

NEONATOLOGY TODAY

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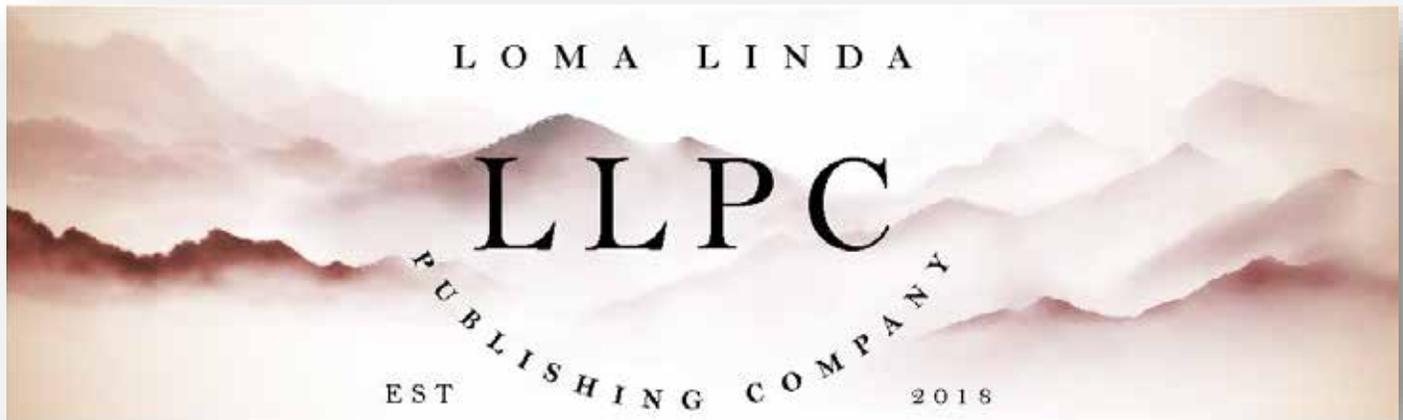
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CPR Training of Parents of Preterm Babies before Discharge - Experience from a Tertiary Care NICU

Mathew Jisha, MBBS, DNB, Nagar Nandini, MBBS, DCH, DNB, Rajagopal Kumar Kishore, MBBS, DCH, MD, FIAP, DCH, MRCP, FRCPC, FRCPI, FRACP, FNNF, MHCD

Abstract:

Objectives:

To evaluate the feedback of CPR training given to parents of preterm babies discharged from the NICU.

Methods:

This was a retrospective study conducted using a questionnaire sent to parents of preterm neonates admitted to a neonatal intensive care unit (NICU) from January 2007 to May 2020. All parents of newborns under 30 weeks gestation who survived to discharge were considered eligible. Parents were given CPR training on a manikin by a Neonatal resuscitation provider (NRP) certified doctor. Babies less than 30 weeks were sent home with a disposable bag and mask after the training of the parents. The responses thus received were analysed.

Results:

We analysed data from 60 responses (48.3%). 85% of the parents were given one-on-one training, the rest as classroom training. 68.3% felt that the addition of video demonstrations would be beneficial. 95% of parents said that the training helped increase their confidence in taking care of their babies. 78% felt it did not add to unnecessary parental anxiety. 5 babies received CPR at home, and all were told that the home CPR was successful on assessment at the hospital after the episode. 65% felt a repeat training would be helpful. All the parents educated about CPR opined that this training is essential for discharge preparation.

Conclusion:

We conclude that parental CPR training backed by video demonstration prior to the instructor-led session and followed by repeat training after 3 months is desirable in the holistic care of preterm babies post-discharge.

Keywords - Critical care, Patient education, Discharge policy

Key Message - Routine CPR education of parents of preterm neonates, backed by video demonstration and repetition of training after 3 months is desirable; it improves the confidence of parents and reduces anxiety in the care of their premature infants.

“Routine CPR education of parents of preterm neonates, backed by video demonstration and repetition of training after 3 months is desirable; it improves the confidence of parents and reduces anxiety in the care of their premature infants.”

Introduction

Cardiopulmonary resuscitation (CPR) is an emergency lifesaving procedure performed when the heart stops beating. Around the turn of the 20th century, preterm infants were discharged only when they achieved a certain weight, typically 2000 gm(5lb). Studies (1-3) have shown that preterm neonates can be sent home earlier without adverse health effects based on physiologic criteria rather than body weight. Evidence has shown that preterm neonates with low birth weight who require neonatal intensive care experience a much higher rate of hospital readmission and sudden deaths during the first year after birth than healthy term infants (1,4). The most important predictor of infant survival from an acute life-threatening event (ALTE) is the time from cardiopulmonary arrest to resuscitation (2,3,5,6). More so in neonates, this is the case, who are likely to suffer a respiratory arrest that responds quickly to resuscitation (7). This emphasizes the importance of systematic preparation for discharge and good follow-up thereafter of high-risk preterm neonates to reduce the chances of such life-threatening events (4).

“This emphasizes the importance of systematic preparation for discharge and good follow-up thereafter of high-risk preterm neonates to reduce the chances of such life-threatening events (4).”

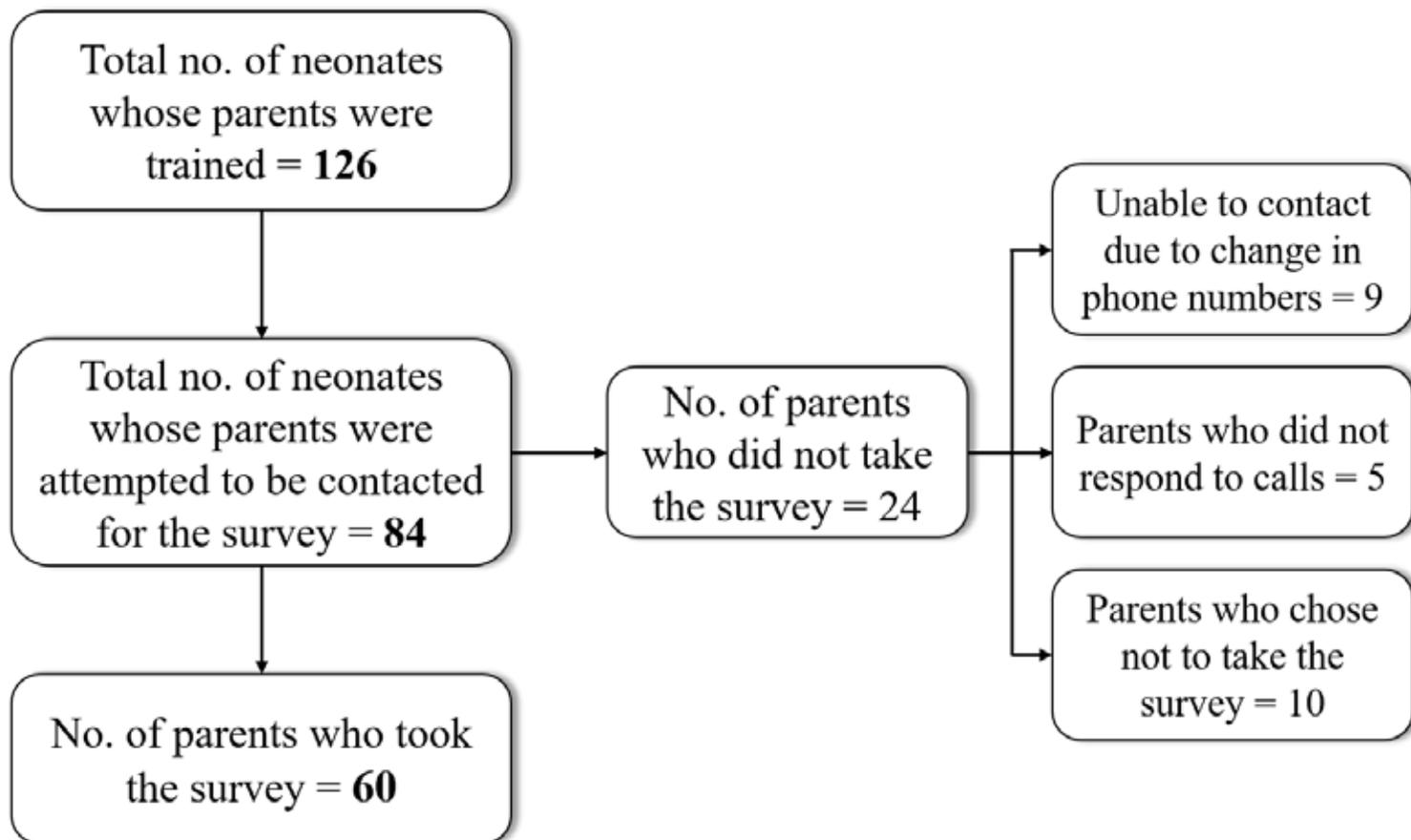
Preterm neonates should demonstrate some physiologic competencies before being discharged from the hospital. These include oral feeding sufficient to support appropriate growth, thermoregulation in a home environment, and sufficiently mature respiratory control. The first two are usually achieved around 34-36 weeks' postmenstrual age (4,13,19), but the maturation of respiratory control to the point that allows safe discharge may occasionally take up to 44 weeks' postmenstrual age (6,7). Infants born as very or extremely preterm and have a prolonged and complicated stay in the hospital tend to take longer to achieve these competencies. But they may be discharged home much earlier if they exhibit thermostability and reasonable weight gain, as plotted on the Fenton's growth chart. NICU graduates are discharged when they satisfy the above criteria. Their parents have demonstrated the necessary skills to provide all care components at home, including CPR,

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should the need arise.

At the time of discharge, most parents lack confidence and are anxious about their capability to handle the babies at home. Hence, we thought that our intervention of training parents of neonates born <34weeks would help in the holistic care of these babies, including handling emergencies at home post-discharge. Many studies have emphasized that pre-discharge infant cardio-pulmonary resuscitation training is essential or highly desirable. As shown by literature, it is a routine pre-discharge requirement in most developed countries, but this training is not reported or published in our country. Based on our hospital protocols, we initiated this training at its inception 13 years ago. We wanted to review our data over these years to see if it has made an impact or a difference.

“As shown by literature, it is a routine pre-discharge requirement in most developed countries, but this training is not reported or published in our country. Based on our hospital protocols, we initiated this training at its inception 13 years ago. We wanted to review our data over these years to see if it has made an impact or a difference.”

Materials and methods:

This retrospective study was conducted at a tertiary care neonatal intensive care unit in India from January 2007 to May 2020. Informed consent for the survey was taken, and the Institutional Review Board approved the study. Initially, only parents of babies less than 30 weeks gestation were being given the training to perform CPR; however, since December 2019, due to a change in the unit protocol, all parents of babies with gestational age less than 34 weeks were admitted to the NICU were trained and included in the study. Babies (less than 30 weeks initially and less than 34 weeks later), deceased, and babies more than these respective gestational age groups were excluded. Parents of these babies were given CPR training (AHA NRP guidelines) in a language they could understand using a manikin, on the day of the transfer to wards or discharge from the NICU, by an NRP-certified doctor who is recertified every 2 years. The training included a brief description of CPR, when it needed to be initiated, and the steps of CPR, and ended with a physical demonstration of the same on a manikin. Parents were also given a chance to practice the steps on the manikin. Each session lasted around 20 minutes. At no additional cost, a new disposable self-inflating bag and mask were procured for each of these neonates and sent home at discharge after their parents underwent CPR training. The authors prepared a questionnaire/survey in English or the local language on request, with 22 questions. Parents were first called and spoken to and were then messaged a web link to complete this survey. All parents had access to the internet and the necessary device. The data from the survey was later analysed and reported.

Table 1. Overview of the survey

| CHARACTERISTICS | Total number n=60 (%) |
|---|----------------------------------|
| Gestational age of the baby at birth (weeks) | |
| ≤ 28 | 13 (21.6) |
| 29-31 | 19 (31.6) |
| 32-34 | 28 (46.6) |
| Single/Multiple births | |
| Singleton | 33 (55) |
| Multiple gestations | 27 (45) |
| Mode of CPR training | |
| One on one session | 51 (85) |
| Classroom session | 9 (15) |
| No. of those who wanted an addition of video demonstration | 41 (68.3) |
| Did you receive training with bag and mask? | |
| Yes | 35 (58.3) |
| No | 25 (41.7) |
| No. of parents who wanted to be taught the use of bag and mask | 38 (63.3) |
| Would you be able to identify the need for CPR in your baby? | |
| Yes | 54 (90) |
| No | 6 (10) |
| Do you think it increased your confidence level in the care of the baby? | |
| Yes | 57 (95) |
| No | 3 (5) |
| Do you feel the training caused unnecessary anxiety and nervousness? | |
| Yes | 13 (21.6) |
| No | 47 (78.4) |
| No. of people that felt that the training was an essential part of discharge | 60 (100) |
| No. of parents who do not remember all the steps of the training | 20 (33.3) |
| No. of parents who want repeat sessions within | |
| > 3 months | 20 (33.3) |
| < 3 months | 17 (28.3) |

Results:

During the study period, parents of 126 preterm babies were trained, out of which parents of 84 neonates were attempted to be contacted. The overall response rate to the survey was 71.4%, as shown in Figure 1. We analysed the data of 60 responses we received, and the following results refer to only those that participated in the survey. 46.6% of the babies were between 32-34wks as seen in Table 1. 27 were twins (with one survivor of a pair), and the rest were singleton babies. 85% of the parents were given one-on-one training, the rest as classroom training; however, only 23% of these parents perceived that classroom training may be better than one-on-one training. A majority of 95% found that the training given was easy to follow, and 68.3% thought that providing a video demonstration and one-on-one training would be more helpful. Bag and mask were used in 58% for demonstration. Only

manikins with the demonstration of mouth-to-mouth breathing and chest compressions were used for the rest. 63.3% of parents thought it would be good to use a bag and mask for training.

“A majority of 95% found that the training given was easy to follow, and 68.3% thought that providing a video demonstration and one-on-one training would be more helpful.”

Table 2. Demographics of babies who received CPR at home

| CHARACTERISTICS | No. of neonates | |
|---|---------------------------|---|
| No. of babies who received CPR at home | 5 | |
| Gestational age | ≤ 28 weeks | 1 |
| | 29-31 weeks | 2 |
| | 32-34 weeks | 2 |
| When did it happen | 0-1 week after discharge | 3 |
| | > 1 month after discharge | 2 |
| How many recovered quickly at home | 4 | |
| How many were told of successful CPR by the Doctor on reaching the hospital | 5 | |

Of the total number who responded, 92% understood in what way CPR helped babies in an acute life-threatening event. 90% of them felt that they could identify when their babies required CPR.

“Most parents (95%) said that the training helped increase their confidence in taking care of their babies. 78% felt it did not add to unnecessary parental anxiety. 5 babies received CPR at home.”

Most parents (95%) said that the training helped increase their confidence in taking care of their babies. 78% felt it did not add to unnecessary parental anxiety. 5 babies received CPR at home. Of these babies, 3 received CPR in the first week after discharge and 2 after a month since discharge from the hospital, as shown in Table 2. 4 recovered from the episode quickly following home CPR. All parents correctly followed the steps as they had been advised to initiate CPR according to the assessment at the hospital after the episode. These parents, who found themselves in a situation that needed CPR, felt that they could execute it as taught.

67% of parents said that after three months, they could still recollect the steps of CPR taught during the training session. The need for repetition of training was felt by 65%, and they opined that it should be conducted after a time interval of 3 months since the last session. All 60 parents educated on CPR thought that this training is an essential part of discharge preparation.

Discussion:

The American Heart Association (AHA) educates more than 9 million persons annually about CPR. Parents need to be trained in infant CPR. In the United States, 2230 infants (<1yr of age) died of sudden infant death syndrome (SIDS) in 2005, making it the third leading cause of death there. Drake et al. found that parents considered CPR a priority when asked to rank discharge teaching topics in order of importance (8-10).

We chose to do this study as CPR training is an important aspect of pre-discharge preparation for parents of preterm babies, as has

been shown previously (10). Still, it is not routinely being done in most hospitals in our country, as evidenced by the lack of literature on the same. We hypothesised that getting feedback from parents who had received training in infant CPR would give us an overview of the effectiveness and scope for improvement of what we consider an essential practice.

“Still, it is not routinely being done in most hospitals in our country, as evidenced by the lack of literature on the same. We hypothesised that getting feedback from parents who had received training in infant CPR would give us an overview of the effectiveness and scope for improvement of what we consider an essential practice.”

Conventionally, CPR is taught using a combination of didactic instruction and hands-on practice, followed by a written test. Most of our parents had one-on-one training sessions, occasionally a group training. It was a manual demonstration, and in response to the questionnaire, parents did express that a video-backed demonstration would be more helpful. Brannon et al. used an instructional video as an adjunct to the instructor-led demonstration. The group concluded that CPR is a psychomotor skill, so learning it requires more than just acquiring knowledge. Practice with a manikin is essential to ensure competence. An effective video instruction, while most likely cannot totally replace an instructor-led class, could be helpful in learning infant CPR (11).

A literature review by Parsons et al. (12) opined that teaching infant CPR to parents of high-risk neonates is considered beneficial in decreasing mortality. However, the evidence for this is very limited. The overall trend is supportive of CPR training. It increases parental confidence and decreases anxiety levels. Parents’ memory of knowledge regarding CPR decreases over time. Our survey also showed similar findings. At discharge, the training did seem

to have boosted their confidence in taking care of their newborn, and it did not add to the overall anxiety among most parents.

In those instances where CPR was required at home, parents could resuscitate and then bring their infant to the hospital for continuing care. It was heartening to learn that the training was hugely successful, considering that most parents had understood when to use CPR and how it helps resuscitate. The aim is to increase this to 100%. Parents of one baby who required home CPR could not self-assess the effectiveness of CPR given. Henceforth, our training should also focus on educating parents on assessing the baby post-resuscitation. All parents were given adequate pre-discharge teaching regarding other aspects of their preemies' care and the resuscitation training that we provided.

Wintch et al. showed that 80% (4/5) of their subjects who required CPR post-discharge survived complete resuscitation efforts after full cardiopulmonary arrest and were neurologically intact (14). In all of our 5 babies who required home CPR, parents had correctly followed the steps as they had been advised to initiate CPR as per the post-resuscitation assessment done once they reached the hospital.

“The AHA gives CPR training kits to parents of high-risk neonates at discharge at a nominal fee. Providing these kits to carry home may also be useful (14,15). Hence, we also provide a complimentary manual resuscitator kit with masks of two sizes to parents of those born <30weeks and neonates born at 30-34 weeks who are discharged after a very stormy course in NICU.”

The AHA gives CPR training kits to parents of high-risk neonates at discharge at a nominal fee. Providing these kits to carry home may also be useful (14,15). Hence, we also provide a complimentary manual resuscitator kit with masks of two sizes to parents of those born <30weeks and neonates born at 30-34 weeks who are discharged after a very stormy course in NICU.

The inability to retain learned CPR skills has been researched. Studies have documented deficits in retention and performance skills beginning as early as 2 weeks after initial instruction, with continued deterioration up to one year later (16,17). The peak incidence of SIDS occurs between 1 and 4 months of age (18), so long-term retention of infant CPR skills is critical. Therefore, it has been reported that 3 to 6 months after initial instruction is the optimal timeframe for recertification. Most of our parents, too, felt the need for a repeat training session 3 months after the first one (rearranged words).

The limitation of this study was the sample size, which could have been better. The contact details of many parents were either changed or unavailable. There is also an element of recall bias as the survey was conducted after a long time for some. One of the

main reasons for more responses from parents in recent years was a better recall. As it was a retrospective study, contacting and convincing parents to take the survey was arduous. Not all parents agreed to participate. Some did not receive phone calls and some responded by saying they were busy and would not be able to complete the survey. Also, during the study period, there was a change in unit protocol, and parents of all preterms <34weeks were being trained instead of those only <30 weeks, as was done previously. We noticed that there were babies in the gestational age group of 30-34weeks who had episodes of apnoea at home and thereby changed the Unit protocol to include these parents to improve outcomes in these babies. The study's strengths were the simplicity of the survey method used and the number of responses we received, considering that the oldest of the babies whose parents responded was born 13 years ago.

“Our study shows that parental CPR education seems to have improved their confidence in the care of these preemies and has not added to general parental anxiety. All parents also agreed that it is an essential step in the pre-discharge planning of preterm babies.”

Conclusion:

Our study shows that parental CPR education seems to have improved their confidence in the care of these preemies and has not added to general parental anxiety. All parents also agreed that it is an essential step in the pre-discharge planning of preterm babies. Parental CPR training backed by video demonstration before the instructor-led session and followed by repeat training after 3 months is vital in the holistic care of preterm babies post-discharge and is highly recommended at all centres catering to this major subgroup of neonates admitted to the NICU.

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Conflicting Interest (If present, give more details): Nil

Ethical clearance: Cleared by the Institutional Ethics Committee

Contributor details -

Dr. Mathew Jisha - Coordinated and collected data, drafted the initial manuscript, carried out the initial analysis, and reviewed the manuscript.

Dr. Nagar Nandini - Conceptualized and designed the study, supervised data collection, revised the manuscript, critically reviewed it, and was the guarantor for the study.

Dr. Rajagopal Kumar Kishore - Critically revised and reviewed the manuscript for important intellectual content.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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“Storyteller” painting by Sharron Montague Loree, 1982

Letters to the Editor

Please Consider Spreading the News of a Targeted Way to Help Ukraine: Caritas Texas-Registered Charitable Non-Profit in Texas

Subject: Please consider spreading the news of a targeted way to help Ukraine: Caritas Texas-registered charitable non-profit in Texas

From: **Andriy Batchinsky** <abatchinsky@genevausa.org>

Date: Fri, Apr 29, 2022, at 1:13 PM

<https://www.mightycause.com/story/Caritastexasusall4ukraine>



CaritasTexas provides medical and humanitarian aid to those affected in Ukraine and to refugees

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Dear all:

CaritasTexas is an official charitable organization formed and registered in Texas by a Ukrainian-born surgeon Andriy Batchinsky MD. It was created specifically to support those affected and displaced by war and carry out medical education and training for physicians caring for them.

In contrast to large organizations advertised on TV and mass media soliciting donations for non-specified general causes, Caritas Texas strives to deliver focused help through personal medical school classmates and colleagues of the founder on the ground as well as to churches, orphanages, facilities for handicapped and volunteers to assist with aid on the ground and based on specific needs.

The fundraiser will consist of multiple projects in the order of urgency and based on the need on the ground.

The current urgent need and collection are toward purchasing tourniquets and first aid kits to be delivered to Ukraine and save lives of those with hemorrhage due to gunshot wounds and explosions/trauma.

Upon completing the first urgent project, funds will be diverted to medical supplies in hospitals near the frontline, next to humanitarian aid to refugees distributed through churches, orphanages, and volunteering groups assisting with refugee camps.

100% of raised funds go toward the mission and associated expenses such as shipping etc. No salary or personal expenses unrelated to the cause will be paid.

Please email usall4ukraine@gmail.com with any questions or suggestions

Twitter: @BatchinskyA

Here is another way to help Ukraine, which I am doing through personal contacts. If you would, please consider sending it through your social media contacts.

If you are able, please spread the news to people you know to maintain the integrity of the link and avoid hackers as much as possible.

As a current priority, we are putting together an order for 15000 IFAK kits, I spoke to the owner of North American Rescue, and they will give a special discount on products.

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Also, note that I have a dedicated email: usall4ukraine@gmail.com, but it would go to spam folders if I sent it from this address.

Mitch, thank you, you are the best.

AB

Andriy Batchinsky MD

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Dear Dr. Batchinsky,

Thank you very much for reaching out to Neonatology Today. For many years, I have heard your lectures at Snowbird regarding the logistics of delivering care to those engaged in military deployments worldwide. Although these logistics often defy traditional considerations, they are critically important in teaching those of us who practice in any field of medicine to think outside the proverbial box.

The current situation in Ukraine presents a very different paradigm. We see the desperation of a people persecuted for no reason other than meaningless greed and senseless aggression. Although the United States and its NATO allies are not engaged in this war, many of us have already reached out in any way that we can to assure that essential medical supplies reach a population with such extensive needs.

Although this war affects the Ukrainian population as a whole, mothers and babies are particularly impacted. No location is sacred; no location represents a safe haven. Much needs to be done, and time is of the essence.

Neonatology Today stands with you, Dr. Batchinsky, and your efforts to help raise funds for this effort.

Should there be a hesitancy in donating because the organization is not yet federally recognized as a not-for-profit, Loma Linda Publishing, a 501 C-3 not-for-profit (dba Neonatology Today), will forward 100% of all donations received for Dr. Batchinsky's organization directly to him.

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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Mitchell Goldstein, MD, MBA, CML

Editor in Chief

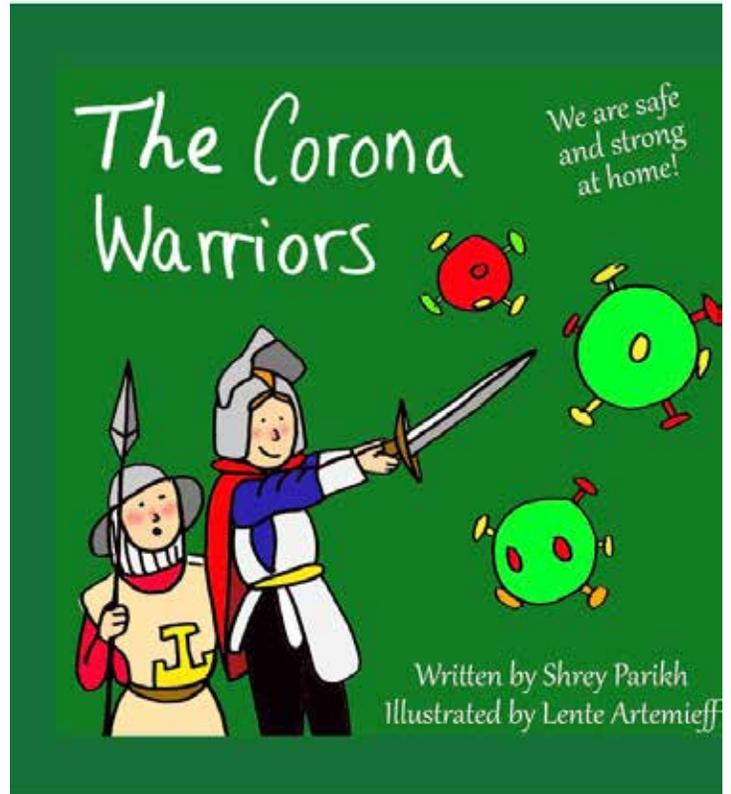


Erratum (Neonatology Today April, 2022)

Neonatology Today is not aware of any erratum affecting the April, 2022 edition.

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

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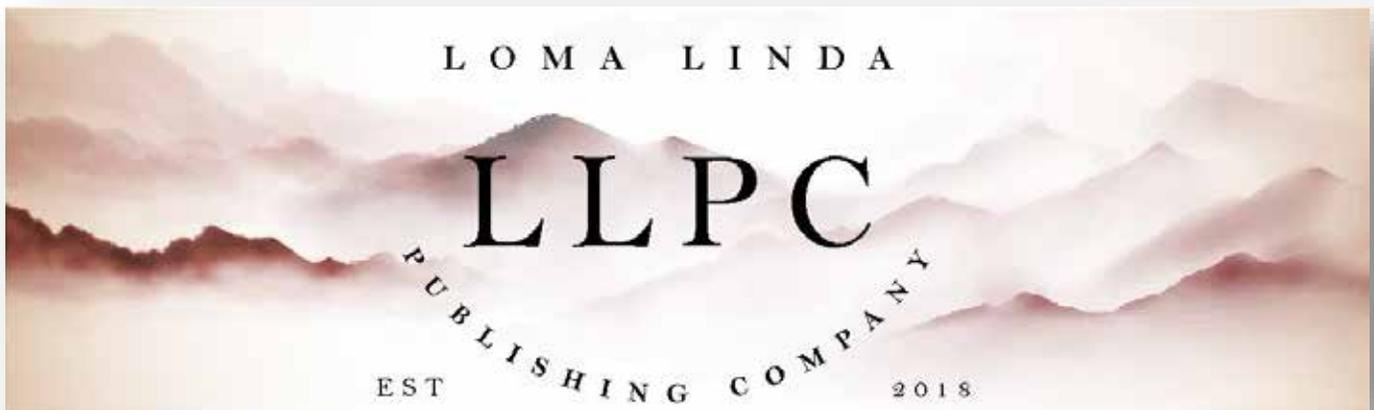
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NT Behind the Scenes: Jeeva Informatics, the Humanitarian Non-Profit Indo US Organization for Rare Diseases

Kimberly Hillyer, DNP, NNP-BC



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The following is an amended transcript for Neonatology Today Media of Dr. Kimberly Hillyer and Dr. Harsha Rajasimha.

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"Jeeva Informatics Solutions is a digital health platform designed to provide a human-centric approach utilizing software technology to help clinical researchers and families dealing connect."

Introduction:

Thank you for joining us on today's broadcast. I'm Dr. Kimberly Hillyer, a Nurse Practitioner and the Media Correspondent for Neonatology Today. This segment features Dr. Harsha Rajasimha.

Dr. Harsha Rajasimha is the Founder and CEO of **Jeeva Informatics Solutions** (<https://jeevatrials.com/>). Jeeva Informatics Solutions is a digital health platform designed to provide a human-centric approach utilizing software technology to help clinical researchers and families dealing connect.

Dr. Hillyer: Thank you for joining us today, Dr. Rajasimha. You have an interesting journey in which you merged your educational concentration in computer software and engineering with the development of human genome sequencing. It seems like it's two very distinct pursuits. Can you explain how you put it together?

Dr. Harsha Rajasimha: Absolutely. I was graduating from my computer science engineering college at Bangalore University in India. I was coming for a Master's and PhD. program at Virginia

Tech in Blacksburg, Virginia, in 2000. That was the year when the Human Genome Project was being completed. Then it was announced that it was really complete in 2002 when the annotations and the gene labels were all getting more cleaned up and formed up, and then again in 2004. So, the Human Genome Project has undergone minor revisions and new versions with the newer assemblies and annotations.

"Even the promise of curing many of those diseases by fixing those potential genes, which may be causative of all genetic diseases. Almost all human diseases have some genetic component. So, the promise and potential of the human genome was enormous and too enormous to ignore."

That was super exciting to me at that time, coming from a computational background to get into the human genome. It seemed to have so much promise and potential to understand human health, aging, and diseases. Even the promise of curing many of those diseases by fixing those potential genes, which may be causative of all genetic diseases. Almost all human diseases have some genetic component. So, the promise and potential of the human genome was enormous and too enormous to ignore.

I started specializing in computational biology within the computer science department and later went on to specialize in my Ph.D. in the highly interdisciplinary program called Genetics, Bioinformatics, and Computational Biology. So, as I was going through those early days between 2000 to 2007, it was mostly bacterial and viral genome sequencing data that we were analyzing with the 454 and the early sequencers as well as the microarray chips. With the advent of the Illumina sequencers coming out in 2007, mammalian genomes could also be sequenced. Then eventually, the entire human genomes could be sequenced at an affordable price point. Now they have, of course, come down close to \$1,000, and you can purchase the human genome sequence using a credit card for most Americans at least. It's becoming affordable in different parts of the world, including India, where the population is more than 1.3 billion. So, it's a really exciting space. A lot of computational algorithms to do string matching, string comparisons, comparative genomics, and even doing hierarchical analysis of the evolutionary basis of human evolution.

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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Dr. Hillyer: Now, after building academic expertise during the genomic boom. Your life merged with this new technology, and this journey became more personal. Can you describe that experience?

Dr. Rajasimha: So, it's been an exciting journey between 2000 to now. In the last 22 years, my career has spanned the National Institutes of Health at the Cancer Institute, the Eye Institute, and the FDA. Really the turning point for me was in 2012 when I had the experience of having a baby born, going to the Neonatal ICU—having to be put immediately in the NICU, and was diagnosed with Edward Syndrome, or Trisomy of chromosome 18. My daughter was named Kahushi. I have two daughters, one before and one after that incident, but the middle daughter Kahushi had Edwards syndrome and did not survive past four or five days in the NICU. So that experience really exposed me to genetic disease, congenital disease, and what patients and families go through in getting a diagnosis. In our case, we got a very quick diagnosis, but the majority of patients with rare diseases go through a seven-year diagnostic odyssey. If they eventually get a diagnosis, it may take about seven years on an average, and then, if they are lucky to be within the 7% or so of diseases that have FDA-approved treatment. Then they have some hope. If not, a majority of patients and diseases do not have any approved treatments.

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Dr. Hillyer: I'm so sorry that you had to go through this heartbreaking and life-transforming ordeal. As you were enduring this, you realized the connection between clinical trials for families dealing with rare diseases and gene therapy. Can you tell me more?

Dr. Rajasimha: So, the best thing that could potentially happen to that group of patients is that there's a clinical trial that they may enroll in, which potentially is a life-saving or curative treatment such as gene therapy. A majority of these known genetic diseases are monogenic and can be essentially fixed using gene therapy, which in simple terms is a treatment that goes in and corrects the mutation in every gene, in every cell, in the affected organ systems.

Certain diseases may only affect the muscle cells or the neuronal cells, or retina, etc. So, the technology is really getting better and more accurate. Certain challenges still have to be overcome, but with much hope and promise, close to 400,000,000 patients with a rare disease can really hope to enroll in a clinical trial or gene therapy. That's where the technologies and Neonatology with genome sequencing offer the opportunity to diagnose thousands of these rare genetic diseases in a single test. That's the promise and potential of genome sequencing.

Dr. Hillyer: By understanding the personal challenges for those with a rare disease and envisioning the future of genetics. You decided that your time with Kahushi, even if it was short, as her father, you would give her a legacy. You were able to combine this technology and advocate for families with a rare disease. Can you tell me about this new life work of yours?

Dr. Harsha Rajasimha: Absolutely, I never felt like I had a job in my entire career, as I really loved my job as a scientist between 2000 to 2012. After 2012, of course, after the life-changing experience of Kahushi being born and passing away. I really could feel the pain of many parents and families that go through this with children. What if the baby had survived and with a lot of special needs? Whether in a wheelchair with limited vision, hearing, and other disabilities. Parents go through a lot, sacrifice thirty years, and change their location and their lifestyle in a very significant way. You know, it becomes a financial, economic, and professional burden on not just the patient but the entire family. So, I started empathizing with that, and I felt like I had to be grateful that that was not the case in our case in some sense, but it could have been if it was a different medical condition, a chronic condition in which patients have to live with. There was so much more work to be done that essentially brought alignment and direction to my career, which was already involved in rare diseases to a great extent in my publications and research but also bringing the patient perspectives.

“That's when the FDA was really advocating for Patient-Focused Drug Development, the PFDD, and had started setting up a patient affairs team at the FDA, which engages with patient advocacy groups and also engages within patient listening sessions where patients with rare diseases were invited to speak, what matters to them for a given rare disease.”

That's when the FDA was really advocating for Patient-Focused Drug Development, the PFDD, and had started setting up a patient affairs team at the FDA, which engages with patient advocacy groups and also engages within patient listening sessions where patients with rare diseases were invited to speak, what matters to them for a given rare disease. What kind of symptoms are families and patients most concerned about? What kind of drugs and treatments would they like to see? That would really help improve their quality of life. As many times cures are not available, but



only palliative treatments or treatments that address one or more symptoms of the disease but do not necessarily cure the cause of the disease. So, it was very important that the FDA allowed the sponsors to listen to what patients had to say and focus on addressing those problems.

It became clear to me that it was very important to the involved in patient advocacy, and informing and educating patients and families is such a critical component. In the United States, there are many nonprofit organizations and foundations, such as the National Organizations for Rare Diseases and also the Global Genes, which work not just in the United States, but on a global scale, helping very early-stage rare disease groups and also mature rare disease groups to work towards patient focus drug development with having the ultimate goal of finding treatments or cures for genetic diseases.

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When I look back at other countries outside of US and Europe, most countries do not have good patient advocacy and nonprofit ecosystem, and that's what I took the vision to India in bringing together a team of philanthropists and parents to form the National Organization for Rare Diseases in India from 2013 to 2019. I was co-chairing the board and contributed to establishing that as a sustainable nonprofit. Then in 2019, I founded the Indo-US Organization for Rare Diseases, which addresses a gap in rare diseases, genetic diseases, ecosystem, which is lack of genetic data, and engagement of the rest of the world with the US and Europe. Now, most of the genetic databases are American and European datasets, which is less than 10% of the world's population. So, we need to really do good science and understand the comprehensive genetic makeup. We need to look at data sets coming from the entire world or the representative of the rest of the world. That was a significant gap that I thought we should address. That's the goal of Indo-US Rare, to bridge collaboration between the United States and the Indian subcontinent, which together form more than a quarter of the world's population. There's also a need to engage Latin America, Africa, and the other neglected regions of the world. So, those are the gaps that we address through advocacy and nonprofits.

Now, technology innovation is also a critical component of this,

and that's my engineering background in computer science and data science during my doctoral dissertations. So, I continue to see how technology innovation can help address these problems. That's where I founded Jeeva as a software service platform posted on the cloud to help clinical researchers accelerate the clinical trial process. Going from phase one, phase two, and phase three clinical trials to getting a regulatory approval which has a very time-consuming process and can cost upwards of two and a half-billion dollars to get one successful therapy to market. Now that's very unsustainable because to spend ten to twelve years of R&D and spend two and a half-billion. Now in rare diseases, there are not enough patients to recover the cost of the investment. So, it's very important that we want to speed up the process as patients are waiting and dying. But also achieve that acceleration without increasing the cost.

In fact, there is a need to decrease the cost by a couple of orders of magnitude for it to be made affordable and accessible to patients, not just in the rest of the world but even to patients in the US or Europe. That's the goal of Jeeva. Jeeva literally means life. Jeeva Informatics is analyzing and helping accelerate patient recruitment, patient retention, and patient engagement in a very flexible, easy manner where patients don't have the undue burden of having to travel to a clinical trial site or a hospital whenever it's not necessary. Making the whole process go streamlined and faster. That's what we do at Jeeva as a technology innovation company.

Dr. Hillyer: You've pointed out ways Jeeva Informatics can help, but it starts with the correct diagnosis. Can you tell me about your experience with Kahushi once you received the diagnosis? Did you have an opportunity to participate in a clinical trial?

“What we were told is that you know this is not a viable baby. The baby is not compatible with life, and that was devastating for me to see my wife hear directly from a doctor. With much hope, we had the second baby, and so that was a pretty disheartening and disappointing experience.”

Dr. Harsha Rajasimha: Yeah, that's a very heartbreaking experience to recollect, Kimberly. Immediately at birth, the Neonatologist observed the visual cues on the baby and predicted that it was Trisomy 18 or Edward Syndrome but sent the samples for confirmatory testing. Then the baby was immediately put on ventilators and in the NICU. What we were told is that you know this is not a viable baby. The baby is not compatible with life, and that was devastating for me to see my wife hear directly from a doctor. With much hope, we had the second baby, and so that was a pretty disheartening and disappointing experience. How that was communicated to us, as to what the diagnosis was, and what it meant. It took us a couple of days to recover from the shock and understand what really was going on. By the time we got the confirmatory diagnosis, we were told you may want to get prepared

to pull the plug because you can't keep the baby on the ventilator forever. If you want to do that, we can do that, but it may be twenty days or ten months, but the baby is not going to be viable. You need to make a decision very soon. So, we had a consult with the spiritual leaders from the faith that we follow, Hindu. We contacted the Hindu priests on what's the right thing to do in a situation like this.

“ In this particular instance, there was no clinical trial going on. No clinical trial aimed to treat or cure Trisomy, so there was no such option. But there are many diseases where that's not the case; about 2,200 clinical trials are registered on clinicaltrials.gov that aim to develop interventions to help patients with rare diseases.”

We had to make the tough decision of having to not forcefully hold the life. You know the baby is unable to sustain life on her own, and we had to let her rest in peace. So, we had to pull the plug on day four, which was a very tough decision and thing to do.

In this particular instance, there was no clinical trial going on. No clinical trial aimed to treat or cure Trisomy, so there was no such option. But there are many diseases where that's not the case; about 2,200 clinical trials are registered on clinicaltrials.gov that aim to develop interventions to help patients with rare diseases. If the child happens to be in that category, then certainly enrolling in a clinical trial would have been the best thing to do, but that was not the case in our case.

The most important thing to note is that getting that faster diagnosis is the very critical first step. Then 93% of the time, rare disease patients fall in a category where there is no FDA-approved treatment. The best thing that they can try and do is be part of databases. Be proactive in identifying patient registries for a particular rare disease or be part of the natural history study, unlike common conditions, like diabetes, cardiovascular, metabolic, and cancer, where the natural history and the progression of how the disease progresses in patients are well understood. There's a number of patients in most countries, and doctors are gathering data researchers are studying that. So, there is a lot of information available and known to understand the natural progression of a disease. Whereas for rare diseases, that's very poorly understood because not many doctors are educated in rare diseases, necessarily. They are not experts or specialized in rare diseases. Medical Genetics is a profession where if it happens to be a genetic disease, which 80% of rare diseases are, they can hopefully help diagnose faster using genome sequencing or other genetic testing methods. Once that's done, the important thing to understand is these genetic diseases are very simple from a genetic test point of view. There are these monogenic diseases. There is a single gene there's a mutation that causes a particular disease, like cystic fibrosis. If there is a mutation in the CFTR gene, it causes cystic fibrosis. When you look at the symptoms, those can be very com-

plex. They may affect multiple organ systems, and the severity of symptoms may vary from patient to patient. Even within the same patient, the severity may vary over a period of time. Also, which symptoms are more severe or less severe, can be very significant. So, there's a lot of heterogeneity in the symptoms that have homogeneity or consistent, easy single mutations. Single gene mutations are easy to diagnose from a genetic point of view.

What that means is that we need to understand the symptoms or the phenotypes of these patients and understand that's called the Natural History Studies. The FDA and NIH have been proponents in advising the rare disease communities to focus on building these patient registries and natural history databases that are a necessary prerequisite before a treatment can be developed for a given rare disease.

