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Important Safety Information

- INOMAX is contraindicated in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of INOMAX may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO_2 levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOMAX on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.
- In patients with pre-existing left ventricular dysfunction, INOMAX may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO_2, inspired NO_2, and methemoglobin during INOMAX administration.
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*INOmax Total Care is included at no extra cost to contracted INOMAX customers.

†Emergency deliveries of various components are often made within 4 to 6 hours but may take up to 24 hours, depending on hospital location and/or circumstances.

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

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INOmax Total Care®

INOmax® (nitric oxide gas)

Brief Summary of Prescribing Information

INDICATIONS AND USAGE

Treatment of Hypoxic Respiratory Failure

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

CONTRAINDICATIONS

INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

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 (NO_2) forms in gas mixtures containing NO and O_2. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO_2 concentration, or if the NO_2 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 NO_2 analyzer should be recalibrated. The dose of INOmax and/or FiO_2 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 NO_2. Elevated NO_2 may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO_2 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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Peer Reviewed

Piloting Music Therapy Support for Preterm Infant Non-Nutritive Suck and Caregiver

Jenna Bollard, MA, MT-BC, CCLS, NICU-MT, RMT, Isabell Purdy Ph.D., NP, Kristina Casale, MT-BC, and Sandra Cheah, MT-BC

Introduction

Premature infants cared for in neonatal intensive care units (NICUs) may experience simple and complex health issues that impact oral motor and suck-swallow coordination. Parent caregivers and NICU healthcare team members alike work hard and closely monitor infant weight gain oral feeding skills that ultimately improve weight gain needed for intact survival. Often delays in feeding are due to poor suck and swallow coordination. This delay may lead to slower weight gain and extended hospitalization. Investigating methods to improve preterm infant oral motor skills. Challenges with oral feeding and the many other medical complications that caregivers of premature infants' face can often place a tremendous strain on caregiver mental health and stress levels. According to previous research, 40% of NICU mothers experience postpartum depression(PPD), and NICU mothers are at much higher risk of developing PPD than mothers who have infants outside of the NICU (Tahirkheli, 2014). Studies also show that up to 60% of NICU fathers experience depressive symptoms at baseline. Up to one-quarter of mothers on the NICU may experience symptoms of PTSD (Lee, 2015).

Music Therapy, as a well-established evidence-based profession of credentialed clinical providers, develop therapeutic relationships to provide developmental, rehabilitative, psychosocial, emotional, and symptom management to support neonates and their families. Music therapists use developmentally appropriate music interventions. This study aims to evaluate the use of a non-pharmacological family-centered method of offering oral motor support to premature infants and psychosocial support to families and caregivers.

The Pacifier Activated Lullaby (PAL) is an FDA approved device (Standley, 2012). PAL provides developmentally appropriate lullaby music that includes the ability to use the caregiver's voices and personalized recorded lullabies as a positive reinforcement measure to entrain and reinforce a non-nutritive sucking response among infants in NICU (Standley, 2012). The PAL intervention, extensively studied nationwide, was identified for improving non-nutritive sucking endurance, increased infant weight gain, and decrease the length of hospitalization (REF & date). The aim of this study was to pilot a Music Therapist driven approach to utilizing the PAL in NICU with babies and their families to identify benefits to preterm infants and their caregiver parents.

Methods:

Study Design: This quality improvement (QI) project evaluated the introduction of PAL as a nutritive sucking tool within a hospital-based cohort of infants cared for in the UCLA Healthcare System at two NICUs, one was a Level 4 and the other a Level 3. This study aimed to serve as an introductory examination of the way in which the PAL could be implemented with the specific population on the UCLA Neonatal Intensive Care Units and to examine the caregiver (staff and parents) perceptions of Music Therapy services when the PAL was integrated into Music Therapy treatment plan. This study aimed to collect information that can be used to inform future investigations geared towards improving the quality of care and identifying areas of clinical need. Before each PAL session, patients were be approved by their RN. Our study examined 17 neonates and their parents over the course of 6 months in addition to examining the perceptions and satisfaction rates of 50 NICU staff members.

> *"The Pacifier Activated Lullaby (PAL) is an FDA approved device (Standley, 2012). PAL provides developmentally appropriate lullaby music that includes the ability to use the caregiver's voices and personalized recorded lullabies as a positive reinforcement measure to entrain and reinforce a non-nutritive sucking response among infants in NICU (Standley, 2012)."*

Inclusion Criteria: All premature infants determined to be medically stable by the medical and nursing teams, and by occupational therapy (OT) and lactation specialist to be able to suck on a pacifier. Exclusion criteria: Neonates who required mechanical ventilation, intubation, vasopressors or otherwise considered unstable, of not eligible for the use of a pacifier by the medical team. Recruitment: Patients and families were identified by speaking with NICU healthcare physicians, nurses, lactation consults, and occupational therapists. Study participants included premature infants born between 32 to 36 weeks gestational age after their first week of life. Once approval was obtained from the multidisciplinary team members, the Music Therapy team obtained consent from interested parents prior to initiation of any study activity. A pre-study survey was reviewed with the parents prior to the introduction of the concept of the PAL and evaluation of its use. The lullaby writing process was described to the family prior to facilitating the writing and recording process (encouraging parents to sing on the recording). Prior to recording, each infants' baseline data for sucking endurance was collected by (who) on the PAL device for a duration of 5 minutes without music by using the PAL device. Following this pre-data collection, the lullaby recording was loaded onto the PAL for each infant participant to use five days per week for 5-15 minutes. During each session, data tracking included the number of sucks, duration, and vital signs. Additional data recorded included the percentage of intake the infant achieved by mouth over a 24 hour period. The PAL sessions repeated daily Monday through Friday before scheduled feeding times until discharge. The caregiver post-survey was collected prior to discharge.

Parental involvement with the regular PAL sessions was encouraged by inviting parents to offer their baby the pacifier, inviting parents to write down the number of sucks after each session, providing the opportunity for the parent to write the lullaby in music therapy sessions and to record their voices singing to be used with the PAL sessions. PAL sessions frequently took place in the midst of Music Therapy sessions and aligned with other clinical goals and interventions besides the PAL. For example, after completing a PAL session, the Music Therapist may have facilitated an emotional release focused music improvisation or lyric analysis/verbal processing with the family caregivers or a patient-focused developmentally appropriate touch intervention with live lullaby music to assist the patient in falling asleep.

Materials

The Pacifier Activated Lullaby (PAL) is a Federal Drug Agency (FDA) approved device for non-nutritive sucking support with premature infants. PAL has a developmentally appropriate speaker for infants to hear music lullabies recorded below a 65 decibel (dB) scale C range when triggered by an infant's sucking on a standard hospital pacifier. The PAL device comes with sensors (individually assigned to each patient). These attach to the standard hospital pacifiers. This device then cues the music to play through the speaker when infants suck the pacifier. The device contains only one small cord connecting the sensor and pacifier to the speaker and is otherwise battery operated. The PAL screen displays the number of sucks in live time. The volume level and contingency were adjustable with the selection of the specific lullaby used for the session. Before and after each session, each device was cleaned using medical-grade sanitizing wipes then rinsed off in hot water.

An iPad stopwatch app was used to time the duration of the PAL sessions. After writing the lullabies with caregivers, a "zoom" field recorder was used to record the lullabies with the caregivers' voice (or with the music therapist's voice featured if the parents declined singing for the recording). A digital music software called "Protools" was then used after the lullaby recording was transferred onto a MacBook laptop. Protools was used to adjust the sound levels of the lullaby in postproduction before transferring to the PAL device as we discovered that the lullaby recordings sounded muffled without post-production adjustments

A PAL Session Data Collection Form was used to record the patient's study code number, the session number, the number of sucks and duration of PAL session and the recorded percentage of PO feeds (feeds taken by mouth) that the infant had achieved that day. The PAL session Data Collection form also was used to record whether or not the caregivers' voice or the therapist's voice was used during the session on the PAL device.

Survey Forms administered throughout this study included seven questions developed with a Likert scale format which examined perceived stress levels, perceived involvement in infant's care, feelings of bonding and attachment and caregiver's perceived feelings of improvement in feeding abilities. Surveys remained anonymous and were geared towards gathering caregiver (parent and staff) initial reactions to the use of this device within the context of Music Therapy sessions. Surveys were not meant to extensively examine each component, rather provide a baseline introduction to caregiver's initial reactions and perceptions of the experience in order to help identify areas for further research in the following year.

Music Therapy interventions included a variety of individualized approaches.

<u>Songwriting sessions</u> involved brief reflection or meditation exercises facilitated by the music therapists to help facilitate the caregiver's creative thinking and help them connect to their feelings related to their baby. It then involved a brainstorming of adjectives to describe the baby (the caregiver's words), brainstorming of messages and wishes from the caregiver to the baby and any other meaningful words and concepts that the caregiver might like to include in the song. Next, the therapist would present two options of songwriting methods to the parents. The first option involved a lyric substitution approach in which the caregiver would select a favorite lullaby song or meaningful song and then together the therapist and caregivers would replace the words of that song with the brainstormed adjectives and messages to the baby. The therapist role would be to help set the caregivers up for success by empowering them yet providing helpful musical guidance to ensure that the song was developmentally appropriate for a premature infant and also had soothing aesthetics, musicality, and flow. The second option involved creating the song "from scratch." In this songwriting method, the music therapist provided multiple chord progression options and melodic suggestions and collaborated with the caregivers in the creation of the original lullaby composition. The therapist maintained the same role with this method, facilitating further discussion, providing empowerment and helping to provide guidance on an individual basis as clinically appropriate while also helping to create a song that contained developmentally appropriate components.

<u>Verbal processing involved</u>: Music Therapy fellows engaged in verbal processing inspired by humanistic psychotherapy approaches to encourage and empower caregivers and to help establish trust and rapport within the therapeutic relationship. Intentions of Music Therapy were clearly explained, and Music Therapists provided active listening, validation, and affirmations to caregivers as they processed emotions regarding hospitalization. Verbal processing remained supportive, and caregivers were held with unconditional positive regard by the therapists. Music Therapists used verbal interns to continue emphasizing the importance of the caregivers' role in the infants care and to empower them in that role. After songwriting sessions and PAL sessions, caregivers oftentimes engaged in verbal processing to further express their concerns and emotions regarding the infant's hospitalization: their worries about the future; medical-related trauma and trauma related to their birthing stories; feelings regarding the medical state of their baby; thoughts and emotions regarding the transition of having baby in their lives; family dynamics; financial concerns; and also feelings of attachment and excitement about their baby and bonding with their baby. Verbal processing often served as an extension of emotional release where caregivers were able to share their stories within a safe, non-judgmental supportive therapeutic relationship.

<u>Recording sessions</u> were utilized in cases where the caregiv-

ers agreed to sing on the PAL lullaby recording for their baby. Recording sessions involved recording software, headphones, microphone, and laptop and were done in a quiet place off the unit. Recording sessions took about 30 minutes, and caregivers always received a copy of the lullaby recording via mp3 file after recording completion.

Lullaby assisted relaxation was offered to families when the infant was agitated or needed assistance falling asleep. Rather than proceeding with the PAL session, Music Therapists would adapt to the medical and developmental needs of the infant at the moment and also respond to the caregiver's emotional/mental state as well. It was not always clinically appropriate to offer the PAL. For example, if an infant had a procedure earlier that day and was fatigued/agitated, the Music Therapist facilitated relaxation focused music interventions rather than the more rehabilitative focused PAL intervention. Music Therapists followed a family-centered, humanistic approach to Music Therapy sessions always.

Caregiver education focused on providing information about the therapeutic use of developmentally appropriate music. Parents also were taught about the implementation of the Pacifier Activated Lullaby. Music Therapists provided caregivers with information regarding infants behavioral signs of overstimulation to music and also signs of a positive response to the music as stimuli. Music Therapists provided information regarding appropriate decibel levels for the infant throughout their stages of development along with providing a helpful framework for playing recording music and singing for each stage of infant development. Music Therapists provided verbal psychoeducation and also provided handouts with developmental information regarding the use of music with neonates when appropriate. Information provided was a culmination of information obtained from Jayne Standley's (Music Therapist) NICU Music Therapy research and information from UCLA's NICU developmental care committee. All recommendations were in alignment with the American Academy of Pediatrics most recent guidelines.

> ***" Music Therapists provided caregivers with information regarding infants behavioral signs of overstimulation to music and also signs of a positive response to the music as stimuli.***

NICU staff perception: of PAL, MT services, developmental impact & psychosocial care.

NICU staff members were provided with a pre and post-survey which was made in a Likert scale format with an optional space for qualitative comments and asked questions regarding staff's perceived feelings of Music Therapy's presence on the unit as a support service. Questions asked the staff about overall feelings of stress on the unit and with their patients, and any notable changes amongst caregiver behaviors as a result of Music Therapy sessions. Surveys were handed out at the beginning of the study and the end of data collection and remained anonymous.

Results

17 premature infants involved demonstrated an increase in endurance with their non-nutritive sucking abilities along with caregiver's reported increased feelings of bonding and empowerment. NICU staff survey results also suggested high levels of satisfaction of Music Therapy services and the implementation of the Pacifier Activated Lullaby device as a developmental support intervention. Data suggests that 70 % of the infant participants demonstrated an increased average number of coordinated sucks during 5 minute long PAL sessions when the lullaby was used in comparison to when there was no music present to provide positive reinforcement and entrainment.

Of the 95% of the caregivers reported feeling their child had improved oral motor skills needed for feeding with the PAL Music Therapy sessions. Additionally, 98% reported stability and/or an increase in bonding with their baby during the study. All caregivers (100%) reported increases in music use in their daily routine with their infant and an increase in their involvement in their infant's care. An increase in hopefulness was reported by 98% by the end of their participation in the study.

NICU Staff Surveys were collected from 50 NICU staff members and demonstrated that 100% of staff members rated their experience working with Music Therapy as a 5/5. 100% of staff also rated Music Therapy a 5/5 as an effective modality for relaxation and agitation management for their patients and NICU staff also reported that they felt Music Therapy was a level 5/5 as an effective empowerment offering for caregivers. 99% of Staff reported that they would recommend Music Therapy services and the use of the PAL device to their qualifying and appropriate patients and families.

> ***"Of the 95% of the caregivers reported feeling their child had improved oral motor skills needed for feeding with the PAL Music Therapy sessions. Additionally, 98% reported stability and/or an increase in bonding with their baby during the study. All caregivers (100%) reported increases in music use in their daily routine with their infant and an increase in their involvement in their infant's care."***

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Staff Survey Comments	Parent Survey Comments
● *“Music Therapy is a key component of providing relaxation as well as interactive stimulation for our babies. I’ve taken care of agitated babies that calmed down with the help of our Music Therapy staff. This is a service I’d highly recommend for any family/baby in the NICU.”* ● *“It is amazing seeing the bonding effect of Music Therapy. It is so incredible seeing how empowered parents appear and how much they seem to bond with their babies during the music therapy sessions.”* ● *“Parents have commented that they love music therapy and wish that they could have it more frequently, every day if possible.”* ● *“The Music Therapy service has been an added bonus involving our parents in the care of their infants. It is a warm addition to parents who experience an infant loss, and the music therapists record the infant's heartbeat and help the parents create a heartbeat song as a memory for the parents to keep. Our infants also always appear more calm content and less agitated when Music Therapy visits.”* ● *“Music Therapy has been a very significant modality that can be used to calm/soothe babies. It gives parents a way to be more involved in their babies care and is a form of comfort to them, learning how to alleviate any signs of discomfort or pain that their baby is experiences.”* ● *“We NEED Music Therapy. We would be devastated if we ever lost this service. It is so good for our patients, and observing the PAL study has been absolutely incredible. Not only are the*	● *"It's been a long journey and a really difficult time, but I can see that music really helps him in many ways, especially in calming him down when his heart rate is high. I am really grateful to have experience Music Therapy while he's here.* ● *"Thank you so much for the BEAUTIFUL song, it has meant a lot to me, especially in the space that I have been separated from my baby for the last week while I have been hospitalized. My husband gave me your note the other day that you came by to sing to my baby, and we are so thankful for that sweet time you provide to him. I especially felt comforted to know that my voice was being used as a way to support my baby through the PAL even when I wasn’t there.”* ● *“Being involved in the PAL study was so inspiring for me. It gave me a way to support my baby in feeding while waiting for my breast milk to drop. I loved the process of writing and recording the song, and I really enjoyed watching him improve each session and last longer on the PAL more and more with each session.”* ● *“Every parent should receive Music Therapy as a support during their time on the NICU. It is relaxing for parents, but it also helps give us hope and feels like a light at the end of the tunnel.”* ● *“Every time I see my baby’s number of sucks increasing, I feel like its a little gold star on his chart. It is really empowering and inspiring to be involved in his care in this way.”* ● *“It's amazing watching how much better our little boy is able to feed when he is receiving music.”*

infants sucking with more endurance when receiving music, the parent's entire demeanor changes and they seem more hopeful and encouraged during feeding times as a result.” ● *“The NICU is very stressful environment. Alarms galore. Moms are trying to remain calm so that they can produce breast milk for their babies, but stress can affect a mom’s ability to pump. Music Therapy not only relaxes the baby and helps the baby sleep and feed, but it also helps with development and relieves the mother’s stress/inspires her. Relieving this stress allows the mothers to pump more effectively. The breast milk serves as a form of medication to the infant and helps their immune systems. Music Therapy also makes skin to skin more enjoyable for the infant and the parents. I have recently traveled internationally across the world; Australia, United Kingdom, New Zealand, Canada, and they all use Music Therapy in their NICU settings. We should strive to be the best in the west and enhance our family integrated care with the continued expansion of our Music Therapy program and research.”* ● *“I have experienced Music Therapy during palliative encounters, and they are professional, courteous, and kind, and often times I feel the energy of the unit becoming calmer as the music begins. The volume of their voices serves as a great model for us all to keep appropriate decibel levels with our own. The families and babies respond well to the music, and it helps their heart rates and respiratory rates to regulate.”* ● *“The Music Therapy program has been a wonderful experience for our families. Being on the NICU can be a pathological insults to our parents which makes them*	● *“It's amazing watching how much better our little boy is able to feed when he is receiving music.”* ● *“I love that you can use my actual voice on the PAL recording even when I can’t be there at bedside because I am with my other children at home.”*

anxious and can cause them to lose confidence. The music therapists show parents how to interact and engage with their babies in a meaningful calm manner. The parents have very positive interactions with their babies during Music Therapy, and the MT helps them to normalize their experience on the NICU."	

Table 1: Staff survey and parent survey comments.

Qualitative Responses on Surveys

Pre and post surveys allowed for room for optional qualitative anonymous comments for both parents and staff members. Staff and parents self-reported that Music Therapy helped to ease stress and help them to feel more comfortable on the unit. Qualitative comments from parents suggest that the use of the PAL within Music Therapy sessions may hold promising psychosocial benefit for the parents in addition to the developmental support it provides for the infant.

Discussion

Study variables include the additional health complications which extend beyond the need for weight gain. Additional medical complications and varied diagnoses may impact study data. Our unit, a level four NICU often treating complex cases differing from the "feeder and grower" population that seems to be more frequently involved with the use of the PAL may call for modified goals of the PAL. For example, rather than the aim of the PAL use to be solely focused on NNS, perhaps shifting the primary focus of its function with certain patients to be aimed at assisting in bonding and caregiver mental health support along with promoting infant self-soothing behaviors and potentially pain management even when nonnutritive sucking practice is not needed as a means to transition to oral feed (for example for infants who are already feeding orally or for infants who will remain fed by G-tube). Parents regularly verbally reported feeling an ease in stress levels during sessions in regards to Music Therapy sessions involving the PAL which piqued the researcher's interest in potentially further investigating stress levels in future studies with an official standardized and evidenced-based measure in the next term. The survey forms used were not standardized therefore may be lacking in reliability and have the potential to be influenced by bias in the wording of the questions which would need to be adapted and more formalized by any researchers who intend to investigate further any of the psychosocial components introduced in this study. Other variables included infant sleep schedules, procedure times, changes in medical stability, rounding from medical teams or the infants being seen by other specialists during PAL session attempts and a lack of consistency in the lullaby recordings due to the nature of the creative process and different voices of caregivers. Out of the 17 families, only nine families agreed to use their voices. 55% of the participants who had lullaby featuring their caregivers' voice demonstrated an increase in non-nutritive sucking abilities. Our team also noticed that at times, having visitors at the bedside or other distracting noises on the unit impacted the infant's ability to suck the pacifier at their usual performance rate. It has also become apparent when reviewing the data collected that any further investigation of the study would have to be much more refined for example, deciding whether or not the parent's voice must be used in lullaby or not rather than having two separate groups, deciding whether parent stress/involvement be examined, or the infant's NNS be examined or deciding to examine a correlation between the two rather than examining them separately in one study effort. Future research efforts might also include refining which caregiver group to focus on (staff, parents, family). This pilot project has served us in helping to begin the process of identifying areas most in need of further investigation and has helped to inform clinical areas of need that pique the most interest amongst staff and families both as a result of the questionnaires and verbal discussion surrounding the introduction of the PAL device at the bedside.

Our most significant hurdle throughout the beginning stages of this pilot study was the technical difficulties we experience when working with the PAL device. When using caregiver focused lullabies which featured the caregiver voices, the volume was incredible low (even lower than 60dB at times) and extremely muffled and of poor quality. After collaboration with audio engineers, we discovered how to adjust the recording formats to ensure clarity of recordings. However, the initial caregiver data may have been impacted by the poor sound quality of recordings (we hypothesize that the percentage of increased NNS endurance for the infants that received PAL with caregiver voices would be much higher if the recordings were of better quality and clarity.

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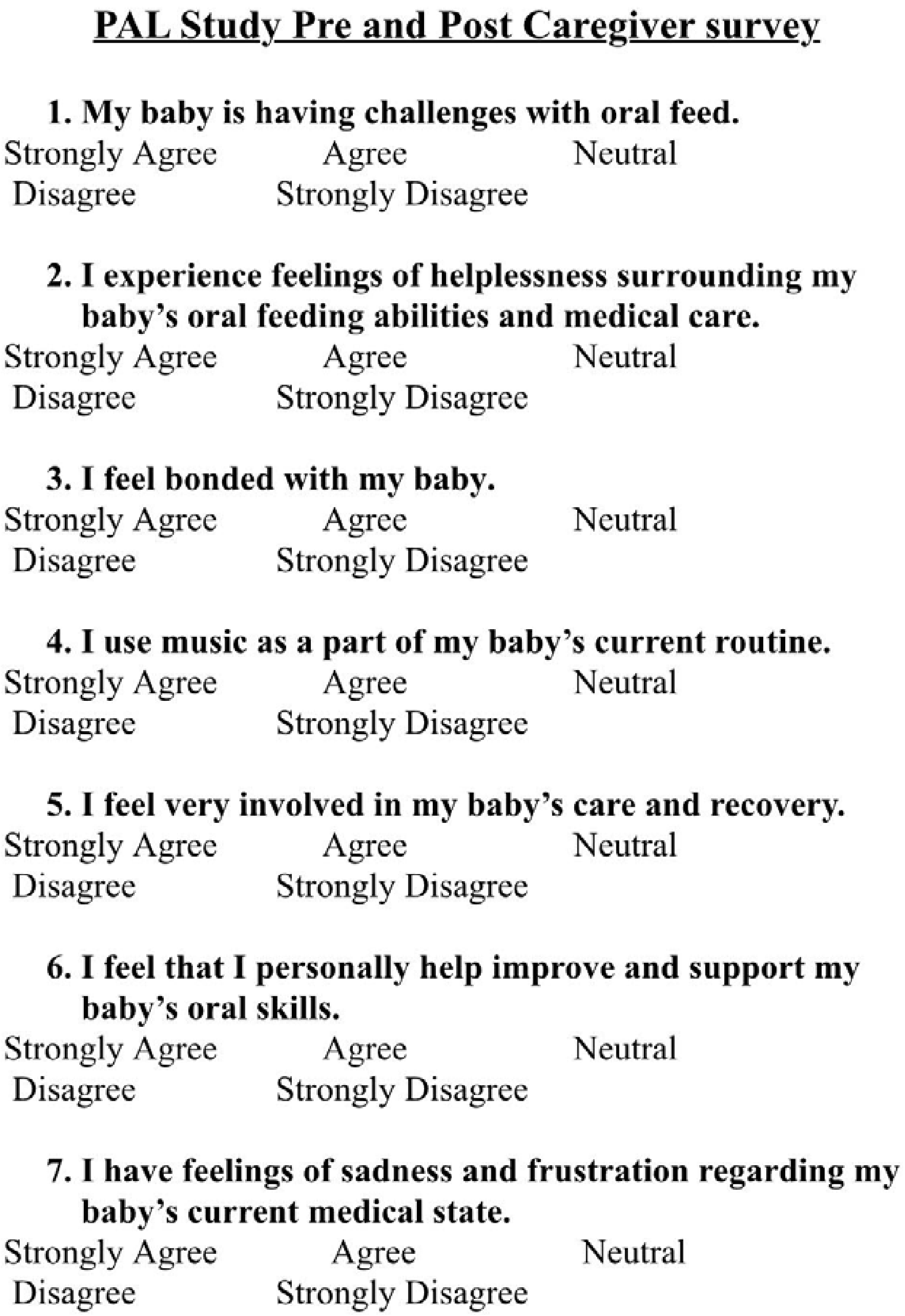

PAL Study Pre and Post Caregiver survey

1. My baby is having challenges with oral feed.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

2. I experience feelings of helplessness surrounding my baby's oral feeding abilities and medical care.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

3. I feel bonded with my baby.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

4. I use music as a part of my baby's current routine.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

5. I feel very involved in my baby's care and recovery.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

6. I feel that I personally help improve and support my baby's oral skills.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

7. I have feelings of sadness and frustration regarding my baby's current medical state.

Strongly Agree Agree Neutral
Disagree Strongly Disagree

Figure 1: PAL Study Pre and Post Carfegiver survey

Potential improvements for this study could include a control group which uses recorded lullaby (without the caregivers' voice) versus an experimental group which does use the caregiver's voice. This group would help us further determine the impact of the caregivers' voice with the use of this device. To increase parental involvement, designing this study to require parents to be at bedside during PAL sessions and more consistently assigning parents a role such as recording the number of sucks or offering the PAL pacifier to their baby during each PAL session may also impact the caregivers sense of autonomy and further validate the importance of their presence.

Other improvements might include intervening with the PAL at a consistent gestational age to promote more consistency within the study and reduce variables. There were challenges in piloting the ideal timing of implementing this device. We aimed to present the PAL after infants had been introduced to the breast but during the transition to bottle feeds and if they were having additional challenges with breastfeeding. Our team worked closely with lactation consultants and occupational therapists, and in collaboration, it was decided to wait until after the breast has been introduced to the infant and to offer sessions about 20 minutes before scheduled feeding times in order to get the muscles engaged and prepared for feedings. However, at times this posed a risk of causing fatigue before the feeding (which would be counterproductive). However, at times, we would offer the device after feedings, and the infant would be tired, and the results were not an accurate representation of the patient's abilities. Finding an appropriate time for PAL sessions in between feedings throughout the day also presented with some challenges such as the infant being seen by other specialists throughout the day, potential effects of medications altering the data, or the patient sleeping. It would also be counterproductive to wake the infant during a sleep cycle as sleep is crucial to the infant's development. However, due to these variables and challenges our consistency within the study regarding the gestational age the PAL was offered, and the timing of PAL sessions were at times broad and inconsistent. For further exploration of this device, it may be of benefit to narrow down the inclusion criteria and protocol (such as the PAL session times).

Another challenge we faced during the implementation of the PAL device was that many of the infants had feeding times scheduled at the same time (meaning with one PAL device available and only two grant-funded research assistants) we were not always able to provide the PAL session during the most ideal time. For example, if five infants had a feeding time scheduled for 11:00 am, it was not always a guarantee that all of the infants would be ready and available for the PAL session between 10:30 and 11:00 and it was not always possible for the therapists to complete all 5 PAL sessions on time.

Additional areas for future exploration include; training other medical professionals on the PAL in order to increase patient impact and study size along with potentially decreasing some of the variables in missed session times or non-ideal session times. Training additional staff members and purchasing additional PAL devices would, in some ways, create consistency and accountability in session times.

Future considerations to examine within our population at UCLA might be the correlation between weight gain and PAL training, the impact of the PAL on the duration of hospital stay and any potential impact the PAL could have on infant pain and agitation levels, all of which have been previously studied at other institutions by Jayne Standley. Additional efforts may also explore and/or investigating the longer-term implications of bonding and development through caregiver's voice. Separating the interventions during data collection by requesting surveys after the songwriting and initial Music Therapy sessions and then collecting a separate survey after the actual use of the PAL device may also help to determine whether or not the results of patient satisfaction, anxiety and stress reduction and the decreased feelings of hopelessness should be attributed to the PAL sessions exclusively or to the experience with the songwriting and the Music Therapy as a whole.

Exploration of parent support groups to focus on stress reduction particularly for breastfeeding mothers might also be another area of study to examine along with beginning the introduction of the Music Therapy process and the idea of planning for PAL sessions sooner (for example within the first week of admission to the NICU or during bed rest/antepartum).

Continuing to explore the impact of Music Therapy and the PAL on maternal mental health/overall stress levels seems to be an area of calling according to this pilot project as the results for caregiver stress management, especially in the form of qualitative comments on the surveys were incredibly promising. Continuing to explore ways in which parents can be provided with autonomy and emotional support with the involvement of this device would benefit future protocol development for a more formalized and refined research study. For example, studying the impact of having parents record the number of sucks with the therapist after each PAL session or assist in providing the pacifier on the caregivers' feelings of involvement or reduction in stress.

Lastly, exploring the use of the PAL as a comfort measure in addition to being a developmental aid may also provide some interesting insights for clinicians and caregivers, especially in level IV NICUs. For example, after an infant has achieved their oral feeding goals yet still must remain on the NICU for other medical reasons, examining the benefit of the PAL for agitation management and comfort as an adjusted clinical goal once they have achieved their oral feed goals.

