cost of comfortable living during their frequent treatment visits. They believed that there was a "happy medium" solution. Hill returned to his Eagle teammates, and rallied monetary support to help families who endured the same emotional and financial hardships. The group's mission was simple: to create a place where parents of sick children could gain respite and be with others who understood their situation and could provide emotional support. The core concept of providing a place and food for the families of sick infants/ kids closest to the hospital where their infants/ kids are admitted to avoid undue hardships still remains the most valuable contribution offered by this innovative organization.

Ronald McDonald House Charities (RMHC) programs support the entire family by providing stability and vital resources to help them focus on what's most important, their child.

Research shows that the Ronald McDonald House® program:

1. Improves the clinical outcomes and overall experience for sick children and their families,
2. Provides psychosocial support helping children cope better and heal faster,
3. Helps to reduce the financial burden that comes with having a sick child,
4. In 2012, families served by the Houses around the world saved $311 million in hotel costs alone.

Since its inception, the organization has added the services of Ronald McDonald Family Rooms within the hospital, mobile services units and grants to hospitals and organizations and scholarships for outstanding and financially deserving students within the USA. The latest figures as of June 2013 shows that there are 328 Ronald McDonald Houses in 33 countries and regions, 185 Ronald McDonald Family Rooms in 23 countries and regions; 106 in the U.S. and 49 Ronald McDonald Care Mobiles in 9 countries and regions; 40 in the U.S.

"Ronald McDonald House Charities (RMHC) programs support the entire family by providing stability and vital resources to help them focus on what's most important, their child."

Children being cared for at over 78% of the world's top children's hospitals have access to at least one core RMHC family-centered program. And, in 2012, RMHC was honored by the American Hospital Association as an exceptional partner in the delivery of health care services. Over the next five years, RMHC will expand its program reach by 37% to meet the increasing demand for services.

For the sake of relevance, only the Ronald McDonald House and Family Room will be discussed here for a better understanding of this organization by neonatologists. Over 40% of the children RMHC serves are infants who need the loving touch and care from their parents in order to heal. "Home Away from Home," could best explain any Ronald McDonald House. A family whose extremely premature infant finally lost the battle after eleven months of struggle was kind enough to share their experience about the feeling of being in home as follows:

"On April 1, 2007, our lives changed forever. Our little family of three was about to become four, 3½ months too soon. Little did we know what trials we would be facing! We had a very sick baby girl, named Emily May, who would be hooked up to a breathing machine, feeding tube and IV's…this was the scariest thing we would ever face. We were also faced with where we would live. We are from Guymon, Oklahoma, which is 2 hours from the hospital. My husband needed to continue to work, while I stayed with the baby. So many questions on where we would live, what were we going to do, we needed to be close to the hospital, but how could we

Figure 1. Volunteers seen during a meal preparation session for the parents.

Figure 2. Miss Martinez with her three boys during a weekend at Ronald McDonald House in Amarillo, with plenty of activities keeping them preoccupied.

Figure 3. Martinez family during weekend: Meeting with school going kids and the mother who takes care of the boys during week days at their house is a big relief for the Miss Martinez.

afford to buy food, pay for a motel or drive back and forth from home to Amarillo?

The social worker from Northwest Texas Healthcare set it all up for us. There was a facility named the Ronald McDonald House. It was a place for families with sick babies and children in the hospital. I remember walking in the Ronald McDonald House the night I had been discharged. I remember being scared. I didn't know these people, I wasn't comfortable staying in a place, alone, without my husband of 12 years and leaving my 4 year old little boy. As I walked through the hallways, I saw other families doing laundry, eating supper and watching TV. This place seemed very comfortable. Day after day, as I walked through those hallways to see my precious baby girl, I grew to love the ladies who worked and volunteered at the house. One in particular, Harriet, would always have a sweet smile on her face, get out of her chair and give me a hug. She was like my own grandma; I needed the compassion and friendship that she provided. During our 11 month stay, I saw people come and go, but I felt secure and at home in the house. It was home to me. I love The Ronald McDonald House, and my family will always be grateful to them for giving us a safe, clean and most importantly, a loving environment to live in."

