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Evaluating Newborns for Critical Congenital Heart Disease: Expanding the Availability of Diagnostic Echocardiography

By Amy L. Peterson, MD; Shardha Srinivasan, MBBS; and John Hokanson, MD

The term Critical Congenital Heart Disease (CCHD) is frequently used, but not always well-defined. Many clinicians define CCHD as those heart defects that are likely to result in death or disability without treatment in infancy. Modern surgical, catheterization, and anesthetic techniques, widespread access to echocardiography, and availability of prostaglandins have revolutionized the care of infants born with CCHD. However, Congenital Heart Disease (CHD) is still the most life-threatening condition in the first month of life, and as a group represents 20% of neonatal deaths.¹ In an effort to improve outcomes, much interest has been generated in facilitating earlier diagnosis.

Two important considerations limit the ability to demonstrate the value of early diagnosis of CCHD. If only those infants who survive to reach a tertiary care center are included for analysis, the adverse consequences of missed diagnoses are greatly understated and the value of early diagnosis underestimated. The failure to differentiate a timely postnatal diagnosis of CCHD (prior to hospital discharge or onset of symptoms) from an untimely postnatal diagnosis (after hospital discharge or onset of symptoms) also limits the available literature's ability to demonstrate the value of early detection of CCHD. Despite these inherent limitations, the available literature still demonstrates the benefit

of early diagnosis. In a study of 309 infants with congenital heart disease who survived to reach a tertiary care center, those with a postnatal diagnosis had higher rates of potentially unnecessary intubation and mechanical ventilation. Twenty-nine percent of postnatally diagnosed infants required more than two transports before they arrived at a facility equipped to treat their heart disease. Nineteen percent of infants had been discharged to home and were subsequently readmitted after presenting with symptoms.² Other studies have suggested similar improvements in outcome with earlier diagnosis.³⁻⁵

"...Congenital Heart Disease (CHD) is still the most life-threatening condition in the first month of life, and as a group represents 20% of neonatal deaths.¹ In an effort to improve outcomes, much interest has been generated in facilitating earlier diagnosis."

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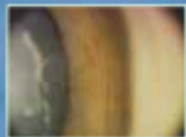


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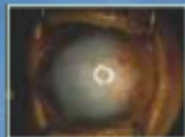


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Bringing Insight Into Vision

The detection of CCHD has evolved into a series of three mechanisms to detect these heart defects before the onset of symptoms and prior to hospital discharge: prenatal diagnosis, newborn physical exam, and pulse oximetry screening. Pulse oximetry screening has recently entered the field as the third safety net to detect CCHD that has not been recognized prenatally or identified by newborn physical examination. With the advent of pulse oximetry, a suspicion of CCHD prior to the onset of symptoms will be more frequently entertained prior to hospital discharge.

Prenatal Detection of Critical Congenital Heart Disease

What of prenatal diagnosis? Advances in routine obstetric ultrasound and the advent of fetal echocardiography have dramatically altered the approach to diagnosis of CCHD. However, even today, many infants with CCHD are not detected prenatally. Most infants born with CCHD are not from “high-risk” pregnancies that would trigger fetal echocardiography as a standard prenatal diagnostic test.⁶ In order to prenatally detect the majority of CCHD, obstetric sonographers and physicians must be able to screen apparently healthy fetuses and identify possible congenital heart disease. This is heavily dependent on the skill level of the operator and the types of cardiac screening views obtained. A large congenital cardiac referral center found low prenatal detection rates for all forms of congenital heart disease amenable to prenatal diagnosis. The overall detection rate for all forms of CHD was 28%, with much higher rates at university-based practices (80%) than community-based practices (23%).² This rate does not differ substantially from rates in other series of reports.⁷⁻¹⁰ Not surprisingly, detection rates varied enormously based on cardiac lesion, with higher prenatal detection rates among infants with heterotaxy, single ventricle physiology, or an atrioventricular canal defect (50-80%). Prenatal detection rates become disappointing with lesions such as Tetralogy of Fallot, mild Left Heart Obstructive Disease, or D-Transposition of the Great Arteries (19-31%).²

These low prenatal detection rates can be partly attributed to inadequate image acquisition technique or errors in interpretation, but this is not the entire explanation. Even with ideal images and interpretation, the expected detection rate for CHD in a low-risk population is only about 50% when a single 4-chamber view of the heart is used. The reason for this is obvious – many forms of CHD will in fact have a normal 4-chamber view. If this is the only view used to screen the heart, disease will be missed. The CHD prenatal detection rate climbs to 70-75% if a more comprehensive cardiac screen is used (4-chamber with outflow tracts and the “three vessel view”).⁹ Importantly, using the comprehensive cardiac screen will detect almost all forms of ductal-dependent CCHD. The importance of improving prenatal diagnosis rates cannot be over-emphasized; however, until the goal of universal prenatal detection is realized, additional tools to detect CCHD prior to the onset of symptoms are needed.

Postnatal Detection of Critical Congenital Heart Disease

Physical examination of the newborn is a vital tool in the detection of CCHD, but has significant limitations in its ability to detect CCHD prior to the onset of symptoms. Many infants with CCHD will not appear visibly cyanotic or have significant physical exam findings. Pulse oximetry screening for CCHD has recently emerged as an additional mechanism to detect CCHD prior to hospital discharge. When a postnatal diagnosis of CCHD is suspected by physical examination or pulse oximetry, echocardiography is the definitive diagnostic tool.