No good tools were available, and even now, there is a scarcity or lack of good affordable, well-designed technologies that can enable faster creation and maintenance. Because these studies may go on for five, ten, fifteen-year duration over a long period of time. It's important to have the necessary patient engagement. The patient should come back and be able to report the data and how the child or the patient is progressing over an extended period of time to help the researchers and doctors understand the disease better. Only then can they find potential treatment options and measure whether the treatment actually helped or not. That's what we enable with the Jeeva technology platform is a consistent, easy, simple, and affordable way of collecting data, engaging patients from the convenience of their homes in uploading lab reports, being able to share data, answering questionnaires, and signing electronically informed consent forms for data sharing. So, that's before the clinical trial begins, during the patient registry and natural history study phases. Once the trial begins, that's where the Biotech and Pharma companies get involved, and they are regulated by the FDA. The more premium version of our software helps Biotech Pharma companies set up and configure a complex clinical trial protocol within our system and run the entire clinical trial, and engage patients during the course of an actual clinical trial. So, it does both.

Dr. Kimberly Hillyer: Thank you for helping us gain perspective from the parents' side of obtaining these types of diagnoses -- Then further describing the aspects of a clinical trial. How can healthcare providers connect and collaborate with Jeeva Informatics? Do we have to wait until the child is born and have the genetic testing done before we can utilize your software?

Dr. Rajasimha: Great question. They can do both at the very early stage or after the baby is born. Either way. It just depends on the goals of the particular group. We are not a clinical care or a Neonatology hospital software. We are software specifically meant for the use of clinical research and for research use only. Hence it depends on the goals of the research that particular neonatology group may be conducting. For example, there is a hospital here in Fairfax which is working on preterm birth, studying, and understanding preterm birth. So, any baby that's born seven months or sooner will be enrolled in a clinical study to understand the mothers' parameters, the babies' parameters, the genetics, the symptoms, and the environmental factors. What causes certain babies to be born premature or preterm? If that is the goal, then certainly the neonatologists will have to be engaged very early during the pregnancy and start a collection of data. They could be leveraging the Jeeva software to enroll mothers, and expectant

mothers. Early during pregnancy, using our apps and a collection of data even after the baby is born, there may be certain sample collection, lab reports, and data collection that may need to occur after the birth.

“If they want to study the comparative study of before, on after, or compare the effectiveness of two different nutritional supplements, or say a certain treatment option meant for treating certain”

So, depending on the goals of a particular research study. All of this is plausible; it's also possible that certain Pharma companies, you know, like Johnson and Johnson, may make baby products and or even for expectant mothers, like the nutritional supplements. If they want to study the comparative study of before, on after, or compare the effectiveness of two different nutritional supplements, or say a certain treatment option meant for treating certain babies with the genetic diseases. That's where Jeeva comes in. The sponsor, either a Biopharma company or a Neonatology clinical researcher, can subscribe to the Jeeva software, which is very simple and easy to set up and it's a subscription-based service. If they have a three-month study or a three-year study, they only need to subscribe for the duration. They need only the features of the software. We have a very comprehensive suite of features for telemedicine, video conferencing, electronic informed consenting, collection of patient-reported outcomes, or obtaining and performing certain critical assessments by the Neonatologist on sort of babies or mothers. Not all of these features may be necessary for every single study because we have modular software; they can pick and choose the specific modules that are relevant to their particular clinical research and can subscribe only to those modules as well.

Dr. Hillyer: There are a lot of elements to what I hear your software is being able to offer. Thinking about one of the barriers you brought up earlier, you highlighted the global discrepancies regarding clinical trials when the concentration of work is in European and US countries. When clinical trials focus on less than 10% of the world, it is apparent that healthcare needs to work on incorporating a framework addressing diversity and the lack of inclusiveness that brings about disparities in the US and globally. How does Jeeva help to bring about change with this software technology?

Dr. Harsha Rajasimha: Great question. You know a number of different ways. One aspect is that most of the clinical trial enrollment has historically been restricted to clinical trial sites. In these neonatology units, for example, if it's a newborn scenario, not all mothers are necessarily going to the hospital systems unless they are in metropolitan areas. Many even now, in the United States, a lot of mothers give birth to babies in their homes, or in the bathtub, or in multiple ways. Having midwives and doing deliveries at home, and other modes of giving childbirth. So, it's very important that we, one reach out to patients and communities and mothers who may be living in far-off regions, rural areas, mountain areas, and other hard-to-reach geographies. These medically underserved populations, who are less likely to go and access the

healthcare system in major medical research centers, which is where clinical trials usually happen. In the community setting, the mothers, even if they go to a community hospital, they will never be offered in a clinical trial. Just because those hospitals are not involved in clinical trials.

It's very important that we enable reaching out on social media, for example, on the internet, and whoever has access to a digital device can now be accessed.

In the United States, 82% of the people have access to stable internet and access through some digital device to the internet. Whereas historically, less than 2% of patients or subjects are offered the opportunity to enroll in a clinical research study. Going from 2% to 82%, if you can go on the internet and inform and educate the potential mothers, who can enroll in a clinical study, that's a significant leap, and that's what the Jeeva software enables that, bring your own device. Where anyone can enroll with any device, whether it's a smartphone, tablet, computer, or laptop, it doesn't matter as long as it's a device with a browser and internet connection. They could be potentially reached through some channel, like Facebook or social channels or email or SMS. We offer multi-channel communication, engagement, and enrollment of patients via social media. Once they are enrolled, they can participate from whatever device they already have without requiring any extra cost of having to purchase a new device, either by the sponsor or by the patients. So, it's very cost-effective. That's how we enable more diverse patient engagement, even in some of our patient registry studies.

“We are working with the University of California, San Francisco, with Dr. Julie Saba on an ultra-rare disease. They have patients distributed globally, so it's not just within the US, but patients may be living in Pakistan, India, or other parts of the world.”

We are working with the University of California, San Francisco, with Dr. Julie Saba on an ultra-rare disease. They have patients distributed globally, so it's not just within the US, but patients may be living in Pakistan, India, or other parts of the world. That may need to be engaged over a long period of time to collect data and information. That is all supported within the same platform with a single login and from any device. That's how we support diversity, equity, and inclusion programs. (32:11)

Dr. Hillyer: Supporting diversity, equity, and inclusion programs is vital. I also hear a logistical problem that plagues participation in these clinical trials. Yet, Jeeva Informatics coming up with the solution is critical. Tell me about your process within the clinical trial? Because one issue that I know is the everyday expense those in clinical trials have, and it appears Jeeva may even help families with that financial aspect.

Dr. Harsha Rajasimha: 100%. Kimberly, there is a direct cost and indirect cost, right? So, the cost of traveling to the site itself is expensive, but that's less than the indirect cost that the mother and father may incur in having to take time off their daytime work.

They are actually losing money from their income and also spending money on travel. The indirect cost of having to go to the site, especially when it's not required, is very unfair to the patients and families. That's what we hear from many of our Children's hospital collaborators at the National Children's Medical Center in Washington DC or other places. Where they say, as much as possible, we should engage patients where they are. It's easy to step out for an hour for consultation than to travel to Washington DC for an hour wait for an appointment, and then they would have spent three extra hours commuting, parking, and waiting, which is where they have to end up taking half a day off.

“It's easy to step out for an hour for consultation than to travel to Washington DC for an hour wait for an appointment, and then they would have spent three extra hours commuting, parking, and waiting, which is where they have to end up taking half a day off.”

That's basically what our platform enables to help clinical researchers to design clinical studies. Keeping, taking these logistical barriers and burdens into account. When they are designing the protocol because once the protocol is set, it's hard to change during the execution phase, whatever is the protocol that has to be executed. Now can we avoid every other visit, or eight out of ten visits, or five out of ten visits that can be done through the report, telemedicine, a video call, or a questionnaire that can be filled out from their own device online, or signing certain documents, and informed consent forms on the electronically from their own device? Just simple things like this, which technology exists, and we have followed a human-centric approach to making sure it's easy to include you. We can even provide training and support to help handhold certain patients who may need more help than others in helping them complete the process in a compliant manner for both the Institutional Review Boards and also for the FDA 21 CFR part 11 compliance. That's basically what I realized, and it's not the hard science of genetics and genomics where we are lacking. They're brilliant science that's going on, but it's really in these human problems in really understanding the logistical burdens. What's the pain that these patients and families go through.

That's what we did in the first year of our Company's existence. We did not develop the software immediately. We interviewed hundreds of patients, families, and researchers to understand what are their barriers and burdens? What do they go through? Where are the barriers and bottlenecks, and problems that we can solve? Most of them were human problems. Those were not scientific problems. If that's what it takes to help accelerate clinical research, let's just fix those problems. That's the difference between a social entrepreneur, and a general business person is that we are motivated to solve societal problems. Whatever tools, technologies, and science it takes to solve them, that's what we bring to the table.

Dr. Hillyer: I love that, and I love this concept of Human Centric software. Think about the barriers you discussed; I know another

barrier is enrolling children, who we consider our most vulnerable population. I imagine getting parents to participate in clinical trials is challenging, especially those families with a child who has a rare disease. How do you help these parents understand this process?

Dr. Harsha Rajasimha: 100%, Kimberly. As we all saw during the COVID-19 pandemic, the vaccines came first for adults, the older adults, the young adults, and then finally the children, twelve plus and then five plus, and then newborns, and others, right. So, it's an underserved population, our children, and women in some cases as well, for certain diseases like cardiovascular, as we have seen over the years.

When we talk about diversity, the first thing that comes to mind is race and color, and so on. But age has been a significant diversity indicator significant lack of investments going in pediatrics for various logistical challenges that we discussed, right? These children have a very low-risk tolerance to drugs because they have an entire lifespan ahead of them, and a clinical trial could potentially affect that. So, the FDA is very right in emphasizing a very high level of scrutiny and setting very high standards for pediatric trials, which makes it hard. The other thing is the complex logistical problems of coordinating with their guardians, many times legal guardians. What one mother may feel is good may not be necessarily approved by the father or vice versa. So, making sure everyone understands the risk and benefits and having an assent that we can obtain in the case of pediatric trials. Whereas adults can consent on their own, the child is dependent on at least two parents many times. That's another challenge. Then finally, the children are growing as the trial begins because many of these clinical studies can last several years. A two-year-old child will grow into a six-year-old by the time a trial is complete, for example. Whereas adults going from twenty-five to thirty wouldn't make much difference. For all these reasons, the investments, in general, going into pediatric trials have been historically very low, and less than 10% of all clinical trials have some applicability in pediatric scenarios. More than 90% of trials target the other populations. What also resulted is a lack of digital engagement tools in the neonatology settings and the pediatric settings. We made it a point that even though the market was not as big for pediatric clinical trials, we still made it a priority to address that unmet need. I'm proud to say that our platform helps obtain remote informed consent in pediatric assent as well as consent in adult trials.

“We are disease agnostic, age agnostic, gender agnostic, and device agnostic. It's a generic platform that addresses these logistical and operational issues, irrespective of all these other factors.”

We are disease agnostic, age agnostic, gender agnostic, and device agnostic. It's a generic platform that addresses these logistical and operational issues, irrespective of all these other factors.

Dr. Hillyer: Your Company is making a huge impact. I love the focus and that you've taken on the societal barriers. The global advocacy that you are looking at and addressing. What type of collaboration do you need from the healthcare community to help

support this goal?

Dr. Rajasimha: Yeah, absolutely. I think there is a need for more clinical research. Now that's the biggest message!

We need to engage, inform, and enroll patients in pediatric settings, and more research is needed. More data collection is needed, more high-quality patient engagement with minimum burden on the patient. So, with those types of tools now being available, there is no excuse or reason to delay any further in really ramping up. Especially with the advent of gene therapies, which offers so much promise or single-gene disorders for which there are more than 1,000 clinical trials going on. For gene therapy, the products call for an urgent need to educate and inform pediatric researchers to take the lead in the picking of multiple studies for various types of diseases where patients can be educated and enrolled in political research and patients are partners. They are not subjects, and they have rare diseases. People realize that more than anywhere else, where patients are driving and pushing the needle, and even pushing the researchers. They are demanding treatments. How can you say that my child has no treatment? You've got to something! You are a doctor! That's when there is no standard of care; clinical research is the answer. For long there has been Clinical Research as a Care Option (CRAACO), which is not a new concept, but that needs to be fully embraced by Neonatologists and Pediatricians to enroll and identify research opportunities when there is no standard of care for certain medical conditions. That's what I would say is the way to engage, and when they do, they can utilize the Jeeva software to enable and run those studies in a very cost-effective and simple matter.

“So now we've discussed how healthcare providers can utilize and collaborate with Jeeva Informatics, but how would you suggest we garner that same kind of collaboration on a national platform? How should we be talking to our healthcare advocacy groups in Washington?”

Dr. Hillyer: So now we've discussed how healthcare providers can utilize and collaborate with Jeeva Informatics, but how would you suggest we garner that same kind of collaboration on a national platform? How should we be talking to our healthcare advocacy groups in Washington?

Dr. Harsha Rajasimha: Great question again. There is a lot of public health focus, the kind of focus that COVID-19, brought about by our Senators, Congressman, local, regional, state-level, and Federal government levels. The same level of public health initiatives should be launched for every single disease. There are more than 7,000 named rare diseases, and most of them do not have any approved treatment right now. So, if we take up any single disease, that is the need to create a national patient registry, and there is a need to engage patients with a given disease in a single database and group on a state level, national level, and international level. Those are the types of things we need to look at. I think there are already a few couple 1,000 patient registry pro-

grams underway, both for common and rare diseases. So, it's not specific to just a rare disease; even for common conditions, patient registries are very important tools for policy decisions and for asking certain economic or policy level questions. Having those public health databases is key for surveillance like we did for COVID-19 surveillance contact tracing. We should be doing that for genetic diseases. In terms of surveillance and keeping a record, there are these genetic disease patients because we say there are more than 30,000,000 people affected in the United States with rare diseases, but a majority of those 30,000,000 patients are not in these databases right now. In any of these databases, we need to have accountability and track these patients in a responsible manner.

Making those datasets available for medical research in a responsible manner, in a compliant way, and in a de-identified manner where they're appropriate. That's what I would say can be done to really speed up. Just like we brought the COVID-19 vaccine in six months, which is never heard of before, that's the fastest that mankind has ever produced a vaccine on a drug in history. It's a very complex process. It really deserves kudos, but the same can be with the will of the government and the stakeholders. We can make that happen for many of these genetic diseases and rare diseases by identifying treatment options and comparing diagnostic tests or vaccines for certain diseases. All those research can be accelerated with a technology platform like Jeeva.

“We can make that happen for many of these genetic diseases and rare diseases by identifying treatment options and comparing diagnostic tests or vaccines for certain diseases. All those research can be accelerated with a technology platform like Jeeva.”

Dr. Hillyer: We live during the age of COVID and being there from the beginning of the pandemic. We were able to see how quickly the world, the government, and healthcare were able to work together and tackle this devastatingly deadly virus. It is exciting to hear how your Company changed the focus and considered the logistical and social aspects that historically delayed medical progress. Your background with Indo-US Organization for rare diseases and this human-centric software could be the necessary change to overcome genetic conditions as we did COVID-19.

To collaborate with you and garner that change of support, how do we find out more?

Dr. Harsha Rajasimha: Absolutely, if you are a patient or patient advocacy group dealing with a genetic or a rare disease. Please contact the Indo-US Organization for Rare Diseases. We have a patient concierge technology where individual patients can look up IndoUSrare.org website. There is a patient contact form that you can submit, and someone will be in touch with you to support your specific need. Now it could be access to diagnosis, access to treatment, and access to critical trials irrespective of where you are located. That may mean that our staff will connect you with

the right researchers, stakeholders, and other organizations that may already be doing the good work. The concierge is meant to make connections with the right organizations and individuals. So, we are very happy to provide that as a free service to patients. So, you can contact us at IndoUSRare.org. The second, if you are a clinical researcher, a biopharmaceutical sponsor dealing with clinical operations, or a clinical research organization, a CRO, you can contact Jeeva Informatic Solutions, the human-centric software as a service platform that helps researchers accelerate patient recruitment, retention, and evidence generation from any device on any disease anywhere in the world on the internet. You can contact Jeevatrials.com, and you can submit a contact us from there or request a demo, and we will be very happy to assist you with your research programs in collaboration.

Thank you so much again. I can be reached at Harsha@JeevaTrials.com, that's my email address. I can also be found easily on LinkedIn or other social channels.

Thank you, Kimberly, for having me today appreciate the opportunity and look forward to collaborating with the Neonatologists and other researchers.

Dr. Hillyer: Thank you so much, Dr. Rajasimha. I enjoyed our conversation and look forward to seeing how you and your software are working on making a social and global change within health-care to address the needs of these vulnerable individuals.

Dr. Harsha Rajasimha: Thank you so much, Kimberly. I'm very hopeful that in collaboration with you and other researchers and patients, we can definitely change the world, and we are committed to doing that.

Preemie Spotlight

Kimberly: Your daughter Kahushi, who changed the way your life course went. Can you tell me what her name means?

Dr. Rajasimha: Absolutely, Kimberly. Kahushi literally means "Happiness" or "Happy," and that's the meaning of my name as well. My first name, literally being happiness, is just a male version, and Kahushi is the female version.

Kimberly: Does your company name Jeeva have a special meaning as well?

“Jeeva Informatics Solutions is the name of the technology human Centric SAS platform for research. Jeeva literally means “Life” cheaper meets life. And so the Company is dedicated to addressing life from, you know, which are mostly human, using digital technology.”

Dr. Rajasimha: Yeah. So Jeeva Informatics Solutions is the name of the technology human Centric SAS platform for research. Jeeva literally means “Life” cheaper meets life. And so the Company is dedicated to addressing life from, you know, which are mostly human, using digital technology.

Disclosure: Dr. Rajasimha is founder and CEO of the decentralized clinical trials software company, Jeeva Informatics Solutions.

NT



About the Author: Kimberly Hillyer, DNP, NNP-BC:



Title: NT News Anchor and Editor

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Neonatology Today in partnership with Loma Linda University Publishing Company.

Bio: Kimberly Hillyer, RN LNC, NNP-BC DNP, completed her Master's degree specializing as a Neonatal Nurse Practitioner in 2006 and completed her Doctorate of Nursing Practice (DNP) at Loma Linda University in 2017. She became an Assistant Clinical Professor and the Neonatal Nurse Practitioner Coordinator at Loma Linda University. Her interest in the law led her to attain certification as a Legal Nurse Consultant at Kaplan University.

As a Neonatal Nurse Practitioner, she has worked for Loma Linda University Health Children's Hospital (LLUH CH) for twenty years. During that time, she has mentored and precepted other Neonatal Nurse Practitioners while actively engaging in multiple hospital committees. She was also the Neonatal Nurse Practitioners Student Coordinator for LLU CH. A secret passion for informatics has led her to become an EPIC Department Deputy for the Neonatal Intensive Care at LLUH CH.

She is a reviewer for Neonatology Today and has recently joined the Editorial Board as the News Anchor.

About the Author: Dr. Harsha Rajasimha



Dr. Harsha Rajasimha has over a decade of experience working on various interdisciplinary projects involving genomics and big data as a consultant for clients, National and International Institutes, and Corporations. He is the founder and chairman of the humanitarian non-profit Indo US Organization for Rare Diseases.

He is a precision medicine data scientist-turned social entrepreneur on a mission to accelerate human-centric clinical research through technology innovation and global advocacy. He is the founder and CEO of the decentralized clinical trials software company, Jeeva Informatics Solutions.



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Implementation of High Reliability Organizing (HRO): The Inherent Vice of Stress, Fear, and Threat

Daved van Stralen, MD, FAAP, Sean D. McKay, Christopher A. Hart, JD Thomas A. Mercer, RAdm, USN (Retired)

Abstract:

The human mind evolved to naturally engage adversity – whether in the environment or from an enemy. Behaviors and our environment will be unpredictable because they are continuously oscillating, creating frequencies, and some of those frequencies have long periods. The long period frequency, acting alone or with other long period frequencies, creates forcing functions. Individuals, organizations, and the environment must respond in some manner to these forcing functions. The human brain will release corticotropin-releasing factor (CRF), which goes to the hypothalamic-pituitary-adrenal axis (HPA), and the HPA terminates ongoing activity, suppresses the executive functions, and impairs abstract cognition. Concurrently, CRF enters the locus coeruleus-norepinephrine system (LC-NE) to reorient cognition for attention and arousal – adaptive cognition is started, the individual focuses on behaviors, and engagement follows.

“Behaviors and our environment will be unpredictable because they are continuously oscillating, creating frequencies, and some of those frequencies have long periods. The long period frequency, acting alone or with other long period frequencies, creates forcing functions. Individuals, organizations, and the environment must respond in some manner to these forcing functions.”

“During times of extreme stress, the brain takes the prefrontal cortex ‘off-line’ in favor of automated flight or fight responses.” This is a common belief held by scientists, healthcare professionals, and the lay public. However, it is the extensive experience of the authors that one can, and must, think clearly in live-or-die situations. William J. Corr, fire captain, and WWII US Navy veteran, South Pacific, admonished firefighters, “When your body moves faster than your mind can work, slow down.”

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As demonstrated in the following vignettes, our brains have the ‘inherent qualities’ necessary to function well in the presence of sudden dangerous situations. These qualities, unfortunately, can act as latent defects that cause serious damage – an ‘inherent vice.’ Consequently, it is common to depreciate their effectiveness. People mislead themselves when they try to make sense of human responses to threats in a way that fits their understanding. These vignettes reveal the strength of our stress, fear, and threat responses.

“People mislead themselves when they try to make sense of human responses to threats in a way that fits their understanding. These vignettes reveal the strength of our stress, fear, and threat responses.”

- A shooting victim from a mass shooting ran into a pediatric clinic for safety. After administering medical aid, the general pediatrician went to the building to see if his associates on the second floor needed help. Because the shooters were still thought to be in the room, he used the stairway next to the entry door of the conference room where the shooting occurred. There was no answer at the door, and police had not yet arrived. He then realized that he might be confused with an assailant because he was of Middle Eastern descent. He ran back to the clinic to continue giving aid to those suffering emotional trauma during the incident. He took these actions in less than six minutes (1).
 - Upon hearing gunshots, teachers in an elementary school evacuated their students towards a back gate, then left the school grounds. They were leaving the school as a group as the first law enforcement officers arrived. There was no evacuation announcement and no discussions between teachers during the evacuation. They had not received ‘active shooter’ training, nor did the school have an active shooter plan. Some students thought they were going on a field trip. School staff had quietly evacuated about 400 children in less than seven minutes (2).
 - A passenger ship with 581 guests and crew sailed into 40-knot winds and 9m-high (30ft) waves, began drifting sideways into the waves and listing back and forth. It was late at night. Chairs began sliding. Passengers moved to sit on the floor. A guitarist observed crew members wearing life jackets racing aft. The lights went out, replaced by emergency lighting. The cruise director reported that the captain had said they should prepare to abandon the ship. Not hearing instructions from the crew, the guitarist and a magician went below decks to learn more. They reached a bulkhead sealed off by water-tight doors. The ship must be taking on water (3).
- Some crew members had lowered lifeboats on the embarkation deck, taking on women and children. However, those in the lifeboats were disproportionately crew and senior officers. There had been no announcement, no alarm sounded.

The guitarist returned to the lower decks to learn more, but he could hear the sound of water flowing this time. The ship was sinking.

“Some crew members had lowered lifeboats on the embarkation deck, taking on women and children. However, those in the lifeboats were disproportionately crew and senior officers. There had been no announcement, no alarm sounded.”

The guitarist, cruise director, the magician, now joined by another magician and a few other mostly female entertainment staff, figured out how to release the lifeboats. They carried out the evacuation of guests. Passengers stopped asking about the ship's officers, realizing the entertainers were now in charge. After the launch of the last lifeboat, 220 people remained on board (4, 5).

The entertainers went to the bridge to seek assistance from the captain and senior officers. The bridge was empty. The guitarist called “Mayday” repeatedly on the radio. A voice answered, “Yes, what is your Mayday?” The guitarist explained that the ship was sinking (3).

“OK. How long have you got left to float?”

“I don't know - we've got the starboard railings in the water, we're rolling around, we've taken on a huge amount of water. We still have at least 200 people on board.”

“OK. What is your position?” “What are your coordinates?” The guitarist had no idea.

“What rank are you?”

“Well, I'm not a rank - I'm a guitarist.” A moment's silence.

“What are you doing on the bridge?”

“Well, there's nobody else here.”

“Who's on the bridge with you?”

“It's me, my wife - the bass player, we've got a magician here...”

The guitarist had no idea where the captain was. The crew remaining on the ship were mostly Filipino cooks and kitchen staff.

During the navy helicopter evacuation, one magician remained on the bridge for radio contact. Another magician joined a navy rescue diver in a Zodiac inflatable boat to rescue anyone who fell or jumped into the sea. The guitarist, bass player-singer, and the cruise director worked together to evacuate passengers by helicopter. The captain was one of the first people rescued by helicopter, stepping in front of elderly passengers. He stated he needed to direct the rescue from land (6).

No lives were lost in the sinking of the passenger ship.

[The captain remains with the ship because the captain knows the capability of the crew and ship, understands and has monitored the damage, and has the knowledge of the ship to direct damage control, salvage, and rescue operations. The crew cannot jettison lifeboats without the captain's order to abandon the ship because the captain needs the full crew

to save the ship. Passengers are safer on the ship than in lifeboats. It would be considered mutiny for the crew to leave the ship on lifeboats without the captain's orders (TAM).]

- A combat medic treated American and allied soldiers after an artillery barrage hit their compound and damaged the perimeter. Treating the more seriously wounded soldiers used up his antibiotics. The allied soldiers made direct threats for him to treat the other wounded with antibiotics. Since the evening was approaching, the area commander denied helicopter pilots permission to evacuate the wounded. That would wait for morning. Enemy soldiers were 800 meters out. He thought he would be killed one way or another.

- In her first day at the school, a kindergarten teacher stood at the door of her classroom as all of her students ran out each of the four exit doors. The sky was black. The school had just received a tornado alert, then an announcement to move students to the designated shelter. Nearby teachers could not assist her because they were escorting their students to the shelter. She lost her students, and now she thought she would lose her job (personal communication from the medic and teacher, DvS).

Helicopter pilots lifted off from their base despite the command to evacuate the wounded. Despite responsibility for their young students, the teachers gathered the scattering kindergarteners. The medic later understood he had a standard supply of antibiotics and learned they were victims of friendly fire. The teacher learned that a tornado had hit the school the year before, killing three students, friends of her kindergarteners. They had run away from fear.

One of the authors (DvS) asked the army medic how he and his experience differed from the teacher and her experience. There was no difference, the medic answered. It was not the fault of either person. The helping responders were not supposed to help. And both individuals have the same brain and had the same response.

“Our circumstances shift between limits in the actual world, much like a pendulum. Some perturbations have long time periods where change has a slow but forceful appearance. Some perturbations are rare but catastrophic. By representing these as frequencies, there is no unique distinction between normal variation, exigencies, or catastrophes.”

Introduction

Our circumstances shift between limits in the actual world, much like a pendulum. Some perturbations have long time periods where change has a slow but forceful appearance. Some perturbations are rare but catastrophic. By representing these as frequencies, there is no unique distinction between normal variation, exigencies, or catastrophes. They are the same but experienced at different time scales (7).

The extent of danger is not often apparent at first glance. The transition to “emergency mode” for subtle presentations is as fraught as the sudden appearance of danger. Individuals have their “normal” thinking processes and what they believe is their “emergency” thinking. Reliance on the singular “fight-or-flight” responses for a crisis is not only maladaptive during the crisis, but it also becomes too readily accepted for almost any demand. It is also not true.

“Reliance on the singular “fight-or-flight” responses for a crisis is not only maladaptive during the crisis, but it also becomes too readily accepted for almost any demand. It is also not true.”

The experience of veteran operators belies the academic and management science focus on the fight-flight-freeze response to stress or fear for emergency operations (8, 9). “In potentially or unsafe situations, the ability to reorient attention to potential threats, mobilize energy resources, and take rapid unpremeditated action is critical to immediate survival” (10). The effective operator searches for “alternative tasks that may provide better solutions during a changing environment or when the present behavior is not optimally adaptive” (11).

For this to happen, the brain resets attention, reframes the situation, and changes its orientation from achieving a goal to performing specific tasks (12). Untrained neuromodulation, abstract thought, and top-down goals will bias one toward preferred signals. For an individual experienced with the situation, this acts as common sense. For the spectator or inexperienced operator, it can easily lead to harm (13). During an environmental change or temporal-spatial correlation, the individual neuromodulates responses to the context. Necessary, automatic bottom-up processes do not depend on top-down attention (10), hence the effectiveness.

For this rapid shift to occur, the brain must decrease the influence of the executive functions while enhancing motor behaviors and cognition. The amygdala responds to a perceived threat by causing the periventricular nucleus of the hypothalamus to secrete corticotropin-releasing factor (CRF). CRF simultaneously stimulates two systems: 1) the hypothalamic-pituitary-adrenal axis (HPA) to inhibit abstract thinking and memory and 2) the locus coeruleus-norepinephrine (LC-NE) system for adaptive thinking and behaviors. This initiates the adaptive cognitive shift necessary for survival.

People inexperienced operating in a dangerous context can combine the brain’s emergency responses with flexible cognitive skills for agile, effective, thoughtful action. The vignettes describe these successes. The brain creates an effective stress response by parallel engagement of its cognitive, hormonal, and emergency functions. Because not all dangers are immediately obvious, the brain can rapidly reorient attention to subtle threats or potential threats.

Oscillations and oscillatory processes are fundamental to the functions of life and the physical world. The entry of noise energy into an open, nonlinear system increases these oscillations. Stochastic resonance amplifies weak or relatively small noise, creating and sustaining significant oscillations. Thus, through resonance, the happenstance of noise amplifies tolerable risk levels, converting small risks into crises.

These oscillatory processes form frequencies within the system, frequencies that can also resonate with other frequencies in neighboring systems. Events are no longer independent of preceding events, becoming autocorrelated (the current behavior correlates with previous behavior). Autocorrelated events are more susceptible to feedback loops, allowing even minor or mundane noise signals to achieve resonance, amplify, and generate meaningful events. More data does not bring more understanding. Rather, more data clouds whatever conclusions we attempt to reach.

The stress, fear, and threat responses of the HPA axis are necessary to engage environmental forcing functions. These qualities, however, can also harm the individual and organization – the ‘inherent vice’ of stress, fear, and threat. The LC-NE system and dopamine networks fill the space by enhancing adaptive cognition and behaviors. We think of stress, fear, and threat as fragility, but they are strengths that can cause fragility.

For operations in dangerous contexts or the liminal zone (9), we make the functional distinction between the drive to escape the threat, that is, to create distance between the individual and the threat, and the drive to disable the threat. The former we call *fear reactions* and the latter *threat reflexes*.

“For operations in dangerous contexts or the liminal zone (9), we make the functional distinction between the drive to escape the threat, that is, to create distance between the individual and the threat, and the drive to disable the threat. The former we call fear reactions and the latter threat reflexes.”

Environment and the Color of Noise

We tend to think about and discuss stress, fear, and threat in danger or risk. Heini Hediger (14) described how animals have an ‘escape reaction,’ the animal moves to maintain a specific ‘flight distance.’ Within a ‘defense distance,’ the animal will attack in self-defense to escape. Because the danger need not be a predator, Hediger used the term “enemy.”

The terms enemy, predator, threat, risk, and danger are subjective. They also too easily become terms for diminishing a person’s perceptions of the stimulus or initiate shows of bravado in some individuals. We find the concept of “forcing functions” not only neutral but more descriptive. Forcing functions arise from reddened noise frequencies or sudden ‘flicker’ events in pink noise. Forcing functions may be singular due to long-period events or result from resonance between several red noise frequencies.

A system’s frequencies generated by natural oscillating processes can be described by their ‘color.’ That is, ‘white noise’ with constrained variance describes a flattened spectrum where no frequencies dominate. Each time interval in a time series is independent of other intervals. The randomness, independence, and discrete-time intervals create a Gaussian distribution to calculate statistics and probabilities. White noise environments support mathematically tractable models and more concise theories while giving greater conceptual clarity (15, 16). White noise is the variance incorporated into academic and scientific models (17). While we use white noise for our mental representations of the environment, predictions, algorithms, rules, and protocols, we must not

mistake it for the actual world.

“Red and pink noise develop from autocorrelation, the feedback when the past influences the present or a system interacts with other systems. Red and pink noise has zero mean, increasing variance, and are autocorrelated in time by feedback. As power distributions, the non-Gaussian nature of red and pink noise distributions impairs our ability to use classical logic, rigid models, and strict concepts.”

Red and pink noise develop from autocorrelation, the feedback when the past influences the present or a system interacts with other systems. Red and pink noise has zero mean, increasing variance with more data, and are autocorrelated in time by feedback. The data in these non-Gaussian systems create power distributions with events of greater magnitude having a lower frequency of occurrence. The non-Gaussian distributions impair our ability to use classical logic, rigid models, and strict concepts. “In comparisons of model predictions and real data, stochastic models often perform as poorly as deterministic ones, John M. Halley (7). Uncommon or long-period events have a greater influence on the system than the larger number of more frequent small events.

The development of autocorrelation, described above, converts white frequencies to red or pink noise. Not as a transition, but more like a phase change to new properties without a change in composition. The long periods of red frequencies or the rare flicker events of the pink frequency ($1/f$) can mislead us into believing we operate in a white noise environment. We can identify this difference when more data or collecting data over a longer time series does not produce a better norm or better stochastic models. Karl Weick (personal communication) described these environments as “a mix of white and red, and that red is the thing to be avoided. Pink is the com penetration of white and red and is the mess that sensemaking tries to untangle.”

“Pink noise shows no preference for short or long timescale disturbances. From seconds to millennia, all natural distur-

bances of various sizes can be seen as part of a seamless $1/f$ -noise process. In this picture we need not make any special distinction between normal environmental variation and ecological ‘catastrophes’: it is the same thing seen at different scales.”

John M. Halley (7)

Autocorrelation

Autocorrelation is present when an observation or the value of data depends on what preceded the observation or measurement, or they depend on surrounding values. In research, the independent variable is not independent.

Time. In a time series, temporal autocorrelation occurs when a previous time interval influences a time interval.

Environment. Spatial autocorrelation describes the patchiness of people or things. Values can partly predict the value at any one locality at neighboring points. People and things are neither distributed uniformly nor randomly (19). They are near others for a reason, such as an environmental forcing function or an internal social process. Spatial autocorrelation can be positive or negative, representing aggregations versus scarcity. In epidemiology, spatial autocorrelation identifies disease clustering in a general or specific region. Spatial autocorrelation measures the degree of similarity between objects that are located near each other (20). *As a form of contextualization, spatial autocorrelation heavily influences stress, fear, and threat.*

“Spatial autocorrelation describes the patchiness of people or things. Values can partly predict the value at any one locality at neighboring points. People and things are neither distributed uniformly nor randomly (19). They are near others for a reason, such as an environmental forcing function or an internal social process. Spatial autocorrelation can be positive or negative, representing aggregations versus scarcity.”

| Color | Structure | Variance | Distribution |
|-------|--|--|---|
| White | No frequencies dominate Flattened spectrum | Data <i>decreases</i> variance | Gaussian distribution - Elements fully independent - No autocorrelation |
| Red | Low frequencies dominate Long-period cycles | Data <i>increases</i> variance | Power law distribution - Elements <i>not</i> independent - Mutual/ reciprocal relations |
| Pink | The midpoint of red noise Slope lies <i>exactly</i> midway between white noise and brown (random) noise | Data <i>continuously increases</i> variance Distinguishes pink noise from red-dened spectra | Power law distribution - No well-defined long-term mean - No well-defined value at a single point |

Table 1. Patterns and Characteristics of Noise (18)

Spatial autocorrelation can cause the appearance of a ‘false’ gra-

dient. In a 'true' gradient, neighboring elements are not coordinated with each other, the changes in value deriving from their coordinates. In a false gradient, the change in value across space is caused by autocorrelation from the values and influences of its neighbors. The change in value is not due to its location (19).

Phylogenetic autocorrelation. Evolvable entities tend to have similar traits the closer the entities are to their recent ancestor (21). For example, in their response to stress, fear, and threat, healthcare specialties have greater similarities than public safety services.

Behavior. People, as social and learning organisms, demonstrate behavioral autocorrelation. Autocorrelation within a group creates culture, and the individual acculturates to that group through autocorrelation. Mirror neurons (22, 23) support team formation through autocorrelation. The autocorrelation of human behavior gives the reddened noise that confounds our ability to predict how others will act.

Forcing Functions

Triggered by environmental noise, mundane elements in our environment develop the power to force a system or population to respond to the environment. Such 'forcing functions' act on a variety of scales. Some simply occupy our attention while other low-frequency events erupt into major crises in our presence. Forcing functions introduce emergent new properties into the system.

“Even when there are no significant events, these unexpected circumstances carry a level of novelty and uncertainty that confounds us, producing a level of unpredictability challenging our ability to bring control to the situation. We can even marvel at the unfolding situation at a distance.”

Even when there are no significant events, these unexpected circumstances carry a level of novelty and uncertainty that con-

found us, producing a level of unpredictability challenging our ability to bring control to the situation. We can even marvel at the unfolding situation at a distance. We may change our approach, putting distance between us and the threat up close. Too sudden and too close brings out surprising reflexive survival behaviors we did not know we had.

Qualities of novelty, uncertainty, unpredictability, and uncontrollability are also the causes of the brain's stress responses to thinking and executive functions. The proximity of an emergent threat to the individual will stimulate fear reactions within the brain and subsequent behaviors. Rapid appearance or impending contact triggers threat reflexes and subsequent unconscious behaviors. We want to retain these inherent adaptive qualities while minimizing their inherent vice. We cannot protect ourselves from low-frequency events, but we can engage them.

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Stress, Fear, Threat

Nobel laureate, Niko Tinbergen, observed that “every animal has to cope in numerous ways with a hostile, at least uncooperative, environment.” He posited that behavior is the most immediately adaptive method for the ability to cope and survive. We cannot identify the precedents of behavior, but we can discuss the *function* of behaviors. He described these functions as achievements to better understand the defensive cascade that protects the organism (24).

The primary defensive and survival functions are 1) hindered memory systems that limit abstract thought (stress responses), 2) volitional behaviors for self-preservation (fear reactions), and 3)

| Condition | Cause | Characteristics | Location | Effects |
|-----------------|---|------------------------------------|---|--|
| Stress response | Novelty Uncertainty Uncontrollability | Objective Neurochemical release | SAM* HPA Axis** Cortisol | Retained motor memory Impaired declarative & working memory Impaired cognition |
| Fear reaction | Proximity | Subjective Feeling | Ventromedial Prefrontal cortex Periaqueductal Gray | Maintain distance by attentive freeze, flight, then fight |
| Threat reflex | Existential harm | Objective Behaviors | Amygdala Prefrontal cortex | Fight, anger Flight, avoid Freeze, vigilance Tonic immobility, nausea Disso- ciation |

Table 2. Stress, Fear, and Threat (25)

* SAM sympathetic-adrenal-medullary

** HPA hypothalamic-pituitary-adrenal axis

reflexive, subcortical actions (threat reflexes). When faced with an exigency, our brain releases cortisol to constrain abstract thought, which permits us to focus cognitive functions on context and action (stress). An approaching threat is detected by our brain below the level of awareness and monitored for distance and direction; we are prepared to run or fight as necessary (fear). Proximal, imminent danger initiates reflexive protective behaviors while maintaining our cognitive functions (threat).

Novelty, uncertainty, and uncontrollability are the causes of objective *stress responses*. The proximity of a threat creates subjective *fear reactions*. Sudden, existential harm will trigger objective *threat reflexes* (Table 2).

We do not spend excess time lost in thinking of abstractions and theories through stress responses. We unconsciously maintain a safe working distance from the threat, and we act before our awareness recognizes the nearby threat. Our brain and body effectively engage in danger through stress, fear, and threat. These desirable qualities can become an undesired 'inherent vice' that causes internal damage to the person. The damage is not a cause; it is an effect.

“Confounding discussions of stress, fear, and threat are beliefs that represent a primitive brain, are instincts, cannot be modulated or prevent thinking. Instincts as behaviors develop from the genome and environment. The behavior is a programmed innate behavioral drive or a psychological need for behavior from genes (the genome).”

Confounding discussions of stress, fear, and threat are beliefs that represent a primitive brain, are instincts, cannot be modulated or prevent thinking. Instincts as behaviors develop from the genome and environment. The behavior is a programmed innate behavioral drive or a psychological need for behavior from genes (the genome). The gene is manifested as the phenotype, a set of behaviors that can act on and respond to the environment. It is instinctive that the behavior can be developed and expressed only in the proper environment (26-28). The behavior is not ballistic, though, acting out past a point of no return. Thinking and learning can be modified and modulated even when instinctual in origin.

Fight and flight are well-known threat reflexes but are also fear reactions. They have different functions as fear or threat, differing in their motor and affective components. While emotions are considered to have five components, discussions commonly combine the motor component and subjective experience rather than describe them separately (29). In some communities, the motor component may predominate, while in others, the subjective experiences of stress, fear, and threat predominate. In professional organizations such as healthcare, the subjective experience predominates. The individual expressing stress, fear, or threat as a subjective experience may deny the emotional state, while those who are the target of the emotion may not recognize the behavior as stress, fear, or threat emotion.

We present the maladaptive behaviors of stress, fear, and threat under the insurance term “inherent vice.” “Inherent vice” means

“any existing defects, diseases, decay or the inherent nature of the commodity which will cause it to deteriorate with a lapse of time” (30). “The decay of a perishable cargo is not a cause; it is an effect” (31). Maladaptive behaviors develop when the individual has not learned to modulate the behaviors, or they have become reinforced through operant conditioning

Cognitive Function

Stress, fear, and threat combine emotion, cognition, and behavior – a broad range for a singular theory. We have described the operational function, harm, and inherent vice of stress, fear, and threat and methods to overcome the problems (9, 25, 32-35). We have also searched the sciences for assistance to help with entry into the liminal zone and improve engagement in dangerous contexts.

