NEONATOLOGY TODAY

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

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Volume 19 / Issue 1 January 2024

NEONATOLOGY TODAY

ISSN: 1932-7137 (Online), 1932-7129 (Print)
All editions of the Journal and associated manuscripts are available on-line:
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Antibiotic treatment of Chorioamnionitis-Exposed Neonates Based Only on Signs of Infection

John Wimmer, MD, Nicole Chandler, MD, Reese Clark, MD, Kaye Gable, MD

Abstract:

Introduction: *Decisions about the management of infants exposed to maternal chorioamnionitis are often based on estimates of the risk of infection determined by a neonatal early onset sepsis risk calculator (NEOSC). Such management, however, results in drawing blood from and starting intravenous lines on many healthy infants. In some institutions, it also results in separating them from their families for treatment in the neonatal intensive care unit (NICU). Our practice for many years has been to do laboratory studies and give antibiotics to chorioamnionitis-exposed (CE) infants only if they show signs of infection. Using this approach, we have evaluated and treated far fewer infants than we would have if we had used the NEOSC. We reviewed our experience over five years to document the differences in patient management and to identify adverse outcomes in these infants.*

Methods: *Charts of CE infants ≥ 35 weeks EGA (estimated gestational age) were reviewed over a 5-year period in 2012 when our institution converted to electronic medical records. Data collected included vital signs, laboratory results, NICU admission, antibiotic treatment, and hospital readmission during the first week after discharge. Their mothers' charts were reviewed for data needed to complete the NEOSC. The number of infants who underwent laboratory evaluations and treatment with antibiotics was compared to the number who would have had such evaluations and treatment according to NEOSC recommendations.*

Results: *We treated 126 (16%) of 768 CE infants with antibiotics vs. 216 (28%) who would have been treated according to the NEOSC recommendations. Another 17 patients had blood cultures but were not treated with antibiotics. None of the untreated infants became ill, had positive blood cultures, were admitted to the NICU, or were readmitted to the hospital within the first week after discharge.*

Conclusion:

CE infants were managed safely in our institution based only on clinical signs of infection. If multicenter studies corroborate our experience, revised recommendations could markedly reduce the number of CE infants evaluated and treated with antibiotics.

"Infants born to mothers with intra-amnionic infection or inflammation or both, "Triple I," (formerly referred to as chorioamnionitis) are at increased risk of early-onset sepsis (EOS) (1)."

Introduction:

Infants born to mothers with intra-amnionic infection or inflammation or both, "Triple I," (formerly referred to as chorioamnionitis) are at increased risk of early-onset sepsis (EOS) (1). Prior to 2018, the Center for Disease Control (CDC) and American Academy of Pediatrics Committee on Fetus and Newborn (AAP/COFN) recommended that these chorioamnionitis-exposed (CE) infants be treated with antibiotics for 48 hours after a limited evaluation, including blood culture and complete blood count (CBC) (2). These recommendations were updated in 2018(3) and included the option of managing these patients based on the Neonatal Early-Onset Sepsis Risk Calculator (NEOSC) (4).

Despite the pre-2018 recommendations of the CDC and AAP CE, infants at our institution during that era were not evaluated with laboratory studies or treated with antibiotics unless they showed clinical signs of sepsis. We report our experience with this approach for five years, from 2012, when we converted to the electronic medical record (EMR), until 2018. We describe how these patients were managed and how they would have been managed based on NEOSC recommendations. Our objectives were: 1. to compare the numbers of CE infants ≥ 35 weeks estimated gestational age (EGA) who were subjected to laboratory evaluation and antibiotic treatment using our approach based on clinical signs only with those who would have been evaluated and treated according to the NEOSC recommendations, and 2. to identify adverse outcomes in CE infants in our institution who were not evaluated and treated. To our knowledge, no published reports describe this type of hands-off management of asymptomatic CE infants.

"We report our experience with this approach for five years, from 2012, when we converted to the electronic medical record (EMR), until 2018. We describe how these patients were managed and how they would have been managed based on NEOSC recommendations. "

Methods:

Selection criteria and study period

Charts of all women who delivered liveborn infants at ≥ 35 weeks EGA from when the EMR was implemented in July 2012 until January 2018 were reviewed. Those containing CPT codes for chorioamnionitis or intrapartum fever were searched, and our study population consisted of those with a clinical diagnosis of chorioamnionitis or a documented intrapartum temperature elevation of ≥ 100.4F.

Data collection and monitoring

Data was entered into a deidentified electronic case report form by a clinical research associate with the supervision of one of the authors to assure adherence to the protocol, accuracy, and privacy in accordance with the International Conference on Harmonization Good Clinical Practice Guidelines and HIPAA Regulations. The Cone Health Institutional Review Board reviewed the protocol, which determined an exempt status.

Maternal and infant data needed to complete the NEOSC was collected. Maternal data included the EGA, the mother's highest antepartum temperature, duration of rupture of membranes, Group B Streptococcus (GBS) status, and type and timing of intrapartum antibiotics given. Neonatal data included the vital signs, laboratory results including CBCs, procalcitonin (used at our institution as an inflammatory marker), blood and cerebrospinal fluid cultures, admission to the Neonatal Intensive Care Unit (NICU), treatment with antibiotics, length of stay, and hospital readmission within the first week after discharge.

Patient stratification and management

Symptomatic infants. Infants were identified as symptomatic if they met any of the following criteria:

1. Need for supplemental oxygen or any respiratory support lasting more than 30 minutes after birth
2. Persistent respiratory distress (even without the need for supplemental oxygen)
3. Persistent abnormal vital signs (heart rate ≥ 160, respiratory rate ≥ 60, or temperature ≥ 100.4F or < 97F)
4. Non-specific signs of infection were noted by attending providers, e.g., poor color/perfusion, lethargy, and irritability.

The NEOSC would have classified these "symptomatic" infants as either having "clinical illness" or as being "equivocal." They were admitted to the NICU for further observation. They underwent laboratory evaluations, including blood cultures and CBCs, and, in most cases, were treated with at least a short course of antibiotics.

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Asymptomatic infants. Infants who met none of those criteria were defined as asymptomatic. They did not undergo any laboratory evaluation, regardless of NEOSC score, and they roomed in with their mothers in the mother-baby unit. They received routine care, including a full assessment within 2 hours of birth by a nurse who had reviewed the mother's prenatal record and delivery information. Vital signs were performed at 30 minutes and 1 and 2 hours of age. If vital signs were outside normal ranges they were repeated every 1 – 2 hours until stable. Attending providers were notified of abnormal vital signs or other concerns at any time.

NEOSC scores. Data collected from maternal records was entered into the "Scenario" fields of the NEOSC to assess the sepsis risk. The CDC national incidence of early-onset sepsis (0.5/1000 live births) was used as the baseline. Data from the neonatal records was used to determine EOS risk after clinical exam based on assessment as well appearing, equivocal, or clinical illness.

Statistical analysis

Our analytical approach to these data was descriptive. We used a Fisher's exact test to compare the recommendations made by the NEOSC to our clinical results (Table). We report the odds ratios and the p values in the Table. All statistical analyses were performed using JMP 11 (SAS Institute, Cary, NC).

Results:

Sample

29,830 infants ≥ 35 weeks EGA were born during the study period, of which 768 (3%) met our selection criteria. Of these 768 infants, 533 (69%) of their mothers received antibiotics before delivery, and 171 (22%) were GBS positive. The median gestational age was 40 weeks (10-90th percentile was 38-41 weeks); 14 patients (1.8%) were late preterm (35 – 36 6/7 weeks EGA) with the remainder ≥ 37 weeks; median birth weight was 3405 grams (10-90th percentile was 2854-4074 grams). The median 5-minute Apgar score was 9 (10-90th percentile was 7-9).

"29,830 infants ≥ 35 weeks EGA were born during the study period, of which 768 (3%) met our selection criteria. Of these 768 infants, 533 (69%) of their mothers received antibiotics before delivery, and 171 (22%) were GBS positive."

Outcomes

Of the 768 infants enrolled in our study, 126 (16%) were identified as symptomatic. They were admitted to the NICU and treated with antibiotics because of clinical illness. Another 17 patients had blood cultures but were not treated with antibiotics. The remaining 642 patients were not symptomatic and received routine care in the mother-baby unit (i.e., no blood cultures or laboratory studies). None had a later onset of illness, received antibiotics, were admitted to the NICU, or had prolonged length of stay. None were readmitted to our hospital within one week after discharge.

NEOSC recommendations

Sepsis risk scores were calculated using the NEOSC for 764 of the 768 infants (data were unavailable to calculate scores in 4 patients). In 216 patients (28%), the NEOSC recommended empiric antibiotics; for another 102 (13%), the recommendation was to

obtain blood cultures and watch closely. For two infants (0.3%), it was to "strongly consider" starting empiric antibiotics. The calculator recommended no culture or antibiotics for the other 444 infants (58%).

Comparison of management (Table)

If we had followed the NEOSC recommendations, we would have treated 90 patients with antibiotics and done blood cultures on 102 patients. None of those 192 patients experienced adverse outcomes.

"If we had followed the NEOSC recommendations, we would have treated 90 patients with antibiotics and done blood cultures on 102 patients. None of those 192 patients experienced adverse outcomes."

Discussion:

This review expands on our previously reported experience using clinical signs alone managing CE infants from 2009 – 2012, in which none of 182 asymptomatic patients had positive blood cultures, significant morbidity, or needed readmission after hospital discharge (5). Recent reports have described limited testing and treatment of CE newborns using the NEOSC. Money et al. (6) confirmed that NEOSC would reduce antibiotic use from essentially all (99.7%) CE infants to only 2.5%. Multiple other studies(7-9) described approaches that reduced the use of antibiotics but, as opposed to our practice,-subjected many to laboratory testing. Joshi et al. (10) suggested that treatment based primarily on clinical signs of illness might necessitate changes in the surveillance of at-risk infants to ensure their safety. We have not implemented cautionary measures for asymptomatic CE infants; they receive routine care and monitoring like the non-CE infants in the mother-baby unit.

As noted by Hooven and Polin(11), many studies indicate that laboratory evaluations of well-appearing CE infants may not be helpful and may have adverse effects, including interference with breastfeeding (12). A 2016 AAP policy statement(13) underscores gaps in knowledge of the effects of pain in neonates but notes that "repeated painful exposures have the potential for deleterious consequences." Franck et al. (14) surveyed parents at 11 NICUs in the United Kingdom and the United States and reported that they were affected emotionally by their infants' pain and worried about long-term effects on their relationships.

If this can be done safely, there are many reasons to avoid antibiotic exposure. Antibiotic exposure is associated with health problems in later childhood, including obesity(15-17), wheezing,(18) allergic rhinitis(19), and asthma (20, 21). Also, of course, it increases hospital costs. Gong(22) showed savings of about $4000/patient when treatment was reduced by using the NEOSC versus adherence to the former CDC/AAP guidelines. Length of stay is undoubtedly reduced by avoiding antibiotic treatment, but we could not measure this since we did not have a comparison group of treated asymptomatic patients.

The safety of approaches restricting evaluation and treatment is difficult to establish since EOS is uncommon, even in CE infants. Using a higher baseline EOS incidence (4/1000 versus 0.5/1000) captured all cases of culture-positive EOS in the study of Sloane et al. (23) but required culturing almost all CE infants and treating three times as many. The multicenter study by Wortham et al. (24) documented an incidence of EOS of about 0.1%, 60% of which occurred in CE infants. They estimated that 60 to 1400 infants would be evaluated and treated for each infected infant. Assuming (hypothetically) that all EOS infants were born to mothers with chorioamnionitis and that 20% of them died, we estimated a sample size of 16,000 to prove perfect safety of our approach in the prevention of death due to EOS. Any single-center study would, therefore, face sample-size limitations.

Also, our outcomes may not be universally applicable since ours is a single-center study. Our careful observation of the routine, low-risk newborn population provides a safety net for untreated infants, which may not be the case in other institutions. Finally, it may be that there were infants readmitted to other institutions for sepsis-related complications, but this is unlikely since our institution has the only pediatric emergency department within 30 miles, and most of our patients are local.

Conclusions:

Most (84%) of the 768CE infants at our institution were managed without laboratory evaluation and antibiotic treatment, and no adverse outcomes were seen. Using the NEOSC would have resulted in significantly greater numbers of infants being cultured and treated. If adequately powered multicenter studies corroborated our results, widespread practice changes could save many at-risk but healthy infants from unnecessary, costly, and detrimental procedures.

"Most (84%) of the 768CE infants at our institution were managed without laboratory evaluation and antibiotic treatment, and no adverse outcomes were seen. Using the NEOSC would have resulted in significantly greater numbers of infants being cultured and treated. If adequately powered multicenter studies corroborated our results, widespread practice changes could save many at-risk but healthy infants from unnecessary, costly, and detrimental procedures."

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Acknowledgment:

Virginia Wimmer Thompson extracted data from the EMRs of patient dyads and entered it into the electronic case report forms.

Statement of Ethics:

This study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice Guidelines and HIPAA Regulations. The Cone Health Institutional Review Board reviewed the protocol, which determined an exempt status.

Data availability statement

Deidentified individual participant data (including data dictionaries) will be made available in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be available upon publication to researchers who provide a methodologically sound proposal for achieving the approved proposal's goals. Proposals should be submitted to john.wimmer@conehealth.com.

Disclosure: *The authors have no conflicts of interests to disclose.*

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JANUARY WEBINAR

1.11.24 @ 11AM PT

Evolution of a Family-Centered Care Program in a California Safety Net NICU

Priya Jegatheesan, MD
she/her

Chief, Division of Neonatology

Director, Regional NICU and High Risk Infant Follow-up Clinic

Santa Clara Valley Medical Center

Sangeeta Mallik, PhD
she/her

Director, Family-Centered Care Team

Santa Clara Valley Medical Center NICU

What it takes to implement Social Determinants of Health screening and referral in the NICU

Erika (Gaby) Cordova Ramos, MD
she/her/ella

Assistant Professor of Pediatrics, Boston University

Neonatologist, Boston Medical Center

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National Perinatal Association 2024 Respiratory Syncytial Virus (RSV) Prevention Clinical Practice Guideline: Clinical Presentation, Prevention Strategies, and Social Impacts in Children: An Evidence-Based Interdisciplinary Collaboration

Mitchell Goldstein, MD, MBA, CML, Benjamin Hopkins, OSMIV, Munaf Kadri, MD, Elba Fayard, MD, Nicole Kraus, DO, Angela Patterson, MD, Melissa Scala, MD, Kristy Love, Cristal Grogan, Colleen Kraft, MD, MBA, Donald Null, MD, T. Allen Merritt, MD, MHA

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.

National Perinatal Association

Educate. Advocate. Integrate.

Introduction:

Respiratory syncytial virus (RSV) causes a spectrum of respiratory illnesses in infants and young children. It is the leading cause of lower respiratory tract infections (LRTI) in newborns in the first five years of life and is especially concerning in the first year of life. (1-4) RSV can lead to hospitalizations, with the most common admitting diagnosis of bronchiolitis, pneumonia, and septicemia. (3, 5) There is an increased risk of severe lower respiratory tract RSV in infants born prematurely, with hemodynamically significant congenital heart disease, bronchopulmonary dysplasia, neuromuscular disease, congenital and inherited airway anomalies, immunosuppression, and male sex. (2, 6) However, most hospitalizations happen to otherwise healthy infants. (3) Upon admission, the median age was three months, and the median length of stay was three days (5). RSV is associated with adverse long-term outcomes, such as asthma, excess morbidity, and reduced quality of life (2, 5). RSV is a global illness considered a global health priority; in 2019, a meta-analysis estimated that RSV was associated with 33 million acute lower respiratory tract infections and 3-6 million hospitalizations for acute lower respiratory tract infection annually. (1, 3)

"Respiratory syncytial virus (RSV) causes a spectrum of respiratory illnesses in infants and young children. It is the leading cause of lower respiratory tract infections (LRTI) in newborns in the first five years of life and is especially concerning in the first year of life. (1-4) RSV can lead to hospitalizations, with the most common admitting diagnosis of bronchiolitis, pneumonia, and septicemia. (3, 5)"

RSV has traditionally been a seasonal disease observed primarily in winter; however, multiple countries reported out-of-season RSV resurgences. (1, 2) During the winter of 2020-2021, at the height of the COVID-19 pandemic, non-pharmaceutical interventions, such as hand hygiene and social distancing, slowed the spread of RSV. (1) These non-pharmaceutical interventions decreased population immunity due to a prolonged period of minimal RSV exposure (1). RSV is now appearing year-round, with spikes in spring, summer, and fall. (1)

"Current prevention strategies include hygiene, breastfeeding, maternal immunizations, and immunization with either Nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS), monoclonal antibodies (mAb). (2, 3) Before 2023, palivizumab (SYNAGIS) was the only mAb available and had been indicated for only for preterm infants and infants with co-morbidities, which left most of the infant population unprotected. (4)"

Prevention remains the most effective strategy to decrease RSV-related morbidity and mortality. Current prevention strategies include hygiene, breastfeeding, maternal immunizations, and immunization with either Nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS), monoclonal antibodies (mAb). (2, 3) Before 2023, palivizumab (SYNAGIS) was the only mAb available and had been indicated for only for preterm infants and infants with co-morbidities, which left most of the infant population unprotected. (4)

However, new RSV prevention strategies have been developed (2, 7-9). Thirty-one RSV prevention treatments are in clinical development, with seven preventative therapies in phase 3 clinical trials, focusing on the methods of recombinant vector, subunit, particle-based, live attenuated, chimeric, and nucleic acid vaccines,

and monoclonal antibodies. (7) Vaccine development has encountered numerous challenges, primarily the immaturity of the infant's immune system (3). With these challenges, there are new treatment strategies that are now FDA-approved, including maternal RSVpreF (ABRYSVO) and infant immunization with a long-acting nirsevimab-alip (BEYFORTUS). (3)

Nirsevimab-alip (BEYFORTUS) is a long-acting intramuscular recombinant neutralizing human IgG mAb against the RSV F protein (8, 9). The extended half-life allows a single dose of Nirsevimab to cover the entire RSV season and can be given to preterm, high-risk, and term infants (8, 9). A single dose of Nirsevimab protected hospitalizations throughout the RSV season in 74.5-78.6% (10). nirsevimab-alip (BEYFORTUS) protects against RSV subtypes A and B, lower respiratory tract infection, and hospitalization due to lower respiratory tract infection (10). nirsevimab-alip (BEYFORTUS) adverse events were on par with placebo at 1.3% and 1.5%, respectively (10). Even with the recent approval of nirsevimab-alip (BEYFORTUS), there remains a need for an RSV vaccine and additional treatment options.

RSVpreF (ABRYSVO) is a vaccine for pregnant individuals between 32 and 36 weeks of pregnancy to prevent respiratory syncytial virus (RSV) related lower respiratory tract disease (LRTD) in infants up to six months old. If timed correctly, it may provide similar protection to infants as nirsevimab-alip (BEYFORTUS). (11, 12)

"RSVpreF (ABRYSVO) is a vaccine for pregnant individuals between 32 and 36 weeks of pregnancy to prevent respiratory syncytial virus (RSV) related lower respiratory tract disease (LRTD) in infants up to six months old. If timed correctly, it may provide similar protection to infants as nirsevimab-alip (BEYFORTUS). (11, 12)"

Even with new preventative treatment options, there are still significant disparities in medical treatment depending on race, ethnicity, and socioeconomic status. Twice as many children from racial/ethnic diverse minorities are admitted to the hospital with RSV infections when compared to all other admissions during the same year (5). Infants less than a year from a low socioeconomic status accounted for the most significant proportion of RSV-related respiratory hospitalizations (13, 14). RSV causes a considerable burden in young children, varying socioeconomic groups (14). The financial burden caused by RSV affects both the individual and the hospital system. Under current standards of care, RSV causes hospitalizations to cost $1.2 billion annually (2021 USD) (15). Implementing universal immunization with nirsevimab-alip (BEYFORTUS) may reduce costs by up to $612 million (15). It is crucial to understand the burden of hospitalizations and disparities between population groups, and there is a need for systemic analysis of the impacts of RSV on minority groups as well as those affected by disparity. Interestingly, the impact of the Vaccines for Children Program may create instances where those considered most at risk for disparity are more likely to receive prophylaxis. (16, 17)

The health impacts of RSV go beyond the acute episode phase and represent a burden for healthcare costs and resources. (2, 4, 6) Interventions should reduce RSV infection's effects through health education, information, monitoring of population immunity, and prevention in high-risk populations. (1, 6) One of the key concerns is that healthcare decision-makers and systems must be capable of taking advantage of upcoming technological advancements in prophylaxis and resources to make sure that at risk individuals have access to these enhancements (4). This can be approached through a multi-stakeholder implementation to cover data gaps and ensure knowledge is available to parents and doctors about prevention options. (4)

"One of the key concerns is that healthcare decision-makers and systems must be capable of taking advantage of upcoming technological advancements in prophylaxis and resources to make sure that at risk individuals have access to these enhancements (4). This can be approached through a multi-stakeholder implementation to cover data gaps and ensure knowledge is available to parents and doctors about prevention options. (4)"

Protecting all infants against RSV is critical by implementing an immunization strategy with Nirsevimab to reduce infants' health and economic burden. (4, 15) Most infants, including high-risk palivizumab (SYNAGIS)-eligible infants, will benefit from nirsevimab-alip (BEYFORTUS) immunization if maternal RSVpreF is not given or timed correctly. (15, 18) Newer immunizations and vaccines may further leverage additional advantages and protections that are even more durable resulting in single dose protection. The need for monthly prophylaxis may be problematic for compliance in some situations.

RSVpreF (ABRYSVO) (maternal vaccination):

RSVpreF (ABRYSVO) is a vaccine with an antigen component containing recombinant RSV preF A and RSV preF B. The RSV preF A and RSV preF B recombinant proteins are lyophilized. After reconstitution, each RSVpreF (ABRYSVO) dose is approximately 0.5 mL. The vaccine is formulated to contain 120 mcg of RSV stabilized prefusion F proteins (60 mcg RSV preF A and 60 mcg RSV preF B) per 0.5 mL. (11)

RSVpreF (ABRYSVO) is a vaccine for pregnant individuals between 32 and 36 weeks. It can prevent respiratory syncytial virus (RSV) related lower respiratory tract disease (LRTD) in infants up to six months old. Individuals aged 60 may also be given this vaccine to prevent RSV-related LRTD. Despite other risk factors, This vaccine is not FDA-approved for anyone other than pregnant individuals and those 60 years or older. Notably, it has not been studied in patients under age ten, and there may

not be adequate data to ascertain safety in very young pregnant individuals. (11)

"Two clinical studies found more preterm births in those pregnant individuals receiving RSVpreF (ABRYSVO) compared to placebo. However, there was not enough statistical strength to this finding to categorically link ABRYSVO to preterm birth. RSVpreF (ABRYSVO) should only be given to pregnant individuals between 32 and 36 weeks gestation to minimize the risk of preterm birth at still earlier gestations."

Two clinical studies found more preterm births in those pregnant individuals receiving RSVpreF (ABRYSVO) compared to placebo. However, there was not enough statistical strength to this finding to categorically link ABRYSVO to preterm birth. RSVpreF (ABRYSVO) should only be given to pregnant individuals between 32 and 36 weeks gestation to minimize the risk of preterm birth at still earlier gestations. Immunization of mothers past 36 weeks gestation may not provide enough time for the vaccination to produce the desired effect with the transfer of the antibody across the placenta prior to delivery of the baby. High-risk pregnant individuals were not enrolled in the clinical studies involving RSVpreF (ABRYSVO). The effect of dosing in these individuals on preterm delivery cannot be ascertained. (11)

" High-risk pregnant individuals were not enrolled in the clinical studies involving RSVpreF (ABRYSVO). The effect of dosing in these individuals on preterm delivery cannot be ascertained. (11)"

In the first study, 5.7% of the ABRYSVO group (202 out of 3,568) had preterm births versus 4.7% in the placebo group (169 out of 3,558). In the second, 5.3% of RSVpreF (ABRYSVO) recipients (6 out of 114) had preterm births, while 2.6% of placebo recipients (3 out of 116) did. Some prematurely born infants required hospital care within 30 days after birth, with 83 in the RSVpreF (ABRYSVO) group and 80 in the placebo group. Based on the available data, it is uncertain if RSVpreF (ABRYSVO) directly causes preterm birth.

A similar trend with an increase in the rate of prematurity was seen among infants born to participants vaccinated between 32 and 36 weeks of gestation, with 4.2% in the RSVpreF (ABRYSVO) group (68 out of 1,631) and 3.7% in the placebo group (59 out of 1,610). RSVpreF (ABRYSVO) has not been studied in pregnant individuals under 24 weeks gestational age or those at increased risk for preterm birth. (11)

Within the first month of life, 37.1% of infants whose mothers received RSVpreF (ABRYSVO) experienced adverse events, compared to 34.5% of those whose mothers received a placebo. Higher delivery rates were at a low birth weight (5.1% in the RSVpreF (ABRYSVO) group versus 4.4% in the placebo group). Congenital abnormalities occurred in 5.0% of the RSVpreF (ABRYSVO) group and 6.2% in the placebo group. Neonatal jaundice was observed in 7.2% of the RSVpreF (ABRYSVO) group and 6.7% of the placebo group. (11)

Severe adverse reactions were observed in pregnant individuals at a higher rate in the RSVpreF (ABRYSVO) group compared to the placebo group, including preeclampsia (1.8% versus 1.4%) and gestational hypertension (1.1% versus 1.0%). Both may contribute to a higher rate of preterm birth. (11)

Concerning safety data, there were ten fetal deaths (0.3%) in the RSVpreF (ABRYSVO) group and eight (0.2%) in the placebo group. Regarding mortality during the neonatal period for babies born to pregnant individuals, there were two deaths in the RSVpreF (ABRYSVO) group and five in the placebo group. There were five deaths in the RSVpreF (ABRYSVO) group and 12 in the placebo group, looking at overall mortality, including deaths beyond the neonatal period.

"The presence of RSVpreF (ABRYSVO) in human milk has not been studied adequately, and there is no data on how it may affect breastfed infants or milk production. Should a pregnant individual need RSVpreF (ABRYSVO), weighing the benefits of breastfeeding for the infant's development (i.e., the result of a previous pregnancy) and health against any potential risks from the vaccine or the pregnant individual's condition is crucial."

Among the infants born to individuals in the RSVpreF (ABRYSVO) group and the placebo group, 202 (5.7%) and 169 (4.7%), respectively, were delivered prematurely. 180 (5.0%) and 220 (6.2%) had congenital malformations or anomalies, respectively. 10 (0.3%) fetal deaths occurred in the RSVpreF (ABRYSVO) group and 8 (0.2%) in the placebo group. (11)

The presence of RSVpreF (ABRYSVO) in human milk has not been studied adequately, and there is no data on how it may affect breastfed infants or milk production. Should a pregnant individual need RSVpreF (ABRYSVO), weighing the benefits of breastfeeding for the infant's development (i.e., the result of a previous pregnancy) and health against any potential risks from the vaccine or the pregnant individual's condition is crucial. No data suggests a significant increased risk to the infant following breastfeeding.

A trial assessed the effectiveness of RSVpreF (ABRYSVO) in preventing RSV-related lower respiratory tract disease (LRTD) in

babies born to individuals who were vaccinated during pregnancy. The study measured how well RSVpreF (ABRYSVO) prevented severe RSV-associated LRTD in infants after birth. Participants were randomly assigned to receive RSVpreF (ABRYSVO) or a placebo, and this study included sites worldwide. Vaccine efficacy (VE) gauged the risk reduction of severe LRTD caused by RSV and LRTD caused by RSV in infants born to vaccinated individuals compared to those born to individuals who received a placebo. Maternal participants were also randomly divided into those who received RSVpreF (ABRYSVO) and those who received a placebo. RSV-associated LRTD in infants was diagnosed through a medical visit with confirmed RSV illness using specific respiratory symptoms. Severe RSV-associated LRTD identified those with more severe symptoms. Hospitalizations due to RSV were also tabulated. (19)

A medically attended visit with an RT-PCR (reverse transcription-polymerase chain reaction) confirmed RSV with one or more of the following tachypnea: respiratory rate ≥60 breaths/minute, ≥50 breaths/minute, ≥ 60 days to 1 year of age, or ≥ 40 breaths/minute ≥12 months to one year of age; SpO2 measured in room air <95%; retractions ("chest wall indrawing") or was defined as a RSV-associated LRTD.

RSV-associated severe LRTD was defined by having tachypnea respiratory rate ≥70 breaths per minute <60 days of age, ≥ 60 breaths per minute ≥ 60 days to one year, or ≥50 bpm ≥ one to two years; SpO2 measured in room air <93%; high-flow nasal cannula (greater than 2 LPM in the younger infants) or mechanical ventilation (invasive or noninvasive), ICU admission for >4 hours or loss of consciousness. Hospitalizations due to RSV were monitored as a secondary endpoint.

"The results showed a statistically significant reduction in severe lower respiratory tract disease in infants under six months of age but did not demonstrate a reduction for non-severe respiratory tract disease; however, clinically efficacy was present after 90 days through 180 days after birth. Moreover, these infants were not hospitalized and may have seen a reduction in disease severity based on maternal vaccination."

The results showed a statistically significant reduction in severe lower respiratory tract disease in infants under six months of age but did not demonstrate a reduction for non-severe respiratory tract disease; however, clinically efficacy was present after 90 days through 180 days after birth. Moreover, these infants were not hospitalized and may have seen a reduction in disease severity based on maternal vaccination. This decreased efficiency in the non-severe respiratory tract disease cohort to 90 days may indicate the need for additional prophylaxis with palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) during this interval for high-risk individuals. However, no data exists as to the effectiveness or safety of this strategy.

Nirsevimab-alip (BEYFORTUS):

Nirsevimab-alip (BEYFORTUS) is a respiratory syncytial virus F protein-directed fusion inhibitor based on a recombinant human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody. The molecular weight is approximately 146.3 kDa. There is a correlation between a serum nirsevimab-alip (BEYFORTUS) AUC of at least 12.8 mg day/mL and decreased medically attended RSV lower respiratory tract infection (MA RSV LRTI). No formal drug interaction studies with other medications, including RSVpreF or Palivizumab (SYNAGIS), have been studied with nirsevimab-alip (BEYFORTUS). (19)

"Nirsevimab-alip (BEYFORTUS) is a respiratory syncytial virus F protein-directed fusion inhibitor based on a recombinant human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody. The molecular weight is approximately 146.3 kDa. There is a correlation between a serum nirsevimab-alip (BEYFORTUS) AUC of at least 12.8 mg day/mL and decreased medically attended RSV lower respiratory tract infection (MA RSV LRTI)."

The PK of nirsevimab-alip (BEYFORTUS) is dose-proportional and ranges from 25 mg (0.5 times the lowest approved recommended dosage) to 200 mg in the index population. The nirsevimab-alip (BEYFORTUS) serum exposures were similar in those born during or entering the first RSV season and in those born at ≤ 35 weeks (including ≤ 29 weeks GA) in the first RSV season and up to two years in those patients with CLD or CHD in the first and second RSV season. (19)

Nirsevimab-alip (BEYFORTUS) provides passive immunity by targeting the RSV F protein. The triple amino acid substitution (YTE) in the Fc region extends serum half-life. Nirsevimab-alip (BEYFORTUS) binds to antigenic site Ø with dissociation KD = 0.12 nM and KD = 1.22 nM for RSV subtypes A and B, respectively. The F protein, which causes fusion of the viral and cellular membranes and facilitates viral entry, is effectively prevented from causing virulence. Nirsevimab-alip (BEYFORTUS) neutralized clinical RSV isolates collected worldwide between 2003 and 2017 with median EC50 values for RSV A of 21 pM (3.2 ng/mL); and for RSV B, of 19 pM (2.9 ng/mL). (19)

No resistance-associated substitutions occurred at ≥ 25% frequency. Of those who received a single dose of 50 mg Nirsevimab-alip (BEYFORTUS), 5% (2 of 40) of subjects with RSV infections had a variant containing nirsevimab-alip (BEYFORTUS) resistance-associated substitutions. The two subjects each received less than the recommended nirsevimab-alip (BEYFORTUS) dose but had different substitutions. (19)

Some data show that variants resistant to nirsevimab-alip (BEYFORTUS) could have cross-resistance to palivizumab (SYNAGIS). Palivizumab (SYNAGAIS) retained full neutralization potency against resistance-associated substitutions identified in nirsevimab-alip (BEYFORTUS). Nirsevimab-alip (BEYFORTUS) retained activity against recombinant RSV harboring palivizumab (SYNAGIS) resistance-associated substitutions. (19)

" The efficacy of nirsevimab-alip (BEYFORTUS) against MA RSV LRTI with hospitalization in infants of GA > 29 weeks to < 35 weeks, receiving a single dose of 50 mg nirsevimab-alip (BEYFORTUS), based on the relative risk reduction was 78.4% (p=0.0002), through 150 days post-dose. (19)"

A double-blind, placebo-controlled multicenter trial to prevent Medically Attended Respiratory Syncytial Virus Lower Respiratory Tract Infection (MA RSV LRTI) was performed in preterm infants born at gestational age (GA) ≥ 29 weeks and < 35 weeks. All subjects in the nirsevimab-alip (BEYFORTUS) arm received 50 mg IM of nirsevimab-alip (BEYFORTUS) regardless of body weight. The nirsevimab-alip (BEYFORTUS) dose for those during the first RSV season is a single (not monthly) IM 50 mg (< 5 kg) or 100 mg dose (≥ 5 kg, respectively. 20% were GA ≥ 29 weeks and < 32 weeks; 80% were GA ≥ 32 and < 35 weeks. The efficacy of nirsevimab-alip (BEYFORTUS) against MA RSV LRTI with hospitalization in infants of GA ≥ 29 weeks to < 35 weeks, receiving a single dose of 50 mg nirsevimab-alip (BEYFORTUS), based on the relative risk reduction was 78.4% (p=0.0002), through 150 days post-dose. (19)

Nirsevimab-alip (BEYFORTUS) was evaluated in a randomized, double-anonymized, placebo-controlled multicenter trial to prevent MA RSV LRTI in term and late preterm infants GA > 35 weeks into their first RSV season. At randomization, 14% were GA ≥ 35 weeks and < 37 weeks; 86% were GA ≥ 37 weeks. (19)

" Nirsevimab-alip (BEYFORTUS) demonstrated decreased MA RSV LRTI with hospitalization in infants born at > 35 weeks, receiving a single IM 50 mg or 100 mg dose for those < 5 kg and > 5 kg, respectively. The relative risk reduction was 60.2% (p=0.09) up to 150 days post-dose."

Nirsevimab-alip (BEYFORTUS) demonstrated decreased MA RSV LRTI with hospitalization in infants born at ≥ 35 weeks, receiving a single IM 50 mg or 100 mg dose for those < 5 kg and ≥ 5 kg, respectively. The relative risk reduction was 60.2% (p=0.09) up to 150 days post-dose. This group, based on increased gestational age at birth, may have a statistically decreased risk of severe disease. (19)

" There were no MA RSV LRTI through Day 150 post-dose cases in subjects who received either nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS). (19)"

Another study enrolled certain infants at a higher risk for severe RSV disease during the first RSV season: preterm infants (< 35 weeks) and infants with CLD related to prematurity or hemodynamically significant CHD. Other high-risk groups with other anatomical malformations or immunological issues that could place them at higher risk for infection were not studied. Infants were randomized to preterm (n=615) and CLD/CHD (n=310) cohorts to receive nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS). Infants received a single IM dose of nirsevimab-alip (BEYFORTUS) (50 mg if < 5 kg body weight or 100 mg if > 5 kg body weight at the time of dosing), followed by four once-monthly IM doses of placebo or five once-monthly IM doses of 15 mg/kg palivizumab (SYNAGIS), respectively. At randomization, 77 infants (13%) were < 29 weeks GA and 499 (81%) were GA ≥ 29 to < 35 weeks. In the CLD/CHD cohort, 70% had CLD of prematurity; 34% had hemodynamically significant CHD; 123 (40%) were < 29 weeks GA, 28% were ≥ 29 weeks to < 35 weeks GA; and 32% ≥ 35 weeks GA. In the first RSV season, the incidence of MA RSV LRTI through 150 days post-dose was 0.6% (4/616) in the nirsevimab-alip (BEYFORTUS) group and 1.0% (3/309) in the palivizumab (SYNAGIS) group. (19)

"For infants born outside the RSV season, nirsevimab-alip (BEYFORTUS) should be administered once before the RSV season starts, subject to whether the patient's mother received RSVpreF (ABRYSVO) or palivizumab (SYNAGIS), considering the duration of protection provided by nirsevimab-alip (BEYFORTUS)"

Those with CLD of prematurity or hemodynamically significant CHD up to two years of age continued in the trial for a second season. Subjects who received nirsevimab-alip (BEYFORTUS) during the first season received 200 mg of nirsevimab-alip (BEYFORTUS) entering the second season, followed by a monthly placebo. Subjects who received palivizumab (SYNAGIS) during their first RSV season were randomized to receive either nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS) during

the second season. There were no MA RSV LRTI through Day 150 post-dose cases in subjects who received either nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS). (19)

Nirsevimab-alip (BEYFORTUS) is indicated for preventing MA RSV LRTI in the first season. Children up to two years of age may remain susceptible to severe disease through two years of age. Nirsevimab-alip (BEYFORTUS) may be administered shortly after birth. For infants born outside the RSV season, nirsevimab-alip (BEYFORTUS) should be administered once before the RSV season starts, subject to whether the patient's mother received RSVpreF (ABRYSVO) or palivizumab (SYNAGIS), considering the duration of protection provided by nirsevimab-alip (BEYFORTUS). Patients should receive dosage based on weight, with those less than 5 kg receiving 50 mg by IM injection and those above 5 kg 100 mg by IM injection.

During the first RSV season, if surgery is performedwithin 90 days after nirsevimab-alip (BEYFORTUS), an additional dose based on body weight should be given. If more than 90 days have elapsed since nirsevimab-alip (BEYFORTUS), the additional dose should be 50 mg. For children up to two years of age with increased risk in the second season, the recommended nirsevimab-alip (BEYFORTUS) dosage is a 200 mg dose given in two IM injections (2 x 100 mg). If more than 90 days have elapsed since receiving nirsevimab-alip (BEYFORTUS), the additional dose should be 100 mg, regardless of weight. (19)

"During the first RSV season, if surgery is performedwithin 90 days after nirsevimab-alip (BEYFORTUS), an additional dose based on body weight should be given. If more than 90 days have elapsed since nirsevimab-alip (BEYFORTUS), the additional dose should be 50 mg. For children up to two years of age with increased risk in the second season, the recommended nirsevimab-alip (BEYFORTUS) dosage is a 200 mg dose given in two IM injections (2 x 100 mg). "

In either case, for children undergoing cardiac surgery with cardiopulmonary bypass or ECMO, an additional dose of nirsevimab-alip (BEYFORTUS) is recommended as soon as the child is stable off bypass following surgery to ensure that nirsevimab-alip (BEYFORTUS) is not filtered from the serum or diluted by the circuit. (19)

Nirsevimab-alip (BEYFORTUS) may be given with other vaccines. There is no information regarding the co-administration of nirsevimab-alip (BEYFORTUS) with other immunoglobulin products. There is no data regarding substituting nirsevimab-alip (BEYFORTUS) for palivizumab (SYNAGIS) once prophylaxis treatment is initiated with palivizumab (SYNAGIS) or whether palivizumab (SYNAGIS) may be given following administration of nirsevimab-alip (BEYFORTUS) or RSVpreF (ABRYSVO) received by the patient's mother. No data suggests that nirsevimab-alip (BEYFORTUS) may not given during the second season to children up to 2 years of age who are at significant risk of severe RSV disease and who received palivizumab (SYNAGIS) in their first RSV season or whose mothers received RSVpreF (ABRYSVO). Palivizumab (SYNAGIS) may also be administered with the appropriate indication during the first or second year of eligibility. In certain circumstances, policy limitations may curtail the use of nirsevimab-alip (BEYFORTUS). In these circumstances, it is essential to remember that palivizumab (SYNAGIS) may be used. (12, 19)

"No data suggests that nirsevimab-alip (BEYFORTUS) may not given during the second season to children up to 2 years of age who are at significant risk of severe RSV disease and who received palivizumab (SYNAGIS) in their first RSV season or whose mothers received RSVpreF (ABRYSVO). Palivizumab (SYNAGIS) may also be administered with the appropriate indication during the first or second year of eligibility."

Nirsevimab-alip (BEYFORTUS) is contraindicated in infants and children with a history of severe hypersensitivity, including anaphylaxis, to nirsevimab-alip (BEYFORTUS) or related compounds. Severe hypersensitivity reactions and anaphylaxis have occurred by administering other monoclonal antibodies. With IM injections, the risk of thrombocytopenia, coagulation disorder, or individuals on anticoagulation therapy should be taken into consideration.

A randomized, double-blind, controlled multicenter trial in infants at high risk for severe disease evaluated the safety of nirsevimab-alip (BEYFORTUS). Palivizumab (SYNAGIS) was given to the control group. Subjects received nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS) (SYNAGIS). Six hundred fourteen infants received nirsevimab-alip (BEYFORTUS). 214 and 103, respectively, had CLD associated with prematurity or hemodynamically significant CHD. 12 infants had both CLD and CHD. Subjects with CLD or hemodynamically significant CHD could continue receiving nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS) before the second RSV season. All subjects who received nirsevimab-alip (BEYFORTUS) also received nirsevimab-alip (BEYFORTUS) in the second RSV season (N=180). Those who received palivizumab (SYNAGIS) in the first season were randomized to receive nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS) in the second RSV season. The safety profile of nirsevimab-alip (BEYFORTUS) during their second RSV season was comparable with the safety profile during the first RSV season. (12, 19)

The safety and effectiveness of nirsevimab-alip (BEYFORTUS)

have been established for preventing RSV lower respiratory tract disease up to two years of age for those who remain vulnerable to severe RSV disease. The indications for risk should be similar to those reported for palivizumab (SYNAGIS). The use of nirsevimab-alip (BEYFORTUS) is supported by evidence from controlled studies in neonates and infants from birth up to one year, with additional pharmacokinetic and safety data in children up to two years of age. (12, 19)

"There has been some concern about the possibility of associated preterm birth if RSVpreF (ABRYSVO) was given sooner than 32 weeks gestation. It takes approximately two weeks for maternal antibodies to cross the placenta, and passage of these antibodies is more certain during the later part of the third trimester. (11, 20) Passage of the immune active antibody is optimal in late gestation."

There has been some concern about the possibility of associated preterm birth if RSVpreF (ABRYSVO) was given sooner than 32 weeks gestation. It takes approximately two weeks for maternal antibodies to cross the placenta, and passage of these antibodies is more certain during the later part of the third trimester. (11, 20) Passage of the immune active antibody is optimal in late gestation. According to the FDA indication, babies at term will have at least six months of protection from more severe illness. This means that a term baby born in October at term will have protection through the typical duration of the RSV season, but this protection may wain if the season is prolonged. '

"Babies born in November through March at late preterm or term gestation will be protected during the season. The additional protection may not provide benefits if the RSV season ends in April. This analysis may not be valid if COVID continues to produce alterations in the RSV season. (21)"

Babies born in November through March at late preterm or term gestation will be protected during the season. The additional protection may not provide benefits if the RSV season ends in April. This analysis may not be valid if COVID continues to produce alterations in the RSV season. (21) For babies born at term in April, nirsevimab-alip (BEYFORTUS) will only protect through October; these babies may require additional prophylaxis as the protective effect may decrease before the RSV season starts. In deciding whether to use nirsevimab-alip (BEYFORTUS) or palivizumab (SYNAGIS), the mother's history of receiving RSVpreF (ABRYSVO) is essential. (11, 12, 19, 20, 22)

Financial, availability, and contracting may drive the use of one versus another prophylaxis strategy. The current indication of RSVpreF (ABRYSVO) extends prophylaxis to all babies born at least two weeks after immunization except those born to mothers at risk of a reaction from the immunization administration. (22) Palivizumab (SYNAGIS) remains indicated for preterm infants born up to 35 6/7 weeks and those with significant risk factors. Palivizumab (SYNAGIS) may be used instead of nirsevimab-alip (BEYFORTUS), subject to availability in these patients. (23) Although palivizumab (SYNAGIS) has been used in term gestation neonates with additional risk factors (e.g., congenital heart disease), palivizumab (SYNAGIS) has an FDA indication for those neonates. This guidance does not endorse the dosing of term neonates with palivizumab (SYNAGIS) as this purpose is not compliant with the FDA indication. A cost-effective strategy should include analyzing whether maternal RSVpreF (ABRYSVO) will provide significant protection during the RSV season, the potential need for palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS), and whether a second season is indicated. (17, 22) Again, this guidance provides a roadmap for navigating the FDA indication. Abridging the indication by shortening the eligibility interval in the first or second seasons is not recommended and not to full FDA indication.

"A cost-effective strategy should include analyzing whether maternal RSVpreF (ABRYSVO) will provide significant protection during the RSV season, the potential need for palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS), and whether a second season is indicated. (17, 22) Again, this guidance provides a roadmap for navigating the FDA indication. Abridging the indication by shortening the eligibility interval in the first or second seasons is not recommended and not to full FDA indication."

Palivizumab (SYNAGIS)

Palivizumab (SYNAGIS) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody that prevents severe LRTD caused by RSV in pediatric patients who were born prematurely (≤35 weeks gestational age) and who are ≤ six months of age at the beginning of RSV season, with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous six months and who are ≤ two years at the beginning of RSV season,

with hemodynamically significant congenital heart disease (CHD)

and who are two years of age or younger at the beginning of RSV season. Synagis's safety and efficacy are unknown for treating RSV disease. (12)

Palivizumab (SYNAGIS) is dosed at 15 mg per kg of body weight intramuscularly before the RSV season. The remaining doses are administered monthly throughout the RSV season.

After cardio-pulmonary bypass, patients should receive an additional dose of palivizumab (SYNAGIS) promptly following the cardio-pulmonary bypass. After that, monthly doses should be administered. (12)

Anaphylaxis or severe acute hypersensitivity reactions have been reported. If such reactions occur, discontinue palivizumab (SYNAGIS) and administer appropriate medications. Palivizumab (SYNAGIS) should be given with caution to children with thrombocytopenia or any coagulation disorder. Palivizumab (SYNAGIS) may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays. Fever and rash occur in greater than or equal to 10% and at least 1% more frequently than placebo. (12)

Safety and effectiveness in children older than two years old have not been established.

"Palivizumab (SYNAGIS) is indicated to prevent RSV-related severe lower respiratory tract disease in those with a history of premature birth (< 35 weeks gestational age), six months of age or younger at the start of the season, with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous six months and who are two years or younger at the beginning of RSV season, with hemodynamically significant congenital heart disease (CHD) and who are two years or younger at the beginning of RSV season. (12)"

Palivizumab (SYNAGIS) is indicated to prevent RSV-related severe lower respiratory tract disease in those with a history of premature birth (≤ 35 weeks gestational age), six months of age or younger at the start of the season, with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous six months and who are two years or younger at the beginning of RSV season, with hemodynamically significant congenital heart disease (CHD) and who are two years or younger at the beginning of RSV season. (12)

The first palivizumab (SYNAGIS) dose should be administered before the RSV season. The subsequent doses should be administered monthly. Those who are symptomatic with RSV infection should continue to receive monthly doses. In the northern hemisphere, the RSV season typically commences in November and lasts through April. However, it may begin earlier or persist later due to geographical considerations or modulation of the pattern secondary to COVID-19 or influenza seasonality and control measures. (12)

"The first palivizumab (SYNAGIS) dose should be administered before the RSV season. The subsequent doses should be administered monthly. Those who are symptomatic with RSV infection should continue to receive monthly doses. In the northern hemisphere, the RSV season typically commences in November and lasts through April. However, it may begin earlier or persist later due to geographical considerations or modulation of the pattern secondary to COVID-19 or influenza seasonality and control measures. (12)"

Other acute severe hypersensitivity reactions have been reported on exposure to palivizumab (SYNAGIS), including urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, and unresponsiveness. (12)The relationship between these reactions and developing antibodies to palivizumab (SYNAGIS) is unknown. If a significant hypersensitivity reaction occurs with palivizumab (SYNAGIS), its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, a risk-benefit analysis should guide further palivizumab administration (SYNAGIS). (12)

Palivizumab (SYNAGIS) may interfere with immunological-based diagnostic tests, including RSV antigen detection-based assays. In addition, palivizumab (SYNAGIS) inhibits virus replication in cell culture and may also interfere with viral culture assays. Palivizumab (SYNAGIS) does not interfere with reverse transcriptase-polymerase chain reaction-based assays. These diagnostic test results and clinical findings can guide medical decision-making. The safety and efficacy of palivizumab (SYNAGIS) have not been established for treating RSV disease. (12)

Palivizumab (SYNAGIS) has been studied in randomized control clinical trials. One study involved children two years or younger with BPD or infants with premature birth (≤ 35 weeks) who were less than or equal to 6 months of age at study entry. Another study evaluated consecutive seasons among children two years or under with hemodynamically significant congenital heart disease. In the combined studies, fever and rash were more frequent among palivizumab (SYNAGIS) than those who received placebo, 27% versus 25% and 12% versus 10%, respectively. (12)

The incidence of anti-palivizumab antibodies was not significant. In children receiving palivizumab (SYNAGIS) for a second

season, a transient, low titer reactivity was identified in a single individual. This reactivity was not associated with adverse events or alteration in serum concentrations. (12)

These findings represent the percentage of test results indicating antibodies to palivizumab (SYNAGIS) in an enzyme-linked immunosorbent assay (ELISA), and the assay's sensitivity and specificity heavily influence their accuracy. The ELISA has notable limitations in detecting anti-palivizumab antibodies when palivizumab is present. Immunogenicity samples tested using the ELISA assay likely contained palivizumab at levels that could hinder the detection of anti-palivizumab antibodies. To address this, an electrochemical luminescence (ECL)-based immunogenicity assay, which exhibits greater tolerance for the presence of palivizumab compared to the ELISA, assessed anti-palivizumab antibodies from two additional clinical trials. The rates of positive results for anti-palivizumab antibodies in these trials were 1.1% and 1.5%. (12)

Adverse reactions have been identified during the post-approval use of palivizumab (SYNAGIS). These reactions are from a population with unknown dimensions and compliance. One cannot estimate frequency or establish a causal relationship to palivizumab (SYNAGIS). Severe thrombocytopenia has been associated with receiving palivizumab (SYNAGIS) as well as injection site reactions. Post-marketing reports suggest that, within a single RSV season, adverse events after six doses of Synagis are no different than if the patient received only five doses.

No formal drug-drug interaction studies were conducted. The safety and effectiveness of palivizumab (SYNAGIS) in children older than two years or persons of reproductive age have not been established. Overdoses up to 85 mg/kg have been reported. In some cases, adverse reactions were reported.

"No formal drug-drug interaction studies were conducted. The safety and effectiveness of palivizumab (SYNAGIS) in children older than two years or persons of reproductive age have not been established. Overdoses up to 85 mg/kg have been reported. In some cases, adverse reactions were reported."

Palivizumab (SYNAGIS), a humanized monoclonal antibody (IgG1κ) produced through recombinant DNA technology, targets an epitope of the F protein of RSV (the "A" antigenic site). Its human heavy chain sequence (95% human and 5% murine antibody sequences) originates from constant domains of human IgG1 and variable regions of the VH genes Cor and Cess. The human light chain sequence is sourced from constant domains of Cκ and the variable framework regions of the VL gene K104 and Jκ -4. Murine sequences are sourced from a murine monoclonal antibody, Mab 1129, with a process involving grafting the murine complementarity-determining regions into the human antibody frameworks. Palivizumab consists of two heavy chains and two light chains, possessing a molecular weight of approximately 148,000 Daltons. Palivizumab (SYNAGIS) is a recombinant humanized monoclonal antibody with anti-RSV F protein activity. (12)

In children under two years of age without congenital heart disease (CHD), the average half-life of palivizumab (SYNAGIS) was 20 days. Monthly intramuscular doses of 15 m /kg resulted in mean ± SD 30-day trough serum drug concentrations of 37 ± 21 mcg/mL after the initial injection, 57 ± 41 mcg/mL after the second injection, 68 ± 51 mcg/mL after the third injection, and 72 ± 50 mcg /mL after the fourth injection. Trough concentrations were comparable between children with CHD and those without cardiac conditions. For children receiving Synagis for a second season, the mean ± SD serum concentrations after the first and fourth injections were 61 ± 17 mcg/mL and 86 ± 31 mcg/mL, respectively. (12)

"In children, < two years with hemodynamically significant CHD who received palivizumab (SYNAGIS) and underwent cardio-pulmonary bypass for open-heart surgery, the mean serum palivizumab (SYNAGIS) concentration declined by 58%. (12)"

In children, ≤ two years with hemodynamically significant CHD who received palivizumab (SYNAGIS) and underwent cardio-pulmonary bypass for open-heart surgery, the mean serum palivizumab (SYNAGIS) concentration declined by 58%. (12)

Palivizumab (SYNAGIS) serum trough concentrations were independent of gender, age, body weight, or race in those with CHD (≤ two years) receiving monthly IM palivizumab (SYNAGIS). (12)

A pharmacokinetic analysis described palivizumab (SYNAGIS) pharmacokinetics. Palivizumab pharmacokinetics are best described as a two-compartment linear model with an elimination half-life of 24.5 days. Clearance of palivizumab (SYNAGIS) in a typical pediatric patient (body weight 4.5 kg) ≤ two years without CHD was estimated to be 11 mL/day with a bioavailability of 70% following IM administration. (12)

Palivizumab (SYNAGIS) is a recombinant humanized monoclonal antibody that provides passive immunity against RSV by binding the envelope fusion protein (RSV F) on the virus surface. This configuration blocks a critical step in the membrane fusion process. Palivizumab (SYNAGIS) also prevents cell-to-cell fusion of RSV-infected cells. This process prevents the formation of the syncytial membrane that makes up the name of the virus. (12)

Palivizumab (SYNAGIS) activity was assessed in a microneutralization assay. Following an incubation period of 4-5 days, the RSV antigen was quantified using an ELISA assay. The neutralization titer, represented as the 50% effective concentration (EC50), denotes the antibody concentration needed to decrease the detection of RSV antigen by 50% in comparison to untreated virus-infected cells. Palivizumab (SY

nAGIS) exhibited median EC50 values of 0.65 mcg/mL and 0.28

mcg /mL against clinical RSV A and RSV B isolates. These isolates encoded the most common RSV F sequence polymorphisms among clinical isolates worldwide. (12)

Palivizumab serum concentrations greater than or equal to 40 mcg/mL have reduced pulmonary RSV replication *in vitro* by 100-fold. Palivizumab (SYNAGIS) binds a highly conserved region on RSV F, antigenic site II or site A, encompassing amino acids 262 to 275. Resistance to palivizumab (SYNAGIS) has been observed with specimens with mutations in this region. (12)

Virus escape from palivizumab demonstrated a correlation between antibody binding and virus neutralization. RSV variants with substitutions in antigenic site A did not bind to palivizumab (SYNAGIS). No association between the antigenic A site sequence changes and disease severity was demonstrated. (12)

Clinical isolates collected from immunoprophylaxis-naïve subjects revealed palivizumab (SYNAGIS) resistance-associated substitutions in only two specimens. There is a resistance-associated mutation frequency of 0.79%. Palivizumab (SYNAGIS) susceptibility of common F protein sequence polymorphisms proximal to antigenic site A has been studied. No known polymorphic or non-polymorphic sequence variations external to antigenic site A on protein F confer RSV resistance to neutralization by palivizumab (SYNAGIS). (12)

Palivizumab (SYNAGIS) has been shown to interfere with immunologically-based RSV assays, such as rapid chromatographic/enzyme immunoassays (CIA/EIA), immunofluorescence assays (IFA), and direct immunofluorescence assays (DFA). It is essential to exercise caution when interpreting negative results from immunological assays, especially if clinical observations align with RSV infection. A reverse transcriptase-polymerase chain reaction (RT-PCR) assay, unaffected by palivizumab (SYNAGIS), can be utilized to enhance laboratory confirmation. (12)

"The safety and efficacy of palivizumab (SYNAGIS) prophylaxis were studied in randomized, double-masked, placebo-controlled trials in children at high risk of RSV-related hospitalization. The IMPACT RSV was conducted during a single RSV season and studied children less than or equal to two years with BPD or infants with premature birth (< 35 6/7 weeks) who were less than or equal to 6 months of age at study entry."

