

NEONATOLOGY TODAY

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WARNINGS AND PRECAUTIONS

Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation

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

Hypoxemia from Methemoglobinemia

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

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

Airway Injury from Nitrogen Dioxide

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

If there is an unexpected change in NO₂ concentration, or if the NO₂ concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO₂ analyzer should be recalibrated. The dose of INOmax and/or FiO₂ should be adjusted as appropriate.

Worsening Heart Failure

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

DRUG INTERACTIONS

Nitric Oxide Donor Agents

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

OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO₂. Elevated NO₂ may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO₂ levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

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

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Abstracts from National Perinatal Association 2019 Annual Conference on April 3-5, 2019 in Providence, RI: Improving Access to Perinatal Care: Confronting Disparities and Inequities in Maternal-Infant Health

Erika Goyer, Family Advocate

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.



NPA2019-1

Surveillance and Care Management of Zika Virus-Affected Families in Philadelphia (2016-2019)

Rachel Blumenfeld, MPH, Sharon Starr, MSN, RN, Mariah Menanno

INNOVATIVE MODELS OF CARE

Background

Since 2015, Zika virus has affected populations worldwide throughout the Caribbean, Central and South America, Southeast Asia, and small areas of the southern United

States. Zika virus infection of pregnant women places their infants at risk for contracting congenital Zika syndrome, characterized by brain malformations, other birth defects, and concurrent developmental delays. Zika virus was monitored globally as an emerging infectious disease. In 2017, epidemiological response to Zika virus infection showed more immune response and less acute disease, necessitating changing protocols in screening, testing and clinical management. Approximately 12% of Philadelphia's 1.5 million residents routinely travel to their home countries, many of which are or were endemic for Zika virus infection. Potential exposure to Zika virus posed a great risk for Zika virus infection in the individual, sexual partner(s), and possible vertical transmission to the newborn.

Content/Action

The Philadelphia Department of Health (PDPH) utilized an ecological approach to provide active surveillance of Zika-associated birth defects, analysis and reporting of surveillance data and systems, engagement and referral services for families affected by maternal Zika infection, long-term follow-up of children born to mothers infected with Zika virus, and capacity building among clinical partners in recognizing and supporting families at risk for Zika virus infection.

Lessons Learned

This model of care focuses on multidisciplinary and multi-level interventions in response to the Zika virus outbreak. Philadelphia identified 41 mothers on the U.S. Zika Pregnancy Registry, per the Centers for Disease Control and Prevention inclusion criteria guidelines, with 32 completed live births. Collaboration between the fields of public health, medicine, nursing, environmental professionals, and community-based education and outreach influenced Zika virus responses for surveillance and patient care management. These respons-

es promote improvements in monitoring pregnancy and infant outcomes that inform clinical guidance and public health response.

Implications for Practice

Actively engaging a Zika Clinical Champion at each of the nine delivery hospitals in the Philadelphia area has been crucial to active surveillance, data collection and management, as well as referral to local services and effective patient follow-up. Utilizing a home visiting strategy allows PDPH and clinicians to engage client families both in the home and in the provider's facility.

NPA2019-2

Bryant

Meeting NICU Moms Where they Are: Understanding and Improving Postpartum Health Care for Mothers of Medically Fragile Infants

RESEARCH

Introduction: Mothers of medically fragile infants (MMFI) face a host of challenges following childbirth. Compared to mothers of well babies (MWB), MMFIs have a greater burden of chronic disease and are at increased risk for mental health problems, while at the same time are navigating the health care system on behalf of their medically complex infant and managing their own postpartum recovery. The neonatal intensive care unit (NICU) parenting experience has been fairly well researched but comparably limited information is available focusing on NICU mothers' postpartum recovery, health needs, and access to services for her own well-being. Using quantitative and qualitative methods, our work focused on identifying MMFI postpartum health conditions, needs and concerns, and health care services received in the 90 days following delivery, as well as health



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care systems-related barriers to care, with an eye to improving access to care for mothers of medically fragile infants in the postpartum period.

Methods: We conducted a retrospective cohort study of mothers of live-born infants born at the NC Women's Hospital from July 1, 2014 to June 30, 2016 (n=6,849) to measure prevalent conditions, health care utilization, and receipt of recommended services. We defined MMFI as mothers of infants with a total neonatal intensive care unit and pediatric critical care unit length of stay ≥ 3 days. We defined MWB as mothers of infants who were not admitted to an intensive care unit and were discharged to home. Over the course of a year, from April 2017 to June 2018, we conducted in-depth interviews with 44 adult English-speaking MMFIs and more than 50 key stakeholders who provide services to or have knowledge about the health care needs of these women (e.g. postpartum and NICU nurses, lactation specialists, hospital administrators), to identify maternal health needs, barriers and facilitators to accessing services, and suggested systems improvements.

Results: We found that mothers with infants in the NICU have a greater burden of chronic disease and postpartum morbidity than mothers of well babies. Compared to MWB, MMFI were more likely to have a BMI >30 (35% vs. 25% MWB) and chronic hypertension (17% vs. 7%). MMFI were also more likely to undergo general anesthesia for delivery (8.6% vs. 0.9% MWB), undergo hysterectomy (1.6% vs. 0.1%) and to have had a blood transfusion (5.7% vs. 2.2%). Thirty-two percent experienced gestational hypertension or preeclampsia compared to 12% of MWB, and more than half of MMFI were recovering from a cesarean section while caring for their infant in the NICU (54% vs. 24% MWB). Some key elements that MMFI identified as part of their postpartum NICU experience include: significant social-emotional health needs and difficulty accessing mental health services and support; unmet practical needs causing significant burden, such as lack of a place to sleep while visiting the NICU, lack of childcare for other children, and parking difficulties; and an overriding desire to be at baby bedside coupled with the minimization of their own health needs so as to attend to baby. While MMFI described confidence in how their babies were cared for, they reported that there was no one checking on their own health and their needs, beyond being asked a generic "How are you doing?". They described a lack of connection to health care and support services where (near the NICU) and when (urgently) they needed it. When asked, MMFI strongly

supported the idea of a postpartum nurse rounding on them in the NICU. Health systems barriers identified by key informants included: limited awareness of services provided by other units resulting in an assumption that MMFI needs are being met by other providers; lack of clarity across types of providers as to who is responsible for providing care for MMFI; and scarce resources. Key informants voiced an awareness of the unique needs of MMFI and expressed interest in exploring alternative models of care delivery such as MMFI-assigned patient navigator or a nurse checking in on moms. MMFI and key informants alike suggested systems improvements including NICU-based mental health and medical health care and access to a place to rest (e.g. a nap room).

Discussion: Despite evidence of greater prevalence of chronic conditions and postpartum morbidity, MMFI reported little attention paid to their postpartum health needs from medical professionals. They described significant need for mental health care in particular, coupled with challenges in accessing that care. Similarly, key informants described a fragmented system that result in lack of clarity about who is responsible for providing care for NICU moms, suggesting a need to clarify roles and identify a provider designated for MMFI during their NICU stay. The overwhelming drive of NICU moms to be at the baby bedside further suggests the need to build access to care in the context of the NICU stay, particularly for MMFI whose home communities are great distances from the NICU. As MMFI cannot, or will not, seek care away from baby, an alternative is to meet them where they are and bring the care to them. One possible model is to assign a postpartum nurse to round on mothers in the NICU, a suggestion that was met with strong support by MMFI interviewees and interest by key informants. System-level challenges such as billing and payment procedures and staffing structure would need to be addressed to support such a model of care. Meeting NICU moms where they are holds great promise for improving access to health care and addressing the unique needs of mothers of medically fragile infants.

Previously Presented

Study and results previously described in poster presentation at the Association of Maternal Child Health Programs (AMCHP) annual conference in March 2019.

AMCHP Poster Title: The New Mother Friendly NICU: Understanding and Improving the Postpartum Experience for Mothers of Medically Fragile Infants

Additional limited results of study findings have been shared at ACOG, SMFM, and AMCHP.

NPA2019-3

Downtin

Collaborative Psychological Services in the NICU: Caring for the Care Teams

INNOVATIVE MODELS OF CARE

Background

Stanford University's Lucile Packard Children's Hospital (LCPH) currently has a 40-bed level IV neonatal intensive care unit (NICU). In 2017, the child and adolescent psychiatry department partnered with the neonatology department to create a 1-year clinical child psychology postdoctoral fellowship. The fellowship was designed to establish a dedicated psychiatry/psychology service specific to the NICU and allow specialized training in perinatal mental for the NICU fellow. Through that fellowship, the fellow worked to modify an evidence-based psychotherapy intervention that was originally designed for individual psychotherapy with mothers of premature infants. The intervention was modified and is currently being used to address the needs of mothers in group-format who are exhibiting symptoms of trauma, anxiety and depression.

Within a year of establishing the NICU psychology fellowship, families began receiving mental health screening, psychological evaluation, bedside follow-up, and individual and family therapy from the NICU fellow and psychology/psychiatry attendings. Additionally, mothers of premature infants receive the group-based trauma-focused psychotherapy intervention. However, support services for NICU residents, fellows, and nurses continued to be an area of needed growth.

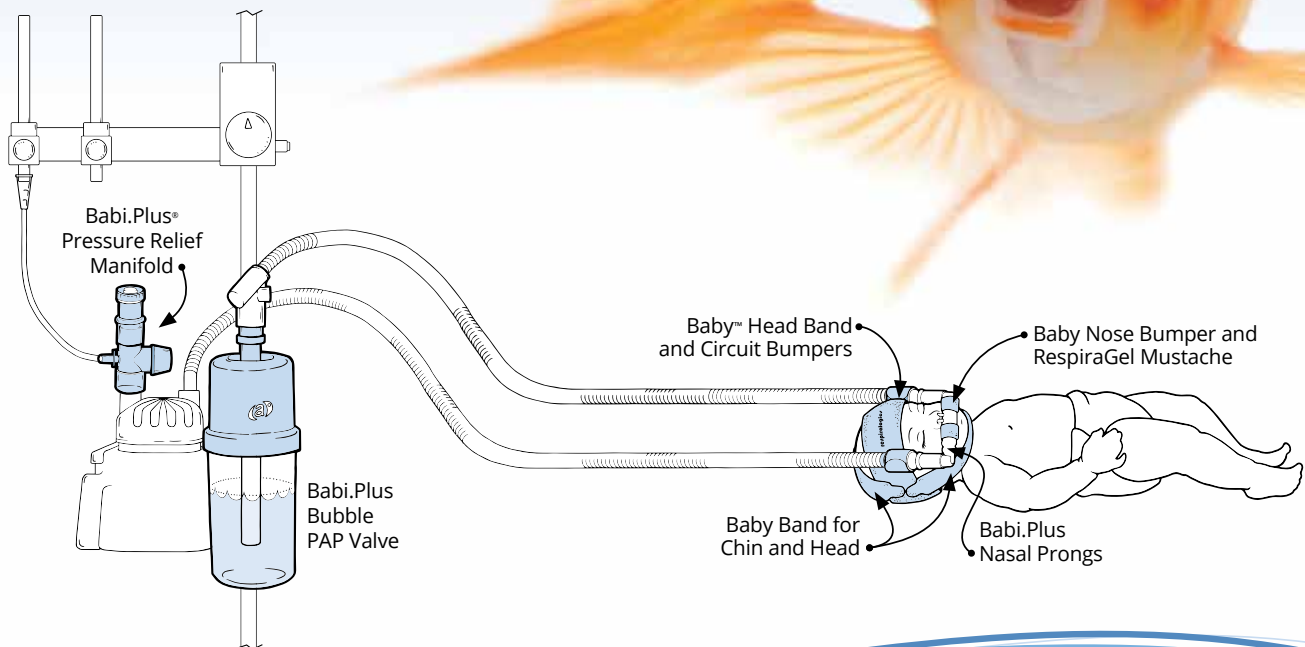
Action

The 2018-2019 NICU psychology fellow at LCPH collaborated with the NICU social work intern to begin addressing the needs of NICU nurses and trainees. Through meetings and thoughtful discussions with a neonatology attending, nursing management, a nurse educator, a neonatal nurse practitioner, the fellow and intern were able to pilot a NICU service for nurses and trainees. This poster will outline the workflow for those meetings and provide a brief overview of the initial NICU staff and train-

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Lessons Learned

This poster will discuss lessons learned through meeting with the identified department representatives including addressing barriers to providing supports for union nurses, timelines need for establishing care, providing culturally-informed care in the NICU, psychological impact of trauma on NICU staff and families, and common topics and themes requested by the trainees and nurses.

Implications for Practice

NICU nurses and trainees often choose their specialty because they have a passion for helping infants and their families through challenging times. Working in the NICU can be rewarding. Staff and trainees may end their day knowing that they positively impacted a family or families through their direct care or indirect interactions. The NICU can also be an emotionally perplexing experience for staff and trainees. The goals of this project were to: 1) identify needs of NICU staff and trainees, 2) establish the appropriate support services, and 3) implement those services. This poster will discuss the feedback from NICU staff and trainees to help other hospitals explore supporting the psychosocial needs of their NICU nurses and trainees to improve outcomes for women, infants, and their families.

NPA2019-4

Co-Designing Mobile Technology and Care Delivery to Improve Family Integrated Care in NICUs

Linda Franck, Brittany Lothe, Scott Bolick,

Robin Bisgaard, Sharon Sossaman, Jeremy Sossaman, Anne Shamiyeh, Kathryn Millar, Tanya Johnston, Rebecca Kriz, Diana Cormier MPH RNC-NIC, Priscilla Joe, Nicole Hansen, Holly Christensen, Nadia Tsado, Pallavi Bekal, Samantha Ngo, Yao Sun.

INNOVATIVE MODELS OF CARE

Background: Extensive research has shown that an integrated person- and family-centered approach to healthcare (FCC) leads to better outcomes for babies and families. This approach is endorsed by the World Health Organization and many other national and international groups. FCC is particularly important for small and sick newborns. Yet most Neonatal Intensive Care Units (NICUs) lack the policies, resources and structures needed to ensure FCC is consistently practiced and parents have the support they need to become competent and confident caregivers for their babies.

Family Integrated Care (FICare) transforms the culture of the NICU by training and supporting parents to be their baby's primary caregiver and a partner in the care team. A cluster randomized trial of FICare (O'Brien et al. 2017) showed better growth for infants and increased rates of breastfeeding. It also showed decreased stress levels for parents. Notably, all FICare intervention NICUs continued to practice FICare after the trial was completed.

Content/Action: While the FICare outcomes are significant and show promise, adaptation may be needed for the US context – most notably to because many parents do not have parental leave and are unable to be physically present in the NICU to the same degree as participants in the Canadian-led trial. Therefore, we

conducted a process of co-design with healthcare professionals and parents of former preterm infants to adapt and implement FICare in California. Using user-centered design principles and practices, we co-designed a new mobile enhanced adaptation of the FICare model, called 'm-FICare', to extend the support for families to those who cannot be physically present in the NICU during daytime hours. We also developed an innovative approach to the conduct of NICU clinical research in partnership with families.

The We3health mobile app is a secure, HIPAA compliant, mobile app co-designed with parents to increase access and quality of parent support to enable greater involvement in their infant's care planning and caregiving. The We3health app also facilitates parent tracking of data for research and NICU quality improvement. We also co-developed a parent mentor program that serves all preterm parents and aims to increase access and depth of involvement for parents who live at a distance from the NICU or are from underserved communities. Finally, we implemented and are evaluating the mFICare model in California NICUs.

Lessons Learned: Co-design is an extremely useful strategy for increasing patient and family involvement and there are a number of challenges and opportunities in implementing co-design, depending on the context. These include negotiating the scope of the work and how best to meet the needs of the main stakeholder groups, i.e., parents and NICU health professionals. A mutual deep understanding of each stakeholder group's main challenges and developing empathy are key to success of the co-design approach. Parents have amazing insights that substantially improve research design and implementa-

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tion. Ongoing attention and recalibration is essential to maintain equity in implementation and avoid creating or worsening disparities in access and quality of care. True co-creation requires give-and-take. Parents are impatient for change, and that is good - and challenging - for traditional research.

Implications for Practice: Parent and healthcare professional co-design is a powerful approach to addressing access and equity issues in patient and family care delivery and in research.

Previously presented at the Institute for Patient and Family Centered Care International Conference, Baltimore, MD, June 2018, and at the March of Dimes California Annual Conference, Irvine, CA, November 2018.

NPA2019-5

Collaborative research priority setting by parents of preterm infants and neonatal intensive care unit professionals

Linda Franck PhD RN, Kathryn Millar RN MPH, Dawn Gano MD MAS, Rebecca Kriz RN MS, Diana Cormier DNP APRN-CNS MPH RNC-NIC, Priscilla Joe MD, Nicole Hansen RN, Holly Christensen RN, Nadia Tsado BA, Pallavi Bekal MS, Samantha Ngo MPH MSW.

Introduction: Community-based participatory research improves the relevance and application of research findings to affected communities. Little is known about research priorities of parents and clinicians who care for preterm infants. Since preterm birth disproportionately affects communities of color, understanding their perspectives is necessary to achieve health equity in research. The UCSF California Preterm Birth Initiative's (PTBi-CA) community advisory boards provided the unique oppor-

tunity to generate research questions and consensus priorities from women at high risk for preterm birth from three centers in California using the Research Prioritization by Affected Communities (RPAC) protocol (Franck, et al. 2018).

Context: Participants included Parent Clinician Advisory Board (PCAB) members from PTBi-CA's Newborn Family Research Collaborative located in San Francisco, Oakland, and Fresno, California. PCAB members include neonatal intensive care unit (NICU) professionals and parents of former NICU infants. RPAC was conducted separately at each site, and collaboratively at the network level to generate the top two priorities.

PCAB participants were racially and ethnically diverse. Each site generated between 50 and 80 original research questions and reached consensus on research priorities. Priority similarities and differences were noted across sites. The top priorities across all sites, determined by consensus, included postnatal interventions to improve transition from NICU to home, follow-up support after discharge, and infant development and/or family wellbeing. Participants felt empowered, developed a sense of community with the group, and increased engagement in research.

Practice Application: The RPAC protocol enabled rapid generation of research priorities among diverse parents of preterm infants from communities that have often not been engaged in research and clinicians who care for their babies. The results of this research prioritization process have informed the research agenda within our network to ultimately promote health equity and improved outcomes for premature infants.

Previously presented at the Preterm Birth Initiative Annual Symposium, Kigali, Rwanda, October 2018, and at the American Public Health Association Annual Meeting, San Diego, CA, November 2018.

NPA2019-6

Relationship between kangaroo care activity during neonatal intensive care unit hospitalization and early parent-infant contact

Linda Franck PhD RN, Caryl Gay, PhD, Rebecca Kriz RN MS, Robin Bisgaard, RN, Dawn Gano MD MAS, Diana Cormier DNP APRN-CNS MPH RNC-NIC, Priscilla Joe MD, Kathryn Millar RN MPH, Nicole Hansen RN, Holly Christensen RN, Nadia Tsado BA, Pallavi Bekal MS, Samantha Ngo MPH MSW, Yao Sun, MD PhD.

Introduction: Family Integrated Care (Fi-Care) is a novel package of evidence-based interventions that enables parents to more effectively become primary caregivers for their preterm infants in the neonatal intensive care unit (NICU). As part of a multi-site trial of FiCare in California, a mobile application (We3health app) was developed to support families during their NICU stay. Because FiCare strongly promotes kangaroo care (KC), We3health includes a module for tracking KC. This analysis describes relationships between parent and infant characteristics and KC activity recorded in We3health.

Method: Parents of preterm infants <33 weeks gestation enrolled in the baseline (usual care) phase of the study completed an online survey and used We3health to record frequency, duration and subjective experience with KC from the time of study enrollment until discharge.

Results: To date, 66 parents (61 mothers; 5 fathers) from three of the NICUs completed both survey and We3health data for analysis. KC frequency was unrelated to parent race, gender, prior NICU or child hospitalization, infant gestational age or length of NICU stay.

Parents able to see their infant within 1 hour of birth reported KC on a larger proportion of days during their infant's hospitalization compared with parents who first saw their infant 1-24 or >24 hours after birth, after controlling for GA (Figure 1, $p=.004$). This difference in KC frequency likely accounted for longer mean durations of KC day across the infant's hospitalization, controlling for GA (Figure 2, $p=.021$). Accounting for the differences in KC frequency, however, there was no difference in mean KC duration on the days KC was reported based on when parents first saw their infant.

Parents able to hold their baby within 24 hours after birth also reported KC on a larger proportion of days, after controlling (Figure 1, $p=.012$), and a slightly longer mean duration of KC per day of the infant's NICU stay ($p=.060$). Note that only 9 of the 23 parents who held their baby within 24 hours were among the 23 who first saw their infant within 1 hour.

Discussion: Early parent-infant contact within 24 hours of birth is an important factor influencing KC frequency and duration. Evidence-based, protocol driven quality improvement strategies are urgently needed to improve early parent-infant contact for preterm infants.

Previously presented at the International Conference on Kangaroo Mother Care,



NPA-2019-7

Breastfeeding and Marijuana Use: An Ethical Analysis of Current Practice

Research Submission for National Perinatal Association 2019 Conference

Marielle S. Gross, MD, MBE¹, Carla Bos-sano, MD², Nadine Rosenblum, RN, IB-CLC³, and Lorraine Milio, MD, MPH²

Johns Hopkins Berman Institute of Bioethics, Johns Hopkins School of Medicine, and Johns Hopkins Hospital³; Baltimore, Maryland

Introduction: U.S. guidelines recommend breastfeeding women avoid marijuana given concerns about infant neurodevelopment. Unfortunately, this has resulted in many physicians and hospitals prohibiting women who use marijuana from breastfeeding despite inconclusive evidence of harm and well-known benefits of breastfeeding. Meanwhile, marijuana use is increasing among reproductive-aged women, and complex personal/socioeconomic factors affect feeding choices. We assess evidence and ethical justification for current practice.

Methods: We review: (1) Harm to infants from breastmilk marijuana exposure vs. avoiding breastfeeding, (2) Maternal health and psychosocial considerations, and (3) Current practices in light of principles of beneficence, justice, and autonomy.

Results: (1) First, delta-9-tetrahydrocannabinol (THC) is excreted in breastmilk and limited data (three studies with human subjects and three animal studies) suggest neurobehavioral changes among infants whose mothers use marijuana during breastfeeding, though effects of in utero vs. breastmilk exposure are difficult to distinguish and interpretation is limited by socioeconomic and other confounders. There are also concerns that marijuana use negatively impacts safe infant care and that the average concentration of THC in marijuana has increased in the years since the relevant studies were completed. Meanwhile, avoiding breastfeeding increases infants' risk of sudden infant

death syndrome, sepsis, necrotizing enterocolitis, diabetes, asthma, and obesity. Available evidence is unclear regarding whether infants who were already exposed to THC in utero would be worse off with continued exposure through breastmilk vs. with increased risks associated with formula feeding. (2) Women who do not breastfeed have increased risk of cardiovascular disease, reproductive cancers, diabetes, depression and unintended pregnancy, all major sources of morbidity and mortality for U.S. women. Marijuana use is highest among underserved minority women who disproportionately suffer from the health consequences that breastfeeding may mitigate, and who are especially vulnerable to punitive damages (e.g., criminal charges related to drug use or Child Protective Services involvement). Maternal desire to bond with her infant through breastfeeding, cultural norms, values, and social pressures, and the financial burden of formula all may exacerbate the harm of telling women to avoid breastfeeding. (3) The national recommendation that women who breastfeed should avoid marijuana is interpreted by some physicians and hospitals as a policy that women who use marijuana should not breastfeed. This practice fails to account for the risks of avoiding breastfeeding for both infants and women, possibly exaggerating the strength of available evidence about harms from breastmilk THC exposure, and thus may not optimize health outcomes. In addition to potentially exacerbating existing health disparities, this practice may be unjust if women who screen positive for THC during pregnancy are told they are 'not allowed' to breastfeed regardless of whether they are actively using at time of delivery. Given the clinical equipoise regarding the best feeding method for infants whose mothers use marijuana, particularly if they were already exposed to THC in utero, and the large range in frequency/intensity of maternal marijuana use, an individualized, shared decision-making approach is appropriate. Furthermore, a woman's autonomy may be compromised if crucial postpartum lactation support is withheld while she is in the hospital postpartum or if she is concerned that breastfeeding against recommendations may jeopardize custody of her infant.

Discussion: Ultimately, failure to account for risks of avoiding breastfeeding for infants and women, with attention to epidemiology of marijuana use and breastfeeding-associated health effects, may result

in policies which do not optimize health outcomes. Restrictive breastfeeding practices for women who use marijuana which do not utilize an individualized, shared decision-making approach are neither medically sound nor ethically justified, and may disproportionately undermine the health of underserved women and infants. Unbiased, culturally-informed and evidence-based counseling would promote open patient-provider communication may improve long-term health.

NPA-2019-8

Breastfeeding and Marijuana Use: An Ethical Analysis of Current Practice

Research Submission for National Perinatal Association 2019 Conference

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Introduction: U.S. guidelines recommend breastfeeding women avoid marijuana given concerns about infant neurodevelopment. Unfortunately, this has resulted in many physicians and hospitals prohibiting women who use marijuana from breastfeeding despite inconclusive evidence of harm and well-known benefits of breastfeeding. Meanwhile, marijuana use is increasing among reproductive-aged women, and complex personal/socioeconomic factors affect feeding choices. We assess evidence and ethical justification for current practice.

Methods: We review: (1) Harm to infants from breastmilk marijuana exposure vs. avoiding breastfeeding, (2) Maternal health and psychosocial considerations, and (3) Current practices in light of principles of beneficence, justice, and autonomy.

Results: (1) First, delta-9-tetrahydrocannabinol (THC) is excreted in breastmilk and limited data (three studies with human subjects and three animal studies) suggest neurobehavioral changes among infants whose mothers use marijuana during breastfeeding, though effects of in utero vs. breastmilk exposure are difficult



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to distinguish and interpretation is limited by socioeconomic and other confounders. There are also concerns that marijuana use negatively impacts safe infant care and that the average concentration of THC in marijuana has increased in the years since the relevant studies were completed. Meanwhile, avoiding breastfeeding increases infants' risk of sudden infant death syndrome, sepsis, necrotizing enterocolitis, diabetes, asthma, and obesity. Available evidence is unclear regarding whether infants who were already exposed to THC in utero would be worse off with continued exposure through breastmilk vs. with increased risks associated with formula feeding. (2) Women who do not breastfeed have increased risk of cardiovascular disease, reproductive cancers, diabetes, depression and unintended pregnancy, all major sources of morbidity and mortality for U.S. women. Marijuana use is highest among underserved minority women who disproportionately suffer from the health consequences that breastfeeding may mitigate, and who are especially vulnerable to punitive damages (e.g., criminal charges related to drug use or Child Protective Services involvement). Maternal desire to bond with her infant through breastfeeding, cultural norms, values, and social pressures, and the financial burden of formula all may exacerbate the harm of telling women to avoid breastfeeding. (3) The national recommendation that women who breastfeed should avoid marijuana is interpreted by some physicians and hospitals as a policy that women who use marijuana should not breastfeed. This practice fails to account for the risks of avoiding breastfeeding for both infants and women, possibly exaggerating the strength of available evidence about harms from breastmilk THC exposure, and thus may not optimize health outcomes. In addition to potentially exacerbating existing health disparities, this practice may be unjust if women who screen positive for THC during pregnancy are told they are 'not allowed' to breastfeed regardless of whether they are actively using at time of delivery. Given the clinical equipoise regarding the best feeding method for infants whose mothers use marijuana, particularly if they were already exposed to THC in utero, and the large range in frequency/intensity of maternal

marijuana use, an individualized, shared decision-making approach is appropriate. Furthermore, a woman's autonomy may be compromised if crucial postpartum lactation support is withheld while she is in the hospital postpartum or if she is concerned that breastfeeding against recommendations may jeopardize custody of her infant.

Discussion: Ultimately, failure to account for risks of avoiding breastfeeding for infants and women, with attention to epidemiology of marijuana use and breastfeeding-associated health effects, may result in policies which do not optimize health outcomes. Restrictive breastfeeding practices for women who use marijuana which do not utilize an individualized, shared decision-making approach are neither medically sound nor ethically justified, and may disproportionately undermine the health of underserved women and infants. Unbiased, culturally-informed and evidence-based counseling would promote open patient-provider communication may improve long-term health.