Threat identified through the sympathetic-adrenal-medullary axis (SAM) stimulates the paraventricular nucleus of the hypothalamus to release corticotropin-releasing factor (CRF) into the anterior pituitary and the locus coeruleus (LC). This release activates both hypothalamic-pituitary-adrenal (HPA) axis and the locus coeruleus-norepinephrine (LC-NE) system. The HPA axis suppresses the executive functions to support engagement, while the LC-NE system supports the cognition and behaviors necessary for engagement. CRF from the central nucleus of the amygdala may also activate the LC.

Locus Coeruleus and Norepinephrine

The release of norepinephrine appears to terminate the resting cognitive state. The brain reorients from the current activity to a new behavioral response—cortical, subcortical, and autonomic activity shift to facilitate focused attention for task-oriented behaviors.

LC-NE system operates at three levels of tonic activity:

- low in the unaroused state, facilitating sleep and disengagement from the environment
- moderate when engaged in a focused task, enhancing performance, filtering out irrelevant stimuli
- high when not committed to a task, exploring the environment

Attention and arousal

From a thorough review of the literature, Jennifer Ross and Elisabeth Van Bockstaele (36) have identified the two themes of attention and arousal. More critical is their finding that LC-NE mediates selective attention for salient stimuli with concurrent silencing of irrelevant stimuli. During a challenge from threat, both excitation and inhibition occur simultaneously throughout the brain.

“ More critical is their finding that LC-NE mediates selective attention for salient stimuli with concurrent silencing of irrelevant stimuli. During a challenge from threat, both excitation and inhibition occur simultaneously throughout the brain.”

While combined excitation and inhibition seem straightforward, the method used in the models is effective in engaging the threat. NE can silence some signals while enhancing others. The LC has

increased response to strong stimuli with decreased response to weak stimuli, enhancing the signal-to-noise ratio. The brain can encode and filter salience (36).

Attention and attentional modulation. Inhibitory neurons modulate attention by the ability to suppress the sensitivity of some stimuli while increasing high-frequency synchronous oscillations associ-

“Forcing function as a neutral term can drive investigation into the various reddened frequencies and stochastic interactions that make them so troublesome. Focus on error and safety as persuasion implies telling someone what they are not – mistaken and unsafe.”

ated with other stimuli. Using red noise behavior to amplify desired signals (increased sensitivity and decreased noise correlations). This *inhibitory control*, or response inhibition, is the executive function that inhibits impulses and dominant, pre-planned (prepotent) behavioral responses to stimuli. This executive function helps select behaviors consistent with one’s goals (37).

The focus on the effects of stress on attention led to the idea that active attention processes information from the top-down, and the individual directs attention to attain a goal. Passive attention processes information from the bottom-up, driven by environmental stimuli. Attention is intentionally focused (top-down) or attention is attracted (bottom-up) (36). Humans may innately and subcortically evaluate the environment before environmental cues reach awareness, trigger emotions, or initiate higher-order cognition (38).

Arousal from emotional events. Emotional events selectively enhance and impair perception and memory. Based on the priority of a stimulus, this arousal can enhance or suppress cognitive processes. Norepinephrine (NE) from the locus coeruleus influences perception and memory to select salient ensembles of signals while suppressing lower priority ensembles. To achieve this differential effect, glutamate and NE are co-released by arousal in prioritized regions for an excitatory effect. Magnifying the excitatory effect, NE intensifies suppression of weaker, low-priority responses through inhibitory processes, the inhibitory control of the executive functions (39). These signals produce oscillatory synchrony, a red noise effect that makes the signals relevant.

Salience. As stress research increased, the threat became the focus of the stimulus that caused stress. A threat can compromise survival. To suppress threats would involve any number of tasks. Specifically, it would involve selecting specific tasks at the opportune time. Ross and Van Bockstaele (36) posit that prioritizing tasks to meet the threat led to the consideration of salience as a cognitive process.

Large Scale Networks

We think of pathways when we discuss neurotransmitters. Neuroscientists recently identified brain regions connected through networks rather than nerve tracts or pathways. The understanding of the neural basis of cognition had shifted. These networks form Intrinsic Connectivity Networks (ICNs), highly connected large-scale brain regions active during a specific set of cognitive responses (36).

These networks operate independently, coming into opposition from environmental threats. As described below, the Ventral Attention Network interrupts the Dorsal Attention Network, and the central executive network suppresses the default mode network.

Dorsal and Ventral Attention Networks

Two neuroanatomically defined systems appear to control the top-down and bottom-up information processing during the orienting reflex. Environmental cues from a novel or infrequent events interrupt ongoing task-related cognitive activities. This bottom-up processing of sensory cues quickly reorients cognitive attention (40).

- Dorsal Attention Network (DAN), top-down cognitive information processing, task-related stimulus-response, pairs cognitive cues with motor responses
- Ventral Attention Network (VAN), bottom-up identification of salient or novel stimuli in the environment

DAN, left-lateralized in the prefrontal cortex, may control attention involved in motor responses to task-related stimuli. When encountering a novel or infrequent sensory stimulus, the right-lateralized VAN may facilitate reorientation. When VAN detects unexpected or novel stimuli, it interrupts DAN to reorient from the current activity to a new behavioral response. This VAN activity depends on norepinephrine delivered from the locus coeruleus (41).

“When VAN detects unexpected or novel stimuli, it interrupts DAN to reorient from the current activity to a new behavioral response. This VAN activity depends on norepinephrine delivered from the locus coeruleus (41).”

The Triple Network

Brain regions do not respond to stress in isolation. Organized, functional, dynamic networks interact across brain regions (42).

- *The salience network (SN)* responds to salient stimuli, orienting and coordinating attention towards internal or external information. SN may support hypervigilance.
- *The default mode network (DMN)* is activated during stimulus-independent tasks or internal thought, forming perceptions of others, or retrieving memories; usually suppressed during CEN activation
- *The central executive network (CEN)* supports higher-order cognitive tasks, attention, manipulating information, working memory, decision making for goal-directed behavior

Combined Networks

The science has not settled, causing inconsistent naming and regionalization. However, the SN (salience) is highest in the hierarchy. The Attention and Triple Networks interact, suggesting that cognition under stress is a balance between three core ICNs: DMN, CEN, and SN. From their coordination emerges cognition, goal-directed, and stimulus-directed behavior (36).

- Connections from SN (salience) and DAN (information processing) to DMN (stimulus-independent) are inhibitory, while reverse connections are weakly excitatory.
- Bidirectional connections between SN (salience) and DAN (information processing) are excitatory.
- VAN (environmental reorienting) has shared regions with SN

(salience).

Stress Research

In this paper, we presented stress research from the operator's perspective. Difficulties develop when we bring models created for conceptual clarity into a chaotic environment. The liminal environment, particularly in a dangerous context, may or may not be a source of stress for all participants (9). A typical team has people with various experiences and stress capacities, creating new social autocorrelations with each incident. No team is ever the same, even when the members do not change.

Science can, and should, inform practice. Though practice should inform science, it is impractical for a laboratory approach (43). Red noise, even pink noise, characterizes the fields that create stress during operations. Collecting more data increases variance. Below we describe how science can advance from science interactions, the environment, and the scientific operator. Specific to dangerous contexts, we honor the finding of Vanessa Heggie. About science and Mount Everest: "Predicting what would happen to the first human beings to climb that high [27,000 feet] was therefore literally a matter of life or death – here inaccurate models could kill" (44).

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Field Experience, Research

As stories that caution against discounting experience, we describe the attempts to climb Mount Everest, the development of cholera treatment, and assisted ventilation.

Mount Everest (8). From 1921 to 1952, eleven expeditions to climb Everest failed to climb higher than about 27,000 feet (45-49), an attitude that seemed to the limit of human endurance. George Finch, a mountaineer and scientist with engineering skills, developed the oxygen equipment for the 1922 expedition. It would be similar to that used for the successful 1953 expedition. He believed that above 23,000 feet, the physical deterioration from poor sleep and appetite outweighed the benefit of acclimatization (50). He strongly advocated for better food, including pre-packed rations (50). Despite setting an altitude record of 27,320 feet on the 1922 Everest expedition, Finch was excluded from the 1924 expedition and had been denied membership to the London Alpine Club because of his personality. His ideas did not match the high altitude science at the time. Science developed in pressure chambers for aeronautics (50, 51).

International pressure forced the London Alpine Club to use science. In 1952, they brought in Gifford Pugh, a physiologist, experienced climber, and mountain warfare instructor. He focused on diet, oxygen, fatigue, and acclimatization. The expedition leader for the preparatory expedition suggested that the expedition "carry out experiments in the use of oxygen apparatus; to study physiological problems of high altitude climbing, such as acclimatization and deterioration, diet and liquid consumption; and test clothing and equipment" (52). In 1953, Sir Edmund Hillary and Tenzing

Norgay reached the summit of Everest, smiled, removed their oxygen set, and took photos. John Hunt lauded Finch for showing how the physiological problems might be solved (51)

Cholera. For hundreds of years, treatments for cholera included fluids with salt and a form of sugar. SEATO and WHO research stations in South Asia studied treatments for cholera using skilled observation. One medical researcher stated, "The author places little reliance on clinical evidence of rehydration. He points out that there may be no difference in the appearance of an individual with a plasma-specific gravity of 1.037 (associated with an extracellular deficiency of 2 liters) and one well hydrated with a plasma-specific gravity of 1.027. Similarly, the plasma CO₂ can fall from the normal 28 mEq./litre to 18 without evident change in the clinical condition" Robert A. Phillips (53).

In 1962, a team of researchers, some had not yet completed their medical residencies, arrived in South Asia to research cholera treatment. By 1970, they overturned the current theory of cholera pathology: that cholera toxin poisoned the sodium pump. The use of a solution consisting of sugar, salts, and water could save the lives of severely dehydrated adults, children, and infants. However, the prevailing scientific theory prevented the publication of their research findings until 1983, when it became a chapter in a book on Diarrhea and Malnutrition (54, 55).

"In 1962, a team of researchers, some had not yet completed their medical residencies, arrived in South Asia to research cholera treatment. By 1970, they overturned the current theory of cholera pathology: that cholera toxin poisoned the sodium pump."

Assisted ventilation. In the late 18th Century, it was "generally known that a child, born dead, may be brought to life by inflating its lungs, that the mother herself, or some other person, might have tried the experiment" (56). In 1814, a medical officer used mouth-to-mouth resuscitation: "there was reason to believe that life had not been long extinct. The child's lungs were, therefore, immediately inflated from my own, while the body was immersed in hot water, and volatile spirit occasionally applied to the nose, mouth, and chest." Again, "Interposing a piece of muslin inflated the lungs from my mouth, closing the nostrils by the pressure of my fingers. The thorax was compressed after each inflation, and thus artificial respiration was maintained, observing the natural periods of frequency, and keeping in mind the difference of capacity between the child's lungs and my own. In about half an hour, I felt a faint pulsation of the heart; a little fluttering, I thought I had perceived, once or twice at intervals, a few minutes before, but I was hardly sure of it." And again, several more times (57).

The officer also worked with spectators and scientists who told him it would not work. "I am aware this practice has been objected to. It has been urged that inflating the lungs with air so charged with carbonic acid gas is more likely to destroy than restore life. This objection is plausible but cannot possibly be true. Were it so, no case, such as those detailed where this method was used, could have been restored. A thing of which the uniform tendency is to destroy life, never can in a single instance reanimate, so that these cases show most satisfactorily that expired air may be taken not only safely, but salubriously, into the lungs of another... [B]ut I am sure the usual method of blowing into the lungs does

not merit that censure which has been cast upon it. While I would place my chief reliance on insufflation, persevering to repeat it at short intervals" (58).

We can use mouth-to-mouth resuscitation to model bag-valve-mask (BVM) resuscitation. BVM is associated with barotrauma and gastric insufflation (59, 60), complications rarely observed with mouth-to-mouth resuscitation. During mouth-to-mouth resuscitation, the rescuer feels the pressure change in lung compliance on inspiration and the end of expiration by the cheek. One of the author's (DvS) experience administering mouth-to-mouth breathing in the field to an infant, adolescent, and adult later informed his approach to BVM and mechanical ventilation for spontaneously breathing patients (61). As noted by Dr. Wilson in 1829, "I am aware this practice has been objected to."

Military combat. Several academicians criticized a study of soldiers in the operational area (62):

- As important as their study could be, however, problems in its design and execution limit any attempt to conclude it.
- [The authors] do not indicate that these quotes are statistically representative.
- [The authors] conclusions, if valid, would challenge the conventional wisdom about cohesion by showing that contrary to the consensus findings of the vast literature, the distinction between social and task cohesion is irrelevant.

"Strong research design and statistical analysis assume a Gaussian curve from a white noise environment. Conventional wisdom develops in an environment that is either white noise or long-period white noise and was encountered in several of the vignettes above."

Strong research design and statistical analysis assume a Gaussian curve from a white noise environment. Conventional wisdom develops in an environment that is either white noise or long-period white noise and was encountered in several of the vignettes above. The authors of the critiqued publication had deployed to an active war zone.

"Interviews were conducted in the active combat zone with infantry soldiers who were fully armed and prepared to engage the enemy without notice. Each soldier or marine interviewed had at least one member of his organization wounded or killed in the preceding thirty days—several uniforms still bore bloodstains left by the evacuation of comrades—dark blotches over the chalky-white salt from daily living in 112-degree heat."

"Is [it] scientifically appropriate to assume that the extensive work done in peaceful settings will necessarily generalize to combat?"

"Previous work by the author that was based on data collected in combat has been criticized based on its ability to generalize to research done in routine, peaceful settings. The idea that behavioral and social scientists may test the robustness of their theories by studying the same phenomenon across *in extremis* settings is explored. Research involving human participants conducted in safe,

peaceful settings will not necessarily generalize to combat; combat findings may differ from those developed elsewhere. The appropriate scientific approach is to replicate and extend, in the combat context, findings already well established in peacetime work."

Thomas A. Kolditz (63)

Conclusion

Forcing functions are an abiotic feature of ecosystems that influence, if not create, the organization's environment. By design, some organizations regularly operate in adverse environments while others prepare for the sporadic but expected red noise forcing function. The science of risk management addresses the possibility that all organizations must respond to a forcing function of some magnitude.

"Forcing functions are an abiotic feature of ecosystems that influence, if not create, the organization's environment. By design, some organizations regularly operate in adverse environments while others prepare for the sporadic but expected red noise forcing function. The science of risk management addresses the possibility that all organizations must respond to a forcing function of some magnitude. "

Individuals and organizations create and rely on the created structure. Patterns of defenses differ based on expected risk: predictability, controllability, variability, and the costs of defense (64). Note several elements are also causes of stress. Organizations that do not routinely experience forcing functions are more likely to use proactive defense mechanisms. Individuals, however, often use inducible reactive defense mechanisms, as illustrated by the vignettes in this article.

Risks will vary by location or over time, and defenses carry costs (64):

- Risks are predictable and controllable – proactive defenses have the greatest effectiveness
- Risks are increasingly unpredictable or uncontrollable – Reactive defenses are more effective and reliable
- Risks are consistently high, or defensive costs are low – fixed constitutive defenses become effective (spines, shells)
- Absence of the predator – vigilance, a defense cost, sustains the stress response with chronically elevated glucocorticoid levels (65, 66)

Inducible antipredator responses allow the selection of antipredator behaviors with variable expression, increased behaviors for elevated risks, and decreased expression as the risk abates [5]. We have an inducible antipredator response – terminate ongoing behaviors (the stress HPA axis) while initiating attention-arousal behaviors (the LC-NE system), which utilizes broad attention networks to sustain adequate cognition under stress.

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Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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



Limit Contact with Others

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



Provide Protective Immunity

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



Take Care of Yourself

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



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



WARNING

Never Put a Mask on Your Baby

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



If you are positive for COVID-19

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



We can help protect each other.

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Fellow's Column: Food Insecurity: Does Infant Formula Shortage Count?

Ariana Bolumen MD, Viviana Juarez MD, Hannah Cummins DO, Shabih Manzar, MD

Abstract:

This article briefly discusses the food insecurity issue created by the recent recall of infant formulas. The reasons for the problem and solutions are provided with the CDC reference.

“Food insecurity (FI) in infancy sounds like a problem of the developing world, but recently a relatively large community of parents encountered food insecurity after the formula recall. Abbott Nutrition recalled various brands and lot codes of powdered infant formula because of possible *Cronobacter sakazakii* contamination.”

Food insecurity (FI) in infancy sounds like a problem of the developing world, but recently a relatively large community of parents encountered food insecurity after the formula recall. Abbott Nutrition recalled various brands and lot codes of powdered infant formula because of possible *Cronobacter sakazakii* contamination. This recall has created a “food insecurity” for certain families, as they cannot access the formula due to the disruption of the supply. Food insecurity affects an estimated 15 million Americans, with high rates among children aged 0-17 years living in a food-insecure household. (1) The problem is further aggravated by low breastfeeding rates (BF). Although BF rates in the United States have increased from 1973 to 2015, social and racial disparity still exists. (2) In developing countries, the rate is relatively higher, but it has been shown that mothers from food-insecure homes were less likely to breastfeed exclusively than mothers from food-secure households. (3) Therefore, the reliance on infant formula is high, creating food insecurity with any break in the supply chain.

What about promoting BF? This is not simple. The global infant and young child feeding practices (IYCFP) showed a 42-49% initiation rate in BF, but only 37% of children younger than six months were exclusively breastfed. (4) The other issue is with the marketing and trade policies. Salmon (5) pointed out the conflicting policy between promoting and protecting the BF. She highlighted the role of the trade environment that facilitates the marketing and consumption of breast milk substitutes.

Alternatives/advice for the families (see Appendix- Formula Guide for Parents):

The CDC provides useful information on the infant formula use (<https://www.cdc.gov/cronobacter/infection-and-infants.html> and <https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html>)

1. Use another brand. The US Food and Drug Administration (FDA) regulates all commercial infant formula brands to en-

sure they meet the minimum nutritional and safety requirements. You may use another brand but make sure that the ingredient requirements match with the recalled formula. Special formulas have special formula alternatives. Refer to your pediatrician.

2. **Homemade Infant Formula:** The FDA and the American Academy of Pediatrics (AAP) discourage and warn against using different recipes to make homemade infant formula. In a recent study, DiMaggio et al. (6) found that out of 2,315 respondents, 14% of the respondents used European infant formula, 5% used toddler formula, and 2% made homemade infant formula.
3. **Imported Infant Formulas:** The FDA does not review these formulas. These illegal formulas may not have been shipped and stored per regulations. AAP warns against using these illegally imported formulas. So, the risks associated with these formulas are even much higher.
4. Talk to the local community health worker, public health officer, and social worker. They could be a good resource.
5. The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) office could provide help. Call your local WIC office and ask for help.
6. Consider shopping for the alternative formulas in different retail stores or even in different neighborhoods. Unfortunately, many parents have to drive many miles to get the right formula for their infants. Do not shop from an online marketplace or third-party distributors.

While families still struggle with the business side of acquiring the required infant formula, and we hope that this will resolve soon, the whole scenario provides pediatricians an opportunity to further encourage the families to follow the AAP guidelines, which state:

“The AAP reaffirms its recommendation of exclusive breastfeeding for about six months, followed by continued breastfeeding as complementary foods are introduced, continuing breastfeeding for one year or longer as mutually desired by mother and infant.” (7)

“Imported Infant Formulas: The FDA does not review these formulas. These illegal formulas may not have been shipped and stored per regulations. AAP warns against using these illegally imported formulas. So, the risks associated with these formulas are even much higher.”

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Formula Guide for Parents

| Categories | Indications | Commonly Used | Alternatives |
|---|---|---|---|
| <u>Term Formulas</u> | | | |
| <p>Milk-Based</p> <ul style="list-style-type: none"> - 20 kcal/oz - Carbohydrate source: lactose - Protein Source: Cow's milk protein | <ul style="list-style-type: none"> - Standard term infant formula | <p>Similac Advance/ProAdvance*</p>  <p>Similac 360</p> <p>Total Care* [Launched 11/2021] The first and only infant formula containing a blend of five different human milk oligosaccharides (HMOs) closely resembling the prebiotic blend found in breastmilk.</p>  | <ul style="list-style-type: none"> - Enfamil Infant/neuropro* - Enfamil Enspire - Gerber Good Start - Parent Choice Advantage/Infant Up & up Advantage - Member's Mark Infant - Kirkland Infant/ Procare - Earth's Organic Infant  |
| <p>Milk-Based Caloric Density</p> <ul style="list-style-type: none"> - 24 kcal/oz - Carbohydrate source: lactose - Protein Source: Cow's milk protein - Only available in liquid concentrate form | <ul style="list-style-type: none"> - Infants with higher energy requirements and fluid restriction - Failure to Thrive, Low Birth Weight, Heart Disease | <ul style="list-style-type: none"> - Similac with Iron 24*  | <ul style="list-style-type: none"> - Enfamil  |
| <p>Milk-Based Reduced Lactose</p> <ul style="list-style-type: none"> - 20kcal/oz - Carbohydrate source: reduced lactose ~ 5% - Protein source: Milk protein isolate | <ul style="list-style-type: none"> - Fussiness, excess flatulence and mild spitting up - Due to lactose insensitivity | <p>Similac</p>  <p>Sensitive</p>  <p>Similac 360 Total Comfort Sensitive</p>  | <ul style="list-style-type: none"> -Enfamil Sensitive - Gerber Good Start GentlePro - Parent Choice Sensitivity - Kirkland Sensitive - Member's Mark Sensitivity - Up & Up Sensitivity - Earth's Organic Sensitive  |

| | | | |
|--|--|---|---|
| <p>Soy-Based</p> <ul style="list-style-type: none"> - 20 kcal/oz - Carbohydrate source: fiber oligosaccharides, glucose polymers from corn syrup, and sucrose. Lactose-Free - Protein source: Soy protein | <ul style="list-style-type: none"> - Infants with an inability to breakdown lactose - Lactose intolerance (primary or secondary), Galactosemia, vegetarian/Vegan families | <p>Similac Soy Isomil</p>  | <ul style="list-style-type: none"> - Enfamil ProSobee - Enfamil Simply Plant-Based - Gerber Good Start Gentle Soy - Parent Choice Soy - Up & Up Soy - Earth's Organic Soy  |
| <p>Partially Hydrolyzed/Reduced Lactose</p> <ul style="list-style-type: none"> - 20 kcal/oz - Carbohydrate source: Sucrose, Galactooligosaccharides, reduced lactose - Protein source: partially hydrolyzed whey protein - NO casein | <p>Infants that experience colic, fussiness, flatulence, and/or other digestive symptoms</p> <ul style="list-style-type: none"> - Due to milk intolerance - Usually next step if Sensitive formulas are not tolerated well | <p>Similac Total Comfort</p>  | <ul style="list-style-type: none"> - Enfamil Gentlease - Gerber Good Start SoothePro - Parent Choice Gentle - Member's Mark Gentle Up & Up Gentle - Earth's Organic Gentle  |
| <p>Prethickened</p> <ul style="list-style-type: none"> - 20 kcal/oz - Milk-Based - Mixed with pregelatinized waxy rice starch | <ul style="list-style-type: none"> - Spitting up due to GERD | <p>Similac Spit-Up</p>  | <ul style="list-style-type: none"> - Enfamil A-R  |

| Categories | Indications | Commonly Used | Alternatives |
|---|---|--|---|
| <u>Preterm Formula</u> | | | |
| Standard <ul style="list-style-type: none"> - Only while in NICU - 20 kcal/oz or 24 kcal/oz - Carbohydrate source: lactose - Protein source: cow's milk protein | <ul style="list-style-type: none"> - Prematurity, Weight <1,800g, or poor growth | Similac Special Care 20 Similac Special Care 24 HP  | Enfamil Premature 20 Enfamil Premature 24 HP  |
| Premature High Calorie <ul style="list-style-type: none"> - Only while in NICU - 30 kcal/oz - Carbohydrate source: lactose - Protein source: cow's milk protein | <ul style="list-style-type: none"> - High-calorie needs or fluid restriction in prematurity - VLBW (<1,500 g) and ELBW (<1,000g) [receive parenteral nutrition with glucose, protein, and electrolytes +/- trophic feeds] - Failure to Thrive, Low Birth Weight, Heart Disease | Similac Special Care 30  | Enfamil Premature 30  |
| Premature Transitional <ul style="list-style-type: none"> - Prior to discharge from NICU - 22 kcal/oz - Carbohydrate course: lactose - Protein source: Cow's Milk protein | <ul style="list-style-type: none"> - Weight > 1800g or 24 weeks gestation | Similac Special Care Neosure 22  | Enfamil  Enfacare |
| Soy formula is nutritionally inappropriate for preterm infants because of the associated risk of osteopenia, rickets, aluminum toxicity, and prevention of adequate absorption of zinc, phosphorus, and iron. | | | |

| Categories | Indications | Commonly used | Alternatives |
|---|---|--|---|
| <p>Specialized Infant Formulas</p> <ul style="list-style-type: none"> - Extensively Hydrolyzed - 20kcal or 24 kcal/oz - Carbohydrate source: Lactose free - Protein source: peptide-based; containing hydrolysates of casein or whey. extensively hydrolyzed cow's milk protein - Component of medium-chain triglycerides (MCT 30-35%) - Partially true hypoallergenic | <ul style="list-style-type: none"> - First-line management of cow's milk protein allergy - Fat malabsorption - Resolution within months is common. | <p>Similac Alimentum*</p>  | <ul style="list-style-type: none"> - Pregestimil* - Pregestimil 24* (liquid only) - Enfamil Nutramigen - Parent Choice - Hypoallergenic - Up & Up Hypoallergenic  |
| <ul style="list-style-type: none"> - Free Amino Acid - 20kcal/oz - Non-allergenic amino acids - Lactose-free - Contain medium-chain fatty acids (MCT) - True hypoallergenic | <ul style="list-style-type: none"> - Severe cow's milk protein allergy - multiple food allergies (including eosinophilic esophagitis) - Short bowel syndrome if human milk is not available (these infants are prone to food allergies) | <p>Elecare Infant</p>  | <ul style="list-style-type: none"> - Puramino - Extensive HA Gerber - Neocate  |
| <ul style="list-style-type: none"> - Fat-Modified - 30 kcal/oz - balances high levels of medium-chain triglycerides (MCT) oil for easier absorption (up to 85% of MCT) - Easy to digest 60:40 whey-casein ratio - Suitable from birth to one year as a sole source of nutrition - Suitable for use as a supplementary feed in children >1 year of age and adults | <ul style="list-style-type: none"> - Fat malabsorption (LCHAD deficiency) - Chylolthorax | <p>-Enfaport Lipid</p>  | <p>-Monogen</p>  |
| <ul style="list-style-type: none"> - Renal - Standard infant formula used with phosphate binders - Reduced mineral/electrolytes - Mineral levels closely resemble human milk - Calcium-to phosphorus ratio and content | <ul style="list-style-type: none"> - Serum calcium disorders—both hypercalcemia and hypocalcemia due to hyperphosphatemia - Additional iron should be supplied from other sources - Supply LBW infants weighing less than 1500 g at birth with additional calcium, phosphorus, and sodium during periods of rapid growth | <p>Similac PM 60/40</p>  | <p>RenaStart</p>  |
| <p>Monitor closely if on Neocate, associated with hypophosphatemia and rickets.</p> | | | |

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- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
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- **The Lancet:** COVID-19 and pregnancy
- **MotherToBaby:** Coronaviruses
- **WHO:** Emerging respiratory viruses

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INFANT AND FAMILY-CENTERED DEVELOPMENTAL CARE (IFCDC)

STANDARDS AND SAMPLE RECOMMENDATIONS FOR INFANTS IN THE INTENSIVE CARE UNIT

SYSTEMS THINKING IN COMPLEX ADAPTIVE SYSTEMS



- Are the baby and family central to the mission, values, environment, practice & care delivery of IFCDC in the unit?
- Are the parents of each baby fully integrated into the team and treated as essential partners in decision-making and care of the infant?
- What are the strategies and measurements used to improve and sustain IFCDC in the unit?

POSITIONING & TOUCH FOR THE NEWBORN

- Are the positioning plans therapeutic and individualized, given the care needs and development of the baby?
- Are the positioning and touch guidelines continually reviewed by the team, including the parents, and adapted to meet the changing comfort needs of the baby?



SLEEP AND AROUSAL INTERVENTIONS FOR THE NEWBORN



- Can the team confidently describe the "voice" or behavioral communication of the baby?
- Are the baby's unique patterns of rest, sleep, and activity documented by the team and protected in the plan of care?

SKIN-TO-SKIN CONTACT WITH INTIMATE FAMILY MEMBERS

- Is the practice of skin-to-skin contact supported and adjusted to the comfort needs of each baby, parent, & family member?
- Are the parents & family members supported to interact with the baby to calm, soothe, & connect?



REDUCING AND MANAGING PAIN AND STRESS IN NEWBORNS AND FAMILIES



- Are parents supported to be present and interactive during stressful procedures to provide non-pharmacologic comfort measures for the baby?
- Are there sufficient specialty professionals to support the wellbeing of the team, including parents, families, and staff? Examples include mental health, social, cultural, & spiritual specialists.

MANAGEMENT OF FEEDING, EATING AND NUTRITION DELIVERY

- Are the desires of the m/other central to the feeding plan? Is this consistently reflected in documentation with input of the m/other?
- Does the feeding management plan demonstrate a feeding & nutrition continuum from in-hospital care through the transition to home & home care?



WANT TO KNOW MORE ABOUT THE STANDARDS AND RECOMMENDATIONS? VISIT: [HTTPS://NICUDESIGN.ND.EDU/NICU-CARE-STANDARDS/](https://nicudesign.nd.edu/nicu-care-standards/)

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About PAC/LAC

The Perinatal Advisory Council: Leadership, Advocacy and Consultation (PAC/LAC) has been a leading maternal and child health organization since its incorporation as a non-profit agency in 1981. PAC/LAC's mission is to improve perinatal health outcomes by providing leadership, education and support to professionals and systems caring for women and their families. Children's health and well-being start with a healthy pregnancy and the events that occur during an infant's first few hours of life. PAC/LAC strives to make those first health experiences the best by ensuring that pregnant women, babies, and families are cared for by the most competent professionals in well-equipped health care settings. PAC/LAC has a long-standing reputation of excellence in the community for our work with hospitals and health care professionals.

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- education and networking plus access to the leaders who are making a difference in perinatal care.

Objectives

- Assess the maternal mortality and severe morbidity in California and current initiatives.
- Define substance use disorder and various substances that impact fetal development, infants, and children.
- Give examples of various types of environmental exposures affecting reproductive health and development.
- Define implicit bias and care equity and its impact on healthcare disparity.
- Describe the standard of care for consistent management of prenatal, intrapartum and postpartum patients with Diabetes.
- Discuss the effects of Diabetes on the neonate and breastfeeding.
- Understand the data and current practice recommendations for COVID-19 in perinatal and women's healthcare.

CONFERENCE AGENDA

7:30am Registration & Breakfast

7:55am Opening Remarks

Sherri Mendelson, PhD, RNC, CNS, IBCLC
PAC/LAC Board President

8:05am Keynote Speaker

Elliott K. Main, MD
Obstetrics & Gynecology, Stanford, CA Clinical Professor Obstetrics & Gynecology
Medical Director CMQCC
Stanford University School of Medicine

**9:00am Maternal & Fetal Medicine/High Risk Substance Abuse:
Mother/Baby**

Margaret Lynn Yonekura, MD
Maternal-Fetal Medicine
Director Community Health,
Dignity Health-California Hospital Medical Center

10:00am Break and Exhibits

**10:15am Generation Chemical: Environmental Exposures are Affecting
Reproductive Health and Development**

Marya Zlatnik, MD
Associate Director of the Maternal-Fetal Health and the Environment Program
at the UCSF Western States Pediatric Environmental Health Specialty Unit

11:15am Implicit Bias & Care Equality

Wenonah Valentine, MBA
Founder in Residence and Executive Director

12:15pm Lunch

12:35pm Poster Session

1:00pm Award Presentations

1:30pm Medical Management of Diabetes in Pregnancy

Gladys (Sandy) Ramos, MD
Director, Diabetes and Pregnancy Program
Department of Obstetrics, Gynecology and Reproductive Sciences
UC San Diego Health System

2:15pm Effects of Diabetes on Neonates; Including Breastfeeding

Christine Bixby, MD, FAAP, IBCLC
Division of Neonatology, CHOC Children's
Specialists Medical Director, CHOC Lactation

3:00pm Break

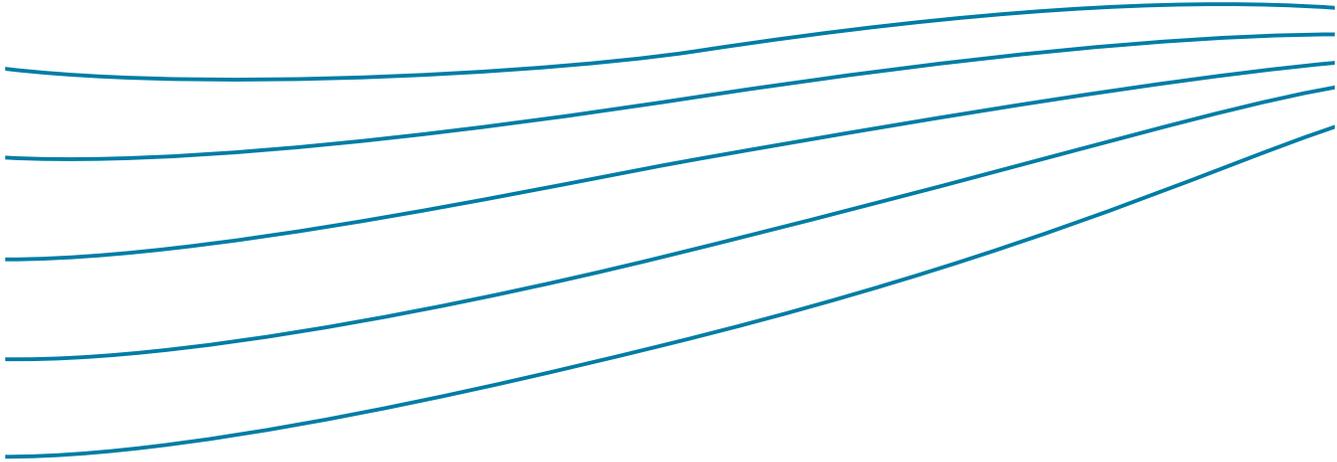
3:15pm COVID, The Vaccine and Women's Health Care

Hellen Rodriguez, MD
Medical Director, Maternal-Fetal Medicine
Pomona Valley Hospital Medical Center

4:15pm Door Prizes and Closing Remarks

PAC/LAC Staff

*Agenda is subject to change without notice.



Conference Fees:

Registration fees include: breakfast, lunch, snacks, CEUs, CMEs, CHES, LCSW and LMFT. Registration fee is refundable if cancellation is received by May 20, 2022. No refunds will be granted after that time.

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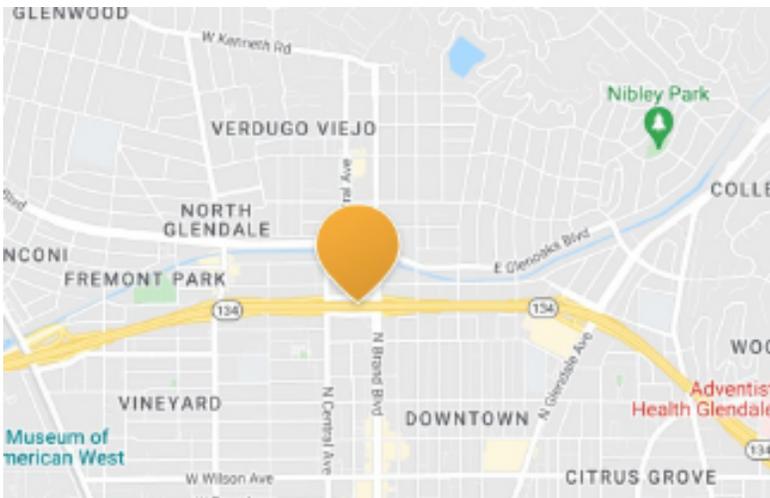
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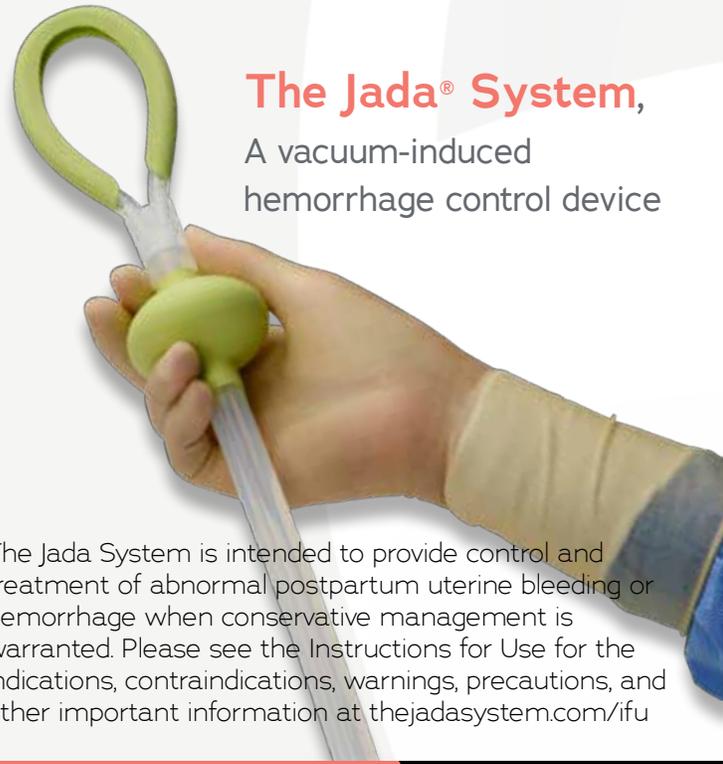


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Randall Bell, Ph.D.

Cold Stress in Emergency Room Leads to Adverse Outcome

Maureen E. Sims, MD, Barry Schifrin, MD

Fact pattern

A 28-year-old G3P1 patient at 34 weeks gestation developed contractions and was admitted for premature labor with intact membranes. Her Group B streptococcus (GBS) status was unknown at admission but a vaginal/rectal culture collected 7 hours after admission was positive. She received penicillin 3 hours before delivery. She made normal progress in labor and delivered spontaneously 1 hour after membranes were ruptured. The membranes were artificially ruptured 1 hour prior to delivery. A 34-week female infant with a birthweight of 2170 grams was delivered and received Apgars scores of 7 and 8, at 1 and 5 minutes, respectively. The baby was cared for in the Newborn Intensive Care Unit (NICU). The physical exam was unremarkable and was considered appropriate for gestational age (AGA). She received an evaluation for sepsis, including a lumbar puncture and two days of antibiotics. She remained asymptomatic, and all laboratory values were unremarkable, including blood and cerebral spinal fluid cultures. She was discharged after eight days. The placental examination was normal.

“A 34-week female infant with a birthweight of 2170 grams was delivered and received Apgars scores of 7 and 8, at 1 and 5 minutes, respectively. The baby was cared for in the Newborn Intensive Care Unit (NICU). The physical exam was unremarkable and was considered appropriate for gestational age (AGA). She received an evaluation for sepsis, including a lumbar puncture and two days of antibiotics.”

A week after discharge, she visited her pediatrician for a well-baby check and was doing well. However, 12 days after that visit, when she was a month old, she stopped eating, became listless, developed pallor, and had fewer wet diapers and diminished crying compared to previously. She was brought to the Emergency Department (ED), where examination revealed a 2.7 kg child with poor muscle tone, flat to sunken fontanel, dry mucous membranes, and poor air movement. Her heart rate (HR) was 200 beats per minute (bpm), her respiratory rate (RR) was 56 breaths per minute, and her temperature was **96.5°F**. Her oxygen saturation (SaO₂) was 95%. A peripheral intravenous venous line was started with a bolus of normal saline. Studies were ordered, including bilirubin, blood culture, and urine analysis,

and about an hour after admission, she was started on ampicillin and cefotaxime. A chest radiograph showed non-specific bilateral perihilar interstitial prominence. The white blood cell count (WBC) revealed a low count of **2.9 x 10⁹/L**, the hematocrit was 46%, and the platelet count was 302 x10⁹/L. The electrolytes and urinalysis were unremarkable. An hour and a half after admission, the baby was transported to the radiology department for computerized axial tomography (CT) of her head. Following removal from the scanner, the child was noted to have profound bradycardia with severe desaturation. Upon her immediate return to the ED, the baby was pale and not breathing, and cardiopulmonary resuscitation was instituted immediately. A review of the events revealed that the nurse accompanying the baby had not assessed either the monitoring strips or the baby during the trip to the radiology department, during the procedure, or even shortly after departure from the Radiology Department. The radiologist called the ED to inform the physician that the CT was negative.

“ Upon her immediate return to the ED, the baby was pale and not breathing, and cardiopulmonary resuscitation was instituted immediately. A review of the events revealed that the nurse accompanying the baby had not assessed either the monitoring strips or the baby during the trip to the radiology department, during the procedure, or even shortly after departure from the Radiology Department.”

After the baby's normal HR was restored, non-meningitic doses of ampicillin and cefotaxime were administered. A normal saline bolus was given, and a blood gas was drawn, which showed a pH of 7.13, a PCO₂ of 77mmHg, a pO₂ of 71 mmHg, and a base deficit of 3. The ED physician decided at this point to do a lumbar puncture (LP). After five attempts, the transport team arrived, and attempts to obtain cerebral spinal fluid were abandoned. The baby's HR was 160 bpm, the SaO₂ was 100%, and her temperature was **93.9°F** (33.8°C). At this point, she was apneic and was being manually ventilated by the respiratory therapist. Her blood pressure (BP) was 88/56 with a mean of 67 mmHg. This was her only BP in the ED. Five hours after being admitted to the ED, the baby was transported to a higher-level medical facility. The transport team slowly and appropriately warmed the baby during transport.

