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Caffeine Auto-Wean Strategy in Premature Infants

Shabih Manzar, MD, MPH; Marissa K Johnston, PharmD, MPH

Abstract:

Objective: *There is a gap in the literature regarding the weaning plan of caffeine in stable, low-risk preterm infants. As a quality improvement initiative, this study aimed to decrease caffeine utilization and cost by following an auto-wean strategy.*

Methods: *We implemented a practice change by not adjusting the dose of caffeine after 32 weeks of postmenstrual age on stable, low-risk preterm infants. The staff was educated through protocol presentation and discussion through emails. The caffeine utilization and cost were calculated for 32 weeks (actual) and then for 34 weeks (predicted). The differences were obtained by subtracting the actual from the predicted dose.*

Results: *A total of sixteen infants were evaluated in the study period. The total actual utilization of caffeine was 10.64 mL, with a mean of 0.67 mL, while the total predicted utilization was 13.73 mL, with a mean of 0.86 mL, p = < 0.001. The total actual cost was $32.66, with a mean of $2.04, while the total predicted cost was $42.14, with a mean of $2.63, p = < 0.001. We noted a 22.4% reduction in caffeine utilization and 22.4% in cost.*

Conclusions: *We demonstrated effective auto-weaning of caffeine in stable, low-risk preterm infants. As this is a single institutional study, more studies are needed at other institutions to examine our findings' external validity.*

Abbreviations: GA, gestational age; PMA, postmenstrual age; IHI, Institute for Healthcare Improvement; IRB, Institutional Review Board; CF, conversion factor; IH, intermittent hypoxia

Keywords: Caffeine, preterm infants, cost, utilization, quality improvement, autowean

Introduction:

Caffeine is used in premature infants to treat apnea of prematurity. Generally, it is started at admission on all infants < 32 weeks gestational age (GA). For neonates between 32–34 weeks GA, caffeine is initiated per clinical symptoms or at the provider's discretion. There are no clear guidelines for when to discontinue caffeine. Most clinicians discontinue caffeine around 33–34 weeks postmenstrual age (PMA) or if the infant has been apnea-free for more than or equal to 5–7 days. (1,2) Although there is wide variability in the timing of caffeine discontinuation, caffeine is usually discontinued at 34 weeks PMA in our institution. (3) The current practice is to weight-adjust caffeine until discontinued. We do not monitor serum caffeine levels because concentrations are predictably within the therapeutic range when standard doses are given. (4,5)

"Caffeine is used in premature infants to treat apnea of prematurity. Generally, it is started at admission on all infants < 32 weeks gestational age (GA). For neonates between 32–34 weeks GA, caffeine is initiated per clinical symptoms or at the provider's discretion. There are no clear guidelines for when to discontinue caffeine. Most clinicians discontinue caffeine around 33–34 weeks postmenstrual age (PMA) or if the infant has been apnea-free for more than or equal to 5–7 days."

Caffeine clearance and volume of distribution are significantly influenced by postnatal age and current body weight. The half-life of caffeine citrate is 100 hours at birth and 5 hours at a GA >29 weeks. There is a remarkable shortening of the half-life during neonatal maturation. (6,7) Caffeine is rapidly absorbed with complete bioavailability; therefore, no dose adjustments are needed when switching from parenteral and oral doses. Caffeine has a broad therapeutic index in preterm newborns. A level of 2 mg/L has measurable efficacy on the respiratory drive. Caffeine competitively inhibits adenosine receptors (A1 and A2A) at these levels. (8)

Koch et al. suggested that the caffeine maintenance dose should be increased by 1 mg/kg every 1–2 weeks to ensure stable caffeine concentrations during the first eight weeks of life. (9) However, to date, there is no commonly agreed standardized protocol on dose adjustments and timing of caffeine. (10)

Caffeine use in preterm infants has been demonstrated to prevent bronchopulmonary dysplasia, improve survival without neurodevelopmental disability at 18–40 months, and improve motor function at 11 years. (11,12) Conversely, caffeine has been associated with a marked reduction of cerebral and intestinal blood flow, temporarily reduced weight gain, and an increase in episodes of tachycardia, reflux, and feeding intolerance. (11,13,14,15) It is, therefore, essential to attempt to wean caffeine in stable, low-risk preterm infants once they reach a certain gestational age.

"Conversely, caffeine has been associated with a marked reduction of cerebral and intestinal blood flow, temporarily reduced weight gain, and an increase in episodes of tachycardia, reflux, and feeding intolerance. It is, therefore, essential to attempt to wean caffeine in stable, low-risk preterm infants once they reach a certain gestational age."

There is a gap in the literature regarding the weaning plan of caffeine in stable, low-risk preterm infants. As a quality improvement initiative, we planned this study to decrease caffeine utilization and cost by following an auto-wean strategy. The secondary aim is to see if caffeine auto-wean could be done successfully and safely.

Material and Methods:

The Institutional Review Board (IRB) approved this study. The protocol number was STUDY00002307. The need for consent was waived as data was collected as the standard of care. All infants received the same treatment. This study was conducted to improve healthcare quality by reducing cost and drug exposure to the patient. The rationale and specific aims were addressed per the SQUIRE 2.0 guidelines. (16) We implemented a practice change by not adjusting the dose of caffeine after 32 weeks of PMA on stable, low-risk preterm infants. The staff was educated through protocol presentation and discussion through emails. The concerns raised about the need for change were addressed, and a final agreement was reached to apply the change after the IRB approval. We used the quality improvement framework of the Institute for Healthcare Improvement (IHI) method of improvement using the SMART AIM. (17) The driver diagram is shown in Figure 1. The study was started on February 5, 2023 and completed on April 20, 2023.

Once the infant reached a PMA of 32 weeks, the caffeine dose was not weight-adjusted (Supplementary material, S1, Flow diagram chart). The number of apneic or desaturation episodes (> 3 from baseline) was monitored as a balancing measure. Apnea was defined as cessation of breathing for > 20 seconds. Significant desaturation was defined as saturation < 90 for > 5–10 seconds or need for intervention (stimulation or increase in FiO_2). (18)

The utilization was primarily assessed as the total milliliters (mL) of caffeine used. The cost was calculated for each mL used. In converting milligrams (mg) to mL, a conversion factor (CF) of 0.05 was used. The CF was obtained by deduction method (20 mg in 1 mL, so 1 mg = 1/20 = 0.05 mL). In converting the mL to cost ($), a conversion factor (CF) of 3.07 was obtained by the deduction method (oral caffeine is supplied as a 60 mg/3 mL [20 mg/mL] vial). A pack of 10 vials cost $92.12 ($9.21/vial); therefore, the cost per mL is $3.07 ($9.21/3 mL). The caffeine utilization and cost were calculated for 32 weeks PMA (actual) and then for 34 weeks PMA (predicted). The differences were obtained by subtracting the actual from the predicted dose. Microsoft Excel program was used for all calculations. Student t-test was used for comparison.

"Once the infant reached a PMA of 32 weeks, the caffeine dose was not weight-adjusted (see S1, Flow diagram chart). The number of apneic or desaturation episodes (> 3 from baseline) was monitored as a balancing measure. Apnea was defined as cessation of breathing for > 20 seconds. Significant desaturation was defined as saturation < 90 for > 5–10 seconds or need for intervention (stimulation or increase in FiO_2)."

Ethical Approval and Informed Consent:

The Institutional Review Board of Louisiana State University Health Sciences approved this study. The protocol number was STUDY00002307. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation. The need for consent was waived as data was collected as the standard of care.

Results:

A total of sixteen infants were evaluated in the study period. The median birth weight was 835 grams (470 – 2350 grams). The median GA was 26 weeks (range 23 – 31weeks). The male-to-female ratio was 1:1. Out of sixteen, eleven infants were African American, four infants were White, and one infant was Hispanic. Table 1 displays the individual details of each infant. None of the infants had apnea or significant desaturation episodes during the two-week auto-wean observation period (32–34 weeks). One infant was excluded from the analysis as the caffeine dose was increased at 31 weeks by the on-call provider to 15 mg/kg/day for frequent desaturations. Later, it was found to be related to the dislodgment of the nasal cannula. Two infants were continued on caffeine until 35 weeks PMA at the provider's discretion. The dose per weight at 34 weeks PMA was used in those cases.

The total actual utilization of caffeine for 16 infants was 10.64 mL, with a mean of 0.67 mL, while the total predicted utilization was 13.73 mL, with a mean of 0.86 mL, p = < 0.001. The total actual cost was $32.66, with a mean of $2.04, while the total predicted cost was $42.14, with a mean of $2.63, p = < 0.001. We noted a 22.4% reduction in caffeine utilization (Figure 2A) and 22.4% in cost (Figure 2B).

Discussion:

The study was aimed primarily at reducing caffeine utilization by

Figure 2A: Graph showing a 22.48 % reduction in Caffeine (mL) use.

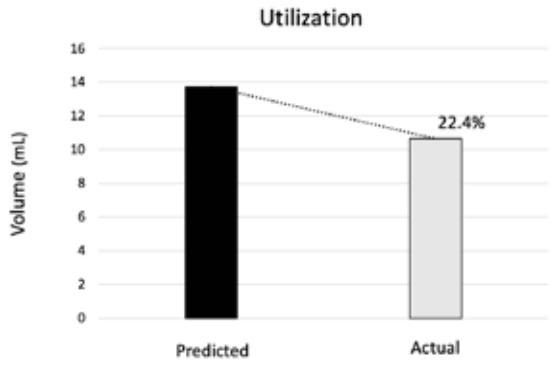
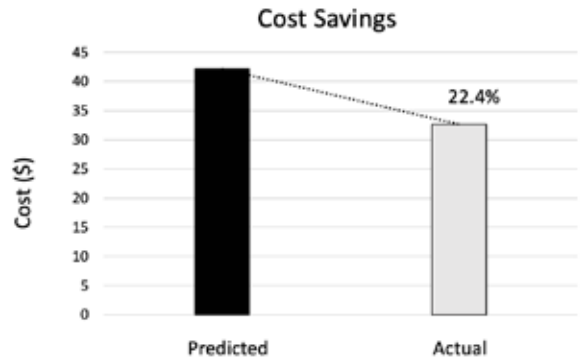


Figure 2B: Graph showing a 22.48% reduction in the cost ($) of Caffeine.



"The total actual utilization of caffeine for 16 infants was 10.64 mL, with a mean of 0.67 mL, while the total predicted utilization was 13.73 mL, with a mean of 0.86 mL, p = < 0.001. The total actual cost was $32.66, with a mean of $2.04, while the total predicted cost was $42.14, with a mean of $2.63, p = < 0.001. We noted a 22.4% reduction in caffeine utilization (Figure 2A) and 22.4% in cost (Figure 2B)."

10%. We demonstrated a reduction of 22.4% without any clinical change in the status of the infants related to caffeine. A significant reduction in medication utilization supported the concept of value-based care (i.e., quality of health outcomes per dollar spent). (18,19) We also observed a cost reduction of 22.4%. Although caffeine is not an expensive medication in terms of total dollars, the magnitude of cost savings noted in the study was substantial.

"The study was aimed primarily at reducing caffeine utilization by 10%. We demonstrated a reduction of 22.4% without any clinical change in the status of the infants related to caffeine. A significant reduction in medication utilization supported the concept of value-based care (i.e., quality of health outcomes per dollar spent). (18,19) We also observed a cost reduction of 22.4%. Although caffeine is not an expensive medication in terms of total dollars, the magnitude of cost savings noted in the study was substantial."

There have been concerns raised about intermittent hypoxia (IH) and the possible role of caffeine beyond 34 weeks PMA. Recently, Rhein et al. suggested prolonged caffeine use to prevent IH after 34 weeks PMA. (20) They used an oral maintenance dosage of 6 mg/kg/day. Oliphant et al. studied the effect of caffeine on the rate of reduction of IH among late-preterm infants. (21) They reported that 10 mg/kg/day and 15 mg/kg/day doses significantly lower the incidence of IH. They did not find 15 mg/kg/day as effective as 10 mg/kg/day, suggesting a non-dose-dependent response. Also, infants in the placebo group were clinically asymptomatic. Recently, Conlon et al. suggested that a dose of > 6 mg/kg/day effectively decreases IH in preterm infants, questioning over-treating. (22) As noted in the study, even without weight adjustment, each patient's caffeine dose was greater than the minimum dose of 6 mg/kg/day associated with IH (Supplementary material, Table S2).

The study limitation was a small sample size. As this is a quality improvement project, we will continue to perform plan-do-study-act cycles to see the sustained improvement observed in the current study. One could argue that not adjusting the caffeine dose to weight change may lower the serum caffeine level and lead to clinical symptoms. None of the infants had any clinical issues related to the dose of caffeine non-adjustment. We did not measure the serum caffeine level in any infants because concentrations are predictably within the therapeutic range when standard doses are given. (4,5) We used 10 mg/kg/day as a maintenance dose. As noted in the study, the final dose each infant received during the weaning period (32–34 weeks PMA) was greater than 6 mg/kg/day, which should be adequate to prevent IH. The study's strength

Figure 1. The Driver diagram

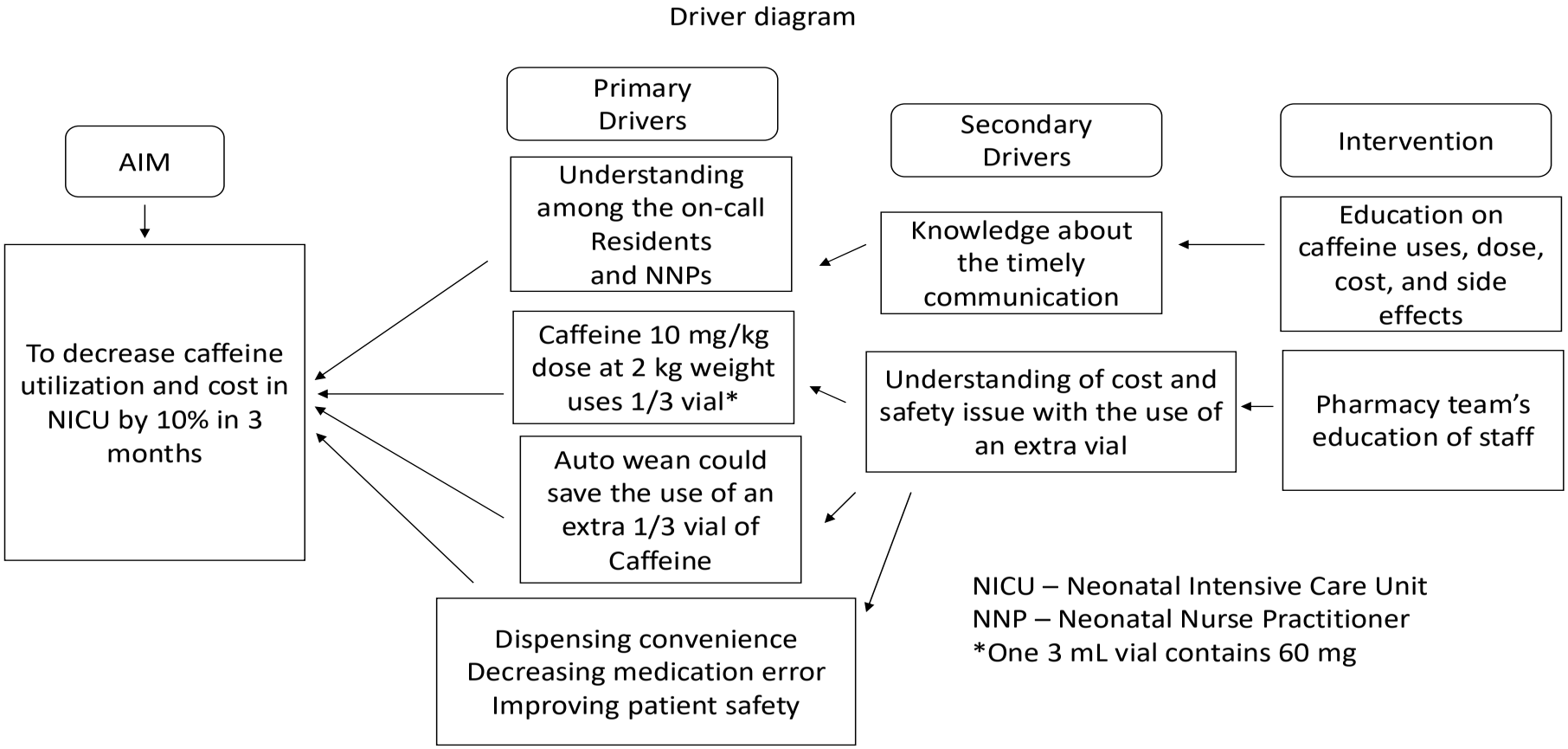


Table 1: Summary of The Findings

Case no	Birth weight	GA	Sex	Race	Weight at 32 weeks (kg)	Caffeine dose (mg) at 32 weeks	Caffeine dose (mg per kg) [dose/wt]	Actual ml [dose x 0.05 CF]	Weight (kg) at 34 weeks	Caffeine expected 10 mg/kg dose at 34 weeks	Predicted mL [dose x 0.05 CF]	Difference in mL [predicted – actual]	Cost $ (conversion factor) 3.07 for PO [ml x 3.07]
Case 1	1.100	27.0	F	W	2.000	17.2	8.60	0.86	2.520	25.2	1.26	0.40	1.22
Case 2	1.680	31.5	M	W	1.590	16.8	10.57	0.84	2.005	20.05	1.00	0.16	0.50
Case 3	1.250	31.4	F	B	1.200	12.6	10.50	0.63	1.355	13.55	0.68	0.05	0.15
Case 4	0.470	23.6	F	B	1.070	8.6	8.04	0.43	1.360	13.6	0.68	0.25	0.77
Case 5	2.350	31.5	M	H	2.330	23.6	10.13	1.18	2.430	24.3	1.22	0.03	0.11
Case 6	1.280	30.1	F	B	1.318	12.8	9.71	0.64	1.830	18.3	0.92	0.28	0.84
Case 7	0.870	30.1	F	B	0.915	9.6	10.49	0.48	1.250	12.5	0.63	0.15	0.44
Case 8	0.670	26.6	M	B	1.125	10.8	9.60	0.54	1.380	13.8	0.69	0.15	0.46
Case 9	0.685	23.6	M	B	1.345	13.4	9.96	0.67	1.705	17.05	0.85	0.18	0.56
Case 10	0.550	26.0	F	B	1.165	11.2	9.61	0.56	1.410	14.1	0.71	0.15	0.44
Case 11	0.800	25.6	M	B	1.755	16.8	9.57	0.84	2.130	21.3	1.07	0.23	0.69
Case 12	0.670	25.5	F	B	1.240	12.2	9.84	0.61	1.530	15.3	0.77	0.16	0.47
Case 13	1.005	28.2	F	B	1.285	12	9.34	0.60	1.760	17.6	0.88	0.28	0.86
Case 14	0.545	26.5	M	W	1.195	10.2	8.54	0.51	1.450	14.5	0.73	0.22	0.66
Case 15	0.755	26.5	M	W	1.320	13	9.85	0.65	1.640	16.4	0.82	0.17	0.52
Case 16	1.035	30.0	M	B	1.280	12	9.38	0.60	1.695	17	0.85	0.25	0.77

Footnote for the Table:

GA: Gestational age in weeks

BW: Birth weight, expressed in kilograms.

