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Sudden Unexpected Postnatal Collapse: One Newborn Death is One Too Many Part 2: Collaborative Quality Initiatives

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Reference: 1. Data on file. Hampton, NJ: Mallinckrodt Pharmaceuticals.



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Brief Summary of Prescribing Information

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Treatment of Hypoxic Respiratory Failure

INOmax[®] is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

CONTRAINDICATIONS

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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.

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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 (NO₂) forms in gas mixtures containing NO and O₂. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO₂ concentration, or if the NO₂ concentration reaches 3 ppm 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 NO₂ analyzer should be recalibrated. The dose of INOmax and/or FiO₂ should be adjusted as appropriate.

Worsening 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.

DRUG INTERACTIONS

Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO₂. Elevated NO₂ may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO₂ 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.

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Sudden Unexpected Postnatal Collapse: One Newborn Death is One Too Many Part 2: Collaborative Quality Initiatives

Nancy A. Garofalo, PhD APN, NNP, Matthew Pellerite, MD, Michael Goodstein, MD, David A. Paul, MD. Joseph R. Hageman, MD

Introduction

A In Part one of our paper, we presented definitions, estimates of the incidence and quality initiatives to improve the recognition of the infant at risk for Sudden Unexpected Postnatal Collapse (SUPC) and potential strategies to prevent SUPC events(1-10). In part two we present quality improvement initiatives to help to document the incidence of SUPC in the United States, using a retrospective analysis of events felt to be consistent with SUPC in collaborating institutions with a de-identified REDCap database storage system.

“ In part two we present quality improvement initiatives to help to document the incidence of SUPC in the United States, using a retrospective analysis of events felt to be consistent with SUPC in collaborating institutions with a de-identified REDCap database storage system. ”

Next, we have designed an initiative based on the hypothesis that a percentage of SUPC events may be preventable by the implementation of a safety monitoring bundle for all newborn infants (2). The efficacy and generalizability of each approach need to be determined through further implementation and evaluation. Some portion of SUPC events may be effectively prevented by frequent assessment post-delivery of the mother/infant dyad, and educating staff and parents to ensure that the infant is “pink and positioned” (11) during “distraction-free” breastfeeding and skin-to-skin contact, as recommended by the AAP (12). We present and discuss these initiatives in detail in Part 2 of our paper.

Aims:

Short-term Aims:

1. To organize a multi-center collaborative quality improvement project (QIP) with a number of Level II and III hospitals, to implement a SUPC-Prevention Safety Monitoring Bundle (SPSMB)
2. To determine if the implementation of this safety initiative (SPSMB) is effective as a preventative strategy against SUPC.
3. To determine the effects of SPSMB on the interaction of the mother/infant dyad, in particular, making sure there is no negative impact on breastfeeding initiation or maintenance
4. To utilize a standardized assessment tool for infant positioning during breastfeeding, post-implementation of the SPSMB

5. To determine the response of post-partum mothers to the SPSMB, particularly the impact on their breastfeeding experience, using a standardized Likert-type questionnaire
6. To determine staff response to the practice changes associated with the implementation of the SPSMB
7. To enable collaborating hospitals to share de-identified data for quality improvement and a better understanding of SUPC risk factors.

Long-term Aims:

1. To collect data prospectively to track future cases of SUPC and to identify additional potential risk factors.
2. To develop a risk-assessment tool that can be incorporated into the electronic medical record (EMR), to alert caregivers if an infant is at higher risk for SUPC events or falls.

Methods:

1. Development of a secure electronic database (REDCap)
2. Collection of retrospective data related to SUPC events, within the past five years, at all collaborating sites. The data will be de-identified so that everyone (except the statistician) remains blind and the hospitals and patients cannot be identified.
3. Implementation of the SUPC-prevention Safe Monitoring Bundle (SPSMB) across all collaborating sites. The SPSMB includes the following:
 - Completion of an online SUPC-prevention Educational Module by Obstetric clinicians including physicians, nurse midwives, staff nurses, and patient care technicians (PCTs). This module is intended to teach staff about SUPC so that they can then teach parents about SUPC-prevention, but provide the counseling in a manner that does not frighten parents and discourage breastfeeding or skin-to-skin contact sessions. The module provides an overview of SUPC and includes three videos. The first video demonstrates a simulated SUPC event and its devastating consequences for families and staff. The second and third videos demonstrate a nurse, then physician, teaching a mother about SUPC-prevention, using a positive approach and never using the words SUPC or suffocation in the beginning. The teaching is provided in a positive manner, focusing on what to do rather than what not to do. The teaching is provided using the words “Pink and Positioned.” This has been found to be a superior health communication method (11) and may avoid creating unnecessary parental anxiety. Importantly, “distraction-free” breastfeeding and skin-to-skin contact (SSC) are emphasized. (11)
 - Practice changes include:(1) teaching parents about “Pink and Positioned” in the immediate post-partum period and documenting this teaching in the EMR, (2) observing the first breastfeeding session and reinforcing the teaching, (3) frequent post-natal assessment of the newborn, using a standardized checklist, (every 15 minutes for the first 2 hours post-birth) followed by immedi-

ate documentation of 'Pink and Positioned' status into the EMR. (4) having mothers sign a standardized form, acknowledging receipt and understanding of "Pink and Positioned" information, the importance of ensuring safe positioning of their infant during SSC and breastfeeding (BF) sessions, pledging to not text or use social media during SSC/BF, and to call for help in case of extreme fatigue. (5) placement of signs in each post-partum room, reminding parents to ensure their infant is "Pink and Positioned" during "distraction-free" breastfeeding and skin-to-skin contact, with photos demonstrating proper positioning.

- Continued Assessment: After the first 2 hours post-partum, we will utilize a standardized assessment tool for infant positioning, during every breastfeeding session, until hospital discharge.
4. We will collect data prospectively to track any future cases of SUPC, near misses and falls, and to identify additional potential risk factors.

Outcome Measures:

Short-Term Outcomes:

1. Maternal interaction with their infants will be assessed, beginning 2 hours post-delivery. We will utilize a standardized assessment tool to determine whether mothers are retaining the "Pink and Positioned" teaching, by demonstrating proper (safe) positioning of their infant during breastfeeding sessions, until hospital discharge. We will also consider audits to confirm proper SSC, by staff during checks within the first 24-hour post-delivery.
2. Pre- and post-education survey to document maternal SSC safety knowledge.
3. SPSMB impact on breastfeeding during hospitalization, as measured by a standardized questionnaire (using a 5-point Likert scale) to determine maternal response to breastfeeding assessments. We will also track the number of breastfeeding sessions, for each infant, during the hospital stay.
4. Pre- and post-education survey to determine the impact of SUPC training (online module) on staff knowledge

Long-Term Outcomes:

1. SUPC events post- SPSMB implementation with specific details about etiology, management, outcomes, and 'near miss' event rates. We may also consider including a review of neonatal falls and resuscitation of the term and near term infants.
2. Staff knowledge and staff satisfaction with the SUPC prevention Safe Monitoring Bundle in the form of audits and a survey.

Anticipated Outcomes:

We will use a standardized assessment tool to determine whether infants are positioned safely, as a result of the education provided to mothers. This will demonstrate the effectiveness of the "Pink and Positioned" teaching. We anticipate better breastfeeding outcomes as a result of SPSMB implementation. Mothers may actually breastfeed more often since they will be actively encouraged to breastfeed, so that the nurse can assess positioning. We anticipate that mothers will respond favorably to the SPSMB, may feel more confident holding their infant, and will appreciate the

frequent assessments and positive reinforcement, during SSC and breastfeeding sessions. We anticipate that staff will respond favorably to the SPSMB education and practice changes. Their response to survey questions will further establish the feasibility of easily implementing a safety bundle, such as ours, for SUPC prevention. Importantly, we anticipate that not only SUPC but also infant falls may be prevented, using our approach.

Given the low incidence of SUPC, falls and near misses, it is not possible to compare pre- and post- SPSMB implementation data. Nonetheless, we will track SUPC cases, neonatal falls, and near misses at collaborating sites and we anticipate that, as a result of SPSMB implementation, these events will be prevented. We plan to recruit additional sites where a baseline pre-intervention rate can be determined and compared to the intervention phase. Our project will yield important evidence that will advance the understanding of SUPC, guide clinical practice and improve health outcomes for infants nationwide.

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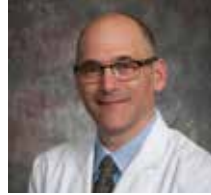
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The Score of Seven: Will Resuscitation Selection Criteria Improve the Survivability at the Limit of Viability of Neonates Born at Twenty-Three Weeks Gestation?

Husam Salama, MD, Hilal Al. Rifai, MD, Nazla Mahmoud, MD, Mai Al. Qubasi, MD, Sawsan Al. Obiedly, MD, Ismail Sabry, MD, Olfa Ben Hadj Khalifa, MD, Amr Mousa, Amal Sabouni, MD

ABSTRACT:

Aim:

To evaluate the outcome of a cohort of infants born at 23-weeks' gestation age after introducing a new resuscitation selection score (The Score of Seven) for infants born at 23 weeks gestation.

Methods:

This is a population-based, retrospective cohort study using data from Pearl-Peristat Maternal and newborn registry, Vermont Oxford database related to WWRC-THE NICU and patient's chart for infants born since 2016 until mid-2018 of ELBW infants born at 23 weeks gestation age. Infants with significant lethal congenital anomalies were excluded. In February 2018, we introduced a new protocol to streamline the delivery room resuscitation decision making regarding ELBW infants born in 22-24 weeks gestation. This pilot protocol did include a designed score specific to 23 weeks gestation age. The score components were chosen to address the most relevant factors associated with poor outcome at this gestation age. Seven elements were chosen: four antenatal and three immediate postnatal. Each component received a zero, one or two according to its presence or absence at or soon after birth.

Using this scoring system a baby would not be resuscitated if the score below 7 and will receive active resuscitation and admitted to the NICU if the score is equal to or above 7. A short satisfaction survey was conducted after six months from the application of the guideline to identify the comprehension, practicality and ethical comfort of the medical staff using this scoring system guideline.

Results:

Sixty infants delivered from January 2016 until June 2018 were investigated for mortality associated risk assessment. The DR death rate was 23/60 (38.3%). The NICU admission was 37 infants (61.7%). Half of the admitted infants died before two weeks of age. Survival rate to discharge was 37% (13/37). From only 37/60 infants were we able to retrieve the full description of the selected components of the "score of seven," and these were subjected to the analysis. However, infants who died in the DR with a score < 7 were 13/20 (65%) versus 0/17 when the score was ≥ 7. Amongst those infants admitted to the NICU (37), seven infants were admitted with a score less than 7; 2/7 infants survived to discharge (~29%) while among 17 infants admitted with a score ≥ 7, nine infants survived to discharge 51%. A satisfaction survey was administered to thirty-three neonatal physicians, and thirty-two felt that the score was easy to comprehend, and 26 concluded that it was easy to implement. Thirty physicians found that using the resuscitation provided ethical relief and moral comfort.

Conclusions

While managing 23 weeks' gestational age at delivery, a decision using resuscitation score (and a score of seven or more) was associated with improved survival rate until discharge. The score was described by the NICU physicians as functional and convenient. It offers ethical reassurance to the dedicated medical staff and provides a practical platform for delivery room resuscitation decision making. Applying the score was not associated with an

increase in the number of delivery room deaths and did not differ from that reported in the literature.

Abbreviations:

| | |
|-------|--------------------------------------|
| DR | Delivery room |
| ELBW | Extreme low birth weight |
| NICU | Neonatal intensive care unit |
| PNX | Pneumothorax |
| PIE | Pulmonary Interstitial Emphysema |
| VD/CS | Vaginal delivery/Cesarean section |
| WWRC | Women's Wellness and research center |

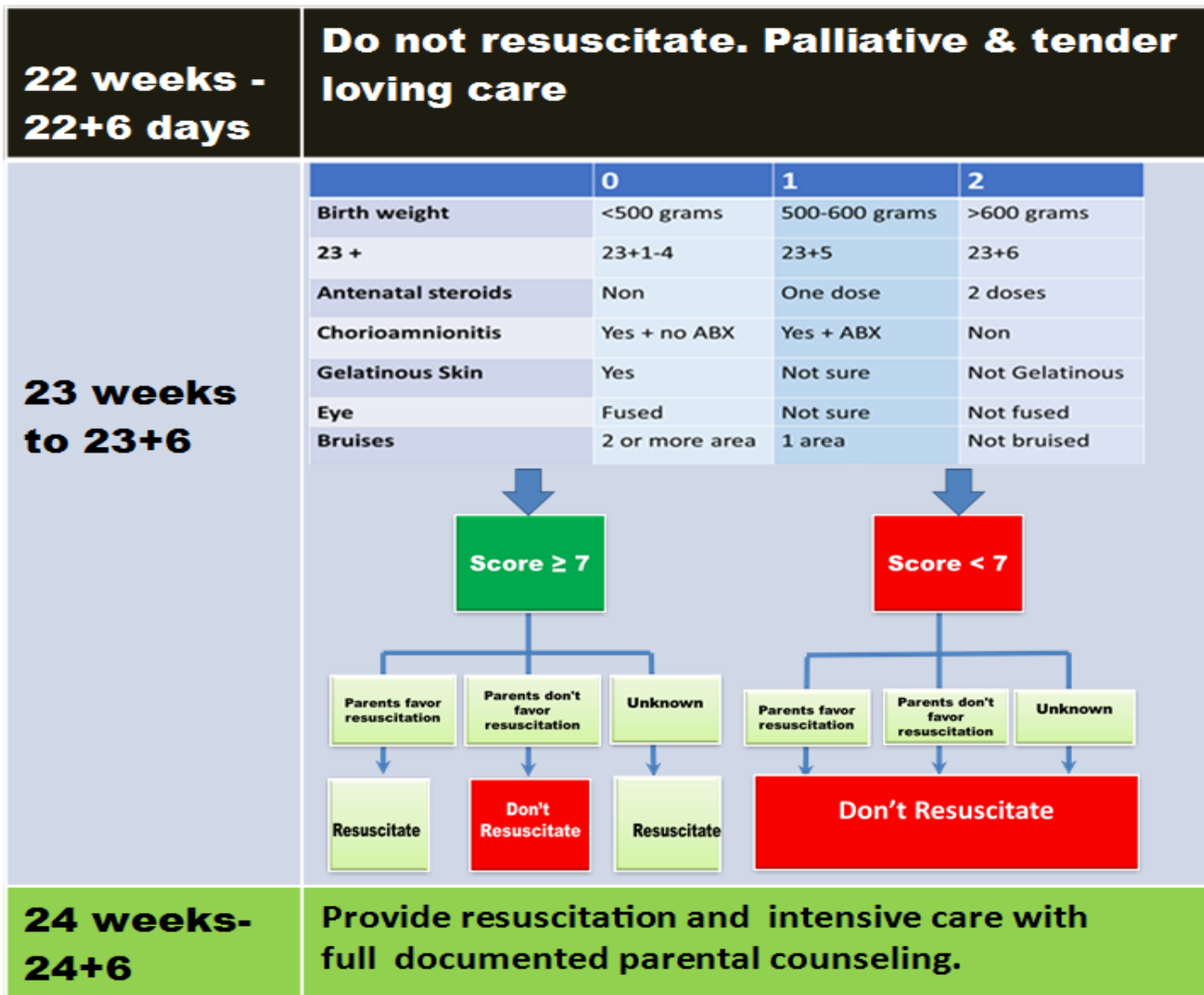
Introduction:

Neonatologists operating in tertiary NICUs have mixed feelings toward resuscitation, admission and managing newborn infants born at 23 weeks' gestation age. NICU services are judged by their level of sophistication in managing infants born at the limits of viability and their survival until discharge. These NICUs are keen to achieve a favorable two-year neurodevelopmental outcome showing minimal developmental handicap among these infants. (1) This approach was undertaken based on published reports regarding the survival of infants born at 23 weeks and their outcomes, as well as ethical and cultural obligations to provide care for all infants, and social and political expectations of being good stewards of the healthcare dollar. Hence it was reasonable for advanced health care policymakers to demand similar outcomes in their NICUs (2) In Japan, Nazomi et al. reported survival of 65% and cerebral palsy as low as 18%. These encouraging reports drive expectations in other tertiary NICUs to achieve similar outcomes. It is crucial to comprehend the embryology and physiology of this gestation age, the immaturity of the body organs and its impact on the survival of those tiny infants and evidence-based medical practice to care for these immature infants. (2) The American Academy of Pediatrics published a guideline report in 2009 which was updated in 2015 that noted wide variation of approaches, outcomes, and decision-making process when managing infants born at the limits of viability. (3)

“The American Academy of Pediatrics published a guideline report in 2009 which was updated in 2015 that noted wide variation of approaches, outcomes, and decision-making process when managing infants born at the limits of viability.”

Over the past several decades, advances in perinatal and neonatal care have improved the survival of even the most immature infants, increasing and diversifying our knowledge of the causes of death in preterm infants. (3, 4) The Epicure study reported that 64% of infants

Figure 1: limits of viability 22-24 weeks gestation resuscitation decision-making guideline



Unknown:

1. Rapid delivery without meeting parents.
2. No antenatal consultation.
3. Mother cannot be approached (in active labor) or unapproachable husband/partner.
4. Multiple pregnancies: each is evaluated as an individual case.

Chorioamnionitis: active clinical symptoms within one week of labor.

Assisted pregnancy due to extended infertility (IVF): needs special consideration

Significant bruises: bruises involve 2 or more of (head & scalp), trunk & limbs.

Figure 2. Total number of infants died within the first 2 weeks versus those died after two weeks versus lived till discharge (infants)

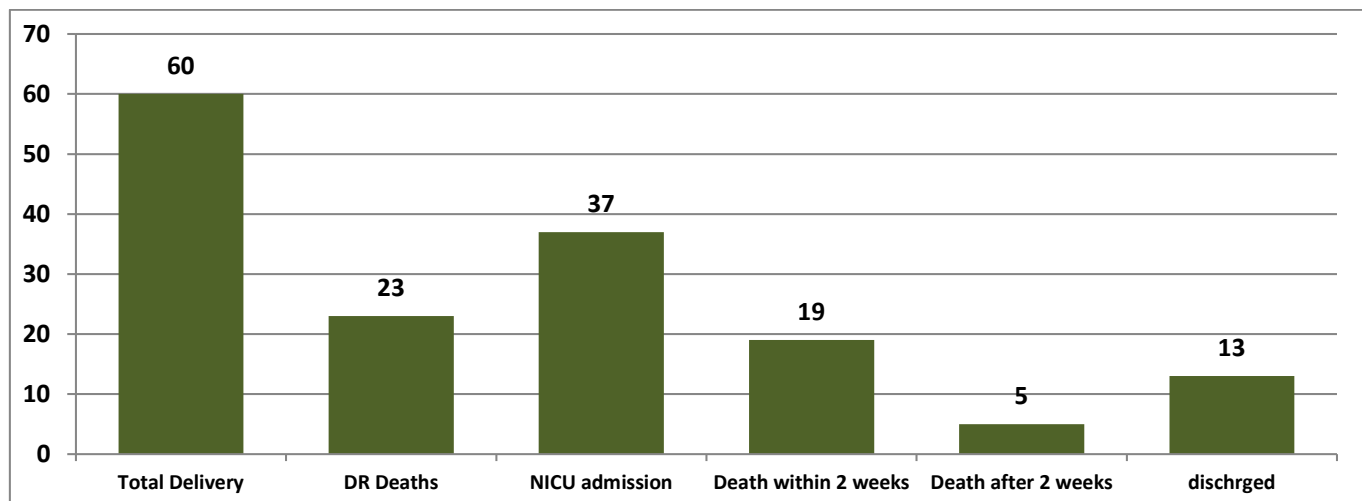
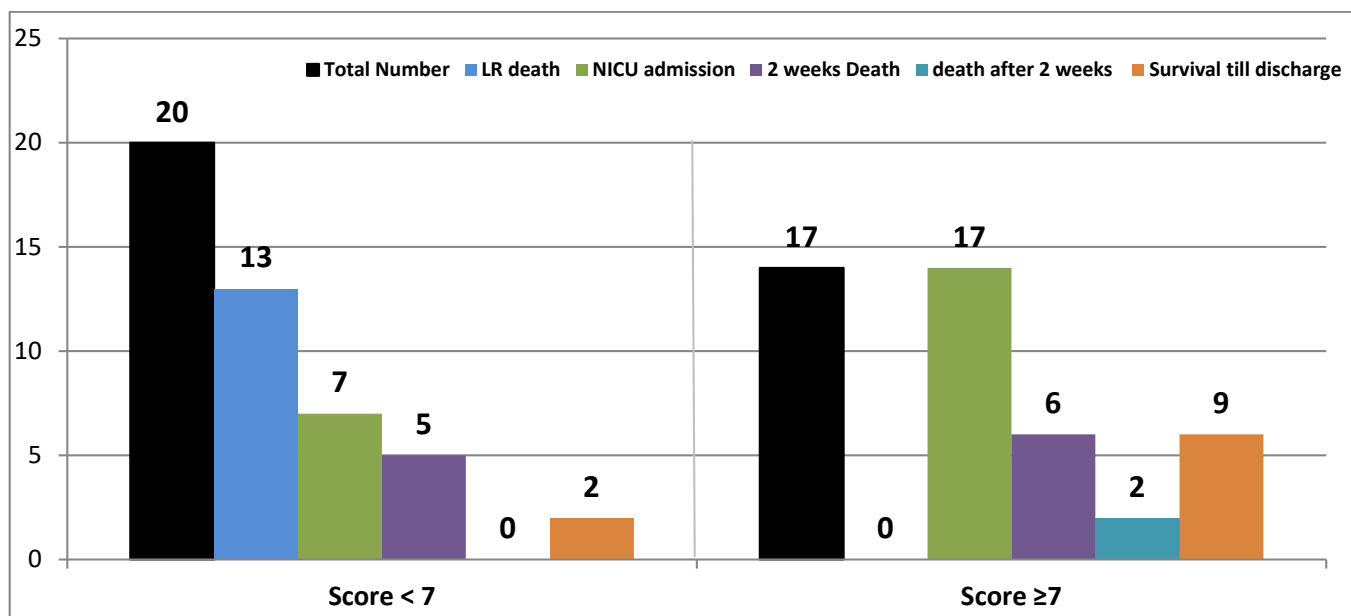


Figure 3. Impact of applying resuscitation score on the 23 weeks gestation infants*



* Only 37/60 received the full score characteristics.

born at 23 weeks were resuscitated and admitted alive to The NICU, and 40% of them survived until 28 days, while 30% survived to be discharged home. (5) In the Epicure study review in 2014, the number of live births, infants born at 23 gestation age with intended care was 284, while the number of those infants admitted to the NICU was 217 (76%), and infants died before discharge was 151(69%).