The technique to detect CCHD with pulse oximetry has been well-described.^{11,12} New Jersey was the first state to legally mandate pulse oximetry screening and recently published their first 9 months of data. Of 75,324 births in 52 different facilities across the state, a total of 72,694 neonates were screened with pulse oximetry. Forty-nine failed (yielding a failure rate of 0.067%), and of those, 30 infants had no other signs or symptoms that would have prompted clinicians to evaluate them further. Of those 30, all of whom received a diagnostic evaluation, 3 had

CCHD and 17 had another significant finding (sepsis, pneumonia, pulmonary hypertension, or a non-critical form of congenital heart disease). Of the 30 cases, only 6 infants required a transfer to a different facility that was triggered solely by the failed pulse oximetry screen (and 5 of those infants had potentially significant echocardiogram findings).¹³ Other studies have also demonstrated that when used appropriately, pulse oximetry screening has a very low false-positive rate.¹¹ For a state like New Jersey, with a relatively small geographical area, a high population density, and readily available on-site neonatal echocardiography, transportation of the small number of neonates a short distance to a facility with neonatal echocardiogram capabilities may be a good option.

Contrast those circumstances to those of Wisconsin, a state with a larger geographical area and lower population density. Ninety-nine hospitals in Wisconsin routinely deliver babies. Of 88 hospitals responding to a 2012 survey, 50 hospitals delivered less than one baby per day on average (Figure 1). A total of 55 Wisconsin hospitals, representing 25% of annual births, did not have same-day neonatal echocardiography available in house and would have to transport a baby to another institution to exclude CCHD, averaging 53 miles per transport.¹⁴ Given the very low rate of pulse oximetry screening failures, even the highest-volume maternity hospitals might see very few screening failures per year. For the lowest-volume hospitals, there could be years between screening failures.

Expanding the Availability of Neonatal Echocardiography

How then does one provide the appropriate diagnostic tools for such a rare event? Under many circumstances, a baby could be transported to

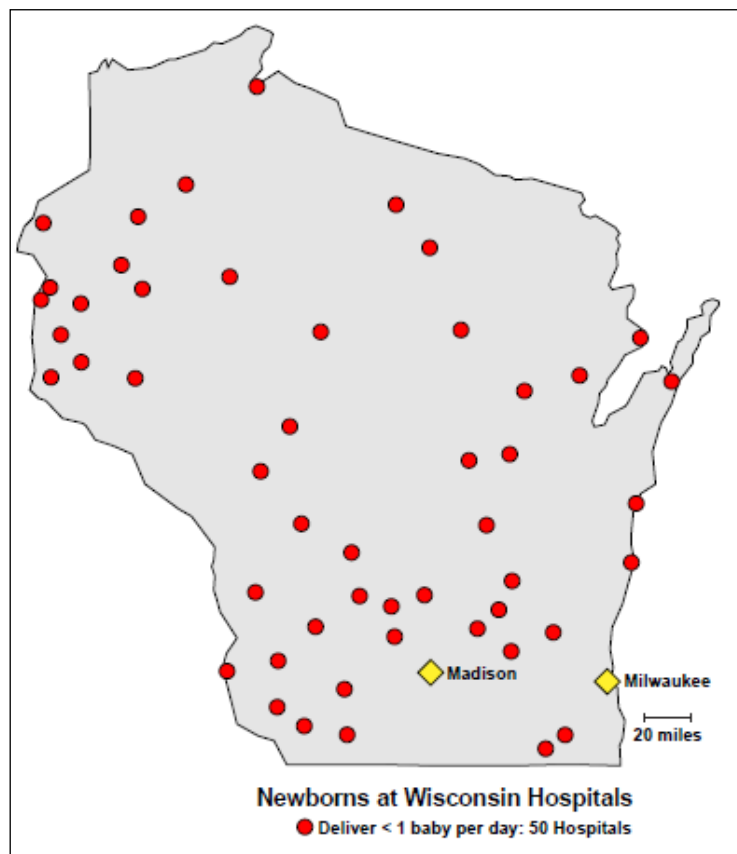


Figure 1. Geographic distribution of hospitals in Wisconsin. Circles show location of hospitals that deliver, on average, less than 350 babies annually. The diamonds identify Madison and Milwaukee, the two largest cities in Wisconsin. They are the only two locations in Wisconsin with pediatric cardiothoracic surgery and interventional cardiology services available.

an institution with available neonatal echocardiography, often separating a new mother from her baby. In extremes of weather (a not-uncommon event in many less densely populated regions), transport of a potentially healthy baby for a diagnostic test may not be the safest option for all involved. If the echocardiogram findings did indicate CCHD, the infant may also require a second transport to an institution able to provide tertiary-level cardiac services. How will a neonatal echocardiogram be performed and interpreted under these circumstances?

Telemedicine is one potential solution. Webb et al reported infants with congenital heart disease born in an institution with access to telemedicine required less transports, had a shorter time to diagnosis, and had a shorter length of both hospital and ICU stay. In this study, echocardiography was performed by sonographers experienced in adult and pediatric echocardiography and interpreted by a pediatric cardiologist.¹⁵ This intuitively makes sense. If a sonographer with substantial pediatric experience can obtain images and electronically send them to a pediatric cardiologist for interpretation, a diagnostic study can be performed without the cardiologist at the bedside. However in many centers that deliver babies, a sonographer with substantial pediatric experience is not available.

In most circumstances, the limiting factor in providing neonatal echocardiography is the availability of personnel who can obtain diagnostic images, not the technology required to transfer those images to a pediatric cardiologist for interpretation. Various solutions could be considered, including the utilization of personnel such as adult cardiac sonographers, general (non-cardiac) sonographers, physicians, or other individuals. However, given that a pulse oximetry screen failure in a smaller rural hospital will be such a rare event, a strategy of maintaining expertise in neonatal echocardiography among a group of people who do not routinely image the heart becomes impractical.

