The Joint Council on Congenital Heart Disease (JCCHD) National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) held its first face-to-face Learning Session at Cincinnati Children’s Hospital on September 11th and 12th, 2009. Clinical teams from 29 pediatric cardiology programs (Table 1) came together with a shared goal of working together to improve care for infants with complex congenital heart disease. The 87 attendees of the Learning Session included parents, pediatric cardiologists, nurses and nurse practitioners, dietitians, and patient outcomes (Figure 2). The plenary talks included a moving presentation by Michael Katchman, parent of a son with a univentricular heart, and an enlightening discussion on medical home and care coordination for children with complex healthcare needs led by Chris J. Stille, MD (University of Massachusetts Medical School) and W. Carl Cooley, MD (Crotched Mountain Foundation, New Hampshire). An in-depth plenary talk on methods to optimize nutritional status of infants with complex heart disease was presented by Karen Uzark, RN, PhD (Cincinnati Children’s Hospital). Nancy Rudd, MS, RN, CPNP-QC, Medical College of Wisconsin, led breakout sessions on interstage surveillance.

The National Pediatric Cardiology Quality Improvement Collaborative

By Robert H. Beekman, III, MD and Carole Lannon, MD, MPH

The Joint Council on Congenital Heart Disease (JCCHD) National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) held its first face-to-face Learning Session at Cincinnati Children’s Hospital on September 11th and 12th, 2009. Clinical teams from 29 pediatric cardiology programs (Table 1) came together with a shared goal of working together to improve care for infants with complex congenital heart disease.1 The NPC-QIC is led by a task force of pediatric cardiologists (Table 2) working closely with the Center for Health Care Quality, which has a track record of success organizing other pediatric improvement networks.

In 2006 the NPC-QIC task force agreed on a set of Guiding Principles for the initiative (Table 3). Subsequently, the task force defined the key criteria for an initial improvement project:

1. clinically important;
2. potential for improvement;
3. under the purview of pediatric cardiology;
4. specific and measurable; and
5. generates enthusiasm in the field.

Using these criteria, the initial project selected by the task force is focused on improving the

“"The JCCHD National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) is a multi-center research and improvement network intended to improve care processes and outcomes for children with complex congenital heart disease.""
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Neonatology Today (NT) is the leading monthly publication that is available free to qualified Board Certified (BC) neonatologists and perinatologists. Neonatology Today provides timely news and information to BC neonatologists and perinatologists regarding the care of newborns, and the diagnosis and treatment of premature and/or sick infants. In addition, NT publishes special issues, directories, meeting agendas and meeting dailies around key meetings.

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Key Contacts
Tony Carlson - Founder & President - TCarlsonmd@gmail.com
Richard Koulbanis - Group Publisher & Editor-in-Chief - RichardK@neonate.biz
John W. Moore, MD, MPH, Medical Editor - JMoore@RCHSD.org


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care of infants during the “interstage” period following a Norwood procedure.

The Initial Improvement Project

The Aim of the NPC-QIC initial project is:

“To improve survival and optimize quality of life for infants between discharge after stage I Norwood and admission for bidirectional Glenn (i.e., during the “interstage” period).”

The project has two components:

1. A patient registry for clinical and population management, as well as research; and
2. A quality initiative focused on improving care and outcomes.

The Registry

The registry will capture data from participating pediatric cardiology centers on all infants in the “interstage” period after discharge from the Norwood or Norwood-variant procedure and prior to admission for the bidirectional Glenn shunt. Registry data are collected and managed using REDCap (Research Electronic Data Capture developed by Vanderbilt University) electronic data capture tools. Information on “interstage” clinical processes and outcomes for each infant is collected in seven data entry forms: enrollment; neonatal surgery and hospital course; discharge after Norwood; clinic visits; readmissions; Glenn surgery; death. This database is designed to provide robust information that will be valuable for both clinical research, population management and quality improvement projects.