Few publications addressed and focused on this particular gestation age. (6,7) Our hospital is a "state of the art," new tertiary referral women's hospital where 40 to 50 deliveries occur daily. WWRC accom-

modate 214 Maternity beds and 110 The NICU cots distributed on two floors. WWRC is a referral hospital for three governmental and five private maternity services. In 2004 and 2005, 12 infants at 23 weeks 'gestation were admitted to our the NICU, and only one baby survived to discharge (9%). Since 2009, we have been encouraged to admit infants of this gestation age to our NICU, but the cumulative survival rate throughout ten years did not exceed 18%, with an average length of stay is 140 days for those who survived. In this study, we measured the probability of death before and after introducing the resuscitation score (The score of seven) targeting the 23 weeks gestation age.

Methodology:

This population-based retrospective study was designed to assess mortality and survival rate of all ELBW infants born at 23 weeks gestation delivered among residents of Qatar in WWRC from 2016 to mid-2018. We evaluated the outcomes of these infants after introducing the resuscitation guideline concerning the limits of viability 23 weeks gestation. We retrieved the data from the medical records of each infant, the Pearl-Peristat Maternal and newborn registry and Vermont Oxford database related to our hospital. We defined cases as live-born at 23 weeks plus zero days to 23 weeks plus six days who were born, died or admitted to the NICU. The estimation of the gestation age was verified from the maternal ultrasound, in-vitro fertilization dates, first-trimester ultrasound and or from menstrual dating confirmed by second-trimester ultrasound. The study excluded confirmed intrauterine fetal death and infants with significant anomalies. The study included infants in whom resuscitation was attempted in the delivery room. The rate of NICU admission, death before two weeks of age and death before discharge were assessed. In this study, we as well evaluated complications during the first two weeks associated with death to measure the probability of dying in case such complications occurred.

We evaluated the best evidence available from the world's literature (19-27) reflecting antenatal risk factors associated with death in this gestation age and level of intrauterine growth maturation. We selected seven parameters which are supported by the evidence as the most crucial for potential survivability or death in this gestation age (figure 1). We allowed room for the ambiguity of the clinical features and subjectivity of the evaluation. We as well, left a window to accommodate unknown clinical information.

The designed score took in consideration, parental wishes not to proceed with the resuscitation based on the information conveyed to them before delivery, but this score did not allow the parents to dictate resuscitation in case of score less than seven as this was an adopted policy of the institution's NICU. We relaxed this policy in exceptional circumstances such as an in-vitro fertilization case and a history of infertility. We omitted the influences of gender, multiple births and birth order or ethnicity from the decision score component. Each baby was assessed independently from those three factors. Before applying the score, we obtained the approval of the NICU then Women's Hospital Board of Ethics. Seven elements were chosen, four antenatal before delivery (gestation age, chorioamnionitis, estimated birth weight, and antenatal steroids) and three immediate postnatal (confirmation of birth weight, bruises, skin friability and fusion of the eyelids). Each component received zero, one or two according to its presence, "not sure," or absence. Babies were not to be resuscitated if the score was below 7 and actively resuscitated and admitted to the NICU if the score was greater than or equal to seven.

A satisfaction survey was conducted six months after the application of the score to identify the comprehension, practicality and ethical comfort of the NICU medical staff.

Results:

Sixty infants delivered from January 2016 until June 2018 were investigated for mortality associated risk assessment. The DR death rate was 23/60 (38.3%). The NICU admission was 37 infants (61.7%). Half of the admitted infants died before two weeks of age. The Survival rate to discharge was 35% (13/37). Only 37/60 infants were able to retrieve the full description of the baby's selection components of the "score of seven" and subjected to the analysis of the survival rate using this score. However, infants died in the DR with a score below 7 was 13/20 (65%) versus 0/17 when the score was equal to or above 7. Amongst those infants admitted to the NICU (37), seven infants admitted with a score less than seven; 2/7 infants survived till discharge (~29%) while among 17 infants admitted with a score equal to or greater than 7, 9 infants survived to discharge (51%). A survey was conducted that

included full-time thirty-three neonatal physicians. Thirty-two indicated that the scoring system was easy to comprehend, twenty-six said it was easy to implement, and thirty physicians indicated that the guideline provided ethical support for both parents and medical providers leading to less moral distress over what is the best evidence-based care for these extremely premature infants.

Discussion:

Birth at less than 24 weeks gestation remains frightening and ethically challenging for both parents and caregivers. Parents often lack knowledge of the outcomes and complications among these very premature infants and have ambiguity regarding the future and fear of having a disabled child. While for caregivers, there is the medicolegal and ethical responsibility to each infant and family, the concern regarding resources availability and consumption, the high possibility of an unfavorable outcome, as well as, the need for utmost and vigilant attention to outcome measures for a very long time.

The 'optimal' perinatal care of infants born at the limits of viability remains unclear and vary significantly among several reports (2,3,8-11). These complexities are well established, but there is increasing evidence from NICUs in Japan and other regions of a more favorable outcome. However, in the State of Qatar and across the world, there is no formally agreed upon national consensus in practice, leading to variation between tertiary institutions and their referring regional hospitals at this particular gestation. Differences in local and international practice make comparisons between centers difficult. In some centers, it might reflect the level of deficiency in expertise and technology. Many centers report widely different rates of antenatal corticosteroid use, operative birth and other perinatal care strategies that may explain the variation in morbidity and mortality (9,11,12).

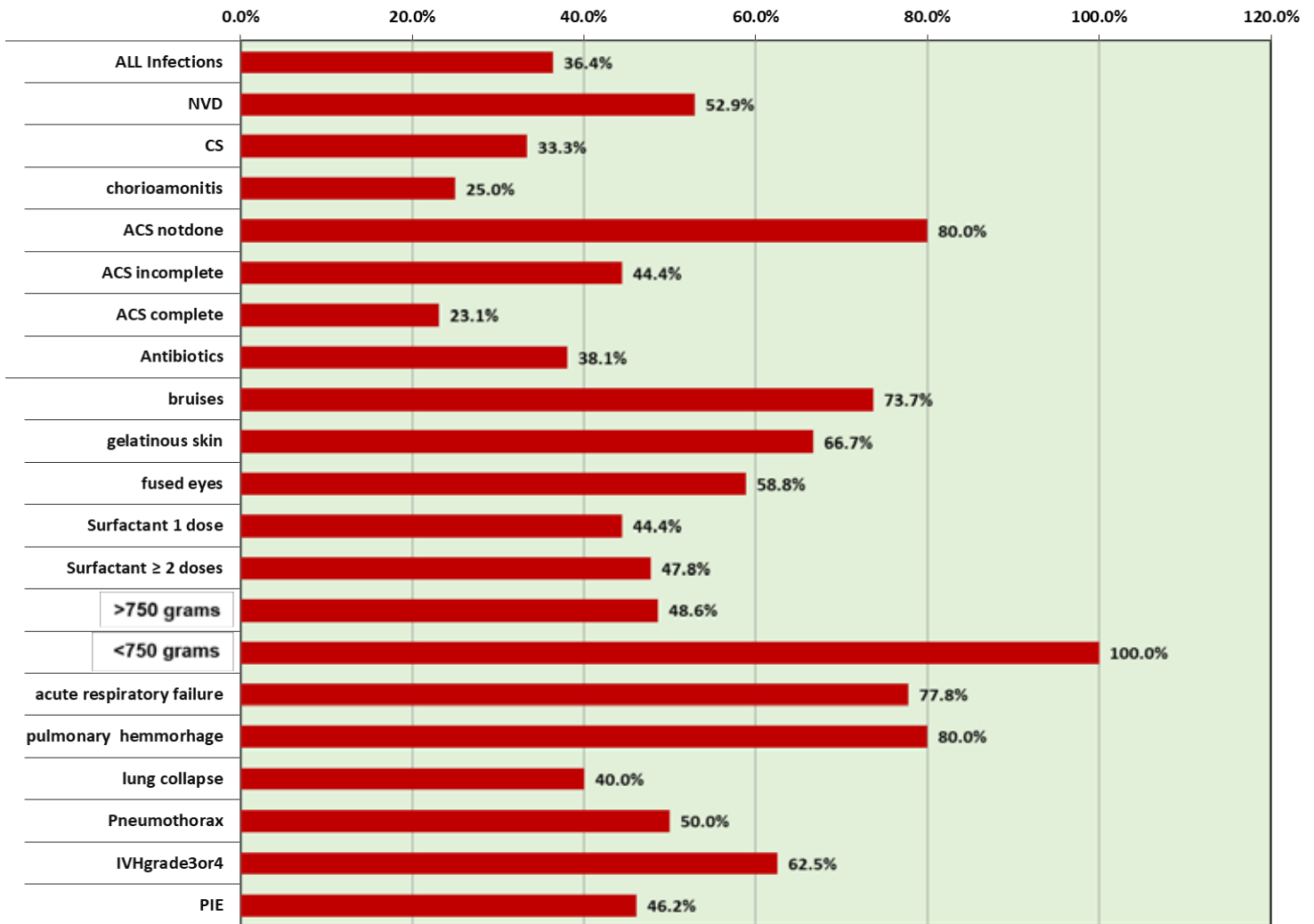
Furthermore, early trimester dating scans have a margin of error of at least one week. This margin undermines treatment threshold decisions based on gestational age alone (13)

Similarly, the effect of other variables, including corticosteroid exposure can modify survival risk significantly (14). The medicolegal conflicts, the very long hospital stay, the eventual death after long days of struggle, the parent's frustration including separations and even divorce are crucial factors to consider when developing and imple-



Figure 4. death related risk factors in 60 preterm 23 weeks gestational age infants

Risk Factors related to death (%)



menting a meaningful scoring system. Evidence-based knowledge is complicated by human subjectivity and possible sub-optimal decision-making skills. The score of seven distinguishes those infants with a strong potential to resuscitate while providing more guidance for those who present with less potential. The score was designed to accommodate unsure physical signs, particularly when addressing signs of maturation. We report the survival rate rather than the two-year outcome as the primary objective in this study. Applying this score did not increase labor room deaths, which were marginally less than before applying the score (by 7%). The score may have helped the physicians decide when to attempt resuscitation before birth, as four out of seven components of the score are calculated before delivery. Support by the hospital administration and ethical reassurance from the Board of Ethics approval helped the attending resuscitation team to more comfortably take on overwhelming ethical decisions and responsibilities. In the current study, we report a survival rate of 35% to discharge. It is lower than some centers (15,16) and equivalent or higher than other centers. (2,17, 18)

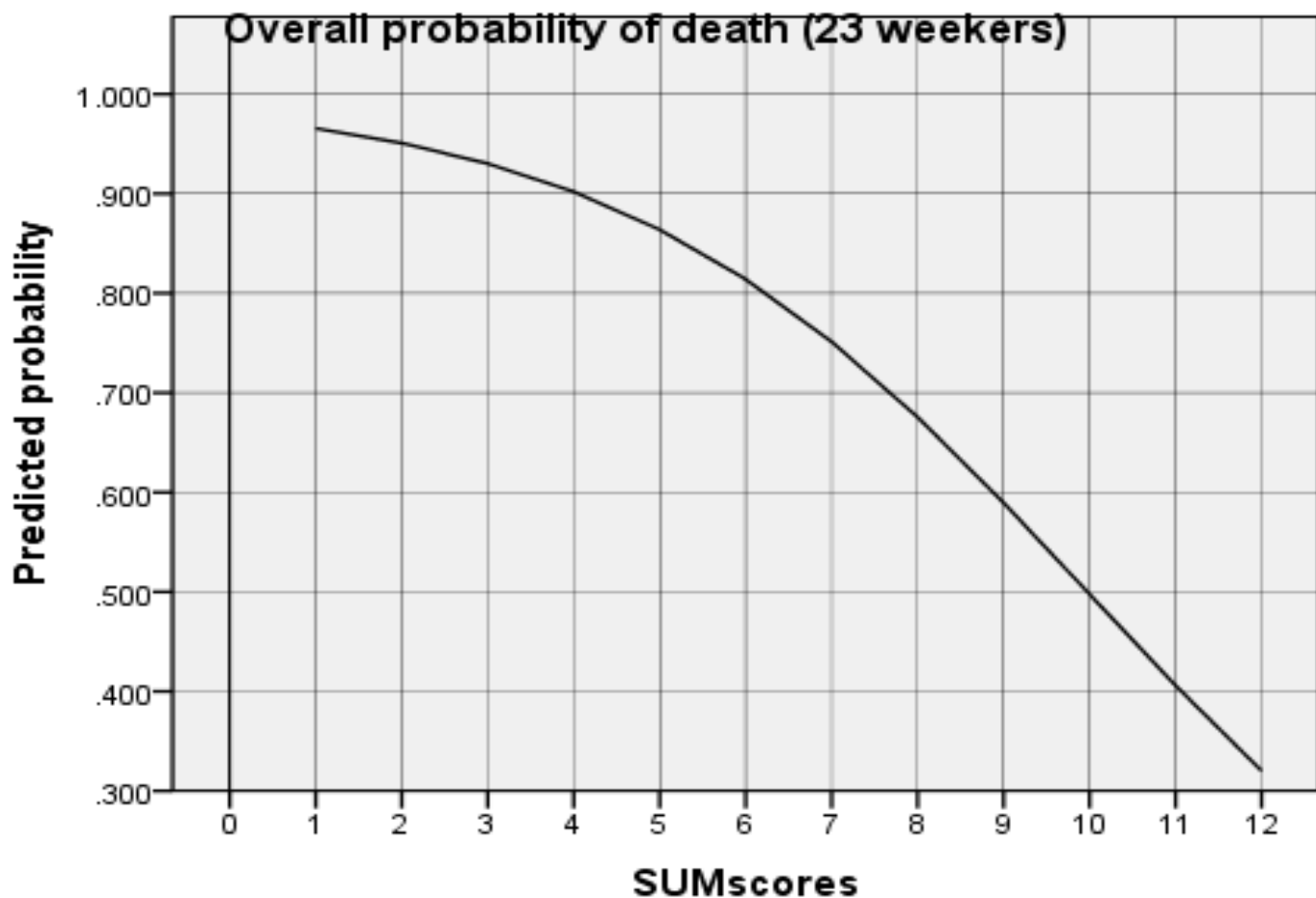
We propose a practical, convenient and ethically sound approach to this particular gestation age founded on evidence-based literature that

can solve significant confusion among health caregivers. Although this score should be applied consistently to achieve maximal benefit, an individual approach and custom decision making must be used where applicable.

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PLOTS = probability of death *100 (P value =0.126)



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Table 1. Odds Ratios for death at two weeks of 60 infants at 23 weeks Gestation.

| | | OR | 95% C. I |
|--|------------|------|------------------------------|
| Maternal infection | No | 0.21 | (0.05 - 0.87) [†] |
| Maternal antibiotics | No | 8.9 | (1.56 - 51.18) [†] |
| Antenatal steroids | None | 13.3 | (2.19 - 81.23) [†] |
| | Incomplete | 2.7 | (0.42 - 16.83) |
| Bruises | Yes | 7.7 | (1.66 - 35.69) [†] |
| Gelatinous skin | Yes | 2.2 | (0.55-9.02) |
| Fused eyes | Yes | 1.4 | (0.38 - 5.44) |
| Birth weight | ≤750g | 1.9 | (0.305-13.02) [†] |
| Age at intubation | ≥5 mins | 1.0 | (0.20 - 4.96) |
| IPPV & Fio2 > 50 % at 2 weeks of age | Yes | 22.8 | (3.55 - 145.8) [†] |
| Surfactant doses | ≥ 2 doses | 1.15 | (0.24-5.39) |
| Blood transfusion | Yes | 0.1 | (0.02 - 0.49) [†] |
| Pulmonary hemorrhage | Yes | 5.0 | (0.49 - 50.83) |
| IVH III/IV | Yes | 2.5 | (0.46 - 13.52) |
| Mode of delivery | NVD | | |
| | CS | 0.44 | (0.04 - 5.38) |
| Lung collapse | Yes | 0.6 | (0.09 - 0.32) |
| Pneumothorax | Yes | 1.1 | (0.07 - 20.02) |
| Pie | Yes | 0.8 | (0.21 - 3.47) |

† Statistically significant at p<0.05

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TOP 10

RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS



Essential evidence-based practices that can transform the health and well being of NICU families and staff

based on the National Perinatal Association's Interdisciplinary Recommendations for Psychosocial Support of NICU Parents

1 PROMOTE PARTICIPATION

Honor parents' role as primary caregiver. Actively welcome parents to participate during rounds and shift changes. Remove any barriers to 24/7 parental involvement and avoid unnecessary separation of parents from their infants.



2 LEAD IN DEVELOPMENTAL CARE

Teach parents how to read their baby's cues. Harness your staff's knowledge, skills, and experience to mentor families in the principles of neuroprotection & developmental care and to promote attachment.



3 FACILITATE PEER SUPPORT

Invest in your own NICU Parent Support program with dedicated staff. Involve veteran NICU parents. Partner with established parent-to-parent support organizations in your community to provide continuity of care.



4 ADDRESS MENTAL HEALTH

Prioritize mental health by building a team of social workers and psychologists who are available to meet with and support families. Provide appropriate therapeutic interventions. Consult with staff on trauma-informed care - as well as the critical importance of self-care.



5 SCREEN EARLY AND OFTEN

Establish trusting and therapeutic relationships with parents by meeting with them within 72 hours of admission. Follow up during the first week with a screening for common maternal & paternal risk factors. Provide anticipatory guidance that can help normalize NICU distress and timely interventions when needed. Re-screen prior to discharge.



6 OFFER PALLIATIVE & BEREAVEMENT CARE

Support families and NICU staff as they grieve. Stay current with best practices in palliative care and bereavement support. Build relationships with service providers in your community.

7 PLAN FOR THE TRANSITION HOME

Set families up for success by providing comprehensive pre-discharge education and support. Create an expert NICU discharge team that works with parents to find specialists, connect with service providers, schedule follow-up appointments, order necessary medical supplies, and fill Rx.



8 FOLLOW UP

Re-connect with families post-discharge. Make follow-up calls. Facilitate in-home visits with community-based service providers, including Early Intervention. Partner with professionals and paraprofessionals who can screen families for emotional distress and provide timely therapeutic interventions and supports.

9 SUPPORT NICU CARE GIVERS

Provide comprehensive staff education and support on how to best meet families' psychosocial needs, as well as their own. Acknowledge and address feelings that lead to "burnout."



10 HELP US HEAL

Welcome the pastoral care team into your NICU to serve families & staff.

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11th International Conference on Brain Monitoring and Neuroprotection in the Newborn February 7-9, 2019

Bob White, MD

Scientists and clinicians from 18 countries gathered at the 11th International Newborn Brain Conference recently to discuss the latest research on care of the newborn brain.

After several workshops opened the meeting, the first plenary session addressed "Environment of the Developing Brain". Session Chair Dr. Terrie Inder presented the current evidence on the sensory development of the preterm infant and implications for care. Dr. Ruth Grunau further discussed noxious influences in the NICU environment, especially pain, then Dr. Joan Smith described how positive sensory input could be organized into a multimodal protocol, with extensive family involvement. Dr. Martha Welch expanded on the value of the family's role, then Dr. Renee Shellhaas reviewed the importance of sleep in preterm infants. Finally, Dr. Bob White presented evidence to support the continued emergence of couplet care and single-family rooms in the NICU as a way to reduce noxious stimuli and improve the likelihood that families will be present and interactive with their baby. Take-away messages from this session included 1) there are profound differences between optimal and actual brain growth of preterm infants in the NICU; 2) to some extent this is due to the adverse sensory environment to which these infants are exposed. In particular, both frequent pain and its treatment with morphine or fentanyl have been shown to cause long-term complications including hormonal, behavioral, and epigenetic; and 3) It is possible to enhance the sensory environment of the premature infant and thereby improve outcomes; the family is the most important agent in this effort, but there are also valuable roles for staff and volunteers.

The second plenary session reviewed current evidence and

practice for the treatment of hypoxic-ischemic encephalopathy (HIE), especially "mild" HIE. While the definition of this category is not uniform it is now apparent that outcomes in these infants are not universally optimal, so the potential for beneficial interventions was considered. Dr. Alistair Gunn presented animal models of mild HIE, typically produced by 10-20 minutes of severe ischemia, which caused selective but significant neuronal loss in untreated controls. Therapeutic hypothermia was successful in this model in reducing long-term brain damage, especially if started within the first hour of life. Dr. Hannah Glass reviewed the current state of clinical practice; the most recent reviews show that 20-40% of babies with mild HIE have abnormal MRIs, especially in the watershed areas of the brain, and a similar percentage have long-term disability. 50-75% of these infants are now being cooled, with a trend in studies suggesting there is a benefit to this care. The primary challenge continues to be creating a rigorous definition so that appropriate studies can be performed; this is hampered by the fact that clinical and laboratory signs often change over the first few hours, creating a broad spectrum of findings even in this sub- category of HIE. The theme that a baby's findings can change considerably over a matter of hours during a time when a decision on starting therapeutic hypothermia needs to be made was reinforced by Dr. Lina Chalak with respect to physical exam, EEG, MRI, and NIRS, and by Dr. Deidre Murray in her review of potentially useful biomarkers. Session chair Dr. Geraldine Boylan described the EEG in a series of normal newborns; her finding that all normal newborns had a continuous background with some evidence of cycling by 2-3 hours of age could be used to identify those infants who had sustained some brain injury and for whom intervention might be considered. The session was completed with an audience response session, in which it was revealed that feedings are being safely given to some infants during therapeutic hypothermia at some centers.

"Frequent administration of morphine can reduce electrical activity in the cerebellum, which correlates closely with reduced brain growth, even after correcting for severity of illness."

A general science session followed, chaired by Dr. Frank van Bel. Dr. Michael Cotton provided preliminary evidence that stem cell administration may improve outcome after HIE or ischemic stroke, and may also reduce the risk for BPD and severe IVH in very preterm infants; a number of early phase clinical trials are being planned. Dr. Gabriel Variante described the development of an extensive telemedicine network for training, collaboration, and standardization in Brazil, with improved outcomes providing validation to extend this throughout Latin America. Dr. Manon Benders elucidated the many roles of the cerebellum in brain development and function; it has the most rapid growth of any brain segment, and can both cause and be adversely affected by injuries to other parts of the brain. Frequent administration of



morphine can reduce electrical activity in the cerebellum, which correlates closely with reduced brain growth, even after correcting for severity of illness. Dr. Christopher Rhee reviewed the cerebral autoregulation and its tenuous status in preterm infants, where increases or decreases in perfusion can cause damage in the form of IVH and PVL. Dr. Dan Licht completed this session with a description of the challenges facing infants with congenital heart disease before, during, and after cardiac surgery, especially related to optimizing O2 delivery to the brain.