At the referral center, the baby continued to be lethargic and had decreased movement. Her temperature was 36.80F, HR 188 bpm, BP 79/50 mmHg, and SaO₂ 100% on arrival. Ampicillin,

cefotaxime, and vancomycin were given at meningitic doses, to which were added Acyclovir, bicarbonate, packed red blood cell transfusion, two normal saline boluses, and Lasix. Lactic acid was moderately elevated and increased as perfusion improved; liver function tests were moderately high. The blood culture drawn at the ED 12 hours earlier was positive for GBS. An LP performed that day when the baby was stable was also positive for GBS. She developed seizures, central diabetes insipidus, and adrenal insufficiency, all ascribed to her GBS meningitis during this hospitalization. The magnetic resonance imaging (MRI) done later that evening was consistent with an acute hypoxic-ischemic injury with abnormal signals in the deep gray matter. Several days later, another MRI and an MR venogram (MRV) showed diffuse pachymeningitis and cerebritis with acute infarcts involving the bilateral occipital and temporoparietal lobes, right thalamus, left lentiform nucleus, bilateral deep white matter, and bilateral frontal lobes as well as extra-axial fluid collections.

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On follow-up evaluations, the child continued to have seizures that were difficult to control. She had global developmental delays, cortical blindness, central hypothyroidism, cerebral palsy, constipation, gastroesophageal reflux, rumination, and sleep disturbance.

Opinions and allegations

1. The baby was in critical condition upon entering the ED. The history of lethargy, poor feeding, poor output, and her abnormal physical findings of low temperature (96.5), tachycardia, dry mucous membranes, and flat to sunken fontanelles required the physicians and nurses to evaluate and stabilize the baby immediately.
2. The history, physical examination, and leukopenia all pointed to infection. Sending the baby to CT was not only detrimental but was unlikely to have diagnostic or therapeutic implications. Inexplicably, she was not monitored during this time and became profoundly hypothermic and hypoxemic and suffered a neurological injury.
3. Thus, it was below a reasonable standard of care

- i. To fail to place the baby immediately under a radiant warmer,
- ii. To fail to insert two peripheral intravenous lines (one for antibiotics and one for fluid support),
- iii. To fail to maintain close vigilance of vital signs, including BP, temperature, HR, and SaO₂,
- iv. To fail to obtain additional laboratory examinations, including polymerase chain reaction (PCR) for herpes and blood gas,
- v. To fail to immediately (within 30 minutes) provide doses of antibiotics sufficient to cover potential meningitis as well as Acyclovir,
- vi. Fail to make immediate plans for transport to a higher center of care even while the evaluation was performed,
- vii. Further, the LP should have been deferred until the baby was stable (and abandoned before five failed attempts!). Similarly, the baby should not have been sent for CT scan. The management of this baby at the ED was reckless.

The defense's position was that the baby had GBS meningitis upon entry to the ED and that the standard of care was met.

Causation

Babies born at 34 weeks gestation are more vulnerable to infection than term babies. Preterm babies are deprived of normal amounts of maternal immunoglobulins transferred from the mother through the placenta to the fetus during the last trimester.

The respiratory arrest was secondary to iatrogenic hypothermia. The baby entered with a temperature of 96.5°F because of sepsis. There was no effort to maintain normothermia during the 5 hours in the ED. She decompensated because of the hypothermic stress, which led to a cardiopulmonary arrest leading to hypoxic-ischemic encephalopathy, while her GBS sepsis (inadequately treated) advanced to meningitis. The antibiotics administered could not adequately combat the GBS since her circulation was profoundly compromised.

“The respiratory arrest was secondary to iatrogenic hypothermia. The baby entered with a temperature of 96.50F because of sepsis. There was no effort to maintain normothermia during the 5 hours in the ED. She decompensated because of the hypothermic stress, which led to a cardiopulmonary arrest leading to hypoxic-ischemic encephalopathy, while her GBS sepsis (inadequately treated) advanced to meningitis.”

The case was settled against the ED.

Discussion

Thermal management of the newborn infant is a cornerstone of neonatal care. Globally, hypothermia contributes to neonatal mortality and morbidity, and the potential impact of optimal thermal care provision on infant health is potentially considerable. Physicians caring for newborn infants have appreciated this important concept for over a century, and neonatologists have made considerable strides in fine-tuning thermal control in the delivery rooms and Newborn Intensive Care Units. However, the infant's thermal care in Emergency Rooms may not have been managed appropriately. In general, adequate thermal management depends at least as much on sound knowledge as on the use of high-tech devices such as incubators, radiant warmers, heat lamps, and heated mattresses, administration of warmed fluids, and the need to closely monitor an infant's temperature. In the ED, assessment, and procedures often require the exposure of a large portion of the infant's body surface, increasing the difficulty of maintaining the infant's temperature.

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Premature infants are at greater risk for hypothermia than older children and adults for several reasons: greater ratio of skin surface to body weight, less subcutaneous and brown fat, decreased ability to increase heat production through shivering, and limited glycogen stores to support heat production. An infant with a coexisting vulnerability is particularly susceptible to cold stress.

The above case described a baby with GBS sepsis whose temperature was 96.5°F upon entering the ED, but because the staff did not appropriately manage her thermal needs, the temperature dropped to 93°F. She developed apnea and bradycardia and required full resuscitation. The antibiotics eventually given to her could not adequately enter his circulation because of profound perfusion issues.

The neutral thermal environment (NTE) has been defined as maintaining the infant's temperature with a stable metabolic state and minimal oxygen and energy expenditure. It is not a fixed temperature but instead varies with gestational age, birthweight,

and the age of the newborn. Effective thermoregulation requires adequate energy stores (primarily glucose), insulation (fat deposits), hypothalamic function, and muscle tone. When environmental temperatures fall below the NTE, metabolic demands increase, increasing oxygen consumption as the infant attempts to restore NTE. If this deterioration continues, compensatory mechanisms are exhausted, and eventually, the infant's temperature decreases further. Increased glucose utilization results in exhaustion of glycogen stores, decompensation of the cardiac and respiratory systems, and death. In order to ensure the NTE is maintained in infants who are unable to achieve this with their physiological measures, it is essential to provide environmental thermostability by blocking avenues of heat loss and applying adequate warmth and adequate temperature monitoring.

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Suggested reading:

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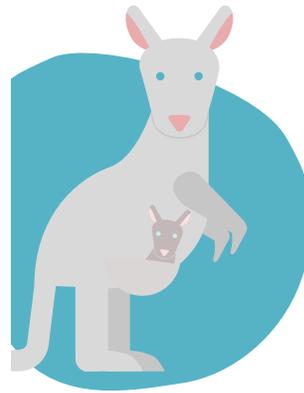
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work with your medical team to create a plan

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- **SEPARATION AND TRAUMA**



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What is the best
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- S**EEK PARTICIPATION
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- A**SSESS PREFERENCES
- R**EACH A DECISION
- E**VALUATE THE DECISION



TRAUMA-INFORMED

Both parents and providers
are confronting significant...

- **FEAR**
- **GRIEF**
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We need to understand more about outcomes for mothers
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Gravens By Design: Common Questions for Designing Today's State-of-the-Art NICU

Judy Smith, MHA

Abstract:

This article guides NICU stakeholders and others planning new construction, renovation, or evaluation of NICU design. The author poses six common questions related to the strategic and facility planning of a NICU. Responses to these questions are provided within the context of current thinking, best practices, and emerging trends. Keeping up with information about planning state-of-the-art NICUs helps achieve more informed decisions and better designs.

“Responses to these questions are provided within the context of current thinking, best practices, and emerging trends. Keeping up with information about planning state-of-the-art NICUs helps achieve more informed decisions and better designs.”

The annual Gravens Conference includes a design track where NICU participants, families, researchers, planners, architects, and others share evidence-based design, experience, and new ideas. Stories abound about NICU stakeholders who arrived at the conference with design plans in hand and then went home with changed plans when rich discussions and research illuminated their perspectives.

Over the years, the conference has framed common questions for planning today's NICU design. While questions and objectives may not have changed significantly, the responses have evolved with research and experience.

Well-informed decisions help achieve the best possible NICU design. This article elaborates on a few typical topics that arise early in planning a NICU project. This information might also help dispel myths about NICU design that could surface during design plan-

ning exercises.

The following six questions are typically discussed during strategy and design planning. Each will be addressed in the context of current thinking and best practices.

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What NICU design models prevail?

NICUs continue to include more single-family room designs, the prevailing model for new construction in the United States (US). The movement to better control the high-risk infant's environment, such as lighting, noise, temperature, infection prevention, and privacy, began many decades ago. In the spirit of “form following function,” more NICUs continue to explore physical designs that better support practices related to developmental and family-centered care.

Many of today's newly constructed NICUs have all single or single and twin/triplet rooms exclusively. However, several hybrid models have emerged with a mix of multi-bed/multi-function rooms to address couplet care, babies without parents' presence, capacity surges, and other flexible uses. These multi-function rooms tend to be a smaller portion of the total beds in their NICUs than the percentage of single bedrooms.

While still prevalent, NICUs with mostly open ward designs are rare for recent new construction or major renovation in the US. According to a Vermont Oxford Network (VON) study of member NICUs, a large NICU group in North America, the number of NICUs that cared for 90+% of very low birth weight infants in single-family rooms climbed from 13% in 2009 to 27% by 2020. (1) Based on my knowledge of current projects in the planning phase, this proportion will increase as more facilities are refreshed or replaced.

1. What NICU design models prevail?
2. What sizes are today's NICU rooms and units?
3. What is the status of neonatal couplet care?
4. What factors are NICUs considering to decide on highly specialized versus universal design for patient care areas?
5. How are NICUs addressing the senses and neuroprotective best practices?
6. What's on the horizon for future NICU design?

| When might NICUs need more square feet? | When might NICUs need less square feet? |
|--|---|
| <ul style="list-style-type: none"> • Couplet care rooms • Individual bathrooms • Universally sized for PICU/other patient care • Satellite pharmacy, large milk lab, MRI, simulation suite, OR, and other dedicated support services within NICU • Academic teaching center • Significant structural/circulation space | <ul style="list-style-type: none"> <input type="checkbox"/> Centralized off-unit equipment and bed storage <input type="checkbox"/> Off-unit equipment cleaning <input type="checkbox"/> Off unit other spaces such as NICU offices and on-call rooms <input type="checkbox"/> Configured to share support space in ideally-sized clusters (e.g., groupings of 12 bed vs. small #s) <input type="checkbox"/> A significant amount of multi-bed rooms <input type="checkbox"/> Minimum room sizes are used - NICU is not providing high level III or Level IV capability |

What sizes are today's NICU rooms and units?

Hot off the press, the Facilities Guidelines Institute (FGI) has released their 2022 publication that includes NICU design standards. (2) These standards are used or referenced as minimum codes for approximately 43 US states. These guidelines and their rationale were proposed by the consensus committee that develops *Recommended Standards for Newborn ICU Design (2019)*, (3) evaluated by FGI's Health Guidelines Revisions Committee, submitted for public comment, and accepted after thorough vetting.

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Minimum Size - NICU Patient Care

- 180 square feet clear floor area for single infant room - not room size
- 150 square feet clear each, if multiple infants are in the room

These sizes are minimum clear areas and not room sizes. Hospitals should size patient care areas based on how they function. Most large, newly-constructed units that I have been involved in planning include an average of 180-220 square feet in a single infant room. The highest risk, academic teaching hospital NICUs usually need more than the minimum square feet around the infant. Additional space is needed for more bedside procedures, learners, advanced equipment and therapies, parents, and other staff. Better sizing of NICUs can be accomplished by staff testing the proposed size and configuration by simulating activities in a “mocked up” space. Examples of simulated activities usually include patient transfers to resuscitation, parent participation in care, material/medication delivery, and bedside procedures.

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Another metric commonly reviewed during planning is departmental gross square feet (DGSF). Based on my experience with dozens of recent NICU projects, NICUs are built with 650-1,000 DGSF per bed. DGSF includes NICU “department” support spaces for clinical care, operation, and families. This space can vary widely. Below are examples that impact NICU department size.

What is the status of neonatal couplet care?

Neonatal couplet care rooms reduce the separation between hospitalized mothers and NICU babies compared to the traditional approach of moving mothers to a postpartum unit and their babies

| Minimum Size - NICU Bed Area | Minimum Size - Postpartum Bed Area |
|--|--|
| <ul style="list-style-type: none"> • 180 square feet clear floor area for single infant room - not room size • 150 square feet clear each, if multiple infants in a room | <ul style="list-style-type: none"> • 150 square feet clear floor area • Excludes bathroom, vestibule, wardrobe/closet, alcove, etc. • Bathroom required • Exterior window required |

to a NICU after birth. The status for neonatal couplet care appears to be in an early adoption stage. As of early 2022, I have been able to identify the concept at hospitals in 15 US states, several European countries, and Canada. Iterations are emerging with different nomenclature and approaches. A few Swedish and US hospitals have operated neonatal couplet care in their facilities for two decades. The selection criteria and staffing model for using these rooms vary by NICU, as does the percentage of total patient beds that are designed for this model.

While operating standards are not widely standardized, the aforementioned FGI Guidelines (2022) provide design standards for the minimum size of a neonatal couplet care room.

“These rooms usually require 360-460 square feet each, which includes a minimum of 300 square feet clear for patient care and the remaining 60-160 square feet for the bathroom, fixed spaces such as columns, floor-based fixtures, family area, and staff workspace.”

These rooms usually require 360-460 square feet each, which includes a minimum of 300 square feet clear for patient care and the remaining 60-160 square feet for the bathroom, fixed spaces such as columns, floor-based fixtures, family area, and staff workspace. If the neonatal couplet care concept combines a labor/delivery/recovery/postpartum room (LDRP) and a NICU room, the minimum size increases significantly to accommodate labor and birth in addition to postpartum/NICU baby care. This combination model exists, but it is less common at this time. Most, but not all, stakeholders prioritized the adjacency between the neonatal couplet care rooms and the NICU rather than with the labor and delivery area or postpartum unit. Many of the latter areas had already offered mother/baby recovery and postpartum care for babies not requiring intensive care before adding neonatal couplet care.

What factors are NICUs considering to decide on highly specialized versus universal design for patient care areas?

The practice of building NICUs with multiple, differently-designed units based on acuity seems to have waned. Although it is still a practice, graduating and moving babies three or more times is less common now. New NICUs are often planned with more acuity-adaptable spaces that reduce the restrictions on where a baby

can be accommodated. Here are some of the reasons provided when a NICU has moved away from the more customized design by acuity:

- Desire for flexibility of patient care spaces when the mix of patients by acuity changes over time
- Standardized patient care spaces for medical safety/ease of practice for staff
 - ⓐ Fewer staff handoffs for safety considerations
 - ⓐ Consistent, familiar set-ups for staff to provide infant care from room to room
- Supports minimal patient movement for family satisfaction
- Balanced staffing, although patients can still be cohorted
- Perception of facility equity by families

Some NICUs include patient care spaces that are specialized by type of care. Several reasons provided for this practice have included:

- Customized for functions and sized/configured differently (e.g., ECMO, palliative care)
- Dedicated, separate space for sub-units or different levels of care
- Supports patient movement – desire to continue graduation approach
 - ⓐ Clear criteria for patient placement by area help parents understand facility differences
- Specialized staffing assigned to a subset of the NICU (intermediate care nurses who do not provide neonatal intensive care; staff specializing in cardiac, neuro, or small baby care)

Some NICUs provide a blend of mostly acuity adaptable with some specialized patient care spaces. With limited comparative research, the individual hospital usually relies on their research and circumstances regarding this question.

How are NICUs addressing the senses and neuroprotective best practices?

What are some of the state-of-the-art design topics that are common considerations related to protecting the fragile newborn’s brain and supporting sensory development? Planning teams should review the evidence through literature searches, studies, conferences, and expert panel discussions by medical professionals, scientists, NICU staff, and families. This high-level list of ideas are a few of the considerations that should be researched when designing a NICU.

- Lighting Innovations

- Programmable system – circadian rhythm considerations
- Indirect lights – not in the baby’s face
- Flicker/Spectrum/Lumen Metrics
- Auditory Exposure
 - Remove noxious sound and test noise using published threshold guidelines
 - Consistent parent/other voices – live and virtual
 - Music – distinguishing best practices for different uses of music: targeted music therapy, therapeutic music, and music exposure
- Touch
 - Skin-to-skin parent furniture/space
 - Making parent space comfortable
- Smell
 - Mom/parent scent
 - Aromatherapy
- Stimulation
 - Appropriate rather than disruptive
 - Sleep research
- Taste
 - Taste exposure during tube feeding
- NeuroProtection
 - Consultation with Brain Sensitive Care Committees and design to support Brain Protection Bundles
 - All of the above ideas and much more
- Holographic wayfinding, welcoming, and education
- Scent cameras
- Parent-designed family space in the NICU, from layout and furniture to colors that better reflect the diversity and equity of NICU families
- Special delivery units aligned with NICUs and located in freestanding children’s hospitals

We must be on the lookout for emerging trends to make informed decisions. I believe that, similar to a statement known as Amara’s Law,(4) we can overestimate the impact of phenomena like neonatal couplet care in the short run but underestimate its long-term impact that could potentially transform neonatal care. While the chance for rapid, widespread success may be minimized due to the challenges of such a radical shift, it does not mean that this type of care might not take hold and transform practices in the future.

“More recent VON surveys show that the percentage of hospitals with mostly single room NICUs is closer to 30%, and signs indicate it will continue to evolve and grow in the long run, at least in industrialized countries. It may take a few more decades, but eventually, the noisy, open warehouse-type facilities for hospitalized premature and ill infants could become only history.”

“Strategies are always subject to the context of the times and issues the hospital faces. Predicting the future is very difficult at best, but we have the wisdom of research and experience to guide decisions about future design.”

What is on the horizon for future NICU design?

Strategies are always subject to the context of the times and issues the hospital faces. Predicting the future is very difficult at best, but we have the wisdom of research and experience to guide decisions about future design. Here are a handful of emerging design ideas that are likely to become more mainstream in near-future NICUs.

- Changes in power and outlet requirements as energy solutions and devices evolve
 - Ⓞ Virtual/wearables for notification and tracking
 - Ⓞ Extinction of beeping monitors
 - Ⓞ Voice-activated/biological communication

A 2002 poll of the audience at the Graven’s Conference exemplifies this “law.” The participants were asked to predict the percentage of US hospitals likely to embrace single room NICUs in 15 years (by 2017). Approximately 41% of participants predicted that less than 20% of NICUs would go for the model. This percentage was the most frequent response. They were close in their prediction if you consider that VON research showed that 21% of NICUs reported single-room care for their smallest patients in 2016. In the short run, people estimated the barriers were too much for most hospitals. More recent VON surveys show that the percentage of hospitals with mostly single room NICUs is closer to 30%, and signs indicate it will continue to evolve and grow in the long run, at least in industrialized countries. It may take a few more decades, but eventually, the noisy, open warehouse-type facilities for hospitalized premature and ill infants could become only history.

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Judy Smith

Judy Smith has devoted her career and significant personal time to improving the health environment with a great passion for women and children's health. Her consulting experience includes successfully completing hundreds of birth service, NICU, women's and children's healthcare planning projects. She served for several decades on the Facility Guidelines Committee as a women and children's specialist to help shape facility standards for US hospitals. Judy is a founding member of the Consensus Committee that develops and updates *Recommended Standards for Newborn ICU Design*. She is also a facilitator for the newly formed Pediatric Environment Network for the Center for Health Design and a frequent author and lecturer.

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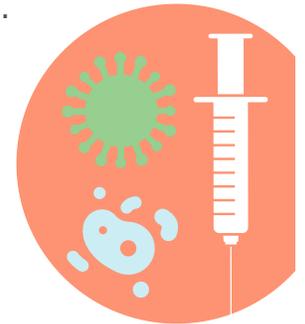


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often with soap and water for 20+ seconds. Dry well.

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for flu and pertussis. Ask about protective injections for RSV.



COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.



USE A HAND SANITIZER THAT IS 60%+ ALCOHOL.



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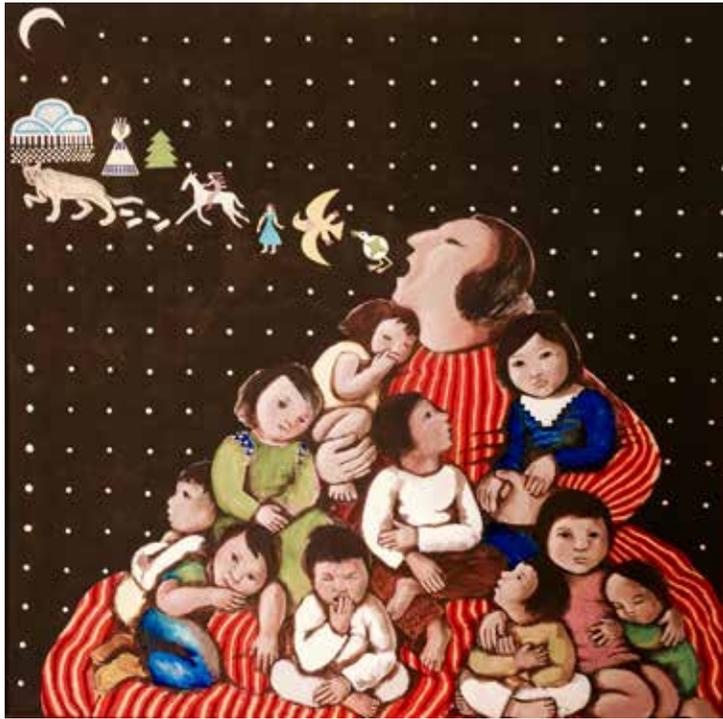
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The First Fragile Infant Forum for Integration of Standards: Implementing the Eating, Feeding, and Nutritional Delivery Standards of Infant and Family Centered Care

Erin Sundseth Ross, Ph.D., CCC-SLP, Carol B. Jaeger, DNP, RN, NNP-BC, Joy V. Browne, Ph.D., PCNS, IMH-E



The First Fragile Infant Forum for Integration of Standards (FIFIS) will provide an opportunity for interprofessional leaders, staff, and parents to discuss and plan the implementation of the feeding, eating, and nutrition delivery standards, one area of infant and family-centered developmental care in intensive care units (<https://nicudesign.nd.edu/nicu-care-standards/>). The Gravens Conference on “The Physical and Developmental Environments of Care” sponsors the work of the Consensus Committee on Infant and Family-Centered Developmental Care (IFCDC), which published the evidence-based *Report of the First Consensus Conference on Standards, Competencies and Best Practices for Infant and Family-Centered Developmental Care in the Intensive Care Unit* in 2020. (1) The committee comprises an interprofessional group of leaders, neonatal nurses and medicine, therapies, perinatal social workers, infant mental health specialists, psychologists, and parents committed to improving services for infants and families within intensive care settings.

Evidence-based standards of care for IFCDC in intensive care

Developmental care is essential to the medical plan of care; it integrates the emotional, relational, and sensory support essential to the baby’s physical, social, and cognitive development. The conceptual model for IFCDC includes the essential elements of care that include a) family involvement, b) neuroprotection of the developing brain, c) environmental protection, d) individualized

care, e) infant mental health, f) collaboration with the infant who is considered as a competent communicator and interactor, and g) systems’ thinking for implementation. Using the essential elements, the committee developed evidence-based standards and competencies for key areas such as sleep and arousal, skin-to-skin contact, feeding and nutrition, touch and positioning, infant and family pain and stress management, and organizational systems. The consensus panel has invited public comment and revision and professional input. The standards and guidelines provide credible, quality practice-to-outcome evidence.

“The IFCDC Feeding Standards state that feeding experiences in the intensive care unit (ICU) shall be behavior-based and baby-led. It is important to note that baby-led principles are similar whether applied to enteral, breast-, or bottle-feeding experiences.”

Evidence-based standards for feeding, eating, and nutrition delivery:

The IFCDC Feeding Standards state that feeding experiences in the intensive care unit (ICU) shall be behavior-based and baby-led. It is important to note that baby-led principles are similar whether applied to enteral, breast-, or bottle-feeding experiences. Every mother shall be encouraged and supported to breastfeed and/or provide human milk for her baby. Nutrition shall be optimized during the ICU period by measuring and monitoring growth and fortifying the human milk as needed to meet full nutritional needs. M/other(s) must be supported to be the primary feeders of their baby. M(other) = describes the dyad and signifies the baby as an active interactor in the nurturing relationship with the mother (biologic or other) and with the interactive and integrated influence of the father/partner/significant other. Family members reinforce and enhance the supportive relationship. Feeding management shall focus on establishing safe oral feedings that are comfortable and enjoyable. Further, caregiving activities shall consider the baby’s response to input, especially around the face/mouth, and aversive non-critical care oral experiences shall be minimized. Professional staff shall consider smell and taste experiences that are biologically expected. Support for the baby’s self-regulation shall be encouraged, primarily related to sucking for support. Environments shall support an attuned feeding for both the feeder and the baby to minimize distractions and enhance comfort measures. ICUs shall include interprofessional perspectives to provide the best feeding management for the individual baby and parent dyad. Additionally, feeding management shall consider short and long-term growth and feeding outcomes. (<https://nicudesign.nd.edu/nicu-care-standards/>)

The rationale for the implementation of the feeding, eating, and Nutrition delivery standards:

Too often, healthcare providers prescribe how and when the baby should be managed and fed—the recipe of clinical guidelines. The joy to an infant of eating and feeding is lost to a task that must be completed. Feeding is often the focus of the last weeks of hospitalization and is seen as a “barrier” to discharge. (2) Infants must achieve the earlier milestones that support eating before successfully integrating the skills to eat. Like every other developmental milestone, infants do not reach full oral feedings at the same time or age. Milestones are achieved within windows of time; the average age of achieving full oral feedings is consistently reported as approximately 36 ½ weeks, plus or minus two weeks. (3, 4) This is despite interventions that have focused on speeding this process. The IFCDC standards recognize that the process of eating and feeding should be natural, determined by the biophysiological and neurodevelopmental ability of the baby. Based on the baby’s gestation, behavior, and communication, professional caregivers and families identify the capability and message of the baby and support the neurodevelopment of eating. It is essential to assist the m/other and father/partner in interpreting the behavior and communication of the baby and to feed the baby throughout the ICU experience, all the while becoming a confident nurturing caregiver. Feeding is the most complex skill required of an infant and therefore is often the last milestone achieved before discharge; eating continues to develop well after discharge. Parents also identify feeding as a primary concern as they transition to home. (5, 6, 7) And the evidence is mounting that focusing on the quality of the feeding experience does not increase the length of stay nor delay the achievement of full oral feedings. (8, 9) This evidence is a foundation for the standards and competencies.

“It is essential that nutritional management and feeding are individualized to the baby and planned collaboratively among health professionals and the m/other and parent/partner. Consistency in caregiving is important to the regulation of the baby and is best provided by the m/other and parent/partner.”

It is essential that nutritional management and feeding are individualized to the baby and planned collaboratively among health professionals and the m/other and parent/partner. Consistency in caregiving is important to the regulation of the baby and is best provided by the m/other and parent/partner. The intensive care period sets a foundation for developing healthy nutrition and eating habits; feeding management and plans need to consider short- and long-term outcomes. Health professionals can partner with parents to share education, clinical guidance and encouragement, and decision-making to support the baby’s individualized care and strengthen the parents’ confidence and competence.

Implementing the evidenced-based feeding standards requires a

collaborative process among health professionals and parents, using systems’ thinking to plan, prioritize, integrate, evaluate, and sustain change. Professional caregivers can assess the current feeding practice within the intensive care unit and evaluate the metrics such as individual baby growth and nutrition, parent caregiving, parent competence and/or confidence with feeding experiences, and staff performance. They can also consider the long-term outcomes of infants who are discharged from the intensive care setting eating reflexively but transitioning to volitional eating around two months post-term. Research shows that approximately 40% of infants who appear to eat “well” during the hospitalized time period have feeding and/or nutrition problems after discharge. (10, 11) It is not enough to get an infant to eat and go home; the goal should support long-term enjoyment of eating and feeding. The IFDSC standards identify gaps between current practice and the standards and current outcome metrics compared with standardized expectations. These gaps can assist in designing strategic initiatives to improve practice and metrics. The standards also engage and educate providers, caregivers, and parents on the evidence, competencies, and expected outcome of the change initiative. Intensive care settings should also measure and evaluate outcomes and adjust strategies. These standards and competencies provide a guideline for establishing infant and family-focused outcomes., The goal is to incorporate the change initiative through the unit staff and parents using system’s thinking. Finally, the IFCDC standards and competency’s goal is to support units to monitor and adjust the initiative to sustain practice continually. (12,13)

“We hope you will join the IFCDC Consensus Committee members at the FIFI S on July 13 to 15, 2022, to understand the standards and competencies more fully and work with colleagues to develop a system thinking, evidence-based feeding implementation plan in your ICU.”

Join us at the first Forum for Implementation of Standards:

We hope you will join the IFCDC Consensus Committee members at the FIFI S on July 13 to 15, 2022, to understand the standards and competencies more fully and work with colleagues to develop a system thinking, evidence-based feeding implementation plan in your ICU. You will enjoy the opportunity to interact with like-minded health professionals and become an influencer of practice change in your unit.

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Fragile Infant Forums for Implementation of Standards (FIFI S)

Formerly Fragile Infant Feeding Institute

July 13-15, 2022

Rationale: The FIFI S initiative is to promote, facilitate and provide strategies for implementation of the published standards of care for Infant and Family Centered Developmental Care in intensive hospital units in the US. Each of the forums will focus on one of the established sets of standards, competencies and best practices (feeding and nutrition, handling and positioning, promotion of states and arousal, pain and stress, skin to skin care and systems issues) with the goal of:

1. Raising awareness of availability of and need for implementation of current evidence based standards into practice.
2. Developing effective and reproducible strategies for assuring implementation of the competencies and best practices into intensive care and
3. Assuring that systems integration will lead to permanent changes in clinical practice.

The first of the forums will focus on the evidence based section of Feeding, Eating and Nutrition Delivery. Faculty will include influencers and researchers in the field. Audience participants will include professionals who will benefit from current research and systems implementation approaches to clinical care and contribute to discussion of best practices.

Hospitals will be encouraged to send their team of professionals who are leaders, influencers and those who have been selected to support change in their hospitals. A letter of support/commitment from the administration will be required for participation.

The two day intensive forum will bring together thought influencers, researchers, clinical professionals and parents who are invested in assuring practice excellence by implementing the IFCDC Standards, Competencies and Best Practices into baby and family intensive care systems.

Objecives:

- Discuss current best evidence based infant feeding practices
- Establish essential systems issues that guarantee implementation of best practices
- Determine best practice implementation strategies for the Feeding and Nutrition standards in national NICUs

Organizing Committee:

- Joy Browne
- Carol Jaeger
- Erin Ross
- Mitchell Goldstein

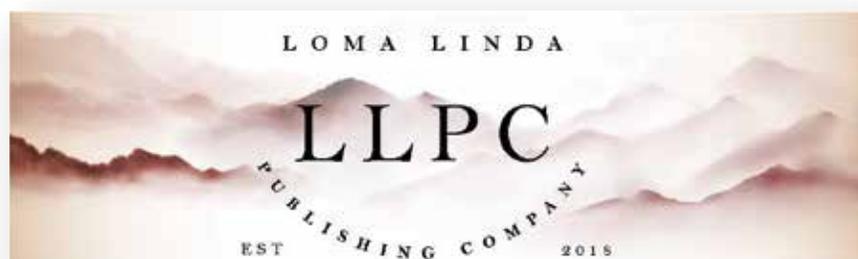
Program Consultants:

- Joan Arvedson
- Jacqueline McGrath
- Kelly McGlothen-Bell

Proposed Faculty:

- Suzanne Thoyre
- Barbara Medoff-Cooper
- Erin Ross
- Carol Jaeger
- Kelly McGlothen-Bell
- Carol Kenner
- Pamela Dodrill
- Britt Pados

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You are invited to register for the First Fragile Infant Forum for Integration of Standards— FIFI-S Hybrid Conference July 13-15, 2022

The initial Forum will address the Standards, Competencies, and Best Practices for Infant and Family-Centered Developmental Care, focusing on the

Best Practices for FEEDING, EATING, and NUTRITION developed by the Gravens interprofessional consensus panel.

<https://nicudesign.nd.edu/nicu-care-standards/>

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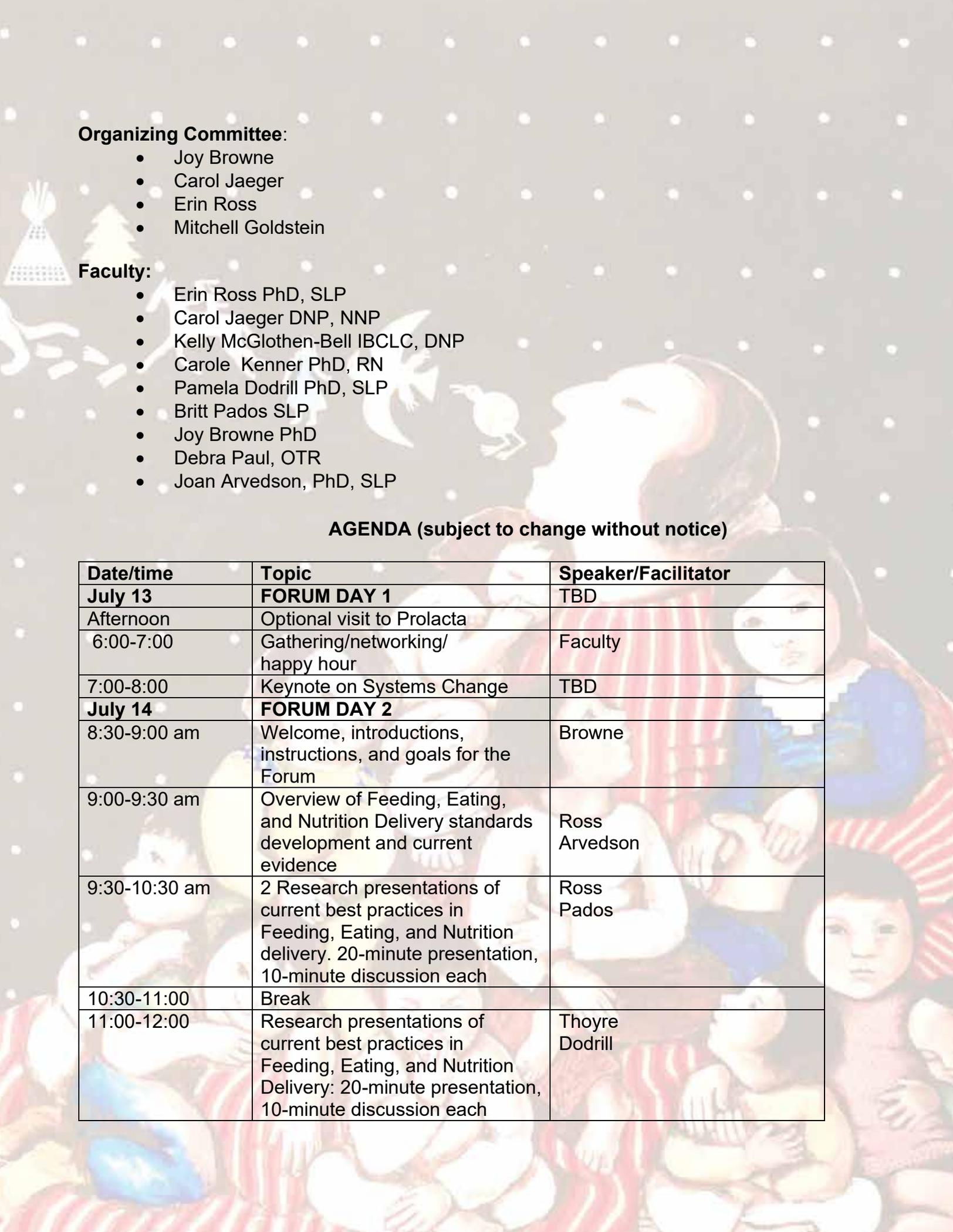
Registration: [Hotel Reservations](#)

The Forum allows discourse on current research and implantation of the Standards into intensive care practice. Scholars, administrators, and clinicians are invited to attend to develop a series of recommendations for implementing these competencies and best practices. An emphasis on evidence, system change, and adaptation to a new way of practicing will be the focus of workgroups. Dissemination of implementation recommendations will follow.

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Objectives:

- Discuss current best evidence-based infant feeding practices
- Establish essential systems issues that guarantee the implementation of best practices
- Determine best practice implementation strategies for the Feeding and Nutrition standards in intensive care



Organizing Committee:

- Joy Browne
- Carol Jaeger
- Erin Ross
- Mitchell Goldstein

Faculty:

- Erin Ross PhD, SLP
- Carol Jaeger DNP, NNP
- Kelly McGlothen-Bell IBCLC, DNP
- Carole Kenner PhD, RN
- Pamela Dodrill PhD, SLP
- Britt Pados SLP
- Joy Browne PhD
- Debra Paul, OTR
- Joan Arvedson, PhD, SLP

AGENDA (subject to change without notice)

| Date/time | Topic | Speaker/Facilitator |
|------------------|--|----------------------------|
| July 13 | FORUM DAY 1 | TBD |
| Afternoon | Optional visit to Prolacta | |
| 6:00-7:00 | Gathering/networking/ happy hour | Faculty |
| 7:00-8:00 | Keynote on Systems Change | TBD |
| July 14 | FORUM DAY 2 | |
| 8:30-9:00 am | Welcome, introductions, instructions, and goals for the Forum | Browne |
| 9:00-9:30 am | Overview of Feeding, Eating, and Nutrition Delivery standards development and current evidence | Ross Arvedson |
| 9:30-10:30 am | 2 Research presentations of current best practices in Feeding, Eating, and Nutrition delivery. 20-minute presentation, 10-minute discussion each | Ross Pados |
| 10:30-11:00 | Break | |
| 11:00-12:00 | Research presentations of current best practices in Feeding, Eating, and Nutrition Delivery: 20-minute presentation, 10-minute discussion each | Thoyre Dodrill |

| | | |
|-------------|--|-------------------------------------|
| 12:00-12:30 | Discussion across speakers with generalities of the barriers they faced, who they included, and what they forgot | All am speakers Moderator: Browne |
| 12:30-1:15 | Lunch | |
| 1:15 – 1:45 | Systems thinking 20-minute presentation 10-minute discussion | Jaeger Kenner |
| 1:45-2:00 | Instructions and assigned to workgroups to develop strategies for implementation | Browne |
| 2:00 – 2:45 | Workgroup discussion of potential strategies for implementation (systems and eating integrated) | Faculty member to each group |
| 2:45-3:15 | Strategies for implementation workgroup feedback | Designated facilitator and recorder |
| 3:15-3:30 | Break | |
| 3:30-4:15 | Workgroups: Identifying barriers to clinical implementation | Faculty assigned to each workgroup |
| 4:15-4:45 | Reports from workgroups | Designated facilitator and recorder |
| 4:45-5:00 | Synthesis of Day 1 topics | Paul |
| 5:00 | Adjourn | |

| Day/time | Content/Topics | Presenter/facilitator |
|-----------------|--|------------------------------|
| July 15 | FORUM DAY 3 | |
| 8:30-9:00 | Continued discussion, review of the previous day, and goals for the second day. | Browne |
| 9:00 -9:30 | System implementation: Realistic strategies | Kenner Jaeger |
| 9:30-10:00 | Clinical implementation approaches including how to address barriers | Paul |
| 10:00-10:15 | Break | |
| 10:15-11:00 | The importance of and how to measure progress (metrics) | Jaeger/Ross |
| 11:00-11:45 | Open forum discussion: Integration of standards into systems and clinical practice | Moderators Paul Kenner |
| 11:45-12:30 | Lunch | |
| 12:30-12:45 | Assign to workgroups | Browne |

| | | |
|-------------|---|-------------------------------------|
| 12:45-1:30 | Workgroups: Recommendations for implementation of standards to include systems thinking | Faculty assigned to each workgroup |
| 1:30-2:00 | Reports from workgroups | Designated facilitator and recorder |
| 2:00 – 2:45 | Summary and discussion of recommendations from workgroups to include recommendations, system and clinical implementation strategies, barriers | Browne Ross |
| 2:45-3:00 | Break | |
| 3:00-3:30 | How to use systems thinking to address recommendations, implementation, and barriers (full circle) | Kenner Jaeger |
| 3:30-3:45 | What have we forgotten? Check-in with group | Arvedson |
| 3:45-4:00 | Next steps, action plan development and statement of accountability | Browne |
| 4:00 | Adjourn | |

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July 13-15, 2022**

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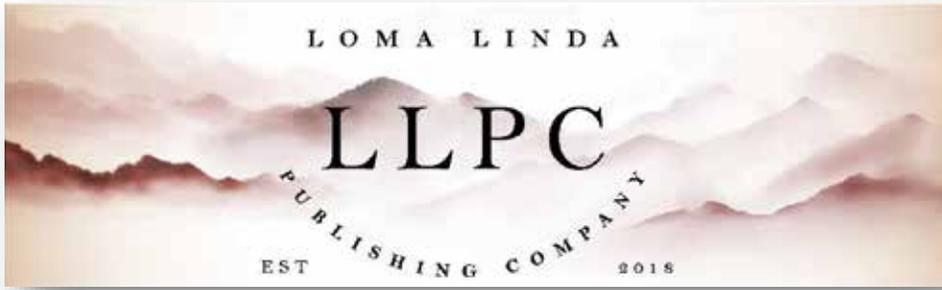
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**18th Annual Fragile Infant Feeding Institute: A Forum for Implementing Standards
July 13-15, 2022**

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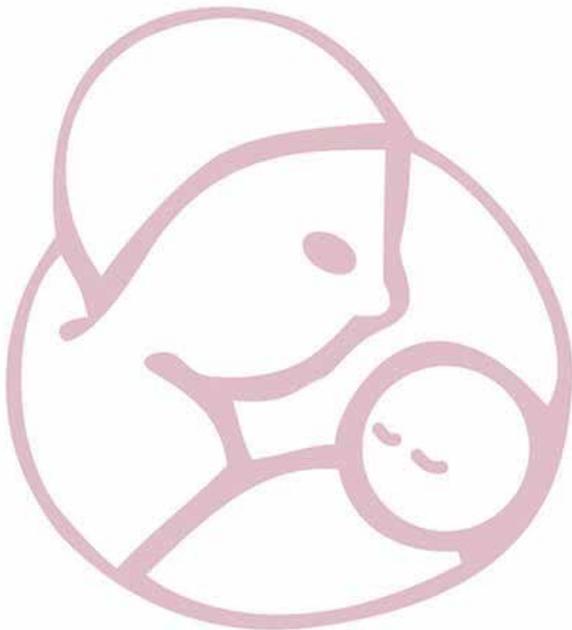
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COVID-19

STOP THE SPREAD AT HOME

What to do when you or a loved one is infected.