Conclusions

Results from this study indicate that the PAL device paired with Music Therapy services could improve the endurance of non-nutritive sucks amongst medically stable neonates along with promoting bonding and decreased feelings of helplessness amongst caregivers while simultaneously boosting staff morale. Based

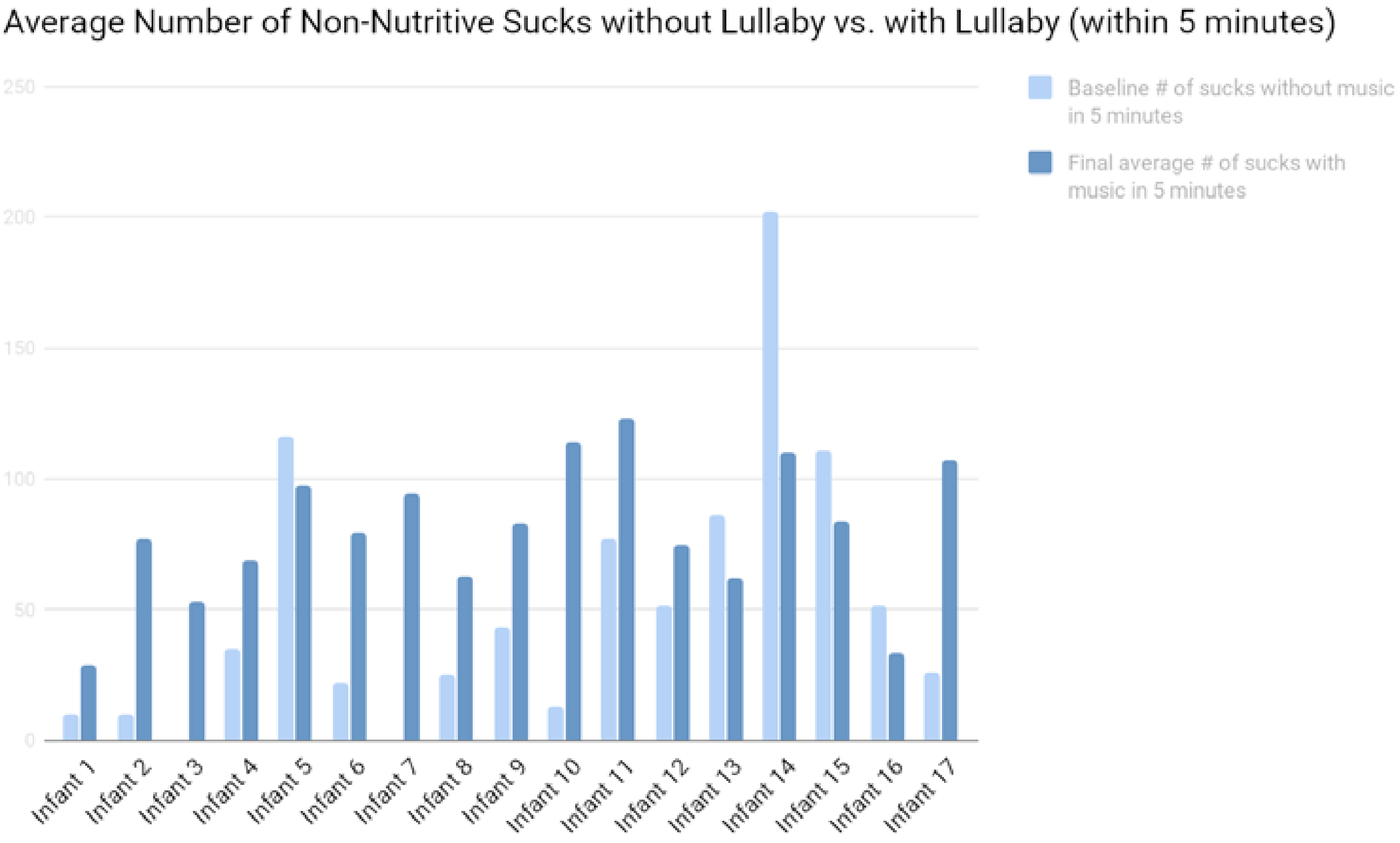

Figure 2: Av erage Number of Non-Nutritive Sucks without Lullaby vs. with Lullaby (winin 5 minutes)

upon this small pilot project, the involvement of Music Therapy, more specifically the process of creating parent-written and parent-performed recorded lullaby with the PAL device could improve the quality of care provided in the NICU both from a psychosocial standpoint and also in terms of developmental care. As our study results have found a 100% rate of parents reporting to feel more involved in the care of their infant due to the PAL process and 98% of caregivers reported an increase in feelings of hopefulness this study suggests that including involvement with the PAL and Music Therapy services as part of the neonates routine care would be of benefit to caregiver mental health and patient satisfaction. This increase in hopefulness raises questions regarding the PAL (and Music Therapy's) ability to potentially decrease symptoms of "baby blues" and postpartum depression, Medical-related PTSD/ other mental health strains that caregivers may be experiencing when their infant is hospitalized in the NICU. The study results demonstrating 70% of increased sucking endurance within the first 5 minutes of using the PAL is promising. However, these findings require more refining of our PAL protocol and recording process and a closer look at the variables -- for example, perhaps refining the timing of the PAL introduction and the inclusion criteria or providing longer PAL sessions as clinically appropriate at more consistent opportune times. The results from this study have led us to our next cycle of research which will be funded by the Music Man Foundation beginning in June 2019 where we will more intensely examine the role of Music Therapy services as a stress reduction for caregivers on the NICU. Our next study cycle will also examine the relevance of mental health support through Music Therapy services earlier on during patient care for example, in antepartum while parents are on bed rest and on maternity/ labor and delivery units in tandem with continued Music Therapy services in the NICU. We hope to continue improving our protocol with the PAL device for our unique patient population, order more PAL sensors and streamline ways in which to provide the PAL as part of routine care to premature infants in the NICU who are requiring assistance with their NNS endurance.

Funding and Approvals

This study was reviewed by the Institutional Review Board (IRB) and approved as a quality improvement study. All participants involved in this study opted to participate, signed consent forms and were informed that they would continue to receive the same quality of Music Therapy support regardless of whether or not they decided to participate in the optional and anonymous study.

This study was funded by the Music Man Foundation and the Peterson Family Foundation.

About The Music Man Foundation: The Music Man Foundation is named after the Tony-winning musical written by Meredith Willson. Meredith's widow, Rosemary, started the Foundation in 1998 as the Meredith and Rosemary Willson Charitable Foundation and substantially increased the Foundation's endowment upon her death in 2010. With a mission to empower people using the transformative energy of music to make positive changes in their own lives and the lives of others, the Foundation currently focuses its investments in two initiative areas: core-curriculum music education and music therapy. Besides "The Music Man," Meredith Willson wrote the musical, "The Unsinkable Molly Brown," and beloved songs "It's Beginning to Look a Lot Like Christmas" and the University of Iowa fight song.

About the Peterson Family Foundation:

The Peterson Family Foundation's main focus is sustaining and creating pediatric music therapy programs, as well as funding childhood leukemia research. Through an integrative approach to healthcare, we are bringing together music therapy and cancer research to support all aspects of treatment. Their primary mission is to seek out and support experts and institutions dedicated to enhancing and improving the lives of children and teens afflicted by life-threatening and life-long diseases.

The PFF believes in supporting the whole child and striving for an integrated approach to healthcare. The PFF supports medical research into childhood leukemia as well as music therapy programs to improve psychological and emotional well-being.

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Interpreting Umbilical Cord Blood Gases

Jeffrey Pomerance, MD, MPH

Introduction

The purpose of this series is to assist clinicians in better understanding the indications for testing umbilical cord blood gases, in recognizing the pitfalls involved in collecting and handling specimens, and incorrectly interpreting umbilical cord blood gas values. Most of the text comes from my book: Interpreting Umbilical Cord Blood Gases: For Clinicians Caring for the Fetus or Newborn, 2nd edition, published in 2012.

Some areas have been altered for clarity, and not all of the book will appear in this or future installments.

To illustrate these points, I use a series of clinical cases drawn from actual experience with patients. The information is presented by category, and most often each successive case within the category is of increasing complexity. The care provided was not necessarily optimal or even acceptable. As with every endeavor, regular practice produces better results. In many situations, more than one interpretation of umbilical cord gases is possible. Of critical importance is the reasoning behind the interpretations. In general, much additional information is provided, both antenatal and postnatal, along with the blood gas results. Of course, not all of this information is available as the baby is being delivered; however, the goal is the correct interpretation of cord blood gas results. It is important to make sense of the data, not simply to note the presence of respiratory, metabolic, or mixed acidosis. Fairly often, this requires integrating information about the fetal monitoring strip, details of the delivery, the follow-up blood gas results taken directly from the infant, and other post-delivery information.

In each example, the clinical and laboratory data are presented first, with my interpretation presented on the following page. This will allow readers to compose their thoughts prior to reading my conclusions and, more importantly, to develop the reasoning behind them. Some of the clinical presentations occurred many years ago and, not unexpectedly, the standard of care has evolved. For example, initiating use of 100% oxygen as a standard part of resuscitation and use of sodium bicarbonate to correct a base deficit are no longer recommended. Nonetheless, in many of the cases presented, these therapies were employed. Additionally, the clinical expertise of the care providers varied from excellent to poor. Therefore, one should not assume that the care provided represents the state of the art.

The objectives of this text are to help the reader to:

(1) Become familiar with normal umbilical cord blood gas values;

(2) Understand the usual relationship between pH and blood gas values found in the umbilical vein and the umbilical artery;

(3) Recognize how best to interpret the results when technical problems have occurred;

(4) Recognize patterns of abnormal umbilical cord blood gas values and understand their pathophysiology;

(5) Recognize when asphyxia has been associated with delivery and when it has not;

(6) Be able to decipher even complex issues in the interpretation of umbilical cord blood gas results, and,

(7) To boldly interpret where no one has interpreted before.

Following each of the installments, "Key Points" will be listed.

In my experience, clinicians often ignore the results of umbilical cord blood gas values or, at most, simply record them. It is rare that a clinician comments on the results or offers an interpretation. No blood gas value, or other test result for that matter, is self-explanatory; every test result requires clinical validation. I hope this text encourages readers to think about the results and then record their interpretations. This information will help clinicians on both the obstetric and neonatal sides understand the underlying physiology and pathophysiology that contribute to umbilical cord blood gas values. This understanding may assist in improving the outcome of future pregnancies on the obstetric side while helping the immediate care of the newborn on the neonatal side, especially if i-STAT blood gases are run in the delivery room. Although in the United States millimeters of mercury (mmHg) are used as the unit of measure for PCO2 and PO2, many other countries use kilopascals (kPa) as the unit of measure. Accordingly, both units are provided in all tables.

When to Order Cord Gases

The frequency of umbilical cord blood gas sampling ranges from almost universal to almost never. Routine universal sampling will not miss any important abnormalities and has the advantage of providing maximal experience and enhanced skills to those who draw blood for cord gases. The cost for this approach is not great, likely representing only the cost of materials and reagents, as no additional personnel are necessary. A four-year observational study of universal cord blood gas and lactate analysis was conducted at the only Western Australian tertiary level obstetric hospital.

Results suggest that the introduction of universal paired cord blood gas analysis may have resulted in improved perinatal outcomes independent of obstetric intervention. The authors postulate that regular, objective feedback via cord blood gas results close to the time of delivery may positively influence future obstetric management. I favor this approach.

If universal cord gas analysis is not adopted, a more modest approach is to establish criteria for drawing samples that are mutually agreed upon by the obstetrical and neonatal-pediatric services. The American Congress of Obstetricians and Gynecologists suggests that physicians should "attempt to obtain venous and arterial blood cord samples in circumstances of cesarean delivery for fetal compromise, low 5-minute Apgar score, severe growth restriction, abnormal fetal heart rate tracing, maternal thyroid disease, intrapartum fever, or multifetal gestation." Very similar criteria used for many years at Cedars-Sinai Medical Center in Los Angeles are as follows:

1) All infants perceived to have had non-reassuring fetal heart rate tracings or other evidence of concern for fetal well-being, irrespective of Apgar score or other delivery room evaluation;

2) All infants with Apgar scores of 6 or less at any time; and

3) Any infant for whom anyone present at delivery deems cord blood gases necessary.

If cord blood gases are drawn in the delivery room and run with i-STAT, results may directly and positively affect immediate care of the newborn. Additionally, results may be directive in the triage of the baby.

Obtaining Cord Gas Samples

A 10-20 cm segment of the umbilical cord is clamped immediately following delivery with two adjacent clamps near the neonate and two adjacent clamps nearer the placenta. Cutting between each of the two sets of adjacent clamps then separates this segment. Placing an additional clamp midway between the other two has been suggested so that a second set of gases may be drawn if the first set turns out to be unsatisfactory.

Typically, blood for umbilical cord gases is obtained by inserting a short, small-gauge needle attached to a plastic syringe into the umbilical vein and a separate needle with a syringe attached into an umbilical artery. A short, small-gauge needle permits optimal control with minimal injury to the vessels. There is a risk of RBC lysis if the needle gauge is too small or the syringe is drawn up too quickly. This might lead to an artificially elevated lactate level. Alternatively, umbilical venous and arterial samples may be drawn from the vessels on the chorionic plate (see, Analyzing Cord Gases below, regarding the need for rapidly obtaining these samples). Drawing blood from this site is very simple as it is similar to starting an IV in a large vessel without any intervening tissue that might make visualization difficult. Distinguishing veins from arteries is not difficult as veins are larger and less muscular than arteries. Additionally, arteries reliably cross over veins.

A complete blood gas analysis can be performed on samples as small as 0.1 cc; however, 0.3 cc or more is optimal as it permits retesting, if necessary.

Historically, there has been a discussion about the impact of excessive heparin within the collecting syringe on cord blood gas values. The pH of heparin is about 7.0. As PCO2 and PO2 approach room air values, approximately 0.4 mmHg and 160 mmHg, respectively, excess heparin will result in decreasing pH and PCO2 values, worsening base excess and increasing PO2 in umbilical cord blood. This issue has become moot, as syringes used for blood gas analysis today come pre-heparinized with powdered heparin. If the blood gases are to be analyzed immediately after being drawn, heparin is unnecessary.

Analyzing Cord Gases

Umbilical cord blood gases should be analyzed as soon as possible after birth. In practice, the attention required by the mother or newborn may preclude attention to the cord blood gas sample. No clinically important changes in blood gas values are seen in a doubly clamped , umbilical cord at room temperature, , or drawn into a plastic syringe and left at room temperature, , for 60 minutes following delivery. Blood analyzed from vessels in the chorionic plate, however, must be drawn into a syringe quickly, as significant deterioration of values (increasing respiratory and metabolic acidosis) occurs when there is a delay of more than 15 minutes following clamping the cord.12 Presumably, blood in the chorionic vessels deteriorates more rapidly because it is in juxtaposition to a dense collection of metabolically active tissue in the placenta. The cord, in contrast, is mostly composed of the umbilical vessels themselves and metabolically inactive Wharton's jelly. Perlman et al. had reported significantly "better," although clinically insignificantly different, umbilical artery values when samples were obtained from the cord within 10 cm of the newborn compared to specimens obtained within 10 cm of the placenta. These differences also may represent faster sample degradation when in close proximity to the cell-rich site of the chorionic plate or perhaps actual contamination of cord blood with blood in the adjacent chorionic plate.

Blood gases stored on ice and not analyzed for many hours are still capable of providing useful and relevant data. Chauhan et al. studied umbilical arterial cord blood gas values from 23 infants stored in pre-heparinized syringes kept on ice for up to 60 hours. Separate equations were derived that permit calculation of original pH and base excess values from the time of birth. As expected, over time, pH falls, and base excess becomes increasingly negative.

When Cord Gases Do Not Reflect Fetal Condition

It has been argued that a newborn with no signs of life, whose fetal heart rate had been at approximately 60 bpm for 15 minutes or more prior to delivery, has not been asphyxiated because umbilical cord blood gas values are normal or near normal. You should never accept an umbilical cord blood gas as correctly reflecting the condition of an infant when your common sense tells you it does not. There are reasons for noncorrelation (especially of umbilical venous cord gases) including terminal fetal bradycardia secondary to either cord occlusion or fetal heart failure, and acute fetal hemorrhage. Sometimes we may have sufficient insight to explain the noncorrelation, and sometimes we may not. However, even when we are unable to explain confusing data, this does not mean that no explanation exists, only that our understanding of the data available is not sufficient to do so.

The best correlation between umbilical cord blood gas values and fetal acid-base status exists when blood is freely exiting the umbilical vein and entering the umbilical arteries. In other words, the fetal blood pressure must be adequate to perfuse the umbilical arteries, and the cord must not be occluded. Umbilical vein occlusion occurs much more easily than umbilical artery occlusion. Typically, in cord occlusion, both vein and arteries are occluded initially. Occlusion of the umbilical arteries results in arterial hypertension and reflex fetal bradycardia. If the occlusion continues, arterial hypertension may overcome the occlusive force, resulting in a net transfer of blood to the placenta as the umbilical vein remains occluded. Failing to relieve the obstruction to flow, the fetus becomes progressively asphyxiated, oxygen supply to the heart becomes inadequate to support forceful contractions, blood pressure falls and eventually becomes insufficient to perfuse the umbilical arteries. Once this occurs, an umbilical artery blood gas sample progressively fails to reflect a continuing deterioration of the acid-base status of the fetus.

Umbilical cord venous blood gas samples should not be expected to accurately reflect fetal status following cord occlusion with terminal fetal bradycardia. Additionally, umbilical cord arterial blood gas samples will not fully reflect fetal tissue acidosis when fetal circulation is poor or non-existent at birth. These potential causes of poor correlation between umbilical cord arterial blood gas values and blood gas values at the fetal tissue level should not lead to the notion that umbilical cord blood gas values cannot be relied upon. The overwhelming majority of newborns have both umbilical cord venous and arterial blood gas values that accurately reflect uteroplacental and uteroplacental-fetal status, respectively.

An umbilical cord arterial blood gas represents the mixed venous return of all fetal tissues and does not indicate the acid-base status of any specific tissues. Indeed, severe intracellular acidosis of a specific fetal structure may not be detected in the umbilical artery sample if there is no venous return from that structure; an example would be an ischemic area resulting from a cerebral infarct.

Lastly, a fetus might have sudden ventricular fibrillation or other rapidly fatal arrhythmias. Blood in the umbilical cord would abruptly

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cease flowing and could result in perfectly normal umbilical venous and arterial blood gas values and a clinically dead newborn. Critically ill newborns who are already severely acidotic and moribund may have terminal arrhythmias. Most neonatologists have almost no familiarity with defibrillators, suggesting the extreme rarity of ventricular fibrillation. Therefore, this scenario must certainly be quite rare.

Fetal Heart Rate Present / Neonatal Heart Rate Absent

Practitioners who regularly attend high-risk deliveries will recognize the occasional scenario of a delivery in which the fetal heart rate was present prior to delivery, but the neonatal heart rate is absent after delivery. In the usual situation, there has been a "crash" cesarean section done for severe fetal distress. At delivery, the infant has an Apgar score of 0. Some of these infants are successfully resuscitated, and some are not. Yet all of these infants had a recorded heart rate shortly before delivery.

The fetal heart rate is recorded by either a Doppler device or by a direct fetal electrode. The Doppler device evaluates fetal heart rate by detecting motion of the fetal heart, especially the valves, and converting the detected beats into a calculated heart rate. It does not differentiate a forceful heartbeat from a slight twitch. A minimal contraction would not be expected to generate any significant cardiac output. At birth, the neonatal heart rate typically is evaluated by auscultation, palpation, or observation (seeing heart movement on a quiet chest). A very slow heart rate is frequently very soft or even inaudible.

Furthermore, one might need to listen carefully in a quiet environment (no artificial ventilation, no chest compressions, or excessive noise) for 10-20 seconds to be sure of these findings. In the emergency atmosphere that exists in all such situations, this luxury is often unavailable. The stroke volume may easily be so low as to generate no palpable pulse at all. The very slight heart movement that might be visible on a quiet chest is not discernable on a chest that is moving with each artificial breath. Practically, there is likely little physiologic difference between a non-beating heart and one in which the movement is so slight that it goes undetected by physical exam.

A direct fetal electrode detects electrical activity generated by the fetal heart. However, there is no assurance that electrical activity is translated into mechanical activity. Under severely hypoxic conditions, electromechanical dissociation (also known as pulseless electrical activity) is not rare. Patients with this condition have an especially poor survival rate.

Occasionally, the fetal monitor (especially if the tracing appears "normal") may have been tracking the maternal heart rate. , , Helpful signs that the heart rate being tracked is maternal rather than fetal include: a maternal heart rate similar to the rate in the tracing, an abrupt change in the baseline rate or rhythm associated with a discontinuity in the tracing, or a rise in heart rate associated with maternal pushing. To distinguish maternal from fetal heart rate recordings, the mother's pulse may be taken and compared with the electronic fetal monitor tracing. If they are very similar, the tracing may be maternal.

Key Points

- Blood from the umbilical vein is preferentially channeled through the foramen ovale providing better-oxygenated blood to the fetal heart and brain.
- Umbilical venous blood reflects uteroplacental status.
- Umbilical arterial blood reflects fetal as well as uteroplacental status.
- Leaving umbilical cord blood left double clamped in an umbilical cord or a syringe at room temperature for up to 60 minutes, results in no clinically important changes in blood gas values.
- Typically, umbilical cord venous blood gas samples would not be expected to accurately reflect fetal status following terminal fetal bradycardia associated with either cord occlusion.
- Umbilical cord arterial blood gas samples will not fully reflect fetal tissue acidosis when fetal circulation is poor or non-existent at birth.
- Severe intracellular acidosis of a specific fetal structure may not be detected in the umbilical artery sample if there is no venous return from that structure.
- The great majority of newborns have umbilical venous and arterial blood gas samples that accurately reflect fetal status.
- You should never accept an umbilical cord blood gas as correctly reflecting the condition of an infant when your common sense tells you it does not.
- Many infants with low Apgar scores have normal or near-normal umbilical arterial blood gas values.
- Occasionally, an infant is delivered without an apparent heartbeat when a fetal heart rate was recorded just prior to delivery. Either an unobservable, feeble heart contraction or electromechanical dissociation (pulseless electrical activity) explains this apparent non sequitur. Alternatively, the fetal monitor may have been tracking the maternal heart rate.

Below are normal umbilical cord blood gases. These are the values that will be used in future umbilical cord blood gas examples. Please retain this page.

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Normal Umbilical Cord Blood Gases		
	Venous Blood Normal Range (Mean ± 2SD)	**Arterial Blood Normal Range (Mean ± 2SD)**
pH	7.25 – 7.45	7.18 – 7.38
P_{CO_2} (mmHg) **(kPa)****	26.8 – 49.2 / 3.57 – 6.56	32.2 – 65.8 4.29 – 8.77
P_{O_2} (mmHg) **(kPa)****	17.2 – 40.8 / 2.29 – 5.44	5.6 – 30.8 / 0.75 – 4.11
HCO_3^- (mmol/L)	15.8 – 24.2	17 – 27
BD* (mmol/L)	0 to 8	0 to 8

Table

Reprinted with permission from Elsevier, in part from Yeomans ER, Hauth JC, Gilstrap LC III, Strickland DM. Umbilical cord pH, P_{CO_2}, and bicarbonate following uncomplicated term vaginal deliveries Am J Obstet Gynecol 1985;151:798-800.

Data are mean values ± 2 standard deviations (SD).

* Base deficit, estimated from data.

** 1 kPa = 7.50 mmHg; 1 mmHg = 0.133 kPa

Note: “Normal” is arbitrarily defined as the mean ± two times the standard deviation (approximately 95.4% of a normally distributed population).

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Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

Track national data and trends at the CDC's website www.cdc.gov/rsv

Identify babies at greatest risk including those with CLD, BPD, CF, and heart conditions

Teach families how to protect their babies from respiratory infections

Advocate for insurance coverage for palivizumab prophylaxis so more babies can be protected *

Use your best clinical judgement when prescribing RSV prophylaxis

Tell insurers what families need and provide the supporting evidence

National Perinatal Association

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

What you need to know about RSV

RSV stands for Respiratory Syncytial Virus

RSV is a **R**eally **S**erious **V**irus

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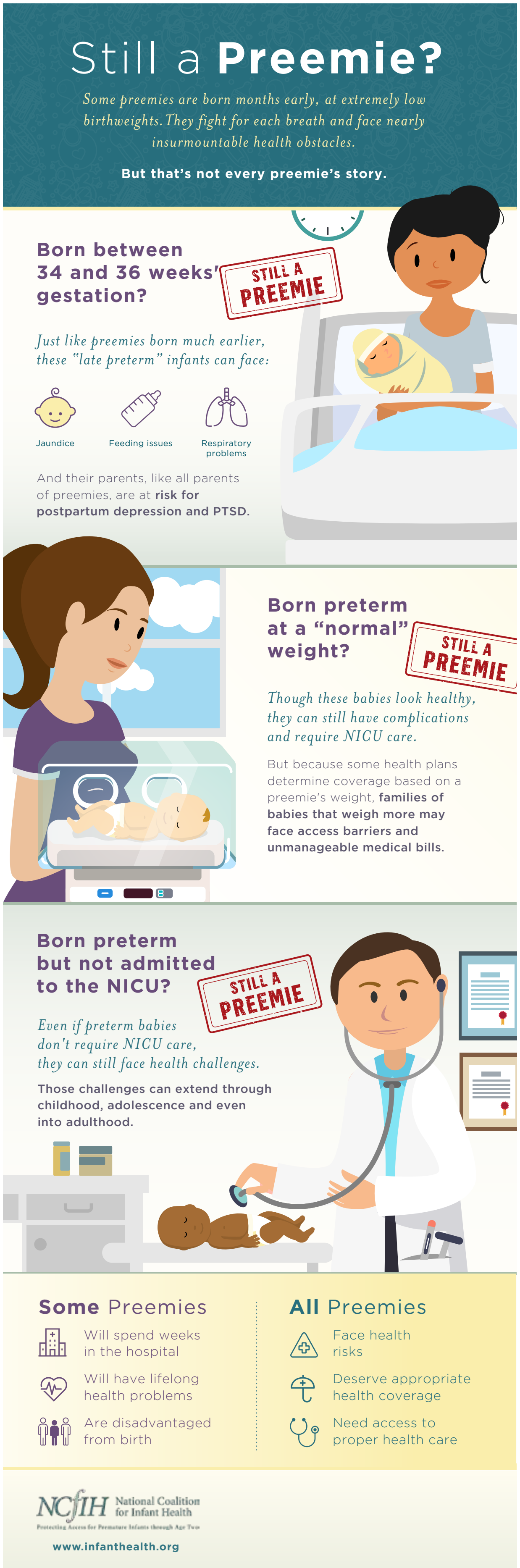

Still a **Preemie?**

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

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation?

STILL A PREEMIE

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

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

Born preterm at a "normal" weight?

STILL A PREEMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREEMIE

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

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

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

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TO CELEBRATE

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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.

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Health Insurance

Eugene L. Mahmoud, MD

Neonatologists, as well as all health-care providers, should keep abreast of the benefits of health insurance guidelines and the negative effects of inadequate health coverage. Children in poverty who otherwise would not have access to health care have greatly benefited from Medicaid and the Children's Health Insurance Care Act. Recent data from the Centers for Medicare & Medicaid Services show the number of children enrolled in Medicaid and the Children's Health Insurance Program (CHIP) nationwide fell by more than 840,000 in 2018. The AAP and its members have undertaken robust advocacy efforts to protect against ongoing threats to health insurance coverage, such as proposed cuts to Medicaid and policies to undermine the Affordable Care Act. On January 22, 2018, Congress passed a six-year funding extension for CHIP. Private insurance is more likely than public insurance to cover the provisions needed but does less well than public coverage in leaving families with reasonable health care expenses. In the last three decades, there has been a major transformation in the way in which private and public health insurance is offered. Once the most common form of coverage, indemnity plans accounted for 73% of employment-based health insurance as late as 1988. Over the next 20 years, only about 3% of workers with employer coverage were enrolled in indemnity plans in 2007, whereas 57% were enrolled in preferred provider organizations (PPOs), 21% in health maintenance organizations (HMOs), and 13% in point-of-service plans, which combine features of HMOs and PPOs. Consumer-directed health plans (CDHPs) have emerged. These plans, which trade lower premiums for higher deductibles, account for a small but growing segment of employer-based coverage. Health insurance entities that provide finance along with private insurance, employers, and government must continue to work together to ensure that all children have health insurance that meets their needs.

> ***"Health insurance entities that provide finance along with private insurance, employers, and government must continue to work together to ensure that all children have health insurance that meets their needs. "***

One service within the healthcare industry that has experienced notable growth is independent medical peer review, conducted by independent review organizations (IROs). A big contributor to this growth is the Affordable Care Act as it allows for the use of external IROs to serve as unbiased, third-party reviewers of denied medical claims to determine whether or not a healthcare service is appropriate and medically necessary. IROs play an important role in the goal of making healthcare safer and more affordable for every U.S. resident. They also offer advantages for health plans and their patients, including reduced costs, access to clinically trained resources, improved compliance, and objective decision-making. IROs have become a popular choice for medical reviews because they offer unbiased decisions and eliminate conflicts of interest. They ensure that each party is considered through a resolution that examines clinical documentation, applies evidence-based guidelines and plan language, and oftentimes includes peer-to-peer calls in which the treating physician and reviewing physician confer over a case. The peer-review calls allow for an explanation of the medical necessary benefits, which may not have been provided in the original request. When a requested service from the provider or patient is denied for insurance coverage, it may be subject to a series of review processes. With the internal appeals process, the insurance client is free to request internal guidelines, plan language, and/or medical literature being used to support the rationale and make a recommendation. And with the external appeals process, evidence-based, peer-reviewed medical literature should be consulted and used to support recommendation.

Private insurance carriers with expert medical involvement generate clear policies and procedures with criteria to their subscribers delineating which medical services are covered by insurance and which medical services are not covered by insurance. Medical providers are expected to make available all medical documentation to ensure that the request for medical care insurance coverage is consistent with what is the standard care of practice commonly provided.

> ***"This relates to Neonatal Care, children with disabilities, and developmental delays often have unmet needs for rehabilitation therapy services, especially if they have inadequate insurance. Some insurance plans have coverage for rehabilitation therapy services."***

This relates to Neonatal Care, children with disabilities, and developmental delays often have unmet needs for rehabilitation therapy services, especially if they have inadequate insurance. Some insurance plans have coverage for rehabilitation therapy services. And these may have high copay fees, high coinsurance rates, or cap the number of visits or services. As a result, many families may report unmet health needs on account of inadequate coverage. When this is the situation, the physician is needed to help coordinate services as much as possible and make the needed referrals to an advocacy organization that helps families find appropriate health providers. Working with Social Services to keep a list of agencies and organizations to which the families may access is recommended. Inpatient and

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outpatient therapy services are based on goals for developing new skills, regaining lost skills (due to illness or medical intervention), maintaining skills at risk of decreasing, making adaptations for functional loss, and providing accommodations. Determining the appropriate dose of therapy is elusive and subjective. Children with chronic health conditions disabilities often need therapy on an ongoing basis with variable intensities for their individual functional goals.

> ***“Care of each high-risk neonate after discharge must be carefully coordinated to provide ongoing multidisciplinary support for the family, including the neonatologist, nurse practitioner, pediatric medical subspecialists, nursing staff, respiratory, physical, occupational, and speech therapists, social services, and discharge planner”***

With increasing numbers, children with unresolved medical problems or special health care needs (such as hospice and palliative care) have been discharged requiring some form of supportive technology. For newborn and premature infants, as well as those with complex medical conditions, gavage feeding may be used safely in the home. In addition, home intravenous nutritional support may be needed when enteral feeding is not possible with home health care support. Care of each high-risk neonate after discharge must be carefully coordinated to provide ongoing multidisciplinary support for the family, including the neonatologist, nurse practitioner, pediatric medical subspecialists, nursing staff, respiratory, physical, occupational, and speech therapists, social services, and discharge planner This is especially required when oxygen therapy or pulse oximetry is involved with newborns having respiratory conditions requiring continued use. Management of continued use is under the direction of a physician. For those infants needing mechanical ventilator support by endotracheal or tracheostomy tube, home health nursing is indispensable for at least part of the day.

For those families who need to provide the medical childcare in the home, this may produce somewhat of a crisis by not being able to work outside of the home in order to care for the child, which complicates how much health insurance may be available for the child’s medical health care. Parents in lower-income families raising children with special health care needs are especially overburdened by debt that may be incurred. Cost-sharing burdens among the privately insured have grown over time. Medical bills are a leading cause of financial harm associated with poor health outcomes and reduced quality of life.

As a nation, we spend 17.9% of our gross domestic product on health care or ~$10 348 per person per year. The largest share of this spending comes from the federal government. Because the increased focus has been turned to curbing health care costs, a possible approach to reducing federal health care spending would be to tighten eligibility requirements for public insurance, including Medicaid and the Children’s Health Insurance Program (CHIP). Indeed, President Trump’s proposed 2018 budget included a plan to reduce eligibility for CHIP, which was projected to result in a net saving of $5.8 billion over 10 years. Although Congress recently reauthorized the CHIP at stable funding levels, the administration’s 2019 budget proposal continues to propose >$1 trillion in Medicaid cuts over a decade, with the reallocation of some funds coming in the form of block grants to states.

Medicaid and the Children’s Health Insurance Program (CHIP) provide health care to over 30 million children. Income eligibility limits for Medicaid have historically directed Medicaid-funded health care to children in poverty. In 1997, the introduction of CHIP (hereafter, Medicaid and CHIP will be referred to simply as “public insurance”) expanded health care access for children, including many in low-income working families.