The final session, entitled “Prognosis After Early Brain Injury” was chaired by Dr. Hannah Glass and explored several aspects of this challenge. Dr. Lena Hellstrom-Westas described the value of EEG in the first days of life; when multiple components of the EEG are considered, including background activity, synchrony, cyclicity, and seizures, the prognostic value is high. Dr. Terrie Inder detailed the many components of an MRI exam that should be interrogated to maximize accuracy. Timing of the MRI was another important component to consider; the false negative rate at 12 hours of age is up to 30%, with a maximal prognostic value of conventional MRI after 7 days of age, though lactate levels by MRI spectroscopy can provide useful information on day one. Even so, MRI is better at predicting motor outcomes based

on white matter changes than it is for cognitive outcomes. Dr. Monica Lemmon then gave a humbling overview of the challenges in discussing potential outcomes with parents. There is rarely concordance in understanding after family conferences to convey prognosis, so she identified several strategies and resources for providers to improve their skill in giving families what they want and need in this regard. Finally, Dr. Sonia Bonifacio presented a case that illustrated many of the topics discussed throughout the meeting, reinforcing both what we have learned and how much remains to be determined in order to provide optimal care for high-risk infants.

The next meeting of the International Newborn Brain Conference will be in Ireland in the second half of 2020, then the conference will return to Clearwater Beach, FL in mid-February 2022. In the meantime, Dr. Mohamed El-Dib has begun a Special Interest Group on Neonatal Neurocritical Care, with a website at www.NNCC-SIG.org and plans to meet at PAS in Baltimore in April. All who have an interest in this field are welcome to join via the web site.

The author has indicated no relevant disclosures.

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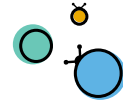
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|---|--|---|
| TIME | SESSION / EVENT | |
| 7:00 AM | REGISTRATION OPENS | |
| 7:30 – 8:30 AM | CONTINENTAL BREAKFAST IN EXHIBIT HALL (PALM/BAY) | |
| WORKSHOPS (separate registration) | | |
| WORKSHOP A (ISLAND II) | WORKSHOP B (SAND KEY) | WORKSHOP C (ISLAND I) |
| 8:30 AM – 10:00 AM | 8:30 AM – 10:00 AM | 8:30 AM – 10:00 AM |
| Neurologic Examination of the Neonate (Robert R. Clancy, MD) | Early Diagnosis of Cerebral Palsy (Nathalie Maitre, MD, PhD; Betsy Ostrander, MD) | aEEG/EEG workshop (Lena Hellstrom-Westas, MD, PhD; Geraldine Boylan, PhD) |
| 10:00 AM – 10:30 AM: BREAK | | |
| WORKSHOP D (ISLAND II) | WORKSHOP E (ISLAND I) | 12:15 – 1:15 PM PRIVATE LUNCH EVENT (SAND KEY) |
| 10:30 AM – 12:00 PM | 10:30 AM – 12:00 PM | |
| EEG Seizures (Robert R. Clancy, MD) | Utility of NIRS to Avoid Suboptimal Cerebral Oxygenation in the Preterm: Case Presentations (Frank van Bel, MD; Petra Lemmers, MD, PhD) | |
| 12:00 PM – 1:25 PM: LUNCH ON OWN | | |
| MAIN CONFERENCE BEGINS (ISLAND II-I) | | |
| 1:25 – 1:30 PM | Welcome <i>Environment of the Developing Brain</i> (moderator: <i>Terrie Inder, MBCHB</i>) | |
| 1:30 – 2:00 PM | Development of the Immature Brain and Implications for the NICU Environment (Terrie Inder, MBCHB) | |
| 2:00 – 2:30 PM | Experiential Influences in the NICU on Brain Development: Noxious (Ruth Grunau, PhD) | |
| 2:30 – 3:00 PM | Experiential Influences in the NICU on Brain Development: Nurturing (Joan Smith, PhD, RN, NNP-BC) | |
| 3:00 – 3:30 PM | BREAK IN EXHIBIT HALL (PALM/BAY) | |
| 3:30 - 4:00 PM | Family Based Interventions in the NICU: Impact on Outcomes (Martha Welch, MD) | |
| 4:00 – 4:30 PM | Causes and Consequences of Abnormal Sleep in the NICU (Renee Shellhaas, MD) | |
| 4:30 – 5:00 PM | The NICU of the Future: Will we even recognize it? (Robert White, MD) | |
| 5:00 – 5:45 PM | <ul style="list-style-type: none"> ➤ Individual Variability in the Infant's Pain Response: Can We Predict an Infant's Response to Noxious Events from Spontaneous Brain Activity? (Luke Baxter, PhD student) ➤ Characterizing Infant Brain Activity During Retinopathy of Prematurity Screening (Miranda Buckle, MBBC, FRCO) | |
| 5:45 – 7:15 PM | RECEPTION IN EXHIBIT HALL (AND POSTER WALK 6:30 – 7:15) | |

The 11th International Conference on Brain Monitoring and Neuroprotection in the Newborn
AGENDA
February 7-9, 2019

Friday, February 8, 2019

| TIME | SESSION / EVENT |
|------------------|--|
| 7:00 – 5:30 PM | REGISTRATION DESK OPEN |
| 7:00 – 8:00 AM | CONTINENTAL BREAKFAST IN EXHIBIT HALL (PALM/BAY) |
| 7:55 – 8:00 AM | Welcome <i>HIE (moderator: Geraldine Boylan, PhD)</i> |
| 8:00 – 8:30 AM | Animal Models of Mild/Moderate HIE (Alistair Gunn, MBCHB, PhD) |
| 8:30 – 8:45 AM | “Mild” HIE: What’s in a Name? (Hannah Glass, MD) |
| 8:45 – 9:15 AM | NIRS in Mild and Moderate HIE (Lina Chalak, MD) |
| 9:15 – 9:45 AM | Can Blood Biomarkers Distinguish Between Mild and Moderate HIE? (Deirdre Murray, MB BAO, PhD) |
| 9:45 - 10:15 AM | BREAK IN EXHIBIT HALL (PALM/BAY) |
| 10:15 – 10:45 AM | What are the EEG Features of Mild and Moderate HIE, and Can Machine Learning Help? (Geraldine Boylan, PhD) |
| 10:45 – 11:45 AM | <ul style="list-style-type: none"> ➤ Early Exit from Neonatal Therapeutic Hypothermia: A single institution experience using MRI to guide decision-making (Yasmine White, MD) ➤ Abnormal Electroencephalographic Findings in Infants with Mild Neonatal Hypoxic Ischemic Encephalopathy (Rafaela Pietrobom, MD) ➤ Brain Injury following Hypoxic-Ischemia is Associated with Worsening Trend of Cerebral Autoregulation During Therapeutic Hypothermia (Zachary A. Vesoulis, MD) ➤ Low Blood Pressure Variability is an Early Predictor of Abnormal EEG Infants with Hypoxic Ischemic Encephalopathy (Abigail Flower, PhD) |
| 11:45 – 12:00 PM | ARS: What are People doing in Their Practices? (John Barks, MD; John Hartline, MD) |
| 12:00 – 1:25 PM | LUNCH ON OWN |
| 12: 15 – 1:15 PM | PRIVATE LUNCH EVENT (ISLAND II) |
| 1:25 – 1:30 PM | Welcome <i>General Science (moderator: Frank van Bel, MD, PhD)</i> |
| 1:30 – 2:00 PM | Stem Cell Therapy for Brain Injury in the Newborn (Michael Cotten, MD) |
| 2:00 – 2:30 PM | Protecting Brains in the Developing World (Gabriel Variane, MD) |
| 2:30 – 3:00 PM | The Cerebellum: How do We Diagnose, Monitor and Treat Injuries to Newborns? (Manon Benders, MD, PhD) |
| 3:00 – 3:30 PM | BREAK IN EXHIBIT HALL (PALM/BAY) |
| 3:30 PM | POSTERS NEED TO BE DOWN |
| 3:30 – 4:00 PM | New Developments in Understanding Cerebrovascular Autoregulation (Christopher Rhee, MD) |
| 4:00 – 4:30 PM | Protecting the Brain, Before, During, and After, Cardiac Surgery (Daniel Licht, MD) |

The 11th International Conference on Brain Monitoring and Neuroprotection in the Newborn
AGENDA
February 7-9, 2019

| | |
|----------------|--|
| 4:30 – 5:30 PM | <ul style="list-style-type: none"> ➤ Validation of Global Brain Injury Scoring Applied by a Novel 1T Neonatal MRI System in Comparison to a Conventional 1.5T MRI System in Very Preterm Infants at Term Equivalent Age (Alona Bin-nun, MD) ➤ Nonlinear Transfer Entropy to Assess the Neurometabolic Coupling in Premature Neonates (Dries Hendrikx) ➤ Therapeutically Reducing Neuronal and White Matter Impairment in the Growth Restricted Newborn Brain (Julie Wixey, PhD) ➤ Using Cerebral NIRS Measures for an Individualized Approach to RBC Transfusions in Premature Infants (Halana V. Whitehead, MD) |
| 5:30 – 5:45 PM | OPTIONAL: SPECIAL INTEREST GROUP (Mohamed El-Dib, MD) |

Saturday, February 9, 2019

| TIME | SESSION / EVENT |
|------------------|--|
| 7:15 – 12:30 PM | REGISTRATION DESK OPEN |
| 7:15 – 8:00 AM | BREAKFAST |
| 7:55 – 8:00 AM | Welcome Prognosis After Early Brain Injury (moderator: Hannah Glass, MD) |
| 8:00 – 8:45 AM | Utility of the EEG in Establishing the Prognosis (Lena Hellstrom-Westas, MD, PhD) |
| 8:45 – 9:30 AM | Utility of the MRI in Establishing Prognosis (Terrie Inder, MBCHB) |
| 9:30 – 10:15 AM | Communicating Neurologic Prognosis to Families (Monica Lemmon, MD) |
| 10:15 – 10:45 AM | BREAK (CHECK OUT OF HOTEL) |
| 10:45 – 11:30 AM | Cases, Questions and Panel Discussion (Sonia Bonifacio, MD) |
| 11:30 – 12:00 PM | <ul style="list-style-type: none"> ➤ A Web-Based Calculator for Prediction of Severe Neurodevelopmental Impairment in Preterm Infants Using Clinical and Imaging Characteristics (Zachary A. Vesoulis, MD) ➤ aEEG and NIRS Monitoring in Term Neonates Diagnosed with Perinatal Arterial Ischemic Stroke and the Association with Neurodevelopmental Outcome (Daphne van den Berk, MD) |
| 12:00 – 12:30 PM | ARS (John Barks, MD; John Hartline, MD) |
| 12:30 PM | CONFERENCE ADJOURNS |

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and provide the supporting evidence

Non-invasive Ventilation (NIV): Are we throwing some babies out with the bathwater?

Rob Graham, R.R.T./N.R.C.P.

I dedicate this and future columns to the late Dr. Andrew (Andy) Shennan, the founder of the perinatal program at Women's College Hospital (now at Sunnybrook Health Sciences Centre). To my teacher, my mentor and the man I owe my career as it is to, thank you. You have earned your place where there are no hospitals and no NICUs, where all the babies do is laugh and giggle and sleep.

Since before I watched Dr. Jackie Coalson present her baboon model of non-invasive continuous positive airway pressure (CPAP) vs. invasive ventilation at the 21st Snowbird conference in 2004, (1) I was convinced early extubation, use of non-invasive ventilation (NIV) and avoidance of invasive ventilation where appropriate was the future. Years later most of us are riding happily along on the NIV bus on the road we assume leads to better outcomes. Speeding along, however, no one seems to have checked the brakes. Who are these "appropriate" babies? And how do we decide when NIV is leading us in the wrong direction?

"Speeding along, however, no one seems to have checked the brakes. Who are these "appropriate" babies? And how do we decide when NIV is leading us in the wrong direction?"

Since the journey began, things have changed. The COIN trial (2) examined infants stratified at 25-26 weeks and 27-28 weeks. It did not show any benefit to NIV and showed more air leak in the CPAP group. Examining the management, to me, could be a clue as to why. The CPAP level used was 8 cmH₂O. "PEEPaphobia" (3) it seems persists in the absence of an endotracheal tube (ETT). To quote Dr. Bert Bunnell, "meaningful, sustained recruitment will not occur below a mean airway pressure (MAP) of 10 cmH₂O". In my experience and practice, I concur. I soon discovered on the admission table using the first HFO capable machine I'd ever had that a frequency of 10, MAP of 10 cmH₂O, and 100% amplitude (it was a weak machine) worked most of the time. The increased risk of an air leak in the trial's CPAP group to me indicates air trapping, which can occur with CPAP if adequate pressures are not reliably maintained. Whatever pathological label one gives it, these babies' lungs can get quite crappy, and quite quickly at that. Figure 1 is a chest film of an infant on CPAP, never intubated. There are signs of de-recruitment despite "good volume" by rib count. Figure 2 is the same baby. This is not a post-extubation

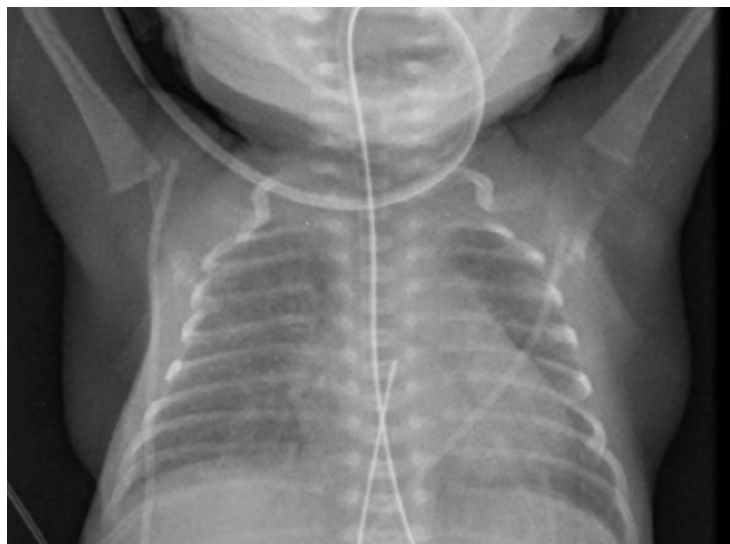


Figure 1

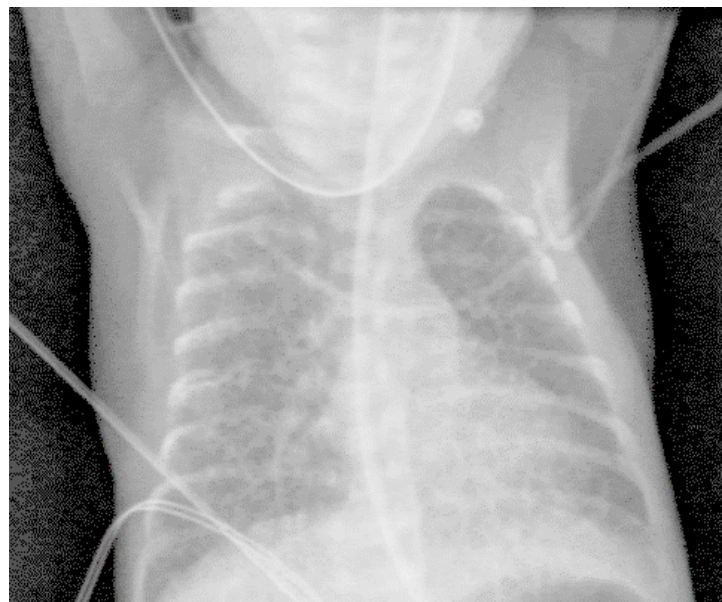


Figure 2

film. This baby has never been intubated at this point. This is not what we expected when we boarded the NIV bus. Figure 3 is the post-intubation chest film, the first with an ETT in situ.

As with any therapy, it is best to choose patients wisely. Many centres are now approaching the resuscitation of sub-23-week gestation infants the way sub-25 week infants were 20 years ago, and many are keen to prevent chronic lung disease (CLD) by avoiding an ETT. As my mother would say, "you can't make a silk purse from a sow's ear." From a physiological perspective, it is unrea-

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Figure 3

sonable to expect a structure that is not yet a lung to be a fully functioning lung, nor an immature respiratory centre to maintain spontaneous breathing. My own experience suggests only 5-10% of sub-25-week infants will avoid an ETT. Hence the necessity of knowing how to ventilate is still de rigueur.

Why, even though approached with gusto, the best of intentions and the appropriate patient, is NIV failing some? Those enamored with conspiracy theories will surely love this tale, for indeed conspiracy and double-crosses abound. The nature of the patient, limitations of equipment, and sometimes misguided practices share the blame.

The Patient

Many of the same challenges facing clinicians when mechanically ventilating are present without an endotracheal tube. The primitive lung is lacking in both structure and function. Decreased surface area for gas exchange may require higher minute volumes for ventilation and oxygenation, and lack of vasculature compounds the problem. It can be difficult to oxygenate without hyperventilating since CO_2 diffuses twenty times more readily than O_2 . Babies may hyperventilate on CPAP when they do not achieve proper functional residual capacity (FRC) just as when genuinely hyperinflated. Floppy airways collapse easily and require substantial CPAP levels to maintain patency. Failure to do so will result in air trapping downstream, and airways are still small with accompanying high flow resistance. While the ETT may be absent, the gastric tube (GT) is quite present. Required for venting and feeding, the GT may also help gas enter the stomach when pressures are high; more gas in the stomach and abdomen leave less room for gas in the lungs, requiring ever higher pressures contributing to feeding intolerance and perhaps aspiration. And then there's that respiratory centre... always asleep at the switch! While non-invasive positive pressure ventilation (NIPPV) may help, the evidence is lacking to support this mode unless accompanied by diaphragmatic triggering. I was using NIPPV via a nasopharyngeal tube in the late '80s. Babies graduated to CPAP when someone forgot to turn the machine back on after an NPT change, and the baby didn't notice.

"Many of the same challenges facing clinicians when mechanically ventilating are present without an endotracheal tube. The primitive lung is lacking in both structure and function. Decreased surface area for gas exchange may require higher minute volumes for ventilation and oxygenation, and lack of vasculature compounds the problem. "

I think there is a case to be made to have micro-prems intubated and ventilated lung protectively to reduce the risk of cerebral hemorrhage: stimulation to breathe is startling, a response we do not want to elicit in the first 72 hours of a micro-prem's life. Finally, there is oxygen. To quote Dr. Martin Keszler, "CPAP with high FiO_2 indicates atelectasis and may be worse than intubation, surfactant administration, and lung protective ventilation". (4) The micro prem has little to no endogenous antioxidant protection and is very prone to oxidative stress and injury. Recent studies out of the U.K. allude to increased, sustained oxygen levels leading to poorer one second forced expiratory volumes in children managed with NIV as babies and another out of Australia suggests the overall incidence of CLD is not falling despite the use of NIV. (5) Last but not least, the extreme susceptibility to intraventricular hemorrhage let alone pain leave a clinician ill-advised to intubate without proper anesthesia unless an infant is flat. This requires time. Should apnea be the only problem and FiO_2 is low, this is not a problem. If FiO_2 is high, however, the clock is ticking, but instead of a bomb going off all at once, the damage starts immediately and grows exponentially. We see the inflammatory response about a week later. In the old days, that's when babies who were in room air (and by my current standards over ventilated and with an archaic mode) suddenly jumped up in oxygen requirements.



The chest films were BPD or the start of it.

The Equipment

A challenge to the successful delivery of NIV is MAP; the maintenance of sufficient MAP at pressures above 12 cmH₂O with current equipment is, I think, a challenge everywhere, and if using the Viasys@Sipap@ impossible due to the pressure blow off on the machines. A large amount of dead space, the absence of synchronization with NIPPV, and difficulty measuring tracheal pressure in NIV all collude to lessen the chance of success in the micro prem. Leaks, whether around the interface or through the mouth, dead space, and the dreaded skin breakdown and pressure sores are all very real problems we face today when higher MAP is required. I use non-invasive high-frequency oscillation (NIHVO) in my practice frequently. While there are no clinical trials to support this mode (and it is not at this time available in the U.S.), it seems to work quite well on little babies and is less affected by leaks than NIPPV. As for gastric distention, I cannot say it is better or worse, but minimising amplitude may help. CPAP is, I think, the best tolerated of NIV modes in the absence of persistent apnea.

The Clinician

Any mode of ventilation will fail if the clinician will not provide the pressure required to achieve and maintain adequate FRC. This is as true with NIV as with any invasive mode. There seems to be a great reluctance to use "high" CPAP pressures during resuscitation. One should not be afraid to use pressures of 10-15 cmH₂O or more during initial recruitment. It's not about the size of the baby; it's about the stiffness of their lungs. Once airways are open pressure can be decreased to 10 or less providing there is not a rebound in O₂ requirements. A baby gasping and grunting to try and achieve FRC is quite capable of blowing a spontaneous pneumothorax, and that happens when one doesn't provide enough support. Another common clinical approach is the acceptance of high FIO₂ levels, sometimes greater than 0.60. An adult cannot live indefinitely in 70% O₂, what makes anyone think a 25 weeks gestation infant can? I think this may be well intentioned, but it is wrong. The old idea that 40% O₂ is okay comes from back in the days when a 29 weeks infant was considered a micro prem and surfactant was a dream. Most patients then were above 30 weeks and far less prone to oxygen toxicity than the extremely prema-

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ture infants we treat today. With the only crude, conventional and non-synchronised ventilators to use and no surfactant, 40% O₂ wasn't okay either, but it was necessary. NIV CPAP/MAP should be titrated as tolerated to the lowest possible FiO₂ requirements, for it is there that one has achieved the best balance between ventilation, perfusion, and compliance. Finally, I think that failure must be recognized when it happens, and failure criteria that reflect the needs of the baby and not the wishes of the clinician should be well established when using NIV. Quoting Dr. Keszler again, "If CPAP level is not sufficient to achieve the "open lung," the lung is subject to volutrauma and atelectotrauma just like with mechanical ventilation". (4) I concur. Once this happens, an inflammatory cascade ensues. The lung is most prone to damage when being recruited, and since de-recruitment is rarely homogeneous, the lung is even more prone to damage during recruitment at this point than during resuscitation.

"Delayed recruitment and early oxidative stress may actually impair the outcome of these babies compared to immediate, appropriate mechanical ventilation and control of CO₂ levels for 72 hours for neuroprotection."