As a point of comparison, consider another application of cardiac ultrasound by non-sonographers. The use of Focused Cardiac Ultrasound (FCU) is endorsed by the American Society of Echocardiography (ASE). FCU is performed by ED and ICU physicians and is limited to a very specific evaluation of global myocardial function and pericardial effusion. To maintain proficiency in FCU, which is far less complex than a diagnostic neonatal echocardiogram, a three-part training approach is recommended, including didactic sessions, image acquisition, and image interpretation. The image acquisition portion of training generally takes the longest to achieve proficiency.¹⁶ In their consensus statement, the ASE FCU committee recommended a formal training program for FCU because the interpretation of the study will have a "direct impact on patient care." The importance of regular performance of FCU to maintain competency is also emphasized. Maintaining proficiency in neonatal echocardiography among noncardiac sonographers responding to such rare events is not a realistic proposal without a massive, and unjustifiable, expenditure of resources.

For a state like Wisconsin, if a sonographer experienced in adult echocardiography could be educated and coached to perform a neonatal echo on an infant who failed a pulse oximetry screen, the availability of in-house neonatal echocardiography expands considerably. A review of

the ARDMS (American Registry for Diagnostic Medical Sonography) database shows that in Wisconsin in 2013, there are 415 registered sonographers RDMS-certified in adult echo and 58 sonographers certified in pediatric echo. Looking at their distribution across hospitals that deliver babies, 33/88 hospitals had the capability for same-day neonatal echocardiography already in place, with 75% of Wisconsin's babies born at one of these facilities. Forty-three additional hospitals had the capability for same-day adult echocardiography. If adult echocardiographers in those facilities could be trained to perform newborn studies, same day echocardiography would be available to 97% of Wisconsin newborns.¹⁴ The availability of adult cardiac sonographers in all but the smallest hospitals is a resource that could be utilized to significantly expand the availability of same day neonatal echocardiography.

Echocardiographic Assessment of the Asymptomatic Newborn with a Failed Pulse Oximetry Screen

When a newborn fails pulse oximetry screening, once the possibilities of pulmonary disease or sepsis have been excluded, CCHD must be excluded by echocardiography. In this asymptomatic baby, the fundamental question to be answered is whether the baby needs immediate medical attention, needs outpatient cardiology follow-up, or can be sent home to receive normal newborn care. In a birth setting where definitive neonatal echocardiography performed by a pediatric trained cardiac sonographer is not available, the precise anatomic diagnosis may not be necessary as long as a distinction between normal and abnormal can be made. In a baby with no hemodynamic compromise, the risks of a missed diagnosis of CCHD must be balanced with the inconvenience, cost, and risk of transporting a newborn for echocardiography.

In our experience, a cardiac sonographer with adult training and the direct support of a remote pediatric cardiologist can perform echocardiography which answers the fundamental question of whether a baby has critical congenital heart disease. In nearly all situations, the pediatric cardiologist can be confident making one of three recommendations:

- 1) The echocardiogram demonstrates serious congenital heart disease or some other significant cardiac pathology necessitating immediate medical attention.
- 2) The echocardiogram is within normal limits and no further cardiovascular evaluation is necessary.
- 3) The echocardiogram demonstrates minor cardiac findings such as a small ventricular septal defect, a small patent ductus arteriosus, or a normally functioning bicuspid aortic valve that can be addressed with outpatient cardiology evaluation.

The need to transport an infant because the study could not confirm or exclude CCHD is quite rare.

Sonographer Education with the Wisconsin SHINE Project

This strategy, to educate adult sonographers in neonatal echocardiography technique, is one we have embraced at the Wisconsin SHINE (Screening Hearts In Newborns) project. A joint effort is being undertaken, combining the already-extensive cardiovascular imaging skill set of the adult sonographer with additional training and support from the pediatric cardiologist. To provide additional training, the Sonographer Education portion of the SHINE project is designed to assist sonographers who are not familiar with differences between congenital and adult echocardiography when faced with an asymptomatic neonate that has failed their pulse oximetry screen. This approach is not designed to be a comprehensive instruction in critical congenital heart disease, but to provide a basic framework that the adult cardiac sonographer can use to evaluate a newborn with remote support from a pediatric cardiologist. Sonographers are reminded that the goal of this echocardiogram is to assess for the presence of CCHD and determine whether or not advanced care is necessary for the neonate, not to make an exhaustive anatomic diagnosis.



The program is housed in the Wisconsin SHINE website (www.wisconsinshine.org) and will introduce sonographers to “The Terrible Ten” echo findings in critical congenital heart disease. These ten findings (Table 1) are ones that can be identified using the skill sets of an adult cardiac sonographer. The goal of this type of assessment is not to differentiate between the various forms of CCHD, but to determine if the infant requires immediate referral to a pediatric cardiac center for additional evaluation.

Additional defect-based segments are provided to foster better understanding of CCHD and echocardiography for CCHD. (Table 2). Sonographers are eligible for 2 SDMS CME credits free of charge upon completion of a pretest and posttest.

Conclusion

Under many circumstances, telemedicine may be an appropriate solution to providing diagnostic testing for an asymptomatic infant that has failed a pulse oximetry test. However, in the modern era of digital image acquisition and rapid electronic data transfers, image transfer technology is unlikely to be the limiting factor. The limiting factor is the skill of the sonographer performing the study and the

ability of the physician to both remotely assist the sonographer and interpret the study. For routine, widespread use of pulse oximetry screening to be successful, both these human factors will need to be adequately addressed. Training adult sonographers to perform neonatal echocardiography under the guidance of a pediatric cardiologist appears to be the most viable solution.