Reducing public insurance eligibility may potentially result in a large number of children who are currently publicly insured having to either purchase commercial insurance or become uninsured. With these findings, we can also predict substantial shifts in costs to lower-income families, commercial insurance (if obtainable by families), and/or the health care institutions that serve them. Increases in child health care access resulted in more consistent primary care use, decreases in avoidable hospitalizations, and decreases in child mortality. Rollbacks in public insurance eligibility criteria may potentially result in large increases in both non-insurance and underinsurance owing to the cost of obtaining commercial insurance coverage for low-income working families.

Reducing public insurance income eligibility criteria may place health care institutions at greater financial risk, especially safety-net hospitals, which already operate at narrower financial margins and other hospitals serving large numbers of newborns and low-income families. Any reductions in state-level funding for pediatric public insurance programs may result in lowering of eligibility thresholds. Reducing public insurance eligibility limits would have resulted in numerous pediatric hospitalizations not covered by public insurance, shifting costs to families, other insurers, or hospitals. Without adequately subsidized commercial insurance, this reflects a potentially substantial economic hardship for families and hospitals serving them.

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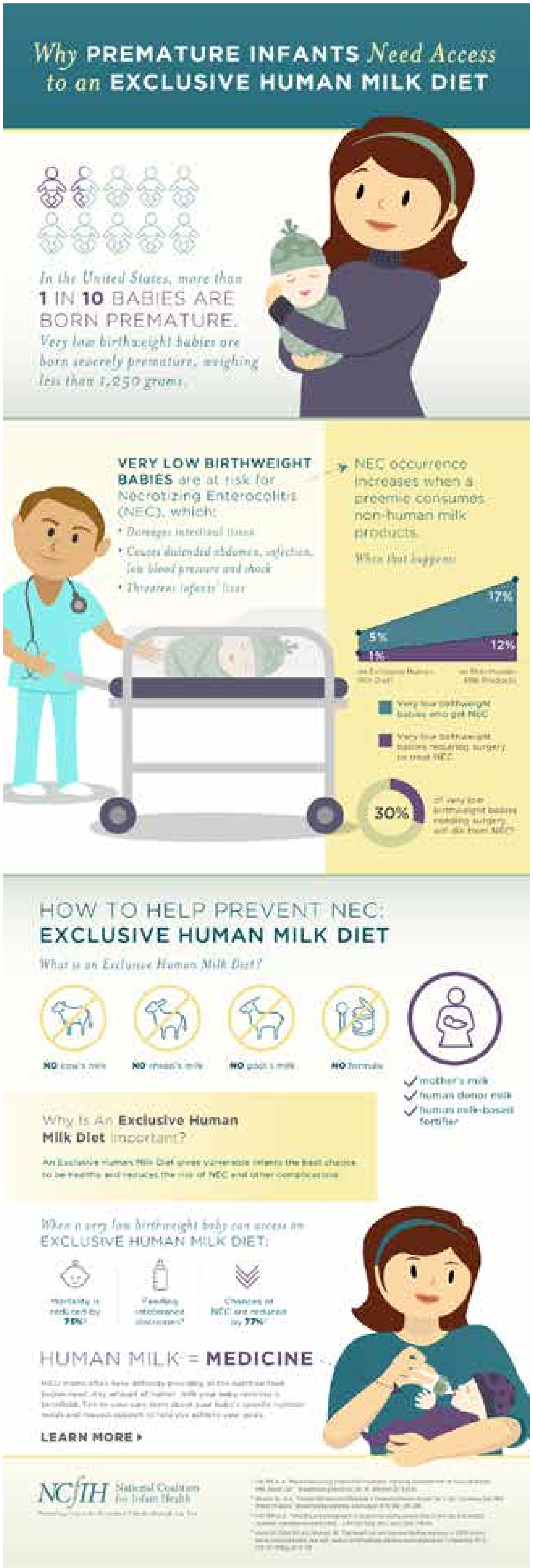

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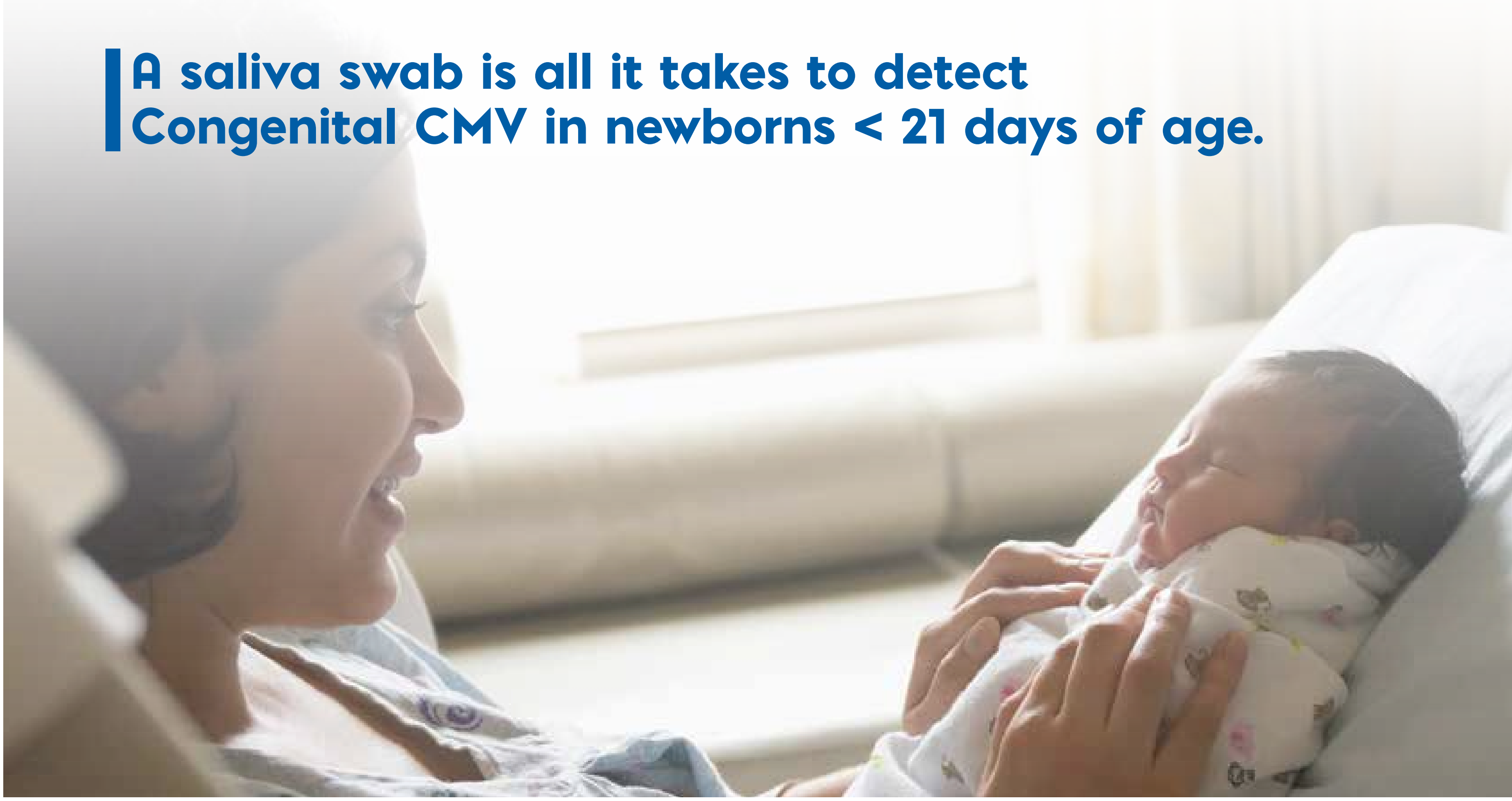

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References: Congenital CMV Facts. Centers for Disease Control and Prevention. https://www.cdc.gov/features/cytomegalovirus/index.html. Published 2018.

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Respiratory Report:
The Edge of Viability
Tiny Patients, Big Questions

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 NICU staff typically view potential outcomes of the smallest, most premature infants more negatively than published evidence would suggest is not a new phenomenon. (1) As we push the limits of what we can and cannot do for these patients, I suspect this view will become even more commonplace. It is unquestionable that there is a line to be drawn when it comes to viability but where to draw that line is a subject of debate.

Anyone who works in an NICU has seen one of their "graduates" who was never expected to survive, come back to visit looking far better than anyone expected. While this is unquestionably a great outcome, it can be a source of moral distress for caregivers. No health care professional takes withdrawal of care (or the withholding of resuscitation) lightly, even when the circumstances suggest that doing so is the correct course of action. Adding to that emotional burden is the knowledge that, no matter how bad things seemed, every now and again, there will be that one child who beats the odds and may well come back with "You wanted to turn me off."

But that babies were born with a label: "Keep," or "Return to sender." Unfortunately, they are not. Here, on the edge of viability evidence takes over and we must rely on that data and our experience as clinicians to try and sus out which babies are viable and which are not. I believe that all life deserves a chance. When life-sustaining interventions are started; however, there is great reluctance to stopping them once a baby demonstrates their inability to survive in an extra-uterine environment. At this point, the question must be asked: are we helping, or harming?

The debate over who should make decisions regarding end of life care has raged for as long as life support has been available to clinicians. In Western healthcare, these decisions predominantly fall on the parents. Some ethicists do not favour this approach. While deference to parents should always be maintained, placing the burden of making the decision to end their baby's life is, I believe, inherently unfair. Parents do not have the knowledge or experience of the NICU team, and there is the possibility that parents will carry a burden of guilt over that decision. (1) In addition, parents typically do not fully understand what "I want everything done" means, and will hold on to the faintest glimmer of hope in the face of overwhelmingly poor odds, as is human nature.

Medicine has a history of throwing treatments and therapies at patients whose prognoses are hopeless to demonstrate to families that everything has been done. I believe the sentiment behind this is, although honourable, ought to be examined. We are loath to assign a cost to human life; however, when treatments are futile and expensive, clinicians must account for costs associated therewith and be transparent with loved ones. Be it for insurance providers or, as is the case in most of the first world, the cost to the public purse, I believe it is counterproductive to spend scarce healthcare dollars in a futile attempt to sustain a life which cannot be sustained.

> ***"Be it for insurance providers or, as is the case in most of the first world, the cost to the public purse, I believe it is counterproductive to spend scarce healthcare dollars in a futile attempt to sustain a life which cannot be sustained."***

Let us consider the use of nitric oxide (iNO) as an example. Despite the National Institute of Health (NIH) consensus opposing this treatment for premature infants, this treatment continues to be utilized and, in some cases, has escalated in frequency. Is it responsible to spend money on a treatment for which there is no evidence to support its use? iNO does not improve outcomes in very premature infants, and to date, researchers have failed to replicate Dr. Roberta Ballard's results. (2,3) Indeed, at the NIH consensus conference on the use of iNO in prematurity, researchers were urged not to study iNO unless attempting to replicate Dr. Ballard's research. Data indicates the practice is widespread in NICU's in the U.S. (and I suspect, although lacking hard evidence, Canada) evidence to the contrary notwithstanding. Reference 3 suggests a small segment of these infants may benefit from iNO, but that widespread use is not indicated.

The decision to resuscitate is, of course, made at birth. Until the baby hits the admission bed, the team has only obstetrical information on which to base decisions. Parents are offered resuscitation on an extremely premature infant based on gestation age and any gestational complications but are they truly aware of the expected outcomes?

When I started my career in the NICU thirty years ago, resuscitation was recommended at 25 weeks gestation (GA), discouraged at 24 weeks, and not offered at 23 weeks. Where resuscitation was offered, parental wishes to the contrary were always respected. Keep in mind this was before antenatal steroids were routinely given, and ventilator technology was very basic and offered only one mode: intermittent mandatory ventilation (IMV). Not surprisingly, chronic lung disease (CLD) rates were astronomical.

Thirty years later, technology has advanced significantly. We now have sophisticated ventilators that offer multiple modes and are capable of providing more lung-protective ventilation than those of old, provided they are used correctly. As the technology available improved, we began to push the limits of viability. Now the resuscitation of 23-week GA babies is offered routinely, and many units are resuscitating babies at 22 weeks GA. This trend may be based on evidence that indicates that while the mortality rate increases as gestational age decreases, especially below 25 weeks, outcomes between 23-25 weeks are similar. Other data, however, show a statistically significant increase in major neurodevelopmental disability with each declining week of GA.4 More worrisome is that as few as 4% of infants survive at 22 weeks GA, and at 22-23 weeks GA less than half survive. Of those, 66% will have more than one major disability. Of course, there is considerable variance in outcomes between NICU's.5 Typically, those that treat more micro-prems have better outcomes than those who do not, although that is not a guarantee. Compounding this is the fact that those unfortunate infants born in a centre without a level 3 NICU are not only less likely to survive, but also more likely to suffer major morbidities.6 This reality bodes poorly for these infants since the costs associated with disabilities are very high.

> ***"In Canada, what little support available for special needs children ends at 25 years of age, at which time long-term financial support is directed primarily to the patient rather than the family. This support is well below the poverty line."***

In Canada, what little support available for special needs children ends at 25 years of age, at which time long-term financial support is directed primarily to the patient rather than the family. This support is well below the poverty line. In the U.S. available support for these children hinges on a myriad of factors, predominantly financial. Lack of funding for follow up care is a travesty, since children with developmental problems can only be helped if they are diagnosed, and the earlier remedial treatment is started, the better the results.

In addition to the obvious concerns associated with the long-term financial burden, other factors pose significant concerns. All parents and all families are not created equal. There are those who can take on the enormous task of caring for a profoundly disabled child and find joy in that task, and those that simply cannot. Emotional and psycho-social factors must be considered, as well as the impact on siblings if there are any. We have all seen families disintegrate under the pressure of caring for a completely dependent child, and as is the predominant nature of our society, the mother is most often left to pick up the pieces. We must be careful not to judge, but rather respect parental ability or inability to cope with their reality

Looking back to the days when resuscitation was not offered to infants under 24 weeks GA, one must consider the reasons for this, and how much has changed since then. The lack of antenatal steroids made the ventilatory management of these infants extremely difficult, and CLD rates were already high in those of significantly greater GA. Surfactant was just coming onto the scene, and ventilator functionality was limited. We have always known that premature infants not delivered in a perinatal centre do not do as well as those that are. This concept is especially true as GA decreases. (My personal experience with 23-week GA infants transferred in from peripheral hospitals reflects this.) Exacerbating this is that not having time to transfer in utero often means not having sufficient time for antenatal steroids to take effect if they are given at all.

A 23-week GA infant of a mother who did not receive antenatal steroids is substantively different from one whose mother has. For this reason, it calls into question, should micro-premies born at peripheral centres be offered resuscitation at all and are parents given the information they need to appreciate and understand the likely outcomes for a micro-prem to make an informed decision? I submit the current approach to the management of expectant micro-prems at peripheral centres is sub-optimal, and that the outcomes thereof could be improved with a radically different approach.

Finally, we must be pragmatic. Physiology is physiology. There is the issue of endotracheal tube (ETT) size. Ventilatory management of a baby with a 2.0 ETT in situ is impractical, to say the least. Airway resistance increases exponentially as size decreases, making high-frequency jet ventilation the mode of choice for tiny patients in my opinion. Additionally, the tiny lumen of a suction catheter small enough to insert in a 2.0 ETT makes effective suctioning nigh to impossible. Declining survival rates as GA decreases allude to a GA limit on viability. There are many who say we have already reached this at 22 weeks GA. Of course, back in the day, many said the same thing about 25 weeks GA, and before that 28 weeks GA, and so on. Be that as it may, the lack of pulmonary and gastrointestinal development, the size of the airways, oropharynx, tiny veins (peripheral and umbilical) and the limited capability of current technology conspire to thwart whatever motions we make to keep these babies alive.

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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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WE NEED MORE RESEARCH

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Peer Reviewed

"Re" Imagining Breastfeeding: What the National Perinatal Association Learned about the Power of Images

Erika Goyer

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.

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"The Image is more than an idea. It is a vortex or cluster of fused ideas and is endowed with energy." – Ezra Pound

August is National Breastfeeding Month. The United States Breastfeeding Committee (USBC) started this initiative in 2011 and it continues each year as a time when breastfeeding coalitions, member and partner organizations, and individual supporters are invited to join in online actions and conversations to build support for the policy and practice changes needed to build a "landscape of breastfeeding support." Because Breastfeeding Awareness Month is largely a social media effort and because the currency of social media (and, really, any good health education campaign) is visual, the National Perinatal Association went to work creating new "sharable" social media content. This meant creating new images.

What is in a Symbol?

The history of the images we have used to represent infant feeding is a problematic one. In the past, pictures of baby bottles were used to represent feeding and to designate spaces where it was acceptable for parents to attend to their babies' needs. Clearly, there was advocacy work to be done. If we were going to normalize breastfeeding, we needed a new symbol. So in 2006 Mothering Magazine sponsored a contest. The winning design for the International Breastfeeding Icon was created by Matt Daigle – a new imagining of infant feeding was born! It is now recognized universally, and it is celebrated for its affirming message. However, while the International Breastfeeding Icon's symbolism is powerful and purposeful, it was not right for our campaign.

> ***"Members of the NPA firmly believe that breastfeeding and breast milk are the standards for newborn and infant feeding. Supporting and normalizing breastfeeding of newborns and infants is a cornerstone of NPA's advocacy work."***

Members of the NPA firmly believe that breastfeeding and breast milk are the standards for newborn and infant feeding. Supporting and normalizing breastfeeding of newborns and infants is a cornerstone of NPA's advocacy work. But because our organization is interdisciplinary and intersectional, we have always known that supporting breastfeeding requires solutions that work across different environments and in varied contexts. It is clear that there is no one way of breastfeeding that works for everyone. We need diverse solutions. So when representing breastfeeding, one symbol would not do; we would need a diverse library of images.

Reimagining

By its nature, the International Breastfeeding Icon emphasizes simplicity and clarity. The goal of NPA's images is different. We wanted to represent infant feeding in all its modes and methods.

Because you are reading Neonatology Today, you certainly understand the issues that face infants and families in the NICU. When a baby is born early or sick, their nutritional needs are different from the typical newborn's. And their ability to feed at the breast can be seriously delayed or impaired. They might have an immature gut. They may be unable to coordinate their abilities to suck, swallow, and breathe. They can potentially burn more calories than they can take in. Yet they need the highest quality nutritional care and nurturing that we can provide if they are going to survive and thrive.

We also understand that when a baby is born sick or early, their parent may be sick and healing too. They are certainly almost always in shock or distress over a traumatic birth. This complicates their capacity and ability to initiate breastfeeding. When we are focusing on saving lives, even the best-laid breastfeeding plan can be abandoned. So we need to put measures in place to support families' breastfeeding goals under these challenging circumstances. These include:

- Assuring the family that their baby's nutritional needs will be met.
- Making time to talk about their feeding goals and how you will create a plan to support them.
- Describing what their babies' feeding progression might look like.


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- Delivering trauma-informed lactation support.
- Explaining different feeding modes and methods (including TPN, gavage, and tube feedings) as well as their pros and cons.
- Offering all the information parents need about feeding interventions (including formula, donor breast milk, and supplemental nutrition) so that they can make informed decisions.
- Supplying high-quality electric breast pumps and appropriate, supportive spaces to pump.
- Feeding parents and supporting their health and nutrition so that they can - in turn – nourish their baby.
- Most importantly, being responsive and flexible.

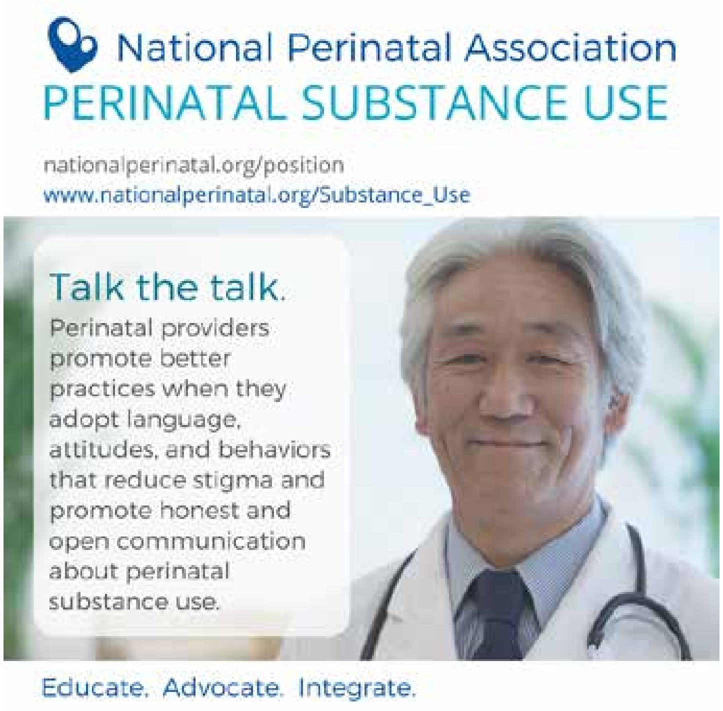
This is why NPA's Breastfeeding Awareness library includes images of dyads using NG-tubes, G-tubes, supplemental feeding systems, and breast pumps.

Once a family's medical needs are being met, we need to appreciate the larger context that feeding decision-making takes place in.

How Families Make Feeding Decisions

Parents and babies are not just part of a family - they are part of a community. How their community has set norms and expectations around breastfeeding will depend on their shared experience. We need to acknowledge that we have not supported communities equally and equitably – and sometimes that has understandably led to estrangement, resentment, and mistrust. If we want to truly address disparities and inequities, the medical profession needs to acknowledge this history, address our biases, and take actions that show cultural humility. We need to demonstrate respect if we are going to begin to remediate the damage and restore trust.

This is why NPA's Breastfeeding Awareness library includes images of members of diverse communities - including Muslim, African-American, and indigenous nations - as well as larger people, young parents, and people with disabilities.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Talk the talk.
Perinatal providers promote better practices when they adopt language, attitudes, and behaviors that reduce stigma and promote honest and open communication about perinatal substance use.

Educate. Advocate. Integrate.

Each of us is a unique individual with unique needs. And it is important that we acknowledge that. The way that people choose to use their bodies is a deeply personal decision. We have responsibilities to support parents' decisions, including when those are decisions that are different from the ones we want them to make.

We also have a responsibility to respect and embrace the way people define and describe themselves, their families, and their bodies. This is why NPA's Breastfeeding Awareness library includes images of dyads that do not conform to gender norms and embraces terms like chestfeeding.

> ***"The way that people choose to use their bodies is a deeply personal decision. We have responsibilities to support parents' decisions, including when those are decisions that are different from the ones we want them to make."***

It is Not All about Formula

The discussion around whether or not to use a formula to feed babies instead of breast milk is an emotionally-charged one. It is a conversation that touches on personal, political, and social issues. And it has resulted in resentment and hurt feeling on nearly all sides.

It is complicated by the fact that there is broad consensus that the history of the marketing and distribution of formula has included many bad actors, dangerous practices, and irresponsible policies that undermined the choice to breastfeed. There is justification for the criticism formula companies have received.

One issue is whether that has given justification to the criticism of formula as a product or of the parents who use it. The vast majority of people who advocate for breastfeeding would want it to be known that they understand the necessity of using formula under specific circumstances. And they do not intend to shame or show contempt for families who choose it. Unfortunately, their intentions may be irrelevant. If I say something and the result is that I hurt or offend you – even if I did not mean to – that hurt is still real. We need to figure out how we will understand, accommodate, and address differing values, choices, and opinions in a way that improves outcomes and builds supportive relationships.

Ultimately, we need to honor that some families will not choose to breastfeed exclusively or use breast milk. They may choose to add formula to their babies' diet. When they do, we need to respect that they are making the choice that is right for them. We have a responsibility to provide them with reliable information and support. We need to believe that families are sophisticated consumers who can advocate for safer and better products that are well-regulated and marketed responsibly.

This is why NPA's Breastfeeding Awareness library includes images of dyads using donor milk, donating breast milk, and using a formula in combination feeding.

Our Responsibility to Build a Supportive Community

Whether or not a family is going to reach their feeding goals depends on multiple factors. Some of them are arguably within our control. Others are not.

We can offer families education and options. We can connect them with specialists who support lactation and infant feeding. And we can make sure they have the tools and equipment they require. But we have to acknowledge that there are other factors to be considered.

We live at a time and in a place where breastfeeding is not well supported. Very few families can access family and parental leave. Even fewer have the benefit of paid leave. Despite laws and mandates, workers are not being protected from pregnancy discrimination and their right to breastfeed and work is not adequately supported or defended. Insurance coverage is varied and unreliable. Co-pays and deductibles – even on what should be considered preventive health care – can make the costs of breastfeeding inappropriately or prohibitively high.

These structural and systematic barriers demonstrate how important provider advocacy is. It needs to be on an individual level when we do things like write letters of medical necessity for electric breast pumps and donor milk. It must be on the personal level when we reliably exercise our rights to FMLA benefits and support our colleagues' needs as parents and nurturers. It should be on the legislative level where we help draft policies, testify in support of legislation, rally our professional organizations, and vote.

Representation Matters

The overwhelming and enthusiastically positive response to the creation and dissemination of the NPA's diversity in breastfeeding image library has meant so much to its creators and has affirmed our admiration for the families and providers we serve. The images have been shared thousands of times and generated respectful and meaningful conversations about how we feed our babies and how we support each other.

Please join us. www.nationalperinatal.org

The goal of the National Perinatal Association's work (in general) and this campaign (specifically) will always be to find the intersection of promoting evidence-based, optimal feeding for newborns and infants while respecting and addressing the personal, cultural, and economic realities that parents face.

This is the foundation of our Best Milk Project, which is setting interdisciplinary guidelines for optimal nutrition during the first two years of life. As we develop and promote these guidelines we want our perinatal community to know…

No matter how you do it...

- nursing
- pumping
- hand expressing
- breastfeeding
- chestfeeding
- on your own
- with support
- with the help of a donor
- for one day
- or one year
- or maybe longer

and especially when you make the choice that is best for you and your baby.

We recognize and honor everyone who does their best to give our babies what they need. Because what babies need are people who love them, care about them, and nurture them.

References:

- *National Perinatal Association* http://www.nationalperinatal.org/
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- *United States Breastfeeding Committee (USBC)* http://www.usbreastfeeding.org/nbm19
- *Mothering Magazine announces winner of International Breastfeeding Icon Design Contest* https://web.archive.org/web/20080506030338/http://www.mothering.com/newsletter/pressrelease-nov06.html
- *Poetry Foundation: A brief guide to Imagism* https://poets.org/text/brief-guide-imagism

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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Co-Chair NPA 2018 conference, Perinatal Substance Use: Evidence-Based Solutions and Support for the Family
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NICU Awareness 2019

EACH SEPTEMBER WE CELEBRATE

Neonatal Intensive Care Awareness

When a Baby Needs Specialized Care

Pregnancy is a time filled with hope and expectation.
Every family hopes for an uncomplicated birth and a healthy baby.
But sometimes the unexpected happens.

Every year more than half a million babies are admitted to a neonatal intensive care unit, otherwise known as a NICU.

Did You Know? It's not just preemies.

- Advances in neonatal medicine mean that more infants can benefit from the specialized care that NICUs can offer.
- Nearly half of all babies in the NICU are born at normal-birth-weight and are 37 weeks gestation or older.
- We need to do more research and collect more data. While the efficacy of NICU care for premature babies is undeniable, we don't know if this is true for the entire NICU cohort.

Conditions that NICUs Treat:

- complications of prematurity
- birth anomalies
- brain injury
- cardiac conditions
- infection
- jaundice
- Neonatal Abstinence Syndrome (NAS)
- respiratory distress

Level I	Level II	Level III	Level IV
Newborn Nursery	Special Care Nursery	Neonatal Intensive Care Unit	Neonatal Intensive Care Unit +
Routine Care	+ Temporary breathing support	+ Full respiratory support	+ Available pediatric surgical subspecialists.

* See *Guidelines for Perinatal Care, 8th Edition*

Sept. 26	NICU Remembrance Day
Sept. 27	NICU Giving Day
Sept. 28	NICU Staff Recognition Day
Sept. 29	Sibling Support Day
Sept. 30	Neonatal Intensive Care Awareness Day

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NICU Awareness

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Did You Know?

Most NICU babies have special needs that last longer than their NICU stay. Many will have special health and developmental needs that last a lifetime. But support is available.

Learn about the programs in your community. Seek out other families like yours. Then ask for help. Working together we can create a community where our children will grow and thrive.

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

Find more resources at nationalperinatal.org/NICU_Awareness

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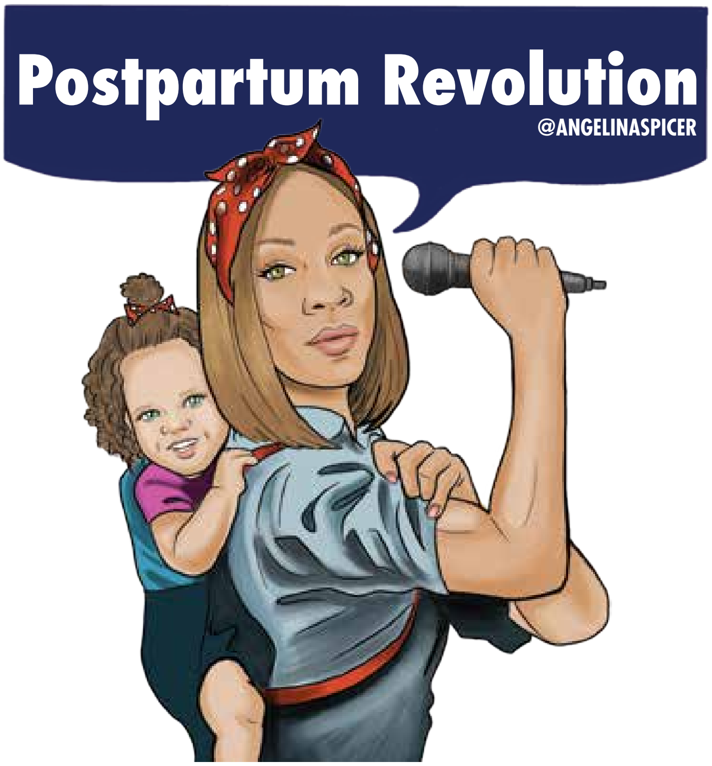


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Fellow's Column: Conservative Management of Urinary Stasis in Prune Belly Syndrome

Brian S. Allen, MD, Shabih Manzar, MD

Brian S. Allen, MD is a pediatric resident at Louisiana State University Health Sciences Center Shreveport.

Case Report:

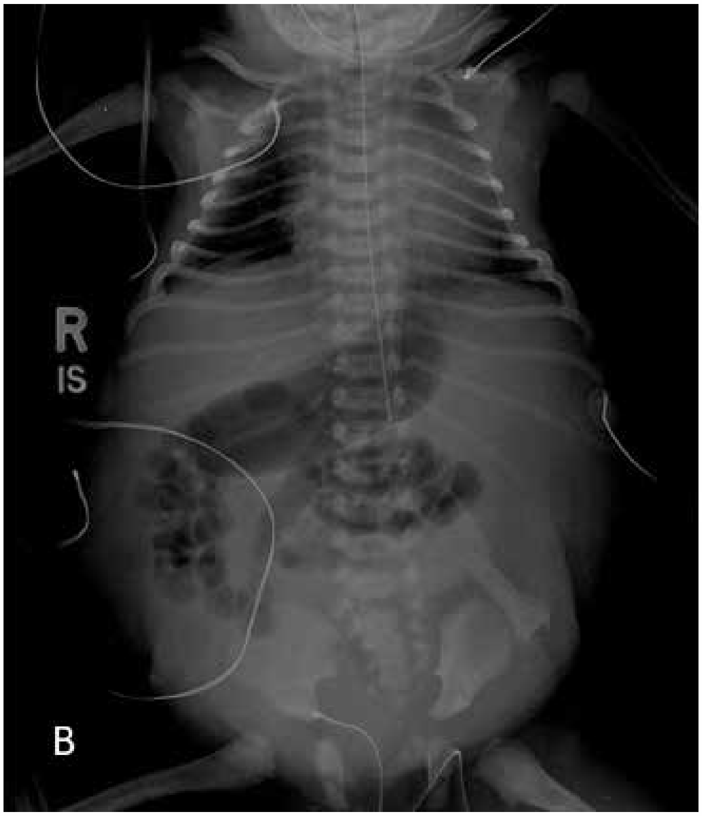
We are writing in follow up to the interesting case of Prune Belly Syndrome (Eagle-Barret syndrome) presented by Khan et al. 1 published in the June 2019 issue of Neonatology Today. A baby boy was born at 40weeks, 1day gestation to a 35-year-old G3P2012 mother by C-Section. All maternal prenatal laboratory including RPR, HIV, hepatitis B, chlamydia, and gonorrhea were negative. Blood group was B positive. Apgar scores were 8 and 9. Birth weight was 4040 grams, length 51 cm, head circumference 36 cm.