The mg to mL Conversion Factor (CF) of 0.05 was obtained from:

20 mg in 1 mL

1 mg = 1/20 = 0.05 mL

Actual dose (mL) = Caffeine dose at 32 weeks x 0.05 (CF)

Predicted dose (mL) = Caffeine dose expected at 34 weeks (if adjusted for weight at 10 mg/kg) x 0.05 (CF)

The mL to cost ($) Conversion Factor (CF) of 3.07 was obtained from:

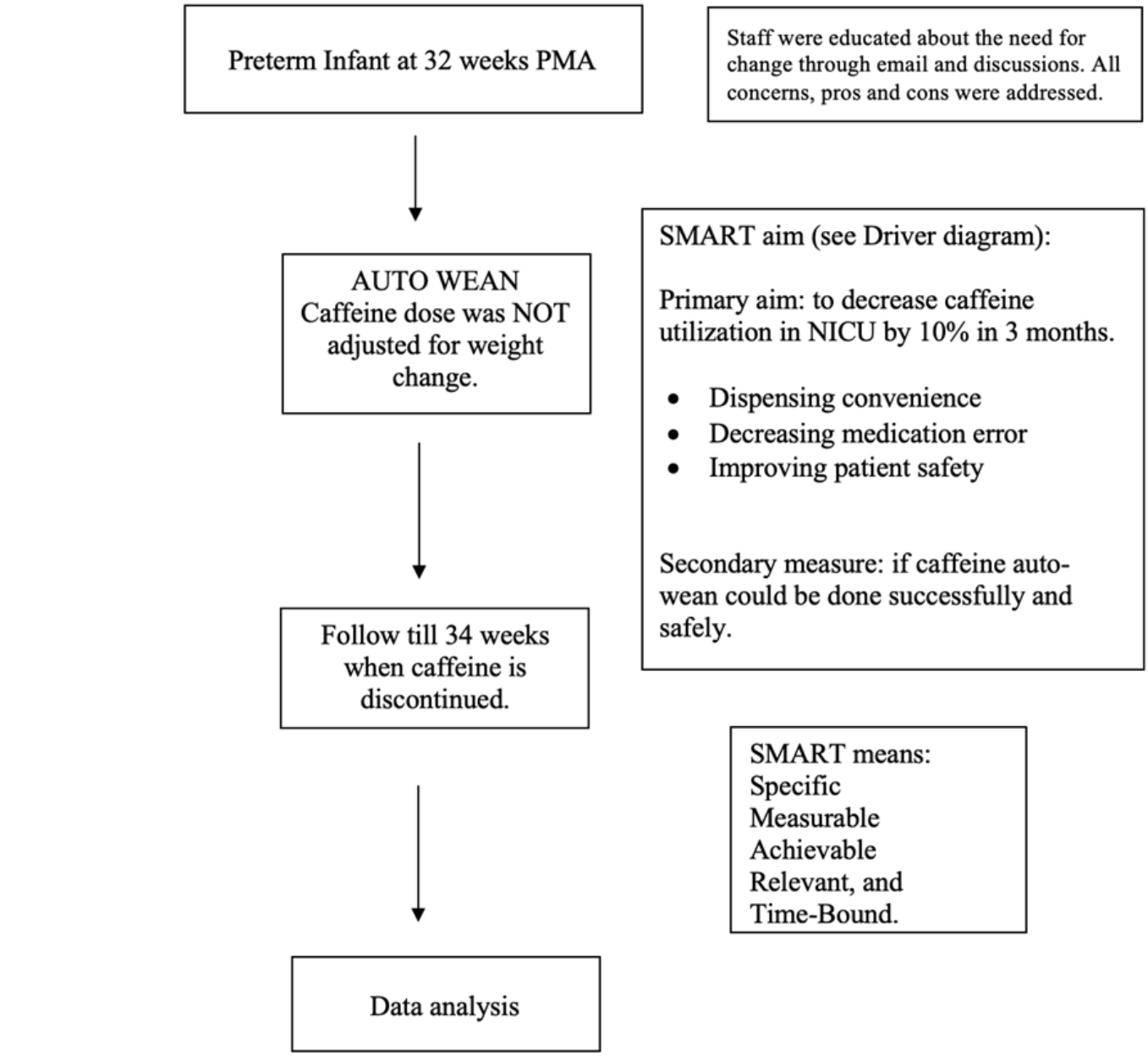
Oral Caffeine is supplied as 20mg/mL in 3mL Vials. The cost is $92.12/Pack of 10

So, one vial would be $9.21 ($92.12 divided by 10)

Cost per vial of 3 mL =$9.2 or $3.07 per mL ($9.21 divided by 3)

Appendix A

CAFFEINE AUTO WEAN STUDY
Study Flow Diagram



Balancing factors:
Number of apneic episodes (apnea > 20 seconds)
Desaturations < 90% (> 5-10 seconds, requiring stimulation or increase oxygen/flow)

as a quality improvement project was achieving the preset aim of a change in the process resulting in decreased resource utilization and cost within the three-month period.

"One could argue that not adjusting the caffeine dose to weight change may lower the serum caffeine level and lead to clinical symptoms. None of the infants had any clinical issues related to the dose of caffeine non-adjustment."

Conclusion:

We demonstrated effective auto-weaning of caffeine in stable, low-risk preterm infants. This being a single institutional study, more such studies are needed at other institutions to examine our findings' external validity.

"We demonstrated effective auto-weaning of caffeine in stable, low-risk preterm infants. This being a single institutional study, more such studies are needed at other institutions to examine our findings' external validity."

Supplementary Material (Table S2)

Appendix B: Actual dose at 34 weeks (dose/weight)

Caffeine dose (mg) at 32 weeks	Weight (kg) at 34 weeks	Actual Final dose at 34 weeks (mg/kg)
17.2	2.520	6.8
16.8	2.005	8.4
12.6	1.355	9.3
8.6	1.360	6.3
23.6	2.430	9.7
12.8	1.830	7.0
9.6	1.250	7.7
10.8	1.380	7.8
13.4	1.705	7.9
11.2	1.410	7.9
16.8	2.130	7.9
12.2	1.530	8.0
12	1.760	6.8
10.2	1.450	7.0
13	1.640	7.9
12	1.695	7.1

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A part of this study was presented as an E-Poster Presentation at the Annual Meeting 2023 of the Swiss Society of Neonatology at the Kultur und Kongresshaus in Aarau, Switzerland.

Acknowledgments: *All the NICU team members and families of preterm infants*

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Protecting Infants from RSV: Understanding Guidance on New Prevention Tools

Susan Hepworth, Bob Hopkins, Jr., MD, Jefferson Jones, MD, Karen Crowley, DNP

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

The National Coalition for Infant Health is a collaborative of more than 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.

Susan Hepworth: Thanks, everybody, for joining. We've got almost everyone who RSVP'd has joined. We will get started with today's webinar, Protecting Infants from RSV: Understanding Guidance on New Prevention Tools. My name is Susan Hepworth. I serve as executive director at the National Coalition for Infant Health, one of the hosts of today's webinar. I am delighted to be joined by three speakers here today with us. We're joined by Dr. Kieran Crowley of the Association of Women's Health, Obstetric and Neonatal Nurses. We're also joined by Dr. Jefferson Jones of the CDC and Dr. Bob Hopkins of the National Foundation for Infectious Diseases.

"My name is Susan Hepworth. I serve as executive director at the National Coalition for Infant Health, one of the hosts of today's webinar. I am delighted to be joined by three speakers here today with us. We're joined by Dr. Kieran Crowley of the Association of Women's Health, Obstetric and Neonatal Nurses. We're also joined by Dr. Jefferson Jones of the CDC and Dr. Bob Hopkins of the National Foundation for Infectious Diseases."

I want to recognize the co-hosts of today's webinar, the Association of Women's Health, Obstetric and Neonatal Nurses, and NFIB, the National Foundation for Infectious Diseases. I also want to thank our sponsors, Merck, Pfizer, and Sanofi, who helped make today's webinar possible. To quickly outline the objectives of today's webinar, we will receive an overview of RSV from Dr. Bob Hopkins at NFID. Then, we will hear from Dr. Jefferson Jones about new options to prevent RSV and what the CDC guidance says about their use. Then, we will hear from Dr. Karen Crowley, who wants to talk about resources for providers, patients, and caregivers to educate about these new prevention tools.

We have reserved a few minutes at the end for Question and Answer, so feel free to send those questions as they come to your mind. With that, I will start with a concise video that the National Coalition for Infant Health produced last year, based on a survey conducted at the end of 2022.

Video https://www.infanthealth.org/rsv#videos

Nearly every child catches RSV by age two. Respiratory Syncytial Virus affects the lungs and airways and can cause bronchiolitis, pneumonia, coughing, wheezing, or other cold-like symptoms. But for many families, that's only the beginning. A national survey of parents and healthcare providers found that the disease also leaves an emotional, financial, and social burden. Of the 340 parents whose child caught the virus, more than two-thirds said it landed their child in the hospital. 68% of parents reported the experience affected their mental health while their child was sick. Parents felt afraid, sad, helpless, and frustrated. Many felt guilty they couldn't do more to prevent their child's sickness. RSV also dealt excessive financial hardships to black families, who faced medical bills, loss of potential income, childcare costs for siblings, and transportation expenses.

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Meanwhile, some parents had to request paid time off, take unpaid leave, or cut back on work. Nearly 20% left their job or were fired as a result. Perhaps that's why more than two-thirds of surveyed parents described RSV as a financial burden or financial crisis. RSV impacted families' social balance, too. Over one-third of parents said the experience strained their relationship with their partner. They had to turn to family members and friends to help with childcare, and all the while, siblings struggled to understand what was happening. RSV's impact is multifaceted. So, how can policymakers help? [They can help by] supporting innovation and ensuring timely and equitable access to care and preventive interventions. Surveyed healthcare providers agreed that immunization and vaccine-like interventions could help minimize the burden of RSV. 82% of parents agreed they would want their child to receive such an intervention with good policy and innovation. Families and their healthcare providers can work together to reduce the burden of RSV.

Susan Hepworth: As you can see there, the burden of RSV goes

well beyond the clinical or the medical burden on an infant or child, but the burden extends to the family as well, as represented in those survey results. I want to welcome Dr. Hopkins from NFID, who will give us a presentation about the overview of RSV.

Bob Hopkins: I appreciate you all inviting me to be here. I want to spend just a few minutes discussing RSV disease and epidemiology. To set the stage for those who may not know about the NFID, the National Foundation for Infectious Diseases, a 501(c)(3) organization that was founded in 1973 with the goal of healthier lives for all through effective prevention and treatment of infectious diseases, through education, engagement of the public and other partners in collaboration to improve the health of all.

RSV is a widespread respiratory illness. From the scientific standpoint, it's an enveloped negative-strand RNA virus from a family known as Pneumoviridae. There are two major subtypes of RSV known as A and B, and there are numerous different phenotypes or genetic groups, but A and B are the two that we need to consider. The symptoms of RSV overlap with other respiratory pathogens like COVID-19, influenza, the common cold, and others. In infants, RSV is the most common cause of bronchiolitis and pneumonia in children aged under one. Those at the highest risk are premature infants, those that have heart and lung disease, and all children, even children born at normal term with no other health issues less than six months of age. Most of those who are infected with RSV have a mild upper respiratory illness or cold, a classic illness that many of us in pediatric practice are used to seeing, or a child that comes in with a cough, then over a day or two develops fever or wheeze and copious nasal drainage area. RSV can cause that, but it can also cause other respiratory symptoms.

"The symptoms of RSV overlap with other respiratory pathogens like COVID-19, influenza, the common cold, and others. In infants, RSV is the most common cause of bronchiolitis and pneumonia in children aged under one. Those at the highest risk are premature infants, those that have heart and lung disease, and all children, even children born at normal term with no other health issues less than six months of age."

Adults, mainly those who are older age and who have chronic health conditions or those who are immunosuppressed, are also at increased risk for severe disease. Our focus is on the neonatal childhood burden, but it's essential to recognize that there's also significant disease in older adults.

Did you know that RSV is a common respiratory disease? In most years, RSV circulates in the fall and winter months in the U.S. It often starts earlier in the country's southeastern part. I'll show you some of that epidemiologic data in a moment. It's spread through contact with others and in contact with contaminated surfaces. Unfortunately, the RSV virus can live on hard surfaces for many hours. It's often spread through coughing, sneezing, kissing, or touching those infected surfaces and then touching your nose, mouth, or eyes. So, as I tried to teach my children and patients, keep your hands away from your face as much as possible.

Almost all children are infected by two years of age, but unfortunately, immunity following RSV infection is not durable. It's not uncommon to see children and adults who get RSV multiple times a year. This is data from our friends at the Centers for Disease Control showing the seasonality of RSV from the 2018 season through the 2023 season (Table 1). The dark green line here with the high peak over October-November was a 2023 season. We had a very early onset and a severe RSV season in 2021, 2022, and 2023. In the following line that you see down in the panel to the left, you see it was a less severe season, less of a peak. And then, in the other colors, you see different seasons. We've seen a change in seasonality patterns, some early and others late; some years are more severe than others. With RSV, we see outbreaks in our population almost every year with slight differences in timing. The incubation period after exposure is typically considered 4 to 6 days, and you can transmit it to others before you develop symptoms. Generally, you can transmit the virus within three to eight days of infection. As previously mentioned, the typical symptoms are runny nose, cough, fever, and sneezing, and in small infants, you might see fussiness, wheezing, decreased appetite, irritability, and reduced feeding. It would be best to be suspicious about RSV when there's RSV in the community or the time of year.

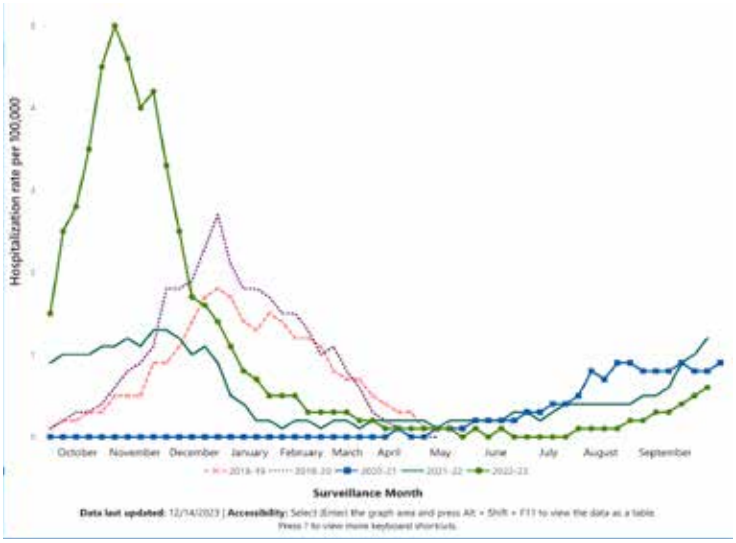

Table 1: Seasonality of RSV from the 2018 season through the 2023 season

We expect RSV and its symptoms not to be reliably distinguished from other respiratory viruses, which makes testing very important to distinguish between influenza, COVID-19, and other viruses. PCR or molecular testing is the most accurate way to test for RSV, although antigen tests are also reasonably accurate in children. Recovery from the illness usually takes 1 to 2 weeks. Still, it's essential to recognize that those persons who are immunocompromised can continue to shed RSV virus, which can infect others for up to a month even after their symptoms are resolved. So, beyond thinking about taking care of yourself, you also need to think about what we can do to prevent transmission of RSV to others. COVID-19 and RSV are uncommon. COVID-19, you commonly see difficulty breathing, a little bit less so with RSV, but that's still a common symptom that you can have on RSV. For people of all ages who have more severe diseases, fatigue is not typically a common issue with RSV. Fever can occur with any of these illnesses, although less likely in colds, and we think of loss of taste and smell as COVID-19. Sore throat is uncommon with RSV; wheezing is common in RSV patients. So again, RSV illness tends to be most severe in premature infants, infants less than six months of age, and persons with immunocompromised heart and lung diseases.

It is important to remember that over 80% of children who were hospitalized with RSV before two years of age have no risk factors. RSV can affect people regardless of whether they have chronic health conditions or not. RSV is the number one cause of bronchiolitis and pneumonia in children. Every year, approximately 2.1 million outpatient visits a year in children due to RSV illness, with 58,000 to 80,000 hospitalizations a year and, unfortunately, 100 to 300 pediatric deaths in children under five a year. This doesn't even include the significant additional burden of RSV disease in older adults. So, what's the treatment for RSV infection? We can suction those copious nasal secretions I mentioned. Oxygen can be provided for those with low oxygen saturation; bronchodilators may help with some of the coughs but have not been shown to change the direction or the duration of illness and nutrition support. It is essential to provide nutrition to help those infected with RSV use their muscles to breathe effectively. There are no currently effective available antiviral medications for us. So that's one of the reasons that prevention of RSV is so vital. If we can prevent somebody from getting the infection, we don't have to worry about whether we have effective antivirals.

"It is important to remember that over 80% of children who were hospitalized with RSV before two years of age have no risk factors. RSV can affect people regardless of whether they have chronic health conditions or not."

Regarding the prevention concepts around RSV, hand-washing, surface decontamination, and masks probably have a modest effect on reducing RSV transmission. Still, they are essential, and we should implement these in our daily lives, particularly in the clinical setting. It's also important to remind people that if you're sick or your child's sick, don't get them out around others or take a chance on transmitting the virus to others. We have selective benefits. Palivizumab is a monoclonal antibody that's been recommended and approved. The AAP recommendations are to use it for the highest-risk infants. It has to be administered intramuscularly and once a month throughout the season it's used. We have great potential with our new preventive tools, including honesty, vaccines, and the app, which Dr. Johns will discuss shortly.

That is my brief presentation. I look forward to answering some of your questions in the webinar.

Susan Hepworth: Thank you, Dr. Hopkins. Before I turn it over to Dr. Jones to discuss those prevention tools Dr. Hopkins just spoke about, I want to share the video of one more family who RSV impacted.

Video https://www.infanthealth.org/rsv#videos

Melanie: Life in the Rogers House is very chaotic. My name is Melanie, and this is my husband, Dan. We live in the suburbs of Chicago with our four kids. Our kids are nine, Dylan, six, Reagan, and then we have twins who are three, Austin and Holden. Reagan was four months old, and when she woke up in the morning, I could tell her breathing was not right. Those ten days in the hospital were grueling. They were exhausting.

Dan: The one word I would use to describe the RSV experience is helpless. I never even heard of RSV before. So it's like, oh, they have RSV, and you're like, what's that?

Melanie: Her breathing was not right. She was breathing very deeply, very quickly, and it was really scary. It's a waiting game. When they finally did tell us that we could go home. I'd be lying if I said I wasn't panicking, thinking, can I do this at home by myself? It's very frustrating because there's nothing we can do to speed up their getting better, and you're just stuck. As a family of six, we tried to do what we could to keep them from it. We still got it with the twins. For everyone who's had a child or has dealt with hospitalizations, the bills are all calling at once. They start trickling in; you don't know when they will stop. You have all the emotions flowing through when it's happening. You feel helpless because you're there with your child in the hospital, and then you feel guilty because you're not at home with the other children. It can be really scary with how contagious it is. You need to trust your instinct with something like this because even though some may say it's just a cold, these babies cannot handle it. They need supportive care and help. Be bold and call your pediatrician's emergency line in the middle of the night. If you're worried about their breathing, don't be afraid to show up at the E.R. when uncomfortable with your baby's breathing. This is not something to take lightly. It's very scary, and you feel very helpless, and this is just something we shouldn't have to watch our children go through.

Susan Hepworth: The good news is that hopefully, with two newly approved prevention tools available, fewer families will have to experience what the Rogers did, which was three of their four children being hospitalized with RSV. Dr. Jones, I'll now turn it over to you.

Jefferson Jones: Thanks so much for having me today and for the other presentations. We, as general pediatricians, were undoubtedly excited about this time of being able to prevent severe disease from RSV. So today, I'll discuss our two new immunization products and CDC recommendations for their use. First, I'll be going over the efficacy and safety. The two products are nirsevimab and the Pfizer maternal RSV vaccine. Then, the CDC recommendations and clinical guidance for health care facilities. These are assuming a sufficient nirsevimab availability with respect to the shortage of nirsevimab and interim recommendations for healthcare facilities experiencing limited availability. Finally, there are considerations for implementing these RSV immunizations.

First is efficacy and safety. Two products could protect infants in their first RSV season. The maternal vaccine for pregnant people is from Pfizer, and the trade name is Abrysvo. Then, the monoclonal antibody or nirsevimab with the brand name Beyfortus. This is given to the infant after birth. Please note that there is an additional RSV vaccine by GSK with a trade name, Arexvy, which is not approved or recommended for use in pregnant people.

"So today, I'll discuss our two new immunization products and CDC recommendations for their use. First, I'll be going over the efficacy and safety... Then, the CDC recommendations and clinical guidance for health care facilities... Finally, there are considerations for implementing these RSV immunizations."

To protect eligible children at increased risk in their second RSV season, the only option is nirsevimab. The efficacy of nirsevimab was initially evaluated through two multi-country trials, including preterm and term infants. Efficacy was assessed 150 days after

injection in the trials, and the pooled efficacy from these two trials was 79% in preventing medically attended RSV, lower respiratory tract infection (LRTI), or allergy and then 80.6% in preventing RSV LRTI with hospitalization. Nirsevimab has an acceptable safety profile, and it's generally well tolerated. The most commonly reported adverse reactions were injection site reactions and rash, which were present in less than 1% of recipients. In trials, the incidence of serious adverse events was not significantly different between the nirsevimab placebo arms.

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The efficacy of Pfizer's maternal RSV vaccine was also evaluated in a multi-country trial, and the vaccine was administered during 24 through 36 weeks gestation. The efficacy was assessed through 180 days of birth, and it was 51.3% in preventing medically attended RSV associate LRTI and 56.8% in preventing hospitalization for RSV-associated LRTI; the side effects tend to be mild or moderate and temporary like those experienced after other vaccinations and the most common local and systemic adverse reactions during the trials were pain at the injection site, headache, muscle pain, nausea, more preterm births, and reports of hypertension during pregnancy, including pre-eclampsia receiving the vaccine group, as well as the placebo group in the clinical trials. However, these differences were not statistically significant, and whether these were related to the vaccine or simply due to chance is unknown. So restricting vaccination to 32 to 36 weeks, as discussed in the recommendations, also reduces any potential risk of preterm birth. The Advisory Committee for Immunization Practice (ACIP) judges that the benefits of maternal RSV immunization at 32 through 36 weeks gestation outweigh any potential risk for preterm birth and hypertensive disorders of pregnancy.