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Table 1:

“The Terrible Ten” Echo Findings that Could Indicate CCHD

- There is Retrograde Filling of the Ascending or Transverse Aorta
- The Aortic Arch Cannot Be Demonstrated in the SSN View
- There Is Exclusive Right-to-Left Shunting at Atrial or Ductal Level
- The Apical 4-Chamber View Is Abnormal
- An AV Valve Leaks... A Lot
- The Cardiac Apex Is Midline or Rightward
- A Normal Parasternal Long Axis View of the LV and Aorta Cannot Be Demonstrated
- A Normal Parasternal Short Axis View of the RV/PV/MPA Cannot Be Demonstrated
- The Aortic Valve and Pulmonary Valve Are Parallel
- Something Just Does Not Look Right

Table 2:

Types of Potentially Critical Congenital Heart Disease a Sonographer Might Encounter

- Cardiomyopathy
- Coarctation of the Aorta
- Critical Aortic Stenosis
- D-Transposition of the Great Arteries (including discussion of restrictive atrial septum)
- Ebstein’s Anomaly
- Hypoplastic Left Heart Syndrome
- Interrupted Aortic Arch
- L-Transposition of the Great Arteries
- Single Ventricle Physiology
- Tetralogy of Fallot
- Total Anomalous Pulmonary Venous Return (including discussion of obstructed TAPVR)
- Tricuspid Atresia and Pulmonary Atresia with Intact Ventricular Septum



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“Under many circumstances, telemedicine may be an appropriate solution to providing diagnostic testing for an asymptomatic infant that has failed a pulse oximetry test. However, in the modern era of digital image acquisition and rapid electronic data transfers, image transfer technology is unlikely to be the limiting factor. The limiting factor is the skill of the sonographer performing the study and the ability of the physician to both remotely assist the sonographer and interpret the study.”

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Corresponding Author



*Amy L. Peterson, MD
Assistant Professor of Pediatrics
Division of Pediatric Cardiology
University of Wisconsin School of
Medicine and Public Health
600 Highland Ave., MC 4108
Madison, WI 53792 USA
Tel: 608.263.8536; Fax: 608.265.8065
apeterson@pediatrics.wisc.edu*



*Shardha Srinivasan, MBBS
University of Wisconsin School of
Medicine and Public Health
600 Highland Ave.
Madison, WI 53792 USA*



*John Hokanson, MD
University of Wisconsin School of
Medicine and Public Health
600 Highland Ave.
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INDICATION

SURFAXIN[®] (lucinactant) Intratracheal Suspension is approved by the FDA for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS.

IMPORTANT SAFETY INFORMATION

SURFAXIN (lucinactant) Intratracheal Suspension is intended for intratracheal use only. The administration of exogenous surfactants, including SURFAXIN, can rapidly affect oxygenation and lung compliance. SURFAXIN should be administered only by clinicians trained and experienced with intubation, ventilator management, and general care of premature infants in a highly supervised clinical setting. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status.

Most common adverse reactions associated with the use of SURFAXIN are endotracheal tube reflux, pallor, endotracheal tube obstruction, and need for dose interruption. During SURFAXIN administration, if bradycardia, oxygen desaturation, endotracheal tube reflux, or airway obstruction occurs, administration should be interrupted and the infant's clinical condition assessed and stabilized. Overall the incidence of administration-related adverse events did not appear to be associated with an increased incidence of serious complications or mortality relative to the comparator surfactants.

SURFAXIN is not indicated for use in acute respiratory distress syndrome (ARDS).

For more information about SURFAXIN, please visit www.SURFAXIN.com and see accompanying brief summary on the next page.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full prescribing information.

INDICATIONS AND USAGE

SURFAXIN® is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Acute Changes in Lung Compliance

Administration of exogenous surfactants, including SURFAXIN, can rapidly affect lung compliance and oxygenation. SURFAXIN should be administered only by clinicians trained and experienced in the resuscitation, intubation, stabilization, and ventilatory management of premature infants in a clinical setting with the capacity to care for critically ill neonates. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status.

Administration-Related Adverse Reactions

Frequently occurring adverse reactions related to the administration of SURFAXIN include bradycardia, oxygen desaturation, reflux of drug into the endotracheal tube (ETT), and airway/ETT obstruction.

Increased Serious Adverse Reactions in Adults with Acute Respiratory Distress Syndrome (ARDS)

Adults with ARDS who received lucinactant via segmental bronchoscopic lavage had an increased incidence of death, multi-organ failure, sepsis, anoxic encephalopathy, renal failure, hypoxia, pneumothorax, hypotension, and pulmonary embolism. SURFAXIN is not indicated for use in ARDS.

Clinical Trials Experience

The efficacy and safety of SURFAXIN for the prevention of RDS in premature infants was demonstrated in a single randomized, double-blind, multicenter, active-controlled, multi-dose study involving 1294 premature infants (Study 1). Infants weighed between 600 g and 1250 g at birth and were 32 weeks or less in gestational age. Infants were randomized to received 1 of 3 surfactants, SURFAXIN (N = 524), colfosceril palmitate (N = 506), or beractant (N = 258). Co-primary endpoints were the incidence of RDS (defined as having a chest x-ray consistent with RDS and an FiO₂ ≥ 0.30) at 24 hours and RDS-related mortality at 14 days. The primary comparison of interest was between SURFAXIN and colfosceril palmitate with the intent of demonstrating superiority. Beractant served as an additional active comparator. Compared to colfosceril palmitate, SURFAXIN demonstrated a statistically significant improvement in both RDS at 24 hours and RDS-related mortality through Day 14. A second multicenter, double-blind, active-controlled study involving 252 premature infants was also conducted to support the safety of SURFAXIN (Study 2). Infants weighed between 600 g and 1250 g and were less than 29 weeks in gestational age. Infants received 1 of 2 surfactants, SURFAXIN (N = 119) or poractant alfa (N = 124).