Physical examination showed normocephalic head, flat anterior fontanelle and preauricular pit on the left side. Pupils were equal, round, and reactive to light. Cardiovascular examination was normal. The chest appeared small, but no distress was noted. The abdomen was soft and distended with wrinkled skin (Figure 1-A). Testes were undescended bilaterally. Bilateral clubfeet were noted. The skin was warm and dry.

Chest x-ray showed a bell-shaped chest (Figure 1-B). Renal ultrasound showed bilateral hydronephrosis (Figure 2). Pediatric urology and nephrology services were consulted. A voiding cystourethrogram (Figure 3) and Tc-99m MAG3 (mercaptoacetyltriglycine) scan (Figure 4) were ordered. The VCUG showed no reflux and MAG3 showed normal renal perfusion with normal uptake but delayed excretion of tracer by both kidneys. Figure 5 depicts that both ureters and bladder are not seen indicating urinary stasis or obstruction.

> ***"Prenatal history was significant for poor prenatal care and perinatal ultrasound consistent with protruding abdominal wall mass suspecting omphalocele."***

Kidney functions were monitored. Serum creatinine (Figure 6) and urine output (Figure 7) remained normal. In view of the preserved renal function, normal serum creatinine, and urine output, the urology team decided against doing a percutaneous nephrostomy tube or vesicostomy. They felt trace retention was most likely due to urinary stasis rather than true obstruction. The infant remained stable and tolerated full enteral feeds of Similac PM 60/40 formula. He was started on amoxicillin 50mg daily for UTI prophylaxis and circumcised at the bedside by urology. He was discharged home with follow up with pediatric urology, pediatric nephrology, and NICU high-risk clinic.



References:

1. *Khan A, Hafeez M, Khan W. Case Report: Prune Belly Syndrome- With An Unusual Presentation. Neonatology Today; June 2019:20-23*

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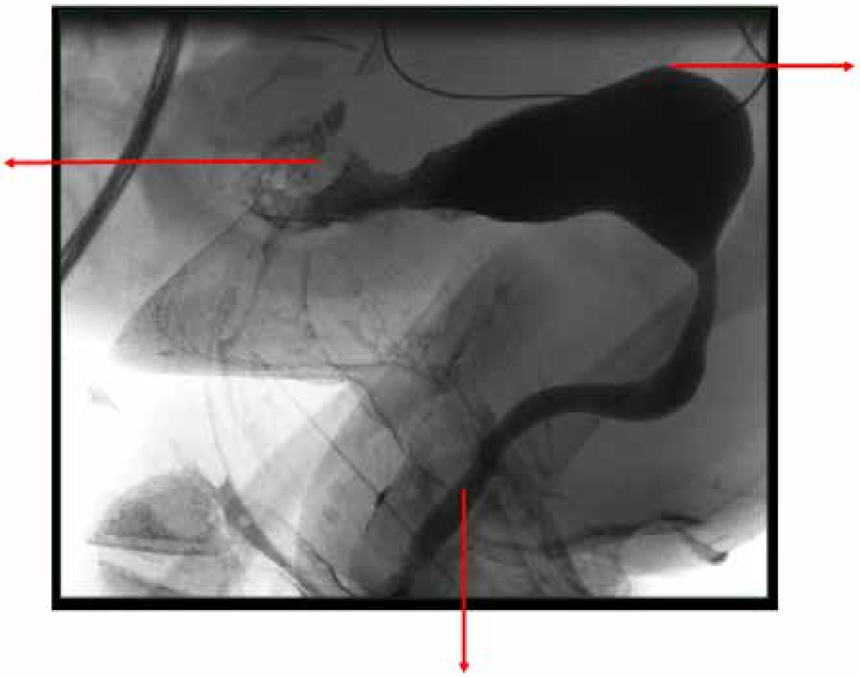
Disclosure: The authors do not identify any relevant disclosures.

Figure 2: Renal ultrasound showing hydronephrosis



No vesicoureteral reflux was demonstrated

A defect in the anterior superior region of the bladder possibly due to urachal diverticulum

The urethra was normal in caliber and demonstrated no strictures or obstructions

Figure 3: Voiding cystourethrogram (VCUG)- no vesicoureteral reflux, normal urethra

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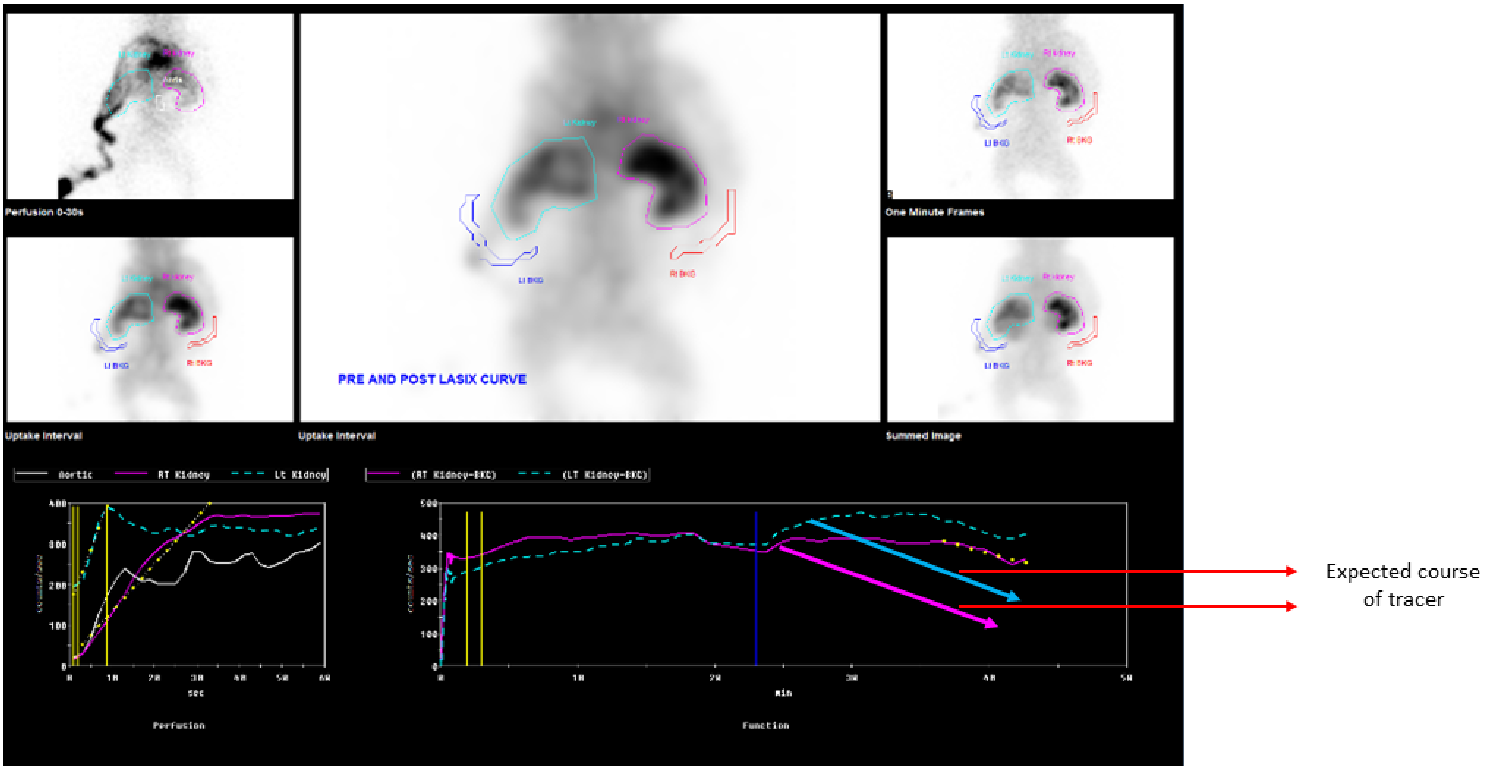

Expected course of tracer

Figure 4: Renal scan: Tc-99m MAG3 (mercaptoacetyltriglycine). Posterior abdominal radionuclide angiogram.

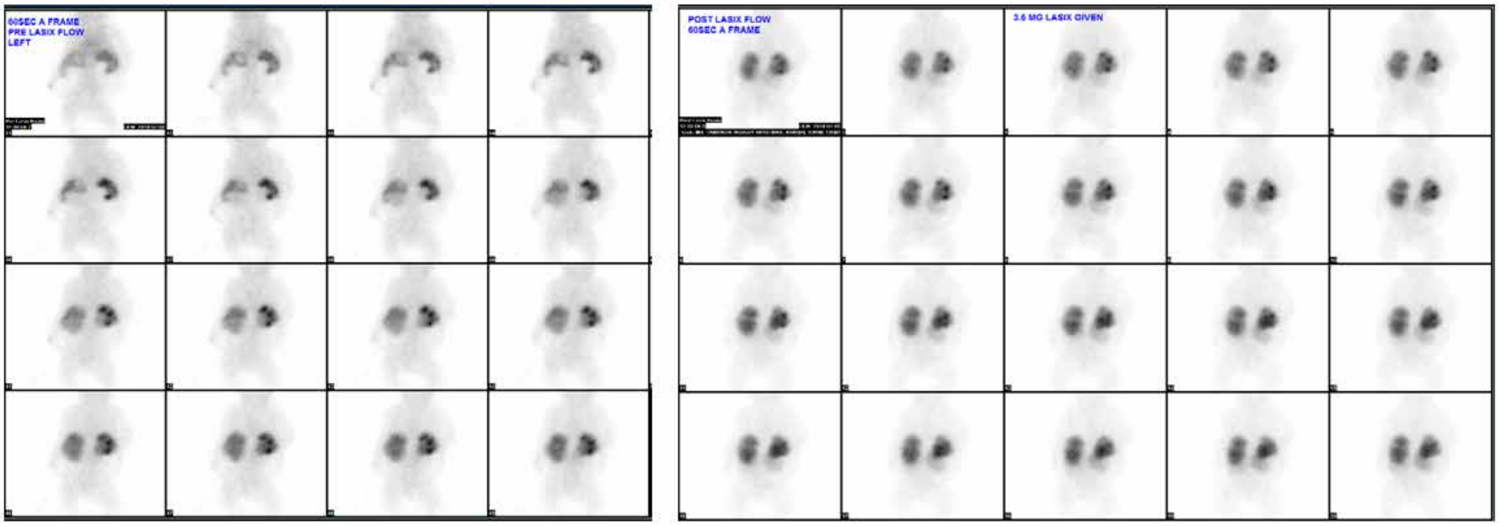

Figure 5: Pre and post Furosemide scan

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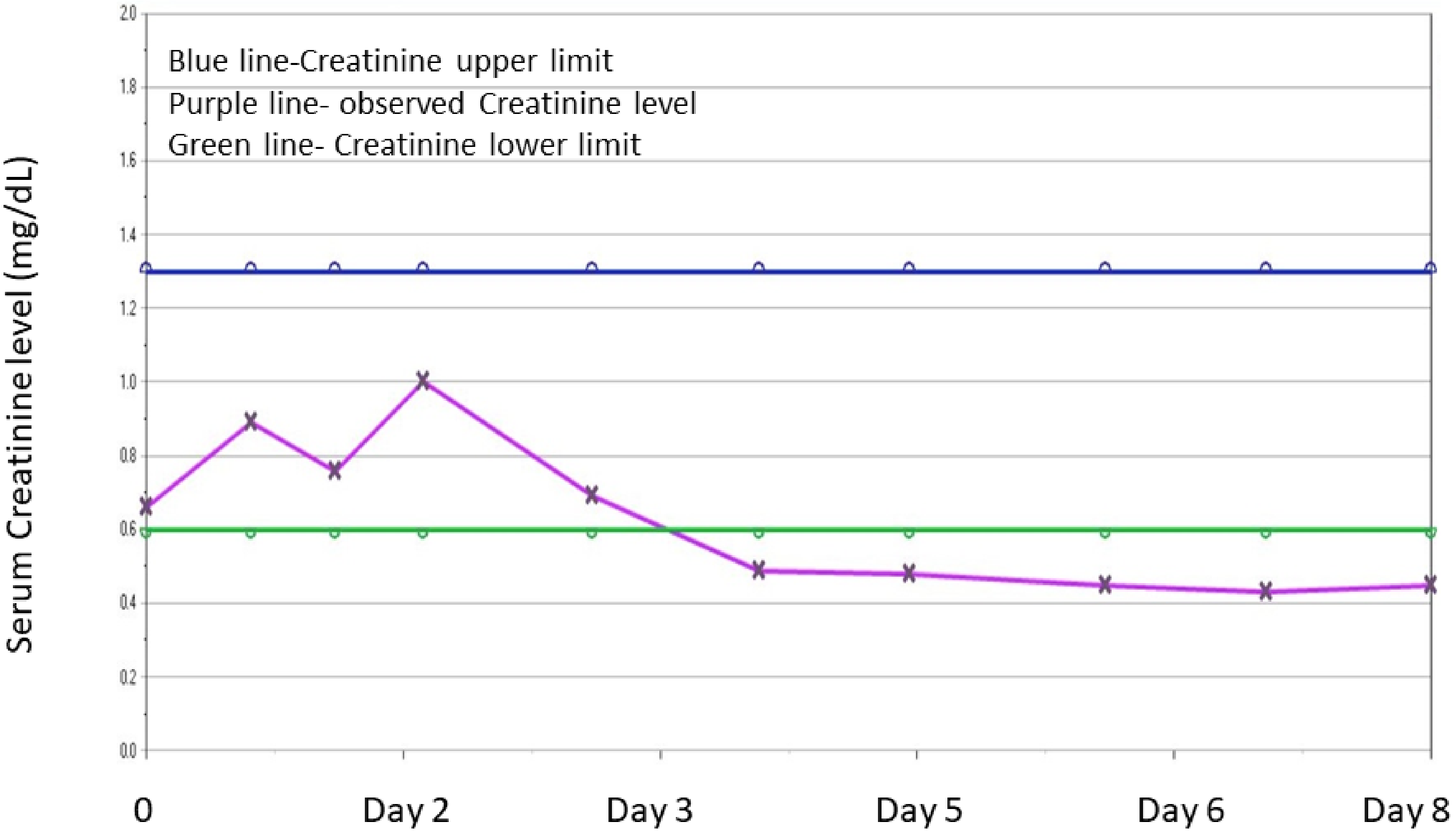

Figure 6: Serial serum creatinine level

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The Brett Tashman Foundation is a 501©(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to "TheBrettTashmanFoundation.org" or phone (909) 981-1530.

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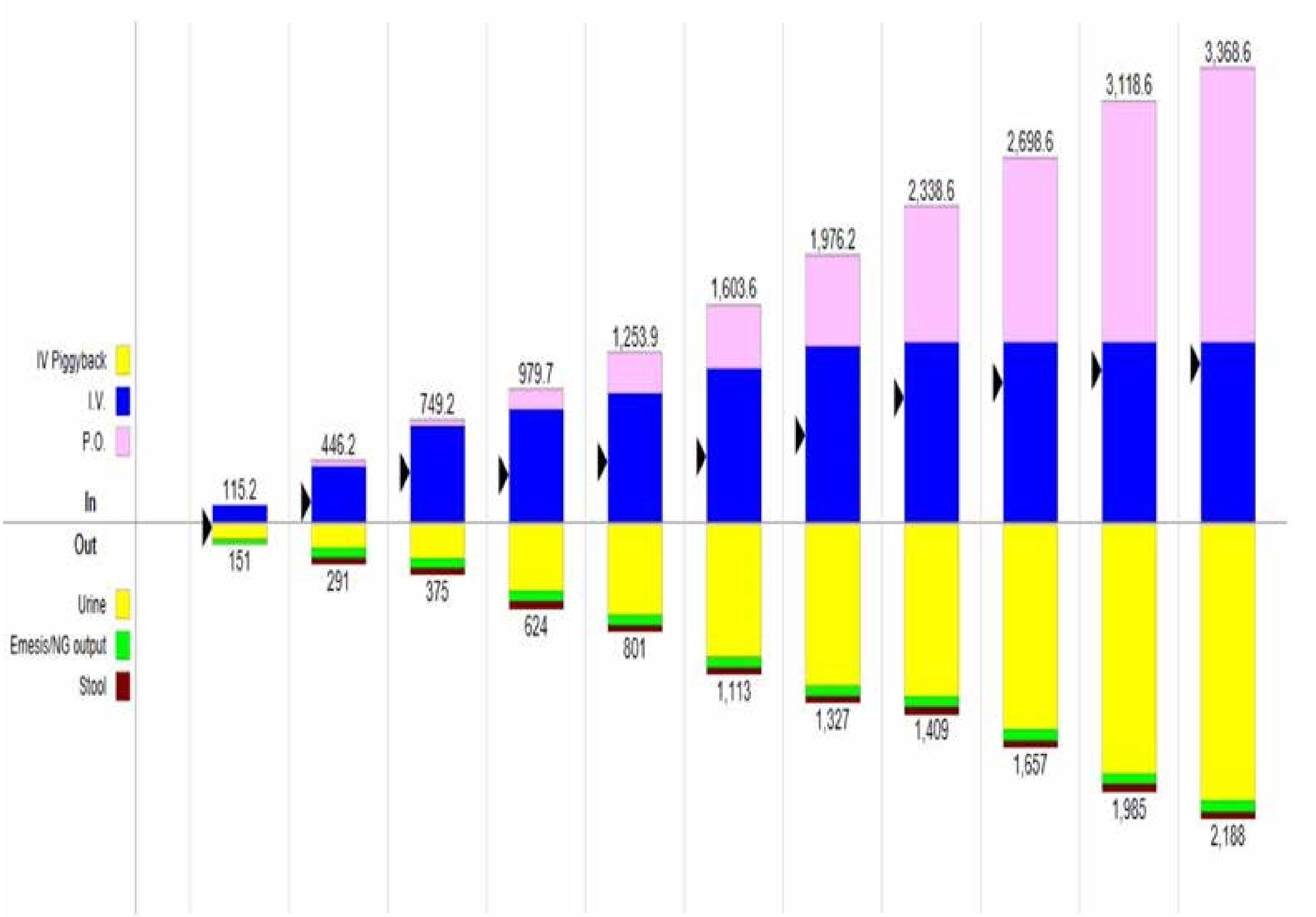

Figure 7:Graphic representation of cumulative intake and output (days)

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Fellow's Column is published monthly.

- Submission guidelines for “Fellow's Column”:
- 1250 word limit not including references or title page.
- QI/QA work, case studies, or a poster from a scientific meeting may be submitted..
- Submission should be from a resident, fellow, or NNP in training.
- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
- No more than 7 references.
- Please send your submissions to:

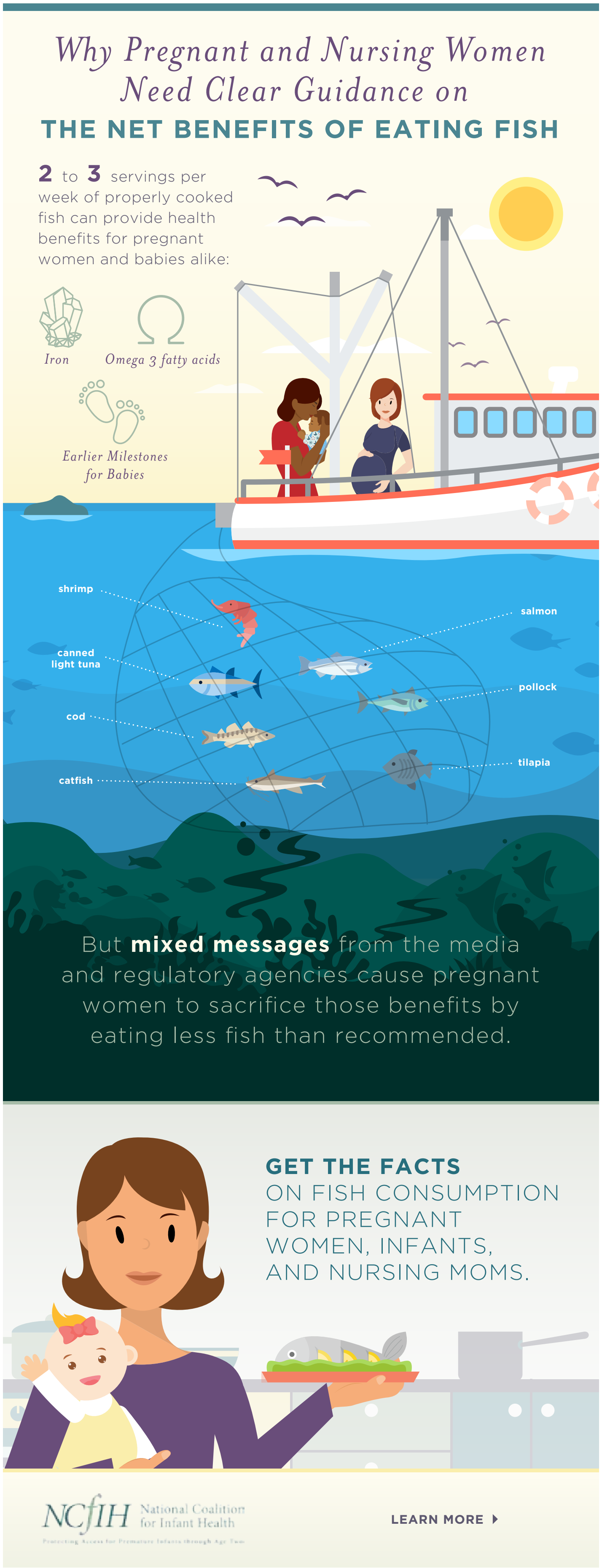
Elba Fayard, MD
Interim Fellowship Column Editor
lomalindapublishingcompany@gmail.com

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



Peer Reviewed

Childhood Vaccine Policies: Preterm Infant Edition

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.

Researchers, health care officials, and legislators across the country have been debating vaccination policies and legislation. As outbreaks of vaccine-preventable diseases have increased, different approaches are emerging, including studying access for vulnerable populations, expanding authority to increase vaccinations and a focus on vaccination exemptions.

Preterm Infant Vaccination Study

Annika M. Hofstetter (Assistant Professor of Pediatrics, University of Washington; Principal Investigator, Seattle Children’s Research Institute) led a team to study the “Early Childhood Vaccination Status of Preterm Infants” published by the American Academy of Pediatrics Journal. (1)

The Hofstetter study was based on the premise that preterm infants face a higher risk of vaccine-preventable diseases and other complications, but only limited studies have been made to detail the impact of delay and timeliness of infant vaccinations on this vulnerable population. Premature birth (birth before 37 weeks of gestational age) and its complications are the number one cause of death of babies in the United States, which makes the findings of this new study particularly valuable.

According to Dr. Hofstetter, the United States Advisory Committee on Immunization Practices recommends that all medically-stable preterm infants receive a full panel of early childhood vaccinations. For the study, her team investigated preterm infants compared to vaccinations of term and post-term infants (those born at 37-43 weeks gestation) — 10,300-plus infants total made up the study.

> ***“Unfortunately, the study found that a lower percentage of preterm infants completed the recommended 7-vaccine series of immunizations by 19 months of age, compared to term/post-term infants. “Over half of preterm infants were under-vaccinated at 19 months; one-third failed to catch up by 36 months,” the study concluded. "***

Unfortunately, the study found that a lower percentage of preterm infants completed the recommended 7-vaccine series of immunizations by 19 months of age, compared to term/post-term infants. “Over half of preterm infants were under-vaccinated at 19 months; one-third failed to catch up by 36 months,” the study concluded.

As a result of the findings, it was recommended that a road map and “strategies” were needed to improve vaccination timeliness for preterm babies, as they are already deemed “high-risk” at birth based on their gestational age. (2)

New York - Measles Outbreak & Lowering the Age of Vaccination

Health care officials in New York are looking at limitations on infant vaccinations and delays based on age - policies that may be changed by health officials based on exigent circumstances.

New York has seen a significant increase in the rise of measles cases. In May 2019, The Verge reported that New York health officials had made a policy change to give “doctors the go-ahead to lower the vaccination age to six months in areas with ongoing

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outbreaks" of measles alone - to ensure the early vaccination of infants (before one year old).

The article noted a policy change for earlier dosing of babies was unusual, and the age was lowered only because of the particular circumstances of the measles outbreak. It was mentioned that immune response and longevity of the vaccine would vary baby to baby, hence the hesitation in lowering the age.

The early dose protection was described as applying to infants in general. "Making sure everyone who can be vaccinated is vaccinated is the best way to keep the virus from gaining traction in the US again, according to the CDC." (3)

California - Vaccines & Exemption Policy Tighten

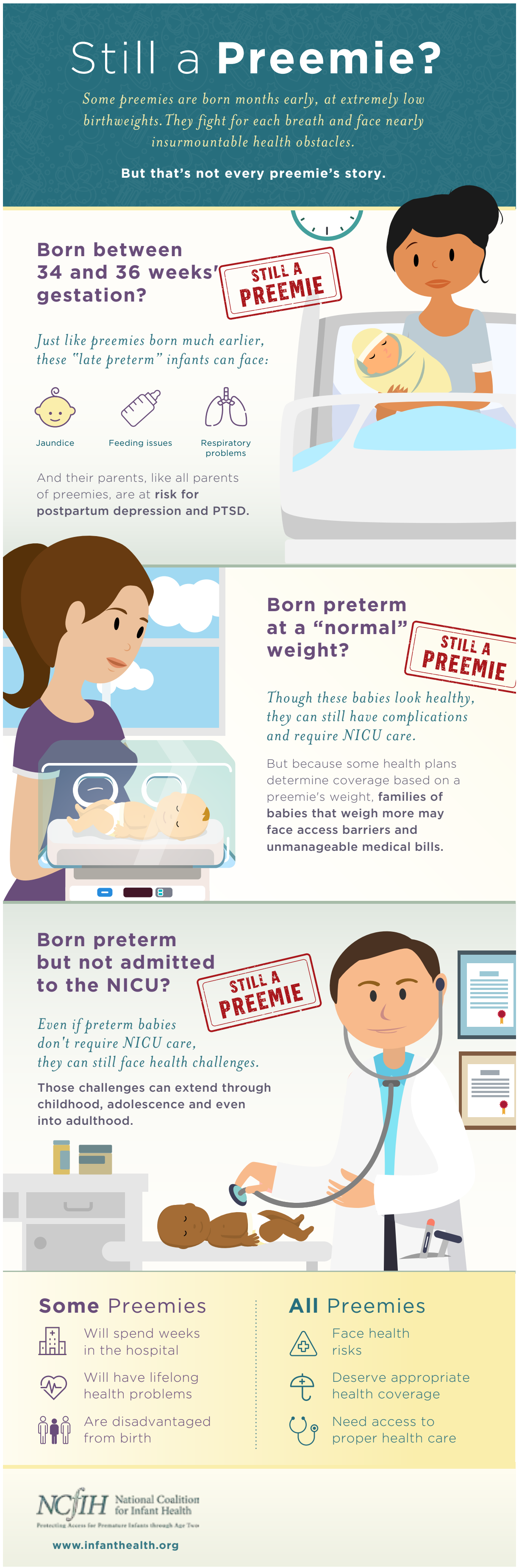
Late this summer the California Assembly and Senate sent a controversial immunization measure to the state's governor. SB 276 would give state public health officials oversight of doctors who provide more than five medical exemptions annually (with the ability to reject those medical exemptions), and the bill calls for scrutiny by the Public Health Department of schools with vaccination rates less than 95%.

"SB 276 was introduced amid the worst measles outbreak in more than two decades, with more than 1,200 people diagnosed with the disease this year," wrote the Los Angeles Times.

Demonstrating the controversial nature of vaccination exemptions - California Governor Gavin Newsom is seeking last-minute changes to the vaccination bill before deciding whether to sign it into law.

Conclusion

Given the findings of the Hofstetter study, policymakers would be well-served to receive and review additional studies on infant health and immunization, particularly in their state. If they knew more about the vaccination disparity that preterm infants are woe-



Still a **Preemie?**

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

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation?

STILL A PREEMIE

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

Jaundice

Feeding issues

Respiratory problems

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

Born preterm at a "normal" weight?

STILL A PREEMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREEMIE

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

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

Some Preemies	**All** Preemies
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

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

fully behind in their immunizations compared to term/post-term infants, perhaps then the child vaccination debates - perpetually shrouded by controversy - would focus on more vulnerable populations.

References:

1. *Hofstetter AM, Jacobson EN, deHart MP, Englund JA. Early Childhood Vaccination Status of Preterm Infants. Pediatrics. 2019;144(3):e20183520.*
2. *Fighting Premature Birth: The Prematurity Campaign | March, https://www.marchofdimes.org/mission/prematurity-campaign.aspx (accessed September 09, 2019)*
3. *New York State Is Allowing Early Vaccination For Infants .., https://news.2dms.com/posts/3429/new-york-state-is-allowing-early-vaccination-fo (accessed September 09, 2019).*

The author has not indicated any disclosures.

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Medicolegal Forum: Surrogacy

Gilbert Martin, MD and Jonathan Fanaroff MD, JD

Surrogacy is a contractual arrangement which is basically divided into two types.

The first is” traditional surrogacy.” This first type is an arrangement where the woman is impregnated with the sperm of a married man. The understanding is that the offspring is to be legally the child of the married man and his infertile wife. The second type of surrogacy is labeled “gestational surrogacy” where the sperm of the married man is fertilized artificially with the egg of his wife and the resulting embryo is implanted in the surrogate women.

“The surrogate mother is providing an important service without any expectation that the child will be “her own.” The prepared contract seems simple, but the words on paper often cannot reflect the feelings of the surrogate mother. ”

The surrogate mother is providing an important service without any expectation that the child will be “her own.” The prepared contract seems simple, but the words on paper often cannot reflect the feelings of the surrogate mother. The environment of the fertilized egg, which is genetically programmed needs to be nutritious and toxic-free. After the contract is signed, what can the biological parents do if the mother decides to smoke, drink, or participate in other activity which may not be in the fetus’s best interest?

Another potential but very real problem is separating the biological from the custodial. That is, the surrogate mother may bond with this growing fetus inside of her and not want to honor the existing contract.

The surrogate mother advises the parents regarding her feelings and what can the parents do?

They have paid the surrogate mother for this service and now are challenged in deciding how to proceed. If they hire an attorney to enforce this contract, the mother now facing financial loss, might create a “hostile” environment for the fetus.

Commercial surrogacy, for example, is legal in India and California, but it is illegal in most other states in this country. In fact, India is now promoting “fertility tourism.” In theory, a mother who needs money achieves her goal. The infertile couple now has a biologically related child, but there are commercial agencies, minimal legislation, and poor transparency.