Hope for the Future

A study has been done using diaphragmatic monitoring (EDI) comparing CPAP with a conventional interface and the RAM® cannula to compare workload between the two. (6) I mention this only because of the use of EDI in NIV. I would like to see similar studies done on NIHF0 and NI jet ventilation. Managing babies on the former routinely and having done the latter once (I'll tell you about it, I promise!) I am curious to see the utility of EDI in assessing proper PEEP/MAP settings both in NIV and invasive modes. If we can avoid X-rays and simply allow the baby to show us what they need in terms of MAP it would be a godsend clinically, and perhaps be the tool that improves the success of any mode of ventilation. Optimal compliance should be reflected as the least work on EDI. It is hoped the technology is made available through license eventually or a portable interface made for clinical monitoring applications. Those on a budget will balk at spending over \$70k to provide non-invasive ventilation no matter what song the machine plays, but from an evidence-based standpoint, I think it a relative bargain if it can be shown to reduce costs later in life if not in the hospital. Proteomics hold promise in helping to find markers for those at risk of damage from not just a pulmonary, but whole system standpoint. And NIV research is really just beginning. When oscillation with volume control becomes available in the U.S., so will the research on HFO.

That mechanical ventilation comes at a cost is without question; there is, however, an ongoing need for it. It is possible to mechanically ventilate micro prems protectively. If a unit has high CLD rates amongst infants who are ventilated but who are good candidates for NIV stops ventilating these infants and, rather, adopts an NIV approach to management, CLD rates will indubitably drop. A unit having relative success mechanically ventilating smaller, less mature babies may not see such a dramatic decrease applying the same approach; they may even see them rise. Infants less than 25 weeks are very likely to require mechanical ventilation. Delayed recruitment and early oxidative stress may actually impair the outcome of these babies compared to immediate, ap-

propriate mechanical ventilation and control of CO₂ levels for 72 hours for neuroprotection. My bias is towards HFO and HFJV; a bias gained through witness. In my practice I have seen CLD rates decline and remain low even though gestational age is decreasing. I know it can be done. NIV is, I think irrefutably, part of the solution, that is, as long as it does not get in the way of it.

References:

- 1 <http://www.ped.med.utah.edu/vent/sbbroch04.pdf>
- 2 <https://www.nejm.org/doi/full/10.1056/NEJMoa072788>
- 3 *PEEPaphobia: an unreasonable or irrational fear of PEEP, generally greater than 6 or 7.*
- 4 *University of Ottawa Neonatology Ventilation Day, personal attendance.*
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Disclosures: The author receives compensation from Bunnell Inc for teaching and training users of the LifePulse HFJV in Canada. He is not involved in sales or marketing of the device nor does he receive more than per diem compensation. Also, while the author practices within Sunnybrook H.S.C. this paper should not be construed as Sunnybrook policy per se.

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The Feeding of Sick and Vulnerable Newborns: Urgent Call for an Independent Inquiry

Leith Greenslade, MPA, MBA

No single vaccine or medicine has the life-saving power of breastmilk, which has been described as, “the most specific personalized medicine” babies are ever likely to receive. (1) If all babies were breastfed within an hour of birth and then exclusively for the next six months, estimates suggest that more than 800,000 deaths among children under five could be prevented every year. (2)

“If all babies were breastfed within an hour of birth and then exclusively for the next six months, estimates suggest that more than 800,000 deaths among children under five could be prevented every year.”

Breastfeeding's greatest benefits accrue to the most vulnerable babies, (2) including the 22 million babies who are born too small, (3) the 15 million who are born too soon, (4) the 8 million born with congenital anomalies, (5) and the 47 million born in fragile settings. (6) The risk of death for these newborns is higher. Low birth weight is a factor in 70% of the estimated 1.8 million newborn deaths, 649,000 babies die from preterm birth complications, and 502,000 from congenital defects every year. (7)

Despite these stakes, not much is known about feeding practices among sick and vulnerable newborns. To date, the major breastfeeding policies and programs, including the [International Code of Marketing of Breastmilk Substitutes](#), the [Baby-friendly Hospital Initiative](#), and the Bill & Melinda Gates Foundation-funded [Alive & Thrive](#) initiative, have not prioritized sick and vulnerable newborns. Even the landmark [Lancet Breastfeeding Series](#) was released in 2016 without a focus on sick and vulnerable newborns.

This lack of attention is all the more concerning as new evidence emerges of breastfeeding's significant benefits for sick and vulnerable babies, (8) alongside reports of the harsh realities of feeding these newborns in low resource and fragile settings. Recent evidence of extremely low levels of breastmilk feeding among babies in Neonatal Intensive Care Units (NICUs) in South Asia, babies born with disabilities in sub-Saharan Africa, and newborns in refugee populations in the Middle East are deeply disturbing. (9)

To rally governments and all stakeholders to invest in a deeper understanding of this issue and to advance new solutions, there is now a global effort calling for a large-scale, independent inquiry into sick and vulnerable newborn feeding practices. This research would provide the world's first assessment of how sick and vulnerable newborns are fed in the days and weeks following birth, and of the health and wellbeing of their mothers during this critical period, across several different settings.

Under the umbrella of the [Breastfeeding Innovations Team](#), a global network of more than 400 individuals committed to the development and adoption of innovations with the greatest potential to break down barriers to breastmilk feeding, more than 40 organizations have signed an [Open Letter](#) (10) calling for an independent inquiry which would:

1. Document maternal lactation and expression behaviors and feeding behaviors and practices among sick and vulnerable newborns in different settings;
2. Determine the breastfeeding/breastmilk initiation rate and typical daily diets for babies during hospital stays;
3. Describe the infant-feeding “eco-system” in the hospital and the level of lactation support;
4. Assess the amount of breastmilk that mothers are expressing and infant milk intake to determine how effectively mothers are able to initiate, build, and maintain their milk supplies;
5. Report mothers' own experience of feeding support in facilities;
6. Describe relevant government and hospital policies and their implementation both helping and inhibiting access to breastmilk for sick and vulnerable newborns; and
7. Recommend specific strategies to improve access to breastmilk for the sickest and most vulnerable newborns appropriate for the various settings.

It is anticipated that the results of such a multi-year, multi-country inquiry would encourage national, state, and local governments to mandate ambitious goals for optimal feeding of sick and vulnerable newborns, and require hospitals and health facilities in both the public and private sectors to invest in new programs that ensure sick and vulnerable babies receive priority access to breastmilk and that their mothers are supported to achieve their breastfeeding goals during this challenging period.

The inquiry should also seek clear statements backed by policy guidelines from global health authorities that optimal access to breastmilk for sick and vulnerable newborns (11) is critical to achieving the new Sustainable Development Goals, especially reducing newborn deaths (Goal 3.2), ending child malnutrition (Goal 2.2), and reducing deaths from noncommunicable diseases by one third (Goal 3.4), and should be a new priority in all breastfeeding policies and programs.



Several new players and initiatives are emerging with innovations that make it easier and more cost-effective to increase breastfeeding rates among the most vulnerable babies. In 2016, [Laerdal Global Health](#) announced “Helping Babies Grow,” a family of training and therapy products to help save lives of newborns, especially low birth weight babies through breastfeeding and skin-to-skin contact. The tools include MamaBreast (hand breastmilk expression), PreemieNatalie (care of the newborn), the Nifty cup (breastmilk for babies who can’t suckle), and CarePlus (for skin to skin care).

The [All India Institute of Medical Science](#) (AIIMS) recently released the results of an experiment to increase breastmilk feeding in their own NICU from a very low baseline of 12%. Following the introduction of a new education and training program and technologies that enabled pumping, they increased the breastmilk feeding rate to 83% in just four weeks. Health technology NGO, [PATH](#), just released the first Resource Toolkit for Establishing and Integrating Human Milk Banks into routine newborn care in hospitals, with a special focus on low resource settings.

WHO and UNICEF are also starting to take a closer look at breastfeeding and newborn survival. The [Global Breastfeeding Collective](#) has highlighted the importance of early initiation of breastfeeding and a new [Field Guide](#) (12) in partnership with Save the Children offers special guidance on feeding newborns in humanitarian settings. There have also been efforts ([Neo-BFHI](#)) to update the Baby-friendly Hospital Initiative so that it addresses the needs of sick and vulnerable newborns. (13)

Increasing breastfeeding rates and access to breastmilk among the newborns most at risk of death and disability is an urgent need - arguably the top priority on the global breastfeeding agenda. Ultimately, however, little will change until governments set ambitious goals for optimal feeding of sick and vulnerable newborns and invest in programs that make sure these babies have access to the most lifesaving — and too often the only — “medicine” available: breast milk.

To support the Open Letter, please email the Chair of the Breastfeeding Innovations Team, Leith Greenslade (leith@justactions.org).

“ Ultimately, however, little will change until governments set ambitious goals for optimal feeding of sick and vulnerable newborns and invest in programs that make sure these babies have access to the most lifesaving — and too often the only — “medicine” available: breast milk.”

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Disclosure: Leith Greenslade is the founder and CEO of JustActions.

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Editor's Note:
 Neonatology Today and Loma Linda Publishing Company endorse the Open Letter.
 Mitchell Goldstein, MD
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In Memoriam: Bernadette Hoppe, Esq.

Jerry Ballas, MD, MPH

The National Perinatal Association (NPA) is an interdisciplinary organization that strives to be a leading voice for perinatal care in the United States. Our diverse membership is comprised of healthcare providers, parents & caregivers, educators, and service providers, all driven by their desire to give voice to and support babies and families at risk across the country.

Members of the NPA write a regular peer-reviewed column in Neonatology Today.



Bernadette Hoppe was already a legend by the time I joined the Board of Directors of the National Perinatal Association in 2013. I was a newly minted Maternal-Fetal Medicine specialist when I received the invite from Susan Altman, midwife extraordinaire and one of my former teachers during my OB/GYN residency at SUNY Stony Brook. I was flattered that Susan would think of me for this position, and even though I knew very little about NPA, I jumped at the opportunity.

I attended my first official NPA Board meeting in January of 2014 and immediately felt like a fish out of water. Bernadette, I would come to learn, had been elected to a two-year term as President of NPA, but had to take time off due to a new diagnosis of colon cancer. I barely knew anyone on the Board at that point, but I could tell they were still reeling from the news. Despite this diagnosis and her first round of treatment, Bernadette still managed to participate by phone. And by participate, I mean

she created the kind of presence through thoughtful commentary and well-timed humor that I could only dream of emulating in-person, let alone remotely. She exuded an enthusiasm for NPA's mission that was infectious, and I was hooked. To that point in my young academic career, I had siloed myself comfortably within the world of OB/GYN and MFM, looking at issues facing pregnant women through a clinical lens of randomized trials, expert opinion, and, quite frankly, what had been driven into me by those who trained me in residency and fellowship. Suddenly, I found myself amongst a passionate group of midwives, nurses, pediatricians, social workers, parent advocates, lawyers, nutritionists and psychologists who were looking at the very same perinatal issues I thought I had cornered clinically though lenses I barely knew existed. To be honest, within the first few hours of that meeting, I was questioning if I was the right person for this organization.

Then Bernadette turned to me (virtually, of course, since she was on the conference line) and asked if I'd be interested in looking over NPA's draft paper addressing Maternal Mortality in the United States. She explained how it could benefit from my input as an MFM and improve the document's multidisciplinary credentials. I was suddenly at ease. Not only was this a topic I felt comfortable with clinically, but it was a position paper written from a social justice point of view that I rarely considered in the past. Looking back now, I realize that beyond simply connecting a specialty with a task, Bernadette had exhibited one of the greatest qualities of a leader: assessing a team member's strength and setting them on a course for success.

From that point on, despite our limited face-to-face interactions, Bernadette's influence over my path within NPA would only grow. I would finally meet her in person a few months later at our annual meeting in St. Louis. She would not let the rollercoaster of her cancer treatment slow her down. I found the presence I had felt by phone a few months prior paled in comparison to the woman I met in person. She was fierce in a way only Bernadette could be, with an eye for detail and razor-sharp wit honed from her years as a liti-

gator combined with a sense of justice for women that was as unyielding as she was in the face of cancer. As native New Yorkers, we clicked on a level that I felt privileged to share.

“She was fierce in a way only Bernadette could be, with an eye for detail and razor-sharp wit honed from her years as a litigator combined with a sense of justice for women that was as unyielding as she was in the face of cancer.”

Over the next five years, Bernadette would encounter painful bouts of chemotherapy and treatment setbacks and still produce the kind of timely, high-level work most would struggle to produce without such adversity. She kept NPA abreast of important amicus briefs, advanced and modernized our organization's stance on substance use disorders in pregnancy and, during one of the most difficult points in her life, created an amazing module entitled “Opiates in Pregnancy: Using Science in Family Court Matters” to serve as a practical (and factual) reference for providers to fairly treat this vulnerable and often-maligned patient population. On a personal note, during this time, Bernadette would contact periodically to gauge my interest in one day taking on a leadership position within NPA, offering not only advice and encouragement, but giving me a glimpse of the future she envisioned for the organization.

This past January, with the confidence instilled in me over the years by Bernadette, I took on the position of President of NPA. At our first Board Meeting of the year, one of the most pressing orders of business was extending the position of Emeritus Board Member to Bernadette. Needless to say, it was passed enthusiastically. In responding to our nomination, Bernadette



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replied: "Thank you very much for the honor of being selected for an emeritus member of the board of directors of NPA. I accept this nomination with enthusiasm and gratitude. Because of my current health status, I will not be able to attend the board meeting in person. However, I am happy to attend via electronic means."

"For the rest of us, whose lives she touched through her storied career in family law, her fierce advocacy on behalf of those who had no voice and her unwavering sense of humor in the face of insurmountable odds, we will continue to honor Bernadette through the kind of deeds and calls to action she fearlessly championed regardless of the odds. "

Ten days later, she would pass away peacefully surrounded by those she loved. She is survived, first and foremost, by her wife Mary, who stood by her in a way only true love could endure. For the rest of us, whose lives she touched through her storied career in family law, her fierce advocacy on behalf of those who had no voice and her unwavering sense of humor in the face of insurmountable odds, we will continue to honor Bernadette through the kind of deeds and calls to action she fearlessly championed

regardless of the odds. If we can do this as providers for women, newborns, and their families, then we can finally be the agents of change Bernadette strove to be every day of her life.

Jerry Ballas, MD, MPH

President, National Perinatal Association

Associate Professor, Maternal-Fetal Medicine

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To learn more about Bernadette and her passion for advocacy, follow these links:

- [Buffalo Law Journal: Right to die is personal for Buffalo attorney](#)
- [Hoppe & Associates](#)
- [NPA Position Paper on Substance Use Disorder in Pregnancy](#)

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Editor's Note:
I was privileged to know Bernadette. She was always absolutely committed to the causes that were most important to her. She never wavered and never let anything get in the way of her boundless altruism. I am so proud of the NPA in advancing Bernadette to emeritus status. Although she was only in this role for a short time, as an emeritus, I can think of no other individual who was more deserving and whose selection would further enhance and elevate the meaning of emeritus status. May her motivation and commitment be remembered and serve as an example to all of us of how we can better ourselves.

Respectfully,

Mitchell Goldstein, MD
Past President and Emeritus Board
National Perinatal Association



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Improving the Evidence: Can a Prematurity Registry Change the Game?

Deb Discenza, MA, and Andrea Schwartz Goodman, MSW, MPH

Deb Discenza, MA is the Founder/CEO/Publisher of PreemieWorld, LLC and the founder and community leader of the Inspire Preemie Community at <http://preemie.inspire.com>. Deb is the co-author of The Preemie Parent's Survival Guide to the NICU and the publisher of two newsletters, Preemie Family and Preemie Pro. She is a founding member of the Preemie Parent Alliance and the original National Coalition for Infant Health. Deb can be reached at deb@preemieworld.com.

Andrea Schwartz Goodman, MSW, MPH, a leader in scaling maternal and child health programs, is most passionate about finding solutions that meet families where they are. She serves on the Steering Committee of the National Coalition for Infant Health, as Senior Editorial Project Director for [Neonatology Today](#), and as Director of Engagement at Genetic Alliance, an organization with 32 plus years of experience serving the disease advocacy community through a people-centered lens. Genetic Alliance created the Platform for Engaging Everyone Responsibly (PEER), a unique, award-winning technology solution for collecting health data directly from individuals. The platform, which has been designed to accommodate a variety of attitudes about data sharing and privacy, meets individuals where they are by giving them complete control over how their data is shared for research

Research has always been a slow path toward the pursuit of peer-reviewed publication and the hopeful implementation into medical practice. With expanding technology and opportunities for global collaboration, the research enterprise finally has its chance to speed up and spread evidence near and far. Disease-focused communities have become robust, intimate, and activated—ready to share ideas, knowledge, and data that could ultimately be the answer for affected babies and their families. Imagine the potential for innovation of therapies, pharmaceuticals, and medical devices!

But without robust patient input, data loses its humanity, its quality. The power of the patient's story adds nuance, critical wisdom, and attaches real faces to the issue. These pearls provide research projects with an opportunity to shift from pragmatic study to a fully evolved, 360-degree view of the disease state, directly from the lens of the patient. What we know from the literature is that patient-centered research gives way to improved clinical practice, stronger therapeutic drug development, and innovative solutions aimed at supporting affected individuals and their families in reaching their goals. At the forefront of neonatal practice, we must remember that medical

and clinical innovation is fruitless if we do not understand the human value.

To date, many disease communities have benefited from this type of “deep dive” patient registry: from Alzheimer's disease to rare cancers and even Cerebral Palsy. Yet, with the exception of one robust registry ([The Morgan Leary Vaughan Fund's Necrotizing Enterocolitis \(NEC\) Registry](#)), prematurity has not had the infrastructure in place to collect patient data in survey questions, oral history, or video collection. With so many health variables and disease states affecting premature infants, there is a rampant opportunity to gather better data, not only for researchers and health professionals but also for the patients and families they serve.

Imagine what knowledge we can gain by understanding the human and family experience behind the NICU: premature birth outcomes—with multi-pronged ailments leading to either life-long disabilities or even death—has yet to bring about an explosion of therapies targeted at these tiny infants. With the vast majority of neonatal drugs never being studied in low birth-weight infants, we still have so much left to learn. Our babies, families, and neonatal providers deserve better data, faster drug development, effective implementation of evidence, and—ultimately—answers and solutions for families.

“Our babies, families, and neonatal providers deserve better data, faster drug development, effective implementation of evidence, and—ultimately—answers and solutions for families.”

So, imagine for a minute how we could grow the power of the patient and unleash the potential of medical research through an online, international patient registry on prematurity. In traditional research settings, neonatal sample sizes average 10-1,000 patients, even though 15,000,000 premature infants are born around the world each year. (1) These samples only begin to tell the real story. The depth behind patient-entered data could add a rich set of endpoints and incredible ideas for innovation that incorporate medicine with real-life implementation. Imagine if instead of concluding manuscripts with the ever-elusive, “more research is needed,” we could truly learn more about the science from the holistic lens of the patient and families experience it, and effective provider solutions to support families and communities through next steps. It is not outside of our reach.

NEONATOLOGY TODAY is interested in publishing manuscripts from Neonatologists, Fellows, NNPs and those involved in caring for neonates on case studies, research results, hospital news, meeting announcements, and other pertinent topics.

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“Working collaboratively with the parent and neonatology community, [PremieWorld](#) is embarking on a community-wide global patient registry of its own. ”

Working collaboratively with the parent and neonatology community, [PremieWorld](#) is embarking on a community-wide global patient registry of its own. The registry will transform research through the ability to include patient-focused data, improve recruitment and diverse participation, and increase the ability to study outcomes data in real time while connecting the patient connection to foster community and decrease isolation. The NICU stay is critical, but prematurity’s focus is not entirely on birth; it spans the life course. With more than 15,000,000 babies born too early each year, we have a rich cohort of teens, young adults, and older adults living out the outcomes of prematurity and contributing to critical wisdom for better solutions. It is time that all stakeholders benefit, from neonatal researchers to industry leaders and patients and families. Stay tuned for an update from PremieWorld on registry progress in the coming months.

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Disclosure: Deb Discenza is the founder and CEO of Premieworld. Andrea Schwartz Goodman has no relevant disclosures.

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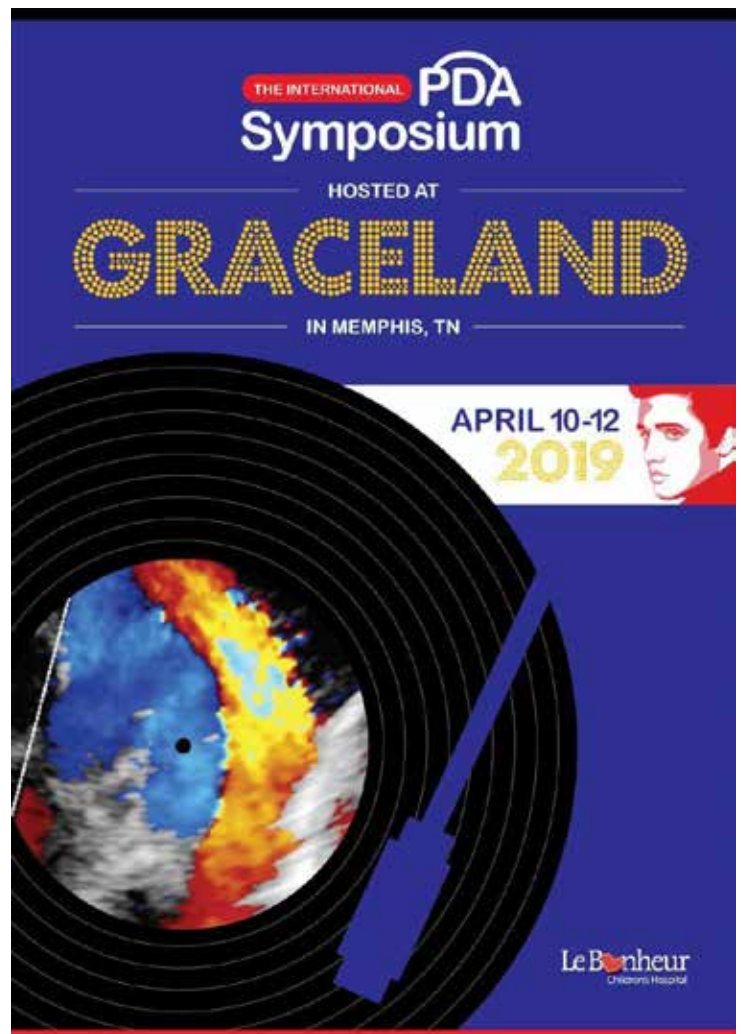
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“What about Pharmacy Benefits Managers (PBMs)?”

Darby O'Donnell, JD

The Alliance for Patient Access (allianceforpatientaccess.org), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access.



A 2018 study released from the University of Southern California found that patients overpay for their prescriptions 23 percent of the time.

Politico noted in an August 2018 article: “There’s a big target on the backs of pharmacy benefits managers [PBMs] lately with both the drug industry and HHS drawing attention to the role they play in the pricing of medicines.”

At the center of the drug pricing policy storm are the pharmacy benefit managers, or PBMs for short. PBMs are the middlemen pervasive in the drug supply chain.

But why are PBMs coming under scrutiny and facing negative reactions from consumers, health care providers, and the Trump administration when it comes to lowering drug costs?