NPA-2019-9

Improving Staff Knowledge and Attitudes towards Providing Psychosocial Support to NICU Parents through an Online Education Course

Institutions: St. John's Regional Medical Center, Oxnard, CA, USA; University of Mississippi Medical Center, Jackson, MS, USA.

Authors: SL Hall MD; ME Famuyide MD; S Mosher RN, MHA; TA Moore RN, PhD; K Sorrells BSFCS; CA Milford EdS; J Craig PhD, MBA, OTRL, CNT; SN Saxton PsyD.

Introduction

Provider-parent communication is a critical determinant of how NICU parents cope with their situation and of how satisfied they are with their overall experience and with the care their infant received. NICU parents desire and benefit from psychosocial support from staff, and yet are not always satisfied with the communication and support they receive in the NICU. Many neonatologists and neonatal nurses do not

feel they have adequate skills to communicate with distressed and anxious parents. Subsequently, this skill deficit increases staff's own stress and can contribute to on-the-job burnout. Additionally, as more NICUs are moving towards providing the model of family-integrated care, roles of NICU care providers are changing towards forming a more egalitarian partnership with parents and encouraging greater involvement of parents at their baby's bedside. This paradigm shift calls for new skill development among multidisciplinary staff.

Objective

This study sought to determine whether NICU staff would demonstrate improved knowledge and attitudes about their ability to provide psychosocial support to parents as a result of taking an online education course.

Design

This was a time series pre/posttest comparison of responses provided to a 33-item survey among NICU staff before and after taking an online education course on providing psychosocial support to parents. Content in the 7-hour course covered the categories as described in the "Interdisciplinary Recommendations for the Psychosocial Support of NICU Parents" (Hall and Hynan, J Perinatol, 2015).

Setting

Two NICUs participated in this project: St. John's Regional Medical Center (SJRMC), a 16-bed Level III community NICU with 250 admissions annually, and The University of Mississippi Medical Center (UMMC), a level IV academic NICU with 102 beds.

Participants

Staff at both NICUs, including physicians, nurses, occupational therapists, and social workers, were invited to take the online course and participate in the study.

Methods

Participants provided demographic information, then took a 33-item survey before (pretest) and after (posttest) taking the comprehensive course called "Caring for

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Babies and Their Families” using a Likert scale of 1-6 (1 = strongly disagree, 6 = strongly agree). Pre- and posttest scores were analyzed using non-parametric paired t-tests.

Results

Of the 114 staff who registered for the course, 87.9% were nurses with a mean of 9.6 years of NICU service. All survey items showed posttest mean scores higher than pretest mean scores; in 30/33 (90.9%) these differences were significant, $p < 0.05$. Night shift staff and staff with shorter periods of NICU service had lower pretest scores on several items; these differences were eliminated on the posttest. Educational needs for staff were identified on both the pretest and posttest.

Discussion

This education course was highly effective in improving staff knowledge and attitudes about how to support NICU parents, and in eliminating differences between day and night staff, and between those with shorter vs. longer periods of service in the NICU. Areas in need of further education were identified. Ninety percent of participants would recommend the course to their peers. Results are most applicable to nurses, who represented the majority of participants.

NPA-2019-10

Causal attributions of pregnancy loss amongst women who experienced fertility treatment

Alison R. Hartman, B.A., Victoria Grunberg, M.S., & Pamela Geller, Ph.D.

Introduction: One in four women in U.S. will experience a pregnancy loss during their lifetime. Many women who experience a pregnancy loss attribute the loss to their own behaviors or character; that is, they blame themselves. Self-blame is also common among women who experience infertility, and is associated with adverse psychosocial consequences including an increased suicide risk and decreased relationship satisfaction. It remains unclear as to whether women who have experienced pregnancy loss after conceiving with fertility treatment attribute the cause of their loss differently than women who have experienced a pregnancy loss without undergoing fertility treatment. The current study was conducted to examine whether women who underwent fertility treatment tend to blame themselves for their loss more often than women who did not.

Methods: The present online survey study includes women from diverse backgrounds ($N = 825$; Age: 18 - 66 years, $M = 31.87$, $SD = 8.69$) who have experienced a pregnancy loss at some point in their lifetime. By utilizing social media platforms, a large proportion of minority women were included in the sample ($N = 391$; 47.40%). Participants reported whether fertility treatment was used to achieve the index pregnancy, and self-reported causal attributions of their most recent loss using the Pregnancy Loss Attributional Questionnaire. Examples from this questionnaire include, If I were a different age, this loss might not have happened; Others deserve to be a parent more than I did, which helps to explain why I had the loss; and If I rested more, the loss might not have happened.

Results: Descriptive statistics indicate that, on average, women’s most recent pregnancy loss occurred 4.21 ± 3.55 years prior to the time of survey completion ($N = 825$). Further, 5.78% of participants ($n = 48$) reported that they used fertility treatment to achieve the pregnancy that was lost. Independent t-tests were conducted to determine which causal attributions (e.g., external attribution, internal characterological attribution, or internal behavioral attribution) were more prevalent among women who experienced a pregnancy loss following fertility treatment compared to women who experienced a loss without fertility treatment. Results indicated that women who underwent fertility treatment were more likely to attribute their loss to their age, $t(668) = -2.49$, $p = .013$, and lack of rest, $t(668) = -2.33$, $p = .020$. Further, women who underwent fertility treatment were more likely to report that the loss was related to punishment for “the person I am,” $t(668) = -1.92$, $p = .056$, and that “others deserve to be a parent more than I did,” $t(668) = -2.79$, $p = .005$.

Discussion: Findings indicated that women who underwent fertility treatment were more likely to blame their age and lack of rest for the loss. Notably, these women were also more likely to endorse that they were less deserving of parenthood and that the loss was a form of punishment. Women who undergo fertility treatment and experience pregnancy loss may be at increased risk for negative psychosocial sequelae due to elevated feelings of self-blame. It is important that healthcare providers, clinicians, and researchers be aware of the role of self-blame within these reproductive life events to facilitate psychoeducation and open communication with patients.

NPA2019-11

Supporting LGBTQ/T Families

Rachel Hess, MS, Postpartum Doula

Background:

In my practice, I’ve had requests by providers to learn how to offer truly respectful and competent care. In my work with LGBTQ/T families, every single family has encountered some form of oppression and/or discrimination due to their LGBTQ/T identity during the perinatal period. The research backs up this anecdotal experience.

In a study about lesbian mothers, Dr. Gregg writes: “In all studies reviewed, researchers reported that lesbian women seeking maternity care experienced some amount of heteronormativity or homophobia in their health care encounters.” (“The Health Care Experiences of Lesbian Women Becoming Mothers,” by Isabel Gregg, *Nursing for Women’s Health*, February 2018 Volume 22, Issue 1, Pages 40–50).

Additionally, transgender and gender non-conforming individuals experience a great deal of oppression and discrimination when attempting to access health care. “One-third (33%) of those who saw a health care provider in the past year reported having at least one negative experience related to being transgender, with higher rates for people of color and people with disabilities. This included being refused treatment, verbally harassed, or physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care. In the past year, 23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person, and 33% did not see a doctor when needed because they could not afford it. (2015 U.S. Transgender Survey, Executive Summary, December 2016, page 8)

Content/Action:

In this interactive workshop, participants will explore the basics of LGBTQ and Transgender identities. We will also gain a deeper understanding of the barriers to care LGBTQ/T families face. There will be research presented on the experiences LGBTQ/T individuals have with the medical community in general and we will discuss how this could impact families in the perinatal period. There will also be ample time and activities for participants to examine and explore their own potential biases. Participants will have a deeper understanding of structural, cultural, and interpersonal homophobia/transphobia/oppression and how it affects LGBTQ/T

families when accessing care. Teaching methods include, but are not limited to, defining terms and levels of oppression as well as activities brainstorming oppression in perinatal care. Participants will have a deeper understanding of the range of LG-BTQ identities, families, terms, and potential needs during the childbearing years.

Learning:

Participants will reflect on their own work, how they may perpetuate structural oppression, and what they can do to change their materials/practices to be culturally competent. We will do this by exploring gender-neutral language in a variety of ways. We will brainstorm gendered language used in perinatal work, look at their own materials and practice making them more inclusive. We will also role-play interview/class using gender neutral language. I work to create a safe learning environment where participants can understand the depth of biases and the structural nature of trans/bio/homophobia. Participants will have an opportunity to ask questions, examine their experiences, and understand the difference between intent and impact.

Plan for Action:

Participants will walk away with an understanding of how to make their work culturally humble, anti-biased, and what resources and information they need to follow up with and continue to learn.

NPA2019-12

Providing education on PPD in a hospital setting may be a good way to help women become more aware of the signs and symptoms of PPD

Kendra Flores Carter

Introduction/Background

According to Keefe, Brownstein-Evans, Lane, Carter, and Polmanteer (2016) research on postpartum depression (PPD) has increased substantially, however the population being studied for postpartum depression has been mostly White women with access to mental health services.

PPD affects between 13% and 19% percent of new mothers (Mann, Gilbody, & Adamson, 2010), with much higher rates among Black women reaching upward of 38% (Gress-Smith, J. L., Luecken, L. J., Lemery-Chalfant, K., & Howe, R, 2012; Keefe et al., 2015). Davis and Townsend (2005) almost 25% (7.5 million) of Black Americans have been diagnosed with a mental illness and Black women are at a higher risk of development.

Gavin et al (2005) posit that 10% to 15% of new mothers will experience PPD. Lack of support, distress, lower economic status, along with elevated PPD symptoms, sometimes results in an increased risk for poor pregnancy outcomes including preterm birth among Black women. Black women have double the risk of white women for preterm births and low birth weight (Orr, James, & Blackmore, 2002). The increased risk for preterm and low birth weight births among Black women contributes to the high rate of infant mortality/deaths within the first year of life. Knitzer, Theberge, and Johnson (2008) found that infants with mothers who are depressed may experience loss of early connections and may develop decreased sensitivity, attentiveness, and cognitive stimulation. Likewise, children whose mothers experience depression are also at high risk for psychopathology.

Methods

Research Design

This study is an exploratory pre-test and post-test survey design. Black female patients were recruited with fliers that were provided to them when they checked in for their prenatal visit or upon admission to postpartum, labor, and delivery units.

Sample

The study was conducted using a convenience sample (N = 43) of postpartum Black women. Inclusion criteria included: (a) English speaking Black women, (b) 18 years of age or older, (c) pregnant or postpartum women, and (d) women who self-identify as Black. Exclusion criteria included: Women who had experienced miscarriages, fetal demises, and stillborn deaths. Prisoners and hospital employees were also excluded from participation in

study.

Data Collection and Measures

Participants were first provided a total of three questionnaires in a private office. The first questionnaire asked for demographic information including age, education, number of children, welfare services, psychiatric history, employment status, income and marital status. The second measurement, a pre-test /post-test questionnaire, was created by the PI to test subjects' baseline and post intervention knowledge of PPD. The 4-minute video intervention highlight the signs and symptoms of PPD. The third instrument, Inventory of Attitudes towards Seeking Mental Health Services (IATSMHS) (MacKenzie, Knox, Gekoski, & Macaulay, 2004) was used to measure subjects' attitudes about mental health services. IASMHS is a 24-item measure with three subscales: Psychological openness, help-seeking propensity, and indifference to stigma. Subjects indicate their level of agreement with each statement using a 5-point Likert scale (range is from 0 to 4, 0=disagree, 4=agree).

Knowledge of Postpartum Depression by Pre-test and Post-test

To test the hypothesis that viewing the "You Are Not Alone" video intervention would improve knowledge pre-test (M = 4.07, SD = 2.02) and knowledge post-test (M = 5.48, SD = 1.88) with Black women a paired sample t-test was conducted. The hypothesis was found statistically significant (p < .000).

Attitudes Towards Seeking Mental Health Services by Pre-test and Post-test

To test the hypothesis that the "You Are Not Alone" video intervention would influence attitudes pre-test (M = 27.11, SD = 11.97) and attitudes post-test (M = 30.47, SD = 10.81) held by subjects, a paired sample t-test was done. No significant difference between attitudes towards seeking mental health services for PPD pre-test and post-test (p = 0.75) was found.

Discussion

The results suggested that providing education on PPD in a hospital setting may be a good way to help women become more



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aware of the signs and symptoms of PPD. Black women gaining education on signs and symptoms may help them reach out for help the moment they start noticing symptoms of PPD. The results indicated that the intervention did not influence the participants' attitude towards seeking mental health services as hypothesized. The results further suggested that there is a grave need for the creation of interventions that could positively influence Black women's attitudes towards seeking services. In Conclusion, current results suggest that cultural differences and beliefs systems may play a small but significant role in influencing Black women's attitudes in seeking mental health services and future research is therefore encouraged to better determine the role of diversity in the utilizations of mental health services.

NPA2019-12

NICU and Beyond- Assessment and Intervention for Infants and their Parents.

Kgomez

NICU and Beyond: Assessment and Intervention for Infants and their Parents.

Research shows high emotional distress in parents during their newborn's NICU (Newborn Intensive Care Unit) stay, resulting in 20-30% diagnosable mental health disorders in the first year. Parents experience grief, anxiety, fear and guilt. Early detection and intervention improves mental health, parent-infant attachment, and can significantly reduce adverse childhood experiences.

We report on an interdisciplinary outpatient NICU follow up clinic model we developed at the UMass Medical School in Worcester, MA, to screen for maternal depression while providing medical and developmental evaluations of their infants.

This weekly clinic includes a child psychologist, a neurodevelopmental pediatrician and a physical therapist. Infants are evaluated using the Mullen Scales of Early Learning, or the Newborn Behavior Observation, and physical therapy evaluation. Infants receive a developmental and neurologic examination. Mothers are asked about post-partum stressors, depression and/or anxiety.

Over the course of 10 months, we evaluated 80 infants and their mothers. Majority of infants were in early intervention (80%). Mothers reported feeling overwhelmed while their infant was in the NICU. About half of them reported receiving support

from a family member, or from a community organization. Some are following with their own therapist. All reported coming to clinic because this was a service for their child. However, when they were offered individual therapy, most declined.

Current interdisciplinary NICU model highlights the need for an integrative approach to mental health screening starting earlier with mothers of high risk infants, such as in the NICU. This would decrease stigma and resistance to treatment.

NPA2019-13

Improving Access to Perinatal Care: Confronting Disparities and Inequities in Maternal-Infant Health

Legnetto

Background: As part of an initiative to reform the Medicaid system in New York State, in 2014 over 8 billion dollars were reinvested into the NYS Medicaid system to address various aspects of health care. A portion of these funds have been used to fund projects that work towards promoting integrated delivery of services, preparing providers for Value Based Payment (VBP) and using patient centered approaches to health care delivery. Many of these projects focus on improving maternal and infant health outcomes, as these groups make up a large portion of Medicaid enrollees.

In NYS, premature birth is the leading cause of death in infants and affects 1 out of every 10 babies born. In Central New York (CNY), the premature birth rates per county range from 7.6% to 12.5%, and have shown no significant change in the past 10 years. In September 2017, St. Joseph's Health, a hospital located in Syracuse, NY received grant funds to develop and promote a program that focuses on reducing the rate of premature births in six CNY counties. The program partners with participating birthing hospitals and outpatient obstetrical care providers to address four specific risk factors associated with premature birth: tobacco use, alcohol and substance use, stress and oral care by ensuring evidence-based screening tools are built into the medical record.

Content/Action: Our Premie Prevention team has developed a Clinical Standards Educational Protocol Model of Care to address comprehensive screening practices by making system changes. Following Medicaid and ACOG guidelines, this

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



model serves as a roadmap of how to implement program and policy changes that can help practices improve screening for these factors during the prenatal care period. It provides risk assessment tools, educational materials, policy templates, information on reimbursement and VBP, a quality improvement plan and a system to screen, make referrals and follow up part of the routine practice and sustainable. The model of care is the focal point of our provider toolkit, which features additional educational materials and risk prevention resources. All information is available on our website as well.

Our team has formal contracts with 12 birthing hospitals and outpatient prenatal care providers and continues to meet with and sign on potential partners. We have gained support from over 40 state and local community based organizations, government entities and additional businesses including health departments, third party payors, pharmacies and pharmaceutical companies. Several of these organiza-

tions have agreed to post the program's educational "posterzine", a patient-friendly graphic that highlights risk factors that can lead to a preterm birth and how to address each one. Kinney Drugs, a local pharmacy chain, has posted the posterzines in all of their locations and the Onondaga County Health Department has posted these in their public breastfeeding pods across the county. Our posterzine has been featured on a local news media segment during premature awareness month and used as a marketing and educational piece at several events including the 2018 NYS Fair. In November 2018, our team organized and held an educational conference titled, Healthy Moms, Healthy Babies: Your role in Preemie Prevention with speakers from NYSDOH, parent and partnering organizations, vendors and audience attendees of 80+ from CNY and adjacent counties. Speakers at the conference focused on: Current status of Maternal-Infant Mortality in NYS, Obstetrics and Value Based Payments, Clinical approach to better birthing outcomes and sharing positive practice outcomes from using our model of care.

Lessons Learned: The concern of premature birth is one that involves much more than just these four risk factors. Through our developmental research and many conversations with nurses, clinicians and health care professionals, we have found that in addition to these social risk factors, women and families are faced with several other clinical, societal, environmental and other issues that could lead to a premature birth. Therefore, one of the lessons learned is that addressing premature birth should start when a woman is considering becoming pregnant, so as to assess her current way of life and connect her with any needed clinical or community services before pregnancy.

In talking with many providers and office staff, we came across a few reoccurring issues. The first issue being that there are so many patient education materials in circulation, it is difficult to find time to research the "best" for an office and to use to correspond with provider teachings. In addition, we found a second issue to be that patient education was not being fully done after screening because providers did not know where to send patients for additional and follow up care. Learning these lessons early on in developing our model of care, gave us time to compile comprehensive and commonly used materials (and create our own posterzine) and a list of referring providers and community based organizations, specific to each risk factor, additional area of need and geographical location. These materials and information was shared and well received from providers.

Implications for Practice: In creating this educational model of care, we have come across three significant implications for practice. First, the process of screening, educating and referring to additional treatment needs to be a part of any health care appointment for any woman of childbearing age and/or those who are trying or are currently pregnant. Women who are engaging in or exposed to risky behaviors and environments should be supported, educated and if needed referred, to aid in increasing their own health and decrease negative health risks to their baby. This is extremely important for women who have language or cultural barriers, as this may be one of the only times she seeks health care and can be helped. A health care provider, especially a nurse educator or social worker, can be a very influential part of her support system.

Second, screening for women of childbearing age and/or those who are trying or are currently pregnant needs to be universal, regardless of age, race, ethnicity, socioeconomic status or any other potentially distinguishing characteristic. This is important in establishing and ensuring health equity for all patients and avoiding bias or discrimination. All women should be provided the same level and courteousness of care.

Finally, after performing these screening practices, comprehensive documentation must be kept in the medical record. Comprehensive and accurate documentation is important for compliant health care practices. Building reportable fields is crucial for internal and external auditing and will be used in the future for reimbursement for services.

NPA2019-14

Neonatal outcomes following dual exposure to medication assisted treatment for opioid use disorder and psychotropic medication in utero

A. Meyer, M. Sharp, PhD, M. Prasad, DO, MPH, C. Lynch, PhD, MPH, K. Carpenter, Ph.D.

Introduction: Medication assisted treatment (MAT) for opioid use disorder (OUD) decreases the risk and severity of neonatal abstinence syndrome (NAS) compared to illicit exposure to opioid drugs. Concurrent prenatal exposure to psychotropic medications and MAT may be associated with more severe NAS, including longer duration of opioid treatment, withdrawal symptoms, and total hospital stay. The purpose of this study was to examine NAS

in a sample of neonates with dual MAT and psychotropic medication exposure born to mothers seeking outpatient MAT for opioid use during pregnancy.

Method: Retrospective medical chart review was conducted for women undergoing prenatal care at a multifaceted substance abuse treatment clinic and their newborns (N = 460). Medical chart abstraction included information regarding demographics, MAT, pregnancy/childbirth characteristics, and neonatal medical care. Maternal characteristics: majority Caucasian (90%), unmarried (77%), insured through Medicaid (91%); Mage = 28 years. Infant characteristics: Mgestational age at birth = 38 weeks. Psychotropic medications: SSRIs, benzodiazepines, Clonidine. Outcome variables of interest included NICU admission, diagnosis of NAS, days until onset of NAS, maximum Finnegan score, median neonatal morphine dose, and if the infant was discharged home with the mother.

Results: About half the sample had a psychiatric diagnosis documented in pregnancy (54%) and 51% of participants were prescribed a psychotropic medication. In general, there were no differences between women who had a psychiatric diagnosis and/or were prescribed psychotropic medication and those women without psychiatric diagnosis/medication. Women who took benzodiazepines during pregnancy gave birth to infants who needed a higher morphine dose (M = .11, SD = .28) than infants without benzodiazepine exposure (M = .07, SD = .09), $t(423) = 2.70$, $p = .007$, 95% CI -.08, -.01. Infants with benzodiazepine exposure also had higher maximum Finnegan scores (M = 11.20, SD = 3.50) than those without exposure (M = 10.36, SD = 3.83), $t(399) = 2.04$, $p = .008$, 95% CI -1.66, -.03.

Discussion: Having a documented psychiatric diagnosis and/or treatment with psychotropic medication was not associated with any neonatal outcomes. However, benzodiazepine use, either prescription or illicit, appeared to be associated with more severe NAS requiring more intensive NICU intervention. This information may help MAT and general obstetric providers counsel mothers regarding the risks of benzodiazepine use during pregnancy. MAT programs should regularly screen for psychotropic medication use and incorporate education into standard practice.

NPA2019-15

PSS:NICU - Understanding aspects of Postpartum Stress

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Background

Parenting an infant in the Neonatal Intensive Care Unit (NICU) is often distressing, as parents must navigate the challenges of complex medical systems and begin to develop their parental identities. For many, this experience is accompanied by severe psychological distress. Parents are at heightened risk for adverse mental health outcomes, including depression, anxiety, and post-traumatic stress. The rate of Perinatal Mood and Anxiety Disorders (PMADS) for mothers and fathers who have a baby in the NICU (up to 70% & 70%, respectively) is significantly higher when compared to those who do not have a child in the NICU (10-20% & 10-14%, respectively). These responses continue beyond the NICU hospitalization experience (Holditch-Davis et al, 2003; Shaw et al, 2006) and are known to be risk factors for disruption in the parent-infant relationship, and delays in infant development.

Content/Action

In an effort to parse out and explore specific NICU environmental features contributing to the emotional stressors parents face, we administered the Parent Stress Scale, NICU version (PSS:NICU). The

PSS:NICU is a validated survey which asks parents to rate their level of stress associated with 37 items in four categories: sights and sounds of the NICU, the baby's appearance, parental role, and staff communication. Responses were recorded on a 5 point likert type scale (1 = not at all stressful, 5 = extremely stressful).

Our goal was to identify specific environmental contributors and then address them through later programming – psychoeducation, exposure, coping strategies.

Lessons Learned

Overall, 45% of responses were reported as either very or extremely stressful. Parents reported the highest levels of stress relating to "The appearance of my baby" and "Relationship with infant and parental role." In the subcategory of "The appearance of my baby", over 25% of parents found the following items to be very or extremely stressful: Being separated from my baby (50%), Not feeding my baby myself (26%), Not being able to care for my baby myself (24%), Not being able to hold my baby when I want (39%), Feeling helpless and unable to protect my baby from pain (46%), Feeling helpless about how to help my baby during this time (45%). For the subcategory of "The appearance of my baby", 25% or more parents reported that the following items were stressful: When my baby looked to be in pain (47%), When my baby looked sad (33%), Tubes and equipment on or near my baby (25%), Bruises, cuts or incisions on my baby (27%), and My baby's unusual or abnormal breathing pattern (31%). One subquestion in the Sight and Sounds category that scored above 25% was The sight of having a machine breathe for their baby (27%).

Surprisingly, parents were not very or extremely stressed by The unusual color of my baby (19%), The small size of my baby (4%), or Seeing needles and tubes put in my baby (21%). Parents were also not very or extremely stressed by the staff behaviors and communication or the Sights and Sounds in the unit.

Implications for Practice

The intent of this abstract is to identify aspects of the NICU experience that cause

high parental stress. Using this information, we will create a strategic program to help parents cope with NICU stress and measure whether such intervention can successfully mitigate risk for Perinatal Mood and Anxiety Disorders (PMADS).

NPA2019-16

Supporting Parent-Infant Bonding and Parental Mental Health

Gabrielle R. Russo, B.S. and Pamela A. Geller, Ph.D.

Introduction: The first year of human life involves substantial physical, emotional, and social development. An infant is influenced significantly by their immediate social environment and caregivers. Parents can facilitate growth and demonstrate emotion regulation and social interactions for their children. Therefore, the health of the parent-infant relationship and substantial parent-child interactions are crucial for maximizing exploration and learning opportunities for the child.

Previous studies have evaluated the relationship between satisfaction with social support and mental health. For example, social support from partner and peers was negatively associated with mother's postpartum depression (Dennis & Letourneau, 2007) and dissatisfaction with social support from parents was positively correlated with maternal postpartum depression scores (Heh et al., 2004). Additionally, prior research has assessed the relationship between parental mental health and parent-infant bonding; Parfitt, Pike, and Ayers (2013) observed an association between parental prenatal anxiety as well as father's postnatal depressive symptoms and poor parent-baby interaction. Notably, Lutz et al. (2012) observed an interaction effect of informational social support on maternal-child interactions for mothers with high levels of stress. Thus, evidence suggests reason to investigate the role that increased social support may play in promoting parent-infant bonding. The current study seeks to understand this relationship and extend current knowledge regarding this concept in order to stimulate clinical practice for parents' mental health, directly impacting the mental and physical health

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of their child. The current study will also consider relationship satisfaction which has been shown to play a crucial role in the mental health of parents, where decreased relationship satisfaction may be a common predictor of poor mental health (Dudley et al., 2001). Additionally, evidence suggests a positive association between parental relationship satisfaction and the parent-child relationship (Erel & Burman, 1995).

Finally, in order to thoroughly address factors impacting parental-child interactions, it is critical to measure a parent's perception of their child's temperament. As described by DiLalla and Jones (2000), infant temperament is based on the behaviors and reactions of infants to life events. A great deal of research has shown significant association between parental behavior and parental mental health with infant temperament (Whiffen & Gotlib, 1989; Greenwell, 2015). In fact, negative infant temperament at 8 weeks was significantly associated with not only maternal postpartum depression, but poorer face-to-face interactions between infant and mother (Murray et al., 1996). It is hypothesized that:

- 1) A direct relationship exists between satisfaction with social support and parent-infant bonding,
 - a) Greater satisfaction with social support is associated with a healthier bond between parent and infant.
 - b) Satisfaction with social support from partner has a stronger association with parent-infant bonding than does satisfaction with social support from others.
- 2) Parent mental health mediates the relationship between satisfaction with social support and parent-infant bonding:
 - a) Greater satisfaction with social support is associated with better mental health.
 - b) More positively scored mental health is associated with a healthier parent-infant bond.
- 3) Parental mental health is associated with more parental perceptions of infant temperament:
 - a) More positively scored mental health is associated with more positive perceptions of infant temperament.

Methods: The current study has a cross-sectional design consisting of one online

self-report survey. The self-report measures included in this study assess parent-infant bonding, satisfaction with social support, depressive symptoms, anxiety symptoms, parental stress, and relationship satisfaction. The relationship between parent-infant bonding and satisfaction with social support will be analyzed. Depression, anxiety, and parental stress will be examined as potential mediators. Parents of 3 to 12-month-old infants with a current romantic partner, all in cohabitation, will be eligible to complete the 110-item survey administered on Amazon Mechanical Turk with compensation provided. Primary and secondary hypotheses will be analyzed using a series of linear and multiple regressions. Participants will be workers of Amazon Mechanical Turk (MTurk) and recruited through the TurkPrime website. The study will be posted on TurkPrime and distributed throughout the months of January and February. Data collection will conclude, and results will be analyzed in the month of March.

Results: It is expected that more satisfaction with social support will be correlated with and predict higher quality bonding between parents and infants. Additionally, results are expected to show that parental mental health mediates this relationship, specifically, that having greater satisfaction with social support results in more positively rated mental health, ultimately leading to higher quality parent-infant bonding. Finally, it is expected to be shown that positively rated mental health will be associated with better perceived infant temperament.