Jeff, Veneisa, Luke and our precious heavenly angel, Emily May.

Another family who is currently enjoying the amenities of Ronald McDonald House describes their experience as follows:

"My son was born at 26 weeks. He has already spent over 120 days in the NICU. I lived over 30 min away from his hospital. Luckily Northwest Texas Hospital was associated with the Ronald McDonald House of Amarillo. I was able to be close to my very sick newborn and keep my other children with me as our family went through this trying time. I truly don't know what I would have done without Ronald McDonald House" (Figures 2,3).

April Martinez

Each House and Family Room is owned and managed by a local chapter of RHMC, which in turn has a board of directors. The initial cost of building the House and Family Room is dependent upon the individual chapter and community. In most cases, there is a salaried staff for day-to-day operation of the House and the Family Room whose salaries are paid by the money collected during various donation drives and personal donations from individuals and corporate donors. Later on, the expenses are maintained by monetary and in-kind donations.

Each facility is uniquely built according to the perceived needs of the community and supported entirely by the board members who are selected at regular intervals. The inside facilities are also variable, but uniformly consists of comfortable rooms with beds. In fact, the Amarillo location offers donated Tempur-Pedic® beds, a luxury by any standard. The guests enjoy a full-fledged kitchen and the amenities allow the parents to cook and bake according to the local guidelines. The Amarillo location provides a decent size refrigerator for each family. In addition, local businesses and families donate their time and money to prepare meals and bake according to their availability within the facilities (Figure 1). The businesses also help in maintaining a well-stocked pantry for the House and the Family Room. Coupons, both for free items and discounts also help the resident families, especially for dining.

The rules for allowing the families to stay also depend upon the individual location. Some of them entirely serve one particular set of patients like cancer. In almost cases, after the need is determined, the charge nurse with the help of a social worker initiates the process. Families are asked to pay a minimal per day fee for their stay ($15 in Amarillo facility), but in reality, it is also optional, as some families could not afford this amount as well. No one is turned away due to their inability to pay.

The Family Room is usually located inside the hospital and may consist of more than one room. Depending upon the particular entity, it may or may not have a place to shower. The main purpose of this is temporary stay for up to few hours at the most, enjoy some snacks and drinks, and watch TV while still on hospital premises. Some facilities also provide rooms for meditation and meeting place for large number of family members by the physicians and/or religious leaders in difficult cases of uncertainty about life continuation. The Ronald McDonald Family Room at Northwest Texas Hospital has a small kitchen area, dining area, a quiet room and a conversation area. Laundry facilities and a private shower are also available nearby. Volunteers staff the Family Room to offer families refuge from hallways and waiting rooms with privacy and personal comforts. It extends the comfort and support of Amarillo's Ronald McDonald House to the hospital setting.

The House and Family Room are excellent venue for volunteer activities as well. The author has been blessed to be involved in various volunteer activities with his entire family including wife and three kids for last thirteen years. Their activities are listed below for the sole purpose of providing a greater perspective to the readers so that their immediate family members, relatives and friends could serve as a helping hand to a great organization, where there is constant need of volunteers. My wife had donated hundreds of hand knitted wool hats and baby blankets for the newborns in the neonatal intensive care unit. My oldest daughter organized a gift collection for Christmas in Harlingen, Texas to be distributed to the infants in neonatal intensive care and pediatric intensive care units. My son and other daughter have participated during their high school and college years and both finished two projects at the Amarillo location. Additionally, they were volunteering their time on weekends at the Ronald McDonald House and the Family Room, for various volunteering activities ranging from doing the laundry at the house to be the managing person in the family room. My son was able to finish two projects between middle and high school years.