There are penalties in many states which need to be considered. For example, Michigan, New York, Indiana, and other states have declared traditional surrogacy agreements null, void and contrary to public policy. Often gestational surrogacy is not addressed. On the other hand, states like North Dakota and Washington generally allow surrogate contracts but within very strict parameters. Other states, (Arkansas, Florida, and Illinois) for example allow surrogacy with complicated design contracts which require interruption from a sophisticated legal analysis.

In California, a very liberal state, some believe that the surrogacy law violates the 14th Amendment, which is the denial of due process and equal protection rights. Petitions have been filed with the Supreme Court. There is a generation of children that are severed from their biological parents. Are we responsible and turning these babies into “commodities”?

We have emphasized some of the ethical and emotional considerations. Unfortunately, financial issues must be considered, as well. The surrogate mother may ask the parents for extra funds to provide better nutrition and improved living arrangements. Does this include a new car or condominium in a fashionable area?

It is an ethical, legal, financial, and emotional “tug-of-war.” What happens in this age of advanced technology if the fetus is not “perfect”? Do the parents get their money back? Frequently, the desire for a baby outweighs the future consideration of how this “special child” will affect the composition and structure of the entire family.

“It is an ethical, legal, financial, and emotional “tug-of-war.” What happens in this age of advanced technology if the fetus is not “perfect”? Do the parents get their money back?”

A cottage industry was “born.” But ... too many contingencies. Too many variations. There certainly is “contract law.” Is there biological law? Is scientific technology interfering with the needs of society? Why are there so many different state laws regarding surrogacy?

We describe today “baby-friendly” hospitals in many states. Do agencies that market to individuals seeking surrogate mothers advertise in “surrogate friendly states”? We have yet to see an advertisement attempting to attract families to move to a specific state stating, “we have liberal surrogacy laws.”

The poem below was written in 1987 and entitled “Ode to Surrogation.” It seems quite appropriate to include this in this month’s medicolegal forum.

99nicu

The United States of America,
A proud progressive nation.
Has become deeply involved,
In maternal surrogation.

A contact was drawn up you see,
In simple terms, to please.
Now attorneys and magistrates,
Have added LEGALEEZE.

This issue friends, is not that new,
With no concern for libel.
Hagar bore Abram a son,
It says so in the Bible.

No notes were drawn, no cash did pass,
The deal lacked compensation.
Sarah was miffed however at Hagar's
Successful incubation.

Centuries passed, the practice grew,
With gold and diamond purses.
In Dicken's day, infants were fed,
By loving gals…wet nurses.

Governesses, adoptive parents,
All have roles to play.
It is no wonder, that we've reached,
This quandary of today.

Renting space to nurture life,
Artificial insemination.
No different in a Petri dish,
Or test-tube procreation.

Ethical considerations,
Are legally complex.
It's not surprising that these techniques,
Obfuscated sex.

The agreement of the service type,
Like one you'd buy at Sears.
The contract not for Baby M,
So why then all the tears?

The answer lies within emotions,
The psyche that governs all.
Separation after bonding,
Mom hears her baby bawl.

This problem will not go away,
Support groups now add style.
They've made a biological process.
Become quite mercantile.

Surrogate Mothers Limited,
A business with a range.
Has offered shares to new investors,
On the OTC exchange.

First will come the legal statutes,
Then full blown legislation.
As supply and demand do flux,
There will be regulation.

The industry will process, I'm sure,

Profits and laissez-faire.

Finally forced to de-regulate,

The public will see air.

A cottage industry born in Genesis,

Though technically, no sweat.

Has now become child battering,

Or, "whose kid will you get?"

We cannot separate human feelings,

From contractual restitution.

Back to basics…consultation,

The U.S. Constitution.

Where do we go from here? Ethical and Medicolegal issues abound.

The authors have no conflicts of interests to disclose.

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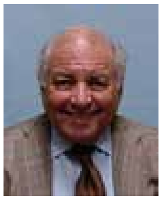

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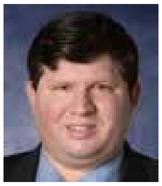

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Disclaimer:

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.

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Millennium Neonatology: Building a Better Pathway for Preemies

Saturday, November 16, 2019
8 a.m. to 5 p.m.

Women & Infants Hospital
Malcolm and Elizabeth Chace Education Center
101 Dudley Street, Providence, RI

Women & Infants
A MEMBER OF CARE NEW ENGLAND

About Women & Infants South Pavilion

In September 2009, Women & Infants opened the South Pavilion with The Carter Family Neonatal Intensive Care Unit, a new 80-bed, single-family room NICU, The Malcolm and Elizabeth Chace Education Center, and a state-of-the-art antenatal care unit. Since then, many centers have opened single-family room NICU's. Longitudinal prospective studies of the impact of this innovative model of care on developmental outcomes published in *Pediatrics* in 2014 and in the *Journal of Pediatrics* in 2016 demonstrated significant improvement in neurodevelopmental outcome in graduates of our single-family-room NICU. These improvements were mediated by increased maternal involvement in care afforded by the single-family room setting. Follow up after two years demonstrated these effects were sustained. It was noteworthy that there was also a demonstrable effect of maternal involvement in care in our open bay NICU. However, the effect was substantially greater in the single-family-room NICU and was attributable to increased maternal care, skin-to-skin care and visitation.

In concurrent studies, we also showed that the model of care and patient characteristics were significantly associated with alterations in epigenetic effects on the glucocorticoid receptor in low birth weight infants. Since report of these studies, extensive literature has emerged on the importance of the environment of care and clinical context for long-term developmental outcome. Environmental factors have emerged as critical underpinnings of epigenetics. While we have made substantial progress in the prevention and treatment of complications of prematurity, there is increasing recognition of the interplay between major organ system disorders and abnormal developmental outcome. The complex interplay of physiology, metabolism, and organ system function that all have measureable and lasting effects of developmental outcome lead to the question: How DO WE build a better pathway for preemies?

Confererence description

This symposium will bring together experts in the fields of neurodevelopment, lung biology, environment of care and neuroimaging. We will be exploring ways to leverage the partition between nature and nurture. We will examine the care of these children in the postnatal environment and post-hospitalization to prevent continuing illnesses, hospitalizations, and unrealized developmental potential.

Capping off the 10th anniversary celebration of our Carter Family Neonatal Intensive Care Unit (NICU) will be a story of one of our NICU babies and his incredible connection to the creator of the Disney-Pixar movie, *Finding Nemo*.

Learning objectives

1. Explain the biological, genetic, and epigenetic mechanisms underlying the long-term effects on neurobehavioral pathways and developmental outcomes.
2. Describe the strategies for an optimal neurodevelopmental environment and assessment of neurodevelopmental potential.
3. Identify the ways to maximize care in the NICU and during early discharge in order to avoid continuing morbidities, hospitalizations, and to optimize developmental potential.

Nursing breakout session

Single Family Room Model, 10 Years Later: A Nurses View
Please join us for a panel discussion with nurses who moved with the unit 10 years ago. Neonatal nursing is at the heart of the successful impact of the single-family-room NICU on developmental outcome. A model utilizing family-centered care, communication and a welcoming environment that partners families and staff contributes significantly to measurable developmental improvements. Learn about their perspective of the single-family-room style NICU and what they have learned over the years.

Registration required. No additional fee.

Target audience

Neonatologists
Developmental Specialists
Neonatal Nurses
Residents
Nurse Midwives
Occupational Therapists
Pediatricians
Perinatologists
Neonatal Nurse Practitioners
Fellows
Social Workers
Physical Therapists
Psychologists
Obstetricians
Respiratory Therapists
Clinical Educators
Nursing/Medical Students
Nutritionists

All health care professionals responsible for Perinatal and Neonatal Care

CME accreditation

Women & Infants Hospital is accredited by the Rhode Island Medical Society to sponsor continuing medical education for physicians.

Designation statement

Women & Infants Hospital designates this live activity for a maximum of *5.75 AMA PRA Category 1 Credits*™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

Nursing continuing education credit

This activity has been submitted to the American Nurses Association Massachusetts for approval to award contact hours. ANA Massachusetts is accredited as an approver of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. For more information regarding contact hours, please call Emily Brequet, 401-274-1122, ext. 44520.

NICU tours

There will be tours of The Carter Family Neonatal Intensive Care Unit by our own staff with ample opportunity for questions and answers. Sign-up at registration.

Program

8-8:30 a.m.	**Registration, continental breakfast & NICU tour sign-up** Upon arrival, please check in at the registration table to pick up your name badge and sign-up for a NICU tour. A continental breakfast will be available.
8:30-8:45 a.m.	**Opening Remarks** James Padbury, MD William and Mary Oh – William and Elsa Zopfi Professor of Pediatrics for Perinatal Research The Warren Alpert Medical School of Brown University Pediatrician-in-Chief, Women & Infants Hospital
8:45-9:30 a.m.	***Making Better Preterm Babies*** Alan H. Jobe MD, PhD Professor of Pediatrics/Neonatology Cincinnati Children's Hospital
9:30-10:15 a.m.	***The Importance of the Placenta in Programming Children's Health*** Carmen J. Marsit, PhD Professor of Department of Environmental Health Emory University Rollins School of Public Health
10:15-10:30 a.m.	**Break & NICU Tours**
10:30-11:15 a.m.	***Cartesian Dualism in the NICU - Is the End in Sight?*** Robert D. White, MD Director, Regional Newborn Program Beacon Children's Hospital
11:15-12 p.m.	***The Developing Human Connectome*** David Edwards, DSc, FMedSc Professor of Paediatrics and Neonatal Medicine Director, Institute for Women's and Children's Health King's College London and Evelina London Children's Hospital
12-1:15 p.m.	**Lunch & NICU Tours**

12:15-12:45 p.m.	**Nursing Panel Discussion – Lunch and Learn** ***Single Family Room Model, Before & After: A Nurses View*** *Registration required* Facilitator: Katheleen Hawes, PhD, RN Psychiatric Clinical Nurse Specialist Clinical Assistant Professor of Pediatrics Warren Alpert Medical School of Brown University
1:15-2 p.m.	***Neonatal Neurobehavior: A Window into the Future?*** Elisabeth C. McGowan, MD Assistant Professor of Pediatrics Warren Alpert Medical School of Brown University
2-2:45 p.m.	***Neonatal Abstinence and the Importance of Family-Centered Care*** Adam J. Czynski, DO Assistant Professor of Pediatrics (Clinical) Warren Alpert Medical School of Brown University
2:45-3 p.m.	**Break & Tours**
3-3:45 p.m.	***Parents and Play in the NICU: Critical Ingredients for Successful Outcomes*** Betty R. Vohr, MD Professor of Pediatrics Warren Alpert Medical School of Brown University
3:45-3:50 p.m.	***Just Keep Swimming*** Discover what the creator of *Finding Nemo* and a baby from Rhode Island have in common.
3:50-4 p.m.	**Closing remarks** Evaluations CME/Contact Hour Certificates
4 p.m.	**Reception**

General information

The conference will be held in the Malcolm and Elizabeth Chace Education Center of Women & Infants Hospital. For additional information, please visit womenandinfants.org/millennium.

Hotel accommodations

Hampton Inn & Suites Providence Downtown
58 Weybosset Street, Providence, RI 02903
(401) 608-3515

A special meeting rate of $149/night, single or double occupancy has been arranged. Room rates are quoted exclusive of applicable state and local taxes.

Group Name: Millennium Neonatology: Building a Better Pathway for Preemies

Group Code: WIF
https://hamptoninn.hilton.com/en/hp/groups/personalized/P/PVDWYHX-WIF-20191114/index.jhtml?WT.mc_id=POG

The Hampton Inn & Suites Providence Downtown is located 1.3 miles (7 minutes) from the hospital and provides valet parking at a rate of $28.00 per night.

Conference parking

Parking will be available on site in Lot W-4 on Dudley Street, event parking signage will be at the lot entrance.

Registration information

Online or Brochure Form. Conference fee includes attendance at the conference, participant syllabus, continental breakfast, lunch, afternoon break, and reception.

No at the door registrations.

Cancellation Policy: A fee of $10.00 will be assessed if cancellation notice is received by Thursday, October 31, 2019. A fee of $25.00 will be charged if cancellation notice is received November 1 through November 15, 2019. No-shows are responsible for full registration fee; however, substitutions are welcome without penalty. Please provide substitution information prior to the meeting.

Methods of Payment: Personal checks or money orders. Please make checks payable to Women & Infants Hospital. Visa, MasterCard or Discover are also accepted. Sorry, no American Express.

For More Information: Please visit our website at womenandinfants.org/millennium or contact Mary Tucker at mtucker@wihri.org/(401) 274-1122 x 47405 or Brenda Vecchio at bvecchio@wihri.org /(401) 274-1122 x 47404.

Registration form

Millennium Neonatology: Building a Better Pathway for Preemies

Register and pay on line at womenandinfants.org/millennium.

Name ____

Position/Title ____

Affiliation ____

Address ____

City______________________ State________ Zip______________

Telephone______________ Email Address ____________________

Registration fee (includes conference attendance, participant syllabus, continental breakfast, lunch, afternoon break and reception)

Limited Seating to 150 participants

Please check appropriate options

☐ $99 for physicians ☐ $89 for nurses ☐ waived for fellows, residents and students

Nursing Breakout Session – Lunch and Learn

☐ Yes, register me for the Nursing Breakout Session

☐ Please check box for dietary restrictions. Specify restriction:
☐ Please check box if you require special assistance. Specify assistance:

Payment must accompany your registration form:

1. Check or Money Order – made payable to:
   Women & Infants Hospital
2. Credit card information – check one ☐ Visa ☐ Mastercard ☐ Discover

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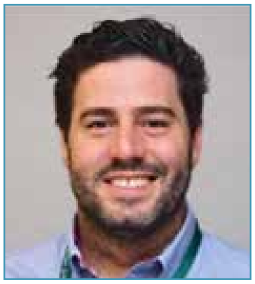
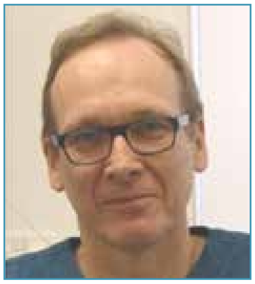
Presenter biographies



Adam J. Czynski, DO is medical director of the Mother Baby Unit and oversees the Newborn Nursery and the Family Care Unit. Dr. Czynski and his team have developed a service line that cares specifically for this patient population. The service line utilizes a multidisciplinary team to treat the infant while preserving the mother-infant bond.



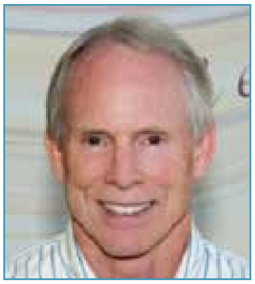
David Edwards, DSc, FMedSc is chair of Pediatrics and Neonatal Medicine at Kings College London. He and his colleagues have developed a bench to bedside research strategy to investigate the mechanisms of perinatal brain injury, and have developed treatment for birth asphyxia and hypothermic neural rescue therapy.

Alan H. Jobe, MD, PhD is one of the foremost leaders in neonatal pulmonary medicine and lung biology. He pioneered the development of natural surfactants. He has contributed to our understanding of the effects of antecedents in the intrauterine environment on developmental outcome.

Carmen J. Marsit, PhD is an authority on placental biology, the effect of antenatal intrauterine environment on the placental genome and epigenome and its association with developmental outcomes.

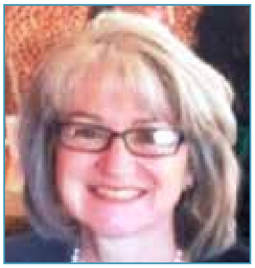
Elisabeth C. McGowan, MD is associate director of the Neonatal Follow-Up Clinic, conducting research at both the clinic as well as the Brown Center for the Study of Children at Risk. Her areas of interest include infant neurobehavior and long term neurodevelopmental outcomes, in the context of maximizing family health and support.

Betty R. Vohr, MD has been the director of the Neonatal Follow-Up Clinic at Women & Infants Hospital/Alpert Medical School of Brown University since 1974 and Coordinator for the NICHD Neonatal Research Network Follow-up Studies from 1993 - 2017. Her primary clinical and research interests focus on improving the long-term outcomes of high-risk premature infants and infants with hearing loss.



Robert D. White, MD is a pioneer in the concept of single-family-room NICU's. He has led international forums and discussions on single-family-room NICU from Gravens to around the world. He is one of the foremost advocates for incorporation of families and to the intensive care unit.

Nursing panel facilitator biography



Katheleen Hawes, PhD, RN provides clinical services in the Neonatal Intensive Care Unit and at the Perinatal and Postpartum Clinic at the Center for Children and Families at Women & Infants Hospital, where she treats women and their partners experiencing perinatal mood and anxiety issues.

NICU Symposium Planning Committee

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- Abbot Laptook, MD
- Elisabeth McGowan, MD
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Brown University and Women & Infants Hospital

OPIOIDS and NAS
When reporting on mothers, babies, and substance use
LANGUAGE MATTERS

I am not an addict.

I was exposed to substances in utero. I am not addicted. Addiction is a set of behaviors associated with having a Substance Use Disorder (SUD).

I was exposed to opioids.

While I was in the womb my mother and I shared a blood supply. I was exposed to the medications and substances she used. I may have become physiologically dependent on some of those substances.

NAS is a temporary and treatable condition.

There are evidence-based pharmacological and non-pharmacological treatments for Neonatal Abstinence Syndrome.

My mother may have a SUD.

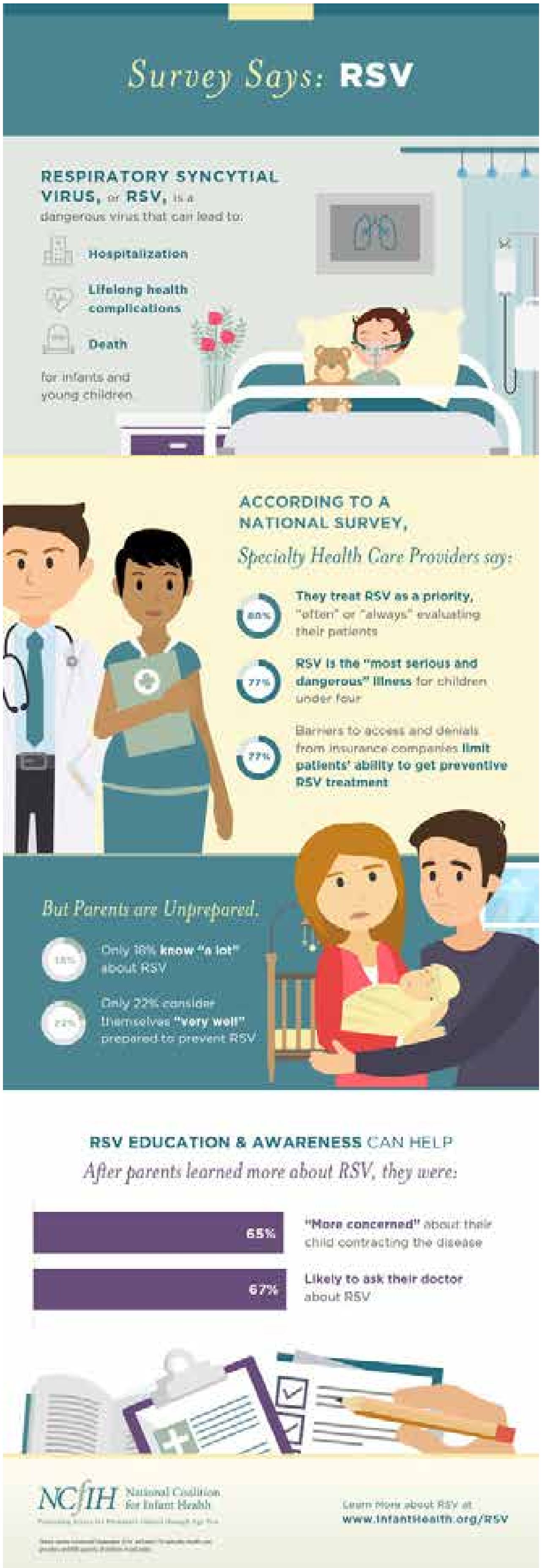
She might be receiving Medication-Assisted Treatment (MAT). My NAS may be a side effect of her appropriate medical care. It is not evidence of abuse or mistreatment.

My potential is limitless.

I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!

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

National Perinatal Association



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.

16% Only 16% **know "a lot"** about RSV

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

RSV EDUCATION & AWARENESS CAN HELP

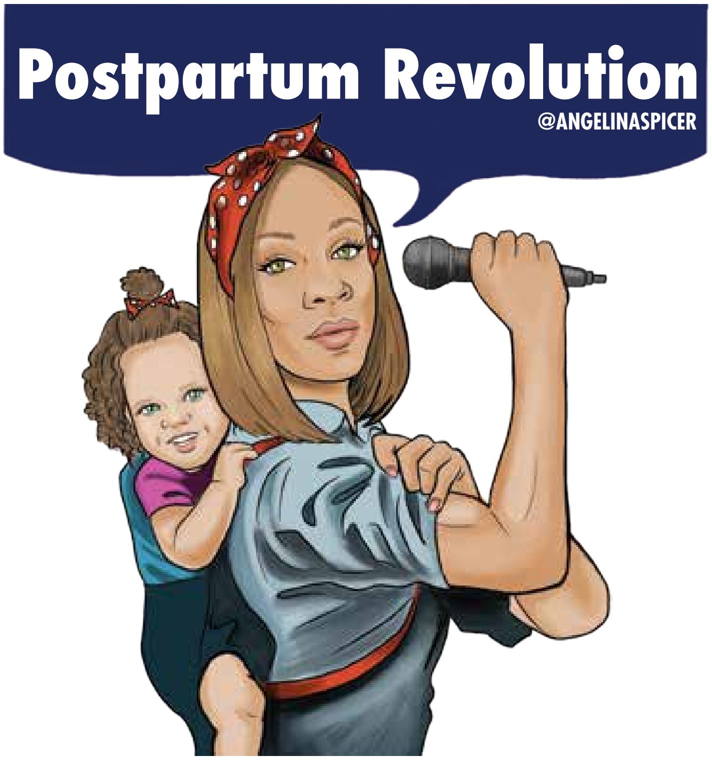
After parents learned more about RSV, they were:

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

67% **Likely to ask their doctor** about RSV

NCfIH National Coalition for Infant Health

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



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

National Perinatal Association

Patient Safety MOVEMENT
Patient Safety Movement Foundation
2019 Midyear Planning Meeting
CO-CONVENER: UCI Health
FOUNDER: Masimo Foundation for Ethics, Innovation & Competition in Healthcare
BENEFACTOR: Medtronic
INVITATION REQUEST

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Special issue on Kangaroo Care Published Last Week

Our special issue devoted to the research on Kangaroo Care is out in the journal Birth Defects Research Volume 111, Issue 15.

The guest editors Drs. Raouth Kostandy and Susan Ludington-Hoe and I welcome you to invite your community of neonatology specialists to learn about the special issue through your newsletters (AAP News or). Attached is the preliminary version of our press release. Drs. Raouth and Ludington are the guest editors. Access will be free for a short time (two months) after the publication date (Sept 10, 2019) at this site https://doi.org/10.1002/bdr2.v111.15

09/15/2019

Eight comprehensive reviews on Kangaroo Care research are now available collected in one place in the journal Birth Defects Research Volume 111, Issue 15 (September 2019 issue).

Kangaroo Care researchers Drs. Kostandy and Ludington-Hoe recently guest edited a special issue to be published in the September 2019 volume 111 issue 15 of the journal Birth Defects Research, the official journal of the Society for Birth Defects Research and Prevention, which features 8 reviews from national and international experts on Kangaroo Care and highlights the growing use of Kangaroo Care as a non-pharmacologic neonatal treatment therapy for many newborn problems including premature birth and congenital heart defects. Kostandy and Ludington-Hoe hope continued research and further dissemination of its effectiveness will also lead to increased adoption in hospitals dealing with newborn drug withdrawal across the country.

Cleveland State University nursing professor Dr. Raouth Kostandy and the Carl W. and Margaret Davis Walters Endowed Chair of Pediatric Nursing at Case Western Reserve University's Frances Payne Bolton School of Nursing Dr. Susan Ludington Hoe are collaborating to advance health and well-being for some of our most vulnerable medical patients: infants. They are working with local hospitals to increase the use of Kangaroo Care (KC) to for babies suffering from a range of illnesses and complications, with the goal of improving outcomes and ultimate health for patients and their families.

Kangaroo Care is regular, round the clock, skin-to-skin contact between an infant and a parent to reduce anxiety, improve breathing, regulate body temperature and increase microbe transfer from parent to child. Originally developed in Cleveland in the 1970's and popularized by physicians from the Republic of Columbia in South America in the 1980's Kangaroo Care has been shown to improve development in premature infants and assist in treatment for a wide variety of conditions and illnesses.

"By utilizing the natural connection between the infant and parent, both mother and father, KC reduces stress, enhances the development of regular sleeping patterns and improves responses to various treatments as well as providing needed therapy. For example, a baby who is having spells in which breathing stops experiences a 75% reduction in those spells when held in Kangaroo

neo

The conference for neonatology

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www.nucdf.org | Phone: (626) 578-0833

CALL FOR ABSTRACTS

The 33rd Annual Gravens Conference on the Environment of Care for High Risk Newborns

March 4-7, 2020

Abstract due date is October 28, 2019. Late Abstracts will not be accepted.

The Gravens Conference is dedicated to providing a forum for the continuing education of NICU professionals. In particular, the conference focuses on the science of fetal and infant development, developmental care practices, NICU design, family support programs, and the influential role the NICU environment has on the neurodevelopment of the infant, and the well-being of families and staff.

The conference committee invites you to submit an abstract for a variety of presentation options: oral abstract session (20-ish minutes), workshop session (75 minutes), or poster presentation, regarding NICU design, the study of creative approaches to developmental and environmental issues of the NICU, care practices and/or programs to assist staff, parents and families. This conference offers an opportunity to share your work and experiences with colleagues.

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.**

Care," Kostandy says. "Through Kangaroo Care research, I hope to further opportunities to utilize Kangaroo Care in neonatal medicine and nursing and develop state of the art metrics to document the effectiveness of Kangaroo Care broadly.

Kostandy and her research partner Ludington-Hoe are currently working with Metro Health Medical Center to improve treatment for infants suffering from neonatal abstinence syndrome, an illness of babies born to drug addicted mothers that can cause serious birth defects and even death. Kostandy, Ludington-Hoe, and their Metro Health collaborators are working with a group of newborn infants on the Mother-Baby unit to specifically evaluate Kangaroo Care's effectiveness as a technique for pain management and in reducing withdrawal symptoms in these newborns.

"Infants suffering from this illness experience significant pain and agitation during withdrawal and obviously can only be given restricted pain killers," Kostandy adds. "It is our hope that Kangaroo Care will serve as a natural painkiller and reduce suffering for these newborns."

"KC has seen significant adoption in Latin America and Europe but has not been as widely used in the USA, due to in large part to bureaucratic and cultural factors" she says. "It is my distinct hope that a broader understanding of the tremendous positive impacts of Kangaroo Care will help break down these barriers and increase its use as a means for improving infant health in the USA."

Contact Information:

Michiko Watanabe <mxw13@case.edu>

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

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

- Connect with other AAP members who share your interests in improving effective drug therapies and devices in children.
- Receive the SOATT newsletter containing AAP and Section news.
- Access the Section's Website and Collaboration page – with current happenings and opportunities to get involved.
- Network with other pediatricians, pharmacists, and other health care providers to be stronger advocates for children.
- Invitation for special programming by the Section at the AAP's National Conference.
- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

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

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

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

Mitchell Goldstein, MD, FAAP, Section Chairperson, MGoldstein@llu.edu and

Christopher Rizzo, MD, FAAP, Membership Chairperson, crizzo624@gmail.com

Jackie Burke

Sections Manager

AAP Division of Pediatric Practice

Department of Primary Care and Subspecialty Pediatrics

630.626.6759

jburke@aap.org

Dedicated to the Health of All Children

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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


Patient Safety
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meeting program and other relevant meeting information through the AAP meeting website at http://www.aapexperience.org/

NT

The Pyramids will be Orange on World Patient Safety Day

There's still time to light-up your city ORANGE on World Patient Safety Day

Thursday, September 12, 2019 07:06

NeSeptember 17th, World Patient Safety Day, is less than one week away. We've heard exciting news that some major city "monuments" will be lit up to help raise patient safety awareness on September 17th.

What monuments can you advocate to light up on September 17th? Some ideas include:

- The three Pyramids of Giza, Cairo
- Jet d'Eau, Geneva
- Kuala Lumpur Tower, Malaysia
- Johns Hopkins Dome, Baltimore, Maryland, USA
- The Red Castle and Martyr Square Fountain, Libya, Tripoli
- The National Palace of Culture in Sofia, Bulgaria
- Fountains in the center of Bucharest, Romania
- National Memorial Chorten and Buddha Point, Bhutan
- BJ Habibie, Francisco Amaral and Mandarin roundabouts in Dili, Timor Leste
- Zakim bridge, Boston, Massachusetts, USA
- One of the signature constructs of the city of Ankara, Turkey
- 7 buildings in Germany, one of those will be the famous "Bettenhaus" of the also famous Charité, which is a hospital high-rise building located right in the center of Berlin

Share what you plan to "light up" through your social media channels and tag us so we can share/repost!

About the Patient Safety Movement Foundation

Each year, more than 200,000 people die unnecessarily in U.S. hospitals. Worldwide, 4.8 million lives are similarly lost. The Patient Safety Movement Foundation (PSMF) is a global non-profit that offers free tools to help achieve ZERO preventable deaths from hospital errors. The Patient Safety Movement Foundation was established through the support of the Masimo Foundation for Ethics, Innovation, and Competition in Healthcare to reduce that number of preventable deaths to ZERO. Improving patient safety requires a collaborative effort from all stakeholders, including patients, healthcare providers, medical technology companies, government, employers, and private payers. PSMF's World Patient Safety, Science & Technology Summit brings together the world's best minds for thought-provoking discussions and new ideas to challenge the status quo. Our Actionable Patient Safety Solutions (APSS) provide evidence-based processes to help hospitals eliminate errors. Our Open Data Pledge encourages healthcare technology companies to share the data for which their products are purchased. Visit patientsafetymovement.org.

NT

FDA Sends Warning to Company for Selling Unapproved Umbilical Cord Blood and Umbilical Cord Products that May Put Patients at Risk; Continues to Warn Patients of the Risk of Unapproved Stem Cell Therapy

Stemell sold stem cell products without required FDA approval

For Immediate Release:
September 03, 2019

The U.S. Food and Drug Administration has warned Stemell, Inc. (Stemell), of San Juan Capistrano, California, and its president and Chief Executive Officer, Peyman Taeidi, Ph.D., for manufacturing and distributing unapproved products derived from umbilical cord blood and umbilical cord and for significant deviations from current good tissue practice (CGTP) and current good manufacturing practice (CGMP) requirements, including deficient donor eligibility practices and environmental monitoring, creating potential significant safety concerns that put patients at risk. Stemell's unapproved products derived from umbilical cord blood and umbilical cord are StemL UCB-Plus and StemL UCT-Plus.

