

NEONATOLOGY TODAY

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



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

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 NO₂ 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 PaO₂, inspired NO₂, and methemoglobin during INOMAX administration.
- INOMAX must be administered using a calibrated INOMax DSIR® Nitric Oxide Delivery System operated by trained personnel. Only validated ventilator systems should be used in conjunction with INOMAX.
- The most common adverse reaction is hypotension.

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



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

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

Worsening Heart Failure

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

DRUG INTERACTIONS

Nitric Oxide Donor Agents

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

OVERDOSAGE

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

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

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Neonatal Digital Home Healthcare

Ross Sommers, MD

Definition of Terms

According to the Institute of Medicine, an estimated 26.2 billion dollars are spent on medical care for premature infants annually. (1) As staggering as these figures are, they don't even include post-NICU medical spending which averages \$33,000 for each infant per year, with 72% directed toward inpatient care. (2)

Digital healthcare is defined as the convergence of digital technologies with health, healthcare, living, and society to enhance the efficiency of healthcare delivery. (3) It is a rapidly growing industry with an estimated 4.2 billion dollars invested in companies during the first half of 2019 alone. (4) Many devices and platforms have been developed, enabling adults with chronic conditions to receive quality care at home. Despite the high cost of caring for NICU graduates, there is, at present, no digital healthcare solution for this population.

There are several possible explanations for this finding. As with other novel therapies, whether device or pharmaceutical, the pediatric population is all but insignificant when compared to adults with similar morbidities. Consequently, industry is reluctant to invest in a small market. Another possible concern is that historically, the adoption rate for digital health tools has been relatively low. (3) Moreover, the viability of the use case for newborns is contingent upon the acceptability of such a service to parents.

Several recent trends put many of these concerns to rest.

Numbers

In a retrospective analysis of 4973 NICU Medicaid patients, the one-year readmission rate was 36.8%. (2) Based on the estimated 3,800,000 USA births per year and a 10% NICU admission rate, this comes to an additional 12.5 billion dollars of annual healthcare spending. This value is similar to the estimated annual expenditure of 17.4 billion dollars for the 34% of Medicare patients requiring read-

mission during the first 90 days post-discharge. (5)

On a positive note, in the era of accountable care where hospitals are fined for [Medicare readmissions](#), the numbers for adults are improving. (6) It is also giving rise to a new generation of digital analytics companies such as [Jfvion](#) that provide hospitals with predictive tools to identify patients at higher risk for readmission, [Care Centrix](#) that offers post-acute home care services, and remote monitoring management companies such as [Vivify Health](#), that was just acquired by the healthcare insurance United Healthcare. (7)

“As the cost of post-discharge care for NICU graduates is nearly equal to the cost of caring for the elderly Medicare population, it is only a matter of time before hospitals will be penalized for NICU readmissions. Despite the smaller size of our patient population, the high post-NICU readmission rates are not sustainable in today’s healthcare cost-conscious environment.”

Medicaid, which is increasingly covering the cost of newborn care, has not yet started to penalize hospitals for NICU readmissions. There is an increasing level of dissatisfaction on the part of the public as well as policymakers with the ever-increasing spending on healthcare. As the cost of post-discharge care for NICU graduates is nearly equal to the cost of caring for the elderly Medicare population, it is only a matter of time before hospitals will be penalized for NICU readmissions. Despite the smaller size of our patient population, the high post-NICU readmission rates are not sustainable in today's healthcare cost-conscious environment.

User Adoption

In a recent report on home care for babies with BPD, half of the 125 parents of affected infants still in the NICU indicated a preference for earlier discharge with home oxygen therapy. (8) However, three months post-discharge, 78% of 110 parents stated that they would have preferred to have been sent home earlier with oxygen, including 97% who initially preferred home oxygen and 60% who preferred to stay longer in the NICU to wean off oxygen. The authors concluded that “earlier education to increase comfort with home technology may facilitate NICU discharge planning”. These findings provide support



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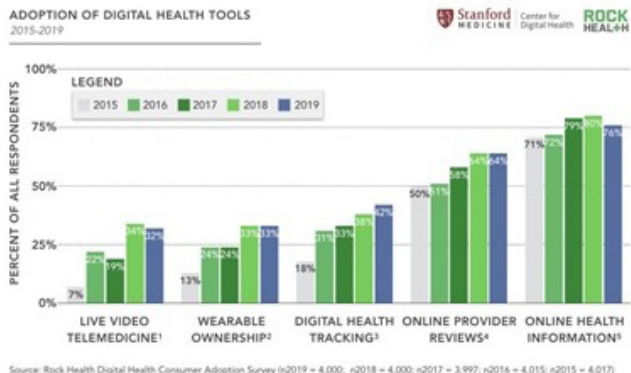
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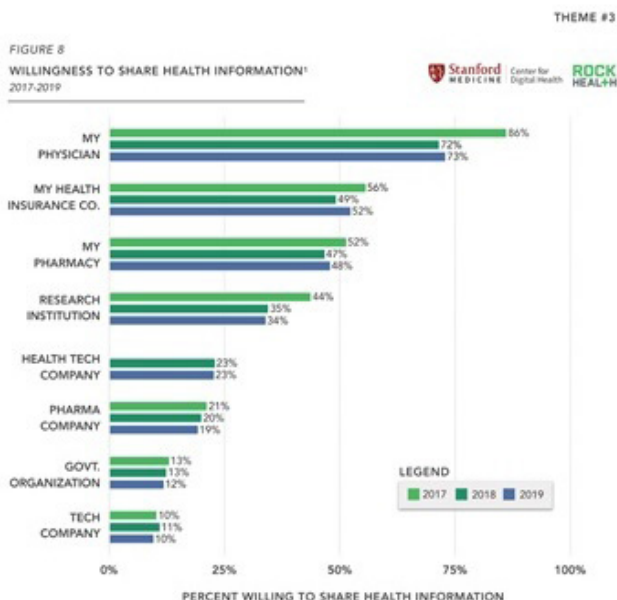
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for the move toward reduced length of stay made possible through increasing adoption rates of digital health tools.

A recent survey published by Rock Health and the Stanford Center for Digital Health demonstrated several interesting findings. (4) First, the overall acceptance of digital health tools is increasing over time.

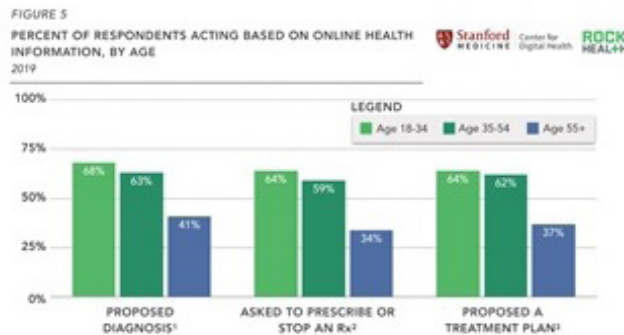


Second, healthcare consumers appear eager to share health data, both analog and digital metrics, with their healthcare providers. Naturally, the willingness is greatest when the provider is the patient's personal physician. This is particularly relevant to the NICU environment where parents have spent months in the hospital, building trust and developing a level of comfort with the physicians, nurses, and NNPs who have been caring for their infant.



“This is particularly relevant to the NICU environment where parents have spent months in the hospital, building trust and developing a level of comfort with the physicians, nurses, and NNPs who have been caring for their infant.”

Third, online health is reshaping the physician-patient relationship with patients increasingly asking physicians to prescribe or discontinue a medication, propose a diagnosis, or propose a treatment based on online information. This is particularly evident in the younger millennial Uber generation, accustomed as they are to placing the control of much of their lives in the realm of digital tools.



It is clear that there is a transition to a progressively more digital consumer healthcare experience, and the post NICU discharge population should be no different.

Current status

NICU transition home programs already currently exist. Women and Infants Hospital of Rhode Island has developed a transition home program consisting of a team of four clinical social workers and seven family resource specialists (FRSs) who previously had an infant in the NICU and were paid employees. FRSs were matched with families based on primary language and common backgrounds. The FRS provided education and supportive intervention services under the guidance of social workers. Post NICU intervention included a call within 24 hours from an NNP home visit within the first week, transmittal of summaries to PCP referral to early intervention, and round the clock on-call by study physicians by telephone up to 90 days post-discharge. Medicaid savings related to decreased readmissions over the 90 days was \$4590 per infant or \$18,360 per year. (9) Based on the average \$33,000 spent per year on NICU graduates a 56% cost savings and based on the 12.5 billion spent per year post NICU care for these infants this would correlate to about 7 billion dollars saved per year if this service were offered to all NICU graduates. Social tools are a critical component of an NICU discharge service in conjunction with a digital health service.

Our Experience

We created Firstday Healthcare for the families of our NICU graduates to assist them with a successful transition home. Our universal platform consists of remote continuous vital sign monitoring, 24/7 telemedicine, and a user smartphone app with a built-in EMR.

Continuous vital sign monitoring

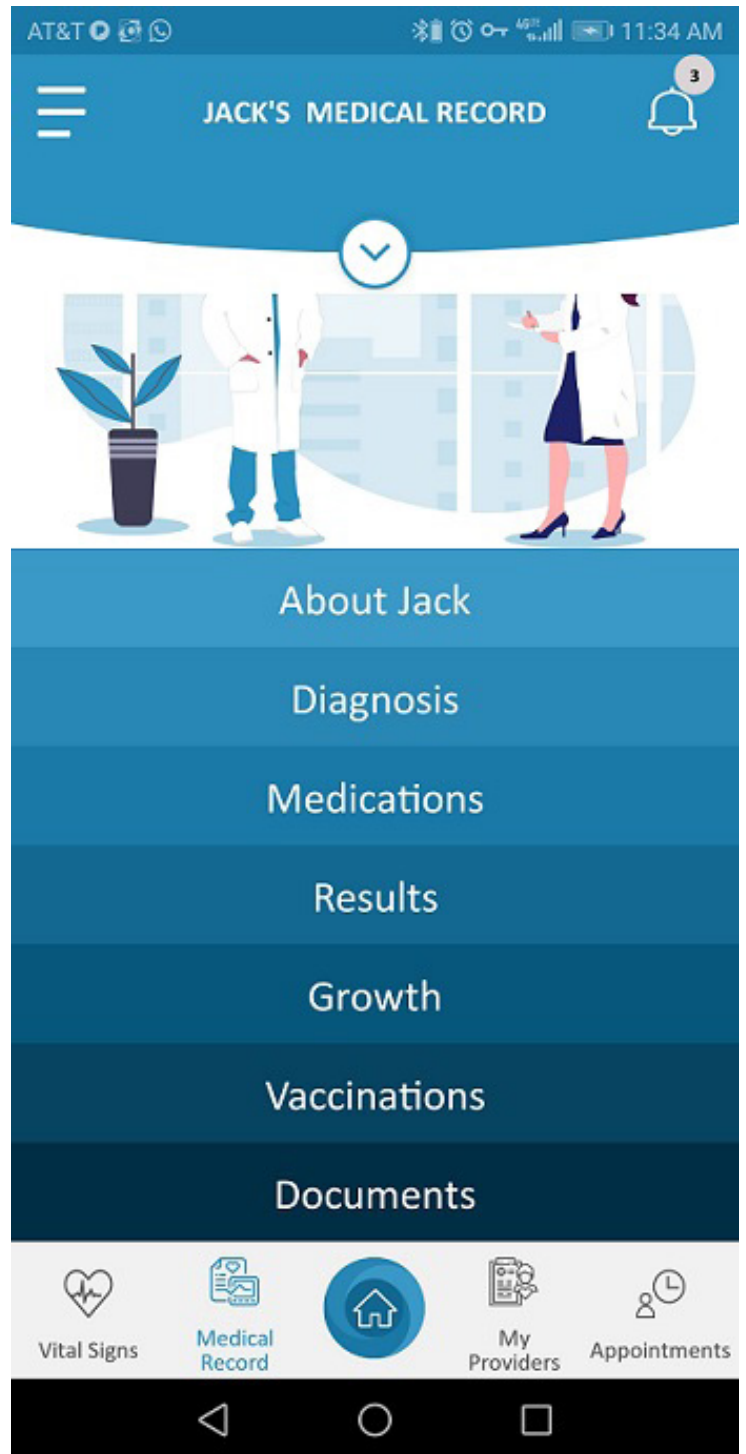
Continuous remote vital sign monitoring signals are acquired using the [Isansys Healthcare platform](#). A single-use, neonatal specific, 7-gram sensor that utilizes reusable standard EKG leads placed on the chest takes the average heart rate, respiratory rate, and cutaneous temperature. In addition, a [Nonin WristOX](#) may also be placed on the foot. Data is sent by Bluetooth to a dedicated tablet gateway device where one-minute average values are sent to the cloud. Our platform takes these values from the cloud for display on the monitoring provider's desktop as well as on the parent's Firstday Healthcare app. If the value triggers an alarm for predefined values, an alert is sent by SMS text to the parents and a master phone list of providers.

Telemedicine

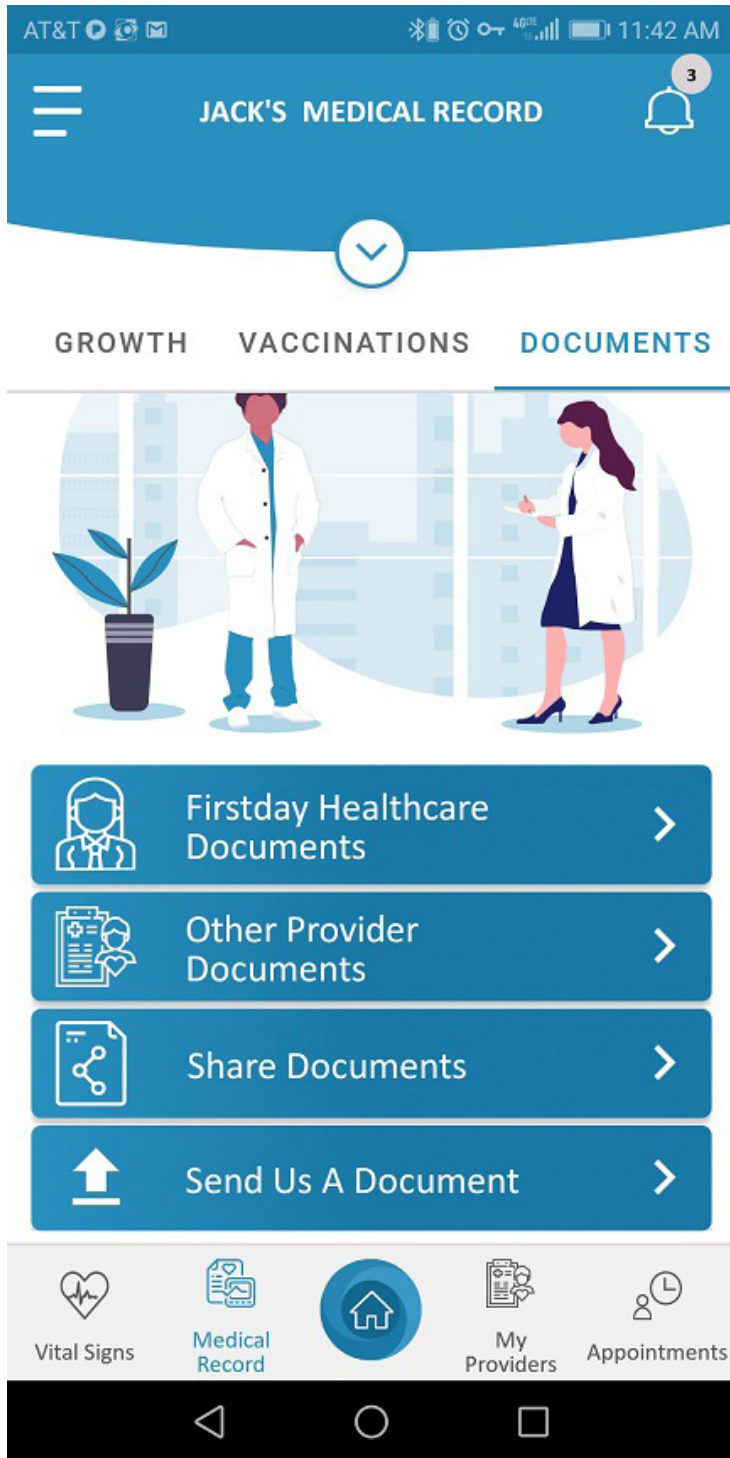
Our app features built-in HIPPA compliant text, video chat, and file attachment. In this way, we are able to securely communicate with families for concerns they may have that are beneath the threshold for detection by vital sign monitoring. High definition photos and videos are stored in a HIPPA compliant cloud account and associated with the user EMR. If a more detailed exam is required, we utilize a [Tyto device](#) that is given to all of our parents. All interactions are shared with the infant's pediatrician. In the event of a true emergency, our staff assist in contacting EMS services and alert the hospital to the infant's arrival.

User App

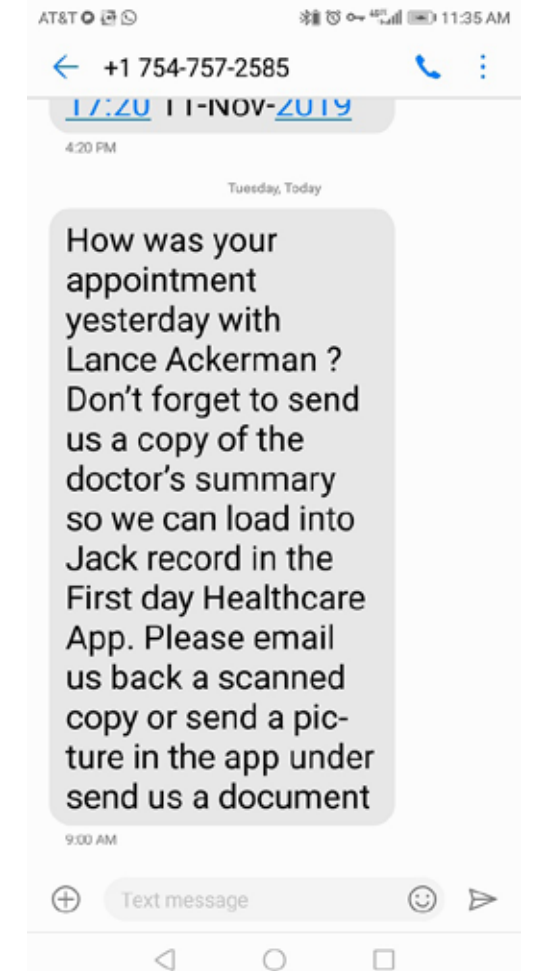
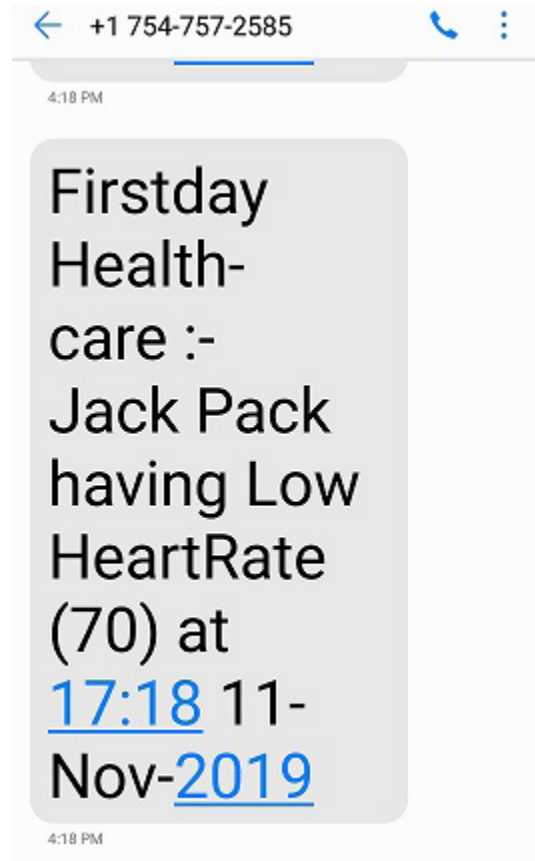
In addition to accessing their infant's vital signs, the user app was

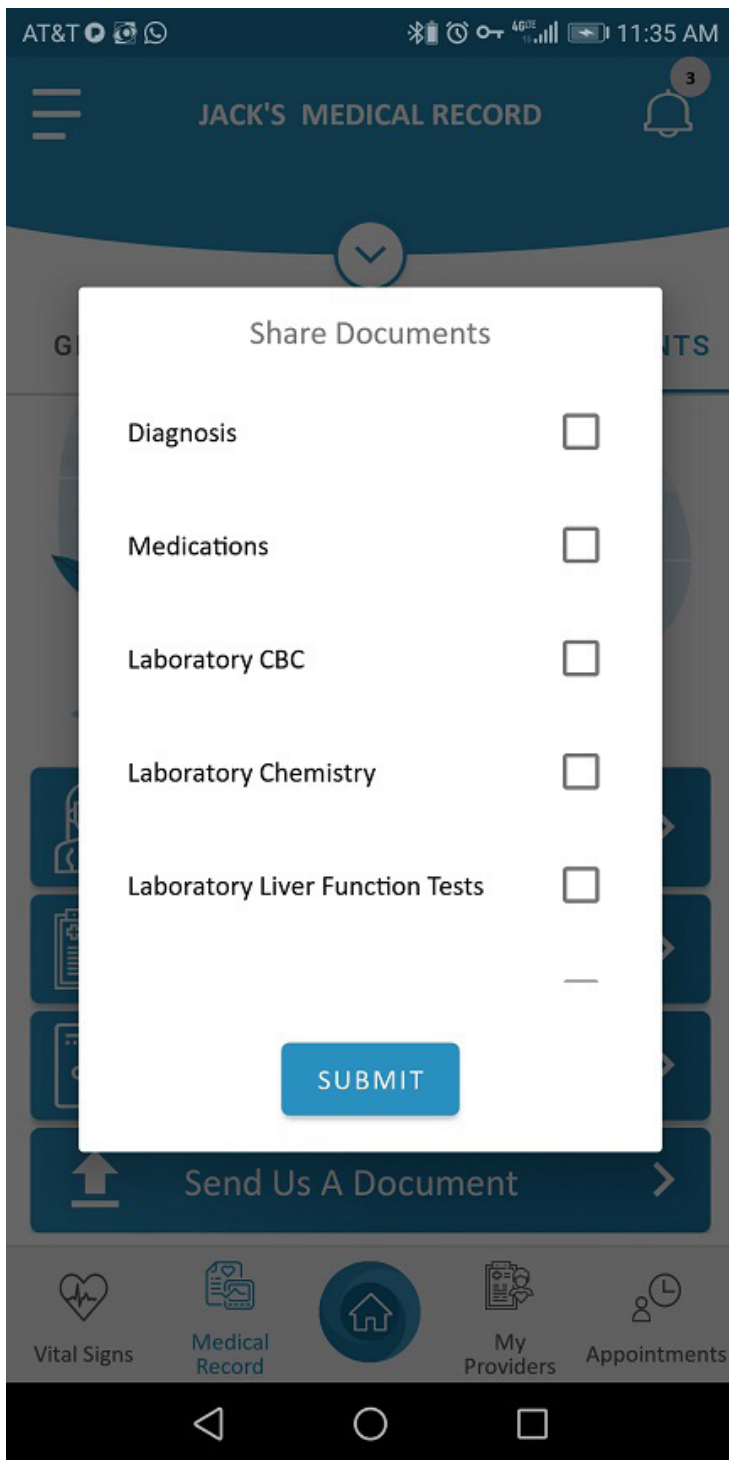


“In the app, parents will find a simple explanation of their infant’s ongoing medical diagnoses with the plan of care, current medications, laboratory and imaging results, vaccinations, as well as the ability to plot their growth parameters using Fenton and WHO curves.”



built with an integrated, simple EMR prepopulated with the infant's NICU medical course prior to discharge. In the app, parents will find a simple explanation of their infant's ongoing medical diagnoses with the plan of care, current medications, laboratory and imaging results, vaccinations, as well as the ability to plot their growth parameters using Fenton and WHO curves. The app also includes the contact information of their follow up providers as well as dates and times of appointments with built-in SMS reminders. Parents are encouraged to share with us documents from appointments with all of their ongoing care providers by taking a photo of the document with their phone's camera. Our team then transcribes the summary and attaches a copy of the original document. In this way, parents are able to find a summary of all ongoing interactions with our providers as well as other specialists all in one location. If necessary, parents are





able to export all or parts of the infant's records as a PDF to share with other providers.