Table 2. Members of the JCCHD Quality Improvement Task Force

<table>
<thead>
<tr>
<th>Dr. Robert Beekman</th>
<th>Cincinnati Children’s Hospital Medical Center, Cincinnati, OH</th>
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<tbody>
<tr>
<td>Dr. Kathy Jenkins</td>
<td>Children’s Hospital Boston, Boston, MA</td>
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<tr>
<td>Dr. Tom Klitzner</td>
<td>Mattel Children’s Hospital at UCLA, Los Angeles, CA</td>
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<tr>
<td>Dr. John Kugler</td>
<td>Children’s Hospital &amp; Medical Center, Omaha, NE</td>
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<tr>
<td>Dr. Gerard Martin</td>
<td>Children’s National Medical Center, Washington, DC</td>
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<tr>
<td>Dr. Steven Neish</td>
<td>Texas Children’s Hospital, Houston, TX</td>
</tr>
<tr>
<td>Dr. Geoffrey Rosenthal</td>
<td>University of Maryland Hospital for Children</td>
</tr>
</tbody>
</table>

Table 1 Programs Attending Learning Session #1

September 11-12, 2009

Arizona Pediatric Cardiology Consultants
Arkansas Children’s Hospital
Children’s Hospital Boston
Children’s Healthcare of Atlanta
Children’s Hospital & Medical Center, Omaha
Children’s Hospital Los Angeles - USC
Children’s Hospital of Wisconsin
Children’s Memorial Hospital
Children’s National Medical Center
Cincinnati Children’s Hospital Medical Center
Duke University Medical Center
Johns Hopkins University School of Medicine
Mayo Clinic - Rochester
Nationwide Children’s Hospital
NYU Medical Center
Oklahoma Children’s Heart Center
Oregon Health Sciences University
Pediatric Heart Institute at Vanderbilt Children’s
Penn State Hershey Children’s Hospital
Primary Children’s Medical Center
Riley Hospital for Children
Seattle Children’s Heart Center
Stanford Children’s
Texas Children’s Hospital
UC Davis Children’s Hospital
UCLA - Mattel Children’s Hospital
University of Chicago Comer Children’s Hospital
University of Texas Health Science Center
University of Virginia Children’s Hospital

Figure 1. Michael Katchman, parent of a child with a uni-ventricular heart, addressing the Learning Session.

Figure 2. NPC-QIC Collaborative Director Divvie Powell, MSN, RN discusses the structure of the Learning Collaborative.

Figure 2. NPC-QIC Collaborative Director Divvie Powell, MSN, RN discusses the structure of the Learning Collaborative.
The National Pediatric Cardiology Quality Improvement Collaborative

**Key Driver Diagram**

**Possible Change Strategies**

- Assign staff to coordinate discharge for each patient
- Utilize checklist to prompt and document standard process
- Provide parent/caregiver with written action plan including:
  - Medications
  - Nutrition/Feeding plan
  - Home monitoring plan (O2 sat, Intake, weight)
  - Red Flag plan - when to call cardiology team and who to call
- Send written action plan to medical home, and outpatient cardiologists (Include immunization issues)
- Discharge and monitoring materials are culturally and language appropriate
- Talk-back methods used for teaching at discharge and clinic visits for medications, feeding plan, cardiac status
- Document family ability to obtain medications and refer for additional resources as needed
- Follow-up appointments (cardiology CT surgery) made and given to parents

**Key Drivers**

**Aim**

Improve survival and optimize quality of life for infants between discharge after Stage 1 Norwood and admission for Stage 2 surgery

**Care Transition:** discharge protocol & communications

**Optimize nutritional status during interstage period**

**Care coordination with parents and medical home:** including interstage surveillance for changes in cardiovascular status

**Access nutritional status at every clinic visit**

- Adjust target goals for infant nutrition at each clinic visit (daily Kcal; weight targets)
- Provide nutritional plan to families and medical home as part of overall management plan (see above)
- Discuss feeding/intake at each visit with parents to assess progress towards goals
- Involve nutritionist (at every clinic visit as needed)
- Home monitoring of intake and weight; include Red flag indicators