Discussion: Studying the relationship between a parent's satisfaction with social support and the health of the parent-infant bond within the first year postpartum may provide valuable insights. For example, if a direct relationship is found to exist, it would support the need to evaluate the parent's social support network and parent-infant bonding in addition to parental mental health following the birth of a child. Few studies have analyzed the relationships between the current variables. The current study builds upon and extends the current literature as it is the first study to attempt to distinguish a direct association between satisfaction with social support and parent-infant bonding. Previous studies have primarily assessed heterosexual mothers, making the proposed project unique in that fathers and individuals who are members of a non-heterosexual couple are eligible for participation.

Qualitative investigation of characteristics of social support related to traumatic childbirth

Meghan Sharp, PhD, Burkle Bradley, BA, Christyn Dolbier, PhD

Introduction: About half of women report dissatisfaction with their childbirth experience, and some women appraise their childbirth as a traumatic event. Traumatic childbirth appraisal is associated with postpartum emotional distress that can interfere with mother-infant interaction. While postpartum social support may provide a buffer against distress, negative social interactions may have the opposite effect. The purpose of this study was to explore women's descriptions of their traumatic childbirth and types of childbirth-specific postpartum social support.

Method: Women who had given birth in the prior year (N = 129) were recruited via social media for an online study regarding difficult childbirth experiences. The majority was White (84%), married (76%), employed (56%), and had private insurance (69%). Participants typed responses in an open-ended format to prompts to describe their difficult childbirth, identify childbirth characteristics that contributed to trauma appraisal, and to describe positive, negative, and hoped-for social support related to childbirth.

Results: Common themes identified in difficult childbirth descriptions and trauma appraisal included medical characteristics of childbirth (e.g., emergent C-section, 83-92%), elevated perception of risk (e.g., nursing staff rushing, 25-40%). Dissatisfaction with healthcare support (e.g., perceived negative comments from medical providers) was reported by 26% of participants in their difficult childbirth description, but only 4-6% of trauma characteristics. Women reports positive reactions to emotional (73%) and tangible (15%) support related to birth. Negative social interac-



NPA2019-17

tions were described as minimizing (23%), personally insulting (e.g., commenting on maternal age, 28%), blaming the mother (14%), dismissing the mother's needs (10%), and lack of support from medical professionals (10%). Women reported that they wished they had received better postpartum emotional support (40%), greater explanation/understanding of childbirth events (17%), and more support from medical professionals (17%).

Conclusions: Several themes related to medical care were common in descriptions of difficult and traumatic childbirths. These themes are reflected in participants' descriptions of negative social interactions related to birth and types of support they would have liked to receive, in retrospect. Women's accounts can inform recommendations for peripartum doctor-patient communication. This information may be particularly useful for obstetric providers caring for women who have high risk pregnancies or deliveries that require escalated medical intervention.

NPA2019-18

Utilizing Evidence to Develop a Home Visiting Program for Zika Virus Affected Families

Sharon Starr, MSN, RN, Rachel Blumenfeld, MPH, Mariah Menanno

Background

In 2016, Zika virus affected populations throughout the Caribbean, Central and South America and small areas of southern United States. Zika infection of pregnant women places infants at risk for congenital Zika syndrome characterized by brain malformations, other birth defects, and concurrent developmental delays. Zika was monitored as an emerging infectious disease. Approximately 12% of Philadelphia's 1.5 million residents routinely travel to their countries of origin, many of which are Zika endemic countries, risking Zika virus infection of the individual or the sexual partner and possible vertical transmission to the newborn.

Action

The Philadelphia Department of Health (PDPH) provided surveillance of Zika-associated birth defects as well as family support services. Mothers of the U.S. Zika Pregnancy Registry were engaged in home visiting activities for education, developmental screening, and support in caring for themselves and their offspring. The home visiting program was developed

utilizing Parents as Teachers (PAT) as an educational model and activities were measured using the Wheel of Interventions defined by the Minnesota Department of Health.

Lessons Learned

The results of this study show that 21 client families were engaged in services using Parents as Teachers model or PAT health topics. Thirteen clients declined home visiting services. Engaging clients in home based services enhanced Zika related surveillance and collaboration between clients, their primary providers, and the health department.

Implications

Utilizing a home visiting strategy allowed client families to engage in family supports for their children and connect parents and children with their community. Parents as Teachers model is a valuable strategy for educating families while screening for developmental and other needs. The Wheel of Interventions provides a unique method of measuring process outcomes. Active surveillance was enhanced with this collaboration.

NPA2019-19

Partnering with patient advocacy groups to identify challenges and solutions for postpartum mental health care.

Marjorie Stewart-Hart¹, Emily Gusse¹, Zo Ratansi², Chris Zealey², Devra T. Densmore¹

Affiliations: 1 Sage Therapeutics, Inc., Cambridge, MA, USA; 2 Sixsense Strategy Group, Toronto, ON, CA

Abstract Category: Innovative Models of Care

Background: Postpartum depression is the most common complication of childbirth. In the United States, estimates of new mothers experiencing symptoms of PPD vary by state from 8-20%, with an overall average of 11.5%, and in the absence of universal screening, approximately 50% of PPD cases may go undiagnosed. Additionally, it has been reported that approximately 50% of women receiving referrals for perinatal mental health services do not receive care.

Content/Action: This presentation will illustrate the positive outcomes resulting from engagement with the postpartum depression (PPD) advocacy community, including

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

the ideation of solutions for challenges facing those affected by PPD. Four meetings were held with 31 patient advocates/advocacy groups in Baltimore, Chicago, Houston, and San Francisco, with participants from the surrounding geographic areas. Each meeting included a one-on-one information sharing session and a group work session. These sessions were focused on the following questions: 1. What can be done to reduce/eliminate the stigma associated with PPD? 2. What can be done to improve the collaboration amongst Advocacy Groups, Providers, Government, etc.? 3. What can be done to ensure that programs, tools, services, communication, etc. serve the needs of the diverse population of women and families that are impacted by PPD? 4. What can be done to better reach women and families in rural and/or underserved communities? 5. What can be done to improve screening and diagnosis of PPD? 6. What can be done to improve a PPD patient's ability/opportunity to connect with care providers? and 7. What is needed to support the effectiveness and development of Patient Advocacy Organizations?

Lessons learned:

The learnings from these meetings provided key insights into the needs of PPD patients and their advocates. These meetings also demonstrated how, through listening and tapping into the strength, spirit and determination of advocates, we can unlock solutions for the challenges facing the PPD community. Major learnings focused on: how to improve collaborative care, ensure that programs/tools/services meet diverse patient needs, and how best to interact with patient advocacy organizations.

Implications for Practice:

The learnings from these meetings provided key insights into the needs of PPD patients and their advocates. Sharing the information gathered from these meetings is an important step towards establishing greater collaboration between patients, patient advocates, health care providers, and other organizations to enhance postpartum mental health care and make a difference in the lives of moms, babies and families. Fostering such coordinated action and collaborative care may be one way to enhance postpartum mental health care.

NPA2019-20

Baby Carriers: Bridging the Gap of Health Disparities for Mothers and Babies

Tello

Background:

The transition into parenthood can be prepared for, but the course of events cannot always be predicted. When looking at the bigger picture there is no doubt that socioeconomic and sociocultural factors (i.e. family stability, access to resources, academic competency, ethnicity, etc.) play a role in the staggering rates of maternal and infant health issues. Forming healthy bonds and secure attachments with babies early in life will positively impact their development, while decreasing stress on new parents. Access to baby carriers and best practices education can help decrease health disparities because they facilitate hands-free, close contact and meets the evolutionary needs of all

parties involved—regardless of the above mentioned factors. In my experience as an expecting mom, I found there was not much access to information about ways to care for my babies that would safely meet all three of our needs while positively supporting my transition into my new role as their mother.

Content:

In this presentation, I will share how the benefits of regular baby carrier access and usage can help bridge the gap created by health disparities and inequities. I will highlight how this culturally historic practice can improve the infant and parent's health and well-being as evidenced through attachment theory and the theory of psychosocial development. I will address the public health benefits that naturally occur when using an infant carrying device. Furthermore, I will share the specific ways babywearing empowered me as a new mother and how it supported me during the transition into my new life after the birth of my twins in ways that would have otherwise been unobtainable.

The mother's chest is the natural habitat for her newborn during the transition to being outside of her womb. Infant carrying devices bring babies back to that habitat, and can be used with skin-to-skin contact or a clothed baby. Babywearing is the best way to ensure baby and mom—or any emotionally involved caregiver—continue to reap the benefits of kangaroo care and close contact over the first few years, which is a crucial time for baby's social, emotional, and cognitive development.

Some of the benefits for babies include greater physiologic stability, more regular sleep patterns, improved weight gain, and more successful breastfeeding rates.* Babies who are carried in an infant carrier are more easily soothed, more likely to be calm and less likely to cry because they are with a familiar adult. They become one unit with their caregiver and can feel and hear the familiar heartbeat, breathing pattern, movements and voice while still leaving caregivers hands free. Additionally, because the baby is so close, the caregiver is likely to talk to baby, stimulating brain development and enhancing language nutrition. The physical closeness

of babywearing increases oxytocin levels, which supports connectedness, bonding, and love. Especially when taking into consideration the fact that infant abuse and shaken baby syndrome are overwhelmingly caused by the inability to calm a crying baby, it is evident that baby carrier education has a role to play in increasing the likelihood that caregivers will respond more sensitively and appropriately to their baby's needs.

Lessons Learned:

Promoting the use of baby carriers can be an effective way to confront health disparities and inequities during the perinatal time period and beyond. In this presentation, I will share how having my twin babies so close to me decreased the severity of my own perinatal mood and anxiety disorders while promoting an unbreakable bond with my daughters. Babywearing made it possible for my babies to sleep peacefully on me while I tended to the daily demands of my adult life, thus building my confidence as a mother and in my abilities to care for them. This hands-free caregiving option also helped me exceed my breastfeeding goal of 2 years. Most importantly, babywearing helped me maintain my sanity during difficult life situations and circumstances. The close contact facilitated by the baby carrier played the most significant role in allowing me to thrive as a mother, which in turn helped my girls thrive and find their own confidence and independence when they were ready.

In addition to describing my personal experiences as a mother of twin girls, now 5.5 years old— and still tandem worn—, I will share how my journey has influenced my passions and why this work is so important. My current work involves empowering new and expecting moms during their transition into motherhood through the use of baby carriers in a way that will positively impact her infant's socioemotional and cognitive development.

Implications for Practice:

Babywearing is a practice being adopted by a growing number of parents worldwide. Both healthcare providers and parents should have a better understanding of this growing phenomenon, its impact on



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when prescribing RSV prophylaxis

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and provide the supporting evidence



*See the NPA's evidence-based guidelines at www.nationalperinatal.org/rsv

public health issues, and the infant's social, emotional, and cognitive development. All those involved in infant care should have a better understanding about the benefits of utilizing baby carriers and be aware of the best practices. Evidence that babywearing can positively support maternal and infant health and development is mounting and deserves more research. Implementing access, education, and the regular use of baby carriers will not only help address current public health and other maternal-infant related concerns, but it can also help positively influence the health and development of generations to come.

*Source: Kangaroo Care -Cleveland Clinic

Note: This presentation was previously given at the 2017 National Perinatal Association Conference, and discussed how babywearing my twins positively impacted my perinatal mental health and transition into motherhood. It has since been updated to include information that focuses on how babywearing can support overall mental and public health for both infants and parents.

NPA2019-21

Development and Implementation of a Postpartum Depression Screening Program in the Neonatal Intensive Care Unit.

Angela Vaughn RN, NNP-BC

Background:

Postpartum depression (PPD) is an unexpected complication of pregnancy (Association of Women's Health & Neonatal Nurses, 2015). Risk factors associated with PPD include: prior history of depression anxiety, unplanned pregnancy, disadvantaged socioeconomic status, difficult relationships and recent stressful life events (Hawes, McGowan, O'Donnell, Tucker, & Vohr, 2016). The exact cause of PPD is unknown but thought to be a multifactorial dyad of physical and emotional changes (Ugarte et al., 2017). Rapid decline of estrogen, progesterone, and increase of circulating autoimmune thyroid antibodies are physical changes following childbirth thought to be attributed to PPD development. (Beil, 2017). Emotional components of PPD include mood swings, sleep deprivation, exhaustion, physical discomfort associated with postpartum recovery and difficulty with self-identity (Dunlop, Logue, & Thorne, 2016).

Untreated postpartum depression negatively effects maternal/child health. Prior to PPD identification and treatment, mothers experience dysfunction of maternal/infant bonding, poor nutrition, relationship challenges and poor healthcare compliance (Farhat, Saeidi, Mohammadzadeh, & Hesari, 2015). Infants and children born to mothers with untreated PPD experience longer lengths of hospitalization, bonding/attachment issues, abnormal sleep patterns, poor growth, developmental delay and behavior disorders of childhood (Ward, Kanu, & Robb, 2017). The Centers for Disease Control and Prevention estimate 10-15% of childbearing women will develop PPD (American Academy of Pediatrics. aap.org (2015); Hawes, McGowan, O'Donnell, Tucker, & Vohr, 2016). The incidence of PPD increases to approximately 40% in mother's whose infants are admitted to the Neonatal Intensive Care Unit (NICU) (Cherry, Blucker, Thornberry, Heatherington, & McCaffree, 2016). Postpartum depression screening improves identification, referral and treatment for mothers and is recommended by key national women and infant organizations (American College of Obstetricians and Gynecologist, 2015; Association of Women's Health & Neonatal Nurses, 2015; Earls, 2010). In addition to PPD screening, national organizations recommend PPD referral, treat-

ment and follow-up program development in facilities providing care to women and infants. Supporting the evidence-based PPD screening recommendations published by key professional organizations aimed at women, infants and children, I propose developing and implementing a PPD screening program for use in the NICU.

Content/Action:

Unrecognized postpartum depression has long-term adverse effects for infant growth and development. The American Academy of Pediatrics (AAP) periodicity schedule includes a series of well-child screening and assessments designed to foster the parent and provider relationship while focusing on disease prevention, tracking growth and development and addressing health and wellness concerns from infancy through adolescents. During the one-month, two-month, four-month and six-month well-child screening assessments the AAP recommends universal PPD screening. Well child visits in a Pediatricians office are ideal for PPD screening due to the established primary care provider relationship and congruency with the onset of PPD. Some infants require prolonged hospitalization and remain admitted to the Neonatal Intensive Care Unit (NICU) and are not eligible to attend well-child visits with a Pediatrician during one or more of the AAP recommended PPD screening intervals. Although well-child visits are ideal for screening most mothers for PPD screening, the NICU mother, who has a 40% risk of PPD, lacks access to AAP recommended universal screening since their infant will not attend routine well-child until post NICU discharge. Early detection of PPD improves maternal and infant outcomes. Overlooking the AAP PPD screening recommendations for NICU mothers with infants who remain hospitalized potentially increases long-term maternal and infant health complications. In response to the AAP PPD screening recommendations, this practice improvement strategy utilized the Plan-Do-Study-Act method to develop postpartum depression screening program including: postpartum depression education for staff, implementation of PPD screening at intervals recommended by the AAP, providing referral resources for mothers with positive PPD screens and following up with mothers who were provided with referral resources while their infant remains in the NICU.

Lessons Learned:

Navigating PPD can be a complicated and lengthy process. Successful implementation of a PPD screening programs in the NICU requires a multidisciplinary team approach. It is important to identify key members of the teams to serve as champions to improve program compliance and acceptance. Program barriers were present due to PPD screening of NICU mothers who are no longer a patient of the facility. Who is responsible for referral, screening, treatment and where should results be documented. Additionally, all mother's will not agree to PPD screening and cri-

sis plans should be in place.

Implications for Practice:

Development of PPD screening programs and screening for PPD in the NICU has short and long-term benefits for the NICU patient and family. Maternal and infant health suffers from undiagnosed PPD. Infants admitted to the NICU are at risk for neurodevelopmental delay, difficulty feeding, poor weight gain and lengthy hospitalization due to prematurity. Mothers of infant's in the NICU are at increased risk for PPD. Early recognition of PPD prompts maternal treatment, improves maternal/infant bonding, infant nutrition, family relationships and overall healthcare compliance. (Farhat, Saeidi, Mohammadzadeh, & Hesari, 2015). Infants and children born to mothers with treated PPD experience shorter lengths of hospitalization, improved bonding/attachment issues, predictable sleep patterns, improved growth, and less incidence of developmental delay and behavior disorders of childhood.

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Fellow Column: Quality Improvement Initiative: Reducing the Interval from Birth to NICU Admission and Initial Blood Glucose Determination in Very Low Birth Weight (VLBW) Infants

Aleksandra M. Adamczak, MD, Christian Castillo, MD, Vishakia Nanda, MD

At the John H. Stroger Hospital's NICU and Perinatal Center, Very Low Birth (VLBW) infants are at risk for hypoglycemia for various reasons including decreased glycogen stores owing to prematurity or being small for gestational age at birth. One of the goals of the "Golden Hour" is to decrease the occurrence of hypoglycemia (Accucheck of 40 mg/dL or 2.2mM) by the prompt institution of intravenous glucose and fluid supplementation within the first hour of life. The admission of an infant to the NICU is a complex procedure affected by the duration of resuscitation, comorbidities of the infants requiring procedures soon after birth, the distance of the delivery site from the NICU, and mode of transfer. It was observed previously that any delay in the time of admission to the NICU appeared to increase the likelihood of an infant experiencing hypoglycemia.

We sought to document the relationship between the time of delivery and admission time and its relation to the occurrence of hypoglycemia in VLBW infants. We conducted a retrospective review of time of delivery to time of admission (in minutes) and the occurrence of hypoglycemia in our high-risk population. We analyzed data for the 12 months of 2018 in terms of the time of admission and occurrence of hypoglycemia. Our goal of an admission time of <30 minutes from birth and initiation of initial Accucheck determination and institution of intravenous dextrose in water fluids is 30 minutes or less for 2019 and 2020. To assist in achieving this goal, we implemented a 20 minute after birth alert (or warning)

"It is critical that neonatologists, and those in training to become neonatologists, realize the impact that a NICU experience can have on a family—both the infant, the infant's parents individually and as a couple, and the entire family—and that the potential adverse developmental outcomes for the infant and adverse mental health outcomes for parents are well-described and documented"

to encourage prompt the admission process. This Quality Assurance program has the approval of the Neonatology faculty and key nursing leaders to achieve this quality improvement.

Our average admission time from birth to NICU in VLBW infants in the last year is 29 min. The distance between most deliveries

• Table 1. Time between birth and admission to NICU in VLBW from January 2018 to December 2018 per quarters.

	Average time to NICU admission
2018q1	28 min
2018q2	26 min
2018q3	32 min
2018q4	37 min

- **Table 2. Comparison between glucose level and IVF initiation to time of admission to NICU.**

	Average time to NICU arrival	Average time to IVF initiation
Infants with low glucose <40 (n= 11)	33.6 minutes	56 minutes
Infants with normal glucose (n=29)	27.7 minutes	55 minutes

and the NICU is approximately 100 meters and did not change during the study period. Data from 2018 identified that all infants with an initial Accucheck of <20 mg/dL; 1 mM) had an admission time of >30 minutes after birth. Fifty percent of these infants have Apgars < or equal to 5 at 5 minutes, and 75% had intravenous access delayed >60 minutes. Among all infants with an initial Accucheck of <40 mg/dL the mean time to NICU arrival was 33.6 ± 10.9 minutes; those with normal glucose were admitted after 27.7 ± 8.9 minutes. (P = 0.17) (See Table 2). Figure 1 illustrates 2018 data by quarter, of the relationship between average times of admission, time of initial IV fluid initiation and percent of infants with hypoglycemia.

NICU admission time and, more specifically, that if this takes more than 30 min, there is increased risk for severe hypoglycemia.

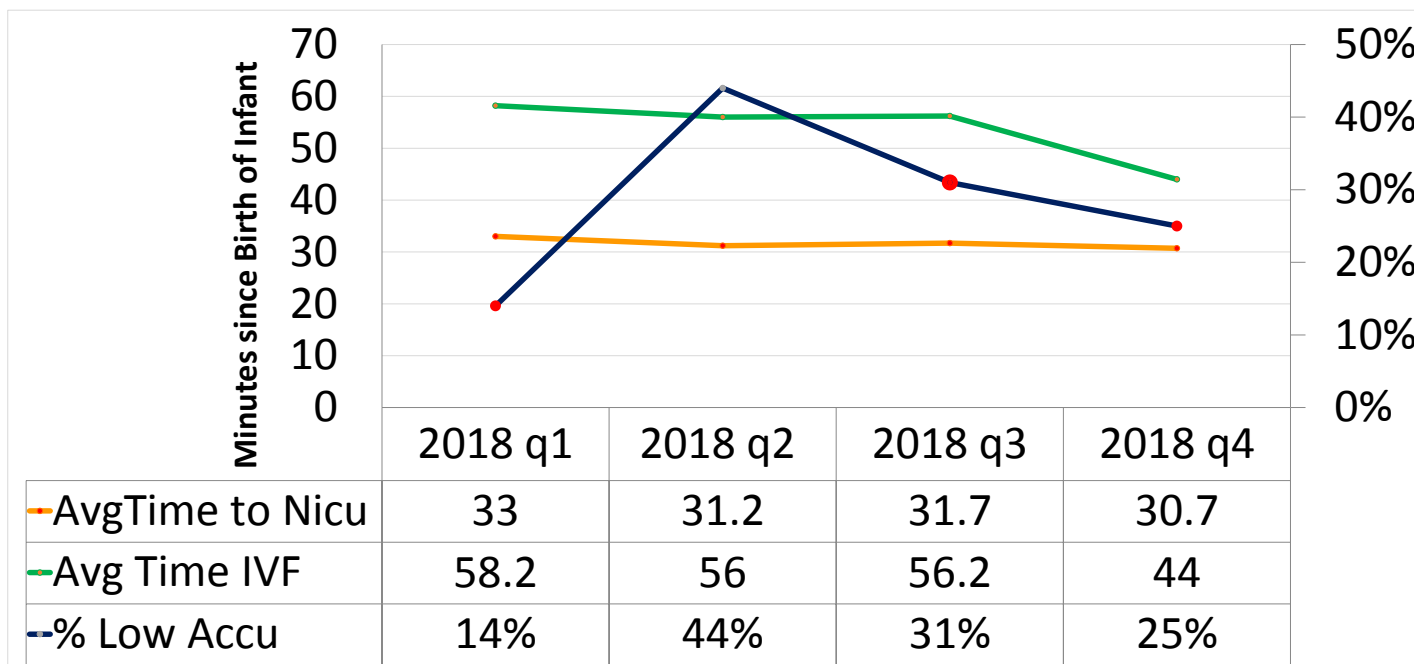
Other factors contribute to delay in NICU admission, including needing respiratory support, delays in achieving oxygen saturation levels of >85-90%, procedures required during resuscitation

“ In 2019 our QA project is focused on reducing the NICU admission time and the institution of IV fluids as the highest priority on NICU admission.”

In 2019 our QA project is focused on reducing the NICU admission time and the institution of IV fluids as the highest priority on NICU admission. Possible factors that affect this time is the complexity of the resuscitation (50% has APGAR < 5 at 5 min) and the time needed to insert a PIV after admission to the NICU (75% have PIV/ IVF started after one hour of life). Although one case had an IVF started before one hour after birth, it was close to one hour (54 min of life). Although statistical significance was not achieved, we are reporting a trend towards a correlation between birth time to



• **Figure 1. Graph showing average NICU admission time per quarter and average IVF time and % low Accu-check.**



and stabilization for transport, and distance from the birth site and the NICU. A warning or alert at 20 minutes after birth will permit delivery room insertion of intravenous lines for fluids and dextrose prior to transport if admission time is projected to be >30 minutes. We are currently analyzing the impact of this QA project on admission times, and initial Accucheck for 2019, and will continue this project through 2020 until our goals are achieved.



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Disclosure: There are no conflicts identified.

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- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
- No more than 20 references.
- Please send your submissions to:

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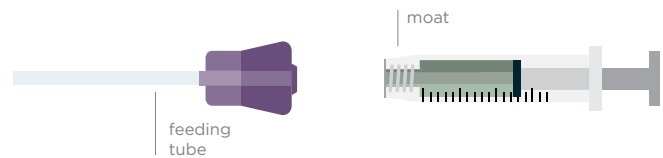


**Breastfeeding
Innovations
Team**

SAFETY IN THE NICU

New tubes, new problems?

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



DOSING ACCURACY

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

INFECTION RISK

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

WORKFLOW ISSUES

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

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

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

ENFit® is a registered trademark of GEDSA

NCfIH National Coalition
for Infant Health

Protecting Access for Premature Infants through Age Two

A collaborative of professional, clinical, community health, and family support organizations focused on the health and safety of premature infants.

infanthealth.org

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The conference
for neonatology

FEBRUARY 19-21, 2020

One of the Premier Meetings
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neoconference.com

NEO addresses cutting-edge, yet practical aspects of newborn medicine. Educational sessions are conducted by many of the foremost experts, who address neonatal-perinatal topics for which they have become renowned.

Target audience: All neonatal-perinatal providers, including neonatologists, advanced practitioners and staff nurses.

Themes covered:

- Strategies for Improving Neonatal Health Care
- NICU Centers Presenting Successful Quality Programs
- Update on Medications in the NICU
- Seizure Management in 2020
- Updates on Human Milk and Sepsis
- Genetics in the NICU; From Testing to Ethical Dilemmas

New in 2020! Ask the Expert

Join us for a roundtable discussion and interact with leaders in neonatology. Topics include:

- Respiratory Treatments in the NICU: iNO, Non-Invasive Ventilation, High Frequency Ventilation
- Early Onset Sepsis: Evaluation and Treatment



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Review Course in
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- Full coverage of all topics relevant to neonatal-perinatal certifying examinations
- Cardiovascular and respiratory physiology review with interactive tutorials

Battle of the Boards Quiz Bowl

Join us for one of Specialty Review’s most popular events, a Jeopardy-style rapid fire team competition, complete with dinner, music and camaraderie.

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Center for
Research, Education, Quality & Safety

A Mom's Grief from the Loss of Her Baby Is Unique and Profound

Alison Jacobson



Saving babies. Supporting families.

First Candle's efforts to support families during their most difficult times and provide new answers to help other families avoid the tragedy of the loss of their baby are without parallel.

Prolonged grief disorder (PGD) is common, distressing, and persistent in mothers whose infants have died from Sudden Infant Death Syndrome (SIDS) and have lasting implications for their health and well-being. This comes from a study released in Pediatrics that was conducted by Dr. Rick Goldstein, Program Director, Robert's Program on Sudden Unexpected Death in Pediatrics and Assistant Professor of Pediatrics, Harvard Medical School.

"Prolonged grief disorder (PGD) is common, distressing, and persistent in mothers whose infants have died from Sudden Infant Death Syndrome (SIDS) and have lasting implications for their health and well-being."

SIDS is the leading cause of death for babies one month to one year of age and, combined with other sleep-related infant deaths, claims the lives of 3,600 babies every year. Formerly known as Complicated Grief and alternately called Persistent Complex Bereavement Disorder, PGD is distinct from PTSD or depression. It involves persistence of "separation distress," characterized by significant emotional pain and yearning, in addition to cognitive, emotional, and behavioral symptoms, more than six months after a significant loss. It is also associated with diminished health and quality of life for the mother and can affect the lives of living and subsequent children in the family.

"These findings are important to how pediatricians and bereavement support programs such as First Candle can help address a mother's grief months and even years after a SIDS death."

Bereaved parents in the study reported difficulties discussing their experiences of loss and seeking assistance to support the grief, which is further compounded by the stigma of blame that surrounds many SIDS and sleep-related infant deaths.

These findings are important to how pediatricians and bereavement support programs such as First Candle can help address a mother's grief months and even years after a SIDS death. While every bereaved mother grieves differently, many turn to each other to find support from people who know what they are going through. To find somewhere to talk about and share memories of their child. Especially when it seems other people in their lives have stopped asking — a silence that can add to the pain.

Barb Himes, Director of Education and Bereavement for First Candle and a SIDS mom herself, notes that the organization's bereavement support program is a central focus of their mission. "Every day, we receive calls and engage in online conversations with parents who are struggling with grief that is paralyzing. For many, their families, friends, and colleagues simply cannot understand the level of despair they live with for months and even years. Dr. Goldstein's study demonstrates that the grief a mother experiences after the death of her baby is unlike any other."