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In IMPACT-RSV, RSV hospitalization reduction was observed in children with BPD 12.8% versus 7.9% and in premature infants without BPD 8.1% versus 1.8%. In the CHD trial, reductions were observed in acyanotic children at 11.8% versus 5.0% and cyanotic children at 7.9% versus 5.6%. (12, 24)

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The studies do not suggest RSV infection was less severe among those hospitalized with RSV infection who received palivizumab (SYNAGIS) for RSV prophylaxis compared with placebo. (12)

"For infants and young children who were supposed to receive nirsevimab-alip but received Pfizer (ABRYSVO) or GSK (AREXVY) RSV vaccine in error, it is recommended to administer a dose of nirsevimab-alip (BEYFORTUS) or initiate palivizumab (SYNAGIS). (11, 12, 19, 25) Pregnant individuals who received the GSK RSV vaccine (Arexvy) in error should not be given the Pfizer RSV vaccine (ABRYSVO). Instead, if the infant is younger than one year, they should receive nirsevimab-alip during the RSV season."

RSV Prophylaxis In Non-Indicated Patients or Indications for Redosing:

Healthcare providers who have inadvertently administered incorrect RSV vaccine products are advised to take specific actions. For infants and young children who were supposed to receive nirsevimab-alip but received Pfizer (ABRYSVO) or GSK (AREXVY) RSV vaccine in error, it is recommended to administer a dose of nirsevimab-alip (BEYFORTUS) or initiate palivizumab

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To prevent vaccine administration errors, healthcare providers and facilities should ensure that the correct RSV prevention product is used in the correct population. This involves implementing error prevention alerts in electronic health record systems, providing proper education and training, paying attention to labeling, and following storage and administration best practices. Healthcare providers are strongly encouraged to report vaccine administration errors to VAERS; questions can be submitted to NIPINFO@cdc.gov for inquiries. Additionally, healthcare providers with complex vaccine safety questions may request consultation through the Clinical Immunization Safety Assessment (CISA) Project. (25)

I. Background:

Respiratory Syncytial Virus (RSV) is a virus that typically causes mild, cold-like symptoms in adults, children, and most term infants. In premature and "at-risk" infants, as well as those over age 60, RSV can cause severe disease and is a grave health concern. RSV is a leading cause of worldwide morbidity and mortality in children less than five years of age and causes approximately 3.4 million hospitalizations and more than 66,000 deaths per year in this group. (26) Although 99% of these deaths occur in developing countries, of all infectious diseases affecting children worldwide, only malaria is more deadly. (27)

"Many different strategies have been studied to reduce the risk of RSV. Although efforts to reduce droplet transmission, good handwashing, and avoidance of known infected patients are practical, palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) are currently the only FDA-approved biologics for RSV prophylaxis following delivery. (12, 19)"

Many different strategies have been studied to reduce the risk of RSV. Although efforts to reduce droplet transmission, good handwashing, and avoidance of known infected patients are practical, palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) are currently the only FDA-approved biologics for RSV prophylaxis following delivery. (12, 19)There is a high level of evidence that RSV prophylaxis is effective. The best data available at this time supports continuing to ensure access to RSV prophylaxis for neonatal and pediatric patients at the most significant risk. (28-31) Over the past several years, the proportion of infants eligible for RSV prophylaxis who have received it has decreased as providers and insurers have increasingly followed guidelines and policies that do not comply with Food and Drug Administration (FDA) indications, resulting in needless morbidity and increased hospitalization. (32, 33) Many babies at risk for RSV are now deemed ineligible for complete prophylaxis by such guidelines and policies. (24, 34, 35) Although the guidance for nirsevimab-alip (BEYFORTUS) is more relaxed than previously for palivizumab (SYNAGIS), parent groups concerned about this trend have published recommendations for obtaining FDA-approved coverage for RSV prophylaxis using appeals, letter-writing campaigns, and political activism. Several examples are documented on the "preemiebabies101" website http://www.preemiebabies101.com/2014/08/12-tips-getting-synagis-injections-approved/ as well as the "Hand to Hold" website http://handtohold.org/resources/helpful-articles/rsv-101-what-every-nicu-parent-needs-to-know/. The continued need to appeal what should be covered by FDA indication, delays in the appeals process, and complete denials have all contributed to delays in the administration of immunization to babies at risk, resulting in irregular, sub-optimal dosing regimens and a reduction of palivizumab (SYNAGIS) levels necessary to prevent illness. This leads to leads to increased hospital admission as well as increased morbidity. (33, 36)

"Provider confusion is a serious concern. Although there is no substitute for clinical judgment, recommendations on dosing and timing should be issued consistent with the broadest FDA indication for dosing to accommodate provider discretion. (32) Guidelines do not apply to every condition and case. Variation from the guideline is still acceptable; however these guidelines should never deny access."

Provider confusion is a serious concern. Although there is no substitute for clinical judgment, recommendations on dosing and timing should be issued consistent with the broadest FDA indication for dosing to accommodate provider discretion. (32) Guidelines do not apply to every condition and case. Variation from the guideline is still acceptable; however these guidelines should never deny access. A policy that mandates attenuated palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) administration is unreasonable when that policy countermands the FDA indication. (12, 19)The indication provides the most clarity in preventing the use of a pharmaceutical product outside of its carefully studied parameters. Following the FDA indication is essential from a medico-legal perspective, as insurers should use the FDA indication to guide remuneration without *a proviso* for denials due to consensus guidance that deviates from the FDA indication. Significant deviation from the established FDA indication and insurance reimbursement based on policy statements created from consensus guidance contributes to much confusion for providers and parents. It may also lead to provider disenfranchisement and a lack of universal acceptance of a standard of practice (http://www.infanthealth.org/rsv). This situation is unfortunate. Despite precise Medicaid regulation, State Medicaid formularies have not met all of the requirements of section 1927(d)(4)(C) of the Social Security Act since they exclude

treatment with an approved therapy despite clear FDA indication. Palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) meet all the criteria (significant and clinically meaningful therapeutic advantage, safety profile, and effectiveness in clinical outcomes) necessary for coverage by Medicaid programs via the "medically acceptable indication" criteria. The ramifications of a policy for reduced dosing are concerning, as it restricts access and causes state Medicaid programs to violate their legislative mandate. Under the legal doctrine of "loss of chance," practitioners assume legal liability for not offering and advocating for the use of the only approved pharmaceutical for a specific approved indication. (37)

"Of particular public concern has been a de-emphasis on the best available evidence and a focus on adjudicated studies to generate selective expert opinion. Regimens with fewer doses than FDA indication or decreased months of eligibility were not tested in a randomized clinical trial (RCT). The use of an abbreviated dosing or calendar schedule for immunoprophylaxis of RSV to ration therapy and reduce costs is contrary to published evidence and the FDA-approved product indications for palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS). (38)"

Of particular public concern has been a de-emphasis on the best available evidence and a focus on adjudicated studies to generate selective expert opinion. Regimens with fewer doses than FDA indication or decreased months of eligibility were not tested in a randomized clinical trial (RCT). The use of an abbreviated dosing or calendar schedule for immunoprophylaxis of RSV to ration therapy and reduce costs is contrary to published evidence and the FDA-approved product indications for palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS). (38) Not dosing according to indication (underdosing) is considered an "off-label" use of medication. (39) Although cost-effectiveness is increasingly essential, decisions regarding appropriate RSV prophylaxis must be based on the evidence. (40-43) Denial of full coverage based on gestational age, without consideration of other risk factors, discriminates against certain populations of infants and may put specific populations at even greater risk due to health disparities. (44, 45) Making RSV a reportable disease may be necessary to document the extent of RSV prevalence and costs. (44) To date, despite widespread efforts to protect infants according to the FDA indications, further restrictions on the use of palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) have made prophylaxis potentially unavailable for as many as 75% of the infants in whom it is indicated by FDA guidance. (32, 46)

Even in high-risk infants from 32-35 wGA (weeks' gestational age), RSV can result in severe morbidities. Ambrose et al. evaluated 1642 subjects across many outpatient clinics in 38 states and the District of Columbia in one study. In two RSV seasons (2009-2011), ED visits, outpatient respiratory infection, and other clinical factors that place babies at risk for RSV disease were evaluated. Of the preterm infants 32-35 wGA who were <6 months on November 1, 4.9% were hospitalized with RSV-related illnesses each season. Pre-school-aged siblings and daycare attendance increased the risk of RSV disease. Among the subset of 32-34 wGA infants eligible under risk-related criteria, the RSV-related hospitalization rate was 9.1%. (36, 47) A study by Blanken et al. supports the original evidence presented in the IMpact RSV trial. Palivizumab (SYNAGIS) decreased RSV-related hospitalization in 33-35 wGA infants by 82%, whereas the original IMpact study described a 78% decrease. (24, 48) A Cochrane review using data from many randomized controlled trials found high-quality evidence to support the association of palivizumab (SYNAGIS) and reduction in RSV-related hospitalization (RR 0.49, 95% CI 0.37-0.64) as well as high-quality evidence to support an association of palivizumab (SYNAGIS) and reduction in RSV ICU admissions (RR 0.5, 95% CI 0.3-0.81). (24, 49-51) Data regarding nirsevimab-alip (BEYFORTUS) and changes to the FDA indication by various current guidelines have not been covered adequately.

Confoundation by indication limits the effectiveness of well-designed randomized control studies designed to study the efficacy of palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS). Farber et al. described a 38% lower hospitalization rate for RSV in infants born at 29 to 32 wGA, with ≥1 insurance claim for palivizumab (SYNAGIS). (52) This group received ≤ 50% of the indicated doses. Studies that are retrospective, nonrandomized, and with confounding of the indication should not supersede the data from carefully designed randomized trials. (53)

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Winterstein et al. evaluated 247,566 patients in Florida and Texas to determine the age at which at-risk infants born from 32-34 wGA experienced a risk of developing RSV equivalent to that of term

babies. At one month of age, these babies had a risk of being hospitalized comparable to that of term babies. The RSV-related hospitalization rate of these preterm infants was 3.1% in Florida and 4.5% in Texas. Incomplete coding and testing for RSV was a consistent issue. Increased prematurity was associated with a higher risk for hospitalization, and the disparity issues could not be separately identified in the populations studied. (54) In another at-risk population in Florida, Winterstein et al. demonstrated that palivizumab (SYNAGIS) prophylaxis was associated with reduced severe RSV infection. (55) Analysis of the Kids' Inpatient Database of hospitalizations between 2000-2009 (n=325,494) showed that while, overall, bronchiolitis-related hospitalizations were decreased by 17% among all children less than two years of age, bronchiolitis hospitalizations increased by 29% in the sub-group in which there was an FDA indication for palivizumab (SYNAGIS) prophylaxis. (35, 56) As nirsevimab-alip (BEYFORTUS) does not yet have significant clinical data with changes to the FDA indication in clinical practice, whether this proposed guidance and protocols will impact prophylaxis remains to be seen.

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In a study by Hall et al., RSV-related hospitalizations among preterm and term infants were evaluated in three United States counties. RSV acute respiratory illnesses were tallied, and relative risk was identified by age from birth certificate data. This study has been used to justify reduced immunoprophylaxis of prophylaxis with palivizumab (SYNAGIS), yet the study included insufficient premature infants to justify generalizing the results to this population. Premature infants represented only 10% of the 2,140 subjects studied. RSV rates in this study were not found to be significantly different between preterm and term infants, an expected result since 70% of the palivizumab (SYNAGIS) - eligible patients in the study populations had received palivizumab (SYNAGIS) (supporting the efficacy of palivizumab (SYNAGIS) in decreasing the rate of RSV infection in preterm infants to be closer to that of term infants). Black infants greater than or equal to 6 months of age were hospitalized more often, documenting ethnic disparities in RSV-related health risks. (45) Previous studies, such as that by Boyce et al., had identified a two-fold higher hospitalization rate for preterm infants. (57) This higher hospitalization rate might drop if adequate compliance with RSV prophylaxis could be assured. (58)

Since 2014, more restrictive control over the prescription of palivizumab (SYNAGIS) has resulted in increased morbidity. Zuccotti et al. demonstrated worse outcomes in the 29-32 wGA group who did not receive prophylaxis and increased hospitalization costs. (59) In another study, Capizzi et al. found a high proportion of admission for the <36 wGA infants, the great majority born at 33 to <36 wGA and a chronological age of <6 months. Of those admitted, many preterms were treated with high-flow nasal cannula ventilation, delivering continuous positive airway pressure. These results suggest the need to re-evaluate the role of prophylaxis in infants up to 36 wGA.(60) In a multicenter test case negative control study, palivizumab (SYNAGIS) efficiency for preventing Intensive Care Unit (ICU) admission of infants 29-35 wGA and ≤6 months of chronologic age (without chronic lung disease of prematurity or congenital heart disease) was 74% (95% CI 56%-85%).(61)

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SENTINEL1 evaluated 29-35 wGA < 12 months old infants hospitalized for confirmed RSV disease who had not received prophylaxis. 42% were admitted to the ICU, and 20% required intubation and mechanical ventilation. In the younger group, 29-32 wGA and < 3 months of age, 68% required ICU admission, and 44% required intubation and mechanical ventilation. These results corroborate the original RSV IMpact study and provide additional information regarding the hospitalization course's acuity level. (33)

Following a change in palivizumab (SYNAGIS) dosing patterns for the 2014-2015 season, the TRUVEN database study demonstrated that with a decline in RSV prophylaxis, hospitalization increased among infants born at 29-34 wGA and aged <3 Months. Compared with the 2013–2014 season, RSV hospitalization increased by 2.7-fold (p = 0.02) in the at-risk group. RSV hospitalizations for infants 29-34 wGA were up to seven times higher than for normal-term infants. (62)

"Increased risk for hospitalization is not the only factor to consider. Several studies document RSV's association with wheezing and the risk of subsequent development of reactive airway disease. (63-65) Blanken et al., demonstrated a significant reduction in wheeze in an at-risk group of infants born at 33-35 wGA that received palivizumab (SYNAGIS) prophylaxis."

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that received palivizumab (SYNAGIS) prophylaxis. Recurrent wheeze was ten percentage points lower in patients treated with palivizumab (SYNAGIS) (11% vs. 21%, p=0.01). (48) Yoshihara et al. demonstrated reduced wheeze in patients who received palivizumab (SYNAGIS) prophylaxis regardless of whether an at-risk patient was documented to have contracted RSV.(66) Subclinical RSV disease that is not identified in the course of a provider interaction may be clinically significant and result in increased long term morbidity. (41)

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In an observational case-control prospective multicenter trial of palivizumab (SYNAGIS) prophylaxis, Mochizuki et al. were able to establish a two-fold increase in the development of recurrent wheezing (15.3% versus 31.6% in the treated and untreated groups (p=0.003). Although the study did not show a difference in atopic asthma, the risk for subsequent development of asthma and morbidity associated with recurrent wheezing cannot be discounted. (67) Feldman et al. discussed how RSV infection may not be necessary but is sufficient to increase the likelihood of pediatric asthma. Immune mediation and cytokine production common to both conditions may be set into the process if RSV infection occurs at a certain point. (68) REGAL (RSV Evidence-a Geographical Archive of the Literature) reviewed 20 years of RSV-related research. Of the 74 prospective epidemiologic studies qualified by the review, the meta-analysis consistently demonstrated that RSV infection early in life is a significant risk factor for respiratory morbidity characterized by early wheezing and recurrent wheezing, as well as asthma within the first decade of life and possibly later. (69) An expert panel sponsored by the Bill and Melinda Gates Foundation concluded that the association between early onset RSV and subsequent wheezing and asthma has been well-defined. The effect of prevention of RSV in infancy on the reduction of recurrent wheezing and asthma across multiple gestational ages may ultimately demonstrate a causal link. (70)

Children at high risk for RSV include those with other co-morbidities besides prematurity, including chronic lung disease and congenital heart disease. Using a structured case analysis of the Medline database, Welliver et al. described a series of patients with severe underlying comorbidities, as well as those with nosocomial RSV who appear to be at increased risk for death after RSV hospitalization. (71) Actual RSV worldwide fatality data may help determine whether including co-morbidities in evaluating acceptable risk is appropriate. (26, 41, 72)

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II. Financial Considerations:

Cost stewardship is essential. Patients should receive the best possible care at the lowest possible cost. (38) However, any reduction in qualification for RSV prophylaxis must be associated with a model that demonstrates the unequivocal financial benefit without increased attendant morbidity and mortality. Maternal vaccination not withstanding; estimates of cost savings must incorporate realistic estimates of palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) cost and all hospitalization and follow-up care costs. Included in this consideration must be a risk-stratified cost analysis of a patient likely to be hospitalized for RSV-related disease as well as an estimate of actual prophylaxis cost related to the month of birth, extrapolated or actual dosing weight at the time of prophylaxis and level of discount applied to the list price of palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS). McLauren et al. analyzed modeled costs of 55 to 85% less than list pricing using a blended drug discount of 33% coupled with seasonal and patient weight considerations. (41, 73, 74) For this model, contemporary hospitalization claim data were used to quantify payer-related costs, and cost neutrality was demonstrated in patient groups up to 34 wGA.(41, 75) Medicaid-related cost discounts were most significant, and prophylaxis of patients in this cohort produced cost savings.

"Changes to nirsevimab-alip (BEYFORTUS) eligibility proposed by various guidance and policies require a more complete analysis. Long-term epidemiologic data from 16 seasons of national palivizumab (SYNAGIS) prophylaxis in Austria, reported by Resch et al., demonstrated an unequivocal seasonal benefit and long-term societal cost savings. (76)"

However, commercial or government insurance programs did not consider physician fees, follow-up costs, parent time off work, and patient factors, including the "cost" of discomfort. Extending this model to include these considerations and dosing according to the full FDA indication may provide additional cost reduction and further tip the balance toward financial justification for prophylaxis. Changes to nirsevimab-alip (BEYFORTUS) eligibility proposed by

various guidance and policies require a more complete analysis. Long-term epidemiologic data from 16 seasons of national palivizumab (SYNAGIS) prophylaxis in Austria, reported by Resch et al., demonstrated an unequivocal seasonal benefit and long-term societal cost savings. (76)

"RSV is the leading cause of hospitalization for all children less than 12 months of age in the United States. (57, 77, 78) The majority of these hospitalizations occur in otherwise healthy infants. Sixty percent of the top five hospital discharge diagnoses are attributable to bronchiolitis."

III. Introduction:

RSV is the leading cause of hospitalization for all children less than 12 months of age in the United States. (57, 77, 78) The majority of these hospitalizations occur in otherwise healthy infants. Sixty percent of the top five hospital discharge diagnoses are attributable to bronchiolitis. Certain groups of infants and children have higher rates of re-hospitalization, including those with Chronic Lung Disease (CLD)/Bronchopulmonary Dysplasia (BPD), Congenital Heart Disease (CHD), and a history of preterm birth. (79-86) Treatment options for RSV are limited, but opportunities for prophylaxis have increased over the previous. Supportive care is the only medical therapy available. In addition to strategies to minimize exposure to RSV, prophylaxis with RSV monoclonal antibodies effectively decreases hospitalization. The best approach to RSV in at-risk groups is prevention. (24, 51, 81, 87-89) In patients with CLD/BPD and premature infants born at less than 36 wGA, prophylaxis decreased hospitalization by 55%; in the subgroup of patients born between 32-35 wGA, hospitalization rates decreased by 80%. (24) Risk reduction in the larger cohort, including term newborns from administration of nirsevimab-alip (BEYFORTUS), is anticipated, subject to supply considerations. Although palivizumab (SYNAGIS) may be safe for term infants with no underlying co-morbidities, immunization of otherwise healthy term infants is considered outside the accepted FDA indication for palivizumab (SYNAGIS).

IV. Respiratory Syncytial Virus Prophylaxis

A. Prophylaxis to prevent RSV is available as an intramuscular monoclonal antibody preparation (palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS)). (90, 91)

B. Maternal vaccination may preclude the need for further immunization during the first season, depending on the timing and gestational of the patient.

C. RSV infection is responsible for significant hospitalizations, morbidity, and mortality in infants less than 24 months of age who have chronic lung disease, congenital heart disease, compromised respiratory or immune systems, or impaired nutritional status and growth. (51, 87, 92)

D. Candidates for RSV Prophylaxis: Areas where robust data exist.

"Risk reduction in the larger cohort, including term newborns from administration of nirsevimab-alip (BEYFORTUS), is anticipated, subject to supply considerations. Although palivizumab (SYNAGIS) may be safe for term infants with no underlying co-morbidities, immunization of otherwise healthy term infants is considered outside the accepted FDA indication for palivizumab (SYNAGIS)."

1. All infants whose mothers did not receive vaccination and who do not otherwise have a contraindication for the administration of palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS)
2. Infants with bronchopulmonary dysplasia (BPD) or chronic lung disease (CLD) will benefit from RSV prophylaxis using either palivizumab(SYNAGIS) or nirsevimab-alip (BEYFORTUS).
    a. BPD may be defined by oxygen requirement at 36 weeks corrected gestational age or at 28 days, regardless of the birth gestational age.
    b. CLD includes these infants and others who have subsequently developed an oxygen requirement or other pulmonary condition requiring treatment or close medical observation.
    c. Infants with CLD/BPD who are less than 24 months of age at the start of the RSV season and who have required intervention or maintenance therapy for their BPD/CLD within six months of the start of the RSV season will benefit from RSV prophylaxis. The administration of palivizumab (SYNAGIS) in a previous month may be sufficient to qualify for administration in a subsequent qualified month.
    d. Other interventions for CLD/BPD may include the use of corticosteroid preparations, methylxanthines (e.g., aminophylline or caffeine), supplemental oxygen, bronchodilators, home apnea monitoring, home pulse oximetry, or diuretics. (84, 93, 94)
3. Infants born at 32 wGA or less without CLD/BPD will also benefit from prophylaxis. (95) Maternal vaccination generally occurs after this gestation and should not be a factor in guiding prophylaxis.
    a. Infants born at less than 28 0/7 wGA will

benefit from prophylaxis if they are less than 12 months of age at the start of the RSV season. Infants born during RSV season who are less than 12 months of age at the start of the subsequent RSV season are still candidates for prophylaxis. Although all of these babies qualify for nirsevimab-alip (BEYFORTUS), management in the neonatal intensive care unit and continuous positive airway pressure in this cohort to promote lung growth will qualify these infants for palivizumab (SYNAGIS).

b. Infants born at 28 0/7-32 0/7 wGA will benefit most from prophylaxis if they are less than six months of age at the start of RSV season if only palivizumab (SYNAGIS) is available; however, their course in the neonatal intensive care unit should be evaluated carefully. These patients are eligible for nirsevimab-alip (BEYFORTUS) for up to 12 months.

"Infants born at a late preterm gestation (34 0/7-36 6/7 wGA) may merit special consideration. (96-98) However, prophylaxis with palivizumab (SYNAGIS) for infants born at 32 1/7-35 6/7 wGA should be reserved for those infants with additional risk factors that increase the risk of RSV exposure or morbidity from RSV disease. These infants are eligible for nirsevimab-alip (BEYFORTUS) for up to 12 months."

4. Infants born at a late preterm gestation (34 0/7-36 6/7 wGA) may merit special consideration. (96-98) However, prophylaxis with palivizumab (SYNAGIS) for infants born at 32 1/7-35 6/7 wGA should be reserved for those infants with additional risk factors that increase the risk of RSV exposure or morbidity from RSV disease. These infants are eligible for nirsevimab-alip (BEYFORTUS) for up to 12 months.

    a. An RSV relative risk scale has been proposed and may be helpful to the practitioner in identifying at-risk patients who may benefit from RSV prophylaxis. (99) A neonatologist, pediatrician, or other primary care provider is often best positioned to assess and interpret relative risk factors. Universal prophylaxis with nirsevimab-alip (BEYFORTUS) is consistent with the FDA indication. Where supply is limited, consideration should be given to whether the patient is eligible for palivizumab (SYNAGIS).

    b. The most consistently identified factors that are associated with increased risk of RSV disease are childcare attendance, school-aged siblings, twin or greater multiple gestation, young chronological age at the start of RSV season, and parental smoking; however, exposure to environmental air pollutants, congenital abnormalities of the airways, or severe neuromuscular disease may also justify concern. (65, 93, 100-103) Correlations exist between air quality and respiratory function. (64, 102-112) Thus, environmental air quality assessment is vital for these patients with special consideration given the unique circumstances of unwarranted air pollution, such as residence near a bus station or industrial plant or use of a wood-burning or coal-burning stove as a primary heat source. Efforts to reduce risk by isolation of the at-risk child, smoking cessation strategies for the parents/caregivers, or relocation to an area with cleaner air may not be practical or workable.

    c. Certain risk factors may have a more significant impact based on the level of exposure (i.e., one school-aged sibling versus three school-aged siblings in three different schools); however, no identifiable risk factor is unique in its predictive value, and frequently many risk factors may exist simultaneously. (64, 86) The greater the risk factors, the higher the likelihood of RSV hospitalization. (113) A history of maternal smoking during pregnancy may be ameliorated as a risk factor by a history of breastfeeding for greater than two months. (106, 114-117) The risk assessment must account for these circumstances.

"The provider must know the risk created and enhanced by diversity, equity, and inclusion (DEI) based disparity. Minority African American and Hispanic populations in blighted inner-city neighborhoods are at a higher cumulative risk. (44) "

    d. The provider must know the risk created and enhanced by diversity, equity, and inclusion (DEI) based disparity. Minority African American and Hispanic populations in blighted inner-city neighborhoods are at a higher cumulative risk. (44)

    e. After assessment of an individual patient, if a provider determines that the patient is at high risk for RSV disease complicated

by hospitalization, prophylaxis should be provided. (118) Planning for prophylaxis must begin before discharge if the at-risk patient has been hospitalized for any conditions that have a known association with increased risk. In one study, more than 50% of eligible patients received no prophylaxis before or after discharge. (119) Lack of parental education, language difficulties, transportation challenges, vaccines for children access and potential problems with insurance coverage must be resolved before the patient's discharge home. (120-122)

f. The cost of prophylaxis should be weighed against the risk of severe RSV disease requiring hospitalization and associated costs to the family, as well as the potential for long-term sequelae. Direct costs are not the only expenses involved in the long-term care of a child who has had RSV. Costs associated with loss of family income with a parent taking time off for initial hospitalization and later to care for a child with chronic disability, frequent follow-up appointments, and indirect costs involved in providing support for developmental disability, as well as loss of academic potential, must also be considered. (123-126)

"Infants with congenital heart disease have been shown to benefit from palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS). (51, 127-129) The degree and severity of the heart disease may factor into the decision to provide RSV prophylaxis. Cyanotic heart disease places a patient at considerable risk since oxygen delivery is already compromised."

5. Infants with congenital heart disease have been shown to benefit from palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS). (51, 127-129) The degree and severity of the heart disease may factor into the decision to provide RSV prophylaxis. Cyanotic heart disease places a patient at considerable risk since oxygen delivery is already compromised. Although acyanotic heart disease has been shown to increase the relative risk for RSV-related hospital admission to even higher than that of cyanotic disease, admission rates of palivizumab (SYNAGIS)-immunized infants are similar in both categories. (51) Infants with complex congenital heart disease are at risk. They should be considered for RSV prophylaxis, including babies with hypoplastic left or right heart syndrome, truncus arteriosus, tetralogy of Fallot, pulmonary atresia, transposition of the great arteries, interrupted aortic arch, ventricular septal defect or patent ductus arteriosus with demonstrated heart failure, cardiomyopathies, arrhythmias capable of causing hemodynamic compromise, and infants who are candidates for potential heart transplant. Children who are post-cardiac transplantation are in a particularly high-risk group and should be given RSV prophylaxis. (127, 129, 130) No data suggests that patients cannot receive prophylaxis in the second RSV season with palivizumab (SYNAGIS) if nirsevimab-alip (BEYFORTUS) is unavailable. To exclude an infant from receiving palivizumab (SYNAGIS) in the absence of nirsevimab-alip (BEYFORTUS), the infant must have a documented waiver provided by a board-certified pediatric cardiologist, which documents that their cardiac defect is hemodynamically insignificant and poses no additional risk for RSV. During RSV season, children who have received Extracorporeal Membrane Oxygenation (ECMO) or any other form of cardiac bypass should receive monthly prophylaxis. If the baby is receiving palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) during the active RSV season, an extra dose of prophylaxis or a series of prophylaxis should be considered as soon as the baby comes off bypass support. (131)

"During RSV season, children who have received Extracorporeal Membrane Oxygenation (ECMO) or any other form of cardiac bypass should receive monthly prophylaxis. If the baby is receiving palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) during the active RSV season, an extra dose of prophylaxis or a series of prophylaxis should be considered as soon as the baby comes off bypass support. (131)"

E. Candidates for RSV Prophylaxis: Areas where decisions regarding the appropriateness of RSV prophylaxis must be individualized during the second season.

1. Infants with severe neuromuscular disease affecting respiratory function (e.g., myotonic or muscular dystrophy) may be candidates for palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) prophylaxis, including those with neuromuscular maturational disease common in premature infants. (132) CNS injury prior to,

during, or after delivery including, but not limited to, intraventricular hemorrhage (IVH), hypoxic-ischemic encephalopathy (HIE), spinal cord injury, disease of the peripheral nervous system, disease of the neuromuscular junction, and periventricular leukomalacia (PVL) are all possible indications for RSV prophylaxis. (92, 94, 132) IVH, HIE, and PVL may cause cerebral palsy (CP) later. CP alone may qualify an infant for RSV prophylaxis if there is any association with impaired respiratory function. (133, 134)

2. Patients with congenital abnormalities of the airways that compromise respiratory function should receive prophylaxis. (80, 135-138) Other respiratory viruses may also be implicated in morbidity, including persisting wheeze, symptomatology and family history that suggests the possibility of later asthma or disorders of abnormal lung growth. (66) Congenital diaphragmatic hernia is included in this category. Although large-scale randomized control trials have not been performed, patients with surfactant protein deficiencies may also benefit from prophylaxis, as may infants with childhood interstitial lung diseases such as neuroendocrine hyperplasia of infancy (NEHI) or pulmonary interstitial glycogenosis (PIG).

3. Although large-scale randomized control trials in patients with individual at-risk respiratory disorders have not been performed, patients with cystic fibrosis and other diseases such as α1-antitrypsin deficiency where there is a genetic basis for changes in the lung milieu may also benefit from prophylaxis. (139) Respiratory symptomatology is not generally associated with α1-antitrypsin deficiency during infancy; based on pulmonary involvement, palivizumab (SYNAGIS) may only be considered if the respiratory compromise is associated with another qualifier (e.g., prematurity). (140) Primary Ciliary Dyskinesia may also be an indication of prophylaxis. (141) Identification of cystic fibrosis on a newborn screen may merit special consideration. (136, 139, 142-144) Cystic fibrosis occurring with transient infantile wheezing has been associated with worse lung function in later life, and RSV is the most common cause of transient infantile wheezing. (145) Infants who would otherwise qualify for palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) based on the indication should be screened for cystic fibrosis if the clinical course and history indicate.

4. Immune deficiencies are rare disorders and require collaborative management by pediatricians, infectious disease specialists, and immunologists. (146, 147) HIV, SCID, primary or secondary bone marrow depletion, and any defect of humoral or cellular immunity, including that occurring with transplantation, place a patient at risk of severe infection. Palivizumab (SYNAGIS) prophylaxis has been associated with improved survival after bone marrow transplantation. (148) Data do not exist for nirsevimab-alip (BEYFORTUS). Although no conclusive evidence exists for any particular disease category, RSV prophylaxis is indicated because of the understood high risk of any infectious process unless a waiver can be obtained from a board-certified pediatric immunologist or infectious disease specialist.

5. Certain genetic diseases may place a patient at more cumulative risk for RSV. For the present time, patients should receive prophylaxis to the extent that other qualifiers are met. However, including infants with Trisomy 21 in the recommendations for immunoprophylaxis of RSV disease should be considered. (149)

6. Exceptional risk circumstances may occur in homes where another individual is at high risk for RSV infection (e.g., an elderly immunocompromised relative) who may not be able to receive RSV prophylaxis or vaccination (i.e., less than age 60). Although palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) do not prevent RSV infection, decreased cough and aerosolization of RSV may provide some protection. Providers should determine if providing prophylaxis to other household members is reasonable. (26, 150, 151)

"Although palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) do not prevent RSV infection, decreased cough and aerosolization of RSV may provide some protection. Providers should determine if providing prophylaxis to other household members is reasonable. (26, 150, 151)"

F. Administration (See Table 1.)

1. The National Perinatal Association Guidelines for RSV Prophylaxis are interdisciplinary peer-reviewed and evidence-based guidelines but do not represent the sole management criteria for medical care of at-risk infants. Depending on individual case presentations, in selected populations and unique circumstances, these recommendations may not apply. There is no substitute for the clinical judgment of a neonatologist, pediatrician, nurse practitioner, or other licensed provider of pediatric services.

2. RSV prophylaxis should be initiated prior to the onset of the RSV season and terminated at the end of the RSV season. (30, 152, 153) Although regional variations exist in the United States, RSV outbreaks begin as early as October and decrease between March and May. During the COVID-19 pandemic, disruptions in RSV seasonality occurred regularly. (21) Providers

should review local historical RSV surveillance data to assist in decision-making. Some locales in the Southern United States (e.g., Florida), Hawaii, and Alaska have a high enough incidence of RSV to justify initiation in the late summer months and continuation of monthly prophylaxis into the late spring. (154-158) Transport distance of ill infants and resource allocation, as well as socioeconomic factors (e.g., lack of running water), may be considered in the justification of enhanced RSV prophylaxis coverage where the costs to provide hospitalization for patients at great distances greatly exceed that of most urban locales (e.g., Alaska and Canadian Arctic). (159) The burden of severe RSV disease on healthcare resources is more significant than other respiratory viruses. (160) Although various cost containment models have been proposed to provide relative risk adjustment based on post-conceptual age at a specific month during RSV season, there is a risk that adequate levels of palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) will not be achieved or maintained during months when RSV is widespread using this type of model. (24, 36, 153, 161) Use of an abbreviated schedule of RSV prophylaxis is contrary to published evidence and FDA-approved product indication for palivizumab (SYNAGIS) and nirsevimab-alip (BEYFORTUS) and is strongly discouraged. (162) Recent issues with COVID-19 and shifting of RSV seasonality may change the demographic, resulting in a prolonged duration of risk, risk during the summer months, or a season with no identified RSV-related risk. In these situations, a modified schedule may be considered. Although second-season data is available for nirsevimab-alip (BEYFORTUS) after initial palivizumab (SYNAGIS), data does not exist for palivizumab (SYNAGIS) following nirsevimab-alip (BEYFORTUS). A risk-based model should be considered when there is a shortage of supply.

"Although second-season data is available for nirsevimab-alip (BEYFORTUS) after initial palivizumab (SYNAGIS), data does not exist for palivizumab (SYNAGIS) following nirsevimab-alip (BEYFORTUS). A risk-based model should be considered when there is a shortage of supply."

3. Once an infant begins RSV prophylaxis for the RSV season, if the infant does not receive an initial dose of nirsevimab-alip (BEYFORTUS), the infant must receive palivizumab (SYNAGIS) monthly through the end of the season unless a subsequent dose of nirsevimab-alip (BEYFORTUS) is given. (49)
4. During the first season, nirsevimab-alip (BEYFORTUS) 50 mg IM as a single injection or Palivizumab (SYNAGIS) 15 mg/kg IM monthly should be given during the RSV season to increase the likelihood of achieving and maintaining appropriate levels for prophylaxis. (90) A dose should be given 24-48 hours before discharge from the hospital if the patient meets the criteria or at the earliest possible interval well child appointment before the start of the season. (90) If a second season is indicated, nirsevimab-alip (BEYFORTUS) dosing is increased to 200 mg IM as a one-time injection.

"Although prophylaxis during active infection will not impact the course of the symptomatology, RSV disease is not a contraindication to continuing palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) prophylaxis. Infection does not confer lasting immunity. "

5. Although prophylaxis during active infection will not impact the course of the symptomatology, RSV disease is not a contraindication to continuing palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) prophylaxis. Infection does not confer lasting immunity. There is more than one genotype of RSV. Although less common, patients can be re-infected with RSV multiple times during the same RSV season. Thus, one-time dosing with nirsevimab-alip (BEYFORTUS) or monthly dosing with palivizumab (SYNAGIS) should be continued even if the patient has been infected with RSV.(90)
6. Fever or other illnesses, including viral syndromes such as COVID-19, are not contraindications to administering palivizumab (SYNAGIS), nirsevimab-alip (BEYFORTUS), or another monoclonal antibody.
7. There are no restrictions on concurrent RSV prophylaxis with any immunization. (163) Immunization with Measles-Mumps-Rubella (MMR) and Varicella vaccines need not be deferred in infants receiving RSV prophylaxis. RSV prophylaxis does not interfere with the Hepatitis B vaccine, Diphtheria, Tetanus, Pertussis (DTaP) primary immunization schedule, H. Influenza type B (Hib), seasonal influenza vaccination, Pneumococcal Conjugate Vaccine (PCV), or Inactivated Poliovirus Vaccine (IPV).
8. The safety and efficacy of palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) have not been demonstrated for treating established RSV

disease. RSV prophylaxis does not alter an active RSV infection's disease severity or course.

9. Contraindications and Adverse Reactions

   a. Palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) should not be used in pediatric patients with a history of a severe prior reaction to RSV prophylaxis. (90) It is unknown whether a history of a severe prior reaction to one will crossover to the other.

   b. Fever, irritability, and injection site reactions are the most commonly reported adverse events. (164)

V. Nosocomial Infection

   A. RSV may be horizontally transmitted in the hospital setting and causes severe disease in high-risk infants and young children.

   B. The best way to prevent RSV disease is strict adherence to infection control practices and in-hospital screening studies to identify and isolate RSV-infected infants. (77) Proper hand washing is of paramount importance.

"Cohorting of children with suspected RSV disease is not recommended. Not only are there other contagious viral and bacterial diseases that mimic RSV, but infection with RSV does not preclude co-infection with bacteria, other viruses, or another subgroup of RSV. The advice of infectious disease and hospital-based infection control experts should be obtained to manage suspected nosocomial outbreaks of RSV occurring within a pediatric ward, pediatric critical care unit, or neonatal intensive care unit. (77, 165)"

   C. Cohorting of children with suspected RSV disease is not recommended. Not only are there other contagious viral and bacterial diseases that mimic RSV, but infection with RSV does not preclude co-infection with bacteria, other viruses, or another subgroup of RSV. The advice of infectious disease and hospital-based infection control experts should be obtained to manage suspected nosocomial outbreaks of RSV occurring within a pediatric ward, pediatric critical care unit, or neonatal intensive care unit. (77, 165)

VI. Using palivizumab (SYNAGIS) or nirsevimab-alip (BEYFORTUS) outside of the FDA indications constitutes off-label use (12, 19)

   A. Off-label use of any medication places the provider at medico-legal risk. The FDA's Center for Drug Evaluation and Research (CDER) has initiated the Bad Ad outreach program to encourage healthcare providers to recognize and report suspected untruthful or misleading drug promotion. "Assuring prescription drug information is truthful, balanced, and accurately communicated" is the intent. Led by the Division of Drug Marketing Advertising and Communications (DDMAC), this effort informs providers about what constitutes misleading promotion and provides a process for reporting suspected violations to the FDA. Violators may include state or professional organizations, those who may profit by modifying FDA-approved dosing or indications for a medication, manufacturers, or individuals who make unrealistic claims about the enhanced action of a medication. There is no safe harbor for government-sponsored organizations that make recommendations outside the FDA indication (e.g., Advisory Committee on Immunization Practices).

   B. Reports can be initiated by contacting the United States Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications at 855-RX-BADAD or (855-792-2323), E-Mail: BadAd@fda.gov, by mail: FDA/CDER/DDMAC, 5901-B Ammendale Rd., Beltsville, MD 20705-1266, or Fax: 301-847-8444.(166) In the past, however, the FDA has not had the resources to act quickly on reports of wayward drug misinformation. The False Claims Act provides another alternative to the Bad Ad outreach program. This fraud-fighting law not only provides substantial rewards for whistleblowers but also includes an action-enforcing mechanism that statutorily requires the government to investigate allegations of fraud. If providers want to ensure that the government will consider their concerns, a False Claims Act *qui tam* action may be filed.

"Reports can be initiated by contacting the United States Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications at 855-RX-BADAD or (855-792-2323), E-Mail: BadAd@fda.gov, by mail: FDA/CDER/DDMAC, 5901-B Ammendale Rd., Beltsville, MD 20705-1266, or Fax: 301-847-8444.(166) In the past, however, the FDA has not had the resources to act quickly on reports of wayward drug misinformation."

Table 1. Proposed Strategy for RSV Prophylaxis

Prophylaxis Indication	Chronological Age	Dosing
Areas Where Strong Data Exist		
Born at < 28 0/7 weeks' gestational age (wGA)	Less than 12 months at the start of the RSV season	Nirsevimab (BEYFORTUS) once or palivizumab (SYNAGIS) monthly during the RSV season
Born at 28 0/7-32 0/7 wGA	1. Less than 12 months at the start of the RSV season 2.Less than six months at the start of the RSV season	1. Nirsevimab (BEYFORTUS) once or 2. palivizumab (SYNAGIS) monthly during the RSV season
Born at 32 1/7-35 6/7 wGA	1. Less than 12 months at the start of the RSV season 2. Less than six months at the start of RSV season with significant provider-identified risk factors	1. Nirsevimab (BEYFORTUS) once or 2. palivizumab (SYNAGIS) monthly during the RSV season
Born at 36 wGA or greater, no other risk factors	Less than 12 months at the start of the RSV season	Maternal RSVpreF (ABRYSVO) (first season) or nirsevimab (BEYFORTUS) once
Chronic lung disease requiring medical management	Less than 24 months at the start of the RSV season	Maternal RSVpreF (ABRYSVO) (first season) or nirsevimab once or palivizumab (SYNAGIS) monthly during the RSV season
Hemodynamically significant congenital heart disease	Less than 24 months at the start of RSV season unless a cardiology waiver is obtained	RSVpreF (ABRYSVO) (first season) or nirsevimab once or palivizumab (SYNAGIS) Monthly during the RSV season
Areas Where Individualized Guidance is Indicated		
Neuromuscular disease affecting respiratory function	Less than 24 months at the start of the RSV season	RSVpreF (ABRYSVO) (first season) or nirsevimab once or palivizumab (SYNAGIS) Monthly during the RSV season
Congenital abnormalities of the airways (e.g., Congenital Diaphragmatic Hernia)	Less than 24 months at the start of the RSV season	RSVpreF (ABRYSVO) (first season) or nirsevimab once or palivizumab (SYNAGIS) Monthly during the RSV season
Immune disorders (e.g., HIV, SCID, DiGeorge, IgA deficiency, Hypergammaglobulinemia)	Less than 24 months at the start of RSV season unless infectious disease or immunology waiver is obtained	RSVpreF (ABRYSVO) (first season) or nirsevimab once or palivizumab (SYNAGIS) monthly during the RSV season
Cystic Fibrosis, Primary Ciliary Dyskinesia, or other rare lung disease resulting in chronic respiratory insufficiency	Less than 24 months at the start of RSV season; consultation with pediatric pulmonology suggested	RSVpreF (ABRYSVO) (first season) or nirsevimab once or palivizumab (SYNAGIS) monthly during the RSV season

The MEDLINE database, the Cochrane Library, and the National Perinatal Association's internal resources and documents were used to search the literature to identify relevant articles published on Respiratory Syncytial Virus (RSV). The search was restricted to articles published in the English language. Priority was given to the outcomes of the original research. Review articles and commentaries were also consulted when their inclusion added substantively to the guidance. Abstracts of research presented at scientific conferences were eligible for inclusion in this document if the abstract was peer-reviewed prior to its publication. Guidelines published by other organizations were evaluated for merit and included where their inclusion was both elucidative and topical. Further, sources from the bibliographies of these guidelines were evaluated and included where appropriate. While necessary for interpreting the studies, expert opinion was not judged to be valid independently without substantiating high-level evidence.

Studies were evaluated for quality using the metric provided by the United States Preventive Services Task Force (167, 168)

I. Evidence obtained from at least one properly designed randomized controlled trial.

II-1. Evidence obtained from well-designed controlled trials without randomization.

II-2. Evidence is obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3. Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III. Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations based on good and consistent scientific evidence.

Level B – Recommendations based on limited or inconsistent scientific evidence.

Level C – Recommendations based largely on consensus and expert opinion

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Disclosures: *There are no reported disclosures*

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The Indirect Impact of **RSV**

NCfIH National Coalition for Infant Health
Protecting Access for Premature Infants through Age Two

OVERVIEW

RSV impacts not only infants and young children, but also entire families.

The National Coalition for Infant Health and the Alliance for Patient Access sought to examine the multifaceted burden that RSV places on families and to identify potential policy solutions.

Two surveys were conducted, one of parents who had at least one child contract RSV and one of health care providers who treat infants and children with RSV.

Both surveys were conducted with YouGov, a global public opinion and data company. Parents and providers were recruited from a pool of pre-selected respondents to ensure they met the survey's requirements. Participants received an honorarium.

RSV PARENT SURVEY

340 parents who had at least 1 child sick with RSV

67% of parents said their child was hospitalized for RSV

RSV HEALTH CARE PROVIDER SURVEY

175 health care providers across various pediatric and neonatal subspecialties

67% worked in an outpatient facility

33% worked in a hospital

RESULTS

FINANCIAL BURDEN

More than ⅔ of parents said the costs of RSV posed a financial burden or financial crisis.

7% of parents said they were fired as a result of caring for their child with RSV.

32% of parents reported losing potential income while their child had RSV.

EMOTIONAL BURDEN

68% of parents said watching their child suffer affected their mental health.

69% of parents felt guilty that they could not do more to prevent their child's RSV.

When parents found out there was no treatment for RSV, only supportive care:

- **48%** felt angry
- **46%** felt helpless

SOCIAL BURDEN

43% of parents had never heard of RSV before finding out their child was sick.

54% of parents had to rely on family and friends for sibling care, transportation and other responsibilities.

42% of parents said they struggled to care for their other children when one faced RSV.

RESULTS

PARENT EDUCATION & AWARENESS

86% of providers said they include RSV education as part of routine care.

99% of providers agreed that parents need more information about RSV.

TREATMENT CHALLENGES

Nearly ⅓ of providers have been reluctant to test for RSV because no treatment exists.

48% of providers said it was difficult to decide whether to send an infant or child with RSV to the emergency room.

92% agreed that if an immunization were available, it should be added to the Vaccines for Children program's list of pediatric vaccines.

MISCONCEPTIONS

A majority of providers (60%) explained that around 50% or more of the babies they see hospitalized for RSV were born healthy, despite many people thinking severe RSV only impacts premature infants or those with preexisting conditions.

CONCLUSION

Both surveys highlighted that the burden of RSV extends well beyond its physical symptoms.

The virus may lead to:

- **Long-lasting health challenges** for babies and young children
- **Financial, social and emotional burdens** for families
- **Frustration for providers,** who lack a cure or viable preventive interventions

This burden is not experienced by the few. Most infants and children contract RSV by the time they are two, and challenges that accompany RSV may impact anyone who has been affected.

Moving forward, the many burdens of RSV demonstrate the need for:

- **More RSV education**
- **Research and innovation** for preventive interventions
- **Access to prevention and treatment** for all babies and children

The challenges caused by RSV can reach far and wide, and its indirect impacts often leave families struggling.

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Which Infants are More Vulnerable *to Respiratory Syncytial Virus?*

RSV is a respiratory virus with cold-like symptoms that causes 90,000 hospitalizations and 4,500 deaths per year in children 5 and younger. It's 10 times more deadly than the flu. For premature babies with fragile immune systems and underdeveloped lungs, RSV proves especially dangerous.

But risk factors associated with RSV don't touch all infants equally.*

*Source: Respirator Syncytial Virus and African Americans

Caucasian Babies	Risk Factor	African American Babies
11.6%	Prematurity	18.3%
58.1%	Breastfeeding	50.2%
7.3%	Low Birth Weight	11.8%
60.1%	Siblings	71.6%
1%	Crowded Living Conditions	3%

AFRICAN AMERICAN BABIES bear the brunt of RSV. Yet the American Academy of Pediatrics' restrictive new guidlines limit their access to RSV preventative treatment, increasing these babies' risk.

AfPA

15 Trees to Negate the CO_2 Effect of Living #15treesformylife

Minesh Khashu MD, MBBS, FRCPCH

"I'm not here today wanting to talk to you about my work as a neonatologist, as a professor of perinatal health, or some of the other roles I play. I want to talk to you about something I was much before I became a neonatologist, much before I became a professor of perinatal health, and that is my role as a human being."

Namaskar,

This is the traditional Indian greeting. What does this greeting mean? I'll discuss it some other time. Today, I need a few minutes, just a few minutes of your vast lifetime, to talk to you about something fundamental.

I'm not here today wanting to talk to you about my work as a neonatologist, as a professor of perinatal health, or some of the other roles I play. I want to talk to you about something I was much before I became a neonatologist, much before I became a professor of perinatal health, and that is my role as a human being.

As a human, as part of a species, as part of an inhabitant of this lovely mother earth, I want to talk to you about something essential for all of us: the sustainability of ourselves as a species and our sustainability on planet Earth.

"An intelligent guy has calculated that looking at an average human life, the amount of CO_2 we produce just for our part as living creatures on this planet, we would need about 15 trees to negate that CO_2 effect."

As you know, one of the common ways we discuss sustainability is through carbon dioxide emissions, or CO_2 emissions, as we call them. When most people talk about CO_2 emissions, they talk about industrialization, fossil fuels, and us flying to different parts of the globe. These are essential aspects of CO_2 emissions, but an important, and perhaps a more critical aspect of CO_2 emissions is our emissions for just being alive. As an animal species, we breathe in oxygen and throw out CO_2. Without doing anything else, just standing still in one place would still add CO_2 to this planet.

An intelligent guy has calculated that looking at an average human life, the amount of CO_2 we produce just for our part as living creatures on this planet, we would need about 15 trees to negate that CO_2 effect. Forgetting everything we do to generate CO_2 emissions, if we get started on negating the CO2 emissions we generate for breathing and being alive, we should plant at least 15 trees in our lifetime.

"Please think about this and pledge to plant at least 15 trees in your lifetime to negate the CO_2 emissions you have generated for being alive. That's the least we can do for this planet; the pledge would be 15 trees for my life. So, #15treesformylife."

Please think about this and pledge to plant at least 15 trees in your lifetime to negate the CO_2 emissions you have generated for being alive. That's the least we can do for this planet; the pledge would be 15 trees for my life. So, #15treesformylife.

Please share this message with others and follow me for similar content. I wish you all the best, Namaste.

Thank you. #15treesformylife

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Disclosure: *The author has no conflicts of interests to disclose.*

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Peer Reviewed

Ethics and Wellness Column: Grit and Wellness in Neonatology: The Path to Leadership and Career Fulfillment

Mitchell Goldstein, MD, MBA, CML, T. Allen Merritt, MD, MHA

Introduction:

Neonatology is a demanding field and professional calling that requires unwavering commitment, resilience, and a deep sense of purpose. In pursuing excellence, healthcare professionals in Neonatology often find that grit plays a pivotal role in their success. This essay explores the intersection of grit and wellness in Neonatology, emphasizing the importance of commitment, perseverance, selflessness, and leadership in achieving professional success and personal fulfillment. No formula or matrix of these qualities and varying attributes fits everyone. (1) These qualities are inculcated during the fellowship.

"Neonatology is a demanding field and professional calling that requires unwavering commitment, resilience, and a deep sense of purpose. In pursuing excellence, healthcare professionals in Neonatology often find that grit plays a pivotal role in their success."

Grit in Neonatology:

In Neonatology, success is not solely determined by academic prowess or innate intelligence, instead, it hinges on the capacity to be more committed to patients, their parents, as well as colleagues. Those who excel in this discipline work harder, persevere longer, and are willing to sacrifice their time for a noble cause – and the well-being of newborns and their families. Grit in Neonatology goes beyond mere aptitude; it is characterized by fortitude and unwavering determination to overcome challenges, adversities, and emerging threats to their professional autonomy. (2, 3)

"Grit in Neonatology goes beyond mere aptitude; it is characterized by fortitude and unwavering determination to overcome challenges, adversities, and emerging threats to their professional autonomy. (2, 3)"

Leadership Through Example:

Grit is exemplified in the ability to endure and demonstrate leadership through example. While servant leadership is crucial, the true mark of a leader in Neonatology is the ability to endure and persevere when faced with challenges in clinical care, critical analysis of new information, and the encroachment of DRG payment systems. This endurance not only garners support but also establishes a leader's credibility and true potential. Grit in this context is not about being tough; it is about being a caring, compassionate, genuine advocate for neonatal well-being and not backing down in the face of adversity. (1, 3, 4)

"This endurance not only garners support but also establishes a leader's credibility and true potential. Grit in this context is not about being tough; it is about being a caring, compassionate, genuine advocate for neonatal well-being and not backing down in the face of adversity. (1, 3, 4)"

Success and Grit:

Ultimately, success in Neonatology is often synonymous with possessing grit. Leaders in this field understand the context, the stringent requirements, and the imperative to complete tasks despite numerous obstacles. Grit drives their success, propelling them to navigate complex medical scenarios, advocate for vulnerable patients, and inspire their teams to strive for excellence. (5)

"While grit is essential for success in Neonatology, it is equally important to couple it with wellness. In this context, wellness is not just about achieving a degree of work-life balance; it involves shaping a career that aligns with one's personality and ambitions while fostering leadership potential."

Coupling Grit with Wellness:

While grit is essential for success in Neonatology, it is equally important to couple it with wellness. In this context, wellness is not just about achieving a degree of work-life balance; it involves shaping a career that aligns with one's personality and ambitions while fostering leadership potential. A well-rounded healthcare professional in Neonatology understands the importance of self-care, mental well-being, and finding a harmonious balance between personal and professional life. (4)

"In Neonatology, grit and wellness are interwoven elements that shape successful leaders. The commitment to patients, enduring perseverance, and leadership through example are vital components of grit that distinguish leaders in this challenging field. (3,4) Wellness complements grit by ensuring that healthcare professionals maintain a healthy work-life integration, foster personal fulfillment, and sustain their passion for exceptional care for newborns and their families."