- Home monitoring (daily O2 sat, weight, intake)
- Red flag action plan
- System for rapid medical response to Home Monitoring data and/or to Red Flag events
  - Parents know when to call and whom to call
  - Cardiology program is prepared to act on calls
- Review action plan and update red flags with family at every visit
- Provide updated medical home action plans after every visit

**The Quality Improvement Initiative**

The project’s quality improvement initiative aims to improve care and outcomes for infants with a Norwood procedure during the “interstage” period. Because there are no formal published care guidelines for this population, the project team reviewed the medical literature, interviewed parents of these infants, considered expert (Task Force) consensus, and assessed variation to develop a Key Driver Diagram (Figure 3). A key driver diagram is typically used in a quality improvement project to provide a framework for the proposed changes that focuses on the factors most likely to lead to the goal of improved outcomes for these infants.

The key drivers are:

- **Assuring Safe Care Transitions**

  When an infant is discharged home after a Norwood, a number of important care transitions occur. The patient transitions from a highly technical inpatient environment to the home setting; responsibility for most aspects of care shifts from the inpatient team to the family, and a hand-off occurs from the pediatric cardiology subspecialist to a primary caregiver.

- **Optimizing Interstage Nutrition**

  Infants with a Norwood procedure fail to grow normally during the interstage period, prior to the Glenn shunt. A recent retrospective study documented poor interstage weight gain in infants with a single ventricle prior to the Glenn, and demonstrated that infants with the poorest pre-op weight gain had worse early post-Glenn outcomes.²

---

“Benefits of this collaborative project are likely to extend well beyond the care of infants with a Norwood.”
Table 3: JCCHD NATIONAL QUALITY IMPROVEMENT INITIATIVE
Guiding Principles
Adopted September 18, 2006

1. The goal of the QI Initiative is to improve care and outcomes for children with cardiovascular disease.
2. The JCCHD will determine the major directions in the development of this QI Initiative through its delegation to the QI Initiative Steering Committee. A strategy will be developed and implemented to facilitate communication about the Initiative with the larger pediatric cardiology community.
3. The QI Initiative, through multiple improvement projects, will address the spectrum of pediatric cardiovascular inpatient and outpatient care: including case finding, diagnosis, treatment, recovery, discharge and follow-up (including handoffs). The initiative will begin with an initial well-focused project.
4. A national, multi-institutional database for the purpose of supporting quality-improvement projects will be a part of this initiative. Where related databases exist that may be beneficial to the QI Initiative, they will be utilized to the extent possible.
5. The QI Initiative will seek to involve all Pediatric Cardiology programs and practices, from small to large. We will make an effort to emphasize inclusion of all programs with Pediatric Cardiology Fellowships because they are our future.
6. Quality improvement science, emphasizing the Model for Improvement, will be the preferred approach taken by these projects.
7. An emphasis will be placed on including: patients, parents and families in the design and implementation of projects. We will strive to be inclusive of diverse cultures and values.
8. The QI Initiative will take a collegial approach to the involvement of important related specialties, including Cardiothoracic Surgery, Pediatric Critical Care Medicine, Anesthesiology, Nursing, Social Work and Child Life.

Facilitating Care Coordination with Parents and the Medical Home

Interstage care for these infants is complex, with a clear need for improved care coordination among the families, cardiologists, primary care providers and the medical home. Participating teams are engaging in a series of face-to-face workshops, webinars and a listserv as part of a modified learning collaborative based on the Institute for Healthcare Improvement Breakthrough Series Model. This model involves a 12-month longitudinal learning community that is based in improvement science theory and evidence about continuing education methods.

It is expected that additional useful clinical process changes will be identified through this collaborative network of cardiology centers. Quality improvement control charts documenting clinical processes and patient outcomes will be provided to each center on a secure, password-protected site. These charts will display data from individual centers to enable them to track their improvements, and to allow comparison against aggregate collaborative data.