To every NICU nurse who has cared for these precious babies we say.....
"Thank you."

Did you know that premature and low birth weight babies have a 4x greater risk for SIDS?

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org

As Dr. Goldstein notes in his study the painful ‘pangs of grief’ although not a mental disorder per se, are a key feature of pathological grief and the strength and severity of separation distress suggests the importance of attachment bonds between mothers and their deceased babies. This can have an impact on a woman’s bonding experience in a subsequent pregnancy or their parenting of other children.

In the traditional grief cycle, acceptance eventually becomes the major factor; however, with moms experiencing PGD, this is not the case. Participants in the study noted that the emphasis on acceptance fails to recognize their challenges as mothers who are responsible for maintaining memories and the value of their deceased child’s life. They shared the difficulties they face over time as their deceased infant is less remembered or considered, noting that it contributes to their anger and their inability to embrace acceptance.

In recognizing the signs of PGD, pediatricians, and OBs can help parents deal with their grief and support them in their journey.

First Candle is a national non-profit committed to ending SIDS and other sleep-related infant deaths while providing bereavement support services to families who have experienced a loss. Learn more [here](http://www.firstcandle.org/). (1)

References:

1. <http://www.firstcandle.org/>

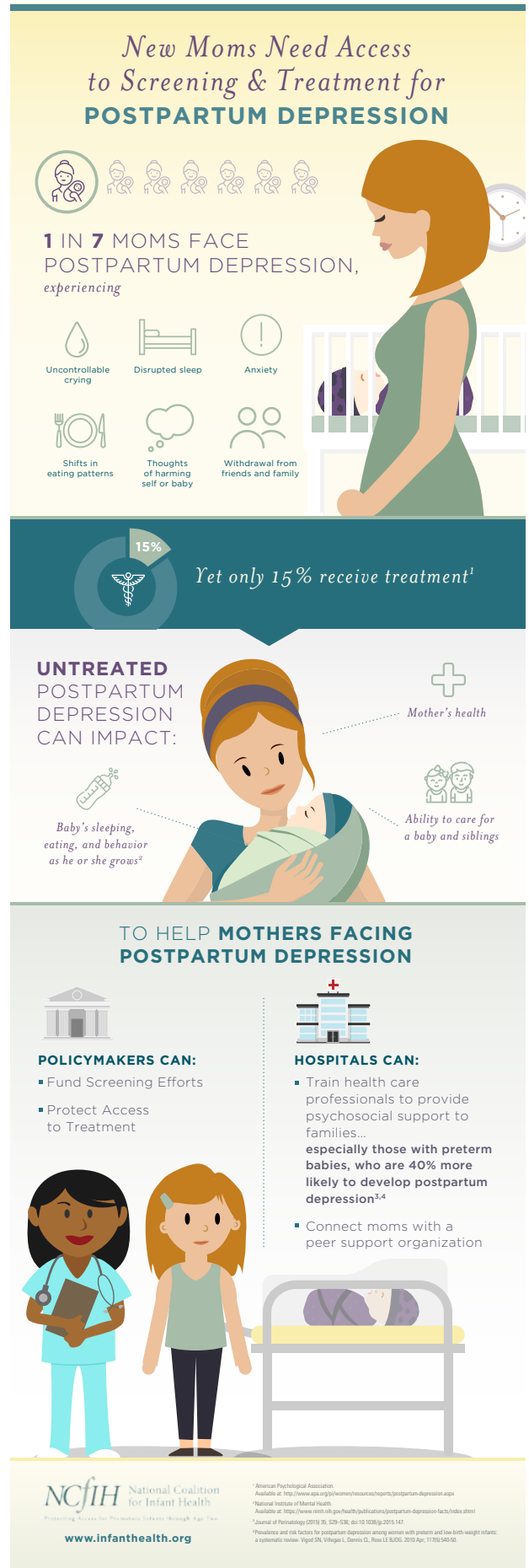
Disclosure: The author is the Director of Education and Bereavement Services of First Candle, Inc., a Connecticut not for profit 501c3 corporation.

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www.firstcandle.org






New Moms Need Access to Screening & Treatment for
POSTPARTUM DEPRESSION

1 IN 7 MOMS FACE POSTPARTUM DEPRESSION, experiencing

- 
 Uncontrollable crying
- 
 Disrupted sleep
- 
 Anxiety
- 
 Shifts in eating patterns
- 
 Thoughts of harming self or baby
- 
 Withdrawal from friends and family

15% *Yet only 15% receive treatment¹*

UNTREATED POSTPARTUM DEPRESSION CAN IMPACT:

- 
 Baby's sleeping, eating, and behavior as he or she grows²
- 
 Mother's health
- 
 Ability to care for a baby and siblings

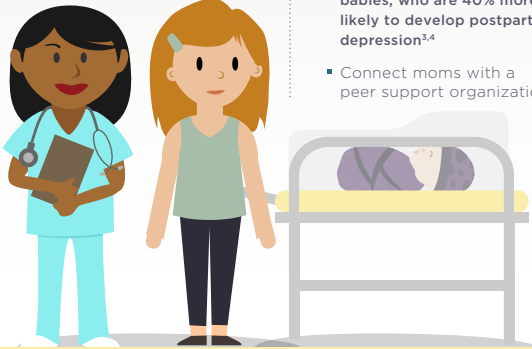
TO HELP MOTHERS FACING POSTPARTUM DEPRESSION


POLICYMAKERS CAN:

- Fund Screening Efforts
- Protect Access to Treatment

HOSPITALS CAN:

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




National Coalition for Infant Health
 Promoting Access for Preterm Infants through Age Two
www.infanthealth.org

¹ American Psychological Association. Available at: <http://www.apa.org/press/releases/newsreports/postpartum-depression.aspx>
² National Institute of Mental Health. Available at: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology (2019) 35, 525–526, doi:10.1097/JP.0000000000000141
⁴ Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

*Through the darkness of my grief
I light a candle to show the world
my love for you.*

**At First Candle we
provide bereavement
support to the over
27,000 families who
will experience the loss
of a baby every year.**

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Still a Premie?

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

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation?

STILL A PREMIE

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

- Jaundice
- Feeding issues
- Respiratory problems

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

Born preterm at a "normal" weight?

STILL A PREMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREMIE

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

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

Some Preemies	All Preemies
<ul style="list-style-type: none"> Will spend weeks in the hospital Will have lifelong health problems Are disadvantaged from birth 	<ul style="list-style-type: none"> Face health risks Deserve appropriate health coverage Need access to proper health care

The Survey says RSV



What you need to know about RSV

RSV stands for **Respiratory Syncytial Virus**

RSV is a **Really Serious Virus**

WHEN IS RSV SEASON?

Typically RSV season runs from November - March. But it can begin as early as July in Florida and end as late as April in the West.

Protect babies and families this RSV season
Educate. Advocate. Integrate.

National Perinatal Association

Consult the CDC's RSV Census Regional Trends to learn more www.cdc.gov/rsv/census/tech/rsv-surveillance.html

www.nationalperinatal.org

5 THINGS

YOU CAN DO
TO CELEBRATE



NICU AWARENESS

1

Educate Yourself

Did you know that more than half of the babies admitted to NICUs were not born prematurely? See our fact sheets.

2

Post on Social Media

See examples at nicuawareness.org and nationalperinatal.org/NICU_Awareness

3

Recognize NICU Staff

Let them know the difference they are making in our babies' lives. Write a note, send an email, or deliver a gift to show them that you appreciate them.

4

Share Your Story

Most people have never heard of a NICU before. Let others know about the extraordinary care that NICUs provide.

5

Join Our Community

Get involved. Become a member of our organizations and share your talents.

This project is a collaboration between



www.nicuawareness.org

www.nationalperinatal.org/NICU_Awareness



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.



Medical Legal Forum – Use and Abuse of the Apgar Score

Gilbert Martin, MD and Jonathan Fanaroff MD, JD

“So members of the jury,” said the defense attorney, “baby Marie’s cerebral palsy, cannot be secondary to birth asphyxia since her Apgar scores were 6 at one minute, 7 at five minutes and 8 at 10 minutes”. Apgar scores this high do not lead to a diagnosis of cerebral palsy secondary to hypoxic-ischemic encephalopathy or neonatal encephalopathy as it is called today”.

A statement like the one above is not uncommon in today’s presentations by attorneys who are using the Apgar score as a prognosticator for future neurological delay. Since the Apgar score is well accepted by the international community and is the most common hospital care form appearing on the newborn chart, it is not surprising that the relationship of the score to future disability is common.

However, there are many facets of the Apgar score, which need to be considered before using these numbers prognostically.

Virginia Apgar was an anesthesiologist at Columbia University and in 1953, proposed a new method of evaluation of the newborn infant. The actual Apgar epigram (A-appearance, P-pulse, G-grimace, A-activity, R-respiration) was devised by a pediatrician named Mervyn J. Covey. This epigram was created in 1961. Today we would consider this an acronym (a word formed from the first letter of each of the words in a phrase) rather than an epigram, which is a witty, ingenious, or pointed saying which is tersely expressed.

“Virginia Apgar was an anesthesiologist at Columbia University and in 1953, proposed a new method of evaluation of the newborn infant. The actual Apgar epigram (A-appearance, P-pulse, G-grimace, A-activity, R-respiration) was devised by a pediatrician named Mervyn J. Covey.”

Virginia Apgar’s objectives were to provide an advocate for the baby and to encourage closer observation. In addition, she wanted to prevent asphyxiated infants from being incorrectly assessed, to ensure that healthy infants did not receive unnecessary resuscitation and to provide a shorthand for reporting the status of the newborn and the response to resuscitation.

It is important to realize that an Apgar score assigned during resuscitation is not equivalent to a score assigned to a spontaneously breathing infant. For that reason, there is no accepted standard for reporting an Apgar score in infants undergoing resuscitation after birth because many of the elements contributing to this score are altered by resuscitation.

Further complicating matters revolve around the criteria for defining perinatal asphyxia. ACOG Bulletin 163 (often quoted by attorneys) states that an Apgar score of less than 3 at five minutes is an essential criterion for perinatal asphyxia. In 2003, a second ACOG treatise entitled, “Neonatal Encephalopathy and

Cerebral Palsy,” stated that an Apgar score of less than 3 at five minutes is not an essential criterion but a suggested criterion. The latest ACOG treatise in 2014 titled, “Neonatal Encephalopathy and Neurological Outcome” no longer defines essential criteria but states that an Apgar score of less than 5 at five minutes and 10 minutes (with acidemia and signs of encephalopathy) correlates the risk of cerebral palsy. Additionally, the 2014 monograph states that “if the Apgar score at 5 minutes is >7, it is unlikely that peripartum hypoxia-ischemia played a major role in causing neonatal encephalopathy.”

Many factors affect the Apgar score. These include preterm birth, maternal sedation, congenital malformation, trauma, interobserver variability, cardiorespiratory conditions, infection and, most commonly, the transitional state after birth.

We often forget that the most important goal of Doctor Apgar was to provide an advocate for the newborn infant immediately after birth.

The limitations of the score are that it only measures vital signs; it is too subjective; it has a limited timeframe; and to be abnormal (less than 3 at more than five minutes), the biochemical disturbance must be severe. For that reason, it is ideal to document whether the Apgar score is assisted or not assisted.

“The original Apgar score was assigned to a spontaneous breathing infant. However, in today’s world, Apgar scores are assigned frequently after resuscitative efforts.”

The original Apgar score was assigned to a spontaneous breathing infant. However, in today’s world, Apgar scores are assigned frequently after resuscitative efforts. That is, there may be positive pressure utilized initially. Oxygen is often provided, as are chest compressions when indicated. Therefore, the practitioner needs to know how the score was derived if prognosis, and further neurologic conditions are predicted.

For that reason, an assisted Apgar score form was developed and appeared in Guidelines for Perinatal Care (7th Edition), and in the October 2015 issue of the journal, Pediatrics. Although the recommendations are such that this expanded Apgar score reporting form should be utilized, this has not been the case. In most hospitals in the United States, the reporting on the Apgar



score form remains without any mention of assistance. The expanded Apgar score reporting form appears below.

was practicing anesthesia.

APGAR SCORE

Gestational Age _____ weeks

SIGN	0	1	2	1 minute	5 minute	10 minute	15 minute	20 minute	
				COLOR	Blue or Pale	Acrocyanotic	Completely Pink		
HEART RATE	Absent	<100 minute	>100 minute						
REFLEX IRRITABILITY	No Response	Grimace	Cry or Active Withdrawal						
MUSCLE TONE	Limp	Some Flexion	Active Motion						
RESPIRATION	Absent	Weak Cry; Hypoventilation	Good, crying						
TOTAL									
Comments:				Resuscitation					
				Minutes	1	5	10	15	20
				Oxygen					
				PPV/NCPAP					
				ETT					
				Chest Compressions					
				Epinephrine					

Figure 1: Expanded Apgar scoring.

A true abuse of the Apgar score occurs when it is utilized alone as evidence of asphyxia. To make a diagnosis of perinatal asphyxia, many other factors need to be considered in addition to the Apgar score. These include non-reassuring fetal heart rate patterns, abnormal umbilical cord gasses, neuroimaging and neonatal electroencephalography, evidence of histologic placental dysfunction, and clinical findings that corroborate neurological dysfunction.

In addition, we continue to use the Apgar score prognostically in premature infants. Since one measure of the score is “activity” and premature infants often have decreased activity, how can we utilize the score in the premature infant prognostically?

Another less appreciated fact is that Dr. Apgar believed that at least two people should provide an independent score. She discussed variation in scoring and noted that this variation is decreased in infants with high or low scores. In addition, it was clear that the variation in the score was less if the numbers were decided quickly. How many times do you recall that after delivery and resuscitation, you were asked to assign a score since at 1, 5, and 10 minutes retrospectively since the physician and the resuscitation team were actively pursuing other activities?

Consider the following poem which was penned in the Journal of Perinatology in 1989. In addition, Joe Butterfield, an icon in neonatology, lobbied for a stamp to be created in her image. This is a 20 cent stamp, which appears below. Unfortunately, very few of these stamps have ever been utilized.

A Timely Scenario (September 1989)

Virginia Apgar, in '53,

*She said to colleagues with great frustration,
 “The newborn babe needs observation.
 Correct assessment with more attention,
 leads to appropriate intervention.
 If we pick numbers that seem to jive,
 can this predict who will survive?”
 A scale devised that very year
 was clinically oriented, and did seem fair.
 Heart rate, reflex irritability, and muscle tone
 were numbered singly, each one alone.
 Respiratory effort and color too,
 Hence, the score—but what to do?
 Measured at minutes, one, five, and ten,
 Instructed what to do and when---
 Problems arose with such a roar,
 Who should assign this “Apgar Score”?
 The obstetrician called numbers high,
 for perfect babies would not die.
 The pediatrician, not wanting blame,
 called numbers low—this was a shame.*

*This left the task to the poor nurse,
 who often found the job a curse.
 Five clinical signs made up the score,
 but in reality, there were several more.
 The obstetricians yelled and booed,
 wailing that they'd soon be sued.
 Pediatricians countered, "Don't be afraid,
 Asphyxia's a term that soon will fade."
 And then some babies born premature,
 could not be measured with the score.
 Cord pH, gestational age
 Made the number a poor gauge.
 Faulty recall, postdated noting
 had the lawyers really gloating.
 Potential help for this condition
 mimics Olympics competition:
 Skaters, gymnasts, and divers, too,
 are all assigned a score by few.
 A special team of five or more
 could redefine the Apgar score.
 In house, on-call for deliveries,
 their Apgar scores would surely please.
 A 3, 4, or 7.1,
 hold up your cards—we've just begun.
 Three and one-half million births a year,
 Who will fund a cost so dear?
 Perhaps the answer is soporific,
 as we attempt to be scientific.
 Encourage closer observation,
 adapt a score without inflation.
 Modify existing terms—
 We've opened up a can of worms.*



Figure 2: The Virginia Apgar Stamp

Although most infants with low Apgar scores will not develop neurological dysfunction the numbers on the score, continue to be utilized in the medical-legal community. We opened up a “can of worms,” and although the Apgar score is provocative, it should not be used in this way in medical-legal investigations.

What is most interesting is that Virginia Apgar was also a fine musician and made string instruments as a hobby. It has been said that the wood she fashioned her instruments from was taken from the telephone booths in New York City. I am not certain that this fact is actual but I do know that Virginia Apgar’s instruments are now enshrined in the American Academy of Pediatrics Administrative Building.

The authors have no conflicts of interests to disclose.

NT

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Disclaimer:

This column does not give specific legal advice, but rather is intended to provide general information on medicolegal issues. As always, it is important to recognize that laws vary state-to-state and legal decisions are dependent on the particular facts at hand. It is important to consult a qualified attorney for legal issues affecting your practice.

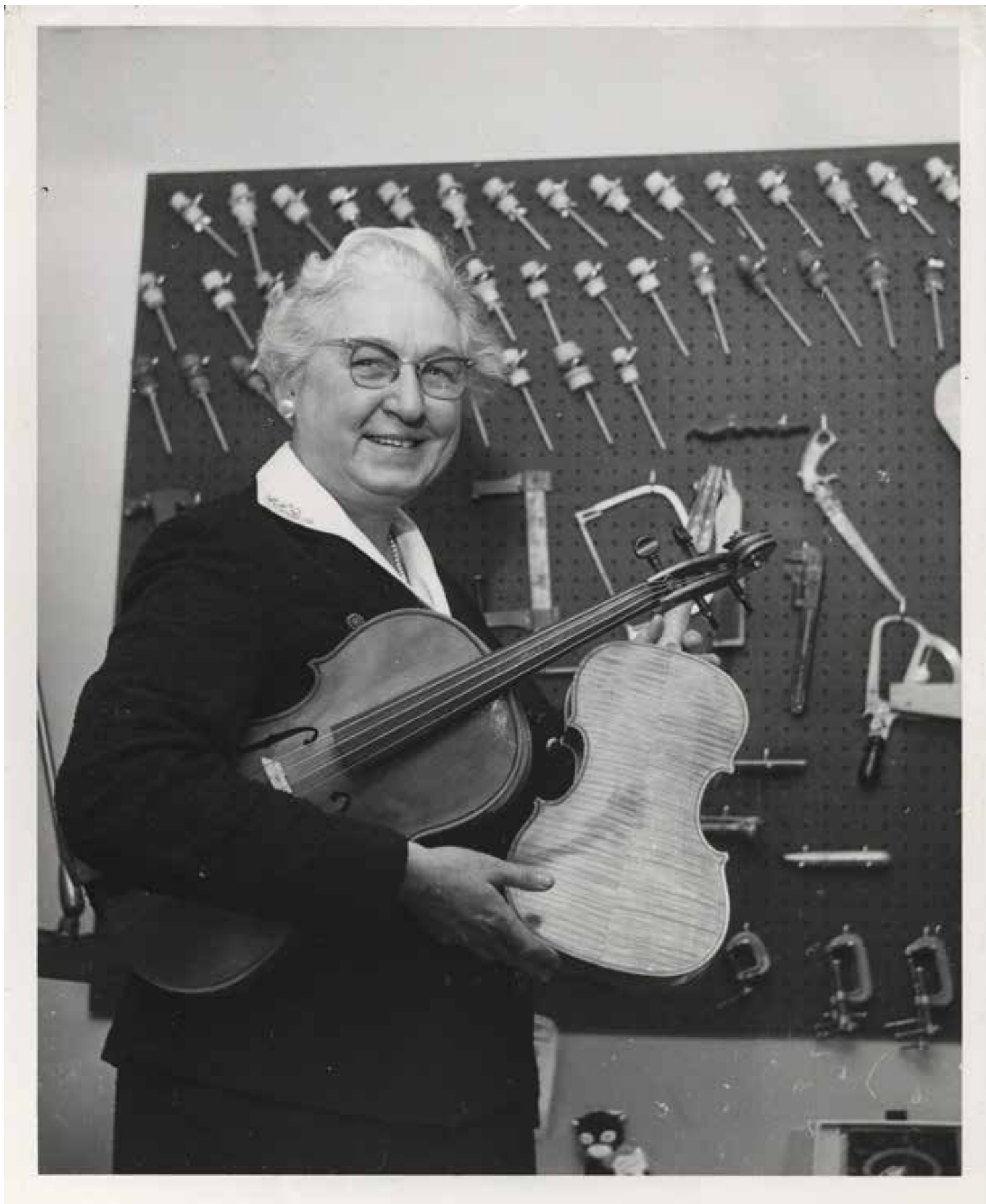


Figure 3: Virginia Apgar and her string instrument

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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



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*Biophysiology of
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MOVEMENT

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March 5-7, 2020



pac/lac

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March 24-28, 2020; Snowbird, UT

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

Respiratory Care and its Impact on Neurodevelopmental Outcomes: What's Good, What's Bad, and How Can We Do Better

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.

That respiratory outcomes impact other outcomes is well known; significant respiratory disease often is linked with other morbidities. What we do as respiratory clinicians is obviously front and centre when it comes to respiratory outcomes, whether chronic lung disease (CLD) or pulmonary function later in life. When it comes to neurodevelopmental outcomes (NDO), the link to respiratory care is less widely known. This may be due to a lack of strong evidence or the perception of some neurodevelopmental practices as "soft science," however, just as the knee bone is connected to the thigh bone, respiratory care plays a part in neurodevelopment and outcomes thereof.

When I started my NICU career some 30 years ago, the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) was being initiated in the Women's College Hospital NICU (now at Sunnybrook Health Sciences Centre). NIDCAP was frowned upon then as the epitome of "soft science," dare I say thrown into the "granola pile" of wishy-washy concepts. Fortunately, times have changed, and that "wishy-washy" concept has been widely adapted into the realm of NICU care. It has brought us to view what we do in terms of medical intervention through a developmental lens. As such, it has also forced a reevaluation of how we do what we do and when we do it. In a sense, we have begun to learn the non-verbal language of premature babies, the cues they give us.

Intubation:

Endotracheal intubation under rapid sequence induction (RSI) should now be a standard of practice for both developmental and physiological reasons. What medication(s) are used may be subject to debate and study, but the concept of pain management and regulation of cerebral blood flow should not be part of that debate. Given the high risk of intraventricular hemorrhage associated with the first seventy-two hours of life, RSI is especially important during resuscitation. Every effort should be made to support the baby non-invasively until vascular access is obtained unless the baby is apneic and bradycardic despite resuscitative efforts.

The placement of an endotracheal tube (ETT) may influence outcomes. Nasal intubation has always been routine in the unit in which I practice. Since very few NICU's nasally intubate, finding evidence to justify this practice is rather difficult as evidence is either non-existent or sparse. From a philosophical standpoint, one can, I believe, make a case for it except in emergent situations. Even in those cases, a clinician skilled at nasal intubation can place an ETT nasally as deftly as orally, if not more so, with most babies.

As a general rule, what goes into a premature baby's mouth

should feel good and taste good. We know that infants are orally fixated, and it follows that premature infants would be as well. Oral aversions are a huge obstacle to establishing proper feeding and discharge home, not to mention the costs associated with gavage feeding or more invasive interventions. Self-soothing is also more challenging when an orally placed ETT is taking up most of the oral cavity, leaving little room for a pacifier.

In my experience, nasally placed ETT's are more easily secured and stabilized than oral ones: they are less prone to inadvertent movement and are less affected by oral secretions. This may result in less tube re-taping and fewer unplanned extubations. In turn, the risks associated with repeated intubations such as tracheal stenosis and thus the need for tracheostomy or corrective surgery are reduced. These complications are high to non-existent in our NICU. It is my practice to offer sucrose to a baby undergoing an ETT re-taping, in conjunction with comfort measures such as hand hugging provided by a second caregiver. Anything that reduces an infant's stress level is a good thing.

"It is my practice to offer sucrose to a baby undergoing an ETT re-taping, in conjunction with comfort measures such as hand hugging provided by a second caregiver. Anything that reduces an infant's stress level is a good thing."

Ventilation:

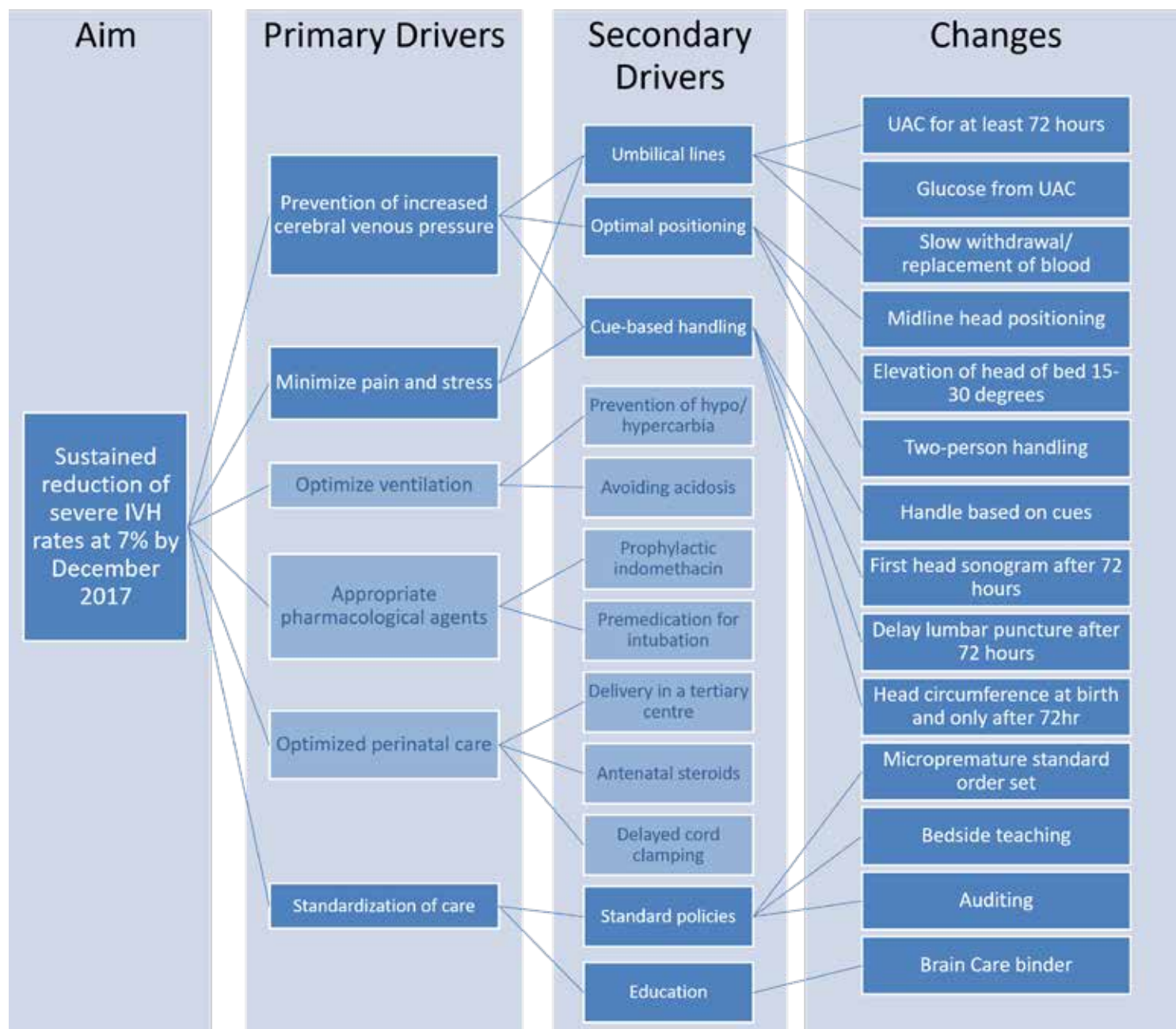
Many factors muddy the waters when examining the evidence supporting one mode of ventilation over the other, be it for reducing chronic lung disease (CLD) or providing neuroprotection. Different machines and variation in clinical practice, even within the realm of a study, make it hard to compare apples to apples, or apples to onions as it were. Be that as it may, there are ventilatory practices that we have a pretty good idea affect outcomes adversely.