"Although most neonatologists may be partially aware of this organization, the author strongly suggests all practicing neonatologists visit the nearest Ronald McDonald House and Family Room, and meet in person with the executive of their local House to brainstorm different ideas for improving the services at that particular Home and Family Room with the involvement of their families and friends."

One project consists of donating two sets of desktop computers with monitors, high end video cameras attached with each desktop for video chatting and a wireless printer. This allowed the parents to remain in contact with their families and browse internet and print essential documents. The other project involved landscaping consisting of planting rose bushes and installation of solar LED lights. The first project of my younger daughter consisted of building a library of books, videos and CDsS. The second project, for her *Girl Scouts Golden Award*, consisted of creating digital CDs of the pictures taken of the infants admitted in the neonatal intensive care unit, whose parents were staying in the Ronald McDonald House. However, after completion of this project, all parents overwhelmingly wanted this volunteer activity to be continued for all the parents and not restricted to the Ronald McDonald House parents. A generous grant by the local Ronald McDonald House of Amarillo for about $8500 made it possible for us to initiate this innovative service as a standard of care, which has been published as well, so that other units could benefit from it as well.

Although most neonatologists may be partially aware of this organization, the author strongly suggests all practicing neonatologists visit the nearest Ronald McDonald House and Family Room, and meet in person with the executive of their local House to brainstorm different ideas for improving the services at that particular Home and Family Room with the involvement of their families and friends. Additionally, they could acquire a grant for improvement of their clinical unit with specific needs.

Acknowledgment: Latest facts and figures were provided by Miss. Clara Carrier of Ronald McDonald House of Charities (Global Office of RMHC) via email.

Some facts are an excerpt from the brochure of the local Amarillo House and Family Room brochure, courtesy of Shelley Cunningham and Jan Plequette.

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ICUs for Newborns in Nine States See Sharp Drop in Bloodstream Infections

Newswise — Central line associated bloodstream infections (CLABSIs) in newborns were reduced by 58% in less than a year in hospital neonatal intensive care units (NICUs) participating in an Agency for Healthcare Research and Quality (AHRQ) patient safety program. Frontline caregivers in 100 NICUs in nine states relied on the program's prevention practice checklists and better communication to prevent an estimated 131 infections and up to 41 deaths and to avoid more than $2 million in health care costs.

CLABSIs are healthcare-associated infections (HAIs) that cause serious illness and death in infants as well as adults. A central line is a tube (catheter) that goes into a patient's vein or artery and ends in the central bloodstream. In newborns, especially premature infants, central lines can remain in place for weeks or months to provide nutrients and medications as babies become able to function on their own.

Health care teams in the project states, caring for a total of 8,400 newborns, used AHRQ's Comprehensive Unit-based Safety Program (CUSP) to improve safety culture and consistently implement catheter insertion and maintenance guidelines. CUSP is customizable and helps hospitals understand and apply the science of safety and take actions to improve teamwork and communications. This 11-month project used CUSP to help clinical teams focus on safe practices and appropriate steps when using central lines based on guidelines from the Centers for Disease Control and Prevention.

Each state-based team was led by a neonatologist who worked with the state's hospital association to implement the project. When the project began, participating NICUs had an overall infection rate of 2.043 per 1,000 central line days. At the end of the project, that rate was reduced to 0.855 per 1,000 central line days, a relative reduction of 58%. For more information on how NICUs achieved this reduction, visit www.ahrq.gov/qual/clabsi-neonatal/.

"The CUSP framework brings together safety culture, teamwork and best practices—a combination that is clearly working to keep these vulnerable babies safer," says AHRQ Director Carolyn M. Clancy, MD. "These remarkable results show us that, with the right tools and dedicated clinicians, hospital units can rapidly make care safer."