Benefits of this collaborative project are likely to extend well beyond the care of infants with a Norwood. It is expected that many of the clinical improvements identified during this project will be generalizable to the care of other infants and children with congenital heart disease. As an added bonus, NPC-QIC will allow cardiologists participating in this project to satisfy the American Board of Pediatrics Part 4 “Maintenance of Certification” requirements.

References


Ask a few of your neonatologist colleagues what the Perinatal Section of the AAP does for them and you are likely to receive a shrug of the shoulders, or perhaps a few vague guesses. We know they collect dues and make pronouncements, but apart from that the activities and value of the Section seem rather remote from our everyday practice of medicine.

In reality, the Section offers many opportunities for professional success, all of them on display at the Spring Workshop.

Conferences have a character – some of them are focused on clinical practice, others on research, still others on a particular aspect of medical science. The Perinatal Section’s Spring Workshop is unique in that it addresses all of these elements, as well as additional aspects needed for a successful practice, most notably leadership – a character trait that every physician needs, whether he/she is at the bedside or at a national meeting.

Personal and professional growth is fostered by the Perinatal Section, especially during the Spring Workshop, in the following areas:

**Improving Clinical Skills**

The Spring Workshop allows clinicians an opportunity to interact directly with the Committee on Fetus and Newborn (COFN). COFN members discuss new statements at each stage of development so participants are able to offer input and gain clarification from COFN before these statements are published.

In addition, a number of areas where clinical practice is evolving will be discussed during plenary or breakout sessions, including diagnosis and management of seizures in preterm infants, very early prenatal steroids, new treatments for Persistent Pulmonary Hypertension (PPHN, targeted neonatal echo, and family-centered care.

**Enhancing the Success of Your Practice**

A half-day coding seminar has been a highlight of this meeting for many years. With new codes this year, this seminar and an additional “Beyond Coding” breakout will provide valuable practical guidance.

Business-oriented breakout sessions include presentations on “Eliminating Waste in NICU Operations”, “Managing Budgets and NICU Finance” (one for early career neonatologists and another for those with some prior familiarity with this topic), and “The Intricate Dance of Leadership and Management.” The recent changes in academia, social media, research funding, and medicolegal issues which affect us all to at least some extent will also be explored in breakout sessions.

Much of what happens in our neonatology practices is dictated by the federal government, and the AAP has been very active in speaking for us in Washington. “A Leader’s Guide to Producing Positive Impact from the ACA and Health Care Delivery System” will summarize where the Academy is headed on our behalf, and solicit our input in that regard. Dr. James Perrin, the AAP President-Elect, will also be there to further elaborate the AAP’s agenda, especially how it pertains to neonatologists.

**Becoming an Effective Advocate**

Neonatologists can maximize their impact by teaching others lessons they have learned at the bedside. Wally Carlo will present the Butterfield Lecture entitled “How to Save One Million Lives Per Year:..."
Helping Babies Breathe and Essential Newborn Care Training Programs" and Robin Steinhorn will speak on "The Power of Gender Equality in Medicine."

Growing as a Leader

Leadership is a valuable trait at every level of medical practice. It makes us better clinicians, entrepreneurs, teachers, and advocates. Leadership training is a thread that runs throughout this meeting, but is especially emphasized in two half-day seminars entitled “Leading the Way to the Future: A Short Course in Producing Everyday Miracles” and “Developing a QI Project.” Both will offer extensive practical training to help attendees be successful in their everyday endeavors.

The Spring meeting is also an opportunity for neonatologists to hear what the Section is doing, with reports from David Burchfield, the Chairman of our Section’s Executive Committee and from the Trainees and Early Career Neonatologists group. Just as importantly, there will be many chances to talk informally with Section leadership, both to offer suggestions and to learn of ways to become involved in Section activities.

Neonatologists derive considerable benefit from the activities of the Perinatal Section of the AAP. Attending the Spring meeting is an excellent way to improve your skills while learning about the Section and taking a more active role in directing the future of our profession.

“Leadership is a valuable trait at every level of medical practice. It makes us better clinicians, entrepreneurs, teachers, and advocates.”