"We know that there are manufacturers and clinics across the country that manufacture or market violative stem cell products to patients, claiming that they don't fall under the regulatory provisions for drugs and biological products. The FDA has consistently stated that this is not true," said Acting FDA Commissioner Ned Sharpless, M.D. "This company failed to take appropriate measures to protect patient safety. The FDA will

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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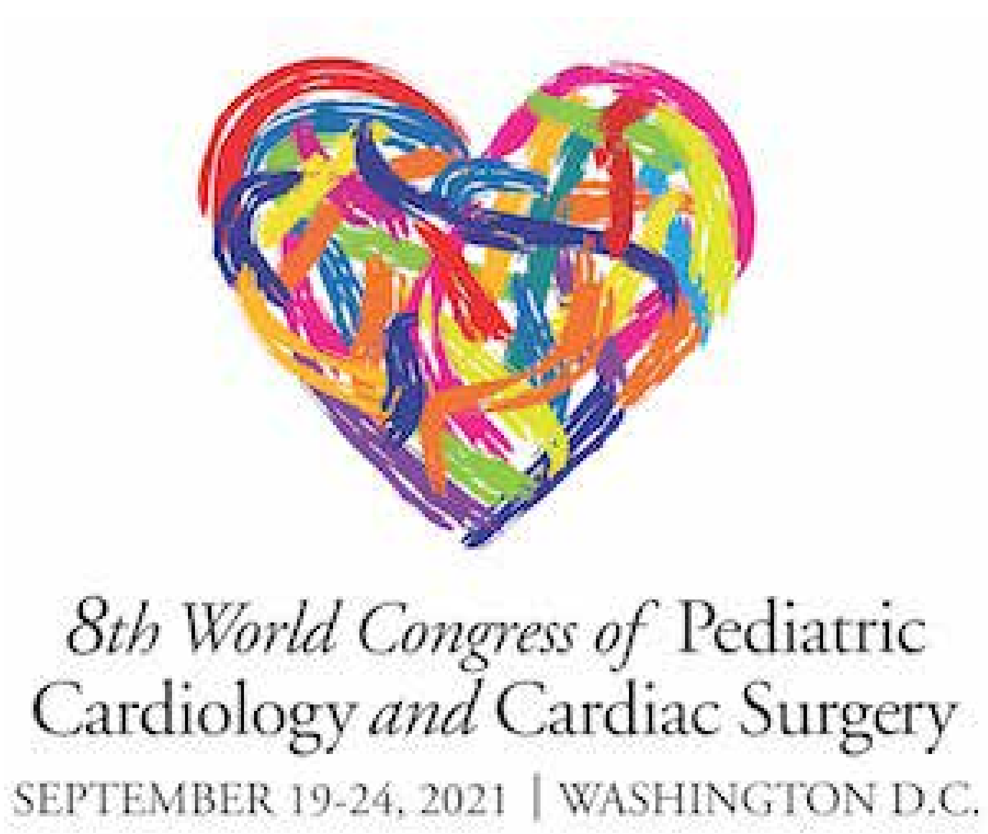
be increasing our oversight related to cell-based regenerative medicine as part of our comprehensive plan to promote beneficial innovation while protecting patients. Those who are manufacturing or marketing unapproved, potentially unsafe products must understand that there's a clear line between appropriate development of these products and those practices that sidestep important statutory and regulatory controls that are in place to protect patients."

The FDA's recent inspection of the Stemell facility in March revealed that the company was manufacturing products derived from human umbilical cord blood and umbilical cord for use in recipients unrelated to the donors of the products. Because these Stemell 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. 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 these Stemell products.

During the inspection, the FDA documented evidence of significant deviations from CGTP and CGMP requirements in the manufacture of Stemell's products, including deficient donor eligibility practices, unvalidated manufacturing processes, deficient environmental monitoring and inadequate aseptic processes. These deviations pose a risk that the products may be contaminated with viruses or microorganisms or have other serious product quality defects.

"The FDA remains highly committed to facilitating the development and availability of safe and effective cellular therapy products. However, we will not hesitate to take appropriate action to protect people from being harmed by products with potential significant safety concerns," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "In addition to the warning letter issued today, we sent another 20 letters to manufacturers and health care providers across the country who may be offering unapproved stem cell products, reiterating the FDA's compliance and enforcement policy. We remain very concerned that countless clinics across the country continue to market violative stem cell products to patients that have not been appropriately evaluated for safety or efficacy."


8th World Congress of Pediatric Cardiology and Cardiac Surgery
SEPTEMBER 19-24, 2021 | WASHINGTON D.C.

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 intends to apply 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 FDA's investigational new drug 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 potential significant safety concern to patients. As reflected by this warning letter, the other letters issued today, and other correspondence issued recently, the FDA will take appropriate steps to protect the public health.

The FDA offers opportunities for engagement between potential manufacturers and the agency, such as through the INTERACT program, to facilitate product development. It also encourages the use of its expedited programs whenever applicable, in addition to the collaborative development of products as the former FDA Commissioner and Center for Biologics Evaluation and Research director discussed in a New England Journal of Medicine

External Link Disclaimer perspective. 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 products are regulated.


CDH International
A global initiative to stop Congenital Diaphragmatic Hernia

Perinatal Advisory Council:
Leadership, Advocacy and Consultation

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www.paclac.org

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

Leadership

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

Advocacy

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

Consultation

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

The FDA requested a response from Stemell, 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 companies and owners 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 Stemell 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 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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Inquiries

Media:
Stephanie Caccomo
301-348-1956

Consumer:
888-INFO-FDA

NT

Statement on data accuracy issues with recently approved gene therapy

Questions exist regarding new approved gene therapy.

For Immediate Release:

August 06, 2019

Statement From:

Director - Center for Biologics Evaluation and Research (CBER)

Dr. Peter Marks M.D., PhD.

As a public health agency, we believe that it is critical to facilitate the development of innovative safe and effective medical products, like the cellular and gene therapy products that have shown enormous potential to treat previously untreatable diseases. As part of the approval process for biological products, the agency reviews extensive information submitted by manufacturers, including details of how the product is made in a reproducible manner, how it has been tested in animals, and how it has been investigated in human clinical trials to demonstrate its safety and efficacy.

It is the manufacturer's responsibility to submit complete and accurate information in marketing applications for evaluation by the FDA. If we become aware of a concern with data submitted to the agency as part of our review of a product application, it is in the best interest of patients, their caregivers, and the public that we disclose such information, to the extent permitted by law.

On May 24, the FDA approved Zolgensma, a gene therapy product intended to treat children less than two years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 gene — the most severe form of SMA. SMA is a leading genetic cause of infant mortality. Subsequently, on June 28, following the FDA's approval of the product, the agency was informed by AveXis Inc., the product's manufacturer, about a data manipulation issue that impacts the accuracy of certain data from product testing performed in animals submitted in the biologics license application (BLA) and reviewed by the FDA.

The FDA is carefully assessing this situation and remains confident that Zolgensma should remain on the market. Out of the large amount of submitted information reviewed by the agency, our concerns at this time are limited to only a small portion of the product testing data that was contained in the marketing application. This product testing data was used by the manufacturer to support the development of its production process for the product. These data do not change the agency's positive assessment of the information from the human clinical trials that were conducted as part of the development program. The totality of the evidence demonstrating the product's effectiveness and its safety profile continues to provide compelling evidence supporting an overall favorable benefit-risk profile. However, the integrity of the product testing data used in the development of the product's manufacturing process is still a matter that we are continuing to evaluate and take very seriously.

Ensuring truthful, complete and accurate data in product applications is a critical component of industry's responsibility as they work to demonstrate the safety, purity, and potency of biological products. The submission of such truthful, complete and accurate data is also critical for the FDA to be able to protect the public health, and the law requires it. We are carefully assessing the issue of the manipulation of the product testing data used in the production process and are conducting a thorough assessment of the information from a recently completed inspection. In part, this will allow us to determine the implications for the FDA's scientific review of the information in the BLA and will allow us to amend our publicly posted BLA reviews, as appropriate.

We are also aware that AveXis became aware of the issue of the data manipula-

pac/lac

The 37th Annual Advances in Care Conference – *Advances in Therapeutics and Technology*

March 24-28, 2020; Snowbird, UT

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

tion that created inaccuracies in their BLA before the FDA approved the product, yet did not inform the FDA until after the product was approved. The agency will use its full authorities to take action, if appropriate, which may include civil or criminal penalties.

We recognize that parents of, and health care professionals for, children with SMA may have questions or concerns about this information. Parents and health care professionals may contact the FDA at (800) 835-4709 or AveXis for more information. The FDA will continue to provide updates related to this statement as we learn more.

As with all biological products, health care professionals and patients (or for Zolgensma, their caregivers) should be aware of both the product's benefits and risks. The most common side effects of Zolgensma are elevated liver enzymes and vomiting. Zolgensma has a boxed warning that acute serious liver injury can occur. Health care professionals and caregivers should refer to the product package insert for additional risk information.

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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Statement on improving adverse event reporting of compounded drugs to protect patients

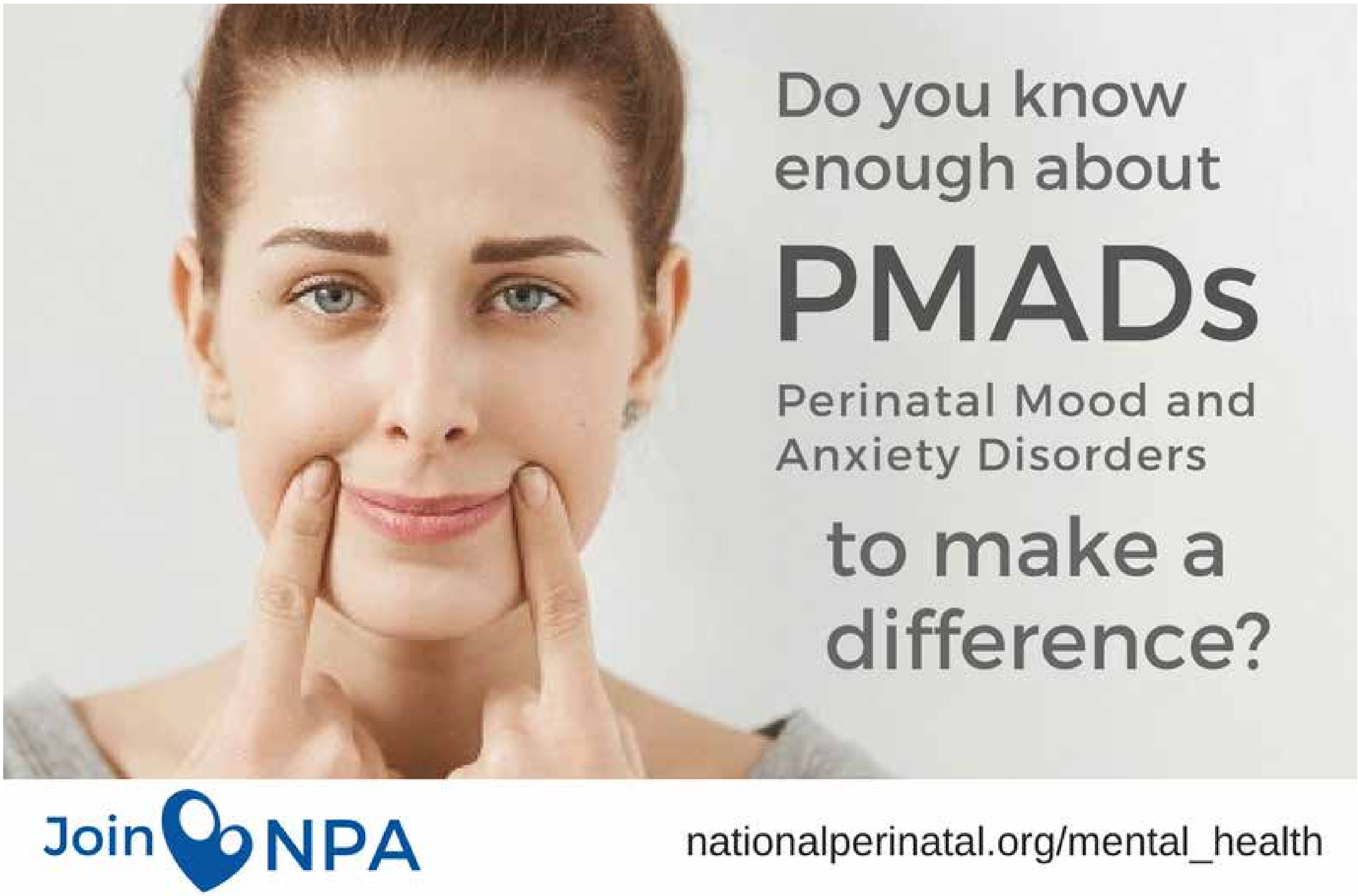
Adverse reporting mechanism must be improved.

For Immediate Release:
September 09, 2019

Statement From:
Director - Center for Drug Evaluation and Research

Janet Woodcock M.D.

Compounded drugs can serve an important medical need for certain patients, however, they also present risks to patients since they are not evaluated by the FDA for safety, effectiveness and quality. The FDA's compounding program aims



to help protect patients from poor-quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them. Along with the development of policy and enforcement of the law, and collaboration with states and industry, our inspections of compounding facilities are vital aspects of this effort. Understanding the nature of the activity these compounders—especially outsourcing facilities— are engaged in helps minimize the risks to patients. While the FDA inspects outsourcing facilities regularly according to our risk-based schedule, we also rely on them to do their part in alerting us to issues that may endanger the health of patients.

As part of this work, several colleagues and I recently called attention to a particular issue associated with compounded hormones (specifically, in the form of pellets). During an inspection in 2018 of BioTE Medical, our investigators uncovered information about 4,202 adverse events that had never been reported to the agency. The adverse event information our investigators found suggested compounded hormone pellets were possibly associated with endometrial cancer, prostate cancer, strokes, heart attacks, deep vein thrombosis, cellulitis and pellet extrusion. However, because the reports lacked certain critical information, the FDA was able to attribute only a small percentage of the adverse events (61 reports), such as pellet extrusion and cellulitis, to the use of compounded hormone pellets containing testosterone. The company that collected the adverse events did not send them to us during the five years they occurred between 2013 and 2018. However, in light of this discovery, the FDA is continuing to take multiple steps to help protect patients, which we wanted to highlight today in the interest of public health.

Compounded bioidentical hormone replacement therapy (BHRT) products such as progesterone and testosterone, are used at times instead of FDA-approved drugs for hormone replacement therapy. Some compounders market BHRT products as superior to FDA-approved drugs by making assertions that they are more natural, safer or better for patients than FDA-approved drug products. FDA-approved hormone therapy treatments have been reviewed for safety and effectiveness for specific uses, and the FDA has measures in place to ensure quality during manufacturing. However, because, compounded BHRT products are not approved by the agency, there is no assurance of safety and efficacy. Outsourcing facilities, such as those that produced these products, are required to report certain adverse events to the FDA.

The agency uses adverse event reports to monitor safety issues to help protect the public. Adverse event reports can assist the FDA in identifying potential safety problems with a particular product. However, this is more difficult when information is outdated or missing. We maintain a public database to ensure patients and health care professionals can access adverse event data about drugs. Outsourcing facilities are required to report adverse events to the agency and include adverse event reporting information on compounded drug labeling, and we encourage all companies, health care professionals and patients to report adverse events as soon as they know about them. Every year, the FDA receives adverse event reports of patient illnesses and deaths associated with compounded drugs. Information on the safety history of compounded drugs, through the reporting of adverse events is vital to protecting the public health.

Because compounding can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug, we must work to protect patients from the risk of contaminated or otherwise harmful products. As we develop our policy and oversight program, the FDA continually strives to strike a balance between preserving access to compounded drugs for patients who have a medical need for them while protecting patients from the risks associated with compounded drugs that are not made in accordance with applicable quality standards or other requirements.

In this case, outsourcing facilities, Carie Boyd's Prescription Shop and AnazaoHealth Corporation, produced the pellets, but they were marketed by BioTe Medical, which was not registered with the agency as an outsourcing facility. While BioTe had an online portal to collect adverse event data from its customers, it never reported that information to the FDA nor did it provide this information to the outsourcing facilities.

The FDA is still investigating this matter, with respect to Carie Boyd's Prescription Shop, AnazaoHealth Corporation or BioTe and we cannot discuss the status. Outsourcing facilities are subject to regulatory and enforcement action if they do not appropriately label their drugs with adverse event reporting information and to report events to the FDA. The agency intends to take appropriate action if outsourcing facilities do not comply with the adverse event reporting requirements. We remind outsourcing facilities to develop thorough procedures to compile and investigate adverse event reports and share them with the FDA.

We're also using the information we learned from this episode to take steps to improve adverse event reporting and

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analyses to ensure we're doing the most we can to protect patients. We will continue to work with outsourcing facilities to improve mechanisms for obtaining reports of adverse events associated with their products and for providing adverse event reports to the agency. Furthermore, we continue to work with our state regulatory partners to finalize a standard memorandum of understanding under which states would agree to, among other things, investigate complaints of adverse events associated with certain compounded drugs from pharmacies operating under section 503A and report serious adverse events and serious product quality issues to the agency. States that sign the memorandum of understanding with the FDA will agree to investigate and share their findings. Collaboration with states has the potential to help prevent serious and widespread problems by helping to better identify adverse events and product quality issues across the country.

For example, if a compounder distributes drugs to multiple states, it can be difficult to gather information about possible adverse events associated with those drugs, connect them to the compounder and undertake coordinated action to address a potentially serious public health problem. Collaboration with our state partners would be crucial in such an instance. While adverse event reports have some limitations, this information is one of the best safety tools we have at our disposal. The FDA is dedicated to increasing public awareness about drug safety issues and we're continuing our efforts to improve reporting for all types of drugs, including compounded medicines. We anticipate finalizing our MOU with the states later this year.

To further enhance our understanding of the safety of compounded hormones, the FDA has contracted with the National Academy of Sciences, Engineering, and Medicine (NASEM) to conduct a study on the risks associated with compounded hormone products. Our collaboration with NASEM will also continue to examine the clinical utility of treating patients with compounded products and the available evidence of the safety and effectiveness of multi-ingredient compounded topical pain creams. The FDA plans to share updates about this study with the public as information is available.

We'll continue to work to ensure patients have appropriate access to compounded medications. However, we must also ensure that all steps are taken to help reduce risks to patients. Patient health and safety is the FDA's highest priority.

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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Leading Children's Health and Medical Groups Urge Action Following Increase in Number of Uninsured Children

Increased number of uninsured children requires action.

9/10/2019

Washington, DC—Leading children's health and medical organizations are urging comprehensive and immediate action by Congress and the Administration following new data released today by the U.S. Census Bureau showing 425,000 fewer children had health insurance coverage in 2018.

In response to these numbers, the American Academy of Pediatrics, Children's Defense Fund, Children's Dental Health Project, Family Voices, First Focus on Children, Georgetown University Center for Children and Families, March of Dimes and the National Association of Pediatric Nurse Practitioners issued the following statement:

"Today's report shows that in 2018, 4.3 million children in the United States were uninsured – an increase of 425,000 uninsured children in a single year. This is an urgent call to action for Congress and the Administration. The data is especially alarming considering the relatively healthy economy and low unemployment rate, which counters claims that children are leaving public coverage to instead be covered by private insurance. When the number of children enrolled in Medicaid and CHIP fell by over 800,000 nationwide in 2018, we feared it foreshadowed a sizeable drop in coverage, and today, our fears were confirmed. This decline in public and private coverage harms children's health.

"Nearly one-third of America's children rely on Medicaid and CHIP for comprehensive, affordable medical and dental coverage, including children in foster care, children who live in or near poverty, and children with disabilities or special health care needs. For these kids, no coverage often means no care. No care means fewer preventive screenings to catch conditions before they become severe and costly. No care means more missed school and work days for parents. It means no access to affordable dental coverage, or prenatal services for pregnant mothers. We can do better, and we must.

"Make no mistake: the Administration's actions—such as harmful policies that discourage immigrant families from enrolling in Medicaid and CHIP and adding more red-tape to Medicaid—have contributed to this erosion of children's coverage. There are signs that coverage losses for children will continue to get worse.

"We call on Congress and the Administration to protect and improve health coverage for all children so that we can renew the bipartisan efforts that led to the historically low number of uninsured children in recent years. Using our principles as a guide, Congress and the Administration should take action to make it easier and more affordable for children and families to enroll—and stay enrolled—in coverage that meets their needs. This is a problem we must solve before it becomes a crisis."

###

About the American Academy of Pediatrics

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 aap.org and follow us on Twitter @AmerAcadPeds.

About the Children's Defense Fund

The Children's Defense Fund (CDF) is a 501(c)(3) nonprofit child advocacy organization that has worked relentlessly for more than 40 years to ensure a level playing field for all children. We provide a strong, effective and independent voice for all the children of America who cannot vote, lobby or speak for themselves. We pay particular attention to the needs of poor children, children of color and those with disabilities. CDF educates the nation about the needs of children and encourages preventive investments before they get sick, drop out of school, get into trouble or suffer family breakdown.

About the Children's Dental Health Project

The Children's Dental Health Project (CDHP) is a Washington, DC-based policy organization that advances solutions so that, one day, no child will suffer from tooth decay. We believe no family should be held back from its dreams due to dental disease. Learn more at www.cdhp.org, on Twitter at @Teeth_Matter or Facebook at @childrensdentalhealth

About Family Voices

Family Voices is a national, nonprofit, family-led organization promoting quality health care for all children and youth, particularly those with special health care needs. Working with family leaders and professional partners at the local, state, regional, and national levels since 1992, Family Voices has brought a respected family perspective to improving health care programs and policies and ensuring that health care systems include, listen to, and honor the voices of families.

About First Focus on Children

First Focus on Children is a bipartisan advocacy organization dedicated to making children and families the priority in federal policy and budget decisions. First Focus on Children leads a comprehensive advocacy strategy, with its hands-on experience with federal policymaking and a commitment to seeking policy solutions.

About the Georgetown University Center for Children & Families

The Georgetown University Center for Children & Families (CCF), part of the Health Policy Institute at the McCourt School of Public Policy, is an independent, nonpartisan policy and research center with a mission to expand and improve high-quality, affordable health cov-


Save the Date: March 4-7, 2020 **Call for Abstracts:** Due Monday, October 28, 2019

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About March of Dimes

March of Dimes leads the fight for the health of all moms and babies. We support research, lead programs and provide education and advocacy so that every baby can have the best possible start. Building on a successful 80-year legacy of impact and innovation, we empower every mom and every family.

Visit marchofdimes.org or nacersano.org for more information. Visit shareyourstory.org for comfort and support. Find us on Facebook and follow us on Instagram and Twitter.

About the National Association of Pediatric Nurse Practitioners
The National Association of Pediatric Nurse Practitioners (NAPNAP) is the nation's only professional association for pediatric nurse practitioners (PNPs) and their fellow pediatric-focused advanced practice registered nurses (APRNs) who are dedicated to improving the quality of health care for infants, children, adolescents and young adults. Representing more than 9,000 healthcare practitioners with 19 special interest groups and 50 chapters, NAPNAP has been advocating for children's health since 1973 and was the first NP society in the U.S. Our mission is to empower pediatric-focused PNPs and their interprofessional partners to enhance child and family health through leadership, advocacy, professional practice, education and research.

###

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 and follow us on Twitter @AmerAcadPeds

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

Consider the following:

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

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

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

See what they found by emailing info@grahamsfoundation.org to request a free copy of the 2017 whitepaper, "Reaching Preemie Parents Today" (*Heather McKinnis, Director, Preemie 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.

Graham's FOUNDATION
Fighting for Premature Babies

Visit **www.GrahamsFoundation.org** to learn more.

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37th Annual Conference

The Cliff Lodge
Snowbird, Utah

This conference provides education and networking opportunities to healthcare professionals who provide care for pediatric patients with a focus on advances in therapeutics and technologies including telemedicine and information technologies. Along with featured speakers, the conference includes abstract presentations on research on advances in these areas. Registration open mid June, 2019! http://paclac.org/advances-in-care-conference/

Physician, Nursing, and Respiratory Care Continuing education hours will be provided.

Call for Abstracts – Deadline December 15, 2019

Abstract submission: As are currently being accepted. Download the Abstract Guidelines from the website.

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The Neonatal Intensive Care Unit Directory

Scott Synder, MD

The NICU Directory by Neonatology Solutions, LLC, aims to be a comprehensive, interactive, up-to-date, and FREE resource for neonatologists, neonatology fellows, and neonatal nurse practitioners to locate NICUs and neonatology programs across the United States and Canada.

Our goal is to provide information regarding the size and scope of programs, as well as key contact names, email addresses, and phone numbers to facilitate networking, collaboration, and career planning. To do this, we need your help. Click the link to the Directory, search for your program, and update any missing or incorrect information. We greatly appreciate this grassroots effort to build a shared resource to benefit our field."

> ***"Our goal is to provide information regarding the size and scope of programs, as well as key contact names, email addresses, and phone numbers to facilitate networking, collaboration, and career planning."***

References:

1. *https://neonatologysolutions.com/explore-nicus-and-programs/*

The author is a principal of Neonatology Solutions, LLC.

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

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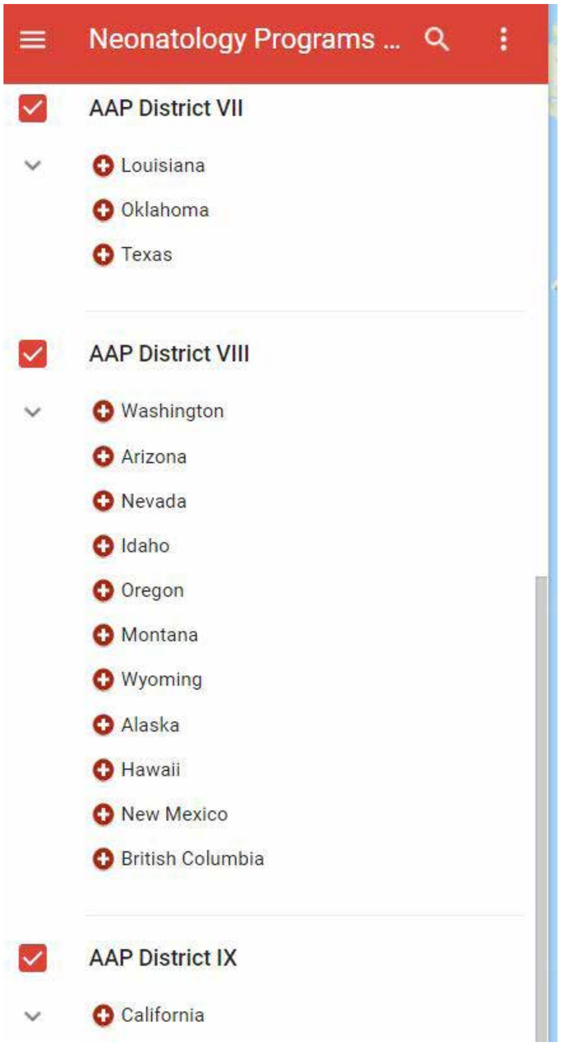

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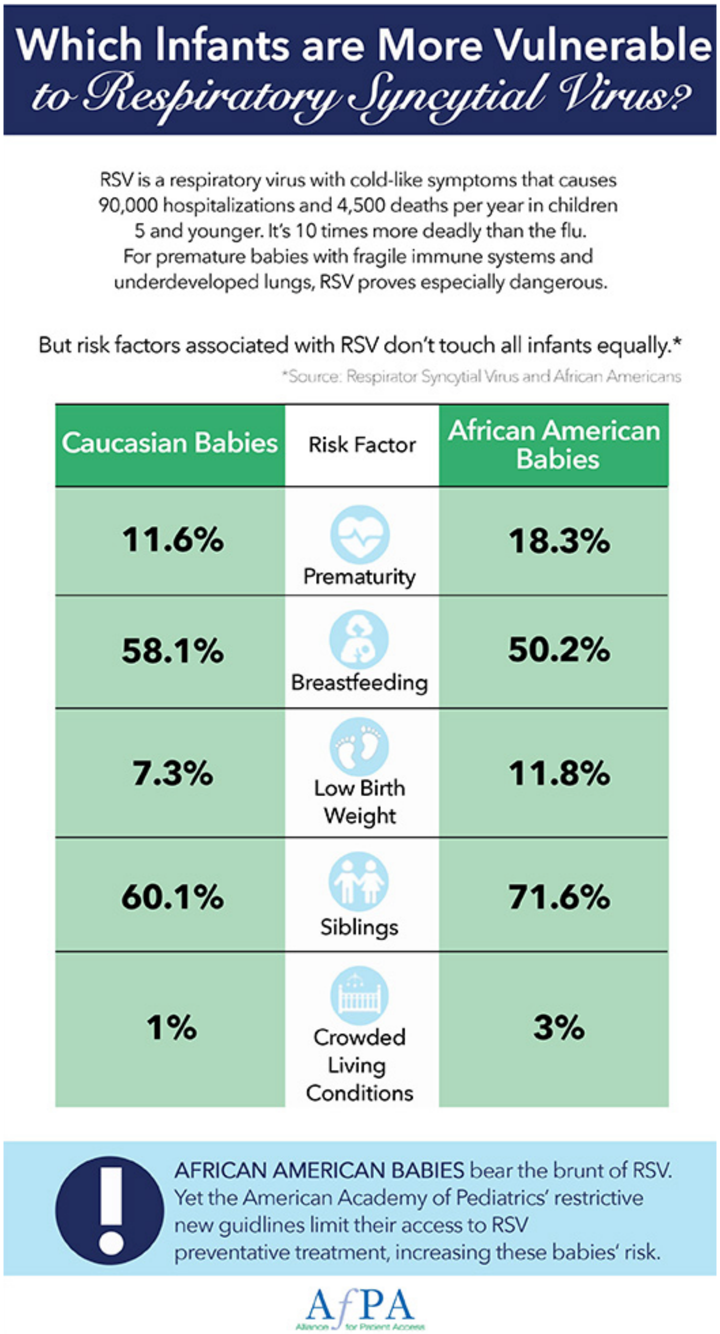

Which Infants are More Vulnerable *to Respiratory Syncytial Virus?*

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

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

*Source: Respirator Syncytial Virus and African Americans

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

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

AfPA
Alliance for Patient Access

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Survey Says: RSV

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

- **Hospitalization**
- **Lifelong health complications**
- **Death**

for infants and young children

ACCORDING TO A NATIONAL SURVEY,

Specialty Health Care Providers say:

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

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

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

But Parents are Unprepared.

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

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

RSV EDUCATION & AWARENESS CAN HELP

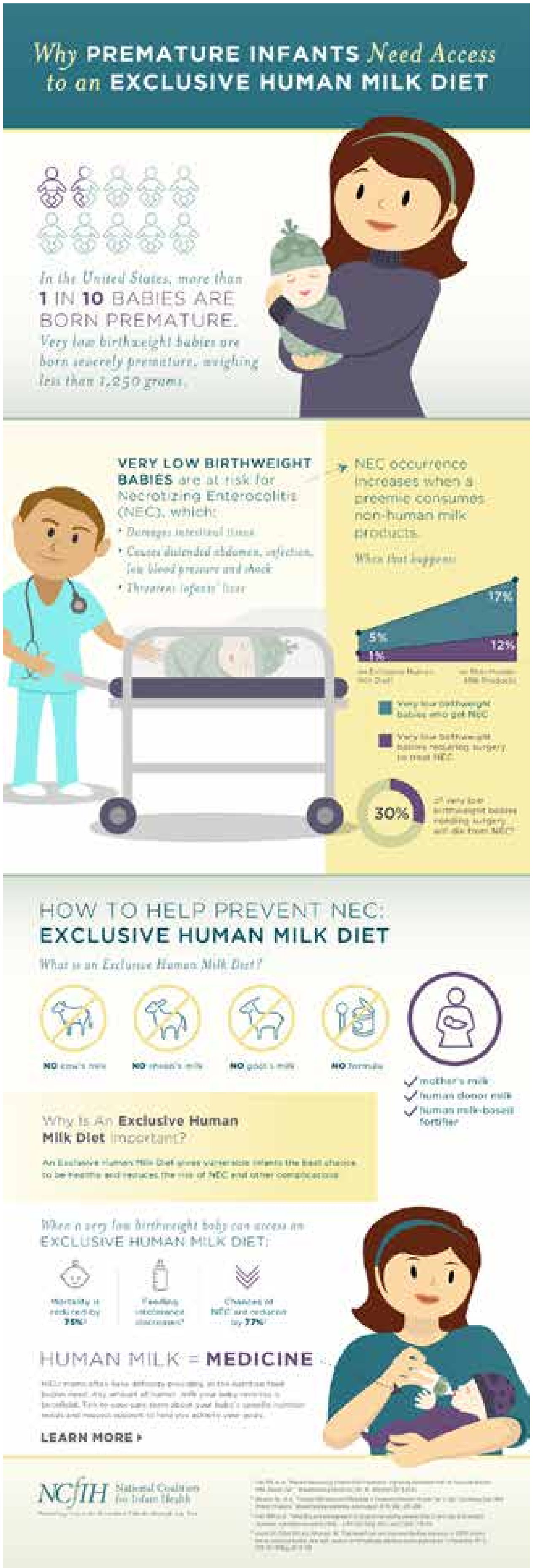
After parents learned more about RSV, they were:

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

67% **Likely to ask their doctor** about RSV

NCfIH National Coalition for Infant Health

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



Why PREMATURE INFANTS *Need Access to an* EXCLUSIVE HUMAN MILK DIET

In the United States, more than
1 IN **10** BABIES ARE BORN PREMATURE.
Very low birthweight babies are born severely premature, weighing less than 1,250 grams.