HYGIENE TIPS

- MOUTH**
 - Wear a face mask or face shield.
 - If in car, wear mask & put windows down.
 - NO cloth face masks for children younger than 2yrs.
 - Avoid kissing.
- EYES**
 - Wear protective eye gear (glasses)
- HANDS**
 - ALWAYS wash your hands.
- CLOTHING**
 - Wear a jacket when dealing with infected.
 - DO NOT share clothing, sheets, or pillows.

BATHROOM

- Sanitize EVERYTHING.
- Clean after every use.
- Patient gargle Listerine every morning & night.

PROTECT

- If infected, notify everyone in contact from the past 10 days.
- Ask Dept. of Health for further assistant.
- Call 211 for FREE delivery services.

If you are feeling sicker, DON'T WAIT. Call your doctor immediately.

COVID-19

DETENER LA PROPAGACION EN CASA

Qué hacer cuando usted o un ser querido está infectado.

CONSEJOS DE HIGIENE

- BOCA**
 - Use una mascarilla o careta.
 - Si está en el automóvil, use una máscara y baje las ventanas.
 - NO mascarillas de tela para niños menores de 2 años.
 - Evitar besos.
- OJOS**
 - Use equipo de protección para los ojos (lentes)
- MANOS**
 - SIEMPRE lávate las manos.
- ROPA**
 - Use una chaqueta cuando se trata de infectados.
 - NO comparta ropa, sábanas o almohadas.

BAÑO

- Desinfecte TODO.
- Limpia después de cada uso
- El paciente hace gárgaras con Listerine todas las mañanas y noches.

PROTEGER

- Si está infectado, notifique a todos los contactos de los últimos 10 días.
- Pídale al Departamento de Salud por más ayuda.
- Llame al 211 para obtener servicios de entrega GRATUITOS.

Si te sientes más enfermo, NO ESPERES. Llame a su médico de inmediato.

SELF ISOLATION

- Sick should be separate from household.
- Room with window preferred.
- Aerate room 3x day.
- Create a room divider with sheet.
- Keep water and sanitation liquids near room.
- Don't cuddle with pets.

KITCHEN

- Use SEPARATE utensils.
- Clean utensils separately.
- If sick avoid the kitchen.



Visit Miora.org



AISLAMIENTO

- Los enfermos deben estar separados del hogar.
- Habitación con ventana preferida.
- Alinea la habitación 3x al día.
- Crear un separador de ambientes con sábanas.
- Mantener agua y líquidos de saneamiento cerca.
- Mantenga una bolsa de basura en la habitación.

COCINA

- Use utensilios SEPARADOS.
- Limpie los utensilios por separado.
- Si está enfermo, evite la cocina.



Visitar Miora.org



Ways to Manage Covid 19 @ Home

Household

- Stay 6 feet apart from others at all times.
- Wear protective covering over mouth and eyes (mask AND shield/goggles/glasses) when near others. (Do not put masks on children under 2 years old)
- Gargle with antiseptic mouthwash in the morning and evening.
- Wash hands 10-12x a day, before each meal for at least 20 seconds.
- Keep good ventilation throughout home. (open windows/doors) where possible
- Do not share towels, blankets, pillows with sick.
- Call 211 for assistance/free delivery of services.
- Wear protective clothing (jacket, gloves, mask) that can be removed after being around infected.

Sick

- Self-isolate by staying in separate room with separate bathroom where possible. Don't go into shared spaces.
- Create a room divider with sheet, if shared space is unavoidable.
- Ventilate room with fresh air at least 3x per day.
- Keep water and sanitation products in room.
- Keep plastic garbage bag in room.
- Protect pets - don't cuddle.
- Notify contacts in last 10 days.
- Don't wait! Call doctor if symptoms get worse.

Stop the Spread at HOME Miora



Maneras de manejar COVID-19 en casa

Hogar

- Manténgase 6 pies de distancia de los demás en todo momento. Use una cubierta protectora sobre la boca y la máscara para los ojos y el protector / gafas / anteojos cuando esté cerca de otras personas. No ponga máscaras a niños menores de 2 años.
- Hacer gárgaras todas las mañanas y noches con productos de enjuague bucal antiséptico que contienen alcohol.
- Lavé la manos 10-11 veces al día, y antes de cada comida por lo menos 20 segundos.
- Mantenga Buena ventilación en toda la casa. Abra las ventanas y puertas cuando sea posible.
- No compartá toallas, cobijas, y almohadas con personas que estén infectados.
- Llame al 211 para obtener servicios de entrega gratuitos.
- Use ropa protectora, chaqueta, guantes, máscara que se pueda quitar después de estar cerca de infectados.

Enfermo

- Aíslase permaneciendo en una habitación separada con baño separado. No vayas a espacios compartidos
- Si no se puede aislar crea un separador de ambiente con una sábana.
- Ventile la habitación con aire fresco por lo menos 3 veces al día.
- Mantenga agua y productos de saneamiento en la habitación.
- Mantenga una bolsa de basura en la habitación.
- Proteja a las mascotas, no las abraza.
- Notifique a todos los contactos de los últimos 10 días.
- No espere! Si se siente peor llame a su médico.

Detén la propagacion en CASA Miora



WEAR A MASK

PROTECT PARENTS + BABIES

COVID-19

When we all wear masks...

We protect parents and babies.



USA UNA MASCARILLA

PROTEGER A LOS PADRES Y BEBÉS

COVID-19

Cuando todos usamos mascarillas ...

Protegemos a los padres y los bebés.





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In Loving Memory

August 9, 1996 - April 3, 2010



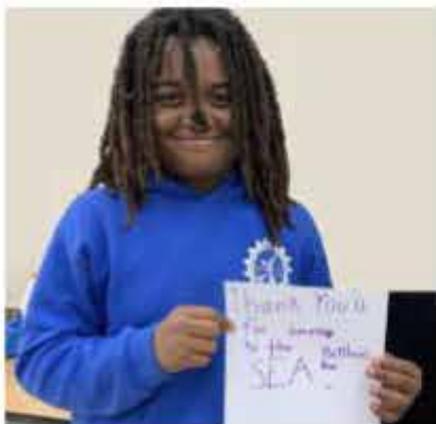
Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring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

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|--------------------|---------|
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| 1 week _____ | \$30 |
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Interpreting Umbilical Cord Blood Gases: Section 8: Low Apgar Scores Without Intrapartum Asphyxia

Jeffrey Pomerance, MD, MPH

“The FHR was 140 bpm, without decelerations but with absent variability. After one hour, the patient had an uncomplicated vaginal delivery of a male infant with Apgar scores of 3 and 6 at one and five minutes, respectively. Amniotic fluid was clear. The placenta was not sent to pathology.”

Case 23: Asphyxia Prior to Hospital Admission

The mother was a 41-year-old, gravida 4, para 3, aborta 0, with an intrauterine pregnancy at 42 0/7 weeks gestation. (1) She complained of decreased fetal movement beginning the day before admission and felt no fetal movement on the morning of admission. At the hospital, she had uterine contractions every five to seven minutes; her cervix was five cm dilated, completely effaced, and at zero station. The FHR was 140 bpm, without decelerations but with absent variability. After one hour, the patient had an uncomplicated vaginal delivery of a male infant with Apgar scores of 3 and 6 at one and five minutes, respectively. Amniotic fluid was clear. The placenta was not sent to pathology.

Cord blood gas results were as follows:

| | Umbilical Vein | Umbilical Artery |
|-------------------------------|----------------|------------------|
| pH | 7.35 | 7.31 |
| Pco ₂ (mmHg) (kPa) | 48 6.40 | 52 6.93 |
| Po ₂ (mmHg) (kPa) | 21 2.80 | 14 1.87 |
| BD (mmol/L) | -1 | 0 |

Blood gases obtained from the infant at 30 minutes of age were as follows:

| | CBG |
|-------------------------------|------------|
| pH | 7.33 |
| Pco ₂ (mmHg) (kPa) | 42 5.60 |
| Po ₂ (mmHg) (kPa) | 41 5.47 |
| BD (mmol/L) | 4 |

The NRBC count was not elevated. Subsequently, the infant had a seizure in the neonatal intensive care unit and showed signs of moderate renal failure, from which he ultimately recovered.

Interpretation

Both the umbilical venous and arterial cord blood gas results are entirely normal. In the presence of FHR monitoring that continues until close to the time of delivery and in the absence of significant FHR decelerations, intrapartum fetal asphyxia can be excluded. However, in the presence of low Apgar scores, it is prudent to obtain a follow-up blood gas directly from the infant soon after birth to document the infant's blood gas status. One would expect complete cord occlusion (both venous and arterial), a complication that could explain normal or near-normal cord gas values, to have resulted in severe fetal bradycardia. However, bradycardia was not observed, and the follow-up capillary blood gas was normal. This infant was not suffering from asphyxia at the time of delivery.

“One would expect complete cord occlusion (both venous and arterial), a complication that could explain normal or near-normal cord gas values, to have resulted in severe fetal bradycardia. However, bradycardia was not observed, and the follow-up capillary blood gas was normal. This infant was not suffering from asphyxia at the time of delivery.”

Intrapartum asphyxia is not the only cause of low Apgar scores. Another cause of Apgar score depression is recent *antenatal*, but not *intrapartum*, moderate to severe *in utero* asphyxia with acid-base recovery before delivery. Such a baby may have neurological findings during the neonatal period. This deficit would corre-

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spond with the maternal history of decreased fetal movement and the absence of variability in an otherwise stable heart rate pattern. Usually, but not always, problems of uteroplacental insufficiency increase over time. Occasionally, uteroplacental insufficiency or a cord problem may injure the fetus, allowing fetal acid-base recovery before delivery.

In this case, the neonatal clinical course strongly suggests hypoxic-ischemic encephalopathy and acute tubular necrosis with recovery. The FHR tracing on the day of admission, the normal umbilical cord blood gas values, and the normal follow-up capillary blood gas shortly after delivery suggest the insult occurred before fetal monitoring was initiated. Absent variability on the fetal monitoring strip, right from the beginning of the tracing, confirms this. The absence of an elevation in the NRBC count (2) suggests the insult was relatively acute and was not ongoing during labor and delivery. It is highly unlikely that earlier delivery during fetal monitoring would have resulted in a baby with a different clinical course or a better outcome.

“The differential diagnosis of normal or near-normal cord gases associated with low Apgar scores is the rare finding of complete cord occlusion (both venous and arterial), without a widened umbilical cord venoarterial pH difference. However, there was no associated evidence of a vulnerable cord, such as variable decelerations or severe fetal bradycardia prior to delivery.”

The differential diagnosis of normal or near-normal cord gases associated with low Apgar scores is the rare finding of complete cord occlusion (both venous and arterial), without a widened umbilical cord venoarterial pH difference. However, there was no associated evidence of a vulnerable cord, such as variable decelerations or severe fetal bradycardia prior to delivery.

Key Point

- Even in the presence of low Apgar scores, absence of significant decelerations on FHR monitoring, presence of normal or near-normal umbilical cord blood gas values, and a normal follow-up blood gas soon after delivery all suggest the absence of *intrapartum* asphyxia and likely recent *antepartum* asphyxia.

Case 24: Renal Agenesis with Hypoplastic Lungs

The mother was a 27-year-old, gravida 2, para 1, aborta 0, with an intrauterine pregnancy at 40 1/7 weeks gestation. (3) The mother reported spontaneous rupture of membranes five hours before admission with the escape of a small amount of clear fluid. The FHR monitor showed variable decelerations. Over the next several hours, the patient’s cervix became completely dilated and effaced, and the head was at plus two station. The FHR monitor revealed deep variable decelerations that lasted 60-90 seconds. The infant was delivered vaginally 30 minutes later. Apgar scores were 2, 2, and 3 at one, five, and 10 minutes.

Cord blood gas results were as follows:

| | Umbilical Vein | Umbilical Artery |
|-------------------------------|----------------|------------------|
| pH | 7.31 | 7.26 |
| Pco ₂ (mmHg) (kPa) | 44 5.87 | 53 7.07 |
| Po ₂ (mmHg) (kPa) | 19 2.53 | 14 1.87 |
| BD (mmol/L) | 4 | 3 |

A pediatric resuscitation team was present at the time of delivery. The infant was intubated and bag ventilated with 100% oxygen.

After 30 minutes, the infant’s arterial blood gas results were:

| | Infant’s ABG |
|-------------------------------|--------------|
| pH | 6.92 |
| Pco ₂ (mmHg) (kPa) | 87 11.60 |
| Po ₂ (mmHg) (kPa) | 19 2.53 |
| BD (mmol/L) | 15 |

Interpretation

The normal umbilical cord blood gas results suggest that one can exclude intrapartum asphyxia as the cause of neonatal depression. However, complete cord occlusion should be considered, especially in light of the moderate to severe variable decelerations and the oligohydramnios suspected based on the mother’s reporting only a scant amount of clear fluid.

“The normal umbilical cord blood gas results suggest that one can exclude intrapartum asphyxia as the cause of neonatal depression. However, complete cord occlusion should be considered, especially in light of the moderate to severe variable decelerations and the oligohydramnios suspected based on the mother’s reporting only a scant amount of clear fluid.”

The follow-up blood gas at age 30 minutes demonstrates both respiratory and metabolic acidosis. The events that led up to this blood gas have many possible etiologies. The most likely ones include unilateral or bilateral pneumothorax, congenital diaphragmatic hernia, cystic adenomatoid malformation, and Potter’s syndrome with associated hypoplastic lungs. ETT placement, patency, and chest-wall rigidity have been addressed previously (see Section 1).

Unilateral or bilateral tension pneumothoraces should also be considered whenever there is a poor response to resuscitation. Poor breath sounds over one side (and sometimes both sides), increased anterior-posterior diameter of the chest, or the presence

of subcutaneous emphysema should make one seriously consider an underlying pneumothorax. Transillumination, chest X-ray or thoracentesis may be diagnostic. Taking an x-ray and obtaining results takes too long in a delivery room setting, especially if the child is in extremis. Unilateral or bilateral pneumothoraces are common sequelae of attempting to ventilate hypoplastic lungs.

“This infant had Potter’s syndrome, and an oligohydramnios sequence was established at autopsy. The diagnosis was strongly suspected clinically based on a history of a small amount of amniotic fluid, amnion nodosum – debris, such as squames and hair intermixed with sebum, normally suspended in amniotic fluid, form nodules on the fetal side of the placental surface, (4) (see Figure 1 below), a Potter’s facies and other associated deformations, and a poor response to appropriate resuscitation.”

This infant had Potter’s syndrome, and an oligohydramnios sequence was established at autopsy. The diagnosis was strongly suspected clinically based on a history of a small amount of amniotic fluid, *amnion nodosum* – debris, such as squames and hair intermixed with sebum, normally suspended in amniotic fluid, form nodules on the fetal side of the placental surface, (4) (see Figure 1 below), a Potter’s facies and other associated deformations, and a poor response to appropriate resuscitation. Chest x-ray showed a good position of the ETT and a left tension pneumothorax. Chest tube placement did not result in improvement. An ultrasound of the abdomen demonstrated an absence of the kidneys bilaterally.



Figure 1. Amnion nodosum in the placenta of a newborn with renal agenesis. Note the uniform presence of fine granules, mostly sparing the vessel surfaces and not present on the cord. (From Benirschke K, Kaufman P: *Placental Membranes in Pathology of the Human Placenta*, 2nd ed. New York, Springer-Verlag, 1990, p160. Reproduced with permission.)

At four hours of age, the infant died in her parents’ arms, following a discussion with the parents and withdrawal of life support.

Normal umbilical cord blood gas values likely reflect the absence of asphyxia at the time of delivery. The very abnormal arterial blood gas obtained from the infant at 30 minutes of age reflects the inability of hypoplastic lungs in this infant to support extrauterine life.

Whenever an infant responds poorly to resuscitation, one must also consider severe anemia, hypovolemia, and other issues (see Section 6 on Cord Occlusion and Case 22 on acute fetal hemorrhage). However, with severe anemia or severe hypovolemia, one would not expect normal or near-normal umbilical cord blood gas values.

Key Points

- Low Apgar scores have many causes other than current fetal asphyxia (see differential diagnosis, Table 3, Section 1).
- In the absence of other complications, a newborn with renal agenesis would be expected to have normal or near-normal umbilical cord blood gas results.
- Chronic, severe oligohydramnios may be suspected in the delivery room by obtaining a good history, carefully examining the infant for findings suggestive of oligohydramnios sequence, and carefully examining the placenta for *amnion nodosum* on the chorionic plate.

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Mechanisms for Brain-Damaging Acute Birth Asphyxia Associated with Normal or Near-Normal Umbilical Acid-Base balance

Marcus C. Hermansen, MD

Abstract:

It is a common misconception to believe that brain-damaging birth asphyxia is consistently associated with an umbilical cord arterial pH of less than 7.00 at the time of birth. Approximately 40% of infants with brain damage attributable to birth asphyxia have an umbilical artery (UA) pH of 7.00 or greater. This paper describes the various explanations for observing brain-damaging acute birth asphyxia associated with normal or near-normal UA pH values.

What is known: Approximately 40% of infants with brain damage attributable to birth asphyxia have a UA pH of 7.00 or greater.

What this study adds: Various explanations are presented to explain the occurrence of brain-damaging asphyxia with normal or near-normal acid-base values. This phenomenon has not been previously described.

Key messages:

- Approximately 40% of infants with brain-damaging birth asphyxia have an umbilical artery cord pH of 7.00 or greater, with most having of these having a pH greater than 7.20.
- Technical explanations for this phenomenon include sampling only the umbilical vein and sampling blood with air bubbles.
- The two most common pathophysiologic mechanisms to explain the lack of acidemia are complete occlusion of the umbilical cord and circulatory collapse.
- Other brain-damaging processes without fetal acidemia include birth trauma, synergism, intra-uterine resuscitation, and post-asphyxial hypoxia.

“Various explanations are presented to explain the occurrence of brain-damaging asphyxia with normal or near-normal acid-base values. This phenomenon has not been previously described.”

Introduction:

It is a common misconception to believe that brain-damaging birth asphyxia is consistently associated with an umbilical cord arterial (UA) pH of less than 7.00 at the time of birth. (1,2) In reality, many infants with brain damage attributable to birth asphyxia have a UA pH of 7.00 or more at birth. (3-7) Most infants have a *normal* UA pH of 7.20 or more. (6, 7) This paper describes the various

explanations for observing brain-damaging acute birth asphyxia associated with normal or near-normal UA pH values.

Normal umbilical cord blood gas values are shown in Table 1 and derived from Yeomans and colleagues' data. (8, 9) All blood gases are expressed as: pH / pCO₂ (mmHg) / pO₂ (mmHg) / base excess (mmol/L). This paper is not intended to serve as an instructional manual for umbilical cord gas interpretation. The reader is referred to the Pomerance's authoritative text *Interpreting Umbilical Cord Blood Gases*. (9)

*“This paper is not intended to serve as an instructional manual for umbilical cord gas interpretation. The reader is referred to the Pomerance's authoritative text *Interpreting Umbilical Cord Blood Gases*. (9) ”*

Technical considerations:

Occasionally umbilical cord blood gas analysis will not identify fetal acidemia for technical, not physiologic, reasons. The most common of these technical sources of errors are 1) failure to sample the umbilical artery and 2) air bubble(s) in the sample.

Failure to sample the umbilical artery:

The pH of the umbilical UV is always greater than that of the UA. Under normal circumstances, the 95th percentile range of difference between the UV and UA pH is between 0.04 and 0.10 pH units. (9) One might be tempted to analyze blood from the UV, then extrapolate those values to estimate the acid-base values in the UA. (10) However, sometimes, there may be a vast discrepancy between the pH of the UV and the UA, in which case such extrapolation would produce errant results.

The most common cause of a wide pH difference between the UV and UA is partial umbilical cord occlusion (11), where the thin-walled UV becomes occluded while the thick-walled UA remains patent and free-flowing. As the fetal tissues become progressively more acidotic, the UA pH falls. However, the blood flow in the UV had already ceased at the time of the occlusion, and the UV pH will not fall after that time of occlusion. The UV pH analysis is being performed on blood that entered the cord at the time of the occlusion when the fetus had not yet become acidemic and is not representative of fetal blood or tissues from the time of birth when the infant was severely acidemic. In these cases, it is not uncommon to observe a normal UV pH associated with a UA pH of less than 7.00. (9) If only the UV is sampled, one would not be aware of the severe fetal acidemia.

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Theoretically, if only one sample is analyzed, the sample may be from either the UV or UA. However, because it is technically easier to obtain blood from the relatively large UV than from the smaller UA if only one sample is obtained, it is usually from the UV. (9,10) And because of the possibility of a wide disparity in pH values in partial umbilical cord occlusion, a UV blood gas cannot be used to extrapolate the blood gas values of the UA. Because of this, it has been recommended that both UV and UA blood samples be analyzed and compared. (12,13,14)

Even when two samples are analyzed, sometimes they are drawn from the same blood vessel. (10) When this happens, the samples are usually from the umbilical vein because of its ease of sampling. If the pH difference is less than 0.02 (10, 15) or 0.04 (9), the clinician should compare the other components of the blood gases. The samples are likely from the same vessel, most likely the umbilical vein, if they are very similar. If the UV is sampled twice, there is no reliable way to estimate the UA blood gas values. For example, if the UV showed 7.23/45/38/-12 and the UA was reported as 7.22/46/40/-12, then it is likely that both samples are from the same vessel because the pH difference is so small with the pCO_2 , pO_2 , and base excess values also being very similar. In this example, we can conclude that the UV pH was 7.22 or 7.23, and the UA values are unknown.

“If the pH difference is less than 0.02 (10, 15) or 0.04 (9), the clinician should compare the other components of the blood gases. The samples are likely from the same vessel, most likely the umbilical vein, if they are very similar. If the UV is sampled twice, there is no reliable way to estimate the UA blood gas values.”

Air Bubbles:

Air bubbles in the sample will alter the blood gas analysis results. An air bubble will cause an elevation of the pO_2 , with a decrease in the pCO_2 and a corresponding rise in the pH. (9) If a baby's true UA pH is less than 7.00, an air bubble may demonstrate an elevated pO_2 , a decrease in the pCO_2 , and a normal or near-normal pH. Of note, an air bubble does not affect the determination of the base excess. (9) Thus, a UA blood gas showing 7.41/15/95/-16 is most consistent with an air bubble (high pH/low pCO_2 /high pO_2) in the presence of a severe fetal metabolic acidemia (very negative base excess).

Pathophysiologic mechanisms:

Complete occlusion of umbilical cord blood flow

With complete umbilical cord occlusion, blood flow stops in both the UV and UA, and acid-base analysis will yield results representing the blood in the cord at the occlusion. Findings often do not represent the fetal acid-base status at birth. If the fetus has a normal acid-base status at an acute cessation of cord blood flow, the UV and UA blood gases will demonstrate normal values. But a simultaneous arterial blood gas analysis from the baby, not the umbilical cord, might demonstrate severe fetal acidemia at the time of birth. Common examples of this phenomenon include umbilical cord prolapse, shoulder dystocia, and breech delivery with an entrapped head. (16)

Circulatory collapse, impaired tissue perfusion, and the re-perfusion acidemia

Anaerobic metabolism results in the production of lactic acid, primarily in the body's muscles. As blood perfuses the tissues, the lactic acid enters the bloodstream resulting in metabolic acidemia. However, if there is complete or near-complete circulatory collapse, from whatever cause, there will be inadequate perfusion of the muscles, and lactic acid may not enter the fetal circulation. Additionally, circulatory collapse results in a cessation of blood flowing from the fetus into the umbilical arteries, and whatever acid that may have entered the fetal bloodstream from the tissues are not pumped into the umbilical cord. After resuscitation, blood begins to reperfuse the tissues, lactic acid enters the circulation, and a corresponding fall in the blood pH is termed a “reperfusion acidemia.” Typical cord gases might show UV 7.31/42/44/-5 and UA 7.26/45/22/-8, with an arterial blood gas at 30 minutes of age showing 6.99/52/75/-18. Common causes of this phenomenon include massive hemorrhage with hypovolemia and severe fetal bradycardia or asystole. (9,16,17) These infants are usually extremely depressed at birth, with a one-minute Apgar score of 0 or 1 indicating impaired circulation.

Asphyxia with intrauterine resuscitation and recovery

An infant may suffer severe asphyxia during labor, followed by intrauterine resuscitation. (18) The infant may then be born with a normal or near-normal acid-base status, albeit with a recent brain injury. Examples include maternal hypotension, uterine tachysystole, and umbilical cord compression.

“Maternal hypotension may be caused by the administration of conduction anesthesia or maternal supine position in labor and can result in significant fetal hypoxia and ischemia. The hypotension can be corrected with intravenous infusions and changing the maternal position. Similarly, uterine hypertonicity may result in decreased or absent maternal-fetal oxygen exchange and severe fetal hypoxia.”

Maternal hypotension may be caused by the administration of conduction anesthesia or maternal supine position in labor and can result in significant fetal hypoxia and ischemia. The hypotension can be corrected with intravenous infusions and changing the maternal position. Similarly, uterine hypertonicity may result in decreased or absent maternal-fetal oxygen exchange and severe fetal hypoxia. This can be relieved with changes in maternal position, administration of supplemental oxygen to the mother, decreasing or stopping oxytocin administration, and the use of tocolysis. (18) Finally, umbilical cord occlusion can lead to fetal hypoxia and asphyxia. Intrauterine resuscitation may include changing the maternal position or amnioinfusion. In each of these examples, the infant may experience brain-damaging asphyxia during the labor but be born following intrauterine resuscitation and with a normal or nearly-normal UA acid-base status.

Birth trauma and head compression

Infants can develop traumatic brain damage following any difficult delivery. Volpe states, "potential overlap between mechanical trauma and hypoxic-ischemic cerebral injury is important to recognize because perinatal mechanical insults may also result in hypoxic-ischemic cerebral injury, perhaps secondary to disturbances of disturbances of placental or cerebral blood flow." (19) The damages are usually detected on neuro-imaging with a cerebral contusion, intracranial hemorrhages, skull fractures, and scalp hemorrhages. While the brains of these traumatized infants may produce a modest amount of metabolic acid, if the placenta is functioning adequately and umbilical cord blood flow is maintained, acid does not accumulate in the fetal circulation.

Prolonged or excessive pressure on the fetal head has been associated with brain ischemia. (19,20) Common causes of this phenomenon include cephalopelvic disproportion, prolonged labor, uterine tachysystole (hyperstimulation), head presentation anomalies, and cranial compression from vacuums and/or forceps. The external pressure on the infant skull results in decreased cerebral perfusion. There may also be a decrease in venous drainage, contributing to further cerebral ischemia. Additionally, compressions of the fetal skull can cause intracranial hemorrhage that results in further brain hypoxia and ischemia. And as with other forms of traumatic brain injury, any acid produced by the fetal brain can be cleared if the placenta and cord are functioning adequately, explaining why these infants are commonly born with normal acid-base status.

"The external pressure on the infant skull results in decreased cerebral perfusion. There may also be a decrease in venous drainage, contributing to further cerebral ischemia. Additionally, compressions of the fetal skull can cause intracranial hemorrhage that results in further brain hypoxia and ischemia."

Post-natal hypoxia

Infants with mild or moderate asphyxia may be born with a normal acid-base status but develop brain-damaging complications of the asphyxiation after birth. Potential complications of asphyxia commonly causing brain damage include necrotizing enterocolitis, (21) meconium aspiration syndrome, (22) tension pneumothorax, and persistent pulmonary hypertension (PPHN) (23). The most common cause of PPHN is birth asphyxia. (24) Heritage reviewed 71 cases of PPHN and found that 36 (51%) were due to birth asphyxia. (25) PPHN can cause brain damage due to relentless hypoxia. (26,27)

One treatment of PPHN is the use of hyperventilation with associated hypocarbia. However, this therapy exposes the infant to the additional risk of cerebral ischemia caused by hypocarbia. (28,29) Cerebral blood flow in the newborn depends on the infant's pCO₂. Studies in lambs demonstrated abrupt decreases in cerebral blood flow almost immediately upon the onset of hypocarbia. (30) Every decrease of pCO₂ of 1 mmHg caused an approximate 3% decrease in cerebral blood flow – an effect that could exacerbate the cerebral ischemia of birth asphyxia. The decreased cerebral blood flow associated with hypocarbia became less prominent over time (30); however, after the hypocarbia was terminated, there was a

| | Venous Blood | Arterial Blood |
|--|---------------|----------------|
| | Normal Range | Normal Range |
| | (Mean ± 2 SD) | (Mean ± 2 SD) |
| pH | 7.25 – 7.45 | 7.18 – 7.38 |
| pCO ₂ (mmHg) | 26.8 – 49.2 | 32.2 – 65.8 |
| pO ₂ (mmHg) | 17.2 – 40.8 | 5.6 – 30.8 |
| H C O ₃ ⁻ (mmol/L) | 15.8 – 24.2 | 17 – 27 |
| Base excess | -8 to 0 | -8 to 0 |

Table 1: Normal Umbilical Cord Blood Gases*

* From the data of Yeomans (8) as modified by Pomerance (9)

sudden increase in cerebral blood flow to greater than baseline levels. If this occurs in the human newborn, it could result in cerebral hyperemia, an increased risk of intracranial hemorrhage, and reperfusion injury. Studies of human newborns who had PPHN demonstrated worse outcomes in those who had longer periods of hyperventilation and hypocarbia (23,31), although it remains possible that the brain injury was due more to severe PPHN than to the prolonged hypocarbia.

Asphyxiated newborns are frequently hypotensive after birth because of either acute blood loss with hypovolemia or post-asphyxial cardiomyopathy. (3) In either case, the asphyxiated infant may have lost his or her ability to autoregulate cerebral blood flow across a range of blood pressures. (32, 33) Thus, any degree of hypotension in the post-asphyxial stabilization period can contribute to a newborn's cerebral ischemia and brain injury.

Approximately 80-90% of infants with brain-damaging asphyxia will demonstrate findings of encephalopathy with seizure activity. (3-6) Although asphyxiated infants with seizures have worse outcomes than asphyxiated infants without seizures, it remains controversial whether the seizures *per se* result in additional brain injury. Numerous animal studies have demonstrated brain injury following prolonged or recurrent seizures (34,35,36), but methodological considerations prevent a clear understanding of the harm of seizures *per se* in the human newborn.

Synergism

There are situations where two processes occur together, and while neither alone would be of sufficient severity to cause brain damage, the two processes combined result in brain damage. At least three such situations may arise in the asphyxiated newborn – asphyxia acting synergistically with intrauterine infections, hyperbilirubinemia, and hypoglycemia.

Combined exposure to infection and intrapartum asphyxia exert synergistic harmful effects on the fetal brain. (37) Neonates exposed to intrauterine infection who also had potentially asphyxiating obstetric complications are at a much greater risk of cerebral palsy than those with only the obstetric complications. (37-40) Nelson and Grether found that combined exposure to infection and intrapartum hypoxia dramatically increased the risk for spastic cerebral palsy (odd ratio = 78) compared to hypoxia alone.

normal acid-base determination at birth

Technical

1. Failure to sample the umbilical artery
2. Air bubbles in the sample

Pathophysiologic

3. Complete umbilical cord occlusion
4. Circulatory collapse and impaired tissue perfusion
5. Birth trauma/head compression
6. Synergism
 - chorioamnionitis
 - hypoglycemia
 - hyperbilirubinemia
7. Intrauterine resuscitation
 - maternal hypotension
 - uterine hypertonicity
 - cord compression or occlusion
8. Post-asphyxial hypoxia
 - necrotizing enterocolitis
 - meconium aspiration syndrome
 - tension pneumothorax
 - persistent pulmonary hypertension
 - hypocarbia
 - hypotension
 - ? seizures

Table 2: Explanations for an acute asphyxial brain injury associated with a normal or near-

(40) Sameshima and Ikenoue found that intrauterine infection was capable of causing brain damage in preterm infants, but that intrauterine infection only caused brain damage in term infants when it was associated with intrauterine hypoxia. (41)

“Hypoglycemia is a common complication of birth asphyxia due to depleted glycogen stores and hyperinsulinemia.”

Severe hyperbilirubinemia can cause neonatal encephalopathy and kernicterus. The risk of kernicterus increases as free bilirubin crosses the blood-brain barrier resulting in neuro-toxicity. Asphyxia and fetal hypoxia are known to dislodge bilirubin from albumen, creating increased amounts of free bilirubin and disrupting the blood-brain barrier, allowing easier entry of the free bilirubin into and impairing bilirubin clearance from the brain. (42,43) Thus asphyxia of only mild or moderate degree and with a normal acid-base balance at birth can be a significant contributing factor to the development of kernicterus and cerebral palsy.

Hypoglycemia is a common complication of birth asphyxia due to depleted glycogen stores and hyperinsulinemia. (44) Hypoglycemia is known to increase an asphyxiated infant's risk of brain injury. (45) This has been demonstrated in hypoxic newborn rats (46), asphyxiated newborn dogs (47), asphyxiated newborn lambs (48), and ischemic newborn dogs. (49) Studies from human newborns (50,51) also support the belief that hypoglycemia combined with hypoxia may result in brain injury, even when either condition alone might not have resulted in brain damage.

Summary:

Most babies who suffer brain damage from birth asphyxia will have a UA pH of less than 7.0. (7) As the pH falls progressively below 7.0, the risks of adverse outcomes increase. (52,53) But the fact that an individual's risks increase as the UA pH falls progressively below 7.0 does not eliminate the presence of risk when the UA pH is 7.0 or more. As demonstrated in this paper, there are multiple technical and pathophysiologic explanations for brain-damaging birth asphyxia with a normal or near-normal umbilical acid-base analysis. If the remaining facts of the case indicate that the likely time of the insult was in the peripartum period, the report of a normal or near-normal UA pH should not preclude one from attributing an infant's neonatal encephalopathy or long-term brain damage to birth asphyxia

Clinicians are encouraged to obtain samples from the UA and UV for complete acid-base analysis. The blood gases should then be analyzed in light of all the clinical events of the pregnancy, labor, delivery, and newborn period.

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The Village Son



A Life's Journey

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

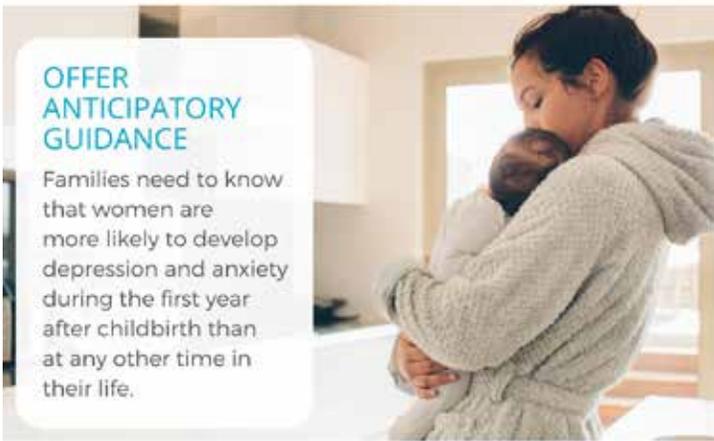
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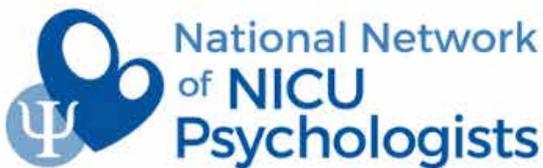


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Using a Community Approach to Address Sudden Unexplained Infant Death

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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.

"The introduction in 1994 of the Safe Sleep Guidelines developed by the American Academy of Pediatrics (AAP) led to a 50% reduction in SIDS rates, which remain level while SUID rates have increased, with rates twice as high among Black and Native American infants than white."

Approximately 3,500 infants in the U.S. die annually within the first year of life from Sudden Unexplained Infant Death (SUID) and Sudden Infant Death Syndrome (SIDS), making it the leading cause of infant mortality. The introduction in 1994 of the Safe Sleep Guidelines developed by the American Academy of Pediatrics (AAP) led to a 50% reduction in SIDS rates, which remain level while SUID rates have increased, with rates twice as high

among Black and Native American infants than white.

In the years since our involvement in the Safe Sleep campaign launch, we have come to learn anecdotally that compliance with the guidelines is not a given, even when the evidence indicates this reduces sleep-related infant mortality. In 2020 and 2021, First Candle commissioned online focus groups in Michigan, Connecticut, and Georgia to understand this issue better to explore what parents, extended family members, and caregivers thought about the guidelines and their feelings about following them. (1)

We learned that context and trust matter – who is giving the advice and how it is being given – and that families often feel there is a gap between the health care universe and the realities of daily life they face.

We came to realize that education would be far more effective if it reflected the realities of lived experiences, helped by communication that is clear, positive, sensitive to literacy levels and language needs, and included outreach that involves local communities.

"Straight Talk will continue its train-the-trainer work to help health care providers counsel families on safer sleep practices in constructive and culturally sensitive ways, and the Let's Talk Community Chat will offer families the chance to receive education and support around safer sleep and breastfeeding every month at a convenient and accessible location."

With that in mind, we decided to expand our [Straight Talk for Infant Safe Sleep](#) training program and also introduce the Let's Talk Community Chat initiative, which launches this month. (2) Straight Talk will continue its train-the-trainer work to help health care providers counsel families on safer sleep practices in constructive and culturally sensitive ways, and the Let's Talk Community Chat will offer families the chance to receive education and support



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

around safer sleep and breastfeeding every month at a convenient and accessible location.

These community events will bring together new parents with doulas, lactation consultants, fathers, and grandparents from the community who have gone through Straight Talk and become trained facilitators. This program addresses the issue that not all families may have the opportunity to talk in-depth with health care providers about safer sleep best practices or receive support around breastfeeding or get to well-baby visits. It also recognizes that the information they may have received could have come across as a directive rather than a conversation.

Safer sleep messaging is not a one-size-fits-all scenario and should meet families where they are “at” so they are receptive to it. We also know that fathers want to speak with other fathers or male figures, which holds true for grandparents.

The goal is to provide everyone in the family – parents, siblings, relatives, and other caregivers – clear information about safer sleep practices, the reasoning behind the AAP Safe Sleep guidelines and talk with them about the challenges, obstacles, and choices they make about where and how their baby sleeps. Supplies such as diapers, sleep sacks, and other items will also be offered, and connections to agencies and other resources families may need.

“The first Let’s Talk Community Chat is being held in Harlem in New York City, with subsequent sessions held once a month. This session is in partnership with Hope Center Harlem and the Northern Manhattan Perinatal Partnership and with support from the Ryan Wolfe Kossar Foundation.”

The first Let’s Talk Community Chat is being held in Harlem in New York City, with subsequent sessions held once a month. This session is in partnership with Hope Center Harlem and the Northern Manhattan Perinatal Partnership and with support from the Ryan Wolfe Kossar Foundation. The program will also be introduced in Brooklyn, Queens, and the Bronx, New York.

By expanding our reach to include families and healthcare providers, we can deepen our understanding of what works and does not work in advancing infant safer sleep and breastfeeding and help both professionals and consumers approach each other in partnership and community.

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Disclosure: The author is the Director of Education and Bereavement Services for First Candle, a 501c (3) non-profit organization.

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About First Candle

First Candle, based in New Canaan, CT, is a 501c (3) committed to eliminating Sudden Infant Death Syndrome and other sleep-related infant deaths while providing bereavement support for families who have suffered a loss. Sudden unexpected infant death (SUID), which includes SIDS and accidental suffocation and strangulation in bed (ASSB), remains the leading cause of death for babies one month to one year of age, resulting in 3,600 infant deaths nationwide per year.



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

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

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

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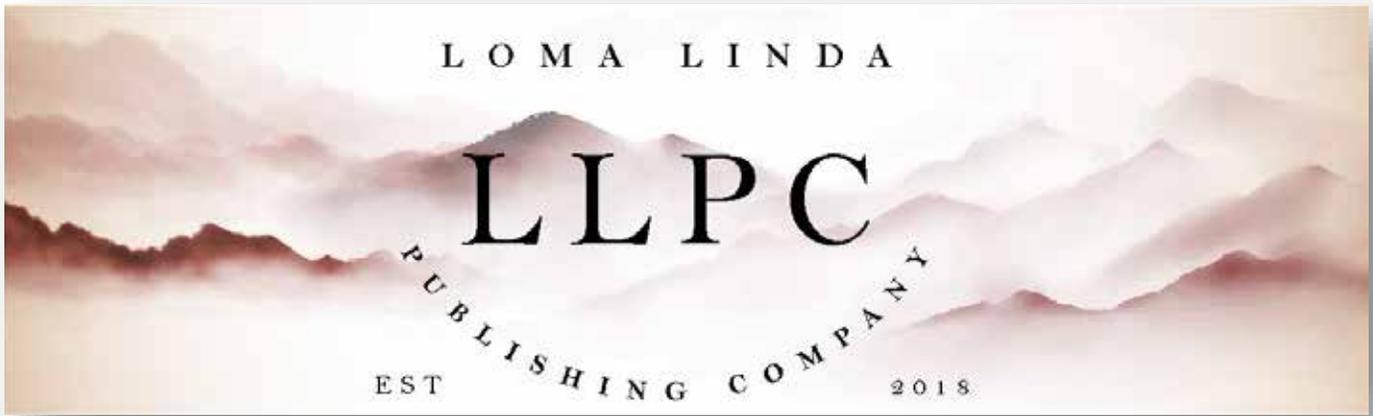
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RVU and Census Based Payment for The NICU Physicians

Shabih Manzar, MD

“The most common method for measuring physician productivity is the work relative value units (wRVU) used to determine reimbursement payments. The wRVUs are linked to the procedure, which has created a debate among procedural-based specialties.”