Robert White, MD
Chairman, Planning Committee for the Perinatal Section Spring Workshop
Pediatrix Medical Group
Memorial Hospital
South Bend, IN 46601 USA
Phone: 574-647-7351
Fax: 574-647-7248
Robert_White@pediatrix.com

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New Prenatal Test, Microarray, Proposed as Standard of Care

Newswise — A large, multi-center clinical trial led by researchers from Columbia University Medical Center (CUMC) shows that a new genetic test resulted in significantly more clinically relevant information than the current standard method of prenatal testing. The test uses microarray analysis to conduct a more comprehensive examination of a fetus's DNA than is possible with the current standard method, karyotyping—a visual analysis of the fetus’s chromosomes. Results were published in the Dec. 6, 2012, issue of The New England Journal of Medicine (NEJM).

The prospective, blinded trial involved 4,400 patients at 29 centers nationwide; the data took four years to compile. The study involved women with advanced maternal age and those whose fetuses were shown in early screening to be at heightened risk for Down Syndrome, to have structural abnormalities (as seen with ultrasound), or to have indications of other problems. Ronald J. Wapner, MD, Professor and Vice Chairman for Research at the Department of Obstetrics and Gynecology at CUMC and Director of Reproductive Genetics at NewYork-Presbyterian/Columbia, was principal investigator. This is the first and only study to prospectively compare karyotyping with microarray in a blinded head-to-head trial.

The trial found that microarray analysis, which compares a fetus’s DNA with a normal (control) DNA, performed as well as karyotyping in identifying common aneuploidies (an abnormal number of chromosomes—an extra or missing chromosome causes genetic disorders such as Down Syndrome and Edwards Syndrome); it also identified additional abnormalities undetected by karyotyping.

Among fetuses in which a growth or structural anomaly had already been detected with ultrasound, microarray found clinically relevant chromosomal deletions or duplications in one out of 17 cases (6%) that were not observed with karyotyping. In cases sampled for advanced maternal age or positive screening results, microarray analysis picked up an abnormality in one out of every 60 pregnancies (1.7%) that had a normal karyotype.

“We hope that in the future—when microarray can be done non-invasively—every woman who wishes will be offered microarray, so that she can have as complete information as possible about her pregnancy,” said Dr. Wapner.

In a second paper published in the same issue of NEJM, about the use of microarray in stillbirth, results showed that microarray produced a clinical relevant result in 87% of 532 cases, which were analyzed with both karyotyping and microarray. In contrast, standard methods for analyzing a stillbirth, which include karyotyping, have been shown in previous research to fail to return information in 25–60% of cases.

“Microarray was significantly more successful at returning clinically relevant information because, unlike karyotyping, it does not require cultured cells. Viability does not come into play at all—DNA can be extracted from tissue that is no longer living,” said study senior author, Brynn Levy, MSc(Med), PhD, Associate Professor of Pathology and Cell Biology, and Co-Director of the Division of Personalized Genomic Medicine at CUMC, and Director of the Clinical Cytogenetics Laboratory at NewYork-Presbyterian/Columbia. “Not being able to explain why a stillbirth occurred can be very hard for families. These findings are important because they give us a significantly more reliable method to provide information to families and their physicians.”

“The primary benefit of using microarray analysis rather than karyotype analysis is the greater likelihood of obtaining results,” said Uma Reddy, MD, MPH of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health, first author of the paper. “Microarray analysis is especially useful in stillbirth cases in which the karyotype has failed or there is a birth defect present. However, microarray analysis is currently more expensive than karyotyping—and this may be a barrier to some.”

The study used data compiled by NICHD’s Stillbirth Collaborative Research Network (SCRN), a population-based study of stillbirth in five geographic catchment areas.

Both microarray and karyotyping reveal clinically relevant information about conditions that can be life-threatening for a newborn baby or that can signal a possible health threat that might be treatable. However, as with all current genetic testing including karyotyping, the results may reveal findings that have not been described in the literature or about which the exact implications are known.