The nine-state project in NICUs is part of a larger AHRQ-funded effort to implement CUSP to prevent CLABSIs nationwide. Preliminary results of the larger project were announced in September 2012; final results from the national implementation project are now available and show that CLABSIs were reduced by 41% in adult ICUs. The final report is available at www.ahrq.gov/qual/clabsi-final/.

AHRQ provided funding to the Health Research & Educational Trust (HRET), the educational arm of the American Hospital Association (AHA), to conduct both projects. For the NICU project, HRET partnered with the Perinatal Quality Collaborative of North Carolina and the Missouri Center for Patient Safety to support Colorado, Florida, Hawaii, Massachusetts, Michigan, New Jersey, North Carolina, South Carolina and Wisconsin.

"The successes of the project are proof that a great deal of improvement can happen in a relatively short timeframe," says Maulik S. Joshi, DrPH, President of HRET and Senior iP of the AHA. "We are excited by the outcomes of the collaborative, and we look forward to applying what we've learned about leveraging existing infrastructures to spread improvement in ongoing and future projects."

AHRQ's HAI Program contributes to the US Department of Health and Human Services' National Action Plan to Prevent Healthcare-Associated Infections (www.hhs.gov/ash/initiatives/hai/index.html) and the Partnership for Patients (www.healthcare.gov/compare/partnership-for-patients), which offer a coordinated approach to making care safer by drawing on the strengths and expertise of the HHS agencies.

Details about AHRQ's CUSP projects, including a report on the NICU project and the final report from the national implementation project, are available at www.ahrq.gov. AHRQ's CUSP toolkit, which was developed from the national implementation project and used in the NICU project, is available at www.ahrq.gov/cusptoolkit/.

The concept of CUSP was first developed by Peter J. Pronovost, MD, PhD, Director of the Armstrong Institute and Senior VP for Patient Safety and Quality at Johns Hopkins University, with funding from AHRQ. It was first tested statewide in over 100 adult ICUs in Michigan hospitals (the Michigan Keystone ICU Project) and then expanded to other states. Now, hospitals nationwide are using CUSP as a result of the national implementation project.

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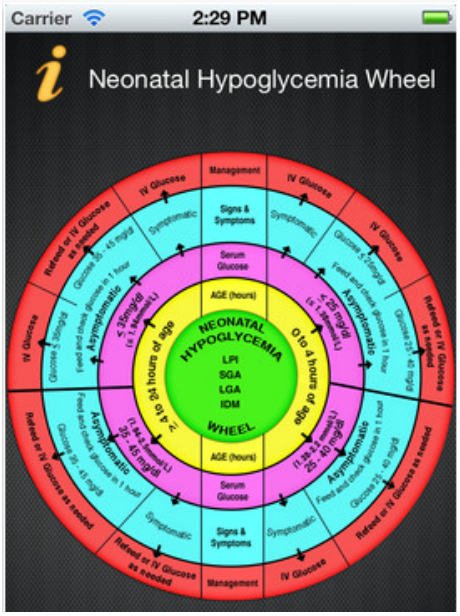

Management of Neonatal Hypoglycemia is a challenge especially when it comes to high risk neonates such as Infant of Diabetes Mellitus (IDM), Small for Gestational ages (SGA) and Large for Gestational Age (LGA) and Late Preterm Infants (LPI). Dr. David Adamkin, lead author of the AAP committee on Fetus and Newborn (COFN), recently published practical guidelines for screening and subsequent management of Neonatal Hypoglycemia in at risk Infants such as Late Preterm Infants (LPI), Small for Gestational Age (SGA), Large for Gestational Age (LGA) and Infants of Diabetic Mothers (IDM). These guidelines were used by Drs. Adamkin and Morarji Peesay, and Corazon B. Papageorgopoulos, BSN, RN to make an iPhone App called '*Sugar Wheel*.' [Postnatal glucose homeostasis in late-preterm and term infants. Committee on Fetusnand newborn, Adamkin DH. Pediatrics.2011 Mar;127(3);575-9.doi:10.1542/peds.2010-3851.Epub 2011 Feb28].