That CO₂ plays a role in cerebral blood flow, and intraventricular hemorrhage (IVH) is well known, but the relationship may be more complicated than a simple set of values. Since CO₂ has a direct effect on cerebral vasculature tone, it is easy to point to it as the culprit when IVH occurs. Certainly, very low levels are bad, as are very high levels. What, exactly, those levels are is somewhat nebulous. Some studies link high levels to white matter injury, and it is well accepted that levels ≤ 30 mm Hg are to be avoided at all costs. Equally important is the avoidance of rapid changes in CO₂ levels; the body prefers stasis. Many have a "knee-jerk" reaction when they see either very high or very low CO₂ levels and adjust ventilation too rapidly to what is acceptable for the patient. This may create reperfusion injury as vasculature rapidly dilates or constricts, similar to the effects of swings in serum oxygen levels. It is better to make slower adjustments, which allow a more gradual change in vascular tone to avoid this type of scenario unless, of course, pH is life-threatening.

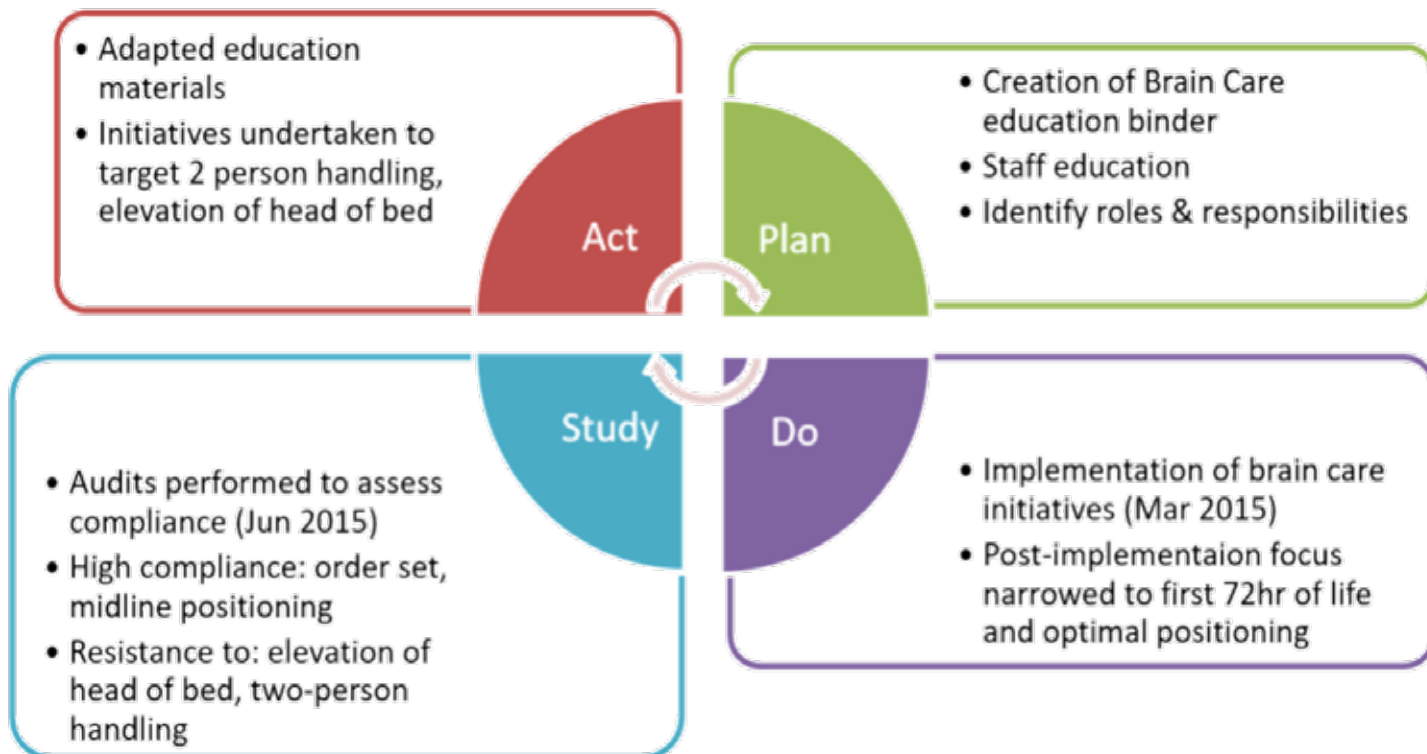
“Acceptance of hypercapnia in the initial 72 hours of life is not advisable in the premature infant already at high risk of IVH. Unfortunately, determining what a baby’s CO₂ is during the first hour or so of life can be very difficult since transcutaneous monitoring is very unreliable with low perfusion. ”

controversy for a very long time. It is accepted that moderate hypercapnia can reduce lung injury, but there are variations in clinical practice as to how much hypercapnia is acceptable. In my practice, relatively high levels of hypercapnia (70-90 mmHg) are tolerated, provided pH is compensated, and the baby is well into their NICU stay. This does not appear to have influenced our rates of IVH or periventricular leukomalacia (PVL).

Acceptance of hypercapnia in the initial 72 hours of life is not advisable in the premature infant already at high risk of IVH. Unfortunately, determining what a baby’s CO₂ is during the first hour or so of life can be very difficult since transcutaneous monitoring is very unreliable with low perfusion. Vascular access is time-consuming and active resuscitative measures make capillary sampling impractical, not to mention blood gas turnaround time that may exceed thirty minutes. Much can happen in this time since as the lung is recruited; ventilation improves dramatically. It is my strong belief that paediatric societies and the Neonatal Resuscitation



The concept of “permissive hypercapnia” has been a subject of



Program should mandate the availability of point of care testing for blood gas analysis in every resuscitation room.

When it comes to modes of ventilation, establishing the superiority of one over another involves so many variables as to make it almost impossible. Having said that, there are some existing studies that provide food for thought. A British study showed significant differences in pulmonary function tests at age 11-14 in premature infants supported with HFO c.f. conventional ventilation (CV), and educational attainment also favoured the HFO group. Emotional issues were greater in the HFO group but were not supported by parent or teacher observations. (1) While a French study initially showed increased IVH with HFO, later analysis showed increased mild IVH but decreased severe IVH and less cerebral palsy in the same group. This is in line with a meta-analysis of IVH and high-frequency ventilation, which showed no increase in the incidence of IVH or PVL with HFO once the results of the disastrous "HIFI" trial of the early 1980s were excluded. (2) Thus it would appear HFO/HFJV ventilation is at least as safe as CV and may result in better long-term developmental outcomes. The caveat with HFO/HFJV ventilation is one must be vigilant regarding CO₂

levels as both modes are capable of dropping CO₂ very quickly, especially when first initiated. Again, point of care testing for blood gases should reduce inadvertent alkalosis/hypocapnia. There is evidence to support HFO over CV, and also evidence suggesting the use of synchronized intermittent mandatory ventilation plus pressure support (SIMV/PS) should be avoided. (3)

The increased utilisation of non-invasive ventilation (both CV and HFO) may be helpful in reducing CLD; however clinicians must recognize that high FiO₂ for prolonged periods of time is detrimental to long-term pulmonary function, and if pressures are not adequate to provide proper functional residual capacity (FRC) there is no benefit to this approach and, as suggested by the HIFI study, may be detrimental. (4)

Positioning, handling and interventions

A quality improvement project in the unit in which I am employed concentrated on reducing severe IVH. Among the changes involved was positioning of the head, and raising the head of the bed to 15 to 30 degrees. Also included were the routine placement

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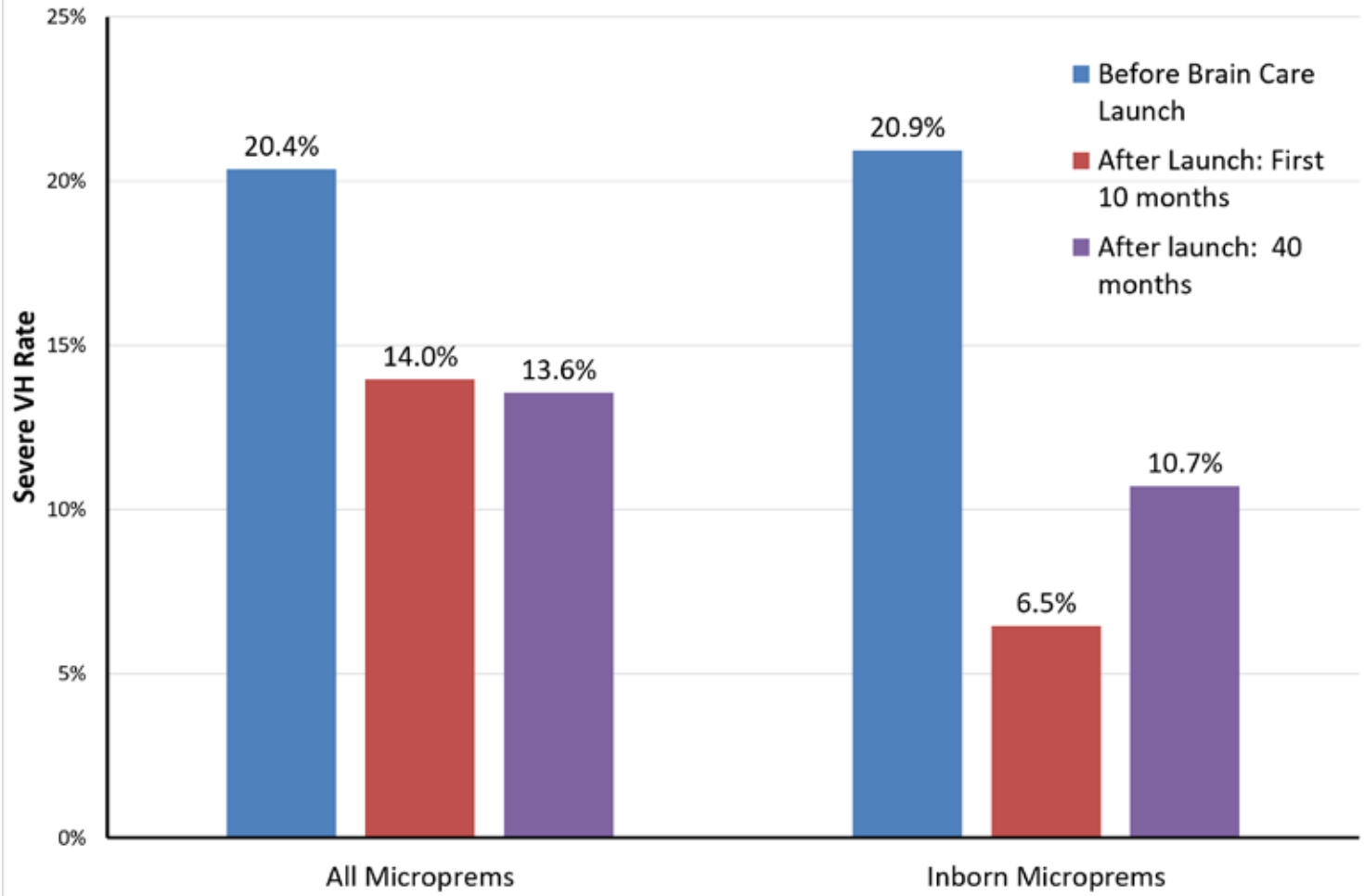


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Severe IVH Rate in Micropremature Infants



of umbilical lines, minimal, cue-based handling, and 2-person handling. Limiting handling during the first 72 hours is critical; placement of umbilical lines minimizes any disturbances to the baby associated with blood sampling, and the second person involved with 2-person handling provides comfort to the baby (hand hugging, etc) during necessary interventions. The results are shown below (with apologies for the quality of the images).

Clearly outcomes can be improved, and a reduction of severe IVH bodes well for longer-term developmental outcomes.

Parental interaction/Kangaroo care (KC)

The link between neurodevelopment and parental interaction with their child has been slow to establish; however there is now evidence to support direct parental involvement in the care of their child in the NICU. The concept of parents as a nuisance, to and in the way of, routine care is being replaced with the reality of parents being an essential part of that care and a positive influence on outcomes, although barriers to its implementation remain among care givers. (5) Respiratory clinicians can actually be one of the greatest enablers of KC; they can also be the greatest obstacles. Concerns regarding ETT stability and extubations are well-founded but can be mitigated, and the benefits, in my opinion, outweigh the risks.

KC was first used as an adjunct to temperature regulation and has

been shown to be beneficial in that regard. It is now known that KC affords much more than thermoregulation, it changes the way the premature infant's brain wires itself. Benefits include earlier establishment of breast feeding, (6) improved cognitive and behavioural performance even after 20 years, (7) decreased nosocomial infections, and increased survival.(8)

Kangaroo care may be offered to ventilated infants and is a routine event in the NICU at Sunnybrook, even for babies on HFJV. Care must be taken to avoid the risk of inadvertent extubations.

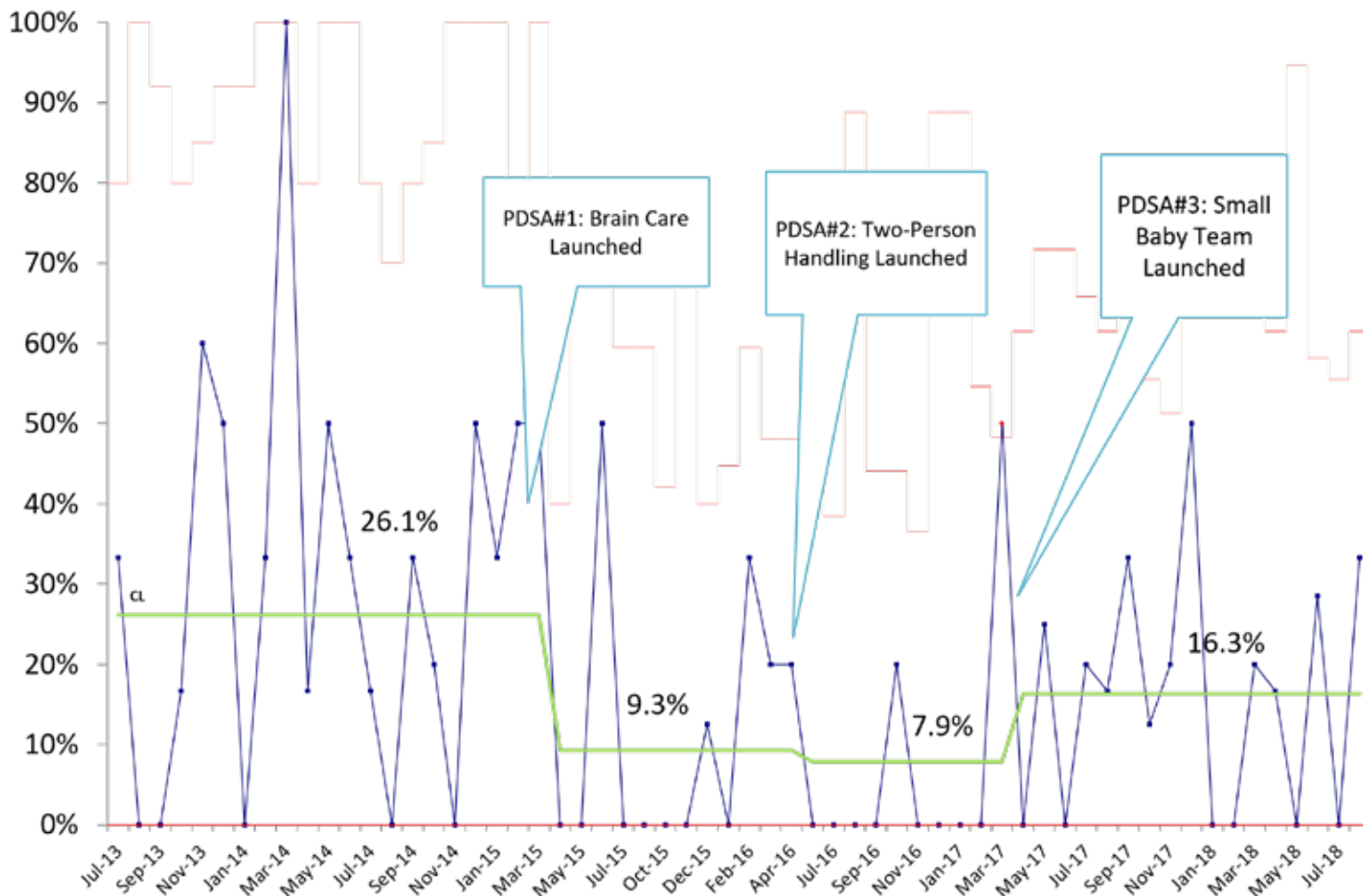
Supporting evidence for "cycling" infants on NIV, particularly NC-

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p Chart: Severe IVH Rates in Micropreterm Inborn Infants



PAP, is lacking. One of the reasons for this is that studies tend to examine the length of stay or days on respiratory support as a primary outcome. While this is, of course, an important factor for a multitude of reasons, there are “softer” outcomes that may be of importance. One of these is the barrier ventilatory support has on the likelihood of being offered or accepting KC. As well, I believe there is a positive psychological effect on parents when they are able to KC their baby without the cumbersome CPAP apparatus getting in the way, and the challenges associated with maintaining proper pressures while doing so are no longer a factor. In my experience, this practice does not have any adverse effects on infants; providing selection criteria is appropriate, i.e., minimal FiO₂ and supporting pressure. I suspect that should the duration of positive pressure ventilation, and parental comfort/anxiety were added to outcome measures, the findings would be favourable.

Conclusion

While ventilation strategies in the NICU remain varied and controversial, the evidence does provide a link to neurodevelopmental

outcomes and respiratory support as well as adjunctive measures improving those outcomes. To quote Robert Frost, “we have long to go before we sleep.”

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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.

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Coping with Infant Illness in the NICU During the Holiday Season

Navy C. Spiecker, BA, Pamela A. Geller, Ph.D., & Chavis A. Patterson, Ph.D.

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.

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Educate. Advocate. Integrate.

"From now on, your troubles will be miles away..." sings Frank Sinatra in the classic holiday song; however, this is not the case for many individuals. For some, the winter holidays tend to be associated with elevated rates of anxiety, nostalgia, and particularly perinatal depression (Goyal, 2018)—a reaction has been referred to historically as "the holiday syndrome" (Cattell, 1955). For families with an infant in a neonatal intensive care unit (NICU), the winter holiday season can be particularly difficult. Many parents experience a sense of disillusion, as their anticipated joy is swiftly replaced with long nights by their child's bedside. Parents may also grieve the loss of expected holiday events and experiences during their first winter holiday season with the newborn. NICU providers have the unique opportunity to assist fami-

lies in anticipating and combating these challenges. This article introduces ways to help families in the NICU cope with during the winter holidays season, and perhaps bring a spark of joyful spirit into their lives.

"No matter the time of year, it can be challenging to face the demands of daily life and simultaneously cope with an infant's illness and hospitalization. Financially, balancing family responsibilities and the NICU can create difficulties."

No matter the time of year, it can be challenging to face the demands of daily life and simultaneously cope with an infant's illness and hospitalization. Financially, balancing family responsibilities and the NICU can create difficulties. Time spent traveling and at the hospital means increased expenses for travel, childcare for older siblings, and less availability to work (Treyvaud, 2014). These restraints can create more stress and associated burden for the family. Additionally, spiritual faith may be questioned during times of crisis (Clark, 2003). The winter holidays only compound these challenges.

A normative challenge for families, in general, is the additional expenses associated with the holiday season. This can be exacerbated for families with an infant in the NICU, particularly if the hospital is located at a distance from the family's home and involves significant travel or necessitates overnight accommodations. In addition to financial and logistical barriers, the holiday

season places more pressure on parents to spend time with extended members of the family. By spending time in the NICU, parents may miss traditional familial gatherings and celebrations. Parents may become overwhelmed, and siblings may find themselves spending much of the holiday season with extended family members or caregivers instead of their immediate family. Notably, a key challenge for families in the NICU is adjusting to a new normal (Doering, Moser & Dracup, 2000). These parents likely envisioned a warm holiday at home with their new infant, surrounded by family. However, the NICU can be a harsh contrast to the comfort of home; the lights, sounds, emergency situations, and multiple machines can be a jarring experience (Carter, Mulder & Darlow, 2007). Providing the quality care families with an infant in the NICU receive, the complexity of these factors must still be considered, particularly during the holidays.

There are several avenues through which providers can help. Financially, families can benefit from assistance with affordable transportation and overnight housing (Dobbins, Bohlig, & Sutphen, 1994). Organizations such as the Ronald McDonald House provide financial support to aid with medical care and transportation, and overnight housing for families in need ("Ronald McDonald House Charities – What We Do," 2019). Providers should also be knowledgeable about nonprofit organizations dedicated to the provision of assistance during the holidays, specifically to families with a child in the NICU, such as Silvie Bells ("Silvie Bells – About," 2019). The utilization of these resources could make a significant difference in reducing families' financial barriers.

There are a number of NICUs that have utilized parent support groups to increase social support and adaptive coping. These groups have been shown to aid parents in navigating their relationships with nursing staff, as well as connecting with other families (Turner, Chur-Hansen, & Winefield, 2015). During the holidays, more emphasis on these groups can be useful, such as



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creating specific holiday-themed group topics. Implementation of themed parent activities, such as crafting gifts for their child, can be a great way to provide a distraction and offer a creative outlet. At the Children's Hospital of Philadelphia (CHOP), parent activity groups include decorating onesies or knitting seasonal infant hats. Holiday family photoshoots within the NICU, like the ones held at the Rush Medical Center in Chicago (Rush SpecialKare Keepsakes), can also help to maintain a sense of normalcy (Schwarz, Fatzinger, & Meier, 2004).

Other holiday activities that can be integrated within the NICU for parents and siblings may include pictures with Santa Claus, caroling, gathering candy from Mrs. Claus, snowflake stations, and gift drives available for families to participate in the festivities without the need to leave the hospital. Additionally, providers may consider enlisting volunteer assistance from past graduate families of the NICU. As they have previously experienced the NICU with an infant of their own, these families can provide first-hand support and expertise. These volunteers could also assist with running parent activity groups, infant cuddling, or participating in holiday activities during this difficult time.

It is well-documented that utilizing a family-centered approach to care encourages partnership between families and providers, and improves parent, child, and family outcomes (Griffin, 2006; Harbaugh & Brandon, 2008). With that in mind, it is important to remember that each family experiences the holidays differently. Among those that observe specific religious holidays in the winter season, customs and sentiments can differ vastly. To accommodate this range of experiences within the NICU, there can be an increased focus on creating a welcoming and supportive environment overall.

It is very important to ask families what holidays they celebrate, if any, to get a better grasp of their individual perspective during this season. A non-exhaustive list of common winter holidays includes Christmas, Hanukkah, Kwanzaa, Yule, St. Lucia's Day, St. Nicholas Day, Fiesta of Our Lady of Guadalupe, Three Kings Day, Omisoka, and the Winter Solstice ("December: A Month of Multicultural Holiday Celebrations," 2017). Further, it is important to keep in mind that not all families observe religious holidays in this

season or at any point in the year. Some families may benefit from leaning on their religious practices and spiritual faith, which can become strengthened by the challenging NICU experience (Brelsford & Doheny, 2016). However, it is important always to exercise caution when approaching the subject of religion or spirituality. Keep the focus on each individual family's unique values, practices, and traditions. Additionally, providers should be aware of resources within their medical center dedicated to pastoral care/religious services that families can utilize, if applicable.

"An extended stay in the NICU can be a challenging experience for families, especially during the holidays. Fortunately, there are many ways that NICU providers can help to ease parents' distress, and maintain a sense of holiday cheer in their NICU."

An extended stay in the NICU can be a challenging experience for families, especially during the holidays. Fortunately, there are many ways that NICU providers can help to ease parents' distress, and maintain a sense of holiday cheer in their NICU. As a final note, it is important for providers themselves to practice self-care. Check-in with yourself regularly. Remember to take time to tend to your physical and emotional needs the same way that you would care for your patients, and finally – happy holidays!

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Disclosure: The National Perinatal Association www.nationalperinatal.org is a 501c3 organization that provides education and advocacy around issues affecting the health of mothers, babies, and families.

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NICU Awareness

Did You Know?

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Special Health Needs

Babies who have had a NICU stay are more likely to need specialized care after they go home. **Timely follow-up care is important.**

NICU babies have a higher risk for re-hospitalization. So every medical appointment is important. Especially during cold and flu season when these babies are especially vulnerable to respiratory infections.

Who Can Help

- pediatricians
- neonatal therapists
- pulmonologists
- neurologists
- gastroenterologists
- cardiologists
- nutritionists
- CSHCN - Programs for Children with Special Health Care Needs

Special Developmental Needs

Any NICU stay can interrupt a baby's growth and development.

Needing specialized medical care often means that they are separated from their parents and from normal nurturing.

While most NICU graduates will meet all their milestones in the expected developmental progression, it is typical for them to be delayed. This is especially true for preterm infants who are still "catching up" and should be understood to be developing at their "adjusted age."

Who Can Help

- IBCLCs and lactation consultants
- Early Childhood Interventionists
- developmental pediatricians
- occupational therapists (OTs)
- physical therapists (PTs)
- speech therapists (SLPs)
- WIC - Special Supplemental Nutrition Program for Women, Infants, and Children
- social workers and case managers

Special Educational Needs

Every child has their own unique developmental needs and **every student has their own unique and special educational needs.**

Take advantage of the services and support that can meet your child where that are and help them reach their future educational goals.

Call your local school district to request a free educational evaluation. Learn about all the available programs and support.

Who Can Help

- Preschool Program for Children with Disabilities (PPCD)
- Special Education programs under the Individuals with Disabilities Education Act (IDEA)
- educational psychologists
- speech therapists (SLPs)
- occupational therapists (OTs)
- reading specialists



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Weight-Based Approach to Phototherapy Initiation in Preterm Infants

Shabih Manzar, MD

Abbreviations:

LBW- Low Birth Weight, less than 2500 grams
VLBW- Very Low Birth Weight, less than 1500 grams
ELBW- Extremely Low Birth Weight, less than 1000 grams

Introduction:

Hyperbilirubinemia is a common problem in neonates. Established guidelines are available for phototherapy (PTx) treatment for neonates greater than 35 weeks¹ but data is scarce about the guidelines in preterm infants less than 35 weeks.² In preterm infants, weight rather than gestational age is used for certain calculations and therapeutic interventions. Therefore, there is a need for a weight-based guideline for PTx. We present a simple weight-based approach to the initiation of PTx in preterm infants.

We used the percent body weight as a factor determining the need for phototherapy. For infants < 750 grams, we used 1% of body weight, 0.75% for 751-1500 grams and 0.5% for 1501-2500 grams (Appendix).

Maisels et al.² approach for phototherapy for premature infants is a practical option but the ranges for phototherapy initiation in this guideline are very narrow. We compared our weight-based approach with their data. The table depicts our findings. For each gestation, we selected the corresponding mean weight using the Fenton chart for boys. We used the boys' chart for uniformity. As noted in the Table, our ranges were close to the

ranges reported by Maisels et al.², however, with a broader scale.

The approach to the treatment of hyperbilirubinemia with PTx can be conservative or aggressive, depending upon the ranges of TSB used.³ When we compared our approach to the Norwegian guidelines⁴, we noted our strategy to be conservative. In conclusion, the weight-based approach, by using percent body weight as a factor, to initiate phototherapy in preterm infants is a simple way of managing hyperbilirubinemia. Further studies should be done to investigate the validation of this approach.

“In conclusion, the weight-based approach, by using percent body weight as a factor, to initiate phototherapy in preterm infants is a simple way of managing hyperbilirubinemia. Further studies should be done to investigate the validation of this approach.”

Footnote (Tips):

- If TSB is greater than cBili, start Phototherapy (PTx)
- Start single PTx, irradiance of 15-20 $\mu\text{W}/\text{cm}^2/\text{nm}^*$
- If TSB level is 50% above the cBili, start double PTx, ir-

Gestational age (Weeks)	Initiate Phototherapy Total Serum Bilirubin (mg/dL) (Maisels et al ²)	Mean weight for Gestational age (Grams)	Initiate Phototherapy Total Serum Bilirubin (mg/dL) Weight-based approach
< 28 0/7	5-6	500-1100	5-8.2
28 0/7-29 6/7	6-8	1101-1400	8.2-10
30 0/7-31 6/7	8-10	1401-1750	8.7-10
32 0/7-33 6/7	10-12	1751-2200	8.7-11
34 0/7-34 6/7	12-14	2201-2500	11-12.5

Table 1: Key Driver diagram

Appendix

Factor = Percent Body Weight (BW)

500-750 grams, 1% of BW

751-1500 grams, 0.75 % of BW

1501-2500 grams, 0.5% of BW

Example 1:

Birth weight (BW) = 1300 grams, % birth weight factor = 0.75%

Total Serum Bilirubin (TSB) = 6.2 mg/dL.