The safety data described below reflect exposure to SURFAXIN administered intratracheally to infants at a dose of 5.8 mL per kg (up to 4 doses) in either 4 aliquots (Study 1) or 2 aliquots (Study 2) in 643 premature infants.

Comparator surfactants colfosceril palmitate and beractant were administered at the recommended doses (5.0 and 4.0 mL per kg, respectively) while the first dose of poractant alfa administered (2.2 mL per kg) was less than the recommended dose of 2.5 mL per kg. Any subsequent doses of poractant alfa were at the recommended 1.25 mL per kg dose.

Overall, the incidence of administration-related adverse reactions was higher in infants who received SURFAXIN compared to other surfactants (Table 1) and resulted in a greater proportion of infants treated with SURFAXIN who experienced administration-related oxygen desaturation and bradycardia. For Study 1, oxygen desaturation was reported in 17%, 9%, and 13% and bradycardia for 5%, 2%, and 3% of infants treated with SURFAXIN, colfosceril palmitate, and beractant, respectively. For Study 2, oxygen desaturation was reported in 8% and 2% and bradycardia in 3% and 2% of infants treated with SURFAXIN and poractant alfa, respectively. These adverse reactions did not appear to be associated with an increased incidence of serious complications or mortality relative to the comparator surfactants (Table 2).

Table 1. Administration-Related Adverse Reactions in SURFAXIN Controlled Clinical Studies^a

| | Study 1 ^b | | | Study 2 ^c | |
|--|----------------------|---------------------------------|---------------------|----------------------|--------------------------|
| | SURFAXIN (N = 524) | Colfosceril palmitate (N = 506) | Beractant (N = 258) | SURFAXIN (N = 119) | Poractant alfa (N = 124) |
| Total Doses Administered | 994 | 1038 | 444 | 174 | 160 |
| Total Number of Events (Events per 100 Doses) | | | | | |
| ETT Reflux | 183 (18) | 161 (16) | 67 (15) | 47 (27) | 31 (19) |
| Pallor | 88 (9) | 46 (4) | 38 (9) | 18 (10) | 7 (4) |
| Dose Interruption | 87 (9) | 46 (4) | 30 (7) | 7 (4) | 2 (1) |
| ETT Obstruction | 55 (6) | 21 (2) | 19 (4) | 27 (16) | 1 (1) |

^a Table includes only infants who received study treatment.

^b Study 1 doses were administered in 4 aliquots.

^c Study 2 doses were administered in 2 aliquots.

Table 2. Common Serious Complications Associated with Prematurity and RDS in SURFAXIN Controlled Clinical Studies Through 36-Weeks Post-Conceptual Age (PCA)

| | Study 1 | | | Study 2 | |
|---|----------------------|-----------------------------------|-----------------------|----------------------|----------------------------|
| | SURFAXIN (N = 527) % | Colfosceril palmitate (N = 509) % | Beractant (N = 258) % | SURFAXIN (N = 119) % | Poractant alfa (N = 124) % |
| Apnea | 52 | 52 | 46 | 66 | 75 |
| Intraventricular hemorrhage, all grades | 52 | 57 | 54 | 39 | 38 |
| -Grade 3/4 | 19 | 18 | 21 | 13 | 8 |
| Periventricular leukomalacia | 10 | 10 | 12 | 4 | 9 |
| Acquired sepsis | 44 | 44 | 44 | 45 | 52 |
| Patent ductus arteriosus | 37 | 35 | 37 | 43 | 44 |
| Retinopathy of prematurity, all grades | 27 | 26 | 25 | 32 | 31 |
| -Grade 3/4 | 6 | 7 | 6 | 5 | 9 |
| Necrotizing enterocolitis, all grades | 17 | 17 | 19 | 13 | 15 |
| -Grade 2/3 | 6 | 8 | 14 | 8 | 8 |
| Pulmonary air leak through Day 7, all types | 15 | 17 | 14 | 9 | 7 |
| -Pulmonary interstitial emphysema | 9 | 10 | 10 | 3 | 5 |
| -Pneumothorax | 3 | 4 | 2 | 4 | 1 |
| Pulmonary hemorrhage | 10 | 12 | 14 | 6 | 9 |

All-cause mortality through 36-weeks PCA was similar regardless of which exogenous surfactant was administered.

Adverse reactions reported in the controlled clinical studies through 36-weeks PCA occurring in at least 10% of infants were anemia, jaundice, metabolic acidosis, oxygen desaturation, hyperglycemia, pneumonia, hyponatremia, hypotension, respiratory acidosis, and bradycardia. These reactions occurred at rates similar to the comparator surfactants.

No assessments for immunogenicity to SURFAXIN were performed in these clinical studies.

Follow-up Evaluations

Twelve-month corrected-age follow-up of 1546 infants enrolled in the 2 controlled clinical studies demonstrated no significant differences in mortality or gross neurologic findings between infants treated with SURFAXIN and those treated with the comparator surfactants (colfosceril palmitate, beractant, or poractant alfa).

OVERDOSAGE

There have been no reports of overdose following the administration of SURFAXIN.

HOW SUPPLIED/STORAGE AND HANDLING

SURFAXIN (lucinactant) Intratracheal Suspension is supplied sterile in single-use, rubber-stoppered, clear glass vials containing 8.5 mL of white suspension (NDC 68628-500-31). One vial per carton.