All data in the infant's EMR is updated by our team. The parents' only responsibilities include sharing with us medical visit summaries and updating the app with the names of new providers and appointment

times. In order to promote coordinated care, we grant access for other providers to the infant's EMR where they are also able to view the latest vital sign data as well as medical information. We believe that in order to prevent ER visits and readmissions, it is important to empower the parents and the infant's providers with both their infant's vital sign data and with a concise, up-to-date medical summary. Work on hospital EMR integration using [FHIR API codes](#) is in progress.

Our findings

We have been offering our solution pro bono to families of high-risk infants who would not have been on monitoring without our service. Parents had received routine NICU discharge teaching including education on safe sleep practices. Moreover, parents were told that the Firstday home monitoring service is not intended to prevent death from SIDS but rather, to serve as an early warning of clinical deterioration. The feedback from the early user experience in this feasibility and acceptability pilot has been used to refine our platform further. Despite the relatively small numbers of infants managed to date, several important clinical findings have already been identified. In one case, a low respiratory rate of 5 and heart rate of 61 triggered an alert. The baby was sleeping alone in his stroller bassinet with his face pressed against the side. The mother responded to the alert by removing the baby from the stroller. Thankfully, the baby appeared stable and well. This event represented a detection of a potential life-threatening event related to an unsafe sleep practice.

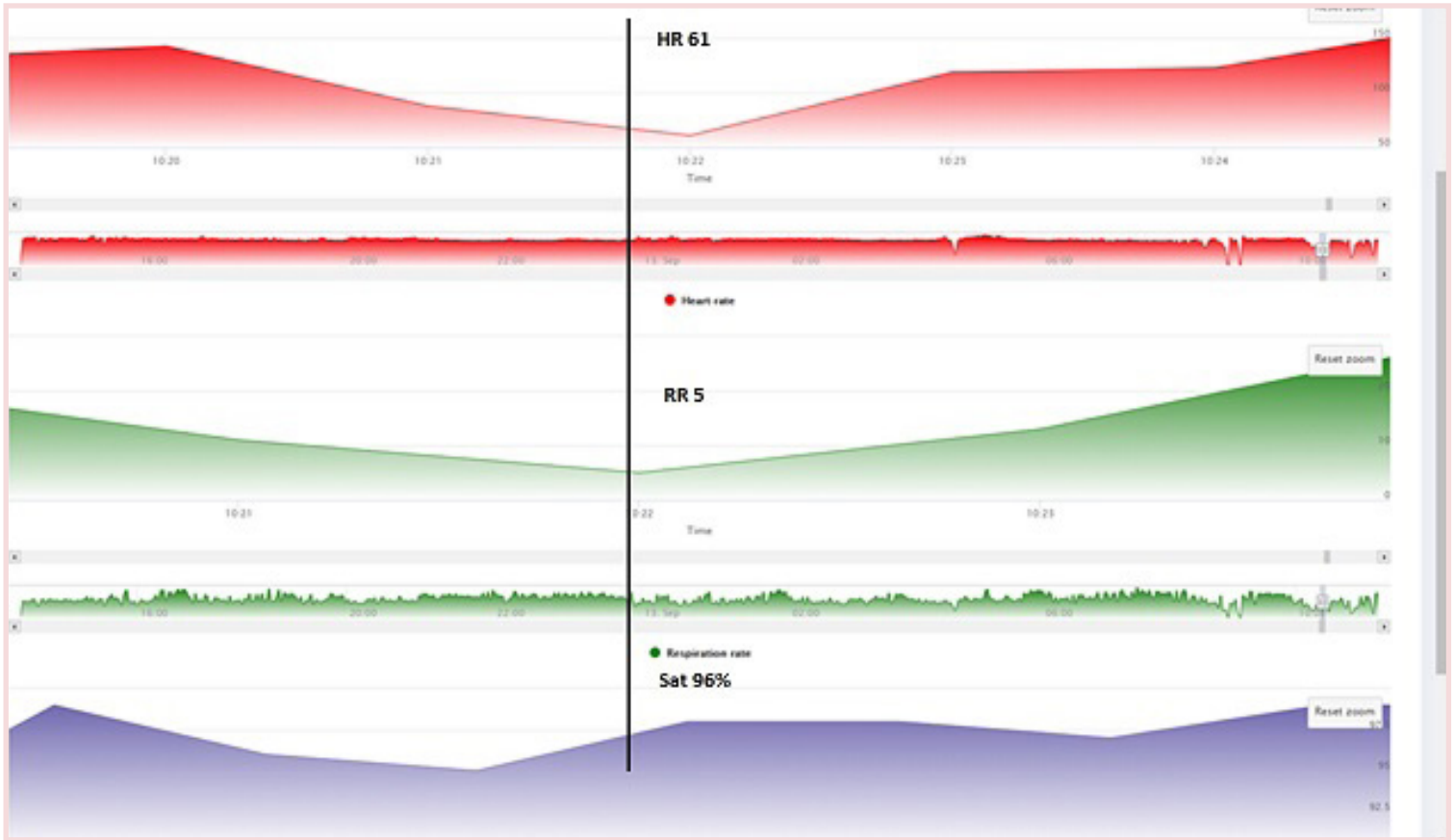
As much as we would like to believe that the NICU infants that we discharge home have resolved all of their medical complications of prematurity, based on post-NICU mortality rates, clearly this is not the case. In a retrospective NICHD study of 4807 infants with an average gestational age of 25 weeks followed to 22 months corrected age, investigators identified a post-NICU mortality rate of 22.3 per 1000 ELBW infants. (10) This rate is approximately 4-fold higher than the national average of 5.9 per 1000 births. (11) It is worth noting that independent risk factors for post-NICU mortality included a length of hospitalization greater than 120 days but did not include being discharged home on oxygen treatment.

“As we expand our cohort of infants monitored at home, we hope to provide further valuable insights into the frequency and time to resolution of changes in our former preterm infants’ vital signs.”

Although parents often tell us that they are willing to wait as long as it takes to take their infant home as long as they are completely well, the point when that milestone is reached is poorly defined. The AAP has issued guidelines for safe discharge from the NICU (12) that are necessarily vague as every hospital establishes its own local protocol for the duration of observation, the “spell watch,” after a change in vital signs is detected. In the absence of remote home monitoring, it

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is impossible to know how many infants continue to have vital sign changes after discharge. As we expand our cohort of infants monitored at home, we hope to provide further valuable insights into the frequency and time to resolution of changes in our former preterm infants' vital signs.

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Disclosure: Dr. Sommers is a practicing Neonatologist and founder of Firstday Healthcare a digital health solution for high risk NICU graduates.

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Fellow Column: New Educational Course for Neonatal Fellows Meets All Requirements of American Board of Pediatrics (ABP) and Accreditation Council in Graduate Medical Education (ACGME) Regarding Psychosocial Support

Sue Hall, MD and Melissa Scala, MD

Recruitment is now actively taking place for a study of an on-line educational program for Neonatal Fellows being conducted through an interprofessional collaboration between teams from the National Perinatal Association, Stanford University Medical School Division of Neonatology and Department of Child Psychiatry, and the NICU Parent Network. The goal of the 2-hour program is to meet the recommendations issued by both the American Board of Pediatrics (ABP) and the Accreditation Council in Graduate Medical Education (ACGME) with respect to trainee education in behavioral and mental health. The development team from Stanford includes Dr. Melissa Scala, neonatologist; Dr. Soudabeh Givrad, mother-infant dyadic psychiatrist; and Dr. LaTrice Dowtin, NICU psychologist. Together with Dr. Sue Hall of NPA and Keira Sorrells of the NICU Parent Network, they revised NPA's original Caring for Babies and Their Families course, which was recently shown to be effective at improving nurses' knowledge and confidence in providing psychosocial support to NICU families. (1) The redesigned course for Neonatal Fellows, NICU attending physicians, and Neonatal Nurse Practitioners is both shorter than the original course, and more dense, with virtually each learning point footnoted with a reference from current literature. Comprehensive bibliographies accompany each course. There are also interactive cases which encourage learners to put their skills into practice in common bedside communication scenarios with distressed parents.

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

It is critical that neonatologists, and those in training to become neonatologists, realize the impact that a NICU experience can have on a family—both the infant, the infant’s parents individually and as a couple, and the entire family—and that the potential adverse developmental outcomes for the infant and adverse mental health outcomes for parents are well-described and documented. It is even more important that those caring for babies and their families learn ways to recognize, acknowledge, and mitigate the distress families frequently experience during a NICU stay, and to promote the resilience and optimal functioning of these families.

The four courses included in the learning program include:

- 1 Using trauma-informed care as a basis for communication with NICU families
- 2 Recognizing and mitigating parental distress; promoting parental resilience
- 3 Recognizing and mitigating infant distress
- 4 Comprehensive support of NICU families (includes peer support, discharge planning, palliative care, and staff support).

The study of this program, which has been funded by the Association of Pediatric Program Directors, will survey Fellows' self-efficacy regarding interactions with NICU parents, as well as their knowledge of the topics covered in the courses at time points before, immediately after, and three months after taking the courses. Participating fellowship programs can also opt to “add-on” experiences to augment learning, such as simulation sessions where the focus will be on managing “every day” situations with NICU parents (as opposed to managing conversations around critical care issues); guided conversations with graduate NICU parents where Fellows can hear their first hand experiences and concerns; and/or evaluation of Fellows' bedside performance by current NICU parents. Stanford's IRB has already approved the study protocol, and centers signing on to participate will have to take this approval letter to their own IRBs to be included.

While Neonatal Fellowship Program Directors won't be participants in the study, they will have the opportunity to go through the learning program themselves outside of study parameters, so that they can familiarize themselves with the content being presented. Other neonatologists and nurse practitioners will be able



to access the courses directly, beginning January 1st, at www.myperinatalnetwork.com.

For more information about how your Neonatal Fellows can participate in this program, please contact the Principle Investigator, Dr. Melissa Scala, at mscala@stanford.edu, or Dr. Sue Hall at suehallmd@gmail.com.

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Fellow's Column is published monthly.

- Submission guidelines for "Fellow's Column":
- 2000 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 20 references.
- Please send your submissions to:

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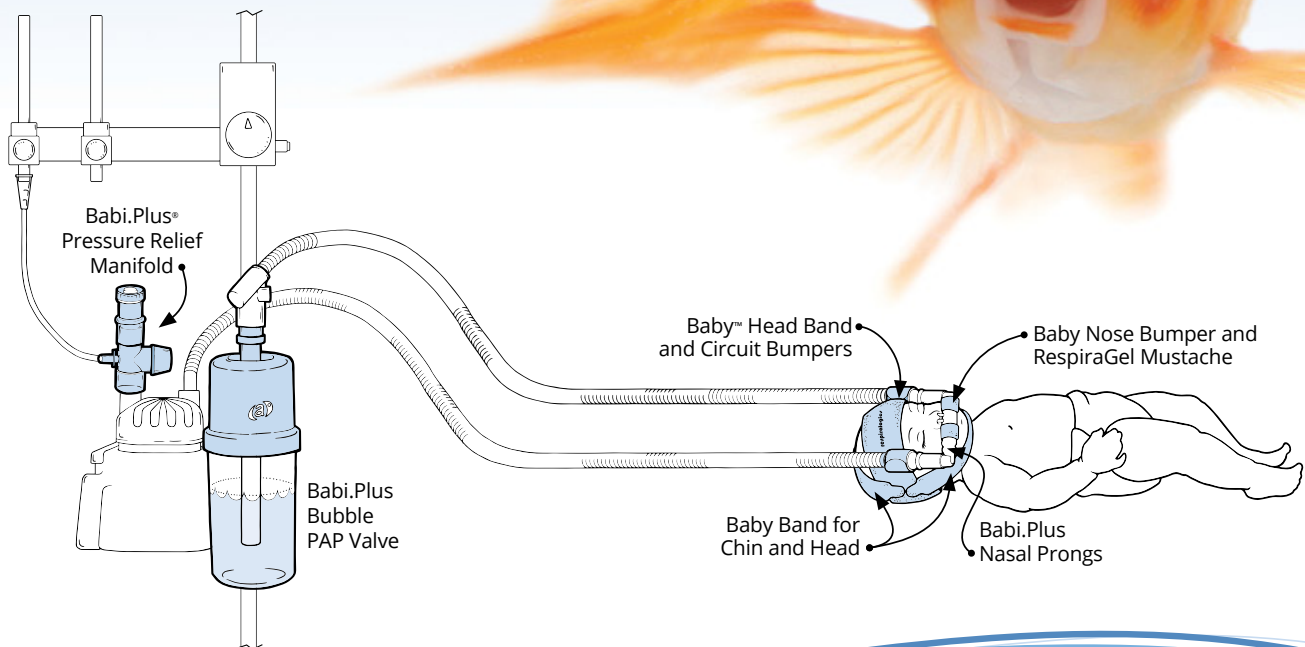
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Prematurity Awareness

EACH NOVEMBER WE CELEBRATE Prematurity Awareness

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 - and a baby is born early.

Every year in the U.S. more than 380,000 babies are born preterm, meaning that they were born before 37 weeks gestation - more than a month early. While babies who are born extremely preterm - sometimes as early as 22 weeks - are surviving, all preemies are vulnerable to medical and developmental complications.

While we are grateful for advances in neonatal care that allow more premature infants to survive and thrive, we know that we have more to learn. We need a better understanding of the factors that lead to preterm labor and delivery - and result in unacceptable disparities.



Did You Know? Preemies Aren't Just Tiny Newborns

Every baby is born vulnerable and immature. They rely on their caregivers to nurture and protect them as they adjust to life outside of the womb. But for babies who are born preterm, these effects are magnified. When a baby is born early they have to continue to grow and mature in an environment that is more challenging than in utero.

- Babies begin to learn to breathe in the womb. So preemies' lungs haven't had time to practice and mature so that they use oxygen effectively. Immature lungs can be easily damaged.
- Babies' brains reorganize and restructure dramatically in the final weeks of pregnancy. Preemies can struggle to control their temperature, breathing, and heart rate. Brain bleeds are common.
- To eat well, preemies must master the rhythm of breathing and swallowing. Their immature stomachs and intestines take time to absorb nutrients and learn to fight infections.

Common Complications of Prematurity:

- chronic lung conditions
- feeding difficulties
- developmental delays

With support and early intervention the negative effects can be minimized

Prematurity is the leading cause of infant mortality and morbidity in the U.S.

Our preterm birth rate continues to climb. In 2017 it grew to 9.9%.

Celebrate World Prematurity Day
November 17th

Knowledge Itself Is Not Enough: Recognizing and Overcoming Social Barriers To Infant Safe Sleep Practices

Barb Himes, IBCLC



Saving babies. Supporting families.

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

At First Candle, we have been raising awareness about SIDS and other sleep-related infant deaths for years, and while we have seen progress, we have also come to realize that public education is very much a long-term proposition. We have also come to realize how much we ourselves learn in the process of working with others, and how our own awareness has been raised about what can be done better to help families engage in infant safe sleep practices.

“At the core of our guidance is the American Academy of Pediatrics set of recommendations for infant safe sleep, which were updated in 2016 . This version is currently in use, and the latest in a series that dates to the original Back to Sleep campaign, which was developed by a coalition including NICHD, the AAP Task Force, NHLBI, HRSA and the SIDS Alliance (now First Candle) in 1994.”

At the core of our guidance is the American Academy of Pediatrics set of recommendations for infant safe sleep, which were updated in 2016. (1) This version is currently in use, and the latest in a series that dates to the original Back to Sleep campaign, which was developed by a coalition including NICHD, the AAP Task Force,

NHLBI, HRSA and the SIDS Alliance (now First Candle) in 1994.

Over the years, the recommendations have increased focus on requiring a supine sleep position on a firm surface, alone, with no extraneous bedding and no bed-sharing – what we call Room Share, Not Bed Share and Keep It Bare.

Between 1994, when Back to Sleep (now Safe to Sleep®) began, and 1999, the overall SIDS rate in the U.S. dropped by more than 50%. (2) However, since that time, the national SIDS rate has changed little. One explanation is that classification has broadened into sudden unexpected infant death (SUID), which includes SIDS and accidental suffocation and strangulation in bed (ASSB), and deaths that may previously have been considered SIDS are being otherwise identified.

“One explanation is that classification has broadened into sudden unexpected infant death (SUID), which includes SIDS and accidental suffocation and strangulation in bed (ASSB), and deaths that may previously have been considered SIDS are being otherwise identified.”

And, whereas the causes of SIDS are still unknown and SIDS is not preventable, the causes of ASSB are. So what particularly concerns us is that, according to the CDC, SUID remains the leading cause of death for babies one month to one year of age, re-

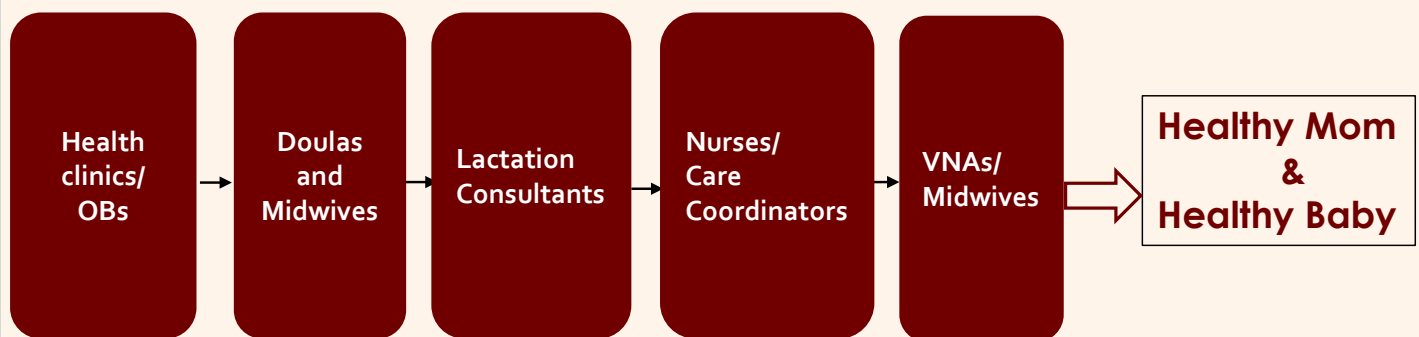


Message must come from everyone

Health care and education needs to start the day a woman realizes she's pregnant.

At each point, care providers have the opportunity to discuss maternal health, breastfeeding and safe sleep practices.

Changing from "It's not my job." to "It's my opportunity!"



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Saving babies. Supporting families

sulting in 3,600 infant deaths nationwide per year. What also concerns us is that even though ASSB can be prevented by following AAP Safe Sleep guidelines, there are barriers to compliance.

Through our work in the field, we have come to learn that this, in part, stems from implicit bias within the guidelines, which mandate a "one size fits all" approach regardless of cultural norms. This is critical, because the rate of SUID among black infants is three times higher than for whites, and for Hispanic babies, it is twice as high.

The AAP guidelines also recommend regular prenatal care for pregnant women, but there is increasing awareness that with regard to maternal health in communities of color, health inequities

result from structural racism in health care, lack of access to quality prenatal and postpartum care, and racial stress. These can contribute to low birth weight, pre-term birth, and birth complications, which are also infant death risk factors.

We saw that preaching the guidelines was not enough, so in 2017 we launched our Straight Talk for Infant Safe Sleep program, a train-the-professional education workshop targeted to a local community's health care providers, social service agencies, doulas, faith-based workers, childcare providers and nurses, which follows a collaborative and culturally sensitive approach.

The program, under which nurses can earn five CEU contact hours, recognizes that many factors influence a parent's safe



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

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

sleep decisions, including family and cultural norms, socio-economic factors, past experience, and the desire to bond or breast-feed (which is we recommend).

In our work across the country, we continue to learn from participants not only about the realities of bias they see but that providers themselves often do not have correct or complete Safe Sleep information. Straight Talk participants are surveyed at the start of the program, and we have found providers often discuss only back-sleeping and nothing else; less than half will have read the APP guidelines and not be able to name more than two, and many are unaware breastfeeding can provide a protective mechanism against SIDS.

The Straight Talk course is therefore designed to provide:

- Clarity on SIDS and other sleep-related infant deaths;
- A thorough understanding of Safe Sleep recommendations and the reasons behind them;
- Recognition of implicit biases that diminish the value of Safe Sleep messages to families and strategies to overcome them.

We also look for and coach to develop a demonstrated ability to listen, learn, and engage in respectful dialogue with families regarding their beliefs and customs around safe sleep and breastfeeding.

In an environment that can be unfamiliar for newly expecting parents and full of new information about pre- and post-natal care, some of it potentially confusing – for example, nurses' infant sleep practices in hospital settings may differ from AAP guidelines – we must help providers not only clearly understand how to reduce preventable infant sleep-related deaths, but be able to convey this to parents and families in a desirable and achievable way.