Calculated Bili-Photo level (cBili) = Weight x % BW factor

=1300 x 0.75/100 = 9.7

Interpretation: cBili > TSB

Plan: No Phototherapy (TSB of 6.2 is < 9.7 cBili), Follow bili in 4 hours

Example 2:

Birth weight (BW) = 1800 grams, % birth weight factor = 0.5%

Total Serum Bilirubin (TSB) = 11 mg/dL.

Calculated Bili-Photo level (cBili) = Weight x % BW factor

=1800 x 0.5/100 = 9

Interpretation: cBili < TSB

Plan: Start Phototherapy (TSB is > cBili), Follow bili in 4 hours

Example 3:

Birth weight (BW) = 600 grams, % birth weight factor = 1%

Total Serum Bilirubin (TSB) of 7 mg/dL.

Calculated Bili-Photo level (cBili) = Weight x % BW factor

=600 x 1/100 = 6

Interpretation: cBili < TSB

Plan: Initiate PTx with single light, irradiance of 15-20 $\mu\text{W}/\text{cm}^2/\text{nm}$, Check TSB in 4 hr.

- radiance of 20-30 $\mu\text{W}/\text{cm}^2/\text{nm}$
- If TSB is 100% above the cBili, start triple PTx, irradiance of 30-40 $\mu\text{W}/\text{cm}^2/\text{nm}$
- Check TSB in 4 hr. Expected decline is 0.2-0.5 mg/dL per hour.
- A decline in TSB indicates adequate PTx.
- If TSB continues to trend down, start weaning PTx, Double \rightarrow Single \rightarrow Discontinue.

- If TSB is up, add another light. Follow TSB in 4 hrs.
- If TSB continues to incline up despite intensive PTx, consider Exchange transfusion.
- Follow gestational-aged based exchange transfusion guidelines, Maisels et al. 2
- *Irradiance range of 15-40 $\mu\text{W}/\text{cm}^2/\text{nm}$, Morris et al. 3

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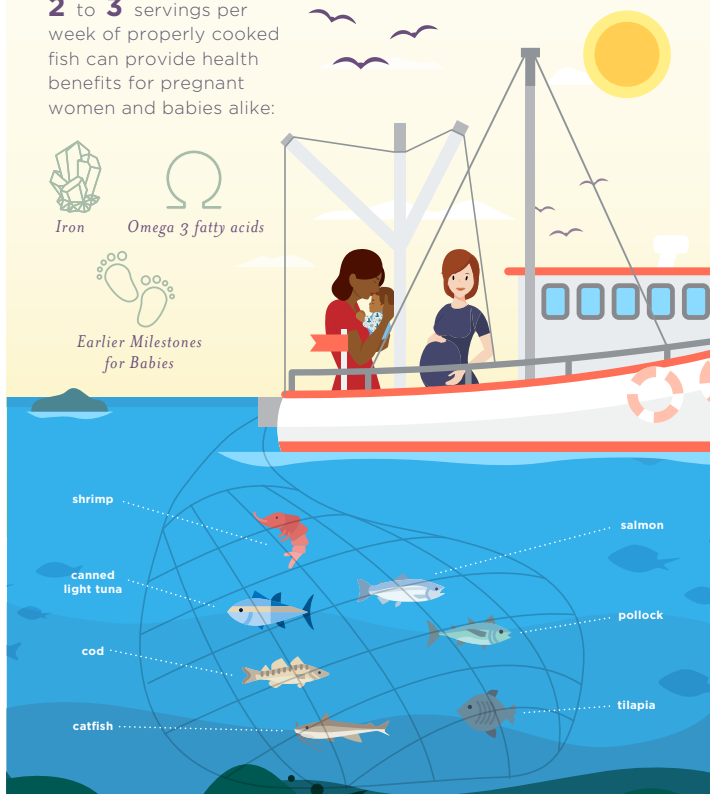
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- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
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Looking Ahead - 2020 Federal Health Policy Outlook

Darby O'Donnell, JD
Alliance for Patient Access (AfPA) Government Affairs Team

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.



Controlling the Cost of Medicines

As Congress nears the end of the calendar year, drug pricing legislation aimed at lowering costs seems to be the health legislation "flavor of the month," as it has been for a good portion of the last MANY months. U.S. House Speaker Nancy Pelosi is charging ahead with her legislation with broad Democratic support in the House, but with little to no chance of passage in the Republican-controlled Senate. In the Senate, Chairman Charles Grassley and Ranking Member Ron Wyden have a competing bill. This is also struggling to find sufficient support.

As Politico put it recently, "Most Republicans have long opposed federal intervention when it comes to the cost of prescription drugs, but public support for action as well as [President Donald] Trump's embrace of the issue may be shifting the party's stance."

Expect more of the drug-pricing debate in 2020.

Surprise Medical Billing

So-called "surprise" billing - high medical costs received by an insured patient for care provided by an out-of-network provider - has also been a hot button issue, and in recent months has stalled

in Congress over proposals on payment rates to resolve out-of-network service disputes. "Lawmakers and the health industry all agree that insured patients should not get slapped with hefty bills for inadvertently seeking out-of-network care. However, how exactly to resolve payment disputes between plans and providers has been contentious," read Politico. As of this writing, compromise legislation has been reached and should see action before the end of the year. However, The Hill reports that some doctor and hospital lobbies are ramping up their opposition to the legislation in the closing weeks of the calendar year.

"So-called "surprise" billing - high medical costs received by an insured patient for care provided by an out-of-network provider - has also been a hot button issue, and in recent months has stalled in Congress over proposals on payment rates to resolve out-of-network service disputes. "

Focus on Children's Health and Healthcare

At the American Academy of Pediatrics's (AAP) 2019 National Conference and Exhibition this fall, many new policy challenges in children's health were mentioned, including:

- the return of measles as a threat to public health;
- the emergence of lung illness related to vaping;
- decreasing numbers of children with healthcare coverage;
- increasing numbers of child deaths from firearms.

As we have outlined previously, vaccinations and vaping products are political hot potatoes that will likely continue to permeate the children's health debate in the new year and will likely remain divisive. Congress will continue efforts to protect and improve maternal and infant healthcare with a focus on disparate outcomes.

Democratic Primary Contest

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The new year is also an election year - and a presidential election year at that.

Democratic presidential candidates are contemplating (and trying to distinguish their own political goals from their Democratic primary opponents) reforms and varying degrees of an overhaul of the U.S. health care system. Their demonstration of original ideas and health policy chops are also a means to tell the American public why they would be the best choice to lead.

“Others in the race have shied away from calling the move to a single-payer a slam dunk and believe a slow progression to eliminate private insurance is the answer.”

Many have supported a government-run, i.e., single-payer system, as the solution. Others in the race have shied away from calling the move to a single-payer a slam dunk and believe a slow progression to eliminate private insurance is the answer.

A comprehensive, helpful discussion of where the dozen-plus Democratic presidential candidates stand may be found in a recent Washington Post article. <https://www.washingtonpost.com/graphics/politics/policy-2020/medicare-for-all/>

The 2020 presidential debates, as in election years past, can be a key barometer of health policy attitudes in America.

Change in the Trump Administration

President Donald Trump nominated Stephen Hahn, a radiation oncologist at a large research center in Houston, Texas, to replace acting FDA Commissioner Ned Sharpless to lead the Food and Drug Administration (FDA). The previous FDA commissioner, Scott Gottlieb, M.D., stepped down from the Administration earlier this year. Dr. Hahn awaits a full Senate confirmation vote, but last month cleared two, essential hurdles in the confirmation process - he received a Senate confirmation hearing, followed by a positive vote to move forward his nomination by the Senate Committee on Health, Education, Labor, and Pensions (HELP).

Dr. Hahn, based on the discussion at his confirmation hearing, would face policy challenges (and potential decisions in the next year) as FDA's new commissioner related to flavored e-cigarette bans and children, a regulatory framework for CBD, and food safety & labeling issues.

All three branches of government will have the power to influence or delay major health care decision-making in 2020. The presidential election and political turn-over in Congress that may result from an election cycle are key pieces to who sets health policy in the next decade, beyond the upcoming calendar year

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Still a Premie?

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

But that's not every preemie's story.

Born between 34 and 36 weeks gestation?

STILL A PREMIE

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

- Jaundice
- Feeding issues
- Respiratory problems

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

Born preterm at a "normal" weight?

STILL A PREMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREMIE

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

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

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

NCJFH National Coalition for Infant Health
Protecting Access for Premature Infants through Age Two
www.infanthealth.org

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Babies are just tiny adults, right? So ... half?

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The candidate should be Board certified in Pediatrics and Board eligible/certified in Neonatology. He/She should have excellent communication skills with an interest in academic pursuits and be committed to the community we serve. The candidate is expected to participate in quality and performance improvement projects.

Please contact Marina Weisz MBA |Administrator | Pediatrics; Tel: 718-240-7333; email: MWeisz@bhmcny.org or Kusum Viswanathan, MD, FAAP, Chair, Department of Pediatrics, Tel: 718 240 5904; email: kviswana@bhmcny.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



Survey Says: RSV

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children

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

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

But Parents are Unprepared.

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

RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:



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

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



To every NICU nurse who has cared for these precious babies we say.....
"Thank you."

first candle

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Neonatal Coding and Documentation: The History

Gilbert I Martin, MD

The neonatal healthcare provider needs to be knowledgeable about Current Procedural Terminology (CPT) and the International Classification of Diseases (ICD) which are the diagnostic codes that accompany the CPT codes.

The CPT codes are descriptive and report procedures and medical services performed by healthcare professionals. The language involved in the CPT codes must be universal so that it can provide a template for communication with neonatal healthcare workers. The first CPT Edition appeared in 1966. The language in CPT itself states the following: "The CPT code set is useful for administrative management purposes such as claims processing and the development of guidelines for medical care review. The uniform language is also applicable to medical education and outcomes, health services, and quality research by providing a useful basis for local, regional, and national utilization comparisons". (1)

Over the years, the number of CPT codes has increased and has adapted to both private and governmental guidelines. "The CPT code set has been designated by the Department of Health and Human Services as the national coding standard for physicians and other healthcare professional services and procedures under the Health Insurance Portability and Accountability Act (HIPAA)." (2)

There is a CPT Editorial Panel which ensures that the CPT codes are timely and reflect current medical care. The American Medical Association publishes the Current Procedural Terminology Editions.

The International Classification of Diseases (ICD) is published by the World Health Organization (WHO). The first revision of ICD covered the years 1900-1909. In the United States, we are dealing today with the 10th revision (originated in 1999) and the 11th edition of ICD is now completed and now is available for implantation.

The American Academy of Pediatrics is involved in publishing the Pediatric International Classification of Diseases code set (Pediatric ICD-10-CM). Diagnostic coding expands as the number of diseases, and their sub-classifications increases. The manual is extensive, and condensing these codes to make them manageable has been a difficult process. There have been many modifications of this ICD code set, and guidance, clarifications, and assistance to the practitioner are available. There is even an AAP coding hotline that can be accessed at aapcodinghotline@aap.org.

This column will deal with examples of both CPT codes and ICD codes so that the practitioner will make correct choices for their patients. There are several monographs available to assist the healthcare professional. These include CPT 2020; Pediatric ICD-10-CM 2020; A Quick Reference to Neonatal Coding and Documentation; Non-Physician Practitioner Handbook 2019; CPT Changes 2020 and Coding for Pediatrics. There is also a Coding Toolkit, which is simple to carry around and lists all pertinent neonatal CPT codes.

In 1997, the Perinatal Section of the American Academy of Pediatrics

created a Neonatal/Perinatal Coding Committee under the direction of Rich Molteni, to educate other healthcare professionals and to develop new codes and discuss the "business of neonatology." Over the years, this committee developed comprehensive codes that bundled all of the patient encounters into one daily code. Although we have captured all of the evaluation/management codes, the ICD codes continue to expand.

It is noteworthy that many payment models exist in the spectrum of

"The number of healthcare professionals that can code for patient interactions has expanded greatly. We are now dealing with non-physician practitioners especially neonatal nurse practitioners (NNP). Although neonatologists have become accustomed to using the term NNP, the more generic term used in most publications is an Advanced Practice Provider (APP).

neonatal/perinatal disease. We have evolved from fee for service to discounted care to capitation, and now there are models of Diagnostic Related Groups (DRGs).

To make things even more confusing, the Center for Medicare and Medicaid Services (CMS) produces a CMS Medicare Physicians Fee Schedule (MPFS) every year. There is a Final Rule which elucidates a conversion factor (CF), which is directly related to remuneration.

The number of healthcare professionals that can code for patient interactions has expanded greatly. We are now dealing with non-physician practitioners especially neonatal nurse practitioners (NNP). Although neonatologists have become accustomed to using the term NNP, the more generic term used in most publications is an Advanced Practice Provider (APP). This term encompassed the broader cadre of nurse practitioners in all fields, as well as Physician's Assistants. Within CPT publications, the term Qualified Healthcare Provider (QHP) is often used. This term is inclusive of physicians and advanced practice providers.

Coding previously was a seemingly simple billing sheet that was filled out daily. Now it takes a coding and billing office to capture all of the CPT and ICD codes, submit an invoice, keep track of payments and organize an appeal process.

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

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Future columns will be organized to discuss specific coding issues and include patient examples.

The following is the first of our coding questions.

You are asked by an obstetrician to attend the delivery of a 44-year-old woman who is a G4P2 and the intrapartum period was complicated by several variables and terminal late decelerations. Fortunately, the delivery was uneventful. The baby cried immediately and was alert and pink. The examination was normal and Apgar scores were 7 (1 minute) and 9 (5 minutes). You discuss the care of the patient with the delivering obstetrician and the parents and send the baby to the well-baby nursery.

What is the correct code?

- A. 99464
- B. 99465
- C. 99460



The correct answer, "A."

99464 – Represents attendance at delivery when requested by the delivering physician and initial stabilization of the newborn. This includes drying, stimulation, a detailed physical examination, Apgar score assignment, and discussion with delivering physician and parents.

99465- Represents delivery/birthing room resuscitation, provision of

positive pressure ventilation (PPV), and/or chest compressions in the presence of acute, inadequate ventilation and/or cardiac output.

99460 – Represents the initial hospital or birthing center care, per day, for evaluation and management of the normal newborn infant.

References:

1. *CPT® purpose & mission* | American Medical Association. <https://www.ama-assn.org/about/cpt-editorial-panel/cpt-purpose-mission>
2. *Moving Beyond Diagnosis Codes in CDI: Documentation ...* <https://journal.ahima.org/2018/06/28/moving-beyond-diagnosis-codes-in-cdi-documentation-improvement-for-cpt/>

Disclosure: The author has no disclosures.

NT

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Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

FDA grants accelerated approval to first targeted treatment for rare Duchenne muscular dystrophy mutation

New therapy of targeted treatment for Duchenne muscular dystrophy

For Immediate Release:
December 12, 2019

The U.S. Food and Drug Administration today granted accelerated approval to Vyondys 53 (golodirsen) injection to treat Duchenne muscular dystrophy (DMD) patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. It is estimated that about 8 percent of patients with DMD have this mutation.

“The FDA recognizes the urgent need for new medical treatments for serious neurological disorders and we have a long-standing commitment to working with researchers, drug companies and patients to facilitate the development and approval of treatments for rare diseases. With today’s accelerated approval, patients with Duchenne — a rare and devastating disease — who have a confirmed mutation of the dystrophin gene amenable to exon 53 skipping will now have available the first treatment targeted specifically for this disease subtype,” said Billy Dunn, M.D., acting director of the Office of Neuroscience in the FDA’s Center for Drug Evaluation and Research. “Use of the accelerated approval pathway will make Vyondys 53 available to patients based on initial data and we look forward to learning more about the drug’s clinical benefit from the ongoing confirmatory clinical trial.”

DMD is a rare genetic disorder characterized by progressive muscle deterioration and weakness. It is the most common type of muscular dystrophy. DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. The first symptoms are usually seen between three and five years of age and worsen over time. The disease often occurs in people without a known family history of the condition and primarily affects boys, but in rare cases it can affect girls. DMD occurs in about one out of every 3,600 male infants worldwide.

People with DMD progressively lose the ability to perform activities independently and often require a wheelchair by their early teens. As the disease progresses, life-threatening heart and respiratory conditions can occur. Patients typically succumb to the disease in their 20s or 30s; however, disease severity and life expectancy vary.

Vyondys 53 was approved under the accelerated approval pathway, which provides for the approval of drugs that treat serious or life-threatening diseases and generally offer a meaningful advantage over existing treatments. Approval under this pathway can be based on adequate and well-controlled studies showing the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit to patients (i.e., how patients feel or function or whether they survive). This pathway provides ear-

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The theme for the 2020 conference is *Biophysiology of Human Interaction*. However, the abstracts may be on any applicable NICU topic.

Abstracts should include the following sections, as applicable.

1. Abstract Title
2. Authors' names, degree(s), and institution
3. Background and Purpose: problem statement or hypothesis as appropriate
What is the hypothesis, or what is the problem you are trying to solve, or what is your scientific question? Why is it important? State this in one or two sentences
4. Budget and Resources: cost of program and materials as appropriate
5. Program, Materials, or Methodology: also include any barriers to implementation and how they have been overcome
What methods did you use to solve or research the problem? How did you collect your data? How big was your sample size? What were the main outcome measurements? This will probably be the longest part of your abstract.
6. Impact or Results: major accomplishment of program/materials; qualitative and quantitative data*; evidence-based results. *If providing data, it must exist; "data to be obtained by conference date" is no longer acceptable.
7. Bibliography: for oral presentations, at least 3 related references that support the program
8. Learner Objectives: 2-3

In the body of the email, please list the following:

1. Title of the abstract
2. Author's name, degree(s), credentials, and position title
3. Author's email address
4. Name of institution, city, and state. City and country if outside the US.
5. If the contact person is someone other than the author, please note that in the body of the email
6. Presentation preference: a) oral abstract session, b) workshop session, c) poster only, or d) no preference. (Please spell it out rather than provide just a lower case letter.)

Length of abstract: 1000 words maximum

Format: WORD, preference is Arial 12 pt, but font choice is optional.

Send abstract as an email attachment to Bobbi Rose at brose@health.usf.edu

You will get a reply within a day or two that the abstract was received. If you do not hear back, please call Bobbi Rose at (813) 974-6158, or send another email. Decisions by the abstract review committee for oral considerations are expected by early December 2019. Notification will be by email. **The conference does not provide any support for abstract presenters, regardless of presentation outcome. Abstract presenters must register to attend the conference.**

lier patient access to promising new drugs while the company conducts clinical trials to verify the predicted clinical benefit.

The accelerated approval of Vyondys 53 is based on the surrogate endpoint of an increase in dystrophin production in the skeletal muscle observed in some patients treated with the drug. The FDA has concluded that the data submitted by the applicant demonstrated an increase in dystrophin production that is reasonably likely to predict clinical benefit in patients with DMD who have a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. A clinical benefit of the drug, including improved motor function, has not been established. In making this decision, the FDA considered the potential risks associated with the drug, the life-threatening and debilitating nature of the disease and the lack of available therapy.

Vyondys 53 was evaluated in a two-part clinical study. The first part included 12 DMD patients, with eight patients receiving Vyondys 53 and four receiving placebo. The second part of the study was open-label, and included the 12 patients enrolled in part one of the study, and 13 additional patients who had not previously received the treatment. In the study, dystrophin levels increased, on average, from 0.10% of normal at baseline to 1.02% of normal after 48 weeks of treatment with the drug or longer.

As part of the accelerated approval process, the FDA is requiring the company to conduct a clinical trial to confirm the drug's clinical benefit. The ongoing study is designed to assess whether Vyondys 53

improves motor function of DMD patients with a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. If the trial fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

The most common side effects reported by participants receiving Vyondys 53 in clinical studies were headache, fever (pyrexia), cough, vomiting, abdominal pain, cold symptoms (nasopharyngitis) and nausea. Hypersensitivity reactions, including rash, fever, itching, hives, skin irritation (dermatitis) and skin peeling (exfoliation), have occurred in patients who were treated with Vyondys 53.

Additionally, renal toxicity was observed in animals who received golodirsén. Although renal toxicity was not observed in the clinical studies with Vyondys 53, renal toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Renal function should be monitored in patients taking Vyondys 53.

The FDA granted this application Fast Track and Priority Review designations. Vyondys 53 also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases. In addition, the manufacturer received a rare pediatric disease priority review voucher. The FDA's rare pediatric disease priority review voucher program is intended to encourage development of new drugs and biologics to prevent and treat rare diseases in children. Approval of Vyondys 53 was granted to Sarepta Therapeutics of Cambridge, Mas-

sachusetts.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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NT

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

Released: Thursday 12/13/2018 12:32 PM, updated Saturday 3/16/2019 08:38, and Sunday 11/17/2019 1020

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

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NT

FDA authorizes first test to aid in newborn screening for Duchenne Muscular Dystrophy

Screening for Duchenne Muscular Dystrophy is now attainable.

For Immediate Release:
December 12, 2019

Today, the U.S. Food and Drug Administration authorized marketing of the first test to aid in newborn screening for Duchenne Muscular Dystrophy (DMD), a rare genetic disorder that causes progressive muscle deterioration and weakness.

"Diagnostics that can safely and effectively screen newborns can help health care professionals identify and discuss potential treatment options with parents and caregivers before symptoms or effects on a baby's health may be noticeable," said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "This authorization reflects our commitment to fostering innovation in devices to help inform and provide options to patients and their caregivers. Early screening can help identify individuals who need additional follow up or treatment."

The GSP Neonatal Creatine Kinase-MM kit authorized today is intended to aid in screening newborns for DMD. Newborn screening is a series of tests to help health care professionals identify serious diseases and conditions shortly after birth. As part of this screening, a newborn screening card is used to collect a small amount of blood from a prick of an infant's heel, sometimes called a heel stick. The collected, dried blood samples are used



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to test for a variety of diseases and conditions.

While the number and type of diseases and conditions tested on each state's newborn screening panel can vary, there has been a national effort to harmonize screening practices across state newborn screening programs in the U.S. As a result of the collaboration between the federal Advisory Committee on Heritable Disorders in Newborns and Children and the American College of Medical Genetics, as well as governmental, non-governmental, advocacy and private partners, the Recommended Uniform Screening Panel (RUSP) was developed and adopted. The RUSP is a list of core and secondary conditions for screening newborns that the U.S. Department of Health and Human Services recommends for states to screen as part of their state universal newborn screening programs.

Today's authorization of the GSP Neonatal Creatine Kinase-MM kit enables laboratories to add this test to their newborn screening panel if they choose to do so, but this authorization does not signal a recommendation for DMD to be added to the RUSP as a condition for which newborn screening is recommended. The GSP Neonatal Creatine Kinase-MM kit is not intended for DMD diagnosis or for screening of other forms of muscular dystrophies.

The GSP Neonatal Creatine Kinase-MM kit works by measuring the concentration of a type of protein called CK-MM, which is part of a group of proteins called creatine kinase. Creatine kinase is found in muscle tissue and CK-MM enters the blood stream in increased amounts when there is muscle damage. This test measures the levels of CK-MM from the dried blood samples collected from the prick of a newborn's heel 24 to 48 hours after birth. Elevated levels of CK-MM detected by the kit may indicate presence of DMD. Results showing elevated CK-MM must be confirmed using other testing methods, such as muscle biopsies, genetic and other laboratory tests.

DMD, while rare, is the most common type of muscular dystrophy. It is caused



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by an absence of dystrophin, a protein that helps keep muscle cells intact. The first symptoms are usually seen between 3 and 5 years of age and worsen over time. The disease often occurs in people without a known family history of the condition and primarily affects boys, but in rare cases it can affect girls. DMD occurs in about 1 in 3,600 male live-born infants worldwide.

People with DMD progressively lose the ability to perform activities independently and often require use of a wheelchair by their early teens. As the disease progresses, life-threatening heart and respiratory conditions can occur. Patients typically succumb to the disease in their 20s or 30s; however, disease severity and life expectancy vary. The U.S. Centers for Disease Control and Prevention (CDC) advises that early diagnosis could lead to more personalized care for each person living with muscular dystrophy and may give each of them a better chance to reach his or her full potential. The CDC has also found that there was an average of two and a half years between when a parent or caregiver noticed the first signs

and symptoms of DMD, and when a diagnosis of DMD was made.

The FDA reviewed the GSP Neonatal Creatine Kinase-MM kit through the de novo premarket review pathway, a regulatory pathway for low-to-moderate risk devices of a new type. During this process, the FDA evaluated data from a clinical study of 3,041 newborns whose dried blood samples were tested for protein levels that are associated with DMD. In the study, the kit was able to accurately identify the four screened newborns that had DMD-causing genetic mutations. The device manufacturer also tested 30 samples from newborns with clinically confirmed cases of DMD, all of which were correctly identified by the test.

Along with this authorization, the FDA is establishing criteria, called special controls, that must be met for tests of this type, including certain design verification, design validation and labeling requirements. When met, these special controls, along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This ac-





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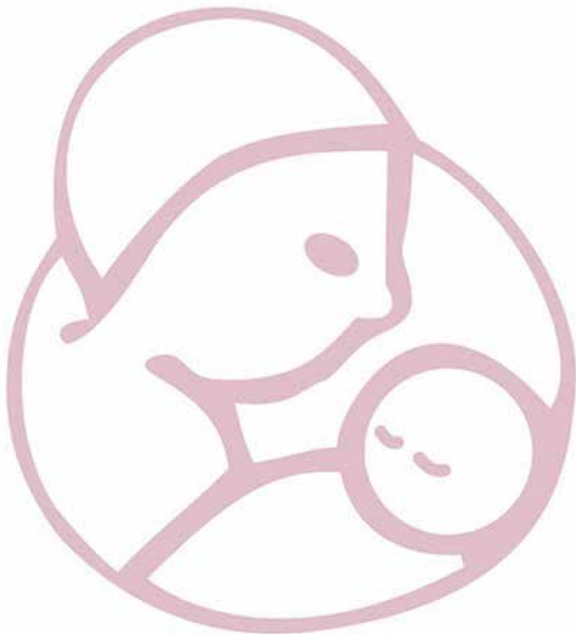
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tion also creates a new regulatory classification, which means that subsequent devices of the same type, with the same intended use, may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

Risks associated with use of the kit include false negative test results. As part of the clinical study, the device manufacturer performed genetic testing, an accepted method of diagnosing DMD, on 173 patient samples including a subset of patients identified as negative by the GSP Neonatal Creatine Kinase-MM kit. Genetic testing on the negative samples did not identify any DMD-causing genetic variants, confirming the negative screening results by the GSP Neonatal Creatine Kinase-MM kit.

The FDA granted marketing authorization of the GSP Neonatal Creatine Kinase-MM kit to PerkinElmer.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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NT

FDA sends warning to companies for offering unapproved umbilical cord blood products that may put patients at risk

Liveyon Labs Inc. and Liveyon LLC warned that their stem cell products lack required FDA approval and represent a potential risk to the public health

For Immediate Release:
December 06, 2019

The U.S. Food and Drug Administration has warned Liveyon Labs Inc. (Liveyon Labs) and Liveyon LLC, of Yorba Linda, California, and their presidents and chief executive officers, Roya Panah and John W. Kosolcharoen, for processing and distributing unapproved products derived from umbilical cord blood. They have also been warned regarding significant deviations from current good tissue practice (CGTP) and current good manufacturing practice (CGMP) requirements, including deficient donor eligibility practices, inadequate aseptic practices to prevent contamination and deficient environmental monitoring. These deviations create potential significant safety concerns that put patients at risk. The companies' unapproved products derived from umbilical cord blood are PURE and PURE PRO.

In addition to the warning letter issued to Liveyon Labs and Liveyon LLC earlier this month, the FDA sent untitled letters to Rich-Source Stem Cells, Inc., and Chara Biologics, Inc., for offering unapproved stem cell products to patients. The agency also recently sent 20 letters to manufacturers and health care providers noting that it has come to our attention that they may be offering unapproved stem cell products, reiterating the FDA's compliance and enforcement policy. "The FDA's mission includes protecting public health by helping to ensure the safety and efficacy of medical products that patients

rely on. The agency is aware that there are establishments who prey upon vulnerable populations by commercially marketing stem cell products with false and misleading claims about their effectiveness for treating serious diseases," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "The FDA is taking this action today because Liveyon Labs and Liveyon LLC failed to take appropriate measures to protect patient safety. As evidenced by the number of actions that the agency has taken this month alone, there are still many companies that have failed to come into compliance with the Federal Food, Drug, and Cosmetic Act and FDA's regulations during the period in which the agency intends to exercise enforcement discretion for certain products with respect to FDA's investigational new drug and premarket approval requirements, when the use of the product does not raise reported safety concerns or potential significant safety concerns. This period, which ends in November 2020, has allowed product manufacturers time to engage with the FDA to determine if they need to submit a marketing authorization application and, if so, seek guidance on how to submit their application to the FDA for approval. The agency continues to urge these manufacturers to engage with the agency about their regulatory requirements in the coming months."