This app has guidelines for management of neonatal hypoglycemia data on a wheel format. Just by following arrows on the wheel and in each sector from innermost to outermost circle one can apply guidelines. Each sector describes management of Neonatal Hypoglycemia

Continued on page 11

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Utilize additional therapies to maximize oxygen delivery with validated ventilation systems.

Reference: 1. Data on file. Hampton, NJ: Ikaria, Inc; 2013.

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INOMAX Important Safety Information

- INOMAX is contraindicated in the treatment of neonates known to be dependent on right-to-left shunting of blood
- Abrupt discontinuation of INOMAX may lead to increasing pulmonary artery pressure and worsening oxygenation even in neonates with no apparent response to nitric oxide for inhalation

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INOmax® is a vasodilator, which, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

Utilize additional therapies to maximize oxygen delivery with validated ventilation systems. In patients with collapsed alveoli, additional therapies might include surfactant and high-frequency oscillatory ventilation.

The safety and effectiveness of INOmax have been established in a population receiving other therapies for hypoxic respiratory failure, including vasodilators, intravenous fluids, bicarbonate therapy, and mechanical ventilation. Different dose regimens for nitric oxide were used in the clinical studies.

Monitor for PaO_2, methemoglobin, and inspired NO_2 during INOmax administration.

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WARNINGS AND PRECAUTIONS

Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation
Wean from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

Hypoxemia from Methemoglobinemia
Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide
Nitrogen dioxide (NO_2) forms in gas mixtures containing NO and O_2. Nitrogen dioxide may cause airway inflammation and damage to lung tissues. If the concentration of NO_2 in the breathing circuit exceeds 0.5 ppm, decrease the dose of INOmax.

If there is an unexpected change in NO_2 concentration, when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO_2 analyzer should be recalibrated. The dose of INOmax and/or FiO_2 should be adjusted as appropriate.

Heart Failure
Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

ADVERSE REACTIONS
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

OVERDOSAGE
Overdosage with INOmax will be manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO_2. Elevated NO_2 may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO_2 levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

DRUG INTERACTIONS
No formal drug-interaction studies have been performed, and a clinically significant interaction with other medications used in the treatment of hypoxic respiratory failure cannot be excluded based on the available data. INOmax has been administered with dopamine, dobutamine, steroids, surfactant, and high-frequency ventilation. Although there are no study data to evaluate the possibility, nitric oxide donor compounds, including sodium nitroprusside and nitroglycerin, may have an additive effect with INOmax on the risk of developing methemoglobinemia. An association between prilocaine and an increased risk of methemoglobinemia, particularly in infants, has specifically been described in a literature case report. This risk is present whether the drugs are administered as oral, parenteral, or topical formulations.

 IMK111-01540 April 2013

Continued from page 8

based on infants age, blood glucose levels and signs and symptoms. Sectors are pinch and expandable. They have also made this app available as Laminated versions so that it can be hooked onto infants warmers/crib, and can be used by all the staff in the NICU/Nurseries/ Delivery rooms. This *Sugar Whee*l iPhone app was shown at the recent *PAS* (Pediatric Academic Societies) annual meeting in May 2013. This app and other neonatal iPhone/iPad apps - *NICU, Neonatal Nurse* and *Bili Whee*l, are FREE to download for limited time at the Apple store from your iPad or iPhone.

New *Journal of Pediatrics* Study Shows Strong Benefits Provided by Nutramigen® LGG®

A new independent, multi-center study on cow's milk allergy has been published in the May 2013 edition of the *Journal of Pediatrics.* The study shows significantly more infants with cow's milk allergy who received Nutramigen LGG, an extensively hydrolyzed formula that includes Lactobacillus rhamnosus GG (LGG), built a tolerance to cow's milk than those fed other formulas in the study. Specifically, nearly four out of five infants (78.9%) fed Nutramigen LGG built tolerance to cow's milk protein at 12 months, compared with infants fed other study products, such as extensively hydrolyzed casein formula (43.6%), hydrolyzed rice formula (32.6%), soy based formula (23.6%) or amino-acid based formula (18.2%). Historically, children with cow's milk allergy didn't build tolerance until three to five years of age.