Next, we'll talk about maternal vaccine recommendations. With seasonal administration, the maternal vaccine is recommended for pregnant people during 32 to 36 weeks of gestation. This means administering from September through January in most continental United States. However, in jurisdictions with seasonality that differs from most of the continental United States, for example, Alaska, and many jurisdictions with tropical climates, a provider should follow state, local, or territorial guidance on timing of administration.

The maternal Pfizer vaccine can be simultaneously administered with other indicated vaccinations. Now, either of the two options, maternal vaccination or the use of nirsevimab in the infant, is recommended to prevent RSV LRTI. However, administration of both products is not needed for most infants. Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient or not and rely on the administration of nirsevimab to the infant after birth.

Later, I will go into more detail on vaccine counseling and the importance of discussing the potential lack of nirsevimab availability as part of this conversation.

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Now, we'll talk about nirsevimab recommendations. It will first apply to healthcare settings where there's sufficient supply. In most of the United States, the RSV season has started. Therefore, the administrator and eligible children should begin nirsevimab as soon as it is available. Nirsevimab should continue to be offered to eligible infants and children through March, and it is mainly vital for those born between October 2023 and March 2024. Infants born shortly before the RSV season or in October 2023 through March 2024 should be immunized with nirsevimab within one week of birth, and administration can occur during the birth, hospitalization, or in the outpatient setting. We encourage immunization of infants with prolonged birth hospitalization shortly before or promptly after discharge. For all other infants younger than eight months, nirsevimab should be administered as soon as it is available if the infant is younger than eight months at the time of immunization. Again, this assumes sufficient doses, and I'll discuss the recommendations if there is a lack of dosing. And because the maternal RSV vaccine is shown to be effective, if the mother was vaccinated 14 or more days before birth year [date of birth], nirsevimab is not needed for most infants.

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There are rare circumstances for which nirsevimab can be considered when the mother has received an RSV vaccine 14 or more days before birth. These are when the clinical judgment of a health care provider for the potential incremental benefit of the nirsevimab administration is warranted. Some examples include but are not limited to, infants born to pregnant people who may not mount an adequate immune response to vaccination or have con-

ditions associated with reduced transplacental antibody transfer. So, this could include pregnant people with immuno-compromised conditions. Another example is infants who might have experienced loss of maternal antibodies. These could consist of infants who undergo cardiopulmonary bypass or ECMO and then infants with substantially increased risk for severe RSV disease, such as hemodynamically significant congenital heart disease for infants that have experienced ICU admission and are requiring oxygen at the time of discharge back at home. Nirsevimab should be administered if the age is 8 to 19 months at the time of the immunization and the child is at increased risk for severe disease, including children with chronic lung disease of prematurity, children with severe cystic fibrosis, children with severe immunocompromised and American Indian or Alaska Native children.

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Next, I'd like to discuss CDC interim recommendations for settings lacking nirsevimab availability. For the current season, the manufacturers reported a limited supply of nirsevimab, particularly the 100-milligram prefilled doses. Based on manufacturing capacity and currently available stock, there needs to be more 100 mg prefilled syringes and/or said MAB to protect all eligible infants weighing five kilograms or more during this current RSV season. Additionally, the supply of the 50 mg prefilled syringes may be limited. On October 23rd, 2023, the CDC released a health advisory describing interim recommendations to provide options for clinicians to protect infants from RSV. In this context of a limited nirsevimab supply, the recommendations for the 50-milligram doses remain unchanged. But to help preserve the 50-milligram doses, providers should encourage pregnant people to receive Pfizer's maternal RSV vaccine during 32 to 36 weeks gestation to prevent RSV-associated LRTI.

In the conversation between providers and pregnant people, stress that there's a limited nirsevimab availability when they're deciding whether or not to receive the RSV vaccination during pregnancy. Now, in healthcare settings with limited 100-milligram doses, providers should prioritize infants at the highest risk of severe RSV disease for receipt of 100-milligram doses. These include infants that are younger than age six months, American Indian or Alaskan native infants aged less than eight months, and infants under age six to eight months that have conditions that place them at high risk of severe RSV disease. These include those that were born prematurely at less than 29 weeks gestation, chronic lung disease, hemodynamically significant congenital heart disease, severe immunocompromised or cystic fibrosis, and neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions. Additionally, 50-milligram doses should be reserved only for infants weighing less than five kilograms, meaning providers should avoid using two 50-milligram doses instead of a 100-milligram dose for infants weighing five kilograms and more. As mentioned, that's because the youngest infants are at the highest risk for severe disease. So prioritizing doses for them is crucial, and providers should follow AAP recommendations for eligible infants when the appropriate dose of nirsevimab is unavailable. In addition, these are for healthcare facilities with limited availability of nirsevimab. Providers should suspend the use of their nirsevimab for children aged 8 to 19 months, with these children receiving nirsevimab per AAP recommendations. Providers should continue offering nirsevimab to American Indian or Alaska Native children aged eight through 19 months, particularly those who live in remote regions where transporting children with severe RSV who need an escalation of medical care may be challenging. These communities have known high rates of severe RSV among this age group.

Lastly, I'd like to review some considerations regarding the cost of implementing these RSV immunizations. The maternal RSV vaccine is $295 per dose. Medicaid should cover the cost without cost-sharing. The VFC program is available for persons under 19 years, and most private insurance plans are required to cover the maternal RSV vaccine but have approximately one year to do so. For nirsevimab, the price is $495 per dose, which is the private sector cost, and payment flexibilities exist this season. For example, providers have 150 days for payments when ordering directly from the manufacturer. For insurance coverage, nirsevimab is covered under the Vaccines for Children program, and most private insurance plans require coverage of nirsevimab, but also one year to do so.

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The storage handling administration for these two products, for the maternal RSV vaccine, is supplied as a three-component kit and requires reconstitution. It has the lyophilized antigen vial, sterile water diluent syringe, and vial adapter. Before reconstitution, it should be stored at refrigerated temperatures and not frozen. After reconstitution, it should be stored at room temperature and used within 4 hours.

The maternal RSV vaccine is given similarly to other vaccines as an intramuscular injection in the deltoid muscle or thigh. The dosage is 0.5 milliliters. Nirsevimab is supplied in two doses, 0.5 milliliter or 60 milligrams, in a prefilled syringe with a purple plunger rod, [and] one milliliter or 100 milligrams prefilled syringe dose in a light blue plunger rod. Nirsevimab should be stored at a refrigerated temperature and used within 8 hours of being removed from

the refrigerator, and it should not be frozen, shaken, and protected from light.

Nirsevimab is administered similarly to traditional vaccines, such as an intramuscular injection in the Vastus lateralis muscle of the anterolateral thigh. Nirsevimab is dose-dependent on weight. For those that are less than five kg, 50-milligram doses will be given, and those in their first RSV season, then for those who are five kg and greater, receive one 100-milligram dose. Children at increased risk of severe disease entering their second RSV season and will be 8 to 19 months of age receive two 100-milligram doses to make up a 200-milligram dose. The maternal RSV vaccine and nirsevimab can be administered with other recommended vaccinations, though there are some considerations for counseling patients on the RSV vaccine. As mentioned, either the maternal RSV vaccine or nirsevimab is recommended for all infants.

Administration of both products is only needed for some infants. Providers of pregnant people should discuss both products and consider the relative advantages and disadvantages of each product, which I'll review next. Patient preferences and the availability of nirsevimab are fundamental. Thus, prenatal providers who do not offer the maternal RSV vaccine should refer patients elsewhere for vaccination. We ask that providers proactively provide a prescription if state law requires vaccination in a pharmacy. This is important because Nirsevimab has limited availability in some areas.

Encouraging maternal vaccination, particularly this season, is essential. Some of the relative advantages that could be discussed are that the maternal RSV vaccine has the advantage of providing protection immediately after birth, which is when infants are at the highest risk for severe disease. The maternal RSV vaccine also might be more resistant to potential mutations in the F protein. RSV does not typically mutate rapidly, but this could occur. Some relative disadvantages are potentially reduced protection in some situations. For example, if the pregnant person is immunocompromised or the infant is born soon after vaccination, then there's also the potential risk for preterm birth or hypertensive disorders of pregnancy.

The advantages of nirsevimab include protection from nirsevimab, which may wane more slowly than the maternal RSV vaccine; nirsevimab is a direct receipt of antibodies. It does not rely on placental transfer from the pregnant person to the fetus. Additionally, there's no risk for adverse pregnancy outcomes. There are some disadvantages, and, importantly, as mentioned several times, there's limited availability during the 2023 to 2024 RSV season. Further, nirsevimab also requires an infant injection.

"Administration of both products is only needed for some infants. Providers of pregnant people should discuss both products and consider the relative advantages and disadvantages of each product..."

A vaccine information statement for the maternal RSV vaccine and an immunization information statement for the nirsevimab are available. It is critically important to document receipt of the maternal RSV vaccine as most infants of vaccinated mothers are not recommended to receive nirsevimab. This can include recording it in an immunization information system, the electronic health record, and written or printed documentation needed for the parent to bring to the birth hospital and pediatrician; this may depend on state policy or laws.

In summary, RSV can cause serious illness in infants and children, and this includes hospitalization and potentially death. To protect eligible infants in the first season, the maternal vaccine or nirsevimab is recommended to prevent RSV and LRTI in infants. Still, administration of both products is optional for most infants. The maternal vaccine from Pfizer and nirsevimab, to protect eligible infants in their second season, nirsevimab is recommended regardless of maternal RSV vaccination. Then, a similar simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. Maternal vaccine is recommended for pregnant people during 30 to 36 weeks gestation, from September through January. It's recommended in most continental United States, but in certain jurisdictions, the seasonality differs; providers should follow state, local, or territorial guidance on the timing in infants younger than eight months. Infants born during or entering their first RSV season are recommended to receive one dose of nirsevimab if the mother did not receive the RSV vaccine during pregnancy, if the mother's RSV vaccination status is unknown, and the infant was born within 14 days of maternal RSV vaccination. Finally, children aged eight through 19 months who are at an increased risk of severe disease while entering their second RSV season are recommended to receive one dose of nirsevimab when available.

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Susan Hepworth: Thank you so much, Dr. Jones, for all that information. I'll turn it over to Dr. Kieren Crowley to discuss patient and provider education resources.

Kieran Crowley: When we think about educating our patients from a provider perspective, it's vital that we consider many factors, especially when discussing vaccinations. It is recommended that preventative health discussions start early and occur throughout the pregnancy, addressing maternal immunization and the infant option. In the prevention of RSV, this anticipatory guidance helps to provide several opportunities for patients and providers to discuss the disease-specific condition we're discussing, in this case, RSV, and the health implications it has on the infant. It's an opportunity to provide preventive health treatment options, including maternal immunization, Pfizer, or the infant preventative treatment, nirsevimab, and how each works to prevent the infant from becoming infected and potential side effects.

It's also essential when discussing vaccinations throughout the pregnancy before the seasonality of the recommendation timeline so that the patient and family can make an informed decision and share their preferences regarding their fears and concerns with their provider. Part of the education should also include if

there are specific reasons why we would avoid or delay the vaccination; in this case, any vaccination avoidance would consist of any history of severe allergic reactions. For the RSV vaccine or treatment options, a delay in administering at a set visit would occur if that person presented with severe signs and symptoms of illness, regardless of whether they might have a fever. I know Dr. Hopkins and Dr. Jones already addressed some of the seasonality issues that we would see in some parts of the United States with a different vaccination schedule. Suppose you're a provider within those states, such as Alaska, Florida, and the U.S. territories. In that case, it's important to discuss those differences regarding the timing of the vaccination with the individual patient so that they're aware of those differences because they may see different messages and websites. In the content that we give, we give them for education. Being proactive in that discussion is essential, and then discussing the simultaneous administration with our other maternal vaccines is important because it is approved for concurrent administration with the flu, Tdap, and COVID-19 vaccinations.

When we talk about patient resources, individuals learn differently, and using varying methods helps to increase comprehension. It makes for a better-informed decision from the patient's perspective. Utilizing varied methods is very important, as you see in this webinar. The use of videos, infographics, and written take-homes is essential. Having verbal and repetitive conversations throughout the pregnancy is helpful so they can identify questions that might need to be answered, and they can share their concerns and fears, which can be addressed factually by the providers. Sharing reputable websites that provide information at a patient level is essential. Everyone uses Google efficiently, but it may guide them to inappropriate websites. We want to help educate our patients on determining which websites are best for them and adults at a level where they can understand the materials they're reading; if they have any questions about those, bring them back to the provider.

"It's also essential when discussing vaccinations throughout the pregnancy before the seasonality of the recommendation timeline so that the patient and family can make an informed decision and share their preferences regarding their fears and concerns with their provider."

There are a couple of patient resources that I can mention; one is the CDC, which has several infographics that you saw in Dr. Hopkins's and Dr. Jones's presentations. These infographics can be used for provider and patient perspectives on different vaccines. We also have various languages to help provide language-proficient infographics to our populations. Another is AWHONN, which has "Healthy Mom and Baby" information. This consumer-facing and patient education platform offers various information on pregnancy, family, childbearing, and childraising issues, including maternal immunizations and the RSV vaccine. Other information sources are ACIP and ACOG. The CDC also has a convenient vaccine schedule that all patients will hopefully follow regarding infant to adult immunization schedules, as presented by Dr. Jones. The fact sheets and the vaccine information statements are crucial and can be used throughout the different visits to help inform the patient of those recommendations.

Regarding providers and their resources, utilizing a professional or a national organization such as the FDA, CDC, and ACIP on the approval and recommendation protocols seen with different vaccinations is extremely important to acknowledge. Each provider professional organization, whether at different provider levels or in specialties, also has statements and/or provides guidance practice advisories on those websites that help guide the professional provider with recommendations to the populations they serve. An example is ACOG for obstetrics and gynecology. The nurse, midwives, pediatrics, and family practice have similar resources. One resource that I find very, very helpful, and that came to light during the COVID-19 pandemic, is the CDC State of Vaccine Confidence and site reports, which provide a thematic analysis of potential impacts on the vaccine, confidence of the public and the demands that we might see out there across the United States.

In addition, thematic analysis provides talking points and strategies to overcome those themes for us to prepare for conversations that might arise during our visits with our patients. They also offer websites that provide fliers and posters for offices to use, which is very helpful. While patients sit in waiting rooms and exam rooms, that helps them think of questions. The websites also have toolkits that help provide social media dissemination opportunities for other providers.

"There are a couple of patient resources that I can mention; one is the CDC, which has several infographics that you saw in Dr. Hopkins's and Dr. Jones's presentations. These infographics can be used for provider and patient perspectives on different vaccines. We also have various languages to help provide language-proficient infographics to our populations. Another is AWHONN, which has "Healthy Mom and Baby" information. This consumer-facing and patient education platform offers various information on pregnancy, family, childbearing, and childraising issues, including maternal immunizations and the RSV vaccine. Other information sources are ACIP and ACOG."

Key take homes are it is essential providers make sure that they are talking early in the pregnancy and frequently throughout the pregnancy, addressing maternal and or newborn treatment prevention options, and providing people information on those options so that in a non-judgmental way, each individual can have their process for decision making. Having that be a shared decision helps reach the goal of the best preference for that person and their infant and prevents RSV. Many of us already know that there's a plethora of research on the adoption of vaccines that is consistent in finding that patient adoption stems from the provider's recommendation. Research on when and how a provider

might recommend and administer vaccines is highly associated with a national professional organization recommendation. For the RSV vaccine, we have that from the FDA, CDC, and professional organizations. Now, it's up to the healthcare team to educate the patients, recommend treatment, and work with patients to understand their preferences for preventing RSV. I can take any questions at the end as well. Thank you.

Susan Hepworth: Thank you, Dr. Crowley. We'll invite Dr. Hopkins and Dr. Jones to also come on screen. We have about 8 minutes, and we have received a lot of questions that have come in. We're just going to dive right in. I will allow any of you who want to answer to go ahead and do so. Let me start with: "Why is the maternal vaccine only recommended in September through January versus through March, like nirsevimab?" Dr. Jones, that might be for you.

Jefferson Jones: The most significant difference between nirsevimab and the maternal vaccine, when it's given, is when protection begins. By the end of March, the RSV season is not an on-and-off; it goes up and then slowly peters off over March and April during pre-pandemic months and in nirsevimab as soon as you give the monoclonal antibody, almost immediately after, protection starts. For the maternal vaccine, you're giving it 30 to 36 weeks, so, for many, it will be up to eight weeks before that infant is born. For infants born after the RSV season or just towards the end of last season, ACIP felt it wasn't a good use of resources.

Susan Hepworth: As a subsequent question: "Shouldn't nirsevimab be administered to a baby that has tested RSV positive this season?"

"Key take homes are it is essential providers make sure that they are talking early in the pregnancy and frequently throughout the pregnancy, addressing maternal and or newborn treatment prevention options, and providing people information on those options so that in a non-judgmental way, each individual can have their process for decision making."

Bob Hopkins: I'd be happy to take that one, Suzanne. Remember that Nirsevimab is trying to prevent RSV infection; one RSV infection does not protect you from additional RSV infections. We also discussed that immunity following RSV infection is minimal. If you have an infant that has an early RSV infection, if they're still in that risk window period, then you could use nirsevimab for prevention of further severe infections.

Jefferson Jones: That's right. The AAP has mentioned that for those that have shortages of nirsevimab, they say you could consider it a non-priority if you don't have enough availability for those that have already been infected, you may not need to give it that the benefit may not be as much as people who haven't been previously infected. But Dr. Hopkins is correct.

Susan Hepworth: Next question: "It was mentioned that at-risk infants entering their second season should get two 100-milligram doses of nirsevimab. Are they given at the same time?"

Jefferson Jones: That's a short one; yes, they are standard. Two immunizations in space, at least one inch apart.

Susan Hepworth: Great. This is a question I have been asked a couple of different ways here: "Do we know how long the maternal vaccination antibodies will last versus nirsevimab?"

Jefferson Jones: This is a bit more complicated. There hasn't been a lot released on the maternal vaccine yet. They are in phase two and have presented some preliminary data and presentations. What we do know is that the efficacy was there. Primary outcomes were measured at 0 to 90 days and 0 to 180 days. We only showed the 0 to 180-day outcomes; for time's sake, we kept it shorter. However, the 0 to 90-day efficacy is higher for the maternal vaccine. So, some waning may be from 90 to 180 days for efficacy. There may be protection that lasts beyond 180 days; there are probably antibodies, but we need to know how many antibodies you need to protect from RSV. For now, there's confidence that there's protection until 180 days after birth. We don't know for sure after that. Based on other vaccines that are given during pregnancy, there's pretty limited, if any, protection offered much later than that.

On nirsevimab, antibody data has been published that shows there is waning over time about a year after nirsevimab is given. It's higher for those who have been given nirsevimab compared to those who were infected during their trials, which is encouraging, but we only know efficacy. It does protect infants for 150 days after administration. Of note is that nirsevimab has been engineered and changed. It lasts longer in the body, the half-life is longer, and compared to antibodies, it persists longer. But how exactly that will lead to potentially prolonged protection beyond 150 days will require further studies, which we're currently working on based on ongoing studies conducted by CDC and other partners.

"This is a question I have been asked a couple of different ways here: "Do we know how long the maternal vaccination antibodies will last versus nirsevimab?""

Bob Hopkins: I agree with what you said. Many will continue asking about the comparative effectiveness of nirsevimab as opposed to maternal immunization. And until we truly have somebody look at a comparative effectiveness trial and we look at the real-world experience with these products, we will continue to ask these questions. As a practicing Med/Peds doctor, the critical point for me is that we wanted to get as many of these pregnant women vaccinated as possible to pass those antibodies onto their infants. In any of the infants born to women who were not vaccinated, we want to get as many of them protected with nirsevimab in their first season at high risk and in their second seasons to reduce the burden of the number of these kids ending up in the hospital. Unfortunately, some have severe outcomes, including death for three.

Susan Hepworth: Well, we're out of time and have answered many of the questions that have come in. I have received a lot of questions about whether these presentations will be made available and whether we can get a recording. The Coalition will send a follow-up email with more information to everybody who attended today's webinar. I want to thank Dr. Crowley, Dr. Hopkins, and Dr. Jones for sharing this essential information with us today, and I appreciate everybody joining. Thank you, and have a great day.