An FDA inspection of the Liveyon Labs and Liveyon LLC facility in May revealed the companies were processing and distributing products derived from human umbilical cord blood for use in patients who were unrelated to the donors. Because these products are not intended for homologous use only (i.e., to perform the same basic function or functions in the recipient as in the donor) and fail to meet other criteria set forth in applicable FDA regulations, they are regulated as both drugs and biological products. Therefore, to lawfully market these products, an approved biologics license application is needed. While in the development stage, the products may be used in humans only if an investigational new drug application (IND) is in effect. However, no such licenses or INDs exist for the PURE and PURE PRO products marketed



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by Liveyon Labs and Liveyon LLC.


During the inspection, the FDA documented evidence of significant deviations from CGTP and CGMP requirements in the manufacture of the PURE and PURE PRO products, including deficient donor eligibility practices, such as failing to screen donors' relevant medical records for risk factors for communicable diseases; inadequate aseptic practices, such as failing to follow procedures to prevent microbiological contamination; and deficient environmental monitoring, such as failing to establish a system for cleaning and disinfecting the processing room and equipment. These deviations pose a significant risk that the products may be contaminated with viruses or other microorganisms or have other serious product quality defects, which could potentially lead to patient harm. In addition to the warning letter released today, the FDA has issued a safety alert about exosome products. Certain clinics across the country, including some that also manufacture or market violative "stem cell" products, are now also offering exosome products to patients. FDA's safety alert informs the public, especially patients, health care practitioners and clinics, of multiple recent reports

of serious adverse events experienced by patients in Nebraska who were treated with unapproved products marketed as containing exosomes. These reports were brought to the FDA's attention by the Centers for Disease Control and Prevention, among others, and the agencies worked with the Nebraska Department of Health and Human Services. The FDA is carefully assessing this situation along with our federal and state partners.

As highlighted in 2017 with the release of the FDA's comprehensive regenerative medicine policy framework, including the FDA's final guidance (Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use), the FDA is applying a risk-based approach to compliance and enforcement of cell-based regenerative medicine products, taking into account how products are being administered as well as the diseases and conditions for which they are intended to be used. The agency noted that it intends to exercise enforcement discretion for certain products until November 2020 with respect to the FDA's IND application and premarket approval requirements when the use of the product does not raise

reported safety concerns or potential significant safety concerns. However, the FDA does not intend to exercise such enforcement discretion for those products that pose a reported safety concern or a potential significant safety concern to patients. As reflected by this warning letter and other correspondence issued by the agency, the FDA will continue to take appropriate steps to protect the public health.

The FDA continues to facilitate the development of safe and effective cellular therapies and offers opportunities for engagement between potential manufacturers and the agency, such as through the INTERACT program. The agency also encourages the use of its expedited programs whenever applicable, in addition to a collaborative development of products with industry and the agency. In addition, the FDA recently announced a temporary program called the Tissue Reference Group (TRG) Rapid Inquiry Program (TRIP), which is intended to assist manufacturers of human cells, tissues and cellular and tissue-based products (including stem cells) to obtain a rapid, preliminary, informal, non-binding assessment from the agency regarding how their specific



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products are regulated.

The FDA requested a response from Liveyon Labs and Liveyon LLC within 15 working days of the letter's issuance that details how the deviations noted in the warning letter will be corrected. Deviations not corrected by the companies and responsible individuals could lead to enforcement action such as seizure, injunction or prosecution.

Health care professionals and consumers should report any adverse events related to treatments with the PURE or PURE PRO products or other stem cell treatments to the FDA's MedWatch Adverse Event Reporting program. To file a report, use the MedWatch Online Voluntary Reporting Form. The completed form can be submitted online or via fax to 1-800-FDA-0178. The FDA monitors these reports and takes appropriate action necessary to ensure the safety of medical products in the U.S. marketplace.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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NT

FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns

Violations include marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human, animal foods

For Immediate Release:

November 25, 2019

Today, the U.S. Food and Drug Administration issued warning letters to 15 companies for illegally selling products containing cannabidiol (CBD) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA also published a revised Consumer Update detailing safety concerns about CBD products more broadly. Based on the lack of scientific information supporting the safety of CBD in food, the FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.

Today's actions come as the FDA continues to explore potential pathways for various types of CBD products to be lawfully marketed. This includes ongoing work to obtain and evaluate information to address outstanding questions related to the safety of CBD products, while maintaining the agency's rigorous public health standards. The FDA plans to provide an update on its progress regarding the agency's approach to these products

in the coming weeks.

"As we work quickly to further clarify our regulatory approach for products containing cannabis and cannabis-derived compounds like CBD, we'll continue to monitor the marketplace and take action as needed against companies that violate the law in ways that raise a variety of public health concerns. In line with our mission to protect the public, foster innovation, and promote consumer confidence, this overarching approach regarding CBD is the same as the FDA would take for any other substance that we regulate," said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. "We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD 'can't hurt.' Aside from one prescription drug approved to treat two pediatric epilepsy disorders, these products have not been approved by the FDA and we want to be clear that a number of questions remain regarding CBD's safety – including reports of products containing contaminants, such as pesticides and heavy metals – and there are real risks that need to be considered. We recognize the significant public interest in CBD and we must work together with stakeholders and industry to fill in the knowledge gaps about the science, safety and quality of many of these products."

Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. The revised Consumer Update outlines specific safety concerns related to CBD products, including potential liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood. In

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addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels and impair sexual behavior in males. Questions also remain about cumulative use of CBD and about CBD's impacts on vulnerable populations such as children and pregnant or breastfeeding women.

CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, food products such as chocolate bars and teas, and topical lotions and creams. As outlined in the warning letters issued today, these particular companies are using product webpages, online stores and social media to market CBD products in interstate commerce in ways that violate the FD&C Act, including marketing CBD products to treat diseases or for other therapeutic uses for humans and/or animals. Other violations include marketing CBD products as dietary supplements and adding CBD to human and animal foods.

The companies receiving warning letters are:

- Koi CBD LLC, of Norwalk, California
- Pink Collections Inc., of Beverly Hills, California
- Noli Oil, of Southlake, Texas
- Natural Native LLC, of Norman, Oklahoma
- Whole Leaf Organics LLC, of Sherman Oaks, California
- Infinite Product Company LLLP, doing business as Infinite CBD, of Lake-wood, Colorado
- Apex Hemp Oil LLC, of Redmond, Oregon
- Bella Rose Labs, of Brooklyn, New York
- Sunflora Inc., of Tampa, Florida/Your CBD Store, of Bradenton, Florida
- Healthy Hemp Strategies LLC, doing business as Curapure, of Concord, California
- Private I Salon LLC, of Charlotte, North Carolina
- Organix Industries Inc., doing busi-

ness as Plant Organix, of San Bernardino, California

- Red Pill Medical Inc., of Phoenix, Arizona
- Sabai Ventures Ltd., of Los Angeles, California
- Daddy Burt LLC, doing business as Daddy Burt Hemp Co., of Lexington, Kentucky

The FDA has previously sent warning letters to other companies illegally selling CBD products in interstate commerce that claimed to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, or otherwise violated the FD&C Act. Some of these products were in further violation because CBD was added to food, and some of the products were also marketed as dietary supplements despite products which contain CBD not meeting the definition of a dietary supplement.

Under the FD&C Act, any product intended to treat a disease or otherwise have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. The FDA has not approved any CBD products other than one prescription human drug product to treat rare, severe forms of epilepsy. There is very limited information for other marketed CBD products, which likely differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body.

Unlike drugs approved by the FDA, there has been no FDA evaluation of whether these unapproved products are effective for their intended use, what the proper dosage might be, how they could interact with FDA-approved drugs, or whether they have dangerous side effects or other safety concerns. In addition, the manufacturing process of unapproved CBD drug products has not been subject to FDA review as part of the human or animal drug approval processes. Consumers may also put off getting important medical care, such as proper diagnosis, treatment and supportive care due to unsubstantiated claims associated with CBD products. For that reason, it's important that consumers talk to a health care professional about the best way to treat diseases or conditions with existing, approved treatment options.

Additionally, some of the products outlined in the warning letters issued today raise other legal and public health concerns:

Some of the products are marketed for infants and children – a vulnerable population that may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute or excrete a substance such as CBD.

Some of the products are foods to which CBD has been added. Under the FD&C Act, it is illegal to introduce into interstate commerce any human or animal food to which certain drug ingredients, such as CBD, have been added. In addition, the FDA is not aware of any basis to conclude that CBD is GRAS among qualified experts for its use in human or animal food. There also is no food additive regulation which authorizes the use of CBD as an ingredient in human food or animal food, and the agency is not aware of any other exemption from the food additive definition that would apply to CBD. CBD is therefore an unapproved food additive, and its use in human or animal food violates the FD&C Act for reasons that are independent of its status as a drug ingredient.

Some of the products are marketed as dietary supplements. However, CBD products cannot be dietary supplements because they do not meet the definition of a dietary supplement under the FD&C Act.

One product outlined in a warning letter to Apex Hemp Oil LLC is intended for food-producing animals. The agency remains concerned about the safety of human food products (e.g. meat, milk, and eggs) from animals that consume CBD, as there is a lack of data establishing safe CBD residue levels.

The FDA has requested responses from the companies within 15 working days stating how the companies will correct the violations. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction.

The FDA encourages human and animal health care professionals and consumers to report adverse reactions associated with these or similar products to the agency's MedWatch program.

The FDA, an agency within the U.S. Department of Health and Human Services,

promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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NT

Collaboration and Competency Criteria Key to Addressing Neonatal Provider Workforce Challenges

New document addresses issues of challenge in providing Neonatal Care.

11/18/2019

With collaboration among neonatal intensive care unit (NICU) providers increasingly important, a new American Academy of Pediatric technical report outlines the training and practice scope of different professionals who care for high-risk, hospitalized newborns. The "Neonatal Provider Workforce" report in the December 2019 Pediatrics (published online Nov.18) also suggests ways to establish and monitor quality and safety of care, as well as potential solutions to current and future NICU provider workforce shortages. Accreditation Council for Graduate

Medical Education changes to how many consecutive hours physicians-in-training can work has limited the availability of pediatric residents to care for patients in the NICU. As a result, much of the care provided in NICUs has shifted from residents onto other providers, such as pediatric hospitalist physicians, neonatal nurse practitioners (NNPs), and physician assistants (PAs). At the same time, a growing national shortage of NNPs and insufficient numbers of PAs and pediatric hospitalists practicing in neonatal intensive care challenges many programs' abilities to adequately staff their NICUs. Some are using various providers in different roles across NICU settings. The AAP outlines ways that could help address provider workforce shortage and reduce the workload to improve outcomes and decrease provider "burn out." It also recommends developing and periodically reviewing competency criteria for all NICU providers, perhaps using the well-established training model for NNPs, to ensure high-quality, safe, and cost-effective care.

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Call for Abstracts: Due Monday, October 28, 2019



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

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American Academy of Pediatrics: Universal Screening Urged for Developmental Delays

The AAP supports universal screening for developmental delay.

12/16/2019

The American Academy of Pediatrics (AAP) equips pediatricians with new clinical recommendations to screen young children for developmental delays, autism and behavioral problems in a newly published clinical report that updates 2006 recommendations.

“Promoting Optimal Development: Identifying Infants and Young Children with Developmental Disorders Through Developmental Surveillance and Screening,” encourages pediatricians to work closely with families and incorporate input from preschool educators and childcare providers into their patient evaluations. The report is published in the January 2020 Pediatrics (Dec. 16 online).

“Through comprehensive screenings, we hope to identify problem areas and missed milestones before a child turns 3,” said Paul H. Lipkin, MD, FAAP, lead author of the clinical report. “With

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99nicu

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

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



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

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

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

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

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



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continued surveillance, early learning and attention problems often become more apparent by age 4 or 5. The earlier we can address these problems, the better.”

The AAP describes children who are at higher risk of developmental or behavioral delays, based on their medical history or adverse experiences, such as poverty, effects of racism, abuse or neglect. The AAP Council on Children With Disabilities and the AAP Section on Developmental and Behavioral Pediatrics worked together to author the report, which calls for a unified system of screening. The report provides a new clinical algorithm to guide clinicians, as well as a table of developmental and behavioral screening tools that may be used in pediatric practice.

The AAP provides recommendations for the medical home, for policy and advocacy, and for research and development. They include:

- Physicians should perform developmental surveillance at every well child visit from early childhood through adolescence.
- Physicians should refer a child to early intervention or preschool special education as well as for complete developmental and medical evaluations when the child is determined to be at risk for a developmental disorder based on screening or surveillance.
- Standardized developmental screenings should be conducted at the 9-, 18-, and 30-month well-child visits. In addition, physicians should administer a screening for autism spectrum disorder during the 18- and 24-month health supervision visits.
- Medical providers should identify and address barriers to screening in the medical home -- such as payment, profes-

sional education and office workflow -- to achieve universal screening of all children during early childhood.

- Ongoing investigation into screening and referral rates should continue, with the goal of achieving universal screening of all children.
- More research should be conducted to increase the evidence base for effectiveness of developmental surveillance and screening tools.
- “Research tells us that, as children grow older, problems with development or behavior may worsen in severity if they go undetected,” said Michelle M. Macias, MD, FAAP, coauthor of the AAP report.

“We encourage families to tell their doctor what they have noticed about their children’s milestones and behavior, as well as any concerns that other care providers have shared with them about their child. There are helpful therapies and sometimes medical treatments that can ease those symptoms considerably.”

###

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

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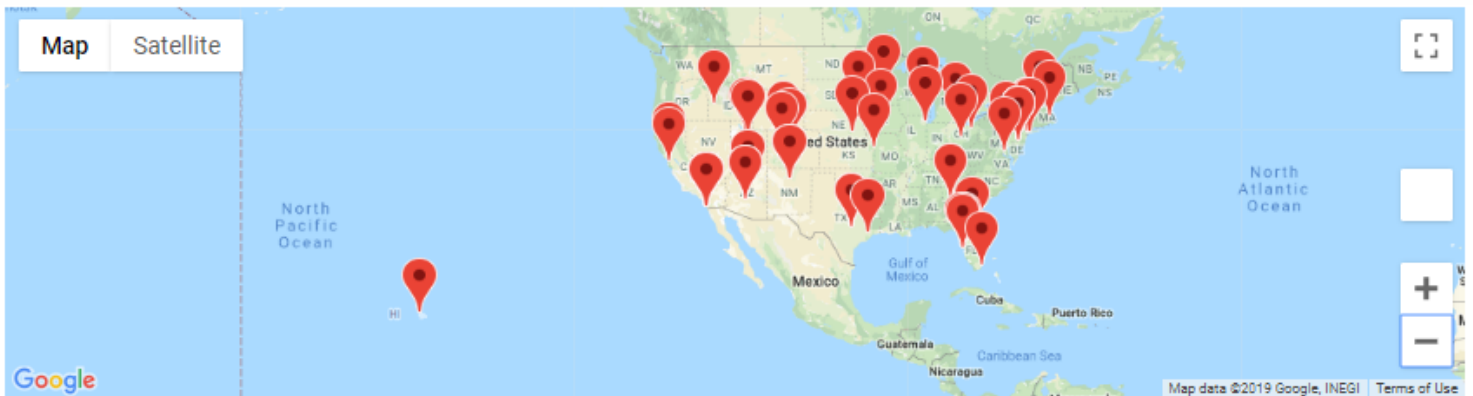
The Neonatal Intensive Care Unit Directory - New Web Resources

Scott Snyder, MD



"Neonatology Solutions continues to methodically grow our NICU Directory into what will ultimately be the most comprehensive go-to resource for NICU and Neonatology Practice content on the web. With the recent additions of NICUs from KY, TN, VA, NC, SC, VT, ME, NH, MA, CT, and RI, we have grown to 650 NICUs within the Directory. We have received very positive feedback regarding the search functionality that allows users to find NICUs and contact information by State, NICU level, AAP District, city size, and especially the "Currently Hiring" feature. There are now 60 neonatology job postings listed, with more being added regularly. Next up are the daunt-

"Additionally, we've been hard at work improving the functionality of the Upcoming Conference page. Networking and education are a key focus for not only neonatology fellows but also practicing Neos, and as such, we have added map-based search features to our Neonatology Conference roster."



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2019

DECEMBER

December 8 - 11, 2019

Conference: [Hot Topics in Neonatology](#)

Organization: Nemours Children's Health System

Location: National Harbor, Maryland

December 11, 2019

Conference: [PAPQC Learning Collaborative](#)

Organization: Pennsylvania Perinatal Quality Collaborative

Location: Harrisburg, Pennsylvania

International

Click on map marker for conference details.



December 12 - 15, 2019

Conference: [Neocon](#)

Organization: National Neonatology Forum

Location: Hyderabad, India

February 13 - 14, 2020

Conference: [2nd Launch \(Lung Ultrasound in Neonates and Children\)](#)

Organization: MCA Scientific Events

Location: Paris, France

ing and populous states of NY, TX, CA, and FL. Should you wish to assist us in this endeavor, please visit the site, check the programs in your region, and share any missing or erroneous information with us via the easy to use site links.

Additionally, we've been hard at work improving the functionality of the Upcoming Conference page. Networking and education are a key focus for not only neonatology fellows but also practicing Neos, and as such, we have added map-based search features to our Neonatology Conference roster. Education and network opportunities can now be easily located both by the time of year as well as regionally. Currently, there are 51 perinatal-neonatal medicine conferences scheduled domestically in the U.S., and nine internationally.

If you have a conference you would like to post; you can provide your information here: Add Your Conference <https://neonatalogysolutions.com/add-your-neonatology-conference-here/> or you can email Celinda Snyder directly at celinda@neonatalogysolutions.com.

Thanks to those who have visited the site and let us know how we can continue to make this a valuable tool for Neonatologists and all who are passionate about caring for newborns."

References:

1. <https://neonatalogysolutions.com/explore-nicus-and-programs/>

The author is a principal of Neonatology Solutions, LLC.

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NCfIH National Coalition for Infant Health

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 *Based on a 2018 study published in Pediatrics. <https://doi.org/10.1542/peds.2018-000000>
 †Based on a 2018 study published in Pediatrics. <https://doi.org/10.1542/peds.2018-000000>
 ‡Based on a 2018 study published in Pediatrics. <https://doi.org/10.1542/peds.2018-000000>
 §Based on a 2018 study published in Pediatrics. <https://doi.org/10.1542/peds.2018-000000>
 ¶Based on a 2018 study published in Pediatrics. <https://doi.org/10.1542/peds.2018-000000>

Genetics Corner: Genetic Counseling and Family Screening after Prenatal Diagnosis Of Hypoplastic Left Heart Syndrome: Is It Warranted?

Robin Clark, MD and Nivedita Rajakumar, MA, MS

Case Summary:

A 33-year old G2P1 Lebanese woman was referred for consultation to high-risk obstetrics at an outside hospital because of pre-term delivery at 34 weeks gestation in her first pregnancy. The nuchal translucency measurement and first trimester maternal serum screening tests were normal in the current pregnancy. A comprehensive fetal ultrasound exam at 18 weeks gestation revealed a small left ventricle, suggesting hypoplastic left heart syndrome in an otherwise normal male fetus. The patient was referred to our institution for a fetal echocardiogram that confirmed hypoplastic left heart syndrome with severe hypoplasia of the left ventricle, mitral hypoplasia, aortic atresia, and endocardial fibroelastosis. In anticipation of the need for cardiac surgery after delivery, her prenatal care was transferred to our tertiary care facility. Although tricuspid regurgitation was noted on subsequent fetal echocardiograms, interval fetal growth was appropriate, and no extracardiac anomalies were present. The patient and her partner, who is also Lebanese, were counseled about the poor prognosis for survival, and, at 36.5-weeks' gestation, they are considering palliative care versus surgical repair. The patient denied other affected relatives. The pediatric cardiologist recommended genetic testing after delivery.

The Challenge:

The prenatal genetic counselor suggested a genetic counseling appointment and screening echocardiograms for family members, but the maternal-fetal medicine attending physician felt that this was not indicated. We took up the challenge posed by our MFM colleague and sought data to address his concerns:

1. Is genetic counseling warranted in families with prenatally diagnosed isolated HLHS in the absence of other anomalies or positive family history?
2. Is a screening echocardiogram justified in the first-degree relatives of patients with HLHS?

Summary of Medical Literature:

Hypoplastic left heart syndrome (HLHS) is the most severe expression of left ventricular outflow tract obstruction (LVOTO), which describes a related group of congenital left-sided heart defects that includes Shone complex, coarctation of the aorta (COA), congenital aortic valve stenosis (AVS) and bicuspid aortic valve (BAV). Familial clustering of LVOTO lesions has been reported in many epidemiologic studies and prospective studies of first-degree relatives of affected patients.

BAV and/or thoracic aortic aneurysm (TAA) are inherited in an autosomal dominant manner with variable expression and incomplete penetrance (OMIM 109730). Isolated aortopathy or TAA has been reported in first-degree relatives of patients with BAV. The incidence of BAV in first-degree family members of individuals with BAV is as high as 9-10%, and routine echocardiographic screening of all first-degree relatives has become standard practice at many institutions. The 2010 guidelines endorsed by the American College of Cardiology/American Heart Association and the American Association for Thoracic Surgery include a class I recommendation that first-degree relatives of patients with BAV undergo screening for BAV and asymptomatic thoracic aortic disease.

Given the risk of early dissection and death, ongoing echocardiographic screening of relatives at regular intervals is recommended by some authors whether BAV is present or not.

“An increased incidence of congenital cardiovascular malformations in family members of HLHS probands was first reported by Brenner et al. (1989) in the Baltimore-Washington Infant Study. These authors found cardiac anomalies in 5/41 relatives (12%) of 11 patients with isolated HLHS.”

The incidence of congenital cardiovascular malformations in first-degree relatives of patients with HLHS is even higher. An increased incidence of congenital cardiovascular malformations in family members of HLHS probands was first reported by Brenner et al. (1989) in the Baltimore-Washington Infant Study. These authors found cardiac anomalies in 5/41 relatives (12%) of 11 patients with isolated HLHS. Since that time, a variety of primarily left-sided cardiac lesions has been reported in up to 17% of family members of HLHS probands.

Hypoplastic left heart syndrome has been described in families with both autosomal dominant and autosomal recessive inheritance patterns (OMIM 241550, 614435). Wessels et al. (2005) described four families with a presumed autosomal dominant inheritance of LVOTO: some members had severe anomalies such as HLHS, and others had only AVS. The authors concluded that all anomalies of the LVOTO spectrum are developmentally related.

Hinton et al. (2007) studied 38 probands with HLHS and their families. Overall, 21 of 38 (55%) families had more than one affected individual. The heritability of HLHS alone and with associated cardiovascular malformations was 99% and 74%, respectively. The sibling recurrence risk for HLHS was 8% (4/51), and for cardiovascular malformations, 22% (11/51).

McBride et al. (2005) studied 124 families ascertained by an index case with AVS, COA, or HLHS. Results were positive in 32/413 relatives (7.7%): LVOTO malformations were detected in 30 relatives, and significant congenital heart defects in 2 others. The relative risk for first-degree relatives in this group was 36.9, with a heritability of 0.71-0.90, implying a complex but most likely oligogenic pattern of inheritance.

In their review of 52 HLHS probands, Kelle et al. (2015) obtained echocardiograms on 152/188 first-degree relatives, with complete screening performed on 34/52 families. A cardiovascular anomaly was identified by echocardiography in 17/152 (11.2%), and 11/17 diagnoses (65%) were previously unknown. Overall, at least one affected family member was identified with a cardiovascular malformation in 14/52 families (26.9%). There was more than one affected relative in 3/52 families. Abnormalities were found in 5/46

fathers (10.9%), 5/51 mothers (9.8%), and 7/55 siblings (12.7%). Four relatives had isolated BAV, and one relative had BAV with dilated aortic root and COA for a total incidence of BAV in 3.3% (5/152). Four family members had aortic dilation with normal valves. One mother, who had a history of chest pain with exercise, had an anomalous origin of the right coronary artery that required surgery. Interestingly, chromosome microarray identified duplications or deletions in 9/48 probands, but no significant difference in the occurrence of familial cardiac lesions was observed based on proband microarray anomaly.

“This supports our recommendation for genetic counseling and screening first-degree relatives following the prenatal or postnatal diagnosis of HLHS, even when it is present as an isolated anomaly and without a significant family history.”

Conclusions:

Data from various reports in the medical literature support the high heritability of LVOTO lesions and specifically the genetic nature of HLHS. This supports our recommendation for genetic counseling and screening first-degree relatives following the prenatal or postnatal diagnosis of HLHS, even when it is present as an isolated anomaly and without a significant family history. Genetic counselors have an important role in the management of HLHS by documenting the family history, counseling families about the increased recurrence risks for cardiovascular malformations in general, and HLHS in particular and supporting efforts to screen first-degree relatives.

Practical Applications:

1. Recognize that HLHS is a genetic disorder with an increased recurrence risk for HLHS and other cardiovascular malformations in future pregnancies.
2. Refer families of patients with HLHS for genetic counseling.
3. Document congenital cardiovascular malformations in the family by taking a careful three-generation family history.
4. Inform family members of individuals with HLHS and other LVOTO about the increased risk of asymptomatic thoracic aortic dilation and/or BAV and subsequent increased risk for aortic aneurysm and dissection
5. Recommend screening echocardiograms for first-degree relatives of patients with HLHS and other LVOTO lesions

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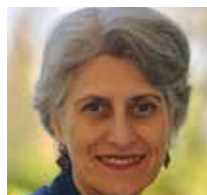
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The authors have no relevant disclosures.

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Perinatal Substance Use

5 ways you can improve care during pregnancy and beyond

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



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



Use the Right Words

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



Screen Every Patient

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



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

*opioid treatment program



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TOP 10



RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

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

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

1 PROMOTE PARTICIPATION

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



2 LEAD IN DEVELOPMENTAL CARE

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



3 FACILITATE PEER SUPPORT

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



4 ADDRESS MENTAL HEALTH

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



5 SCREEN EARLY AND OFTEN

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



6 OFFER PALLIATIVE & BEREAVEMENT CARE

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

7 PLAN FOR THE TRANSITION HOME

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



8 FOLLOW UP

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

9 SUPPORT NICU CARE GIVERS

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



10 HELP US HEAL

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

SUPPORT4NICUPARENTS.ORG

From The National Perinatal Information Center: Do You Know Your Community? NICU Care within the Lens of Social Determinants of Health

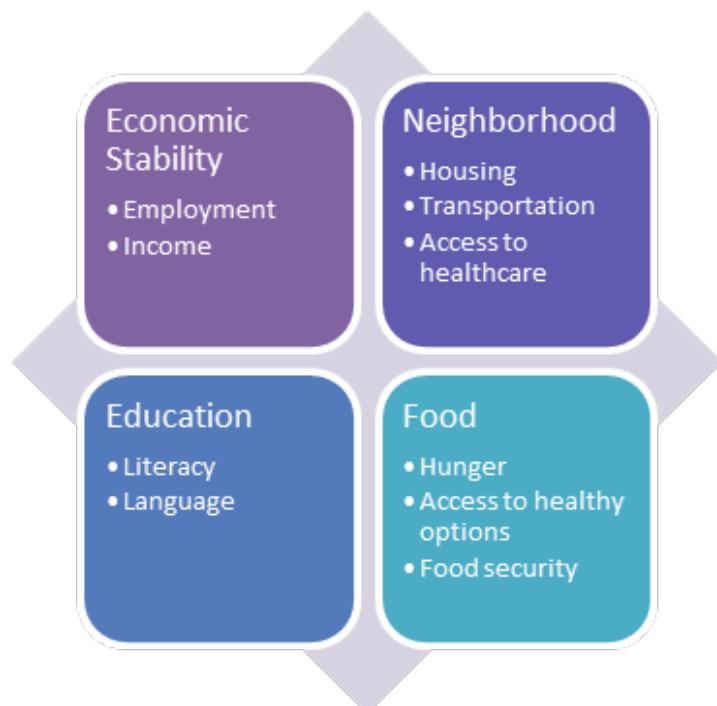
Elizabeth Rochin, PhD, RN, NE-BC

The National Perinatal Information Center (NPIC) is driven by data, collaboration and research to strengthen, connect and empower our shared purpose of improving patient care.