The most common method for measuring physician productivity is the work relative value units (wRVU) used to determine reimbursement payments. The wRVUs are linked to the procedure, which has created a debate among procedural-based specialties. Orthopedic physicians have reported concerns with the RVU system of payment. (1,2) Similarly, RVUs were poorly correlated with surgical efforts and complexity. (3)

The neonatal intensive care unit (NICU) is a procedural-based specialty area. Most billings in the NICU are done via bundled charges, so a NICU patient brings in a set number of RVUs each day, depending on the billing tier. As most of the billings are done during the day shift, night shift on-call physicians do not generate enough RVUs putting them at a productivity disadvantage. This issue is very well highlighted by Mercuria. (4) By following the RVU model, the productivity of the night call physician could be limited except for the new admissions, as the morning physicians already bill all admitted patients. Similarly, the night call physicians (locum, moonlighter, per diem) are paid at an hourly rate not based on the RVU or census. Thus, there is a need for a payment model for the night call physician to narrow the disparity in productivity and payments.

“Most billings in the NICU are done via bundled charges, so a NICU patient brings in a set number of RVUs each day, depending on the billing tier. As most of the billings are done during the day shift, night shift on-call physicians do not generate enough RVUs putting them at a productivity disadvantage.”

Physician payment is based on the guidelines provided by the Centers for Medicare & Medicaid Services. (5) Every CPT code has a median intra-service time (MIST) based on the amount of time and effort needed. Similarly, each CPT code has an assigned relative value unit (RVU). Payments are calculated by multiplying the RVU with an established conversion factor (CF). (6,7) Using this model, we suggest an approach to payment for the night on-call physician. The variability in the payment is based on productivity. Productivity is measured as the critical need of the NICU, represented by the RVU-based billing tier. For example, when critical billing patients increase, productivity is rated as high. Figures 1A and B present two examples. In example 1, the night call physician is paid more as the total productivity, as measured by total dollars generated during the day, is high compared to example 2. We used the four categories of CPT commonly billed in the NICU in these examples. These categories include all possible subsequent care tiers that represent most NICU patients. As the on-call physician could bill the new admissions, these CPT codes are not included in the calculation.

The suggested model is fair for both administrators and physicians, as it considers the RVU, census, and workload measured by the level of CPT code and billing tier. It could be quickly adopted, and MS Excel (or any accounting program) could be used to generate the final payment based on RVU and census. The suggested model would exclusively work for the physicians working part-time, locum, per diem, or moonlighter in the NICU; however, the full-time physician could also benefit from the suggested payment model if they are asked to provide extra night coverage for staff shortages (which is already happening with Covid pandemic).

“The suggested model is fair for both administrators and physicians, as it considers the RVU, census, and workload measured by the level of CPT code and billing tier. It could be quickly adopted, and MS Excel (or any accounting program) could be used to generate the final payment based on RVU and census.”

The model presented is only one side of the coin. We still need to find ways to acknowledge and document the productivity of the night call NICU physician.

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Figure 1 – A (Example 1 – RVU and Census based)

| CPT code | MIST (Mins) | wRVU | CF | Payment (RVU based) | NICU Census | Day Payment (RVU based) | Average (Total/Census) | Night Payment (Average x hours) |
|----------|-------------|------|----|---------------------|-------------|-------------------------|------------------------|---------------------------------|
| 99469 | 128 | 7.99 | 32 | \$255 | 5 | \$1275 | x | x |
| 99478 | 30 | 2.75 | 32 | \$88 | 6 | \$528 | x | x |
| 99479 | 30 | 2.50 | 32 | \$80 | 12 | \$960 | x | x |
| 99480 | 30 | 2.40 | 32 | 76.8 | 4 | \$307 | x | x |
| Total | x | x | x | x | 27 | \$3070 | \$113 | 113 x 12 = \$1356 |

CPT code: 99469- subsequent critical care, 99478- subsequent care weight < 1500 grams

99479- subsequent care weight 1500- 2500 grams, 99480- subsequent care weight >2500 grams

MIST - Median Intra Service time (MIST), wRVU - work Relative Value Unit, CF - Conversion factor

Payment RVU based = wRVU x CF, Average day payment = Total RVU/ Census, Average night call = Average day payment x hours

Figure 1 – B (Example 2 – RVU and Census based)

| CPT code | MIST (Mins) | wRVU | CF | Payment (RVU based) | NICU Census | Day Payment (RVU based) | Average (Total/Census) | Night Payment (Average x hours) |
|----------|-------------|------|----|---------------------|-------------|-------------------------|------------------------|---------------------------------|
| 99469 | 128 | 7.99 | 32 | \$255 | 3 | \$765 | x | x |
| 99478 | 30 | 2.75 | 32 | \$88 | 5 | \$440 | x | x |
| 99479 | 30 | 2.50 | 32 | \$80 | 8 | \$640 | x | x |
| 99480 | 30 | 2.40 | 32 | 76.8 | 2 | \$153 | x | x |
| Total | x | x | x | x | 18 | \$1422 | \$79 | 79 x 12 = \$948 |

CPT code: 99469- subsequent critical care, 99478- subsequent care weight < 1500 grams

99479- subsequent care weight 1500- 2500 grams, 99480- subsequent care weight >2500 grams

MIST - Median Intra Service time (MIST), wRVU - work Relative Value Unit, CF - Conversion factor

Payment RVU based = wRVU x CF, Average day payment = Total RVU/ Census, Average night call = Average day payment x hours

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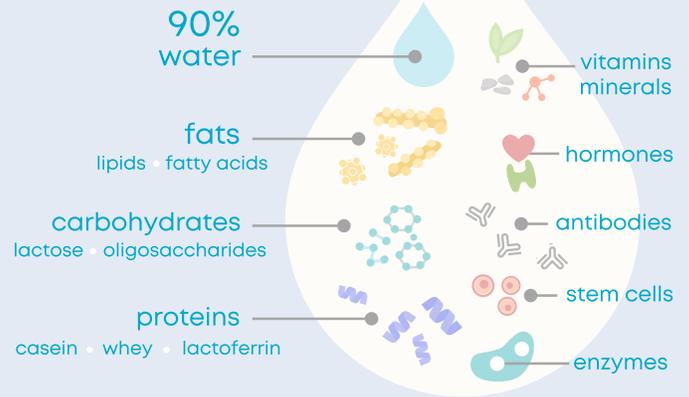
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TOP 10

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

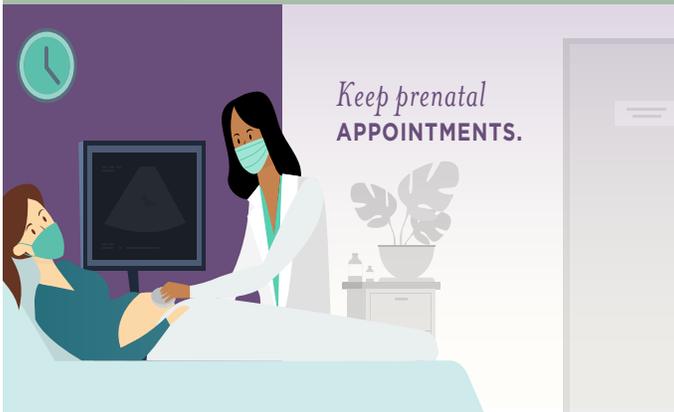
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SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN
WASH YOUR HANDS, ARMS, and CHEST

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



PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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



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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.



Non-Invasive Ventilation: Who, How and For How Long?

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.

“Non-invasive respiratory support in the NICU pre-dates invasive mechanical ventilation (IMV). Initially, bubble CPAP was the only adjunct available to clinicians.”

Non-invasive respiratory support in the NICU pre-dates invasive mechanical ventilation (IMV). Initially, bubble CPAP was the only adjunct available to clinicians. It is still widely used in units worldwide; its simplicity and low cost make it particularly attractive where available healthcare resources are limited. Today, there are more options for providing NIV. There are also several different modes as well.

With the introduction of mechanical ventilators, IMV became the standard of care for most premature infants. That IMV was not a panacea was almost immediately apparent: bronchopulmonary dysplasia (BPD), now referred to as chronic lung disease (CLD), became the hallmark of prematurity. Before the availability of surfactant supplementation, it was a necessary and undeniably life-saving therapy, CLD notwithstanding. As my late mentor, Dr. Andrew Shennan, would say, “you have to survive to have complications.”

Surfactant therapy did not eliminate CLD as much as was hoped, and post-natal steroid use became commonplace as a treatment for CLD and to facilitate extubation to NIV. Concerns about brain development and neurodevelopmental outcomes led to steroid use falling out of favour in the late 1990s until demonstrably safer regimens such as the “DART” protocol were introduced.

The undeniable link between IMV and CLD begged the question

of whether the duration of IMV could be decreased or avoided altogether. While gestational age alone was once the sole determinant of the need for intubation and IMV, it was also a common determinant for the transition from IMV to NIV. Intubating all infants of less than 30 weeks post-conceptual age (PCA) and/or continuing IMV until 30 or more weeks PCA may seem absurd today, but it was standard a generation ago.

“While gestational age alone was once the sole determinant of the need for intubation and IMV, it was also a common determinant for the transition from IMV to NIV. Intubating all infants of less than 30 weeks post-conceptual age (PCA) and/or continuing IMV until 30 or more weeks PCA may seem absurd today, but it was standard a generation ago.”

Earlier extubation was followed by selective intubation and increased use of NIV as first-line therapy, and later research supported its use at lower PCA. Intubation for surfactant administration followed by extubation to NIV (INSURE) is now common practice, and alternative “less invasive” methods of surfactant administration “LISA, MIST” are gaining acceptance. There is evidence to support both approaches. I suspect variations in how surfactant is delivered after intubation have implications for potential lung damage, i.e., hand-bagged in or delivered while on the ventilator, and may favour less invasive methods. The benefit may be secondary to not handbagging the baby, c.f., not intubating. To the best of my knowledge, no comparison study has examined whether handbagging surfactant contributes to poorer outcomes. (I suspect it does).

Although CLD, among other morbidities, has not declined, NIV is now routinely chosen as the first-line modality for respiratory support in ever younger and smaller infants (1). As PCA at birth decreases, the risk of lung damage increases. It has also been shown that extubation failure bodes poorly for outcomes, including CLD (2). The lungs are most susceptible to damage during

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the recruitment phase, whether during initial resuscitation or de-recruitment. Oxidative stress is most deleterious in premature infants at birth, especially as PCA decreases. Stubbornly refusing to change course as a baby's FiO_2 increases will likely exacerbate the problem through progressive atelectasis, prolonged oxidative stress, and delaying surfactant administration (however given) should it be needed. Providing NIV should be weighed against the increasing likelihood of treatment failure as PCA falls.

“Radiologically diagnosed severe RDS increases the odds of failure but not uniformly; 50-80% will fail NIV but fewer than a third of infants failing NIV have radiological evidence of severe RDS. Not all babies with severe RDS will fail CPAP, and not all failing NIV have severe RDS (1).”

Other than PCA, other indicators are pointing to NIV failure. Surfactant deficiency (SD) is one. Historically chest films and FiO_2 have been used to determine SD, but their sensitivity is lacking; high FiO_2 correlates well with SD but may result from under-recruitment. Radiologically diagnosed severe RDS increases the odds of failure but not uniformly; 50-80% will fail NIV but fewer than a third of infants failing NIV have radiological evidence of severe RDS. Not all babies with severe RDS will fail CPAP, and not all failing NIV have severe RDS (1). Observationally it is not uncommon in units that do not administer surfactant prophylactically to see very premature infants who have not received surfactant in a FiO_2 of 0.21. It stands to reason that these infants are not SD but respond to adequate recruitment.

Another problem with incorporating FiO_2 into failure criteria is the lack of consensus on what level represents failure; some define failure at 0.6, some at 0.4, and some at 0.3. Decreasing failure criteria from 0.6 to 0.35 increases the failure rate by 16% and results in surfactant being given 2.5 hours earlier, ostensibly a good thing, especially at lower PCA. Interestingly, an FiO_2 of 0.3 on NICU admission has a 60% sensitivity in predicting NIV failure (1). This supports the European recommendation of $\text{FiO}_2 > 0.3$ as a failure criterion. Higher FiO_2 criteria decrease failure rates and result in truly SD infants not receiving surfactant (1). This management may be one reason pulmonary function in babies “successfully” managed on NIV is decreased later in life.

“Another problem with incorporating FiO_2 into failure criteria is the lack of consensus on what level represents failure; some define failure at 0.6, some at 0.4, and some at 0.3.”

Several modes of NIV are available today that were not available to our colleagues of yesteryear. In addition to CPAP, non-invasive positive pressure ventilation with or without synchronisation (Si) NIPPV, non-invasive HFO (NI-HFO), and non-invasive neurally assisted ventilation (NIV-NAVA) are available. Evidence favouring one mode over the other has been historically inconsistent or lacking, but more recent studies show decreased NIV failure with NIPPV (particularly if synchronised) and possibly NI-HFO. NIV-NAVA is the newest kid on the block and shows great promise, and those using the mode report great success, but further studies are needed (3). NIPPV should be initially considered as the first mode for those most at risk of failing NIV. NI-HFO is frequently used to good effect in my practice. Babies should be transitioned to CPAP as soon as possible.

How long babies should remain on NIV is a topic of great debate. Antenatal steroids (ACS) have increased dramatically since early NIV trials and have changed our patient population even as their PCA has become much lower. Trials involving non-ACS exposed infants and higher PCA are not applicable today, nor is it reasonable to expect the course of the extremely premature to mirror that of more mature infants. Before resuscitation of the sub-25-week PCA became routine, it was relatively uncommon (at least in the unit where I practice) for NIV to be required beyond 30 weeks PCA, give or take. An infant born at 23 weeks PCA cannot generally be expected to be free of NIV until much before 32 weeks PCA, perhaps much longer (4).

“How long babies should remain on NIV is a topic of great debate. Antenatal steroids (ACS) have increased dramatically since early NIV trials and have changed our patient population even as their PCA has become much lower. Trials involving non-ACS exposed infants and higher PCA are not applicable today, nor is it reasonable to expect the course of the extremely premature to mirror that of more mature infants.”

Some propose leaving all infants on NIV until at least 32 weeks. I believe this blanket approach may not be in our patient's best interest as it will indubitably result in many infants being maintained on NIV longer than necessary. The proven benefits of NIV have blinded many to the fact that the modality is not benign and the duration of therapy increases the risk of adverse effects. Air leak, distal airway over-extension, reflux (itself, contributory to lung damage), and nasal injury are not beneficial. In addition, NIV can delay oral feeding and interfere with Kangaroo care, and may increase the length of stay if used unnecessarily. NIV can also result in many of the same problems as invasive ventilation, including cardiopulmonary compromise (4). I do not think it is a stretch to

say any medical intervention should not be continued beyond its utility.

“Treatment creep,” the use of a proven therapy on patients for whom its beneficence has not been established, may not be appropriate in the case of NIV and may lead to unintentional harm. More research reflecting today’s NICU patient population is needed before the indiscriminate application of NIV. That research should establish consistent failure criteria and involve long-term follow-up before the safety and efficacy of NIV in the highly premature can be established.

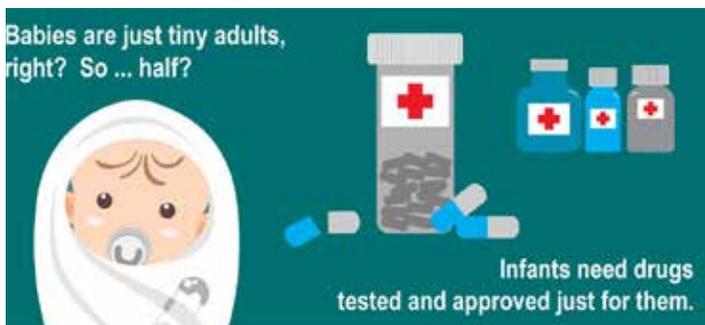
“More research reflecting today’s NICU patient population is needed before the indiscriminate application of NIV. That research should establish consistent failure criteria and involve long-term follow-up before the safety and efficacy of NIV in the highly premature can be established.”

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August 9, 1996 - April 3, 2010



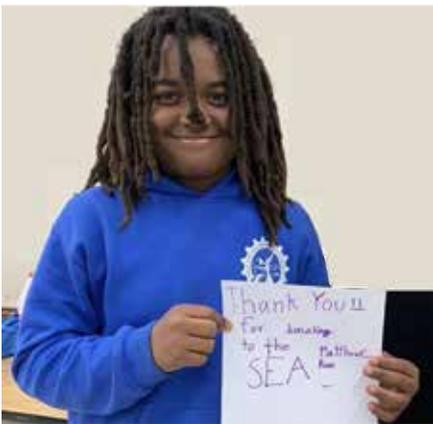
Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring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

Make a Difference in the Life of a Student in Need Today!

Please visit emilyshane.org

Sponsor a Child in the SEA Program

The average cost for the program to provide a mentor/ tutor for one child is listed below.



| | |
|--------------------|---------|
| 1 session_____ | \$15 |
| 1 week _____ | \$30 |
| 1 month_____ | \$120 |
| 1 semester_____ | \$540 |
| 1 year_____ | \$1,080 |
| Middle School_____ | \$3,240 |

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

Statement from the National Perinatal Association Regarding Reproductive Rights and Abortion Care.

Jerry Ballas, MD, MPH, Cody Miller Pyke, JD, LLM, MSBE

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.



“Reproductive rights are human rights. The National Perinatal Association will continue to learn from, advocate for, and provide a voice to individuals, families, and healthcare providers who believe that all people should have Constitutionally protected reproductive autonomy.”

Reproductive rights are human rights.

The National Perinatal Association will continue to learn from, advocate for, and provide a voice to individuals, families, and healthcare providers who believe that all people should have Constitutionally protected reproductive autonomy.

Choice is a bedrock of Birth Justice.

The National Perinatal Association stands for freedom of choice in all realms of an individual's reproductive life, from contemplation and contraception to fertilization, carrying a pregnancy, or choosing termination.

The right to privacy is paramount to patient care.

The National Perinatal Association affirms the value of lived experiences and the need for medical expertise and therefore rejects undue governmental intrusion into the private, complicated decisions made between patients and their healthcare providers.

Abortion care is healthcare.

The National Perinatal Association acknowledges that the harmful history of illegal abortions in the United States predates the Roe v. Wade decision, and we will continue to fight to prevent history from repeating itself.

“And while Congress may ultimately decide whether that care remains legal, safe, equitable, and free from legal repercussions, the choice to obtain an abortion will always remain with an individual, and providing access to medically sound abortion care will always be the responsibility of healthcare providers.”

To be clear, regardless of any decision made by this Supreme Court, abortions and abortion care will continue. And while Congress may ultimately decide whether that care remains legal, safe, equitable, and free from legal repercussions, the choice to obtain an abortion will always remain with an individual, and providing access to medically sound abortion care will always be the responsibility of healthcare providers. This is why the National Perinatal Association will continue to ally with individuals, families, nonprofit organizations, and patient advocates to fight for ongoing safe and legal abortion care.

“This is why the National Perinatal Association will continue to ally with individuals, families, nonprofit organizations, and patient advocates to fight for ongoing safe and legal abortion care.”

Reference:

1. https://www.nationalperinatal.org/files/ugd/209d80_c5ed8a-3c6a5e4f268bda2e150178f8ae.pdf

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



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PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis

RSV



WASH YOUR HANDS
often with soap and warm water.

GET VACCINATED
for flu and pertussis.
Ask about protective injections for RSV.



COVER COUGHS AND SNEEZES.
Sneeze and cough into your elbow.

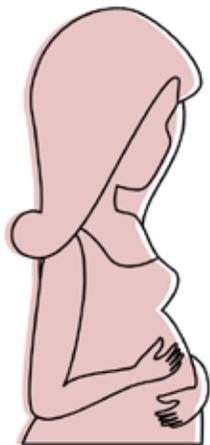
USE AN ALCOHOL-BASED HAND SANITIZER.



STAY AWAY FROM SICK PEOPLE
Avoid crowds.
Protect vulnerable babies and children.

NATIONAL PERINATAL ASSOCIATION

Update: CORONAVIRUS COVID-19



According to data published in The Lancet

Pregnancy and the risk of VERTICAL TRANSMISSION
LOW



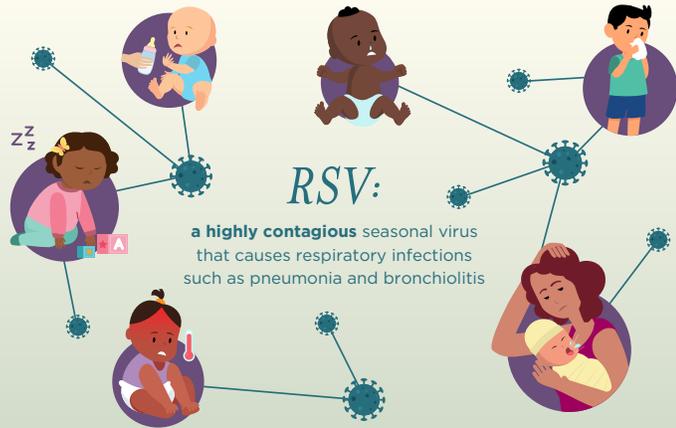
www.nationalperinatal.org

www.nationalperinatal.org



Respiratory Syncytial Virus

DID YOU KNOW?



The Gap Baby: An RSV Story



Infants under age 1



RSV is the leading cause of hospitalization



16x more likely to get RSV than the flu



Postpartum Revolution

@ANGELINAPICER



Kids under age 5 experience



500,000 emergency room visits for RSV each year



57,000 hospitalizations for RSV each year

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

LEARN MORE >

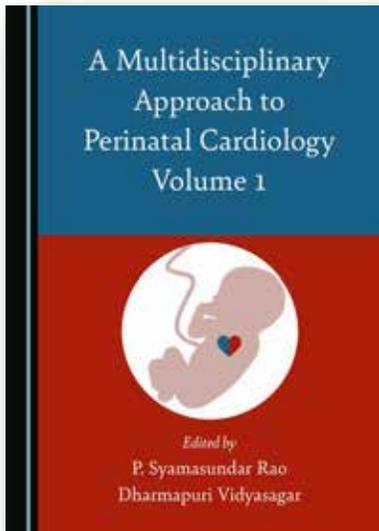
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A Multidisciplinary Approach to Perinatal Cardiology Volume 1

Edited by P. Syamasundar Rao and Dharmapuri Vidyasagar



Hardback

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24/04/2021

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794 / A5

Price:

£99.99

Book Description

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

About the Editors

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

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

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



Online L&D Staff Education Program

Caring for Pregnant Patients & Their Families:
Providing Psychosocial Support During
Pregnancy, Labor and Delivery

WWW.MYPERINATALNETWORK.ORG



Continuing education credits provided by



About the Program

- **WHO SHOULD TAKE THE PROGRAM?** This program is designed for both office and hospital staff in all disciplines that interact with pregnant patients and their families. A key focus is recognizing risk factors for perinatal mood and anxiety disorders, and mitigating their impact through provision of trauma-informed care.
- **WHY TAKE THE PROGRAM?** Families will benefit when staff have improved skills, through enhanced parental resilience and better mental health, and improved parent-baby bonding leading to better developmental outcomes for babies. Benefits to staff include improved skills in communicating with patients; improved teamwork, engagement and staff morale; reduced burnout, and reduced staff turnover.
- **HOW DOES THE PROGRAM ACHIEVE ITS GOALS?** Program content is representative of best practices, engaging and story-driven, resource-rich, and developed by a unique interprofessional collaboration of obstetric and neonatal professionals and patients. The program presents practical tips and an abundance of clinical information that together provide solutions to the emotional needs of expectant and new parents.
- **HOW WAS THE PROGRAM DEVELOPED?** This program was developed through collaboration among three organizations: a multidisciplinary group of professionals from the National Perinatal Association and Patient + Family Care, and parents from the NICU Parent Network. The six courses represent the different stages of pregnancy (antepartum, intrapartum, postpartum), as well as perinatal mood and anxiety disorders, communication techniques, and staff support.

Program Objectives

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

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

PROGRAM CONTENT



COMMUNICATION SKILLS CEUs offered: 1

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

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



PERINATAL MOOD AND ANXIETY DISORDERS CEUs offered: 1

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

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



PROVIDING ANTEPARTUM SUPPORT CEUs offered: 1

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

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



PROVIDING INTRAPARTUM SUPPORT CEUs offered: 1

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

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



PROVIDING POSTPARTUM SUPPORT CEUs offered: 1

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

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



SUPPORTING STAFF AS THEY SUPPORT FAMILIES CEUs offered: 1

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

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

Cost

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

Contact help@myperinatalnetwork.org to learn more.

Faculty

Linda Baker, PsyD

Psychologist at Unstuck Therapy, LLC, Denver, CO.

Jerasimos (Jerry) Ballas, MD, MPH

Associate Clinical Professor, UCSD Health System, Maternal-Fetal Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California at San Diego, San Diego, CA.

Amanda Brown, CNM, MSN, MPH

University of North Carolina-Chapel Hill Hospitals, Chapel Hill, NC.

Sara Detlefs, MD

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

Sue L. Hall, MD, MSW, FAAP

Neonatologist, Ventura, CA.

Claire Hartman, RN, IBCLC

Labor & Delivery, University of North Carolina Hospital, Chapel Hill, NC.

MaryLou Martin, MSN, RNC-NIC, CKC

Women's and Children's Services Nurse Educator, McLeod Regional Medical Center, McLeod, SC.

Cheryl Milford, EdS.

Former NICU and Developmental psychologist, in memoriam.

Karen Saxer, CNM, MSN

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

Amina White, MD, MA

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

Parent/Patient Contributors:**Brittany Boet**

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

Angela Davids

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

Crystal Duffy

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

Tracy Pella, MA

Co-Founder and President, Connected Forever, Tecumseh, NE.

Erin Thatcher, BA

Founder and Executive Director, The PPROM Foundation, Denver, CO.

CANCELLATIONS AND REFUNDS

For Individual Subscribers:

- If you elect to take only one course, there will be no cancellations or refunds after you have started the course.
- If you elect to take more than one course and pay in advance, there will be no cancellations or refunds after payment has been made unless a written request is sent to help@myperinatalnetwork.com and individually approved.

For Institutional Subscribers:

- After we are in possession of a signed contract by an authorized agent of the hospital and the program fees have been paid, a 50% refund of the amount paid will be given if we are in receipt of a written request to cancel at least 14 (fourteen) days prior to the scheduled start date for your hospital's online program.
- Refunds will not be given for staff members who neglect to start the program. Also, no refunds for those who start the program, but do not complete all 6 courses within the time frame allotted.

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

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

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

Follow us online at [@MyNICUNetwork](https://www.instagram.com/MyNICUNetwork)

www.myperinatalnetwork.org Phone: 805-372-1730



SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS

DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing
the risks of...

- **HORIZONTAL INFECTION**
- **SEPARATION AND TRAUMA**



EVIDENCE

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



PARTNERSHIP

What is the best
for this unique dyad?

SHARED DECISION-MAKING

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



TRAUMA-INFORMED

Both parents and providers
are confronting significant...

- **FEAR**
- **GRIEF**
- **UNCERTAINTY**

LONGITUDINAL DATA

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

- **MENTAL HEALTH**
- **POSTPARTUM CARE DELIVERY**



NEW DATA EMERGE DAILY. NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

Partnering for patient-centered care
when it matters most.

nann.org nationalperinatal.org



National
Association of
Neonatal
Nurses



National
Perinatal
Association

Coping with COVID-19



A viral pandemic

A racial pandemic within a viral pandemic



Will mental illness be the next inevitable pandemic?

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COVID-19

National Network of NICU Psychologists FREE for our NICU COMMUNITY

- Helping Children and Families Cope
- Bonding with Your Baby
- Caregivers Need Care Too



Download at www.nationalperinatal.org/psychologists

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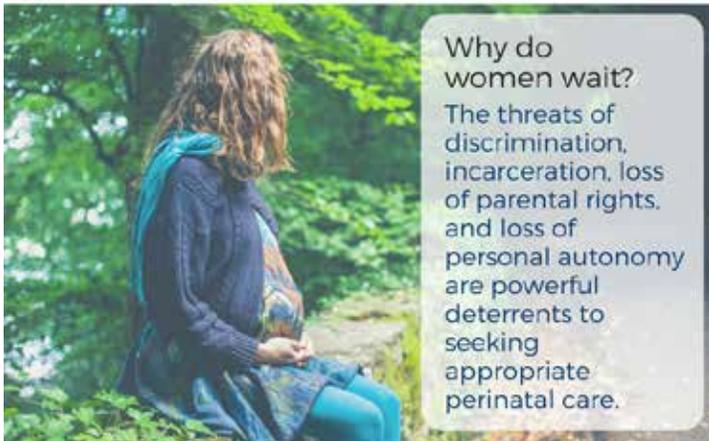
Caring for Babies and their Families: Providing Psychosocial Support to NICU Parents

7- Module Online Course in NICU Staff Education



National Perinatal Association PERINATAL SUBSTANCE USE

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The Value of Innovation Policy Forum in Five Quotes

Michelle Winokur, DrPH, Executive Director of the Institute for Patient Access

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.



“What is medical innovation worth? To explore this question, the Institute for Patient Access recently convened health policy and patient advocacy professionals for the Value of Innovation Policy Forum in Washington, D.C.”

What is medical innovation worth? To explore this question, the Institute for Patient Access recently convened health policy and patient advocacy professionals for the Value of Innovation Policy Forum in Washington, D.C.

If you missed it, here's a summary of the meeting in five quotes.

1. “My patients deserve to define value on their terms – to appreciate innovation for not only what it does for their health, but also for the meaning it brings to their daily lives.”

In his opening remarks, David Charles, MD, reminded attendees that patients' definitions of medications' value have nothing to do

with money. For example, they more often frame value as quality of life – feeling good enough to enjoy time with family and be productive at work.

“My patients deserve to define value on their terms – to appreciate innovation for not only what it does for their health, but also for the meaning it brings to their daily lives.”

2. “We’re going to need more innovation in drug development for Alzheimer’s.”

Geriatrician Howard Fillit, MD, of the Alzheimer's Drug Discovery Foundation, emphasized that while beta-amyloid drugs might affect disease progression, there's also a need to look at the effects of aging – the leading risk factor for Alzheimer's. Transferring what is known about aging into the therapeutics for Alzheimer's will be essential.

3. “The reason we can debate whether the pandemic is over is because of the vaccines.”

It took just 338 days from when Chinese scientists revealed the sequence for a new coronavirus to the day an ICU nurse on Long Island became the first person in America to roll up her sleeve and get the shot. In his keynote address, author David Health provided the backstory to this feat and explained how vaccine science has changed forever.

“It took just 338 days from when Chinese scientists revealed the sequence for a new coronavirus to the day an ICU nurse on Long Island became the first person in America to roll up her sleeve and get the shot.”

4. “It’s hard for innovation to continue if it’s not paid for.”

Pam Traxel of the American Cancer Society Cancer Action Network implored policymakers to provide adequate payment for innovative diagnostics and treatments. For example, Medicare reimburses for only five types of cancer screening. It's impossible to beat cancer if it's not diagnosed – and doing that requires meaningful insurance coverage.

5. “My name is Emily Bonnell. I have CF, and I’m going to die.”

In the event’s closing video, parent and advocate Laura Bonnell described her daughter Emily as a kindergartner grappling with cystic fibrosis. Laura explained that the breakthrough drug that corrects the underlying condition that causes cystic fibrosis worked for only one of her daughters – Molly, not Emily. Laura advocates for continued innovation in hopes that both of her daughters will get to live.

“Laura Bonnell described her daughter Emily as a kindergartner grappling with cystic fibrosis. Laura explained that the breakthrough drug that corrects the underlying condition that causes cystic fibrosis worked for only one of her daughters – Molly, not Emily. Laura advocates for continued innovation in hopes that both of her daughters will get to live.”

Even though the event didn’t focus on innovation in neonatology, the need for it – and the policy that supports it – are undeniable. Watch the recording of the event on IfPA’s [website](#).

Michelle Winokur, DrPH, is the Executive Director of the Institute for Patient Access.

This content article was also published at [Institute for Patient Access.org](#)

NT



SHARED DECISION-MAKING
PROTECTS PARENTS + BABIES COVID-19

INFORMED PROVIDERS

- S** seek participation
- H** help explore options
- A** assess preferences
- R** reach a decision
- E** evaluate the decision

CARE DELIVERY REQUIRES **PARTNERSHIP**

nationalperinatal.org/NPAandNANN

NPA NANN

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DID YOU KNOW?

Postpartum
depression
affects

10%

of fathers

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Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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



Limit Contact with Others

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



Provide Protective Immunity

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



Take Care of Yourself

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



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



WARNING

Never Put a Mask on Your Baby

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



If you are positive for COVID-19

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



We can help protect each other.

[Learn more](#)

www.nationalperinatal.org/COVID-19



The Gap Baby: An RSV Story



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



The National Coalition for Infant Health advocates for:

- **Access to an exclusive human milk diet** for premature infants
- **Increased emotional support resources** for parents and caregivers suffering from PTSD/PPD
- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
- **Clear, science-based nutrition guidelines** for pregnant and breastfeeding mothers
- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

www.infanthealth.org

I CAN Digitally Involved (I CANDI): 2022 Summer in Lyon

Amy Ohmer



“The summit will be held in-person in Lyon, France, from July 11th to July 15th, 2022, at the University of Lyon.”

With just two months until our global youth advisory event, you and your colleagues are invited to join the International Children's Advisory Network, Inc. (iCAN) at the [2022 iCAN Summit presented by Jumo Health](https://www.icanresearch.org/2022-summit). (1) This exciting week-long summit offers interactive and engaging sessions through the support and expertise of our youth members from around the world and our many adult community partners (scientists, doctors, researchers, pharma, parents, and many other stakeholders). The summit will be held in-person in Lyon, France, from July 11th to July 15th, 2022, at the University of Lyon. To learn more about the summit, including registering, reserving a discounted hotel room, or making a charitable contribution, please head to our website at www.icanresearch.org/2022-summit. (1) iCAN is a patient-engagement resource to many organizations worldwide, focusing on pediatric medicine, clinical research, medicine development, and medical device innovation. Don't forget to download the complimentary app designed by youth members of iCAN's KIDS France chapter to stay on top of the latest summit planning, speaker announcements, cultural activities & more.

“iCAN is a patient-engagement resource to many organizations worldwide, focusing on pediatric medicine, clinical research, medicine development, and medical device innovation.”

Did you know... iCAN has multiple leadership and chapter opportunities? Read more to learn how you can join iCAN and share your voice.

iCAN Chapter Startups: iCAN welcomes interested hospitals to join at no cost. Chapter groups can be as small or large, emphasizing helping to spotlight the youth voice. To learn more, check out <https://www.icanresearch.org/chapters>. (2)

iCAN Youth Council: The next leadership stage for youth members interested in significantly supporting iCAN. The iCAN Youth Council is active in creating, overseeing, executing, and disseminating pediatric issues/topics through the unique perspective of youth throughout research, science, advocacy, technology, and medicine. Interested young people can learn more at <https://www.icanresearch.org/our-youth>. (3)

iCAN Young Adult Professionals: This dedicated group of young adults ages 18+ helps to support iCAN at a professional and higher educational level. iCAN offers internships and more significant leadership roles in helping retain and engage young adults as they begin their careers. To learn more about this group, head over to <https://www.icanresearch.org/ican-young-adult-professionals>. (4)

iCAN Parents: Welcome to Deb Discenza and Jennifer Degl, iCAN's new co-chairs of the revamped iCAN Parent Chapter. All parents (and family members) are welcome to join iCAN as advisors for the littlest patients (0-7 years old). Joining is free and can be done by visiting www.icanresearch.org (5) or sending an [email](mailto:icanparent@icanresearch.org) to icanparent@icanresearch.org. To learn more, check out this page at <https://www.icanresearch.org/parents-families>. (6)

At iCAN, we understand sharing experiences to help support a better community.

We invite everyone to join us for a special monthly event called “iCAN Ask the Experts” (ATE). This event focuses on youth member small group discussion on relevant topics within pediatric healthcare and research. After each session, iCAN provides a written summary of issues and a video recording of the session to ensure that information is shared to help improve the patient experience. To participate in our ATE sessions, please email us at info@icanresearch.org.

iCAN is working with the Duke Clinical Research Institute (DCRI) to support a new anthology created by iCAN Youth Members to share their creative work participating in clinical research trials. Using the prompt: “If you could go back in time to tell yourself what you know now about research, what would you say?” iCAN Youth Members will be submitting ideas using short stories, poems, illustrations, electronic art, and original photographs to be included in a book to be shared at the 2022 iCAN Summit. Everyone is welcome to participate, and the deadline is May 15th for all submitted materials. To see all of the [projects and opportunities](https://www.icanresearch.org/open-projects) available for kids to join in, visit this link at <https://www.icanresearch.org/open-projects>. (7)

2022 SUMMIT



SAVE THE DATE

July 13th through July 17th, 2022

To be held in-person at the University of Lyon, France

Hosted by iCAN KIDS France

Registration Opens May 15th, 2022



Sign up for for updates at
www.iCANResearch.org





2022
iCAN Summit
International Children's Advisory Network

Presented by  **jumohealth**

**July 11-15th to be held at the
University of Lyon, France**

Register Today!

www.iCANResearch.org



**Join Us In-Person for 2022
Kids - Make Your Summer Count!**

- Travel to France
- Share your expert voice
- Shape the future of clinical research
- Support new pediatric innovation
 - Engage with global leaders
- Make friends around the world
- Learn about careers in healthcare



iCAN is not responsible or liable for any and all travel arrangements (including but not limited to flights, trains, cars, transport of any kind, accommodations, meals, reservations or other rental / vacation services acquired) by/for participants for any reason. iCAN is not responsible for any attendee medical needs. iCAN advises attendees to purchase travel insurance for the iCAN Summit.

The 'I CAN' Book is now available for purchase at www.icanresearch.org for \$25.00 using our unique PayPal link on the home page under donations. (5) After payment, please contact us at info@icanresearch.org with your name and mailing address to receive your copy. This beautiful hard-bound book is created by iCAN Youth Members worldwide and filled with positive statements about overcoming challenges to be the best you can be. This beautiful book is fully illustrated by our KIDS Bari chapter. This beautiful book is a treasure you and your family will treasure for years to come.

“If you have research to be shared and would like to showcase your work at the 2022 iCAN Summit presented by Jumo Health from July 11th to July 15th, 2022, please send your submissions for the poster session at info@icanresearch.org no later than 6/1/2022”

SAVE THE DATE:

- Register NOW for the iCAN Summit held July 11th - July 15th, 2022, in Lyon, France. Discounted hotel rooms are available. Sessions include professionals, young people, and hands-on learning to support pediatric research, rare disease innovation, and medicine worldwide.
- iCAN's own unique youth series, 'Ask the Experts,' has a new session planned for **May 21st, 2022, at 10:00 a.m. EST**. To join this fun and free event, please register at www.icanresearch.org/events. (8) All are welcome to attend, and kids of all ages are invited to join. Additional sessions are open for registration, and we welcome all doctors, researchers, and community leaders to join us.
- Calling ALL KIDS - Submit your materials to participate in the **DCRI Anthology** by May 15th, 2022, by sending a .jpeg of your art, short stories, and other creative pieces to info@icanresearch.org.
- The **iCAN Summit Poster Session** submissions deadline is June 1st, 2022. If you have research to be shared and would like to showcase your work at the 2022 iCAN Sum-

2022

Ask the Experts
With Anthony Chang, MD

International Children's Advisory Network
www.icanresearch.org

iCAN

Hosted by:
Dr. Anthony Chang, MD

2022 Sessions Presented by iCAN and Dr. Anthony Chang:

| | |
|---------------|--------------------------------------|
| January 15: | Kids and Covid-19 |
| February 19: | Leadership |
| March 19: | Insight Into Pediatric Heart Disease |
| April 16: | Innovation in Pediatrics |
| May 21: | Advisors vs. Advocates |
| June 18: | What does it mean to be Rare? |
| July 11: | 2022 iCAN Summit Week |
| August 20: | What Can Kids do to Help? |
| September 17: | Insight into Pediatric Cancer |
| October 15: | Specialty Careers in Medicine |
| November 19: | Patient Rights |
| December 17: | Hot Topics in Pediatrics |

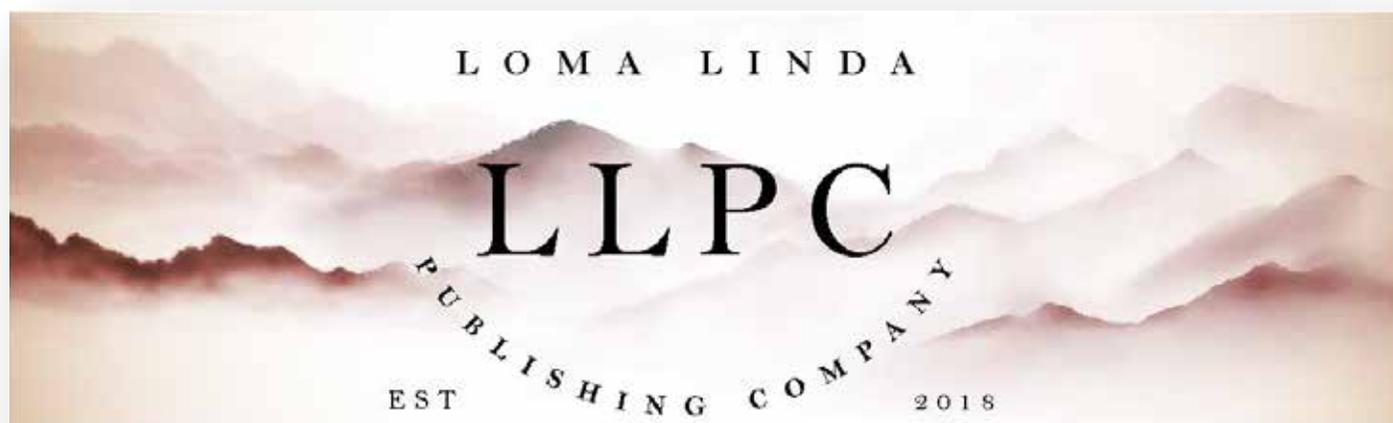
iCAN Approved
International Children's Advisory Network

Register Today
iCANResearch.org/events

mit presented by Jumo Health from July 11th to July 15th, 2022, please send your submissions for the poster session at info@icanresearch.org no later than 6/1/2022.