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National Coalition for Infant Health Values (SANE)

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

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

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

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

Jefferson Jones, MD, MPH, FAAP
Centers for Disease Control and Prevention

The Indirect Impact of **RSV**

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

OVERVIEW

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

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

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

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

RSV PARENT SURVEY

340 parents who had at least 1 child sick with RSV

67% of parents said their child was hospitalized for RSV

RSV HEALTH CARE PROVIDER SURVEY

175 health care providers across various pediatric and neonatal subspecialties

67% worked in an outpatient facility

33% worked in a hospital

RESULTS

FINANCIAL BURDEN

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

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

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

EMOTIONAL BURDEN

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

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

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

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

SOCIAL BURDEN

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

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

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

RESULTS

PARENT EDUCATION & AWARENESS

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

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

TREATMENT CHALLENGES

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

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

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

MISCONCEPTIONS

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

CONCLUSION

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

The virus may lead to:

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

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

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

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

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

infanthealth.org

Dr. Munaf Kadri Honored for 25 Years of Dedication to Community Healthcare

Andrew Hopper, MD, Mitchell Goldstein, MD, MBA, CML, Munaf Kadri, MD

UMMA COMMUNITY CLINIC

"Dr. Munaf Kadri, a member of the founding board of the University Muslim Medical Association (UMMA) Community Clinic, was recently recognized for his outstanding contributions to community healthcare."

Dr. Munaf Kadri, a member of the founding board of the University Muslim Medical Association (UMMA) Community Clinic, was recently recognized for his outstanding contributions to community healthcare. Dr. Kadri's journey began in the aftermath of the 1992 riots in South Los Angeles when he and other founding members initiated the UMMA Community Clinic as a volunteer effort to provide high-quality care to the underserved.

"What started in an abandoned building has now become a remarkable achievement: the UMMA Community Clinic has evolved into a Federally Qualified Health Center (FQHC), operating across six locations and serving over 35,000 patients annually with a staff of 73+ full-time employees who provide an array of integrated healthcare services."

UMMA Community Clinic's (UMMA) mission is to promote the well-being of the underserved by providing access to high-quality

health care for all, regardless of ability to pay. UMMA envisions itself as part of a larger network of institutions addressing the health and well-being of the underserved and indigent, mindful of the cultural, spiritual, social, and economic realities impinging upon them and the traditional barriers to accessing care.

What started in an abandoned building has now become a remarkable achievement: the UMMA Community Clinic has evolved into a Federally Qualified Health Center (FQHC), operating across six locations and serving over 35,000 patients annually with a staff of 100+ full-time employees who provide an array of integrated healthcare services. This year marks the 25th anniversary of UMMA's commitment to providing comprehensive medical, dental, behavioral health, and community services.

UMMA's patient population is 72% Latino and 21% African Ameri-

United States Congress

Certificate of Recognition

presented to

Dr. Munaf Kadri

on celebrating

Dedicated Years of Service

On behalf of California's 37th Congressional District, I want to thank you for your exceptional leadership, dedication, and tireless commitment to the betterment of our community. As founding board member and Chairman of Umma Community Clinic, your unwavering efforts have significantly contributed to the growth, prosperity, and well-being of over a million Angelenos. You embody your mission of improving the lives of the underserved all over the world and in particular our own backyard – all while simultaneously teaching at Loma Linda University Medical Center. We genuinely thank you for your dedication to the Umma Community Clinic!

4th day of November 2023

Congresswoman Sydney Kamlager-Dove
California's 37th District

CALIFORNIA LEGISLATURE

Assembly

CERTIFICATE OF RECOGNITION

PRESENTED TO:

Munaf Kadri

In recognition of your unwavering commitment to service and your substantial contributions to the well-being of our community. Your earnest dedication not only elevates the mission of UMMA Community Clinic but significantly resonates with our shared goal to promote the well-being of the underserved by providing access to high-quality healthcare for all,. Your endeavors have made a marked difference in the lives of many, embodying a spirit of community and compassion that inspires us all. I commend your tireless efforts towards the betterment of both UMMA and the broader community, laying down a legacy of service that continues to inspire and uplift."

November 4, 2023

Reginald Byron Jones-Sawyer, Sr.

REGINALD BYRON JONES-SAWYER, SR.
Assemblymember, 57th District

can. More than 41% of the patients live 100% below the Federal Poverty Level (FPL), 31% are uninsured, and 62% are enrolled in public insurance programs that are often underinsured. UMMA serves people of all ages. 23% of the patients are under 17, 69% are aged 18-64, and 8% are 65 or older. More than 47% of the patients are best served in a language other than English.

"What started in an abandoned building has now become a remarkable achievement: the UMMA Community Clinic has evolved into a Federally Qualified Health Center (FQHC), operating across six locations and serving over 35,000 patients annually with a staff of 73+ full-time employees who provide an array of integrated healthcare services."

Amid the COVID-19 pandemic, UMMA has rapidly seen the demand for critical medical, behavioral, oral health, and social services increase in South Los Angeles. In response, UMMA invested in a Mobile Health Clinic through a Health on Wheels Initiative to make primary care services more accessible to the underserved community. During this time, UMMA also doubled its Fremont Food Fair free services in response to a 200% increase in demand for food aid during the pandemic, reaching more than 2,500 community members in need and distributing more than 360,000 pounds of fresh fruits and vegetables in 2020. UMMA distributed 371,053 pounds of fresh produce through the Fremont Free Food Fair in 2021. Considering UMMA's patients' unique digital and economic barriers, telehealth and telephonic services were introduced into UMMA's care modalities in March 2020. UMMA completed 13,728 telehealth visits (video, telephone, and hybrid) in 2021.

UMMA community clinic has been recognized as a Patient-Centered Medical Home (PCMH) and Health Resources and Services Administration (HRSA) Health Center Quality Leader. This designation reflects a commitment to increasing access to care for the community. The Los Angeles County Board of Supervisors, the Los Angeles City Council, the United States House of Represen-

Dr. Elba Fayard congratulates Dr. Munaf Kadri on his receipt of the California State Assembly Award

Dr. Elba Fayard congratulates Dr. Munaf Kadri on receiving the United States Congress Certificate of Recognition, acknowledging his dedicated service over the past 25 years

tatives, and the White House have honored UMMA for their work in South Los Angeles. In October 2020, UMMA was recognized by Assemblymember Reginald Byron Jones-Sawyer, Sr. as the 2020 California Nonprofit of the Year for the 59th Assembly District for UMMA's commitment to increasing access to high-quality healthcare and addressing critical social needs in South Los Angeles.

Dr. Munaf Kadri has played a pivotal role in UMMA's growth, serving in various capacities. Dr. Kadri's impactful leadership has evolved from a dedicated volunteer physician to his role as Chairman of the Board and currently Chair of Development and Quality Improvement. Beyond his local contributions, Dr. Kadri has led mission-driven healthcare projects on a global scale, setting up clinics in South Asia and providing vital care in the Middle East.

In recognition of his tireless efforts, Dr. Kadri was awarded the United States Congress Certificate of Recognition, acknowledging his dedicated service over the past 25 years. Additionally, the California State Assembly honored him for his unwavering commitment to service and substantial contributions to the well-being of the South Los Angeles community.

"In recognition of his tireless efforts, Dr. Kadri was awarded the United States Congress Certificate of Recognition, acknowledging his dedicated service over the past 25 years. Additionally, the California State Assembly honored him for his unwavering commitment to service and substantial contributions to the well-being of the South Los Angeles community."

"We are so proud of Dr. Munaf Kadri and his incredible achievements," said Dr. Elba Fayard, Neonatal-Perinatal Division Chief, expressing the sentiment of the Department of Pediatrics at Loma Linda. "His vision and dedication have not only transformed a volunteer initiative into a thriving healthcare network but have also

touched the lives of thousands, both locally and globally."

"Dr. Kadri's recognition is a testament to the impact of community-driven initiatives and the transformative power of sustained dedication to healthcare. As UMMA celebrates its 25th anniversary, the spotlight on Dr. Munaf Kadri inspires future generations of healthcare professionals and community leaders."

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

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

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

*Source: Respirator Syncytial Virus and African Americans

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

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

AfPA
Alliance for Patient Access

Peer Reviewed

Case Report: A Review of Neonatal Lupus Erythematosus with a Case Illustration

Kundan Malik MS, Jeffrey Sugarman MD, PhD

Introduction:

Neonatal Lupus Erythematosus (NLE) is a rare autoimmune disease of the newborn caused by the passive transplacental transfer of maternal autoantibodies, particularly anti-SSA/Ro and anti-SSB/La (1). The global incidence of NLE remains uncertain due to numerous undiagnosed cases, but in the USA, it affects one in every 20,000 live births (1). NLE was first reported in 1954 in a baby born to an ANA-positive mother, and it is characterized by a constellation of manifestations affecting various systems, including the cardiovascular, cutaneous, hepatobiliary, and hematological systems (6).

Case Illustration:

A six-month-old female presented with a five-month history of an erythematous, itchy facial rash exacerbated by sun exposure. Born full-term following an uncomplicated pregnancy and birth, she had achieved age-appropriate developmental milestones. Notably, her family history revealed a grandmother with lupus.

Clinical Examination:

Upon examination, pronounced erythematous patches were noted on her face, particularly around the periorbital region, and a more reticulated eruption on the left arm. However, the rest of the systemic examination was normal, with no evidence of hepatosplenomegaly.

.

Assessment and Management:

NLE was the primary consideration given the striking periorbital distribution (so-called “raccoon eyes”), exacerbated by sun exposure. Atopic dermatitis was also considered, and the baby was managed with hydrocortisone 2.5% topical ointment since the parents reported associated pruritus. To confirm the clinical suspicion of NLE, maternal serologies were ordered. Due to the slow waning of maternal antibodies, it was deemed that serological testing on the infant, who was already five months old at the time of presentation, might yield false-negative results.

“Due to the slow waning of maternal antibodies, it was deemed that serological testing on the infant, who was already five months old at the time of presentation, might yield false-negative results.”

Maternal serology confirmed positive anti-Ro/SSA at >8.0 and positive anti-La/SSB antibodies at 2.3, far exceeding the range values of <1.0 Neg AI. Following the confirmation of NLE, a re-

ferral to pediatric cardiology was made, and subsequent ECG and cardiac ultrasound showed a structurally normal heart with minor T-wave abnormalities. A follow-up EKG was planned for six months later. Notably, the mother was referred by us to rheumatology and was subsequently diagnosed with Sjögren's syndrome.

"Following the confirmation of NLE, a referral to pediatric cardiology was made, and subsequent ECG and cardiac ultrasound showed a structurally normal heart with minor T-wave abnormalities. A follow-up EKG was planned for six months later. Notably, the mother was referred by us to rheumatology and was subsequently diagnosed with Sjögren's syndrome."

Clinical Presentation in NLE:

Cutaneous Manifestations: The disease typically presents with cutaneous lesions, which can emerge at birth or in the first few weeks of life. These rashes are commonly found on the scalp, face, and neck, often forming a periorbital "raccoon-eye" pattern. The rash varies in appearance, showing characteristics like redness, circular shape with or without central scaling, and other forms such as polycystic plaques, urticarial, ulcerative, or bullous (4,5). While sunlight exposure is not a requirement for rash development, it can worsen existing lesions or trigger new ones. Infants with neonatal lupus erythematosus (NLE) may also exhibit symptoms like petechiae, persistent cutis marmorata, and discoid lesions (4)

Cardiac Manifestations: The most severe cardiac manifestation is congenital heart block (CHB), which carries a 2% recurrence risk in subsequent pregnancies. It is often irreversible and necessitates pacemaker placement (5). Conduction pathway damage usually occurs in utero and is already established at birth. Mortality associated with cardiac NLE, particularly CHB, remains significant, with a rate of around 10% in the neonatal period. The damage the conduction system usually occurs in utero (5). Other cardiac issues can include endocardial fibroelastosis or dilated cardiomyopathy (5). The risk factors for cardiac complications in NLE include maternal antibody status, antibody titers, timing of exposure, and previous affected siblings.

Long-term Concerns: While skin lesions usually resolve within the first six months of life, complications like CHB can have lifelong implications (4). Additionally, a history of NLE does not predispose the child to develop systemic lupus erythematosus (SLE) or other autoimmune diseases later in life.

Other Manifestations: NLE can also manifest with hematologic (thrombocytopenia, hemolytic anemia), hepatic (transient liver enzyme elevation), and neurologic (chorioretinitis, hydrocephalus, etc.) abnormalities.

Diagnostic Assessment:

Maternal Serology: Detection of anti-SSA/Ro and anti-SSB/La antibodies in the mother is diagnostic. The risk of NLE is higher if both antibodies are present, but not all infants born to mothers with these antibodies will develop NLE. This suggests a multifactorial etiology. Higher titers of these antibodies and earlier detection during gestation are associated with an elevated risk (7).

Infant Evaluation: Infants suspected of having NLE should undergo a complete blood count, liver function tests, and urgent referral to a pediatric cardiologist or at least the local emergency department for an electrocardiogram (ECG) (6).

Management and Follow-Up:

Cutaneous NLE: Topical corticosteroids and strict sun protection are the mainstays of treatment (6).

Cardiac NLE: Infants with cardiac NLE require close monitoring. Those with third-degree CHB may require a pacemaker (7).

Pregnancy Monitoring: Pregnant women with anti-SSA/Ro and/or anti-SSB/La antibodies should have fetal echocardiography to monitor for CHB.

"This case illustrates the complex and varied presentation of NLE in infants arising from the passive transfer of maternal autoantibodies. While the presented child primarily exhibited cutaneous manifestations and did not show major cardiac complications, this case emphasizes the need for a high index of suspicion, as early recognition of the diverse manifestations of NLE may be lifesaving."

Conclusion:

This case illustrates the complex and varied presentation of NLE in infants arising from the passive transfer of maternal autoantibodies. While the presented child primarily exhibited cutaneous manifestations and did not show major cardiac complications, this case emphasizes the need for a high index of suspicion, as early recognition of the diverse manifestations of NLE may be lifesaving. A collaborative, multidisciplinary approach with dermatology and cardiology specialties working together to ensure early detection, vigilant monitoring, and management is crucial for improving outcomes for affected infants.

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

Priya Jegatheesan, MD
she/her

Chief, Division of Neonatology

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

Santa Clara Valley Medical Center

Sangeeta Mallik, PhD
she/her

Director, Family-Centered Care Team

Santa Clara Valley Medical Center NICU

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

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

Assistant Professor of Pediatrics, Boston University

Neonatologist, Boston Medical Center

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Ethics and Wellness Column: Where Training Can Fall Short of Career Expectations and Work-Life Balance

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

The delicate interplay between professional time and personal well-being, particularly when work-life balance results in difficult personal choices, is critical to professional development. The adage that "timing is everything" sentiment holds across various spheres of life, including career trajectories and personal well-being. Medical professionals are guided by a commitment to patient care that often requires an urgent response, whether during the day or night, and continuity of care is emphasized in training programs. (1-3)

"Medical professionals are guided by a commitment to patient care that often requires an urgent response, whether during the day or night, and continuity of care is emphasized in training programs."

Our medical educational system, particularly at the university level and beyond, requires a commitment to dedication to learning, and as one enters a medical specialty, training often shapes individuals with the anticipation of a linear progression into their chosen profession. However, this reality is more nuanced, and individual circumstances may alter professional choices. Timing of decisions and decisions to pursue opportunities impact the professional landscape in which a trainee both "feels" competent, and educators and professional boards affirm her or his competency. (4, 5) Once an individual embarks on a career, the chance to revisit certain educational or training opportunities becomes more limited, and the available options may differ substantially. For instance, consider the training of cardiovascular surgeons and psychiatrists.

"Our medical educational system, particularly at the university level and beyond, requires a commitment to dedication to learning, and as one enters a medical specialty, training often shapes individuals with the anticipation of a linear progression into their chosen profession."

This is notably apparent in medicine, where career paths can be heavily influenced by decisions made during residency. The evolving landscape of residency programs, trending toward reducing working hours and overnight in-house calls completely, raises important questions about the long-term implications for trainees, patients, and their potential employers. While these changes may enhance immediate well-being and work-life balance, they inadvertently limit the breadth and depth of experiences contributing to a well-rounded physician regardless of specialty choice. (6)

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The shift in residency program structures is predicted to compromise the future opportunities available to residents and fellows both in clinical experience and a dedication to lifelong learning. The ability to handle in-house decisions both during the day and at night and the demands of a rigorous training program are often considered essential skills contributing to a successful and impactful career, especially in critical care and interventional specialties. (2, 5, 7) Limiting exposure to these experiences around the clock will make a workforce less prepared for the challenges of specific medical practices and may set a poor example for further expectations of future employers.

"The emerging trend of requiring remediation or retraining for incoming attending physicians to an institutional academic and practice culture and mandating new graduates to work elsewhere before applying for specific positions suggests a growing concern about the preparedness of recent graduates."

The emerging trend of requiring remediation or retraining for incoming attending physicians to an institutional academic and practice culture and mandating new graduates to work elsewhere before applying for specific positions suggests a growing concern about the preparedness of recent graduates. (8, 9) While the intention may be to ensure a higher competency standard, it raises questions about the impact on individuals seeking a balance between their professional and personal lives. (10)

"The ability to handle in-house decisions both during the day and at night and the demands of a rigorous training program are often considered essential skills contributing to a successful and impactful career, especially in critical care and interventional specialties. Limiting exposure to these experiences around the clock will make a workforce less prepared for the challenges of specific medical practices and may set a poor example for further expectations of future employers."

While pursuing work-life balance, it is crucial to strike a harmonious equilibrium that prepares trainees adequately for the challenges they will face in their respective specialties and specific practice requirements. Striking the equilibrium between well-being and professional development is an ongoing challenge, and the direction taken by educational and medical training programs requires careful consideration lest graduates fail to meet the assumed obligations of their future colleagues who survived a more demanding training process. (2) As these issues are carefully addressed and navigated by program directors, assessing whether the quest for immediate work-life balance is inadvertently compromising the preparedness of individuals in their chosen specialty is imperative to both excellence in practice and commitment to patients. (5, 11, 12)

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Letters to the Editor

Letter to the editor: "Clinical Pearl: Maternal Marijuana Use and Its Lasting Impact"

Dear Editor:

We sincerely appreciate student-doctor Suha Godil's article, "Fellows Column: Clinical Pearl: Maternal Marijuana Use and Its Lasting Impact." In this article, the author chooses to address a phenomenon that has become almost ubiquitous in our patient populations: marijuana consumption. As "natural" and "homeopathic" approaches to health care continue to gain widespread prevalence, patients often choose to treat their symptoms of anxiety, stress, nausea, and loss of appetite with marijuana in place of traditional pharmacologics. A 2017 Gallup poll found that 45% of Americans have tried marijuana at least once in their lives, and 15% have tried marijuana in the past year (1). Patients are generally unaware of the side effects of marijuana and often overlook informing their healthcare providers about their consumption unless prompted. Therefore, now more than ever, understanding the rates of prenatal and maternal marijuana consumption and the associated outcomes for neonates is a crucial subject that warrants further analysis.

"Patients are generally unaware of the side effects of marijuana and often overlook informing their healthcare providers about their consumption unless prompted. Therefore, now more than ever, understanding the rates of prenatal and maternal marijuana consumption and the associated outcomes for neonates is a crucial subject that warrants further analysis."

In this article, the author takes the opportunity to explore research findings on maternal marijuana usage and its lasting effects on their infants. We found the author's focus on the social justice aspect of marijuana legalization to be important, as it provides insight into the rising rates of marijuana consumption in the United States. Though one of the primary narratives of marijuana legalization was rooted in social equality, one study highlighted that transgenerational health impacts are disproportionately affecting minority populations, shedding light on a broader spectrum of consideration (2). However, despite the trend of the legalization of marijuana throughout the United States, the author notes that recreational consumption is only permitted in 23 states, two territories, and the District of Columbia. With marijuana consumption remaining federally illegal and the ethical concerns associated with providing pregnant mothers with marijuana, the topic of marijuana consumption in expectant and new mothers remains a complex subject of research. Consequently, research on marijuana consumption in pregnant patients focuses on retrospective cases with adverse outcomes.

"It has been shown that oral administration of THC offers a greater absorption at 90% but is limited by its bioavailability (less than 20%) secondary to first-pass hepatic metabolism (3). In contrast, smoking marijuana bypasses the first-pass hepatic metabolism and results in reduced THC absorption (2-56%) due to its degradation from the process of pyrolysis (3)."

Furthermore, this article does an effective job of covering maternal marijuana use from the prenatal to the postnatal period. The connection between marijuana use during pregnancy and adverse perinatal and neurodevelopmental outcomes is alarming. However, we questioned whether the amount or route of marijuana consumption during pregnancy could be a deciding factor in the adverse perinatal and neurodevelopmental outcomes seen in the newborn period of these exposed infants. It has been shown that oral administration of THC offers a greater absorption at 90% but is limited by its bioavailability (less than 20%) secondary to first-pass hepatic metabolism (3). In contrast, smoking marijuana bypasses the first-pass hepatic metabolism and results in reduced THC absorption (2-56%) due to its degradation from the process of pyrolysis (3).

"However, at almost three weeks of life, the infant began showing signs of sepsis with elevated WBCs and CRP, presenting an intriguing aspect of the scenario. It begs the question of whether we can infer that prenatal marijuana exposure contributed to this septic episode, considering the time frame."