Conclusion:

In Neonatology, grit and wellness are interwoven elements that shape successful leaders. The commitment to patients, enduring perseverance, and leadership through example are vital components of grit that distinguish leaders in this challenging field. (3,4) Wellness complements grit by ensuring that healthcare professionals maintain a healthy work-life integration, foster personal fulfillment, and sustain their passion for exceptional care for newborns and their families. Ultimately, the fusion of grit and wellness creates a path to leadership excellence in Neonatology.

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Disclosure: *The authors have no conflicts of interests to disclose.*

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Letters to the Editor

Letter to the Editor: "Prevalence of and Factors Associated with Neonatal Seizures in the United States, 2016-2020"

Corresponding Author: Ramesh Vidavalur MD MBA FAAP Assistant Professor of Clinical Pediatrics Cayuga Medical Center/Weill Cornell Medicine

Dear Editor,

We want to congratulate and acknowledge the work done by Vadavalur et al. regarding their study entitled "Prevalence of and factors associated with neonatal seizures in the United States, 2016-2020." This project shed light on the notable antenatal, intrapartum, and infant risk factors most closely correlated with infant seizures across the country and reported a prevalence of 1 in 2500, which is not insignificant.

"We appreciate the strength of the study in the broad and reflective sample size and reliable sourcing through birth certificate registration. A sample size of 18,935,854 patients across four years is an adequate representation. However, our question to this authoring team lies in the stratification of these collected data."

We appreciate the strength of the study in the broad and reflective sample size and reliable sourcing through birth certificate registration. A sample size of 18,935,854 patients across four years is an adequate representation. However, our question to this authoring team lies in the stratification of these collected data. The study covered the prevalence of neonatal seizures across the entire United States, which, though comprehensive, does not consider the known variety in access to care between rural and urban communities or across state lines with differences in general and neonatal healthcare outcomes. Though the study claims no significant difference between state reports of neonatal seizures, according to the CDC Infant Mortality "Stats by States" Map (1), the state-to-state disparity between infant health outcomes from any cause is quite clear. For example, the map cites the highest current death rate (number of deaths per 1,000 live births) to be in Mississippi at 9.39% versus the lowest state death rate in North Dakota at 2.77%. We cannot help but wonder whether such a clear and significant difference in outcomes across states could in of itself be presented as a risk factor, along with the studies' other notable identified factors of birth prior to 28 weeks of gestation, 5-minute APGARs of less than 7, and maternal intrapartum disease states, as well as considering the overall infant mortality rate of 5.8% in infants with seizures.

"We propose expanding this study to analyze the effect of COVID-19 on infant seizure risk and compare whether the previous risk factors are altered or remain relevant in the face of a COVID-19 diagnosis antenatally, intrapartally, or of the infant."

It is also pertinent to discuss the possible impact of the COVID-19 pandemic on the prevalence of neonatal seizures and adverse outcomes such as maternal and fetal deaths. Maternal deaths alone in the United States increased from 754 in 2019 to 861 in 2020, a 56% increase, and again to 1178 in 2021, a 37% increase, and of those deaths, 102 in 2020 and 401 in 2021 were attributed to COVID-19 (2) which indicates a significant effect on the course of gestation and general health outcomes for the mother-child unit. We propose expanding this study to analyze the effect of COVID-19 on infant seizure risk and compare whether the previous risk factors are altered or remain relevant in the face of a COVID-19 diagnosis antenatally, intrapartally, or of the infant.

When discussing maternal health outcomes, it is vital to acknowledge disproportionate mortality rates across specific populations. According to Simpson et al., the maternal death rate among non-Hispanic Black women increased from 44.0 per 100,000 live births in 2019 to 55.3 in 2020 and 68.9 in 2021 (2). Additionally, the maternal death rate for Hispanic women went from 12.6 in 2019 to 18.2 in 2020 and 27.5 in 2021, while for non-Hispanic White women, it was 17.9 in 2019, 19.1 in 2020, and 26.1 in 2021 (2). It is evident that racial disparities widened as a result of the COVID pandemic; therefore, it would be interesting to compare the prevalence of neonatal seizures stratifying for differences across populations.

"Additionally, the maternal death rate for Hispanic women went from 12.6 in 2019 to 18.2 in 2020 and 27.5 in 2021, while for non-Hispanic White women, it was 17.9 in 2019, 19.1 in 2020, and 26.1 in 2021 (2). It is evident that racial disparities widened as a result of the COVID pandemic; therefore, it would be interesting to compare the prevalence of neonatal seizures stratifying for differences across populations."

In summary, we appreciate the author's work establishing a starting point in the quest for clarity on neonatal outcomes, particularly seizure risk. We hope to see an expansion of this work to cover

the effect of the COVID-19 pandemic on this risk and further development of the social, racial, and state-stratified risks to maternal and infant mortality that might be at play in parallel to this work. Above all, it remains clear that there is much to be desired in studying the environmental-maternal-fetal connection and that this work remains at the forefront of bettering healthcare for mothers and infants.

"We hope to see an expansion of this work to cover the effect of the COVID-19 pandemic on this risk and further development of the social, racial, and state-stratified risks to maternal and infant mortality that might be at play in parallel to this work."

Sincerely,

Grace Ahuja OMS-III, Melissa Kreutz OMS-III, Joshua Hernandez OMS-IV

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Subject: Editorial Response and Considerations on Vadavalur et al.'s study

Dear Grace Ahuja OMS-III, Melissa Kreutz OMS-III, Joshua Hernandez OMS-IV,

I appreciate the feedback provided on the study by Vadavalur et al., titled "Prevalence of and Factors Associated with Neonatal Seizures in the United States, 2016-2020." While I acknowledge your congratulations, I think addressing areas where further scrutiny is warranted is imperative.

The recognition of the study's significance in highlighting antenatal, intrapartum, and infant risk factors associated with neonatal seizures across the United States is duly noted. However, I find it necessary to critically evaluate the extent of the study's strength, particularly regarding the broad sample size and reliance on birth certificate registration. While a sample size of 18,935,854 patients over four years seems impressive, its adequacy hinges on the quality and representativeness of the data.

"The recognition of the study's significance in highlighting antenatal, intrapartum, and infant risk factors associated with neonatal seizures across the United States is duly noted. However, I find it necessary to critically evaluate the extent of the study's strength, particularly regarding the broad sample size and reliance on birth certificate registration."

The inquiry into the stratification of collected data aligns with concerns raised by the editorial team regarding the study's comprehensive scope. The failure to consider variations in access to care between rural and urban communities and disparities across state lines raises questions about the study's applicability and its potential oversight of significant regional variations. The assertion of no significant difference between state reports of neonatal seizures contradicts state-to-state disparities in infant health outcomes, as indicated by the CDC Infant Mortality "Stats by States" Map.

"The inquiry into the stratification of collected data aligns with concerns raised by the editorial team regarding the study's comprehensive scope. The failure to consider variations in access to care between rural and urban communities and disparities across state lines raises questions about the study's applicability and its potential oversight of significant regional variations."

The proposal to explore the impact of the COVID-19 pandemic on neonatal seizures is interesting. However, it prompts a more critical examination of the study's limitations in addressing contemporary influences. The surge in maternal deaths, particularly

those attributed to COVID-19, indicates a significant gap in the study's temporal relevance and its failure to capture the evolving landscape of neonatal health amid the ongoing pandemic.

I agree with your emphasis on acknowledging and addressing disproportionate mortality rates across specific populations, especially in the context of racial disparities exacerbated by the COVID-19 pandemic. However, questioning the study's effectiveness in presenting a comprehensive view of neonatal outcomes without a more explicit focus on the intersectionality of race and socioeconomic factors is necessary.

"I agree with your emphasis on acknowledging and addressing disproportionate mortality rates across specific populations, especially in the context of racial disparities exacerbated by the COVID-19 pandemic. However, questioning the study's effectiveness in presenting a comprehensive view of neonatal outcomes without a more explicit focus on the intersectionality of race and socioeconomic factors is necessary."

In summary, while I appreciate your engagement and recognize the study's potential, I urge a more critical examination of its limitations and a concerted effort to address the concerns raised. We anticipate that further data analysis may provide a more nuanced and contextually relevant exploration of neonatal health.

Sincerely,

Mitchell Goldstein, MD, MBA, CML

Editor in Chief

NEONATOLOGY TODAY

Loma Linda Publishing Company

A Delaware "not for profit" 501(c) 3 Corporation.

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Erratum (Neonatology Today December, 2023)

Neonatology Today is not aware of the erratum affecting the December, 2023 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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Neonatology Today welcomes your editorial commentary on previously published manuscripts, news items, and other academic 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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Navigating Toward Neonatology: Pediatric and Neonatal Seizure Considerations

Benjamin Hopkins, OSMIV, Elba Simon-Fayard, MD

"Welcome back to my third installment. My name is Benjamin Hopkins, and I am currently a fourth-year medical student at Western University of Health Sciences in Pomona, California. When 'I grow up,' I want to be a Neonatologist. Look at last month's journal for my previous article and follow along with this column as I navigate my way to becoming a Neonatologist."

Welcome back to my third installment. My name is Benjamin Hopkins, and I am currently a fourth-year medical student at Western University of Health Sciences in Pomona, California. When 'I grow up,' I want to be a Neonatologist. Look at previous months' journals for my earlier articles and follow along with this column as I navigate my way to becoming a Neonatologist.

Currently, I am interviewing for pediatric residency programs. Knowing that I am heading toward a fellowship, my application prioritized "Categorical pediatrics" programs with high match rates in Neonatology and programs that will offer me broad exposure to neonatal patients with close connections to multiple hospitals with different levels of neonatal ICUs.

I am currently rotating with a pediatric neurologist specializing in pediatric seizures. It has been a fantastic experience, with various "bread-and-butter" and complex patients and many unique patients in the inpatient and outpatient settings. The attending neurologist I work with is an excellent instructor who offers individualized patient care, exceptional treatment options, and education to each patient and their family. Most of my time was spent treating patients with chronic seizure disorders, along with general pediatric neurology consults.

One of my patients on this rotation is a young man with Juvenile Myoclonic Epilepsy (JME). JME is a seizure disorder that is characterized by myoclonus, absences seizures, and generalized tonic-clonic seizures and is most likely due to an underlying genetic defect (1). This patient had been dealing with JME since he was an adolescent, and only within the past six months has he gotten it under control with a good regimen of Depakote. Although this is a genetic-based disease, the only genetic testing that had been done was a Micro-array, which showed normal results. There was no further genetic workup at the parent's request, as the symptoms have been well controlled. Genetics plays a significant role in various disease processes and should always be considered part of the whole picture when treating pediatric patients with seizures. JME is a lifelong diagnosis and requires treatment even when asymptomatic (1). It is critical to assess and treat seizures of all types as soon and effectively as possible to mitigate potential damage to the brain.

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Neonatal and pediatric patients are both at risk for seizures and seizure-like activity from a variety of causes. Neonates in the first weeks of life have an increased susceptibility to seizures due to age-depend physiologic features of the developing brain, unique risk factors associated with gestation, delivery, and the immediate post-natal period, as well as a symptom of acute brain injury but are rarely due to neonatal-onset epilepsy syndromes (2, 3). Neonatal-onset epilepsy syndromes are often related to underlying structural, metabolic, or genetic disorders (3). Pediatric seizure patients' etiologies range from obvious masses to subtle gray matter heterotopias, in addition to metabolic and genetic disorders (4).

"Neonatal and pediatric patients are both at risk for seizures and seizure-like activity from a variety of causes. Neonates in the first weeks of life have an increased susceptibility to seizures due to age-depend physiologic features of the developing brain, unique risk factors associated with gestation, delivery, and the immediate post-natal period, as well as a symptom of acute brain injury but are rarely due to neonatal-onset epilepsy syndromes. Neonatal-onset epilepsy syndromes are often related to underlying structural, metabolic, or genetic disorders."

Neonatal seizures are harmful to a developing brain and can be a challenge to identify; in addition, pediatric seizures with status epilepticus carry a substantial risk for morbidity and mortality (2, 3, 5). Healthcare providers should have a high clinical suspicion for seizures in those with increased risk, even without prodromal

symptoms. Early identification and treatment are critical for short and long-term outcomes (3, 6). For suspected seizures, monitoring with electroencephalogram (EEG) should be started as soon as possible (2). EEG will help assess concerning events, screen for sub-clinical seizures, and measure the EEG background (2). In addition to EEG, computed tomography (CT) and magnetic resonance imaging (MRI) can be used to assess for masses, calcifications, cortical dysplasia, and ectopic gray matter (4).

"Neonatal seizures are harmful to a developing brain and can be a challenge to identify; in addition, pediatric seizures with status epilepticus carry a substantial risk for morbidity and mortality. Healthcare providers should have a high clinical suspicion for seizures in those with increased risk, even without prodromal symptoms. Early identification and treatment are critical for short and long-term outcomes."

Initial treatment for acute seizure is similar regardless of etiology; however, long-term treatment and prognosis vary greatly depending on underlying seizure etiology (3). Initial treatment for neonatal seizure is often phenobarbital, while for pediatric seizure, it is often a benzodiazepine (6). Current international guidelines indicate that antiseizure medication be administered as soon as possible but do not guide a specific timeline to follow (5). Numerous studies have shown that infants and pediatric patients who have a documented seizure via EEG and are treated within one hour of seizure onset have the lowest seizure burden and fewer additional seizures in the following 24 hours (6). Seizure burden is similar in those receiving antiseizure medication after the one-hour cutoff, regardless of length past the cutoff (6). Even though the relationship between seizure burden, treatment, and outcomes is not entirely understood, it has been observed that the higher the seizure burden, the worse the long-term outcomes (5, 6). This has been seen even after adjusting for possible confounders such as age, etiology, illness severity, therapeutic hypothermia status, age at initiation of EEG, and age of first seizure (5, 6).

Recognition of seizures remains a challenge, and undertreatment and overtreatment are an ongoing concern, as studies have documented that antiseizure medication can lead to neuronal apoptosis, poor brain development, and later cognitive impairments (2, 3, 6). As there are no clear protocols, neurologists, neonatologists, and pediatricians must develop a systemic approach to precise etiologies (2, 6). The relationship between seizures and outcomes is complex and will depend on numerous individual and generalized factors; however, with advances in genetic medicine, the option for personalized medicine will increase (3, 5). Each seizure must be evaluated for an individual etiology in parallel to treatment initiation; this can help streamline medical decision-making and optimize acute and chronic patient outcomes.

"Numerous studies have shown that infants and pediatric patients who have a documented seizure via EEG and are treated within one hour of seizure onset have the lowest seizure burden and fewer additional seizures in the following 24 hours. Seizure burden is similar in those receiving antiseizure medication after the one-hour cutoff, regardless of length past the cutoff. Even though the relationship between seizure burden, treatment, and outcomes is not entirely understood, it has been observed that the higher the seizure burden, the worse the long-term outcomes."

This month, I had the pleasure of talking with Dr. Elba Fayard, the current neonatal division chair at Loma Linda University Children's Hospital. We spoke about what makes a great neonatologist, critical care physicians' mental wellness and feeling of purpose, the current decreased interest in the NICU, and how to increase interest for future providers.*

1. **What qualities are "most essential" to excel as a neonatologist?**

Caring and having an extraordinary feeling for babies with tremendous needs. Those special heartstrings that people feel when they see little innocent babies suffering, those unique caring feelings that overwhelm you, cause you to think, "I want to help them." Compassion and caring that is primarily directed at innocent, powerless patients.

If you want to go more specifically to Neonatology, someone who thrives in details and likes high-stress situations with rapid outcomes. Type A personalities that enjoy being busy helping but also could work with teams. The work of a neonatologist is not solitary. They need to be humble enough to realize that they cannot do everything by themselves but be able to work with others, receive help and support, and find the common goal of helping the baby and their family.

"If you want to go more specifically to Neonatology, someone who thrives in details and likes high-stress situations with rapid outcomes. Type A personalities that enjoy being busy helping but also could work with teams."

Another is going from one patient to the next to see something much bigger than the baby. Which is the family around the baby; they are a unit with the baby itself. Then, in terms of timing, it is

just not here and now. I want to know how my current work will impact the future. All that will help the person to say, this is my work.

I like the track of intense work; it is very stressful and emotional at times, but as overpowered by that compassion and caring, I will selflessly try to work with others to help the baby, the family, and the kid for the future.

2. What do you now know that you wish you had known before going into Neonatology?

One thing now that I did not know before, and I wonder if it is good or not, is that technology is constantly changing. It is not just changing access and having increased knowledge but also leading to changes in the business model and health insurance.

Medicine, in general, is changing, and Neonatology is with it. A lot of business impacts Neonatology that was not there before. You see a lot of big institutions merging and a lot of decisions being made, not necessarily based on the better care or the best outcomes for the babies, but just on the survival of the institutions and the medical care that we need to deliver.

Other things that are very different from before are why physicians pick specialties; the reasons differ from what they used to be. If you pick Neonatology for financial reasons, you will be wrong. If you pick it for ease of living a well-balanced life, you must think twice. Decades ago, that did not necessarily impact our field, and we had a lot of good, excellent doctors going to Neonatology because of their passion for helping babies and taking care of babies and their passion for research. Attracting the new generations toward these goals is getting harder and harder. There are different priorities in life, and I do not know that I would have done something different, but it is different now.

"If you pick Neonatology for financial reasons, you will be wrong. If you pick it for ease of living a well-balanced life, you must think twice. Decades ago, that did not necessarily impact our field, and we had a lot of good, excellent doctors going to Neonatology because of their passion for helping babies and taking care of babies and their passion for research. Attracting the new generations toward these goals is getting harder and harder."

One thing I did not know I would have to do was how much I had to adapt to the changes in society, trainees, and medicine. I thought that whatever I saw in a new medical field would stay like that. Is it society, or is it all the issues we have had to encounter? Of course, COVID is on the top of that. It turned many things upside down, and recruiting trainees for our field is more challenging.

3. How are you drawing more people toward Neonatology because of the decreased interest in the field?

I love that question because we are constantly brainstorming about what I am saying. We are presented with different challenges, and we still believe this to be one of the best medical fields. We are trying to see how the new or future doctors make their choices in different ways than we did in our time. I'm not saying it's better or worse; it is just different. We need to learn to find those who love babies.

We are looking into getting more active with medical schools, for example, exposing the medical schools to these specialties. It's not something terrifying that you eventually are made to rotate through, and you are quivering in your knees to make sure you're not going to break the babies when you touch them, and they're not going to die on your watch. But to get you more acquainted with the good and the positive side of it, having more exposure early in the formation of the physician's training. We want to ensure they know this is out there because there are still people trying to become a physician with this passion for babies. If they were allowed to get more involved, for example, in rotations and electives where the students have more exposure to more direct interaction with the families, the parents, and doctors.

It is a similar thing with pediatricians. The direction in which the Board of Pediatrics and the pediatric residents are moving towards is more and more general pediatrics and outpatient. They think that is what they need to learn; they believe the need to learn in these intensive settings is a waste of time. Yet many people would like to be doing that for their lives and should be allowed to experience it. We are now trying to expose more students to Neonatology and have electives for the residents interested in going for fellowship.

"The direction in which the Board of Pediatrics and the pediatric residents are moving towards is more and more general pediatrics and outpatient. They think that is what they need to learn; they believe the need to learn in these intensive settings is a waste of time. Yet many people would like to be doing that for their lives and should be allowed to experience it. We are now trying to expose more students to Neonatology and have electives for the residents interested in going for fellowship."

Another possibility we are opening is that there could be a group of doctors and pediatricians who could not care less about research. Still, they are very passionate about taking care of babies. We are starting a program for neonatal hospitalists. It is a shorter program where you have more clinical experience with the neonates and then work in the NICU. You do not necessarily get the board of Neonatology, but you work with babies and their families, and if that is what you like, it is a beautiful life.

We are very actively coming up with ideas and changing the ways we do rotations and exposures from lectures to expose our students or residents sooner and support the ones that finish as pediatricians if this is something they would like to do without necessarily going through the fellowship. Those are ideas and things that we are trying to do to increase exposure and open

up different venues for people who would like to do this, not necessarily in the traditional way.

"Another possibility we are opening is that there could be a group of doctors and pediatricians who could not care less about research. Still, they are very passionate about taking care of babies. We are starting a program for neonatal hospitalists. It is a shorter program where you have more clinical experience with the neonates and then work in the NICU. You do not necessarily get the board of Neonatology, but you work with babies and their families, and if that is what you like, it is a beautiful life."

4. How do you think the critical care scenario of the NICU affects the chance of burnout? And how should we counter it?

If you look at statistics, yes, you could have a lot of burnout within physicians. Neonatologists and obstetricians have a high rate of burnout. I have a different view than other people too regarding burnout. People usually equate burnout with a lot of work. In my experience, that is one part of it, but it's not all of it, and I do not wonder if it is the most essential part of it. You get burnout when you do not get what you want. You work a lot and are exhausted, and you need to get out of it what you want.

It might accompany my spiritual life, but burnout correlates with a lack of purpose. When you do not feel that you are there with a special mission accomplishing something for somebody, you do not see why you work extra and get upset and tired. But if you finish your shift and stay an extra two hours to do an exchange transition because you wanted to learn it, and after that, you see the mother crying in the hallway, and you spend an extra half hour calming the mother down and giving them your heart and your mind. You go home with such a sense of satisfaction that if you have an hour less sleep than you wanted, the rest of your sleep will be worth it, and you will feel fulfilled, refreshed, and want to return.

The burnout person is unsatisfied and sees work as a burden, and they want to avoid returning. When you get up in the morning, and it gets tough to get to work, it is a moment to start thinking, what is the problem? Why am I so dissatisfied? It is not necessarily money, at least not all the time, and it's more than just the amount of work. It is what I am getting from it. My emphasis with my faculty and trainees is you have to know why you are here. You have to want to be here. You have to feel that you have been placed here with a purpose. Your purpose in life is to serve; you will be so happy when you do that with compassion, care, and love. That is not burnout that's going to get you down. Of course, that's easier said than done; we have ups and downs, and when we also lose a baby and we have not had a good rest for a whole week, you may cry, and you will need a little rest to recover. We are all human, flawed, you know. I could use purpose and service as the best antidotes for burnout.

Work-life balance is essential. I applaud the new generation, as work-life balance is what you find everywhere, and that is important. Still, again, it is not the most important; you need to have time for family, your time for rest, your time for spiritual activities, your time for work, and all the other aspects in places where I find people who elevate that work-life balance to such a degree. They are jealous to protect their free time that they cannot do anything worthwhile or serve. They are always just looking at themselves and protecting their free time. In saying that, work-life balance is necessary, based on working and enjoying your work.

"The burnout person is unsatisfied and sees work as a burden, and they want to avoid returning. When you get up in the morning, and it gets tough to get to work, it is a moment to start thinking, what is the problem? Why am I so dissatisfied? It is not necessarily money, at least not all the time, and it's more than just the amount of work. It is what I am getting from it. My emphasis with my faculty and trainees is you have to know why you are here. You have to want to be here. You have to feel that you have been placed here with a purpose. Your purpose in life is to serve; you will be so happy when you do that with compassion, care, and love. That is not burnout that's going to get you down."

5. What are you currently working on?

I do not have as much research because my administrative demands are enormous. However, I am very involved in the nutrition of the newborn; that is one of my passions, so I am looking at how changing the balance of the macronutrients and adding some things like DHA to the diet and increasing phosphorus and other things will also help with the energy and growth in the babies and how that growth will decrease lung disease. That is an area that I find very interesting.

In QI, I have a lot of projects that I am trying to get through, such as hand hygiene, discharge preparedness, and things like that where bringing people together and trying to achieve optimal care are essential things like the use of central lines and the decrease of infections. Hence, all those things are significant projects that we have. We always ask students, nurses, and fellows who would like to participate. There is so much to be done. It is gratifying to see the difference that the little things make in the lives and outcomes of these babies.

Every area of medicine has further research and understanding to be had. Each encounter we get has something to teach us and gives us opportunities to improve on current approaches. I appreciate the NICU's dedication to research and continuous drive

to improve patient outcomes. I also want to send a special thank you to Dr. Elba Fayard for meeting with me this month. Continue to follow along as I navigate my way to becoming a neonatologist.

*Answers paraphrased from video/voice call.

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Disclosure: *The authors have no conflicts of interests to disclose.*

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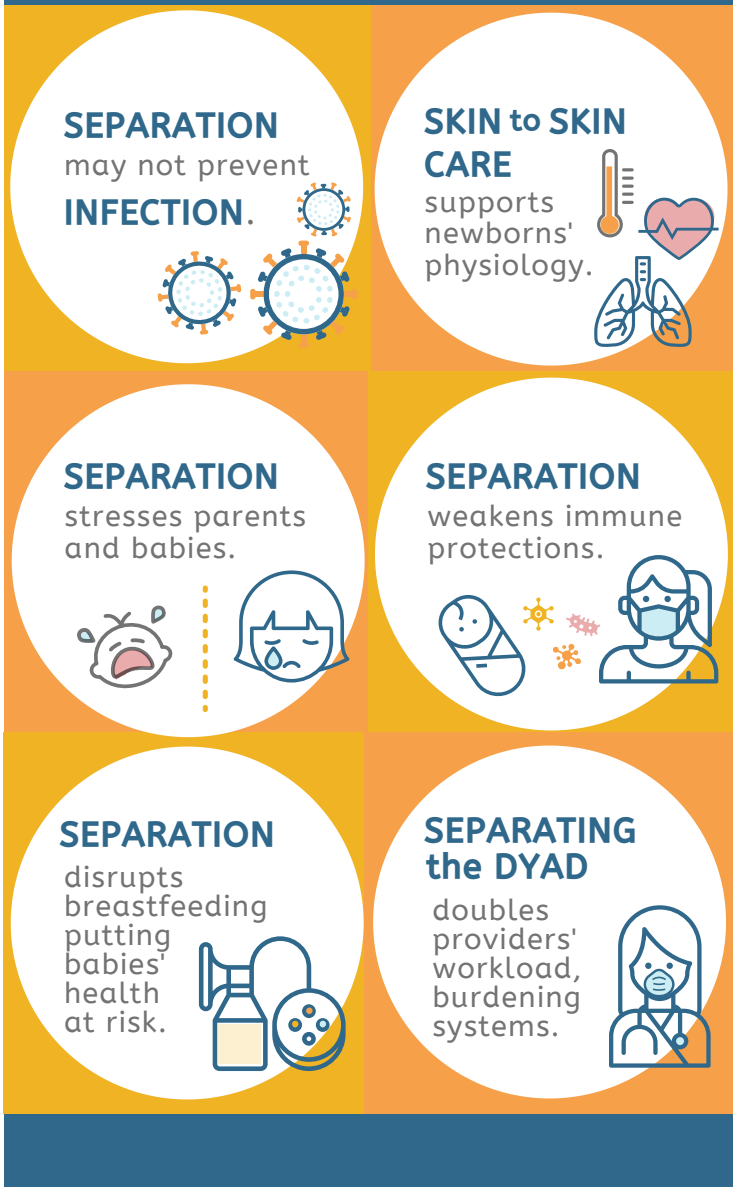
Should Infants Be Separated from Mothers with COVID-19?

FIRST DO NO HARM



BASED ON THE ARTICLE:

Should Infants Be Separated from Mothers with COVID-19? First, Do No Harm

Peer Reviewed

Fellows Column: Navigating Parental Psychiatric Illness in the NICU

Zeeruk Iqbal, MS4, Saba Saleem, DO, Darakshan Adam, MD

"The Neonatal Intensive Care Unit (NICU) can be a frightening and distressing environment for parents, especially given the sick infant's appearance and behavior, the complex medical language and technology, invasive procedures, and the threat of potential loss of their child's life (1). As such, it has been widely observed that parents of an infant admitted to the NICU are at higher risk of developing a mental health disorder. Research shows that at least 50% of parents in this situation will experience anxiety, post-partum depression, Acute Stress Disorder (ASD), or Post-traumatic Stress Disorder (PTSD). "

Introduction:

The Neonatal Intensive Care Unit (NICU) can be a frightening and distressing environment for parents, especially given the sick infant's appearance and behavior, the complex medical language and technology, invasive procedures, and the threat of potential loss of their child's life (1). As such, it has been widely observed that parents of an infant admitted to the NICU are at higher risk of developing a mental health disorder. Research shows that at least 50% of parents in this situation will experience anxiety, post-partum depression, Acute Stress Disorder (ASD), or Post-traumatic Stress Disorder (PTSD). While symptoms decline over time for most parents, about 25% are still suffering 1 year after the birth of their child (9). This is alarming because poor parental mental health negatively influences parent-child interactions and child development. Premature infants are already at high risk for adverse developmental, cognitive, academic, and mental health outcomes (8). This paper will explore the risk factors and long-term consequences of common psychiatric illnesses that impact parents in the NICU. We will also investigate how having a parent with a pre-existing mental health disorder may contribute to preterm birth and what preventative treatment can mitigate this event.

Risk Factors:

The most common health disorder seen in parents with an infant in the NICU is post-partum depression (PPD). Maternal post-partum depression is the most common complication of childbirth and affects 10-15% of women with term deliveries and 40% of women with preterm deliveries (1, 2). One of the strongest predictors of PPD among mothers of preterm infants is a perceived lack of social support. Other risk factors for maternal PPD include previous history of depression, marital conflict, poverty, stressful life events, and low maternal education (3). There has also been heightened awareness of paternal PPD in NICU fathers. One study found that 60% of men with an infant in the NICU had a higher score on the Center for Epidemiologic Studies-Depression Scale (CES-D) and thus, exhibited elevated depressive symptoms at baseline (4). Interestingly, CES-D scores were independent of infant illness and more influenced by socioeconomic factors. This may be due to fathers reporting three common psychological themes after their premature infant was admitted to the NICU: vividly recalling their experiences (even years later), worrying about their significant other, and stressing about work/life balance (5). These themes may stem from socioeconomic challenges that have a more significant impact on the primary income earner for the household. I NICU hospital stay can average around $76,164, while the cost of care for infants born prior to 32 weeks' gestation is approximately $280,811. If a NICU father is the primary income earner, this expense can produce lasting stress that goes beyond the course of hospitalization. Nonmodifiable factors, such as age, can also predispose fathers to higher stress levels. One study discovered that paternal age was a significant predictor of NICU-related stress, with younger fathers being more susceptible to it (6). This is significant because it has been reported that almost one-fifth of NICU fathers continue to report post-traumatic stress symptoms up to two years after birth (7).

"Maternal post-partum depression is the most common complication of childbirth and affects 10-15% of women with term deliveries and 40% of women with preterm deliveries (1, 2). One of the strongest predictors of PPD among mothers of preterm infants is a perceived lack of social support. Other risk factors for maternal PPD include previous history of depression, marital conflict, poverty, stressful life events, and low maternal education (3). There has also been heightened awareness of paternal PPD in NICU fathers."

Health Outcomes in Premature Infants and Parents:

The negative infant health outcomes associated with parental psychiatric illness include avoidant attachment, behavioral and emotional difficulties, and cognitive delay. Parents diagnosed with ASD or PTSD in response to their infant's NICU admission often experience intense fear or helplessness. Common symptoms of ASD or PTSD are re-experiencing the event, dissociation, and physiological arousal. Re-experiencing occurs through intrusive thoughts, dreams, and flashbacks. Dissociation and avoidance of reminders occur through depersonalization, derealization, amnesia, or numbing behaviors, such as drug and alcohol intoxication. Lastly, physiological arousal manifests as sleep disturbances, hypervigilance, and irritability. ASD diagnosis is made if the presence of these symptoms is between 2 days and 4 weeks after the traumatic event or NICU admission. PTSD is diagnosed when symptoms persist for at least 1 month or longer (10).

"The negative infant health outcomes associated with parental psychiatric illness include avoidant attachment, behavioral and emotional difficulties, and cognitive delay. Parents diagnosed with ASD or PTSD in response to their infant's NICU admission often experience intense fear or helplessness."

Parental Psychiatric Illness Risk Factor for Preterm Birth:

Current literature suggests that infants are more likely to be born prematurely if either their mother or father has a psychiatric diagnosis (11). Stress-related disorders, such as ASD or PTSD, are the diagnoses associated with the highest risk of preterm birth. The risk of preterm delivery increases by 23% if the father has a stress-related disorder and by 47% if the mother has it. The risk increases by 90% if the diagnosis is present in both parents. The risk of preterm delivery is lower in other parental psychiatric illnesses unless they occur comorbidity. For example, the risk prematurity increases by 25% if the mother has depression, by 39% if she has depression and schizophrenia, and by 65% if she has depression, schizophrenia, and an anxiety disorder. Similar patterns occur in fathers with multiple psychiatric disorders (12). The mechanism appears to be related to maternal stress setting off biological pathways that induce preterm labor, for instance, high cortisol levels inducing premature contractions (13).

Prevention:

Screening for psychological distress is essential for identifying families in need of referrals for psychiatric care and mental health resources. While NICU fathers experience mental health problems similar to their female partners, they are more susceptible to inadequate emotional support and not receiving essential information regarding care for their premature infant (5). For instance, one study found that fathers feel more excluded, helpless, and inactive in their infant's care because the medical team approaches the mother more frequently when discussing prognosis and making decisions. Additionally, some fathers will suppress their emotions to appear strong for their family despite not coping well internally (5). Identifying parents at risk for psychological distress is essential and feasible with the use of well-validated screening instruments. Prevention requires us to provide adequate care to both parents, as the research shows that the father's support during pregnancy moderates the effects of maternal stress. One study demonstrated that women with chronic stress who have better emotional and financial support from the baby's father are at lower risk of preterm delivery (12).

"Screening for psychological distress is essential for identifying families in need of referrals for psychiatric care and mental health resources. While NICU fathers experience mental health problems similar to their female partners, they are more susceptible to inadequate emotional support and not receiving essential information regarding care for their premature infant (5)."

Treatment Recommendations:

It is not uncommon for women to present with the first onset of psychiatric illness while pregnant. Many pregnancies are unplanned and may unexpectedly occur while women are receiving treatment with medications for psychiatric disorders. Although many women consider abruptly stopping their medications after learning they are pregnant, this decision carries substantial risks. Untreated psychiatric illness in the mother may cause significant morbidity in both her and the child. Thus, discontinuing or withholding medications during pregnancy is not always the safest option. Clinicians must perform a thorough risk/benefit analysis of pregnant women with psychiatric illness, including evaluating the impact of untreated illness on the baby and the mother (14).

Conclusion

The mental health issues experienced by NICU parents, such as postpartum depression and PTSD, can range from one month up to seven years post-discharge (15). Parents who are at greater risk of developing a psychiatric illness include those who have a lack of social support, a history of a mental health disorder, younger age, and lower education and income levels. It is critical to identify these parents and provide psychological support and resources as their premature infants are also at increased risk for adverse developmental, cognitive, academic, and mental health outcomes. Furthermore, mothers with a pre-existing mental illness, such as bipolar disorder or Schizophrenia, are more likely to deliver prematurely and then develop postpartum psychosis due to their infant's hospitalization. Postpartum psychosis is a psychiatric emergency that can lead to death. Thus, proper screening tools and comprehensive interventions, like cognitive behavioral therapy, home visitation programs, and medication compliance, are essential in helping create better outcomes for both NICU par-

ents and their premature infants.

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Disclosure: *The author has no conflicts of interests to disclose.*

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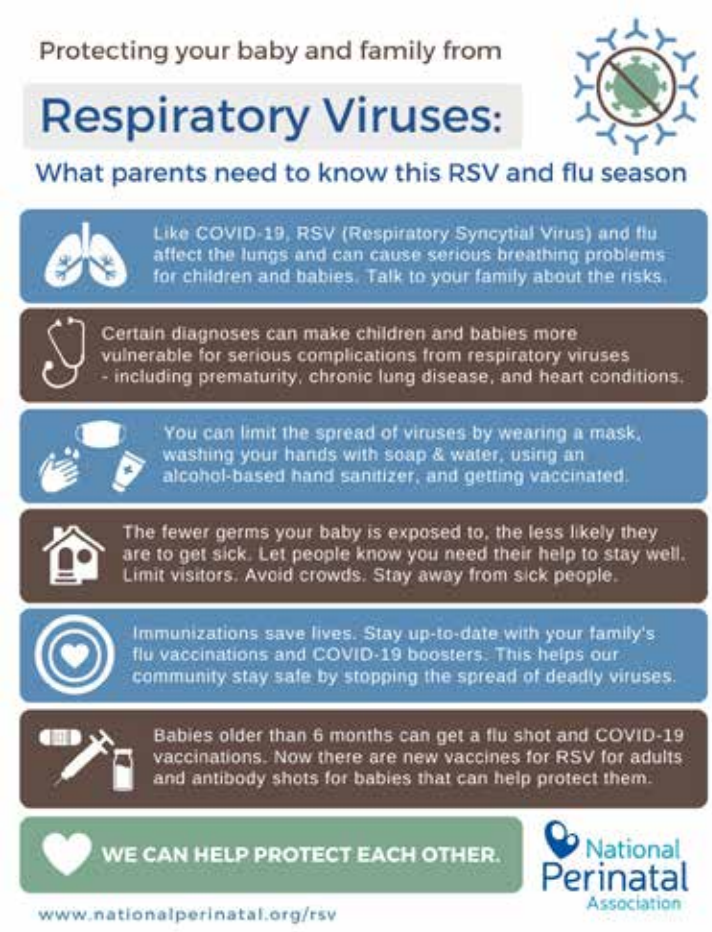

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High-Reliability Organizing Fundamentals: The Distinct Dimension of Time

Daved van Stralen, MD, FAAP; Sean D. McKay, Element Rescue, LLC; Thomas A. Mercer, RAdm, USN (Retired)

Abstract:

The manuscript delves into the challenge of establishing order in chaotic, hazardous environments, emphasizing the interplay between human actions and dissipating energy. Identifying which actions resolve or worsen disruptions is complicated, often dependent on timing and context.

The inadequacy in recognizing the capabilities of organized human actions to restore order is highlighted. Oscillatory phenomena, with temporal components, are discussed, distinguishing noise from stochastic waves. The environment, inherently unstable, undergoes self-organization through local feedback loops, a process often unnoticed due to memory deficits and linguistic challenges.

"The inadequacy in recognizing the capabilities of organized human actions to restore order is highlighted. Oscillatory phenomena, with temporal components, are discussed, distinguishing noise from stochastic waves. The environment, inherently unstable, undergoes self-organization through local feedback loops, a process often unnoticed due to memory deficits and linguistic challenges."

The temporal dimension is undervalued in response plans for unstable environments, overshadowed by Euclidean space's three dimensions—environmental self-organization's impact, driven by nonlinear feedback loops, challenges predictability. The philosophical exploration of time questions its objectivity and introduces Einstein's theories, emphasizing the limitations of absolute time in nonlinear contexts.

In high-risk organizations, time as a dimension influences responses to environmental changes. Autocorrelation generates red noise, necessitating timely responses. The integration of time and context influences perception, cognition, and environmental communication.

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The discourse advocates a more comprehensive understanding of human responses by distinguishing mechanistic causation from adaptive traits over time. Criticisms of high-reliability organizations lacking temporal consideration hinder comprehension. Incorporating time as a distinct dimension is proposed to enhance understanding of complex environments.

Introduction:

From observation and experience, we know order will eventually come to a chaotic environment. Sometimes, the cause of that order is the dissipation of the initial energy. Sometimes, the cause is human action. More often, the cause is a combination of the two.

The conundrum we face with hazardous environments is determining which human actions help resolve the disruption and which make it worse. It appears that what works and what hurts may depend on timing and context. We have not identified the capabilities of organized human action that bring order to such chaos, nor have we reliably reproduced the methods we have identified.

"The conundrum we face with hazardous environments is determining which human actions help resolve the disruption and which make it worse. It appears that what works and what hurts may depend on timing and context."

Oscillations occurring with a time component form waves that have frequencies. Noise, which does not carry information, is a disorganized pattern of these waves. Stochastic waves carry energy, and their stochastic character means their probability values will unexpectedly change. Environmental stochastic noise describes the ambient noise of the world in which we live. Red noise frequencies have long periods and have greater power to cause forcing functions to which we must respond. Pink noise brings abrupt, catastrophic change.

Our environment is intrinsically unstable. Entry of energy destabilizes the environment even as order emerges from self-organization by local environmental constituents. Humans also self-organize by using self-direction from within the event. The ephemeral nature of local feedback loops that comprise self-organization is not visible to distant spectators, and they are only fleetingly noticed by the actors who must quickly move to the next series of feedback loops. Memory deficits and the failure of words necessary for accurate description impair the ability of individuals to describe their motives and actions.

Those looking for causation or a rational plan of response soon become frustrated. These spectators use their knowledge to fill in the blanks, knowledge similar to knowledge by enactment (1)—untested because it is unquestioned, it becomes privileged over knowledge by acquaintance gained through experience (2). The knowledge and the lessons that were learned in blood are lost. Operators have lost the conundrum.

Though we know it occurs, identifying how we achieve effectiveness in an unstable, dangerous environment continues to vex educators, academicians, and leaders of high-risk organizations outside the military and public safety. This runs into the problem Niko Tinbergen identified with animal behavior: we do not notice the behavior until it happens, and we do not know the individual's mind. Unknown are the antecedents and cognitive-affective processes. However, we can discuss the function of behaviors, described by Niko Tinbergen (3) as achievements, to understand better the defensive cascade that protects the organism. Therefore, it may serve us better to identify the function of our responses to unstable, dangerous environmental change.

"Though we know it occurs, identifying how we achieve effectiveness in an unstable, dangerous environment continues to vex educators, academicians, and leaders of high-risk organizations outside the military and public safety. This runs into the problem Niko Tinbergen identified with animal behavior: we do not notice the behavior until it happens, and we do not know the individual's mind. Unknown are the antecedents and cognitive-affective processes."

To be clear, the change in the physiological environment of a neonate is of a different proportion than a national emergency. We maintain that the dynamic response is the same.

Time as a valuable dimension for unstable, dangerous environments has been poorly incorporated into response plans and methods to increase capabilities. Instead, we use the three dimensions of Euclidean space for planning and operations. Euclidean space is helpful because it consists of points with measurable distances between two points. Euclidean space provides a structure for organizational charts, rules, protocols, and planning. For tractability, we can treat a curve as linear over short distances. In a dynamic, topological space, local areas are Euclidean spaces. We can apply the rules of Euclidean space with three dimensions over any local space mapped onto a topological manifold. (The shape of a topological space is called a manifold.) Rather than lines, we use relations in a topological space. Relations can be deformed but never destroyed.

Environmental self-organization from nonlinear local feedback loops changes the context of any circumstance. The feedback time of local loops dictates the rate of change within any context. Long time lags describe a slowly changing system. Short time lags can accelerate change because each change occurs within a shorter time. Feedback loops between the system and the environment alter the direction change, with short time lag feedback loops altering the trajectory much quicker. The future becomes less than predictable to the consternation of those using the structure of Euclidean space.

Time and changing context generate frames of reference that differ based on a person's position. Does time have a frame of reference? Is time objective, and does it have an absolute value to which we can compare other time measurements?

Objective time is linear and unidirectional, evolving in the same sequence of past, present, and future. Objective time is homogeneous, elapses uniformly, and is quantitative. Independent of events and individuals, objective time is absolute and universal.

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Isaac Newton asked if we could determine the absolute velocity of the Earth through the ether that pervades space. This restricted Principle of Relativity (Newtonian Relativity) relies on absolute time. In this relativity, the motion of bodies amongst themselves is the same—they are only moving only concerning each other. Because the system itself is moving, everything appears the same. There is no acceleration—Euclidean space conflicts with the idea that our frames of reference can move at different speeds.

Time in Newtonian Relativity and Euclidean space is a prothetic process, a quantitative continuum that we add to. We discriminate prosthetic-process categories based on our sensitivity to differences (1). Context changes as elements change in time. When time differences are negligible, we can disregard the effect of time on context, making it possible to decontextualize a situation or process. This supports the use of decontextualized concepts and theories.

The Special Theory of Relativity described frames of reference that moved at different speeds. To develop the Special Theory, Albert Einstein demonstrated that there was no *absolute* time. Instead, time is a separate dimension. This changes Euclidean space into Relativity space. Time is relative just as space is—space-time.

The General Theory of Relativity combines matter-energy and

space-time from the Special Theory through their interactions. This interaction creates the force of gravity in the Euclidean space. As time passes, the approach's reference frames (mass) dilate with speed, and clocks run slower. Then, as it moves away, time contracts with speed, and clocks run faster.

We do not imply that this happens during a crisis. We want to point out that absolute time, as a prothetic measure, does not work well with nonlinearity. Further, Newtonian physics and Euclidean space restrict function and constrain the adaptability of any system.

HROs operate in unstable and dangerous environments *because* time has a dimension in those environments. Autocorrelation, internal feedback, creates environmental energy frequencies, red noise, with forcing functions that people and a system must respond to or cause abrupt, destructive change. When noise occurs at a specific frequency, $1/f$ or f^{-1}, it causes abrupt, severe change—red or pink noise, resulting from feedback with various time lags change context. Time as a dimension has broad, penetrating influences in these environments.

"HROs operate in unstable and dangerous environments because time has a dimension in those environments. Autocorrelation, internal feedback, creates environmental energy frequencies, red noise, with forcing functions that people and a system must respond to or cause abrupt, destructive change."

Time as a dimension and context also influences how we perceive, think, and communicate about the environment. Understanding time and context affects our focus on the cause of our responsive behaviors and actions and how we adapt to these events.

"Time as a dimension and context also influences how we perceive, think, and communicate about the environment. Understanding time and context affects our focus on the cause of our responsive behaviors and actions and how we adapt to these events."

As discussed above, we can explain the function of responding. Following Tinbergen's questions regarding animal behavior, we can *proximate the cause* of the response using mechanistic explanations based on how the structures of individuals and the organization work. We can explain the *ultimate function* of an emergency response as adaptation—that is, to have or develop traits that contribute to the survival of the individual, system, and organization in the current environment. This differentiates two distinct levels of analysis: the *proximate* causation developed within a human lifetime and the *ultimate* causation that continues over lifetimes, an evolutionary level (3).

We propose that the dimension of time has not been fully identified and characterized as an integral of unstable, dangerous environments. Also, time is missing as a dimension in analyzing human responses to these events. Further, the human response to these events must be distinguished between the mechanistic immediate causation at the point of contact from adaptive traits developed over years of experience. As Scott A. MacDougall-Shackleton stated, arguing across levels of analysis creates false debate (3).

In this article, we present examples of the effect of time and context on response to dangerous contexts and the effect of arguing across levels of analysis. Next are examples of how context and time as a dimension influence our emotional response, time preference, epistemology and philosophical stance, logic and reasoning, problem characterization and problem-solving, and analysis.

Social and Task Cohesion in Dangerous Contexts:

To demonstrate the influence of time and context on scientific studies, we open with an academic criticism of a US Army study of combat troops during the Iraq War. The researchers entered zones close to combat areas. They sought to identify specific determinants of successful unit performance: social cohesion (the strength of interpersonal bonds among members) versus task cohesion (a shared commitment to the unit's mission).

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Three academicians pointed out that the research findings did not comport with knowledge developed from a scientific methodology away from combat. We start with some of the criticisms of the findings and methodology. Next, we present some responses from one of the original researchers.

The criticism comes from Robert MacCoun, Elizabeth Kier, and Aaron Belkin in their paper, "Does Social Cohesion Determine Motivation in Combat? An Old Question with an Old Answer" (4).

> "Their findings are intriguing because they appear to contradict long-standing research in organizational theory and sociology on the relationship between cohesion and

performance, as well as more recent studies of unit cohesion and military effectiveness."

"They provide no evidence for the representativeness of the interview quotes they cite as evidence for the reliability or validity of their measures [and] no indication that these quotes are statistically representative. Their methodology fails to meet social science standards for causal inference (e.g., ruling out causal rival factors)."

"[The authors] must be congratulated for having completed a brave research project. Under dangerous conditions, they conducted over eighty interviews with Iraqi Regular Army prisoners of war, US combat troops, and journalists embedded with coalition forces."

"There is broad agreement among social scientists that people are often unable to reliably and validly perceive and report on the causes of their behavior. People are not fully aware of the causes of their behavior."

"Every scholar recognizes the important distinction between correlation and causation. To determine whether two phenomena are causally related, there are straightforward guidelines that scholars adopt."

Thomas Kolditz, one of the original authors, responded to this criticism in his paper, "Research in Extremis Settings Expanding the Critique of 'Why They Fight'" (5).

"Previous work by the author that was based on data collected in combat has been criticized based on its ability to generalize to research done in routine, peaceful settings. A small team … [had] deployed to the active war zone in Iraq to witness, record, and report on the human dimension of combat."

"Noncombatant civilian scientists are usually treated as elites, well cared for, and confined to relatively safe rear areas and after-the-fact research methods."

"Interviews were conducted in the active combat zone with infantry soldiers who were fully armed and prepared to engage the enemy without notice. Owing to the rapid advance to Baghdad and beyond, no one in the sample had eaten hot food, showered, or received mail in the thirty days prior. Each soldier or marine interviewed had at least one member of his organization wounded or killed in the preceding thirty days—several uniforms still bore bloodstains left by the evacuation of comrades—dark blotches over the chalky-white salt from daily living in 112-degree heat."

"On the basis of that report, a small group of political scientists have criticized the publicly released portion of the team's work as "unscientific" [reference above]. In addition, they characterize our findings as inconsistent with some earlier noncombat studies…Much of the criticism directed at the methods used in our work focuses on the inability to compare the team's work with existing laboratory or field studies or to generalize the team's findings across a number of settings."

"Research involving human participants conducted in safe, peaceful settings will not necessarily generalize to combat; combat findings may differ from those developed elsewhere."

"Is [it] scientifically appropriate to assume that the extensive work done in peaceful settings will necessarily generalize to combat? Raising such a question does not devalue social science research but instead raises healthy skepticism about the application of research findings from one context (peacetime) to another, profoundly different context (combat)."

"'Is [it] scientifically appropriate to assume that the extensive work done in peaceful settings will necessarily generalize to combat? Raising such a question does not devalue social science research but instead raises healthy skepticism about the application of research findings from one context (peacetime) to another, profoundly different context (combat).'"

"Empirical work relevant to combat should ideally be conducted in situ, under circumstances where death must be actively avoided. Leadership researchers have referred to such situations with a unique term: *in extremis*, or 'at the point of death.' Soldiers, law-enforcement personnel, mountain-climbing guides, firemen, and extreme-sport coaches live and work in in extremis settings—circumstances where outcomes mean more than mere success or failure at task performance but instead, involve life or death."

Misunderstandings versus Different Levels of Analysis

A concern for leaders in an HRO is an undue emphasis on the normative stance at the expense of the pragmatic stance (6, 7). This emphasis impairs the "organizing" component of HRO and can remain covert in an untested system. HRO, conventional organization management, and all reliability, safety, and resilience programs perform well in stable environments. What differentiates HRO from other programs is its origins within dangerous contexts, the capability to modulate abrupt disruptions, horizontal translation between industries, vertical translation within an organization, and, most significantly, the ability to extend an organization into uncertain or treacherous environments.

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We can learn from industries operating in dangerous environments but not through studies conducted in a controlled laboratory (8, 9). Laboratory research constrains the ability of the subject to respond, which does not represent the actual world environment. Neither can a researcher mimic a live-or-die circumstance (8). Field research incorporates the heterogeneity of populations and practices, group expertise, and the spaces and concepts

created by science (10). Field experience identifies gaps between theory and practice (11), the effect of granular, local influences, manifestations of stress and fear, and the local effects of threats (6).

"Predicting what would happen to the first human beings to climb that high [27,000 feet] was therefore literally a matter of life or death—here inaccurate models could kill" (9). The gap between a protected study environment and a dangerous field environment appears minor to those in the protected environment. Today, efforts to reproduce the sensation of existential threat are unethical.

While the above interchange comes from differences in belief systems, we also saw this in mountaineering when scientists in the first half of the 20th century applied the physiology of high-altitude ballooning to that of high-altitude mountain climbing (12). Information supporting sudden collapse at high altitudes came from aviation tests in pressure chambers (9, 13, 14). In 1862, a meteorologist and his assistant reached 26,000 feet and became paralyzed, unable to release the gas valve. The assistant finally reached the valve with his mouth, and they descended but not until after reaching 30,000 feet. The second incident in 1875 led to the deaths of two passengers. The scientist survived. That balloon also reached 30,000 feet.

High-altitude mountain climbers knew the stories, but the stories belonged to the scientists, not the climbers. The climbers' empirical experience differed from the scientists' empirical studies. Mount Everest climbers had acclimatized without oxygen, attained the exact altitudes as the balloonists, and could still climb without oxygen (15). Somervell (16) described an accident with the oxygen apparatus: the climber did not become immediately unconscious. The apparatus was then disconnected and repaired. The scientists had warned that they could not reach such heights without oxygen, but the climber stayed conscious despite the sudden loss of oxygen.

This is not an esoteric discussion. Behaviors and skills developed in dangerous contexts do translate well to stable environments. *The reverse does not happen*. The difficulty is the mistranslation by people whose knowledge is limited to that by description. The significant difficulty is describing the experience at the granular level in a way that outsiders can understand and appreciate.

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Bertrand Russell (2) addressed this as the difference between knowledge by acquaintance and knowledge by description. We are acquainted with an object when we "have a direct cognitive relation to that object," that is, direct awareness of it. We know an "object answering to a definite description, though we are not acquainted with any such object." "An object is 'known by description' when we know that it is 'the so-and-so,'" i.e., when we know that there is one object, and no more, having a certain property, and it will generally be implied that we do not know the same object by [an] acquaintance."

One function of our HRO series in Neonatology Today is to improve the description of the HRO environment and the nature of the cognition necessary to engage the problem within that environment.

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Next are examples of how context and time as a dimension influence our emotional response, time preference, epistemology and philosophical stance, logic and reasoning, problem characterization and problem-solving, and analysis.

Our Emotional Response

When instability and danger become existential threats, the threat is expected to elicit phenotypic survival behaviors. As adaptations are shaped by selection for survival utility, fear responses escalate as a function of proximity to danger (17). Stefan Bracha's (18) "Neuroevolutionary Time-depth Principle" "takes into account factors such as the relative role of natural disasters and non-conspecific anthropophagic predators, versus the role of human conspecific (thus mostly non-anthropophagic) predators in driving selection of fear-circuitry-related allele variants (and possibly of relevant gene dosages) in the human genome."

We can, therefore, conclude that the emergency survival behaviors we observe and experience are common to all humans. This also means the practical survival and adaptive behaviors observed in members of an HRO are also available for all people.

Human stress, fear, and threat responses drive safe and effective engagement of environmental threats. The *executive functions* integrate, from opposite ends of the brain, perception, hastily created plans and motor activity. During a crisis, the hypothalamic-pituitary-adrenal (HPA) axis enables survival behaviors by releasing cortisol to "disarm" the executive functions. Novelty, uncertainty, and uncontrollability in executive functions cause stress responses. Fear reactions at the subcortical level maintain a safe distance from threat. Threat reflexes rapidly initiate protective behaviors. However, these same responses, when unmodulated, can harm the individual, distorting thinking as *situational cognitive distortions*. The prevalence of unmodulated stress and fear makes them appear unpreventable if not expected. This is the inherent vice of stress and fear. By describing their function and location in the brain, we can identify these behaviors to begin modulation for effective responses to threats (19).

The authors never heard shouted anger during an incident in their respective fields. Nevertheless, the first trauma resuscitation witnessed by one of the authors (DvS) not only had yelling but later ridicule by one service toward another. One of the authors (DvS) observed negative behavior toward colleagues in healthcare from early experience in 1982 through this current year of publication, 2024.