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

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New Moms Need Access to Screening & Treatment for
POSTPARTUM DEPRESSION

1 IN 7 MOMS FACE POSTPARTUM DEPRESSION, experiencing

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

15% Yet only 15% receive treatment¹

UNTREATED POSTPARTUM DEPRESSION CAN IMPACT:

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

TO HELP MOTHERS FACING POSTPARTUM DEPRESSION

POLICYMAKERS CAN:

- Fund Screening Efforts
- Protect Access to Treatment

HOSPITALS CAN:

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

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

¹ American Psychological Association. Available at: <http://www.apa.org/press/releases/newsreports/postpartum-depression.aspx>
² National Institute of Mental Health. Available at: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology (2015) 35, 629–636, doi:10.1097/01.jp.0000000000.00000.00
⁴ Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Olesen CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

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

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support to the over
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will experience the loss
of a baby every year.**

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Saving babies. Supporting families.

Prematurity Awareness

EACH NOVEMBER WE HONOR

NICU Professionals

Who Care for Preterm Infants and their Families

Caring for premature infants isn't like caring for other babies; premature infants aren't tiny newborns.

Neonatology is a highly specialized field. Providing specialized care for preemies requires extraordinary expertise and teamwork.

NICU professionals exemplify the best in interdisciplinary care and collaboration.



Did You Know?

Providers Need Support Too

Caring for fragile babies doesn't just require specialized clinical skills, it demands extraordinary kindness, compassion, and caring. This means that NICU staff are vulnerable to burnout, compassion fatigue, and secondary traumatic stress syndrome.

Staff need to know that resources are available that can improve communication, promote mental health, and support professional development. When we invest in the health and wellness of NICU professionals we demonstrate our appreciation for the work they do.

Who Cares for Families in the NICU:

- neonatologists
- nurse practitioners
- nutritionists
- neonatal therapists
- respiratory therapists
- nurses
- perinatologists
- parent advocates
- psychologists
- social workers
- pharmacists
- IBCLCs - breast feeding consultants

NICU Staff Education

Learn more about our innovative online course, *Caring for Babies and Families: Providing Psychosocial Support in the NICU* by visiting support4nicuparents.org

Celebrate World Prematurity Day
November 17th

Bringing Technology to Enteral Feeds: Less Art, More Science

Tammi Jantzen

As survival rates for extremely preterm infants improve, attention is now being focused on improving the quality of survival through optimal nutritional management. Optimal nutrition during this critical period in early life can positively impact preterm infants' physical growth, as well as neurological development. Conversely, suboptimal nutrition early in the neonatal period contributes to the accumulation of growth deficits. For example, infants provided only glucose solutions as nutrition in the first few days of life rapidly develop large protein and essential fatty acid deficits, with the smallest, most immature infants suffering the worst postnatal malnutrition. (1)

Yet, optimizing nutrition management in the NICU, particularly through a successful progression of enteral and oral feeding of preterm infants, remains a major challenge for clinicians. Some feeding difficulties are related to immature gastrointestinal systems, but failure to start and advance enteral feedings more commonly are due to suspicion and fear of necrotizing enterocolitis (NEC), aspiration syndromes, and other life-threatening events. (2,3) Many less critical and unsubstantiated concerns about presumed causal associations between enteral feeding and adverse clinical conditions further limit successful feeding advancement. (4) As a result, preterm infants commonly are subjected to delayed onset of enteral feeds, longer duration of trophic feeds that provide inadequate nutrition, lack of progressive tolerance to increased feeding volumes, longer time to full enteral feeds, and longer transition times to oral feeding.

Feeding difficulties are the primary contributor to increased NICU resource utilization and length of stay (LOS) and result in the prolonged duration of central line days, parenteral nutrition (PN), and intra-gastric feeding (5), all leading to an increased risk of hospital-acquired infections. (6,7) In addition, clinician variability in individual practice attitudes, experience, and knowledge can influence the implementation of a feeding strategy. (5)

All of these factors contribute to significant variation in the practice of feeding in the NICU – the feeding schedule, feeding quantity, feeding advancement, feeding contents, and the

decision-making process for feeding/not feeding. While a certain amount of variation is to be expected, existing variations are significant enough to affect health outcomes for preterm infants. Standardizing the process for preterm infant feeding is one way to ensure the successful progression of enteral and oral feeding, and thus optimal nutrition management.

Evidence in Favor of Standardized Feeding Guidelines in the NICU

In a Nationwide Children's Hospital study aimed at process optimization, the implementation of a standardized feeding strategy in the NICU was shown to effectively minimize practice variability, accelerate the attainment of enteral and oral feeding milestones, and decrease LOS without increasing adverse morbidities. (5) To monitor compliance with this quality improvement initiative, multi-disciplinary feeding rounds were held each week on each infant to provide education regarding the factors that were helping or impeding feeding progress.

Compared to preterm infants whose feeding strategy was prescribed by the individual attending physician and implemented by the clinical care providers, preterm infants who were placed on a standardized feeding program demonstrated a reduction in:

- Duration of trophic feeding by 7.2 days
- Time to full enteral feeds by 4.9 days
- Time from oral feeding onset to oral feeds by 16.3 days
- Duration of ventilation by 35%
- Duration of CPAP by 23%
- Duration of PN by 3.5 days
- Duration of central lines by 4.4 days
- Length of stay by 14.9 days

Mortality, NEC rates, readmissions within 30 days, and comorbidities were similar in both cohorts.

“In a similar study conducted at the Monroe Carell Jr. Children's Hospital NICU at Vanderbilt University (5), researchers showed that adherence to a new nutrition protocol improved linear and head circumference growth, reduced postnatal growth restriction, and decreased comorbidities in very low birth weight infants.”

In a similar study conducted at the Monroe Carell Jr. Children's Hospital NICU at Vanderbilt University (5), researchers showed that adherence to a new nutrition protocol improved linear and head circumference growth, reduced postnatal growth restriction, and decreased comorbidities in very low birth weight infants. The incidence of sepsis and sepsis-like episodes was reduced, possibly attributed to earlier discontinuation of central lines and improved

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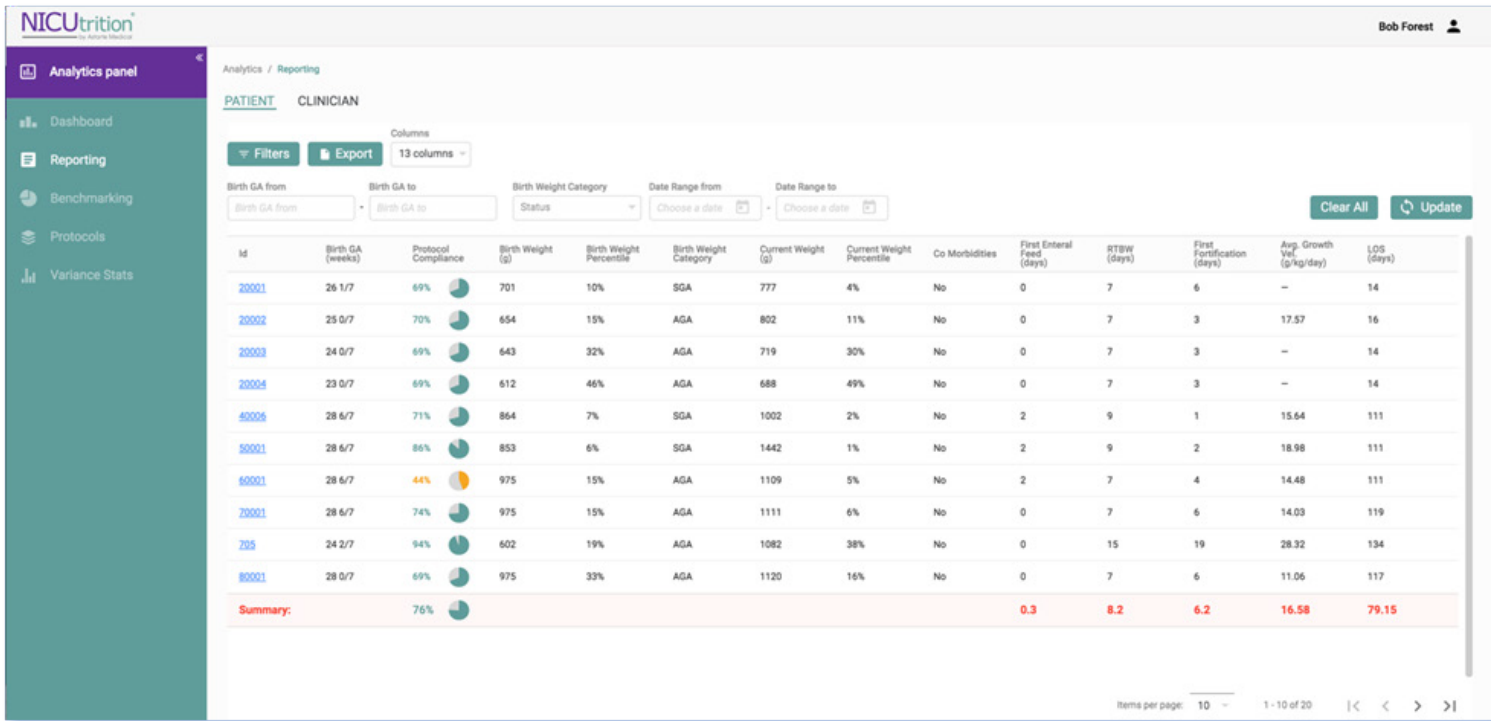


Figure 1. NICUtrition® Analytics Reporting Screenshot: A NICU departmental snapshot of protocol compliance, feeding metrics, and growth milestones.

nutritional status resulting in improved host defenses. (8) Other recent studies have demonstrated that implementing standardized feeding protocols can also improve growth outcomes in addition to reducing adverse events. (9-12)

Strides Toward Standardization

As the benefits of standardization become clearer to hospitals, many clinical practice groups have developed consensus-based enteral feeding protocols for nutrition management to provide evi-

dence-based care with less variability. However, to be truly effective, compliance monitoring at feeding rounds is necessary to overcome the challenges of attaining feeding milestones. Educating clinicians about feeding methods will also help ensure the achievement of feeding-related goals. It is essential to help clinicians understand when, how, and why to advance feeds to attain targeted milestones.

Currently, though, there is no practical way to evaluate the adherence to nutrition guidelines or assess desired feeding and nutrition-related outcomes to improve the practice of care. Protocol implementation and management is still a manual, self-reported process. There was an early promise of using the electronic medical record (EMR) to support research and provide clinical decision support, but the reality is that EMRs have created workflow disruption and do not provide insights related to feeding and nutritional goals in real-time. Furthermore, many clinical practice groups end up with a wealth of collected data and no tool or process to mine the data for useful insights to benefit their patients.

NICUtrition®: Digital Tools to Standardize Feeding and Optimize Nutrition for Preterm Infants

To overcome the challenges of manual standardization, understand protocol adherence or lack thereof, and to gather useful insights from feeding data, clinical practice groups could benefit from an operational tool to more effectively implement a hospital's feeding



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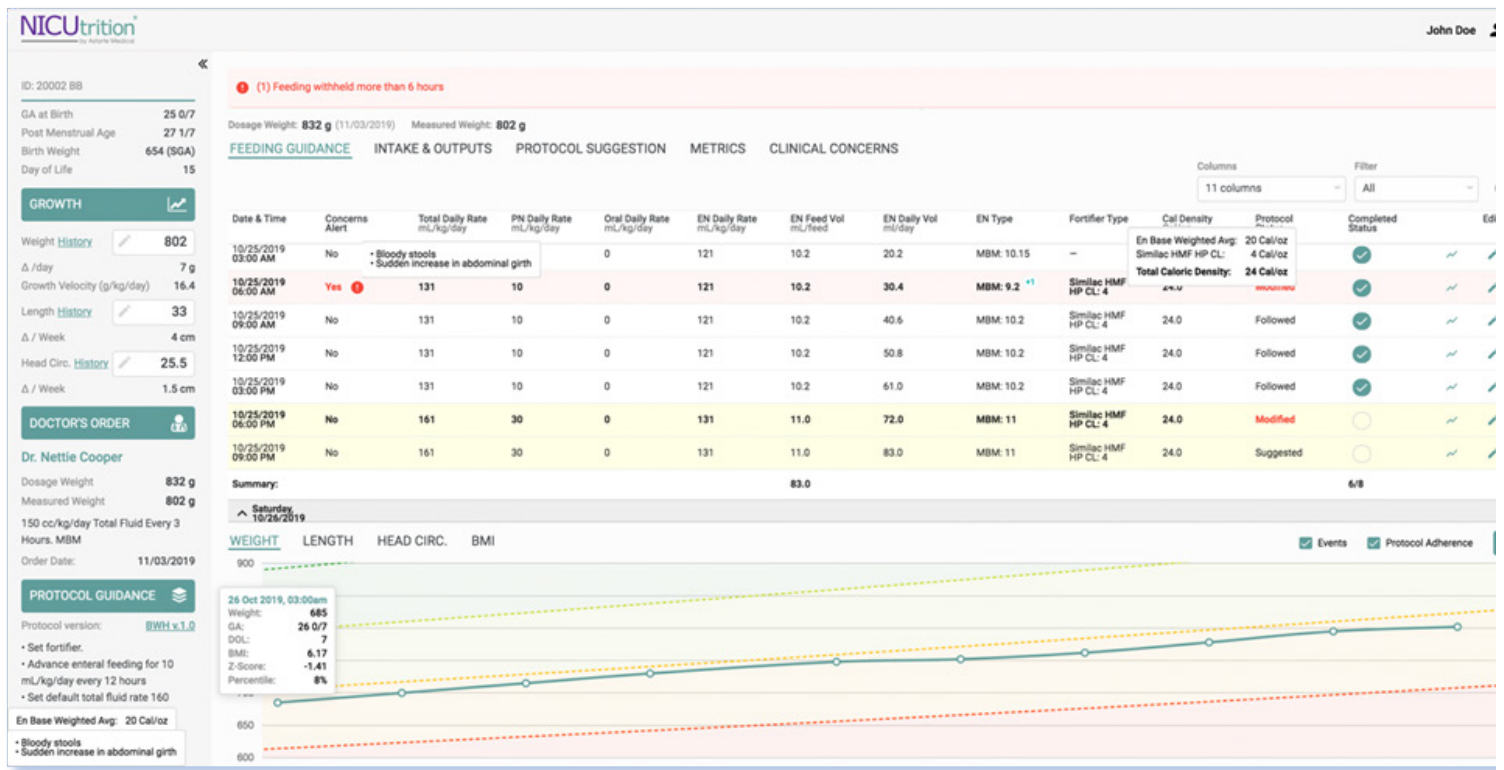


Figure 2 NICUtrition® Guidance Screenshot: prospective feeding plan based on the hospital's own enteral feeding protocol shown in an interactive dashboard to chart feedings and view historical data.

protocol and promote compliance.

“ In addition, by streamlining and standardizing data extraction, the Analytics tool provides an efficient and cost-effective way for hospitals to meet quality collaborative reporting requirements (like Vermont Oxford Network). It also allows hospitals to compare their outcomes and quality metrics to other appropriate peer NICUs at a more granular level than what is currently compiled by most quality collaboratives, helping to raise the standard of care among hospital neonatal intensive care units.”

NICUtrition® by Astarte Medical supports feeding protocols, feeding practice, and decision-making in the NICU with a suite of digital tools designed to standardize feeding and optimize nutrition for preterm infants. NICUtrition® uses a hospital's feeding protocol and creates a rules engine based on those guidelines. It provides for structured documentation of the reason(s) why protocols are not being followed, which today is either not captured or is buried in

flowsheet notes. NICUtrition® has bi-directional integration with a hospital's EMR so that duplicate documentation is not required. With the ability to integrate through FHIR standards or Epic's App Orchard, implementation of this digital tool is much simpler than custom integration projects or EMR reports with manual review.

The NICUtrition® suite currently consists of NICUtrition® Analytics – an audit and monitoring tool for protocol compliance – and NICUtrition® Guidance – a real-time feeding decision support tool to standardize the practice of feeding and reduce documentation time.

By extracting a hospital's historical feeding data, NICUtrition® Analytics (Figure 1) measures adherence and correlates it to outcomes. As a one-time audit, Analytics can identify a hospital's historical levels of adherence to protocols and provide a baseline to measure compliance and outcomes, bringing to light areas for improvement.

NICUtrition® Analytics also can provide continuous insights into reasons why feeding protocols are not adhered to or why minimal outcomes are achieved despite adherence through real-time, ongoing monitoring of protocol adherence correlated with patient outcomes. This information enables clinical teams to continuously educate and train their staff on established protocols and make the appropriate adjustments as needed to meet expected outcomes more effectively.

In addition, by streamlining and standardizing data extraction, the Analytics tool provides an efficient and cost-effective way for hospitals to meet quality collaborative reporting requirements (like Vermont Oxford Network). It also allows hospitals to compare their outcomes and quality metrics to other appropriate peer NICUs at a more granular level than what is currently compiled by most quality collaboratives, helping to raise the standard of care among hospital neonatal intensive care units.

Can Standardized Care Also Be Personalized Care?

Standardized protocols alone are insufficient if they do not also allow for some degree of personalization to the specific preterm infant. Standardization and personalization do not have to be mutually exclusive and can complement each other. Standardization can enhance personalization by supplementing physician experience and reducing guesswork for clinicians. In fact, standardizing care and measuring outcomes enables providers to create personalized treatment plans for patients by taking a variety of factors into account, such as outcomes for similar patients.

NICUtrition® Guidance (Figure 2) is a real-time feeding decision support tool to standardize practice and reduce documentation time of feedings, while also allowing for patient personalization. It is an interactive, bedside dashboard that, for each feed, pre-populates how the infant should be fed based on that institution's clinical practice guidelines. It provides one-click approval if the protocol is being followed, but also allows for alterations and notations by the NICU team, in a structured format, based on observations or other indicators. The Guidance tool ensures consistent delivery of care by presenting protocols in an intuitive format, reducing the possibility of individual interpretation of the protocols – providing the when, how, and why to the clinical team in a structured format that can be analyzed without the need for a costly data study.

The NICUtrition® suite of digital products provides a more effective way to implement an institution's established feeding guidelines and serves as a useful tool in providing insights into individual infant feeding metrics and nutrition-related goals, as well as NICU-wide results.

Standardized and Personalized Feeding: Helping Preterm Infants Survive and Thrive

By optimizing nutrition through both standardized and personalized feeding strategies, a real impact can be made in the most critical time of growth for preterm infants. Moving away from manual processes to digital tools can move the neonatal nutrition field forward and provide a measurable benefit to all stakeholders - administrators, physicians, nurses, and, most importantly, our tiniest, most vulnerable patients.

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BABIES**
are
ADMITTED
to the
**NEONATAL
INTENSIVE
CARE UNIT.**



Educate. Advocate. Integrate.

About the Founders

After working together for 15 years in venture capital, Tracy Warren and Tammi Jantzen set out to blaze a path investing in companies they were most passionate about – those with technologies focused on women's and children's health and wellbeing. As a largely underserved area of innovation and investment, they wanted to make an impact. To gain insights into clinical needs and pain points, they visited women's and



children's hospitals across the country, talking to innovation groups and researchers. It was during a visit to Brigham and Women's Hospital in Boston that they met Katherine Gregory, RN, Ph.D. Kate has a unique background having hands-on clinical experience alongside academic and research credentials. She started her career as a NICU nurse and has a Ph.D. in mucosal immunology. She had been doing research on preterm infant microbiome and gut health for several years. In that initial meeting, Kate opened their eyes to the challenges of feeding preterm infants and early life nutrition, and they were immediately hooked. Founded in 2016, Astarte Medical is a precision medicine company using software and predictive analytics designed to standardize feeding, optimize nutrition and quantify gut health to improve health outcomes for preterm infants.

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



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Still a Premie?

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

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation?

STILL A PREMIE

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

- Jaundice
- Feeding issues
- Respiratory problems

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

Born preterm at a "normal" weight?

STILL A PREMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREMIE

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

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

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



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Sponsored by the Section on Neonatal - Perinatal Medicine

March 27-29, 2020

**Paradise Valley DoubleTree Hotel
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Case Report: Conservative Approach in the Management of Congenital Skull Depression

Dr. Muzammil Hafeez, Dr. Mahmoud Galal, Dr. Anwar Khan, Dr. Mostafa Bolkini, and Dr. Abdulla Qasim

Case Presentation

A male baby was born to a gravida 3 para 2 mother at 35 weeks of gestation by normal vaginal delivery. Antenatally there was suspicion of intrauterine growth restriction at 31 weeks, and on follow up at 35 weeks, there was IUGR corresponding to 27 weeks of gestation. The baby was born with good APGAR scores of 9 and 10 at 1 minute and 5 minutes, respectively. The liquor and Doppler study were normal. His weight at birth was 1.56 kg, (below the 3rd centile). Head circumference was 30 cm (below 10th centile), length 43.5 cm below 10th centile.

On examination, the baby's vitals were stable. He maintained his oxygen saturations well in room air. He had a depression of the skull on the right parietal area 5 cm x 3 cm (Figure 1). The rest of the systemic examination was normal. CT scan was done, which revealed a depression of the right parietal bone. The neurosurgeon reviewed the baby. Skull fracture and intracranial pathology were ruled out, and this was diagnosed as a skull depression most probably due to intrauterine position. On the advice of the neurosurgeon, the baby was managed conservatively.

“Skull fracture and intracranial pathology were ruled out, and this was diagnosed as a skull depression most probably due to intrauterine position. On the advice of the neurosurgeon, the baby was managed conservatively.”

The baby was discharged and followed in the neonatal clinic. The baby was seen in the clinic at the age of 2 months. The skull depression had completely resolved (Figure 2 and 3). He is active, recognizing mother, fixing and following objects well, has partial head control, and no neurological deficits.



Figure 1: At Birth

His other investigations, including, Full blood count was normal. TORCH profile and Urine CMV were negative.

Discussion

Physical examination of the newborn baby revealed a depression in the right parietal region 5 cm x 3 cm. The baby was active. CT scan (figure 4) revealed a depression of the right parietal bone with no evidence of fracture. After evaluation by



Figure 2 and 3: at 2 months of age



Figure 4: CT demonstrating skull depression

the neurosurgeon, the baby was managed conservatively and discharged.

“Depression of the skull in newborn babies is rare, occurring with an incidence of 1 in 10,000 live births. (1) The cause of the depression is usually unknown, but may be due to the pressure of the baby’s limbs or the pressure from the maternal pelvic bones at the time of the delivery.(2)”

Depression of the skull in newborn babies is rare, occurring with an incidence of 1 in 10,000 live births. 1 The cause of the depression is usually unknown, but may be due to the pressure of the baby’s limbs or the pressure from the maternal pelvic bones at the time of the delivery. (2) Neonatal skull depressions can occur with or without fractures. (3) CT scan of the head helps reveal fractures, underlying haematomas, and cortical

compression. (3) Skull fractures are usually linear, affecting the parietal bones, or depressed, forming the so-called ping-pong ball-type fracture. Linear fractures usually do not require any intervention. (4) Nonsurgical techniques, such as digital pressure, a breast pump, and an obstetric vacuum extractor have been utilized if there are no neurological deficits. Neurosurgical intervention may be required if there are fragments of bone in the cerebrum, or there are any neuro deficits. 4 Most of the uncomplicated skull bone depressions in newborn babies resolve spontaneously, with conservative management, over a period of 6 months. (3)

“On follow up of our patient in the clinic at two months of age, examination showed complete resolution of the depressed part of the bone, and the baby is thriving well with normal developmental milestones.”