VERY LOW BIRTHWEIGHT BABIES are at risk for Necrotizing Enterocolitis (NEC), which:

- *Damages intestinal tissue*
- *Causes distended abdomen, infection, low blood pressure and shock*
- *Threatens infants' lives*

NEC occurrence increases when a preemie consumes non-human milk products.

When that happens:

■ Very low birthweight babies who got NEC
■ Very low birthweight babies requiring surgery to treat NEC

30% of very low birthweight babies needing surgery will die from NEC

HOW TO HELP PREVENT NEC: EXCLUSIVE HUMAN MILK DIET

What is an Exclusive Human Milk Diet?

NO cow's milk
NO sheep's milk
NO goat's milk
NO formula

✓ mother's milk
✓ human donor milk
✓ human milk-based fortifier

Why Is An **Exclusive Human Milk Diet** Important?

An Exclusive Human Milk Diet gives vulnerable infants the best chance to be healthy and reduces the risk of NEC and other complications

When a very low birthweight baby can access an EXCLUSIVE HUMAN MILK DIET:

Mortality is reduced by **75%**
Feeding intolerance decreased
Chances of NEC are reduced by **77%**

HUMAN MILK = **MEDICINE**

NICU moms often have difficulty providing all the nutrition their babies need. Any amount of human milk your baby receives is beneficial. Talk to your care team about your baby's specific nutrition needs and request support to help you achieve your goals.

LEARN MORE ▸

NCfIH National Coalition for Infant Health

Peer Reviewed

Genetics Corner: Down Syndrome Tool Kit- a Resource for Physicians Taking Care of Neonates

Robin Clark, MD, Daisy Hernandez, Subhadra Ramanathan, MS, MSc

Case summary

A 40-year-old mother delivered monochorionic -diamniotic twin girls at 34 weeks gestation who were admitted to the NICU for prematurity. Their prenatal history was significant for a positive maternal serum screen for Down syndrome in the second trimester (California Integrated screen). Subsequently, non-invasive prenatal screening (NIPS) returned a low risk for Down syndrome. The NICU ordered chromosome microarray analysis on both identical twins to evaluate for Down syndrome, presumably because of the lower sensitivity of prenatal screening in twin gestations. There was no comment on the physical exam about features suggesting Down syndrome. The microarray was negative for trisomy 21 but detected a variant of uncertain significance (VUS) on chromosome 8 at 8p23.3. Parental follow-up testing was recommended to help inform the clinical significance of this variant. Many attempts were needed by the Genetics nursing staff after discharge in order to complete parental testing. The VUS was determined to be maternally inherited and reinterpreted to be likely benign. The parents want to test their 18-year-old daughter for the variant as they are concerned and curious to know if she had inherited it as well and it was explained to them that this is not clinically indicated.

This case illustrates several important points about the importance of making a clinical diagnosis of Down syndrome, the appropriate use of different testing modalities and the concerns raised by prenatal screening, even when negative. To better address, these questions, the Genetics service at Loma Linda University Health created a tool kit for Down syndrome as a resource for pediatricians in the newborn nursery and neonatologists to be able to recognize the features of Down syndrome and order appropriate cytogenetic testing and other assessments.

Discussion:

Down syndrome is the most common autosomal aneuploidy, with an incidence of 1/700 liveborn infants. It is also the most common cause of intellectual disability and congenital heart defects. The essential components of the tool kit include clinical and dysmorphic features seen in typical neonates with Down syndrome, pictures of karyotypes (normal and Down syndrome), summary of clinical concerns, setting up the informing interview with parents to deliver the news, summary of health supervision guidelines for Down syndrome from the American Academy of Pediatrics (including growth charts), and Down syndrome resources and support group information.

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> ***"The essential components of the tool kit include clinical and dysmorphic features seen in typical neonates with Down syndrome, pictures of karyotypes (normal and Down syndrome), summary of clinical concerns, setting up the informing interview with parents to deliver the news, summary of health supervision guidelines for Down syndrome from the American Academy of Pediatrics (including growth charts), and Down syndrome resources and support group information."***

Physical exam:

The physical exam is the mainstay of diagnosis in Down syndrome. Infants with Down syndrome have characteristic facial features, which facilitates diagnosis in the neonate. They include upslanting palpebral fissures, epicanthal folds, low nasal bridge, protruding tongue, "sandal gap" between the first and second toes, and single transverse palmar crease. The diagnosis is confirmed cytogenetically by routine karyotyping.

Pediatricians and neonatologists can be confident and comfortable in making an assessment for Down syndrome as >95% of infants with the diagnosis have typical and recognizable features. A Genetics consult should be reserved for atypical patients and those with unusual and/or additional features in the patient or family members, that may not be consistent with the diagnosis or that may raise suspicion for a dual diagnosis.

Testing:

We want to highlight that chromosome analysis remains the first-tier test for Down syndrome; microarray analysis should be reserved for those with atypical features or if there is a family history suspicious of a chromosome abnormality. When the diagnosis is

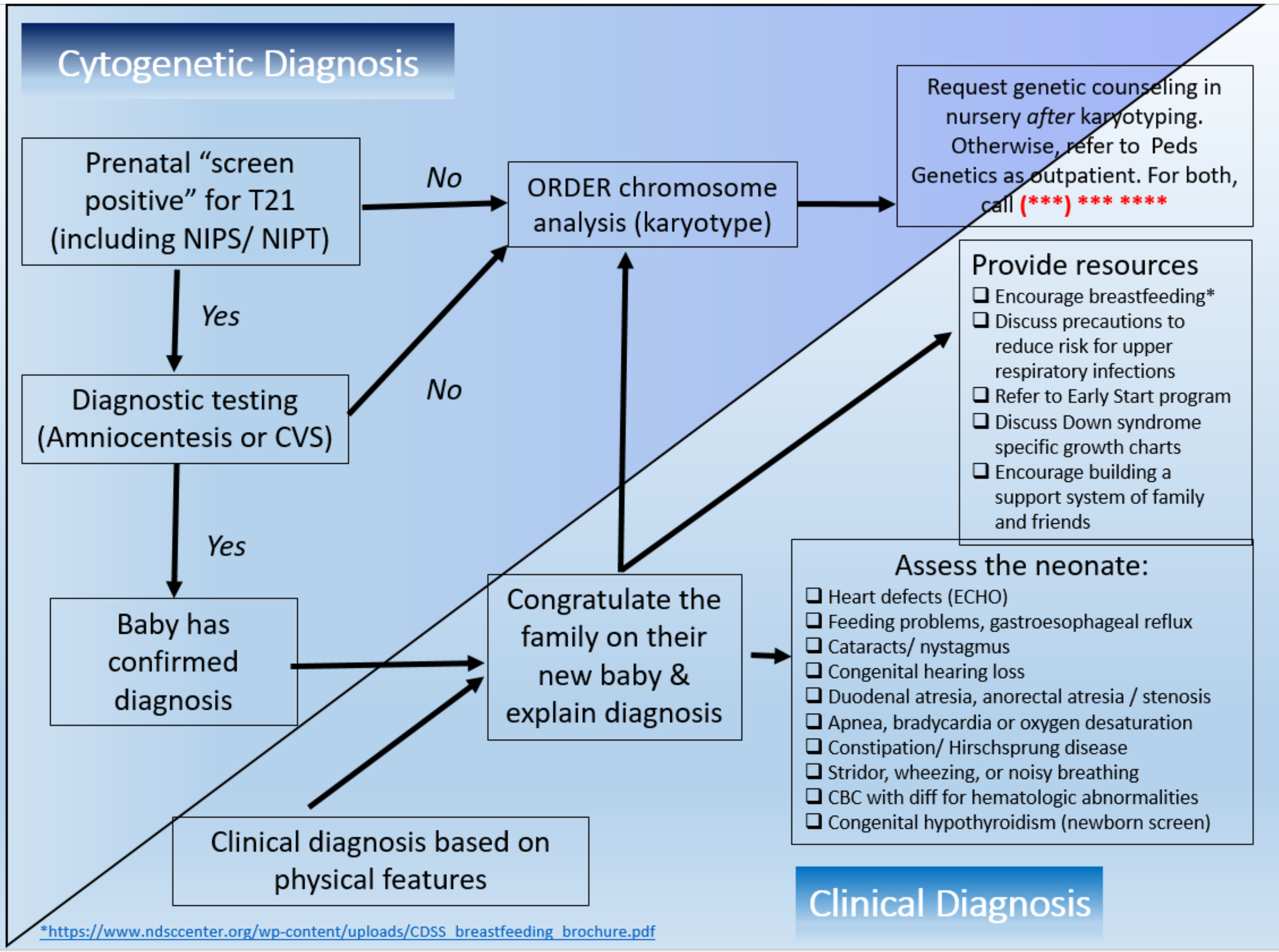


Figure 1: Overview of clinical and cytogenetic diagnostic components

clinically apparent, the parents should be informed and appropriate clinical assessments made in the neonate, as outlined in Figure 1.

Chromosome analysis is usually a confirmatory test, but it also distinguishes the more common trisomy 21 from the less common translocation and mosaic Down syndrome (which differ in their recurrence risks and id therefore necessary for providing appropriate genetic counseling)

The majority of individuals with Down syndrome (95%) have trisomy 21 due to meiotic nondisjunction, and the karyotype is written as:

47,XX,+21 or 47,XY,+21

Parental chromosome analysis is not indicated when the diagnosis is trisomy 21. The risk of recurrence for Down syndrome is low, approaching about 1% for women in their mid-thirties.

In about 4% of cases, Down syndrome is due to a translocation involving chromosome 21. An example of a karyotype for translocation Down syndrome is:

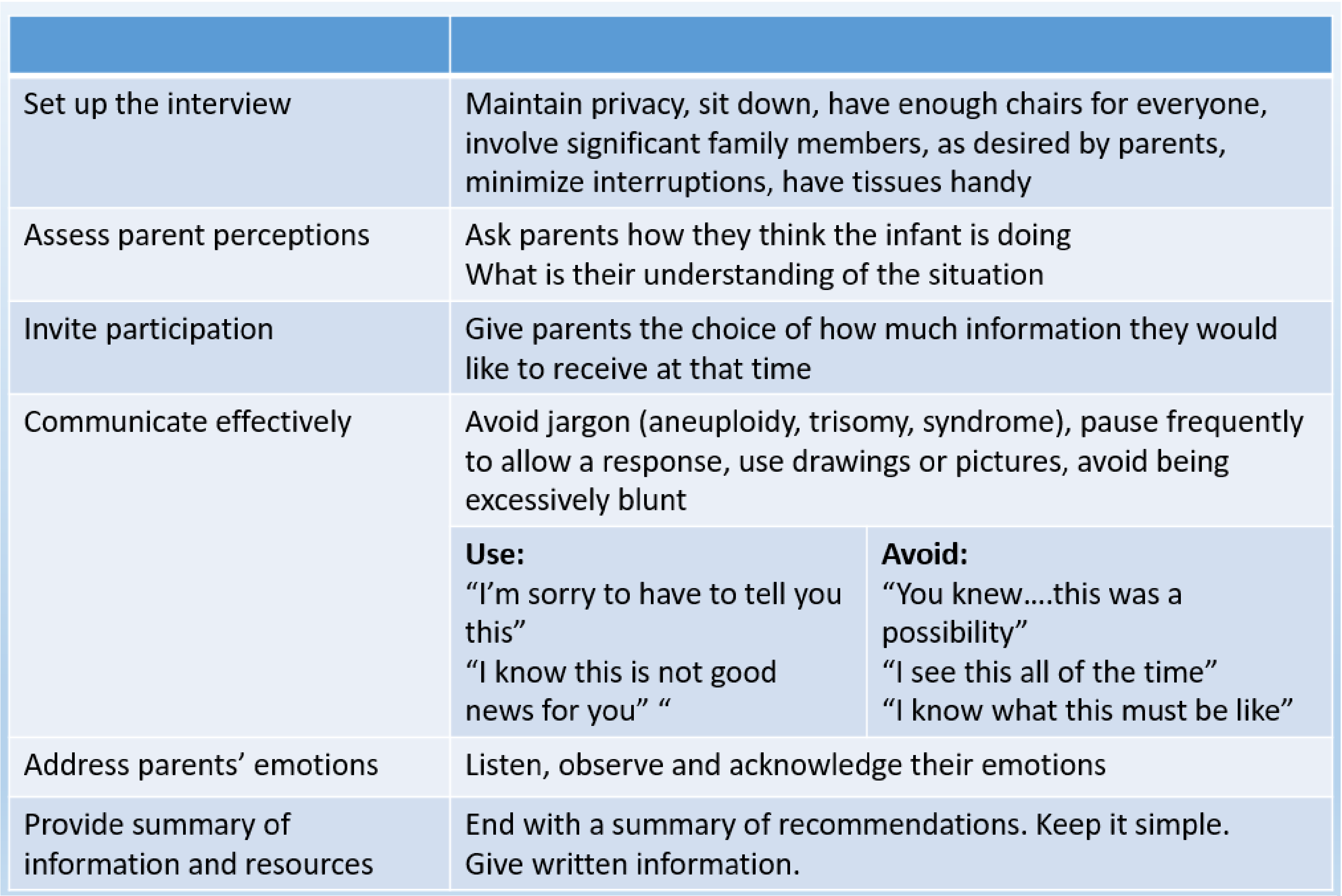
46,XX,der(14;21),+21

In this situation, parental chromosome analysis is recommended, and recurrence risks will be based on whether the chromosome translocation was de novo or inherited, derived from a parent with a balanced chromosome translocation. If the mother is a carrier, the risk to have a liveborn child with Down syndrome is about 10%, while the risk is about 1% if the father is a carrier.

Mosaic Down syndrome accounts for about 1 to 2%, with a karyotype of 47,XX,+21/46,XX (for example) due to postzygotic nondisjunction. The recurrence risk is low and is usually quoted to be similar to that for trisomy 21. Individuals with mosaic Down syndrome may or may not have milder features; karyotyping in the blood is not predictive of the degree of mosaicism in other tissues.

Breaking the news to parents and family:

We provided practical tips on breaking bad news when setting up an interview with parents to inform them of the diagnosis in the nursery, based on the SPIKES 6-step protocol. This is best done in person, before discharge.



<table>
<tr><th></th><th colspan="2"></th></tr>
<tr><td>Set up the interview</td><td colspan="2">Maintain privacy, sit down, have enough chairs for everyone, involve significant family members, as desired by parents, minimize interruptions, have tissues handy</td></tr>
<tr><td>Assess parent perceptions</td><td colspan="2">Ask parents how they think the infant is doing
What is their understanding of the situation</td></tr>
<tr><td>Invite participation</td><td colspan="2">Give parents the choice of how much information they would like to receive at that time</td></tr>
<tr><td rowspan="2">Communicate effectively</td><td colspan="2">Avoid jargon (aneuploidy, trisomy, syndrome), pause frequently to allow a response, use drawings or pictures, avoid being excessively blunt</td></tr>
<tr><td>Use:
“I’m sorry to have to tell you this”
“I know this is not good news for you” “</td><td>Avoid:
“You knew….this was a possibility”
“I see this all of the time”
“I know what this must be like”</td></tr>
<tr><td>Address parents’ emotions</td><td colspan="2">Listen, observe and acknowledge their emotions</td></tr>
<tr><td>Provide summary of information and resources</td><td colspan="2">End with a summary of recommendations. Keep it simple.
Give written information.</td></tr>
</table>

Figure 2: Breaking bad news

At our institution, parents of infants with Down syndrome due to trisomy 21 with typical clinical features are referred for genetic counseling, either while inpatient or in the outpatient Pediatric Genetics clinic. Genetic counseling is best done ideally AFTER karyotype analysis to allow for appropriate genetic counseling regarding recurrence risks in the family. Most pediatricians should be able to provide the basic information about the test result, recurrence risk, and options for prenatal screening and diagnosis in future offspring for parents.

When to order a Genetic consult:

We recommend a Genetics consult when:

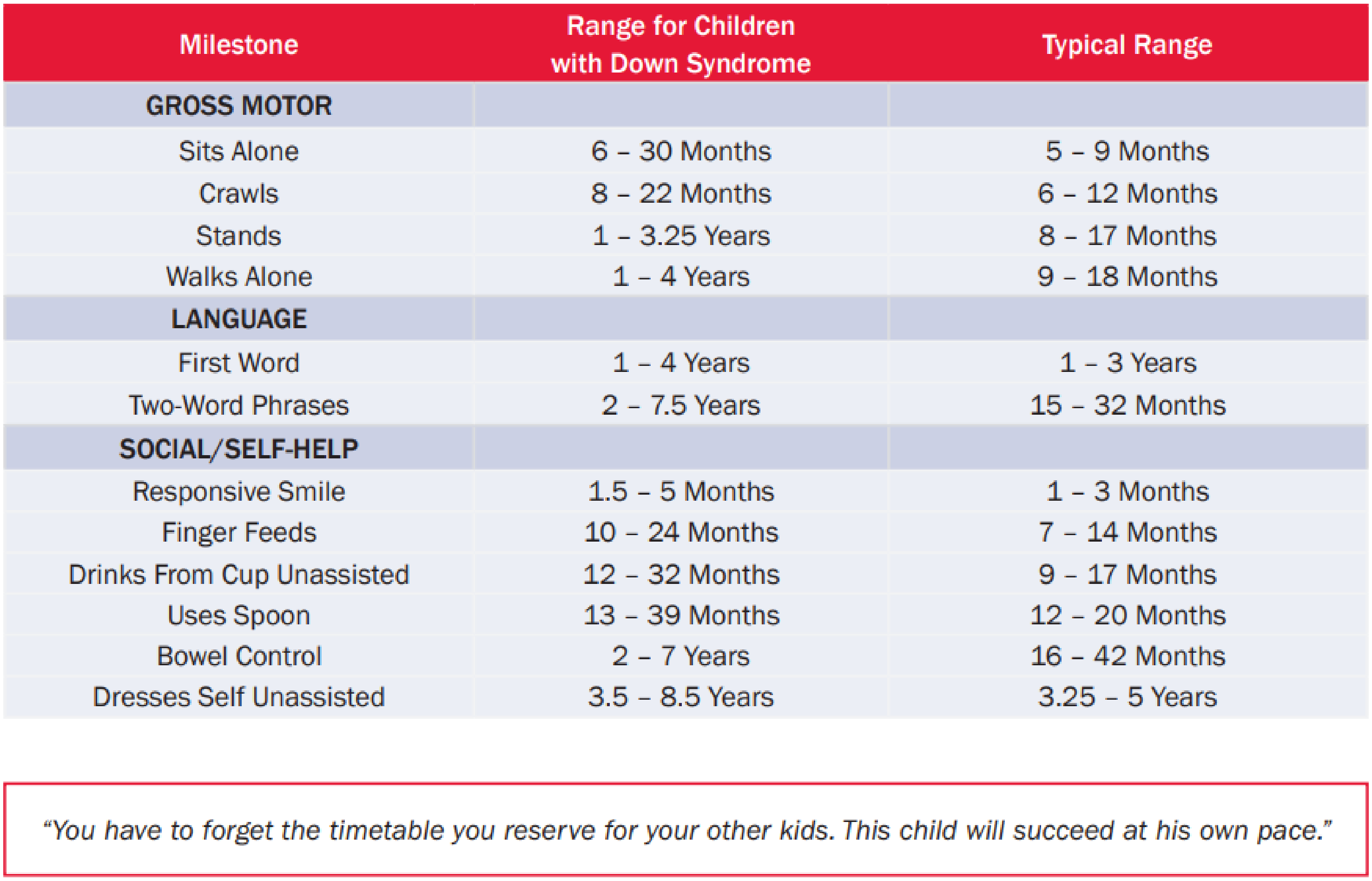
- The baby has features that are NOT typical for Down syndrome with an abnormal chromosome analysis result
- The karyotype confirms translocation or mosaic Down syndrome
- The family history is positive for Down syndrome in another close family member

Resources for parents:
A companion tool kit was also prepared for parents of newly diagnosed infants which include a fact sheet, a short summary of clinical information, support group information, and resources:

- *Fact Sheet about Down Syndrome for New and Expectant Parents*
- *Breastfeeding a baby with Down syndrome*
- Understanding a Down syndrome diagnosis: *https://understandingdownsyndrome.org/*
- National Down Syndrome Society *https://www.ndss.org/*
- Down’s Syndrome Association: *http://downs-syndrome.org.uk*
- Sibling Support: *https://www.siblingsupport.org/*
- National Down Syndrome Adoption Network: *https://www.ndsan.org/*
- Reeces Rainbow Adoption Ministry: *https://reecesrainbow.org/*
- *Welcome to Holland by Emery Perl Kingsley*

We also included a table on developmental milestones in Down syndrome (*ndss.org*):

Practical applications:



Milestone	Range for Children with Down Syndrome	Typical Range
GROSS MOTOR		
Sits Alone	6 – 30 Months	5 – 9 Months
Crawls	8 – 22 Months	6 – 12 Months
Stands	1 – 3.25 Years	8 – 17 Months
Walks Alone	1 – 4 Years	9 – 18 Months
LANGUAGE		
First Word	1 – 4 Years	1 – 3 Years
Two-Word Phrases	2 – 7.5 Years	15 – 32 Months
SOCIAL/SELF-HELP		
Responsive Smile	1.5 – 5 Months	1 – 3 Months
Finger Feeds	10 – 24 Months	7 – 14 Months
Drinks From Cup Unassisted	12 – 32 Months	9 – 17 Months
Uses Spoon	13 – 39 Months	12 – 20 Months
Bowel Control	2 – 7 Years	16 – 42 Months
Dresses Self Unassisted	3.5 – 8.5 Years	3.25 – 5 Years

"You have to forget the timetable you reserve for your other kids. This child will succeed at his own pace."

Figure 3. Table on developmental milestones in Down's Syndrome

1. Examine the infant for typical features of Down syndrome
2. Chromosome analysis is recommended in typical Down syndrome cases
3. Avoid ordering of chromosome microarray analysis in these typical infants
4. Request a Genetics consult if the infant has atypical features and/or if there is a family history that may suggest a dual diagnosis.

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Perinatal Substance Use

5 ways you can improve care during pregnancy and beyond

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

Educate Yourself

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

Use the Right Words

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

Screen Every Patient

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

Get Trained to Offer MAT

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

*opioid treatment program

End the Stigma and Criminalization of Drug Use

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

Your Advocacy Matters

Learn more at
www.nationalperinatal.org

National Perinatal Association

TOP 10

RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

SUPPORT 4 NICU PARENTS

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

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

1 PROMOTE PARTICIPATION

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

Welcome!

2 LEAD IN DEVELOPMENTAL CARE

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

3 FACILITATE PEER SUPPORT

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

4 ADDRESS MENTAL HEALTH

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

5 SCREEN EARLY AND OFTEN

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

6 OFFER PALLIATIVE & BEREAVEMENT CARE

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

7 PLAN FOR THE TRANSITION HOME

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

8 FOLLOW UP

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

9 SUPPORT NICU CARE GIVERS

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

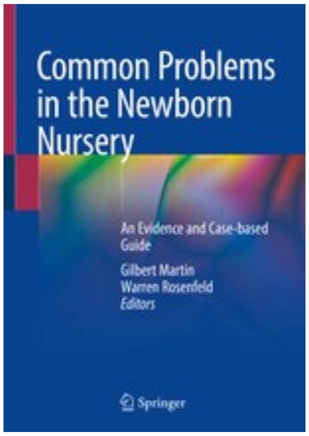
10 HELP US HEAL

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

SUPPORT4NICUPARENTS.ORG

Springer
science+business media

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



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Written by experts in their fields, each chapter begins with a clinical case presentation, followed by a discussion of potential treatment and management decisions and various differential diagnosis. Correct responses will then be explained and supported by evidence-based literature, teaching readers how to make decisions concerning diagnosis encountered on a daily basis.

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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Will Your Preterm Need Early Intervention Services?

Deb Descenza and Mitchell Goldstein, MD

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

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.

Every parent in the NICU is thinking the same thing. With every alarm, with every struggle, the future of their preterm infant is likely to have lasting effects. Discharge day from the NICU is a milestone for sure but every parent feels a clock ticking to get to the "catch up by age 2" mandate given by the NICU team. Walking out the door, parents have no idea that this catch up by age 2 is not hard set and sometimes is never reached. And with state-by-state Early Intervention guidelines being set for a higher percentage of delay, many families will go home with little or no supports in place to help stimulate that baby. This can affect the child and the taxpaying society as well.

> ***"Walking out the door, parents have no idea that this catch up by age 2 is not hard set and sometimes is never reached. And with state-by-state Early Intervention guidelines being set for a higher percentage of delay, many families will go home with little or no supports in place to help stimulate that baby. "***

Preterm infants are at high risk for developmental delays in both the physical and cognitive realms and this can result in 1 in 3 requiring school services for the long-term. Add to this that as that child grows into adulthood it leaves them at risk for ongoing challenges in life. Much as an adult stroke patient responds positively to therapy so we too should push for better supports for these babies as they head home from the NICU. Doing so can dramatically mitigate the effects of prematurity early on and for long-term.

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These delays cannot always be predicted. Although our neurodevelopmental assessments can often give us an idea of the relative risk, there are certain environmental and situational effects that do not enter the rubric until the baby has left the NICU. We emphasize these risks as we go over discharge planning with the parents, but no amount of preparation and counseling can prepare them for the reality of having a child with special needs.

Early intervention provides hope and support. Preterm infants are twice as likely to have developmental delays and other problems related to learning challenges may occur at a rate five times that of those babies born at a term gestation. The reality is that roughly one in three preterm infants will require support services at school.

Early intervention can help preterm infants. By providing appropriate stimulation, language and communication skills can be enhanced. Skilled instruction can help build more effective learning techniques. Social and emotional support can be provided where indicated. Physical challenges can also be amerliorated by early intervention. Importantly, these early interventions can prevent mild difficulties from developing into major problems.

Although services vary from state to state, early diagnosis can qualify their baby for a state's early intervention services. Parents may be unaware of these special services or have limited resources to access the proper channelis. When disparity and proverty complicate discharge, it is vital that extra effort be provided to the discharge plan to ensure that stop gap measures exist to provide for early identification.

> ***"NICU staff, nurses, pediatricians, social workers and anyone involved in discharge planing should talk with NICU families about challenges that their baby may face."***

NICU staff, nurses, pediatricians, social workers and anyone involved in discharge planing should talk with NICU families about challenges that their baby may face.

These services can vary from extra tutoring to those predicated by an individualized education program (IEP). This program defines the individualized objectives of a former preterm infant who has a disability or requires specialized accommodation, as defined by federal regulations. The IEP describes not only the disability but can define how that at risk infant can best learn. Implicit in this process is the selection of the least restrictive learning environment to provide the best possible long term outcome.

The IEP is not meant to be a life long stigma. Rather, it is meant to provide resources for the child until the child can test out and be appropriately mainstreamed. The program is designed to encourage interaction with peers and provide a sense of normalcy while addressing the educational needs of the child.

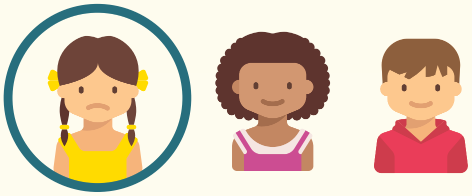
Awareness, referral and timely enrollment in early intervention programs can help infants thrive and grow.

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

Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges



1 in **3** preterm infants will require support services at school

Visit CDC.gov to find additional contact infaormation about state early intervention programs.

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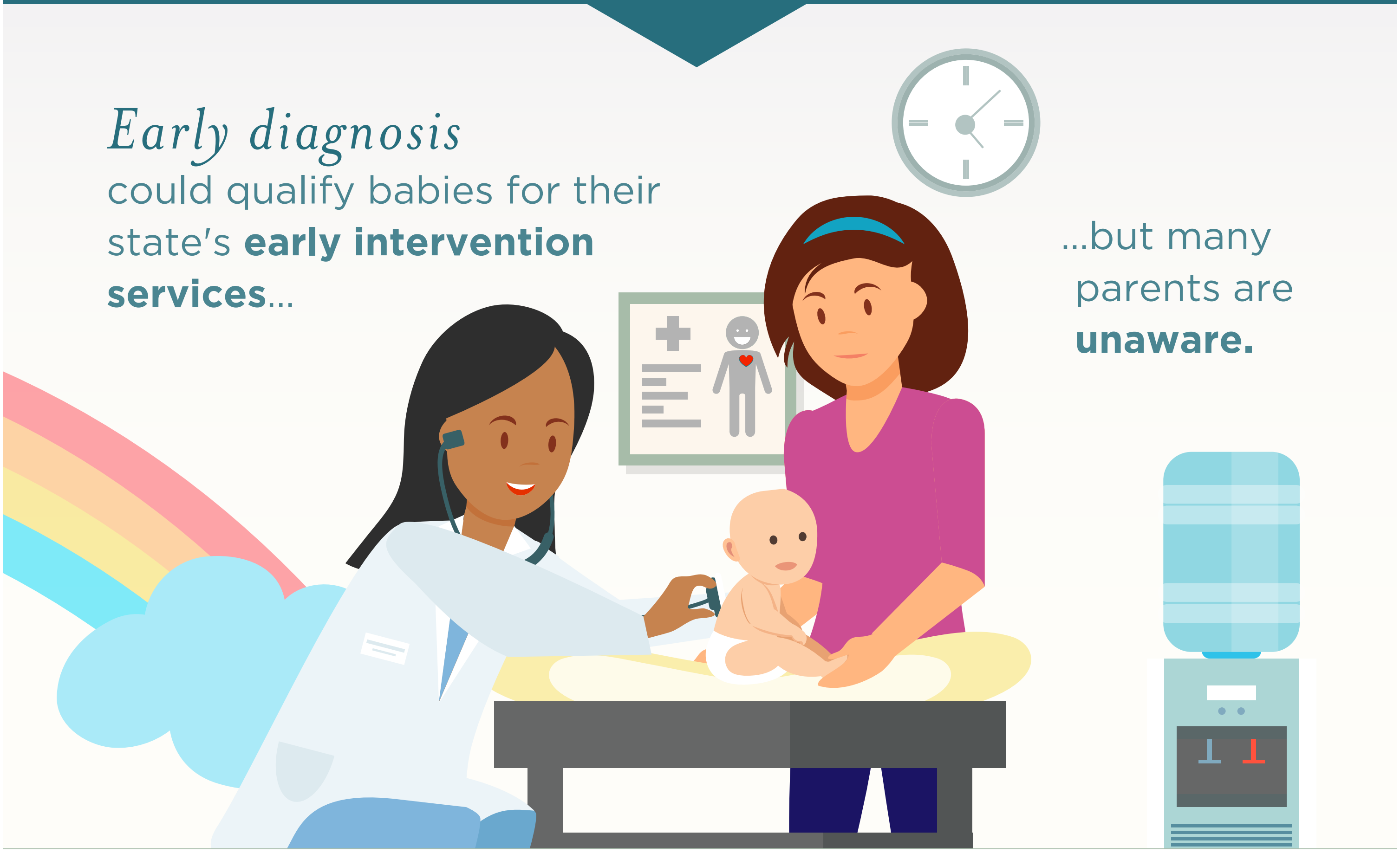
Early intervention can help preterm infants:

- 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.**

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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.