One of the authors (DvS) served on a Los Angeles City Fire Rescue Ambulance (RA) in the 1970s. During this period, he worked in teams of two without firefighters (unless they were called) or police (except for shootings) and no radio communication once they left their rig. They received training for responses to an assault,

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"Rescue 66, take an assault with assailant on scene." The medics knew they would likely arrive on the scene 5-10 minutes before the police.

- A husband did not like the medical treatment for his dying wife. He jumped up to get a gun, telling the medics, "Then I'll make you do it." Everyone in the room ran out, telling the medics where he kept his gun. After ensuring everyone left, including his partner, the author looked at the husband, his face – anguish made physical, "Let me help her." The husband said, "OK." She survived, awakening *en route* to the hospital. The husband hugged the author.
- An angry crowd vigorously attacked the driver in a car accident. He had an angulated, clearly fractured femur. Without time for a police or fire response, the medics extricated the victim amidst the violence, placed him on the RA gurney, laid their bodies across the patient for his protection, and moved to the RA. The crowd punched the medics, not the patient. As they drove away, a man held on to the RA door, punching the author in the head.
- Unless the medics were in an active fight, once they left the RA, they did not return until they had resolved the problem. This required calming a crowd as they approached and leaving with the crowd having good relations. Developing good relations as they gathered information and began treatment was the norm. Leaving an angry crowd endangered any RA team responding to a later incident. Again, the medics had to approach calmly and leave with calm bystanders.

Despite internalizing these characteristics, the author found that supervisors believed the author would cause trouble with patients, families, and staff. This reflects the experience of Kolditz described above: time as a dimension, and greater context granularity impede translation experiences in dangerous contexts. This leads to the mistranslation of knowledge by an acquaintance to knowledge by experience, making it difficult for outsiders to learn.

Time Preference:

Within the environment, time is present through red noise forcing functions, pink noised abrupt catastrophes, feedback loops with the environment, and local self-organizing systems. The greater the presence of time, the more likely interruptions will change the local context—each change representing a change in available information.

We would benefit from a broader view of the environment to identify and obtain this information. With each interruption, we renew our sensemaking. In an actively changing environment, sensemaking becomes the "ongoing attempt to reconcile the continuity of experience with the discontinuity of understanding" (25).

Each interaction produces information; thus, the more we probe, the greater the information we obtain. Multitasking and task shifting increase our ability to garner information in highly contextual environments. As well, we welcome interruptions because we recognize interruptions represent changes.

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Edward T. Hall (20), an American anthropologist, developed the concept of high and low context to describe cultures by the degree they find necessary information within the environment. "High context" cultures are those cultures where the environment, or context, contains necessary information. High-context cultures depend on local information or identify information from the environment.

The cultures also have different preferences for how they orient themselves toward time, perceive time, and allot time. "Polychronic time" is preferred by "high context" cultures, while "monochronic time" is preferred by those in "low context" cultures where environmental context carries less information (21)

A polychronic time system takes a broader view of time because time is not seen as a tangible resource. There is little pressure to complete tasks within a time block. A monochronic time system treats time as a commodity. Time preference is about *how* people allocate time to tasks rather than how quickly those tasks are done (22).

Multitasking in a polychronic time system differs from the standard concept of a person performing two or more tasks simultaneously. The individual readily integrates different activities, working on several tasks by (1) multitasking and (2) task-switching.

- Multitasking divides focus among many tasks, using very short periods, if not instantaneously. This is not simultaneously or at the same time.
- Task-switching is to shift attention or move back and forth between tasks within the same time block.
- Granularity refers to the length of time units used and the level of detail.

People who use monochronic time tend to focus on one thing at a time with a commitment to schedules and promptness. They do not like interruptions in their work. Individuals working in polychronic

time are more receptive to interruptions, often change plans easily, and will feel comfortable doing many things simultaneously (23).

Monochronic time is linear, tangible, and divided into blocks of time, much like an economic approach. A monochronic time system operates one at a time, segmenting time into precise, small units. Time is scheduled, arranged, and managed. Monochronic time emphasizes planning and the establishment of schedules (24).

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The characteristics of polychronic systems contain elements of HRO: vigilance for interruptions and multitasking. Polychronic traits support sensemaking and can be lifesaving. Karl Weick found, "A thread among many discussions of sensemaking is that the process boils down to managing interruptions and recoveries, discontinuity and continuity, differences and sameness across situations." Sensemaking is an ongoing attempt to reconcile the continuity of experience with the discontinuity of understanding (25).

> "One of the more heart-breaking moments of the Mary Pang fire was an incident with a rookie firefighter who was part of the hose crew working above the second-floor fire. The rookie's fire helmet fell off, and when he leaned down to pick it up, he felt how hot the concrete floor was. He said to himself, but to no one else, 'I have to remember to ask my Captain when we get back to the station why concrete gets hot. I didn't know that it did.' We now know that fire was burning under them. And in one sense, the rookie knew this. But in another, he did not know what to make of the strange clue, and he did not ask immediately what the strange clue meant. This points to one of the most crucial aspects of sensemaking: we need other people to do it successfully.
>
> The IC [Incident Commander] thought he was sending firefighters in on the bottom floor of a one-story building. He was sending them in on the second floor of a two-story building. The first floor beneath them was completely engulfed with fire. The fire burned out supports in a wall that was holding up the second floor, the second floor collapsed, and four firefighters fell into the first-floor inferno and lost their lives," Karl Weick (26).

Epistemology:

For scientific research, we follow scientific rationality, decontextualize the problem, use a white noise-controlled environment, and then use the Gaussian curve for statistical analysis. This is an information-sensitive process. That is, increasing information reduces variance. This gives us evidence-based medicine.

The effect of time through feedback loops and auto-correlation creates red noise. Elements are *not* independent, and numerous, mutual, or reciprocal relations exist. Data *increases* variance, forming a power law distribution rather than the Gaussian distribution. A pink noise frequency provides no well-defined, long-term mean or well-defined value at a single point. Data *continuously increases* variance.

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Physicians also resist medical care learned from the field that can help make healthcare more effective and efficient. Several experiences from one of the authors (DvS) are:

Oral fluids for respiratory secretions. In 1974, a pediatrician at Children's Hospital of Los Angeles advised fire RA medics that low humidity contributed to pediatric asthma deaths. This humidity is more common in summer. He recommended giving the patient a glass of cold water to drink. The author used oral fluids several times after a patient failed to respond to bronchodilators. The improvement obviated the need for transport in each patient. In an arid environment, enteric fluids prevent "airway clearance impairment" pneumonia and markedly lessen the severity of bronchospasm. His patients do not need mucolytics and mechanical devices for secretion mobilization (27). Despite almost 50 years of experience supported by the recent science of mucin rheology, physicians remain opposed to this intervention.

Shortly after arriving to [the] PICU, [patient] demonstrated difficulty clearing her thick secretions, and her O_2 saturations dropped to the 40s. She was hand-ventilated and then required intubation for respiratory failure. [From a recent admission history to the Pediatric Intensive Care Unit.] In the pediatric subacute facilities, these children respond to fluids and are not transferred to the PICU (27).

Mask ventilation for a breathing patient. The author administered mouth-to-mouth resuscitation to an infant, adolescent, and adult out of the hospital. He also observed mouth-to-mouth resuscitation given by lifeguards and bystanders—no patient ever vomited from mouth-to-mouth resuscitation. Vomiting only occurred after commencing bag-valve-mask ventilation (BVM). This influenced the author's method of teaching BVM and mechanical ventilator adjustment to provide comfort for patients receiving home mechanical ventilation (28–30). EMS medics show no interest in this method. Physicians react quite strongly, if not passionately, against this approach. None of the physicians had information about administered mouth-to-mouth resuscitation to a patient. Special groups in SOCOM and the Special Forces of six NATO armies rely on this method.

Agitation, fear-escape, and anger-aggression. In the 1970s, during one author's fire RA tenure serving in South Los Angeles, phencyclidine (PCP, angel dust) had become an epidemic. In Los Angeles County, PCP-positive samples increased from 36 to 145 for the same two-month period from 1975 to 1976 (31). LA Fire Department RAs continued the same response with two medics on the RA without fire or law enforcement assistance. The number of "officer needs help" calls to assist the rescue increased from occasional to 2–3 requests per rescue per day. Within about six months, the RA crews dramatically reduced requests for police support.

Through shared experience, the medics built on their experience with patients showing agitation, fear-escape, or aggressive assault. The medics used all their methods while amplifying their actions. They turned all lights off, asked people to leave the area, and made it quiet. Then, they restrained the patient loosely as they routinely did for agitated patients, wrapping the patient loosely in a hospital bed sheet.

What made this remarkable was the effect of phencyclidine on the patient in the antemortem behavior as described by the LA County Coroner (32): "aggressive and threatening behavior, diminished fear, disorientation, and confusion. Since PCP is an analgesic as well as an anesthetic, a user can exert seemingly incredible strength, be harmed, and not know he has been hurt."

The author continues to effectively use this approach for behavior problems in children with neurological deficits from chronic conditions and infants. He teaches the parents and staff the difference between agitation, fear-escape, and anger aggression: how to respond to each, their causes, appearance, and prevention of escalation from agitation to anger aggression. In this manner, the author distinguishes between reversible and more syndromic behaviors. Parents quickly learn these methods. Bedside staff who have observed this also adopt it. Physicians and EMS medics have shown no interest.

Movies and television impede the incorporation of HRO methods into organizations. In 1975, one of the authors (DvS) noticed that family and bystanders on the scene had begun to act differently when medics arrived. They provided less information and had to be spoken to specifically. They stood back, not participating in care or moving the patient. Rather than ask about the patient's condition, they asked about the medical equipment. RA medics advised the author to watch the television show *Emergency!*

After watching a few shows, it became easy to identify those who watched *Emergency!* In medical school, people, particularly men, tended toward some form of intimidation. As film writing and storylines changed, intimidation and physical action replaced observation and thought. This remains a problem.

"Movies and television impede the incorporation of HRO methods into organizations."

Looking back at the criticism of the US Army study on social and task cohesion, we find another twist. The criticism uses "Hollywood depictions of war" for support, specifically, the Internet's "Movie Cliches List." The authors support their criticism further, referring to the "boys-becoming-men-together" and the male bonding clichés—"breaking boundaries, going outside the law to effect moral order as personal loyalty."

One of the authors included the effect of movies on people's behavior in healthcare. One medical student took it to heart. He reported back after a year that if he could identify which movies the resident watched, he would know how the resident would act.

An adolescent was newly admitted to a subacute care facility and dependent on mechanical ventilation. He began to struggle, crying for his father. One of the authors (DvS) entered the room and began hand-ventilating the patient. An RCP followed, shouting to the patient, "Calm Down! Just Calm Down!" The author looked at the RCP and asked if that had ever worked. "No." "Then why do you say it?" queried the author. This patient had been on antipsychotic medication under the care of a psychiatrist for depression and such outbursts. Then, this happened again. A different RCP was in attendance. As the author and RCP entered the room, the patient said he could not breathe while again crying for his father. After hand-ventilated calmed him and re-adjusted the ventilator, he stated he was fine and did not need his father. The difference in response is most likely between movie experience and actual experience.

Theory and Practice

Operators in the field develop their logic of practice built upon contextual relations entwined with people and work (33). For Zundel and Kokkalis (11), the absence of practice within theory is how theoreticians see theory-making as themes in terms of a priori scientific assumptions, the *scientific subject domain*. The theory would move into the practical world by including engagement of practice, closing the gap between theory and practice to create the *practical engagement domain*. The significance of engagement in practice derives from the attitudes taught to military and public safety rookies—always engage in some way, even if to evacuate the area.

A practical domain of engagement illuminates the study of the problems of transferring academic work to organizational practice. A practical domain, as a pragmatic stance, recognizes the overlapping and loose coupling of concepts necessary to complete a task. The practical domain of engagement (as acts of learning by doing in context and being aware of consequences) is not an outcome of rational deliberation and cannot be objectified for theory-making (11).

Engaged action comes from insight and immediate feedback, with negative feedback marking the safe boundary of performance and positive feedback generating growth. All feedback generates information. "Mistakes" indicate a change in circumstances (34) or interference from the environment (35).

> "HRO, as an abstract representation of work done out there, a representation by academics, is the very object that has been turned into a normative frame, a frame you want to replace with a more pragmatic frame." Personal communication from Karl Weick

The gap between theory and practice can be closed by informed practice, that is, by understanding theory and scientific rationality to support practice rather than guide practice. Engaging situations in context bridges the gap by using theory to improve care for practical outcomes (11).

"Engaged action comes from insight and immediate feedback, with negative feedback marking the safe boundary of performance and positive feedback generating growth. All feedback generates information. 'Mistakes' indicate a change in circumstances or interference from the environment."

Logic and Reasoning:

The scientific method uses classical logic closely related to the study of *correct reasoning,* making this the presumptive correct logic for science (36). However, as noted in the vignettes above, our experience belies classical logic as correct reasoning. Classical logic can impair the extension of a discipline.

> At the beginning of the author's (DvS) experience with long-term ventilation, he followed the goal of weaning the child from the ventilator following blood gas evaluation for O_2 and CO_2. One day, a child's grandmother beseeched an LVN to ask if the doctor could leave her grandson on the ventilator. She liked that he smiled, and he had never smiled before. The difference in ventilator management by blood gas versus smile created logical inconsistency with staff from various PICUs. The child's affective response contradicted scientific rationality and logic, along with standard respiratory care references that mechanical ventilation was difficult for a patient to tolerate.

Logical pluralism reflects the possibility that other logic can offer solutions (37). Given the same premises but with different interpretations of "valid," nonclassical logical operators can lead to different logical consequences. What one system captures as valid differs from what the other system captures.

Induction and deduction

Logic supports empirical science. Empirical science develops by evidence from the senses or builds from experience. Logical inference extends evidence in knowledge creation while distinguishing truth from falsity. The ability to prove or disprove the properties of knowledge is fundamental in our use of knowledge. This lies at the heart of inductive and deductive reasoning and influences the selection of formalized logic systems.

Inductivism and inductive reasoning build knowledge from observation, but knowledge is not truth in inductivism. Conclusions from inductive reasoning are plausible rather than having the certainty of truth we see with deductive reasoning. The strength of inductive reasoning comes from the relentless pressure to confirm the plausible conclusion, described by Leonhard Euler (38) in George Pólya (39):

> "[Observations] will lead us continually to new properties which we shall endeavor to prove afterwards. The kind of knowledge which is supported only by observations and is not yet proved must be carefully distinguished from the truth; it is gained by induction, as we usually say…Indeed, we should use such a discovery as an opportunity to investigate more than exactly the properties discovered and to prove or disprove them; in both cases, we may learn something useful."

"Inductivism and inductive reasoning build knowledge from observation, but knowledge is not truth in inductivism. Conclusions from inductive reasoning are plausible rather than having the certainty of truth we see with deductive reasoning. The strength of inductive reasoning comes from the relentless pressure to confirm the plausible conclusion."

Conclusion:

Time has a dimension. There is something more that corrupts understanding of HRO than a pragmatic versus normative stance or a gap between theory and practice. While it is easy to blame movies and television, something more fundamental is present: the incorporation of time as a distinct dimension into a relativity space.

What the criticisms of operators have in common is a frame of reference that has no time dimension. It is not hard to add the dimension of time. We list that in this article and will develop it in subsequent articles. Reviewing the differences in environment, fear-stress-amygdala, and cognition, we find the fallacy of conforming HRO into Newtonian science and Euclidean space.

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Disclosure: *The authors have no conflicts of interests to disclose.*

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Acknowledgments

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William J. Corr, Captain II, Los Angeles City Fire Department (retired)

H. Stefan Bracha, University of University of Hawai'i at Mānoa, United States Department of Veterans Affairs

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Brilliant! Dr. Bell bridges the journey from grief to growth. This is classic wisdom on healing from our heartbreaks and ultimately enjoying a fulfilling life.

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The Art, Science, & Stories of Resilience

Randall Bell, Ph.D.

Enhancing Neonatal Care: A Call for Industry-Wide Collaboration

Mitchell Goldstein, MD, MBA, CML, Suzanne Staebler, DNP, NNP-BC

In neonatal health, a pressing concern has surfaced that demands the attention of industry stakeholders and regulatory bodies. As the National Coalition for Infant Health (NCfIH), we find ourselves at the forefront of advocating for the well-being of our most vulnerable population—infants, particularly those grappling with neonatal seizures.

The catalyst for this discourse is the Citizen Petition filed by Sun Pharma Advanced Research Company Limited (SPARC) on July 24, 2023, spotlighting certain excipients—benzyl alcohol, propylene glycol, and ethanol—embedded in phenobarbital sodium products used for neonatal seizure treatment. Notably, these excipients lack approval from the U.S. Food and Drug Administration (FDA), prompting our call for comprehensive industry-wide collaboration to address these concerns. (1–6)

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Neonatal seizures, impacting infants within their first four weeks of life, require a nuanced therapy response. The NCfIH, as a representative body, emphasizes the imperative of specialized care for infants, considering their unique attributes in terms of size, weight, metabolism, and overall health condition.

Our advocacy extends beyond the immediate concerns raised by the Citizen Petition to encompass a broader perspective on the evolving landscape of neonatal care. It is paramount that industry stakeholders, including pharmaceutical companies, regulatory bodies, and healthcare providers, engage in a collaborative effort to ensure the highest standards of care for neonates. (7)

The historical context surrounding benzyl alcohol serves as a stark reminder of the potential consequences of inadequately scrutinized excipients. Incidents in the 1980s, resulting in severe adverse events and fatalities, underscore the need for heightened vigilance in the development and deployment of pharmaceutical products tailored for neonatal use. The FDA's categorical warnings and restrictions on benzyl alcohol-containing drugs in neonatal patients reinforce the gravity of these risks.

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Similarly, the inclusion of propylene glycol in neonatal medications poses substantial risks, particularly when compounded by the concurrent presence of ethanol. The FDA's 2011 drug safety communication, revealing life-threatening events associated with propylene glycol and ethanol in neonates, underscores the critical importance of vigilant oversight and collaboration among industry stakeholders. (3,6)

However, amidst these concerns lies a significant development—in November of 2022, the FDA's approval of a treatment for neonatal seizures devoid of harmful excipients. This marks a milestone in the quest for safer alternatives, providing healthcare providers with a viable option to ensure the well-being of their neonatal patients.

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As leaders and providers, we are responsible for fostering open communication and collaboration. We urge the FDA to play a pivotal role in disseminating information about the risks associated with phenobarbital sodium products containing unapproved harmful excipients. Furthermore, the FDA's endorsement of a therapeutic intervention free from these excipients should be highlighted to healthcare providers, empowering them with the knowledge to make informed decisions in the best interests of their patients.

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In conclusion, our call for industry-wide collaboration transcends the immediate concerns outlined in the Citizen Petition. It is an invitation to collectively prioritize and elevate neonatal care standards. By fostering a culture of collaboration, transparency, and commitment to the highest patient safety standards, we can pave the way for our neonates' healthier and safer future.

As we navigate these challenges, let us remember that our actions today shape the trajectory of neonatal care tomorrow. Together, we can ensure that every infant receives the specialized and safe care they deserve.

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Disclosures: The authors have no relevant disclosures.

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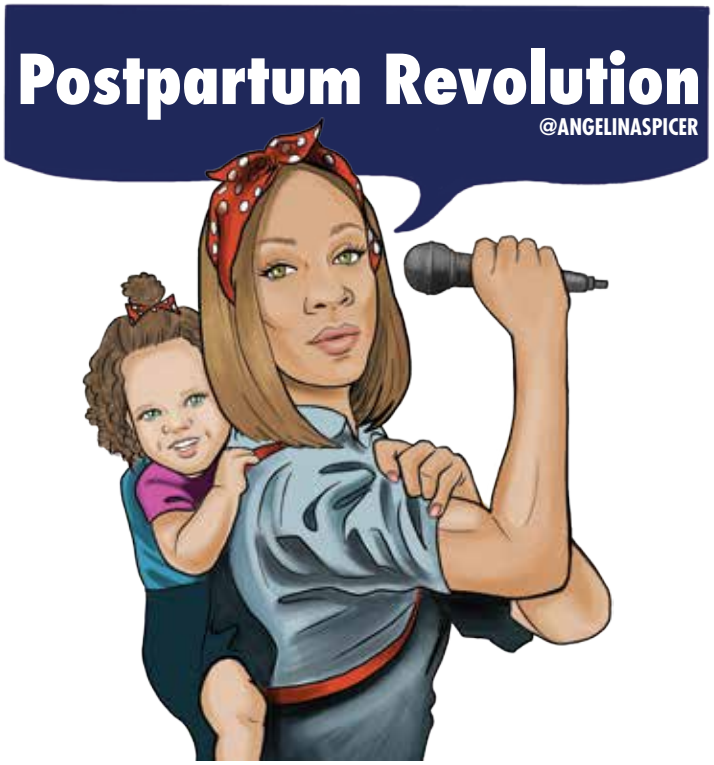
National Coalition for Infant Health Values (SANE)

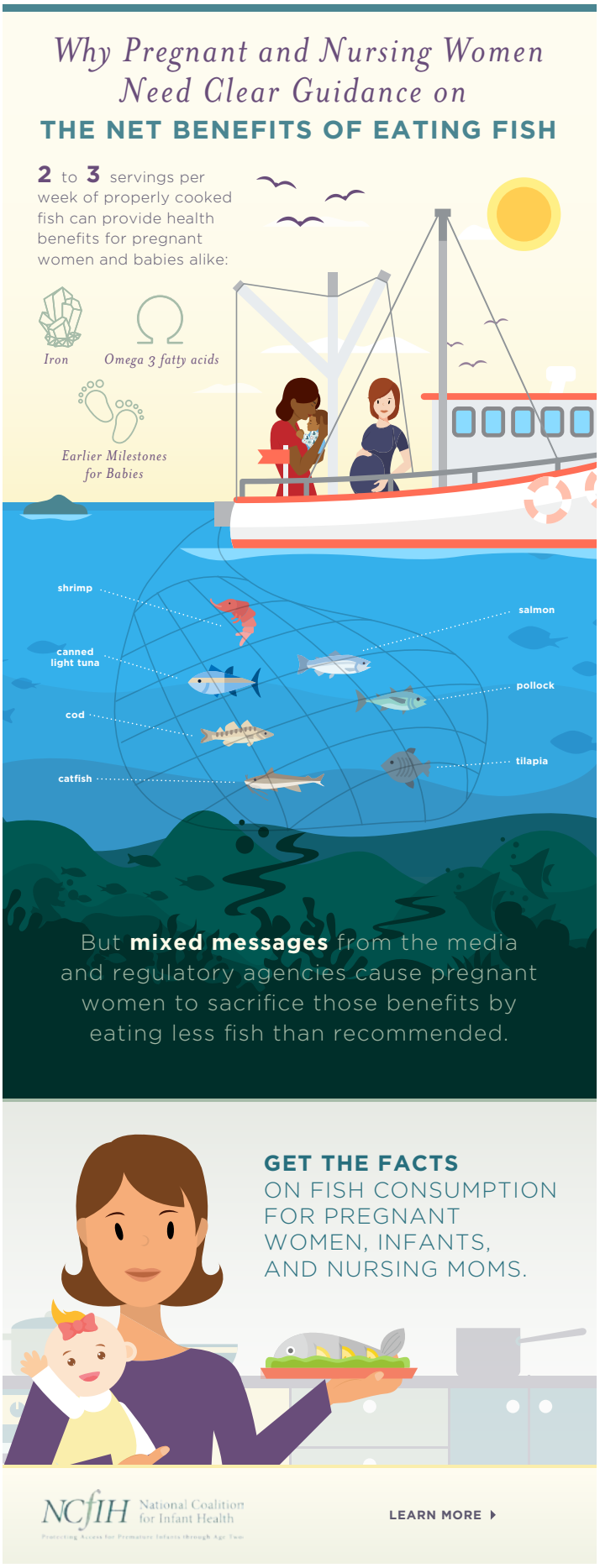
Safety. Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

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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Collateral Damage: Is the Picture We Present Complete Without Discussing it?

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

I dedicate this column 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.

Every consult before a baby's anticipated preterm birth includes a discussion about outcomes, as do subsequent discussions when serious sequelae resulting from their prematurity are expected. The only tools we have at our disposal are statistical outcomes at each post menstrual age (PMA). These statistics, at least emotionally, may mean little to parents for which the only meaningful statistics are "0" and "100" percent; their baby is either going to survive or not, and with or without morbidities (0 or 100) and most cling to the belief that their baby will win the outcomes lottery, statistics notwithstanding.

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Regardless of what information we convey to parents, it invariably focusses on the baby. Since our focus is on the immediate care and treatment of babies this is understandable, but there are factors that influence the outcome of a child, for better or worse, unrelated to their relatively brief stay in the NICU. Those outcomes also impact others in the household.

Many studies have been done examining the quality of life (QOL) of former preterm infants relative to those born at term. From their perspective (self-reporting) the majority of former prems are happy with their lives, although there are several influencing factors. An in-depth analysis of 18 studies found no conclusive evidence to suggest any differences between those born at term or preterm. The studies' participants ranged in age from 18 to 36 years with a birthweight of less than 1500 grams, and while no significant differences were revealed, those with physical disabilities tended to score lower on QOL surveys. (Along with males in general, they were also more likely to decline participation.) The influence of preterm birth on QOL tends to be greatest early and diminish with age, although the study acknowledged that the demands of life later in adulthood could lead to a return in perceived QOL from either a physical or mental health aspect (1). It is noted that recent findings show that extremely premature infants as adults are "lagged behind their term-born peers in related areas of long-term psychosocial outcome, such as wealth and engagement in romantic partnership and sexual intercourse" (1).

"The mechanisms by which SES effects health are multifactorial, but lower SES is associated with shorter life expectancy and overall health (2). This has major implications for those who survive premature delivery with significant physical or mental morbidities."

While the U.S. Declaration of Independence states "…all men are created equal…", this does not play out in the real world. Socioeconomic status (SES) is a major influencing factor on many aspects of life, not the least of which is health. The mechanisms by which SES effects health are multifactorial, but lower SES is associated with shorter life expectancy and overall health (2). This has major implications for those who survive premature delivery with significant physical or mental morbidities. The relationship between SES and preterm birth are not clear, but the rate of preterm birth increases with declining SES via various mechanisms (3). One study found no direct difference in preterm birth and SES, but found food insecurity, stress, and inadequate prenatal care significant risk factors (4). Since these factors are most prevalent in lower SES populations, it is hard to explain why this is not reflected in the study's findings.

"The influence of SES does not end at delivery. Neuroplasticity is a big buzzword in medical rehabilitation circles. With the preterm infant, neuroplasticity is both good and bad. Aside from prematurity, many aspects of the care given and the environment of the NICU adversely affect the developing brain (5)."

The influence of SES does not end at delivery. Neuroplasticity is a big buzzword in medical rehabilitation circles. With the preterm infant, neuroplasticity is both good and bad. Aside from prematurity, many aspects of the care given and the environment of the NICU adversely affect the developing brain (5). Mitigation of the effects of brain injury requires timely identification and intervention. Therapy such as constraint-induced movement therapy to

facilitate the habilitation of babies with cerebral palsy shows great promise but is most effective when commenced early while the brain is still developing and most receptive to intervention (6). This is where things get messy.

"Children of parents with lower SES are much less likely to receive treatment for their morbidities for several reasons. They are more likely to be lost to follow-up where problems are identified and corrective treatment plans are made, and these children have more significant neurological impairment than those not lost to follow-up. Among other factors, children of multiparous mothers are least likely to attend follow-up (7)."

Children of parents with lower SES are much less likely to receive treatment for their morbidities for several reasons. They are more likely to be lost to follow-up where problems are identified and corrective treatment plans are made, and these children have more significant neurological impairment than those not lost to follow-up. Among other factors, children of multiparous mothers are least likely to attend follow-up (7). These families are far less likely to have a breadwinner with healthcare benefits to cover the cost of therapeutic interventions and other expenses necessary for the care of a high-needs child.

"It stands to reason that having other children at home places much greater demands on a mother and the time afforded to provide the care and attention a high-needs child requires. The day of a parent with a high-needs child does not have more minutes than any other day, and more time spent with one child dictates less time spent with another."

That multiparous parents are less likely to bring their children to follow-up clinics for on-going care and assessment brings us to the discussion of collateral damage. It stands to reason that having other children at home places much greater demands on a mother and the time afforded to provide the care and attention a high-needs child requires. The day of a parent with a high-needs child does not have more minutes than any other day, and more time spent with one child dictates less time spent with another. This impacts the childhood and development of "normal" children in the household. A 2013 study of children with high-needs siblings "were more likely to have problems with interpersonal relationships, psychopathological functioning and functioning at school than siblings of non-disabled children" (8). This does not have to be the case. Siblings of autistic children may show beneficial attributes (9), but these decrease as a sibling's responsibilities increase and their inclusion in decision-making decreases (10). Parents of low SES are less likely to have outside help, are more likely to have to work, and have little choice but to off-load caregiving responsibility to their other children. It takes a concerted effort to keep this from happening, some of which can be found here (11).

"A large study out of China reports a protective (but varying) effect of children on a marital relationship, which is reflective of Western studies on the subject (12). Statistics from the Organisation for Economic Cooperation and Development (OECD) do not bear this out. OECD data indicate that having children increases the chance of marital breakup; of reporting OECD countries, an average of 44.4% of marriages without children end in divorce cf 54.6% of those with children (13). "

It is well known that children place a strain on relationships (an old joke about having children being the best form of birth control comes to mind!). A large study out of China reports a protective (but varying) effect of children on a marital relationship, which is reflective of Western studies on the subject (12). Statistics from the Organisation for Economic Cooperation and Development (OECD) do not bear this out. OECD data indicate that having children increases the chance of marital breakup; of reporting OECD countries, an average of 44.4% of marriages without children end in divorce cf 54.6% of those with children (13).

Marital stress is multiplied when a high-needs child is involved. In the U.S., approximately 20% of those married in the 1990s were divorced within 7-8 years (14), and it is widely reported that approximately 50% of marriages end in divorce. When a disabled child is added to the mix, that number jumps to 87%. Parents of autistic (ASD) children have a divorce rate of approximately 80% (15). A large Swedish study showed that extremely premature infants (23-27 weeks PMA) were three times as likely to have ASD as those born at 37-42 weeks PMA (16). The number of children with ASD will increase without a doubt as preterm birth and earlier PMA infants survive.

A large French study found that gestational age had no direct bearing on marital breakup; however, "non-optimal" neurodevelopment increased the risk of breakup, aggravated by low SES. Given the increased risk of abnormal neurological development in the extremely preterm, it stands to reason that this increases risk by extension. In all, 10% of relationships had ended within seven years (median 22 months) (17). Several exclusions in this study might be responsible for the relatively low separation rate reported.

When the family unit breaks apart, children of those with lower SES suffer the most. Children born into affluent families are more

likely to continue to receive support after marital breakup because the amount of child support their custodial parent receives is greater, and they are more likely to be included in at least one parent's benefits. Contrast this with those of poor SES. Mothers almost invariably end up with custody of children after divorce, and since they usually earn less than the non-habiting parent, they are placed in a precarious position. Child support is lower (if collected), and childcare needs can be insurmountable when seeking employment. Even less time can be spent with her high-needs child at a time when maternal attention is most crucial to neurodevelopment. Siblings invariably will be called on to take up the slack, impacting their emotional and social development.

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The final insult to a special needs child occurs as they enter adulthood. While it is sometimes possible to keep a disabled adult child under parental benefits beyond the age of 26, this is far from guaranteed and requires the supporting parent to have benefits that cover them at the time (18). Employers may well balk at the prospect of having a disabled adult adding to the cost of their healthcare coverage, and if no benefits are in place at age 26, there will be no coverage other than that provided by government programs. In Canada, the parents of a child under age 18 who meet the criteria for disability may receive a maximum of $264.41/month (Canadian $). Ontario adds a maximum of $1308 for a maximum of to this and provides basic dental and drug coverage as well as support for assistive devices. The monthly total of $1572.41 is $531.92/month, lower than the Canadian poverty line for a single person. If able to work, a disabled person receiving support may earn up to $1000/month before benefits are reduced. The average cost of a bachelor apartment in Toronto is $1317/month.

"The abysmal support for the disabled and the living conditions forced upon them by it has driven some to seek medically assisted death (legal in Canada). Understandably, this has ignited an ethical firestorm; however, there is no political will to improve the plight of those caught in the trap that poverty is, regardless of cause."

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Beyond discharge outcomes, many factors may negatively influence a child's long-term outcomes. The sad fact is that many families do not have the tools nor the resources to change them, and they may not know this when making the agonizing decision to accept or decline resuscitation of their extremely premature baby. Without this knowledge, are they able to make a truly informed decision?

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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. This article contains elements considered "off label" as well as maneuvers, which may sometimes be very effective but come with inherent risks. As with any therapy, the risk-benefit ratio must be carefully considered before they are initiated.*

NT

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Leadership, Advocacy and Consultation

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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.

Leadership

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.

Thirteen-year-old Emily Rose Shane was tragically murdered on April 3, 2010 on Pacific Coast Highway in Malibu, CA. Our foundation exists to honor her memory.

In Loving Memory

August 9, 1996 - April 3, 2010

Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring of 2012. Due to the COVID-19 outbreak, our work is in jeopardy, and the need for our work is greatly increased. The media has highlighted the dire impact online learning has caused for the very population we serve; those less fortunate. **We need your help now more than ever to ensure another child is not left behind.**

Make a Difference in the Life of a Student in Need Today!
Please visit emilyshane.org

Sponsor a Child in the SEA Program

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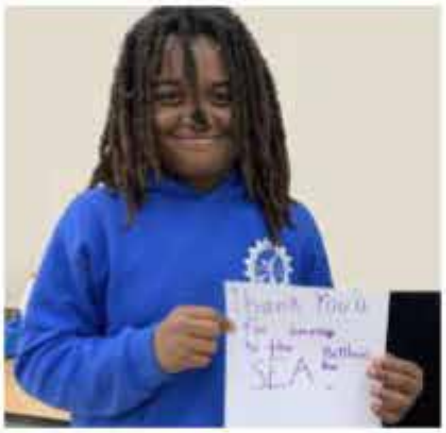


1 session	$15
1 week	$30
1 month	$120
1 semester	$540
1 year	$1,080
Middle School	$3,240

The Emily Shane Foundation is a 501(c)3 nonprofit charity, Tax id # 27-3789582. Our flagship SEA (Successful Educational Achievement) Program is a unique educational initiative that provides essential mentoring/tutoring to disadvantaged middle school children across Los Angeles and Ventura counties. All proceeds directly fund the SEA Program, making a difference in the lives of the students we serve.

The Village Son

A Life's Journey

Iranian village to a university professor in the United States of America in this memoir. As a boy, his unruly behavior was sedated by scholastic challenges as a remedy. At age twelve, he left home for junior high school in a provincial capital. At first, a lack of self-esteem led him to stumble, but he soon found the courage to tackle his subjects with vigor. He became more curious about the world around him and began to yearn for a new life despite his financial limitations. Against all odds, he became one of the top students in Iran and earned a scholarship to study medicine in Europe. Even though he was culturally and socially naïve by European standards, an Italian family in Rome helped him thrive. The author never shied away from the challenges of learning Italian, and the generosity of Italy and its people became part and parcel of his formative years. By the time he left for the United States of America, he knew he could accomplish whatever he imagined.

Houchang D. Modanlou

COPING WITH COVID-19

KEEP PATIENTS UP-TO-DATE WITH CHANGES IN POLICIES SO THEY KNOW WHAT TO EXPECT. LISTEN TO THEIR CONCERNS.

Provide culturally-informed and respectful care.

TELL PARENTS HOW YOU WILL KEEP THEM AND THEIR BABIES SAFE DURING THEIR NICU STAY.

Use technology like video chat apps to include family members who can't visit the NICU.

myNICUnetwork.org

and

National Perinatal Association
NICU Parent Network

My Perinatal Network and My NICU Network are products of a collaboration between NPA and NPN.

TOP 10

RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

SUPPORT 4 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.

Welcome!

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."

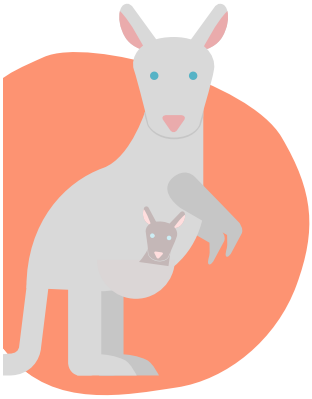
10 HELP US HEAL

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

SUPPORT4NICUPARENTS.ORG

SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

with soap and water for 20+ seconds. Dry well.

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

and ask others to hold your baby when you can't be there

National Perinatal Association

nicuparentnetwork.org

NPN NICU PARENT NETWORK

nationalperinatal.org/skin-to-skin

Position available for Neonatal Nurse Pretensioner (NNP)

Excellent practice opportunity for a NNP in an established Los Angeles neonatal practice. The Neonatal Hospitalist Group (NHG) is interviewing for an NNP to join the practice. The practice includes four NICU's in the Burbank and Glendale area. Call is from home with excellent work life balance. If you are interested, please email Robert Gall, MD, at robertgallmd@gmail.com.

Protecting your baby from

Respiratory Viruses:

What parents need to know this RSV and flu season

RSV (Respiratory Syncytial Virus) and flu infections affect the lungs and can cause serious breathing problems for children and babies.

Certain diagnoses can make children and babies more vulnerable for serious complications - including prematurity, chronic lung disease, heart conditions.

You can limit the spread of viruses by wearing a mask, washing your hands with soap & water, and using alcohol-based hand sanitizer.

The fewer germs your baby is exposed to, the less likely they are to get sick. Limit visitors. Avoid crowds. Stay away from sick people.

Immunizations save lives. Stay up-to-date with your family's flu and COVID-19 vaccinations. This helps stop the spread of deadly viruses.

Babies older than 6 months can get a flu shot. There is no vaccine for RSV, but monthly antibody shots during RSV season can help protect them.

National Perinatal Association

www.nationalperinatal.org/rsv

ONCE UPON A PREEMIE ACADEMY

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Health and Racial in the NICU

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Once Upon A Preemie Academy

+ Dawn Godbolt, Ph.D.
National Birth Equity Collaborative

+ Chavis A. Patterson, Ph.D.
Children's Hospital of Philadelphia

+ Shanté Nixon
Connect2NICU

+ Deidre McDaniel, MSW, LCSW
Health Equity Resources and Strategies

+ Dalia Feltman, MD, MA, FAAP
Univ. of Chicago Pritzker School of Medicine

+ Terri Major- Kincade, MD, MPH
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Raising Global Awareness of RSV

Global awareness about respiratory syncytial virus (RSV) is lacking. RSV is a relatively unknown virus that causes respiratory tract infections. It is currently the second leading cause of death – after malaria – during infancy in low- and middle-income countries.

The RSV Research Group from professor Louis Bont, pediatric infectious disease specialist in the University Medical Centre Utrecht, the Netherlands, has recently launched an RSV Mortality Awareness Campaign during the 5th RSV Vaccines for the World Conference in Accra, Ghana.

They have produced a personal video entitled "*Why we should all know about RSV*" about Simone van Wyck, a mother who lost her son due to RSV. The video is available at www.rsvgold.com/awareness and can also be watched using the QR code on this page. Please share the video with your colleagues, family, and friends to help raise awareness about this global health problem.

RSV GOLD

A Global Mortality Database for Children with RSV Infection

The RSV awareness video was produced in collaboration with the Bill & Melinda Gates Foundation

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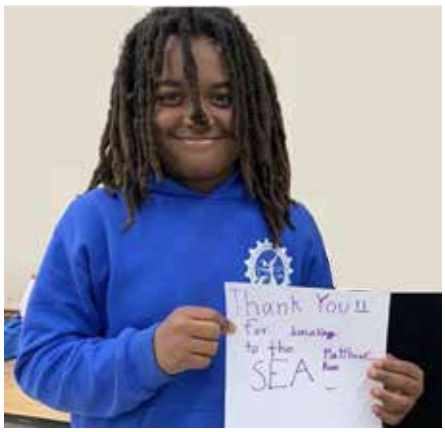

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Peer Reviewed

Gravens By Design: "Hands-Off" and "Hands-On" Care in the NICU: Can They Coexist and be Mutually Reinforcing in the NICU of the Future?

Robert White, MD

In this decade, we have witnessed the steady growth of both "hands-off" and "hands-on" care in the NICU. While at first glance, these would seem to be competing concepts—and indeed, they have been in many respects in the early part of this decade. Experience with both concepts has grown, and now a new factor has emerged—artificial intelligence (AI), which may help us find a way to realize the benefits of both strategies while avoiding most of their downsides.

"In this decade, we have witnessed the steady growth of both 'hands-off' and 'hands-on' care in the NICU. While at first glance, these would seem to be competing concepts—and indeed, they have been in many respects in the early part of this decade. Experience with both concepts has grown, and now a new factor has emerged—artificial intelligence (AI), which may help us find a way to realize the benefits of both strategies while avoiding most of their downsides."

I will define "hands-off" care as the intent to avoid stress in high-risk newborns whenever possible by limiting any "unnecessary" (a concept mostly in the eye of the beholder since there is a paucity of data available to define this) sensory input, to include not only touch but also visual and auditory stimuli. This concept was born out of an era in the early days of NICU care when infants were subjected to excessive stimuli of all sorts—except for human contact, which was extremely restricted.

I will define "hands-on" care as the effort to keep babies in the arms of a parent or surrogate as much as possible, even very soon after birth and even if receiving intensive care in the form of endotracheal intubation, umbilical vessel catheterization, and other similar invasive measures. This, too, can be seen as a reaction to the minimal access given to parents in the early days of NICU care but obviously with a much different philosophy to the "hands-off" approach. Both strategies are intended to minimize the stress on the newborn so they can thrive, but through entirely different methods.

Both "hands-off" and "hands-on" care have advocates who have produced strong scientific evidence that their approach has led to better outcomes than in previous eras. Intraventricular hemorrhage (IVH) prevention protocols embrace a number of "hands-off" practices and, when bundled together, have been shown to reduce the incidence of IVH. (1) However, there is little evidence that any individual component of the bundle (such as minimal touch or continuous dim lighting) is essential to the success of the bundle. In many NICUs, most components of these bundles are continued well beyond the time frame used in the studies to show benefits for IVH prevention; in particular, infants on ventilatory assistance are often kept on "minimal stress" precautions for weeks or months. Notably, one characteristic of these protocols, formal or informal, depending on the NICU, is that parents are given limited opportunities to hold their babies while they are on ventilatory assistance.

"However, there is little evidence that any individual component of the bundle (such as minimal touch or continuous dim lighting) is essential to the success of the bundle. In many NICUs, most components of these bundles are continued well beyond the time frame used in the studies to show benefits for IVH prevention; in particular, infants on ventilatory assistance are often kept on 'minimal stress' precautions for weeks or months."

On the other hand, proponents of "zero separation" have shown that even the highest-risk infants can be safely held by their parents and exposed to various auditory and visual stimuli in the first days of life, with outcomes comparable to the most cautious NICU protocols. (2) A third trend has emerged, that of AI, although it has yet to have practical applications in the NICU with respect to these challenges.

Can we project how each of these well-intentioned strategies might play out in the coming two or three decades (the typical lifespan of a NICU), so that someone currently planning a new

NICU will create an environment of care that gives its babies, families, and caregivers the maximal benefit of all of these trends?

Let us start with basic goals, which I suggest can be identified as follows:

- Support infant homeostasis to the greatest degree possible in order to optimize growth, development, and healing.
- Optimize parent-infant interaction to the greatest degree possible.
- Provide caregivers with as much information as possible to guide their care, packaged and processed, to maximize the accuracy and thoroughness of medical decision-making.

In today's NICU, "hands-off" and hands-on" strategies are intended to support homeostasis, thereby minimizing stress and its related complications, although they seek to achieve that goal through very different methods. Could AI help here? Perhaps so—one of AI's most obvious uses would be detecting imperceptible changes and trends in a patient's status and either alerting a caregiver or implementing a change in clinical support according to the given directions. Consider, for example, our current method of adjusting ventilatory support for a very preterm infant in the first days of life. In the first era of neonatology, we adjusted oxygen input based on visual assessment of color and frequent arterial blood gases; we adjusted ventilator settings based on those same blood gases and ancillary tests such as chest X-rays. With the advent of transcutaneous O_2 saturation and pCO_2 monitors, we obtained real-time continuous data, occasionally confirmed with much less frequent blood gases, but usually could make adjustments in oxygen concentration and ventilator settings based on the transcutaneous information. It is only a matter of time before AI can receive that same information as well as data from the ventilator itself and, based on parameters determined by the clinician, make adjustments in ventilator settings continuously, still with intermittent adjustments in either actual settings or the parameters being used by AI by clinicians as they see fit.

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One can imagine a similar strategy being employed to manage continuous drips to support blood pressure or blood glucose. It is perhaps a little more of a stretch to imagine how sensory input could also be managed with the help of AI. However, let us agree that the goal should be to minimize noxious stimuli and maximize nurturing stimuli. We must only identify how we judge an infant's response to a given environmental input to determine whether it should be limited or encouraged. It is very likely that we already have access to continuous data, such as heart rate, cerebral oxygenation, and brain wave activity, which can be used for this purpose once we learn how to train an AI helper properly.

If AI could provide directed, automatic intervention as well as alert clinicians to times when an infant needed more direct attention, it should be possible to put an infant in the arms of his/her parents with the assurance that homeostasis would be maintained or the clinician alerted when that was not possible within the parameters selected. In this future, but perhaps not too distant scenario, babies could be safely in the arms of a parent or surrogate most of the time.

"What impact would this next era of care have on NICU design? First NICUs will not need to be constructed with "line of sight" considerations...All the information once gained by this design consideration is now available through the interlinking of monitors, cameras, and personal communication devices... Second, it is likely that we can customize each infant's immediate environment—lighting, auditory, temperature, humidity, etc.—to their specific need, rather than using a 'one size fits all' approach that we have been forced to use until now. Third...we can design our NICUs in a way that fully supports a parent or parents who want to essentially live with their baby during the NICU stay, and therefore create patient rooms and support spaces that welcome families as an integral part of our care team, rather than as visitors."

What impact would this next era of care have on NICU design? First —and we are probably already there—NICUs will not need to be constructed with "line of sight" considerations in which nurses would have direct visibility of their baby's bed. All the information once gained by this design consideration is now available through the interlinking of monitors, cameras, and personal communication devices. This does not mean that nurses will not have direct contact with their patients; their bedside duties will remain, but when they are away from the bedside, they will still receive all the information they need about their patient's status electronically. Second, it is likely that we can customize each infant's immediate environment—lighting, auditory, temperature, humidity, etc.—to their specific need, rather than using a "one size fits all" approach that we have been forced to use until now. Third, if we can safely provide care to babies while they are being held for extended periods, we can design our NICUs in a way that fully

supports a parent or parents who want to essentially live with their baby during the NICU stay, and therefore create patient rooms and support spaces that welcome families as an integral part of our care team, rather than as visitors.

It will be a brave new world, but babies will get even better care while minimizing stressors for caregivers and families. The NICUs that do this best will be designed with these changes in mind.

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Disclosure: *The author has no conflicts of interests to disclose.*

Gravens Diversity Travel Award

As part of an initiative to increase diversity at the Gravens Conference, the Gravens Diversity, Equity, Inclusion, and Justice (DEIJ) Committee will provide travel awards to individuals from historically underrepresented groups (i.e., people from racially and ethnically diverse backgrounds, members of the LGBTQ+ population, individuals with cognitive disabilities, individuals with physical disabilities). Applications will open for the 2024 Gravens Diversity Travel Awards on **August 21, 2023**. Applications should be submitted no later than **Monday, October 30, 2023, at 5:00pm EST**.

Several competitive travel awards are expected to be given. The amount awarded will be based on the award availability for that year. Notice of awards are expected to be made no later than December 15, 2023. Please contact Kelly McGlothen-Bell (mcglothen@uthscsa.edu) or Christie Lawrence (Christie_Lawrence@rush.edu) for questions regarding your application.

Eligibility:

- Identify as a member of a historically underrepresented group.
- Must serve the neonatal and/or pediatric intensive care population in a professional capacity.

Application:

- Completion of Gravens Diversity Travel Award Survey, which provides contact information for the applicant and specifies the applicant's eligibility for the award.
- CV or Resume
- Submission of written or video response to the following statements:
    - Describe your personal and professional background.
    - Describe how you believe you will benefit from attending the Gravens Conference.
    - Describe how you'd like to advance DEIJ initiatives for the care of infants and their families.
- Letter of Support detailing the following attributes:
    - Administrative support from applicant's leadership team to participate at the Gravens Conference.
    - Evidence of the applicant's skills, knowledge, experiences in research, practice, service/volunteering, and/or leadership.
    - Commitment to support commitment to DEIJ in practice.

Awardee Responsibilities:

- Plan to attend the full 2024 Gravens Conference.
- Engage with an assigned Gravens Conference buddy.
- Provide post-conference statement (written or video) about the conference experience and how they plan to adopt or incorporate what they've learned at the conference into practice.
- Awardees are highly encouraged to submit an abstract to the subsequent Gravens Conference.

The Gravens Conference
on the Environment of Care for High Risk Newborns

Our message to the supporters, attendees, and participants in the Gravens conferences.

We want to acknowledge concerns regarding holding the 2024 meeting in Florida. For all those who have communicated your thoughts about attending the meeting, we want you to know that we appreciate your forthrightness and wish to offer a statement of our collective thinking on this crucial matter. As our society grows more diverse and connected, we must acknowledge how the social and political climates continue to affect how we live, move, and interact.

Our Gravens community seeks to affirm our commitment to addressing issues of racism and bias and audit our systems to ensure that we are proactive in implementing strategies that promote health equity and social justice. We strive to provide a supportive, inclusive, and welcoming space to all individuals involved in the physical and developmental environment of the neonatal intensive care unit (NICU), including family members, healthcare providers, designers, and industry supporters.

The Gravens community approach is to remain non-political. However, some of the current policies and practices in the state where the Gravens conference is historically held are not consistent with the ideals and values of the Gravens community. The Co-Chairs and Planning Committee are reviewing all opportunities to ensure that the individual identities and lived experiences of those most impacted by the current political landscape are valued and respected.

Should you choose to attend the conference in Clearwater in person, we hope you recognize that there are those whose livelihood depends on tourism and who do not hold the same views as Florida's current prevailing social and political environment. That way, you can support small businesses, specifically those owned by people of color.

As we plan for upcoming Gravens meetings, our priority is to ensure that all attendees can participate in a safe and welcoming environment. The Planning Committee for the 2024 Gravens Conference has discussed the pros and cons of going forward with holding our meeting in Florida, given the recent political decisions that threaten an open and inclusive society. We have explored the possibility of moving the conference to another state; however, we will not be able to do so for the 2024 conference due to fiscal and contractual obligations. We are actively exploring alternative sites for future meetings.

We understand that diversity, equity, inclusion, and justice are principles that must work together to result in fair treatment, access, opportunity, and advancement for all. Therefore, we respect each participant's decision to attend the conference in person or virtually, and we hope you will join us in whatever format suits you best. Through our perseverance and dedication to advancing the care of infants and families, we aim to continue to promote our message of inclusivity and health equity.

Regardless of your position on attending the Gravens conference, you might like to use these strategies right now to make a difference:

- Commit to learning and reflecting on how racism and bias impact us today and how our history led us here.
- Vote for political candidates that are in line with your values.
- Use your voice, lived experience, and privilege to bring awareness and action to address health outcomes and healthcare quality disparities.

We are continuing to work to ensure that the co-chairs, planning committee, and conference attendees reflect both the workforce and the people they serve so that we can best meet the needs of our field. You can support the Gravens Conference Diversity Fund to help ensure the participation and growth of our ever-changing society.

Together, we can create environments where every individual or group will be fully and authentically welcomed, respected, supported, and valued to shape the world for future generations equitably.

For questions or comments, please contact lomalindapublishingcompany@gmail.com.

SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA

EVIDENCE

We encourage families and clinicians to remain diligent in learning **up-to-date evidence**.

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

- **S** EEK PARTICIPATION
- **H** ELP EXPLORE OPTIONS
- **A** SSESS PREFERENCES
- **R** EACH A DECISION
- **E** VALUATE THE DECISION

TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY

LONGITUDINAL DATA

We need to understand more about outcomes for mothers and infants exposed to COVID-19, with special attention to:

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY

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Fragile Infant Forums for Implementation of IFCDC Standards: Key Cornerstone of Interventions for Pain and Stress in the Baby

Jean Powlesland, MS, RN, C-NNIC

Introduction:

The Infant and Family-Centered Developmental Care (IFCDC) Standards, published in 2020 (1) and found at https://nicudesign.nd.edu/nicu-care-standards are embedded in a conceptual model including the key principles of *Infant Mental Health*, *Environmental Protection, Neuroprotection of the Developing Brain*, and *Individualized Care (*see model diagrammed in Figure 1). Also emphasized are the primacy of the parent-baby dyad, the competence of the baby as an interactor, and overall acknowledgment and understanding of the enveloping systems and processes that influence care.

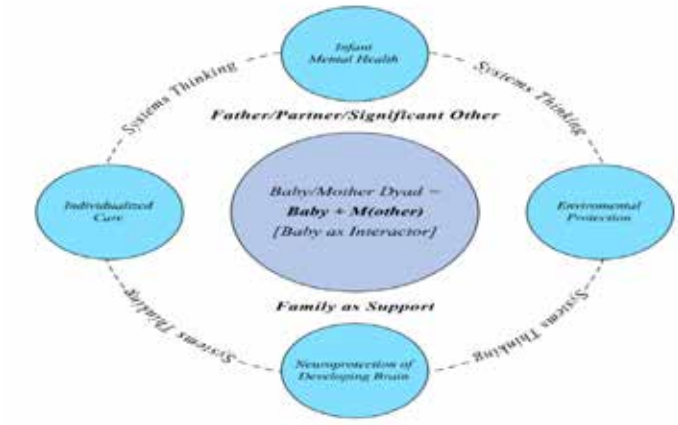

Figure 1: IFCDC Principles – Concept Model

The standards address six domains of evidence-based newborn care. Each standard sets the overall goal and expectation of care, with evidence detailed and referenced on the website. Each standard has a number of competencies that describe components of practice that should be addressed to achieve each standard. The six comprehensive domains include 1) Systems thinking in complex adaptive systems, 2) Positioning and touch for the newborn, 3) Sleep and arousal interventions for the newborn, 4) Skin-to-skin contact with intimate family members, 5) Management of feeding, eating and nutrition delivery, and 6) Reducing and managing pain and stress in newborns and families.

The sixth domain, "Reducing and Managing Stress in Newborns and Families," is broken into two separate standards: the first discusses support of the family, and the second, "Pain and Stress: Babies," The latter focuses on babies' pain and stress will be emphasized in this discussion.

The Standard of Managing Pain and Stress in Families:

A previous Neonatology Today article entitled *Fragile Infant Forums for Implementation of IFCDC Standards: Pain and Stress, Families* discussed the first of these pain and stress standards, focusing on supporting families in intensive care (2). It is important to remember that the delivery of a healthy newborn often presents coping challenges for families; birthing parents and their partners may have major physiologic and hormonal shifts as well as multiple changes in roles and routines, which strain their coping skills and may result in psychological distress. In addition, postpartum mental health issues are known to be more prevalent in populations that are already under stress at the time of childbirth. When parents are faced with the added stress of an infant who may have a prolonged hospitalization or a yet unknown prognosis, the incidence of mental health issues such as anxiety and post-traumatic stress is high and may persist over months (3, 4, 5, 6, 7).