Store SURFAXIN in a refrigerator at 2° to 8°C (36° to 46°F) and protect from light until ready for use. Do not freeze. Vials are for single use only. Discard any unused portion of SURFAXIN. Discard warmed vials of SURFAXIN if not used within 2 hours of warming.

To report SUSPECTED ADVERSE REACTIONS, contact Discovery Laboratories, Inc. at 1-877-SURFAXN (877-787-3296) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

AAP's Perinatal Workshop to be Held at DoubleTree Paradise Valley Resort Scottsdale, AZ

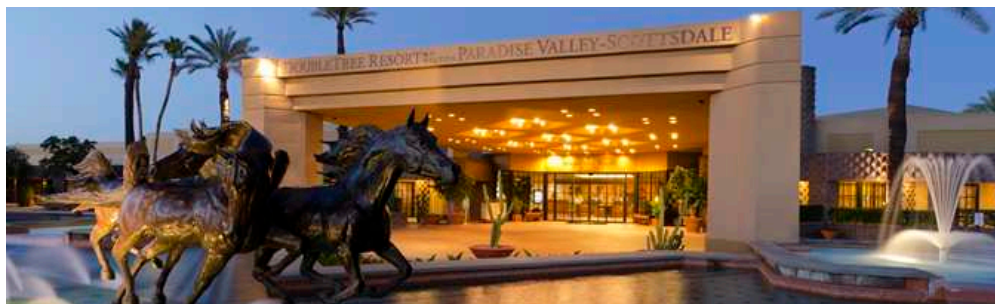
By Howard Kilbride, MD

The *Perinatal Workshop* will again be held at DoubleTree Paradise Valley Resort in beautiful Scottsdale, AZ. The theme of the meeting, which will be held on April 4-6, 2014, will be "Innovation with Evidence." Because many other meetings provide the clinical and research evidence upon which we base clinical decisions, we focus on leading the transition from theory to actual practice. While we will provide new clinical insights, many of the topics of this meeting will focus on: organizational structure, evaluation methods applicable to the NICU, communication challenges, people skills, fiscal expertise and leadership.

As in years past, the 2014 "Scottsdale Meeting" will begin on Friday morning with the optional coding seminar, lead by Stephen Pearlman, Gil Martin and Richard Molteni, AAP coding experts. There will be an initial didactic session to provide background for recent and upcoming coding changes, followed by case presentations, audience participation and discussion to illustrate important points in accurate and complete coding. Because of upcoming changes to diagnostic codes, appropriate coding as per ICD-10 will be discussed for each clinical scenario. For non-physician coding professionals, there will be a special extended discussion and networking opportunity on Friday afternoon.

The *Perinatal Workshop* formally begins on Friday afternoon with the L. Joseph Butterfield Lecture, this year presented by Eduardo Bancalari, former Apgar Awardee and internationally recognized neonatologist, entitled "Respiratory Support in the Premature Infant: Where We Have Been and Where We Are Going." The afternoon continues with Keith Barrington, another internationally renowned clinical investigator, who will offer commentary on "Using Evidence to Innovate Practice: Challenges and Opportunities." Annie Janvier, neonatologist and ethicist, will address a complex challenge: "Intensive Care for Fragile Neonates: What is the Value of Life?" The afternoon will also offer non-medical commentary by Mark Del Monte, Chief Public Affairs Officer for the AAP in Washington, DC, addressing "Advocacy for Newborn Care in a Changing Political Environment." As in years past, the Friday afternoon session will conclude with a town hall meeting with the AAP President-elect.

The meeting will continue on Saturday morning with smaller-venue, concurrent workshop sessions. There will be opportunities to attend sessions on a variety of topics or to select a specific focus, including clinical, business



management, or early career topics. Business management focus will include opportunities for learning more about economic underpinnings of neonatal care, as well as additional budget and coding education. Trainees or junior faculty may find benefit in: attending mock interview sessions, reviewing how to write a grant proposal, hearing a current update on use of social media, and discussing unique career positions, such as "hybrid neonatal practice" (community based academic positions). Diverse clinical topics will be presented, with focus on how to use the evidence to most effectively practice neonatology. Topics include: "Apnea and Desats: When Do We Intervene?," "Counseling Families for Infants with Life-Limiting Diagnoses," "Using the EMR to Improve Evidence-Based Medicine Practice," and "Optimizing Mechanical Ventilation." Those interested in "hands-on" experience will have opportunity to practice advanced simulation techniques for resuscitation training. The faculty for these workshops include well-recognized medical educators, investigators, and clinicians: Judy Aschner, Steve Donn, John Hartline, Richard Martin, Tonse Raju, Renate Savich, Ken Slaw, Brian Smith, and John Zupancic.

Optional seminars will be offered on Saturday afternoon for leadership training (Ken Slaw) or education regarding quality improvement and MOC (John Hartline, Janet Muri, and Stephen Pearlman). For those who attended last year, these sessions will provide further opportunity to build on your knowledge and expertise in these areas. For new attendees, the seminars will provide important introductions to the topics, with an opportunity to learn from others who have been working on these skills.

Members of the Committee on Fetus and Newborn (COFN) will begin Sunday morning with an interactive session, providing an update of guidelines and reports to be published or under consideration. The audience interaction that follows this presentation provides an important opportunity for COFN members to receive feedback from practicing neonatologists about current proposals, as well as input for prioritization for future consideration by the committee. Later in the morning, there will be (possibly) controversial presentations on evidence for treatment of common neonatal prob-



lems, bronchopulmonary dysplasia and gastroenteral reflux, and new information about how we can creatively obtain and use evidence from our practice to improve care.