It would be interesting to explore different dosages and frequencies of marijuana consumption during pregnancy and their subsequent effects in utero. An interesting point made in this article, "No amount of marijuana consumption is safe during pregnancy, as it is associated with adverse perinatal and neurodevelopmental outcomes," warrants further evaluation. The author goes on to explore a case in which a premature baby boy was born at 30.2 weeks to a mother who tested positive for THC at the time of de-

livery. Despite the mother's THC-positive status, the infant tested negative for THC. While the infant required intubation at delivery and initially faced several comorbidities, including RDS, hypoglycemia, hypermagnesemia, and hyperbilirubinemia, all had successfully resolved with time and appropriate management. However, at almost three weeks of life, the infant began showing signs of sepsis with elevated WBCs and CRP, presenting an intriguing aspect of the scenario. It begs the question of whether we can infer that prenatal marijuana exposure contributed to this septic episode, considering the time frame. Further research should be done to explore this topic.

"Another topic brought up in this paper that warrants further evaluation is hyperemesis gravidarum (HG), an extreme version of nausea and vomiting during pregnancy. Interestingly, little research has been done regarding effective treatment for this condition (4)."

Another topic brought up in this paper that warrants further evaluation is hyperemesis gravidarum (HG), an extreme version of nausea and vomiting during pregnancy. Interestingly, little research has been done regarding effective treatment for this condition (4). In one study, respondents stated that they used cannabis primarily because prescribed medications were ineffective. Although the survey approach has its limitations and should therefore be interpreted with caution, cannabis was self-reported to be more effective than prescription medications in alleviating HG symptoms and enabling pregnancy weight gain. Therefore, depending on safety profiles, randomized, double-masked, placebo-controlled trials of cannabis and other antiemetics are warranted to determine whether cannabinoids can provide an effective alternative treatment for HG (4).

"Therefore, depending on safety profiles, randomized, double-masked, placebo-controlled trials of cannabis and other antiemetics are warranted to determine whether cannabinoids can provide an effective alternative treatment for HG (4)."

"Marijuana consumption in the United States continues to increase rapidly, including among expectant and new mothers. The decreased perception of harm among marijuana users poses a significant risk to the healthcare system, and we agree with the author's notion that a multidisciplinary approach toward patient education could serve as a potential solution."

Marijuana consumption in the United States continues to increase rapidly, including among expectant and new mothers. The decreased perception of harm among marijuana users poses a significant risk to the healthcare system, and we agree with the author's notion that a multidisciplinary approach toward patient education could serve as a potential solution. Therefore, healthcare professionals need to obtain a detailed history, often directly prompting marijuana consumption, and to be aware of the potential risks for both the mother and the fetus. Conversations with our patients should prioritize open communication and be free of judgment. Future research should consider safer administration methods, ethically comparing low-dose marijuana consumption with traditional pharmacological approaches, and marijuana alternatives for common pregnancy complications, including nausea, anxiety, and emesis. For now, the discussion surrounding maternal marijuana use during pregnancy is both nuanced and crucial within the realm of maternal-fetal health. It reminds us of the intricate relationship between maternal behavior and fetal growth.

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Sincerely,

Marian Banh, OSM-III, Rohan Chawla, OSM-III, Sara Kohandani, OSM-III, Nobel Enayati, OSM-III

Dear Physicians to Be:

The subject of marijuana is a troubling one. Recognizing the legal and, in some cases, moral obligation to decriminalize its use, the effects of its more extensive albeit now legal consumption are becoming more evident. An especially troubling area is the fetal-maternal dyad, which naturally progresses to the infant-maternal dyad. In certain areas, the fetus is not considered a separate entity until the time of birth. Maternal consumption of cannabis may or may not be regulated, and fetal exposures may be very high, even over laboratory studies designed to study the effects of near "toxic" exposures. (1)

The reasons for this are myriad, but there must be quantization beyond legalization. Just like there are certain levels that society establishes for other controlled substances, such as alcohol, it may not be unreasonable to come to terms with the fact that cannabis comes in many quantities and concentrations. Its effects at these different concentrations on mother and baby will depend on these exposures' timing, level and duration. (2) What is inherently apparent is that there seem to be only two sides to the analysis. We need a system that handles the shades of grey between the two extremes. (3)

" Just like there are certain levels that society establishes for other controlled substances, such as alcohol, it may not be unreasonable to come to terms with the fact that cannabis comes in many quantities and concentrations. Its effects at these different concentrations on mother and baby will depend on these exposures' timing, level and duration."

The state of California has attempted to handle this issue, which they understood would be a problem as they decriminalized cannabis several years ago. There is a proscription regarding the legal use of this formerly controlled substance, which has led to a proliferation of a recreational cannabis industry that has burgeoned in many areas of the state. Still, this change in the legal environment came with significant baggage. Adult maternal use was "fine." Use by minors and those who "fostered" or "caused to foster" the use by a minor of any cannabis were punishable by fines and up to seven years in prison. The obvious thought is, "Let's protect the children by preventing them from getting into their parent's stash."

Yet, translation to the real world is somewhat different. (4) What about a mom who regularly used cannabis during pregnancy and who now wants to breastfeed? To the extent that she is still using or secreting cannabis-related compounds, this practice can be illegal in California. The law is causally related as well. Our "Baby Friendly" initiatives run smack into the legal requirement. An administrator, physician, nurse, or even a well-meaning family member who encourages breastfeeding in the hospital is also at risk for the same penalty regardless of whether they knew of the mother's cannabis status.

"An administrator, physician, nurse, or even a well-meaning family member who encourages breastfeeding in the hospital is also at risk for the same penalty regardless of whether they knew of the mother's cannabis status."

Further, the Department of Health Services will be involved if the mother tests positive for cannabis even if she was using it legally during pregnancy on the advice of her obstetrician, who recommended it for hyperemesis gravadum. Should the mother attempt to breastfeed, she could be looking at serious legal problems, especially if she continues to indulge post-partum. (5)

Meanwhile, studies have shown concern over outcomes in these neonates exposed to increasingly high levels of cannabis. Historical references and beliefs as to the safety of cannabis cannot be used to compare to modern reality because the level of exposure is just so different. (6) For cannabis and its metabolites to be implicated in other long-term problems, including those related to the immune system, requires much more research and long-term follow-up. (7) But why take the risk?

"Historical references and beliefs as to the safety of cannabis cannot be used to compare to modern reality because the level of exposure is just so different. (6) For cannabis and its metabolites to be implicated in other long-term problems, including those related to the immune system, requires much more research and long-term follow-up. (7) But why take the risk?"

In sum, we have just scratched the surface of an issue that will continue to cause management problems in both medical and legal dimensions for the foreseeable future. As for infant health and the presumption that cannabis was "safe," the pendulum is in motion and not swinging in a reasurring direction.

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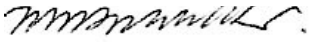
Sincerely,



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Erratum (Neonatology Today November, 2023)

Neonatology Today is not aware of the erratum affecting the November, 2023 edition.

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

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Navigating Toward Neonatology: Neonatal Sepsis

Benjamin Hopkins, OSMIV; Hun-Seng Chao, M.D.

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

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

Currently, I am interviewing for pediatric residency programs. Knowing that I am heading toward a fellowship, my application prioritized "Categorical pediatrics" programs with high match rates in neonatology and programs that will offer me broad exposure to neonatal patients.

Earlier this year, I had the privilege of rotating through Cedars-Sinai's NICU. It was an incredible experience, with a multitude of complex patients and many unique case exposures in a fully equipped level IV NICU. The attending neonatologists I worked with were well-educated, excellent instructors, and offered exceptional patient care. I also had the opportunity to work with neonatal fellows, all eager to learn and helped guide me and my fellow medical students on best practices. Nearly all of my time was spent in the NICU, with an occasional run down to the delivery room for a crash caesarian.

One of my patients on this rotation was an ex-32-week female twin B. The delivery was uneventful, and both twins had a honeymoon period of about five days before they each developed their individual issues. Along with the multitude of problems that are standard when born at 32 weeks, twin A was having frequent apnea/bradycardia/dyspnea events, while twin B contracted bacteremia. Both twins were empirically treated with ampicillin and gentamicin and received caffeine and respiratory support via CPAP. Gavage feeds were being given based on the total fluid protocols of the hospital but were held for twin B when bacteremia was found, and they were transitioned to TPN. Blood cultures (BCx) were taken, and then she was started on ampicillin and gentamicin. A complete blood count (CBC) showed elevated white count, and the C-reactive protein (CRP) was markedly evaluated into the 100's. The BCx showed growth resistant to gentamicin, so it was transitioned to ceftriaxone. The following day, the continued growth on the next BCx showed methicillin-resistant *Staph aureus* (MRSA), so vancomycin was given. There was continued growth on BCx for the next four days, and a central line was being considered for a prolonged course of antibiotics. With the

"One of my patients on this rotation was an ex-32-week female twin B...Along with the multitude of problems that are standard when born at 32 weeks...twin B contracted bacteremia.... Blood cultures (BCx) were taken, and then she was started on ampicillin and gentamicin. A complete blood count (CBC) showed elevated white count, and the C-reactive protein (CRP) was markedly evaluated into the 100s. The BCx showed growth resistant to gentamicin, so it was transitioned to ceftriaxone. The following day, the continued growth on the next BCx showed Methicillin-resistant Staph aureus (MRSA), so vancomycin was given. There was continued growth on BCxs for the next four days,"

continued growth, we consulted Infectious Disease, who started following the case and making recommendations. With two more days of continued growth, Infectious Disease recommended adding rifampin, which has been shown in some studies to increase the capability to penetrate the cells of MRSA (1). With this addition, we had two negative BCx and a negative growth time of 48 hours and could proceed with the central line. This was the third patient in the past month that required the addition of rifampin to clear sepsis. Infectious Disease and the contamination management team were consulted to look into what might be causing the increased incidence in the NICU.

"With two more days of continued growth, Infectious Disease recommended adding rifampin, which has been shown in some studies to increase the capability to penetrate the cells of MRSA."

Bacteremia, and in turn, sepsis, is a challenging diagnosis as there is a large amount of overlap between the clinical signs of sepsis and the regular physiological patterns that newborns transition through post-delivery. Likewise, bacteremia can occur without clinical signs or symptoms (2). The AAP offers three sets of guidelines for managing sepsis: sepsis calculator, categorical risk assessment, and risk assessment on clinical conditions using

serial observations (2). The sepsis calculator is the most used strategy; it uses the clinical condition of the first 6–12 hours of life and continuous and categorical variables to assess the risk of sepsis (2). Using the sepsis calculator has been shown to reduce the use of antibiotics, laboratory testing, and admission to the NICU; however, it also misses a large proportion of newborns with sepsis (2). The AAP guidelines have significantly benefited the rates of antibiotic use, but it is also crucial to approach each patient as an individual.

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Interprofessional collaboration is essential in all patient care but is pivotal in caring for neonatal critical care patients. Collaboration in the NICU has been shown to improve morbidity rates, directly decreasing deaths from chronic lung disease and extrauterine growth restriction (3). Collaboration within the first hour of life, known as the Golden Hour, has improved short- and long-term outcomes (4). With an interprofessional-multidisciplinary team of providers, there are multiple areas for miscommunication, so being straightforward and timely will help improve patient outcomes. Coordination between providers during and after delivery is crucial in improved patient care (4). It has also been shown that standardizing practices during the first hour leads to improved outcomes (4). Of course, there are hidden biological, genetic, or cultural variables that can affect the morbidity rates of critical care neonates; thus, it is essential to bring on specialists early in the course of patient care.

One of the great things about healthcare is working with other professionals from all areas who can help guide and get the patient to full health. Few other specialties utilize interprofessional-multidisciplinary teamwork as often as the NICU does. It is important to remember that not any one provider can know everything, so we must use each other's strengths and areas of expertise to provide the best care possible.

"Collaboration in the NICU has been shown to improve morbidity rates, directly decreasing deaths from chronic lung disease and extrauterine growth restriction. Collaboration within the first hour of life, known as the Golden Hour, has improved short- and long-term outcomes."

This month, I had the pleasure of talking with Dr. Hun-Seng Chao, a retired neonatologist with experience in multiple states and hospital systems. We spoke about the current environment of the medical field as well as important aspects to consider, professionally and personally, when pursuing neonatology.*

My first question is, **"What qualities are 'most essential' to excel as a neonatologist?"**

Certainly, compassion would be up there, especially with their parents, because they're going through probably the worst time of their lives with their baby, depending on why they're in the NICU. It could be a very, very ill child, premature child, one with severe genetic abnormalities, or those two or three-day rule-out infections. But still, even with the three-day rule out of infection, hearing your baby is going to the NICU is very anxiety-provoking. And so, compassion, I feel, can go a long way, not just towards family and parents, but also with coworkers, especially in critical care-type scenarios where stress and anxiety can run high. On the provider side, having compassion towards each other can do a lot of good for teamwork and the best patient care overall.

"...compassion, I feel, can go a long way, not just towards family and parents, but also with coworkers, especially in critical care-type scenarios where stress and anxiety can run high. On the provider side, having compassion towards each other can do a lot of good for teamwork and the best patient care overall."

Next, **"What do you now know that you wish you knew before going into neonatology?"**

I retired years ago, and neonatology and pediatrics are generally different now than when I retired. Having worked for Pediatrix as part of a corporation has its advantages and disadvantages. The advantage is that they take care of all the billing issues. I didn't have to worry about budget or insurance approval for anything—that was lovely while going through it. However, these days, corporations have taken over medicine in general. For the regular practitioner, and I'm not talking about NICU because it is hospital-based, they have to see more patients, get reimbursed less, and have less control over their practice. I also heard that the malpractice insurance was outrageous and almost impossible

to afford in solo practice. It'll be interesting to see where things go and how they develop if they go even further or pull back.

Additionally, **"What would you encourage future neonatologists to prioritize and be involved in?"**

There was nothing specific that I would have recommended; however, there were particular rotations that I liked a lot. I did pediatric surgery rotations both in med school and in residency. I enjoyed it, and of course, they all say that neonatologists are really just frustrated surgeons. We like doing procedures but prefer doing something other than the every-other-night call that many surgery programs do. Another thing would be an infectious disease rotation. They are the closest other specialty you'll work within the NICU because almost every single patient in there is being monitored or ruled out for an infection, plus so many of them have been on antibiotics at one time or another.

Additionally, I recommend an integrated medicine program. I would look into doing a few weeks there because you will learn different things from what they teach you in regular med school. Integrative medicine is more about nutrition and supplements, which we're very ignorant about in our usual medical practice. For patients and caregivers, nutrition can make a huge difference in the quality of life.

Further, **"How do you think the critical care scenario of the NICU affects the chance of burnout? And how should we counter it?"**

Well, first of all, most babies get better, so for the most part, it is a happy subspecialty. Now, of course, some patients do die. I am a very spiritual person, and I've already dealt with death in my personal life before becoming a neonatologist. One of the classes I took in college was on death and dying, and I think we cried through every single class. But spirituality helps; it has helped a lot for me to have already accepted that death is a part of life, and I think sometimes you have to realize that if the baby dies, it's not necessarily your failure or fault or your team's fault. I believe in Eastern religions and think life happens the way it's supposed to. That helped me deal with a lot with things not going the way I wanted them to or having patients die. If the baby dies despite that, and you did everything you could and the best you could, then that's not a failure on your part. If there's nothing more you could have done to prevent this situation from happening, then things happened they would have anyway.

Lastly, **"What are you currently working on?"**

I have retired for a few years and now write futuristic detective fiction novels. It's set in 2060 in Los Angeles. I'm working on my second one, about two-thirds of the way through. I self-published the first one a few years ago, and this is the second in the series. It has the same main characters on different cases. However, I have also used my neonatology training to help with editing this newsletter.

Each patient has something to teach us and deserves the best care possible with all the education and cooperation we can offer. I appreciate the NICU's dedication to a collaborative work environment emphasizing interdisciplinary care. I also want to send a special thank you to Dr. Hun-Seng Chao for meeting with me this month. Continue to follow along as I navigate my way to becoming a neonatologist.

*Answers paraphrased from a voice call.

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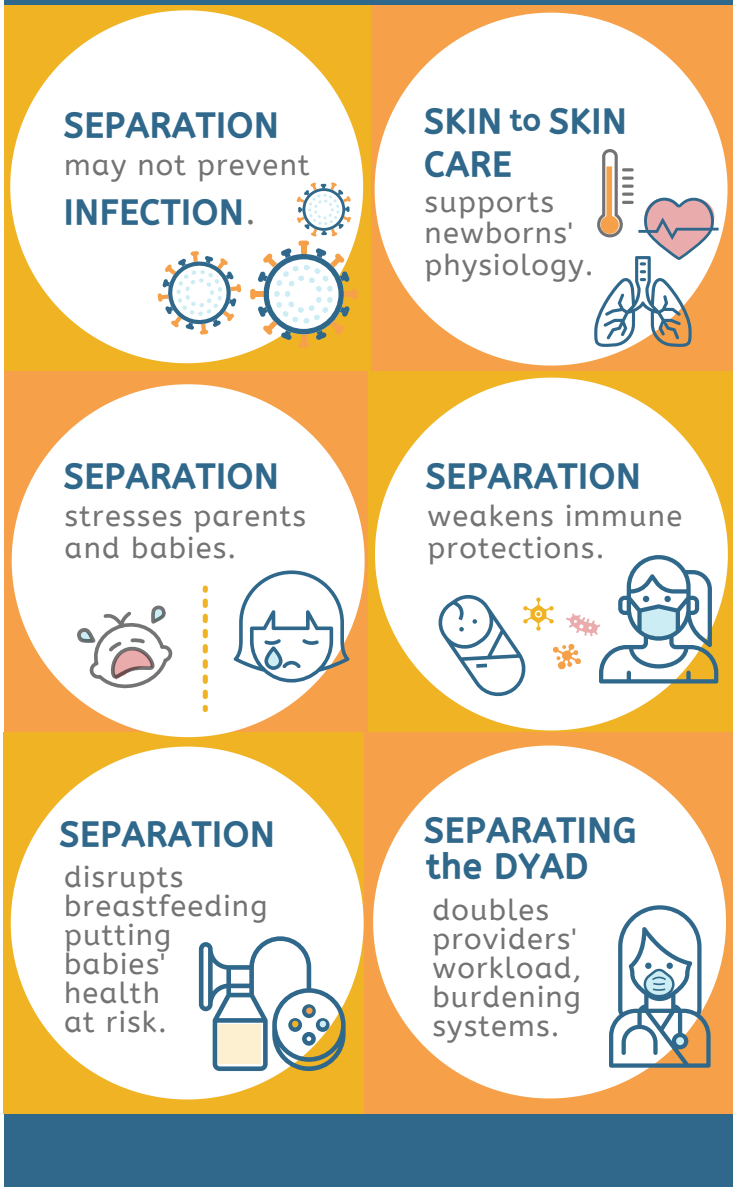
Should Infants Be Separated from Mothers with COVID-19?

FIRST DO NO HARM



BASED ON THE ARTICLE:

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

Peer Reviewed

Fellows Column: Early Identification of PURA Syndrome in a Neonate: Implications on Diagnosis and Management

Samir Alsalek, BS, Lucas J. Saporito, BS, Grace J. Noh, MD, Michael S. Chang, MD, Huy N. Truong, MD

Abstract:

Background: *Protein-rich element binding protein A (PURA) syndrome is a genetic neurodevelopmental disorder that results in profound neurodevelopmental delay and intellectual disability. Few cases of PURA syndrome have been recognized in neonatal life, partly due to heterogenous clinical presentation, low clinical suspicion, and symptom progression that results in a more thorough workup later in life.*

Case Presentation: *We report the case of a newborn who presented with hypotonia, feeding difficulties, and respiratory distress within the first hours of birth. Neonatal screening, infectious workup, and imaging were unremarkable. Clinical exome sequencing revealed de-novo, a pathogenic variant in the PURA gene. The patient received comprehensive rehabilitative care and social support. At one-year follow-up, the patient continued to experience feeding difficulties and apneic events and demonstrated significant neurodevelopmental delay.*

Conclusion: *This report documents the consideration and diagnosis of PURA syndrome in the neonatal period and describes the implications of early diagnosis on prompt symptomatic management and patient outcomes at 1-year follow-up.*

Introduction:

PURA syndrome is a rare genetic, neurodevelopmental disorder that arises from variants in the *PURA* gene and presents with neonatal hypotonia, feeding difficulties, and severe global intellectual and developmental delay. The syndrome was first described in 2014 and is often identified in early childhood in individuals with unexplained severe intellectual disability and neurodevelopmental delay, using clinical or whole exome sequencing (1-3). The *PURA* gene is located on chromosome 5q31.3 and encodes PUR-α, a ubiquitous, purine-rich, DNA- and mRNA-binding protein essential in mammalian brain development (4-6). *PURA*-related disorders typically occur de novo, but inheritance from an unaffected mosaic parent has also been reported (3).