Parental stress is known to decrease responsiveness to the infant and thus may put the infant at risk for poorer developmental outcomes (8). The developmental outcome of children is influenced by the quality of the relationships between the child and caregivers (9). The importance of these relationships is reflected as a core principle of the IFCDC model as *Infant Mental Health* and is embedded implicitly in all the standards and competencies.

Besides their crucial role in overall development, parents are also the best comforters of their infants and can uniquely mitigate the pain and stress experienced during the intensive care stay (10). The family's overall wellbeing is critical to infant wellbeing and is highlighted as the first standard under this domain of *Reducing and managing pain and stress in newborns and families.*

The Standard of Managing Pain and Stress in Newborns:

The standard that deals specifically with the infant's experience of Pain and Stress is worded: ***Standard 2, Pain and Stress, Babies: The interprofessional collaborative team shall develop care practices that prioritize multiple methods to optimize***

baby outcomes by minimizing the impact of stressful and painful stimuli. There are several keywords and phrases in this standard. First, it is an interprofessional and collaborative team that works to manage an infant's pain. Each discipline has relevant expertise to share. While not included in the usual definition of "interprofessional," the competencies in this standard suggest that the infant's family is a key team member and has valuable input when developing a pain management plan. Secondly, the team prioritizes developing multiple strategies to reduce the impact of stress and pain to ensure that options will work in different circumstances and with different infants. Lastly, but most importantly, the goal is to optimize baby outcomes by minimizing stressful and painful stimuli. There is compelling evidence that shows that higher exposure to pain and stress in the neonatal period is associated with adverse outcomes in the development of the brain structure and function as well as long-term physical, social, and emotional outcomes, and thus this is a priority for the team to develop an effective plan (11, 12, 13).

"First, it is an interprofessional and collaborative team that works to manage an infant's pain. Each discipline has relevant expertise to share. While not included in the usual definition of "interprofessional," the competencies in this standard suggest that the infant's family is a key team member and has valuable input when developing a pain management plan. Secondly, the team prioritizes developing multiple strategies to reduce the impact of stress and pain to ensure that options will work in different circumstances and with different infants. Lastly, but most importantly, the goal is to optimize baby outcomes by minimizing stressful and painful stimuli."

Practice competencies for addressing the pain and stress in newborns' standards:

Eleven competencies under this standard (Table 1) can be grouped into three categories.

Education (competencies 2.1, 2.2, 2.3):

All staff should have regular educational sessions focused on pain assessment, management, and the long-term consequences of pain in infants. Policies should enforce that untreated pain is a "never" event for infants. Staff caring for infants should be trained and competent in consistently using a validated pain assessment tool that provides a mutual understanding among all caregivers.

The number of validated tools for pain assessment has proliferated in the past decades. In choosing a tool, one should consider:

Table 1

Standard 2, Pain and Stress, Babies: The interprofessional collaborative team shall develop care practices that prioritize multiple methods to optimize baby outcomes by minimizing the impact of stressful and painful stimuli.
Competency 2.1: Standardized education centered on reduction of pain and stress in babies shall be provided to all interprofessional staff including physicians, NNPs and all newly hired professionals on a regular basis no less frequent than annually.
Competency 2.2: Educational offerings shall include the use of standardized pain assessment tools, recognition of the baby's behavioral communication during stressful or potentially painful procedures, the value of skin-to-skin care in reducing stress, and the appropriate use of pharmacologic and non-pharmacologic interventions.
Competency 2.3: Assessment of pain and/or stress using a validated instrument shall be routinely and regularly administered and documented for all babies.
Competency 2.4: Opportunities for positive interactions with the baby's parents and other caregivers, in particular with familiar loved ones should be prioritized.
Competency 2.5: Opportunities for closeness/skin-to-skin care, as appropriate, and family access to their baby at all times, including during procedures, shall be encouraged, documented and routinely evaluated.
Competency 2.6: Use of non-pharmacologic interventions such as positioning, non-nutritive sucking and appropriate swaddling shall be implemented according to the behavioral communication of the baby, documented and evaluated during routine care protocols within the ICU.
Competency 2.7: Pharmacologic interventions, including the use of sucrose and nonopioids, shall be reserved primarily for episodic painful or stressful procedural events, including retinal exams, intubations, post-operative pain management, etc. Their use shall be balanced against potential negative side effects.
Competency 2.8: When pharmacological therapy is utilized, non-pharmacologic interventions shall be used in conjunction with it as a component of a comprehensive pain and stress management strategy.
Competency 2.9: Pain and stress management should be individualized and based on each baby's behavioral and physiological communication and consideration of the parents' expressed preferences.
Competency 2.10: Appropriate information regarding pharmacological and non-pharmacological pain management options for their baby should be provided to parents; Parents shall be included in discussions and encouraged to participate in decisions about pain management for their baby.
Competency 2.11: Families should be included in the development of protocols for assessment and management of neonatal pain/stress, and these protocols shall be readily available to the interprofessional staff.

Table 1: IFCDC Standard and Competencies for Pain and Stress, Babies

Is the tool validated for the appropriate type of pain (procedural/episodic or prolonged/post-surgical pain)? Is the tool validated for the right age population? Is it user-friendly for the bedside staff and easy to become proficient in its use?

These assessment tools are validated for pain and not stress, and it can be difficult to differentiate between them. The staff must develop skills at observing and understanding infant behavior, such as used in the NIDCAP (Newborn Individualized Developmental Care and Assessment Program) observation techniques (15, 16) to recognize subtle changes in the infant's behavior that may indicate early signs of stress. Learning to recognize the infant's unique stress patterns also serves as a common language for staff and parents to communicate the infant's comfort level and focus attention on the overall regulation and comfort of the baby.

Chronic stress adversely affects the central nervous system (17), so caregivers should intervene when the infant shows signs of early to moderate stress. The education of professionals and family members should focus on common non-pharmacologic measures (including skin-to-skin and breastfeeding) to mitigate stress and pain. Observing and understanding the infant's behavioral communication helps the caregivers evaluate if the strategies being used are effective or if they should try alternatives.

Parents as primary comforters (competencies 2.4, 2.5, 2.10, 2.11):

These competencies reflect the principle of parents having unrestricted access to the infant; non-separation of infant and parent throughout the intensive care stay should be promoted. The parent's role in mitigating stress and having pleasurable, enjoyable interactions is integral to the IFCDC Standards' conceptual model. Skin-to-skin care has powerful effects on the infant's physical and developmental outcomes but also reduces the infant's pain and stress behaviors (18). Breastfeeding also appears to reduce pain behaviors in newborns and combines the pain reduction effects of "sweet solutions," such as sucrose, with the effects of pleasurable touch, taste, and smell, truly providing a multisensory approach that may be more effective in pain expression reduction (19). Having the infant skin-to-skin or breastfeeding during minor procedures should be encouraged when feasible. Parents should be prepared and supported to comfort their child during potentially painful or stressful procedures actively.

"Finally, family members should participate as crucial members of the pain management plan by giving input into their baby's pain management, as well as serving as consultants in developing unit-wide pain management protocols and algorithms."

Intensive care staff often are hesitant to do painful procedures on infants with the parents present as active supporters, so they will benefit from education as well as practical preparation to increase their confidence. Intensive care staff should have opportunities to practice those skills in a simulated environment or with guidance from an experienced mentor. Finally, family members should participate as crucial members of the pain management plan by giving input into their baby's pain management, as well as serving as consultants in developing unit-wide pain management protocols and algorithms.

Choosing pain management interventions and evaluating effectiveness through infant observation (competencies 2.6, 2.7, 2.8, 2.9):

These competencies address the importance of contingent caregiving based on what the infant communicates through their behavior. Treatments for pain should be individualized to the infant's signs of pain or stress and responses to intervention. Parents can partner with staff in observing the infants and collaborating to choose effective interventions. Typical non-pharmacologic interventions for preterm infants that have research support, in addition to skin-to-skin care and breastfeeding, include non-nutritive sucking, facilitated tucking and swaddling (20). Other interventions that may be helpful include reducing noxious stimulation by maintaining a quiet, dimly lit environment, providing positive sensory experiences such as drops of breastmilk, use of a cloth that has the mother's scent, and use of the parent's voice, among others.

"Typical non-pharmacologic interventions for preterm infants that have research support, in addition to skin-to-skin care and breastfeeding, include non-nutritive sucking, facilitated tucking and swaddling (20)."

These strategies are based on diverse sensory modalities, either by reducing stimulation (light, sound in environment), supporting the infant's own inclinations to self-calm (non-nutritive sucking, swaddling to keep the body tucked, keeping hands to face), or adding pleasurable stimulation (breastfeeding, drops of breastmilk, mother's voice). These are all used to comfort the infant, not just as a pain and stress reduction strategy. The desired result is for the baby to have more restful sleep, stable physiologic functioning, and a calm state that promotes healing, growth, and development. Competency 2.8 states that nonpharmacologic measures should be used in conjunction whenever medication is used to treat pain. In some ways, the term "nonpharmacologic" interventions is a misnomer here as it implies that these strategies are used primarily as a substitute for medication rather than on an ongoing basis to promote the infant's regulation.

"In some ways, the term "nonpharmacologic" interventions is a misnomer here as it implies that these strategies are used primarily as a substitute for medication rather than on an ongoing basis to promote the infant's regulation."

The time to address pain management is not just when a procedure is scheduled. Since there is evidence to suggest that a stressed baby may have a more intense reaction to pain, and because chronic stress harms development, the caregiver should continuously observe the baby's behavior for signs of discomfort and dysregulation. It is then possible to modify the environment and care to reduce stressful components to prevent long-term issues and help the infant better manage the next painful procedure.

There are data to show that an infant who is already stressed when a painful procedure occurs may have a heightened brain reaction compared to infants who are not stressed (21). Of note, the difference in brain activity may not be reflected in the infant's behavior. It may be that a stressed infant experiences a painful procedure more intensely than a calmer baby. This suggests that the caregiver should assess the baby's stress level before a procedure and, if necessary, take the time to calm the baby.

Competency 2.7 states that medication therapy (including sucrose and nonopioid therapeutics) should be used only for episodic painful procedures. Opioids, when used, should be used cautiously, given the possible adverse effects on the infant's outcomes associated with long-term use (22). Competency 2.11 recommends that professionals with input from families develop evidence-based protocols. These can be implemented to provide consistency in approach and thus improve the infant's experience of pain and stress (23).

"...medication therapy (including sucrose and nonopioid therapeutics) should be used only for episodic painful procedures. Opioids, when used, should be used cautiously, given the possible adverse effects on the infant's outcomes associated with long-term use (22)."

Conclusion:

Frequent pain events and chronic stress are often part of an infant's intensive care experience and may have deleterious effects on the infant's development. These experiences are associated with adverse effects on brain structure, function, pain perception, as well as future behavioral and mental health issues. It is of the utmost importance that the intensive care team and the infant's family work together to reduce the pain and stress experienced. The Standards, Competencies, and Best Practices for Infant and Family Developmental Care in the Intensive Care Unit has set two standards to guide care: One focuses on the wellbeing of family members while the other focuses on the wellbeing of the infant. Together, these standards acknowledge that the wellbeing and ultimate development of the infant primarily depend on the wellbeing of the family; an overly stressed parent may not be emotionally available or attuned to their infant to provide adequate comfort. It is important to remember how these standards relate to the IFCDC conceptual model, including the non-separation of baby and parent. The parent provides the most consistent and effective opportunity to keep the baby regulated continuously, and their presence and support are essential.

The competencies in the model for "Managing Pain and Stress: Infant" address 1) the knowledge needed by intensive care professionals and family members to understand the significance of pain exposure, how to assess for pain and stress in the infant appropriately, and know effective strategies to manage infant pain; 2) the role of family members in providing comfort, nonpharmacologic pain relief, and supporting the overall regulation of their baby; and 3) choosing the appropriate pain relief strategies based on understanding the baby's behavioral communication, using guidelines to promote consistency of intervention as well as monitoring the infant's responses to interventions.

Finally, the IFCDC Standards are an evidence-based resource that intensive care professionals can utilize and be assured of their value in enhancing practice. While a unit may wish to focus on one or two of the domains of interest, it is important to understand the conceptual model from which they are generated and ensure that the competencies are implemented considering the key principles. In the context of this standard, Infant Mental Health focuses on building attuned relationships and encouraging parents to support their baby through stressful times and routine care. Environmental Protection refers to modifying the aspects of the environment in response to the infant's tolerances; in this instance, facilitating the baby to be calm, especially before a procedure. Individualized Care focuses on understanding what the baby communicates about their tolerances and modifying the care in timing and intensity to respect that. Neuroprotection of the Developing Brain is a critical principle here, as the evidence of the long-term negative sequelae of chronic exposure to pain and stress is strong. When integrated into practice, these principles can create circumstances where the baby and family undergo their intensive care journey in a calmer, regulated manner, which will optimize their outcomes.

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Figure 1: IFCDC Principles – Concept Model

Taken from: https://nicudesign.nd.edu/nicu-care-standards/ifcdc-principles-concept-model/

Table 1: IFCDC Standard and Competencies for Pain and Stress, Babies

Taken from: https://nicudesign.nd.edu/nicu-care-standards/ifcdc--recommendations-for-best-practice-reducing-managing-pain-stress-in-newborns-families/

Disclosure: *The author has no conflicts of interests to disclose.*

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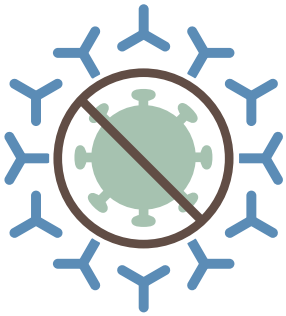

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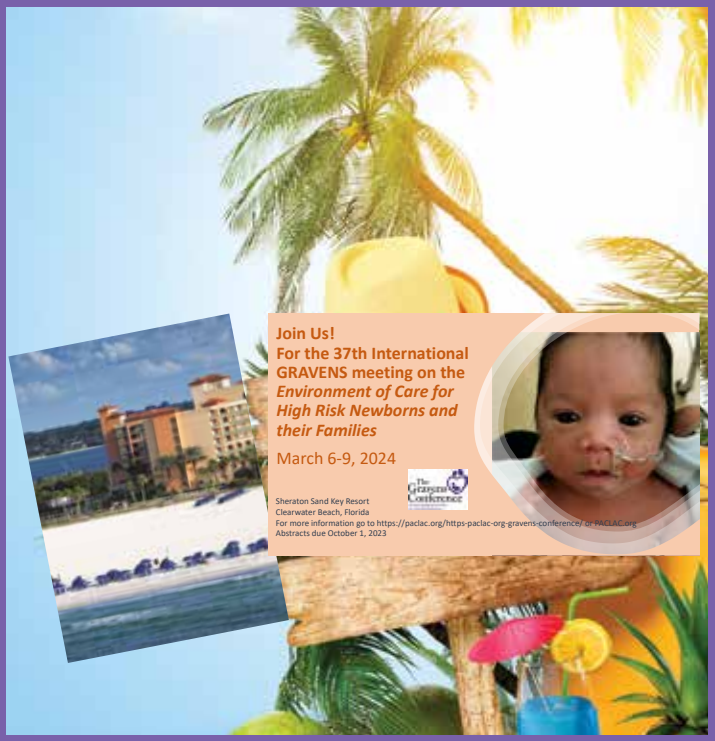

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Full Conference In-person 3/6-3/9	$800.00
Institutional Group Zoom Registration (10 Attendees)	$2,500.00
Institutional Group Zoom Registration (50 Attendees)	$10,000.00
International Low Income Country Zoom Registration	$85.00
International Zoom Registration	$250.00
Diversity Scholarship Participants	$300.00
Donation	

Course Objectives

- At the conclusion of the program, participants should be able to:
- Relate rationale for implementing optimal family centered, developmentally supportive care standards and environmental design approaches in newborn intensive care units.
- Describe rationale and evidence to keep parents and babies consistently together from delivery to discharge
- Identify current environmental design for newborn intensive care units that benefit babies, families and staff.
- Compare and contrast evidence based developmental and family centered care programs.
- Implement evidence based infant and family centered developmental care changes in your unit.

Target Audience

This program has been developed to meet the educational needs of healthcare practitioners such as Neonatal Nurses (RNs, NNPs, ARNPs), NICU Therapists, Neonatologists, Pediatricians, Psychologists, Occupational Therapists, Physical Therapist, Speech-Language Pathologist, Family Support Staff, Architects, Hospital Administration, Infant & Child Development Specialists, Social Workers & Counselors, Parents and Family members and other professionals working with high-risk infants, their families or their physical environment.

Competencies to be addressed

PATIENT CARE AND PROCEDURAL SKILLS;
Medical knowledge; Systems-based practice; Professionalism; Interpersonal and communication skills.

DISCLAIMERS:
Final number of continuing education credits maybe changed based on speakers objectives. PAC/LAC reserves the right to amend speakers, topics and scheduling at any time.

GRIEVANCES:
Any grievances may be made to info@paclac.org

Continuing Education

PAC/LAC is accredited by CMA to provide continuing medical education for physicians.

PAC/LAC is an approved provider by the California Board of Registered Nursing, Provider number CEP 5862.

Pending accreditation approval (application in process)
- Occupational Therapy
- Respiratory Care Therapist

Documentation will be provided for self-reporting:
- Physical Therapy
- Architect
- Speech/Language and Audiology Therapists

Certificate Policy:

After completion of the course evaluation, you will be provided with a continuing education certificate. Make sure to save your certificate.

PAC/LAC will assist you with finding your certificate for up to 1 year from the event without cost. For assistance with any certificates older than 1 year from the time of the event, PAC/LAC charges $20 for the first certificate, and $15 for each additional certificate requested each calendar year. A $10 processing fee will be added to requests needing fulfillment within 24 hours.

Equal Opportunity & Accommodations for Disabilities:

PAC/LAC is an Equal Opportunity /Affirmative Action / Equal Access Institution.

For disability accommodations contact PAC/LAC at 818-708-2850, or email Gayane Pakhanyan at gpakhanyan@paclac.org a minimum of fifteen (15) working days in advance of the event

Faculty

Andy Gomm, MSW

Brian Goldman, MD

Britt Pados

Carol Jaeger, DNP, RN, NNP-BC

Carol McNair RN(EC), PhD, NNP- BC, NP-Peds

Christine Lawrence, DNP, RNC-NIC, APN/CNS

Cuyler Romeo , MOT, OTR/L, SCFES, IBCLC

Cynthia Sparer

Elizabeth Rogers, MD

Erick Ridout

Erin Ross, PhD, CCC-SLP

Gloria Yennaco, RNC-NIC, C-ELBW, BSN

Jean Powlesland

Jeffrey R. Alberts

Jim Greenberg, MD

Juzer Tyebkhan, MBBS, MRCP(UK), FRCP(C)

Kelly McGlothen PhD, RN, IBCLC

Kimberly Novod, MPA

Kristina Reber, MD

Laura Poltronieri, AIA

Malathi Balasundaram, MD, FAAP

Mardelle McCuskey Shepley, D.Arch., FAIA

Mitchell Goldstein MD, MBA, CML

Mia Malcolm, BS

Nathalie Maitre

Raylene Phillips, MD, MA, FAAP, FABM, IBCLC

Rebecca Ames, MS

Robert White, MD

Paige Church MD

Petra Huppi

Co-Chair Executive Planning Committee Members
Robert White, MD
Mitchell Goldstein, MD, MBA, CML
Joy Browne, Ph.D, PCNS, IMH-E
Vincent C. Smith, MD MPH

Please click on the QR Code then click on the Faculty Tab to view Biography and view our Planning Committee Members

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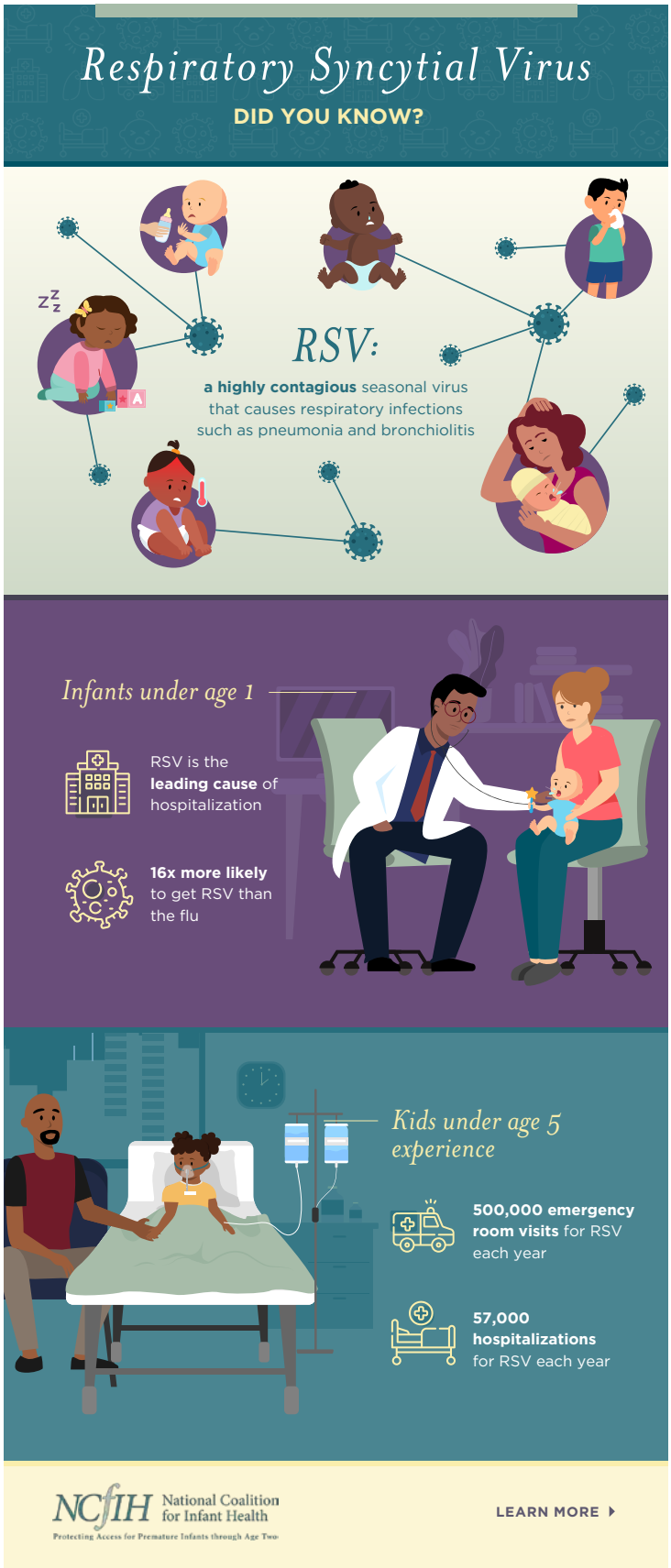
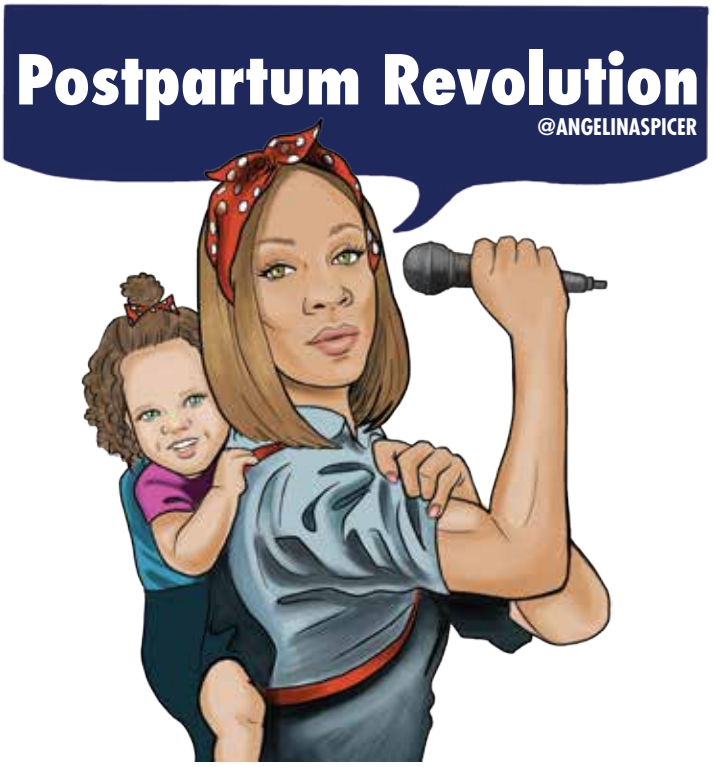


The Gap Baby: An RSV Story



Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY

Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

Even though there are some things we don't know about COVID-19 yet, there are many more things that we do know. We know that there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.
- Wash for more than 20 seconds.
- Use alcohol-based sanitizers.

Limit Contact with Others

- Stay home when you can.
- Stay 6 feet apart when out.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

Provide Protective Immunity

- Hold baby skin-to-skin.
- Give them your breast milk.
- Stay current with your family's immunizations.

Take Care of Yourself

- Stay connected with your family and friends.
- Sleep when you can.
- Drink more water and eat healthy foods.
- Seek mental health support.

Immunizations Vaccinations save lives. Protecting your baby from flu and pertussis lowers their risks for complications from coronavirus.

WARNING

Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask makes it hard for them to breathe.
- Masks pose a risk of strangulation and suffocation.
- A baby can't remove their mask if they're suffocating.

If you are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop the virus from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

We can help protect each other.
Learn more
www.nationalperinatal.org/COVID-19

National Perinatal Association

Neonatology Today's Digital Presence

Neonatology Today's now has a digital presence. The site is operational now and defines the future look of our digital web presence. By clicking on this https://www.neonatologytoday.org/web/., researchers can download individual manuscripts both in digital format and as part of the original PDF (print journal). While the PDF version of Neonatology Today will continue in its present form, we envision that the entire website will be migrated to this format in the next several months. We encourage you to take a look, "kick the wheels," and let us know where we still need to improve.. We are working towards making the website more functional for subscribers, reviewers, authors and anyone else. Although we have not yet applied for inclusion in the National Library of Medicine Database (Pub-Med), this new format meets several of the important metrics for this ultimate goal. As of December, 2020, NT has its own account with CrossRef and will assign DOI to all published material.

As we indicated last month, we look forward to a number of new features as well.

1. An online submission portal: Submitting a manuscript online will be easier than before. Rather than submitting by email, we will have a devoted online submission portal that will have the ability to handle any size manuscript and any number of graphics and other support files. We will have an online tracking system that will make it easier to track manuscripts in terms of where they are in the review process.
2. Reviewers will be able to review the manuscript online. This portal will shorten the time from receipt of review to getting feedback to the submitting authors.
3. An archive search will be available for journals older than 2012.
4. A new section called news and views will enable the submission of commentary on publications from other journals or news sources. We anticipate that this will be available as soon as the site completes the beta phase
5. Sponsors will be able to sign up directly on the website and submit content for both the digital and PDF issues of Neonatology Today.

Neonatology Today will continue to promote our Academic True Open Model (ATOM), never a charge to publish and never a charge to subscribe.

If there are any questions about the new website, please email Dr. Chou directly at:

fu-sheng.chou@neonatologytoday.net

Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

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Neonatology Today Welcomes Carolyn TenEyck, RN as Advocacy Director on its All Volunteer Board

Mita Shah, MD

"Neonatology Today is thrilled to announce the appointment of Carolyn TenEyck, RN, as the new Advocacy Director on its all volunteer board. With an extensive background as a Biopharmaceutical Advocacy Executive, Carolyn brings a wealth of experience, leadership, and a genuine commitment to advancing patient access, education, and empowerment for specialty biologics and therapeutics."

Neonatology Today is thrilled to announce the appointment of Carolyn TenEyck, RN, as the new Advocacy Director on its all volunteer board. With an extensive background as a Biopharmaceutical Advocacy Executive, Carolyn brings a wealth of experience, leadership, and a genuine commitment to advancing patient access, education, and empowerment for specialty biologics and therapeutics.

A Proven Advocate and Leader:

Carolyn TenEyck is a seasoned and highly skilled Advocacy leader with a track record of building and leading successful Advocacy functions for companies both large and small. Her expertise lies in fostering trusted relationships across multiple therapeutic areas, creating mutually-aligned partnerships with organizations and champions, and driving strategic business results with resilience, cross-functional collaboration, and teamwork.

Global Impact at Novavax, Inc:

In her most recent role as Global Vice President, Advocacy at Novavax, Inc., Carolyn created the global Advocacy function to address the healthcare crisis of COVID-19. She conducted a benchmark analysis across continents and strategically aligned with 50 organizations dedicated to educating and elevating the need for ongoing individual and collective immune vigilance. Under her leadership, significant support for equitable access was garnered, leading to successful authorizations with the FDA and CDC.

Carolyn's innovative approach is evident in creating "theVOICESofCOVID.com," an unbranded site providing credible information about COVID and peer-to-peer relatable stories. She also hosted Advocacy Advisory boards capturing patient perspectives in the US, Europe, and the UK.

"Carolyn's innovative approach is evident in creating "theVOICESofCOVID.com," an unbranded site providing credible information about COVID and peer-to-peer relatable stories. She also hosted Advocacy Advisory boards capturing patient perspectives in the US, Europe, and the UK."

Prolacta Bioscience Achievements:

Prior to her role at Novavax, Carolyn served as Senior Director, Advocacy and Government Affairs at Prolacta Bioscience. There, she led a cross-functional team, expanding access to human milk nutrition in Neonatal Intensive Care Units while actively engaging stakeholders at state and federal levels. Carolyn's efforts extended internationally, increasing the company's footprint with Advocacy partners and expanding its therapeutic profile.

During her tenure at Prolacta Bioscience, Carolyn created and led the Advocacy function, building tier-one relationships with 50 patient, professional, policy, and academic organizations. Her "surround sound" approach to education, utilizing webinars, conferences, facility tours, and more, contributed to the success achieved through seamless, cross-functional collaboration across the organization.

Recognitions and Awards:

Carolyn TenEyck's impactful contributions to the field have been recognized with prestigious awards, including the Lifetime Achievement Award from the National Black Nurses Association and the CEO Award as Employee of the Year (2020) from Prolacta

Bioscience.

A Visionary Leader in Advocacy:

With a Bachelor of Science in Journalism/Public Relations and a solid background in nursing, Carolyn TenEyck brings a unique blend of skills to her role as Neonatology Today's Advocacy Director. Her passion for patient-centered advocacy, along with her proven track record, makes her a valuable addition to the Neonatology Today team, and we look forward to the positive impact she will undoubtedly have on the neonatology community.*Disclosures:*

Disclosures: The author has no disclosures

NT

Corresponding Author

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Mita Shah, MD
Assistant Professor
Loma Linda University Childrens Hospital
Loma Linda, CA
Email: mitashah@llu.edu

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
Hilton Los Angeles North/Glendale, Glendale CA

Wednesday, January 31, 2024

Time	Title	Speaker
7:00am	**Registration and Refreshments**	
Presentations: AM Moderated by Dr. Arun Pramanik **PM** Moderated by Dr. Donald Null		
8:00am	**Opening Remarks**	Donald Null, MD Emeritus Professor of Pediatrics University of Utah
8:10am	***Special Lecture*** ***NonInvasive Ventilation: What is New in 2024***	Manoj Biniwale MD Associate Professor of Pediatrics Division of Neonatal Medicine Keck School of Medicine of USC Los Angeles General Medical Center
9:05am	**Special Lecture** **HFJV: Insight into Flow, Frequency, & Time**	Keith Kohutek, BSRC, RRT-NPS Senior Clinical Specialist Bunnel Incorporated
09:55am	**BREAK**	
10:15am	**Special Lecture** **Why HFOV is not Working and How to Fix it**	Donald Null, MD Emeritus Professor of Pediatrics University of Utah
11:05am	**Special Lecture** **Management Strategies for Neonatal NAVA: what are the nuances?**	Kimberly S. Firestone, MSc, RRT Akron Children's Hospital Director, Respiratory Care & Clinical Outreach Service
11:50am	ABSTRACT Resistance is Defined by Impedance in Tube Dynamics: The Effect of Tube Size and Oxygen Content	Mitchell Goldstein, MD, MBA, CML Professor of Pediatrics, Loma Linda University School of Medicine
1:00pm	**Special Lecture** **Quantum Mechanics and High Frequency Ventilation**	Mitchell Goldstein, MD, MBA, CML Professor of Pediatrics, Loma Linda University School of Medicine
1:50pm	**Special Lecture** **Hypotension in Preterm infants: Diagnosis and Management**	Shahab Noori, MD, MS CBTI, RDCS Professor of Pediatrics Keck School of Medicine, USC

***Agenda is subject to change without notice.**

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
Hilton Los Angeles North/Glendale, Glendale CA

2:45pm	**Special Lecture** **Technology Competencies for Pediatric Trainees**	Colleen A. Kraft, MD, MBA, FAAP Professor of Pediatrics Keck School of Medicine at the University of Southern California Division of General Pediatrics Children's Hospital Los Angeles 2018 President, American Academy of Pediatrics
3:30pm-3:45pm	**BREAK**	
3:45pm	Abstract Factors Predictive of serial abnormal neurological examinations in the first 36 months of life in very low birth weight infants	Harini Thirumalai Research Assistant, Neonatology Keck School of Medicine at USC
4:00pm	**Special Lecture** **Neonatal Neuromonitoring in the Critically Ill Infant**	Valerie Chock, M.D., M.S. Epi Arline and Pete Harman Endowed Faculty Scholar, Stanford Maternal & Child Health Research Institute Associate Professor of Neonatology Stanford University School of Medicine
4:55pm	**Closing Remarks**	Dr. Donald Null

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
Hilton Los Angeles North/Glendale, Glendale CA

Thursday, February 1, 2024

Time	Title	Speaker
7:00am	**Registration and Refreshments**	
Presentations: AM Moderated by Dr. Mitchell Goldstein **PM** Moderated by Dr. Arun Pramanik		
8:00am	**Special Lecture** **Update on PDA Occlusions in very low birth weight infants**	Frank Ing, MD Chief, Co-Director, Division of Pediatric Cardiology Pediatric Heart Center UC Davis Health Center
8:55am	**Special Lecture** **Update on Neonatal Seizures**	Arthur Partikian, MD Clinical Associate Professor of Pediatrics & Neurology Keck School of Medicine of USC Director, Division of Child Neurology at LAC+USC Medical Center
9:50am	ABSTRACT Predictors for abnormal neurodevelopmental pattern detection in very low birth weight infants using Bayley Scales of Infant and Toddler Development - III scores in the first 3 years of life	Harini Thirumalai Research Assistant, Neonatology Keck School of Medicine at USC
10:05am	**BREAK**	
10:30am	ABSTRACT Novel technique for managing mucous plugging in the extremely low birth weight neonate using flexible fiberoptic bronchoscopy	Tiffany Campbell, MD Pediatric Resident, PGY2 Joe DiMaggio Children's Hospital Memorial Healthcare System
10:45am	**Special Lecture** **Neonatal PICC Lines are not Benign**	Frank Ing, MD Chief, Co-Director, Division of Pediatric Cardiology Pediatric Heart Center UC Davis Health Center
11:40am	ABSTRACT Advances in Neonate and Pediatric Cardiopulmonary System	Georgette A. Adeyiga, MBBS of Medicine
12:00pm	**LUNCH**	
1:00pm 2:20pm 3:40pm	**Recurring Workshops** **A. Functional Echocardiography** **B. Lung US** **C. aEEG /NIRS Workshop**	**A.** Dr. Yogen Singh, Dr. Shahab Noori, Dr. Rangasamy Ramanathan, Dr. Mahmood Ebrahimi

***Agenda is subject to change without notice.**

	D. Noninvasive Ventilation	**B.** Dr. Amy Yeh & Dr. Jennifer Shepherd **C.** Dr. Valerie Chock & Kathi S. Randall, MSN, NNP-BC **D.** Dr. Manoj Biniwale

***Agenda is subject to change without notice.**

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
Hilton Los Angeles North/Glendale, Glendale CA

Friday, February 2, 2024

Time	Title	Speaker
7:00am	**Registration and Refreshments**	
Presentations: AM Moderated by Dr. Donald Null **PM** Moderated by Dr. Mitchell Goldstein		
8:00am	ABSTRACT Revolutionizing Growth: Unleashing the Power of Targeted Total Parenteral Nutrition Strategies	Mitchell Goldstein, MD, MBA, CML Professor of Pediatrics, Loma Linda University School of Medicine
8:15am	**Special Lecture** **Nutritional approach for neonates with congenital heart disease**	Cynthia L Blanco, MD Professor, Department of Pediatrics Chief, Division of Neonatology Director, Neonatal Nutrition and Bone Institute, University Health System Greehey Family Foundation Chair in Neonatology Research The University of Texas Health Science Center San Antonio
9:00am	***Robert A deLemos Memorial Lecture*** **Is there a Role of Inhaled Nitric Oxide in Premature Infants-Revisited?**	Arun Pramanik, MD, DCH, FAAP, FIAP Professor of Pediatrics LSU Health, Shreveport, LA
9:50am	**BREAK**	
10:15am	**Special Lecture** **Nutritional Management of the NANO Preterm Infant**	Cynthia L Blanco, MD Professor, Department of Pediatrics Chief, Division of Neonatology Director, Neonatal Nutrition and Bone Institute, University Health System
11:05am	**Special Lecture** **Fetoscopy and stem cells in fetal surgery**	Shinjiro Hirose, MD Vice Chair Dept of Surgery Chief Div. of Pediatric Surgery UC Davis Medical Center
12:00pm	**LUNCH**	

***Agenda is subject to change without notice.**

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
Hilton Los Angeles North/Glendale, Glendale CA

1:00pm	**Special Lecture** **RSV New Therapies**	Mitchell Goldstein, MD, MBA, CML Professor of Pediatrics, Loma Linda University School of Medicine
2:00pm	**Special Lecture** **Physiology Based Management of Septic Shock and Cardiocentric Management**	Yogen Singh, MBBS, MD Professor, Pediatrics, Neonatology Division, Loma Linda University School of Medicine
2:50pm	ABSTRACT AVR-48 treatment appears to improve respiratory system mechanics in former preterm lambs	Andrew Rebentisch University of Utah-Department of Pediatrics
3:05pm-3:20pm	**BREAK**	
3:20pm	ABSTRACT Mode of respiratory management of preterm lambs affects long-term outcomes of neurobehavior and insulin-like growth factor-1 expression and epigenetic profile in the hippocampus	Andrew Rebentisch University of Utah-Department of Pediatrics
3:35pm	**Antibiotic Stewardship: The Good the Bad and the Ugly**	Donald Null, MD
4:20pm	ABSTRACT	
4:30pm	**Closing Remarks** **Door Prize**	Donald Null, MD

***Agenda is subject to change without notice.**

40th Advances in Neonatal and Pediatric Cardiorespiratory Care

Attend in person

Jan 31 - Feb 2, 2024

Location:
Hilton Los Angeles North/Glendale
Glendale, CA

This conference is unique because it focuses on physiology based patient care

Confirmed Guest Speakers

- Frank Ing
- Donald Null
- Colleen Kraft
- Shahab Noori
- Amy B. Hair
- Rangasamy Ram
- Mitch Goldstein
- Kevin Kohutek
- Valarie Y-L Chock
- Cynthia L. Blanco
- Shinjiro Hirose
- Arthur Partikian
- Kimberly Firestone
- Arun Pramanik
- Yogen Singh

Hands-on Practice Sessions for FECHO/LUS/aEEG

WHY YOU SHOULD ATTEND?

- Hands on experience with the latest ultrasound techniques for cardiopulmonary hemodynamic assessment using state of the art simulation equipment.
- Hands on experience with the use of various ventilators including the use of nasal high frequency ventilation.
- Learn how technology can help address health disparities in children.
- Trauma and Critical Care in an austere or out of hospital environment.
- Management of Post Discharge Bronchopulmonary Dysplasia associated Pulmonary Hypertension and pediatric patients with pulmonary hypertension.

GENERAL INFORMATION

Agenda

Agenda 2024
https://paclac.org/wp-content/uploads/2023/08/Agenda-2024-2.pdf

Location

Hilton Los Angeles North/Glendale
100 W. Glenoaks Blvd.
Glendale, CA 91202

In the event in-person attendance is canceled or capacity limits modified per CDC or public health guidelines, the conference will be modified accordingly or presented entirely as a live virtual activity.

Registration

We suggest you register early.

Online – To register online, please go to:

https://www.eventbrite.com/e/40th-advances-in-neonatal-and-pediatric-cardiorespiratory-care-tickets-653266115537?aff=oddtdtcreator

Conference Parking

Self Parking: $10.00

Valet Parking: $29.00

Transportation

Metro: 400 W. Cerritos Ave., Glendale, CA. 91204

UBER/LYFT: Estimate $10-$12.00

The nearest airports are:

Hollywood Burbank Airport (BUR) - 12.8km/8mi

Los Angeles International (LAX) - 43.5km/27mi

Ontario International Airport (ONT) - 72.42km/45mi

Long Beach Airport (LGB) - 56.32km/35mi

Refunds

Cancellations must be received in writing by January 2, 2024 and will be subject to a $75 processing fee. No refunds will be given after that date.

Hilton Los Angeles North/Glendale

Accommodations

We have a room block reserved at the Hilton Los Angeles North/Glendale in Glendale for January 31 2024 through February 2, 2024. Booking your room is simple, just select “Book a Room” to receive your group’s preferred rate. Use link to book your room: Booking Link: https://www.hilton.com/en/book/reservation/deeplink/?ctyhocn=BURHGHF&groupCode=PAC&arrivaldate=2024-01-30&departuredate=2024-01-31&flexibleDates=true&cid=OM,WW,HILTONLINK,EN,DirectLink&fromId=HILTONLINKDIRECT

Rate: $189 +Tax
Group Code: PAC
Arrival Date: January 30, 2024
Departure Date: February 2, 2024
There is a 72hr cancellation policy for reservations.

It is strongly advised that you make room reservations early.

With a stay at Hilton Los Angeles North/Glendale in Glendale (Downtown Glendale), you’ll be within a 15-minute drive of Universal Studios, Hollywood and Crypto.com Arena. This hotel is 11. 9 mi (19. 1 km) from University of Southern California and 8. 4 mi (13. 5 km) from Universal CityWalk.

Popular sites/entertainment in the Glendale and Southern CA locations:

- **Disneyland**
- **Beaches**
- **Americana at Brand**
- **Gene Autry Museum**
- **Los Angeles Zoo**
- **Magic Castle**
- **Descanso Gardens**

Faculty

COURSE DIRECTOR

Donald M. Null, Jr. MD
Emeritus Professor of Pediatrics,
University of Utah

FACULTY

Arun Pramanik, MD, DCH, FAAP, FIAP
Professor of Pediatrics,
LSU Health, Shreveport, LA

Mitchell Goldstein, MD, MBA, CML
Professor of Pediatrics,
Loma Linda University School of Medicine Director,
Neonatal ECMO Program Division of Neonatology,
Department of Pediatrics Loma Linda University Children's Hospital
Loma Linda, California

Rangasamy Ramanathan, MD
Professor of Pediatrics Division Chief, Neonatal Medicine,
LAC+USC Medical Center Director, NPM Fellowship,
Program and NICU Keck School of Medicine of University of Southern California Los Angeles, California

Colleen A. Kraft, MD, MBA, FAAP
Professor of Pediatrics Keck School of Medicine at the University of Southern California Division of General Pediatrics Children's Hospital Los Angeles,
2018 President, American Academy of Pediatrics

Amy B. Hair, MD
Associate Professor
Program Director of Neonatal Nutrition,
Co-Director of NICU Intestinal Rehab Team, Director of MCH Neonatal Nutrition Training Program Division of Neonatology Department of Pediatrics Baylor College of Medicine Texas Children's Hospital

Keith Kohutek, BSRC, RRT-NPS
Bunnell
Senior Clinical Specialist
Pacific Region

Valerie Chock, M.D., M.S. Epi
Arline and Pete Harman Endowed Faculty Scholar,
Stanford Maternal & Child Health Research Institute
Associate Professor of Neonatology
Stanford University School of Medicine

Arthur Partikian, MD
Clinical Associate Professor of Pediatrics & Neurology
Keck School of Medicine of USC
Director, Division of Child Neurology at LAC+USC Medical Center

Shahab Noori, MD, MS CBTI, RDCS
Professor of Pediatrics
Keck School of Medicine, USC
Administrative Director & Section Head, Clinical Research
Fetal and Neonatal Institute
Division of Neonatology
Children's Hospital Los Angeles

Cynthia L. Blanco, MD Professor of
Pediatrics Chief, Division of Neonatology
Dept. of Pediatrics UTHealth San Antonio

Shinjiro Hirose, MD, FACS
Surgeon-in-Chief, UC Davis Children's Hospital
Vice Chair, Department of Surgery,
UC Davis School of Medicine
Professor and Chief - Division of Pediatric General, Thoracic, and Fetal Surgery
UC Davis Health, School of Medicine,
Department of Surgery
Director of Pediatric Surgery – Shriners Hospitals for Children – Northern California

Kimberly S. Firestone MSc, RRT
Director of Respiratory Care and Clinical Outreach Services
Akron Children's Hospital

Yogen Singh, MBBS, MD
Professor, Pediatrics, Neonatology Division, Loma Linda University School of Medicine

Workshops

A. Functional Echocardiography

B. Lung US

C. aEEG /NIRS

D. Noninvasive Ventilation

Dr. Yogen Singh, Dr. Shahab Noori, Dr. Rangasamy Ramanathan, Dr. Mahmood Ebrahimi, Dr. Manoj Biniwale, Dr. Amy Yeh, Dr. Jennifer Shepherd, Dr. Valerie Chock, Kathi S. Randall, MSN, NNP-BC

40th Annual Conference, January 31-February 2, 2024

DESCRIPTION

40th Advances in Neonatal and Pediatric Cardiorespiratory Care Conference (formerly: High-Frequency Ventilation of Infants, Children & Adults) will present high quality education and networking opportunities to healthcare professionals who provide care for critically ill neonatal and pediatric with a focus on advances in therapeutics and technologies. Along with featured speakers, the conference includes abstract presentations on research on advances in these areas.

TARGET AUDIENCE

Geared towards multidisciplinary teams of caregivers from neonatal units that include: neonatologists, pediatricians, neonatal nurse practitioners, advanced pediatric providers, registered nurses and respiratory care practitioners.

Attendees who choose to attend the live virtual activities will receive a virtual meeting link and password to access the live virtual conference.

All registrants (live or virtual) will be provided the opportunity to review recorded sessions up to 3 weeks following the conference.

Attendees will be awarded CME credit commensurate with the extent of their participation in the live activity (either in-person or virtual). The recorded sessions are not certified for CME credit.

DISCLAIMERS:

Final number of continuing education credits maybe changed based on speakers objectives. PAC/LAC reserves the right to amend speakers, topics and scheduling at any time.

GRIEVANCES:

Any grievances may be made to info@paclac.org

FEES

MD and PhD Registration	$500.00
RN, RT & Residents	$300.00
MD & PhD Group Rate 4+ Attendees	$400.00
RN, RT & Residents Group Rate 4+ Attendees	$250.00
Students	$100.00
MD & PhD 1 Day Registration	$200.00
MD & PhD 2 Days Registration	$350.00
RN, RT and Residents 1 Day Registration	$200.00
RN, RT and Residents 2 Day Registration	$250.00

CONTINUING EDUCATION

PAC/LAC is accredited by the California Medical Association (CMA) to provide continuing medical education for physicians.

The Perinatal Advisory Council-Leadership, Advocacy and Consultation (PAC/LAC) is an approved provider by the California Board of Registered Nursing, Provider Number CEP-5862

Application has been made to the American Association for Respiratory Care (AARC) for continuing education contact hours for respiratory therapists.

CERTIFICATE POLICY:

After completion of the course evaluation, you will be provided with a continuing education certificate. Make sure to save your certificate. PAC/LAC will assist you with finding your certificate for up to 1 year from the event without cost. For assistance with any certificates older than 1 year from the time of the event, PAC/LAC charges $20 for the first certificate, and $15 for each additional certificate requested each calendar year. A $10 processing fee will be added to requests needing fulfillment within 24 hours.

COURSE OBJECTIVES

At the conclusion of the program, participants should be able to:

1) Discuss new options for RSV prophylaxis, how does everything fit together.
2) How to improve antibiotic stewardship in the NICU.
3) Describe new concepts in Nasal Ventilation in newborns, including setup strategies and risks.
4) Understand the latest thinking in Neuro monitoring and Neonatal seizures.
5) Identify new strategies in the feeding of the “Nano” preemie.
6) Understand how to use the different ventilator modalities, including Jet, NAVA, HFOV, and their indications.
7) Incorporation of Point of Care Ultrasound in NICU practice.
8) Describe the new technology competencies for pediatric Trainees.
9) Understand new advances in fetal surgery.
10) Understand the benefits of a breastmilk in the management of infants with complex congenital heart disease.
11) Hypoxemic Respiratory Failure in very Preterm, Late Preterm & Term Newborns: Diagnosis and Management Consideration.
12) Understand Management of Pulmonary Hypertension in the preterm, the role of iNO.
13) Relate the complications of PICC lines.
14) Discuss the management of hypotension in the preterm infant.
15) Describe the latest innovation in PDA occlusion.
16) Hands-on workshops with the latest equipment in Neonatal, Pediatric, and Adult Critical Care Medicine including functional cardiac, lung ultrasound, AEEG, and noninvasive ventilation.

For accommodations email info@paclac.org
A minimum of ten (15) working days in advance.

Practical Data Analytics for Innovation in Medicine:

Building Real Predictive and Prescriptive Models in Personalized Healthcare and Medical Research Using AI, ML, and Related Technologies

Second Edition

Gary D. Miner, Linda A. Miner, Scott Burk, Mitchell Goldstein, Robert Nisbet, Nephi Walton, Thomas Hill

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Lady Stephenson Library
Newcastle upon Tyne
NE6 2PA
United Kingdom

admin@cambridgescholars.com
www.cambridgescholars.com

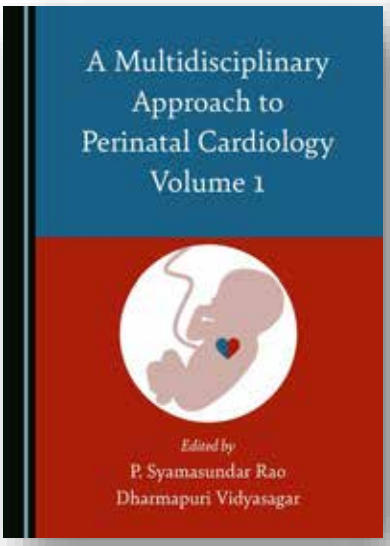
Fax +44 (0)191 265 2056

Cambridge Scholars Publishing is registered in the United Kingdom.

Companies House Reg. Number: 4333775.
VAT Number: 108280727.

A Multidisciplinary Approach to Perinatal Cardiology *Volume 1*

Edited by P. Syamasundar Rao and Dharmapuri Vidyasagar



Hardback

ISBN-13:
978-1-5275-6722-1

ISBN-10:
1-5275-6722-2

Date of Publication:
24/04/2021

Pages / Size:
794 / A5

Price:
£99.99

Book Description

Recent developments in diagnostic and therapeutic aspects of cardiac and neonatal issues have advanced the care of the newborn. To achieve excellence in cardiac care, however, close interaction and collaboration of the pediatric cardiologists with neonatologists, pediatricians, general/family practitioners (who care for children), anesthesiologists, cardiac surgeons, pediatric cardiac intensivists, and other subspecialty pediatricians is mandatory. This book provides the reader with up-to-date evidence-based information in three major areas of neonatology and prenatal and neonatal cardiology. First, it provides an overview of advances in the disciplines of neonatology, prenatal and neonatal cardiology, and neonatal cardiac surgery in making early diagnosis and offering treatment options. Secondly, it presents a multidisciplinary approach to managing infants with congenital heart defects. Finally, it provides evidence-based therapeutic approaches to successfully treat the fetus and the newborn with important neonatal issues and congenital cardiac lesions. This first volume specifically explores issues related to perinatal circulation, the fetus, ethics, changes in oxygen saturations at birth, and pulse oximetry screening, diagnosis, and management.

About the Editors

Dr P. Syamasundar Rao, MD, DCH, FAAP, FACC, FSCAI, is Professor of Pediatrics and Medicine and Emeritus Chief of Pediatric Cardiology at the University of Texas-Houston Medical School. He received his medical degree from Andhra Medical College, India, and subsequently received post-graduate training both in India and the USA before joining the faculty at the Medical College of Georgia, USA, in 1972. He has also served as Chairman of Pediatrics at King Faisal Specialist Hospital and Research Center, Saudi Arabia, and Professor and Director of the Division of Pediatric Cardiology at the University of Wisconsin and St. Louis University, USA. He has authored 400 papers, 16 books and 150 book chapters, and is a recipient of numerous honors and awards.

Dr Dharmapuri Vidyasagar, MD, MSc, FAAP, FCCM, PhD (Hon), is currently Professor Emeritus in Pediatrics at the University of Illinois, Chicago, where he served as Professor of Pediatrics for four decades. He is a graduate of Osmania Medical College, India. He has published over 250 papers and authored several books with a focus on prematurity, neonatal pulmonary diseases and neonatal ventilation. His goal is to reduce neonatal mortality in the USA and around the world, and he has received multiple awards and honors including the Ellis Island Award.

A Multidisciplinary Approach to Perinatal Cardiology Volume 1 is available now in Hardback from the Cambridge Scholars website, where you can also access a free 30-page sample.

My NICU Network
My Perinatal Network

National Perinatal Association + NICU Parent Network

Online L&D Staff Education Program

Caring for Pregnant Patients & Their Families:

Providing Psychosocial Support During Pregnancy, Labor and Delivery

WWW.MYPERINATALNETWORK.ORG

Continuing education credits provided by

pac-lac

About the Program

- **WHO SHOULD TAKE THE PROGRAM?** This program is designed for both office and hospital staff in all disciplines that interact with pregnant patients and their families. A key focus is recognizing risk factors for perinatal mood and anxiety disorders, and mitigating their impact through provision of trauma-informed care.

- **WHY TAKE THE PROGRAM?** Families will benefit when staff have improved skills, through enhanced parental resilience and better mental health, and improved parent-baby bonding leading to better developmental outcomes for babies. Benefits to staff include improved skills in communicating with patients; improved teamwork, engagement and staff morale; reduced burnout, and reduced staff turnover.

- **HOW DOES THE PROGRAM ACHIEVE ITS GOALS?** Program content is representative of best practices, engaging and story-driven, resource-rich, and developed by a unique interprofessional collaboration of obstetric and neonatal professionals and patients. The program presents practical tips and an abundance of clinical information that together provide solutions to the emotional needs of expectant and new parents.

- **HOW WAS THE PROGRAM DEVELOPED?** This program was developed through collaboration among three organizations: a multidisciplinary group of professionals from the National Perinatal Association and Patient + Family Care, and parents from the NICU Parent Network. The six courses represent the different stages of pregnancy (antepartum, intrapartum, postpartum), as well as perinatal mood and anxiety disorders, communication techniques, and staff support.