Although the Workshop offers extensive educational programming, the meeting structure will be informal, and the environment comfortable. There will be ample opportunity for attendees to meet colleagues, develop new friendships, and exchange ideas. The setting for this spring meeting in Scottsdale, Arizona, is great for families or for attendees who want to take some relaxation time around the meeting. The weather is idyllic for outdoor activities, which include hiking, horseback riding, mountain-biking and water sports, like river rafting. Of course, "Old Town" is just a short walk away, with great shopping and lots of restaurants.

This conference is unique! Most meetings talk about how to manage neonates; we focus on how to manage neonatology - its practice, personnel, and environment. For those in practice, it is a great way to get a little "outside the box;" for trainees and early career neonatologists, it provides a great opportunity to learn important concepts not taught in fellowship; and for anyone attending the meeting, the Arizona sun will provide incentive to make sure you don't just stay in the classroom all day! Register online at: www.pedialink.org/cmefinder or call toll-free 800-433-9016, option 3.

NT

Howard Kilbride, MD, FAAP
Workshop Program Chair
Children's Mercy Hospital
Kansas City, MO 64108 USA
Tel: 816.234.3591
hkilbride@cmh.edu

Medical News, Products & Information

Steroid Injections for Premature Babies Linked to Mental Health Risk

Steroid injections given to pregnant women before premature birth may increase the child's risk of later behavioural and emotional difficulties, a study has found.

Mothers who are expected to give birth prematurely are often given an infusion of glucocorticoids, which mimic the natural hormone cortisol. This treatment is vital for helping the baby's lungs mature, but new research suggests it may also increase the risk of mental health problems including attention-deficit/hyperactivity disorder (ADHD). ADHD is the most common behavioural disorder in young people in the UK.

The study, by researchers at Imperial College London and the University of Oulu, Finland, is published in the journal *PLOS ONE*.

Cortisol is produced in the fetus in the late stages of pregnancy to help the lungs develop, preparing the baby for life outside the womb. Lung problems are common in premature babies, and can cause life-threatening breathing difficulties. Synthetic glucocorticoids, which replicate the effects of natural cortisol, are given in anticipation of preterm birth to reduce the risk of these problems.

There has been some concern that exposure to high levels of glucocorticoids in the womb might have harmful long-term effects on brain development. Scientists have previously established a link between stress in pregnancy and symptoms of ADHD in children. As cortisol is produced as a response to stress, it has been suggested that cortisol may be responsible for this link.

The researchers studied 37 children who were exposed to synthetic glucocorticoids before birth and compared them to 185 children who were born at the same gestational age but did not have glucocorticoid treatment. A much larger comparison group of 6,079 children, matched carefully on pregnancy and infant characteristics, was also examined to confirm the findings.

The children who had the treatment had poorer general mental health scores at ages eight and sixteen, and were more likely to show symptoms of ADHD.

Alina Rodriguez, the senior author of the study, Visiting Professor at the School of Public Health at Imperial College London, said, "There are a lot of studies that have found links between stress in pregnancy and effects on children's mental health, especially ADHD, and this might be related to cortisol.

"Synthetic glucocorticoids mimic the biological reaction when the mother is stressed, so we wanted to see if babies who were exposed to this treatment are affected similarly in terms of mental health outcomes."

"This study suggests there may also be long-term risks for the child's mental health. Although this is the largest study so far to look at these risks, the number of children in our group who were exposed to glucocorticoids was still relatively small. More studies will be needed to confirm the findings."

"We would like to reassure parents that in light of all available evidence to date, the benefits of steroid treatment on immediate infant health and survival are well-established and outweigh any possible risk of long-term behavioural/emotional difficulties. Parents who are concerned that their child may be affected by behavioural or emotional difficulties should, in the first instance, contact their GP for advice."

The participants were part of the Northern Finland Birth Cohort, a study that recruited women in early pregnancy in 1985-86 and gathered information about the health of the children at age eight and sixteen.

The research was funded by the Academy of Finland; Sigrid Juselius Foundation, Finland; Thule Institute, University of Oulu, Finland; the National Institute of Mental Health; and EURO-BLCS (biological, clinical and genetic factors for future risk of cardiovascular diseases). Prof Rodriguez received funding partly from FAS (Swedish Council for Working Life and Social Research).

For more information: www.imperial.ac.uk.

Human Error Most Common Cause of Birth Asphyxia

Findings from a 15-year study published in *Acta Obstetrica et Gynecologica Scandinavica*, a journal of the Nordic Federation of Societies of Obstetrics and Gynecology, indicate that human error is the most common cause of infant asphyxiation at birth. Inadequate fetal monitoring, lack of clinical skills, and failure to obtain senior medical staff assistance are most often cited in Norwegian compensation claims following birth asphyxia.

In Norway there are roughly 60,000 births each year, with The Norwegian System of Compensation to Patients (NPE) receiving 65 claims for obstetric injury to the child. A previous study by the current research team found that asphyxia was the most common cause for compensation—between 20 and 25 cases annually. Prior research estimate that lifelong compensation for injury caused by birth asphyxia averages about €430,000 (\$574,000) in Norway, with costs more than 10 times higher in the US.

"While fetal brain injury or death is uncommon during childbirth, when it occurs the effects are devastating," explains Dr. Stine Andreassen with the Department of Obstetrics and Gynecology at Nordlandssykehuset (Nordland Hospital) in Bodø, Norway. "Our study investigates claims made to the NPE for neurological injury or death following birth asphyxia."