Insurance companies hire pharmacy benefits managers, or PBMs, to handle their drug claims. The PBMs negotiate pricing with drug manufacturers - their discounts and rebates - for the insurance company and decide ultimately what drugs are available to patients through control and development of a plan’s drug formulary.

Therein lies one of the issues of concern, that is: the increase of exclusion lists promulgated by PBM-controlled drug formularies.

Last summer, CVS Health - one of the “big three” PBMs, along with Express Scripts and OptumRx (part of UnitedHealth Group Inc) - announced that employers who use its pharmacy benefit management services could cut certain medications from their plan’s formulary of approved drugs. This left patients stable (on a

prescription drug) potentially unable to access the drug because it was now either too expensive and/or the out-of-pocket cost was too high to be affordable at an off-formulary price. Another concern with limited or tiered formularies is that patients waiting for access to break-through treatments or those with chronic disease could be forced to try a prescription drug that already did not work for them or had been exhausted as a treatment option.

“ Another concern with limited or tiered formularies is that patients waiting for access to break-through treatments or those with chronic disease could be forced to try a prescription drug that already did not work for them or had been exhausted as a treatment option”

CVS was not alone in adopting this business practice.

Express Scripts announced later in the same summer that it would drop 242 prescription drugs from its formulary starting in January 2019. On the chopping block were antiretrovirals, drugs for hepatitis C, growth hormones and HIV medications, among others. Express Scripts projected that it would “save” \$3 billion this calendar year by excluding these drugs.

Why should patients care?

Because when PBMs developed formularies of fewer and fewer treatments, the patient suffers. Also, newly-discovered treatments lose their value if they are not reaching the patient because of cost controls and formulary restrictions suggested by PBMs.

State Medicaid programs - that directly impact infants and children - are not immune from contracts with PBMs, either. Low-income and minority families may be the most likely to be impacted by PBMs exclusion lists, in that their prescription medications - even generics - may become unaffordable.

If treatments are unaffordable, families from oldest to youngest may go without much-needed treatment.

So what is the cost to the patient?

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A patient who goes from being stable to an unstable patient because of a switch in their medication(s) can lead to other consequences, for example - increased visits to doctors and specialists, increased strain on health providers' time and resources, heightened the possibility of urgent care and/or hospitalization.

“ The impact of PBMs on patient care in the current health care system is still unknown, but the consequences of their decisions need to be recognized and evaluated further, for patients of all ages.”

PBMs say they are saving money through their role as “middlemen,” but the savings do not accrue to the patient. The decisions may be costing covered patients both money and their health. The impact of PBMs on patient care in the current health care system is still unknown, but the consequences of their decisions need to be recognized and evaluated further, for patients of all ages.

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The author has not indicated any disclosures.

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Still a Premie?

Some preemies are born months early, at extremely low birthweights. They fight for each breath and face nearly insurmountable health obstacles.

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation? **STILL A PREMIE**

Just like preemies born much earlier, these "late preterm" infants can face:

- Jaundice
- Feeding issues
- Respiratory problems

And their parents, like all parents of preemies, are at risk for postpartum depression and PTSD.

Born preterm at a "normal" weight? **STILL A PREMIE**

Though these babies look healthy, they can still have complications and require NICU care.

But because some health plans determine coverage based on a preemie's weight, families of babies that weigh more may face access barriers and unmanageable medical bills.

Born preterm but not admitted to the NICU? **STILL A PREMIE**

Even if preterm babies don't require NICU care, they can still face health challenges.

Those challenges can extend through childhood, adolescence and even into adulthood.

| Some Premies | All Premies |
|------------------------------------|-------------------------------------|
| Will spend weeks in the hospital | Face health risks |
| Will have lifelong health problems | Deserve appropriate health coverage |
| Are disadvantaged from birth | Need access to proper health care |

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Speaking of NEC: Unplugged

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| | | | |
|-----------------------|---|----------------------|--|
| 8:00–8:30 am | Breakfast and Registration Exhibits Open | 12:00–1:00 pm | Lunch and Exhibit Visits |
| 8:30–8:50 am | Welcome and Opening Remarks A Parent's Personal Story #1 | 1:00–2:40 pm | Post Disease A Parent's Personal Story #4 Touch Changes Everything Effects of NEC on Neurodevelopment of Preterm Infants |
| 8:50–10:00 am | The Disease A Neonatologist's Perspective Surgical NEC | 2:40–2:55 pm | Break and Exhibit Visits |
| 10:00–10:20 am | Break and Exhibit Visits | 2:55–3:45 pm | Post Disease (con't) A Parent's Personal Story #5 Short Bowel Syndrome |
| 10:20–11:10 am | Prevention A Parent's Personal Story #2 Improving Human Milk and Breastfeeding Outcomes | 3:45–4:00 pm | Wrap-Up |
| 11:10–12:00 pm | Research & Development A Parent's Personal Story #3 Diagnostics for Necrotizing Enterocolitis: Where We Are and Where We Can Go | | |

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Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Novavax Announces Topline Results from Phase 3 Prepare™ Trial of ResVax™ for Prevention of RSV Disease in Infants via Maternal Immunization

Trial did not meet primary objective of prevention of medically significant RSV LRTI

Trial did show efficacy against secondary objective (RSV LRTI hospitalization); first RSV vaccine to show Phase 3 efficacy

Other pre-specified exploratory endpoints and post-hoc analyses highlight potential to improve global health against RSV disease

Favorable safety and tolerability data

Next step to meet with key regulatory authorities to discuss licensure pathways

AGAITHERSBURG, Md., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX) today announced results from Prepare™, a global Phase 3 clinical trial using ResVax, an aluminum adjuvanted respiratory syncytial virus (RSV) fusion (F) protein recombinant nanoparticle vaccine. ResVax is being developed to protect infants via maternal immunization against RSV disease. In the Prepare trial, efficacy of ResVax against the primary and two secondary endpoints in per-protocol infants with RSV lower respiratory tract infection (LRTI) through 90 days of life was: 39% against medically significant RSV LRTI (97.5%CI, -1% to 64%)
44% against RSV LRTI hospitalizations (95%CI, 20% to 62%)
48% against RSV LRTI with severe hypoxemia (95%CI, -8% to 75%)

Pre-specified exploratory analyses of these same vaccine efficacy endpoints, which include additional data ascertained from hospitalization records, were:

41% against medically significant RSV LRTI (95%CI, 16% to 58%)
42% against RSV LRTI hospitalizations (95%CI, 17% to 59%)
60% against RSV LRTI with severe hypoxemia (95%CI, 32% to 76%)

"Pneumonia stubbornly remains the leading killer of children un-

der the age of five worldwide. The new maternal vaccine from Novavax shows promise in the fight against RSV, the most common cause of viral pneumonia in young children," said Dr. Keith Klugman, Director of the Bill & Melinda Gates Foundation's Pneumonia Program. "We are very encouraged that the Novavax maternal RSV vaccine reduced severe RSV hypoxemia by 60% in the first months of life and believe this vaccine has great potential for reducing RSV-associated deaths in young babies." The Prepare trial was supported in part by a grant of up to \$89.1 million from the Bill & Melinda Gates Foundation.

"Importantly, while this study did not meet the pre-specified success criterion for the primary clinical endpoint of this trial, the data indicate that ResVax protects infants from some of the most serious consequences of RSV, including RSV LRTI hospitalizations and RSV LRTI with severe hypoxemia," said Stanley C. Erck, President and Chief Executive Officer of Novavax, Inc. "The potential to prevent these most serious outcomes during infants' most vulnerable months of life could have a profound impact upon the global burden of RSV disease. Our next steps include meeting with U.S. and European regulators to review these data and to discuss the path forward for licensure. We wish to acknowledge and thank the investigators, the Novavax team and the many mothers and their families around the world that participated in this historic trial, bringing the world one step closer to an RSV vaccine."

Other observations from the Prepare trial:

Reduction in all-cause LRTI hospitalizations (25%) and all-cause LRTI severe hypoxemia (39%) in infants observed through the first 180 days of life

Mothers vaccinated from 28 up to < 33 weeks of pregnancy, showed vaccine efficacy rates against RSV LRTI hospitalization of 53% and severe RSV hypoxemia of 70% through the first 90 days of their infants' lives, compared with 26% and 44% for mothers vaccinated ≥ 33 weeks of pregnancy

Over 90% of RSV LRTI hospitalizations and RSV LRTI severe hypoxemia in the placebo group occurred in the first 90 days of life
99% of vaccinated mothers had measurable antibody responses

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Creating an Interdisciplinary Palliative Care Plan for Each Baby and Their Family

A 3-day intensive training of seminars and hands-on activity sessions to provide an overview of the methods, elements, and strategies needed to create a comprehensive neonatal comfort care plan for the entire perinatal team.

Perinatal detection of congenital anomalies leads to the identification of infants who are affected by life-limiting conditions with a short life expectancy. Moreover, a significant number of newborns admitted to the neonatal ICU in critical condition face potentially adverse prognoses. Perinatal palliative care offers a plan for improving quality of life of the infant and the family, when extending the baby's life is no longer the goal of care or the complexity of the medical condition is associated with uncertain prognosis. The evidence base for perinatal palliative care continues to grow. However, there is no consensus about best clinical practice in promoting support for the family or comfort for the neonate. Support for the family is achieved through appropriate pre- and postnatal consults, shared-decision making, and advance care planning. A state of comfort for the neonate is achieved when relational basic needs such as bonding, maintenance of body temperature, relief of hunger/thirst, and alleviation of pain/discomfort are met.

This three-day training will cover virtually all aspects of perinatal palliative care, including information about the successful experiences of the [Neonatal Comfort Care Program](#) in providing perinatal palliative care for over a decade at Columbia University Irving Medical Center (CUIMC). Faculty will discuss evidence-based rationale, practical aspects and strategies for implementing and applying aspects of the CUIMC to provide support for families and achieve a state of comfort for newborns with limiting or life-threatening conditions. Health professionals at all career stages are welcome to attend. Registration is required.

Elvira Parravicini, MD, Columbia University and New York Presbyterian/Morgan Stanley Children's Hospital, Director of Columbia University's Neonatal Comfort Care Program

Brian Carter, MD, University of Missouri-Kansas City and Children's Mercy Hospital

Charlotte Wool, PhD, RN, York College of Pennsylvania; Perinatal Palliative Care Consultant

See site for full instructor list.

Continuing Medical Education (CME) and Continuing Nursing Education (CNE): This course has been approved for CME credits. CNE credits pending.

Accreditation Statement: The Columbia University Vagelos College of Physicians and Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. **AMA Credit Designation Statement:** The Columbia University Vagelos College of Physicians and Surgeons designates this live activity for a maximum of 18.75 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

More details and registration: mailman.columbia.edu/comfort-care

to the vaccine, with $\geq 100\%$ transplacental transfer for all antibody types measured

ResVax appears safe in mothers and their infants through 180 days post-delivery

Novavax intends to present additional results from the Prepare trial at an upcoming medical meeting.

Webcast Conference Call

Novavax will host a webcast/conference call today at 8:00 a.m. EST. The webcast can be accessed via a link on the home page of the Novavax website (novavax.com) or through the "Investor Info"/"Events" tab on the Novavax website. Listeners who wish to ask questions or don't have internet access can dial-in to the conference call at (877) 212-6076 (domestic) or (707) 287-9331 (international) and use passcode 7679808.

A replay of the webcast will be available on the Novavax website until May 28, 2019 and a replay of the conference call only will be available starting at 11:00 a.m. ET on February 28, 2019 until 11:00 a.m. ET on March 7, 2019. To access the conference call replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and use passcode 7679808.

About RSV in Infants

Globally, RSV (respiratory syncytial virus) is the leading viral cause of severe lower respiratory tract disease in infants and young children.¹ It is the second leading cause of death in children under one year of age.² Estimated annual hospitalizations of 1.4 million and an estimated 27,300 in-hospital deaths were due to RSV acute lower respiratory infection in children under six months of age.³ RSV results in a total global economic burden of \$6.2 billion annually.

In the U.S., RSV is the leading cause of hospitalization of infants, with estimated annual hospitalizations of up to 76,000.^{4,5,6} While RSV can impact all infants, babies

under six months of age are among those at highest risk, as approximately 77% of all first-year RSV infections occur before six months.⁷ In the U.S., the total economic burden is \$2.7 billion annually.

About ResVax™

ResVax is an RSV fusion (F) protein recombinant nanoparticle vaccine with aluminum phosphate as an adjuvant. It is being developed to protect infants from RSV disease via maternal immunization, which may offer the best method of protection from RSV disease in infants through the first months of life. ResVax is being evaluated in Prepare™, a global Phase 3 clinical trial in 4,636 pregnant women, at least 3,000 of whom received the vaccine, and their infants. Prepare is supported by an \$89.1 million grant from the Bill & Melinda Gates Foundation (BMGF).

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that drives improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing urgent global health needs. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is designed to prevent severe lower respiratory tract infection which is the second leading cause of death in children under one year of age worldwide. Novavax is also advancing NanoFlu™, its quadrivalent influenza nanoparticle vaccine, to address key factors that can lead to the poor effectiveness of currently approved flu vaccines.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

Forward-Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of ResVax are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2017 and the Quarterly Report on Form 10-Q for the period ended September 30, 2018 as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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Please check for more information: <http://TheBrettTashmanFoundation.org>

917-209-7163

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American Academy of Pediatrics, Section on Advancement in Therapeutics and Technology

Released: Thursday 12/13/2018 12:32 PM, updated Saturday 3/16/2019 08:38

The American Academy of Pediatrics' Section on Advances in Therapeutics and Technology (SOATT) invites you to join our ranks! SOATT creates a unique community of pediatric professionals who share a passion for optimizing the discovery, development and approval of high quality, evidence-based medical and surgical breakthroughs that will improve the health of children. You will receive many important benefits:

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- Network with other pediatricians, pharmacists, and other health care providers to be stronger advocates for children.
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- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

AAP members can join SOATT for free. To activate your SOATT membership as an AAP member, please complete a short application at <http://membership.aap.org/Application/AddSectionChapterCouncil>.

The Section also accepts affiliate members (those holding masters or doctoral degrees or the equivalent in pharmacy or other health science concentrations that contribute toward the discovery and advancement of pediatrics and who do not otherwise qualify for membership in the AAP). Membership application for affiliates: <http://shop.aap.org/aap-membership/> then click on "Other Allied Health Providers" at the bottom of the page.

Thank you for all that you do on behalf of children. If you have any questions, please feel free to contact:

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Department of Primary Care and Subspecialty Pediatrics

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The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit www.aap.org. Reporters can access the meeting program and other relevant meeting information through the AAP meeting website at <http://www.aapexperience.org/>

NT

Researchers Use Health Data Tools to Rapidly Detect Sepsis in Sick Newborns

CHOP study uses automated models to identify sepsis before clinical recognition

Article ID: 708872

Released: 28-Feb-2019 2:30 PM EST

Source Newsroom: Children's Hospital of Philadelphia

A Newswise — Philadelphia, Feb. 28, 2019 – Automated programs can identify which sick infants in a neonatal intensive care unit (NICU) have sepsis hours before clinicians recognize the life-threatening condition. A team of data researchers and physician-scientists tested machine-learning models in a NICU population, drawing only on routinely collected data available in electronic health records (EHRs).

"Because early detection and rapid in-

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SAVE THE DATE!

April 11th

9 am – 4 pm

1st annual meeting of the SoCal Small Baby Consortium

*Wong Kerlee International Conference Center
11175 Campus St. Loma Linda, CA 92350*



About the Consortium

We would like to invite you, your neonatology colleagues and NICU staff that care for small babies to join the SoCal Small Baby Consortium. The goals of the Consortium will be to share our approaches to common problems that ELBW babies face, share management protocols, identify QI projects that could be done as a group, consider multi-center research projects, and discuss possibilities for shared data collection.

Conference Schedule

- Dr. Kris Reber (from Nationwide Children's Hospital, Ohio State University) will share their group's experience with managing premature, ELBW infants and future directions for caring for these babies. She will also discuss managing feeding problems in the ELBW infant
- Dr. Valerie Chock (Lucile Packard Children's Hospital, Stanford University) will review approaches to assessment of "normal" blood pressure and adequate perfusion using near Infrared spectroscopy (NIRS) with specific emphasis on the management of PDA.
- Dr. John Cleary (CHOC) will discuss controversies in neonatal hemodynamics, review the approach for treating hypotension and the best therapies available and will also moderate a Q & A session on hemodynamic stability and approach to PDA.
- Mindy Morris, DNP (Engage/Grow/Thrive, LLC) will discuss the nursing role in improving outcomes for small babies

An organizational session will be held for planning future meetings and identifying interested people to work on improving clinical strategies for the care of small babies

Nursing CEUs and medical CMEs may be offered for those attending this meeting. ***The tuition and expense for this meeting will be covered by the Loma Linda University Division of Neonatology.***

SoCal Small Baby Consortium Planning Committee: Ana Banerji, Raylene Phillips, Munaf Kadri, Anup Katheria, Maynard Rasmussen, James Fritzell, Tony Soliman, Yona Nicolau, John Cleary, Andy Hopper

Registration:

- **Please send Cathy Winter an email at cwinter@llu.edu to reserve a space**
- **Call 909-558-7448 for additional information**

tervention is essential in cases of sepsis, machine-learning tools like this offer the potential to improve clinical outcomes in these infants,” said first author Aaron J. Masino, PhD, who led the study team’s machine-learning efforts. Masino is an assistant professor in the Department of Anesthesiology and Critical Care Medicine and a member of the Department of Biomedical and Health Informatics at Children’s Hospital of Philadelphia (CHOP). “Follow-up clinical studies will allow researchers to evaluate how well such systems perform in a hospital setting.”

The research team published its findings in the retrospective case-control study Feb. 22 in PLOS One.

A major worldwide cause of infant mortality and morbidity, sepsis begins with a bacterial invasion of the bloodstream. An aggressive immune response can unfortunately cause a progression to septic shock, a severe systemic condition causing multiple organs to fail, sometimes fatally. While relatively rare in healthy, full-term infants, sepsis rates are 200 times higher in premature or chronically hospitalized infants. Survivors of infant sepsis may suffer long-term problems such as chronic lung disease, neurodevelopmental disabilities, and prolonged hospital stays.

Rapid diagnosis of sepsis is often difficult in hospitalized infants, due to ambiguous clinical signs and inaccuracies in screening tests. Delays in recognizing sepsis cause delays in intervention, including antibiotic treatment and supportive care. However, unnecessary use of antibiotics carries its own risks and increases antibiotic resistance, so a clear-cut early diagnosis is important.

The current study aimed to develop a machine-learning model able to recognize sepsis in NICU infants at least four hours before clinical suspicion. “To our knowledge, this was the first study to investigate machine learning to identify sepsis before clinical recognition using only routinely collected EHR data,” said Masino.

Machine learning uses computational and statistical techniques to train computational models to detect patterns from



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data, then perform a desired task. In this case, the study team evaluated how well eight machine-learning models were able to analyze patient data to predict which infants had sepsis. Because the data came from a retrospective sample of NICU infants, the researchers were able to compare each model’s predictions to subsequent findings—whether or not an individual patient was found to develop sepsis.

The study team drew on EHR data from 618 infants in the CHOP NICU, from 2014 to 2017. Many of the infants in the patient registry were premature; the cohort had a median gestational age of 34 weeks. Co-occurring conditions included chronic lung disease, congenital heart disease, necrotizing enterocolitis (a severe intestinal infection) and surgical conditions.

Among the co-authors are pediatrician and biomedical informatics expert Robert W. Grundmeier, MD, and neonatologist and sepsis expert Mary Catherine Harris, MD. Both drew on their clinical experience and knowledge of medical literature to help develop groups of sepsis-related

features available in EHR data. Masino, Grundmeier and Harris, in addition to their CHOP positions, also are faculty members of the Perelman School of Medicine at the University of Pennsylvania.

Grundmeier and Harris, the study’s lead clinical investigators, developed a list of 36 features associated or suspected to be associated with infant sepsis. Those features, grouped under vital signs, laboratory values, co-morbidities and clinical factors, such as whether an infant was on a ventilator, were extracted from EHR entries, and provided input data for the machine-learning models. “The biomedical informatics specialists like myself collaborated with our clinician colleagues to select relevant features from the EHR data,” said Masino.

Six of the eight models performed well in accurately predicting sepsis up to four hours before clinical recognition of the condition.

The team’s findings, said Masino, are a preliminary step toward developing a real-time clinical tool for hospital practice. The researchers plan to follow up this study





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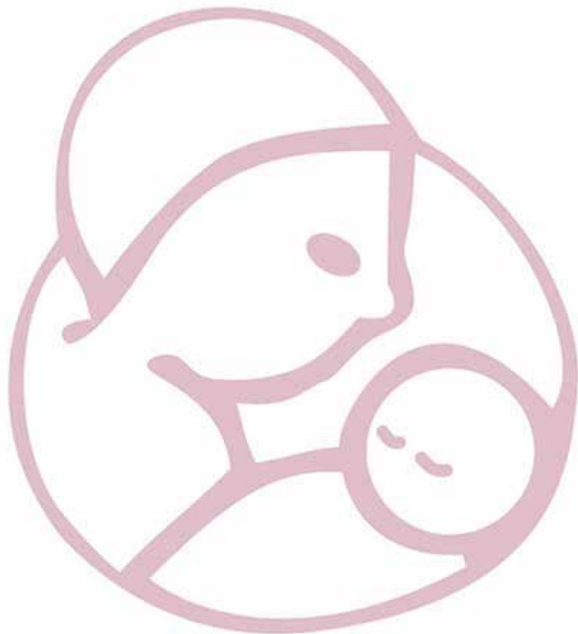
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PAC/LAC's core values for improving maternal and child health have remained constant for over 30 years – a promise to lead, advocate and consult with others.

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Providing guidance to healthcare professionals, hospitals and healthcare systems, stimulating higher levels of excellence and improving outcomes for mothers and babies.

Advocacy

Providing a voice for healthcare professionals and healthcare systems to improve public policy and state legislation on issues that impact the maternal, child and adolescent population.

Consultation

Providing and promoting dialogue among healthcare professionals with the expectation of shared excellence in the systems that care for women and children.

with further research to refine their models and investigate the software tools in a carefully designed prospective clinical study. "If research validates some of these models, we may develop a tool to support clinical decisions and improve outcomes in critically ill infants," he added.

Aaron J. Masino, et al, "Machine learning models for early sepsis recognition in the neonatal intensive care unit using readily available electronic health record data," PLOS ONE, published Feb. 22, 2019. <http://doi.org/10.1371/journal.pone.0212665>

Children's Hospital of Philadelphia: Children's Hospital of Philadelphia was founded in 1855 as the nation's first pediatric hospital. Through its long-standing commitment to providing exceptional patient care, training new generations of pediatric healthcare professionals, and pioneering major research initiatives, Children's Hospital has fostered many discoveries that have benefited children worldwide. Its pediatric research program is among the largest in the country. In addition, its unique family-centered care and public service programs have brought the 564-bed hospital recognition as a leading advocate for children and adolescents. For more information, visit <http://www.chop.edu>

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NT

Study looks at seasonal and geographic trends in syphilis

Syphilis is increasing. This study looks at the new demographics.