“While the vast majority of abnormalities found with microarray are associated with known conditions, not all are. But with time, knowledge and understanding of what these abnormalities mean will continue to grow,” said Dr. Wapner. “When we started this study five years ago, the incidence of findings we did not understand was about 2.5%—now, with more information, that has fallen to 1.5%.”

Dr. Wapner is currently leading phase two of his microarray study. Supported by the NICHD (NIH Grant No. 2U01HD055651-06; Pro-
ject No. GG006961), he has begun a five-year study to follow children born to mothers who underwent microarray, to learn the clinical implications of micro-deletions or duplications that are not yet understood.

"Unfortunately, it is sometimes difficult to predict the full spectrum of some diseases indicated by a particular deletion or duplication," said Dr. Wapner. "Genetic medicine is about obtaining genomic information about an individual and predicting what affect it will have on that person. But we are all different—so genetic abnormality in one person may behave differently than in someone else. For example, an inherited disease could be mild in the mother but severe in her child. We are studying what these mean clinically, and science continues to catch up with our ability to obtain the information."

Dr. Wapner’s paper is titled, “Chromosomal Microarray Compared with Karyotyping for Prenatal Diagnosis.” An abstract was presented in Feb. 2012 at the Society for Maternal-Fetal Medicine annual meeting. The other contributors are: Brynn Levy, Melissa Savage, Vimla S. Aggarwal, and Odelia Nahum (CUMC); Christa Lese Martin, Brian Bunke, and David H. Ledbetter (Emory); Blake C. Ballif, Allen N. Lamb, and Lisa G. Shaffer (Signature Genomic Laboratories); Christine M. Eng, Ankita Patel, and Arthur L. Beaudet (Baylor); Julia M. Zachary and Elizabeth A. Thom (George Washington); Lawrence D. Platt (Center for Fetal Medicine and Women’s Ultrasound); Daniel Saltzman (Carnegie Hill Imaging for Women); William A. Grobman (Northwestern); Susan Klugman (Montefiore/Albert Einstein); Thomas Scholl and Kimberly McCall (Integrated Genetics); Joe Leigh Simpson (Florida International; now at March of Dimes Foundation); and Laird Jackson (Drexel).

Dr. Wapner’s research was supported by grants from the NICHD (R01HD055651-01, R01HD055651-03S1, and RC2HD064525). Agilent Technologies and Affymetrix donated all microarrays and reagents used in the study. The grants.gov clinical trial registration number is NCT01279733.

Drs. Levy and Reddy’s paper is titled, “Karyotype and Microarray Tests of Genetic Abnormalities in Stillbirth.” The other contributors are: Grier Page, Vanessa Thorsten, and Corette Parker (RTI International); George Saade and Radek Bukowski (The University of Texas Medical Branch); Robert Silver and Michael Varner (University of Utah); Halit Pinar and Barbara O’Brien (Brown); Marian Willinger (NIH); Barbara Stoll and Carolyn Drews-Botsch (Emory); Josefine Heim-Hall and Donald Dudley (University of Texas Health Science Center); Robert Goldberg (Drexel); and Ronald Wapner (CUMC).

Drs. Levy and Reddy’s research was supported by grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development Stillbirth Collaborative Research Network (HD45925, HD45944, HD45952, HD45953, HD45954, HD45955).

Combating a Crisis: Global Burden of Preterm Birth Can Be Reduced if Critical Actions Are Taken

Newswise — New surveys of researchers and funders reveal a lack of consensus regarding researching and developing interventions to prevent prematurity and stillbirth, according to an article published in
New Pharmacoeconomic Analysis Shows Lower Rate of Reintubation Observed With SURFAXIN® Treatment May Reduce Hospital Costs Associated with Bronchopulmonary Dysplasia

Discovery Laboratories, Inc. has announced the release of data from a new pharmacoeconomic analysis demonstrating that the previously-reported reduced rate of reintubation in preterm infants treated with SURFAXIN® may also result in an average potential hospital cost savings of $389,247 per 100 treated infants by reducing the frequency of Bronchopulmonary Dysplasia (BPD) when compared with reintubation rates of infants treated with the current global market leading surfactants, Curosurf® and Survanta®. The analysis was presented at the 2012 Hot Topics in Neonatology Annual Meeting held in December in Washington, DC.