Program Objectives

- Describe principles of trauma-informed care as standards underlying all communication during provision of maternity care in both inpatient and outpatient settings.
- Identify risk factors, signs, and symptoms of perinatal mood and anxiety disorders; describe treatment options.
- Define ways to support pregnant patients with high-risk conditions during the antepartum period.
- Describe obstetric violence, including ways that providers may contribute to a patient's experience of maternity care as being traumatic; equally describe ways providers can mitigate obstetric trauma.
- Describe the importance of providing psychosocial support to women and their families in times of pregnancy loss and fetal and infant death.
- Define the Fourth Trimester, and identify the key areas for providing psychosocial support to women during the postpartum period.
- Identify signs and symptoms of burnout as well as their ill effects, and describe both individual and systemic methods for reducing burnout in maternity care staff.

Continuing education credits will be provided for physicians, clinic and bedside nurses, social workers, psychologists, and licensed marriage and family therapists. CEUs will be provided by Perinatal Advisory Council: Leadership, Advocacy, and Consultation.

PROGRAM CONTENT

COMMUNICATION SKILLS CEUs offered: 1

Learn principles of trauma-informed care, use of universal precautions, how to support LGBTQ patients, obtaining informed consent, engaging in joint decision-making, delivering bad news, dealing with challenging patients.

Faculty: Amina White, MD, MA, Clinical Associate Professor, Department of OB/Gyn, University of North Carolina, Chapel Hill, NC; Sue Hall, MD, MSW, FAAP, St. John's Regional Medical Center, Oxnard, CA; Karen Saxer, CNM, MSN, University of North Carolina Maternal-Fetal Medicine, UNC Women's Hospital, Chapel Hill, NC; Tracy Pella, Co-Founder & President, Connected Forever, Tecumseh, NE.

PERINATAL MOOD AND ANXIETY DISORDERS CEUs offered: 1

Identify risk factors for and differential diagnosis of PMADs (perinatal mood and anxiety disorders), particularly perinatal depression and/or anxiety and posttraumatic stress syndrome. Learn the adverse effects of maternal depression on infant and child development, and the importance of screening for and treating PMADs.

Faculty: Linda Baker, PsyD, psychologist at Unstuck Therapy, LLC, Denver, CO; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Angela Davids, Founder of Keep 'Em Cookin', Baltimore, MD; Brittany Boet, Founder of Bryce's NICU Project, San Antonio, TX.

PROVIDING ANTEPARTUM SUPPORT CEUs offered: 1

Identify psychosocial challenges facing high risk OB patients, and define how to provide support for them, whether they are inpatient or outpatient. Recognize when palliative care is a reasonable option to present to pregnant patients and their families.

Faculty: Amina White, MD, MA, Clinical Associate Professor, Department of OB/Gyn, University of North Carolina, Chapel Hill, NC; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Angela Davids, Founder of Keep 'Em Cookin', Baltimore, MD; Erin Thatcher, BA, Founder and Executive Director of The PPROM Foundation, Denver, CO.

PROVIDING INTRAPARTUM SUPPORT CEUs offered: 1

Describe how to manage patient expectations for labor and delivery including pain management; identify examples of obstetric violence, including identification of provider factors that may increase patients' experience of trauma; learn how to mitigate patients' trauma, and how to provide support during the process of labor and delivery.

Faculty: Sara Detlefs, MD, Fellow in Maternal-Fetal Medicine, Baylor College of Medicine, Houston, TX; Jerry Ballas, MD, MPH, Associate Clinical Professor, UCSD Health System, Maternal-Fetal Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California at San Diego, San Diego, CA; MaryLou Martin, MSN, RNC-NIC, CKC, Women's and Children's Services Nurse Educator, McLeod Regional Medical Center, McLeod, SC; Claire Hartman, RN, IBCLC, Labor & Delivery, University of North Carolina Hospital, Chapel Hill, NC; Crystal Duffy, Author of Twin To Twin (from High Risk Pregnancy to Happy Family), and NICU Parent Advisor, Houston, TX; Erin Thatcher, Founder and Executive Director of The PPROM Foundation, Denver, CO.

PROVIDING POSTPARTUM SUPPORT CEUs offered: 1

Define the 4th Trimester and the importance of follow-up especially for high risk and minority patients, learn to recognize risk factors for traumatic birth experience and how to discuss patients' experiences postpartum; describe the application of trauma-informed care during this period, including support for patients who are breastfeeding and those whose babies don't get to go home with them.

Faculty: Amanda Brown, CNM, University of North Carolina Hospital, Chapel Hill, NC; ; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Crystal Duffy, Author of Twin To Twin (from High Risk Pregnancy to Happy Family), and NICU Parent Advisor, Houston, TX.

SUPPORTING STAFF AS THEY SUPPORT FAMILIES CEUs offered: 1

Define burnout and compassion fatigue; identify the risks of secondary traumatic stress syndrome to obstetric staff; describe adverse impacts of bullying among staff; identify the importance of both work-life balance and staff support.

Faculty: Cheryl Milford, EdS, Consulting NICU and Developmental Psychologist, Director of Development, National Perinatal Association, Huntington Beach, CA; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Erin Thatcher, BA, Founder and Executive Director, The PPROM Foundation, Denver, CO

Cost

- RNs: $10/CEU; $60 for the full program
- Physicians, licensed clinical social workers (LCSWs), licensed marriage and family therapists (LMFTs): $35/CEU; $210 for the full program
- Although PACLAC cannot award CEs for certified nurse midwives, they can submit certificates to their own professional organization to request credit. $35/CEU; $210 for the full program

Contact help@myperinatalnetwork.org to learn more.

Faculty

Linda Baker, PsyD
Psychologist at Unstuck Therapy, LLC, Denver, CO.

Jerasimos (Jerry) Ballas, MD, MPH
Associate Clinical Professor, UCSD Health System, Maternal-Fetal Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California at San Diego, San Diego, CA.

Amanda Brown, CNM, MSN, MPH
University of North Carolina-Chapel Hill Hospitals, Chapel Hill, NC.

Sara Detlefs, MD
Fellow in Maternal-Fetal Medicine, Baylor College of Medicine, Houston, TX.

Sue L. Hall, MD, MSW, FAAP
Neonatologist, Ventura, CA.

Claire Hartman, RN, IBCLC
Labor & Delivery, University of North Carolina Hospital, Chapel Hill, NC.

MaryLou Martin, MSN, RNC-NIC, CKC
Women's and Children's Services Nurse Educator, McLeod Regional Medical Center, McLeod, SC.

Cheryl Milford, EdS.
Former NICU and Developmental psychologist, in memoriam.

Karen Saxer, CNM, MSN
University of North Carolina Maternal-Fetal Medicine, UNC Women's Hospital, Chapel Hill, NC.

Amina White, MD, MA
Clinical Associate Professor, Department of Obstetrics and Gynecology, University of North Carolina, Chapel Hill, NC.

Parent/Patient Contributers:

Brittany Boet
Founder, Bryce's NICU Project, San Antonio, TX.

Angela Davids
Founder, Keep 'Em Cookin', Baltimore, MD.

Crystal Duffy
Author of Twin To Twin (from High Risk Pregnancy to Happy Family), and NICU Parent Advisor, Houston, TX.

Tracy Pella, MA
Co-Founder and President, Connected Forever, Tecumseh, NE.

Erin Thatcher, BA
Founder and Executive Director, The PPROM Foundation, Denver, CO.

CANCELLATIONS AND REFUNDS

- For Individual Subscribers:
  - If you elect to take only one course, there will be no cancellations or refunds after you have started the course.
  - If you elect to take more than one course and pay in advance, there will be no cancellations or refunds after payment has been made unless a written request is sent to help@myperinatalnetwork.com and individually approved.
- For Institutional Subscribers:
  - After we are in possession of a signed contract by an authorized agent of the hospital and the program fees have been paid, a 50% refund of the amount paid will be given if we are in receipt of a written request to cancel at least 14 (fourteen) days prior to the scheduled start date for your hospital's online program.
  - Refunds will not be given for staff members who neglect to start the program. Also, no refunds for those who start the program, but do not complete all 6 courses within the time frame allotted.

For Physicians: This activity has been planned and implemented in accordance with the Institute for Medical Quality and the California Medical Association's CME Accreditation Standards (IMQ/CMA) through the Joint Providership of the Perinatal Advisory Council: Leadership, Advocacy and Consultation (PAC/LAC) and the National Perinatal Association. PAC/LAC is accredited by the Institute for Medical Quality/California Medical Association (IMQ/CMA) to provide continuing education for physicians. PAC/LAC takes responsibility for the content, quality and scientific integrity of this CME activity. PAC/LAC designates this activity for a maximum of 6 *AMA PRA Category 1 Credit(s)TM*. Physicians should only claim credit commensurate with the extent of their participation in the activity. This credit may also be applied to the *CMA Certification in Continuing Medical Education*.

For Nurses: The Perinatal Advisory Council: Leadership, Advocacy and Consultation (PAC/LAC) is an approved provider by the California Board of Registered Nursing Provider CEP 5862. When taken as a whole, this program is approved for 7 contact hours of continuing education credit.

For CAMFT: Perinatal Advisory Council: Leadership, Advocacy, and Consultation (PAC/LAC) is approved by the California Association of Marriage and Family Therapists to sponsor continuing education for LMFTs and LCSWs. CE Provider #128542. PAC/LAC maintains responsibility for the program and its content. Program meets the qualifications for 6 hours of continuing education credit for LMFTs and LCSWs as required by the California Board of Behavioral Sciences. You can reach us at help@myperinatalnetwork.org.

SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- **HORIZONTAL INFECTION**
- **SEPARATION AND TRAUMA**

EVIDENCE

We encourage families and clinicians to remain diligent in learning **up-to-date evidence**.

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

- **S** EEK PARTICIPATION
- **H** ELP EXPLORE OPTIONS
- **A** SSESS PREFERENCES
- **R** EACH A DECISION
- **E** VALUATE THE DECISION

TRAUMA-INFORMED

Both parents and providers are confronting significant...

- **FEAR**
- **GRIEF**
- **UNCERTAINTY**

LONGITUDINAL DATA

We need to understand more about outcomes for mothers and infants exposed to COVID-19, with special attention to:

- **MENTAL HEALTH**
- **POSTPARTUM CARE DELIVERY**

NEW DATA EMERGE DAILY. NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

Partnering for patient-centered care when it matters most.

nann.org nationalperinatal.org

National Association of Neonatal Nurses

National Perinatal Association

FREE ONLINE EDUCATION

Coping with COVID-19

A viral pandemic

A racial pandemic within a viral pandemic

Will mental illness be the next inevitable pandemic?

WWW.MYNICUNETWORK.ORG

and

National Perinatal Association
NICU Parent Network

CDC Calls for Infants to be Tested for Hepatitis C

Josie Cooper

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. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of directors. Its physician leadership is supported by policy advocacy management and public affairs consultants. In 2012, AfPA established the Institute for Patient Access (IfPA), a related 501(c)(3) non-profit corporation. In keeping with its mission to promote a better understanding of the benefits of the physician-patient relationship in the provision of quality healthcare, IfPA sponsors policy research and educational programming.

AfPA | Alliance for Patient Access

IfPA | Institute for Patient Access

"Children and infants should be tested for hepatitis C if they may have been exposed at or around birth, according to new recommendations from the Centers for Disease Control and Prevention."

Children and infants should be tested for hepatitis C if they may have been exposed at or around birth, according to new recommendations from the Centers for Disease Control and Prevention.

A nucleic acid test can be given between 2 months and six months of age to ensure timely diagnosis and treatment. The CDC has also recommended screening women for hepatitis C during each pregnancy.

Hepatitis C, Pregnant Women & Newborns

The push for early testing reflects rising rates of hepatitis C in the United States. The incidence has risen significantly over the past several years, coinciding with the increased use of intravenous drugs accompanying the opioid epidemic.

Women of childbearing age have been disproportionately impacted. Perinatal transmission from mother to child is the most common way for children to be infected with hepatitis C. Around 8% of babies born to hepatitis C-positive women contract the infection themselves.

"Women of childbearing age have been disproportionately impacted. Perinatal transmission from mother to child is the most common way for children to be infected with hepatitis C. Around 8% of babies born to hepatitis C-positive women contract the infection themselves."

Because hepatitis C may not be easily identifiable, however, pregnant mothers may not know they are at risk. However, parents are likely to bring their babies to well-child visits in the first six months of life, allowing healthcare providers to test for the virus.

The Benefits of Early Testing

Early testing is predicted to both save lives and reduce healthcare costs.

Early diagnosis in young children can enhance their quality of life and generate fewer long-term health system costs. Unrecognized or incorrectly diagnosed hepatitis C, on the other hand, can damage children's health and increase the risks and costs of later treatment.

"Early diagnosis in young children can enhance their quality of life and generate fewer long-term health system costs. Unrecognized or incorrectly diagnosed hepatitis C, on the other hand, can damage children's health and increase the risks and costs of later treatment."

Providers can now familiarize themselves with the CDC's new recommendation for universal screening of pregnant women and early testing of exposed infants. The nucleic acid test can be administered to infants to ensure they have access to early evaluation and medication, now approved for children as young as three.

Testing both pregnant mothers and infants during the first six months of life provides the best chance of identifying and adequately treating the disease in its most vulnerable victims.

"The nucleic acid test can be administered to infants to ensure they have access to early evaluation and medication, now approved for children as young as three. Testing both pregnant mothers and infants during the first six months of life provides the best chance of identifying and adequately treating the disease in its most vulnerable victims."

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5. https://healthpolicytoday.org/2023/01/20/will-hepatitis-c-testing-for-high-risk-infants-be-expanded/

Disclosure: *Josie Cooper is executive director of the Alliance for Patient Access. This article was also published at healthpolicytoday.org.*

NT

Immunizing Yourself Against **COVID-19**

COVID-19 vaccines have been shown to:

- Lessen the severity of symptoms[1]
- Reduce disease transmission[3]
- Reduce risk of mortality[2]
- Make communities healthier and safer[4]

Understanding the Options

COVID-19 vaccines are available for children, adolescents and adults. There are 3 types to choose from.

mRNA VACCINES

New to market, but research has been ongoing since the 1990s.

HOW THEY WORK: **Instruct cells to make COVID-like proteins that trigger the immune system to fight the virus.**

PROTEIN SUBUNIT VACCINES

Used for three decades against the flu, whooping cough and hepatitis B.

Deliver harmless versions of the COVID protein that train the immune system to fight the virus.

VECTOR VACCINES

Used for decades against chickenpox, malaria and tuberculosis.

Use a modified virus, such as a common cold, to teach the body to fight off COVID.

COVID vaccines are recommended for everyone ages 6 months and older, and boosters for everyone ages 5 years and older, if eligible.[5]

Safe and Sound

COVID vaccines have been:

- **Thoroughly tested** through multi-phase trials with tens of thousands of participants[6]
- **Proven safe and effective** for adults as well as children[7]
- **Vetted and approved** by the US FDA and EMA and endorsed by the WHO[8-10]

Get Your Jab

Vaccines are available at your:

- **Doctor's office**
- **Neighborhood pharmacy**
- **Community health center**

Talk to your **health care provider** or **pharmacist** about which vaccine is right for you.

1. https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963
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GAfPA Global Alliance for Patient Access

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

Even though there are some things we don't know about COVID-19 yet, there are many more things that we do know. We know that there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.
- Wash for more than 20 seconds.
- Use alcohol-based sanitizers.

Limit Contact with Others

- Stay home when you can.
- Stay 6 feet apart when out.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

Provide Protective Immunity

- Hold baby skin-to-skin.
- Give them your breast milk.
- Stay current with your family's immunizations.

Take Care of Yourself

- Stay connected with your family and friends.
- Sleep when you can.
- Drink more water and eat healthy foods.
- Seek mental health support.

Immunizations Vaccinations save lives. Protecting your baby from flu and pertussis lowers their risks for complications from coronavirus.

WARNING

Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask makes it hard for them to breathe.
- Masks pose a risk of strangulation and suffocation.
- A baby can't remove their mask if they're suffocating.

If you are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop the virus from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

We can help protect each other.

Learn more

www.nationalperinatal.org/COVID-19

National Perinatal Association

The Gap Baby: An RSV Story

A collaborative of professional, clinical, community health, and family support organizations improving the lives of premature infants and their families through education and advocacy.

The National Coalition for Infant Health advocates for:

- **Access to an exclusive human milk diet** for premature infants
- **Increased emotional support resources** for parents and caregivers suffering from PTSD/PPD
- **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

www.infanthealth.org

iCAN Chronicle: Nurturing Pediatric Voices, Global Insights, and Empowering Initiatives

Sabina Schmidt Goldstein-Becerra

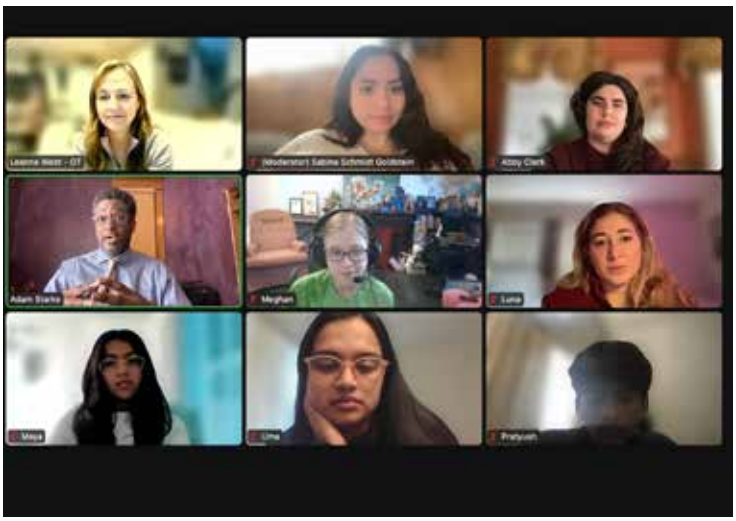
iCAN
International Children's Advisory Network

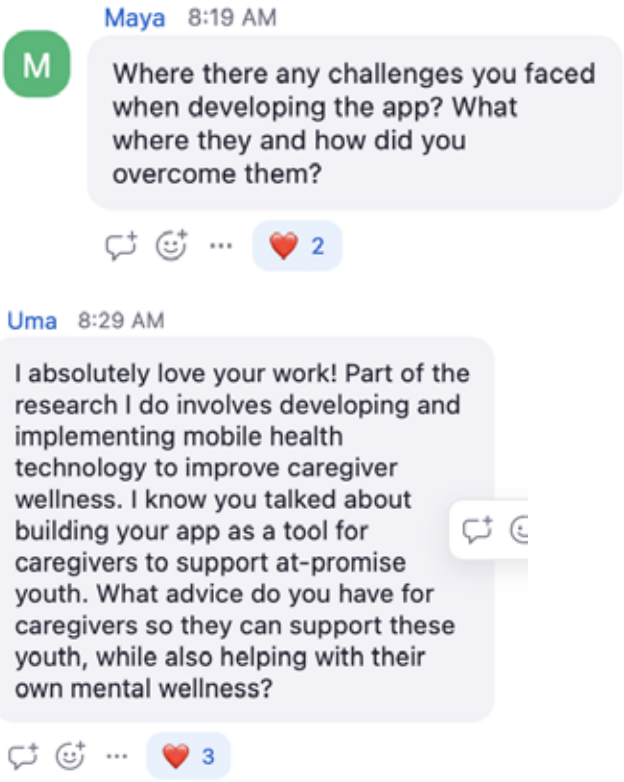
Get involved today and Join the iCAN Parent Council!

"iCAN, or the International Children's Advisory Network, is committed to providing numerous opportunities for the pediatric community to come together and hear from the most crucial stakeholders in healthcare: the patients. Our organization empowers all pediatric patients worldwide by facilitating their active participation in innovation, research, and medicine. "

iCAN, or the International Children's Advisory Network, is committed to providing numerous opportunities for the pediatric community to come together and hear from the most crucial stakeholders in healthcare: the patients. Our organization empowers all pediatric patients worldwide by facilitating their active participation in innovation, research, and medicine. Whether you are a patient, family member, healthcare professional, or supporter of the cause, we welcome you to visit our website at icanresearch.org to learn more about our mission, various programs, and initiatives. Join us to ensure that every child's voice is heard and that their unique experiences are taken into account to improve healthcare outcomes for all pediatric patients.

Ask the Experts - January Recap and Looking Ahead





This month, we had the privilege of hosting a fantastic speaker on *Ask the Experts*—Dr. Adam Starks. His engagement with our young minds was genuinely inspiring. Dr. Starks shared his remarkable journey as a former foster youth, breaking down barriers and founding MNDYRR (mender), a supportive app dedicated to aiding at-promise youth in accessing social services and mental wellness resources. He also authored several books. His passion for socio-emotional wellness truly shone through. Thank you to Dr.

Starks for sharing your journey and insights with us!

Dr. Adam Stark's captivating memoir, "Broken Children Mended Man," is available on Audible. The book explores Adam's personal story: childhood neglect, foster care, and triumph over adversity, showcasing human resilience in its purest form. Despite the lack of a role model, Stark courageously achieves life's milestones through a life of trial and error.

"Looking forward, we have got a fantastic lineup for you at ATE! On February 24, 2024, gear up for "Exploring the Global Frontier: Dive Deep into Medicine and Device Regulations Worldwide" with the dynamic duo, Dr. Martine Dehlinger Kremer and Victor Garcia."

Looking forward, we have got a fantastic lineup for you at ATE! On February 24, 2024, gear up for "Exploring the Global Frontier: Dive Deep into Medicine and Device Regulations Worldwide" with the dynamic duo, Dr. Martine Dehlinger Kremer and Victor Garcia.

Click here to register.

Meet our incredible speakers:

Dr. Martine Dehlinger-Kremer, PhD, MS

Vice President of Scientific Affairs, Pediatric Subject Matter Expert

Drug Development Solutions, ICON PLC

Dr. Dehlinger-Kremer's expertise spans more than 30 years in the research industry, including 30 years of experience in global regulatory affairs, medical affairs, and pediatric leadership. Before joining ICON, she served in several executive leadership roles at global CROs and has experience in global drug development in more than 40 countries. She has contributed to the global development of numerous products, including medicines for children, orphan diseases, and biosimilars. Her vision and leadership extend to service with many professional organizations – she is an observer member of the Coordinating Group of the European Network of Pediatric Research (Enpr-EMA) at the European Medicines Agency, chair of the Pediatric Working Group and also President of the European CRO Federation (EUCROF), serves as chair of the European Forum for Good Clinical Practice (EFGCP) Children's Medicines Working Party and Board Member of the association, and is active in the International Children's Advisory Network (iCAN). In 2015, Dr. Dehlinger-Kremer was named one of PharmaVOICE's 100 Most Inspiring People in Life Sciences. Dr. Dehlinger-Kremer earned a Doctorate in Sciences from the J. W. Goethe University in Frankfurt on the Main, Germany; a Diploma of Advanced Study in Neurophysiology from the University Louis-Pasteur, Strasbourg, France; and a Master of Sciences degree from University Moulin de la Housse in Reims, France.

Victor Garcia

Global VP RA, EHS, & QA Compliance

Global Vice President for Medical Device & SW imaging company with subject matter expertise in regulatory policies affecting medical product classifications across global markets. Foundational experience in biopharmaceuticals, combination products, and companion diagnostics throughout their respective product lifecycles from concept to full commercialization and post-market support. Chair of the Utah Regulatory Affairs Professional Society (RAPS) Chapter and founding member since October 2018. Member of the BioUtah Life Sciences regulatory, compliance and quality committee supporting over 1,000 life sciences local companies to ensure the industry and talent pipeline needs are met through education, program development, and governmental policies. Over 200 international product/facility successful inspections to secure product/facility approvals, maintain regulatory compliance, and support the introduction of novel products, changing the standard of care.

He is a Lecturer for the RAPS continuing education community, a

University of California SD graduate program advisor, a University of Utah graduate advisor and guest lecturer, life sciences industry expert for the Office of SLC Mayor, and supporting mentorship of STEM programs.

He is a University of Mary Washington Graduate, a Bachelor in Biological Sciences, a Certified Manager of Quality and Organizational Excellence, a Clinical Laboratory Scientist license, a Certified Process Excellence Six Sigma Champion, USAF Veteran of the Biomedical Services Clinical Lab Corp.

iCAN Spotlight!

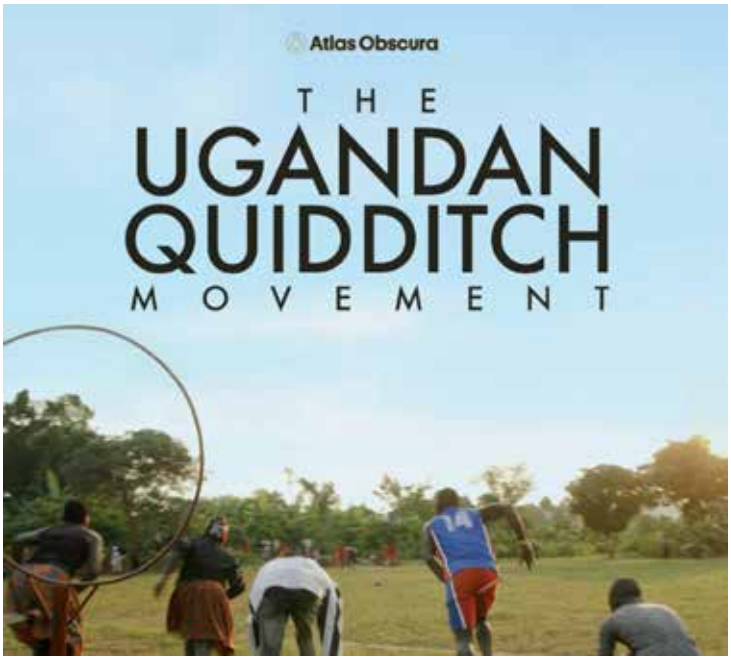
Our KIDS Illinois Chapter Journeys into the Human Body: Exploring the Feinberg School of Medicine's Anatomy Lab!

iCAN Spotlight! Our KIDS Illinois Chapter Journeys into the Human Body: Exploring the Feinberg School of Medicine's Anatomy Lab!

"A special acknowledgment goes to Dr. Angelique Duenas, Assistant Professor of Medical Education at Northwestern, who graciously hosted the event. She introduced the students to innovative Virtual Reality headsets, providing a fascinating 3D exploration of organs—an experience akin to donning special glasses and delving into the human body, resembling a superhero with X-ray vision!"

This image captures the KIDS Illinois field trip to the Northwestern Feinberg School of Medicine's Anatomy Lab. During the visit, the KIDS Illinois participants donned professional gowns to explore actual organs such as the heart, lungs, brain, and GI tract. Highly knowledgeable medical students and educators imparted knowledge about these anatomical structures. A special acknowledgment goes to Dr. Angelique Duenas, Assistant Professor of Medical Education at Northwestern, who graciously hosted the event. She introduced the students to innovative Virtual Reality headsets, providing a fascinating 3D exploration of organs—an experience akin to donning special glasses and delving into the human body, resembling a superhero with X-ray vision! Moreover, the participants had the unique opportunity to utilize a small ultrasound device on their lower arms to observe blood vessels and veins, offering an extraordinary and awe-inspiring glimpse inside their own bodies.

Empowering Education and Enrichment: John Ssentamu's Inspiring Initiative in Masaka, Uganda



"When we joined this community, the enthusiasm for school among children was lacking. We sought something truly distinctive." - John Ssentamu. iCAN is thrilled to highlight John Ssentamu, the

leader of the KIDS Uganda Chapter! Besides being a primary school teacher, John has recently initiated a Quidditch League for his students in Masaka, Uganda. His remarkable efforts include educating students on crucial topics like clinical trials, healthcare, and human rights. He aspires to fund a children's hospital, turning this initiative into a movement that brings joy and enrichment to students and unites the community through the first national Quidditch tournament. Congratulations to John and the children on this outstanding community achievement!

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iCAN's Inaugural Fundraising Challenge: Join Us in Shaping Pediatric Healthcare!

iCAN Challenge: Striving Towards Pediatric Healthcare Excellence

Date: March 30, 2024

Time: 24- Hour

Location: Global

Fundraising Website: bit.ly/iCANchallengeof10

About the Event: Join us in our first-ever iCAN Challenge, a community-driven initiative for children living with rare or complex conditions, dedicated to fundraising for our 2024 Annual Research and Advocacy Summit in Bari, Italy. This event is a collective effort to help provide pediatric patients with a powerful voice in medicine, research, and innovation. Your participation will play a pivotal role in empowering young voices and advancing critical initiatives that will mold the future of pediatric healthcare.

To celebrate our 10th year anniversary, we encourage you to take on challenges based on the number 10.

Here are some inspiring ideas: Bake ten cakes, read ten books, complete ten sketches, pick up ten pieces of litter, do ten good deeds, plant ten trees, run or walk ten blocks, bike 10 miles, knit ten things, dance ten dances, decorate ten rocks, or swim ten laps. The challenge is up to you!

How to Get Started:

1. Decide whether you want to do the challenge as a group or if each member can do it independently and choose a fun challenge.
2. Set a fundraising goal; we suggest aiming for $2500.
3. Find sponsors, either individually or as a group
4. Use Zeffy to collect money – download the app or visit the website, and donors will receive a donation email automatically.
5. Have a blast during the event, wear iCAN gear (if you have it), and take lots of pictures!
6. Send the pictures to abbyclark@icanresearch.org

iCAN's Inaugural Fundraising Challenge: Join Us in Shaping Pediatric Healthcare!

iCAN's 10 Challenge: Striving Towards Pediatric Healthcare Excellence

Date: March 30, 2024

Time: 24- Hour

Location: Global Fundraising

Website: bit.ly/iCANchallengeof10

Upcoming Events: Mark Your Calendar!

1. *Ask the Experts* - February 24, 2024, 8 AM PST/ 11 AM EST

   Session Title: "Exploring the Global Frontier: Dive Deep into Medicine and Device Regulations Worldwide" with Dr. Martine Dehlinger Kremer and Victor Garcia

   Guest Speakers: Dr. Martine Dehlinger Kremer & Victor Garcia
2. Annual Research & Advocacy Summit Registration mid-March
3. *Ask the Experts*- March 16, 2024
4. iCAN Challenge of 10-March 30, 2024
5. *Ask the Experts*- April 6, 2024

Exciting News: iCAN's 2024 Summit in Bari, Italy!

To sponsor our summit, visit bit.ly/iCANsponsorships

"Our upcoming 2024 summit is set to unfold in the picturesque city of Bari, Italy, from July 15 to 19th! The anticipation among our enthusiastic young participants is palpable as they eagerly await this remarkable event. However, to make it truly unforgettable, we need your support!"

Our upcoming 2024 summit is set to unfold in the picturesque city of Bari, Italy, from July 15 to 19th! The anticipation among our enthusiastic young participants is palpable as they eagerly await this remarkable event. However, to make it truly unforgettable, we

need your support!

Our annual summit is a transformative platform for nurturing innovation, compassion, and collaboration in pediatric healthcare among youth.

If you believe in the power of education and inspiration, we invite you to participate in this life-changing event. You can contribute in two meaningful ways:

1. Sponsor the 2024 Summit: Your sponsorship plays a pivotal role in the seamless organization of the summit. Your generous support ensures an impactful experience for all attendees.
2. Sponsor a Child to Attend: Your sponsorship directly impacts a child's life, granting them the chance to attend the summit in Bari. By covering travel, accommodation, and participation, your support offers a world of learning and empowerment.

Together, we shape a brighter future for pediatric healthcare by nurturing the potential of our young members. Regardless of size, your contribution makes a significant difference in fostering innovative advancements.

Thank you for considering this opportunity to support the next generation of healthcare leaders. Your generosity and dedication are deeply valued. Let us unite in Bari, Italy, to create a summit experience that empowers young minds for years to come!

Disclosures: *There are no reported disclosures*

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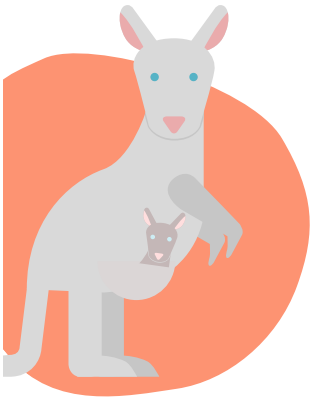
SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

with soap and water for 20+ seconds. Dry well.

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

and ask others to hold your baby when you can't be there

National Perinatal Association

nicuparentnetwork.org

nationalperinatal.org/skin-to-skin

Your Pregnancy and Substance Use

4 Things you can do to improve your health and lower your risk for complications

Get Prenatal Care

Start early. Go to all your visits. Empower yourself with information so you can make smart decisions. Build relationships with providers who understand Substance Use Disorders (SUDs) and know how to help. Partner with them to reach your goals. But remember, you do not need to be abstinent from substance use to get care. Go now.

Reduce Your Use

There are simple things you can do to limit the harm substances might do.

- Use fewer substances
- Use smaller amounts
- Use less often
- Learn how to use safer

Reducing or quitting smoking is a good place to start. Set your goals, then ask for help.
One of the best things you can do is to stop using alcohol. We know that even small amounts are risky. And when combined with benzos and opioids, alcohol can kill.

Use Medications for Opioid Use Disorder (MOUD) if you are opioid dependent

Methadone and Buprenorphine (Subutex® or Suboxone®) are the "Standard of Care" during pregnancy because they:

- Eliminate the risks of illicit use
- Reduce your risk for relapse
- Can be a positive step towards recovery

Take Good Care of Yourself

You deserve a healthy pregnancy & childbirth.

- Eat healthy and take your prenatal vitamins
- Find the right balance of rest and exercise
- Surround yourself with people who care

Your Health Matters

Academy of Perinatal Harm Reduction

National Perinatal Association

www.perinatalharmreduction.org | www.nationalperinatal.org

Education. Anytime, Anywhere.

Academy of Neonatal Care

The Academy of Neonatal Care serves to educate Respiratory Therapists, Nurses, and Doctors in current and best practices in Neonatal ICU care. We prepare RT's new to NICU to fully function as a bedside NICU RT. Our goal is to enrich NICU care at all levels. Beginner to Advanced Practice, there is something for you at:

www.AcademyofNeonatalCare.org.

Keeping Your Baby Safe
from respiratory infections

RSV
COVID-19
colds
flu

How to protect your little ones from germs and viruses

This year is an especially dangerous cold and flu season - especially for vulnerable infants and children. Fortunately, there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.
- Wash for more than 20 seconds.
- Use alcohol-based sanitizers.

Limit Contact with Others

- Stay home when you can.
- Stay 6 feet apart when out.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

Provide Protective Immunity

- Hold your baby skin-to-skin.
- Give them your breast milk.
- Stay current with your family's immunizations.

Take Care of Yourself

- Stay connected with your family and friends.
- Drink more water and eat healthy foods.
- Seek mental health support.
- Sleep when you can.

Get Immunized

Vaccinations save lives. Protecting your baby from COVID-19, flu and pertussis lowers their risks for complications from respiratory infections.

WARNING

Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask makes it hard for them to breathe.
- Masks pose a risk of strangulation and suffocation.
- A baby can't remove their mask if they're suffocating.

If you feel sick or are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop the virus from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

We can help protect each other.
www.nationalperinatal.org/rsv

National Perinatal Association


PROTECT YOUR FAMILY FROM
RESPIRATORY VIRUSES
flu
coronavirus
pertussis
RSV
SOAP
WASH YOUR HANDS
often with soap and warm water.
GET VACCINATED
for flu and pertussis. Ask about protective injections for RSV.
COVER COUGHS AND SNEEZES.
Sneeze and cough into your elbow.
USE AN ALCOHOL-BASED HAND SANITIZER.
STAY AWAY FROM SICK PEOPLE
Avoid crowds. Protect vulnerable babies and children.
www.nationalperinatal.org
National Perinatal Association


FREE RESOURCES FOR YOUR NICU
Coping During COVID-19
Targeted interventions to improve the mental health of parents, infants, families, and providers
BONDING WITH YOUR BABY
HELPING CHILDREN AND FAMILIES COPE
CAREGIVERS NEED CARE TOO
National Network of NICU Psychologists
nationalperinatal.org/psychologists

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

Track national data and trends at the CDC's website www.cdc.gov/rsv

Identify babies at greatest risk

including those with CLD, BPD, CF, and heart conditions

Teach families how to protect

their babies from respiratory infections

Advocate for insurance coverage for palivizumab prophylaxis so more babies can be protected *

Use your best clinical judgement

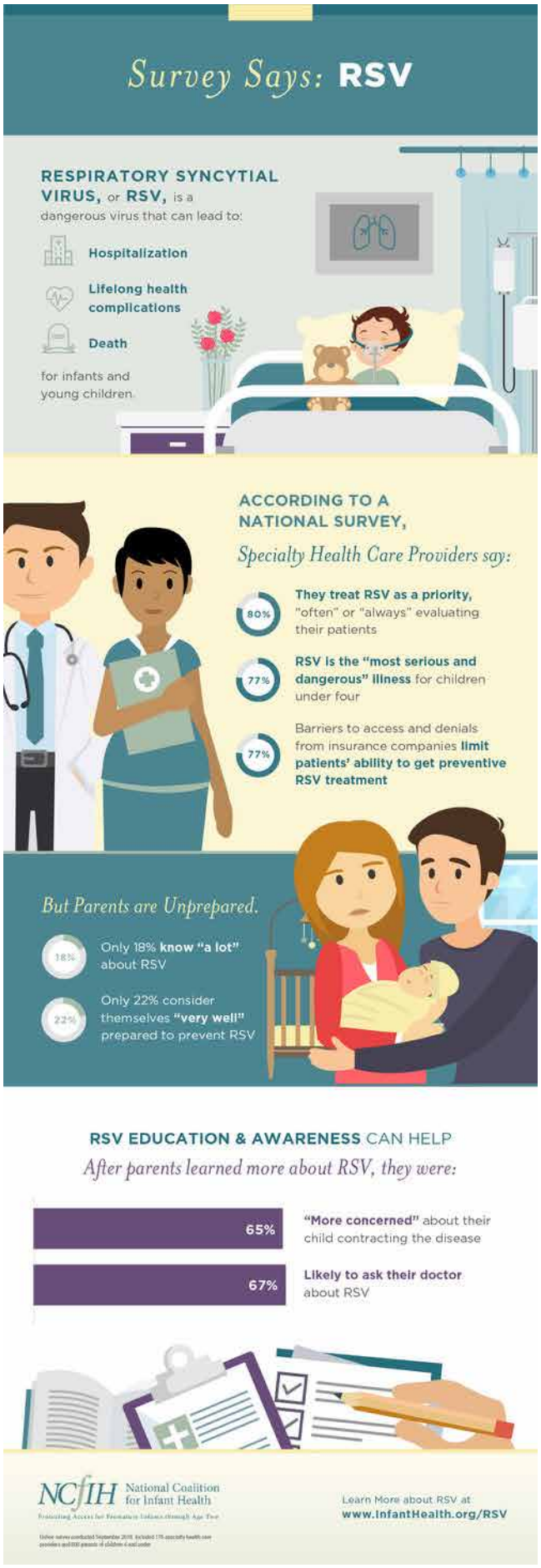
when prescribing RSV prophylaxis

Tell insurers what families need

and provide the supporting evidence

National Perinatal Association

*See the NPA's evidence-based guidelines at www.nationalperinatal.org/rsv



Peer Reviewed

Briefly Legal: Parents Opt not to Pursue Further Surgical Treatment for their Child's Severe Congenital Heart Disease: A Nurse Threatens to Sue the Hospital, the Neonatologists, and the Parents for Withholding Care

Maureen E Sims, MD, Barry Schifrin, MD

A 34-year-old G2P1 with an unremarkable prenatal course developed premature labor at 36 weeks gestation. After an unremarkable 5 hours of labor, a male infant with a birthweight was 1800 grams (<10% percentile), a length of 41 cm (<10 percentile), and a head circumference of 27 cm (<3% percentile) was delivered at a small community hospital. The baby showed mild dysmorphic features, including low set and rotated ears and questionably small palpebral fissures. The infant was assigned Apgar scores of 8 and 8 at 1 and 5 minutes, respectively, with 2 off for color at 1 and 5 minutes. Despite supplemental oxygen, the baby's color did not improve; nevertheless. he remained vigorous and comfortable. His vital signs, including blood pressure, were normal, but his oxygen saturation persisted between 70%-85%. Pre- and post-ductal blood gases were similar and showed pO2s around 70mmHg, with normal pH and pC02 values. A bedside hyper-oxygen test did not improve his oxygen saturation. A chest radiograph showed an abnormal cardiac silhouette with extraordinarily clear lung fields – the combination of the presentation and radiographic findings pointed to a classical presentation of cyanotic cardiac disease. This presentation prompted a stat cardiac consultation, cardiac ultrasound, and the administration of prostaglandins. Shortly after the administration of standard doses of prostaglandin, the baby developed apnea, requiring intubation.

"A chest radiograph showed an abnormal cardiac silhouette with extraordinarily clear lung fields – the combination of the presentation and radiographic findings pointed to a classical presentation of cyanotic cardiac disease."

The cardiac ultrasound revealed a severe variant of Tetralogy of Fallot. A complete blood count (CBC) and a metabolic panel were normal. The cardiologist recommended operative treatment in several stages. Neuroimaging with ultrasound, computerized axial tomography (CT), and later brain magnetic resonance imaging (MRI) were interpreted as normal. The genetic consultation agreed with the dysmorphic findings, but all laboratory evaluations were normal. These investigations were carried out with ongoing updates and discussions with the parents by the neonatologist, who found them to be concerned and available. With each intervention, he encouraged open questions. At their first encounter, he explained to the parents some of the uncertainty of even advanced medical procedures. He shared with the parents that sometimes, neonatologists might get mired in the details of the procedure at hand and lose sight of the "big picture." In this framework, he invited the parents to question him and his colleagues whenever they felt that the medical team was not seeing the "big picture." Both parents worked in the medical field and had an excellent grasp of the benefits, risks, and alternatives of the procedures. The father was a respiratory therapist at a cancer facility, and the mother was a laboratory technician at the birth hospital. They consented to the first cardiac surgical intervention.

"He shared with the parents that sometimes, neonatologists might get mired in the details of the procedure at hand and lose sight of the "big picture."In this framework, he invited the parents to question him and his colleagues whenever they felt that the medical team was not seeing the "big picture.""

After undergoing phase 1 of surgical intervention, the 8-week-old baby continued to have heart failure, and despite maximum nutritional intervention, restricted fluid intake, and diuretics, he could not be extubated. Further, the baby had a very shallow growth curve; the head circumference showed minimal growth from the measurements at birth. After another month, the cardiologist recommended the 2nd phase of the cardiac surgical procedure in the hope of improving the cardiac failure. As the neonatologist was discussing the need for a second surgery with the parents, the parents expressed their concern that the overall picture appeared bleak in terms of ultimate prognosis and the quality of life of their son; they were considering not putting their child through another surgery. The neonatologist did not expect this reaction but appreciated and understood their challenge. The parents expressed their love for the child but that they felt it was in his best interest not to have another surgical procedure and to remove the endotracheal tube and let nature take its course. After much discussion with the nurses, respiratory therapists, cardiologists, and neonatologists agreed to extubate the baby and provide only comfort care. They would not reintubate, irrespective of apnea or further deterioration.

"The parents expressed their love for the child but that they felt it was in his best interest not to have another surgical procedure and to remove the endotracheal tube and let nature take its course. After much discussion with the nurses, respiratory therapists, cardiologists, and neonatologists agreed to extubate the baby and provide only comfort care."

"All the nurses agreed to this approach except one, who stated that withholding care was against her religious beliefs... The cardiologist also did not agree with the parents and neonatologist's plan. He pointed out that despite the potential for severe cognitive impairment in the baby, he thought that further surgical procedures were warranted."

All the nurses agreed to this approach except one, who stated that withholding care was against her religious beliefs. She was reassured that she would not be assigned to the baby and was not asked to provide any care for him. Most of the nurses in this hospital had worked at major university medical centers, and some had worked in institutions where children received chronic care. The one nurse who strongly disagreed with the plan of extubating and comfort care called the parents at home in an attempt to convince them to reconsider. Despite advising that she would not pursue the matter, she persisted. The cardiologist also did not agree with the parents and neonatologist's plan. He pointed out that despite the potential for severe cognitive impairment in the baby, he thought that further surgical procedures were warranted. The neonatologist assured the parents that, if necessary, arrangements could be made to send the baby to a University or Childrens' hospital where their wishes would be honored. The neonatologist had presented the details to a colleague at another facility, who agreed with the plan and who gave assurances of following the same course. The parents preferred to stay at the birthing hospital and have their wishes followed.

"The parents emphasized their love for the baby and that they felt it was in their baby's best interest to let nature take its course without a ventilator and allow him to feed as he could."

At the parents' request. a Bioethics Committee meeting was convened. At the meeting, representatives from nursing, medicine, administration, community and clergy, the parents, and the neonatologists were present. The parents understood that the Committee meeting was a venue to sort out issues and was not a decision-making body, that they had the right to make the decisions for their child, and that the neonatologists were responsible for practicing within appropriate standards of care. At the Committee meeting, the neonatologist voiced his opinion that the parents are considered the best decision-makers for their babies and should be involved in shared decision-making whenever possible. For parents to fulfill this responsibility, they needed relevant, accurate, and honest information about the risks and benefits of each treatment option. The neonatologist felt that the parents, with their medical background, had been fully informed and given adequate time to consider the options and ask questions thoughtfully. The parents emphasized their love for the baby and that they felt it was in their baby's best interest to let nature take its course without a ventilator and allow him to feed as he could. They wanted to hold him and allow their other child, who was eight years old, to be present. Half of the Committee members favored more intervention, with one suggesting a judicial process (obtaining a court order) be initiated if needed. The neonatologist pointed out that if a judicial process were set into motion, the baby would be transported to another facility that would honor the plan the neonatologist and parents had outlined (comfort care). After the father spoke to the Committee members, all agreed with the comfort care plan. The neonatal care nurse who was opposed (not present at the meeting) informed the hospital that she would be contracting an attorney and the press. The hospital was concerned about a conflict of interest since the mother's health insurance was through the hospital where she was an employee; the hospital administration asked for a consult from the Chair of the local Children's Hospital. He consulted and agreed with the plan agreed upon by the neonatologist and parents.

"The baby and his family were provided privacy in a separate room near the NICU. The baby was extubated and expired 18 hours later in his mother's embrace."

The baby and his family were provided privacy in a separate room near the NICU. The baby was extubated and expired 18 hours later in his mother's embrace. The nurse who opposed this plan failed to obtain an attorney willing to take on this case, and nothing was published in the press. Weeks later, the mother contacted the neonatologist and said she would be willing to help support other parents faced with similar situations but decided to resign from her employment at the hospital because of the painful memories of the badgering and the threats of the nurse.

Suggested Reading:

1. Pineda R, Neil J, Dierker D, et al. Alterations in brain struc1. AAP Committee on Bioethics. Informed Consent, Parental Permission and Assent in Pediatric Practice. Pediatrics 1995;95 (2) 314-317
2. Committee on Bioethics. Informed consent in decision-making in pediatric practice. Pediatrics 2016 138:e20161484
3. Guidance on Forgoing Life-Sustaining Medical Treatment Policy Statement AAP Weise, K, Okun AL, Carter BS et al. Committee on Bioethics, section on hospice and palliative medicine, Committee on child abuse and neglect Pediatrics 2017; 140: 2017 e20171995
4. Wasserman JA, Navin MC, Vercler CJ Pediatric Assent and Treating Children Over Objection Pediatrics 2019; 144 (5) e20190382
5. Wyckoff MH, Wyllie J, Aziz K, et al. 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2020 142 (suppl 1) s185-S221

Disclosures: *There are no reported disclosures*

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OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

I was exposed to substances in utero. I am not addicted. Addiction is a set of behaviors associated with having a Substance Use Disorder (SUD).

I was exposed to opioids.

While I was in the womb my mother and I shared a blood supply. I was exposed to the medications and substances she used. I may have become physiologically dependent on some of those substances.

NAS is a temporary and treatable condition.

There are evidence-based pharmacological and non-pharmacological treatments for Neonatal Abstinence Syndrome.

My mother may have a SUD.

She might be receiving Medication-Assisted Treatment (MAT). My NAS may be a side effect of her appropriate medical care. It is not evidence of abuse or mistreatment.

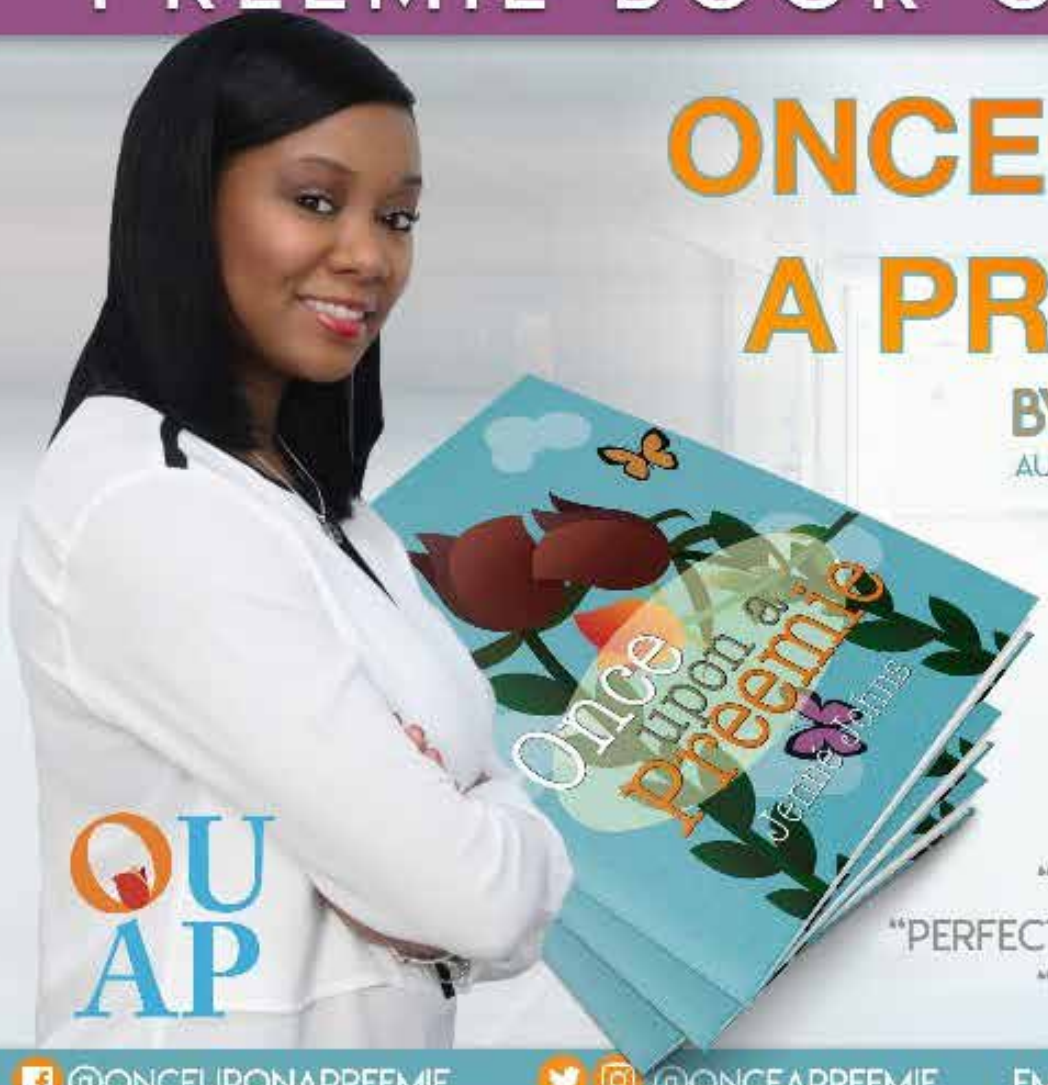
My potential is limitless.

I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!

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

National Perinatal Association

PREEMIE BOOK ON SALE



ONCE UPON A PREEMIE

BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE

QUAP

"ONE OF A KIND"
"PERFECT FOR PREEMIE FAMILIES"
"ENCOURAGING"

@ONCEUPONAPREEMIE @ONCEAPREEMIE EMAIL: HI@ONCEUPONAPREEMIE

ONCE UPON A PREEMIE IS A BEAUTIFUL NEW WAY TO LOOK AT THE LIFE OF A PREEMIE BABY. IT EXPLORES THE PARENT AND CHILD NEONATAL INTENSIVE CARE UNIT (NICU) JOURNEY IN A UNIQUE AND UPLIFTING WAY.

SPEAKING ENGAGEMENTS

PREEMIE PARENT ALLIANCE SUMMIT
NATIONAL ASSOCIATION OF PERINATAL SOCIAL WORKERS
CONGRESSIONAL BLACK CAUCUS ANNUAL LEGISLATIVE CONFERENCE
NATIONAL MEDICAL ASSOCIATION ANNUAL CONFERENCE
HUDSON VALLEY PERINATAL PUBLIC HEALTH CONFERENCE
MATERNITY CARE COALITION ADVOCACY DAY

MEDIA APPEARANCES

Preemie Family

The Joyner Report

PEBBLES of Hope

WDAS 105.3 FM

CBS RADIO

wgts 91.9 Washington, D.C.

MAJIC 102.3 92.7 The Real Sound of the DMV

AVAILABLE FOR $12.99 ON AMAZON OR ONCEUPONAPREEMIE.COM

Still a **Preemie?**

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 PREEMIE

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 PREEMIE

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

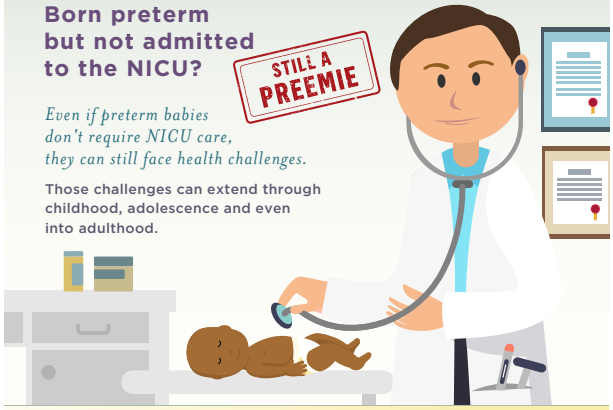
But because some health plans determine coverage based on a preemie's weight, **families of babies that weigh more may face access barriers and unmanageable medical bills.**

Born preterm but not admitted to the NICU?

STILL A PREEMIE

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 Preemies

- Will spend weeks in the hospital
- Will have lifelong health problems
- Are disadvantaged from birth

All Preemies

- Face health risks
- Deserve appropriate health coverage
- Need access to proper health care

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

I was exposed to substances in utero. I am not addicted. Addiction is a set of behaviors associated with having a Substance Use Disorder (SUD).

I was exposed to opioids.

While I was in the womb my mother and I shared a blood supply. I was exposed to the medications and substances she used. I may have become physiologically dependent on some of those substances.

NAS is a temporary and treatable condition.

There are evidence-based pharmacological and non-pharmacological treatments for Neonatal Abstinence Syndrome.

My mother may have a SUD.

She might be receiving Medication-Assisted Treatment (MAT). My NAS may be a side effect of her appropriate medical care. It is not evidence of abuse or mistreatment.

My potential is limitless.

I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!

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

National Perinatal Association

FREE Online CE Activity

Nurses: parents trust you.

You can help reduce the risk of Sudden Infant Death Syndrome (SIDS), the leading cause of death among infants between 1 month and 1 year of age. Take our **free continuing education (CE) activity** to stay up to date on the latest safe infant sleep recommendations. Approved for 1.5 contact hours.