Article ID: 708158
Released: 15-Feb-2019 10:05 AM EST
Source Newsroom: PLOS

NT

Newswise — Much of the public health impact of syphilis revolves around its impact on fetuses and neonates through the mother-to-child transmission of the disease. Researchers reporting in PLOS Neglected Tropical Diseases have now analyzed temporal and demographic patterns in gestational syphilis (GS) and mother-to-child-transmission (MTCT) of syphilis.

Syphilis is a sexually transmitted infection caused by the *Treponema pallidum* bacteria. In Brazil, rates of GD and MTCT of syphilis have been on the rise, with 37,436 pregnant women and 20,474 newborns affected in 2016. Lack of diagnosis is suspected to play a role in stopping outbreaks.

In the new paper, Marcus Vinicius Pimenta Rodrigues of Universidade do Oeste Paulista – UNOESTE, Brazil, and colleagues used the National System of Aggravations and Notifications to calculate the incidence of GS and MTCT of syphilis from 2007 to 2013 in the Pontal do Paranapanema region of Brazil. They used the data to construct maps of the region— which includes 32 cities— showing how incidence rates vary between regions and over time.

Rates of MTCT for syphilis ranged from 0.37 to 2.30 per 1,000 live births between 2007 and 2013. The researchers found that there was no annual endemic period for syphilis, but that the month most susceptible to an endemic event of both GS and MTCT was February. In 2011, there was an especially marked increase in GS cases, followed by an increase in MTCT the following year, suggesting that treatment of GS was not effective. In many cities, however, the number of MTCT cases was larger than the number of reported GS cases, suggesting a failure in the notification system.

"Our study provided a new methodology to understand the syphilis dynamics as a potential tool to improve the success of future measures to control and possibly eliminate MTCT of syphilis," the researchers say.

Large-Scale Initiative Linked to Reductions in Maternal and Newborn Deaths in Indonesia

USAID-funded program aimed at reducing deaths from complications due to childbirth appears to have prompted more efficient care

Article ID: 708880
Released: 28-Feb-2019 12:05 PM EST
Source Newsroom: Johns Hopkins Bloomberg School of Public Health

Newswise — A U.S.-funded initiative to improve quality of care and referrals during pregnancy and childbirth in Indonesia resulted in significant reductions in maternal and newborn mortality at participating hospitals, according to a new study led by scientists at the Johns Hopkins Bloomberg School of Public Health.

The \$55-million initiative, known as Expanding Maternal and Neonatal Survival (EMAS), was sponsored by the U.S. Agency for International Development (USAID) from 2011 to 2017 and supported the Indonesian Ministry of Health's efforts to improve the quality of emergency obstetric and newborn care and referrals in that country.

The study appears in a special supplement of the International Journal of Gynecology & Obstetrics. The researchers found that in the Indonesian health facilities where the EMAS intervention was implemented, maternal and very early newborn mortality rates within 24 hours of birth fell by 50 percent and 21 percent respectively over the four years following the onset of EMAS support.

"These key indicators of the quality of emergency obstetric and newborn care improved significantly at hospitals after



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March 26-30, 2019; Snowbird, UT

<http://paclac.org/advances-in-care-conference/>

EMAS support, suggesting that the program did improve the quality of care,” says study lead author Saifuddin Ahmed, PhD, professor in the Bloomberg School’s Department of Population, Family and Reproductive Health.

The study involved a collaboration with several international and Indonesian institutions including Jhpiego, a Johns Hopkins-affiliated non-profit organization that led the EMAS program in Indonesia.

Ahmed guest-edited the supplement, “Expanding Maternal and Neonatal Survival Opportunities in Indonesia,” in which the study appears, and authored an editorial noting that Indonesia has had persistently high maternal mortality rates, relative to other Southeast Asian nations, of maternal and newborn deaths. More than 10,000 women and 68,000 newborn babies die from childbirth complications each year in the country. “Indonesia has been doing very well economically in recent decades, but economic development doesn’t automatically translate into reductions in maternal and newborn mortality,” he says.

About 70 percent of maternal deaths from childbirth complications in Indonesia occur in hospitals or clinics, in part due to poor quality or delayed care. The EMAS program was intended to improve that care and lower mortality rates for mothers and their newborns. The initiative was focused in six Indonesian provinces which collectively account for more than half of all maternal deaths in the country. The EMAS program included mentoring of staff at more than 450 hospitals and clinics, improvements in these facilities’ health information systems, improving emergency readiness and response, and more rigorous reviews of cases of maternal or newborn mortality.


The new study focused on the largest 101 of these facilities, to which patients presenting at smaller clinics were often referred. Ahmed and his colleagues found that from 2013 through 2016, the overall rate of maternal deaths per 1,000 cases of childbirth complications at these facilities fell from 5.4 to 2.6, a drop of about 50 percent. The rate of newborn deaths within 24 hours of birth also fell sharply, from 4.8 to 3.3 per 1,000 live births, while

the rate of newborn deaths within 7 days of birth fell from 33.6 to 23.9 per 1,000 live births.

The analysis revealed increases of 5 percent and 18 percent, respectively, in the appropriate uses of two key interventions: drugs to induce uterine contractions to reduce postpartum bleeding, and magnesium sulfate to treat pre-eclampsia, a condition that can cause seizures and brain hemorrhaging. By the end of the study, the use rates for these interventions, in cases where objective indicators showed they should have been used, were nearly 100 percent.

“Overall, the efficiency in handling patients seems to have improved in facilities that received EMAS support,” Ahmed says.

Fatality rates—specifically from postpartum hemorrhage and pre-eclampsia/eclampsia complications—fell by about 23 percent and 20 percent, respectively, during the study period—although these declines involved relatively small numbers of cases and were not statistically significant.



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Perinatal Mood and
Anxiety Disorders
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“Sustaining and expanding the approaches of the EMAS program in Indonesia remains critically important to save the lives of mothers and children,” Ahmed says.

“Changes in obstetric case fatality and early newborn mortality rates in hospitals after the implementation of the Expanding Maternal and Neonatal Survival program in Indonesia: Results from a health information system” was written by Saifuddin Ahmed, Maya Tholandi, Alisa Pedrana, Ali Zazri, Nony Parmawaty, Agus Rahmanto, and Reena Sethi.

The research was funded by the United States Agency for International Development (USAID) under the terms of the Cooperative Agreement AID-OAA-A-14-00028. The contents are the responsibility of the Maternal and Child Survival Program and do not necessarily reflect the views of USAID or the United States Government.

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Family Centered Care is trendy, but are providers really meeting parents needs in the NICU?

Consider the following:

Surveys show hospital support groups are being widely underutilized by parents.



And only 10% of NICUs surveyed connect parents with non-hospital support.

Graham's Foundation, the global support organization for parents going through the journey of prematurity, set out to find the missing piece that would ensure all parents have real access to the support they need.

See what they found by emailing info@grahamsfoundation.org to request a free copy of the 2017 whitepaper, "Reaching Premie Parents Today" (*Heather McKinnis, Director, Premie Parent Mentor Program, Graham's Foundation*).

You may be surprised to see what NICUs are doing right and where their efforts are clearly falling short.

Graham's Foundation empowers parents of premature babies through support, advocacy and research to improve outcomes for their preemies and themselves.



Visit www.GrahamsFoundation.org to learn more.

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36th Annual Advances in Therapeutics and Technology: Critical Care of Neonates, Children, and Adults

March 26 to March 30, 2019
The Cliff Lodge - Snowbird, Utah

Registration: <http://paclac.org/advances-in-care-conference/>

Topics and Speakers Include:

Rashmin Savant, MD BPD New Concepts in Pathogenesis and Prevention

Cynthia Blanco, MD Metabolic Disturbances of Prematurity When How and Who to Treat

Sinjo Hirose, MD Fetal Surgery

Arun Pramanick, MD Game Changers in Neonatal-Perinatal Medicine- A View Through a Retroscope

Don Null Persistent Pulmonary Hypertension in the Preterm Newborn Etiologies and Cardiopulmonary Management

Marty Keszler, MD New Modalities in High Frequency Ventilation

Mitchell Goldstein, MD Rediscovering the Denominator

Steve Derdak, DO Pediatric Origins of Adult Disease



Conference Description

This conference will present high quality education to advance pediatric health and well-being through collaboration, communication and education on the discovery and development of therapeutics and technology and their successful translation into practice. The conference aims to improve communication and relationships within industry, academia and government agencies as well as educate on the discovery, development, and implementation processes. Networking opportunities for healthcare professionals who provide care for patients with a focus on advances in therapeutics and technology will be provided. Along with featured speakers, the conference includes abstract presentations on research.

Special Panel Discussion

Avoiding the Conflict, Working to Develop Better Relations with Industry. Don Null, MD and Mitchell Goldstein, MD.

Special Lecture: President of AAP, Colleen Kraft, MD

Continuing Education Credit

The Perinatal Advisory Council: Leadership, Advocacy, And Consultation is providing physician, nursing, and respiratory continuing education units.



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Featured Upcoming Conference

36th Annual Conference - Advances in
Therapeutics and Technology

March 26-30, 2019

The Cliff Lodge and Spa in Snowbird, UT USA

Registration:

<http://paclac.org/advances-in-care-conference/>

Conference Description:

Educational and networking opportunities for healthcare professionals who provide care for pediatric patients including those in critical care environments with a focus on advances in therapeutics and technologies. Includes featured speakers, workshops and abstract presentations on research on advances in these areas.

Continuing Education Credit Provided by:

Perinatal Advisory Council: Leadership, Advocacy, And Consultation. Physician, nursing, and respiratory continuing education credit will be provided.

Special Panel Discussion:

Avoiding the Conflict, Working to Develop Better Relations with Industry. Colleen Kraft, MD, President, AAP with Don Null, MD and Mitchell Goldstein, MD

2019 Snowbird Conference Agenda

Tuesday March 26, 2019

5-5:30 Opening remarks

5:30-6:15 Abstracts

6:15-7:15 Respiratory Syncytial Virus Update 2019: Still a Threat Mitchell Goldstein, MD

Wednesday March 27 AM

8-9:00 Abstracts

9:00-10:00 Persistent Pulmonary Hypertension in the Preterm Newborn Etiologies and Cardiopulmonary Management Don Null, MD

10:30-11:00 Abstracts

11:00- 12:00 Genetic Architecture of Alveolar Formation a Path to Unraveling Pathogenesis of BPD Parviz Minoo PhD

Wednesday PM

5:5:15 Abstract

5:15-6:05 The role of industry and physicians for improved patient care. Colleen Kraft MD, Past President AAP

6:05-7:05- Robert deLemos Memorial Lecture

BPD New Concepts in Pathogenesis and Prevention. Rashmin Savani MD

Thursday March 28 AM

8-8:30 When, Why and How HFJV J. Bert Bunnell ScD

8:30-9:30 Metabolic Disturbances of Prematurity When How and Who to treat. Cynthia Blanco MD

9:30-12:00 Workshops

Thursday PM

5:00-6:00 Abstracts

6:00-7:00 Results of the Drager High Frequency Ventilation Study. Martin Keszler MD

Friday March 29 AM

8-9:00 Abstracts

9:00-10:00 Pending

10:30-11:00 Abstracts

11:00-12:00 Update on Non-invasive Ventilation and Airway Clearance Techniques for Large Patients. Stephen Derdak DO

Friday PM

5:00-6:00 Use of the VDR Percussive Ventilator in Adults with various Respiratory Problems. Stephen Derdak, DO

6:00-7:00 Management of Inhalation Lung Injury Biology, Medications and Respiratory Support. Leopoldo Cancio MD

Saturday March 30 AM

8:00-8:30 Abstracts

8:30 9:30 Present and Future of Telemedicine. Bill Beninat MDi

9:30-10:30 Wearable Combat Resuscitation Organ Support System. Andriy Batchinsky MD

11:00-11:15 Closing Remarks. Donald Null MD

Final Month of Registration

Francesco Cardona, MD, MSc and Stefan Johansson, MD, PhD



It is now down to less than 30 days until our much-anticipated conference takes place (April 7 to 10 2019). Registrations are coming from around the world. This will guarantee a global get-together of neonatal staff from all continents. With just a few seats available, we hope you will also decide to join us for our conference in Copenhagen.

“Our Twitter account is @99nicu (<https://twitter.com/99nicu>). As in previous years, the hashtag will be #99nicuMeetup (<https://twitter.com/hashtag/99nicumeetup>)”

Let me highlight some of our topics from the 99nicu meetup: Lectures will include how to dose antibiotics correctly on the neonatal ward (Karel Allegaert). Another on how to avoid the development of BPD in our preterms (Laila Lorenz) or if it is time to jump on the delayed cord clamping bandwagon (Ola

Andersson).

Geraldine Boylan from Ireland will give an update on treating neonatal seizures, and Haresh Kirpalani will elucidate the role of transfusions in the NICU.

Feeding is a daily issue on neonatal wards - Lise Aunsholt and Nadja Haiden will try to show the way for an evidence-based approach. All sounds appetizing, doesn't it? In any case, we believe we have found a good mix of topics that probably are of relevance to your daily clinical work.

We are also reaching out to younger staff with the continuation of our young lecturer series. Two highly talented young physicians will speak about hypothyroidism and the challenges of NEC diagnosis.

The final day of our conference is dedicated to workshops when we will offer a mix of practical, evidence-based and family-care topics to round up the meetup.

We especially want to encourage younger and nursing staff to come to Copenhagen. It really is easy to contribute and ask questions during and after lectures via the conference app, so you can be sure your questions will get answers as well. In any case, check the schedule for further details on this page.

For more information and registration go to <https://99nicu.org/meetup>

Our Twitter account is @99nicu (<https://twitter.com/99nicu>). As in previous years, the hashtag will be #99nicuMeetup (<https://twitter.com/hashtag/99nicumeetup>)

See you soon in Copenhagen!

Francesco Cardona, MD

A handwritten signature in black ink, appearing to read "F Cardona".

The authors indicate that they have no disclosures

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The hashtag "#99nicuMeetup" in a bold, yellow, sans-serif font on a blue rectangular background.



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Survey Says: RSV

RESPIRATORY SYNCYTIAL VIRUS, or RSV, is a dangerous virus that can lead to:

- Hospitalization**
- Lifelong health complications**
- Death** for infants and young children

ACCORDING TO A NATIONAL SURVEY, Specialty Health Care Providers say:

- 80% They treat RSV as a priority, "often" or "always" evaluating their patients
- 77% RSV is the "most serious and dangerous" illness for children under four
- 77% Barriers to access and denials from insurance companies limit patients' ability to get preventive RSV treatment

But Parents are Unprepared.

- 18% Only 18% know "a lot" about RSV
- 22% Only 22% consider themselves "very well" prepared to prevent RSV

RSV EDUCATION & AWARENESS CAN HELP
After parents learned more about RSV, they were:

- 65% "More concerned" about their child contracting the disease
- 67% Likely to ask their doctor about RSV

NCJIH National Coalition for Infant Health
Preventing Kids' Illnesses Through Age Five

Learn More about RSV at www.infanthealth.org/RSV

Lecture Program, 7-9 April 2019

1730-1830

Welcome Reception (Scandic Sluseholmen)

Venue: Scandic Sluseholmen - Molestien 11 - Copenhagen
SV - [Website](#)

| 7 April SUNDAY | | |
|----------------|---|---|
| 0830-0900 | Registration | |
| 0900-0945 | Welcome! | Stefan Johansson Francesco Cardona Morten Breindahl |
| 0945-1030 | Cord Clamping, 1.0 and 2.0 | Ola Andersson |
| 1030-1100 | <i>Coffee break in the exhibition area</i> | |
| 1100-1145 | Go with the (high) flow | Brett Manley |
| 1145-1230 | Prevention of BPD | Laila Lorenz |
| 1230-1330 | <i>Lunch in the exhibition area</i> | |
| 1330-1415 | Using a count of 3 neonatal morbidities to select high-risk preterm infants for long-term follow-up | Barbara Schmidt |
| 1415-1500 | Infants surviving at the limit of viability – what are the outcomes | Ulrika Ådén |
| 1500-1530 | <i>Coffee break in the exhibition area</i> | |
| 1530-1615 | Periviability – when to act? | Stefan Johansson Gorm Greisen Eduard Verhagen |
| 1615-1700 | Discussion - Periviability – when to act | all |



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8 April MONDAY

| | | |
|-----------|--|---|
| 0830-0900 | Yesterday's Summary (10 Min) Case of The Day (20 Min) | Stefan Johansson |
| 0900-0945 | Y O U N G L E C T U R E R S E S S I O N | |
| | Subclinical hypothyroidism | Dinushan Kaluarachchi |
| | Challenges how to diagnose NEC | Sandra Meinich Juhl |
| 0945-1030 | MRI after preterm birth | David Edwards |
| 1030-1100 | <i>Coffee break in the exhibition area</i> <i>Poster walk in the main lecture hall</i> | |
| 1100-1145 | The many inotropes – what to use when? | Yogen Singh |
| 1145-1230 | Parent participation in decision-making in the NICU (including discussion) | Eduard Verhagen |
| 1230-1330 | <i>Lunch in the exhibition area</i> | |
| 1330-1415 | Prevention of CLABSI | Victoria Payne |
| 1415-1500 | Dosing Antibiotics for term and preterm infants | Karel Allegaert |
| 1500-1530 | <i>Coffee break in the exhibition area</i> <i>Poster walk in the main lecture hall</i> | |
| 1530-1615 | Evidence-based feeding | Lise Aunsholt |
| 1615-1700 | ESPGHAN – what's new in the updated nutritional guidelines | Nadja Haiden |
| 1700-1740 | Intestinal microbiota and probiotics use: Seminar by Chr. Hansen & Neobiomics | Adam Baker Marijn J. Vermeulen Stefan Johansson |
| 1845-2200 | <i>Congress Social Evening at Toldboden</i> <i>The dinner is not supported by the industry</i> 18.45 Pick up by bus at Scandic Sluseholmen 19.10 Canal boat tour starts from Kalvebod Bølge 20.10 Canal boat arrives at Toldboden, dinner starts 22.00 Dinner ends, bus back to Scandic Sluseholmen | |

| 9 April TUESDAY | | |
|-----------------|---|-------------------|
| 0830-0900 | Yesterday's Summary (10 Min) Case of The Day (20 Min) | Francesco Cardona |
| 0900-0945 | Measuring cerebral blood flow in newborn infants - and what then? | Gorm Greisen |
| 0945-1030 | Treating pain in neonates | Karel Allegaert |
| 1030-1100 | <i>Coffee break in the exhibition area</i> | |
| 1100-1145 | Transfusions in preterm infants | Hareesh Kirpalani |
| 1145-1230 | Etiology and diagnosis of neonatal seizures | Geraldine Boylan |
| 1230-1330 | <i>Lunch in the exhibition area</i> | |
| 1330-1415 | Hyperglycemia – how to manage and why? | Kathryn Beardsal |
| 1415-1500 | Neonatal transports – how to do them safe and easy | Morten Breindahl |
| 1500-1530 | <i>Coffee break in the exhibition area</i> | |
| 1530-1615 | How to Explain when NEC rates persist – even when a NICU does everything “right” | Ravi Patel |
| 1615-1700 | Why we should rehearse simulated scenarios | Ruth Gottstein |
| 1700-1715 | Closing words | |

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Post-Conference Workshops, 10 April 2019

Venues: Workshop at Scandic Sluseholmen - Molestien 11 - Copenhagen SV - [Website](#)

10 April WEDNESDAY

0900-1200

When has enough evidence accumulated to change standard of care? How to interpret non-inferiority trials?

*Hareesh Kirpalani and
Barbara Schmidt (US)*

This is an interactive session to strengthen your ability to apply evidence from the medical literature to your patients. During the first half, we will discuss strategies to help decide when enough new evidence has accumulated to change the standard of care. The goal is to ensure that we adopt new therapies at the right time - not too early and not too late. During the second half of the session, we will review how to interpret non-inferiority trials. We will focus on potential pitfalls of non-inferiority trials, including inappropriate choices of the active control group and of the minimum clinically important difference between the comparison groups that would result in a rejection of the claim of “non-inferiority”.

0900-1200

Neonatal Transports

*Morten Breindahl and
Christian Heiring (Denmark)*

Postnatal interfacility transfers of sick newborn infants in need for highly specialized care is a high-risk procedure. At the same time, it is a complicated task to perform in a completely different environment without the back-up from a well-manned and -equipped university hospital. The ultimate purpose of these high-risk neonatal transports is to deploy competence and equipment from a level III-IV NICU to a peripheral hospital, diagnose and treat the patient as well as safeguarding stability during the up-scale transport. This interactive workshop focuses on essential processes, team-work development as well as safety issues related to emergency neonatal transports.

0900-1600

Family-centered care culture in a NICU (full day)

*Liisa Lehtonen and
Sari Ahlqvist-Björkroth (Finland)*

This is an interactive workshop which provides the rationale for integrating parents in the hospital care of their infants and tools to develop more collaborative care culture. Video demonstrations illustrate practices to develop communication with parents at practical care situations and medical rounds. The videos will be reflected upon, together with the audience.

0900-1300

Echocardiography for neonatologists

Yogen Singh (UK)

Neonatologist performed echocardiography (NPE) is rapidly being adopted by the clinicians to make clinical decisions in the NICU. This half day hands-on interactive workshop provides excellent opportunity to introduction to echocardiography – two bespoke lectures on echocardiography views and functional echocardiography views will be followed by the hands-on practical session focused at use of NPE in the NICU. While basic echocardiography techniques needs no previous experience, advanced functional echocardiography techniques may help even the established echocardiographers and neonatologists.



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Perinatal Substance Use

5 ways you can improve care during pregnancy and beyond

Pregnancy presents unique opportunities for patients to make positive changes in their substance use. When you become an informed provider you empower patients to make those changes.



Educate Yourself

Learn more about the pharmacology of substance use. Promote evidence-based care by communicating with patients in a way that separates fact from fiction. Understand the cycles of sobriety and relapse so that you can help patients plan for their recovery. Advise on the risks associated with polysubstance use.



Use the Right Words

Know the difference between substance use, substance misuse, and Substance Use Disorders (SUDs). Recognize that substance use is stigmatized and that stigma is a barrier to seeking care. Reject language that shames. Embrace the principles of Harm Reduction as a way to support any positive change.



Screen Every Patient

Talking about substance use should be a routine part of everyone's medical care. Get comfortable discussing it. Ask questions and listen to what your patients have to say. You may be the first person to ever ask.