"Building a tolerance to cow's milk at an earlier age has the potential to allow for earlier normalization of children's diets, which can result in reduced impact on their development and potentially lower medical costs," said study author and professor of pediatrics at the University of Naples, Roberto Canani, MD, PhD. "This study adds to the growing body of evidence that shows an extensively hydrolyzed formula with LGG helps manage cow's milk allergy fast."

Nutramigen is the only brand with extensively hydrolyzed protein and LGG. It contains a milk protein that is broken down into tiny pieces to virtually eliminate allergic reactions. While LGG is one of the most studied probiotics for allergy, this is the first study to compare the impact of Nutramigen LGG to other formulas based on symptom duration in infants with cow's milk allergy. The study is specific to Nutramigen with LGG infant formula. The results cannot be generalized to other probiotics or other Lactobacillus strains, since they all have different modes of action and varied effectiveness in model immune cell systems.

"We are pleased to see data further proving Nutramigen LGG, a brand trusted by moms and doctors alike, helps infants more quickly build tolerance to cow's milk," said Carol Lynn Berseth, MD, Director of Medical Affairs at Mead Johnson Nutrition. "Recognizing and managing cow's milk allergy early is important to helping infants get back on track to healthy growth and development."

Cow's milk allergy is the most common food allergy in infants 12 months and under. It can cause digestive problems, breathing difficulties, rashes or swelling of the face. Recent studies suggest the severity and duration of cow's milk allergy is increasing, which may limit an infant's diet, potentially leading to growth, development and health

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issues. The European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) guidelines recommend the use of an extensively hydrolyzed protein in most infants with cow's milk allergy. Nutramigen has been widely studied for more than 70 years.

The open non-randomized 12-month trial evaluated the rate of tolerance to cow's milk in 260 children aged 1 to 12 months diagnosed with cow's milk allergy who were fed extensively hydrolyzed casein formula (n=55), extensively hydrolyzed casein formula plus Lactobacillus GG (n=71), hydrolyzed rice formula (n=46), soy formula (n=55) or amino acid based formula (n=33). Full clinical evaluations were performed at 6 and 12 months to evaluate whether subjects had achieved oral tolerance to cow's milk protein.

The rate of children building oral tolerance to cow's milk at 12 months was significantly higher ($p<0.05$) in the groups receiving EHCF + LGG (78.9%) and EHCF (43.6%) compared with the other groups: RHF (32.6%), SF (23.6%) and AAF (18.2%).* Binary logistic regression analysis revealed that the rate of patients building tolerance at the end of the study was influenced by two factors: (1) IgE-mediated mechanism, and (2) formula choice. Patients who built tolerance were re-evaluated 6 months after trial completion to check the continued tolerance. The study was approved by the Ethics Committee of the University of Naples "Federico II."

Study authors include: Roberto Berni Canani, Department of Pediatrics, European Laboratory for the Investigation of Food Induced Diseases, University of Naples "Federico II," Naples, Italy; Rita Nocerino, Department of Pediatrics; Gianluca Terrin, Department of Gynecology-Obstetrics and Perinatal Medicine, University of Rome "La Sapienza," Rome, Italy; Tullio Frediani, Department of Pediatrics, University of Rome "La Sapienza," Rome, Italy; Sandra Lucarelli, Department of Pediatrics, University of Rome "La Sapienza," Rome, Italy; Linda Cosenza, Department of Pediatrics, University of Naples "Federico II," Naples, Italy; Annalisa Passariello, Neonatology and Pediatric Unit, Monaldi Hospital, Naples, Italy; Ludovica Leone, Department of Pediatrics, University of Naples "Federico II," Naples, Italy; Viviana Granata, Department of Pediatrics, University of Naples "Federico II," Naples, Italy; Margherita Di Costanzo, Department of Pediatrics, University of Naples "Federico II, Naples, Italy; Vincenza Pezzella, Department of Pediatrics, University of Naples "Federico II," Naples, Italy; Riccardo Troncone, Department of Pediatrics, European Laboratory for the Investigation of Food Induced Diseases, University of Naples "Federico II," Naples, Italy.