“It has been previously reported that infants who require reintubation are three times more likely to develop BPD compared with those infants who are not reintubated,” said Dr. Russell G. Clayton, Senior VP, Research & Development, of Discovery Labs. “This new pharmacoeconomic analysis suggests that the selection of a specific surfactant could significantly impact hospital costs by potentially reducing the risk of developing BPD associated with reintubation. These data may be important to physicians and pharmacists as they consider SURFAXIN for inclusion on hospital formularies.”

The current standard of care for managing preterm infants with Respiratory Distress Syndrome (RDS) typically requires that the infant undergo intubation (insertion of a breathing tube into the infant’s airway) to allow for surfactant administration and respiratory support via mechanical ventilation. If therapy is successful, the breathing tube is removed to allow the infant to breathe independently. However, over one third of infants have difficulty breathing independently after the breathing tube is removed and require a subsequent intubation, or reintubation. Reintubation and extended exposure to mechanical ventilation is often associated with an increased incidence of other complications such as BPD – a chronic lung condition that affects some preterm infants who were at risk for or afflicted with RDS or required respiratory support via mechanical ventilation during the neonatal period.

This pharmacoeconomic analysis is based on data from a retrospective study, published in the Journal of Neonatal-Perinatal Medicine (Volume 4, Number 2, 2011).
Letters to the Editor

Neonatology Today received a Letter to the Editor regarding the November 2012 (Volume 7 / Issue 11) lead article in Neonatology Today entitled, "Respiratory Syncytial Virus (RSV) Prevention 2012" by Michael Goldstein, MD; T. Allen Merritt, MD; Raylene Phillips, MD and Augusto Sola, MD.

The reader had a series of questions and comments, which follow. For those wishing to refresh themselves with the article, they may read the PDF version: www.neonatologytoday.net/newsletters/nt-nov12.pdf.

Dr. Wlniewski’s Comment/Questions:

From the article’s introduction I understand that authors support suggestion that current AAP (American Academy of Pediatrics) guidelines, as well as many approved recommendations for using Synagis in medical practice issued by Medicaid or private insurance systems are contradicting FDA (US Food & Drug Administration) guidelines. What’s more, it is suggested that a case like this may qualify to be reported under “Bad Ad rules.” My question is, “What did the authors do regarding this issue within the AAP, assuming they belong to this organization? Also, did they report any agency/organization to FDA for violating their guidelines? If yes, what were results of such action?”

W. M. Wlniewski MD, MHPE
First Health MRH-NICU
Pinehurst, NC
Phone: 910-715-5180
Fax: 910-715-2137
WWlnewski@firsthealth.org

Dr. Goldstein’s Response:

The issue has been raised with the perinatal section of the AAP (at the level of the Perinatal Section board) which defers to the Committee on Infectious Disease (COID) the author of the Redbook. The COID has disregarded suggestions from the 2010 guidelines, and has not yet given feedback regarding the most current set. The AAP was reported to the FDA at this Fall’s AAP NCE! There has been no response back from the FDA yet.

Mitchell Goldstein, MD
Associate Professor, Pediatrics
Division of Neonatology
Loma Linda University Children’s Hospital
Loma Linda, CA
Phone: 909-558-7448
Fax: 909-558-0298
MGoldstein@llu.edu

Neonatology Today welcomes and encourages Letters to the Editor (LTE). If you have comments or topics you would like to address, please send an email to: LTE@Neonate.biz, and let us know if you would like your comment published or not.

Those wishing to have their LTE published will be sent a preproduction draft to review.

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Target audience: Neonatologists, residents, fellows and advanced practitioners.

Topics include:

• Maternal-Fetal Medicine
• Neonatal Gastroenterology and Nutrition
• Neonatal Infectious Diseases
• Neonatal Respiratory System
• Neonatal Cardiovascular System
• Genetics and Central Nervous System