Get Trained to Offer MAT

Medication-Assisted Treatment is the Standard of Care during pregnancy, but there are not enough providers. Contact SAMHSA to become an OTP*. Make naloxone available to all your patients who use opioids.

*opioid treatment program



End the Stigma and Criminalization of Drug Use

Embrace people who use substances. Meet them where they are. Abide by your medical ethics. Practice beneficence. Promote public health. Advocate for decriminalization.

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The Genetics Corner: A Genetics Evaluation for Chronic Diarrhea that Revealed Incest

Subhadra Ramanathan, M.Sc., M.S. and Robin Clark, MD

Case History:

A Genetics consult was requested on a 12-week old Hispanic male infant with chronic osmotic diarrhea. This pregnancy was complicated by young maternal age, intra-uterine growth retardation, pruritic urticarial papules and plaques of pregnancy, maternal hyperthyroidism, iron deficiency anemia, and transaminitis. Mother was late to receive prenatal care and followed up inconsistently during pregnancy with her health care provider. The infant was delivered at 36w 6d by induced vaginal delivery for IUGR to a 17-year-old primigravida mother. Birth weight was 2035g (0.08 %ile), birth length was 46.5 cm (3rd percentile), and birth head circumference was 31 cm (0.32 %ile). There were no other post-natal complications, and the baby was discharged home with his mother.

“He was hospitalized with cachexia, severe hypernatremia and hyperchloremia with metabolic acidosis, likely due to malabsorption.”

The infant reportedly breastfed well at home but did not gain weight. He had normal green stools for the first three weeks of life, after which he presented with chronic recurrent diarrhea. He was hospitalized with cachexia, severe hypernatremia and hyperchloremia with metabolic acidosis, likely due to malabsorption.

The family history was non-contributory for chronic diarrhea in infants, young infant deaths or other significant medical problems. Mother declined to provide any information about the infant's father.

The chromosome microarray analysis detected many large regions of the absence of heterozygosity (AOH). These regions of homozygosity (ROH), that were 3 megabases or larger, encompassed 735 megabases in total, or at least 26% of the genome.

Consultant's Report:

The baby was not dysmorphic, but underweight, alert and responsive to the examiner. The tone was normal. Although the chromosome microarray results were not diagnostic of a specific genetic disorder, the extent of ROH implied that the pregnancy resulted from incest. It also increased the possibility of an autosomal recessive disorder due to homozygosity for a pathogenic variant in a gene or genes that were identical by descent.

Within the ROH, there were 28 genes associated with diarrhea (http://firefly.ccs.miami.edu/cgi-bin/ROH/ROH_analysis_tool.cgi). Pathogenic variants in three of them, EPCAM, NEUROG3 and SLC5A1 were associated primarily with congenital/ neonatal onset chronic diarrhea. Molecular genetic testing by sequencing and del/dup analysis was recommended using a gene panel in which these three genes were also included.

The genetic testing detected homozygosity for a likely pathogenic variant in NEUROG3, c. 319C>A (p.Arg107Ser). Pathogenic vari-

ants in NEUROG3 cause congenital malabsorptive diarrhea 4, inherited in an autosomal recessive manner.

The social situation required a social services consultation and the mother, a minor, was placed in the care of Child Protection Services. Her father was arrested.

Chromosome microarray analysis (CMA) can detect copy number variants (CNVs), which are losses or gains of chromosome material that are submicroscopic and undetectable on routine chromosome analysis. CMA analysis that utilizes a single nucleotide polymorphism (SNP) platform can also detect “regions of homozygosity” (ROH) across the genome when SNPs are continuously homozygous with no intervening heterozygosity. These ROH may be due to:

- Uniparental disomy (UPD), which is the inheritance of a chromosome or a portion of a chromosome pair from the same parent
- Parental consanguinity
- Regions inherited from a recent common ancestor that are identical by descent

Identifying ROH can provide the clinical diagnosis, in the case of UPD for a chromosome where the clinical features are consistent with the UPD. ROH can also indicate an increased risk for autosomal recessive disorders due to homozygosity for pathogenic variants in genes within the ROH.

An unintended consequence of CMA analysis on an SNP platform is identifying parental relationships that are unreported, including incest. Theoretically, the fraction of the genome or autosome that is homozygous (Froh), can be calculated for a given parental relationship in a presumed outbred population:

| The degree of parental relationship | Theoretical Froh |
|-------------------------------------|------------------|
| First degree | 25% |
| Parent/ child, full siblings | |
| Second degree | 12.5% |
| Half siblings, uncle/niece | |
| Third degree | 6.25% |
| First cousins | |
| Fourth degree | 3.125% |
| First cousins once-removed | |
| Fifth-degree | 1.5625% |
| Second cousins | |

Adapted from Sund KL, Rehder CW, 2014

Laboratories that detect and report ROH are encouraged to include the percent homozygosity, but not the degree of relationship. It falls to the clinician to interpret and return these results to patients. The laboratory reported homozygosity for 26% of the



genome in this infant, which indicated that the parents are first degree relatives.

Sexual relations between close relatives are illegal in most jurisdictions. The specific laws may vary in how “relatedness” is defined. Practitioners have a duty to report suspected child abuse, although they may not be responsible for reporting incest involving consenting adults, even if this is illegal in their jurisdiction.

Practical Applications:

- Almost all CMA platforms are SNP-based. While the main purpose of the clinical testing is to evaluate for copy number gains and losses, CMA can identify parental consanguinity, including incest.
- The laws regarding duty to report incest/ abuse/ statutory rape vary by state. Knowledge of the legal requirements and compliance is essential when incest is inadvertently identified on clinical testing.
- Young maternal age and homozygosity for the same abnormal allele by themselves should raise concern for incest even without a microarray.

References:

1. Sund KL, Rehder CW. Detection and reporting of homozygosity associated with consanguinity in the clinical laboratory. *Hum Hered* 2014; 77: 217-224
2. Botkin JR et al., Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents. *Am J Hum Genet.* 2015 Jul 2; 97(1): 6–21

The authors have no relevant disclosures.

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New Moms Need Access to Screening & Treatment for POSTPARTUM DEPRESSION



1 IN 7 MOMS FACE POSTPARTUM DEPRESSION, experiencing



Yet only 15% receive treatment¹

UNTREATED POSTPARTUM DEPRESSION CAN IMPACT:

Baby's sleeping, eating, and behavior as he or she grows²



Mother's health
Ability to care for a baby and siblings

TO HELP MOTHERS FACING POSTPARTUM DEPRESSION



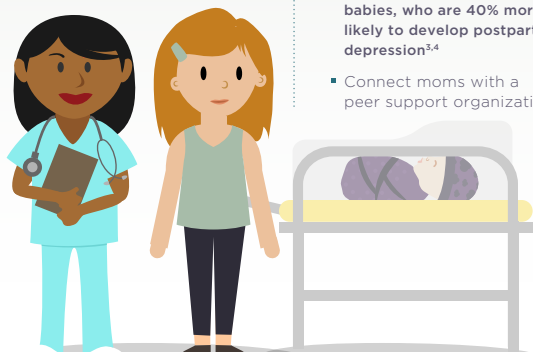
POLICYMAKERS CAN:

- Fund Screening Efforts
- Protect Access to Treatment



HOSPITALS CAN:

- Train health care professionals to provide psychosocial support to families... especially those with preterm babies, who are 40% more likely to develop postpartum depression^{3,4}
- Connect moms with a peer support organization



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¹ American Psychological Association. Available at: <http://www.apa.org/pubs/news/resources/reports/postpartum-depression.aspx>
² National Institute of Mental Health. Available at: <https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology 2015; 30: 526-528. doi: 10.1097/01.jp.0000000000000000
⁴ Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

How to Care for a Baby with NAS



Use the Right Words

I was exposed to substances in utero. I am not an addict. And my mother may or may not have a Substance Use Disorder (SUD).



Treat Us as a Dyad

Mothers and babies need each other. Help my mom and me bond. Whenever possible, provide my care alongside her and teach her how to meet my needs.



Support Rooming-In

Babies like me do best in a calm, quiet, dimly-lit room where we can be close to our caregivers.



Promote Kangaroo Care

Skin-to-skin care helps me stabilize and self-regulate. It helps relieve the autonomic symptoms associated with withdrawal and promotes bonding.



Try Non-Pharmacological Care

Help me self-soothe. Swaddle me snugly in a flexed position that reminds me of the womb. Offer me a pacifier to suck on. Protect my sleep by "clustering" my care.



Support Breastfeeding

Breast milk is important to my gastrointestinal health and breastfeeding is recommended when moms are HIV-negative and receiving medically-supervised care. Help my mother reach her pumping and breastfeeding goals.



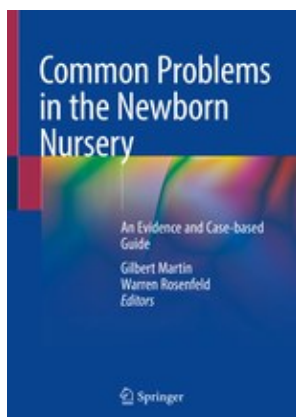
Treat My Symptoms

If I am experiencing withdrawal symptoms that make it hard for me to eat, sleep, and be soothed, create a care plan to help me wean comfortably.

Learn more about Neonatal Abstinence Syndrome at www.nationalperinatal.org



Editors: **Martin, Gilbert, Rosenfeld, Warren** (Eds.)



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Feeding Challenges for Premature Infants

Susan Hepworth and Mitchell Goldstein, MD



The National Coalition for Infant Health is a collaborative of more than 180 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCfIH prioritizes safety of this vulnerable population and access to approved therapies.

One of every ten babies is born prematurely. (1) Many of these babies are temporarily fed through a feeding tube. But as development progresses, most babies transition to traditional oral feeding. This can mean feeding from their mother's breast or from a bottle. Making this leap is hard – for babies and their parents.

Learning to breastfeed or bottle feed may seem simple in comparison with other life-saving care delivered in the neonatal intensive care unit. For some babies, however, it can be a significant challenge. Doctors, nurses, neonatal therapists and lactation consultants all want premature babies to thrive with feeding so they can successfully transition home with their families.

“Learning to breastfeed or bottle feed may seem simple in comparison with other life-saving care delivered in the neonatal intensive care unit. For some babies, however, it can be a significant challenge.”

Q: Which babies are most prone to feeding challenges?

Babies who are born prematurely or at low birth weight are most prone to feeding challenges. Affectionately called, “immature feeders” by the clinical staff in neonatal intensive care units, these tiny infants may have to overcome several medical challenges before being ready to feed orally. These complications may include conditions such as pulmonary hypertension, chronic lung disease or heart conditions, which may require surgery.

While it is less common, late preterm infants and even some full-term infants can also have oral feeding challenges.

Feeding Challenges for Premature Infants

Q: What causes some babies to struggle with feeding?

All of a baby's body systems are affected by being born prematurely. In addition to individual body systems not being ready for

feeding, premature babies may also have tubes in their mouth or nose. These tubes help babies breathe or eat. Moreover, they may be there for weeks or even months. Premature babies may also require repetitive nasal and oral suctioning. These negative sensory experiences, while necessary at the time, can cause babies to develop an aversion to anything coming near with their mouth. (2)

Q: What is the long-term impact of having feeding challenges?

Some babies who start out slowly grow to be excellent feeders with no long-term issues. Other babies, however, continue to have feeding challenges into childhood. Long-term feeding challenges can negatively affect growth and development. Forty percent of children followed in feeding clinics are former preterm infants. (3)

Q: What are the impacts of delayed feeding from a breast or bottle on the baby and his or her family?

Due to the coordination, maturity and physical endurance it requires, often feeding from a breast or bottle is what keeps premature babies hospitalized when they are otherwise ready to go home. (4) While many premature babies leave the hospital ahead of their expected due date, the discharge of an extremely low birth weight baby may not occur until after his or her original due date.

Some activities, and certainly the family dynamic, can be impacted by babies' feeding challenges. Even though a baby gains enough feeding competence to go home, he or she may not be strong enough feeders for parents to leave them in mainstream child care settings. These include daycares and the church or gym nursery.

Q: What can parents do to support their baby with feeding?

Research has shown that touch is essential for babies' physical and psychological development. (5) This concept also applies to feeding. Parents' presence with their premature baby has a significant impact on feeding readiness and success.

The goal of health care providers in neonatal intensive care units is to help parents become expert feeders of their baby. Parents will become more comfortable with their baby's feeding cues the more times they are present and with their baby during feeding.

Q: How can neonatal intensive care unit leadership help promote oral feeding readiness in babies?

Hospital leadership must ensure that their clinical staff members are knowledgeable in all elements of feeding. They should have policies that can increase babies' oral feeding readiness — offering a baby a pacifier and human touch during tube feedings, for example.

Clinical staff must also be experts in recognizing signs of readiness and assessing a baby's feeding quality once he or she begins oral feeding. Encouraging a baby to feed orally as soon as he or she shows maturity and readiness can help the baby successfully transition and be ready to go home sooner.

Finally, when possible, hospital staff should try to reduce obstacles that inhibit parents' presence for feedings. Likewise, parents should also seek resources to help them overcome obstacles, such as reliable transportation or care for other children who may not be allowed in the neonatal intensive care unit.

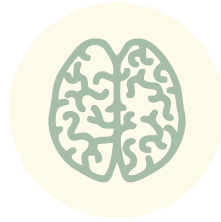
Q: What are the financial and health system impacts of delayed oral feeding?

Caring for premature babies is expensive, especially when their



MUSCLE TONE & STRENGTH:

Feeding is hard work, and premature babies may lack the physical strength and endurance to do it multiple times a day. Sucking pads in the mouth, which help with suction during feeding, are not yet fully developed in premature babies.



BRAIN DEVELOPMENT:

Timing sucking, swallowing and breathing requires coordination.² Premature babies' brain development may not be mature enough to successfully feed. It is, in fact, the first coordinated activity they must perform.



IMMATURE LUNGS:

Oral feeding is taxing on the respiratory system. Every swallow comes with holding one's breath for a heartbeat. This makes feeding like aerobics for a premature baby.

hospital stay is prolonged because of oral feeding challenges. The average cost of a hospital stay for babies born between 34- and 36-weeks gestation is \$51,083. This amount increases for babies born before 32 weeks gestation. Their 46.2-day average length of stay costs more than \$280,000. (6)

These costs are shouldered by infants' families and health insurance systems. Medicaid, for example, paid \$695 million for hospital care of premature and low birth weight babies in 2013. (7)

The societal burden of prematurity is great too. Medical, educational and lost productivity costs associated with preterm birth in the United States cost an estimated \$26.2 billion in 2015. (8)

Conclusion

Prematurity makes oral feeding significant work for babies. It can also be frustrating for parents who want their baby to "get it."

The clinicians caring for premature infants must have the proper training to ensure they are oral feeding experts who can guide parents along this journey properly. Further, neonatal intensive care units should promote policies that support parents and families of the babies in their care.

Engaged parents, expert clinicians and supportive policies provide the best opportunity for premature babies who struggle with oral feeding to successfully gain the ability, to the benefit of babies, their families, and the broader health care system.

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National Coalition for Infant Health Values (SANE)

Safety. Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

Access. Budget-driven health care policies should not preclude premature infants' access to preventative or necessary therapies.

Nutrition. Proper nutrition and full access to health care keep premature infants healthy after discharge from the NICU.

Equality. Prematurity and related vulnerabilities disproportionately impact minority and economically disadvantaged families. Restrictions on care and treatment should not worsen inherent disparities.

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- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
- **Clear, science-based nutrition guidelines** for pregnant and breastfeeding mothers
- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

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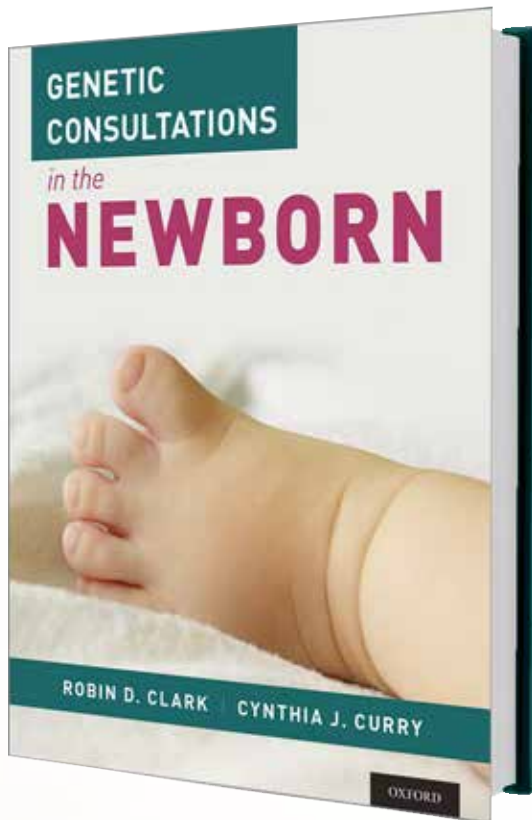
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OXFORD

RSV AWARENESS:

A National Poll of Parents & Health Care Providers

Respiratory syncytial virus, or RSV, is far from the common cold. It can lead to hospitalization, lifelong health complications or even death for infants and young children. **In fact, it is the leading cause of hospitalization in children younger than one.**

Yet a national poll of parents and specialty health care providers reveals a startling divide in attitudes toward the virus. While both groups acknowledge RSV as a significant concern, the two populations vary widely in their reported ability to meet RSV's threat head-on. Health care providers vigilantly

monitor for the virus, which they report seeing regularly in their practices. Parents, however, feel unequipped to protect their young children.

Meanwhile, specialty health care providers overwhelmingly report that health plan rules and insurance denials block vulnerable infants' access to preventive RSV treatment. Such barriers can put unprepared parents at a double disadvantage. The survey does suggest, however, that education can embolden parents to seek more information about RSV and take steps to protect their children.

KEY FINDINGS

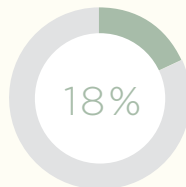
Preparedness

Parents of children age four and under report that understanding of RSV is lacking. That leaves them less than fully prepared to prevent their young children from catching the virus.

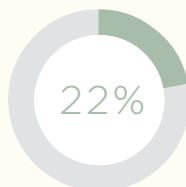
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

PARENTS

Only 18% said parents know “a lot” about RSV, reflecting an awareness level that’s roughly half that of the flu

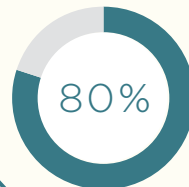


Only 22% of parents consider themselves “very well prepared” to prevent RSV.

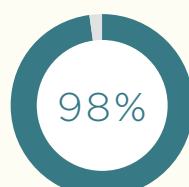


SPECIALTY HEALTH CARE PROVIDERS

They treat RSV as a priority, “often” or “always” evaluating their patients (80% doctors; 78% nurses)



During RSV season, they are especially vigilant about monitoring patients for symptoms or risk factors for RSV (98%).



Medicolegal Forum: Malpractice

Gilbert Martin, MD and Jonathan Fanaroff, MD, JD

The word "malpractice," when mentioned to a health-care professional, is still intimidating and anxiety-provoking. Absolute definitions vary, but basically, it is the "improper, unskilled, or negligent treatment by a physician, dentist, nurse, pharmacist, or other Health Care Professional." (1)

Are the allegations of negligence true? Is the standard-of-care violated? Lawyers believe that this is an important protection to compensate victims and to monitor and police the medical profession.

It is not a simple road to travel when proving that there was negligence. Who determines, and what is the standard-of-care? Are there physical consequences or in today's world consideration of "emotional injury"? Legislation has put a cap on non-economic damages. Finger pointing Finger pointing Finger pointing. On the other hand, what about the health-care-professional (as most are) who practices well, has good results and no allegations of "negligence"? Is there an inherent "value" to this individual?. Should we substitute a "VAL" for a "MAL"? Can we devise a "point system" where value is added for better judgment; improved outcomes (morbidity and mortality); parent satisfaction and some of the lesser known quality indicators.

Progress notes today, once an important factor in communication between health-care professionals is less of a concern since computerization is commonplace. Penmanship is no longer an issue. But, repetitive progress notes which are routinely re-populated on a daily basis is occurring. I remember well a note which stated for three consecutive weeks, "baby is comfortable in mother's arms." The baby might be comfortable, but what about the mother's arms? So what would happen if physicians were offered "Valpractice Points" for better care? In some practices, physicians are compensated by the number of RVUs generated. In other situations reimbursement is determined by an "executive committee" type panel within the practice. There are tiers to this system and contracts vary as do situations.

Once a point system was determined and a panel chosen to delve out these points, physicians would want to work more and be held to higher standards as competition will be pervasive.

“ Malpractice was no longer defined as "poor care" and if an error occurred it was described as of "lesser value.”

Physicians spent more time with families, nurses routinely worked double shifts, and hospital libraries were overwhelmed with literature requests. Instead of taking Malpractice insurance, Physicians were asking for Valpractice policies. Malpractice was no longer defined as "poor care" and if an error occurred it was described as of "lesser value".

Is the above far fetched? Should we dismiss value in practice? Systems change, compensation ideas need to be both generalized and individualized. A baseball player the other day received a 10 year 30 million dollar contract. I am not dismissing the importance of the abilities of this player. But, as I hover over an 850 gram baby, attempting to put in a UA line, I know I

have value both in the short and hopefully the long run. I hope to watch this baby graduate from the NICU, enter kindergarten, graduate from higher education and become a productive member of society.

Damn why doesn't this catheter thread up easily????????????

The authors have no conflicts of interests to disclose.

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Survey Says: RSV

RESPIRATORY SYNCYTIAL VIRUS, or RSV, is a dangerous virus that can lead to:

- Hospitalization**
- Lifelong health complications**
- Death** for infants and young children.

ACCORDING TO A NATIONAL SURVEY, Specialty Health Care Providers say:

- 80% They treat RSV as a priority, "often" or "always" evaluating their patients
- 77% RSV is the "most serious and dangerous" illness for children under four
- 77% Barriers to access and denials from insurance companies **limit patients' ability to get preventive RSV treatment**

But Parents are Unprepared.

- 18% Only 18% know "a lot" about RSV
- 22% Only 22% consider themselves "very well" prepared to prevent RSV

RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

- 65% "More concerned" about their child contracting the disease
- 67% Likely to ask their doctor about RSV

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Learn More about RSV at www.infanthealth.org/RSV



Monthly Clinical Pearl: Neonatal Acute Kidney Injury: Mixed Reviews

Joseph R. Hageman, MD, Vidya Mahavadi, MD, and Shireen Hashmat, MD

I have had the privilege of working with Dr. Shireen Hashmat, who is one of our very bright pediatric nephrologists on a NICU Quality Improvement project for the year and a half. Shireen's idea is to increase the awareness of neonatal clinicians of the existence of acute kidney injury (AKI) in neonates. (1,2) As you probably already know, the criteria for neonatal AKI are derived from criteria originally characterized in the adult intensive care unit, then modified for the pediatric intensive care unit and now applied to infants in the NICU. The criteria we are using in our QI initiative are the Kidney Disease Improving Global Outcomes (KDIGO) criteria, and we are using the criteria, which involves a 100% rise in creatinine within 48 hours of the baseline creatinine (Table 1). Changes in urine output can also be utilized as seen in the table, but we are just using increases in serum creatinine.