"PURA syndrome is a rare genetic, neurodevelopmental disorder that arises from variants in the PURA gene and presents with neonatal hypotonia, feeding difficulties, and severe global intellectual and developmental delay...PURA-related disorders typically occur de novo, but inheritance from an unaffected mosaic parent has also been reported (3)."

Notably, most reported cases of PURA syndrome in the current literature have been detected in late infancy or early childhood. This is expected given that the intellectual and developmental features of the condition become more pronounced with age, prompting thorough investigation. However, detection of PURA syndrome in the neonatal period has seldom been reported, and the implications of early detection on prognosis and management remain unclear (7,8). Diagnosis in the neonatal period is difficult mainly due to the low index of suspicion and broad, non-specific presentation. In this report, we present the case of a neonate with PURA syndrome that was identified and promptly managed during the first few weeks of life. We report follow-up outcomes at one year of life and discuss the potential implications of early diagnosis.

"A 6-hour-old female infant was born to a 36-year-old G6P5 at 39 weeks and 3 days gestation via spontaneous vaginal delivery. The infant weighed 3910g and had APGAR scores of 7 and 9 at 1 and 5 minutes, respectively. At birth, the infant was in the 87th percentile for weight, 94th percentile for length, and 67th percentile for head circumference. Pregnancy was complicated by polyhydramnios, maternal obesity, clindamycin-resistant Group B Strep, and Varicella non-immunity."

Case Presentation:

A 6-hour-old female infant was born to a 36-year-old G6P5 at 39 weeks and 3 days gestation via spontaneous vaginal delivery. The infant weighed 3910g and had APGAR scores of 7 and 9 at 1 and 5 minutes, respectively. At birth, the infant was in the 87th percentile for weight, 94th percentile for length, and 67th percentile for head circumference. Pregnancy was complicated by polyhydramnios, maternal obesity, clindamycin-resistant Group B Strep, and Varicella non-immunity. The parents are of Hispanic descent and non-consanguineous, with four other children. There is a family history of isolated Down Syndrome on the maternal side but no history of neuromuscular disorders, major birth defects, developmental delay, or other significant inherited conditions in the family. Shortly after birth, the infant was noted to be hypotonic, with absent suckling during the first 6 hours and intermittent, poor suckling at 12 hours. The infant also had intermittent episodes of slowed respiration and desaturation, which improved on the nasal cannula. X-ray imaging of the chest and abdomen revealed no abnormalities (**Figure 1**). The infant was subsequently transferred to a different facility's neonatal intensive care unit (NICU) for further evaluation and management. During transportation, the infant was placed on non-invasive intermittent positive pressure ventilation (NIPPV) due to respiratory insufficiency and started on antimicrobial therapy for suspected infectious disease.

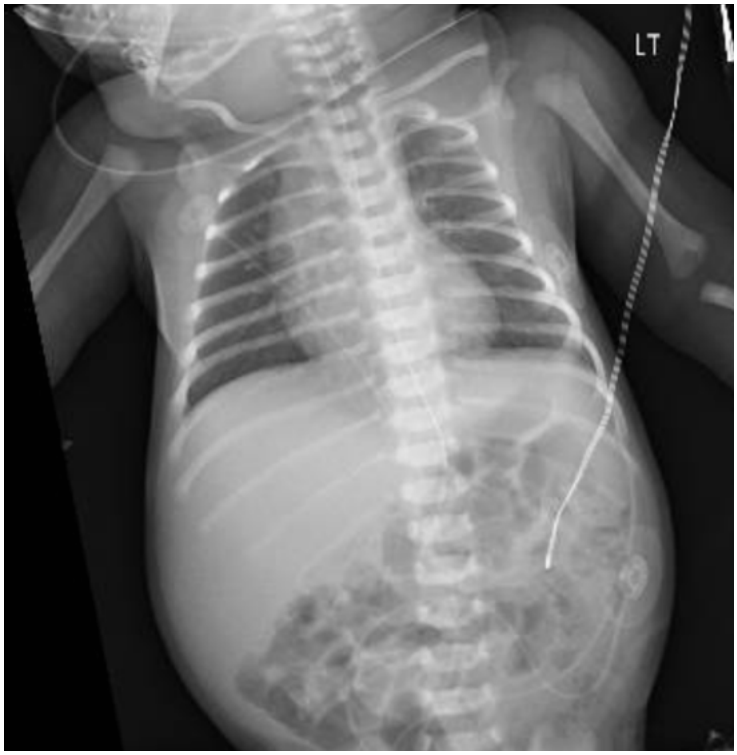


Figure 1. X-ray imaging of the chest and abdomen demonstrating no evidence of active respiratory infection or bowel obstruction. A nasogastric tube tip can be seen in the distal stomach.

Upon arrival to the NICU, the infant continued to have decreased tone, poor suckling and feeding, hypotonia, and absence of the Moro reflex. No dysmorphic facial features or asymmetric muscle activity were noted. Blood cultures investigating neonatal sepsis were negative, and an ultrasound of the head revealed no evidence of intraventricular hemorrhage. Routine newborn screening also revealed no abnormalities. A nasogastric tube was placed to provide feeds due to persistently poor feeding. On day 2, the infant was noted to have intermittent, brief ankle jerks and was later observed to have stronger, single jerks of the right upper extremity. Due to concern for seizures, phenobarbital was initiated, and cerebrospinal fluid (CSF) analysis, electroencephalogram (EEG), and magnetic resonance imaging (MRI) studies were obtained. Neurologic evaluation of the infant revealed moderate-to-severe hypotonia and seizures with normal reflexes, normal eye movements, and no other focal neurologic deficits. The results of the CSF analysis were normal. EEG was normal, with no extremity jerks or seizure activity observed during the study. MRI of the brain showed normal neonatal myelination pattern and structure, with mild enlargement of the subarachnoid spaces but no evidence of effusion or hydrocephalus (**Figure 2**). Microarray and methylation testing for Angelman and Prader-Willi syndrome were also negative. Hypersomnolence was noted on day 4 of life, and the phenobarbital maintenance dose was reduced. Due to persistent hypotonia and feeding difficulties, clinical whole exome sequencing was obtained on day 29 of life, revealing de-novo, heterozygous pathogenic variant (c.573del; p.(A192Rfs*33)) in the *PURA* gene.

"...clinical whole exome sequencing was obtained on day 29 of life, revealing de-novo, heterozygous pathogenic variant (c.573del; p.(A192Rfs*33)) in the PURA gene."

Following the diagnosis of PURA syndrome, seizure prophylaxis was switched to levetiracetam to minimize somnolence. A second EEG study continued to show normal activity, and no further convulsive episodes were observed. Due to continued poor feeding, a gastrostomy tube was placed for enteral feeds and weight-gain support. The patient's family was counseled after the diagnosis, and appropriate follow-up appointments, support, and resources were provided. The infant was discharged two months after birth and was breastfeeding around 75% of all intakes at discharge. The infant was neurologically stable on levetiracetam with increased activity and marked improved respiratory status on the nasal cannula.

On follow-up examination at three months of age, the patient had improvement in feeding and was in the 85th percentile for head circumference, 98th percentile for weight, and 91st percentile for height. The infant continued to demonstrate developmental delay and had episodes of feeding-associated respiratory distress, including inspiratory stridor, aspiration, and cough, requiring supplemental oxygen. At 1-year follow-up, the patient displayed significant developmental delay, including absence of expressive language and delay of fine motor function. The infant relied on supplemental nighttime oxygen for mixed central and obstructive apneic events and gastrostomy for most feeds and received speech, physical, and pulmonary therapy services.

"PURA syndrome is a genetic, heterogenous, neurodevelopmental disorder characterized by neonatal hypotonia, feeding difficulties, respiratory distress, seizures, and progression to moderate-to-severe developmental delay and learning disability. It may additionally present with hypersomnolence, movement abnormalities, epilepsy, and congenital disabilities of the heart, urogenital tract, and skeleton. Infants with PURA syndrome may or may not have dysmorphic features, including high anterior hairline, hypotonic face, almond-shaped palpebral fissures, full cheeks, well-defined philtrum, and retrognathia (2, 3, 6)"

Discussion:

PURA syndrome is a genetic, heterogenous, neurodevelopmental disorder characterized by neonatal hypotonia, feeding difficulties, respiratory distress, seizures, and progression to moderate-to-severe developmental delay and learning disability. It may additionally present with hypersomnolence, movement abnormalities (e.g., dystonia, dyskinesia, dysconjugate eye movements), epilepsy, and congenital disabilities of the heart, urogenital tract, and skeleton. Infants with PURA syndrome may or may not have dysmorphic features, including high anterior hairline, hypotonic face, almond-shaped palpebral fissures, full cheeks, well-defined philtrum, and retrognathia (2, 3, 6). Despite these features, PURA syndrome remains difficult to diagnose in practice, with low rates of detection in neonatal life (7).

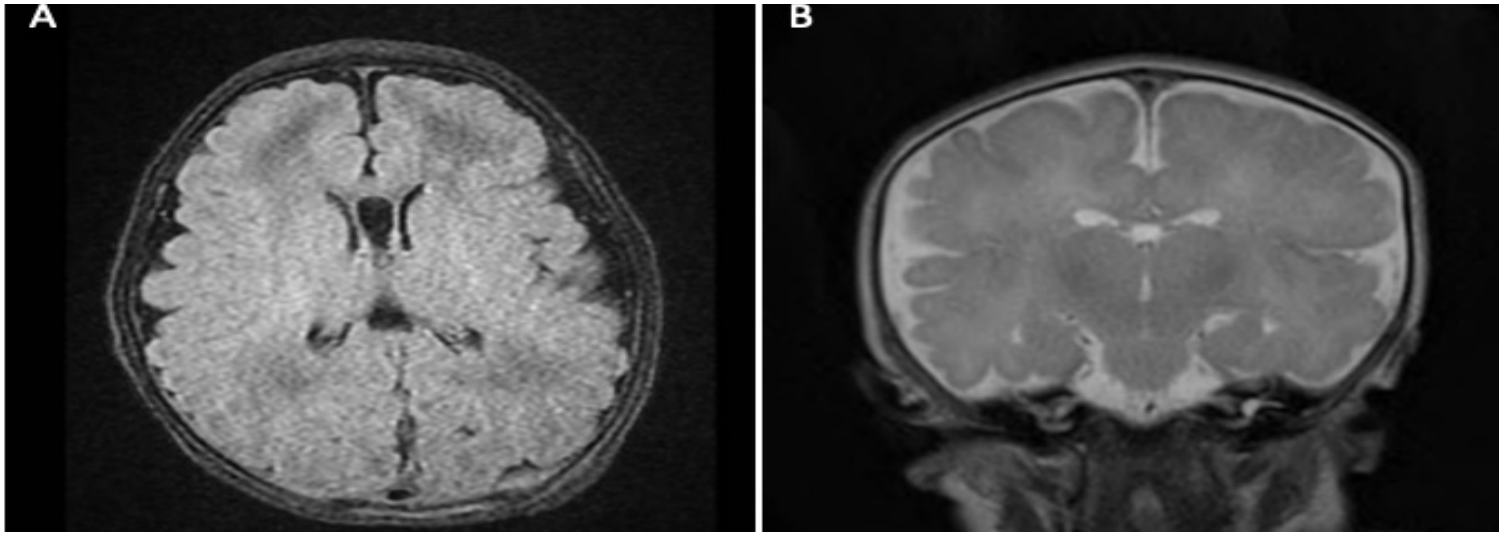


Figure 2. Axial (A) and coronal (B) MRI imaging of the brain demonstrating mild enlargement of the subarachnoid spaces with no extra-axial or subdural effusion and no hydrocephalus. No evidence of parenchymal or intraventricular hemorrhage is seen.

As a recently described genetic syndrome with variable and multi-system phenotypic presentation, PURA syndrome has no definitive treatment, and the mainstay of management is through symptomatic, respiratory, and nutritional support, along with rehabilitation, social support, and parental education. Recent reports have suggested that PURA may share clinical features and pathophysiology with neuromuscular junction disorders (e.g., congenital myasthenic syndrome), indicating potential benefit for acetylcholinesterase inhibitors (8,9). Our patient experienced significant respiratory failure in early life and continues to display respiratory distress at one-year follow-up, which may add clinical support to this hypothesis. However, more query is needed into the exact pathophysiology of the disease and the value of neuromuscular therapies in improving respiratory outcomes. Nonetheless, supportive care should be initiated as early as possible in suspected PURA cases, ideally by a multidisciplinary team of providers, including neonatologists, neurologists, geneticists, respiratory therapists, gastroenterologists, and speech and physical therapists. Special attention should be given to the close monitoring and support of respiration, feeding difficulties, and seizure prophylaxis (6).

"As a recently described genetic syndrome with variable and multi-system phenotypic presentation, PURA syndrome has no definitive treatment, and the mainstay of management is through symptomatic, respiratory, and nutritional support, along with rehabilitation, social support, and parental education."

Our report presents one of the few documented cases of PURA syndrome detection in a neonate. Our patient had profound hypotonia, respiratory distress, and feeding difficulties within the first few hours of life. Although symptomatic management was initiated promptly, extensive workup and genetic sequencing allowed for the precise diagnosis and mobilization of additional resources for the patient and family. This included social support, rehabilitation, and longitudinal patient engagement and education. In addition to excluding alternative diagnoses, early detection of PURA may allow for complete care planning, early coordination between the clinician and family, and prospective follow-up of prognosis and treatment outcomes. In this case, diagnosis within neonatal life allowed for our patient's early rehabilitative and psychosocial services. Future research should investigate the long-term developmental and physical outcomes of PURA patients with early identification and therapy.

Conclusion:

Despite its rarity and heterogeneous presentation, the present case demonstrates how clinical suspicion and genetic analysis can lead to a successful neonatal diagnosis of PURA syndrome in the setting of a non-specific constellation of symptoms. Early detection of PURA syndrome allows for prompt initiation of appropriate symptomatic management, care planning, and access to supportive resources for the patient and family. Further research is needed to determine how early management impacts long-term outcomes in PURA syndrome patients.

"Early detection of PURA syndrome allows for prompt initiation of appropriate symptomatic management, care planning, and access to supportive resources for the patient and family."

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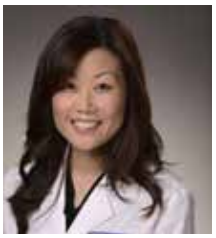

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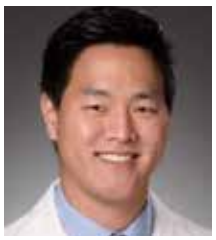

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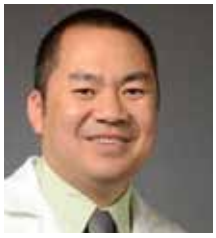

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- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
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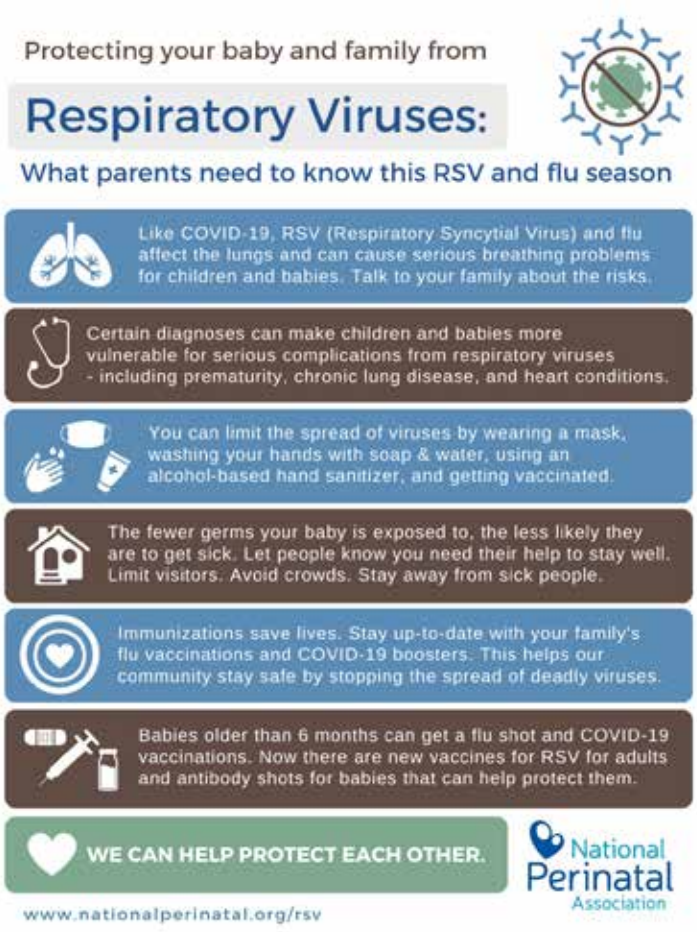

First Candle: Recognizing and Addressing Causes Behind the Infant Mortality Gap

Alison Jacobson

first candle

Saving babies. Supporting families.

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

"The year 2023 is a reminder to healthcare professionals in maternal and infant health disciplines that the U.S. is not where it should be but also that we know more about the reasons why, and this tells us what we must do in 2024 and beyond."

The year 2023 is a reminder to healthcare professionals in maternal and infant health disciplines that the U.S. is not where it should be but also that we know more about the reasons why, and this tells us what we must do in 2024 and beyond.

In November, the Vital Statistics Rapid Release report from the National Center for Health Statistics told us that the 2022 provisional infant mortality rate for the U.S. rose 3% from 2021, the first year-over-year increase in 20 years, after a 22% decline between 2002 – 2021. (1)

Rates also went up for babies born preterm, with significant increases from maternal complications and bacterial sepsis. We also saw SUID rates increase significantly for non-Hispanic Black infants, further widening the disparities with non-Black infants.

"Rates also went up for babies born preterm, with significant increases from maternal complications and bacterial sepsis. We also saw SUID rates increase significantly for non-Hispanic Black infants, further widening the disparities with non-Black infants."

In addition, the 2023 March of Dimes report card (2) gave the U.S. a D+ grade for the second consecutive year in a row due to its preterm birth rate and persistent racial disparities in maternal and infant health, ranking it "among the most dangerous developed nations for childbirth."

What One Challenging Region Can Tell Us:

Exploring the underlying causes is key to changing this, and to that end, we are working with the Healthy Mothers Healthy Babies Coalition of Georgia and the U.S. Health & Human Services to assess infant safe sleep policies with regard to structural racism and to develop community-based practices designed to reduce Black infant sleep-related mortality in the Atlanta, Georgia region.

Georgia has the 11th highest rate of Sudden Unexpected Infant Death (SUID) in the U.S., according to the Centers for Disease Control. SUID includes sudden infant death syndrome (SIDS), accidental suffocation and strangulation in bed (ASSB), and death by unknown cause during the first year of life.

The project is an opportunity to understand better the challenges families face in adopting infant safe sleep recommendations developed by the American Academy of Pediatrics and those by other government agencies, and to create specific solutions to reduce the rates of infant deaths. These results would also benefit healthcare providers as they assist families in making decisions

regarding infant-safe sleep practices.

The program will be evaluated by the Morehouse School of Medicine's Center for Maternal Health Equity, and the results, disseminated to community partners and national networks to support the development of new local, state, and national policies.

What Lies Beneath:

This dovetails with First Candle's commitment to recognizing the many factors that contribute to sleep-related infant death. We have been educators for several decades and were a partner in the original Back to Sleep® campaign in the 1990s, which led to a 50% drop in SIDS deaths, after which the decline leveled off, and babies continued to die.

This led us to look more closely at what was stopping families from adopting infant-safe sleep practices. Through the results of qualitative and anecdotal approaches, we came to realize the critical role that social determinants of health, cultural convictions, and real-world parental challenges play in how families make their decisions – a critical thing to learn because we all now increasingly understand that SIDS risk is tied to maternal and infant health both before and after birth.

"Through the results of qualitative and anecdotal approaches, we came to realize the critical role that social determinants of health, cultural convictions, and real-world parental challenges play in how families make their decisions – a critical thing to learn because we all now increasingly understand that SIDS risk is tied to maternal and infant health both before and after birth."

And this, in turn, led to going out and reaching families where they are through community-based approaches such as our Let's Talk Community Chats, where local partners and peers who have been through our infant safe-sleep training create a space where families can be heard and connected to resources. The reactions have been encouraging, and we believe community-based programs such as this are a hands-on way to save infant lives.

So our concern remains high, but we are also looking forward to this new year, creating more Let's Talk programs throughout the country and continuing close work with our partners in Georgia to understand better the life contexts that drive behaviors around infant safe sleep and family practices.

We look forward to sharing information gained from the Georgia study as it progresses and to responding to interest from healthcare professionals, government agencies, and other groups about our work with providers and families to advance infant safe sleep better.

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Disclosure: *The author is the Executive Director and Chief Executive Officer of First Candle, a Connecticut-based not for profit 501(c3) corporation.*

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About First Candle

First Candle, based in New Canaan, CT, is a 501c (3) committed to eliminating Sudden Unexpected Infant Death 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 3,500 infant deaths nationwide per year.