Learn more about the free online activity at **https://nichd.nih.gov/SafeSleepCE.**

The CE activity explains safe infant sleep recommendations from the American Academy of Pediatrics and is approved by the Maryland Nurses Association, an accredited approver of the American Nurses Credentialing Center's Commission on Accreditation.

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

SAFE TO SLEEP®

Compiled and Reviewed by Sandeep Lankireddy, BA, OMS IV

A Term Neonate with Encephalopathy

NEWS PROVIDED BY

American Academy of Pediatrics

by Shruthi Kumar Bharadwaj, MD, DM; Smriti Bhargava, MD; Sheila Samanta Mathai, MD, DM; Jayashree Purkaysthma, MD

January 1, 2023

Presentation

A male infant is born of a nonconsanguineous marriage at 38 weeks of gestation to a primigravida via normal vaginal delivery at a level 1 hospital. The infant's antenatal history is unremarkable, with normal first- and second-trimester scans. At 30 weeks, a growth scan shows pelvicalyceal system dilation (6 mm) with an amniotic fluid index of 30. The mother perceives decreased fetal movements the week before the delivery, but the biophysical profile is normal. Labor is spontaneous, and she delivers vaginally after a normal duration of labor. The infant does not cry at birth and needs resuscitation for 20 minutes without requiring cardiac compressions. The Apgar score is 5 at 10 minutes after birth, and cord blood gas is unavailable. He is referred to us (level 3 referral hospital) on nasal flow oxygen at 3 hours after birth for further management.

On admission, his weight is 2,500 g, and vital signs are stable; however, he has shallow respiratory efforts. The sensorium is obtunded with reduced spontaneous activity, hypotonia, weak cry, poor suck, incomplete Moro reflex, absent gag reflex, and equal and reactive pupils. He does not have clinical seizures or external dysmorphic features. Arterial blood gas shows a pH of 7.02, Pco2 of 56 mm Hg (7.45 kPa), bicarbonate of 12.2 mEq/L (12.2 mmol/L), base deficit of −14.8 mEq/L (−14.8 mmol/L), and lactate of 126.7 mg/dL (14.06 mmol/L). A diagnosis of moderate encephalopathy secondary to perinatal causes is made, and he is started on therapeutic whole body cooling. Conventional electroencephalogram (EEG), amplitude-integrated EEG, and neurosonogram are normal. He has evidence of end-organ dysfunction with raised creatine kinase of 1,887.0 U/L (31.51 µkat/L), troponin T of 0.092 ng/mL (0.09 µg/L), lactate dehydrogenase of 761 U/L (12.71 µkat/L), aspartate aminotransferase of 67 U/L (1.12 µkat/L), and activated partial thromboplastin time of 46.1 seconds. Serum creatinine is 0.44 mg/dL (38.90 µmol/L), sepsis screen and blood culture are negative, and the chest radiograph is normal. He remains hemodynamically stable but is electively placed on mechanical ventilation because of poor sensorium, inadequate breathing efforts, and carbon dioxide retention. Whole body cooling is performed for 72 hours, and rewarming is completed over 12 hours.

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.

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

Discussion

Progression

The infant's sensorium improved over the next 3 days, with spontaneous opening and normal eye movements, but he remained hypotonic with minimal spontaneous limb movements (Video). Although blood gases were normal, he failed attempts at extubation twice because of persistent pooling of secretions and the absence of a gag reflex. Given normal EEG with persistent hypotonia despite improving sensorium, the possibility of a neuromuscular genetic condition was considered, and whole exome sequencing was ordered.

See video at: https://players.brightcove.net/6056665225001/default_default/index.html?videoId=6338539663112

Actual Diagnosis

Whole exome sequencing reveals Centronuclear Myopathy Type 1 (Autosomal Dominant AD) with Pathogenic strain for DNM2 (+), VARIANT - c.1102G>A, located at EXON 8.

The Condition

Centronuclear myopathy (CNM) is an inherited congenital myopathy (CM), which results in muscle weakness, hypotonia, and myopathic features on muscle biopsy. (4) Congenital myopathies are categorized based on the predominant pathologic features as core myopathies (most common), CNM, and nemaline myopathy. (5)(6) The X-linked form of CNM has a severe presentation at birth with marked weakness, respiratory failure, ophthalmoplegia with hypotonia, and coexisting birth asphyxia. Autosomal dominant forms present late and are milder, whereas autosomal recessive forms have an in-between presentation. (7) Core and nemaline myopathies have a slow progression. The presence of prominent facial weakness with feeding problems with or without ptosis, generalized hypotonia with hyporeflexia, respiratory and bulbar muscle weakness, and the absence of tongue fasciculations hint at CNM from other causes in hypotonic infants. (8) Many of these neonates may succumb in the neonatal period. The infant in our case presented with generalized hypotonia, severe respiratory muscle involvement, and evidence of birth asphyxia. A family history of neonatal deaths or miscarriages is often present. (9) Polyhydramnios and reduced fetal movements are frequent during pregnancy, as in this case. (10)

Management

Electron microscopy of muscle biopsy and genetic testing aid in diagnosis, prognostication, and counseling. Current management is supportive and offers multidisciplinary team care. Some parents opt for early palliative care in severe cases. Infants who survive beyond the neonatal period without significant ventilatory requirements need close respiratory function monitoring and sleep studies. Carrier screening enables parents to make informed decisions regarding subsequent pregnancies.

Patient Course

The infant remained on a ventilator along with enteral tube feeds for 22 days. His parents opted for palliative care with the de-escalation of intensive care. Single-gene sequencing of both parents was negative, suggesting a de novo or sporadic mutation, which is known to have a severe presentation. The parents were counseled and offered follow-up services from the departments of neonatology and medical genetics. However, the infant died soon after.

Lessons for the Clinician

HIE often masks an underlying neuromuscular condition; hence, a deeper understanding and strong index of suspicion are required for timely diagnosis.

In diagnostic dilemmas, the most commonly occurring conditions should be considered first and treated until a definitive diagnosis is established. In this case, treatment for HIE was given.

With affordable and accessible genetic testing, such challenging cases should be considered for further genetic evaluation as it is less intrusive.

American Board of Pediatrics Neonatal-Perinatal Content Specifications

Know the basis for (including genetic), clinical and laboratory features (including associated abnormalities), differential diagnosis, evaluation, management, and outcomes of neonatal hypotonia/neuromuscular weakness.

Know the causes, clinical features, evaluation, and management of hypoxic-ischemic encephalopathy.

Recognize the controversies associated with the introduction of new genetic tests for rare and common diseases that present in the neonatal period.

AUTHOR DISCLOSURES: Drs Bharadwaj, Bhargava, Mathai, and Purkaystha have disclosed no financial relationships relevant to this article. This commentary does not contain a discussion of an unapproved/investigative use of a commercial product/device. See original article for references.

NT

Neonatal Opioid Withdrawal Syndrome Following Prenatal Use of Supplements Containing Tianeptine

NEWS PROVIDED BY

American Academy of Pediatrics

by Kelechi Ikeri, MD; Alexandria Anderson, MD; Fabien Eyal, MD; Richard Whitehurst, MD

January 12, 2024

Tianeptine is an opioid receptor agonist that is prescribed as an antidepressant in many countries. In the United States, tianeptine is not approved for medical use because of its potential for abuse and addiction. Nonetheless, products containing tianeptine are easily obtainable and are marketed as dietary supplements. There are increasing reports of adverse effects and fatal toxicities resulting from tianeptine use among adolescents and adults. This emerging public health threat could escalate the opioid epidemic and drive increased newborn perinatal exposure. The impact of in utero exposure to tianeptine has not been studied, and to our knowledge, the authors of only 1 report have documented possible neonatal effects. Here, we describe a case of chronic prenatal exposure to tianeptine in the setting of maternal dependence on dietary supplements. This infant developed signs of severe withdrawal shortly after birth that were refractory to treatment with oral phenobarbital but responded to subsequent oral morphine therapy. On further questioning, the mother revealed the use of a tianeptine-containing dietary supplement. We did not perform confirmatory toxicology testing because tianeptine is not assayed by usual urine drug screening tests. For infants with clinical signs of opioid withdrawal without known etiology, we suggest that the maternal interview should inquire about the use of neurotropic over-the-counter drugs.

NT

Evaluation of Airborne Chemicals from Neonatal Incubators - Letter to Health Care Providers

NEWS PROVIDED BY

U.S. Food & Drug Administration

Content current as of January 3, 2024

First Released on February 23, 2023

The U.S. Food and Drug Administration (FDA) is informing health care providers and facilities about the potential for exposure to airborne chemicals that may be released from neonatal incubators. The FDA is evaluating published literature that reports elevated levels of formaldehyde, cyclohexanone, and other volatile chemicals (such as human-made chemicals used and produced in manufacturing) from neonatal incubators. Potential sources of these airborne chemicals include materials used to make neonatal incubators as well as natural and human-made sources external to the incubator.

The FDA is working with manufacturers of neonatal incubators to collect and evaluate data from their products to determine whether these airborne chemicals are released, and if so, the amount of exposure and the potential risks to health from such exposure, if any, for newborns and others (such as health care providers). Currently, the FDA is not aware of any reported adverse events related to the use of neonatal incubators and exposure to these airborne chemicals.

Recommendations

At this time, the FDA has the following recommendations for health care providers and facilities:

- Continue to use neonatal incubators. The FDA recognizes that incuba-

tors are critical for neonates (infants less than four weeks old) that cannot maintain their body temperature.

- Be aware that the FDA is working with manufacturers to understand the potential for exposure to airborne chemicals (formaldehyde, cyclohexanone, and other volatile chemicals) that may be released from neonatal incubators, potential health risks, and mitigation strategies, if needed. Remain alert for further updates and recommendations from the FDA and neonatal incubator manufacturers.
- Review your current plan for proper air ventilation in neonatal settings.
- While the FDA further evaluates this issue, as an interim precautionary measure, consider running new neonatal incubators prior to use with patients for a week in a well-ventilated space using clinically relevant conditions for temperature and humidity, as the release of these airborne chemicals may decline over time.
- Follow the neonatal incubator manufacturer's instructions for use, including disinfection and cleaning, prior to first use with patients.
- Report any issues with neonatal incubators to the FDA.

January 3rd, 2024, Update:

Based on new data and information provided by the manufacturer, new neonatal incubators by Drager do not need to be run for a week before clinical use. Testing on Drager's newly manufactured neonatal incubators did not demonstrate concerning levels of airborne chemicals.

Unique Device Identifier (UDI) information provided by Drager:

- Babyleo TN 500; UDI: 04048675000051
- Isolette 8000 plus, UDI: 04049098090612
- TI500 Transport Incubator, UDI: 04049098000208

NT

Advances in the Care of Infants With Prenatal Opioid Exposure and Neonatal Opioid Withdrawal Syndrome

NEWS PROVIDED BY

American Academy of Pediatrics

by Margarida Mascarenhas, MD, MMSc; Elisha M. Wachman, MD; Iyra Chandra, BS; Rachel Xue, BA; Leela Sarathy, MD; Davida M. Schiff, MD, MSc

Address correspondence to Davida M. Schiff, MD, MSc, Division of General Academic Pediatrics, MassGeneral Hospital for Children, 125 Nashua St, Suite 860, Boston, MA 02114. E-mail: davida.schiff@mgh.harvard.edu

January 5, 2024

FUNDING: Dr Schiff received funding

Protecting your baby and family from

Respiratory Viruses:

What parents need to know this RSV and flu season

Like COVID-19, RSV (Respiratory Syncytial Virus) and flu affect the lungs and can cause serious breathing problems for children and babies. Talk to your family about the risks.

Certain diagnoses can make children and babies more vulnerable for serious complications from respiratory viruses - including prematurity, chronic lung disease, and heart conditions.

You can limit the spread of viruses by wearing a mask, washing your hands with soap & water, using an alcohol-based hand sanitizer, and getting vaccinated.

The fewer germs your baby is exposed to, the less likely they are to get sick. Let people know you need their help to stay well. Limit visitors. Avoid crowds. Stay away from sick people.

Immunizations save lives. Stay up-to-date with your family's flu vaccinations and COVID-19 boosters. This helps our community stay safe by stopping the spread of deadly viruses.

Babies older than 6 months can get a flu shot and COVID-19 vaccinations. Now there are new vaccines for RSV for adults and antibody shots for babies that can help protect them.

WE CAN HELP PROTECT EACH OTHER.

National Perinatal Association

www.nationalperinatal.org/rsv

from the National Institute on Drug Abuse (K23DA048169). Dr Wachman received funding from the National Institute of Child Health and Human Development (R01HD096798). The content is solely the responsibility of the authors and does not necessarily represent the official views of the funders.

CONFLICT OF INTEREST DISCLOSURES: The authors have indicated they have no conflicts of interest relevant to this article to disclose.

Abstract

A significant number of advances have been made in the last 5 years with respect to the identification, diagnosis, assessment, and management of infants with prenatal opioid exposure and neonatal opioid withdrawal syndrome (NOWS) from birth to early childhood. The primary objective of this review is to summarize major advances that will inform the clinical management of opioid-exposed newborns and provide an overview of NOWS care to promote the implementation of best practices. First, advances with respect to standardizing the clinical diagnosis of NOWS will be reviewed. Second, the most commonly used assessment strategies are discussed, with a focus on presenting new quality improvement and clinical trial data surrounding the use of the new function-based assessment Eat, Sleep, and Console approach. Third, both nonpharmacologic and pharmacologic treatment modalities are reviewed, highlighting clinical trials that have compared the use of higher calorie and low lactose formula, vibrating crib mattresses, morphine compared with methadone, buprenorphine compared with morphine or methadone, the use of ondansetron as a medication to prevent the need for NOWS opioid pharmacologic treatment, and the introduction of symptom-triggered dosing compared with scheduled dosing. Fourth, maternal, infant, environmental, and genetic factors that have been found to be associated with NOWS severity are highlighted. Finally, emerging recommendations on postdelivery hospitalization follow-up and developmental surveillance are presented, along with highlighting ongoing and needed areas of research to promote infant and family well-being for families impacted by opioid use.

NT

Optimizing Nutrition in Neonates with Kidney Dysfunction

NEWS PROVIDED BY

American Academy of Pediatrics

Abstract

The nutritional management of neonates with kidney disease is complex. There may be significant differences in nutritional needs based on the duration and cause of kidney dysfunction, including acute kidney injury (AKI) and chronic kidney disease (CKD). Furthermore, the treatment modality, including acute (continuous renal replacement therapy and peritoneal dialysis [PD]) and chronic (intermittent hemodialysis and PD) approaches may differentially affect nutritional losses and dietary needs. In this review, we discuss the pathophysiology of compromised nutrition in neonates with AKI and CKD. We also summarize the existing data and consensus recommendations on the provision of nutrition to neonates with AKI and CKD. We highlight the paucity of data on micronutrient losses and the need for future prospective studies to enhance nutritional supplementation to hopefully improve outcomes in these patients.

NT

10 strategies pediatricians can use to achieve breastfeeding equity

NEWS PROVIDED BY

American Academy of Pediatrics

by Tara S. Williams, M.D., FABM, FAAP, and Julie L. Ware, M.D., M.P.H., IBCLC, FABM, FAAP

January 1, 2024

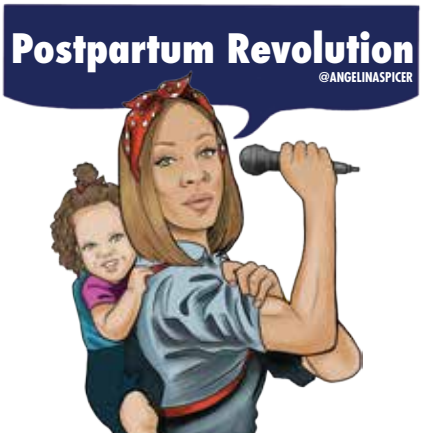
Despite the overall increase in breastfeeding* rates in the U.S., significant disparities continue.

African American women, in particular, face structural barriers that present unique challenges to meeting their breastfeeding goals (Tran V, et al. Matern Child Nutr. 2023;19:e13428). While race is a social construct, implicit bias and structural racism have negative impacts on health outcomes.

Pediatricians can play a significant role in helping to close this gap. Mothers who are encouraged to breastfeed by their physician are four times more likely to breastfeed than women who do not receive encouragement (Lu MC, et al. Obstet Gynecol. 2001;97:290-295). In addition, women who perceive that their pediatrician favors exclusive breastfeeding are 1.5 times more likely to breastfeed exclusively than those without that perception (Ramakrishnan R, et al. J Hum Lact. 2014;30:80-87).

Breastfeeding has been shown to protect mothers from breast cancer, ovarian cancer, type 2 diabetes and cardiovascular disease. Benefits to infants include reduced risk of necrotizing enterocolitis, respiratory and gastrointestinal infections, otitis media, diabetes and sudden unexplained infant death (Victora CG, et al. Lancet. 2016;387:475-490). A recent study of nearly 10 million U.S. infants demonstrated a 33% reduction in the odds of post-perinatal infant death (days 7-364) associated with the initiation of any breastfeeding (Ware JL, et al. Am J Prev Med. https://pubmed.ncbi.nlm.nih.gov/37220859/).

Here are 10 strategies pediatricians can



employ to achieve breastfeeding equity:

1. Check your biases.

Be aware of your biases and learn how they impact the care you provide. Encourage every mother to try breastfeeding and provide needed support. To explore your biases, take the Implicit Association Test.

2. Become skilled at assessing latch and milk transfer.

The key to successful breastfeeding is good attachment. This is evidenced by an asymmetric latch and audible swallows that confirm breastmilk is being transferred. To learn this skill, watch a tutorial at https://bit.ly/3riVi7i(from the 3:58 to 7:58 minute marks).

3. Pause before offering formula supplementation.

Always maximize direct breastfeeding first. If supplementation is required, preferentially use mother's own milk, then pasteurized human donor milk and then formula.

Learn and practice evidence-based guidelines for supplementation. Resources include "Evidence-Based Updates on the First Week of Exclusive Breastfeeding Among Infants ≥35 Weeks;" Academy of Breastfeeding Medicine clinical protocol "Supplementary Feedings in the Healthy Term Breastfed Neonate;" and the Newborn Weight Tool.

4. Stop the pump and dump.

In very rare circumstances, a medication may be contraindicated for breastfeeding. Utilize evidence-based resources to determine if breastfeeding is contraindicated with certain medications. Resources include LactMed, Infant Risk Center, and Trash the Pump and Dump.

5. Learn to triage and manage common breastfeeding concerns (e.g., infant weight loss, maternal engorgement, nipple pain).

Be alert for conditions that may make breastfeeding more difficult. These include maternal factors (e.g., diabetes, obesity, hypothyroidism, polycystic ovarian syndrome, infertility, breast surgery, use of nipple shields) and infant factors (e.g., late preterm, ankyloglossia, cleft palate). To learn more, check out the AAP breastfeeding residency curriculum.

6. Connect moms to culturally matched and competent breastfeeding support.

One example is Reaching Our Sisters Everywhere. The group hosts a twice weekly virtual support platform focused on caring for families of color and has trained many people to help more families achieve breastfeeding success.

In addition, local groups have blossomed, including All Moms Empowered to Nurse in Cincinnati and Black Mothers Breastfeeding Association in Detroit. To find support groups in your area, visit https://web.usbreastfeeding.org/coalitions/search.

7. Be an advocate for equitable maternity care practices.

Hospital compliance with the Ten Steps to Successful Breastfeeding as part of the Baby-Friendly Hospital Initiative (BFHI) strongly correlates with improved breastfeeding rates. In particular, skin-to-skin contact within the first hour of delivery, breastmilk only (no formula supplementation unless medically indicated), 24/7 rooming-in and breastfeeding on-demand have the biggest impact.

Implementation of the BFHI in Mississippi led to a 17% reduction in racial disparities in breastfeeding initiation (Burnham L, et al. Pediatrics. 2022;149:e2020030502), demonstrating that implementation of evidence-based guidelines can help ameliorate the negative impact of structural racism and provider bias on clinical outcomes.

8. Advocate for paid family leave and workplace and child care support for breastfeeding.

Disadvantaged populations often need to return to work in the early postpartum period. Educate families regarding laws that protect breastfeeding. A letter template that you can modify for use in your practice to advocate for workplace lactation accommodations can be found on page 4 of the Breastfeeding Workplace Guide.

9. Create and maintain a Breastfeeding Friendly Office.

Ideally, your practice staff, including physicians, should represent the ethnic and linguistic diversity of the community you serve.

Display culturally representative photos and provide linguistically appropriate written and digital media. See the AAP Breastfeeding-Friendly Pediatric Office Practice for guidance. Posters that show racially diverse patients are available from the U.S. Department of Agriculture at https://bit.ly/3Pn43VR.

10. Monitor the impact of your efforts with quality improvement (QI) strategies.

Get Maintenance of Certification credit by monitoring breastfeeding rates in your practice regularly, being sure to address any noted disparities. QI resources from the AAP are available at http://aapca2.org/qi/ and https://bit.ly/3sVZF8J.

Lastly, join the AAP Section on Breastfeeding to connect with others and learn more about how to support breastfeeding within your community.

**The term breastfeeding is used in this article. Parents who are gender diverse may prefer chestfeeding or other terms besides breastfeeding.*

Dr. Williams is a member of the AAP Section on Breastfeeding Executive Committee and is chapter breastfeeding coordinator chair. Dr. Ware is an Ohio Chapter breastfeeding coordinator and former member of the AAP Section on Breastfeeding Executive Committee.

NT

Advancing Care for Infants with Prenatal Opioid Exposure

NEWS PROVIDED BY

American Academy of Pediatrics

by Lydia Furman, MD, Associate Editor, Pediatrics

January 9, 2024

Prenatal opioid exposure increased broadly across the US from 2000 to 2017. Although some states have seen a decline since then, specific areas and populations continue to see increases, including rural areas, New England, and Appalachia, with disproportionate impact on pregnant persons who are publicly insured and lower income. Infants who have become physiologically dependent on opioids in utero experience an abrupt discontinuation at delivery and present clinically with signs and symptoms of neonatal opioid withdrawal syndrome (NOWS), including nervous system irritability and autonomic dysfunction, leading to difficulties with feeding, sleeping, and consoling.

In a recently released "State of the Art" article in Pediatrics, Dr. Margarida Mascarenhas and colleagues in Boston give a comprehensive, current overview of the identification, evaluation, and care of infants with prenatal opioid exposure from delivery through early childhood, and outline research in progress that will further understanding (10.1542/peds.2023-062871).

The authors' well organized and logical approach walks the reader through the following elements:

- advances in standardizing the clinical diagnosis of NOWS, including a list of guidelines that hospital teams can use to standardize approaches, crucial to equitable care;
- assessment strategies and the evidence in support of each, with a focus on the new Eat, Sleep, Console (ESC) approach with use of a standardized ESC Care Tool;
- treatment strategies including both pharmacologic and non-pharmacologic strategies, with comparison of current evidence supporting specific medication regimens, breastfeeding, formula choice, and newer modalities like vibrating cribs;
- factors that have been shown to affect severity of NOWS presentation, such as prenatal care and maternal treatments for opioid use disorder, potential poly-substance exposure, and infant genetic factors; and
- post-hospital care, including developmental surveillance, family well-being and support, and early childhood considerations.

Throughout the article, the emphasis is on research: comparing completed studies, flagging current ongoing and relevant studies, and outlining areas for future studies. I believe a key take-home point is that discontinuing the use of stigmatizing and inaccurate language regarding NOWS is an important change each of us can make. The words we use matter, and a non-judgmental approach supports equitable care and research. A substance-exposed newborn with NOWS should no longer be labelled as "addicted" or referred to as a "NOWS baby"; the infant's mother is a person with opioid use disorder, not an "addict" or "addicted mother." Dr. Mascarenhas and colleagues end on a positive note, emphasizing the "potential for major breakthroughs in understanding the effects of opioids on the developing brain" as well as the need for research in this area that incorporates personal, social, devel-

Keeping Your Baby Safe
from respiratory infections

RSV
COVID-19
colds
flu

How to protect your little ones from germs and viruses

Cold and flu season can be dangerous - especially for vulnerable infants and children. Fortunately, there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.
- Wash for more than 20 seconds.
- Use alcohol-based hand sanitizers.

Limit Contact with Others

- Stay home when you can.
- Avoid sick people.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

Provide Protective Immunity

- Hold your baby skin-to-skin.
- Give them your breast milk.
- Stay current with your family's immunizations.

Take Care of Yourself

- Stay connected with your family and friends.
- Drink more water and eat healthy foods.
- Seek mental health support.
- Sleep when you can.

Get Immunized

Vaccinations save lives. Protecting your baby from RSV, COVID-19, flu, and pertussis lowers their risks for complications from respiratory infections.

WARNING

Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask can make it harder for them to breathe.
- Face masks and their straps pose a risk of suffocation and strangulation.
- Remember, a baby can't remove their mask if they're having trouble breathing.

If you feel sick or are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop viruses from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

We can help protect each other.
www.nationalperinatal.org/rsv

National Perinatal Association

opmental, and environmental factors for optimal outcomes.

NT

Transfer Patterns Among Infants Born at 28 to 34 Weeks' Gestation

NEWS PROVIDED BY

American Academy of Pediatrics

by Sara C. Handley, MD, MSCE; Elizabeth G. Salazar, MD; Sarah N. Kunz, MD, MPH; Scott A. Lorch, MD, MSCE; Erika M. Edwards, PhD

January 25, 2024

BACKGROUND:

Although postnatal transfer patterns among high-risk (eg, extremely preterm or surgical) infants have been described, transfer patterns among lower-risk populations are unknown. The objective was to examine transfer frequency, indication, timing, and trajectory among very and moderate preterm infants.

METHODS:

Observational study of the US Vermont Oxford Network all NICU admissions database from 2016 to 2021 of inborn infants 280/7 to 346/7 weeks. Infants' first transfer was assessed by gestational age, age at transfer, reason for transfer, and transfer trajectory.

RESULTS:

Across 467 hospitals, 294 229 infants were eligible, of whom 12 552 (4.3%) had an initial disposition of transfer. The proportion of infants transferred decreased with increasing gestational age (9.6% [n = 1415] at 28 weeks vs 2.4% [n = 2646] at 34 weeks) as did the median age at time of transfer (47 days [interquartile range 30–73] at 28 weeks vs 8 days [interquartile range 3–16] at 34 weeks). The median post menstrual age at transfer was 34 or 35 weeks across all gestational ages. The most common reason for transfer was growth or discharge planning (45.0%) followed by medical and diagnostic services (30.2%), though this varied by gestation. In this cohort, 42.7% of transfers were to a higher-level unit, 10.2% to a same-level unit, and 46.7% to a lower-level unit, with indication reflecting access to specific services.

CONCLUSIONS:

Over 4% of very and moderate preterm infants are transferred. In this population, the median age of transfer is later and does not reflect immediate care needs after birth, but rather the provision of risk-appropriate care.

NT

Marijuana Use and Breastfeeding: A Survey of Newborn Nurseries

NEWS PROVIDED BY

American Academy of Pediatrics

by Pearl W. Chang, MD; Neera K. Goyal, MD; Esther K. Chung, MD, MPH

January 22, 2024

BACKGROUND AND OBJECTIVES:

Marijuana use has increased nationally and is the most common federally illicit substance used during pregnancy. This study aimed to describe hospital practices and nursery director knowledge and attitudes regarding marijuana use and breastfeeding and assess the association between breastfeeding restrictions and provider knowledge, geographic region, and state marijuana legalization status. We hypothesized that there would be associations between geography and/or state legalization and hospital practices regarding breastfeeding with perinatal marijuana use.

METHODS:

A cross-sectional, 31-question survey was sent electronically to the 110 US hospital members of the Academic Pediatric Association's Better Outcomes through Research for Newborns (BORN) network. Survey responses were analyzed using descriptive statistics to report frequencies. For comparisons, $\chi 2$ and Fisher exact tests were used to determine statistical significance.

RESULTS:

Sixty-nine (63%) BORN nursery directors across 38 states completed the survey. For mothers with a positive cannabinoid screen at delivery, 16% of hospitals universally or selectively restrict breastfeeding. Most (96%) nursery directors reported that marijuana use while breastfeeding is "somewhat" (70%) or "very harmful" (26%). The majority was aware of the potential negative impact of prenatal marijuana use on learning and behavior. There were no consistent statistical associations between breastfeeding restrictions and provider marijuana knowledge, geographic region, or state marijuana legalization status.

CONCLUSIONS:

BORN newborn clinicians report highly variable and unpredictable breastfeeding support practices for mothers with perinatal marijuana use. Further studies are needed to establish evidence-based practices and to promote consistent, equitable care of newborns with perinatal marijuana exposure.

NT

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Leadership, Advocacy and Consultation

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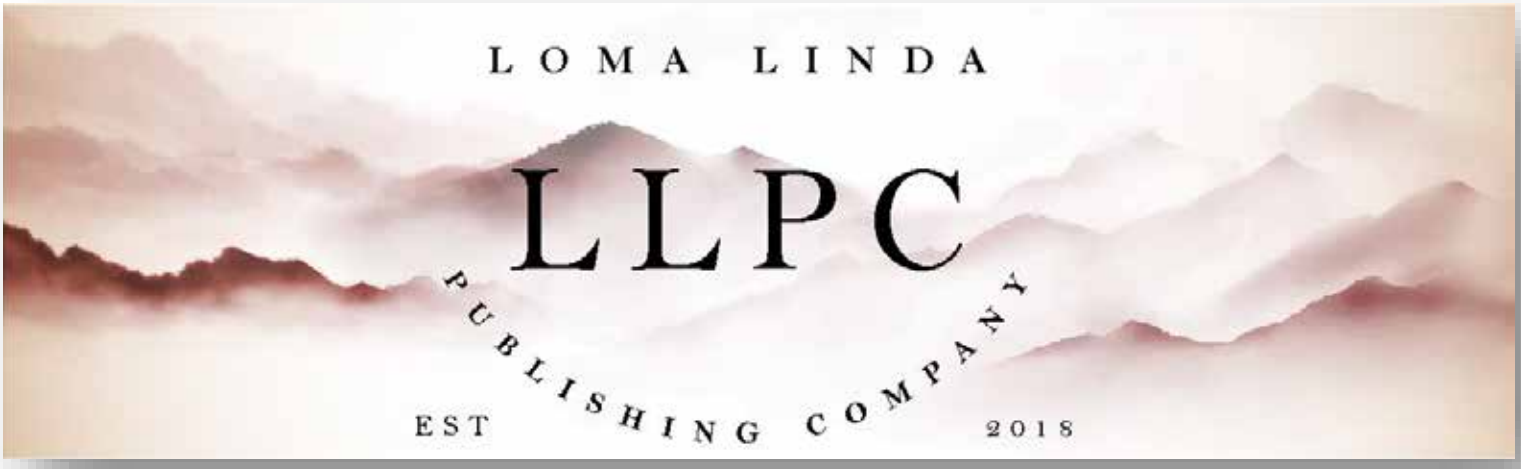

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Genetics Corner: A Premature Infant with Meconium Peritonitis Inspires an Update on the First Cases of In Utero Therapy for Meconium Ileus Due to Cystic Fibrosis

Robin Dawn Clark, MD

Case Summary:

A six-day-old male infant with meconium peritonitis was born prematurely by C-section for breech presentation at 28 weeks 4 days gestational age after spontaneous onset of labor. Polyhydramnios, fetal ascites, and echogenic bowel were noted at the 21-week fetal ultrasound examination. The mother, a 21-year-old primigravida, had Graves' disease that was untreated until the last two months of pregnancy when she was evaluated by a maternal-fetal medicine specialist, who prescribed methimazole. She had normal CFTR gene sequencing, normal maternal serum AFP, and a low-risk result on a cell-free DNA screening test for aneuploidy. An amniocentesis was performed with normal fetal chromosome microarray and negative CMV and toxoplasma studies. Amniotic fluid was meconium-stained. The placenta was large (760 grams, disc, 97th %ile) with abnormal histology: patchy villous edema, fetal vascular malperfusion (multiple foci of avascular villi, occasional stem villous obliteration), and no significant inflammation. The BW was 1.741 kg (99th %ile), Length 37.5 cm (54th %ile), and HC 28.5 cm (94th %ile). The baby had two laparotomies in the first days of life without bowel resection because the bowel was matted, consistent with an in utero perforation and meconium pseudocyst. The family history was negative for cystic fibrosis or consanguinity. The baby's post-operative status limited physical examination, but there were no dysmorphic features.

"A six-day-old male infant with meconium peritonitis was born prematurely...Polyhydramnios, fetal ascites, and echogenic bowel were noted at the 21-week fetal ultrasound examination. The mother, a 21-year-old primigravida, had Graves' disease that was untreated until the last two months of pregnancy...[and was] prescribed methimazole. She had normal CFTR gene sequencing, normal maternal serum AFP, and a low-risk result on a cell-free DNA screening test for aneuploidy."

Discussion:

Meconium ileus, peritonitis, and in utero bowel perforation have many causes. Over half of newborns with meconium ileus (MI) have cystic fibrosis (CF), which is unlikely in this case but will be pursued with CFTR gene analysis in the newborn. Other common causes are in utero infections, including syphilis (1) and congenital atresia of the intestine or bowel mediated by vascular hypoperfusion of the gut, which seems to be the most likely cause in this case. Interestingly, maternal Graves' disease does not seem to increase the chance of meconium ileus, and methimazole therapy cannot be implicated in this case, as the drug was started after the GI anomalies were recognized at 21 weeks gestation.

"Meconium ileus, peritonitis, and in utero bowel perforation have many causes. Over half of newborns with meconium ileus (MI) have cystic fibrosis (CF), which is unlikely in this case but will be pursued with CFTR gene analysis in the newborn. Other common causes are in utero infections, including syphilis and congenital atresia of the intestine or bowel mediated by vascular hypoperfusion of the gut, which seems to be the most likely cause in this case."

Although this infant would likely not benefit, the first issue of Neonatology Today in the new year seems like an auspicious time to bring our readers some good news about advances in therapy for MI due to CF. All of us could use some good news in 2024.

First, let us discuss some background about CF and MI. CF exerts its first effects on the pancreas during fetal life: in ~85% of individuals with CF, fibrosis of the pancreas begins in utero. About 12-20% of infants with CF present with meconium ileus. Reduced secretion of pancreatic enzymes also causes exocrine pancreatic insufficiency, malabsorption, and failure to thrive in patients with CF. Cystic fibrosis therapy has been vastly improved by the recent development of CFTR modulator drugs designed to overcome specific defects in different types of abnormal CFTR proteins. The FDA now approves these drugs for the treatment of cystic fibrosis in children as young as two years old but not, as

yet, in the newborn.

There is evidence that early pancreatic damage in CF may not be irreversible. Early treatment with Ivacaftor, a CFTR modulator drug, increased fecal elastase, with a more significant effect in younger children of 12–24 months and 2–5 years compared to older children (2). CFTR modulator drugs cross the placenta and appear in cord blood and breast milk. When pregnant CF mothers continue their CFTR modulator treatment during gestation, their exposed infants do not experience any harmful effects (3). At least one affected fetus with CF seems to have benefited from maternal CFTR modulator therapy. In New York State, a pregnant woman with CF continued CFTR modulator therapy during her pregnancy. She delivered an infant with CF who had preserved pancreatic function to the extent that the newborn screening test was falsely negative for CF. In New York state, the CF newborn screening test algorithm requires a high immunoreactive trypsinogen (IRT) value in the top 5% for that day to proceed to CFTR gene analysis. In this case, the affected infant with CF had an IRT value that was below the threshold for gene analysis, although she was found to have two copies of the F508del variant (4).

"There is evidence that early pancreatic damage in CF may not be irreversible. Early treatment with Ivacaftor, a CFTR modulator drug, increased fecal elastase, with a more significant effect in younger children of 12–24 months and 2–5 years compared to older children. CFTR modulator drugs cross the placenta and appear in cord blood and breast milk. When pregnant CF mothers continue their CFTR modulator treatment during gestation, their exposed infants do not experience any harmful effects."

Three recent case reports show the efficacy of maternal CFTR modulator therapy initiated in pregnancy in reversing meconium ileus due to CF detected in fetal life when the mothers were themselves healthy carriers. A case report from Charleston, South Carolina, documented CFTR modulator therapy with lumacaftor-lumacaftor-ivacaftor (ETI) treatment in a F508del carrier mother who was pregnant with an affected F508del homozygous fetus. A 23-week fetal ultrasound established the diagnosis of MI with a dilated, hyperechoic bowel that persisted on subsequent imaging. The mother began ETI at 32 weeks, and by treatment day 27, fetal bowel dilation had resolved by imaging. The female infant was born at 36 weeks gestation without complications. The mother continued ETI while breastfeeding. The authors concluded that "maternal ETI treatment likely led to resolution of the MI, and evidence supports continued infant benefit through breastmilk" (5). Authors in Spain (6) reported a healthy pregnant patient who underwent CFTR modulator therapy with ETI to treat her fetus with CF (F508del homozygous CFTR mutation) and MI. Both parents were carriers of the F508del CFTR variant. Ultrasound findings suggestive of MI were observed at 24 weeks. The fetus was diagnosed with CF by amniocentesis at 26+2 weeks. Maternal ETI therapy began at 31+1 weeks. No dilated bowel was observed at 39 weeks, and there were no signs of bowel obstruction after birth. Maternal ETI treatment was continued during breastfeeding, with normal liver function. A third report from Stanford University in California (7) documented fetal therapy with ETI for CF and MI in a heterozygote carrier mother from 26 weeks gestation. Seven weeks after starting therapy, there was apparent resolution of fetal meconium ileus and microcolon on imaging studies. A healthy infant was delivered at 39 weeks gestation, although her IRT was elevated and fecal elastase level was low, indicating that she had pancreatic insufficiency.

"Three recent case reports show the efficacy of maternal CFTR modulator therapy initiated in pregnancy in reversing meconium ileus due to CF detected in fetal life when the mothers were themselves healthy carriers."

Although these are only a handful of case reports and more studies are needed, they show the great potential of treating MI in CF during fetal life (8, 9). This is a hopeful sign that a better prognosis for newborns with MI and CF may be on the horizon as we enter this new year.

Practical applications:

1. Recall that CFTR modulator drugs taken by pregnant women with cystic fibrosis (CF) cross the placenta and appear in cord blood and breast milk.
2. Understand how CFTR modulator drugs given to a pregnant woman can improve and preserve fetal pancreatic exocrine function in the fetus affected with meconium ileus (MI) due to cystic fibrosis.
3. Recognize that a newborn screening algorithm for CF that relies on an elevated immunoreactive trypsinogen (IRT) value could give a false negative result for CF in infants exposed to CFTR modulator therapy during their gestation. For this reason, order comprehensive CFTR gene analysis for all infants exposed to CFTR modulator medications during gestation.

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Disclosures: *There are no reported disclosures*

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Reducing Professional Liability in Neonatal Hypoglycemia

Jonathan K Muraskas, MD, Jay P Goldsmith, MD

A 34-year-old primigravida with positive prenatal care is admitted at 34 and 0/7 weeks for preterm labor and spontaneous rupture membranes approximately 4 hours prior to presentation. There is no clinical evidence for chorioamnionitis. Pregnancy has been complicated by gestational diabetes requiring metformin. The most recent ultrasound, approximately two weeks prior to this admission, demonstrated an estimated fetal weight greater than the 95th percentile at 32 weeks gestation. Labor progressed, and the mother delivered a 2985 g LGA newborn male by spontaneous vaginal delivery at 34 and 0/7 weeks. Apgar scores of 4 and 8 were assigned at 1 and 5 minutes, respectively, and the infant required stimulation and CPAP because of mild respiratory distress. Because of respiratory distress and prematurity, he was admitted to the neonatal intensive care unit. The initial glucose was 12 mg/dL. At approximately 40 minutes of life, an IV was started, a 2 cc/kg bolus of dextrose 10% was given, and a continuous IV rate was established at 80 cc/kg/day. A repeat point-of-care (POC) glucose drawn at 55 minutes of life was 22 mg/dL. Another dextrose 10% bolus at 2 cc/kg was given. At approximately 120 minutes of life, repeat glucose was 36 mg/dL. At 3 hours of life, a glucose value was 55 mg/dL and remained stable throughout the rest of the NICU course.

Despite lower glucose values, there were no clinical signs of hypoglycemia documented. The baby had an unremarkable NICU course consistent with transient tachypnea of the newborn. He was discharged at approximately 36 and 5/7 weeks postmenstrual age and was nippling ad lib with a normal discharge physical exam. The discharge summary listed diagnoses as late preterm male, infant of a diabetic mother, transient tachypnea of the newborn, and hypoglycemia. At approximately eight years of age, this child was diagnosed with mild autism spectrum disorder (ASD). Throughout early grade school, he continued to score less than the 10th percentile relative to proficiency in literacy and mathematics. A malpractice claim was filed against the treating neonatologist, with the plaintiff neonatologist expert claiming that this is a meritorious case and produced literature that he described as "authoritative," demonstrating transient hypoglycemia as the sole causation for all of this child's adverse neurodevelopmental outcomes because no other diagnosis could be responsible. However, no consideration was given to multiple studies demonstrating no significant long-term neurodevelopmental deficits in this population. Furthermore, the plaintiff expert opines that hypoglycemia was listed as a diagnosis in the discharge summary, and the diagnosis of hypoglycemia in a late preterm infant required a more aggressive treatment. This case is still active.

Hypoglycemia describes a low concentration of glucose in the blood. Hypoglycemia affects up to 1 million newborns every year. The annual cost in the United States exceeds 2 billion dollars.

"A 34-year-old primigravida...is admitted at 34 and 0/7 weeks for preterm labor and spontaneous rupture membranes approximately 4 hours prior to presentation...Pregnancy has been complicated by gestational diabetes requiring metformin...the mother delivered a 2985 g LGA newborn male... Apgar scores of 4 and 8...at 1 and 5 minutes, respectively, and the infant required stimulation and CPAP because of mild respiratory distress. Because of respiratory distress and prematurity, he was admitted to the neonatal intensive care unit. The initial glucose was 12 mg/dL. At approximately 40 minutes of life...a 2 cc/kg bolus of dextrose 10% was given, and a continuous IV rate was established at 80 cc/kg/day. A repeat point-of-care (POC) glucose drawn at 55 minutes of life was 22 mg/dL. Another dextrose 10% bolus at 2 cc/kg was given. At approximately 120 minutes of life, repeat glucose was 36 mg/dL. At 3 hours of life, a glucose value was 55 mg/dL and remained stable throughout the rest of the NICU course."

Questions regarding this diagnosis that often arise at the bedside are:

1. How low a glucose concentration is too low?

2. At what level of serum glucose concentration does brain damage occur?
3. How long can serum glucose be low before irreversible brain damage occurs?

Hypoglycemia screening and management practices vary significantly across the United States. Significant "pathologic" hypoglycemia has not been defined by a single number that can be applied universally to all patients. A consistent definition of hypoglycemia does not exist for the first 48 hours of life. Lower glucose values in the first two hours of life are a normal physiologic adaptation to extrauterine life. Most clinicians consider plasma glucose values lower than 35 mg/dL abnormal in the first 48 hours of life, regardless of gestational age. In an attempt to guide clinicians, the AAP has relied on analysis of the lower range of glucose that occurs during the establishment of postnatal glucose homeostasis and advised actionable ranges of 25–40 mg/dL for the first 4 hours of life and 35–45 mg/dL from 4 hours to 24 hours of age. Glucose levels rise and should be similar to older children after the first 48 hours of life. There is no consistent threshold or lower limit single value for plasma glucose concentrations below which neurologic impairment or injury invariably begins or develops. (1) Most reasonable clinicians feel that asymptomatic hypoglycemia is benign for short periods at any level and that prolonged hypoglycemia (i.e., <25 mg/dL) is necessary for many hours to cause brain injury.

"Significant 'pathologic' hypoglycemia has not been defined by a single number that can be applied universally to all patients. A consistent definition of hypoglycemia does not exist for the first 48 hours of life. Lower glucose values in the first two hours of life are a normal physiologic adaptation to extrauterine life. Most clinicians consider plasma glucose values lower than 35 mg/dL abnormal in the first 48 hours of life, regardless of gestational age. In an attempt to guide clinicians, the AAP has relied on analysis of the lower range of glucose that occurs during the establishment of postnatal glucose homeostasis and advised actionable ranges of 25–40 mg/dL for the first 4 hours of life and 35–45 mg/dL from 4 hours to 24 hours of age."

Blood glucose levels are not necessarily a reflection of brain glucose levels. Whole blood glucose values tend to be 10–15% lower than plasma glucose. Therefore, bedside point of care (POC) glucose values done on whole blood are 10–15% lower than plasma glucose levels performed in the laboratory. Whole blood glucose can drop if allowed to stand at room temperature. Glucose oxidase test strips read by the eye or meter are often too unreliable and variable to initiate therapy in an asymptomatic newborn. POC bedside devices can provide a rapid screening of whole blood glucose. (2)

"There is no consistent threshold or lower limit single value for plasma glucose concentrations below which neurologic impairment or injury invariably begins or develops. Most reasonable clinicians feel that asymptomatic hypoglycemia is benign for short periods at any level and that prolonged hypoglycemia (i.e., <25 mg/dL) is necessary for many hours to cause brain injury.."

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Documentation is always the best defense against allegations of malpractice, and treating hypoglycemia in newborns is no exception. The newborn's clinical condition, glucose value, the method by which it was measured, treatment, and clinical response are essential and the standard of care. Most newborns with plasma glucose between 25 and 45 mg/dL without symptoms are usually fed or given glucose gel. Symptomatic hypoglycemia should always be treated with IV glucose with good documentation. Symptomatic hypoglycemia has been associated with neurologic impairment, including developmental delay, cortical visual deficits, cognitive difficulties, and epilepsy. Hypoglycemia could also be secondary to neonatal diseases such as hypoxic-ischemic encephalopathy, respiratory distress syndrome, and sepsis. Signs can include tremors, apnea, jitteriness, cyanosis, irritability, lethargy, tachypnea, grunting, hypotonia (hypertonia during seizures), poor feeding, tachycardia, and seizures. Neuroimaging

of newborns with confirmed symptomatic hypoglycemia classically involves the occipital lobe, although more diverse patterns of injury have been described (3).

"Symptomatic hypoglycemia has been associated with neurologic impairment, including developmental delay, cortical visual deficits, cognitive difficulties, and epilepsy. Hypoglycemia could also be secondary to neonatal diseases such as hypoxic-ischemic encephalopathy, respiratory distress syndrome, and sepsis."

Common malpractice allegations in managing low glucose values include failure to initiate blood glucose monitoring when identifiable risk factors are present. Lower delivery volume—Level 1 and Level 2 nurseries—are more vulnerable to allegations of delay in initiating IV glucose therapy and delayed transfer to a higher level of care in the presence of low glucose values. Allegations can also include not heeding both nursing and parental concerns, such as poor feeding, hypotonia, jitteriness, or low body temperature. As noted, failure to recognize and document abnormal clinical signs with low glucose values, treatment, and resolution with normoglycemia can be problematic (4). Providers should be cautious when listing hypoglycemia as a discharge diagnosis, especially if there is no evidence of clinical signs or symptoms. A preferred diagnosis is "laboratory hypoglycemia." A skilled plaintiff lawyer can blow up the medical record to show a discharge diagnosis of hypoglycemia and go through every adverse effect a low blood sugar can potentially cause in a child who has low glucose values in the nursery. This topic can make a defense difficult when there is a paucity of documentation to refute many of these allegations. The mantra of "if you did not document it, you did not do it" in a trial is pervasive.

"As noted, failure to recognize and document abnormal clinical signs with low glucose values, treatment, and resolution with normoglycemia can be problematic. Providers should be cautious when listing hypoglycemia as a discharge diagnosis, especially if there is no evidence of clinical signs or symptoms. A preferred diagnosis is 'laboratory hypoglycemia.'"

There has been no convincing evidence that one or more brief episodes of low glucose concentrations below a specific value cause brain injury or that the duration of low glucose values is dangerous. However, a retrospective study of transient glucose values <35, <40, and <45 mg/dL in the newborn period was associated with lower achievement test scores at ten years of age in one study (5). The ongoing HypoEXIT trial is the first study to compare neurodevelopmental outcomes using two different glucose thresholds for intervention. In this multicenter, noninferiority trial, asymptomatic at-risk infants-infants of diabetic mothers, late preterm neonates, or newborns with birthweights <10%-ile or >90%-ile with hypoglycemia are stratified into different protocols: a traditional threshold group with plasma glucose <47 mg/dL as the cutoff for treatment and a low threshold group using a value less than 36 mg/dL. Treatment options were the same in both groups and determined by providers. At 18 months, the two groups had no significant differences in psychomotor test scores. (6) In the randomized Sugar Babies trial, a mid-childhood follow-up study (at 10–11 years), which included many late preterm and term newborns with multiple episodes of glucose values <2 mmol/L (<36 mg/dL), did not demonstrate any adverse educational achievement in the non-treated (placebo) group (7).

"There has been no convincing evidence that one or more brief episodes of low glucose concentrations below a specific value cause brain injury or that the duration of low glucose values is dangerous. However, a retrospective study of transient glucose values <35, <40, and <45 mg/dL in the newborn period was associated with lower achievement test scores at ten years of age in one study"

The present consensus, using evidence-based medicine, is that transient asymptomatic low glucose values and symptomatic hypoglycemia promptly treated in the newborn period should not result in adverse neurological outcomes.

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Disclosures: *There are no reported disclosures*

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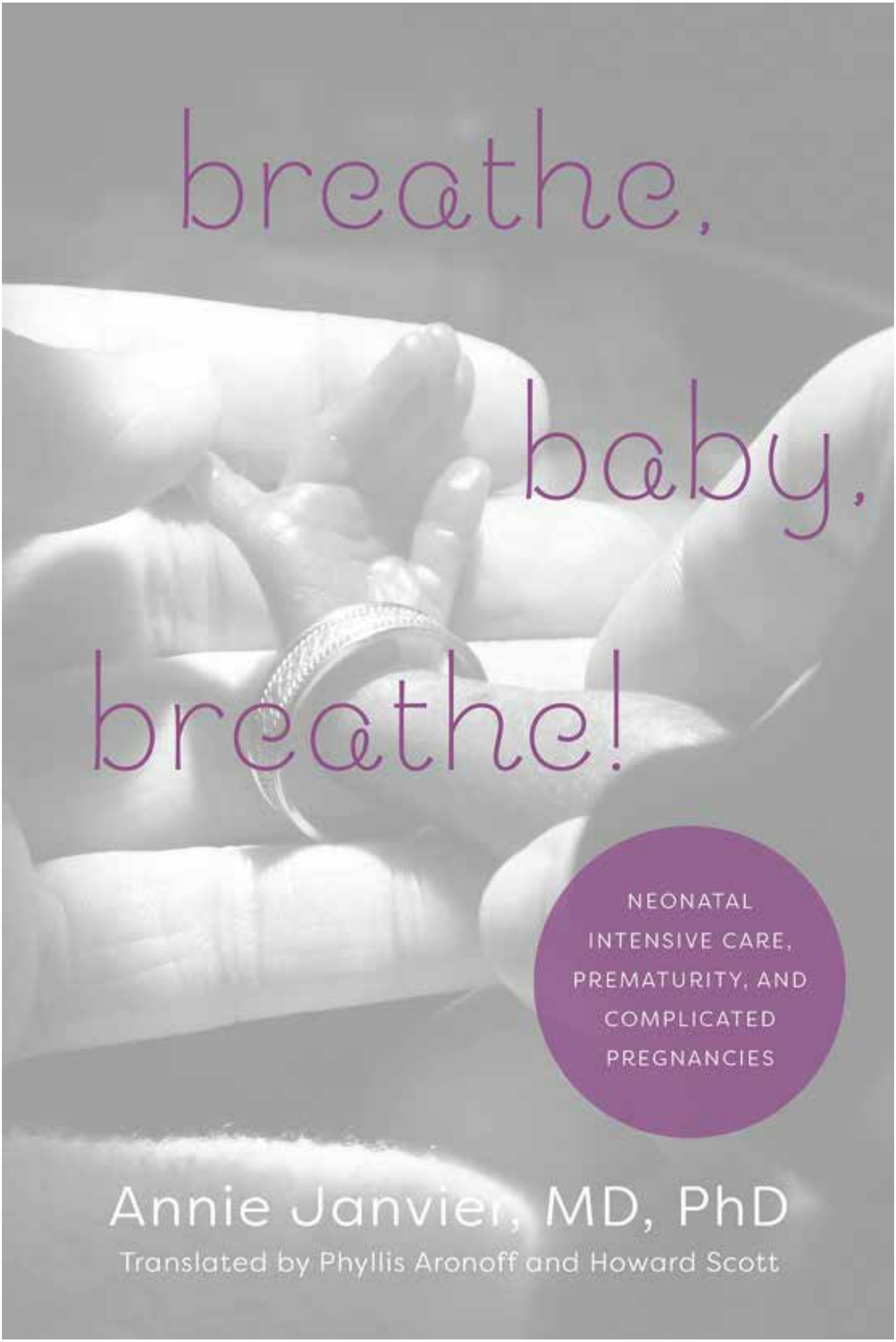
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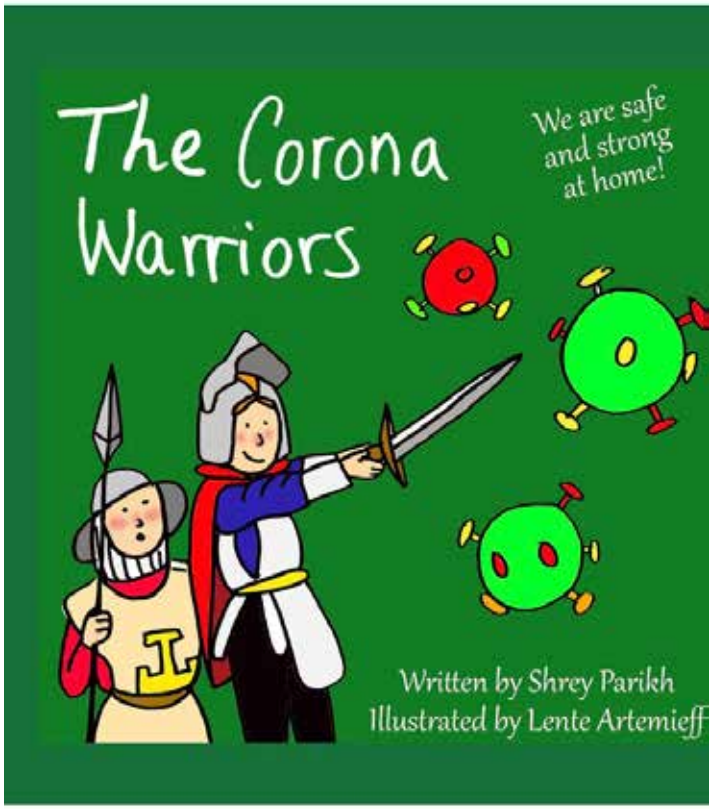
NEONATAL INTENSIVE CARE, PREMATURITY, AND COMPLICATED PREGNANCIES
Annie Janvier, MD, PhD
Translated by Phyllis Aronoff and Howard Scott



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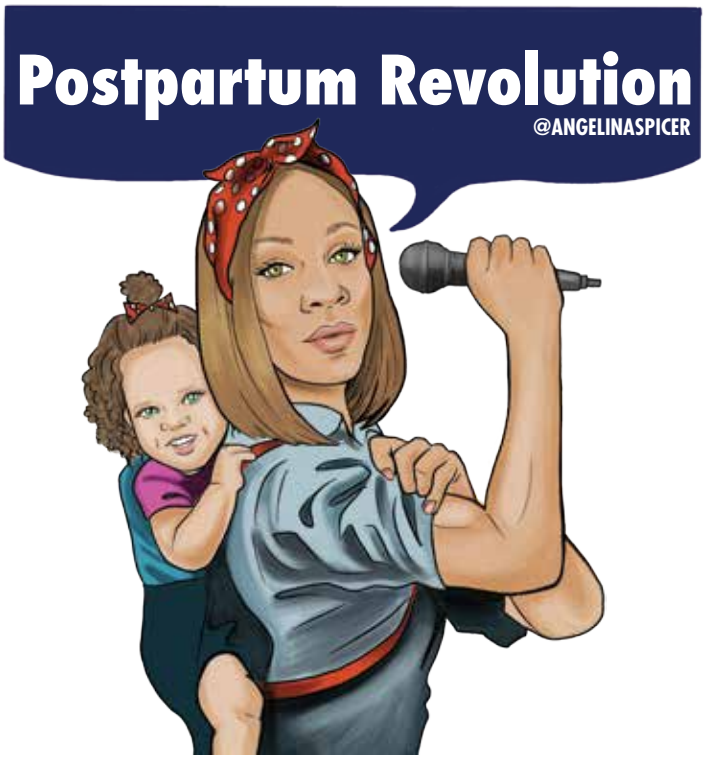

Peer Reviewed

NICU Family Centered Care Program in a Safety Net Hospital

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Introduction:

Family-centered care (FCC) is a critical part of NICU care. Families feel intense stress and anxiety during their infant's stay in the NICU (1–3). Many parents are ill-equipped to handle the adverse experience, which can lead to long-lasting negative impacts on parental well-being and their children's health and development. A family's need to be heard, understood, respected, and supported by NICU staff is the key to establishing a strong partnership between families and the NICU team. Family participation in routine infant care, positive parent-infant interaction, and shared decision-making with NICU staff are shown to decrease parental anxiety and stress levels, as well as later posttraumatic stress disorder (PTSD) (4–6). A supportive and nurturing environment improves the family's overall experience during NICU stay and the family's long-term outcomes, given the manifold early bonding and caring opportunities for families in the NICU with their infants (4, 7–9).