- **Join iCAN on June 4th, 2022, at the New Britain Bees Baseball Game** by registering at www.icanresearch.org/

[events](#). (8) This is a fundraiser event, and you do not need to be there to participate; simply donate by purchasing tickets, and iCAN will give the tickets to a local child that may not have been able to attend a game. For every \$8.00 ticket, iCAN earns \$5.00 in the donation. All are welcome, and we hope to make this a very successful event. Thank you to



Dr. Sharon Smith for helping us to support this effort. If you would like to donate or support iCAN, please contact Amy Ohmer at amyohmer@icanresearch.org.

- **Join iCAN and the American Academy of Pediatrics National Conference and Exhibition from October 7th - 11th, 2022**, at the Anaheim Convention Center, Anaheim, California. We can't wait to see you at our booth #2034! Look for the iCAN colors and stop by and say hello!

References:

1. <http://www.icanresearch.org/2022-summit>
2. <https://www.icanresearch.org/chapters>
3. <https://www.icanresearch.org/our-youth>
4. <https://www.icanresearch.org/ican-young-adult-professionals>
5. <http://www.icanresearch.org/>
6. <https://www.icanresearch.org/parents-families>
7. <https://www.icanresearch.org/open-projects>
8. <http://www.icanresearch.org/events>

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Respiratory Syncytial Virus is a

Really Serious Virus

Here's what you need to watch for this RSV season

Coughing that gets worse and worse



Breathing that causes their ribcage to "cave-in"

Rapid breathing and wheezing



Bluish skin, lips, or fingertips

RSV can be deadly. If your baby has these symptoms, don't wait.

Call your doctor and meet them at the hospital.

If your baby isn't breathing call 911.



Thick yellow, green, or grey mucus



that clogs their nose and lungs, making it hard to breathe

Fever that is higher than 101° Fahrenheit



which is especially dangerous for babies younger than 3 months



www.nationalperinatal.org/rsv



Call for Posters

iCAN 2022 Summit

July 11-15th, 2022

SUBMISSION DEADLINE: June 1st, 2022

The 2022 iCAN Hybrid (Virtual and In-Person) Poster Session is Hosted by:
The International Children's Advisory Network, Inc. (iCAN)
and the collective group of Kids and families Impacting Disease through Science (KIDS) Youth Chapters

Seeking posters on current topics including but not limited to:

iCAN CHAPTER POSTER UPDATES - ALL iCAN Chapter MUST submit a poster of the team by 6/1/22.

In addition, the iCAN Community may share posters on the following topics:

| | |
|---|---|
| Rare and Orphan Disease | Inclusion and Diversity |
| Ethics and Drug Development | Research and Evidence Based Practice |
| Careers in Medicine, Advocacy, Research | Health Equity Research |
| Institutional Review Board | Sports Medicine Research |
| Assent and Consent Processes | Professional Boundaries |
| Research with Family and Youth Perspectives | Personalized Medication |
| Current Social Issues | Youth Engagement in Science, Medicine, Research |
| Pediatric technology and innovation | |

Submission guidelines:

1. Posters must reflect patient and family voice in research or be educational in nature regarding medical research.
2. For posters reporting research activities, research must be started at the same time of submission.
3. Authors whose posters are accepted are responsible for submitting poster content in **.jpeg format** to **info@icanresearch** no later than June 1st, 2022.
4. All posters will be reviewed by iCAN Summit facilitators for approval.

Poster Information to be submitted:

- I. **Author Biography (Brief):** For each author, list full name, academic and professional credentials, position title, affiliation, mailing address, telephone, and email address. Please designate one contact person. All correspondence regarding poster submission will be sent to the contact person. Author information will be listed in the conference program as submitted on the cover sheet.
- II. **Poster:** Overview of a project, process, and outcomes. **Posters** should be no longer than one page. The abstract must include all of the following: the purpose of the presentation, originality, innovation and/or timeliness of the topic, application of the information to youth and family health advocates. Information presented should be relevant to attendees from various organizations and locations, and for individuals ages 8 and older.

Deadline for submissions is June 1st, 2022. Please send all poster information to info@icanresearch.org.

*Education.
Anytime, Anywhere.*

Academy of Neonatal Care



The Academy of Neonatal Care serves to educate Respiratory Therapists, Nurses, and Doctors in current and best practices in Neonatal ICU care. We prepare RT's new to NICU to fully function as a bedside NICU RT. Our goal is to enrich NICU care at all levels. Beginner to Advanced Practice, there is something for you at:

www.AcademyofNeonatalCare.org

SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS

DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA



EVIDENCE

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



PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

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



TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY



LONGITUDINAL DATA

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

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY



NEW DATA EMERGE DAILY. NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

Partnering for patient-centered care when it matters most.

nann.org nationalperinatal.org



The PREGNANT MOM'S Guide To Staying SAFE DURING COVID-19



Take precautions & LIMIT INTERACTIONS.

6 FT



Maintain at least A 30-DAY SUPPLY OF YOUR MEDICATIONS.



Keep prenatal APPOINTMENTS.



Talk to your health care provider about STAYING SAFE DURING COVID-19.

LEARN MORE >

NCFIH National Coalition for Infant Health
Protecting, Nurturing and Promoting Infants through Age Two

NT

newly validated

Caring for Babies and their Families: Providing Psychosocial Support to NICU Parents

7- Module Online Course in NICU Staff Education



National Perinatal Association and NICU Parent Network

mynicunetwork.org

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis

RSV



WASH YOUR HANDS
often with soap and warm water.

GET VACCINATED
for flu and pertussis. Ask about protective injections for RSV.



COVER COUGHS AND SNEEZES.
Sneeze and cough into your elbow.

USE AN ALCOHOL-BASED HAND SANITIZER.



STAY AWAY FROM SICK PEOPLE
Avoid crowds. Protect vulnerable babies and children.

www.nationalperinatal.org

 National Perinatal Association

FREE RESOURCES FOR YOUR NICU

Coping During COVID-19



Targeted interventions to improve the mental health of parents, infants, families, and providers

BONDING WITH YOUR BABY



HELPING CHILDREN AND FAMILIES COPE

CAREGIVERS NEED CARE TOO



 National Network of NICU Psychologists

nationalperinatal.org/psychologists

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

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



Identify babies at greatest risk



including those with CLD, BPD, CF, and heart conditions

Teach families how to protect



their babies from respiratory infections

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



Use your best clinical judgement



when prescribing RSV prophylaxis

Tell insurers what families need



and provide the supporting evidence



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

Survey Says: RSV

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children



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

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



But Parents are Unprepared.

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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

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



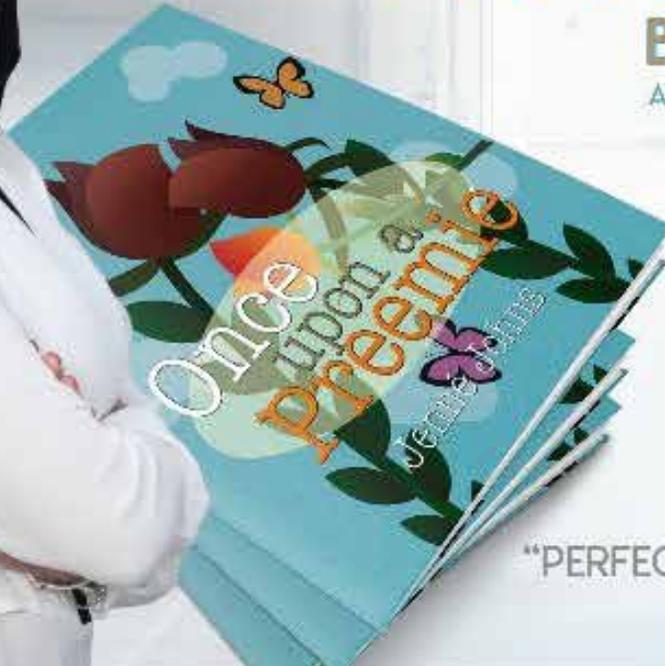
NCJIH National Coalition for Infant Health

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

PREEMIE BOOK ON SALE

ONCE UPON A PREEMIE

BY JENNÉ JOHNS
AUTHOR | SPEAKER | ADVOCATE



“ONE OF A KIND”
“PERFECT FOR PREEMIE FAMILIES”
“ENCOURAGING”

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ONCE UPON A PREEMIE IS A BEAUTIFUL NEW WAY TO LOOK AT THE LIFE OF A PREEMIE BABY. IT EXPLORES THE PARENT AND CHILD NEONATAL INTENSIVE CARE UNIT (NICU) JOURNEY IN A UNIQUE AND UPLIFTING WAY.

SPEAKING ENGAGEMENTS

- PREEMIE PARENT ALLIANCE SUMMIT
- NATIONAL ASSOCIATION OF PERINATAL SOCIAL WORKERS
- CONGRESSIONAL BLACK CAUCUS ANNUAL LEGISLATIVE CONFERENCE
- NATIONAL MEDICAL ASSOCIATION ANNUAL CONFERENCE
- HUDSON VALLEY PERINATAL PUBLIC HEALTH CONFERENCE
- MATERNITY CARE COALITION ADVOCACY DAY

MEDIA APPEARANCES

Premie Family



AVAILABLE FOR \$12.99 ON AMAZON OR ONCEUPONAPREEMIE.COM

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:



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.

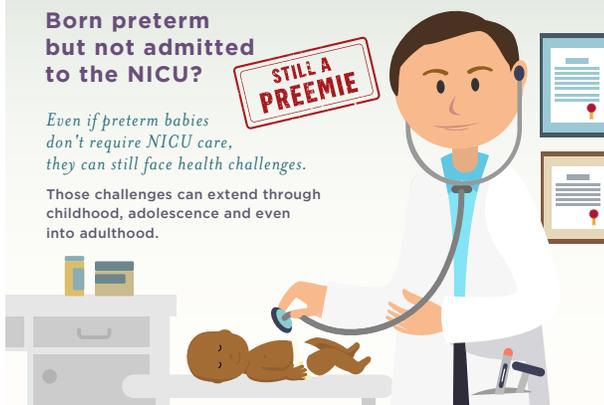


Born preterm but not admitted to the NICU?

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

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

OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS



I am not an addict.

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



I was exposed to opioids.

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



NAS is a temporary and treatable condition.

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



My mother may have a SUD.

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

My potential is limitless.

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



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

National Perinatal Association



Nurses: parents trust you.

You can help reduce the risk of Sudden Infant Death Syndrome (SIDS), the leading cause of death among infants between 1 month and 1 year of age. Take our **free continuing education (CE) activity** to stay up to date on the latest safe infant sleep recommendations. Approved for 1.5 contact hours.

Learn more about the free online activity at <https://nichd.nih.gov/SafeSleepCE>.

The CE activity explains safe infant sleep recommendations from the American Academy of Pediatrics and is approved by the Maryland Nurses Association, an accredited approver of the American Nurses Credentialing Center's Commission on Accreditation.



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



Compiled and Reviewed by David Vasconcellos, MS IV

Baby Formula Shortage Getting Worse

May 03, 2022

Baby formula shortages are increasing across the U.S., and they are expected to continue the rest of the year.

Out-of-stock rates for baby formula hit 31% in April, according to [recent data](#) from Datasembly, a company that tracks grocery and retail pricing records. At the beginning of April, 20 states had out-of-stock rates between 30% and 40%, and several states had rates higher than 40%.

Formula shortages have grown worse each month so far in 2022, the company reported, with out-of-stock rates starting at 23% in January and increasing from there.

"Inflation, supply chain shortages and product recalls have brought an unprecedented amount of volatility for baby formula," Ben Reich, founder and CEO of Datasembly, said in a statement.

"We expect to continue to see the baby formula category being dramatically affected by these conditions," he said. "Baby formula stock, which has been one of the more affected categories so far in 2022, and one that will continue to demonstrate higher than average out-of-stock levels."

In response, major retailers are limiting the amount of baby formula that customers can buy, according to [The Wall Street Journal](#). CVS, Kroger, Target, Walgreens, and Walmart have placed limits on formula purchases, per the FDA's request.

As in many other industries, baby formula shortages have been related to supply chain issues with key ingredients, packaging, and labor shortages, the newspaper reported. Certain formula products have also been recalled in recent months.

In February and March, Abbott Laboratories, one of the largest makers of baby formula, [recalled lots of powdered formulas](#) under several brand names: Similac, Similac PM 60/40, Alimentum, and EleCare.

The FDA and the CDC received consumer complaints about infant illnesses from Abbott's products that were made in September 2021 in the company's facility in Sturgis, Michigan.

Four infants who consumed the products were hospitalized and two have died, the *Journal* reported. The FDA is investigating complaints of *Salmonella* and *Cronobacter sakazakii* that resulted



in hospitalization in Minnesota, Ohio, and Texas.

Cronobacter bacteria can cause life-threatening infections, such as [sepsis](#) or [meningitis](#), an inflammation of the membranes that surround the brain and spine. The bacterial infection is rare but poses particularly high risks for newborns. Symptoms of the bacterial infection include poor feeding, crankiness, temperature changes, jaundice, grunting breaths, and abnormal body movements.

Salmonella bacteria can also cause fever and digestive issues, as well as severe illness among infants.

Abbott is now trying to make more baby formula products available by increasing production at some of its other FDA-registered facilities, bringing in more shipments from Europe by air, and adding facilities that can make formula for infants with specific needs, the newspaper reported.

Sources

Datasembly: "Datasembly's Data Reveals 31% Out-of-Stock Rate in April 2022 for Baby Formula; Up 11% Compared to November 2021."

Wall Street Journal: "Baby-Formula Shortage Prompts Rationing at Target, Kroger, Walgreens and CVS."

FDA: "Abbott Voluntarily Expands Recall of Powder Formulas Manufactured at One Plant."

For more news, follow Medscape on [Facebook](#), [Twitter](#), [Instagram](#), and [YouTube](#). Contact Information:

Carolyn Crist

Medscape, LLC
395 Hudson Street, 3rd Floor
New York, NY 10014

By phone:
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The National Urea Cycle Disorders Foundation



The NUCDF is a non-profit organization dedicated to the identification, treatment and cure of urea cycle disorders. NUCDF is a nationally-recognized resource of information and education for families and healthcare professionals.

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

CDC calls on pediatricians to address challenges in lead poisoning prevention

May 16, 2022

Removing lead from gasoline and paint beginning in the 1970s led to significant declines in childhood blood lead levels (BLLs) across the United States. Underlying this great public health success, however, is a complicated and nuanced story of persistent disparities in exposure to lead, access to testing and services, and health outcomes.

Pediatricians are well-positioned to address these contemporary challenges in lead poisoning prevention.

Ongoing exposure, disparities

Decades of lead use in consumer paint, motor vehicle fuels and other products has made lead a ubiquitous environmental hazard. Data from the [American Healthy Homes Survey II](#) estimate that millions of U.S. children have ongoing exposure to lead-based paint, placing them at risk for

adverse health effects.

[Data from the Centers for Disease Control and Prevention](#) (CDC) demonstrate ongoing disparities in childhood BLLs. Children from low-income households, those living in housing built before 1978 and those who identify as African American are at greater risk for lead exposure. Children from certain other race/ethnicities, immigrants and refugees also are at higher risk due to exposures they faced in their country of origin as well as in the United States.

While these patterns remain important, data from CDC's state partners highlight that childhood lead exposure can occur across all racial and ethnic groups; urban, suburban and rural geography; and any family income level.

Importance of blood lead testing

Though primary prevention of lead exposure remains the goal for both medical and public health communities, strong evidence shows the value of secondary prevention, such as blood lead testing (Kaufmann RB, et al. *Pediatrics*. 2000;106:e79; Christensen K, et al. *WMJ*. 2019;118:16-20).

In October 2021, the CDC [lowered](#)

[the blood lead reference level](#) from 5 micrograms/deciliter (mcg/dL) to 3.5 mcg/dL. However, no level of lead exposure or BLL is safe, and even low levels can impact neurodevelopment.

With approximately 500,000 U.S. children having a BLL of 3.5 mcg/dL or higher, the CDC and state health agencies recommend targeted blood lead testing to identify children exposed to lead.

However, inconsistent state and local testing and reporting policies, inadequate resources and loss to follow-up are important barriers that disproportionately affect certain populations. The COVID-19 pandemic and a recent [recall affecting lead point-of-care testing kits](#) have further impacted testing rates.

Overt lead toxicity is uncommon, with most contemporary lead exposure resulting in subclinical health effects. Therefore, some providers may feel lead exposure is less prevalent and less consequential. While it is important for providers to exercise clinical judgment when deciding which children to test, these decisions should be informed by local data, guidance from local or state health departments and the CDC, and evidence-based approaches such as those

Supporting NICU Staff so they can support families



Providing online education that is...

- Story-Driven
- Trauma-Informed
- Evidence-Based

National Perinatal Association

NPN
NICU PARENT NETWORK

The preeminent provider of compelling perinatal education on psychosocial support created through interprofessional collaboration

www.mynicunetwork.org

outlined in [Bright Futures](#).

Factors such as a belief that one practices in a low-risk area, that only certain populations are at risk or that health effects are unlikely until BLLs reach higher levels can affect decisions on testing and delay or prevent recognition of children exposed to hazardous levels of lead (Markowitz M. *Pediatr Rev.* 2021;42:302-315; Neuwirth LS. *Int J Occup Environ Health.* 2018;24:86-100).

Pediatricians' role in prevention

Pediatricians can help address challenges in preventing childhood lead exposure — including disparities in exposure, testing and follow-up — in several ways:

- Continue to inform and educate families about lead exposure through day-to-day clinical interactions and via broader community outreach through AAP chapters and community-based organizations.
- Help ensure equitable screening, diagnosis and follow-up for children at greatest risk for lead exposure by following guidelines and partnering with local or state health department, health system and community to address disparities.
- Be a voice for policy, systems and environmental change through advocacy, educating policymakers and speaking as a trusted expert in your community.

The CDC is taking steps to increase awareness and promote blood lead testing by health care providers. These include sharing examples of lead exposure in children, with a focus on those who were not initially identified as at high risk; developing materials to encourage health care providers to test children at risk for lead exposures; and working with medical and social services.

Pediatricians have partnered with public health agencies to drive significant reductions in the U.S. population's exposure to lead since the 1970s. The CDC is optimistic that by reengaging with medical professionals, we can strengthen our partnership and redouble our efforts to address contemporary challenges in preventing childhood lead exposure.

Paul Allwood, Ph.D., M.P.H., R.S., and Cdr. Matt Karwowski, M.D., M.P.H., FAAP

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the CDC.

Dr. Allwood is chief of Lead Poisoning Prevention and Surveillance at the CDC. Dr. Karwowski is chief medical officer of the Division of Laboratory Sciences in CDC's National Center for Environmental Health and CDC Liaison to the AAP Council on Environmental Health and Climate Change.

Perri Ruckart Dr.P.H., M.P.H., lead health scientist in the CDC's Lead Poisoning Prevention and Surveillance Branch, and Jonathan Lynch, M.B.A.-P.M., health communications specialist, Division of Environmental Health Science and Practice, contributed to this article.

Resources

- [Information from the CDC on lead poisoning prevention](#)
- [CDC's recommended actions based on blood level results](#)
- [AAP information on lead exposure and prevention](#)

NT

JIA Disease Activity, Disability Linked to Social Factors

Don't feed homemade formula to babies; seek help instead

February 25, 2019

Money is tight and you're low on baby formula. Should you try that homemade formula recipe you saw online?

The answer is: No.

The American Academy of Pediatrics

(AAP) is warning parents not to feed homemade formula to infants. Babies should be fed only breastmilk or iron-fortified infant formula that has been prepared according to the directions on the package.

Homemade formula can harm infants. It might contain too many or not enough nutrients, according to AAP nutrition expert Steven Abrams, M.D., FAAP. Infant formulas are tested by the Food and Drug Administration for quality. They provide the right amount of protein, iron and vitamins that infants need.

Feeding babies homemade formula even for a few days or weeks can have lasting effects and put them at risk of getting sick, according to the AAP.

Do not feed infants the following:

- Homemade formula with ingredients like powdered cow's milk, raw milk or sugar; plain cow's milk; or milk substitutes like almond or soy milk. They do not have the balance of ingredients.
- Imported infant formula. It might have too much or not enough of some ingredients. If it was not stored or shipped correctly, it could be unsafe to use.
- Watered-down formula. It provides an unbalanced diet and can cause serious growth problems.

What should I do if I cannot afford formula?

- **Special Supplemental Nutrition Program for Women, Infants and Children (WIC):** Mothers who qualify based on income can enroll in WIC to receive vouchers for formula, <https://www.fns.usda.gov/wic/wic-how-apply>
- **Supplemental Nutrition Assistance Program (SNAP):** You can use your SNAP Electronic Benefits Transfer card (formerly called food stamps) to buy formula. If you are enrolled in WIC, you also might qualify for SNAP.
- **Temporary Assistance for Needy Families (TANF):** This program

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offers temporary cash assistance to qualified families. Locate your state TANF program at <https://www.acf.hhs.gov/ofa/help>.

Where can I get help if I do not qualify for benefits?

- **Feeding America** is a nonprofit network of 200 food banks. Many provide free baby food, infant formula, diapers and other supplies. Visit <https://www.feedingamerica.org/find-your-local-foodbank>.
- **Dial 2-1-1** to be connected to a community resource specialist who can help you find local resources. The number can be dialed from almost anywhere in the U.S. You also can get help online at <http://www.211.org/services/food>.

Trisha Koriath, Staff Writer

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New AAP main number: 630-626-6000

Related Content

- [Additional Parent Plus columns](#)

NT

FDA, Abbott Nutrition agreement to help reopen infant formula plant

May 17, 2022

Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

A major infant formula manufacturer is moving closer to reopening one of its plants, which could help ease the formula shortage that is plaguing parents nationwide.

The Food and Drug Administration (FDA) has entered into an agreement with Abbott Nutrition on the steps needed to address issues at its Sturgis, Mich., facility so that it can resume operations. Once a judge signs off and the FDA finds initial requirements have been met, Abbott said it can restart the site within two weeks and formula would hit the shelves six to eight weeks later. It will begin with EleCare, Alimentum and metabolic formulas, followed by Similac and other formulas.

"We know many caregivers and parents are feeling frustrated by their inability to access needed or desired infant formula and critical medical foods," FDA Commissioner Robert M. Califf, M.D., said in a press briefing Monday. "Please know we at the FDA are doing everything in our power to address these challenges as quickly as possible."

In February, [Abbott recalled certain lots](#) of Similac, Alimentum and EleCare powdered infant formula following complaints of bacterial infections among four infants who had consumed the formula, including two who died. Dr. Califf said the FDA found *Cronobacter sakazakii* bacteria at the plant and "observed significant operational deficiencies." As health officials investigated, Abbott stopped production at the Sturgis facility to take corrective actions.

The recall and plant closure came on top of supply chain issues related to the COVID-19 pandemic, leaving parents and caregivers struggling to find food for their infants.

"We know millions of parents and caregivers depend on us, and we're deeply sorry that our voluntary recall worsened the nationwide formula shortage," Abbott Chairman and CEO Robert B. Ford said in a [news release](#). "We will work hard to re-earn the trust that moms, dads and caregivers have placed in our formulas for more than 50 years."

In addition to taking steps to help reopen Abbott's Sturgis plant, the [FDA said Monday it is increasing flexibility on formulas](#) being imported from other countries as well as formulas manufactured in the U.S. that typically are exported. Currently, 98% of infant formula consumed in the U.S. is produced here, according to the FDA.

Officials said the new flexibility will not come at the expense of nutrition and safety.

The FDA also has been working with infant formula manufacturers to increase production and has been looking at better ways to expedite the review process and improve distribution. Officials cited progress in a report from Information Resources Inc. showing 80% in-stock rates during the week ending May 8, although specialty and metabolic products continue to be a concern.

Abbott is releasing limited quantities of metabolic and Similac PM 60/40 for patients in urgent need. Health care providers can request them by downloading the form at <http://www.abbottnutrition.com/metabolics> and faxing the completed form with a physician order to 877-293-9145.

Abbott also said in a letter to health care providers it has increased production of liquid infant formulas and Similac Advance 12.4-ounce powder. In addition, it has shipped millions of cans of formula to the U.S. from its FDA-registered facility in Ireland.

The [Biden administration recently announced](#) it is urging states to allow participants in the Supplemental Nutrition Program for Women, Infants, and Children (WIC) to use their benefits on a wider variety of products. The administration also is calling on the Federal Trade Commission and state attorneys general to crack down on price gouging.

The FDA recommends parents and caregivers speak with a child's health care provider for recommendations if their regular formula is not available. Parents should never dilute infant formula or [make their own](#). They also should not purchase imported formula online as it [could be counterfeit](#). [Using cow's milk](#) could be a short-term option for some children 6 months and older who is usually on regular milk-based formula, but families should talk to their pediatrician first. Drinking cow's milk should not become routine for infants.

Resources

- [HHS fact sheet: Helping Families Find Formula During the Infant Formula Shortage](#)
- [USDA Continues Urgent Actions to](#)





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[Address Infant Formula Shortage](#)

- [FDA warning on powdered infant formulas](#)
- Information for parents from HealthyChildren.org on [what to do if they can't find formula](#) and the [risks of homemade formula](#)
- [Information for WIC participants from the Department of Agriculture](#)

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NT

Low Butyrylcholinesterase: A Possible Biomarker of SIDS Risk?

May 16, 2022

Reduced levels of the cholinergic-system enzyme butyrylcholinesterase (BChE) may provide another piece of the puzzle for sudden infant death syndrome (SIDS), preliminary data from Australian researchers suggested.

A small case-control study led by Carmel T. Barrington, PhD, a sleep medicine expert and honorary research fellow at the Children's Hospital at Westmead (Australia), found that measurements in 722 dried blood spots taken during neonatal screening 2 or 3 days after birth were lower in babies who subsequently died of SIDS, compared with those of matched surviving controls and other babies who died of non-SIDS causes.

In groups in which cases were reported as SIDS death (n = 26) there was strong evidence that lower BChE-specific activity was associated with death (odds ratio, 0.73 per U/mg; 95% confidence interval, 0.60-0.89, $P = .0014$). In groups with a

non-SIDS death (n = 41), there was no evidence of a linear association between BChE activity and death (OR, 1.001 per U/mg; 95% CI, 0.89-1.13, $P = .99$). A cohort of 655 age- and sex-matched controls served as a reference group.

Writing online in [eBioMedicine](#), the researchers concluded that a previously unidentified cholinergic deficit, identifiable by abnormal BChE-specific activity, is present at birth in SIDS babies and represents a measurable, specific vulnerability prior to their death. "The finding presents the possibility of identifying infants at future risk for SIDS and it provides a specific avenue for future research into interventions prior to death."

They hypothesized that the association is evidence of an altered cholinergic homeostasis and claim theirs is the first study to identify a measurable biochemical marker in babies who succumbed to SIDS. The marker "could plausibly produce functional alterations to an infant's autonomic and arousal responses to an exogenous stressor leaving them vulnerable to sudden death."

Commenting in a press release, Harrington said that "babies have a very powerful mechanism to let us know when they are not happy. Usually, if a baby is confronted with a life-threatening situation, such as difficulty breathing during sleep because they are on their tummies, they will arouse and cry out. What this research shows is that some babies don't have this same robust arousal response." Despite the sparse data, she believes that BChE is likely involved.

Providing a U.S. perspective on the study but not involved in it, Fern R. Hauck, MD, MS, a professor of family medicine and public health at the University of Virginia, Charlottesville, said that "the media coverage presenting this as the "cause of SIDS," for which we may find a cure within 5 years, is very disturbing and very misleading. The data are very preliminary and results are based on only 26 SIDS cases." In addition, the blood samples were more than 2 years old.

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NT

Update on Children with Acute Hepatitis of Unknown Cause

For Immediate Release: Wednesday, May 18, 2022

The Centers for Disease Control and Prevention (CDC) continues to work with health departments and clinicians nationwide to identify and investigate hepatitis of unknown cause impacting children. As of today, 36 states and territories have reported 180 pediatric [patients under investigation](#) over the past 7 months, which is an increase of 71 from the 109 [publicly reported](#) on May 5.

While this may appear to be a large increase in patients under investigation over the last two weeks, it's important to understand that the vast majority of these are what we consider 'retrospective' patients. Since CDC's investigation looks at patients reported back to October of 2021, most of these numbers involve patients that are just now being reported, rather than new cases of hepatitis – so not all



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are recent, and some may ultimately wind up not being linked to this current investigation. Additionally, there have been no reported deaths since February 2022, and the proportion of patients requiring liver transplants has gone down from 15 percent to 9 percent since May 5.

CDC continues to examine possible causes, including testing for and ruling out some of the viruses that commonly cause hepatitis (hepatitis A, B, C, D, and E). Adenovirus has been detected in nearly half of the children and continues to be a strong lead. Further laboratory tests are being conducted to look more closely at the virus genome and other potential pathogens, such as SARS-CoV-2. In addition, CDC is communicating with key medical groups and continues to provide updated reporting and laboratory guidance for clinicians who may identify hepatitis of unknown cause in children. A Community Outreach and Clinician Activity (COCA) call is scheduled for Thursday, May 19th, where CDC will provide key updates and experts in treating hepatitis will answer clinical questions.

It's important to note that severe hepatitis in children remains rare. However, we encour-

age parents and caregivers to be aware of the symptoms of hepatitis – particularly jaundice, which is a yellowing of the skin or eyes – and to contact their child's healthcare provider with any concern.

CDC will begin posting regular online updates specific to the number of [patients under investigation](#) on a weekly basis. As we learn more, we will share additional information and updates.

###

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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, Sunday 11/17/2019 and Friday 11/20/2020

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

- Connect with other AAP members who share your interests in improving effective drug therapies and devices in children.



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

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

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

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

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

NT

CDC Strengthens Recommendations and Expands Eligibility for COVID-19 Booster Shots

Media Statement

For Immediate Release: Thursday, May 19, 2022

Following today's meeting of the Advisory Committee on Immunization Practices' (ACIP), CDC is expanding eligibility of COVID-19 vaccine booster doses to everyone 5 years of age and older. CDC now recommends that children ages 5 through 11 years should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series. Since the pandemic began, more than 4.8 million children ages 5 through 11 have been diagnosed with COVID-19, 15,000 have been hospitalized and, tragically, over 180 have died. As cases increase across the country, a booster dose will safely help restore and enhance protection against severe disease.

In addition, today CDC is strengthening its recommendation that those 12 and older who are immunocompromised and those 50 and older should receive a second booster dose at least 4 months after their first. Over the past month we have seen steady increases in cases, with a steep and substantial increase in hospitalizations for older Americans. While older Americans have the highest coverage of any age group of first booster doses, most older Americans received their last dose (either their primary series or their first booster dose) many months ago, leaving many who are vulnerable without the protection they may need to prevent severe disease, hospitalization, and death.

Whether it is your first booster, or your second, if you haven't had a vaccine dose since the beginning of December 2021 and you are eligible, now is the time to get one.

The following is attributable to CDC Director, Dr. Rochelle P. Walensky

"Today, I endorsed ACIP's vote to expand eligibility for COVID-19 vaccine booster doses. Children 5 through 11 should receive a booster dose at least 5 months after their primary series. Vaccination with a primary series among this age group has lagged behind other age groups leaving them vulnerable to serious illness. With over 18 million doses administered in this age group, we know that these vaccines are safe, and we must continue to increase the number of children who are protected. I encourage parents to keep their children up to date with CDC's COVID-19 vaccine recommendations.

With cases increasing, it is important that all people have the protection they need, which is why, today, CDC has also strengthened another booster recommendation. Those 50 and older and those who are 12 and older and immunocompromised should get a second booster dose."

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NT

New Law Bans Infant Sleep Products Linked to 200 Deaths

May 17, 2022

A new law will ban certain infant sleep products blamed for the deaths of more than 200 babies in the US.

On Monday, President Joe Biden signed legislation that prohibits the manufacture and sale of crib bumpers or inclined sleepers for infants, due to the risk of suffocation, according to [CBS News](#).

[HR 3182](#), or the Safe Sleep for Babies Act of 2021, notes that sleepers and bumpers will be considered "banned hazardous products" under the Consumer Product Safety Act. It gives manufacturers and retailers 180 days to comply with the new rule.

"The dangers posed to babies have been apparent for years," Teresa Murray, who directs the consumer watchdog office for the US PIRG Education Fund, said [in a statement](#).

"It's unfortunate that this law could take months to take effect," she said. "Parents and caregivers need to recognize the dan-

gers of these products and get them out of their homes now."

HR 3182 defines inclined sleepers as products that have a sleep surface slanted greater than 10 degrees and are intended for babies up to 1 year old. Crib bumpers include any material that is designed to cover the sides of a crib, which includes padding or vinyl bumper guards but not nonpadded mesh crib liners.

The US Consumer Product Safety Commission has received reports of more than 113 deaths involving crib bumpers between 1990 and 2019, as well as 113 non-fatal incidents between 2008 and 2019, according to [a report](#) from the commission.

More than 100 babies have died from infant-inclined sleep products, according to the commission, which has recalled numerous versions in recent years. But older models are still in circulation, CBS News reported.

Last year, the commission approved a [federal safety rule](#) that bans several types of sleep products for babies under 5 months old. Set to take effect next month, the rule requires products marketed for infants to meet the same federal safety standards as required for cribs and similar products.

Parents and advocates have called for a ban on these products for decades, according to CBS, since they can lead to suffocation when an infant's nose and mouth are covered by a bumper or become stuck between a bumper and crib mattress.

Sudden unexpected infant death, or SUID — which includes sudden infant death syndrome, or SIDS — is the leading cause of injury death in infancy, according to the American Academy of Pediatrics. The group's [recommendations for safe sleep](#) advise that infants should sleep on

their back on a firm, flat surface without any extra padding, pillows, blankets, stuffed toys, bumpers, or other soft items in the sleep space.

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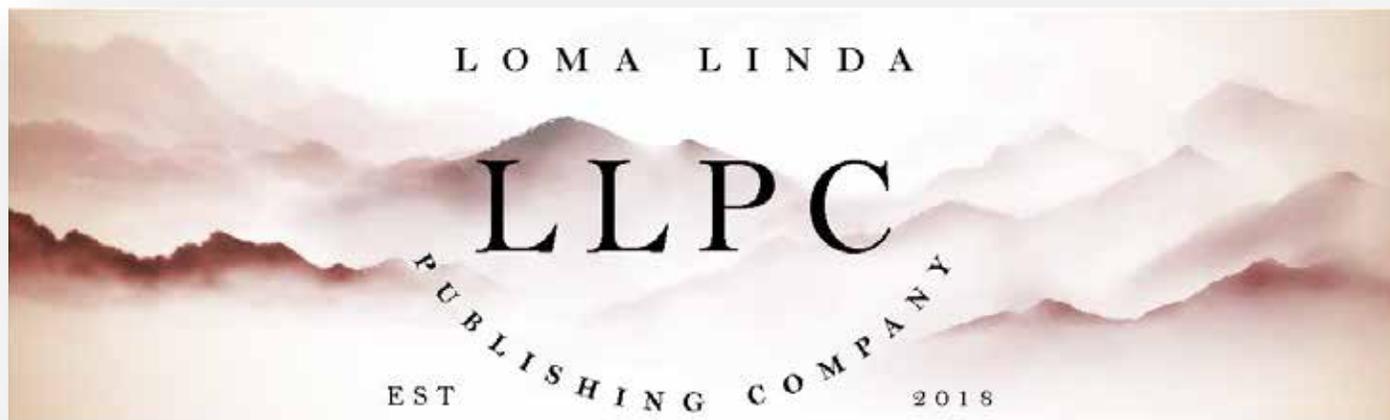
CDC Press Release: Hypertensive disorders in pregnancy affect 1 in 7 hospital deliveries

Rate increases indicate need for better prevention, recognition, and treatment

Press Release

Thursday, April 28, 2022, 1:00 p.m. ET

The prevalence of hypertensive disorders in pregnancy (HDP) among delivery hospitalizations increased from about 13% in 2017 to 16% in 2019, affecting at least 1 in 7 delivery hospitalizations during this period, according to a CDC report. About a third of those who died during hospital delivery had a hypertensive disorder of pregnancy documented.



HDP are common and can cause severe complications for pregnant people, such as heart attacks and strokes, and are a leading cause of pregnancy-related death in the United States. It includes both pregnancy-associated hypertension that begins during or after pregnancy, and chronic hypertension that begins before pregnancy and continues during pregnancy.

“There are many strategies that clinicians can use to identify, monitor, and manage people with hypertensive disorders in pregnancy to prevent severe complications and deaths. A great example is home-monitoring of blood pressure during and following pregnancy,” said Janet Wright, M.D., F.A.C.C., director of CDC’s Division of Heart Disease and Stroke Prevention at the National Center for Chronic Disease Prevention and Health Promotion. “At a systems level, intentional programming like Perinatal Quality Collaboratives can improve the quality of care and health outcomes and translate findings into interventions.”

Characteristics associated with increased risk for HDP, such as advanced maternal age, obesity, and diabetes have increased in the U.S. and may explain the increase in HDP prevalence.

Racial and ethnic disparities of HDP among hospital deliveries are stark, with HDP affecting more than 1 in 5 delivery hospitalizations of Black women and about 1 in 6 delivery hospitalizations of American Indian and Alaska Native women. Factors contributing to racial and ethnic inequities in HDP include differences in access to and quality of health care, and higher prevalence of characteristics associated with increased risk like obesity. Racial bias in the U.S. healthcare system can affect HDP care from screening and diagnosis to treatment. Psychosocial stress from experiencing racism has also been found to be associated with chronic hypertension.

“As healthcare professionals, we must recognize the factors that contribute to racial inequities and work individually and collectively to reduce these rates.” said Wanda Barfield, M.D., M.P.H., director of CDC’s Division of Reproductive Health at the National Center for Chronic Disease Prevention and Health Promotion. “Addressing hypertensive disorders in pregnancy is a key strategy in reducing inequities in pregnancy-related mortality.”

The highest prevalence of HDP was among delivery hospitalizations of women over the age of 45 (31%). HDP was also

high among people who reside in rural counties (16%), reside in lower income ZIP codes (16%), and delivered in hospitals in the South (16%) or Midwest (15%).

Disparities based on location might be due to differences in the prevalence of characteristics associated with increased risk of HDP, including diet, tobacco use, physical activity patterns, experiencing poverty, or access to care. Strengthening regional networks of health care facilities providing risk-appropriate maternal care through telemedicine and transferring people with high-risk conditions to facilities that can provide specialty services are strategies to reduce these disparities.

Severe complications and deaths from HDP are preventable with equitable implementation of public health and clinical strategies. These include efforts across the life course for preventing HDP; identifying, monitoring, and appropriately treating those with HDP with continuous and coordinated care; increasing awareness of [urgent maternal warning signs](#); and implementing quality improvement initiatives to address severe hypertension.



Additional Resources:

- [High blood pressure during pregnancy](#)
- [Preventing Pregnancy-Related Deaths](#)
- CDC’s [Hear Her campaign](#), which raises awareness of [urgent maternal warning signs](#).

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Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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



Limit Contact with Others

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



Provide Protective Immunity

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



Take Care of Yourself

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



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



WARNING

Never Put a Mask on Your Baby

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



If you are positive for COVID-19

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



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Genetics Corner: Klippel-Trenaunay Syndrome in an Infant with a Mosaic PIK3CA Variant, a Target for the Medical Treatment of Asymmetric Overgrowth

Robin D. Clark, MD, Subhadra Ramanathan, MSc, MS, LCGC

Case Summary:

A 16-week-old late preterm female with Klippel-Trenaunay syndrome (KTS) was referred to the Genetics clinic. She was born at 36 wk 6 d gestation by spontaneous vaginal delivery to a 26-year old G2P1 mother, with good prenatal care and uncomplicated pregnancy. A 20 wk prenatal ultrasound exam was normal. All growth parameters were appropriate for gestational age: birth weight 3280 g, birth length 49.1 cm, and head circumference 32.7 cm. Apgar scores were 7 and 8 at 1 and 5 minutes, respectively.

“When she was examined in the newborn nursery, subtle hemihypertrophy of the right leg, a wide right foot with splayed toes, and a port-wine stain on the midback were appreciated.”

When she was examined in the newborn nursery, subtle hemihypertrophy of the right leg, a wide right foot with splayed toes, and a port-wine stain on the midback were appreciated. The genetics service was informally consulted, and a clinical diagnosis of Klippel-Trenaunay syndrome was made. A peripheral blood sample was collected from the affected right foot for *PIK3CA* gene analysis before discharge from the nursery. The baby has been well at home. Family history was noncontributory

*“ The genetics service was informally consulted, and a clinical diagnosis of Klippel-Trenaunay syndrome was made. A peripheral blood sample was collected from the affected right foot for *PIK3CA* gene analysis before discharge from the nursery.”*

Figure 1. In the newborn period (Figure 1a), the right leg and foot were darker in color and subtly larger in circumference than the left leg. The right foot (Figure 1b) was larger and wider, and the right toes were larger and more splayed than the toes of the left foot. A port-wine stain (Figure 1c) extended to the right midaxillary line in the midback. It crossed the midline to the left midback in a few places.