** Infant formula products used in the study included EHCF+LGG (Nutramigen LGG), EHCF (Nutramigen, Nutriben), RHF (Risolac), SF (Isomil, Sinilac and Nutrilon Soya), AAF (Neocate, Nutramigen AA and Sineall).*

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Effect of Different Oxygen Saturation Levels on Death or Disability in Extremely Preterm infants

In a randomized trial performed to help resolve the uncertainty about the optimal oxygen saturation therapy in extremely preterm infants, researchers found that targeting saturations of 85 percent to 89% compared with 91% to 95% had no significant effect on the rate of death or disability at 18 months, according to a study published by *JAMA*. The study was released early online to coincide with its presentation at the *Pediatric Academic Societies* annual meeting.

"Extremely preterm infants are monitored with pulse oximeters for several weeks after birth because they may require supplemental oxygen intermittently or continuously. The goal of oxygen therapy is to deliver sufficient oxygen to the tissues while minimizing oxygen toxicity and oxidative stress. It remains uncertain what values of arterial oxygen saturations achieve this balance in immature infants, who are especially vulnerable to the harmful effects of oxygen," according to background information in the article.

Barbara Schmidt, MD, MSc, of the Children's Hospital of Philadelphia and University of Pennsylvania, Philadelphia, and colleagues conducted a study to compare the effects of targeting lower or higher arterial oxygen saturations in extremely preterm infants on the rate of death or disability. The randomized trial, conducted in 25 hospitals in Canada, the United States, Argentina, Finland, Germany, and Israel, included 1,201 infants with gestational ages of 23 weeks 0 days through 27 weeks 6 days, who were enrolled within 24 hours after birth between December 2006 and August 2010. Follow-up assessments began in October 2008 and ended in August 2012.

Study participants were monitored until postmenstrual ages (the time elapsed between the first day of the mother's last menstrual period and birth [gestational age] plus the time elapsed after birth [chronological age]) of 36 to 40 weeks with pulse oximeters that displayed saturations of either 3% above or below the true values. Caregivers adjusted the concentration of oxygen to achieve saturations between 88% and 92%, which produced two treatment groups with true target saturations of 85% to 89% (n=602) or 91% to 95% (n=599). Alarms were triggered when displayed saturations decreased to 86% or increased to 94%. The primary outcome was a composite of death, gross motor disability, cognitive or language delay, severe hearing loss, or bilateral blindness at a corrected age of 18 months. Secondary outcomes included retinopathy of prematurity and brain injury.

The researchers found that targeting lower compared with higher oxygen saturations had no significant effect on the rate of death or disability at 18 months. "Of the 578 infants with data for this outcome who were assigned to the lower target range, 298 (51.6%) died or survived with disability compared with 283 of the 569 infants (49.7%) assigned to the higher target range," the authors write. "Of the 585 infants with known vital status at 18 months in the lower saturation target group, 97 (16.6%) had died compared with 88 of 577 (15.%) in the higher saturation target group."

Targeting lower compared with higher saturations reduced the average postmenstrual age at last use of oxygen therapy, but had no significant effect on any other outcomes, including the rate of severe retinopathy of prematurity.