“When we presented this project to our clinical neonatologists, their skepticism about the clinical significance of this entity was evident.”

Our basic purpose is to educate the nurses, NNPS, residents, fellows and attending neonatologists about the existence of neonatal AKI, which translates into putting the diagnosis of AKI into the problem list and arranging a follow-up appointment with the pediatric nephrologist. When we presented this project to our clinical neonatologists, their skepticism about the clinical significance of this entity was evident. I have to admit; I had just written a review of neonatal acute renal failure with Drs. Chris Clardy, our other pediatric nephrologist, and Owais Khan, who was one of our neonatal fellows at the time about two years ago. (3) Dr. Hashmat educated all of us about the long term sequelae of neonatal AKI based on data published by Jetton and colleagues. (1,3) Neonates with AKI are at increased risk for hypertension, proteinuria and chronic kidney disease. (1-5) All Shireen wanted the group to do was to document AKI in the problem list and schedule an appointment for follow up with her in the clinic post discharge.

Dr. Vidya Mahavadi, one of our second-year pediatric residents, who has an interest in nephrology, collected the current practice

data at the time the initiative started. In this retrospective analysis from 2014-2016, elevated serum creatinine was noted in 18% of 1414 neonates. AKI was classified in 7% of 1414 infants due to limited information in the rest of the patients' records. A total of 60% had Stage 1 AKI, 25% had stage 2 AKI, and 15% had Stage 3 AKI. A discharge diagnosis of AKI was recorded in 14% of neonates' records, and only 3/105 were referred to the pediatric nephrologist.

We proposed a quality improvement project involving neonatologists, pediatric residents and nephrologists working together to redesign the current workflow. It will include:

1. Quarterly brief educational sessions for residents starting their NICU rotation
2. The KDIGO criteria for neonatal AKI were posted at the computers where the residents wrote their progress notes in the electronic medical record (EMR- EPIC)
3. We presented the background about neonatal AKI in an education session for the nurses, residents, fellows and attending neonatologists
4. Shireen has been collecting the AKI problem list documentation and follow-up data subsequently which she has presented to the group.

Since the initiative began in 2016, we have presented our data at Vermont Oxford Network, Illinois Perinatal Quality Collaborative and Shireen will be presenting at the Pediatric Academic Society Meeting in April 2019 in Baltimore. Our follow up data through a number of Plan-Do-Study-Act (PDSA) cycles has demonstrated that the documentation of neonatal AKI in the problem list has improved. However, follow up appointments in the pediatric nephrology clinic has not improved. When Shireen queried the clinical neonatal providers, they continue not to be convinced about the true clinical significance of AKI, and replied that, although it may be a problem, they are reluctant to discuss AKI with the families because of the potentially possible long term problems...maybe almost theoretical risk. The parents have too many other major issues to worry about with their infants such as bronchopulmonary dysplasia or intraventricular hemorrhage.

What is also interesting is I have had the privilege of presenting our poster for a time at Vermont Oxford, Illinois Perinatal Quality Collaborative (ILPQC), and just more recently at the Illinois Chapter of the American Academy of Pediatrics poster session and I have

Table 1
Neonatal KDIGO (Kidney Diseases: Improving Global Outcomes) acute kidney injury definition.

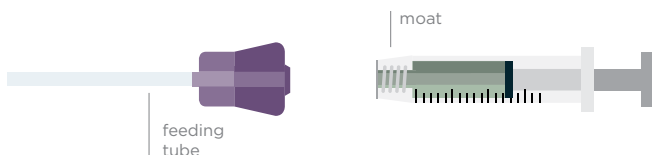
| Stage | Serum creatinine (SCr) | Urine output over 24 h |
|-------|---|-----------------------------|
| 0 | No change in serum creatinine or rise <0.3 mg/dL | >1 mL/kg/h |
| 1 | SCr rise ≥ 0.3 mg/dL within 48 h or SCr rise ≥ 1.5 to $1.9 \times$ reference SCr ^a within 7 days | >0.5 and ≤ 1 mL/kg/h |
| 2 | SCr rise ≥ 2 to $2.9 \times$ reference SCr ^a | >0.3 and ≤ 0.5 mL/kg/h |
| 3 | SCr rise $\geq 3 \times$ reference SCr ^a or SCr ≥ 2.5 mg/dL ^a or Receipt of dialysis | ≤ 0.3 mL/kg/h |

^a Reference SCr is the lowest prior SCr measurement.

SAFETY IN THE NICU

New tubes, new problems?

A new tubing design meant to eliminate tubing misconnections has introduced new challenges for the NICU population. Pediatric providers must deliver medication in small volumes to tiny patients with high levels of accuracy. The new tubing design, known as ENFit®, could present dosing accuracy and workflow challenges.



DOSING ACCURACY

- The moat, or area around the syringe barrel, is difficult to clear. Medication can hide there, inadvertently increasing the delivered dose when the syringe and feeding tube are connected; patients may receive extra medication.

INFECTION RISK

- The moat design can increase risk for infection if residual breast milk or formula remains in the moat and transfers to the feeding tube.

WORKFLOW ISSUES

- Increased nursing workflow is seen with additional steps for clearing syringe moats, cleaning tube hubs, and using multiple connectors.

Improved standards are important to protect patients from the dangers of tubing misconnections. But we must avoid mitigating existing risks by creating new ones.

Individual hospitals should consider all factors impacting their NICU patients before adopting a new tubing design.

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encountered the same level of skepticism from neonatologists and pediatricians.

There are more long term follow up data that are due to be published soon by David Askenazi and colleagues and when I discussed this feedback with him after the VON meeting in October 2018, he offered to come to the next VON meeting to talk about neonatal AKI.

Stay tuned as we progress with our QI initiative and we all get the opportunity to review more long-term follow-up data. Then we can establish the importance of close long term follow up of infants who have AKI in the NICU.

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1250 word limit not including references or title page.

May begin with a brief case summary or example.

Summarize the pearl for emphasis.

No more than 7 references.

Please send your submissions to:

jhageman@peds.bsd.uchicago.edu

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Reading, Writing, Reviewing: “The Anatomy of an Article”

Gilbert Martin, MD

It is clear to all professionals working in the health field today that it is increasingly difficult to keep abreast of the medical literature. The biomedical literature is expanding at a rate that doubles every 10-15 years and increases 10-fold every 35-50 years.

For most of us, the time allotted for reading the literature is decreased as other responsibilities increase. Therefore the need for a process to select material which is interesting, pertinent, valid and applicable is important.

Although reading and reviewing material is a critical and continual part of our professional lives, the writing of a “piece of medical literature” often is not considered. Medical writing has become dull, depersonalized and not interesting. The relationship between editor and author is too formal. Fear of rejection and inadequate training in syntax and the application of the scientific method turn away individuals who do have information which should be shared by healthcare professionals. Worthwhile ideas whether presented as a “letter to the editor,” “book review,” “original article,” or “literature review” can be timely and informative.

This column will present a method of selecting and reviewing material from the medical literature and assist the individual in understanding the requirements of a medical journal and its editorial staff. Using material from the literature, we will dissect different types of articles and outline the writing and editing of an “individual piece of scientific information.”

“ This column will present a method of selecting and reviewing material from the medical literature and assist the individual in understanding the requirements of a medical journal and its editorial staff. ”

The Book Review

As the medical literature expands, the need for interested and competent book reviewers becomes important as we depend upon the judgment of the reviewer as a guide in selecting and buying books. There are specific steps that can be taken in appraising a book. Learning the basic skills of book reviewing will increase the average reader’s ability to understand and appreciate a book. Since the book reviewer is oftentimes a specialist in the field that is being reviewed, bias and nonobjective statements may be offered. The reviewer must be honest, balanced, show enthusiasm and especially courage. Readers expect intellectual appraisal as their decision to buy and read the book can depend upon the review.

Book reviews are either DESCRIPTIVE or EVALUATIVE.

I. Descriptive review:

A. Makes book’s existence known

B. States author, publisher, price

C. Elaborates table of contents

II. Evaluative review:

A. Review material

B. Offer opinions

C. Does not assist in the decision to buy or read the book.

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- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

www.infanthealth.org

The Necessary Steps to Successful Book Review

- I. Read the guidelines which should be provided by the publisher for instructing the author.
 - A. Most "information to authors" sections in journals do not provide this information
 - B. It is important to know the desired length of the review. 350-700 words should suffice.
- II. Read the book
 - A. First reading – skim the book noting table of contents, length of chapters, intended audience, general appearance, legibility, clarity of illustrations. Notes should be taken so that the final review will include this information.
 - B. Second reading – slower with more concentration. Mark passages in the margins or use inserts to make notes. Consider the following:
 1. Is the material well organized?
 2. Is the material presented well?
 3. Are the facts accurate?
 4. Is the information up to date?
 5. Is the experimental work presented?
 6. Is the style clear, informative and most important readable?
 7. Is the syntax clear?
 8. Is there a useful index?
- III. Response decision – book reviewing is not a passive process. The reader depends upon an objective review of the material but wants to know your opinion. It is best to let your thoughts "sit" for a day or two before writing the opinion portion of the review. This part usually is the last paragraph of the review.
- IV. Be aware of your style – It is important to write in an informative, interesting manner. But do not do this at the author's expense. Be wary of the self-promoting reviewer who is as interested in his/her reputation as the material at hand. State your bias early in the review if necessary. Do not compare this work with others in the field. Be critical of organization and material incorrect or left out. Even suggest a method to include such material in a future edition, but do not compete with the author.
- V. Do not review the book of a close friend or distant enemy. The former review will not be objective and the latter will test your true credibility.
- VI. If you are not familiar with the material presented and do not have the time to carefully review the information it is best to return the book and decline the review. Although well-intentioned with the thought of learning new material, the review of a book which has unfamiliar information is difficult to write, and you will lose enthusiasm quickly.
- VII. Do not read other reviews before doing your own. Avoid promotional material as well since quotations from other sources can be misleading and add to bias.
- VIII. The review itself:

- A. The first paragraph should attract the reader's attention. In this section the author's purpose and intended readership should be mentioned.
- B. The second paragraph should deal with a general overview of the content with a statement about the presentation of the scientific material. This part can be expanded to include a more careful content review if applicable. Additions or deletions can also be offered at this time.
- C. The third paragraph should discuss the unique aspect of the book, its strengths and weaknesses.
- D. The final paragraph consists of a summary statement with comments about clarity, style, references, and readability. The reviewer's opinion should be stated in this section.

Example of a Book Review

High-risk Infants: Identification, Assessment and Intervention

L. Rossetti. Boston: College-Hill/Little, Brown. 1986. Pp 238. \$27.50. ISBN 0-316757578.

WHAT happens to babies after discharge from the intensive care nursery? All need careful assessment as they develop; and, when a handicap is detected, the child and family will need continued, skilled help to make the most of his or her abilities. Dr Rossetti is an associate professor of speech pathology whose aim in writing this book has been to equip and inspire psychologists, social workers, teachers, speech and occupational therapists, and other professionals for this important but often neglected aspect of care. He provides a wealth of information for the newcomer to the world of developmental and speech assessment. Unfortunately, it is buried in a mass of circuitous and confusing language: "the high risk infant is an infant who because of low birthweight, prematurity, or the presence of serious medical complications associated with or independent from birth weight or prematurity, has a greater than normal chance of displaying developmental delay or

later cognitive or motor deficits or a combination of these that can be linked with the high risk status present in the neonatal or postnatal period".

The first chapter contains some basic obstetric and neonatal data and a description of the high-risk infant. The second has data on normal infant development, and the third is a rather patchy review of developmental outcome for high-risk infants which omits key references by Saigal and by Stewart, although the latter's review of the world literature (with her name misspelt) is mentioned in chapter 1. The fourth chapter is a helpful review of the needs and difficulties of the parents, while the remaining three discuss infant assessment, early intervention programmes, and co-ordinating the efforts of the professionals who serve high-risk infants and their families.

Of most practical value are probably the 39 pages of appendices, which include a glossary of medical terms, some examples of hospital discharge summaries, and two bibliographies of books and materials for infant assessment. This book has many mistakes and weaknesses, and would have been the better for simpler English. However, it is a step in the right direction, and a highly motivated newcomer would probably find it of some use.

Comments:

1. The first sentence "What happens to babies after dis-

charge from the intensive care nursery?" This sentence is an eye-catching opening and leads the reader to continue.

2. In the first paragraph starting with Dr. Rossetti and ending with speech assessment, the purpose and intending audience are presented.
3. The next sentence starting with the word "unfortunately" and ending with the words "postnatal period" is a run on sentence and although the writer of the review includes some negative comments (which often important) is difficult to get through.
4. The paragraph describing the chapters is helpful, but I believe it is too detailed.
5. In the final paragraph, the word "probably" in the first sentence should be deleted. The writer points out the mistakes and weaknesses and ends by saying that "a highly motivated newcomer would probably find it of some use."
6. The number of words is 380 which is within a range which is not too cumbersome.
7. Based on this review, I would not purchase this monograph.

Disclosure: Dr. Martin indicates no relevant disclosure.

NT

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Every Friday until the end of Congenital Diaphragmatic Hernia Awareness Month on April 30th, CDH International is holding live drawings on Facebook to give away CDH Awareness shirts.

On May 1st, we will announce the grand prize winner - the person who raises the most money between now and April 30th for CDH will win 2 airline tickets to anywhere in the continental United States.

Our goal with this fundraising drive is to create an easy and fun way to raise money and awareness for Congenital Diaphragmatic Hernia. By creating a fundraiser and sharing your CDH story - or donating to someone else's fundraiser - you are helping us to help the 1000's of children (and adults) who fight Congenital Diaphragmatic Hernia every day.

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1. Go to CHERUBS Facebook page (Support) at www.facebook.com/cdhsupport or CDH International's Facebook page (Research) at www.facebook.com/cdhintl
2. Click on the blue button that says "+Raise Money"
3. Set your target amount
4. Set an ending date of April 30th
5. Add your own photos, your own stories or why you want to help
6. Share on social media and Invite friends to donate
7. Invite friends to hold their own fundraisers



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Congenital Diaphragmatic Hernia (CDH) is a devastating birth defect that occurs when a baby's diaphragm fails to fully form, allowing abdominal organs to enter the chest cavity and preventing lung growth. CDH strikes 1 in every 2500 babies, which equates to 1 baby every 10 minutes. It is as common as Spina Bifida and Cystic Fibrosis. The cause is unknown. Learn more at www.cdhi.org

Book Review: Genetic Consultations in the Newborn

Gilbert Martin, MD

Genetic Consultations in the Newborn

First Edition.

Robin D. Clark and Cynthia J. Curry. Oxford University Press, Hardcover

Published: 27 February 2019

400 Pages

8-1/2 x 11 inches

ISBN: 9780199990993

Also Available As:

Ebook

The practicing Perinatal/Neonatal health care provider today has noted a changing frontier in diagnosing genetic abnormalities and determining prognosis.... if at all possible. The simple words "chromosome analysis" has been replaced by an ever-changing vocabulary. There needs to be an understanding of karyotyping, extended banding chromosome studies, Fluorescence in situ hybridization (FISH) studies, microarray analysis, genomics, epigenetics, and whole exome sequencing. These are just a few of the platforms which the perinatal/neonatal health care provider must be conversant.

"There are 42 chapters in this monograph, formatted in a specific manner. Each chapter begins with the presentation of a 'clinical consult.' "

The authors in the preface have determined that their goal is to " make the evaluation of common neonatal anomalies and genetic syndromes accessible and understandable." A very complex subject needed to be simplified with an approach that would be up to date with the general "new approach" to learning.

There are 42 chapters in this monograph, formatted in a specific manner. Each chapter begins with the presentation of a "clinical consult." This immediately involves the reader in a case, parts of which may be familiar. These clinical consults are short and to the point. Following the clinical presentation, the Sections following g include Definitions, Differential Diagnoses, Evaluation and Management and finally a Suggested Reading section. At the end of each Section, a "Pearl" is presented which focuses the reader to return and re-review some of the presented material. The chapters are presented in a

"System Format". That is, for example, the cardiovascular system, and the central nervous system are the main topics of a specific section.

At the end of the book, there is an Appendix of Syndromes that commonly present in the newborn period. The format of the syndromes is identical to the presentations in earlier chapters.

The illustrations, although only in black and white depict many of the clinical findings which are presented in the text. There is an index which is reasonable and not overly detailed. It allows the reader to easily look up the necessary material and follow a suggested blueprint for diagnosis.

This book is not meant to be a compendium of the thousands of genetic disorders which are now part of our genetic environment. The book services as a guide to today's perinatal/neonatal health care provider to make a more accurate diagnosis and to allow for a better understanding of these diseases so that our colleagues and the family can make educated choices for the future of the child.

Disclosure: The author has no relevant disclosures..

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- Time for recreation

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Letters to the Editor

Fri 2/15/2019 9:18 AM

via email

Dear Dr. Goldstein,

Does Neonatology Today have interest/space for NICU fellows to submit interesting cases or experiences? A Fellow's Corner might be a very interesting addition to the Journal. I am a first year NICU fellow and would be very interested in having a space to share my experiences and hear from other fellows as well.

Hope to hear from you.

Thanks!
Luis

Luis Rivera, MD
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Luis,

This is an excellent idea. One of our stated objectives has been to encourage those who are new to our field to explore research and academic interests. Dr. Anamika Banerji, your fellowship director, is Neonatology Today's fellowship editor. I will speak with her regarding this interest and making it a reality. I think that your interest in creating this space for trainees can be coordinated with her role in the creation of a new column which we will call "Fellow's Corner."

Starting in the April edition, we will devote space for Neonatal-Perinatal and Maternal-Fetal fellows worldwide to submit case reports, quality improvement initiatives, interesting educational experiences and other academic works. These will be peer reviewed. Luis, you will have editorial control of the column.

I look forward to working with you in this endeavor and Thank you in advance for all of the hard work and dedication that will be



required to make this column a success.

Sincerely,

A handwritten signature in black ink that reads "Mitchell Goldstein".

Mitchell Goldstein, MD
Editor in Chief

NT NEONATOLOGY TODAY

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Neonatology Today welcomes your editorial commentary on previously published manuscripts, news items, and other material relevant to the fields of Neonatology and Perinatology.

Please address your response in the form of a letter. For further formatting questions and submissions, please contact Mitchell Goldstein, MD at LomaLindaPublishingCompany@gmail.com.

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Erratum (Neonatology Today February, 2018)

Neonatology Today has not identified an erratum affecting the February, 2019 edition. Corrections can be sent directly to LomaLindaPublishingCompany@gmail.com. The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from www.neonatologytoday.net.

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Las nuevas mamás necesitan acceso a la detección y tratamiento para LA DEPRESIÓN POSPARTO



1 DE CADA 7 MADRES AFRONTA LA DEPRESIÓN POSPARTO, experimentando



Sin embargo, sólo el 15% recibe tratamiento!

LA DEPRESIÓN POSTPARTO NO TRATADA PUEDE AFECTAR:



PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO



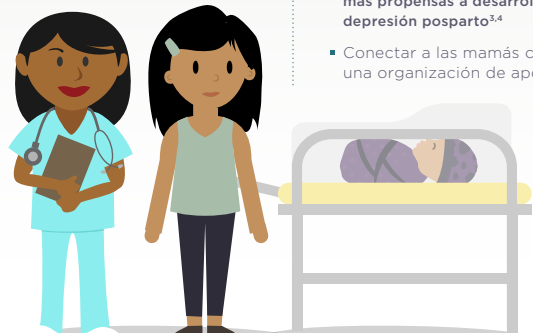
LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

- Financiar los esfuerzos de despistaje y diagnóstico
- Proteger el acceso al tratamiento



LOS HOSPITALES PUEDEN:

- Capacitar a los profesionales de la salud para proporcionar apoyo psicosocial a las familias... Especialmente aquellas con bebés prematuros, que son 40% más propensas a desarrollar depresión posparto^{3,4}
- Conectar a las mamás con una organización de apoyo



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¹ American Psychological Association. Accessed on: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>
² National Institute of Mental Health. Accessed on: <https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology (2015) 35, 529–536. doi:10.1097/JP.0000000000000147
⁴ Prevalence and risk factors for postpartum depression among women with preterm and low birth-weight infants: a systematic review. Vigod SN, Villages L, Olesen CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

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<http://worldneonatology.com/2019/welcome-letter-2>

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New Orleans, LA

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<http://aapexperience.org/>

For Additional Meeting Information, visit NeonatologyToday.net and click on the events tab.

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Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine

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Neonatology and the Arts

This section focuses on artistic work which is by those with an interest in Neonatology and Perinatology. The topics may be varied, but preference will be given to those works that focus on topics that are related to the fields of Neonatology, Pediatrics, and Perinatology. Contributions may include drawings, paintings, sketches, and other digital renderings. Photographs and video shorts may also be submitted. In order for the work to be considered, you must have the consent of any person whose photograph appears in the submission.

Works that have been published in another format are eligible for consideration as long as the contributor either owns the copyright or has secured copyright release prior to submission.

Logos and trademarks will usually not qualify for publication.

This month we feature a new nursery that was just constructed outside of our NICU in West Covina, CA. You might say that we have a "bird's eye" view.

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1. Manuscripts are solicited by members of the Editorial Board or may be submitted by readers or other interested parties. Neonatology Today welcomes the submission of all academic manuscripts including randomized control trials, case reports, guidelines, best practice analysis, QI/QA, conference abstracts, and other important works. All content is subject to peer review.

2. All material should be emailed to: LomaLindaPublishingCompany@gmail.com in a Microsoft Word, Open Office, or XML format for the textual material and separate files (tif, eps, jpg, gif, ai, psd, or pdf) for each figure. Preferred formats are ai, psd, or pdf. tif and jpg images should have sufficient resolution so as not to have visible pixilation for the intended dimension. In general, if acceptable for publication, submissions will be published within 3 months.

3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication (i.e., open access). There is no charge for your manuscript to be published under open access

4. The title page should contain a brief title and full names of all authors, their professional degrees, their institutional affiliations, and any conflict of interest relevant to the manuscript. The principal author should be identified as the first author. Contact information for the principal author including phone number, fax number, e-mail address, and mailing address should be included.

5. A brief biographical sketch (very short paragraph) of the principal author including current position and academic titles as well as fellowship status in professional societies should be included. A picture of the principal (corresponding) author and supporting authors should be submitted if available.

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 5,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard JAMA format. Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

9. Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main file after the references. Captions should be brief.

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