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Visit **CDC.gov** to find contact information for your state's early intervention program.

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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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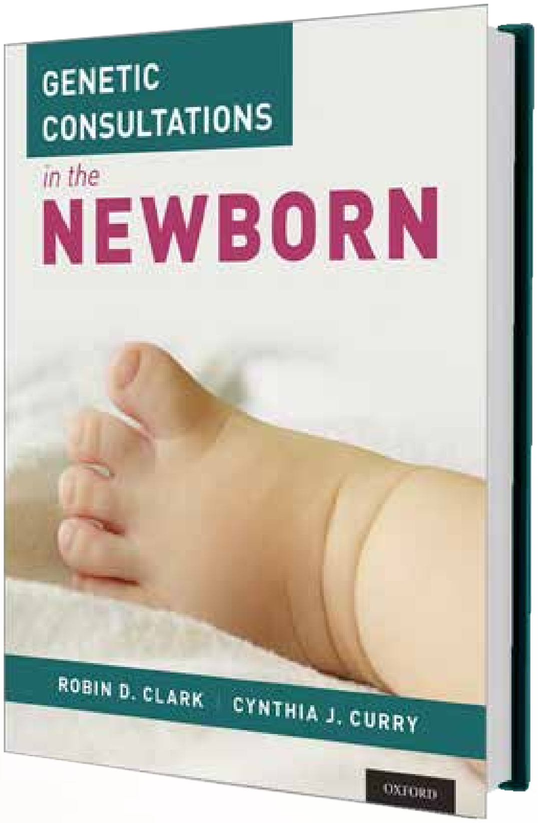

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Order now by clicking here.

OXFORD

RSV AWARENESS:

A National Poll of Parents & Health Care Providers

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

Yet a national poll of parents and specialty health care providers reveals a startling divide in attitudes toward the virus. While both groups acknowledge RSV as a significant concern, the two populations vary widely in their reported ability to meet RSV's threat head-on. Health care providers vigilantly monitor for the virus, which they report seeing regularly in their practices. Parents, however, feel unequipped to protect their young children.

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

KEY FINDINGS

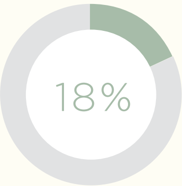
Preparedness

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

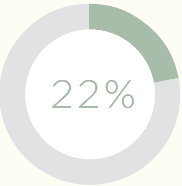
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

PARENTS

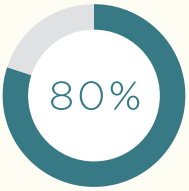
Only 18% said parents know "a lot" about RSV, reflecting an awareness level that's roughly half that of the flu



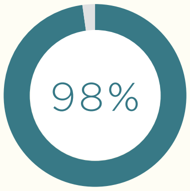
Only 22% of parents consider themselves "very well prepared" to prevent RSV.



SPECIALTY HEALTH CARE PROVIDERS



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



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

Clinical Pearl: Our Self-Expectations and Our Expectations Professionally

Joseph R Hageman, MD

As you may already know, Charles Dickens had an amazingly active mind. One of the quotes from the book entitled 'The Daily Charles Dickens A Year of Quotes' by James R Kincaid, in a letter to his close friend, confidant and financial advisor, John Forster, summarizes his own view of his life: " however strange it is to never be at rest, and never satisfied, and even trying after something that is never reached, and to be always laden with plot, plan, care, and worry, how clear it is that it must be...it is much better to go and fret, than to stop and fret. As to repose-for some men, there is no such thing in this life". Letter April 13, 1856. (1)

> ***"As you may have noted in the Mosby definition, people with "type A" personality have a higher risk of coronary artery disease. Guilty as charged in my case including the "cardiac arrest or heart attack" with 10 minutes of ventricular fibrillation requiring five shocks to convert. "***

As you may know, Dickens would take long walks through different parts of the city of London at night, then come home and write down his observations of people and places. These were his thought and ideas for his books and the characters in them.

Before he started his writing routine at 8 am, he made rounds to the children's' rooms to make sure that everything had been cleaned, made, and appropriately placed. He made a list of those that had not been accomplished and presented them to each of the children. He really loved his kids, but he also had certain expectations as well. I think this quote by Dickens himself, and some of his behavior is consistent with "type A personality described by Freedman and Rosenman originally, who were cardiologists (2). The definition of type A personality is presented in Mosby's Medical Dictionary: "a parent ego state characterized by a behavior pattern described by Meyer Friedman and Ray Rosenman associated with individuals who are highly competitive and work compulsively to meet deadlines. The behavior also is associated with a higher than usual incidence of coronary heart disease." (3)

We can also surmise that Dickens had an element of obsessive-compulsiveness or obsessive-compulsive disorder (OCD) as well. It is clear that there is a spectrum of OCD behaviors. (4)

How many of you describe yourself in your self-assessment as a "type A" and maybe having a bit of "OCD"? I know I have characteristics of both of these "disorders" when I was in clinical practice as a neonatologist, pediatric intensivist, apnea doctor, and the head of inpatient pediatrics. In what I am doing now as director of NICU quality improvement and a resource person for the NICU nurses, NNPs, medical students, residents, fellows, and faculty, as you might guess, I still am "type A" and have some OCD characteristics in "semi-retirement."

Why am I writing about Dickens as a famous example? Why am I also using myself as an example? I think it is safe to say that many of us in medicine -- and I am not just talking about physicians, but also nurses, NNPs, physician assistants as well have these personality characteristics. As you may have noted in the Mosby definition, people with "type A" personality have a higher risk of coronary artery disease. Guilty as charged in my case including the "cardiac arrest or heart attack" with 10 minutes of ventricular fibrillation requiring five shocks to convert. This was followed by a four-vessel bypass and cardiac rehabilitation. I swam laps seven days a week and had been for about 20 years. BTW, status post vagotomy and pyloroplasty 31 years ago and a recurrence of cervical dystonia with q 3 month, botox injections. Enough!

This is another opportunity for you to take a few minutes every day of the week to take care of yourself and "be mindful." Mindful meditation, guided imagery, body scanning are all forms of simple, not time-consuming forms of mind-body therapy (5). If I can learn these and make them an automatic part of my day, so can you. All of this discussion in the literature about physician wellness and resilience is important for all of us to help prevent burnout (6). There were about 300 physician suicides reported last year (or maybe two years ago) in the United States. (7) Women appear to be at great risk. There is a definite risk for depression, as well. In medicine, we are all working in a stressful environment, and each of us develops a method or strategy for dealing with chronic stress. Our work also has an effect on our personal lives as well.

Dr. Hilary McClafferty and I just recorded a "physician resilience" podcast in which I discuss my strategies for dealing with the stress that we experience professionally. Hilary is a pediatric emergency physician and integrative medicine physician who is the first author on the physician wellness curriculum for the American Academy of Pediatrics (AAP). (8) We are working to help people in medicine with the challenges we face in our professional lives.

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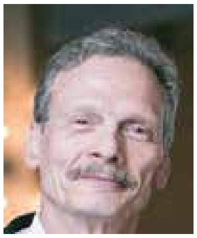

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1250 word limit not including references or title page.

May begin with a brief case summary or example.

Summarize the pearl for emphasis.

No more than 7 references.

Please send your submissions to:

jhageman@peds.bsd.uchicago.edu

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NCfIH National Coalition for Infant Health

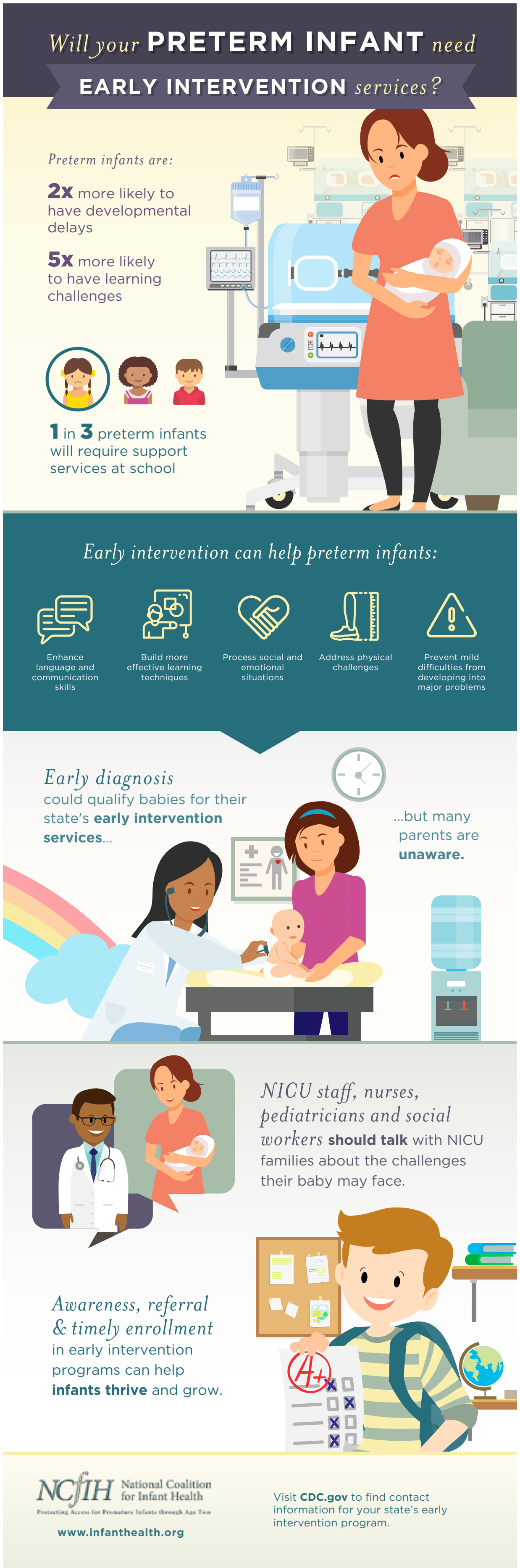
Protecting Access for Premature Infants through Age Two

A collaborative of professional, clinical, community health, and family support organizations 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



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

Preterm infants are:

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5x more likely to have learning challenges

1 in **3** preterm infants will require support services at school

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- Process social and emotional situations
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Early diagnosis could qualify babies for their state's **early intervention services**...

...but many parents are **unaware.**

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Awareness, referral & timely enrollment in early intervention programs can help **infants thrive** and grow.

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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.

16% Only 16% **know "a lot"** about RSV

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

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

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

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

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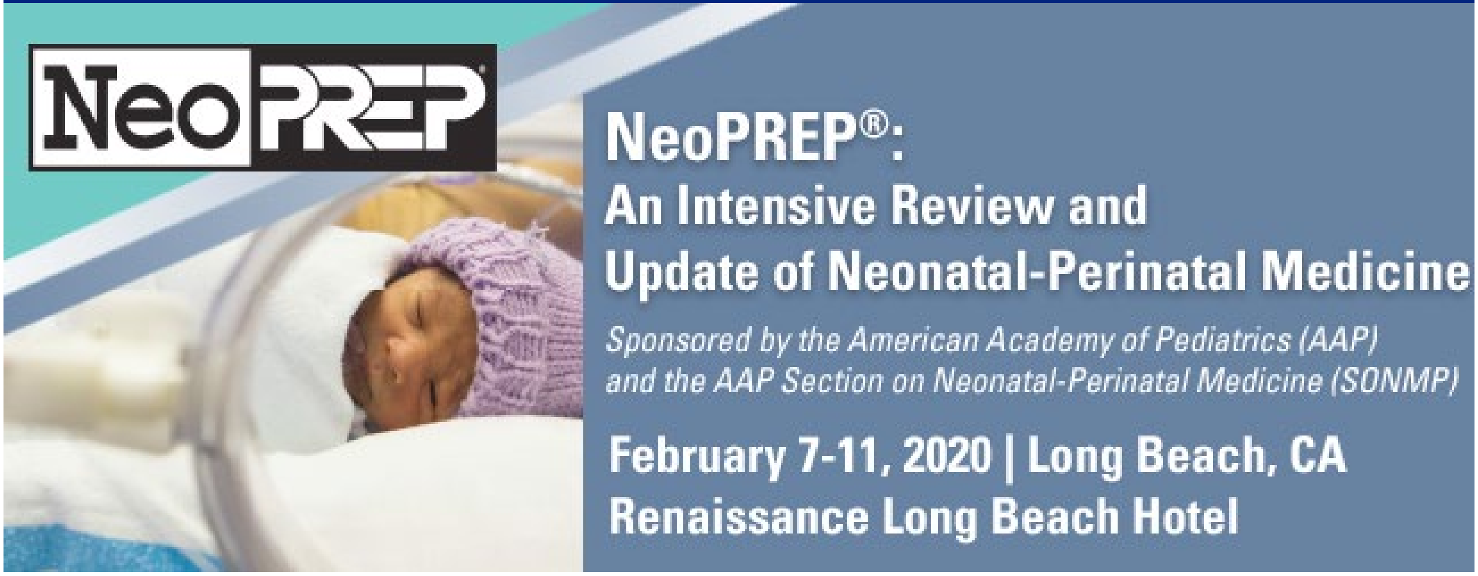

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2020 NeoPREP®
An Intensive Review and Update of Neonatal-Perinatal Medicine
February 7-11, 2020
Long Beach, California
Renaissance Long Beach Hotel
More information coming soon at shop.aap.org/live-activities.

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Letters to the Editor

[EXTERNAL] Letter to the Editor

Monday 7/29/2019 5:26 PM

Dear Dr. Goldstein,

For pregnant women, one of major benefits about being in the U.S. military is the provision for paid maternity leave for 12 weeks or potentially more after the birth of an infant. The recent report of this benefit has been the significant improvement in rates of breastfeeding among women in the military of all ethnic and racial groups, as well as, the duration of breastfeeding that mothers provide their milk with all of its bountiful benefits for their infants and themselves (1). Being a woman Soldier, Sailor, Marine or member of the Coast Guard or Airforce provides paid maternity leave not usually available to women in government or other occupations in our workforce. While certainly less than benefits afforded most European women after pregnancy, data provided by Donne et al., document how extended maternity leave provides a lifetime of benefit for infants of mothers on active duty military. Their report echoes other reports documenting that women who received 12 or more weeks of paid leave were more likely to initiate breastfeeding compared to women with no paid leave (87.3% vs 66.7% (adjusted odds ratio 2.83, and were more likely to to breastfeed at 6 months compared to women with no paid leaves 50.1% vs 24.9%, adjusted odds ratio 2.25. Among women who initiated breastfeeding, having received 12 or more weeks paid leave increased the odds of breastfeeding for six or more months; however, this association was not statistically significant (adjusted odds ratio o 1.81). (2) [Mirkovic KR, Perrina CG, Scanlon KS. Birth 2016 Sept, 43(3):233-9. Systematic reviews of the literature have confirmed the impact of maternity leave on breastfeeding rates and duration of breastfeeding and advocated for public health policies that ensure that all women, especially the most vulnerable, have equal access to the benefits that maternal leave provides (3). (Navarro-Rosenblatt D, Garmendia, M-L. Maternity Leave and Its Impact on Breastfeeding: A review of the literature. Breastfeeding Medicine 2018; 13(9) dol.org/10.1089/bfm,2018.0132.

Currently, only 12% of U.S. firms offer paid maternity leave, and lack of widespread parental leave may explain why less than a quarter of working mothers are still breastfeeding after six months (4). (Kapinos K, Uscher-pines, L. theRANDblog April 27, 2017) Increasing rates and duration of breastfeeding provide benefits to both infants and their mothers and could realize a cost savings of $10.5 billion in health care costs through reducing the incidence of pediatric diseases for breastfed infants during the first year of life.

On June 30, 2019, the Oregon legislature passed legislation that creates a family and medical leave insurance program to provide partially or fully compensated time away from work to cover individuals who meet certain criteria while the covered individual is on family leave, medical leave or safe leave including maternity leave (5). Paid family and medical leave insurance will be available to all Oregonians who made at least $1,000 in a calendar year and will be supported with a payroll assessment, not to exceed 1%, split between the employer and employee. This expanded family and medical leave offers the opportunity to improve rates and duration of breastfeeding for women. (Oregonian July 1, 2019, Borrud, Hillary) that hopefully will match the improvements recently reported by our new mothers in the U.S. military.

References:

1. *Donne AD, Hatch A, Carr NR, Aden J, Shapiro. Extended Maternity Leave and Breastfeeding in Active Duty Mothers. Pediatrics 2019, published online July 22, 2019 doi. 10.1542/peds.2018-3785*
2. *Mirkovic KR, Perrina CG, Scanlon KS. Birth 2016 Sept, 43(3):233-9.*
3. *Navarro-Rosenblatt D, Garmendia, M-L. Maternity Leave and Its Impact on Breastfeeding: A review of the literature. Breastfeeding Medicine 2018; 13(9) dol.org/10.1089/bfm,2018.0132.*

T. Allen Merritt, MD MHA

Dear Dr. Merritt,

The concept of medical leave and its importance to breastfeeding rates is getting much more attention. The United States has lagged significantly behind a number of European countries in providing adequate time for medical leave following childbirth and thus in providing sufficient time for the establishment of successful breastfeeding.

While the U.S. military has in the past been criticized for its lack of medical services in line with the needs of its female enlisted personnel, in this area, U.S. firms would do well to follow the military's example.

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Editor in Chief

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NT

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

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

NT

Erratum (Neonatology Today August, 2019)

Neonatology Today has not identified erratum affecting the August, 2019 edition.

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

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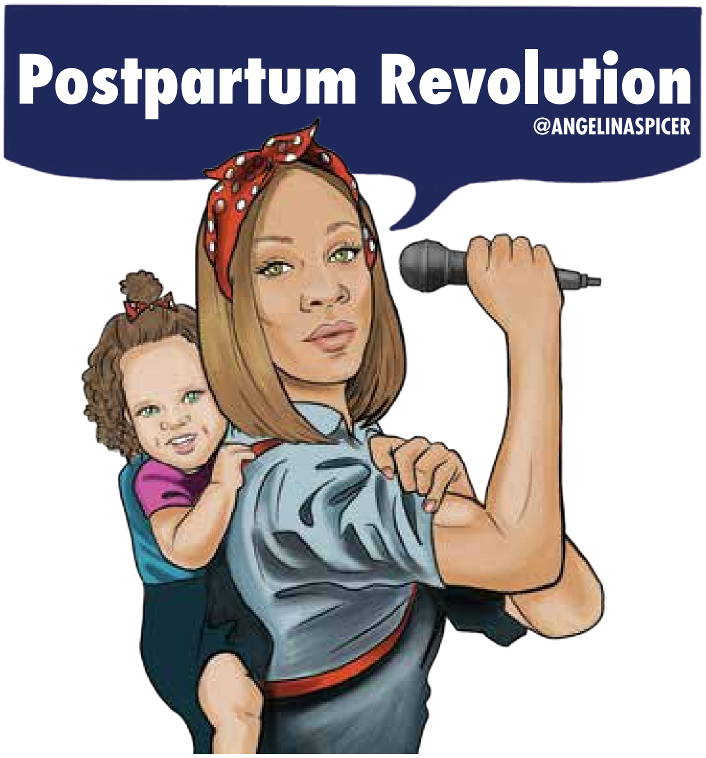

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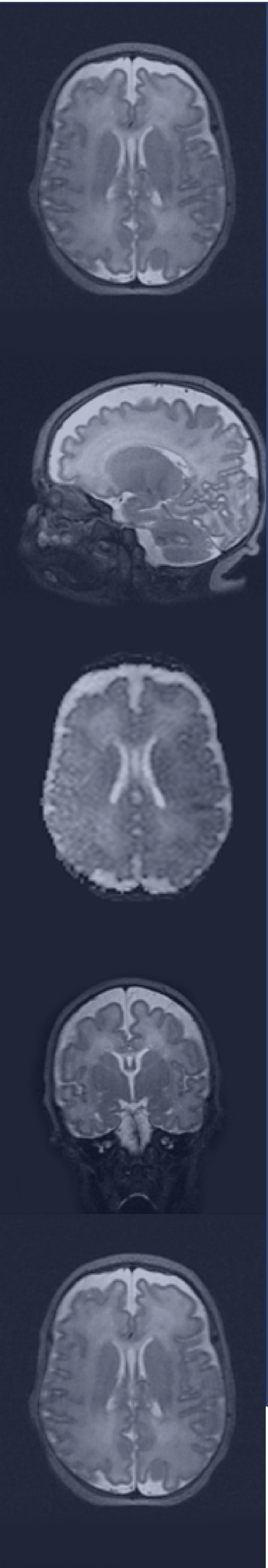

California NICU Professionals

You are invited!

NEONATAL MRI:
THE WHO? WHY? WHEN AND HOW?

Dear Colleagues,
You are invited to a dinner presentation and networking event with the renowned neonatologist Dr. Terrie Inder.

NETWORKING.
WINE RECEPTION.
DINNER.
PRESENTATION.

In this case-based presentation, Dr. Inder will review the state of science on the use of neonatal MRI for both term and preterm infants at risk for brain injury.

She will share an evidence-based approach to developing a neonatal neuro-imaging protocol for your NICU and take a deep dive into the most common misconceptions about the use of MRI for preterm infants at term-age equivalents.

As an early adopter of in-NICU MRI scanners, she will be sharing her experiences from blueprints to their first year of use.

Two Dates to Choose From

Thursday, Sept 19th
5:30pm - 8:30pm
Hyatt Regency SFO Airport
1333 Old Bayshore Hwy
Burlingame, CA 94010

Monday, Sept 23rd
5:30pm - 8:30pm
Sheraton Park Hotel
1855 S Harbor Blvd
Anaheim, CA 92802

Register at rsvp.synapsecare.com *

** Please note that seating for dinner is limited. Please register as soon as possible to secure a spot.*

This event sponsored by Aspect Imaging

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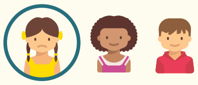
5x more likely to have learning challenges



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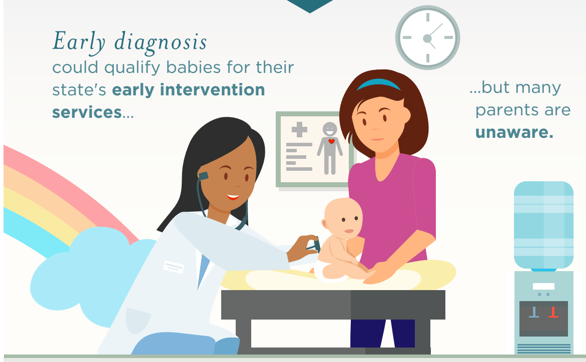

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Protecting Access for Premature Infants through Age Two
www.infanthealth.org

Visit **CDC.gov** to find contact information for your state's early intervention program.

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

1 DE CADA **7** MADRES AFRONTA LA DEPRESIÓN POSPARTO, *experimentando*

- Llanto incontrolable
- Sueño interrumpido
- Ansiedad
- Desplazamientos en los patrones de alimentación
- Ideas de hacerse daño a sí mismas o al bebé
- Distanciamiento de amigos y familiares

Sin embargo, sólo el 15% recibe tratamiento[1]

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

La salud de la madre

El sueño, la alimentación y el comportamiento del bebé a medida que crece[2]

La capacidad para cuidar de un bebé y sus hermanos

PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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

LOS HOSPITALES PUEDEN:

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

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www.infanthealth.org

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[1] American Psychological Association. Accesible en: http://www.apa.org/pi/women/resources/reports/postpartum-depression.aspx

[2] National Institute of Mental Health. Accesible en: https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml

[3] Journal of Perinatology (2015) 35, S29–S36; doi:10.1038/jp.2015.147.

[4] Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Villegas L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

Upcoming Medical Meetings

7th International Conference on Neonatal Care
October 10-11, 2019
Airport Hotel Okecie, Warsaw, Poland
www.neonatus.org

8th Annual Scientific Sessions of the Cardiac Neurodevelopmental Outcome Collaborative
October 11-13, 2019;
Hospital for Sick Children, Toronto, Ontario, Canada
www.cardiacneuro.org/upcoming/

NANN's 35th Annual Conference
Savannah Convention Center
Savannah, GA
October 9-12, 2019
http://nann.org/education/annual-meeting

The AAP Experience
National Convention and Exhibition
New Orleans, LA
October 25-29, 2019.
http://aapexperience.org/

International Lactoferrrin Conference
Lima, Peru
November 4-8, 2019
http://www.lactoferrinconference2019.com/index.html
Chair: Dr. Theresa Ochoa, Theresa.J.Ochoa@uth.tmc.edu

Miami Neonatology 43rd Annual International Conference 2019
November 10-13, 2019
November 13, 2019
Loews Miami Beach Hotel
Miami, Florida
http://pediatrics.med.miami.edu/neonatologyMillennium

Neonatology:
Building a Better Pathway for Preemies
November 16, 2019
8 a.m. to 5 p.m.
Women & Infants Hospital
Malcolm and Elizabeth Chace Education Center
101 Dudley Street, Providence, RI
For More Information Please contact:
Mary Tucker mtucker@wihri.org or Brenda Vecchio bvecchio@wihri.org
/international-neonatal-conference

Hot Topics in Neonatology®
National Harbor, MD
December 8-11, 2019
http://www.hottopicsinneonatology.org/

NEO
The Conference for Neonatology
Coming February 2020
San Diego, CA
http://www.neoconference.com/

The 37th Annual Advances in Therapeutics and Technologies Conference
March 24-28, 2020
Snowbird, UT
http://paclac.org/advances-in-care-conference/

Pediatric Academic Societies 2020 Meeting
April 29 – May 6, 2020
Philadelphia, PA
https://2020.pas-meeting.org/

For up to date Meeting Information, visit NeonatologyToday.net and click on the events tab.

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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.

Loma Linda is located in the center of Southern California. A sunny climate augments the cultural benefits of Los Angeles and Palm Springs and the year-round recreational opportunities of nearby mountains, deserts and beaches.

This opportunity is not eligible for a J1 Waiver.

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- State of the art technology
- 24/7 coverage provided by NNP team and Fellows

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With over 900 beds in four hospitals, we operate some of the largest clinical programs in the nation. We also offer the only Level I Regional Trauma Center and Children's Hospital in the Inland Empire servicing the largest county in the US. We lead in many areas of excellence; pediatrics, cardiac services, cancer treatment and research, mental health, chemical dependency, and other essential clinical disciplines. All this adds up to endless possibilities for our patients and for you.

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.

Contact Us

Please visit our website **http://careers.llu.edu** or contact Jeannine Sharkey, Director of Advanced Practice Services at jsharkey@llu.edu or (909) 558-4486.

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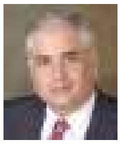

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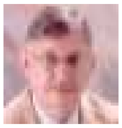

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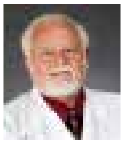

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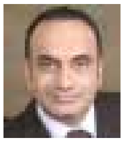

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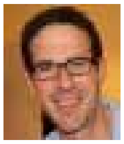

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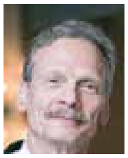

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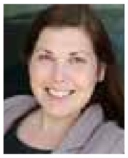

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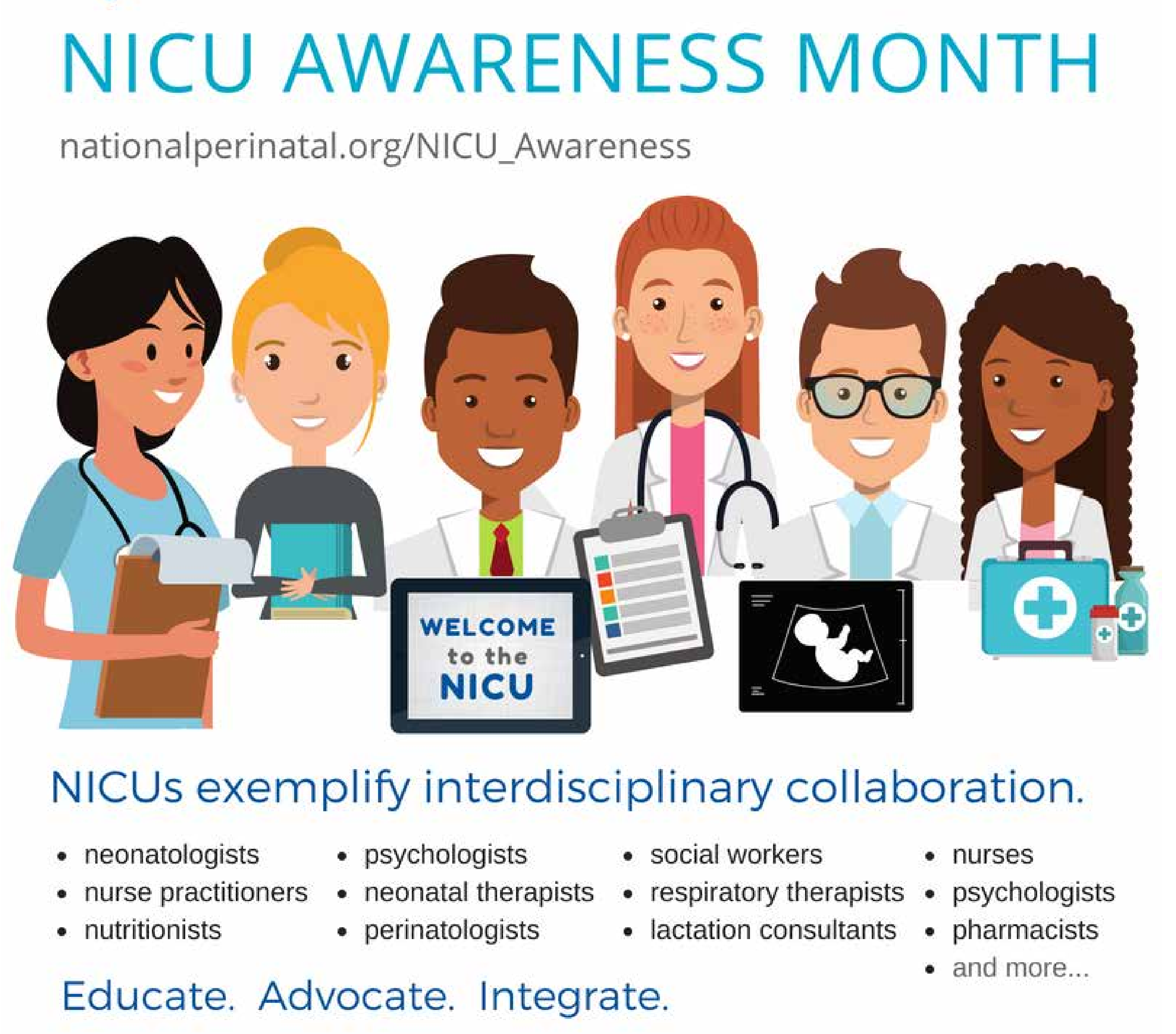

NICU AWARENESS MONTH

nationalperinatal.org/NICU_Awareness

NICUs exemplify interdisciplinary collaboration.

- neonatologists
- nurse practitioners
- nutritionists
- psychologists
- neonatal therapists
- perinatologists
- social workers
- respiratory therapists
- lactation consultants
- nurses
- psychologists
- pharmacists
- and more...

Educate. Advocate. Integrate.

Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

We are stuck on "birds" for this month once again. Gail Levine, MD submitted this wonderful shot. According to Dr. Levine, this is a Mae West Bird. " Why Don't You Come Up and See Me Sometime?" Still, the birds continue to rule.

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Manuscript Submission: Instructions to Authors

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

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

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

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

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

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 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.

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

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