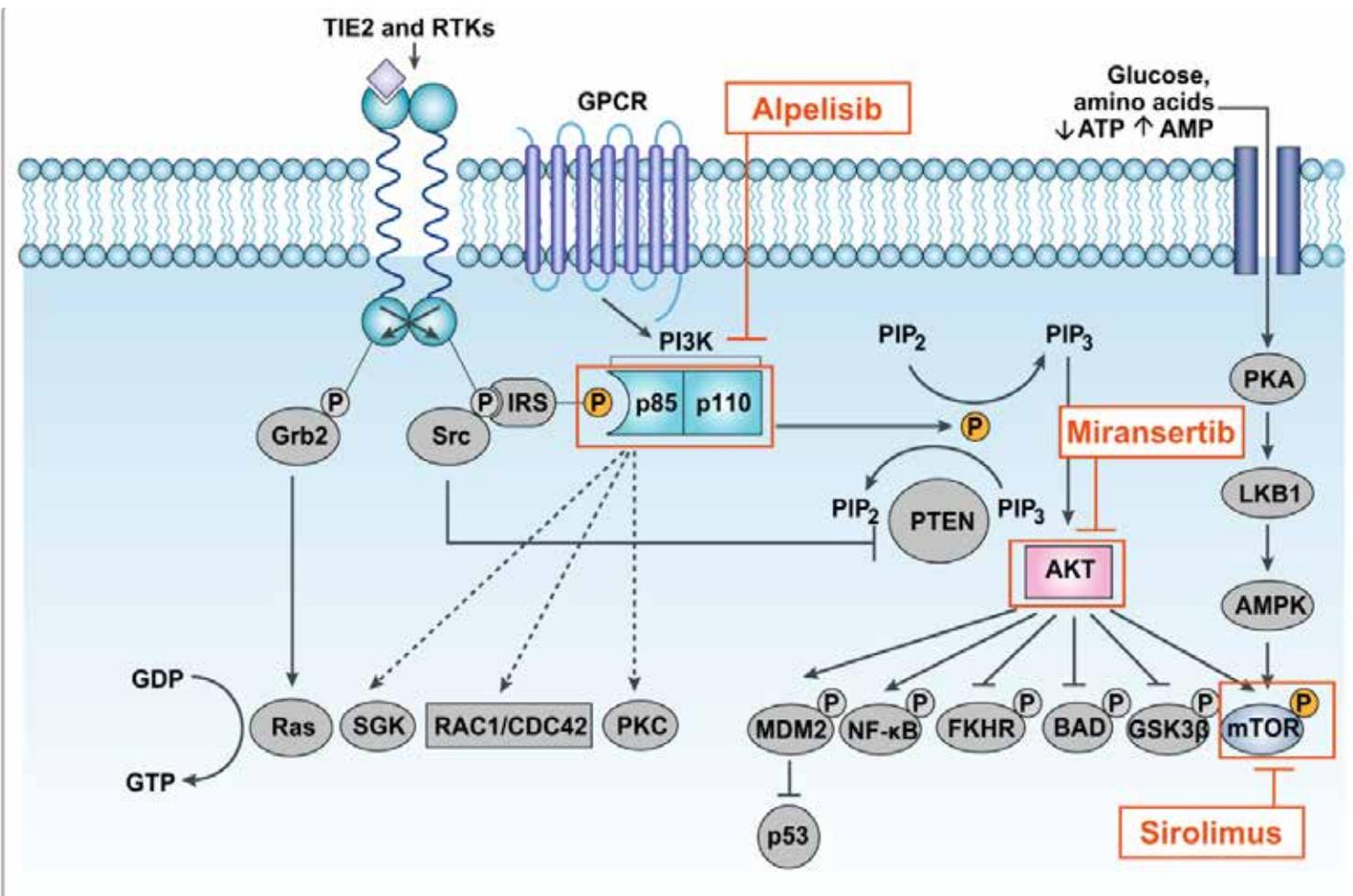


Figure 2. Drugs that inhibit the PI3K/AKT/mTOR pathway are shown in this illustration from Canaud (5). At the top of the pathway, alpelisib inhibits PI3K and diminishes activation of the downstream growth-promoting genes in the pathway. This is the basis for its therapeutic effect in PIK3CA-related overgrowth spectrum (PROS) disorders such as Klippel-Trenaunay syndrome.

In the last two months, the parents noted a new fatty prominence in the right lower quadrant that was soft and non-tender on examination at 16 weeks. There was also mild asymmetry and fatty enlargement of the right labia majora and right buttock. Otherwise, the baby was nondysmorphic. She was developing normally.

naunay syndrome (KTS), a sporadic vascular malformation with asymmetric overgrowth, usually affecting a lower extremity, in an otherwise healthy newborn. Until recently, the genetic cause of this disorder was not appreciated, and there was no available medical therapy. Now that the cause of KTS is understood to be an activating gain-of-function variant in *PIK3CA* that responds to targeted medical therapy, it is time to reconsider our approach to KTS in the newborn period.

“Genetic analysis of peripheral blood (Perelman, U Penn) identified a heterozygous pathogenic mosaic (0.06%) variant in exon 2: c.317G>T (p.Gly106Val) in *PIK3CA*, consistent with a *PIK3CA*-Related Overgrowth Syndrome (PROS).”

“Depending on the developmental fate of the embryonic cell that harbored the original *PIK3CA* pathogenic variant, the various PROS spectrum disorders present with strikingly different phenotypes ranging from bulky lipomatous lymphangiomas (CLOVES) to epidermal nevi to macrodactyly or hemimegalencephaly. KTS is one of the milder presentations of PROS.”

Genetic analysis of peripheral blood (Perelman, U Penn) identified a heterozygous pathogenic mosaic (0.06%) variant in exon 2: c.317G>T (p.Gly106Val) in *PIK3CA*, consistent with a *PIK3CA*-Related Overgrowth Syndrome (PROS).

Discussion:

Neonatologists and pediatricians are familiar with Klippel-Tre-

KTS is one of the *PIK3CA*-Related Overgrowth Spectrum of disorders known as PROS (1). The pattern of overgrowth in PROS is tissue specific. Depending on the developmental fate of the embryonic cell that harbored the original *PIK3CA* pathogenic variant, the various PROS spectrum disorders present with strikingly different phenotypes ranging from bulky lipomatous lymphangiomas (CLOVES) to epidermal nevi to macrodactyly or hemimegalencephaly. KTS is one of the milder presentations of PROS.

The *PIK3CA* variant in PROS is a post-zygotic, somatic, and mosaic change that occurs early in a dividing cell in the developing embryo. The activating variant populates the cells that arise from the first affected cell, and the genetic change is not present in all cells of the body. The blood sample is often normal, and the mosaic *PIK3CA* variant is only detectable in fresh biopsy tissue from an affected body part. We were able to avoid an invasive procedure for this patient. We took a chance on this infant and ordered the blood to be drawn from the *affected* foot, hoping that some affected tissue from the skin or the venous wall might be collected with the blood sample. "Contamination" with a small amount of affected tissue might have been why we could detect low-level mosaicism in this blood sample. We did not, but perhaps in the future might draw a simultaneous blood sample from an unaffected limb to confirm that drawing the sample from the affected limb enhances the detection rate of low-level mosaicism. For now, it is just a hypothesis but one that bears testing.

"We did not, but perhaps in the future might draw a simultaneous blood sample from an unaffected limb to confirm that drawing the sample from the affected limb enhances the detection rate of low-level mosaicism. For now, it is just a hypothesis but one that bears testing."

PIK3CA, a member of the PI3K/AKT/mammalian target of rapamycin (mTOR) pathway (Figure 2), acts as an oncogene in breast and other cancers. Because activation of this pathway promotes cell growth, proliferation, cell survival, and angiogenesis, *PIK3CA* has become a pharmacological target in treating *PIK3CA*⁺ HR⁺ (hormone receptor)/HER2⁻ metastatic breast cancer. Alpelisib, an orally available α -selective *PIK3CA* inhibitor that blocks the PI3K/AKT/mTOR pathway, has effectively treated *PIK3CA*-positive breast cancer (2). The same specific activating variants in *PIK3CA* are often present in breast cancer and the bulky overgrown tissues in PROS. This led researchers to study alpelisib as a possible treatment for children and adults with PROS. These clinical trials have demonstrated that alpelisib effectively reduces bulky masses in severe overgrowth due to PROS (3,4). In April 2022, the FDA approved Alpelisib for use in adults and children over two years of age who have serious manifestations of PROS.

FDA approval was based on real-world evidence from the EPIK-P1 study, a retrospective chart review study showing patients treated with alpelisib experienced reduced target lesion volume and improved PROS-related symptoms and manifestations. Here is a summary of the EPIK-P1 study data submitted to the FDA but has not been published. The primary endpoint analysis conducted at week 24 showed that 27% of patients (10/37) achieved a confirmed response to treatment, defined as a 20% or greater

reduction in the sum of PROS target lesion volume. Nearly three in four patients with imaging at baseline and at week 24 (74%, 23/31) showed some reduction in target lesion volume, with a mean reduction of 13.7%, and no patients experienced disease progression at the time of primary analysis. Additionally, at week 24, investigators observed patient improvements in pain (90%, 20/22), fatigue (76%, 32/42), vascular malformation (79%, 30/38), limb asymmetry (69%, 20/29), and disseminated intravascular coagulation (55%, 16/29). These improvements were observed in subsets of patients across the study population (n=57) who reported symptoms at baseline and at week 24. Professor Canaud discusses EPIK-P1 study data in a short video (6). A prospective trial, EPIK-P2, has already begun.

"These improvements were observed in subsets of patients across the study population (n=57) who reported symptoms at baseline and at week 24. Professor Canaud discusses EPIK-P1 study data in a short video (6). A prospective trial, EPIK-P2, has already begun."

We referred our patient to the Pediatric Hematology/Oncology service to discuss the benefits and limitations of alpelisib therapy, which would be available after age two years. We also recommended serial imaging studies for volumetric analysis prior to therapy to establish the size of the lesion at baseline and the rate of growth.

KTS is only one of the somatic overgrowth disorders that may be treated with drugs that target the PI3K/AKT/mTOR pathway. Vascular malformations in children often show mutations in *PIK3CA* or *AKT*. Drugs that target *PIK3CA*, *AKT*, and other downstream genes in the pathway may provide therapies to a group of somatic conditions that have not been previously amenable to treatment (7).

Practical applications:

1. Recognize that *PIK3CA*-related overgrowth spectrum (PROS) disorders include a wide variety of overgrowth phenotypes that differ based on the tissue-specific developmental fate of the original mutant cell. Klippel-Trenaunay syndrome (KTS) is probably the most common PROS disorder.
2. Appreciate that mosaic (somatic) heterozygous pathogenic activating *PIK3CA* variants stimulate growth pathways in affected tissues, which presents a target for treatment.
3. Expect more overgrowth syndromes to be treated with drugs, such as alpelisib, originally developed to treat cancer.
4. Understand that documentation of a *PIK3CA* variant is necessary in KTS and other PROS disorders in order to offer therapy that specifically blocks the downstream effects of the activating *PIK3CA* gene variant.
5. Order *PIK3CA* gene testing in all infants with features of KTS or asymmetric overgrowth that suggests a PROS disorder. A peripheral blood sample may not detect the *PIK3CA* variant responsible for asymmetric overgrowth in a child with PROS. We speculate that collecting a blood sample from an affected

limb may enhance the detection of a mosaic *PIK3CA* variant but submitting a fresh tissue sample from an affected region for gene testing is the most reliable approach.

6. Refer patients with KTS or other PROS disorders for genetic and oncology consultations

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OPIOIDS and NAS

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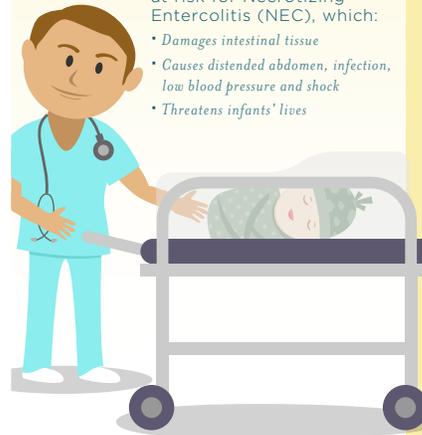
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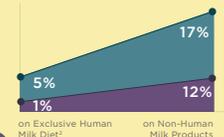


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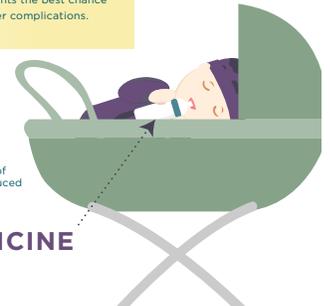
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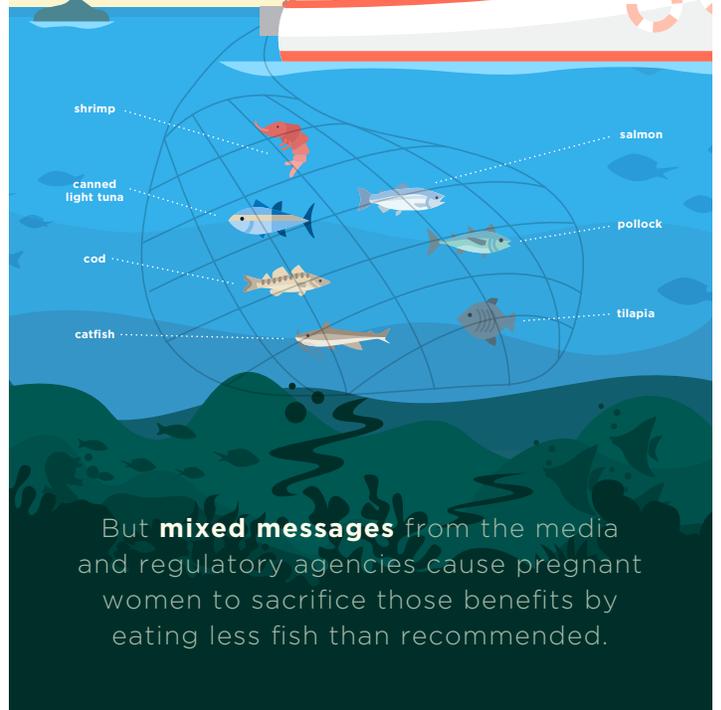
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Medical Legal Forum: Guilty! Safety Implications After Criminal Conviction for a Medical Error

Jonathan M. Fanaroff, MD, JD, Gilbert I. Martin, MD

Guilty! That was the jury verdict on March 25 after former Vanderbilt University Medical Center nurse RaDonda Vaught was criminally charged for a medical error that led to the death of 75-year-old Charlene Murphey. The error, to be clear, was horrendous: On December 26, 2017, Nurse Vaught injected Ms. Murphey with the paralytic vecuronium instead of the sedative versed. She was fired and lost her nursing license after the incident, which was not necessarily unusual. However, what drew national attention was the decision to arrest and charge Nurse Vaught with criminally negligent homicide, gross neglect of an impaired adult, and reckless homicide. She was found not guilty of reckless homicide but guilty of the other two charges, for which she will serve up to 8 years in prison.

“However, what drew national attention was the decision to arrest and charge Nurse Vaught with criminally negligent homicide, gross neglect of an impaired adult, and reckless homicide. She was found not guilty of reckless homicide but guilty of the other two charges, for which she will serve up to 8 years in prison.”

The move to criminally charge a health care professional for a medical error has drawn widespread criticism and condemnation. The American Nurses Association (ANA) released a statement: “We are deeply distressed by this verdict and the harmful ramifications of criminalizing the honest reporting of mistakes.” -American Nurses Association

They raise an additional concern about the verdict’s impact on nurses who are already facing tremendous job-related stresses,

short-staffing, and burnout.

There has always been an aspect of accountability for health care professionals. At the same time, it is also important to recognize that healthcare “is one of the most complex industries in our world.” (1) Other complex industries, such as aviation and nuclear power plants, have prioritized safety and reliability for decades. A national focus on patient safety began in 1999 when the Institute of Medicine released a report estimating that medical errors may be responsible for nearly 100,000 deaths/year. (2) A major factor in improving patient safety is creating a culture of safety in which front-line professionals feel comfortable bringing safety concerns to administration without fear of reprisal. This is important because errors in our complex healthcare environment are rarely the result of one individual issue but rather a series of systemic issues. A common analogy developed by James Reason is that barriers to patient harm are like slices of swiss cheese. Each barrier has a weakness, the ‘hole’ in the cheese, and occasionally those line-up and reach the patient. A culture of safety encourages everyone to work together to close the holes before they reach the patient. When an error does occur, a culture of safety encourages everyone involved to be open and honest about what happened so that measures can be taken to prevent the error from reoccurring in the future.

As noted earlier, Patient safety advocates are rightfully concerned that this prosecution will cause healthcare professionals who commit errors to keep quiet about them to avoid blame and punishment. A culture of silence may increase the risk to patients as reporting errors is crucial to improving the healthcare system. Nurse Vaught reported the error, participated in the investigation, and Vanderbilt did make changes, outlined in a 330-page plan of correction, to prevent this error from occurring in the future. These include taking vecuronium off override, implementing barcode and second nurse verification, and shrink-wrapping paralytic medications. (3) Sentencing is scheduled for May 13. A petition calling for clemency has garnered more than 200,000 signatures.

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Disclosure: There are no reported conflicts.

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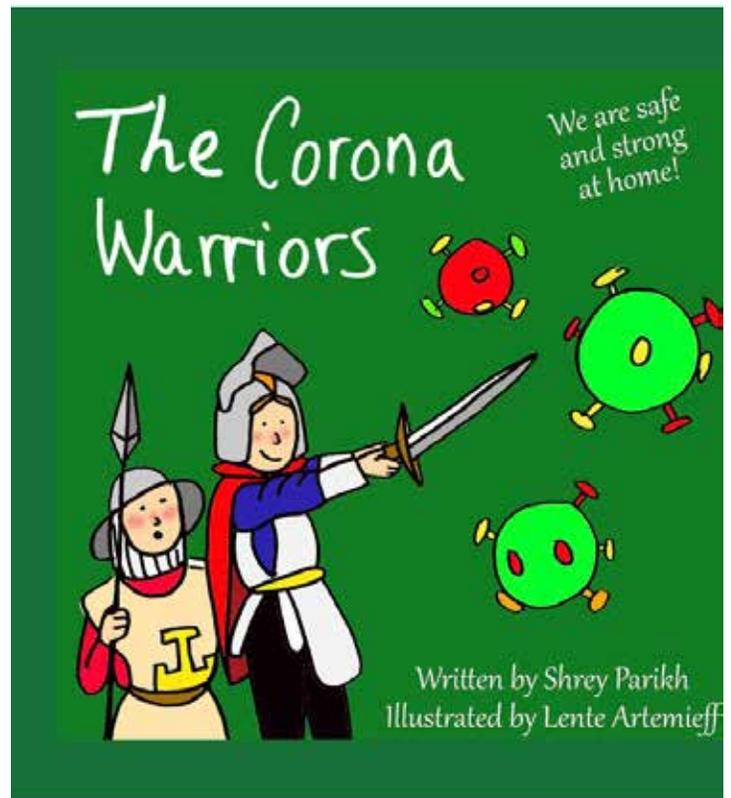
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Disclaimer:

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



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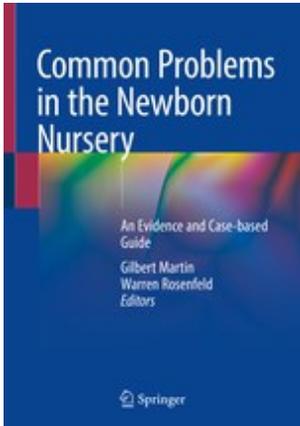
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When A Small Cry is Worth it

Theresa Flint Rodgers, DNP, Pamela H. Bryant, DNP



The National Coalition for Infant Health is a collaborative of more than 200 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.

No parent wants to see their child wince in pain or hear their baby cry. Yet enduring the undesirable for just a minute – as the child is vaccinated – can save heartache down the road.

Most newborns receive their first vaccine before leaving the hos-

pital. Then, they get a series of shots at well-child visits over the next few years.

“According to the Centers for Disease Control and the World Health Organization, getting all the recommended vaccines keeps babies and children protected from infectious diseases, including common conditions such as hepatitis and HPV and less common conditions like polio, measles, and mumps.”

According to the Centers for Disease Control and the World Health Organization, getting all the recommended vaccines keeps babies and children protected from infectious diseases, including common conditions such as hepatitis and HPV and less common conditions like polio, measles, and mumps.



Vaccines Are Still Needed

Some parents think their child doesn't need vaccine protection from less common diseases. "My child is at low risk because there's not much of that disease around," they think. But "out of sight, out of mind" is a dangerous mentality, especially when it comes to preventing disease.

After all, the uncommon vaccine-preventable diseases became uncommon because of widespread vaccination.

But when vaccines lag, outbreaks can occur. That is what happened with the measles in 2014 and again in 2018. In 2014, the first cases were detected in California, but more than 660 people in 16 states, Mexico and Canada, ended up getting sick. Nearly 350 people were infected in the 2018 outbreak. Even though measles had been considered eliminated, experts warned outbreaks could become more common if vaccination rates continue to decline.

"Questions about the development of new COVID-19 vaccines fueled broader mistrust about vaccine safety – even for shots that have been effectively used for decades. That concern has led some parents to question if they want their children to get any vaccines."

Overcoming Hesitancy

Hesitation about vaccinating children also arose during the COVID-19 pandemic.

Questions about the development of new COVID-19 vaccines fueled broader mistrust about vaccine safety – even for shots that have been effectively used for decades. That concern has led some parents to question if they want their children to get any vaccines.

This is particularly alarming because pandemic disruptions caused millions of young children worldwide to fall behind on routine vaccines. Aside from being exposed to preventable illnesses, unvaccinated children can also encounter delays getting into school. Most districts require kids to be up to date on immunizations before enrolling in elementary school. Most colleges and universities have a similar requirements.

Making Up Missed Shots

This National Infant Immunization Week – April 24-30 – is more important than ever. Even though the week emphasizes vaccinations for infants, parents need to know that it is not too late to get their children – no matter the age – caught up on missed shots.

Parents who have questions should consult their health care provider, county health department, or a reputable internet source, such as the Centers for Disease Control and Prevention.

Getting fully vaccinated is a series of small actions that yield a huge benefit – for the individual and the greater community. Skipping shots is not worth the risk.

Disclosure: No relevant disclosures noted

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National Black Nurses Association*

National Coalition for Infant Health Values (SANE)

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

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

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

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

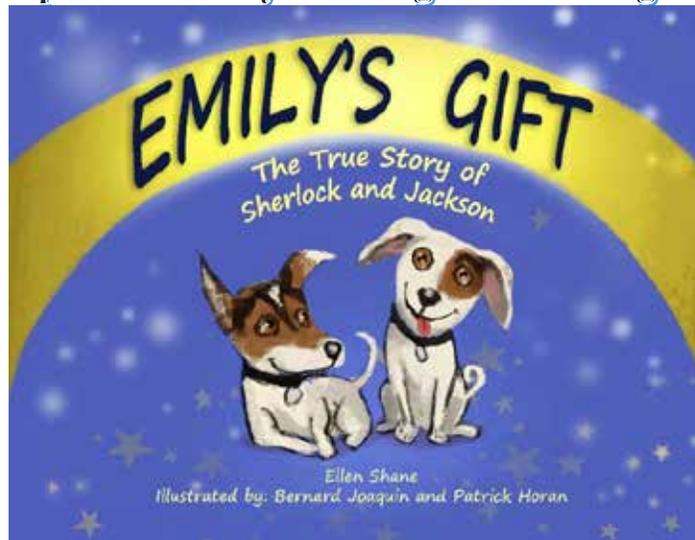
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The Premie Parent's SURVIVAL GUIDE to the NICU

By

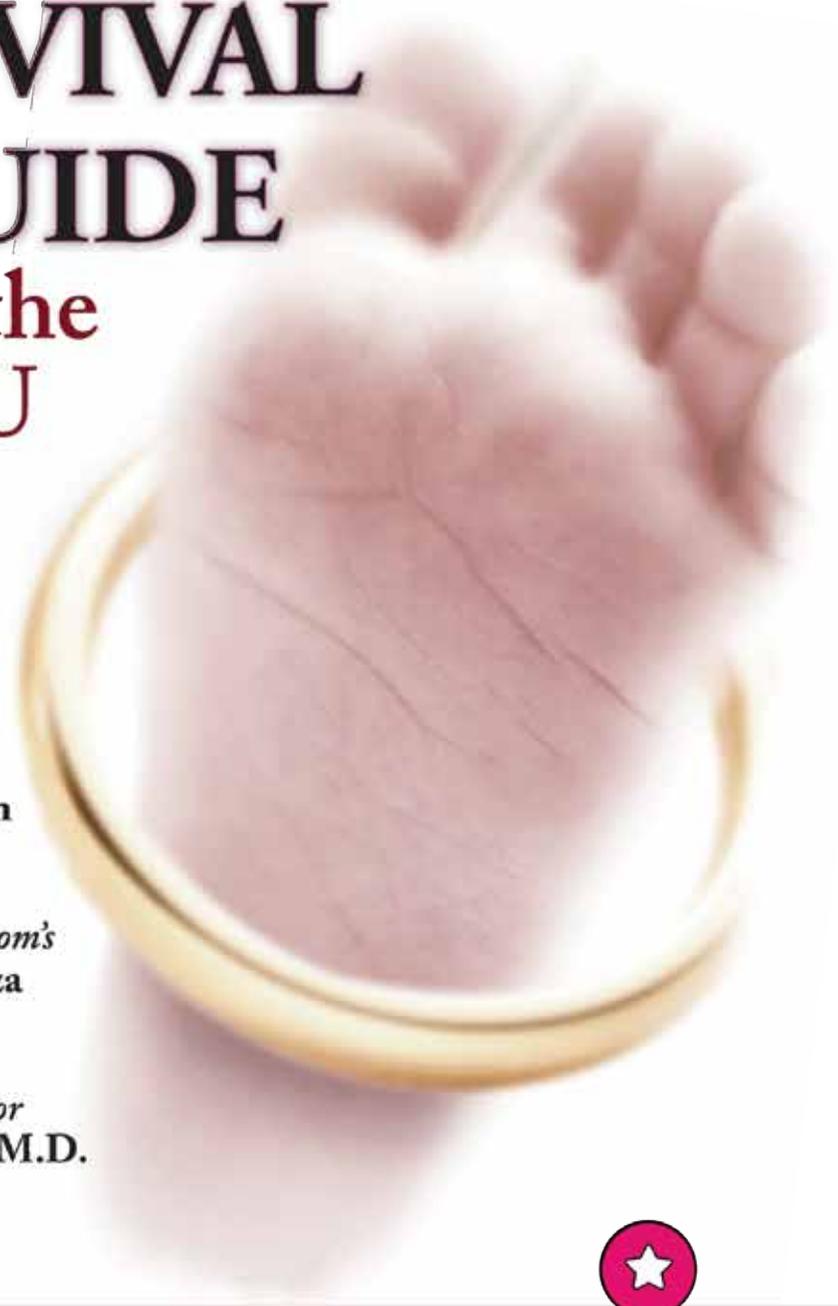
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second edition

The Signs & Symptoms of RSV

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Cough



Runny Nose



Struggling to Breathe
(breastbone sinks inward when breathing)



Difficulty Eating



Lethargy



Wheezing

RESPIRATORY SYNCYTIAL VIRUS

is a highly contagious seasonal virus that can lead to hospitalization for some babies and young children.

Know the Signs.



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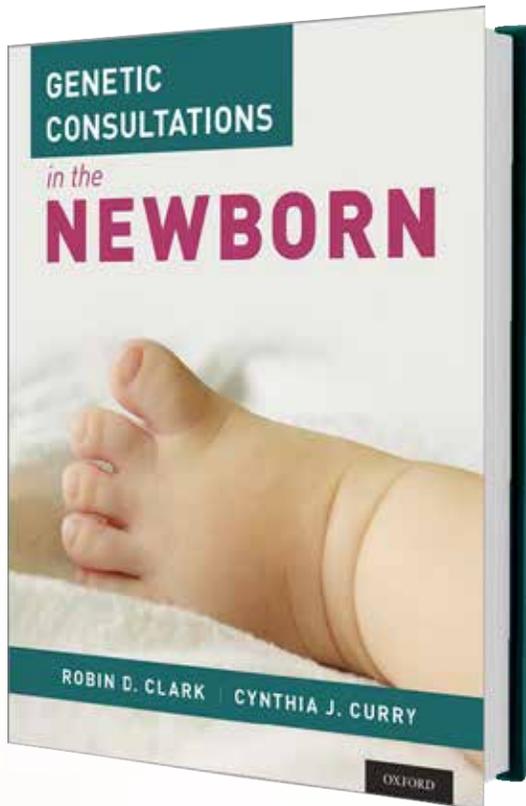


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Clinical Pearl: A New Potential Biomarker for Sudden Infant Death Syndrome (SIDS): Butyrylcholinesterase

Joseph R. Hageman, MD

A new, engaging, and potentially clinically relevant article by Harrington, Hafid, and Waters, investigators in New South Wales, Australia, was just published in *eBioMedicine part of Lancet Discovery Science* about a case-control study in which samples from dried blood spots were used to measure levels of butyrylcholinesterase in a group of infants who died of SIDS. These levels were compared with normal controls and infants who died of what the investigators termed “non-SIDS,” or children who died at age 12-24 months of age of Sudden Unexplained Death of Infancy (SUDI) (1). They found significantly lower butyrylcholinesterase levels in the blood of SIDS infants (1).

“These levels were compared with normal controls and infants who died of what the investigators termed “non-SIDS,” or children who died at age 12-24 months of age of Sudden Unexplained Death of Infancy (SUDI) (1). They found significantly lower butyrylcholinesterase levels in the blood of SIDS infants (1).”

The feedback from SIDS families to members of the board of SIDS of Illinois was discussed at our meeting on Monday, May 16, 2022. “A cure for SIDS” came from some families (personal communication, Nancy Maruyama).

As you already know, a biomarker is an indicator that the infant is at higher risk for SIDS (1,2). Other abnormalities, including cardiac arrhythmias, inborn errors of metabolism, brain stem abnormalities, and genetic abnormalities, have been identified in SIDS infants (1,2). The problem is that these abnormalities have been identified after the fact, and these infants no longer died of SIDS but of prolonged corrected QTc syndrome or medium-chain COA dehydrogenase deficiency (2). As a result, the percentage of infants who die of SIDS is getting smaller.

We now know that lower Butyrylcholinesterase, a cholinergic enzyme with acetylcholinesterase, is active in the parasympathetic nervous system (1). The fact that Butyrylcholinesterase levels are low suggests an abnormality in the cholinergic nervous system, which also works with the serotonergic nervous

system, and abnormalities in the serotonergic nuclei in SIDS infants have been demonstrated by Hannah Kinney and coinvestigators (2).

The problem may be a lack of arousal in the triple risk model in an infant at risk for SIDS(1,2). However, the biomarker suggests a mechanism or abnormality but not a solution. Even with this new information, in an at-risk infant with lower Butyrylcholinesterase levels, until investigators find a way to increase the levels, SIDS cannot be prevented.

“The problem may be a lack of arousal in the triple risk model in an infant at risk for SIDS(1,2). However, the biomarker suggests a mechanism or abnormality but not a solution. Even with this new information, in an at-risk infant with lower Butyrylcholinesterase levels, until investigators find a way to increase the levels, SIDS cannot be prevented.”

References:

1. Harrington CT, Hafid NA, Waters KA. Butyrylcholinesterase is a potential biomarker for Sudden Infant Death Syndrome. *EBioMedicine* 2022; 80, 104041.
2. Hayes RL. Serotonin abnormalities in the brain stem of Sudden Infant Death Syndrome. *Investigation of Sudden Infant Death Syndrome*. Ed. Cohen, MC, Schiemberg 1B

Disclosures: The author has no disclosures

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May begin with a brief case summary or example.
Summarize the pearl for emphasis.
No more than 7 references.
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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.



COVID-19

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- Helping Children and Families Cope
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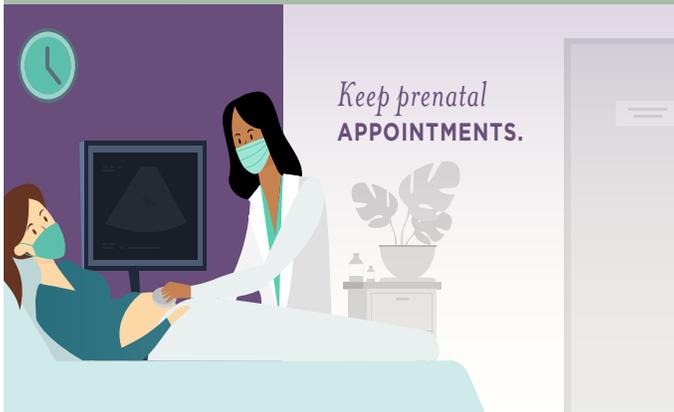
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GET INFORMED ABOUT THE **RISKS + BENEFITS**

work with your medical team to create a plan

GET CLEAN
WASH YOUR HANDS, ARMS, and CHEST

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



PUT ON **FRESH CLOTHES**

change into a clean gown or shirt.



IF COVID-19 + **WEAR A MASK**

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



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Telehealth in the NICU

The thoughtful use of telehealth technology can improve care and minimize the risks of exposure to COVID-19.

Use technology to help parents bond with their babies when they can't be bedside.

The move to telehealth services can compound inequities and disparities. Assess each family's technology skills and needs - including the need to use their preferred language.

Consult with specialists.

Move family education and resources online.

Provide parents lactation support.

Screen for perinatal mood and anxiety disorders (PMADs).

Facilitate shared decision-making.

Support case management.



My Perinatal Network and My NICU Network are products of a collaboration between National Perinatal Association (NPA) and NICU Parent Network (NPN).

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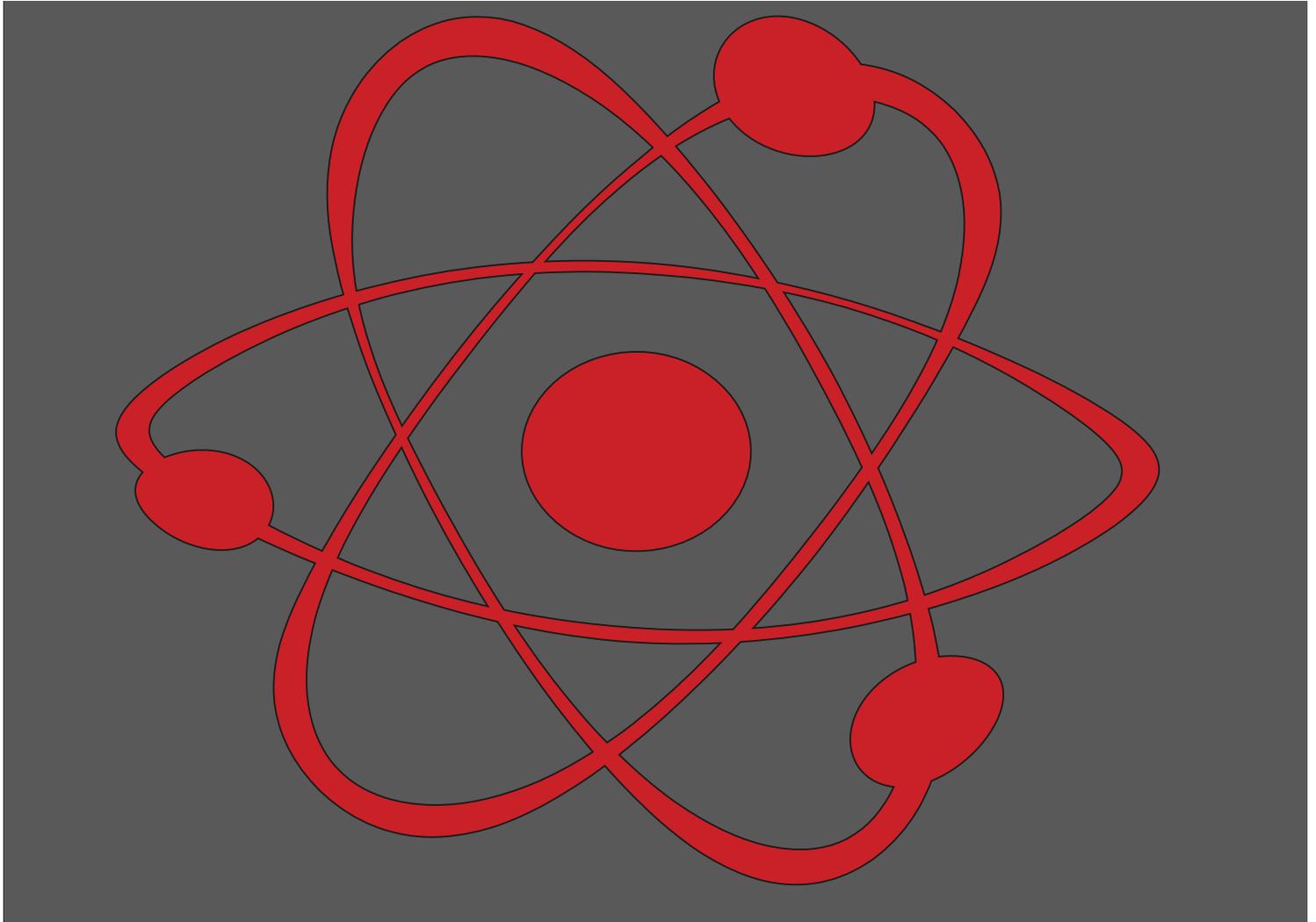
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Will your **PRETERM INFANT** need **EARLY INTERVENTION** services?

Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges



1 in 3 preterm infants will require support services at school



Early intervention can help preterm infants:



Enhance language and communication skills



Build more effective learning techniques



Process social and emotional situations



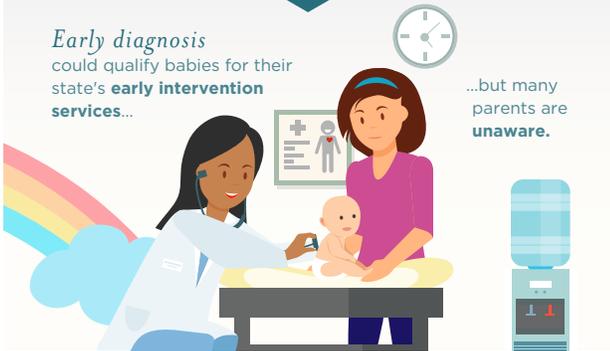
Address physical challenges



Prevent mild difficulties from developing into major problems

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

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



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

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



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

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

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



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



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

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

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



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

PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSTPARTO



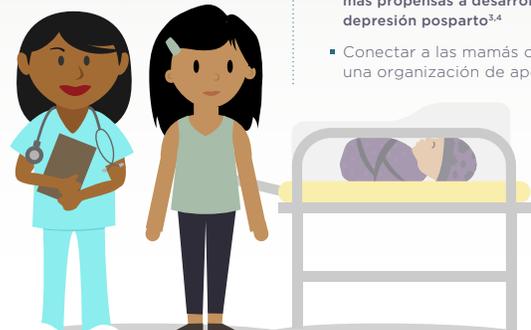
LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

- 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/resources/reports/postpartum-depression.aspx>

² National Institute of Mental Health. Accessed on: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>

³ Journal of Perinatology (2015) 35, 529–536. doi:10.1097/JP.0000000000000147

⁴ Prevalence and risk factors for postpartum depression among women with problem and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Dennis CL. *PLoS ONE* 2010 Apr; 11(7):1540-50.

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Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one page as well as photographs of birds on another. This month's original artwork features Paula Whiteman, MD who graces us with a Tiger. Our bird of the month is a Hummingbird from the San Francisco Botanical Garden at Strybing Arboretum photographed by Ghassan Samara, MD.



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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. There is no charge for your manuscript to be published. NT does maintain a copyright of your published manuscript.

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

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

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 10,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard "NLM" format (APA 7th 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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NEONATOLOGY TODAY is interested in publishing manuscripts from Neonatologists, Fellows, NNPs and those involved in caring for neonates on case studies, research results, hospital news, meeting announcements, and other pertinent topics.

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com



NICU BABY'S Bill of Rights

1- THE RIGHT TO ADVOCACY

My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical records, and prognosis, so they celebrate my achievements and support me when things get challenging.

2- THE RIGHT TO MY PARENTS' CARE

In order to meet my unique needs, my parents need to learn about my developmental needs. Be patient with them and teach them well. Make sure hospital policies and protocols, including visiting hours and rounding, are as inclusive as possible.

3- THE RIGHT TO BOND WITH MY FAMILY

Bonding is crucial for my sleep and neuroprotection. Encourage my parents to practice skin-to-skin contact as soon as and as often as possible and to read, sing, and talk to me each time they visit.

4- THE RIGHT TO NEUROPROTECTIVE CARE

Protect me from things that startle, stress, or overwhelm me and my brain. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time and faster than it ever will again. The way I am cared for today will help my brain when I grow up. Connect me with my parents for the best opportunities to help my brain develop.

5- THE RIGHT TO BE NOURISHED

Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Also, let my parents know that donor milk may be an option for me.

6- THE RIGHT TO PERSONHOOD

Address me by my name when possible, communicate with me before touching me, and if I or one of my siblings pass away while in the NICU, continue referring to us as multiples (twin/triplets/quads, and more). It is important to acknowledge our lives.

7- THE RIGHT TO CONFIDENT AND COMPETENT CARE GIVING

The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help educate them about my unique needs, development, diagnoses, and more.

8- THE RIGHT TO FAMILY-CENTERED CARE

Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9- THE RIGHT TO HEALTHY AND SUPPORTED PARENTS

My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my parents about resources such as peer-to-peer support programs, support groups, and counseling, which can help reduce PMAD, PPD, PTSD, anxiety and depression, and more.

10- THE RIGHT TO INCLUSION AND BELONGING

Celebrate my family's diversity and mine; including our religion, race, and culture. Ensure that my parents, grandparents, and siblings feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

Presented by:



NICU PARENT NETWORK

NICU Parent Network

Visit nicuparentnetwork.org to identify national, state, and local NICU family support programs.

* The information provided on the NICU Baby's Bill of Rights does not, and is not intended to, constitute legal or medical advice. Always consult with your NICU care team for all matters concerning the care of your baby.

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