For the present study, researchers examined 315 claims made to the NPE between 1994 and 2008 that were associated with alleged birth asphyxia. The team looked at hospital records, assessments by experts, along with NPE and courts of law decisions. Of the claims made, there were 161 cases that were awarded compensation.

Results show that in the compensated cases there were 107 infants who survived, with 96 having neurological injury, and 54 children who died. Human error was the most common cause of birth asphyxia with 50% attributed to inadequate fetal monitoring, 14% lack of clinical knowledge, 11% non-compliance to clinical guidelines, 10% failure

2014

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to ask for senior medical assistance, and 4% were errors in drug administration. In cases of substandard care, the obstetrician and midwife were documented as the responsible staff at 49% and 46%, respectively.

"In most compensated cases, poor fetal monitoring led to an inadequate supply of oxygen to the infant," concludes Dr. Andreasen. "Training for midwives and obstetricians, along with high-quality audits, could help to reduce claims for compensation after birth asphyxia."

This study was published in *Acta Obstetrica et Gynecologica Scandinavica*.

Electronic Health Records May Be Used to Measure Patient-Centered Care

Although electronic health records (EHR) are primarily used to store patient clinical data, the non-clinical data they collect may be used to measure patient-centeredness of primary care practices, finds a new study in Health Services Research. In addition, two of the process of care measures collected via EHRs, volume of between clinician e-messages and frequency of in-person patient visits, were associated with better patient health outcomes.

"We were looking for ways to leverage the amount of operational information in a practice's EHR and find measurements of the process-of-care," said Ming Tai-Seale, PhD, MPH, a senior staff scientist at the Palo Alto Medical Foundation Research Institute in Palo Alto, CA, and lead author on the study. "We were pleasantly surprised to see we could do that," she said.

The study collected data on more than 15,000 people with diabetes and more than 49,500 patients with high blood pressure who were patients at a large group practice in Northern California during 2010. The clinical data collected included blood glucose and blood lipid levels and blood pressure readings. Then they examined the relationship between that clinical information and various nonclinical types of EHR information, including the volume of secure electronic communication (e-messages) between physicians and patients, e-messages about patients within the practice, and the time to the third-next-available appointment, a measure of how easy it is to schedule non-urgent visits.

The volume of e-messages, the number of days to the third-next-available appointment, and the volume of internal communications were found to be reliable measures of the processes of care within a patient-centered practice. In addition, better blood lipid management and blood pressure control was associated with frequent e-messaging between doctors and patients with diabetes. Practices with more in-person visits had better blood pressure control in patients with high blood pressure.

These [non-clinical] data are the type of often evaluated by those looking at how well a large practice operates, but had not necessarily been linked to a clinical outcome, Tai-Seale noted. "The reason we also looked at process-of-care measures—emailing, e-messages with staff, and continuity of care—is because these have not been used to study their linkages with patient health outcomes before," she said.

"It seems they are trying to solve a problem kind of backwards," said Jason Mitchell, MD, Director of the American Academy of Family Physicians Center for Health IT in Leawood, KS. The researchers are looking at operational activities and trying to correlate them with clinical outcomes, he commented. "Yes, there is an association, but there isn't any evidence of a cause and effect." There may be other variables that can change this association, he explained.

Many health policy organizations are trying to measure the value of health care, and not just the cost; but, not every area of medicine has clinical outcomes as clear cut as blood glucose and blood pressure levels, commented Mitchell. Most organizations are frustrated that they are not able to get such direct information and are seeking proxies they can measure. "We really need to be looking at those outcomes and use EHRs to get that directly instead of [using] proxies," he noted.

Health Services Research is the official journal of the Academy Health and is published by John Wiley & Sons, Inc. on behalf of the Health Research and Educational Trust.

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Editorial and Subscription Offices
16 Cove Rd, Ste. 200
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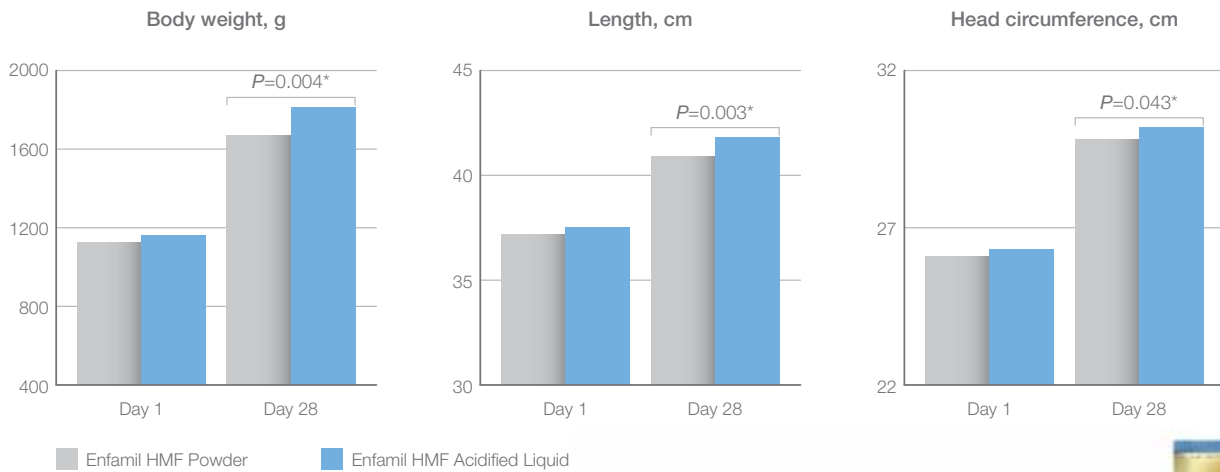
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