On follow up of our patient in the clinic at two months of age, examination showed complete resolution of the depressed part of the bone, and the baby is thriving well with normal developmental milestones.

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Consent from parents: Taken for publishing case material and photographs.

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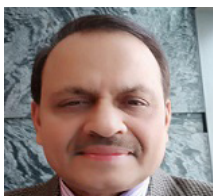
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Raising Global Awareness of RSV

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

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

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



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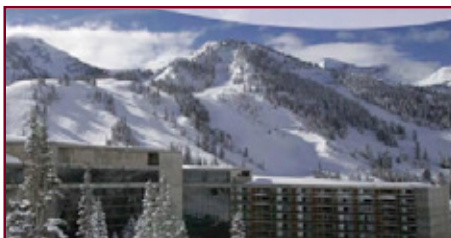
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Respiratory Report: the Outborn Micro-prem: A Horse of a Different Colour

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.

TA common lament amongst NICU respiratory therapists and nurses is "Oh great! Another outborn." Premature infants born in a tertiary setting do not fare as well as those born in a facility offering level three care.

During the thirty years in which I have been managing the ventilation of premature infants, I have seen many changes, advancements, and a volley of smaller and smaller patients. While one might assume improvements in all aspects of neonatal care would make clinicians' work easier, the continued pushing of the envelope has resulted in a net-zero effect on workload. Frequently it has resulted in increasing that workload. As population increases as infants of increasingly lower birth weights and gestation age are offered resuscitation, the number of NICU admissions and the acuity of patients grows.

There are many living their lives thanks to the advancements in neonatology, and we can be justly proud of that fact. Chronic lung disease (CLD) rates have continued to improve. However, there is a sub-set of our patients who are less likely to benefit from technical and clinical advances: those born in a tertiary setting. (1,2)

Some of the reasons behind the poorer outcomes of these babies are lack of available technology, outdated clinical practice, demographics, socioeconomic, and the transport process. Each plays a part.

Technology

Typically in Canada, hospitals that do not have specialised paediatric services or care for premature infants in house often do not have dedicated neonatal equipment such as ventilators or access to special modes, such as oscillation (HFO) or high-frequency jet ventilation (HFJV). Although there are adult ventilators with a neonatal mode (some even offering volume targeted ventilation), these are not ideal for the extremely premature. Volume targeted ventilation is a good thing but may lead to a false sense of security, particularly when recruiting the immature lung. It is worth noting that ventilating at 4 ml/kg volume is equivalent to using 8 ml/kg if the lung is only half recruited.

The transport to a proper facility is an additional source of potential difficulty. While there are some very well-equipped transport services that offer HFO, nitric oxide, and even HFJV, some teams operate with antiquated equipment, with only non-triggered and/or non-volume limited ventilation available. The latest, most modern transport ventilator offers volume control among but HFO mode is yet to be certified. It is my strong belief that the premature lung is not optimally served by conventional ventilators, and the longer it is subjected to conventional ventilation, the more damage is

likely to occur. Transport incubators often lack humidification and struggle to maintain a thermoneutral environment which resulting in hypothermia (particularly in colder climates) that is known to affect outcomes adversely.

Clinical Practice

Many tertiary hospitals are staffed by paediatricians rather than neonatologists, and they are not always in house. Paediatricians have neonatal training, but this training and knowledge deteriorates. "PEEPaphobia" (3) continues to exist in NICU's despite evidence showing its damaging effects. Those removed from the specialty are likely to suffer from this affliction. Without adequate PEEP premature lungs are even more prone to gas trapping and iatrogenic injury.

"The transport to a proper facility is an additional source of potential difficulty. While there are some very well-equipped transport services that offer HFO, nitric oxide, and even HFJV, some teams operate with antiquated equipment, with only non-triggered and/or non-volume limited ventilation available."

Surfactant has been a standard treatment for premature infants for almost 30 years, yet there are still hospitals that, for whatever reason, do not give it or wait for the transport team to arrive before it is given. This compounds the problem since, without surfactant, the lung is stiff and prone to collapse; higher pressures are required to ventilate, and insufficient PEEP exacerbates the problem.

In this regard, there are also transport teams that operate under rigid, dated protocols in relation to PEEP. I often lament PEEP set at 5 cmH₂O on a baby with a FiO₂ of 40% or more. It is not my intent to denigrate transport teams; I am well aware they play the hand that they have been dealt and play it as well as possible.

Antenatal steroids are routinely given to mothers in preterm labour, although it is only recently that evidence supports their use in the sub-25-week gestation population. (4) This important treatment may not be given in a tertiary setting, or there may be insufficient time prior to delivery for it to be effective. This makes ventilation even more challenging for the clinician at the receiving end.

Finally, there may be respiratory therapists in house, but when confronted with a premature baby, there is often abject terror. Most respiratory therapists have a NICU rotation, but it is not long enough to achieve competency in the field and is quickly forgotten through lack of exposure to this patient population.

Demographics

Specialty services like neonatology are typically located in larger, urban centres. There are two reasons for this: higher population density means more premature deliveries are likely, and the high costs involved equipping a level three NICU. A woman in premature labour is not likely to consider the facilities available at a hospital. Even in urban centres it is not uncommon for women in premature labour to head to the nearest facility instead of one properly equipped and staffed to handle the situation. In a suburban or rural setting, this is a given, and outcomes are significantly worse in this case. (4) The longer a premature infant must be transported to an appropriate facility, the more detrimental that trip is likely to be.

“ In a suburban or rural setting, this is a given, and outcomes are significantly worse in this case. (4) The longer a premature infant must be transported to an appropriate facility, the more detrimental that trip is likely to be.”

Socioeconomics

Studies indicate a significant correlation between maternal education and the risk of premature birth, but a similar correlation between income and preterm birth has been more elusive. (5) Smoking has been linked to lower levels of education and, perversely, income. As smoking is a known risk factor for low birth weight and premature birth (7), it may be difficult to separate income and smoking as risk factors. A population-based study out of Missouri found a moderately increased risk of preterm birth in areas with the highest poverty levels. (8) Other studies have failed to identify this as a risk factor. Denmark, for instance, failed to identify income as a major factor. (5) This may (or may not) be reflective of the American health care system compared to countries with free universal health care. It is a fact that the poor are less likely to seek medical attention where free universal health care is not offered, and are more likely to have limited or poor antenatal care. For instance, the rate of inadequate antenatal care in Canada is 18.9% compared to 25% in the U.S. New Canadians, first-time mothers, drinkers, and smokers are less likely to receive (or seek) antenatal care while those whose pregnancies are managed by their family physician are more likely to receive recommended care. In the U.S. African American (32%), Native Americans, and Alaskan Native women (41%) are less likely to receive recommended care. (9,10)

Socioeconomics also plays a role after discharge from NICU. Neurodevelopmental morbidities are costly to deal with not just for the family but also for the educational system and society at large. These morbidities are most successfully treated with early remedial action and extensive parental involvement, but must first be identified. Those who struggle to put food on the table are clearly less able to devote time to the needs of the child. Those without the financial resources and family support are not as likely to seek a diagnosis than the more affluent. Even where a socialised medical system, infants born to those of low socioeconomic status are most likely to have poor outcomes, a classic “catch 22”. (12)

The Transport Process

Premature infants are fragile and as such, are far more prone to being harmed by environmental factors, particularly in the hours

following birth. Aside from pulmonary issues, intraventricular hemorrhage (IVH) and hypothermia are common. While every effort should be made to have premature babies delivered where level three care is readily available, this is often not possible. Noise, positioning, less than ideal ventilation and cold stress are all more likely to contribute to morbidities in the outborn, resulting in more IVH and CLD than those born in house. (11) Where these babies are transported to and who does the transporting also play a role. Those taken to a neonatal facility rather than a general children's hospital and those retrieved by a specialised team fare better. (13,14)

Now what?

You may be asking what this to do with respiratory care?” While respiratory therapists' primary focus is the pulmonary system, navel-gazing leads us to forget the impact our care has on other systems and pathologies and, just as importantly, families. Poor respiratory outcomes bode poorly for every other outcome measure, something that should always be kept in mind. The needs of our patients do not magically disappear after discharge. Knowing the risk factors and susceptibilities of outborn infants should help guide clinicians in managing their ventilation as well as other care.

It is my opinion that outborn micro-prems should be ventilated as gently as possible to mitigate the inflammatory response triggered by ventilation in transport and initial management at the referring hospital. I prefer to place these babies on HFJV immediately on arrival if they are near 25 weeks gestation or less, or have had high ventilatory requirements during transport. Since their airways are more likely to have micro-tears, they are more prone to air leak; something HFJV is well suited for. Older, less acute babies may be placed on HFO, and sometimes I find can be extubated on arrival or soon thereafter.

While I am not a big fan of steroids, they do have their place and are sometimes necessary. Early use of hydrocortisone may be of particular benefit in this group of patients. An ounce of prevention? Perhaps. The caveat here is that steroids cannot be given with indomethacin; hence, indomethacin prophylaxis cannot be offered. (14) Prophylactic indomethacin remains somewhat controversial, but recent data suggest a positive impact not only on the instance of patent ductus arteriosus (PDA) but CLD as well. (15) The increased risk of CLD in outborns may favour the use of hydrocortisone in this population, but data is lacking regarding the use of either hydrocortisone or indomethacin in this subgroup. It is difficult indeed to choose between a rock and a hard place, but the increased risk of intestinal perforation and necrotizing enterocolitis in outborns may lead clinicians to prefer hydrocortisone (16). (Is that the rock or the hard place?) Administering budesonide combined with a surfactant may circumvent this problem, but more study is required regarding the efficacy and to determine if risks associated with concomitant administration of steroids and indomethacin remain using this method.

One must recognize that an infant who has not received antenatal steroids is not the same as one who has and must be managed accordingly. Because HFJV offers a combination of gentle ventila-



tion, excellent CO₂ clearance, and reduction of air trapping without exacerbating air leak makes it the go-to mode in a patient population whose ventilatory management is challenging.

If an ounce of prevention is worth a pound of cure, then the way we manage expectant mothers in preterm labour could use an overhaul. The current approach of getting the baby to an appropriate facility once delivered necessitates the whole transport process, even if a specialised team arrives prior to delivery. In my opinion, a better approach would be to avoid the transport process entirely. Telemedicine is underutilised and could be very helpful to those in a tertiary facility managing less acute prems. If the state of the art equipment is available to the referring centre, then consultative management during the critical first 72 hours may be an option. The best scenario would involve a highly specialised team, and a mobile operative delivery suite /neonatal resuscitation room sent to the facility instead of the other way around, a medical "SWAT" team if you will. (At least dreams are free!)

Delaying transport until the risk of IVH is decreased itself should improve outcomes. Economic constraints may make this difficult, but if such an approach improves outcomes, the cost would later be recouped. If the team is not linked to any particular facility but rather is part of a larger regional system, then costs associated with duplication of effort could be eliminated. We focus on immediate costs associated with the NICU stay; we forget the later cost associated with morbidities, not just in expense to the health care system, but the patient's quality of life. That cost is beyond what can be measured in dollars and cents.

Provided I can liaise with Dr. Paige Church, who specialises in neonatal follow-up and developmental care, next month's focus will be on the impact of bedside care and ventilatory management on neurodevelopment and how we can reduce the impact of what we do on developmental outcomes.

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low number, i.e. 5-6

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- Threatens infants' lives

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When that happens:

Category	Percentage
Very low birthweight babies who get NEC	17%
Very low birthweight babies requiring surgery to treat NEC	12%
Very low birthweight babies requiring surgery will die from NEC	30%

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1% on Non-human Milk Products

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- NO goat's milk
- NO formula

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

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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 **78%**¹
- Feeding intolerance decreases²
- Chances of NEC are reduced by **77%**³

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.

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NCfIH National Coalition for Infant Health
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¹ Paul DE, et al. "Impact of Breastfeeding Intolerance on Prevalence, Severity, Mortality and Duration of Necrotizing Enterocolitis (NEC) in Premature Infants." *Breastfeeding Medicine* 2016; 16(3):143-149.
² Wilson SB, et al. "Growth Retardation and Mortality in Extremely Premature Infants Fed a Donor-Derived Low Milk Protein Formula." *Breastfeeding Medicine* 2016; 16(3):150-156.
³ Paul DE, et al. "Mortality and Compartment of Organ Necrotizing Enterocolitis in Very Low Birthweight Infants: A Prospective Study." *JAMA* 2011; 305(10):1160-1166.
⁴ Koster M, et al. "The Use of Human Milk in the Neonatal Intensive Care Unit." *Journal of Perinatology* 2015; 35(10):1000-1006.

Further Insights and Suggestions to Support the Lesbian, Gay, Bisexual, Transgender, and Queer/Questioning (LGBTQ)-Headed Family in the NICU

Vincent C. Smith, MD, MPH, Jonathan S. Litt, MD, MPH, ScD, and Molly Fraust Wyllie, MA

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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In the United States, the traditional family structure of a man, a woman, and one or more of their biological or adopted children is changing. More commonly, members of the Lesbian, Gay, Bisexual, Transgender, and Queer/Questioning (LGBTQ) community are choosing to become parents. According to a 2010 census, 37% of LGBT-identified individuals have had a child, and 19% of same-sex couples are raising children. LGBTQ-headed families represent a small but growing portion of NICU families.

There is very little beyond personal anecdotes to characterize the experience of LGBTQ-headed families in the NICU. What is clear from these stories is that being in an LGBTQ-headed family affects the NICU experience for the family as well

as for the health care providers. Some of the experiences were positive, and some were negative. Most NICU providers have limited training about and experience with the unique needs and issues for LGBTQ-headed in a NICU setting. There are some national and local resources available to support LGBTQ-headed families and staff who care for them.

“Most NICU providers have limited training about and experience with the unique needs and issues for LGBTQ-headed in a NICU setting. There are some national and local resources available to support LGBTQ-headed families and staff who care for them.”

Definitions and terminology

- **Gender identity** is a self-perceived understanding of one's gender. Terms often used to describe gender identity include female, male, non-binary, gender-fluid, and queer. The term “cisgender” is when the gender matches the sex assigned at birth. The term “transgender” is when gender does not match the sex assigned at birth.
- **Gender expression** is the outward presentation of one's gender identity. Terms often used to describe gender expression include femme, butch, female/male presenting, and gender non-conforming.
- **Sexual orientation** is an enduring pattern of romantic and/or sexual de-

sirability to persons of the same or different gender. Sexual orientation has three components—attraction, behavior, and identity. Attraction refers to the gender that one finds romantically and/or sexually attractive. Behavior refers to with whom one engages in romantic and/or sexual relationships. Identity refers to the self-perceived understanding of one's orientation and is typically linked to public expression and social engagement. Terms often used to describe sexual orientation include lesbian, gay, bisexual, questioning, and straight.

- **Heteronormativity** is a term used to describe the world view that promotes heterosexuality as the normal or preferred sexual orientation

Insights into and suggestions for interacting with LGBTQ-headed families in the NICU

Insight: Most families will be LGBTQ-headed because the children are often not LGBTQ.

Suggestion: Try not to apply typical heteronormative (male/female) paradigm to same-sex couples.

Insight: For LGBTQ-headed families, parental roles and functions may not be based on biology.

Suggestion: Keep an open mind about which parent is doing what tasks. Don't assume that anything in regard to parenting roles. Follow the family's lead. Staff should refrain from assuming that based on a more traditional masculine or feminine appearance or manner that they know what role the LGBTQ person plays in the relationship or in parenting their child.

Insight: The language we use is very important. For some staff, it can be hard to know how to refer to LGBTQ individuals, the proper pronouns to use, and what identifiers are acceptable.



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Suggestion: Ask LGBTQ individuals how they want to be referred, which pronouns are appropriate for them, and which identifiers are acceptable.

Insight: Some cultural norms can be unintentionally marginalizing for LGBTQ-headed families. Forms and handouts that refer to “mother” and “father” can be inadvertently exclusionary.

Suggestion: Review all forms and written materials for inclusive language. For example, use the word “parent” instead of “mother” or “father.”

Insight: Much of the family’s experience will be shaped by interpersonal interactions. Families interact with various staff members from the time they are on the premises to when they are about to return home.

Suggestion: It is important to train all staff that may interact with the family. This includes clinical providers, front desk staff, security, valets, and environmental services staff.

Insight: Overall, the staff do an amazing job with all families.

Suggestion: When staff do not do an amazing job do not ignore it and move on. Instead, try to understand what happened and how it can be prevented from happening again. Use the opportunity as a teachable moment and turn a negative into a positive. Keep in mind that an “isolated event” could be indicative of an underlying problem. Apologize at the beginning for any faux pas that could arise, and provide the family with a standing invitation to correct any gaffe that arises.

Insight: Generally, LGBTQ parents appreciate kindness and a genuine desire by the staff to provide them with the highest level of care. When kindness, caring, and good intent are obvious, many LGBTQ parents can overlook incidental faux pas.

Suggestion: Staff can be open about what they do not know and express a willingness to learn. It is helpful to explain to the LGBTQ individuals about the amount of experience that one has caring for LGBTQ-headed families. Express an eagerness and openness to learn any insight that the LGBTQ family volunteers to

share without insisting that the family educate one about LGBTQ culture.

Final insight: Do not forget that we owe it to all families to provide excellent medical care, a safe and comfortable environment, as well as dignity and respect.

“LGBTQ-headed families expressed gratitude for thoughtful, sensitive care. When kindness, caring, and good intent are obvious, many LGBTQ-headed families can overlook incidental faux pas.”

TAKE HOME POINTS

1. The makeup of American families is changing, with more LGBTQ individuals becoming parents.
2. LGBTQ-headed families expressed gratitude for thoughtful, sensitive care. When kindness, caring, and good intent are obvious, many LGBTQ-headed families can overlook incidental faux pas.
3. Avoid making assumptions about LGBTQ individuals based on physical appearance and/or manner.
4. There are ever-increasing opportunities to improve how we care for all types of families in our NICUs. Each family provides an opportunity to refine the care we provide.

Selected national resources

1. National Network of LGBTQ Family Groups available at <https://www.familyequality.org/family-support/national-network-lgbtq-family-groups/> accessed 9/14/19
2. Gay Parent Magazine available at <https://www.gayparent-mag.com/support-groups> accessed 9/14/19
3. PFLAG (Parents, Families, and Friends of Lesbians and Gays) is the United States' first and largest organization uniting families and allies with people who are LGBTQ available at <https://www.pflag.org/> accessed 9/14/19
4. Children of LGBT Parents available at <https://www.glaad.org/resources/ally/8> accessed 9/14/19

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.

NT

National Perinatal Association PERINATAL SUBSTANCE USE

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Boston, MA



What you need to know about RSV

RSV stands for **Respiratory Syncytial Virus**

RSV is a **Really Serious Virus**

WHEN IS RSV SEASON?

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

Protect babies and families this RSV season
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National Perinatal Association

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

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NICU Awareness

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



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Quality Improvement Initiative to Decrease Fentanyl Use in ELBW Infants

Shabih Manzar, MD and Nitin Walyat, MD

Abstract

Introduction:

Fentanyl has been associated with a higher incidence of cerebellar injury and lower cerebellar diameter in preterm infants. We noticed an increased use of fentanyl among extremely low birth weight (ELBW) infants (birth weight < 1000 grams) in our NICU. To reduce its use by 20%, we launched this quality improvement (QI) project.

Methods:

The potential factors involved in fentanyl use were noted down. A driver diagram was created, and areas of improvement were recognized (Figure). A 20% improvement was calculated as: 14 (baseline use) $- 11$ (expected use) $\div 14$. The QI team met and discussed the plan. The information was disseminated to all NICU nursing staff via group email and handouts. The results were analyzed for the number of doses used in the following two months.

Results:

In the following sixty days, there were seven ELBW infants. The mean gestation age was 27 weeks (range 24 to 31) with the mean birth weight of 818 grams (range 580 to 990grams). One infant received 9 days of continuous drip (infant developed gram-negative septic shock- we eliminated the infant from the analysis). Out of 6 infants, four (67%) received no fentanyl. One infant received one dose while the other received two doses.

Conclusion:

Our preliminary data suggested that non-pharmacological

management of pain and agitation with strict medication guidelines resulted in a reduction in fentanyl use. We expect other units to adopt our policy. A larger pool of infants will enhance and further validate our findings.

Introduction:

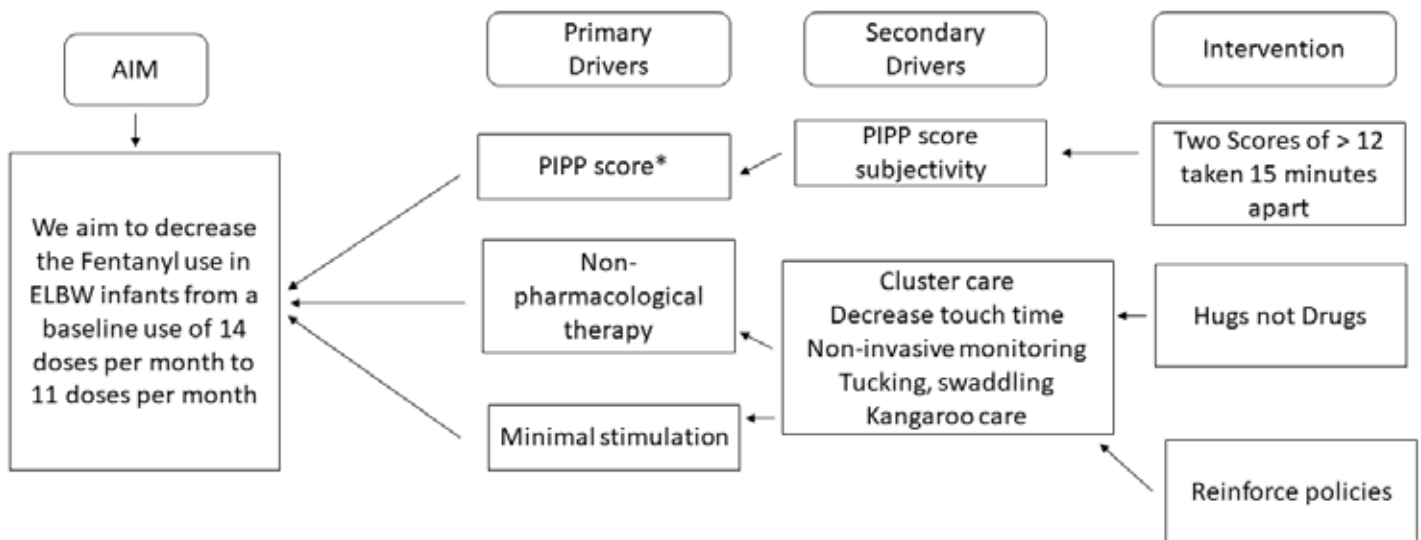
Opioids use has increased in the last two decades. Use of opioids in neonates has been associated with longer duration of mechanical ventilation, longer time to first meconium passage, and higher mean airway pressure levels. 1 In preterm infants, higher cumulative fentanyl dose has been associated with a higher incidence of cerebellar injury and lower cerebellar diameter. 2 Recently, Ancora et al. 3 demonstrated a significant decrease in eye and hand coordination skills in fentanyl exposed infants.