"Clinicians who try to translate the disparate results of the recent oxygen saturation targeting trials into their practice may find it prudent to target saturations between 85% and 95% while strictly enforcing alarm limits of 85% at all times, and of 95% during times of oxygen therapy. Our findings do not support recommendations that

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targeting saturations in the upper 80% range should be avoided. Because it is very difficult to maintain infants in a tight saturation target range, such recommendations may lead to increased tolerance of saturations above 95% and an increased risk of severe retinopathy. Although no longer a major cause of bilateral blindness, severe retinopathy remains a marker of serious childhood disabilities," the authors conclude.

Prenatal Smoke Exposure Associated with Adolescent Hearing Loss

Prenatal smoke exposure was associated with hearing loss in a study of adolescents, which suggests that in utero exposure to tobacco smoke could be harmful to the auditory system, according to a study published June 20th, 2013, *Online First* by *JAMA Otolaryngology–Head & Neck Surgery.*

Exposure to second-hand smoke (SHS) is a public health problem and exposure to tobacco smoke from in utero to adulthood is associated with a wide variety of health problems, the authors write in the study background.

Michael Weitzman, MD, New York University School of Medicine, and colleagues studied data for 964 adolescents (ages 12 to 15 years) from the National Health and Nutrition Examination Survey 2005-2006 to determine whether exposure to prenatal tobacco smoke was associated with sensorineural hearing loss in adolescents.

Parents confirmed prenatal smoke exposure in about 16% of the 964 adolescents. Prenatal smoke exposure was associated with higher pure-tone hearing thresholds and an almost three-fold increase in the odds of unilateral low-frequency hearing loss, according to study results.

"The actual extent of hearing loss associated with prenatal smoke exposure in this study seems relatively modest; the largest difference in pure-tone hearing threshold between exposed and unexposed adolescents is less than 3 decibels, and most of the hearing loss is mild. However, an almost 3-fold increased odds of unilateral hearing loss in adolescents with

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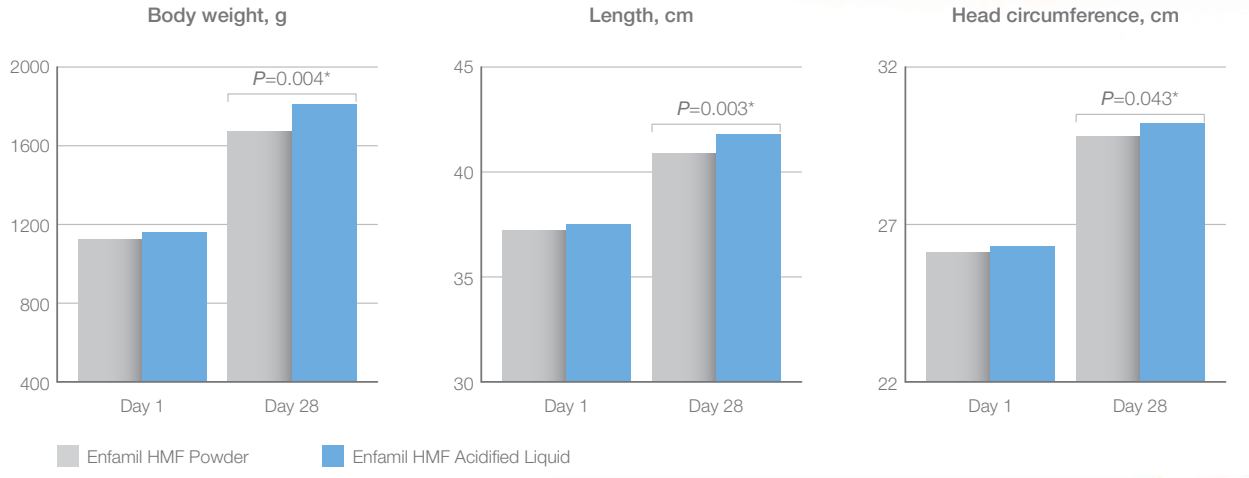

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