For over 30 years, NPIC has worked with hospitals, public and private entities, patient safety organizations, insurers and researchers to collect and interpret the data that drives better outcomes for mothers and newborns.



Social Determinants of Health (SDOH) are the conditions in which individuals are born into, live, grow and work. These include areas such as education, economic stability, neighborhood, safety, and food availability. (1) Understanding these facets of care is critical in any care setting, but particularly the NICU, which provides a unique lens into those social determinants which can yield significant hardship for parental bonding and involvement. Examples of Social Determinants that can impact NICU families include:



Over the past several years, Social Determinants of Health (SDOH) have been of keen interest to clinicians and researchers alike, endeavoring to discern opportunities to positively influence care in clinical settings such as the NICU as well as in communities in which families and newborns live. However, understanding the community influences on prematurity and maternal health cannot be overstated as these forces are inextricably linked. Recognition of community and social influencers on care is a starting point, but only if those influencers are identified during care. Of late, there has been tremendous emphasis on Social Determinants of Health, particularly from a documentation standpoint. In ICD-10, there is a category known as Z-Codes, specifically Z-Codes 55-65, Persons with Potential Health Hazards related to Socioeconomic and Psychosocial Circumstances. It is important to note that the American Hospital Association in 2019 clarified that all coding professionals could use documentation from providers and clinicians (nurses, case managers, discharge planners, etc.) to facilitate documentation of social determinants. (2) Several examples of these SDOH include:

- Z55: Problems related to education and literacy
- Z56: Problems related to employment and unemployment
- Z55.0: Illiteracy and low level literacy
- Z59.0: Homelessness
- Z59.1: Inadequate housing
- Z59.4: Lack of adequate food and safe drinking water
- Z59.6 Low income
- Z62.810: Personal history of physical and sexual abuse in childhood
- A full listing of the current Z-Codes can be found at <https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z55-Z65>

While the Social Determinants of Health may not be directly related to the newborn, the mother's social determinants may create barriers to her ability to bond and be present for her baby in the NICU. For example, homelessness is a tremendous challenge that impacts new mothers across the nation. Compared to women who were not homeless, homeless women were 2.9 times more likely to have a preterm delivery and 6.9 times more likely to have a baby with low birth weight even after applying other risk adjustment factors. (3) Two studies exploring newborns and homelessness (4-5) revealed increased

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incidences of respiratory infection, hospitalization and overall higher healthcare costs after discharge to shelters. Adequate screening during pregnancy and the postpartum period can ensure social needs are identified and addressed prior to delivery and during hospitalization. Long hospitalizations in the NICU may require frequent social assessments as situations may change over time, particularly for mothers and families at risk. More importantly, documentation of these determinants can provide critical information that can drive population analyses to inform health policy.

The National Perinatal Information Center (NPIC) has been reviewing aggregated Social Determinants data from the NPIC Perinatal Center Database and has initiated conversations with member hospitals on the importance of Social Determinants documentation to better identify and respond to the community needs of mothers and newborns. This discussion will use the aggregated data from July 1, 2018 – June 30, 2019. Review and verification of coded data is essential and should be standard practice to ensure accurate reporting of diagnoses and conditions.

During this time, there were 378,857 MDC-14 discharges, and there are several observations that deserve mention:

1. Z59, Problems related to housing and economic circumstances: 586 reports, including 507 reports of homelessness.
2. Z62.810: Personal history of physical and sexual abuse during childhood: 397 patients reported abuse in their history.
3. A total of 1,815 Social Determinants Z Codes were abstracted from patient charts, including events such as unemployment, deployment of family member, or problems with a spouse.
4. It is also important to note that there were situations in which a single patient reported more than one (1) health-related social circumstance during their care.

Within the NICU, these and other identified social determinants could have tremendous impact on the engagement of parents and discharge plan for a newborn, particularly a newborn discharged with complex healthcare needs. There continues to be conversation surrounding frequency and prevalence of Social Determinants. Even if 10% of the general population met at least one (1) health-related social circumstance, this would yield approximately 37,000 events in this particular cohort. If this is true, then the SDOH challenges from this particular population are grossly underrepresented and under reported. Collaboration among caregivers to complete social assessments are critical, particularly in situations that include NICU care. Transportation, parking, meals and childcare can place a heavy burden on families who find themselves the parent(s) of a newborn with complex health challenges.

So, back to the question, “Do you know your community?” Here are several opportunities to better inform care and policy that can drive community resources closer to home:

1. Utilize Z-Codes in documentation. While reimbursement does not yet exist broadly for SDOH, population health studies and capturing data to support local and national decisions is critical.
2. Documentation of Z-Codes is a team sport. Provide awareness and education for Z Codes, and create policies that support the utilization of both provider and clinician reports of social determinant challenges included in documentation.
3. Community resource availability. Greater understanding of Z-codes will also generate discussion of what types of resources exist—and don't exist—within a community. Population data can support the necessity for new and innovative programs to meet the needs of families where they are, particularly in rural and access-challenged areas.

However, there are important considerations for initiating or broadening the screening for Social Determinants. Garg and colleagues (6) caution that screening in isolation and without a plan for referral and appropriate treatment is ineffective and “arguably unethical.” Screening for Social Determinants should always include the patient and family in the process of referral and to engage in shared decision-making when offering referral options. In addition, screening must include all patients and not exclude populations based upon assumptions. Situations that negatively impact the health of a mother carry tremendous risk to negatively impact the health of a newborn, particularly a sick newborn.

Achieving health equity, access to care and guiding teams to fulfilling their mission of service to families and communities will require a robust approach and a community of caring—both inside and outside the walls of the NICU.

Resources

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Advocating for the Health
 and Wellbeing of Families

early identification



of 1 in 7 moms

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specialized help



for at-risk dads

expert care for

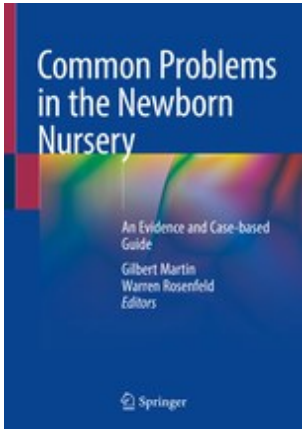


the full spectrum
 of disorders

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



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While this guide is directed towards health care providers such as pediatricians, primary care physicians, and nurse practitioners who treat newborns, this book will also serve as a useful resource for anyone interested in working with this vulnerable patient population, from nursing and medical students, to nurses and residents in pediatrics or family practice.

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Babies Benefit When Mom Eats More Seafood

Susan Hepworth and Mitchell Goldstein, MD



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

New information on seafood consumption during pregnancy could have more mothers-to-be heading to the fish market.

Research reveals that children of mothers who eat seafood, as compared to those whose mothers do not, have:

- An average IQ of 7.7 points higher
- Higher attainment rate of milestones at six and 18 months
- No adverse effects even at the highest seafood consumption levels.

The study looked at seafood consumption during pregnancy and early childhood for 102,944 mother-child pairs and 25,031 individual children. (1)

The findings build on existing nutritional wisdom. The Food and Drug Administration, the Environmental Protection Agency, and the Dietary Guidelines for Americans all advise pregnant women to eat two to three servings of seafood each week. (2)

“The Food and Drug Administration, the Environmental Protection Agency, and the Dietary Guidelines for Americans all advise pregnant women to eat two to three servings of seafood each week. (2)”



Certain seafood that is low in mercury and high in omega-3 fatty acids are particularly healthy. These include:

- Salmon
- Anchovies
- Herring
- Sardines
- Freshwater trout
- Pacific mackerel

“Although there are other ways to introduce mega-3 fatty acids into the diet including certain foods like faxseed, canola oil, walnuts, sunflower seeds, and even soybeans, fish also contains significant amounts of Docosahexaenoic acid, or DHA , which may be important in brain development. (3)”

Other fish that are recommended but that do not have as much omega-3 fatty acids include:

- Shrimp
- Pollock
- Tilapia
- Cod
- Catfish
- Canned light tuna (no more than 6 oz per week of all tuna)



There are specific other guidelines for pregnant women to consume the best quality seafood. These should be followed. Larger predatory fish that are “on top of the food chain” such as shark, swordfish, king mackerel, or tilefish can have excessive mercury and should be avoided. Uncooked or poorly cooked fish and shellfish may contain excessive bacteria and viruses. (3) These include

- Oysters
- Sushi
- Sashimi
- Lox
- Kippered herring
- Fish that is labeled as smoked or jerky

Local fish advisories or warnings should be followed, and all seafood should be cooked thoroughly. Fish is safest when the temperature is ~150 F and when it separates into opaque flakes. All shellfish should be cooked until their shells open and should not be eaten if the shell does not open. Finally, shrimp and lobster should be cooked until no longer translucent. (3)

Although there are other ways to introduce mega-3 fatty acids into the diet including certain foods like faxseed, canola oil, walnuts, sunflower seeds, and even soybeans, fish also contains significant amounts of Docosahexaenoic acid, or DHA , which may be important in brain development. (3)

Nevertheless, many mothers-to-be avoid or under consume seafood. That may be because of persistent myths about prenatal fish consumption. Some misconceptions linger due to early government recommendations and revisions, which lacked concrete evidence and created confusion. Media have played a role, too, sensationalizing risks and downplaying proven benefits.



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Today, however, an abundance of information enables agencies to make concrete, evidence-based nutritional recommendations. Pregnant women can make nutrition decisions based on two certainties: Fish and shellfish provide immense benefits to developing babies both before and after birth. Moreover, benefits increase as seafood consumption increases, though even the lowest levels of consumption can boost babies' development.(4)

Mothers want to do what is best for their babies. With the help of precise data on prenatal fish consumption and a unified voice from nutritional authorities, more mothers will be able to do just that.

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NT



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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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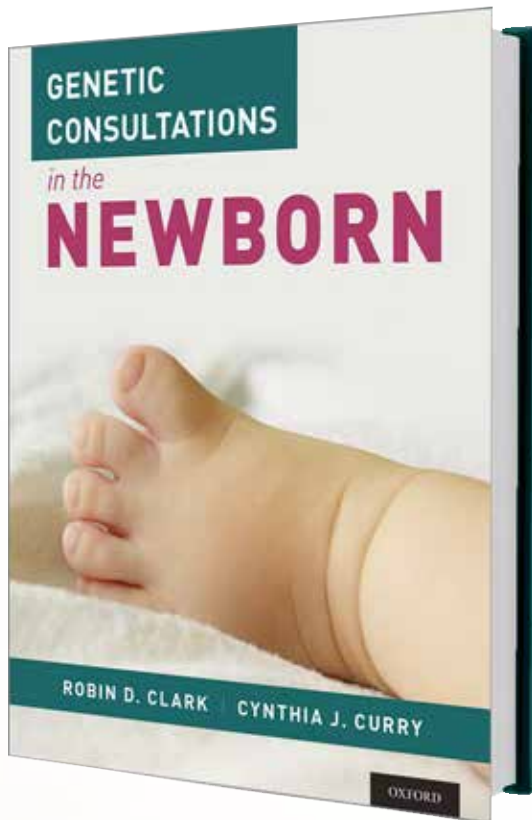
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RSV AWARENESS:

A National Poll of Parents & Health Care Providers

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

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

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

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

KEY FINDINGS

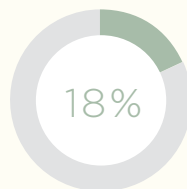
Preparedness

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

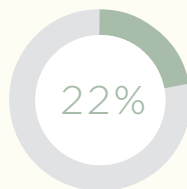
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

PARENTS

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

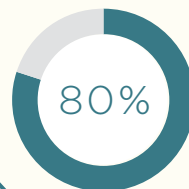


Only 22% of parents consider themselves “very well prepared” to prevent RSV.

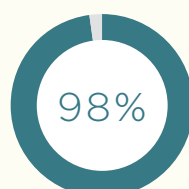


SPECIALTY HEALTH CARE PROVIDERS

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



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



Clinical Pearl: “This is a Great Idea, So Let’s Just Do It”: Implementation Science

Joseph R. Hageman, MD

This is a great idea, so let’s just do it! Why can’t we just implement this new NICU discharge checklist into the EPIC electronic medical record and get started? We can set up a short staff and caregiver survey starting pre-intervention, and then also use the same survey post-implementation to judge the effect on staff and caregiver satisfaction.

Joe, you will need to present this to nursing leadership, the clinicians, and don’t forget legal, and the survey needs to be written at the appropriate educational level. What about intrinsic bias, and have you done your power calculations to figure out how many surveys you will need to show a statistically significant effect? Does it need to be reviewed by the IRB or is this a QI project to improve clinical care?

There is a relatively new discipline; at least it is new to me, called implementation science. I just learned about it yesterday at a Grand Rounds presentation by Dr. Meghan Lane-Fall, an anesthesia-critical care physician from the University of Pennsylvania. Parenthetical my, I have been working with her on a quality improvement panel presentation for Society for Critical Care Medicine (SCCM) for the 2020 meeting.

So, what exactly is implementation science? My first impression, as I was listening, was that it is a name for a process for what I have been trying to implement in NICU and pediatric resident class quality improvement projects for the last five years here. The strategy I have used for has been “just do it!”. This implementation approach has met with some success and a somewhat random process, which has taken a long time.

“So, what exactly is implementation science? My first impression, as I was listening, was that it is a name for a process for what I have been trying to implement in NICU and pediatric resident class quality improvement projects for the last five years here. The strategy I have used for has been ‘just do it!’”

Here is the definition of implementation science from an article by Dr. Lane-Fall and co-authors: “scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and hence to improve the quality and effectiveness of health services and care” (1,2). As Dr. Lane-Fall also notes, implementation science is a

term used in the United States. However, this is also referred to as “dissemination and implementation research” and “knowledge translation” (2). What is helpful in this introductory article is the “subway line” approach, which helps to explain implementation science further and also distinguish it from other related disciplines (Figure). (2)

Thinking about implementation science in a simplistic way, your practice of interest should have been shown to be effective before you move ahead to do your implementation studies. The effectiveness or efficacy should be established. In order to be able to make an informed decision about the effectiveness of the practice, the investigators will need to have a sufficient research knowledge base. The implementation science part of the subway diagram is in green in the figure for your reference.

In her presentation, she explained the design of the study about how to redesign patient handoffs when the patient, in this study, adults, comes to the intensive care unit from the operating room. A team bedside meeting, which included the patient, nurse, intensive care physician, surgeon, anesthesiologist, and respiratory therapist, was convened, and the patient was discussed and examined in a systematic, standardized fashion. On average, this meeting took about 7-8 minutes, and the researchers studied patient data omissions, staff satisfaction qualitatively, and direct observation. The project was entitled Handoffs and Transitions in Critical Care (HATRICC), and over time, the bedside meetings were referred to as “let’s HATRICC this patient!” The protocol significantly improved information exchange with a concomitant increase in handoff duration (3).

I am going to spend some more time reviewing the literature about implementation science before I start to apply what I have learned from Dr. Lane-Fall. However, I have a number of NICU QI projects and will review the status of each of them with this new and valuable information in mind.

As the NICU QI physician, I believe learning more about implementation science is a definitely worthwhile endeavor and should improve the overall quality of our projects and the care of our infants and their families. It may also improve the overall clinical provider satisfaction as well in this university clinical environment.

As Meghan says, as she and her colleagues work through the process and things seem to be going well, “I am cautiously optimistic!”. I will be “pleasantly persistent” in learning more and then applying implementation science.

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Graphic has been tested with colorblindness filters to ensure readability.

* In some cases it may be appropriate to move forward with a hybrid Type 1 trial in the absence of effectiveness evidence (e.g., very strong efficacy, indirect evidence supportive of potential effectiveness in context of interest, and/or strong momentum supporting implementation in a health care context).

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- Implement Sci. 2006;1:1-1.
3. Lane-Fall MB, Pascual JL, Peifer HG et al. A partially structured postoperative handoff protocol improves communication in 2 mixed surgical intensive care units. *Ann Surg* 2018; XX:XX, Month 2018.

The author has identified no conflicts of interest. This manuscript was reviewed by Meghan Lane-Fall, MD, MSHP.

NT

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Clinical Pearls are published monthly.

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1250 word limit not including references or title page.

May begin with a brief case summary or example.

Summarize the pearl for emphasis.

No more than 7 references.

Please send your submissions to:

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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 guidelines limit their access to RSV preventative treatment, increasing these babies' risk.



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Will your **PRETERM INFANT** need
EARLY INTERVENTION services?

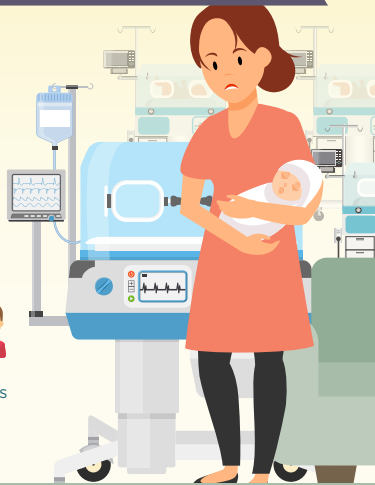
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2x more likely to have developmental delays

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



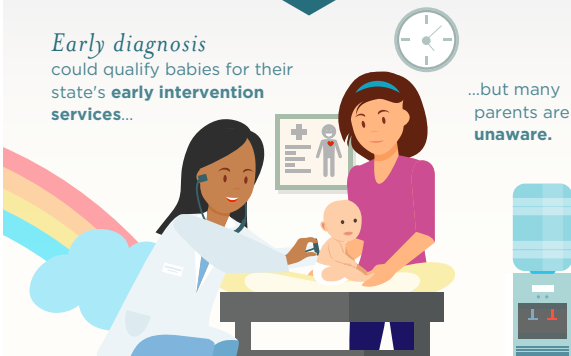
Address physical challenges



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.

Survey Says: **RSV**

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children.



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

80% They treat RSV as a priority, "often" or "always" evaluating their patients

77% RSV is the "most serious and dangerous" illness for children under four

77% Barriers to access and denials from insurance companies **limit** patients' ability to get preventive RSV treatment



But Parents are Unprepared.

18% Only 18% know "a lot" about RSV

22% Only 22% consider themselves "very well" prepared to prevent RSV



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

65% "More concerned" about their child contracting the disease

67% Likely to ask their doctor about RSV



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

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



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Letters to the Editor

LETTER TO THE EDITOR: NEONATOLOGY TODAY

Dear Neonatology Today,

12/17/2019

I have heard of the open-access model of scientific publishing, and that it requires the author to pay a significant amount to have an article published.

I have recently heard that Neonatology Today will publish a meritorious article without charge to the author. I'm just wondering how you handle the costs?

Thanks,

Gail L. Levine, M.D.
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"Kindness builds the world." Psalms 89:3

Dear Dr. Levine,

Thank you for your question. Neonatology Today had always provided free subscriptions for physicians who practice in the fields of Pediatrics, Neonatology, and Perinatal Medicine. With our transition to Journal format, we elected to extend free access to anyone with an interest in these fields. In doing so, we opened access to respiratory therapists, nurses, social workers, physical and occupational therapists, and of course parents.

The so called "open-access" model usually means that access to a specific manuscript is open to anyone who has access to the internet. Usually, open access comes with a price tag in addition to any fees that the journal may charge for publication. In some cases, authors have had to pay composite fees of thousands of dollars to assure that their manuscript receives the proper exposure. Without open access, only subscribers to a particular journal or those who have access through their university or work can read the manuscript.

For many reasons, among them the difficulty that many authors have in paying for publication when the amount requested is a



substantial part of their research budget, Neonatology Today has gone in a very different direction.

We do not charge to publish manuscripts regardless of length, graphics, photographs, color or linkage to external sites. We do not charge for subscriptions either. Our journal is supported by grants and ad fees.

To more clearly emphasize our point, Neonatology Today would like to announce a new initiative based on these principles: the "Academic True Open Model" or ATOM. We will provide a link from Neonatology Today to any other journal's website as well as license to use the ATOM logo (under development) to other publishers who adhere to this model.

We remain committed to engaging those who value academics and peer review and welcome your manuscripts without regard to ability to pay.

I agree, Dr. Levine. "Kindness builds the world."

Sincerely,

A handwritten signature in black ink, appearing to read "Mitchell Goldstein".

Mitchell Goldstein, MD
Editor in Chief

NT NEONATOLOGY TODAY

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Erratum (Neonatology Today November, 2019)

Neonatology Today has identified no erratum affecting the November, 2019 edition.

Corrections can be sent directly to LomaLindaPublishingCompany@gmail.com. The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from www.neonatologytoday.net.

NT

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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Will your **PRETERM INFANT** need **EARLY INTERVENTION** services?

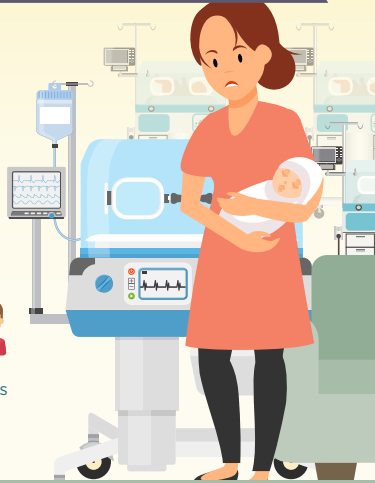
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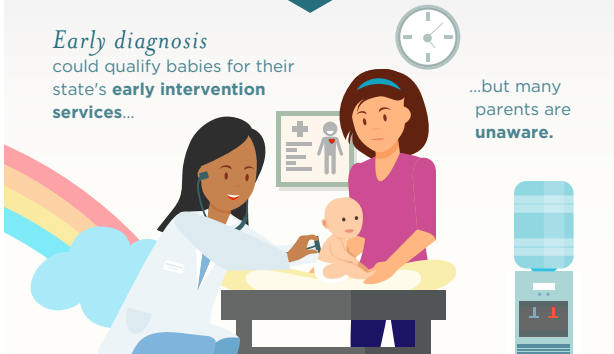
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NCFIH National Coalition for Infant Health
Protecting Access for Premature Infants through Age Two
www.infanthealth.org

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*



Sin embargo, sólo el **15%** recibe tratamiento!

LA DEPRESIÓN POSTPARTO **NO TRATADA PUEDE AFECTAR:**

El sueño, la alimentación y el comportamiento del bebé a medida que crece?



La salud de la madre
La capacidad para cuidar de un bebé y sus hermanos

PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO



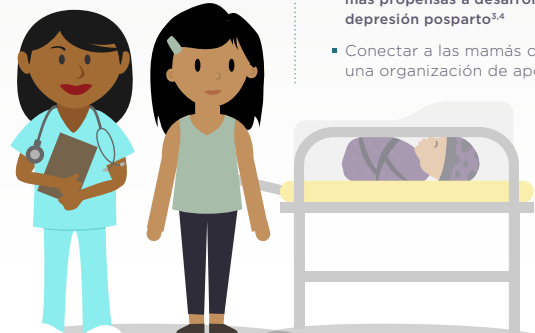
LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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



LOS HOSPITALES PUEDEN:

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



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¹ American Psychological Association. Accessed on: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>
² National Institute of Mental Health. Accessed on: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology (2015) 35, 529–536. doi:10.1097/JP.0000000000000147
⁴ Prevalence and risk factors for postpartum depression among women with problem and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Dennis CL. *PLoS ONE* 2010 Apr; 11(7):1540-50.

Upcoming Medical Meetings

36th Annual Conference
January 2-6, 2020

Obstetrics, Gynecology, Perinatal
Medicine, Neonatology, and the Law
Kohala Coast, Hawaii
[http://chginc.org/conferences-
registration/](http://chginc.org/conferences-registration/)

NEO

The Conference for Neonatology
February 19 – 21, 2020.
San Diego, CA
<http://www.neoconference.com/>

Specialty Review in Neonatology
February 17-22, 2020
<http://specialtyreview.com>

**33rd Annual Gravens Conference on
the EOC for High Risk Newborns**
March 4 - 7, 2020

University of South Florida (USF)
Health
Clearwater Beach, Florida
[https://health.usf.edu/publichealth/
chiles/gravens-conference](https://health.usf.edu/publichealth/chiles/gravens-conference)

**26th Annual Cool Topics in
Neonatology**
March 6 - 8, 2020

California Association of
Neonatologists
Coronado, California
[https://canneo.groupsie.com/main/
summary](https://canneo.groupsie.com/main/summary)

**The 37th Annual Advances in
Therapeutics and Technologies
Conference**

March 24-28, 2020
Snowbird, UT
[http://paclac.org/advances-in-care-
conference/](http://paclac.org/advances-in-care-conference/)

**Perinatal Care and the 4th Trimester:
Redefining Prenatal, Postpartum, and
Neonatal Care for a New Generation**
March 25 - 27, 2020
Aurora, Colorado
[http://www.nationalperinatal.
org/2020conference](http://www.nationalperinatal.org/2020conference)

**1st Annual Innovations in Maternal,
Fetal, and Neonatal Medicine**
March 27 - 29, 2020
Johns Hopkins All Children's
Hospital

St. Petersburg, Florida
[http://www.cvent.com/events/the-
annual-innovations-in-maternal-
fetal-and-neonatal-medicine-the-
continuum-of-care-conference/
event-summary-772b578c0e5348d3b
ba8a80915ffcac8.aspx](http://www.cvent.com/events/the-annual-innovations-in-maternal-fetal-and-neonatal-medicine-the-continuum-of-care-conference/event-summary-772b578c0e5348d3bba8a80915ffcac8.aspx)

**Pediatric Academic Societies 2020
Meeting**
April 29 – May 6, 2020
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<https://2020.pas-meeting.org/>

*For up to date Meeting
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Academic Neonatologist Opportunity in Southern California

Loma Linda University Faculty Medical Group, Department of Pediatrics, Division of Neonatology, is seeking board certified or board eligible Neonatologists to join their team.

The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children's Hospital is committed to providing the highest quality of family-centered medical care with our skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill babies. As one of the few level 4 tertiary centers in Southern California, we are equipped to provide the highest level of care for newborns with the most complex disorders. Our facility has the largest Level IV NICU in California, serving approximately 25 percent of the state.

We have subspecialists in all medical and surgical areas that are available at all times and are supported by hospital staff with technical, laboratory, and service expertise. Pediatric neurologists work together with us in our NeuroNICU to diagnose, treat and monitor babies with neurologic injury or illness and we focus on providing neuroprotective, developmentally appropriate care for all babies in the NICU. Very specialized care is given in our Small Baby Unit to babies born at less than 30 weeks gestation. Babies at risk for developmental delay are followed up to 3 years in our High-Risk Infant Follow-up Clinic. Genetics specialists are available for evaluation and consultation.

Our Children's Hospital is designated as a Baby Friendly Hospital that supports breastmilk feeding for both term and preterm babies. Neonatal Social Workers and Child Life Specialists are important members of our team. It is our goal to support babies and families in culturally sensitive ways as our patients come from many different ethnic and religious backgrounds.

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The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children's Hospital is committed to providing high-quality, family-centered care with our highly skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill infants and a new Tiny Baby Program focusing on improving survival and outcomes of extremely low birth weight infants (<1000g at birth). As one of the only level 3 tertiary centers in Southern California, we are equipped to provide the highest level of care for the most complex disorders. We have subspecialists in all medical and surgical areas that are available at all times and are supported by hospital staff with technical, laboratory, and service expertise.

At Loma Linda University Health, we combine the healing power of faith with the practices of modern medicine. We consist of a University, a Medical Center with four hospitals, and a Physicians Group. These resources have helped us become one of the best health systems in the nation.

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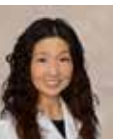
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Theodor Yasko, MD, MBA
Special Projects Coordinator

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.

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This bird reflects holiday cheer. Thank you to Dr. Mitchell Goldstein who found this fine representative on an uncharted counterspace in the wilds of a Neonatal Intensive Care Unit in West Covina, CA.



Herbert Vasquez, MD

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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 "Vancouver" format (APA may also be used). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

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