In May 2019, we undertook an audit to look at the utilization of fentanyl in extremely low birth weight (ELBW) infants (birth weight < 1000 grams) 4. We looked at the 8-months data and found fentanyl usage of 14 doses per month, which was very alarming (the data is reported and is in press). As a quality improvement (QI) initiative, we launched this project. We aimed to decrease fentanyl use by 20% in the following 2-month period.

Methods:

The factors associated with fentanyl use were identified. A driver diagram was created, and areas of improvement were recognized (Figure). A 20% improvement was calculated as: 14 (baseline use) $- 11$ (expected use) $\div 14$. The QI team met and

Figure



*PIPP: Premature Infant Pain Profile

ELBW: Extremely Low Birth Weight (< 1000 grams)

Figure 1: Key Driver diagram

discussed the plan. The information was disseminated to all NICU nursing staff via group emails and handouts. The data was recorded and extracted from Epic Systems, Wisconsin. The data were analyzed for the number of doses used in the following two months.

Results:

There were seven ELBW infants admitted following the QI initiative. The mean gestation age was 27 weeks (range 24 to 31) with the mean birth weight of 818 grams (range 580 to 990 grams). One infant received nine days of continuous drip (infant developed gram-negative septic shock, we eliminated that infant from the analysis as an outlier). Out of the remaining six infants, four (67%) received no fentanyl. One infant received one dose while the other one received two doses. Thus, a total of 3 doses were consumed in 2 months giving a figure of 1.5 doses per month as compared to 14 doses per month in preceding months. By follow our QI initiative, we were able to reduce the fentanyl use by 89% ($14 - 1.5 \div 14 \times 100$).

“The decreased fentanyl use observed in our QI project was encouraging. Among primary drivers, the reinforcement of strict PIPP scoring, skin to skin care and nursing understanding of brief oxygen desaturations, helped in our QI.”

Discussion:

The decreased fentanyl use observed in our QI project was encouraging. Among primary drivers, the reinforcement of strict PIPP scoring, skin to skin care and nursing understanding of brief oxygen desaturations, helped in our QI. Among secondary drivers, cluster care and ensuring that residents and medical students follow the touch time was also an important factor. We have described earlier the dilemma of frequent physical examinations in neonates. 5

Fentanyl is mostly used in intubated ELBW infants during mechanical ventilation. We follow early extubation policies and provide non-invasive ventilation. We postulated that concomitantly use of early extubation and minimal handling, might have contributed to the decreased use of fentanyl. As our baseline data were obtained from similar acuity of ELBW infants, we believe that the changes are true reflection of our initiative. Non-pharmacological management of pain and agitation is gaining popularity in neonatal care. 6 We employed tucking and swaddling for all ELBW infants, which further deterred the medication use. The limitation of our study was the small number of ELBW infants. But this being a preliminary report, we expect to duplicate our findings in the following months of data

collection. A larger pool of infants will enhance and further validate our findings.

In conclusion, we were able to demonstrate a reduction in fentanyl use by our QI initiative. We will continue to collect the data prospectively and hope other units to follow our QI. A decreased use of opioids will not only result in cost reduction but also will not risk preterm brain development.

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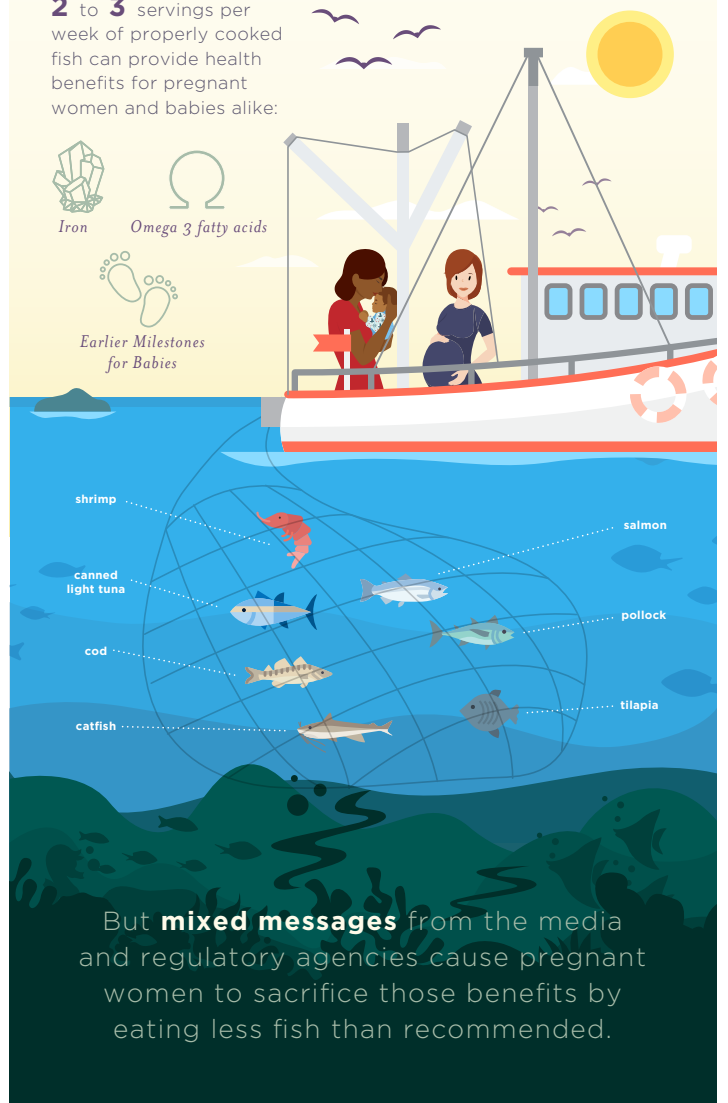
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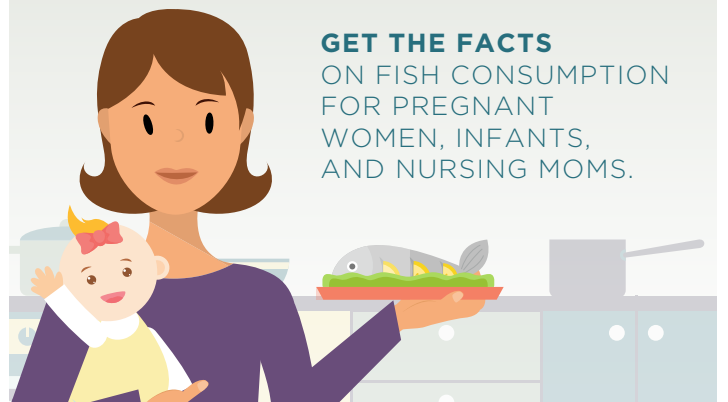


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The Gap Baby: An RSV Story



A collaborative of professional, clinical, community health, and family support organizations improving the lives of premature infants and their families through education and advocacy.



The National Coalition for Infant Health advocates for:

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- **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
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Vaping and Pregnancy: Health and Policy Concerns

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.



The practice of vaping and the use of e-cigarettes by people of all ages have dominated the headlines in 2019. The prevalence of vaping has brought forward many opinions, policy challenges, and proposed policy solutions. Policymakers have proposed to limit sales, reduce nicotine content, end teen use, eliminate flavors, and wait for more access to research and subsequent government guidelines.

Health policy discussions on vaping have largely focused on adult lung illnesses, youth prevention, elimination of e-liquid flavor cartridges, and the contents of vaping products that have led to over 1,000 domestic deaths.

Less attention, if any, has been addressed by the media related to the impacts of vaping on newborns and infants - and subsequent policy changes to educate expectant mothers about the harmful impacts of vaping, during or immediately after pregnancy.

Should society assume that nicotine use during pregnancy has reached such a level of taboo that pregnant women in America simply are not doing it? Where do pregnant women access re-

sources about quitting, if no one is really talking about the act itself?

Unfortunately, resources indicate that some vaping occurs with pregnant women in America, currently. According to the Mayo Clinic, "research suggests that pregnant women who vape believe that using e-cigarettes is less harmful than smoking cigarettes." Mayo Clinic also suggests that pregnant women often are not aware if e-cigarettes contain nicotine. Another reason given why pregnant women may vape during pregnancy is the perception

"Mayo Clinic also suggests that pregnant women often are not aware if e-cigarettes contain nicotine. Another reason given why pregnant women may vape during pregnancy is the perception that the devices can help them quit or reduce cigarette smoking. (1)"

that the devices can help them quit or reduce cigarette smoking. (1)

The Centers for Disease Control and Prevention (CDC) has issued clear statements that any product containing nicotine, including e-cigarettes, is "not safe for use during pregnancy." The well-known harm of nicotine to a fetus is described by the CDC as damage to a developing brain and lungs. The CDC also notes that "some of the flavorings used in e-cigarettes may be harmful to a developing baby." (2)

The CDC also points out there is not substantial evidence to conclude whether or not e-cigarettes help women quit smoking during pregnancy or stay smoke-free after their newborn arrives. The health protection agency includes in their literature, however, that e-cigarettes are not approved by the FDA to help people quit smoking.

For its part, the U.S. Food and Drug Administration (FDA) is explicit - no youth or pregnant women should be using any vaping product, regardless of the substance. (3,4)

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The American Academy of Pediatrics (AAP) — as far back as their 2015 annual meeting — addressed the issue of secondhand smoke from e-cigarettes. This attention came at a time when e-cigarettes were still relatively new in the U.S. market. The AAP warned that secondhand exposure to e-cigarettes might be dangerous and reiterated that “nicotine-containing products could harm children from conception onward.” In 2015, the AAP also challenged the FDA to regulate e-cigarettes as they would other tobacco products.

The FDA has regulated standard cigarette smoking using authorities in accordance with the Family Smoking Prevention and Tobacco Control Act of 2009. Limits and new rules on sales of tobacco products, changes to size and prominence of warning labels on packaging, and elimination of advertisements geared towards children were all employed.

E-cigarettes present a new challenge for the FDA. FDA Acting Commissioner Dr. Ned Sharpless acknowledged in a September newsletter, “this topic is a complicated one with many unknowns.” (How FDA is Regulating E-Cigarettes: <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes>) Dr. Sharpless later acknowledged in that same article that the FDA’s policies on e-cigarettes are “still evolving.”

“E-cigarettes present a new challenge for the FDA. FDA Acting Commissioner Dr. Ned Sharpless acknowledged in a September newsletter, ‘this topic is a complicated one with many unknowns.’”

Studies do suggest that pregnant women are vaping - maybe, if only under the belief that they are not using nicotine, or are using



Still a Premie?

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

But that’s not every preemie’s story.

Born between 34 and 36 weeks’ gestation?

STILL A PREMIE

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

Jaundice Feeding issues Respiratory problems

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

Born preterm at a “normal” weight?

STILL A PREMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREMIE

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

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

Some Premies

- Will spend weeks in the hospital
- Will have lifelong health problems
- Are disadvantaged from birth

All Premies

- Face health risks
- Deserve appropriate health coverage
- Need access to proper health care

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

less nicotine with an e-cigarette.

While the FDA's and CDC's of the world work through policy suggestions, guidance, and regulations, what may really protect the next generation from harm (and prevent vaping by expectant mothers) is a continuing concerted effort by hospitals, health care providers, and caretakers to dispel myths about vaping products and vaping during pregnancy, and to provide encouragement and other resources that will end the mother's dependence on e-cigarettes. The direct impact and personal contact may be more expeditious to end vaping during pregnancy than waiting on policymakers to review the data and enact regulations.

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

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Malcolm and Elizabeth Chace Education Center
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OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS



I am not an addict.

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



I was exposed to opioids.

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



NAS is a temporary and treatable condition.

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



My mother may have a SUD.

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

My potential is limitless.

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



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



Survey Says: RSV

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children.

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

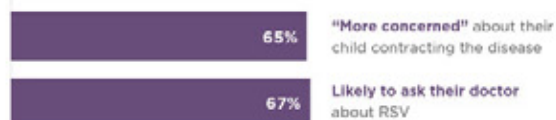
- 80% They treat RSV as a priority, "often" or "always" evaluating their patients
- 77% RSV is the "most serious and dangerous" illness for children under four
- 77% Barriers to access and denials from insurance companies **limit patients' ability to get preventive RSV treatment**

But Parents are Unprepared.

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

RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:



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

Postpartum Revolution

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OPIOIDS and NAS

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



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

first candle

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

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

Interpreting Umbilical Cord Blood Gases: Blood Gas Components

Jeffrey Pomerance, MD, MPH

Definition of Terms

Blood gas samples are measured directly for pH, PCO₂ (partial pressure of carbon dioxide) and PO₂ (partial pressure of oxygen).⁽¹⁾ Bicarbonate (HCO₃⁻), base deficit (also reported as a negative base excess), and oxygen saturation values are all calculated from the measured parameters. Today, the base deficit is most commonly reported as extracellular fluid (BD_{ecf}), although it is usually labeled only as base deficit without a subscript identifier. The extracellular fluid base deficit is a corrected form of blood base deficit for which allowance has been made for the fact that blood makes up only about 37% of the extracellular fluid volume. BD_{ecf} is sampled from blood, not extracellular fluid. Please be aware that the base deficit may be reported as a blood base deficit (BD_b). This can be an issue for any centers that report BD_b, as decisions as to which newborns qualify for cooling as therapy for hypoxic-ischemic encephalopathy are partly reliant upon BD_{ecf}.⁽²⁾ Additionally, there are some web sites on the internet that calculate a base deficit when a pH and a PCO₂ are entered. If the base deficit is not identified as either a BD_{ecf} or a BD_b, be hesitant about relying on such calculations.

Although blood gas analyzers are preset to assume a specific hemoglobin value, (usually between 14.3 and 15.0 g/dL), and a patient

temperature of 37.0° C, in a practical sense, values differing modestly from the preset value of hemoglobin or temperature make little clinical difference in interpretation of the data. Correcting for an elevated maternal temperature of 40.0° C, for example, decreases the analyzed pH by approximately 0.05 for pH between 7.10 and 7.45.⁽³⁾ Increasing temperature increases the PCO₂ and PO₂ results, but bicarbonate and base deficit remain unaffected. Some authorities believe there is no scientific basis for temperature correction.⁽⁴⁾ In modern blood gas analyzers, prior to processing the next blood sample, one may enter a hemoglobin value and/or a patient temperature, and the analyzer will recalculate the results.

“Additionally, there are some web sites on the internet that calculate a base deficit when a pH and a PCO₂ are entered. If the base deficit is not identified as either a BD_{ecf} or a BD_b, be hesitant about relying on such calculations.”

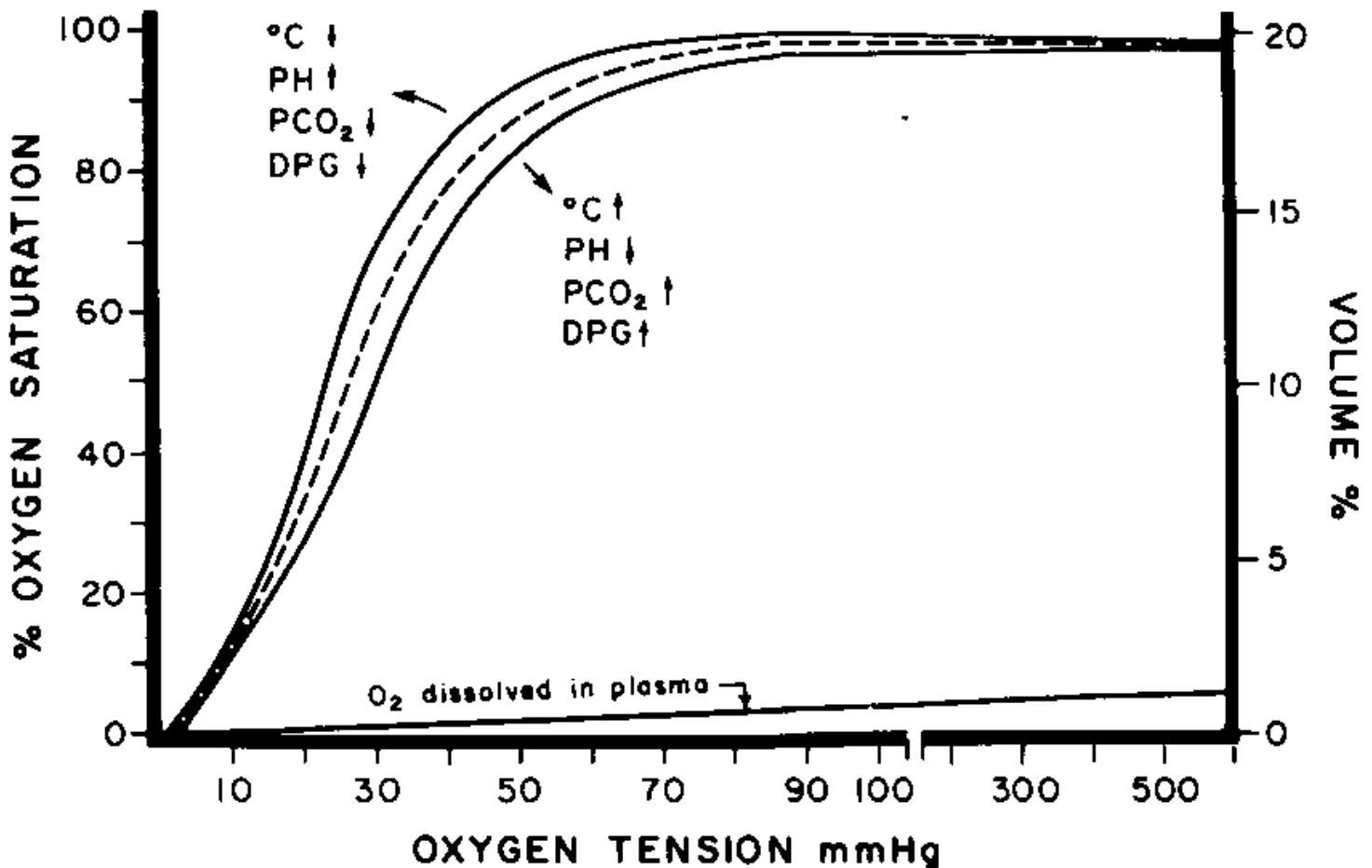


Figure 1. Factors shifting the oxygen dissociation curve of hemoglobin (Fetal hemoglobin is shifted to the left as compared with that of adult hemoglobin.) Reprinted from Martin RJ, et al. Respiratory problems. In Klaus M, et al. [eds]: Care of the High-Risk Neonate. Philadelphia, WB Saunders Co; 1993, p 228, with permission from Elsevier.

The concentration of free hydrogen ion (H⁺) or titratable acid in a solution is usually represented by the term pH. The pH of a solution is inversely proportional to the concentration of H⁺ in that solution. In other words, the lower the pH, the higher the concentration of H⁺ in solution. (5) It is important to remember that pH is a logarithmic scale, as is the Richter earthquake scale. An earthquake of magnitude 7 has an amplitude ten times greater than an earthquake of magnitude 6. A solution with a pH of 6.0 has ten times more titratable acid than a solution with a pH of 7.0. In a more physiologic range, a solution with a pH of 7.0 has approximately 2.5 times the titratable acid as a solution with a pH of 7.4.

In any mixture of gases, the pressure exerted by a single gas is determined by its concentration in the mixture as well as the atmospheric pressure (Dalton's Law of Partial Pressures). The pressure exerted by an individual gas is called the partial pressure of that gas. (6)

Although results of blood gas analysis report percent oxygen saturation in newborns, this value should be ignored (unless specifically stated that the value has been measured) as blood gas analyzers assume hemoglobin to be of the adult type, hemoglobin A (HbA). In the premature between 24 and 28 weeks' gestation, fetal hemoglobin (HbF) accounts for more than 90% of fetal blood, while at term, approximately 75% of hemoglobin is HbF. (7) Fetal hemoglobin shifts the oxygen dissociation curve to the left, as do several other factors (see Figure above). (8) This shift results primarily from the fact that 2,3-diphosphoglycerate (DPG) binds less well to HbF than to HbA. (9) Therefore, the reported oxygen saturation from a blood gas in newborns will be lower than the true oxygen saturation. As the middle portion of the oxygen dissociation curve is quite steep, this underestimation may be large.

Conversely, pulse oximeter readings in the newborn and young infant may be higher than the saturation calculated from the PO₂ in a blood gas. Over time, however, especially in tiny infants, calculated blood gas oxygen saturations approximate oxygen saturation as measured by a pulse oximeter. This happens because of the gradual conversion to the production of HbA over HbF and/or a more rapid replacement of HbF by HbA through repeated phlebotomy and subsequent transfusion of PRBCs containing HbA.

“Over time, however, especially in tiny infants, calculated blood gas oxygen saturations approximate oxygen saturation as measured by a pulse oximeter.”

In healthy adults breathing 100% oxygen, arterial PO₂ exceeds 600 mmHg (torr). The total volume of oxygen carried in arterial blood, however, increases only marginally as ambient oxygen is increased from room air to 100% (see Figure). This occurs because, at room air, hemoglobin is almost entirely saturated with oxygen. Under these circumstances, increasing the concentration of inspired oxygen adds only a small amount of oxygen dissolved in plasma. Experimentally in fetal lambs (10) and in the human fetus just prior to cesarean delivery, (11) umbilical venous PO₂ rises significantly when the mother's ambient oxygen is increased from room air to 100% but is never more than about 60 mmHg. Despite frequent administration of oxygen to the mother at the time of delivery, it is exceedingly rare to see an umbilical venous cord gas with a PO₂ as high as 50 mmHg. When the mother's ambient oxygen is raised to 60%, in the absence of uteroplacental-fetal pathology, the umbilical cord arterial PO₂ has been reported to rise as high as about 38 mmHg.