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High-Reliability Organizing Fundamentals: Time and Acceleration

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

How odd that we engage dynamic, accelerating situations with static, well-defined, and discrete concepts as our frames of reference. It does seem prudent to use well-accepted frames of reference for risky operations. For example, we commonly rely on standards of care and evidence-based medicine for routine and emergency care. Standardized frames of reference, such as the International Classification of Disease and Diagnostic and Statistical Manual, support the collection of information, documentation, and clarity during communication. These frames of reference enable us to understand events and support our predictions about the effectiveness of interventions.

"It does seem prudent to use well-accepted frames of reference for risky operations. For example, we commonly rely on standards of care and evidence-based medicine for routine and emergency care. Standardized frames of reference, such as the International Classification of Disease and Diagnostic and Statistical Manual, support the collection of information, documentation, and clarity during communication. These frames of reference enable us to understand events and support our predictions about the effectiveness of interventions."

Yet, we live in a fluctuating environment. Feedback loops amplify or dampen processes that redden environmental noise. Red noise brings long-period forcing energy to the environment, to which elements and systems must respond. When feedback occurs within a single variable, it is autocorrelation—red noise. Feedback occurring between multiple variables is cross-correlation and can cross scales of space and time (1, 2). Feedback creates stochastic variability within the environment, which gives rise to stability and homeostasis (3).

"Information is contextual, if not transient, in a fluctuating environment. If the truth value of information is variable, changing with time and context, can we rely on the principles of logic and reason? Our theories should predict the same phenomena within the various and changing reference frames that we encounter."

Information is contextual, if not transient, in a fluctuating environment. If the truth value of information is variable, changing with time and context, can we rely on the principles of logic and reason? Our theories should predict the same phenomena within the various and changing reference frames that we encounter (4, 5).

Information is contextual, if not transient. In the dynamics of engagement, what hurts you now will help you later, just as what helps you now will hurt you later. One of the authors (DvS) served on a fire rescue ambulance where teams of two responded to medical emergencies without on-scene support from fire companies and police units or portable radios. They were trained to respond unassisted for calls with "assailant on scene." In this environment, they quickly learned that any stance, countenance, or word was situational. They would learn if their efforts helped or hurt only by scrutinizing faces. Listening to these experiences, people quickly classified what they heard to fit into some familiar standard—a standard used in stable situations without immediate threat. Such stories remain unshared.

"Unfortunately, information then becomes lost. Those present at the operational beginning of a field of study have witnessed how the painful lessons learned become converted to safe and reliable standards. Most commonly, what is lost is the practice of engaging uncertainty and ambiguity. New "arrivals" also have a new baseline; they view the domain at their entry as the standard from which they improve the science..."

Unfortunately, information then becomes lost. Those present at the operational beginning of a field of study have witnessed how the painful lessons learned become converted to safe and reliable standards. Most commonly, what is lost is the practice of engaging uncertainty and ambiguity. New "arrivals" also have a new baseline; they view the domain at their entry as the standard from which they improve the science, if not the more difficult part of their career (6). We have seen this in Neonatology, Pediatric Critical Care, Trauma Surgery, Emergency Medicine, and EMS.

Individuals and designed systems experience these environments locally. The view of the "spectator," far removed in time and space, is one of a technological system with greater emphasis on prediction, design, and commands from the outside. Moving closer, in an environment influenced by events, the "observer participant" has the Whole Field View Specification and contributes to the self-organizing response. The "operator" has the Local Grouping Specification, with an immediate local, nonlinear response to the situation. Nonlinearity now confounds linear time.

"Individuals and designed systems experience these environments locally. The view of the "spectator," far removed in time and space, is one of a technological system with greater emphasis on prediction, design, and commands from the outside. Moving closer, in an environment influenced by events, the "observer participant" has the Whole Field View Specification and contributes to the self-organizing response. The "operator" has the Local Grouping Specification, with an immediate local, nonlinear response to the situation. Nonlinearity now confounds linear time."

> "Technological systems become organized by commands from the outside, as when human intentions lead to the building of structures or machines. But many natural systems become structured by their own internal processes: these are self-organizing systems, and the emergence of order within them is a complex phenomenon that intrigues scientists from all disciplines."
>
> *Eugene F. Yates* (7)

Information carries different salience, relevance, and meaning, depending on context, even when individuals are standing adjacent, see Table 1 (8). Our explanations and theories should predict the same phenomena in any of these specifications or reference frames.

The problem, however, is that for conceptual tractability and theory development, we have separated the individual and organization from the environment. By isolating the study population or sample from the environment, we eliminate variability in the environmental noise. "White noise" is environmental noise that has constant variance per unit frequency. That is, there is an equal and independent representation of energy over all frequencies and *without* autocorrelation (feedback). Much research occurs in controlled and protected white noise environments.

"Elements and events in white noise environments are fully independent, purely random, and without temporal correlation because there is no predominant energy frequency. They form a Gaussian distribution amenable to statistical analysis and calculated probabilities. Variance decreases over time or with increasing data. For these reasons, researchers prefer white noise environments."

Elements and events in white noise environments are fully independent, purely random, and without temporal correlation

Table 1: Specifications of the Whole Field View and Local Groupings (9)

Whole field view	**Local groupings**
Eulerian, quantitative	Lagrangian, qualitative
Decontextualized	Contextual
External, fixed point Select a viewing point Focus on specific location	Within flow Select a starting point Focus on individual moving parcel
Flow	Trajectory
Multiple fixed positions	Continuous measure with position and pressure
Rate of change of system	Individual parcels

because there is no predominant energy frequency (10, 11). They form a Gaussian distribution amenable to statistical analysis and calculated probabilities. Variance decreases over time or with increasing data. For these reasons, researchers prefer white noise environments.

The problem is not with our classifications, theories, logic, or reasoning. The problem lies with the removal of time in our conceptual structures and mental processes. Eliminating time as a variable allows us to use Newtonian constructs within a Euclidean space. The rules of Euclidean geometry, that any two points have a measured distance between them, permit the construction of hierarchies, whether conceptual, structural, or operational.

"The problem is not with our classifications, theories, logic, or reasoning. The problem lies with the removal of time in our conceptual structures and mental processes. Eliminating time as a variable allows us to use Newtonian constructs within a Euclidean space."

Time in Newtonian physics and Euclidean space is a "prothetic" process. That is, time is a quantitative measure that we can add to. Qualitative measures are "metathetic" processes on the physiological level. We substitute additions rather than adding to existing measurements as we are changing the quality of the process. Nonlinearity confounds time when we consider time to be a linear measurement that we can only add to (12).

Another model of time is the branching tree model, where the past is fixed and linear, but the future is open. Time branches into multiple possible futures with a specific modal logic—*temporal logic* (13). Branching tree models are less useful for planning, but they do provide concepts and logic for engagement of novel or uncertain situation.

Temporal logic reasons how time qualifies statements and propositions with two basic operators—future and past. The asymmetry of time describes how the past is fixed, yet the future is branching and open to influence and change (13). This fits the effect of increasing entropy as an increase in possible futures rather than an increase in disorder.

Temporal logic can also be modified for concepts of time. For example, *X* is always true while Y is only sometimes. While the past is fixed and already determined, logical processes can account for the branching of time in the future. "Temporal logic" addresses problems of causality and mechanism, continuous change, planning actions, concurrent or discontinuous events, and the persistence of a fact rather than the truth of a fact.

Temporal logic moves us from a deterministic view of linear time that focuses on the path to the future. While there may be a feeling of security for families to know the percentage survival rate, such discussions do not reflect time experienced as a liminal state. During live-or-die experiences, there is no sense of time.

One model of time differentiates propositions that may change truth value over time from those that are always true or always false. "Tensed" propositions accurately describe the world but can change their truth value over time. "Tenseless" propositions are always true or always false. Tensed propositions permit accurate classification of events as past, present, or future. Reality (present) is complete, reality in the past was different, and reality in the future will be different. Tensed propositions explain why we give significance to the past-present-future distinction; some things in the past will always be good or bad (4).

"One model of time differentiates propositions that may change truth value over time from those that are always true or always false. "Tensed" propositions accurately describe the world but can change their truth value over time. "Tenseless" propositions are always true or always false. Tensed propositions permit accurate classification of events as past, present, or future. Reality (present) is complete, reality in the past was different, and reality in the future will be different. Tensed propositions explain why we give significance to the past-present-future distinction; some things in the past will always be good or bad "

Amplification from positive feedback creates the appearance of acceleration. This comes from a measure of time lag in the feedback. Short, amplified feedback loops rapidly branch and change the direction and velocity of events.

Physiological and neurological limits to time limit response times and lengthen time lags. Individual and group experience, cohesiveness, and capability are unmeasured influences on time lags. We cannot go faster than that, much like the speed of light limits speed. It is common amongst the less experienced to think one must think fast and act fast. Not really, as it is not thinking fast versus thinking slow, rather, it is thinking effectively and acting smoothly.

"It is common amongst the less experienced to think one must think fast and act fast. Not really, as it is not thinking fast versus thinking slow, rather, it is thinking effectively and acting smoothly.

Education, training, and planning tend to use a non-accelerating, inertial reference frame. This is an analogous problem to one addressed by Albert Einstein (5, 14). The principle of relativity

(in the restricted sense), used by Newton, does not hold for motion. In Newtonian physics and Euclidean space, time was considered absolute, and a reference frame became the favored frame. This did not accommodate moving or accelerating frames of reference. In 1905, Einstein addressed the problem that the mutual speed of the frames is constant. This is his Special Theory of Relativity. In 1915, he addressed the problem that the mutual speed of the frames is NOT constant in his General Theory of Relativity:

The theory of relativity (in the restricted sense) appeared to be unsatisfactory only in one point of fundamental importance. It appeared to give preference to one system of coordinates of a particular state of motion (at rest relative to the ether) as against all other systems of coordinates in motion with respect to this one. In this point the theory seemed to stand in direct opposition to classical mechanics, in which all inertial systems which are in uniform motion with respect to each other are equally justifiable as systems of co-ordinates (Special Principle of Relativity). In this connection, all experience also in the realm of electro-dynamics (in particular Michelson's experiment) supported the idea of the equivalence of all inertial systems, *i.e.*, was in favor of the special principle of relativity (5).

In his Special Theory of Relativity, Einstein postulates (14):

- The laws of physics are the same in all inertial frames of reference. The laws of physics have the same form in all inertial reference frames.
- The speed of light in a free space (vacuum) has the same value in all inertial frames of reference. Light propagates through empty space with speed c independent of the speed of the source or observer.
- Hence: the speed of light, which is a consequence of the laws of physics (Maxwell), is the same in all inertial reference frames.

High Reliability Organizing accommodates structural limits on response to a forcing function or abrupt change (Karl Weick, personal communication). We see this in the five characteristics of HRO (15):

- *Preoccupation with Failure* describes vigilance for disruptions, discrepancies, covert compensated failure, or other early signs of an approaching forcing function.
- *Reluctance to Simplify* and its corollary, *Efforts to Complexify*, recognizes the information that is found in noise and that noise may develop toward a crescendo—the situation doesn't stop because information was collected, and authorities notified.
- *Sensitivity to Operations* maintains all operations using authority migration, when necessary, not to become distracted by events; the organization must maintain routine operations to engage a crisis as well as continue its purpose of operations.
- *Commitment to Resilience* distributes decisions to those in the best position to act and encourages information flow toward those who can use it, a generative form of organization (16); short lag feedback loops, emerging from authority migration and distributed decision-making, keep the organization responsive to abrupt changes.
- *Deference to Expertise* accepts various frames of reference without preference and utilizes the different specifications of the flow of events (8).

For the individual and the organization, the five HRO characteristics reduce the influence of "a preference to one system of coordinates of a particular state of motion."

"High Reliability Organizing accommodates structural limits on response to a forcing function or abrupt change. We see this in the five characteristics of HRO: Preoccupation with Failure, Reluctance to Simplify and its corollary, Efforts to Complexify, Sensitivity to Operations, Commitment to Resilience, Deference to Expertise."

In Euclidean Geometry of three dimensions (14):

- Any 2 points have a measured distance between them.
- There is a coordinate system. Distance is independent of the system of coordinates chosen and can be measured with a standard measuring rod.
- With respect to these transformations, the laws of Euclidean geometry are invariant.

In the Special Theory of Relativity (14):

- Corresponding to two neighboring points in *space-time* (point events), there exists a numerical measure (distance ds) which conforms to the equation using time as a 4th dimension.
- An inertial system. It is independent of the inertial system chosen and can be measured with the unit measuring rod *and* a standard clock.
- With respect to these transformations, the laws of physics are invariant.

"Because the order of the members of some pairs of events can be reversed by changing one's reference frame, we must consider whether the events' ability to influence each other can similarly be affected by a change of reference frame."

Causality. "Because the order of the members of some pairs of events can be reversed by changing one's reference frame, we must consider whether the events' ability to influence each other can similarly be affected by a change of reference frame." Situations developing from Red Noise forcing functions or Pink Noise abrupt change have influences on causation similar to those identified by Einstein:

- Feedback can be contingent, indirect, nonlinear, or very short (acceleration).
- Respond more intensely to local influences.

- Have greater granularity.
- Operate more commonly with nonlinearity and self-organization.

Conclusion:

The inclusion of time, feedback, and causation as relativity of reference frames more closely represents the experience of those involved in a Neonatal resuscitation.

Time and its manifestation as rates of feedback within HRO have been overlooked by those with knowledge of HRO solely by description. Appreciating the significance of time and feedback brings forward movement and acceleration as considerations for High Reliability Operations. Time and feedback explain the weakness of hierarchical structures during a forcing function or abrupt change. Veteran HRO operators have long discussed that the first action upon encountering an event is "do something." Any action that breaks a series of feedback loops also decreases amplification, moving the system toward stability.

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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?

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COVID 2023 – The More We Know, the Less We Know: A year in review

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.

As we come to the end of the fourth year of the pandemic that never ends (yes, we're still in it), it gives me no pleasure to be writing my fourth column on COVID-19 (C19). My displeasure notwithstanding, the body of knowledge and plethora of studies and papers on the subject continue to grow. Denial is not science, and wishful thinking is neither treatment nor cure.

"Most public health officials went so far as to proclaim that children posed no risk to adults because they did not spread the virus. This (again mistaken) belief persisted until the evidence to the contrary could not be ignored. The consequences of this overconfidence were disastrous."

Early in the pandemic, neonatology and pediatrics took some comfort in the (mistaken) belief that this virus posed little or no danger to infants or children. From all appearances, it seemed that children's hospitals would be spared the chaos overwhelming the adult healthcare system and our colleagues who work within it. This was indeed true (at least for a while). Children did not suffer the same life-threatening symptoms as adults, many showing no symptoms at all. Most public health officials went so far as to proclaim that children posed no risk to adults because they did not spread the virus. This (again mistaken) belief persisted until the evidence to the contrary could not be ignored. The consequences of this overconfidence were disastrous.

The Chief Medical Officer of Health (CMOH) for British Columbia, Canada, was one of those insisting children posed no risk and that they were not responsible for driving the rapidly increasing numbers infected. This faulty assumption led to the reopening of schools for in-person learning. The public were told this would not significantly impact the number of infections amongst the general public. To validate this assumption, the CMOH et al. studied "waste blood" (blood remaining after routine laboratory tests are completed). Samples were tested for C19 prior to school opening and continued after the fact. The results revealed that the C19 positivity of waste blood samples skyrocketed shortly after schools reopened. In what can only be described as an egregiously unethical move, the message given to the public at large did not change despite the study's findings (1). Regarding children and C19, this was only the beginning of a cascade of research demonstrating how wrong these assumptions were. Not only can children transmit C19, but they are also not immune to sequelae stemming from C19 infection.

"In all cases, PCR testing showed the presence of C19, although 9 of the deceased had no C19 in the nasopharynx. The greater the concentration of C19 virus in the lungs, the less was present in the nasopharynx."

Recently, a study of autopsies was conducted on 23 people who had died suddenly and unexpectedly. The cohort included four children aged 2, 3, 14 months, and 7 years respectively. The deaths of the 2- and 3-month-old infants were initially thought to be due to sudden infant death syndrome (SIDS). The mother of the 7-year-old child had C19, but her child showed no symptoms of C19 infection and also tested negative on a rapid antigen test (RAT). Her daughter's death occurred approximately 30 days after her mother's initial C19 diagnosis. In all cases, PCR testing showed the presence of C19, although 9 of the deceased had no C19 in the nasopharynx. The greater the concentration of C19 virus in the lungs, the less was present in the nasopharynx. All subjects had either no symptoms of C19 infection or very mild ones. Despite this, it is thought the disease entered a latent phase that led to death (2). Because C19 was (is) thought to be of little consequence to children under 12, testing them for C19 was often not done. Clearly, this is not the case.

"At first, it was thought that C19 did not cross the placenta, but this has also been found to be untrue, albeit rare. Not only has the virus been detected in fetuses, but it is also associated with cerebral bleeds."

C19 poses risks during pregnancy as well. Infection during the first and second trimesters (but not the third trimester) increases the risk of stillbirth (3). One investigation found an increase from 2.3 per 100k in non-infected women to 5.8 per 100k for those having been C19 infected. The risk also changed with the C19 variant, with Delta presenting the highest risk and others less so. No data is available for the most recent variants (4). Other research has found an increased risk of preeclampsia and preterm birth in those infected, although the risk of preterm birth appears only to be if infection occurs after 34 weeks PMA (5).

At first, it was thought that C19 did not cross the placenta, but this has also been found to be untrue, albeit rare. Not only has the virus been detected in fetuses, but it is also associated with cerebral bleeds. These findings were from aborted fetuses; thus, it is not clear whether or not they were deleterious. Nevertheless, there are reports of brain damage in babies born to C19-infected mothers, and the virus has been found in the children's brains (5). These are rare findings, but it has been previously reported in this column that some infants born of C19-infected mothers failed to meet developmental milestones between 6 and 8 months of age compared to none in the non-infected comparators (5).

"The severity of last year's RSV season (with 2023 at least initially promising a similar one) certainly gives credence to the possibility of long-term immune system damage."

Once thought to be a primarily respiratory infection, it is now well known that C19 attacks vasculature. As the virus continues to mutate into more and more variants, it appears to target the lungs far less and favour other (all) organs. The speed at which mutations occur makes the prospect of herd or natural immunity impossible. Research on C19 and the risk of repeat infection is all over the map. Some report a decreased risk, while others say each infection increases the risk of repeat infections and secondary infections with once-rare pathogens. The severity of last year's RSV season (with 2023 at least initially promising a similar one) certainly gives credence to the possibility of long-term immune system damage. The damage it does to the immune system (6) is eerily similar to HIV, so much so have some refer to C19 as "airborne HIV." (Many researchers categorically deny this, although it is too early to determine how valid this comparison is in the author's opinion.)

"There are also reports of latent tuberculosis (TB) becoming active, raising the possibility of increased transmission of TB. TB-C19 coinfection may also increase the likelihood of severe disease, although there is insufficient data to confirm this."

The latest "gift that keeps on giving" is discovering viral reactivation post-C19 infection. Epstein Barr and varicella are most notable, but there are also reports of cytomegalovirus, hepatitis B, and other viral reactivations (7), some of which can adversely affect the fetus. (Anecdotally, one physician I correspond with says he has seen more shingles in the past year than in 30 years of practice.). There are also reports of latent tuberculosis (TB) becoming active, raising the possibility of increased transmission of TB. TB-C19 coinfection may also increase the likelihood of severe disease (8), although there is insufficient data to confirm this (9). TB-related deaths have increased since the pandemic, but the mechanism driving the increase is multifactorial (9).

The fact that C19 and TB present with very similar symptoms may lead to missed diagnosis and, thus, delayed treatment. Delaying TB treatment is known to increase the risk of death from the disease (8).

In pregnancy, TB increases the risk of obstetrical complications, premature birth, birth defects, and perinatal mortality. Placental transmission is relatively rare (10), but if the prevalence of TB increases, we are likely to see more cases.

"Even so, 2019-2021 meta-analyses of C19 and perinatal outcomes revealed an increase in maternal death, preeclampsia, fetal distress, caesarian delivery, low 5th minute APGAR, preterm birth, low birthweight, stillbirth, and NICU admission compared to non-infected mothers."

As the bulk of this column does not directly relate to neonatal and pediatric practice, one may ask how it is relevant to them. Research on C19 related to pregnancy, infants, and children is sparse relative to the adult population, but it is growing. For the most part, in the acute phase, life-threatening C19 infection is rare in the pediatric population. Since C19 was initially believed to pose little or no threat to children and infants, the research did not focus on this cohort. Even so, 2019-2021 meta-analyses of C19 and perinatal outcomes revealed an increase in maternal death, preeclampsia, fetal distress, caesarian delivery, low 5th minute APGAR, preterm birth, low birthweight, stillbirth, and NICU admission compared to non-infected mothers (11).