"Family-centered care (FCC) is a critical part of NICU care. Families feel intense stress and anxiety during their infant's stay in the NICU. Many parents are ill-equipped to handle the adverse experience, which can lead to long-lasting negative impacts on parental well-being and their children's health and development."

While increasing evidence has shown the benefits of family-centered and family-integrated care in NICU, establishing and incorporating a sustainable FCC program in routine clinical practice faces many challenges (10). In this paper, we describe how our NICU FCC program, in a safety net hospital, uniquely supports NICU families and how the FCC team, over the years, has become an integral part of the clinical care team, NICU care, and decision-making.

Context: NICU in a Safety Net Hospital Setting:

Santa Clara Valley Medical Center (SCVMC) NICU is an AAP level IV, California regional 40-bed NICU with 300–350 annual NICU admissions housed in a safety net hospital in San Jose, California. Safety net hospitals are committed to providing care for people with limited or no access to healthcare due to socioeconomic circumstances, insurance status, or health conditions. The mission of the Santa Clara County healthcare system is to provide high-quality, accessible healthcare and service to all persons in the county regardless of their socioeconomic status and ability to pay. This healthcare system comprises 3 Hospitals with associated Clinics and supports 20–25% of county births, with approximately 4,500 deliveries annually.

SCVMC FCC Program Development and Growth:

The FCC program journey at SCVMC NICU started in partnership with the March of Dimes program in 2009 when our site became one of their first ten NICU family support sites through a competitive grant application process. The program introduced FCC care into our NICU by providing patient education with a kiosk and staff education. Over the 15 years, the program's focus has been to promote a culture change incorporating FCC in every aspect of NICU care. Since 2012, the FCC program has been supported with extramural funding essential for continuous progress in the FCC and building a team of paid FCC team members in a safety net hospital.

"Since 2009, the FCC program at SCVMC NICU has grown to the current team of three family support specialists (FSS), a family education specialist (FES), and an FCC director (Figure 1)"

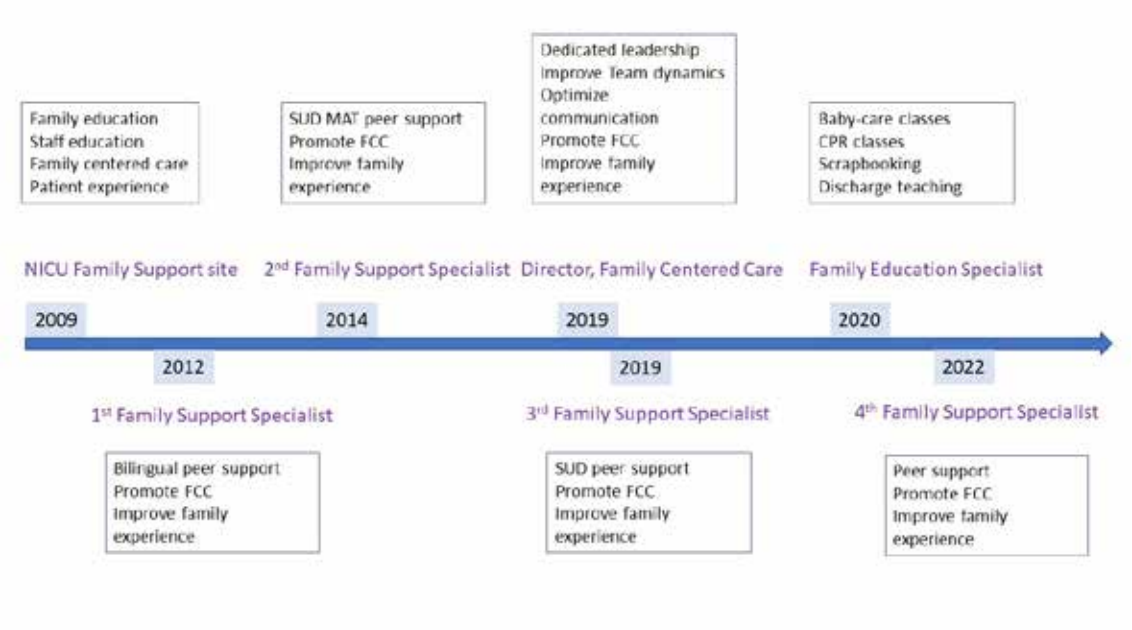
The FCC Team:

Since 2009, the FCC program at SCVMC NICU has grown to the current team of three family support specialists (FSS), a family education specialist (FES), and an FCC director (Figure 1).

Family support specialist

Peer support is a powerful tool to support families through a difficult journey in the NICU. NICUs need to address the psychosocial needs of families during their journey in the NICU. Peer support from NICU graduate parents can help mitigate some of the stressors the current NICU parents face after admission, through the hospital stay, and during the transition from the NICU

Figure 1. SCVMC family-centered care program timeline
FCC – family-centered care, SUD – substance use disorder, MAT – medication-assisted treatment.



to home. In this peer support model, the NICU graduate parent shares a similar lived experience with the NICU parent, and the care provided usually involves sharing information/resources, emotional support, and encouragement. Peer support is flexible in its approach, i.e., services can be provided in person, by phone or email, in groups or individually, and in different settings.

"Peer support from NICU graduate parents can help mitigate some of the stressors the current NICU parents face after admission, through the hospital stay, and during the transition from the NICU to home. In this peer support model, the NICU graduate parent shares a similar lived experience with the NICU parent, and the care provided usually involves sharing information/resources, emotional support, and encouragement."

Our selection of FSS was based on the principle that they reflect the patient population served by the NICU. The first FSS is a Hispanic, bilingual, former NICU mother of a 27-week premature infant and a history of fetal loss. She proactively advocated for her daughter during her NICU stay. She helps primarily Spanish-speaking families, accounting for more than 30–50% of our NICU families. The next FSS is a former NICU mother of a 27-week preterm infant with a history of substance use disorder (SUD) who was in recovery at the time of delivery. She supports the NICU mothers with a history of SUD. As part of that support, she shares her lived experience with recovery programs in the county and has also helped NICU mothers tour residential programs in the county. The most recent FSS is a former NICU mother of a 24-week preterm infant. She is a strong advocate for maternal mental health support and supports English-speaking NICU families.

The FSSs support NICU families in many ways (Table 1). Upon admission, FSSs will reach out to families 1-2 days after admission, introduce themselves, and give them a self-care packet, breastmilk bag with icepacks, a NICU stay booklet that outlines caring for the baby in the NICU, coping as a NICU parent, getting ready for discharge etc., skin to skin brochure, and First 5 resource guides. FSSs connect with families in person or by phone once or twice weekly to support ongoing needs. They attend family conferences with the NICU team with the families' consent for their presence. In addition, they provide additional support to families when their babies are critically ill or dying. FSSs administer family satisfaction surveys 7–8 days after the infant is admitted into the NICU and around discharge time.

Furthermore, they often stay in touch with families following NICU discharge on an as-needed basis. They work closely with our home follow-up program and High-Risk Infant Follow-up program team. They reach out to the appropriate program staff to ensure that parental needs are met during NICU stay and after discharge.

Family Education Specialist

The bedside nurses provide education for families and training explicitly related to their infant's care at beside. However, learning in a stressful environment like NICU can be challenging and overwhelming. Based on the brain state model, learning is better when one is not in a survival or emotional state but in the executive state and ready to learn. To overcome this barrier, our designated FES provides individual and group family education and training away from patient care activities to ensure a calm and stress-free learning environment.

The FES is a former bedside nurse with the experience of having a preterm infant. She focuses on reviewing discharge teaching, including baby care and CPR classes. In addition, she facilitates

Table 1. Structure of FCC team and Roles of FSS

Understand our NICU families' needs and learn their strengths and challenges.
Provide peer support for NICU families by sharing their lived experiences.
Encourage families to express their needs, concerns, and suggestions and participate in their babies' care.
Encourage families to do skin-to-skin kangaroo care, comfort touch, read, breastmilk feeding, and pumping.
Organize activities to reduce families' anxiety and stress and connect NICU families.
Provide additional support to families when their babies are critically ill or dying.
Facilitate family-NICU staff partnership to improve family experience and infant outcomes.
Communicate with NICU leadership and staff to provide family feedback to improve NICU care.
Provide family's perspective to the NICU team by participating in NICU meetings.
Facilitate staff education on topics relevant to family-centered care.
Communicate with Home Follow-up and High-Risk Infant Follow-up program staff.

scrapbooking sessions that bring multiple NICU families together and allow them to connect as an informal support group.

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FCC Director

In the early years of our program, a NICU provider or a staff member served as the FCC director and worked closely with the FCC team. With the expansion of the FCC team and its activities, we recognized that the program required an FCC director whose sole responsibility is to lead and work with the FCC team to ensure the consistency and effectiveness of the FCC for sustaining success and program growth.

The director of our FCC program is a developmental psychologist with her own experience of pregnancy loss at 23 weeks. The director oversees weekly structured communication within the FCC team and between the FCC team and NICU staff. She plays a key role in improving team dynamics, accountability, and transparency of the FCC team's work, actively disseminating FCC achievements to NICU staff. Lastly, the director is also responsible for program building and expanding the breadth of services the team offers both within and outside the NICU.

Enriching Family Experience:

A fundamental goal of the FCC team is to enrich and bring reprieve from stress for NICU families and help build positive, lasting memories. Weekly scrapbooking sessions are one of the favorite activities for many of the families. The scrapbooking sessions away from the bedside help them relax in a calm environment as they connect and focus on creating positive memories of their NICU stay. In addition, the team organizes family-friendly activities to celebrate special occasions throughout the year, including Christmas, Thanksgiving, Halloween, New Year, Valentine's Day, Mother's Day, and Father's Day. They take photographs of babies in special holiday outfits and create mementos for the families. These occasions also provide opportunities to connect with other NICU families in a relaxing environment and to support each other. NICU family picnics and NICU reunions are occasions for current NICU families and graduate NICU families to interact with NICU staff and other families. In 2019, the FCC team worked with the March of Dimes to design and create a Wall of Hope that adorned the walls of our NICU. The "Wall of Hope" consists of several beautifully written stories of NICU babies who survived and thrived after their journey in the NICU. The stories and the pictures of the NICU graduates offer hope to new NICU families as they embark on what can sometimes be a scary journey.

"The director oversees weekly structured communication within the FCC team and between the FCC team and NICU staff. She plays a key role in improving team dynamics, accountability, and transparency of the FCC team's work, actively disseminating FCC achievements to NICU staff. Lastly, the director is also responsible for program building and expanding the breadth of services the team offers both within and outside the NICU. "

While these FCC activities likely occur in many other NICUs, our FCC team has overcome many barriers to provide them to underserved families in a safety net hospital consistently, weekly, year after year, over a decade.

"A fundamental goal of the FCC team is to enrich and bring reprieve from stress for NICU families and help build positive, lasting memories."

FCC Team as Clinical Care Partners:

The FCC team participates in regular clinical care meetings to advocate for the NICU families. They attend weekly NICU clinical rounds and multidisciplinary rounds. They remind the clinical care team of the trauma of the NICU family experience and advocate on behalf of the NICU families. The FCC team provides feedback from families to medical staff at the weekly meetings and shares findings from the patient satisfaction survey in monthly division meetings. The team members liaise regularly with the NICU social worker and work collaboratively to support family members. Thus, the FCC team and their feedback are considered critical to the NICU clinical care decision-making as we reflect the "voice of the family."

"The FCC team participates in regular clinical care meetings to advocate for the NICU families. They attend weekly NICU clinical rounds and multidisciplinary rounds...and advocate on behalf of the NICU families. The FCC team provides feedback from families to medical staff at the weekly meetings and shares findings from the patient satisfaction survey in monthly division meetings. The team members liaise regularly with the NICU social worker and work collaboratively to support family members."

The FCC team actively participates with NICU staff in unit improvement activities. They advocated for improving discharge readiness by highlighting the parents' feedback on being overwhelmed with information at discharge. They suggested addressing language barriers in non-English language Preference families and the educational needs of some families with limited literacy to understand the information in patient handouts. In 2022, the FCC team helped establish a Voice of the Patient (VOP) panel to engage with NICU leadership and staff to raise awareness about the family experience in the NICU and help create a culture of respect for our families. Based on the discussions with the VOP, recommendations were brought on how to communicate daily and effectively with families. In 2023, the FCC team helped establish a Family Staff Advisory Council (FSAC) that provides feedback on several issues pertaining to families, such as welcome to NICU videos for new families and family friendliness in handouts given to families. They educate staff on appropriate ways to communicate with and about families, given that families go through intense trauma during their journey in the NICU.

FCC Team Participates in Staff Education

A critical area that the FCC team participates in and contributes to is NICU staff education in the monthly division meeting. They helped educate NICU staff on appropriate ways to communicate with and about families, given that families may have histories of trauma and go through intense stress during the NICU journey.

The FCC team participates in FCC advocating activities and conferences organized by local, state, and national/international organizations, like March of Dimes, Vermont Oxford Network, California Perinatal Quality Care Collaborative (CPQCC) FCC taskforce, where they learn and share their experience both within and outside our institution. They share webinars and grand rounds from March of Dimes and other organizations on topics of trauma-informed care, staff burnout, and the trauma of NICU family experience.

"A critical area that the FCC team participates in and contributes to is NICU staff education in the monthly division meeting. They helped educate NICU staff on appropriate ways to communicate with and about families, given that families may have histories of trauma and go through intense stress during the NICU journey."

FCC Team Training and Education:

The professional growth of our FCC team is an essential component of program development. All FCC team members have received customer service training and informal training from the medical social worker on how to support the NICU families from the medical social worker. One FSS has undergone further training as a family advisory council member of CPQCC and parent-family partner training certification. The FSS is currently undergoing lactation educator training as well. Our goal is to standardize and provide additional training for all team members on how best to support the families.

Measuring Program Impact:

Ongoing data collection for measuring the impact and success of any program is critical to the program's sustainability. The FCC team collects such data regularly and submits this quarterly and annually to our funding agency. These data include:

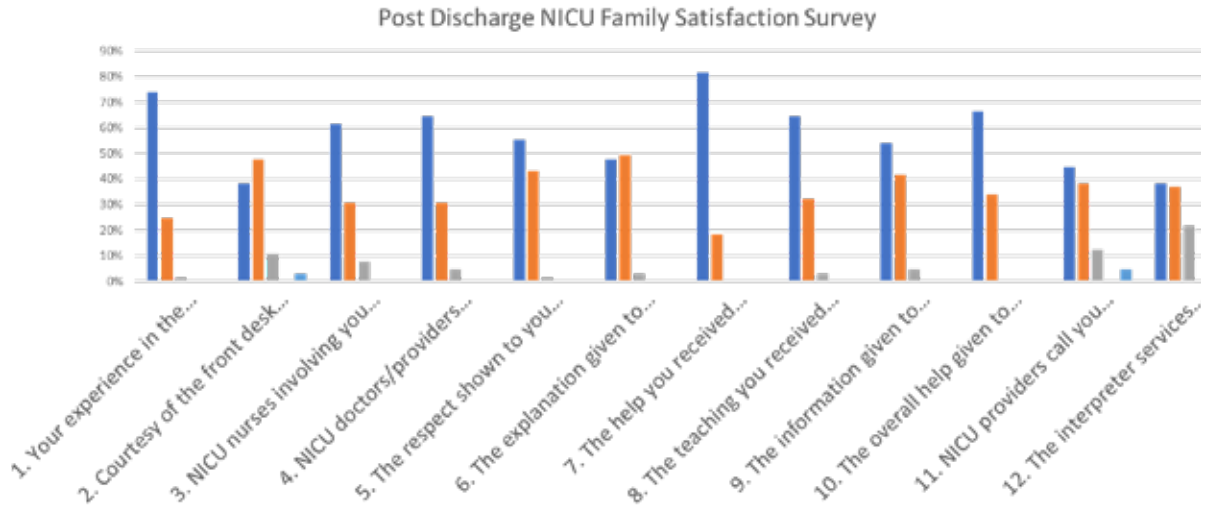
- Process Measures: Demographics report to show how many families our FCC team supports.
- Outcome Measures: Breastmilk feeding rate at the time of discharge, any breastmilk feeding, and neonatal abstinence syndrome reports are outcomes that have been shown to improve with family-centered care.

Table 2 Family Satisfaction Survey Questions

Overall, how satisfied were/are you with:
1. Your experience in the NICU?
2. Courtesy of the front desk staff?
3. NICU nurses involving you in the care of your infant?
4. NICU doctors/providers involving you in caring for your infant?
5. The respect shown to you and your family by the NICU staff?
6. The explanation given to you about why tests, procedures and/or medical treatments were performed on your infant?
7. The help you receive from our parent support/family-centered care (FCC) team?
8. The teaching you receive to take care of your infant after discharge?
9. What information did NICU staff give about you about your infant's follow-up appointments after discharge?
10. The overall help given to you by NICU staff?
11. NICU providers call you during rounds every day to give you daily updates on your baby.
12. Are interpreter services offered in the NICU (by a person or tablet)?

- Success Stories: The NICU families share details of their NICU journey with the FCC team. The team regularly collects this qualitative information in the form of quotes and/or success stories from NICU families that spotlight their experience in the NICU, what worked, what did not work, and how they felt overall about the support provided in the NICU.
- The Family Satisfaction Survey is administered twice by the FSS, a week after NICU admission and once after discharge. The questions on the satisfaction survey center around various topics, such as courtesy of front desk staff, how well nurses and providers treated families, and how well they were prepared for discharge on a Likert scale (very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, very dissatisfied). Table 2 shows the list of questions in the survey, and Figure 2 shows a recent summary of the results of the discharge survey.

Figure 2 Post Discharge Family Satisfaction Survey result



Barriers to implementing FCC team:

NICU staff accepting the FCC team members as essential members of the clinical team is the key to the success of an FCC program. While our NICU staff acknowledged the importance of the FCC, it took time to recognize the role and value of a designated FCC team in the NICU. Initially, introducing our first FSS in the unit met resistance from nursing staff and medical social workers. There were concerns about confidentiality and confusion about the role of FSS. Nursing staff felt that they were the family advocates and that there was no need for FSS. Medical social workers were concerned that the FSS was not adequately trained to talk about social issues, especially when the FSS was helping mothers with SUD, informing them of the available treatment programs. We clarified the roles of the FCC team and arranged for them to get training from social workers. Participation in clinical meetings and close communication with NICU staff gave the FCC team opportunities to provide their

perspective and input to address family/social issues. Over time, NICU staff recognized that families were more open to FSS and often felt more comfortable connecting and communicating with FSS, which helped establish trust and communication between families and NICU staff. Thus, staff came to accept FSS and value their services, often relying on them to communicate with families effectively. This change in the culture of seeing the FCC members as integral parts of the clinical team laid the foundation for the successful implementation of FCC in the NICU.

"NICU staff accepting the FCC team members as essential members of the clinical team is the key to the success of an FCC program. While our NICU staff acknowledged the importance of the FCC, it took time to recognize the role and value of a designated FCC team in the NICU."

Key Components of the FCC Program:

Establishing a well-integrated family-centered care system in a safety net NICU requires several components to be in place:

(1) a strong peer support presence in the NICU helps provide support to families through their NICU journey. Given the population served by our NICU, it is essential to have an FCC team that reflects the population served;
(2) equally significant, FCC members in safety net NICUs like ours must occupy paid positions sustainably. Indeed, we would argue that every NICU should consider having dedicated, paid FCC team members who are considered employees of the NICU;
(3) an essential component of this system is fostering program development. Given the busy workload of NICU staff, employing a dedicated program director is crucial to strengthening and growing the FCC program. The director is responsible for establishing accountability and transparency of the team's work with NICU leadership and fostering active, structured communication both within the team and between the team and NICU staff;
(4) integration of the FCC team into the clinical team is essential to maintain regular lines of communication and amplify the voice of the families. The FCC team should be considered to represent the true voice of the NICU families at weekly meetings;
(5) all QI activities must be informed and participated by NICU families, which has become a responsibility of our FCC team;
(6) continuous NICU staff education on the value of FCC to change unit culture; and
(7) a supportive hospital and NICU leadership that believe in the value of FCC is fundamental for the effectiveness and sustainability of FCC in clinical practice. Our future efforts will further emphasize the role of families in individualized medical and developmental care and provide qualifiable evidence to advocate for FCC as an integrated part of clinical practice in all NICUs.

Conclusion:

FCC is necessary for improving the quality of care and outcomes of high-risk infants and their families' well-being. Our 15-year journey has built a strong, effective, and sustainable FCC program that has transformed the culture of our unit and helped thousands of NICU families. A NICU mother best summarizes the impact of our FCC program: *"The memories of this place and what all the NICU staff did for me truly hit six months after discharge when your baby is hitting their milestones, and they are starting to become healthy. You look back and realize how much hope the NICU gave you. The stories that I heard from my Family Support Specialist and other mothers, and the encouragement that I received from the NICU staff was so profound when I got to the other side—I realized how much they carried me through that time when I was in the NICU."*

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Disclosures: *There are no reported disclosures*

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Acknowledgments

We would like to acknowledge Dr. Balaji Govindaswami for his leadership in establishing the FCC program at SCVMC; our family support specialists Patty Mier, Jennifer Godfrey, and Caitlin Evans; and family education specialist Erin Saucedo, who have been amazing champions supporting the NICU families. We are grateful for all the NICU nurses, nurse practitioners, neonatologists, lactation consultants, and medical social workers who have embraced the FCC team as integral clinical team members and for guidance and support from March of Dimes. This work would not be possible without the funding support from Santa Clara County First Five and Valley Health Foundation.

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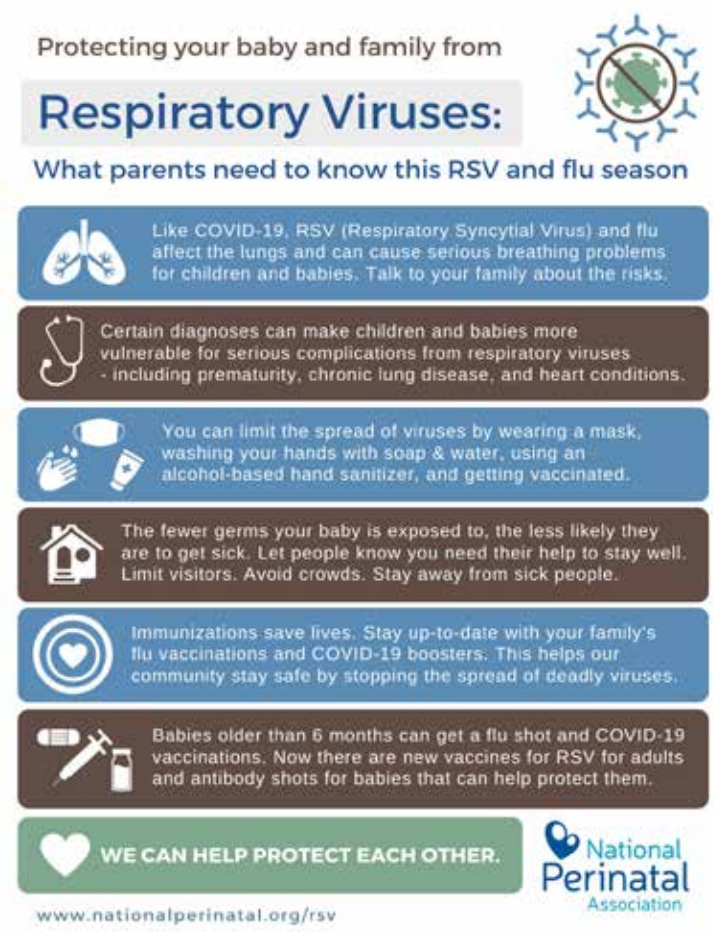

Vaccines and Preventive Monoclonal Antibodies

WHAT'S THE DIFFERENCE?

The Importance of Immunization

Vaccines and preventive monoclonal antibodies are two different types of immunization. While they function differently, they both serve the same purpose: protecting people from serious illnesses and diseases.

Different Technology, Same Protective Value

AfPA

https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work#:~:text=Vaccines%20contain%20weakened%20or%20inactive,rather%20than%20the%20antigen%20itself.

https://static1.squarespace.com/static/5523fcf7e4b0fef011e668e6/t/62445afd0134140ff954f3f6/1648646910485/NCIIH_Monoclonal+Antibodies+Inclusion+in+the+VFC+Program_Position+Paper_Mar+2022.pdf

VACCINES	PREVENTIVE MONOCLONAL ANTIBODIES
Teach the body to create antibodies that fight off a specific disease.	Introduce antibodies that are ready to ward off disease in the body.
How does it work?	
By introducing an inactive piece of a disease or proteins that look like the disease, they trigger an immune response, training the body to create antibodies that defeat the disease.	Instead of teaching the body to create antibodies and defenses, they provide antibodies that are readily available.
Both support the immune system's defenses.	
What are the benefits?	
Many vaccines are readily and easily available. The technology behind vaccines has been around for decades.	Preventive monoclonal antibodies can provide protection for diseases where there isn't an existing vaccine or there isn't an existing vaccine for certain patient groups.
Both protect against disease and provide a public health benefit by decreasing the burden of disease.	
What can this immunization protect against?	
Polio Measles COVID-19 And more	RSV COVID-19
Both can provide tailored protection from a variety of diseases.	
Is it safe?	
Yes	Yes
Both vaccines and preventive monoclonal antibodies undergo extensive testing for safety and efficacy.	

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The Signs & Symptoms of RSV

RESPIRATORY SYNCYTIAL VIRUS

Know the Signs & Symptoms of RSV

- Cough
- Runny Nose
- Struggling to Breathe *(breastbone sinks inward when breathing)*
- Difficulty Eating
- Lethargy
- Wheezing

RESPIRATORY SYNCYTIAL VIRUS
is a highly contagious seasonal virus that can lead to hospitalization for some babies and young children.

Know the Signs.

NCfIH National Coalition for Infant Health
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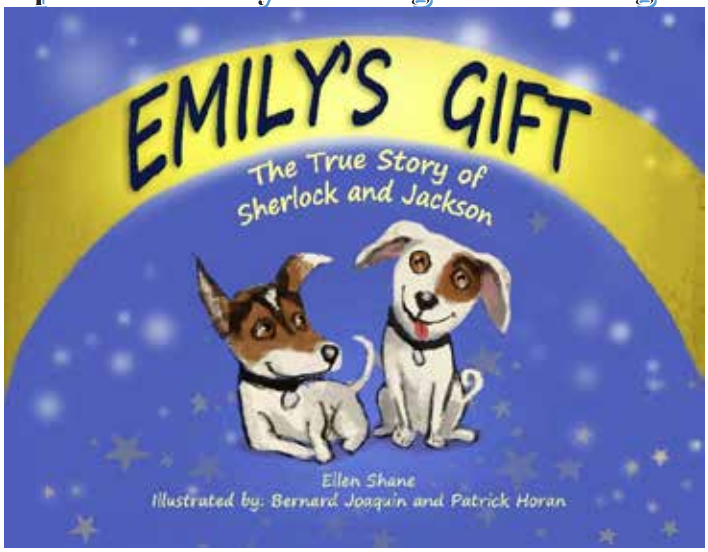

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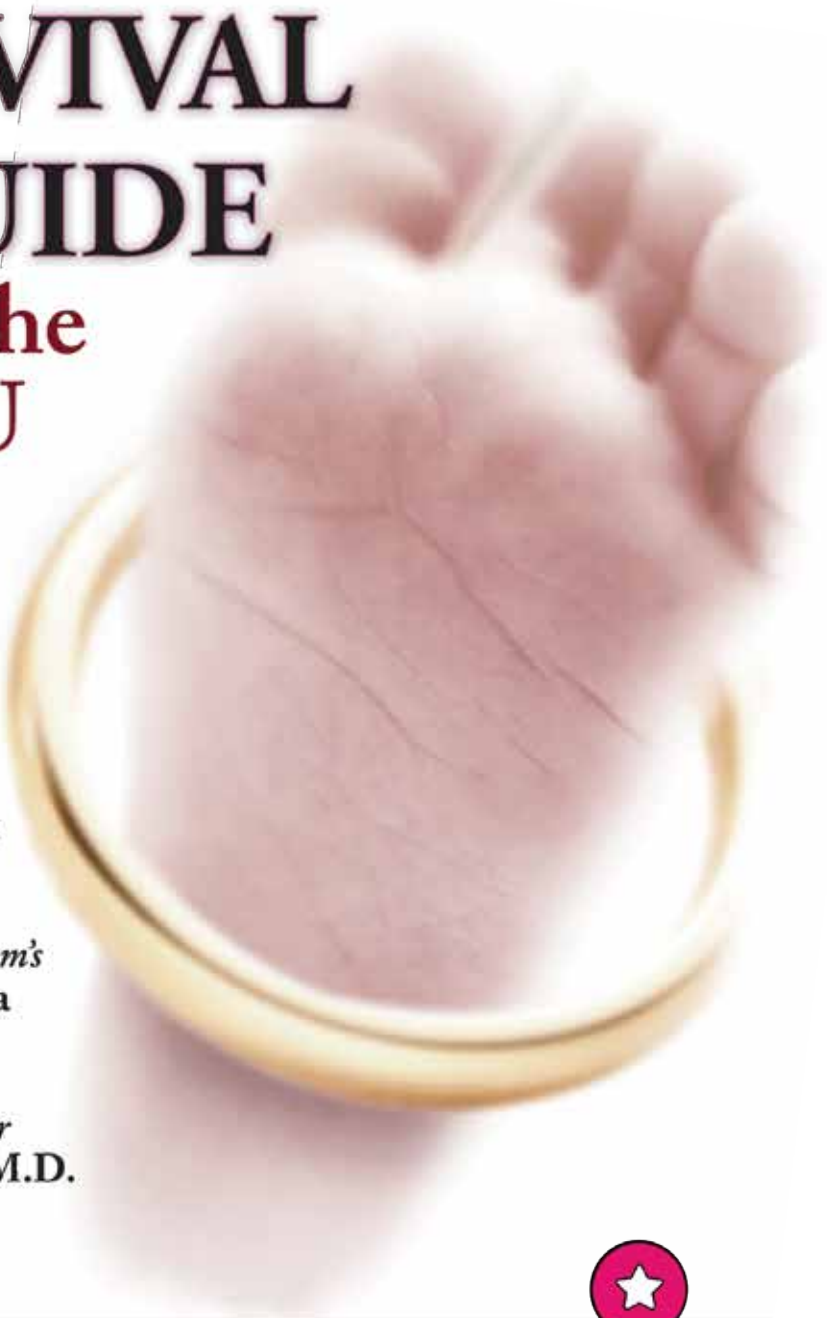

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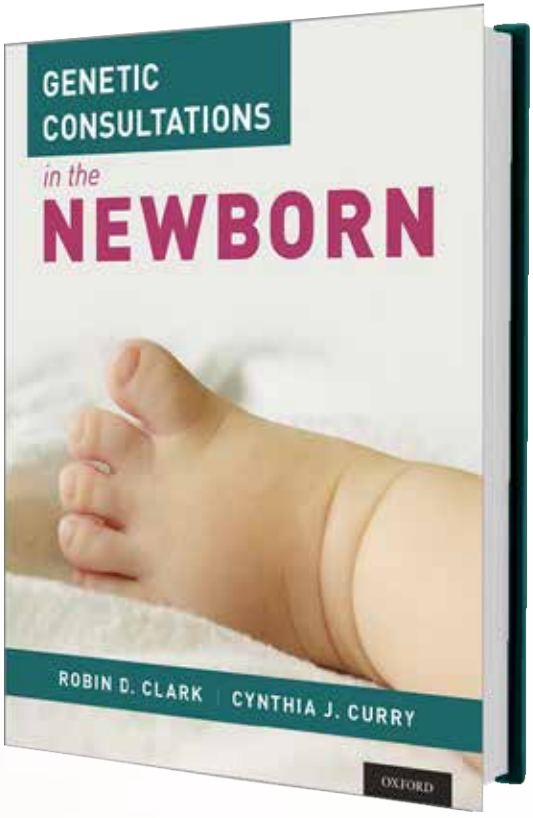

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Clinical Pearl: Artificial Intelligence, Machine Learning Models in Neonatology: Neonatal Acute Kidney Injury

Joseph R. Hageman, MD, Lolita Alkureishi, MD, Walid Hussain, MD, Mitchell Goldstein, MD, MBA, CML

"Artificial intelligence (AI) and machine learning (ML) models are being utilized in several clinical issues in neonatology, including necrotizing enterocolitis, retinopathy of prematurity, and now acute kidney injury (AKI) (1-5)."

Artificial intelligence (AI) and machine learning (ML) models are being utilized in several clinical issues in neonatology, including necrotizing enterocolitis, retinopathy of prematurity, and now acute kidney injury (AKI) (1-5).

AI is a "branch of computer science that develops systems capable of human-like intellectual processes to solve problems. ML, a subset of AI, uses large data sets and some human input (adding or changing parameters) to teach itself patterns and to make predictions (6)".

"Neonatal acute kidney injury (AKI) is a common clinical problem in neonates, especially in both premature infants and term infants who have undergone cardiac or abdominal surgery (2-4), and it holds great promise for the use of AI and ML clinically."

Neonatal acute kidney injury (AKI) is a common clinical problem in neonates, especially in both premature infants and term infants who have undergone cardiac or abdominal surgery (2-4), and it holds great promise for the use of AI and ML clinically. The most recent gold standard definition of neonatal AKI is the neonatal-modified Kidney Disease: Improving Global Outcomes (KDIGO) definition, which is summarized in the table from a review by Coleman et al. (3) as well as by Starr and colleagues and involves AKI staging (0,1,2,3) based on serum criteria and hourly urine output (2,4).

It is also vital to understand embryology and that nephrogenesis begins at five weeks gestation and continues until 34 to 36 weeks gestation (2). The nephron number is highly variable, particularly in premature infants (2). Renal blood flow and perfusion pressure also increase over the first few weeks of post-natal life, as does the proportion of cardiac output to the kidney (2). Several factors affect renal blood flow and perfusion pressure, including hypotension, hemorrhage, hypoxic-ischemic encephalopathy, nephrotoxic medications, sepsis, and congenital heart disease, for example (2).

"There have been a couple of projects using AI and ML models to predict neonatal AKI, as well as to reduce the incidence of AKI in neonates by making clinicians more aware of these factors that contribute to the development of neonatal AKI: 'STARZ risk stratification AI model which was incorporated in the electronic medical record (EMR) and showed a predictive ability of AKI within seven days of NICU admission of the area under the curve (AUC) of 0.93 and AUC of 0.96 in the validation and derivation cohorts, respectively (3)'."

There have been a couple of projects using AI and ML models to predict neonatal AKI, as well as to reduce the incidence of AKI in neonates by making clinicians more aware of these factors that contribute to the development of neonatal AKI: "STARZ risk stratification AI model which was incorporated in the electronic medical record (EMR) and showed a predictive ability of AKI within seven days of NICU admission of the area under the curve (AUC) of 0.93 and AUC of 0.96 in the validation and derivation cohorts, respectively (3)". Also, "in the neonatal population, using the "Baby NINJA" model showed a decrease in nephrotoxic medication ex-

TABLE 1 | Neonatal acute kidney injury diagnostic criteria.

AKI stage	Serum creatinine (SCr) criteria	Urine output criteria (hourly rate)
0	No change in SCr *or* SCr rise < 0.3 mg/dL	≥0.5 ml/kg/h
1	SCr rise ≥ 0.3 mg/dL rise within 48 h *or* SCr rise ≥ 1.5–1.9 × baseline SCr[a]	<0.5 ml/kg/h × 6–12 h
2	SCr rise ≥ 2.0–2.9 × baseline SCr[a]	<0.5 ml/kg/h for >12 h
3	SCr rise ≥ 3 × baseline SCr[a] *or* SCr ≥ 2.5 mg/dL[b] *or* Kidney support therapy utilization	<0.3 ml/kg/h for ≥24 h *or* Anuria for ≥12 h

Modified, neonatal Kidney Disease: Improving Global Outcomes (KDIGO) criteria. [a]Baseline SCr defined as lowest previous SCr value. [b]SCr value of 2.5 mg/dL represents glomerular filtration rate of <10 mL/min/1.73 m^2. SCr, serum creatinine; mg/dL, milligrams per deciliter; h, hours. Adapted from Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Workgroup. KDIGO clinical practice guideline for acute kidney injury. Kidney Int Suppl 2012;2:1–138.

Table reprinted with permission: Coleman C, Tambay Perez A, Selewski DT, Steflik HJ. Neonatal Acute Kidney Injury. Front Pediatr. 2022 April 7;10:842544. doi: 10.3389/fped.2022.842544. PMID: 35463895; PMCID: PMC9021424

posure by 42%, a decrease in the rate of AKI by 78%, and decreased number of days with AKI by 68% (3)". By harnessing the power of information already readily available in the EMR, AI and ML models hold great promise in flagging these at-risk infants, thus helping to stave off AKI injury before it begins.

"Of note, many studies have reported the superiority of using biomarkers to predict AKI in pediatric patients and neonates as well. Future directions include the application of AI along with biomarkers (neutrophil gelatinase-associated lipcalin (NGAL), for example, in a Labelbox configuration to create a more robust and accurate model for predicting and detecting pediatric/neonatal AKI (3,4)."

Of note, many studies have reported the superiority of using biomarkers to predict AKI in pediatric patients and neonates as well. Future directions include the application of AI along with biomarkers (neutrophil gelatinase-associated lipcalin (NGAL), for example, in a Labelbox configuration to create a more robust and accurate model for predicting and detecting pediatric/neonatal AKI (3,4). AI and ML models may be able to take these biomarkers into account, in addition to other clinical predictors, in order to identify at-risk infants correctly.

Finally, methylxanthines, theophylline, and caffeine have demonstrated reno-protective effects by inhibiting adenosine-induced renal vasoconstriction, thereby preventing neonatal AKI (2). The thought is that if the AI or ML model predicts the possibility of the development of neonatal AKI in a patient, an EMR notification would appear, suggesting that possibility with a suggestion of using caffeine therapy to prevent the development of AKI. The same notification could be used for avoiding nephrotoxic medications (2,3).

There is a wealth of information in the EMR that *can* be used for the benefit of our patients; however, doing so can be cumbersome and inefficient. With the entry of AI and ML into the healthcare setting, the EMR can be leveraged in a much more simplified and accessible way such that it can be used to help guide real-time, informed, evidence-based medical decisions (7). The intersection of the EMR platform with AI makes for an inspiring time for health care, and we look forward to seeing how these translate into efficient and intuitive management workflows for clinicians in AKI and beyond.

"Finally, methylxanthines, theophylline, and caffeine have demonstrated reno-protective effects by inhibiting adenosine-induced renal vasoconstriction, thereby preventing neonatal AKI (2). The thought is that if the AI or ML model predicts the possibility of the development of neonatal AKI in a patient, an EMR notification would appear, suggesting that possibility with a suggestion of using caffeine therapy to prevent the development of AKI. "

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Disclosures: The authors have no disclosures

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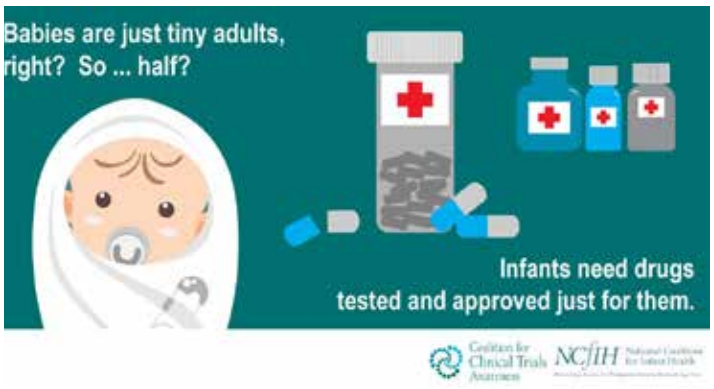

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May begin with a brief case summary or example.

Summarize the pearl for emphasis.

No more than 7 references.

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National Network of NICU Psychologists

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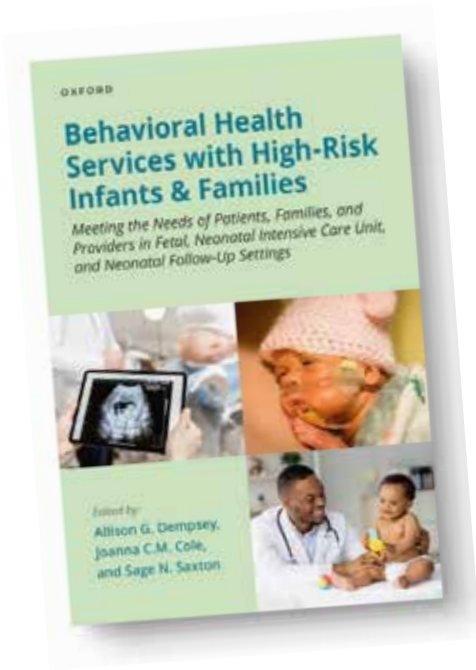

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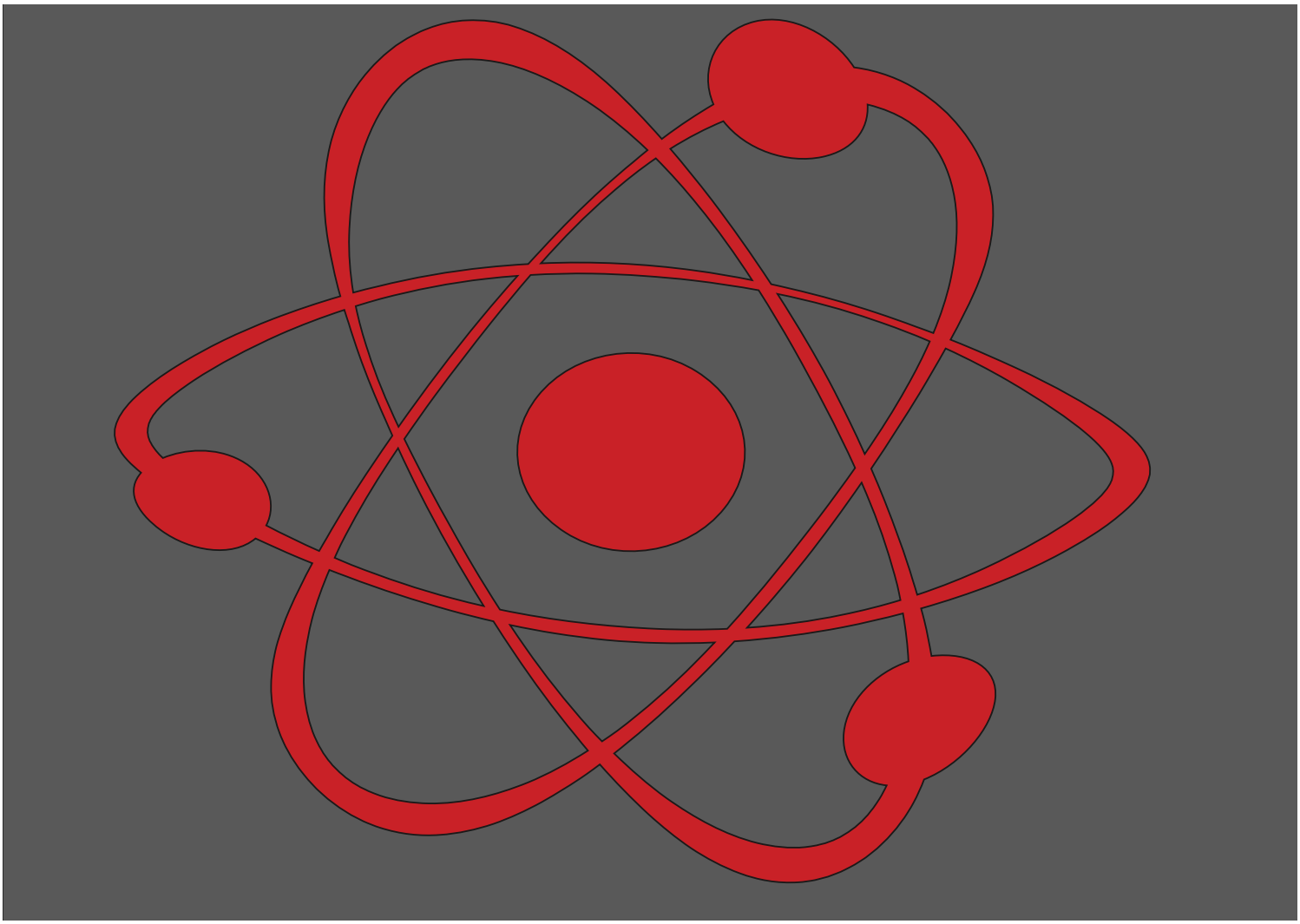

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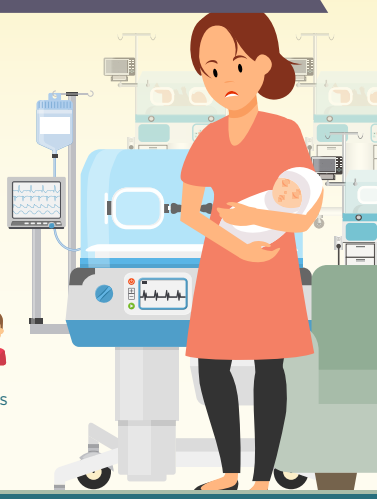
Will your **PRETERM INFANT** *need* **EARLY INTERVENTION** *services?*

Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges

1 in **3** preterm infants will require support services at school

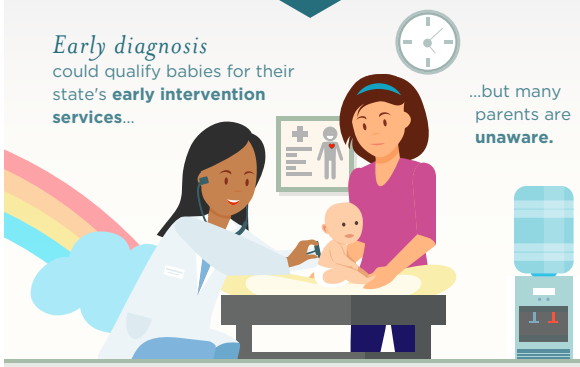


Early intervention can help preterm infants:

- Enhance language and communication skills
- Build more effective learning techniques
- Process social and emotional situations
- Address physical challenges
- Prevent mild difficulties from developing into major problems

Early diagnosis could qualify babies for their state's **early intervention services**...

...but many parents are **unaware.**



NICU staff, nurses, pediatricians and social workers **should talk** with NICU families about the challenges their baby may face.

Awareness, referral & timely enrollment in early intervention programs can help **infants thrive** and grow.

NCFIH National Coalition for Infant Health
Protecting Access for Premature Infants through Age Two
www.infanthealth.org

Visit **CDC.gov** to find contact information for your state's early intervention program.

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

1 DE CADA **7** MADRES AFRONTA LA DEPRESIÓN POSPARTO, *experimentando*

- Llanto incontrolable
- Sueño interrumpido
- Ansiedad
- Desplazamientos en los patrones de alimentación
- Ideas de hacerse daño a sí mismas o al bebé
- Distanciamiento de amigos y familiares

Sin embargo, sólo el 15% recibe tratamiento[1]

LA DEPRESIÓN POSTPARTO **NO TRATADA** PUEDE AFECTAR:

La salud de la madre

El sueño, la alimentación y el comportamiento del bebé a medida que crece[2]

La capacidad para cuidar de un bebé y sus hermanos

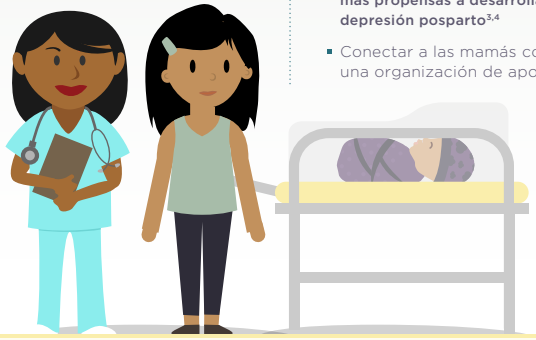
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

- Financiar los esfuerzos de despistaje y diagnostico
- 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. Accesible en: http://www.apa.org/pi/women/resources/reports/postpartum-depression.aspx
[2] National Institute of Mental Health. Accesible en: https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml
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https://www.pediatrix.com/for-clinicians/neo-conference

Mednax: Specialty Review in Neonatology
Feb 19 – Feb 24, 2024
Las Vegas, NV
https://www.pediatrix.com/for-clinicians/specialty-review-conference

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March 6-9, 2024
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NEONATOLOGY TODAY

ISSN: 1932-7137 (Online). ISSN:: 1932-7129 (Print). Published monthly. All rights reserved.

Publication
Mitchell Goldstein, MD
Loma Linda Publishing Company
11175 Campus Street
Suite #11121
Loma Linda, CA 92354
www.NeonatologyToday.net
Tel: +1 (302) 313-9984
LomaLindaPublishingCompany@gmail.com

Editorial and Subscription
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The Clinical Trial Center is actively involved in many multi-center global pediatric trials, which span different Phases of research to advance health care in children. Please reach out to Jaclyn Lopez at 909-558-5830 or JANLopez@llu.edu with further interest. We would love to discuss the exciting research coordinator opportunities at our Clinical Trials Center.

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NEONATOLOGY TODAY

Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine
Loma Linda Publishing Company | c/o Mitchell Goldstein, MD | 11175 Campus St, Ste. 11121 | Loma Linda, CA 92354 |
LomaLindaPublishingCompany@gmail.com

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Neonatology Today's Policy on Animal and Human Research

Neonatology Today's policies ensure the protection and responsible use of animals and humans in all research articles under consideration. Authors are encouraged to follow the guidelines developed by the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3R), International Committee of Medical Journal Editors, and the Guide for the Care and Use of Laboratory Animals and U.S. Public Health Service's Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Authors are expected to demonstrate to their institutional review board or suitable proxy that ethical standards are met. If there is doubt whether research conducted was in accordance with ethical standards, then there must be verification that the institutional review body approved the uncertain aspects. Research not following these policies on participating animal and human subjects may be rejected. Researchers have a moral obligation towards the humane treatment of animals and ethical considerations for humans participating in research and are expected to consider their welfare when designing studies.

https://www.nc3rs.org.uk/arrive-guidelines

http://www.icmje.org

https://olaw.nih.gov/policies-laws/phs-policy.htm

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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 continue to feature artistic works created by our readers on the next to last page as well as photographs of birds on rear cover. For this edition, our art was again graciously provided by Colleen Kraft, MD. It is a work called "Phoenix" done by her son Tim. Our Bird is from "Bolsa Chica" from my collection.

Mita Shah, MD,
Neonatal Intensive Care Medical Director
Queen of the Valley Campus
Emanate Health, West Covina, CA

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Manuscript Submission: Instructions to Authors

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, SVG, or pdf) for each figure. Preferred formats are ai, SVG, psd, or pdf. tif and jpg images with 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. There is no charge for your manuscript to be published. NT does maintain a copyright of your published manuscript.

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 10,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard "NLM" format (APA 7th is no longer acceptable). 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.

10. Only manuscripts that have not been published previously will be considered for publication except under special circumstances. Prior publication must be disclosed on submission. Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

11. NT recommends reading Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals from ICMJE prior to submission if there is any question regarding the appropriateness of a manuscript. NT follows Principles of Transparency and Best Practice in Scholarly Publishing(a joint statement by COPE, DOAJ, WAME, and OASPA). Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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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.

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

NICU Baby's Bill of Rights

1- The Right to Advocacy
My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical records, and prognosis, so they celebrate my achievements and support me when things get challenging.

2- The Right to My Parents' Care
In order to meet my unique needs, my parents need to learn about my developmental needs. Be patient with them and teach them well. Make sure hospital policies and protocols, including visiting hours and rounding, are as inclusive as possible.

3- The Right to Bond with My Family
Bonding is crucial for my sleep and neuroprotection. Encourage my parents to practice skin-to-skin contact as soon as and as often as possible and to read, sing, and talk to me each time they visit.

4- The Right to Neuroprotective Care
Protect me from things that startle, stress, or overwhelm me and my brain. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time and faster than it ever will again. The way I am cared for today will help my brain when I grow up. Connect me with my parents for the best opportunities to help my brain develop.

5- The Right to be Nourished
Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Also, let my parents know that donor milk may be an option for me.

6- The Right to Personhood
Address me by my name when possible, communicate with me before touching me, and if I or one of my siblings pass away while in the NICU, continue referring to us as multiples (twin/triplets/quads, and more). It is important to acknowledge our lives.

7- The Right to Confident and Competent Care Giving
The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help educate them about my unique needs, development, diagnoses, and more.

8- The Right to Family-Centered Care
Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9- The Right to Healthy and Supported Parents
My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my parents about resources such as peer-to-peer support programs, support groups, and counseling, which can help reduce PMAD, PPD, PTSD, anxiety and depression, and more.

10- The Right to Inclusion and Belonging
Celebrate my family's diversity and mine; including our religion, race, and culture. Ensure that my parents, grandparents, and siblings feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

Presented by:

NPN
NICU PARENT NETWORK

NICU Parent Network

Visit nicuparentnetwork.org to identify national, state, and local NICU family support programs.

*** The information provided on the NICU Baby's Bill of Rights does not, and is not intended to, constitute legal or medical advice. Always consult with your NICU care team for all matters concerning the care of your baby.**


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