In the face of uteroplacental insufficiency,(10) maternal oxygen administration may be beneficial. (13,14) However, in cord occlusion, one would expect very limited benefit, if any at all, in the total amount of oxygen delivered to the fetus. It is axiomatic that maternally administered oxygen will benefit the fetus only if the fetal-placental circulation is intact. Accordingly, the main approach to improving fetal oxygenation must come through amelioration of the underlying condition, such as correcting maternal hypotension or relieving umbilical cord compression, for example. In the face of maternal oxygen desaturation (maternal hypoventilation, narcotics, high spinal, etc.), supplemental oxygen will likely be of major benefit to the fetus through improvement in the maternal arterial PO₂. Prophylactic maternal oxygen administration during the second stage of labor resulted in a significant increase in the percentage of arterial cord pH values less than 7.20. (15)

Relationship Between Umbilical Venous and Arterial Blood Gas Values

In vivo, blood from the umbilical vein has a predictable relationship with blood in the umbilical arteries. The “rules” governing the relationship between umbilical venous and umbilical arterial blood are as follows:

- Blood from the umbilical vein always has a higher pH than blood from the umbilical arteries.
- Blood from the umbilical vein always has a lower PCO₂ than blood from the umbilical arteries.
- Blood from the umbilical vein always has a higher PO₂ than blood from the umbilical arteries.
- Usually, base deficit and bicarbonate are approximately the same in umbilical venous and arterial samples.
 - o If the base deficit of one is significantly worse, it must be the arterial sample.
 - o The base deficit is more reliable than bicarbonate as a measure of metabolic acidosis or alkalosis.

If one to three of the four relationships are opposite to these rules, it is likely the samples came from the same vessel. If all four are opposite, consider the possibility of mislabeling of samples. The rules, as stated above, apply only to individual paired blood gas samples, not to population values, in which there is quite a bit of overlap in the normal range. The placenta acts as the lung for the human fetus. Consequently, if we consider that the lung (placenta) transfers carbon dioxide to the placenta and takes on oxygen, then it should come as no surprise that the vessel(s) bringing blood to the lung (placenta) will always contain more carbon dioxide and less oxygen than the vessel(s) bringing blood from the lungs (placenta) to the baby. The pH in the umbilical vein will always be higher than in the umbilical artery because PCO₂ is lowered as blood passes through the placenta. Consequently, pH must rise.



As carbon dioxide falls, so must hydrogen ion (H⁺), the prototype

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acid. The relationship between the values in umbilical venous and umbilical arterial blood is exactly opposite to that found in the systemic veins and arteries of children and adults but is the same as the relationship between pulmonary veins and the pulmonary artery. This is reasonable when we recall that the placenta acts as the fetal lung.

Key Points

- Blood gas samples are measured directly for pH, PCO₂, and PO₂. Bicarbonate, base deficit, and oxygen saturation are all calculated from the measured parameters.
- Blood gas analyzers assume hemoglobin to be of the adult type. Therefore, in newborns, calculated blood gas oxygen saturation values are generally underestimated.
- Blood from the umbilical vein always has a higher pH, a lower PCO₂, and a higher PO₂ than blood from the paired umbilical arteries.
- The base deficit is more reliable than bicarbonate as a measure of metabolic acidosis or alkalosis.
- Usually, the base deficit is approximately the same in umbilical venous and arterial samples, but if one is significantly worse, it must be the arterial sample.
- If one to three of these four relationships are opposite to the rules, it is likely the samples came from the same vessel.
- Be sure your hospital is using extracellular fluid base deficit rather than blood base deficit, as decisions regarding cooling for hypoxic-ischemic encephalopathy are based in part on the former.

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Eunice Kennedy Shriver National Institute
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Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Baby powder manufacturer voluntarily recalls products for asbestos

FDA advises consumers to stop using affected products

For Immediate Release:
October 18, 2019

The U.S. Food and Drug Administration is alerting consumers of a voluntary recall by Johnson & Johnson of Johnson's Baby Powder after FDA testing has found that a sample from one lot of the product contains chrysotile fibers, a type of asbestos. Consumers who have Johnson's Baby Powder lot #22318RB should stop using it immediately and contact Johnson & Johnson for a refund. The FDA stands by the quality of its testing and results and is not aware of any adverse events relating to exposure to the lot of affected products.

During talc mining, if talc mining sites are not selected carefully and steps are not taken to purify the talc ore sufficiently, the talc may be contaminated with asbestos. Asbestos is a known carcinogen. It is important to note that the FDA has been conducting testing of talc-containing cosmetic products for asbestos. Not all talc contains asbestos and the majority of product samples tested by the FDA did not contain asbestos.

"I understand today's recall may be concerning to all those individuals who may have used the affected lot of baby powder. I want to assure everyone that the agency takes these concerns seriously and that we are committed to our mandate of protecting the public health," said Acting FDA Commissioner Ned Sharpless, M.D. "The FDA continues to test cosmetic products that contain talc for the presence of asbestos to protect Americans from potential health risks."

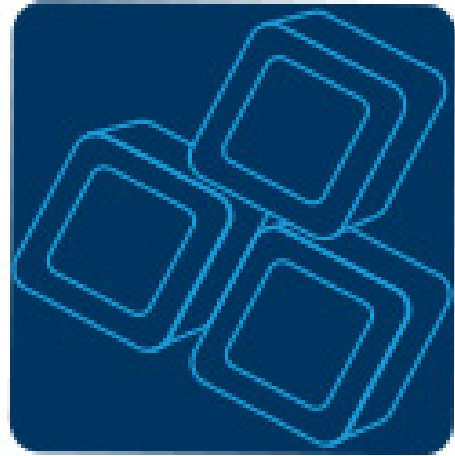
Since 2018, the FDA has been conducting an ongoing survey of cosmetic products for asbestos and to date has tested approximately 50 cosmetic products. As part of this testing, two samples of Johnson's Baby Powder were tested: one sample from lot #22318RB was found to be positive for asbestos; a second Johnson's Baby Powder sample, lot #00918RA, tested negative for asbestos.

The FDA expects to issue the full results from this survey, includ-

ing all tested products having both positive and negative results, by the end of the year. Since undertaking the testing, the agency has warned consumers when products tested positive for asbestos, advising them to stop using affected products, including not to use certain products from Claire's and Beauty Plus Global. The FDA will continue to update its safety alert with new information as it becomes available.

Under the Federal Food, Drug and Cosmetic Act (FD&C Act), cosmetic products and ingredients, with the exception of color additives, do not have to undergo FDA review or approval before they go on the market. Although the FDA doesn't have pre-market review authority, the agency has the responsibility to monitor the cosmetics market and can take appropriate action to protect consumers in the post-market setting. Cosmetics must not be "adul-

neo



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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.**

terated" or "misbranded," meaning they must be safe for consumers when used according to directions on the label, or in the customary or expected way, and they must be properly labeled. The agency is again calling on industry to register and list their products via the FDA's Voluntary Cosmetics Registration Program although under current law, registration and listing are not required.

The FDA continues to focus on protecting Americans from unsafe products and will continue testing samples from cosmetic products containing talc in accordance with our limited available resources. The FDA's current work related to cosmetics also focuses on reviewing reports of adverse events involving cosmetics that are received from consumers and health professionals; reviewing scientific literature; research; surveillance; education and outreach; and pursuing enforcement action against products on the market that are not in compliance with the law, or against firms or individuals who violate the law.

Health care professionals and consumers are encouraged to report any adverse events associated with the use of a cosmetic to the FDA's MedWatch Adverse Event Reporting program by completing and submitting the report online at MedWatch Online Voluntary Reporting Form or downloading and completing the form, then submitting it via fax at 1-800-FDA-0178.

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 hu-

man and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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NT

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

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

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

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- Invitation for special programming by the Section at the AAP's National Conference.
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advancement of pediatrics and who do not otherwise qualify for membership in the AAP). Membership application for affiliates: <http://shop.aap.org/aap-membership/> then click on "Other Allied Health Providers" at the bottom of the page.

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

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NT

FDA, FTC warn company marketing unapproved cannabidiol

products with unsubstantiated claims to treat teething and ear pain in infants, autism, ADHD, Parkinson's and Alzheimer's disease

FDA is also working quickly to evaluate regulatory policies related to cannabis and cannabis-derived ingredients like CBD.

For Immediate Release:
September 27, 2019

Today, the U.S. Food and Drug Administration and the Federal Trade Commission posted a joint warning letter to Rooted Apothecary LLC, of Naples, Florida, for illegally selling unapproved products containing cannabidiol (CBD) online with unsubstantiated claims that the products treat teething pain and ear aches in infants, autism, attention-deficit/hyperactivity disorder (ADHD), as well as Parkinson's and Alzheimer's disease, among other conditions or diseases.

"Cannabis and cannabis-derived compounds are subject to the same laws and requirements as FDA-regulated products that contain any other substance. We are working to protect Americans from companies marketing products with unsubstantiated claims that they prevent, diagnose, treat, or cure a number of diseases or conditions. This is especially concerning when companies are peddling unproven CBD products for use in vulnerable populations like infants and children," said Acting FDA Commissioner Ned Sharpless, M.D. "We've sent numerous warning letters that focus on matters of significant public health concern to CBD companies, and these actions should send a message to the broader market about complying with FDA requirements. As we examine potential regulatory pathways for the

lawful marketing of cannabis products, protecting and promoting public health through sound, science-based decision-making remains our top priority. We appreciate the FTC joining us on these and other actions to protect consumers from fraudulent CBD products."

As described in the warning letter issued to Rooted Apothecary, the company used product webpages, through its online store and social media websites, to make unfounded claims about its CBD products, and some of the products were also unlawfully marketed as dietary supplements. The agency has determined that CBD products cannot be marketed as dietary supplements.

Examples of the unsupported claims made by the company include:

- "Instead of synthetic chemical[s] that can have safety concerns, this blend uses the best of nature to help calm the inflammation and pain of teething, while also promoting sleepiness for your little one."
- "No matter what age, ear aches are a terrible, no good way to live each day! Our main priority was safety, effectiveness . . . as we formulated this for the entire family including our precious little ones. When the pain is bad, this roller goes to work for soothing pain, inflammation, and to battle against the bacterial/viral crit-



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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ters to blame.”

- “Increasing evidence suggests that CBD oil is a powerful option for pain . . . anxiety . . . and autism . . . It seems like an attractive and safe option for children.”
- “CBD oil may have neuroprotective properties and may protect against neurological conditions, such as Parkinson’s and Alzheimer’s disease.”
- “[P]ossible uses for CBD include helping with skin problems such as acne, autism, ADHD, and even cancer. It’s often used in conjunction with traditional treatments to provide extra help. Children can use high amounts of CBD safely and without any risk.”

Additionally, under the Federal Trade Commission Act, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. The FTC is concerned that one or more of the efficacy claims cited may not be substantiated by competent and reliable scientific evidence. These products are also misbranded under the Federal Food, Drug, and Cosmetic (FD&C) Act, because the products’ labels and product information fail to include adequate directions for use. Drugs in the United States must contain directions explaining how a consumer can use a drug safely for its intended purpose. Under the law, there is an exemption for this labeling requirement for prescription drugs that have FDA-approved applications in effect. However, none of Rooted Apothecary’s products are FDA-approved.

The FDA and FTC have requested responses from Rooted Apothecary within 15 working days stating how the company



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will correct the violations. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or administrative cease and desist order, and an order also may require that a company pay back money to consumers.

The FDA continues to be concerned about the proliferation of products claiming to contain CBD that are marketed for therapeutic or medical uses that have not been approved by the agency. The FDA approval process ensures that drugs on the market are safe and effective for their intended therapeutic uses. CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, teas and topical lotions and creams. The FDA has not approved any CBD products other than one prescription human drug product to treat rare, severe forms of epilepsy. There is very limited information for other marketed CBD products, which likely differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body.

The FDA continues to explore potential pathways for various types of CBD products to be lawfully marketed. An important component of this work is obtaining and evaluating information to address outstanding questions related to the safety of CBD products while maintaining the FDA’s rigorous public health standards.

“The FDA is working quickly to further clarify our regulatory approach for products containing cannabis and cannabis-derived compounds like CBD while using all available resources to monitor the marketplace and protect public health by taking action as needed against companies,” said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. “We recognize that there is significant public interest in cannabis and cannabis-derived compounds; however, we must work together to fill in the knowledge gaps about the science, safety and quality of many of these products. We are committed to advancing our regulation of these products through an approach that, in line with our mission, prioritizes public health, fosters innovation and promotes consumer confidence.”





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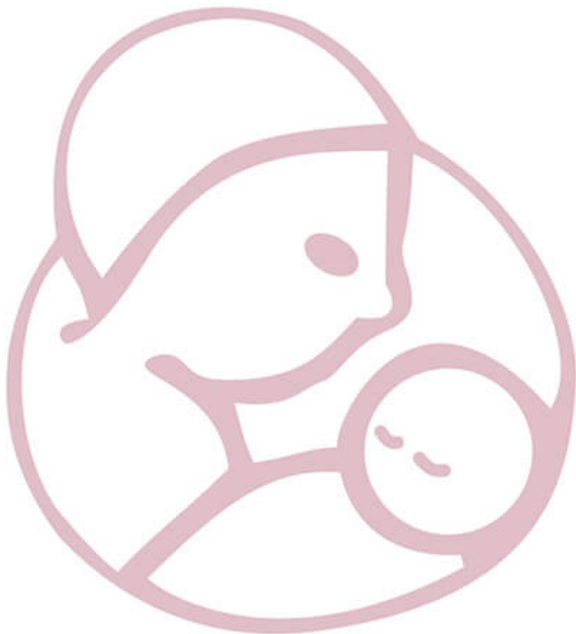
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Unlike drugs approved by the FDA, the manufacturing process of unapproved CBD products has not been subject to FDA review as part of the drug approval process. Further, there has been no FDA evaluation of whether these products are effective for their intended use, what the proper dosage is, how they could interact with FDA-approved drugs, or whether they have dangerous side effects or other safety concerns. Consumers may put off getting important medical care, such as proper diagnosis, treatment and supportive care due to unsubstantiated claims associated with CBD products. For that reason, it's important that consumers talk to a health care professional about the best way to treat diseases or conditions with existing, approved treatment options. The FDA has previously sent warning letters to other companies illegally selling CBD products that claimed to prevent, diagnose, treat or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

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

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

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NT

American Academy of Pediatrics Clinical Report: Rate of Late Preterm Births Rises Nationally After Years of Decline

The rate of late preterm babies is increasing once again.

10/21/2019

Infants who are born late preterm face significant risks in survival, as well as delays in growth and development. This public health concern prompted a national awareness and prevention movement in 2007. Today, the late preterm birth rate, after nearly a decade of steady decreases, has been inching up again as reported by the American Academy of Pediatrics in the November 2019 Pediatrics. The report, "Updates on an At-Risk Population: Late Preterm and Early Term Infants" (published online Oct. 21), defines the sub-categories of preterm births and reports the increase in the late preterm birth rate that began in 2015. The late preterm birth rate had reached its lowest level in a decade of 9.57% in 2014 but rose to 9.97% by 2018. The trend is largely attributed to increases in the rate of late preterm births (infants born between 34 0/7 weeks gestation and 36 6/7 weeks gestation), predominately among black and Hispanic women. Late preterm births account for approximately 70 percent of all preterm births in the U.S., and they account for 7 percent of all live births. Early term births (between

37 0/7 weeks' gestation and 38 6/7 weeks' gestation) also pose significant risks to an infant. AAP recommends continued use of population data to help monitor the rates of late preterm births for trends, changes in practice, and need for interventions. Other recommendations include planning with obstetric providers to understand and to improve the balance of benefits and risk factors surrounding late preterm and early term deliveries.

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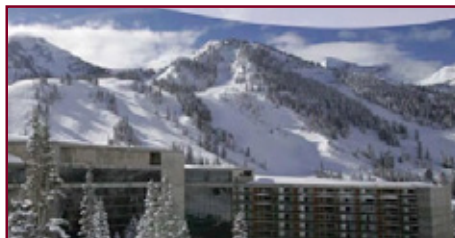
Informal Sharing of Breast Milk Gains Popularity Among Women, Despite Safety Risks

Research focuses on reasons women turn to other mothers for breast milk instead of milk banks. CDC Press Release

10/25/2019

NEW ORLEANS – Women who are unable to produce enough breast milk for their children are increasingly turning to "mother-to-mother" informal milk-sharing, a potentially unsafe practice that is discouraged by the pediatric medical community, according to new research being presented at the American Academy of Pediatrics (AAP) 2019 National Conference & Exhibition.

The research abstract, "Where to get Do-



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nor Breast Milk? Self-Reported Parental Motivations and Concerns Regarding the Choice of Informal Milk Sharing versus Milk Banks,” will be presented on Saturday, Oct. 26 at the Hilton New Orleans Riverside in Grand Ballroom A.

A related research abstract by the same author, “An Analysis of Parental Opinions of Human Milk Sharing Options,” will be presented during the same session.

“Informal milk sharing is becoming increasingly popular and widespread,” said Nikita Sood, researcher at Cohen Children’s Medical Center/Northwell Health in New York. “It is therefore crucial that physicians become aware of this practice and the associated risks so that they can educate patients and address this growing concern.”

More than 50 percent of 650 mothers who responded anonymously to a survey shared on Facebook said they did not have any safety concerns about the informally donated breast milk, and almost 80% did not medically screen the donors because they “trusted them.” AAP

discourages the use of informally shared breast milk because of the risks of potential spreading of disease or exposure to medications, alcohol, illegal drugs or other contaminants.

AAP recommends exclusive breastfeeding until about 6 months of age, followed by continued breastfeeding as complementary foods are introduced. Women who are unable to produce enough milk to exclusively breastfeed their child may supplement infant diets with formula or donor breast milk that is available through formal milk banks. More than half of the survey respondents who do not use a milk bank to obtain breast milk cited concerns about the cost, followed by concerns about quality and ability to obtain a prescription for breast milk.

The related study, “An Analysis of Parental Opinions of Human Milk Sharing Options,” found a majority of online parenting blog posts that discussed milk-sharing focused on informal milk sharing without addressing safety concerns.

“Not only are our patients unaware of the

potential risks that they are undertaking when participating in these informal milk sharing practices, they are also often not informing their physicians,” Ruth Milanaik, DO,

at Cohen Children’s Medical Center/Northwell Health in New York said. “In addition to educating patients, physicians must underscore the importance of discussing these habits with medical professionals so that we have the necessary information to make accurate diagnoses should a medical need arise.”

Nikita Sood will present both abstracts, between 8 a.m. and 1:30 p.m. on Saturday, Oct. 26, during the Joint Section on International Child Health and Section on Breastfeeding Program at the Hilton New Orleans Riverside in Grand Ballroom A.

To request an interview, journalists may contact Northwell Health Public Relations Department Monday-Friday between 9 a.m. - 5 p.m. ET at (516) 321-6701; after-hours and weekends: (516) 840-0644.

In addition, Nikita Sood and Dr. Ruth Milanaik will be among highlighted abstract

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authors will give brief presentations and be available for interviews during a press conference and luncheon on Saturday, October 26, starting at 12:30 p.m. in rooms 208-209 (Press Office) of the Ernest N. Morial Convention Center. During the meeting, you may reach AAP media relations staff in the National Conference Press Room at 504-670-5406.

Please note: Only the abstract is being presented at the meeting. In some cases, the researcher may have more data available to share with media, or may be preparing a longer article for submission to a journal.

###

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NT

Study Identifies Challenges to Neonatal Resuscitation Outside of Hospitals

Simulated 911 calls to a home birth in progress highlight roadblocks emergency medical responders face in adhering to standardized guidelines for helping new-

borns breath.

NEW ORLEANS – With about 62,000 babies born outside of hospitals each year, and 1 in 10 newborns needing help to start breathing, emergency medical services (EMS) responders must be ready to give expert newborn resuscitation care. However, new research being presented at the American Academy of Pediatrics (AAP) 2019 National Conference & Exhibition found many responders lack recent training in resuscitation techniques for infants and experience in caring for newborns.

The research abstract, “When Seconds Matter: Neonatal Resuscitation in the Prehospital Setting,” will be presented on Friday, Oct. 25, at the Ernest N. Morial Convention Center in New Orleans.

“Actions taken during the first seconds to minutes after a child’s birth can make the difference between life, death, and life-long disability,” said abstract author Trang Huynh, MD, FAAP, Assistant Professor of Pediatrics and Director of Neonatal Telemedicine at Oregon Health & Science University.

“When EMS responders are called to help with an out-of-hospital birth, they need to be able to act decisively and effectively if the baby isn’t breathing,” Dr. Huynh said. However, Dr. Huynh said her team’s research shows that the effectiveness of neonatal resuscitation by EMS responders may be limited because pediatric EMS calls are infrequent, age-appropriate pediatric equipment is sparse, and first responders face unpredictable settings.

For the study, funded by the National Institutes of Health’s National Institute for Child Health and Human Development, 45 EMS teams

consisting of 262 paramedics and emergency medical technicians (EMTs) were recruited from public fire and private transport agencies in Oregon. Participants responded to questions about neonatal resuscitation training, which determined that:

66% either never had the training or completed it more than 2 years ago.

16% reported feeling very or extremely comfortable caring for children under 1 month (compared with 71% for children aged 12-18 years), and 8% were not comfortable at all (compared with 1% for children aged 12-18 years).

Half of the EMTs had not provided care for a newborn for more than a total 30 days in the last year.

The researchers also analyzed videos of EMS teams responding to out-of-hospital neonatal simulations, in which the team responded to a simulated 911 dispatch to a home for a birth in progress. Neonatal Resuscitation Program (NRP) guidelines, she said, recommend maintaining body temperature by drying and warming the baby, and using a bag valve mask within the first minute after delivery if the baby is not breathing.

The video analysis showed that 20% of the teams dried and 2% of them warmed the newborn within the first 30 seconds, as according to NRP recommendations. While 100% of teams used bag valve breathing assistance, only 9% of the teams provided it within 60 seconds, as recommended by NRP.

None of the teams had neonatal bags; all had either pediatric or adult bags. In addition, 88% of the teams bagged at a rate that was too slow (less than 40 breaths per minute), and 96% bagged with too

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much volume. Only 59% evaluated for adequate ventilation with a bag valve mask.

Dr. Huynh said the findings highlight the importance of including the needs of pre-hospital EMS in efforts to improve neonatal resuscitation. She said potential improvement interventions include EMS-specific neonatal training, refresher trainings and simulations, and EMS equipment specific for the neonatal population.

Dr. Huynh will present an abstract of the study, available below, at 6 p.m. in rooms 343-345 at the Ernest N. Morial Convention Center. To request an interview, journalists may contact her at huynt@ohsu.edu or (503) 494-2613.

In addition, Dr. Huynh will be among highlighted abstract authors who will give brief presentations and be available for interviews during a press conference starting at 12:30 p.m. on Saturday, Oct. 26, in rooms 208-209 (Press Office) of the Ernest N. Morial Convention Center. During the meeting, you may reach AAP media relations staff in the National Conference Press Room at 504-670-5406.

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Stress, Plastic Additives in Late Pregnancy Raise Risk of Premature Birth

Third trimester is the “critical window” for risk, according to Rutgers researcher

14-Nov-2019 9:00 AM EST Rutgers University-New Brunswick

Newswise — Women exposed simultaneously to stress and plastic additives late in pregnancy are at increased risk for premature birth, according to a study by Rutgers and other institutions.

The study, published in the journal *Environment International*, is the first to analyze a link between stress and phthalates — a group of chemicals in plastics, personal care products and electronics — and premature births. The findings are the latest in the Infant Development and the Environment Study, which tracked 783 women throughout their pregnancies between 2010 and 2012.

“Both exposure to phthalates and high levels of stress have been individually linked to births before 37 weeks gestation, but how these two risk factors may influence each other had not been previously explored,” said co-author Emily Barrett, an associate professor at Rutgers School of Public Health and Environmental and Occupational Health Sciences Institute. “Our research suggests that the third trimester is the critical window for these risks.”

People are exposed to phthalates by eating and drinking foods from containers and products containing the chemicals, through packaging and food handling equipment, through their skin in personal care products and in the air they breathe. While stress itself is not related to the exposure of these plastic additives, stress can affect the immune system, lead to inflammation and change hormone levels, potentially making these women more vulnerable to the adverse effects of phthalates.

Barrett said other factors — how a woman perceives stress, how she uses social supports to lessen stress and the total number of stress events in her life — can affect how stress during pregnancy affects her child’s health. The researcher recommends that pregnant women limit their exposure to phthalates by eating less processed foods and reducing use of plastics and personal care products.

The researchers analyzed urine samples throughout the women’s pregnancies for traces of phthalates and reviewed questionnaires they completed in their third trimester about stressful events — such as job loss, serious illness, family death, relationship difficulties and legal or financial problems — during their pregnancies. About nine percent of the women delivered prematurely, 70 percent of which were spontaneous.

“Mothers who had higher levels of phthalates in their urine and reported stress during their pregnancy as well were more likely to give birth preterm,” Barrett said. “We think that stress may make the body more vulnerable to the impacts of chemicals in our environment, like phthalates.”

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NT

Revised Criteria Lead to More Accurate Screening for Eye Disease in Premature Infants

CHOP Physicians Develop New Screening Approach for Retinopathy of Prematurity with Potential to Reduce Unnecessary Tests

12-Nov-2019 2:30 PM EST Children's Hospital of Philadelphia

Newswise — Philadelphia, November 14, 2019 – A multicenter group of 41 hospitals led by researchers at Children’s Hospital of Philadelphia (CHOP) has confirmed that an improved method for predicting retinopathy of prematurity (ROP), a leading cause of blindness in children, was able to reduce the number of babies having invasive diagnostic examinations by nearly a third, while raising disease detection up to 100 percent. If implemented, this screening approach could considerably reduce both unnecessary health care costs and physically stressful retinal

examinations for premature infants.

The new method described by the study team adds slow weight gain to the existing criteria for ROP screening. Slow growth is a sign of low growth hormones that are involved in the development of ROP. Because nurses routinely measure weight gain in infants, these simple measurements are readily available. The findings of the large, prospective study were published today in the journal *JAMA Ophthalmology*.

ROP is a disorder of the blood vessels of the retina that affects premature babies born with immature retinas. In general, the more premature the baby and the lower the birth weight, the greater the risk for developing ROP. Since the disease has no external signs or symptoms when it first develops, it can only be properly detected through an eye exam. Cases of ROP range in severity, with corrective laser surgery treatment sometimes required for severe cases to prevent progression and blindness.

Each year in the U.S., approximately 70,000 infants meet the existing screening criteria

and receive examinations for ROP. The current criteria have relatively low specificity for predicting which infants are at risk for severe ROP, with just 5 to 10 percent of infants screened requiring treatment, and only about half developing ROP. Additionally, while sensitivity for predicting severe ROP is very high under these criteria, it is not 100 percent with current methods. Therefore, there are opportunities to improve the screening accuracy in multiple ways.

"We developed a new set of criteria that appeared to more accurately predict ROP, but before they could be used in clinical practice, we had to test them thoroughly to ensure that all high-risk infants are examined," said Gil Binenbaum, MD, an attending surgeon in the Division of Ophthalmology and the Richard Shafritz Endowed Chair of Ophthalmology Research at CHOP, Chair of the Postnatal Growth and ROP (G-ROP) Study Group that performed the research, and the first and corresponding author of the study. In a previous study, Binenbaum and his colleagues developed the new criteria using a hybrid modeling approach that combined birth weight and gestational age criteria,

weight gain comparisons to expected growth from infants without ROP, and user-friendly screening criteria. Last year, the study team published the results of a large retrospective study of 7,483 babies that they used to develop what they called the "G-ROP criteria." They found that these criteria were more sensitive than currently used criteria and would greatly reduce the number of infants requiring examinations.

In this latest study published today, the G-ROP criteria were tested prospectively among 3,981 premature infants at risk of developing ROP across 41 hospitals in the U.S. and Canada. The researchers found that the G-ROP criteria correctly predicted 219 of 219 cases of Type 1 ROP, which requires treatment, while reducing the number of infants undergoing examinations by 36 percent. When the cohorts from the two studies were combined, the G-ROP criteria correctly predicted 677 of 677 Type 1 cases, while reducing the number of infants receiving examinations by 33 percent among the 11,464 babies.

"This study successfully validated the accu-

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racy of the G-ROP screening criteria, which now can be used clinically to reduce the number of infants receiving eye examinations for ROP,” Binenbaum said. “Based upon these new findings and the findings of our previous study, we recommend that these criteria are incorporated into national ROP screening guidelines.”

This study was supported by the National Institutes of Health grant R01EY021137.

Binenbaum et al, “Validation of the G-ROP Retinopathy of Prematurity Screening Criteria.” JAMA Ophthalmol, online 14 Nov 2019. DOI: 10.1001/jamaophthalmol.2019.4517.

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

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NT

Low Oxygen-related Release of Neurotransmitter May Lead to Heart Problems in Premies

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99nicu

Sign up for free membership at 99nicu, the Internet community for professionals in neonatal medicine. Discussion Forums, Image Library, Virtual NICU, and more...”

www.99nicu.org

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

Consider the following:

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



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

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

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

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

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



Visit www.GrahamsFoundation.org to learn more.

A new concern for premature infants involving cardiac function.

1-Nov-2019 2:00 PM EDT American Physiological Society (APS)


Article title: Long-term facilitation of catecholamine secretion from adrenal chromaffin cells of neonatal rats by chronic intermittent hypoxia
Authors: Vladislav V. Makarenko, Ying-Jie Peng, Shakil A. Khan, Jayasri Nanduri, Aaron P. Fox, Nanduri R. Prabhakar

From the authors: "Our results demonstrate that chronic intermittent hypoxia induces a hitherto uncharacterized long-term facilitation of catecholamine secretion from neonatal rat chromaffin cells in response to repetitive hypoxia, simulating hypoxic episodes encountered during apnea of prematurity. The sustained catecholamine secretion might contribute to cardiovascular morbidities in infants with apnea of prematurity."


This study is highlighted as one of November's "best of the best" as part of the American Physiological Society's APSselect program. This study was supported by the National Institutes of Health grant R01EY021137.

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NT



Did you know that
PMAD
related suicides
account for
20%
of Postpartum
Maternal Deaths?

Join  NPA
nationalperinatal.org/mental_health

**Support the
Open Letter**



**Breastfeeding
Innovations
Team**



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

**first
candle**

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

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

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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.

Advances in Therapeutics and Technology

Formerly:

High-Frequency Ventilation of Infants, Children & Adults

March 24-28 2020

For more information, contact:

Perinatal Advisory Council: Leadership,
1010 N Central Ave | Glendale, CA 91202

(818) 708-2850

www.paclac.org

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 - New Search Function

Scott Snyder, MD



"The Neonatology Solutions NICU Directory continues to grow, and now contains search functionality that allows users to find NICUs and contact information by State, NICU level, AAP District, city size, and more. The directory has surpassed the 500 mark for NICUs across the US and Canada that have complete or partial information, with new entries being added regularly. The "Currently Hiring" feature can quickly focus down to programs with known open requisitions for Neonatologist positions, and we are working hard to further capture this important content for job seekers. Additional links to community and regional information, cost of living data, and other relevant job search features are now included. Once again we wish to thank those who have contributed data to this free resource! We are so grateful!

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. Please consider participating in this grassroots effort to build a shared resource to benefit our field. Just click the link to the Directory, search for your program, and update any missing or incorrect information. There's a convenient data submission link right on the Directory, or feel free to reach out via the email below.

"Please consider participating in this grassroots effort to build a shared resource to benefit our field. Just click the link to the Directory, search for your program, and update any missing or incorrect information."


[NICU Directory](#)
[New Conferences](#)
[Career Planning](#) - [Clinical Guidelines](#) - [Parent Education](#)

NICU Level

Select One

Hospital Type

Select One

Children's Hospital

Select One

State

Select One

AAP District [\(see map here\)](#)

Select One

City Size

Select One

Currently Hiring

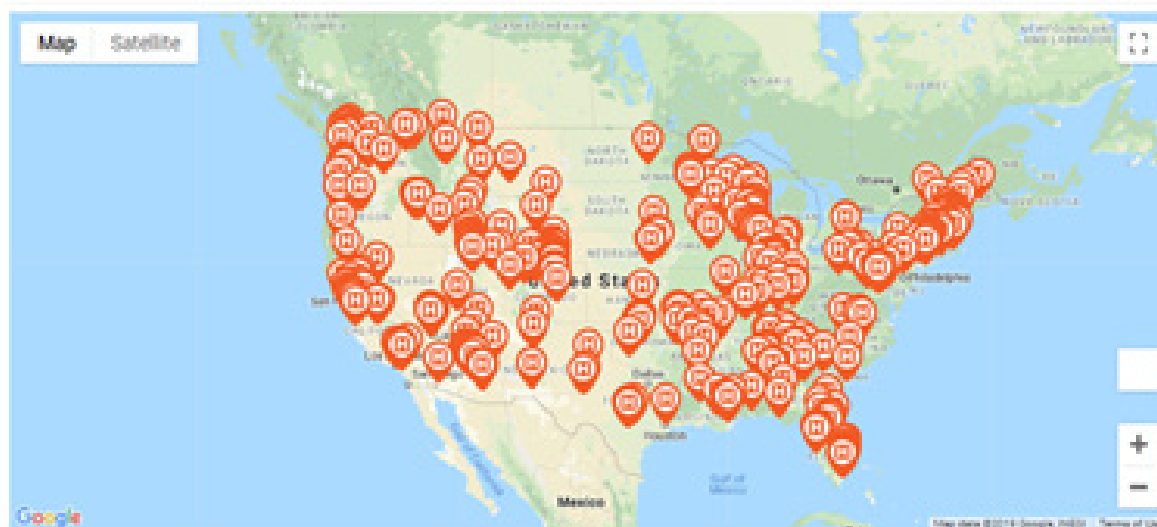
Fellowship Program

VON Member

Hospital

Search by Hospital Name

RESET



In addition, the Neonatology Solutions website provides up to date and easy to navigate resources for fellows and job-seeking neonatologists to assist them in their career planning and job search. At the recent AAP NCE meeting in New Orleans, we were pleased to receive some great feedback from fellows and TECaN members regarding the benefits of the website, as well as excellent and constructive ideas for future content. One example of suggested new content, now under development, is a roadmap and resource list for International Medical Graduates who are navigating the J-1 and H-1B Visa process.

We always welcome comments and feedback on how to make the resource more useful and relevant." <https://neonatologysolutions.com/contact-us/>

References:

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

The author is a principal of Neonatology Solutions, LLC.

NT

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Corresponding Author



Scott Snyder, MD, FAAP
System Medical Director
St. Luke's Neonatology
Founder
Neonatology Solutions, LLC
Scott Snyder Scott@neonatologysolutions.com





Ireland



- 4,500 preterm births
- 1 in every 16 women deliver preterm
- Leading causes:
 - 23% unknown
 - 22.6% ruptured membranes
 - 19% high blood pressure / pre-eclampsia / HELLP syndrome

2012 data National Perinatal Reporting System (NPRS)

6.4%
prematurity rate



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

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.

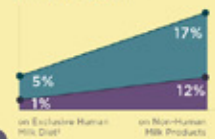


VERY LOW BIRTHWEIGHT BABIES are at risk for Necrotizing Enterocolitis (NEC), which:

- 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:



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:



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 ▶



¹ Park BJ, et al. "Hospital Mortality Following Necrotizing Enterocolitis: Implications for Survival in the Exclusive Human Milk Diet Cohort." *Journal of Pediatric Gastroenterology and Nutrition*. 2017; 64(5):581-587.
² Alvarez SE, et al. "Growth Standards and Mortality in Extremely Premature Infants Fed a Cow's Milk-Containing Diet." *Pediatrics*. 2014; 134(5):e126-132.
³ Park BJ, et al. "Mortality and Implications of Surgical Necrotizing Enterocolitis in Very Low Birthweight Infants: A Prospective Cohort Study." *Journal of Pediatrics*. 2017; 184:101-108.
⁴ Alvarez SE, Park BJ, et al. "Survival and Hospital Length of Stay in Very Low Birthweight Infants: A Retrospective Cohort Study." *Journal of Pediatrics*. 2014; 165(5):911-918.

Genetics Corner: A Consultation for Wolf-Hirschhorn Syndrome

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

Case Summary:

A 9-week-old female had a cleft palate, dysmorphic features, and poor growth caused by Wolf-Hirschhorn syndrome (WHS). She was seen in Genetics Clinic a few weeks after lab results, that had been drawn as a newborn, established the diagnosis. The fetal size was small for gestational age throughout the pregnancy, but fetal movements were normal. The baby was born at a nearby community hospital at term by vaginal delivery to a 22-year old G2P1 mother. The birth weight was 2.49 kg (Z -1.89). She did not require intensive care. She could not latch on to the breast, but she fed from a bottle. She referred bilaterally on her newborn hearing screen.

Chromosome analysis had been sent, without the family's knowledge, before the baby was discharged home with her mother. The results identified a deletion of chromosome 4 at 4p16: 46,XX,del(4)(p16), establishing the diagnosis of Wolf-Hirschhorn syndrome (WHS).

The mother received these abnormal chromosome results by phone when her pediatrician called her a few weeks later, while

she was driving. The mother recalls being told only that her daughter had a "serious chromosome abnormality" and would be referred to Pediatric Genetics to discuss the results in detail.

"The results identified a deletion of chromosome 4 at 4p16: 46,XX,del(4)(p16), establishing the diagnosis of Wolf-Hirschhorn syndrome (WHS)."

In the first weeks of life, she had frequent spit-ups while feeding. Gastroesophageal reflux was diagnosed. Her maternal grandmother was the first to notice her cleft palate at a few weeks of age.

Genetics Evaluation:

The family history was noncontributory. Her interval growth was poor: Weight 3.28 kg (Z -3.71). On physical exam, she had facial features consistent with WHS, including prominent glabella, hy-



Figure 1: This 12-month-old female has the classic facial features of Wolf-Hirschhorn syndrome. Note her widely-spaced eyes, broad and high forehead, prominent glabella, and arched eyebrows. Her philtrum is short.

ptertelormism, hypoplastic eyebrows, broad nasal bridge, v-shaped cleft of the soft palate, wandering eye movements, and hypotonia.

A same-day evaluation was arranged for her in the multidisciplinary Craniofacial team clinic for cleft palate evaluation, where she was given special bottles and instructed in feeding techniques for cleft palate. An echocardiogram and renal US were ordered: atrial septal defect and right ventricle dilation and right pelviectasis were detected. Chromosome microarray identified a 7.32 MB interstitial deletion of 4p16.3->p16.1: arr[hg19] 4p16.3p16.1(1,020,130-8,339,745)x1.

When she was evaluated again at 12 months of age, she was small but doing well developmentally. Her weight was 5.4 kg, (Z -4.45, but 50th%ile on the WHS syndrome specific growth charts.) She said, "mama," waved bye, responded to her name, and to sounds. She was socially engaged and "danced" for her mother. She bore weight well and stood with support but was not cruising.

Discussion:

Wolf-Hirschhorn syndrome (WHS), which is also called 4p minus syndrome, is caused by a variable deletion of the short arm of chromosome 4 (the "p" in p arm is an abbreviation for petit). WHS has a birth prevalence of 1 in 20,000-50,000 live births, and females predominate in a ratio of 2F:1M. Multiple congenital anomalies may contribute to the infant mortality of 17%.

WHS is characterized by a typical craniofacial appearance in infancy. The face is said to give the impression of a 'Greek warrior helmet' with a wide bridge of the nose in continuity with the prominent forehead and arched eyebrows. Microcephaly is common. In this patient, her providers recognized that her features were dysmorphic, but they were not confident enough to broach this with the mother. Her facial features are typical for WHS. There is a high anterior hairline with prominent glabella, widely spaced eyes, epicanthus, highly arched eyebrows, short philtrum, downturned corners of the mouth, and micrognathia small lower jaw). Poorly

Breaking bad news

Set up the interview	Maintain privacy, sit down, have enough chairs for everyone, involve significant family members, as desired by parents, minimize interruptions, have tissues handy	
Assess parent perceptions	Ask parents how they think the infant is doing What is their understanding of the situation	
Invite participation	Give parents the choice of how much information they would like to receive at that time	
Communicate effectively	Avoid jargon (aneuploidy, trisomy, syndrome), pause frequently to allow a response, use drawings or pictures, avoid being excessively blunt	
	<table border="0"> <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> </table>	Use: "I'm sorry to have to tell you this" "I know this is not good news for you" "
Use: "I'm sorry to have to tell you this" "I know this is not good news for you" "	Avoid: "You knew....this was a possibility" "I see this all of the time" "I know what this must be like"	
Address parents' emotions	Listen, observe and acknowledge their emotions	
Provide summary of information and resources	End with a summary of recommendations. Keep it simple. Give written information.	

Figure 2. Breaking bad news to the parents

formed ears with pits/tags (1) are common. Other findings include feeding problems, including GE reflux, oral clefts, both cleft lip and/or cleft palate, skeletal anomalies (60%-70%), congenital heart defects (~50%), hearing loss (mostly conductive) (>40%), urinary tract malformations (25%), and structural brain abnormalities (33%). Seizures occur in 90-100% of children with WHS and can be triggered by fever. Almost one third later develop valproic acid-responsive atypical absence seizures (1).

“The fact that this baby’s medical providers did not diagnose her cleft palate at birth is unfortunate but not surprising. Needless to say, careful examination of the palate should be routine in all newborn babies, but especially in those who are small at birth, dysmorphic, or have trouble feeding. (It has been our personal observation that a tongue blade is more difficult to find in most nurseries than a high-frequency ventilator.) ”

All individuals with WHS have a variable degree of hypotonia, developmental delay, and later, intellectual disability. Poor growth is universal in WHS. Growth deficiency is of prenatal-onset, and it continues postnatally. WHS should be considered whenever a dysmorphic baby has an unexplained small size for gestational age.

The fact that this baby’s medical providers did not diagnose her cleft palate at birth is unfortunate but not surprising. Needless to say, careful examination of the palate should be routine in all newborn babies, but especially in those who are small at birth, dysmorphic, or have trouble feeding. (It has been our personal observation that a tongue blade is more difficult to find in most nurseries than a high-frequency ventilator.)

Approximately 50%-60% of individuals with WHS have a de novo deletion of 4p16; about 40%-45% have an unbalanced translocation with both a deletion of 4p and a partial trisomy of a different chromosome arm that can be inherited from an unaffected parent with a balanced chromosome translocation. Parental chromosome analysis with fluorescence in situ hybridization for 4p16 is recommended to rule out a cryptic balanced translocation in an unaffected parent.

Unfortunately, the manner in which this mother was informed of her daughter’s diagnosis (by phone, while driving), was traumatic

for her. The pediatrician did not offer any information about the condition, which also added to her anxiety. This news was all the more upsetting to this mother because it came as a surprise. She was unaware that her daughter’s doctor suspected a problem. Then she had to wait for an appointment in our clinic to get any information about her daughter’s condition.

With a little preparation, this situation can be avoided. It is better to prepare parents for the possibility of an abnormal result by letting them know whenever any consequential testing (genetic or otherwise) has been ordered prior to discharge. Let them know you will be calling them with the results as soon as it becomes available after discharge. When results are available, set up a time when both parents can be present and deliver the news in person. Use resources, such as GeneReviews, that provide useful summaries of many rare disorders: type “GeneReviews” in the search field at www.pubmed.gov to search through their offerings. Here are some practical tips to use when breaking the bad news to patients and family members based on the SPIKES 6-step protocol.

Practical applications:

1. Consider Wolf-Hirschhorn syndrome in dysmorphic infants who are small for gestational age.
2. Evaluate newborn infants for congenital anomalies when they are dysmorphic, SGA, or feed poorly without an explanation.
 - a. Begin with a thorough physical examination and include the palate (find and use that tongue blade).
 - b. Order imaging studies: echocardiogram, abdominal/renal and head ultrasounds
3. Apprise parents of genetic testing at the time the test is ordered. Share your concerns. Parents may be less anxious about it when you explain that you are trying to be thorough.
4. Use the protocol above when you have to break bad news. These steps help reduce the trauma for patients and families when receiving bad news
5. Consult the disorder summary at GeneReviews before speaking to the parents so you can offer basic information before referring to a specialist

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References:

1. GeneReview summary on Wolf-Hirschhorn Syndrome by Battaglia, A., Carey, J., & South, S. <https://www.ncbi.nlm.nih.gov/books/NBK1183/>.

Permission was obtained from the patient's parents to distribute her picture for education purposes.

The authors have no relevant disclosures.

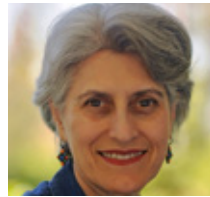
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The Gambia



Perinatal Deaths:

- 29% Preterm birth complications
- 29% Intrapartum related events
- 21% Sepsis, meningitis, tetanus
- 9% Congenital abnormalities
- 6% Pneumonia
- 6% Other conditions

13%
prematurity rate



Perinatal Substance Use

5 ways you can improve care during pregnancy and beyond

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



Educate Yourself

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



Use the Right Words

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



Screen Every Patient

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



Get Trained to Offer MAT

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

*opioid treatment program



End the Stigma and Criminalization of Drug Use

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

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TOP 10



RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

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

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

1 PROMOTE PARTICIPATION

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



2 LEAD IN DEVELOPMENTAL CARE

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



3 FACILITATE PEER SUPPORT

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



4 ADDRESS MENTAL HEALTH

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



5 SCREEN EARLY AND OFTEN

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



6 OFFER PALLIATIVE & BEREAVEMENT CARE

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

7 PLAN FOR THE TRANSITION HOME

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



8 FOLLOW UP

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

9 SUPPORT NICU CARE GIVERS

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

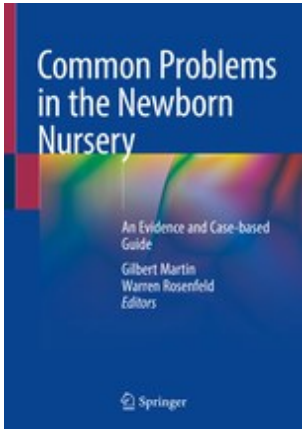


10 HELP US HEAL

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

SUPPORT4NICUPARENTS.ORG

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



Common Problems in the Newborn Nursery An Evidence and Case-based Guide

- Provides practical, state of the art management guidance for common clinical problems in the newborn nursery
- Written by experts in the field in a clear, easy-to-use format
- Utilizes a case-based approach

This comprehensive book thoroughly addresses common clinical challenges in newborns, providing an evidence-based, step-by-step approach for their diagnosis and management. *Common Problems in the Newborn Nursery* is an easy-to-use, practical guide, covering a full range of clinical dilemmas: bacterial and viral infections, jaundice, hypoglycemia, hypotonia, nursery arrhythmia, developmental dysplasia of the hips, newborn feeding, cardiac problems, late preterm infants, dermatology, anemia, birth injuries, ocular issues, and hearing assessments in the newborn.

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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Denying Preventive Treatment Can Have Life-threatening Consequences

Julie Ann Burton



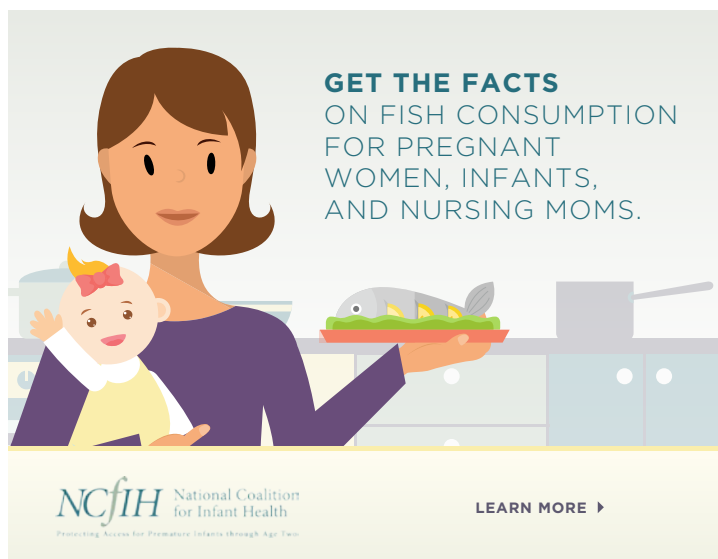
The National Coalition for Infant Health is a collaborative of more than 180 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education,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

There we were, in the same hospital where my son Deskin's twin brother, Jake, passed away at just two days old. Fear washed over me. I looked at my husband, "How did we end up back here?" I asked.

It all started with our insurance company. They denied preventive treatment for respiratory syncytial virus, or RSV when Deskin was three years old. In previous years, Deskin had received the treatment, safeguarding him from the deadly seasonal virus. But at three years old, he no longer qualified, according to the guidelines.

We were told our only option was to pay for it out of pocket – thousands of dollars for monthly doses throughout RSV season. I'm a teacher, and my husband works in commercial insurance. We simply didn't have tens of thousands of dollars lying around. So I tried to convince myself that Deskin was stronger, that he was healthier.

He was, in a way.



Deskin had been born in the 24th week of gestation and spent nearly ten months in the hospital before being released with a tracheostomy tube, ventilator, and oxygen. He progressed year after year, and, at age three, he started preschool with a nurse accompanying him every day.

"Our boy, who had been almost totally weaned off of oxygen, needing just 1/16 of a liter per minute, now needed four liters per minute. A visit to the doctor confirmed he had RSV. "

The school did an excellent job of telling us if another kid was sick, and we kept Deskin home at the first sign of a sniffle. We took every possible precaution to keep him well. We cleaned surfaces, we washed hands, and we disinfected toys. But just before Thanksgiving, he started to get ill.

Our boy, who had been almost totally weaned off of oxygen, needing just 1/16 of a liter per minute, now needed four liters per minute. A visit to the doctor confirmed he had RSV. My heart sank. I knew how serious it was for any toddler, let alone one with Deskin's health history.

He was admitted to the hospital. The doctor wanted to put Deskin back on a ventilator, something my husband and I resisted because we knew Deskin didn't like the machine. We relented knowing it was what he needed. When Deskin didn't fight the ventilator, I was terrified. It suddenly hit me how very sick and helpless he was, how precarious our situation had become.

Soon, diagnoses of pneumonia and rhinovirus followed. Deskin's fever spiked. For nine days, we watched our son get nebulizer treatments, multiple chest x-rays, rounds of steroids. We helped hold him down for procedures and comforted him as he had reactions to new medicines. One made his eyes red and swollen shut.

It was all scary for my husband and me, traumatizing for Deskin. And it was certainly not how our family wanted to spend Christmas.

When he was finally released, our home was once again filled with medical equipment and supplies we'd gotten rid of long ago. There was an increase in our home nursing services too.

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I was so thankful Deskin survived. But amid my joy was frustration. All of the heartache and hundreds of thousands of dollars of medical expenses could have been prevented. Our insurance company's unwillingness to provide a critical treatment wound up costing it – costing all of us – much, much more.

Insurance guidelines built on generalities hurt children like Deskin. Turning three didn't make Deskin's still-fragile lungs magically strong enough to withstand RSV. The special health circumstance of kids like him, who remain medically fragile even as they grow older and slowly stronger, who still use a tracheostomy tube, who still require some oxygen, should be considered.

“Despite all we went through, I consider us lucky. I know other parents whose stories have a much sadder ending – all because their insurers, like ours, were too rigid to make an exception and cover a treatment that could have saved their children’s lives.”

Despite all we went through, I consider us lucky. I know other parents whose stories have a much sadder ending – all because their insurers, like ours, were too rigid to make an exception and cover a treatment that could have saved their children’s lives.

I understand that insurers can't hand out costly medicines indiscriminately. But neither should they cling to generic guidelines when a patient's unique circumstances require a different course of care. In the end, health care that acknowledges each child's needs is the economical thing, the right thing, and the human thing to do.

Disclosures: The author does not have any relevant disclosures.

NT



National Coalition for Infant Health Values (SANE)

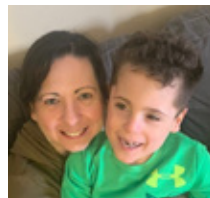
Safety. Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

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

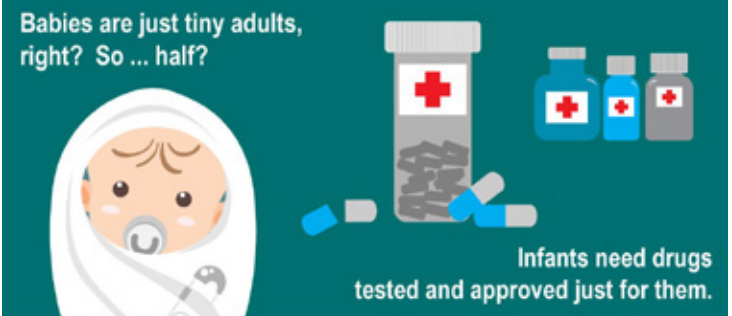
Nutrition. Proper nutrition and full access to health care keep premature infants healthy after discharge from the NICU.

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

Corresponding Author



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Coalition for Clinical Trials Awareness NCfIH National Coalition for Infant Health

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Are you bubbling?



respiralogics

Canada



- Preterm birth accounts for two thirds of infant deaths in Canada.
- The cause of 70 percent of preterm births is unknown.
- The proportion of all births represented by preterm births remained fairly constant throughout the period 2000 to 2013.

7.8%
prematurity rate



SOURCES: Canadian Institutes of Health Research



Brazil



- The United States and Brazil both rank among the top 10 countries with the highest number of preterm births.
- Late preterm was the largest category, accounting for 74% of preterm births.
- Provider-initiated preterm births were 39.3% of the total, due almost entirely (90 %) to pre-labor cesarean section.

11.2%
prematurity rate ↑



SOURCES: WHO, Partnership for Maternal, Newborn & Child Health 2018.
Prevalence and risk factors related to preterm birth in Brazil. *Reprod Health*. 2016; 13(Suppl 3): 127.



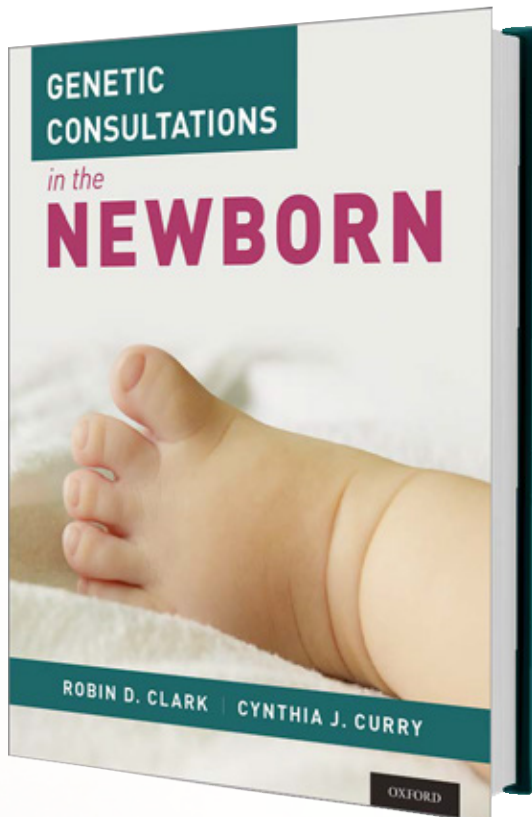
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OXFORD

RSV AWARENESS:

A National Poll of Parents & Health Care Providers

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

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

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

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

KEY FINDINGS

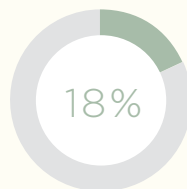
Preparedness

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

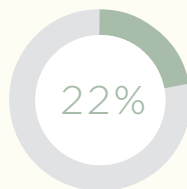
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

PARENTS

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

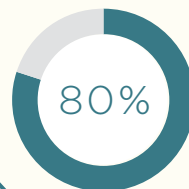


Only 22% of parents consider themselves “very well prepared” to prevent RSV.

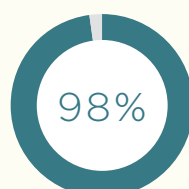


SPECIALTY HEALTH CARE PROVIDERS

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



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



Clinical Pearl:

Young and Old and Your Academic Career in Medicine

Joseph R. Hageman, MD

*"When you are young, you try to make your way...
When you are old, you try to prove you still have something to contribute" (me).*

I had finished my fellowship in neonatology and gotten a job at the hospital of my dreams with a wonderful group of mentors, nurses, respiratory therapists, and clerks. I had a research lab and was asking what we thought were good research questions. I was making my way and was an Assistant Professor of Pediatrics... first in the research and then in the clinical track. I was very active, clinically, and pretty productive as an author...I won the teacher of the year one year from the residents from Children's Memorial Hospital, Northwestern University. I was making my way to Clinical Professor of Pediatrics as well. I got some chronic illness that resulted in not being able to continue practicing as a pediatric hospitalist and pediatric intensivist, apnea doc anymore, and had to retire clinically.

But thanks to the support from my family, friends, colleagues, I was able to reinvent myself. And medicine still had so much to offer! The affiliation changed and I had the opportunity to teach medical students, residents, and fellows from the University of Chicago, and again, thanks to friends and colleagues, I began going to Comer Children's Hospital to teach and help residents with their research projects and became the director of pediatric resident research. Still making my way...but not so young anymore. Fifty-seven years old but still full of life. Thirty national presentations by the residents and over 100 published papers, all but a few were case-based reviews, small case series but a few published in mid-impact level journals. First publications for a lot of the authors.... it was a lot of fun.

"I lost it for about 10 minutes, but thanks to my friends and colleagues, and five shocks, I got it back...at age 62. After five years at Comer and U of Chicago, I got the chance to be Director of NICU Quality Improvement at Comer Children's Hospital."

I lost it for about 10 minutes, but thanks to my friends and colleagues, and five shocks, I got it back...at age 62. After five years at Comer and U of Chicago, I got the chance to be Director of NICU Quality Improvement at Comer Children's Hospital. I am still teaching medical students how to present history and physical examinations. I have the opportunity to be the editor in chief of Pediatric Annals and serve on the editorial board of NeoReviews (2012-2018) and now, Neonatology Today.

Today, almost 68 years old next month, and just finished a couple of national QI presentations and am publishing an editorial and a clinical pearl each month. Over 250 publications, of which the last 160 have been in the last ten years since I have been trying to prove I still have something to contribute.

I am also working as a mentor with the NICU and mother-baby, and obstetrical nurses, neonatal nurse practitioners, as we work on QI projects about safe sleep, and projects for those nurses who are in graduate school for doctorates as nurse practitioners. I have also felt honored to be able to work with the nurses, since the time I was a new faculty member in 1983 at Evanston Hospital in the Infant Special Care Unit trying to make my way, till now, when I am still trying to prove I have something to contribute.

BYW, I am a senior clinician-educator, Pritzker School of Medicine, University of Chicago, and it has not slowed me down at all. I do have the advantage of having 37 (1982-2019) years of experience as an attending pediatrician...reinventing myself with lots of help and support along the way...and still going strong. Parenthetically, I am also still a Professor Emeritus of Pediatrics, as well. I repeat that to myself on a regular basis and when I am asked to write letters of support for your pediatricians who are trying to make their way.... And for some older pediatricians who are working toward promotion in the clinical tracks of their universities.

The major point to be made for those of you who are my colleagues in various stages of your academic careers in medicine is, no matter what challenges you may face along the way, and no matter how you find that you have to reinvent yourself, you still do have something to contribute!

I am reading a book entitled ["The Eureka Factor: Aha Moments, Creative Insight, and the Brain"](#) by Cognitive Neuroscientists, [John Kounios](#) and Mark Beeman and the question I keep asking myself is, is this an "aha moment, the result of creative insight, or analytic thought"...a process that has led me to this conclusion?

That is, the quote that I came up with early one morning a few weeks ago and it was after I started reading this book...

The way Kounios and Beeman describe an "aha moment or creative insight" seemed consistent with how this quote popped into my mind, and at the same time, the quote sounds like the conclusion of an analytic process based on 37 years of experience and thought.

Here is how the authors, neuroscientists Kounios and Beeman, define an aha moment or creative insight: "they have two key features. The first one is they pop into your awareness, seemingly out of nowhere. They don't feel like the product of your ongoing thoughts...they yield a different way of looking at things" (1).

What is also really interesting is how they describe the "more

gradual, conscious process that cognitive psychologists call 'analytic' thought. This involves methodically and deliberately considering many possibilities until you find a solution" (1).

References:

1. Kounios J, Beeman M. *The Eureka factor: Aha moments, creative insight, and the brain*. New York: Penguin Random House. P. 7.
2. *Ibid.* p. 10.

The author has identified no conflicts of interest.

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 1250 word limit not including references or title page.
 May begin with a brief case summary or example.
 Summarize the pearl for emphasis.
 No more than 7 references.
 Please send your submissions to:
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Which Infants are More Vulnerable to Respiratory Syncytial Virus?

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

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

*Source: Respirator Syncytial Virus and African Americans

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



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



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EARLY INTERVENTION services?

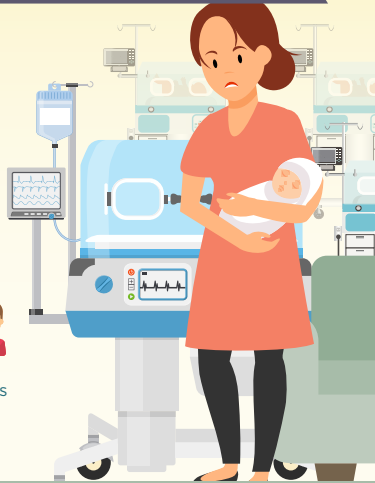
Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges



1 in 3 preterm infants will require support services at school



Early intervention can help preterm infants:



Enhance language and communication skills



Build more effective learning techniques



Process social and emotional situations



Address physical challenges



Prevent mild difficulties from developing into major problems

Early diagnosis could qualify babies for their state's **early intervention services**...

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



NICU staff, nurses, pediatricians and social workers should talk with NICU families about the challenges their baby may face.

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



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

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

Survey Says: **RSV**

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

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

for infants and young children.



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

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

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

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



But Parents are Unprepared.

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

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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

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



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Online survey conducted September 2018. Included US specialty health care providers and 100 parents of children 1-4 years old.



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Letters to the Editor

11/15/19

LETTER TO THE EDITOR: NEONATOLOGY TODAY

MITCHELL GOLDSTEIN, M.D.

Dear Dr. Goldstein:

I read with interest the two articles appearing in the October 2019 issue of Neonatology Today, dealing with early infant death and the response by healthcare professionals in talking with the parents and other family members. The first entitled "What It's Like When your Baby Has Died," written by Allison Jacobson, the CEO of First Candle, which is an organization that supports families after a loss; the second, entitled "Breaking the News: Suggestions for Telling Parents That Their Baby Has Died. From a Bereaved Mother's Perspective", written by Nancy Maruyama, RN, BSN. Both articles are very personal and describe their own personal tragedies.

Ms. Maruyama reaches further and offers guidance to Health Care Professionals in dealing with families after a loss. There are many personnel involved in this entire process, Physicians, Nurses, Ancillary personnel (social work) and Clergy.

I would appreciate some further comments dealing with the physician's role in dealing with this situation. Is the physician the organizer of the process? What can the doctor do to make this situation both professional and personal at the same time?

Gilbert I. Martin, MD

Professor, Pediatrics

Loma Linda University Children's Hospital

Dear Dr. Martin,

Thank you for your comments. The loss of a child is one of the most difficult things for a parent to endure. There are certainly effects on the physician as well. As a practicing neonatologist this situation is unfortunately something that sooner or later occurs in the course of any practice.

Certainly, the physician can be part of the process, but whether it is appropriate for the physician to be the organizer depends on the physician's relationship with the family and how the family feels about the physician's involvement in the process.

As we learned from both of these pieces, there are many things



that we as physicians stumble on and are less capable of when it comes to bereavement. Loss is not a normal part of practice, and it takes a great deal of introspection, sympathy, and education to fully meet the needs of a grieving family.

Yes, the physician can be the organizer of the process, but not absolutely. There may be other members of the team who are more qualified because of their connection to the family and interpersonal dynamics that may make it harder for the physician to relate to an individual circumstance.

Whether the physician is the organizer or not, involvement at some level is obligatory. A message of sympathy, a quiet word, sitting down and having a heart to heart conversation with the family can go a long way towards helping answer the questions and concerns about what happened. We may not have the answers from the medical perspective, but we can provide the personal level of support that will help the family through the most difficult of times.

Sincerely,

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

Mitchell Goldstein, MD

Editor in Chief



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Mitchell Goldstein, MD
 Professor of Pediatrics
 Loma Linda University School of Medicine
 Division of Neonatology
 Department of Pediatrics
mgoldstein@llu.edu

Erratum (Neonatology Today October, 2019)

Neonatology Today has identified an erratum affecting the October, 2019 edition. Scott Snyder's name is misspelled in the table of contents of this edition. NT regrets this error.

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

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

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

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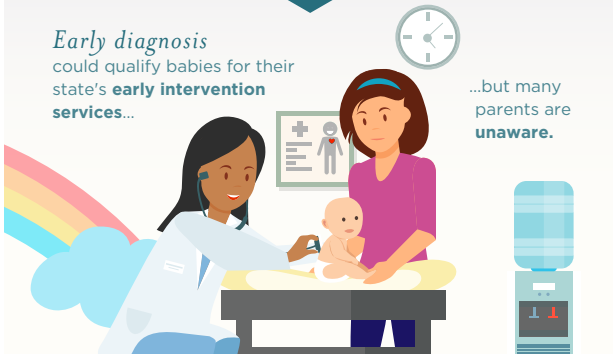
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PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSTPARTO



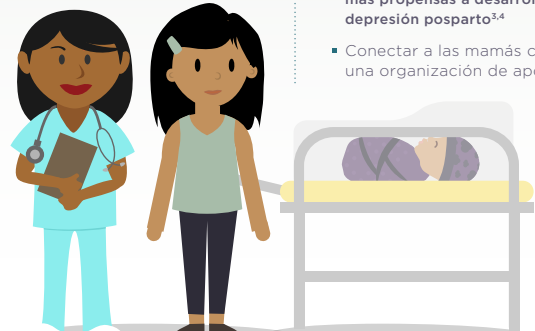
LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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



LOS HOSPITALES PUEDEN:

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



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

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

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

**The Premier Board
Review Course in
Neonatal-Perinatal Medicine**
February 17-22, 2020
<http://specialtyreview.com>

**33rd Annual Gravens Conference on
the EOC for High Risk Newborns**
March 4 - 7, 2020
University of South Florida (USF)
Health
Clearwater Beach, Florida
[https://health.usf.edu/publichealth/
chiles/gravens-conference](https://health.usf.edu/publichealth/chiles/gravens-conference)

**26th Annual Cool Topics in
Neonatology**
March 6 - 8, 2020
California Association of
Neonatologists
Coronado, California
[https://caneo.groupsites.com/main/
summary](https://caneo.groupsites.com/main/summary)

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

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

**1st Annual Innovations in Maternal,
Fetal, and Neonatal Medicine**
March 27 - 29, 2020
Johns Hopkins All Children's
Hospital
St. Petersburg, Florida
[http://www.cvent.com/events/the-
annual-innovations-in-maternal-
fetal-and-neonatal-medicine-the-
continuum-of-care-conference/
event-summary-772b578c0e5348d3b
ba8a80915ffcac8.aspx](http://www.cvent.com/events/the-annual-innovations-in-maternal-fetal-and-neonatal-medicine-the-continuum-of-care-conference/event-summary-772b578c0e5348d3bba8a80915ffcac8.aspx)

**Pediatric Academic Societies 2020
Meeting**
April 29 – May 6, 2020
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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Academic Neonatologist Opportunity in Southern California

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

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

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

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

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
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EOE/AAE

Who We Are

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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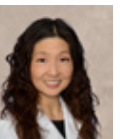
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Theodor Yasko, MD, MBA
Special Projects Coordinator

Neonatology and the Arts

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

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.

The birds are at it again. Dr. Douglas Deming from the Division of Neonatology at Loma Linda University Children's Hospital submitted this stunning group he noticed at the entrance to the Summer Palace (Beijing, China) in the foreground of an arrangement of sculpture and flowers.



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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.

10. Only manuscripts that have not been published previously will be considered for publication except under special circumstances. Prior publication must be disclosed on submission. Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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