A tangential effect of C19 has been increased pediatric admissions for respiratory illness. This is compounded by C19 illness and long-C19 among hospital staff, exacerbating a severe staffing shortage. Supply chains continue to be disrupted, with many items used in the NICU being substituted or on backorder.

For those on "X," I recommend following AJ Leonardi, MBBS, Ph.D. (@fitterhappierAJ) for all the latest C19. While a magnet for controversy, he has been bang-on in his assessments from day one. While C19 research has been and continues to be prolific, so much of the information available is contradictory that reaching any conclusion with a high degree of certainty is challenging.

This book is still being written, and it promises to be long. C19 has opened an epidemiologic Pandora's box. One thing is for sure: C19 is far from done with humankind.

Be well everyone, Happy Holidays, and wishes for a wonderful new year for all. (C19 notwithstanding!)

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Disclosures: *The author receives compensation from Bunnell Inc for teaching and training users of the LifePulse HFJV in Canada. He is not involved in sales or marketing of the device nor does he receive more than per diem compensation. Also, while the author practices within Sunnybrook H.S.C. This paper should not be construed as Sunnybrook policy per se. This article contains elements considered "off label" as well as maneuvers, which may sometimes be very effective but come with inherent risks. As with any therapy, the risk-benefit ratio must be carefully considered before they are initiated.*

NT

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

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

In Loving Memory

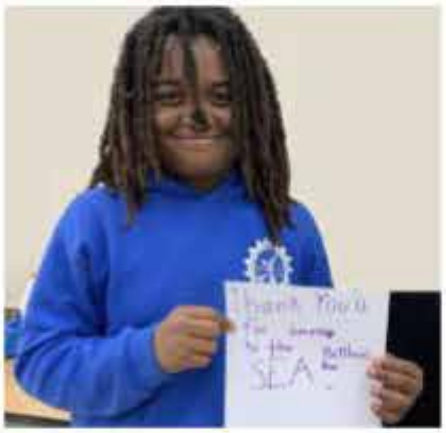
August 9, 1996 - April 3, 2010

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

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

Sponsor a Child in the SEA Program

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.

The Village Son

A Life's Journey

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

Houchang D. Modanlou

Cardiac Corner: Critical Physiological Principles when Caring for Babies with Congenital Heart Diseases

Gil Wernovsky, MD; Benjamin Hopkins, OMSIV (Discussant)

"In this month's edition of Cardiac Corner, I would like to discuss some critical physiological principles necessary for all those caring for babies with congenital heart disease."

In this month's edition of Cardiac Corner, I would like to discuss some critical physiological principles necessary for all those caring for babies with congenital heart disease.

There are three broad concepts which determine chamber and great artery pressures, as well as direction of shunting.

- A hole of any significant size equalizes the pressure on both sides of the hole.
    - "Holes" equalize pressure, but do not determine the direction of shunting

1. Blood rolls "downhill".
    - The differences in the vascular resistance determine the direction of shunting

2. Blue is better than gray.
    - A "low" oxygen saturation with normal cardiac output typically results in improved oxygen delivery than a "normal" oxygen saturation with low systemic blood flow

Let me get into this distinction in more detail. It is not uncommon at the bedside to confuse the crucial distinctions between pressure and resistance. When discussing "holes" such as atrial septal defects, ventricular septal defects, patent ductus arteriosus, and AP window, etc., it is essential to remember that *the pressures are equal on either side of the hole*, particularly at the ventricular and great vessel levels. Therefore, it is also vital to understand the strict definition of pulmonary hypertension: a mean pressure in the pulmonary artery greater than 25 mmHg. Thus, in all patients with a large VSD and with a large patent ductus arteriosus, the pulmonary artery pressure is at the systemic level. Thus, there is "pulmonary hypertension." I will get into this in more detail below.

"When discussing "holes" such as atrial septal defects, ventricular septal defects, patent ductus arteriosus, and AP window, etc., it is essential to remember that the pressures are equal on either side of the hole, particularly at the ventricular and great vessel levels."

The second rule, blood rolls downhill, involves resistance, not pressure. For example, in a baby with a ventricular septal defect, blood will shunt, in most situations, from the left ventricle to the low-resistance pulmonary circuit via the right ventricle. This results in a left to right shunt, pulmonary congestion, and no hypoxemia. If pulmonary vascular resistance is high, or there is an obstruction to pulmonary blood flow, as in Tetralogy of Fallot, blood may go from the right ventricle to the left ventricle, where there is less resistance to flow.

Number three, "blue is better than gray," is the physiologic principle most frequently quoted when discussing complex physiology with my NICU colleagues. By that, we mean that the delivery of oxygen, is more important than the oxygen saturation via pulse oximetry (which, of course, is the percent of hemoglobin, which is bound to oxygen). Indeed, if cardiac output is normal and carrying capacity (hemoglobin) is normal, oxygen saturations in the 60s and 70s, even if sustained, will not result in tissue ischemia, metabolic acidosis, or, importantly, neurologic injury. It is beyond the scope of this article to discuss all of the details of every congenital heart problem. Still, in general, ***not all oxygen saturations that are "higher" are "better."***

The next concept that I'd like to discuss is "shunting." This, by convention in most NICUs, refers to shunting in only one direction, right to left, resulting in hypoxemia, and may be labeled "PPHN". This can easily be determined by pulse oximetry. However, the degree of *left-to-right shunting* cannot be quantified at the bedside but may result in significant clinical illness.

"The next concept that I'd like to discuss is "shunting." This, by convention in most NICUs, refers to shunting in only one direction, right to left, resulting in hypoxemia, and may be labeled "PPHN". This can easily be determined by pulse oximetry. However, the degree of left-to-right shunting cannot be quantitated at the bedside, but may result in significant clinical illness."

I think of "shunting" associated with hypoxemia in two broad categories. The most common scenario in the NICU is *interpulmonary shunting*, where the blood returning from the pulmonary veins is not fully saturated; this is due to lung disease, pneumothorax, pleural effusion, atelectasis, etc. *Intracardiac shunting*, however, results in systemic hypoxemia due to systemic venous return bypassing the pulmonary circulation through an intracardiac or great vessel connection. So, in a hypoxemic newborn with congenital heart disease, it is important to distinguish systemic hypoxemia due to an intrapulmonary shunt, intracardiac shunt, or both.

Finally, "pulmonary hypertension" is a frequently misused term, and I wonder if we will ever get it out of our lexicon. In my world as a congenital cardiologist, pulmonary hypertension needs to be divided into two categories: pulmonary hypertension due to elevated pulmonary vascular resistance (such as seen in PPHN, diaphragmatic hernia, and meconium aspiration), and pulmonary hypertension due to the connection of the ventricles or the great vessels by "holes" (Rule #1), and differences in resistance (Rule #2). For example, echo reports may report "elevated right ventricular and pulmonary artery pressure," which may be assumed by the bedside team that the pressure is elevated due to elevated resistance ("PPHN"), with institution of pulmonary vasodilation. However, it may also be due to Intracardiac or great vessel communications - a very important distinction for management.

As a parting comment, systemic hypoxemia *without* alveolar hypoxia does NOT cause an elevated pulmonary vascular resistance or "worse PPHN" – otherwise, all babies with intracardiac shunts from congenital heart disease would have elevated pulmonary vascular resistance! It is *alveolar hypoxia* which causes elevations in pulmonary vascular resistance, sometimes severe, and should be treated with usual ventilatory maneuvers, inhaled nitric oxide, ECMO, etc. If a baby has hypoxemia with no lung disease, increasing oxygen, non-invasive or invasive mechanical ventilation is likely to do more harm than good.

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COPING WITH COVID-19

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

Provide culturally-informed and respectful care.

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

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

myNICUnetwork.org

and

National Perinatal Association
NICU Parent Network

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

TOP 10

RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

SUPPORT 4 NICU PARENTS

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

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

1 PROMOTE PARTICIPATION

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

Welcome!

2 LEAD IN DEVELOPMENTAL CARE

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

3 FACILITATE PEER SUPPORT

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

4 ADDRESS MENTAL HEALTH

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

5 SCREEN EARLY AND OFTEN

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

6 OFFER PALLIATIVE & BEREAVEMENT CARE

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

7 PLAN FOR THE TRANSITION HOME

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

8 FOLLOW UP

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

9 SUPPORT NICU CARE GIVERS

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

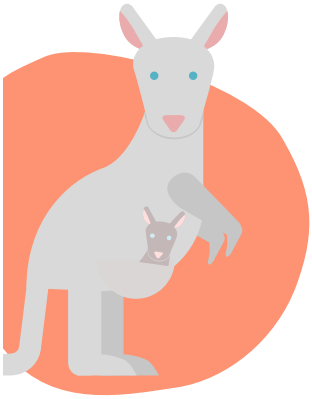
10 HELP US HEAL

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

SUPPORT4NICUPARENTS.ORG

SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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

National Perinatal Association

nicuparentnetwork.org

NPN NICU PARENT NETWORK

nationalperinatal.org/skin-to-skin

Position available for Neonatal Nurse Pretensioner (NNP)

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

Protecting your baby from

Respiratory Viruses:

What parents need to know this RSV and flu season

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

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

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

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

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

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

National Perinatal Association

www.nationalperinatal.org/rsv

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Raising Global Awareness of RSV

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

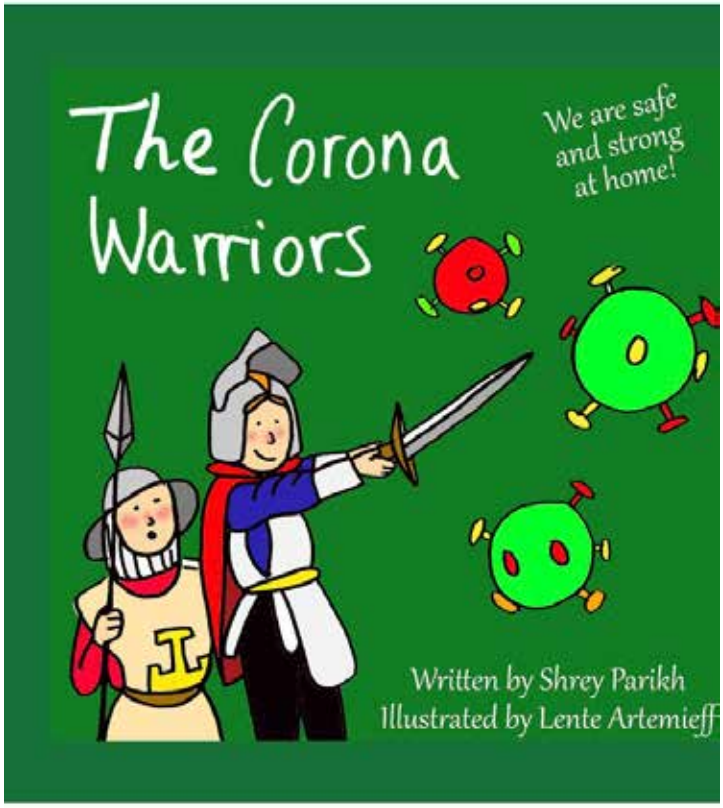
The RSV Research Group from professor Louis Bont, pediatric infectious disease specialist in the University Medical Centre Utrecht, the Netherlands, has recently launched an RSV Mortality Awareness Campaign during the 5th RSV Vaccines for the World Conference in Accra, Ghana.

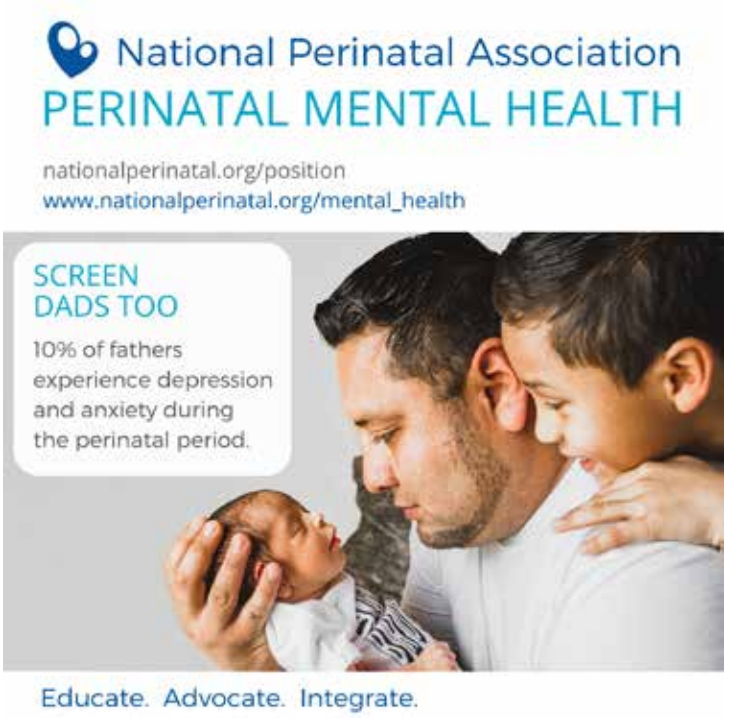
They have produced a personal video entitled "*Why we should all know about RSV*" about Simone van Wyck, a mother who lost her son due to RSV. The video is available at www.rsvgold.com/awareness and can also be watched using the QR code on this page. Please share the video with your colleagues, family,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

RSV GOLD

A Global Mortality Database for Children with RSV Infection

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





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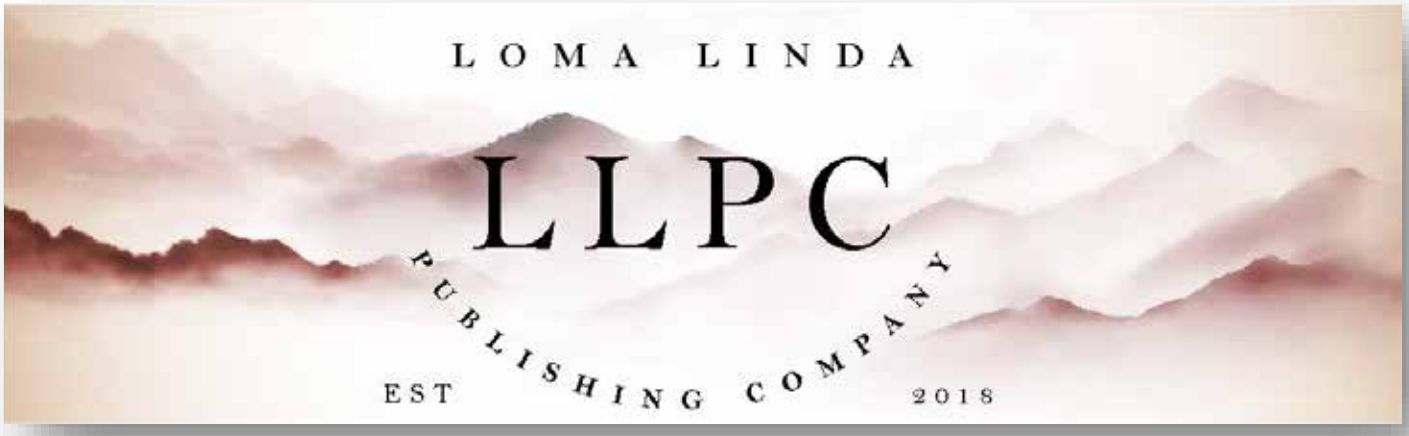

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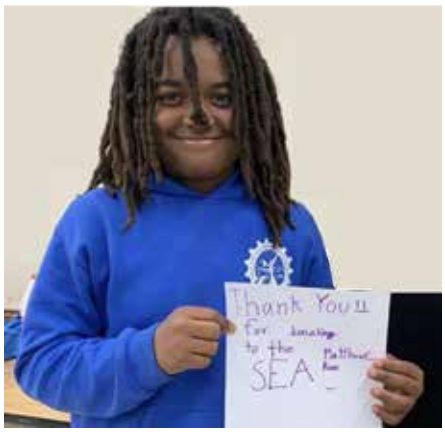

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1 month	$120
1 semester	$540
1 year	$1,080
Middle School	$3,240

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.

Gravens by Design: The 10th edition of the Recommended Standards for Newborn ICU Design

Robert White, MD

"This new edition of the Recommended Standards contains a number of updated standards; most notable is a new standard that specifies the inclusion of couplet care rooms for any new NICU construction in hospitals with a delivery service."

The 10th edition of the Recommended Standards for Newborn ICU Design is being published this month in a supplement to the Journal of Perinatology and several other papers on related topics. (1-3) This new edition of the Recommended Standards contains a number of updated standards; most notable is a new standard that specifies the inclusion of couplet care rooms for any new NICU construction in hospitals with a delivery service.

"Couplet care is the latest step in the evolution of NICUs from large multibed rooms to more suitable care environments for ill newborns and their families. In recent years, many NICUs have transitioned from these multibed rooms to include at least some single-family rooms, but typically, those rooms were not designed to allow for the care of the mother in the same room with the baby while she was still a patient in the postpartum period."

Couplet care is the latest step in the evolution of NICUs from large multibed rooms to more suitable care environments for ill newborns and their families. In recent years, many NICUs have transitioned from these multibed rooms to include at least some single-family rooms, but typically, those rooms were not designed to allow for the care of the mother in the same room with the baby while she was still a patient in the postpartum period. Couplet care rooms permit this simultaneous, adjacent care of the mother and newborn, thus eliminating the separation usually experienced at a crucial and stressful moment in the lives of both the baby and the parents. Couplet care requires modification of several conventional NICU design and operational strategies, so this supplement contains two accompanying articles from pioneering NICUs, one from Bjorn Westrup and his colleagues in the Nordic countries and a second by Christie Bruno and her colleagues from Yale describing their design and operational strategies. Carol Jaeger and Leslie Altimier also provide a paper that describes valuable metrics to guide the implementation of couplet care.

This supplement contains several other papers useful for those planning to build a new NICU or upgrade their existing unit. Carmina Erdei (4) and her team from Brigham & Women's in Boston report their experience in a "hybrid" NICU where babies are cared for in single-family rooms early in their course and then in multibed rooms during their convalescent stage. Sabah Mohammed and her colleagues summarize the results of a "Reimagining the NICU" project undertaken during two recent Gravens conferences in which participants brainstormed many ways we could employ creative, forward-thinking solutions to NICU design and operational challenges. (5) Mardelle Shepley and colleagues outline the value of incorporating color into NICU design and strategies for doing so, (6) while James Greenberg provides similar insight on using light and lighting in the NICU. (7) Joy Browne and her colleagues discuss the importance of family-centered care and describe ways NICU design can facilitate that effort. (1, 8)

"Mardelle Shepley and colleagues outline the value of incorporating color into NICU design and strategies for doing so, (6) while James Greenberg provides similar insight on using light and lighting in the NICU. (7) Joy Browne and her colleagues discuss the importance of family-centered care and describe ways NICU design can facilitate that effort. (1, 8)"

Taken together, the contents of this supplement will provide a strong foundation for teams planning new NICU construction or significant renovation so that their resulting design is innovative and fully supportive of babies, families, and caregivers. Many of these topics and others related to NICU Design and Family-Centered Care will be presented and further elaborated at the upcoming Gravens Conference on March 6-9, 2024.

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Gravens Diversity Travel Award

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

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

Eligibility:

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

Application:

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

Awardee Responsibilities:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA

EVIDENCE

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

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

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

TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY

LONGITUDINAL DATA

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

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY

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.

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Peer Reviewed

Fragile Infant Forums for Implementation of IFCDC Standards: Supporting Regulation of Infant Sleep and Arousal States in the NICU: The Role of Non-Separation in the Revised Infant-Family Centered Developmental Care (IFCDC) Standard

Rosemarie Bigsby, ScD, OTR/L, FAOTA; Amy Salisbury, PhD, APRN, PMH-CNS, BC, FAAN; Christie Lawrence, DNP, RNC-NIC, APN/CNS; Kathleen Kolberg, PhD

Overview:

Physiological and behavioral state regulation and support for the development of sleep and arousal patterns among preterm and sick infants, as well as how this practice can be implemented in the newborn ICU, is described in this article. A decade of studies on infant sleep consistently demonstrates positive relationships between age-appropriate patterns of sleep and arousal, brain development, and developmental outcomes (1–5), leading to sleep being widely accepted as an essential human occupation throughout the lifespan.

Human brain function relies upon age-related sleep patterns and arousal patterns for optimal brain development, including learning, cognition, executive, behavioral, and social/emotional functions. Sleep architecture and states of arousal are known to be affected by individual biological and environmental contexts (6); thus, infants with complex medical conditions who are cared for in the NICU environment, including preterm infants, are at particular risk of negative impacts on sleep and arousal patterns that could ultimately impede their overall development (7). The current evidence, addressed in the Infant-Family-Centered Developmental Care (IFCDC) Standards and Competencies (https://nicudesign.nd.edu/nicu-care-standards/ifcdc--recommendations-for-best-practice-to-support-sleep-and-arousal/) supports opportunities for close parent-infant contact, including skin-to-skin contact, as early and as often as possible, and addresses state development and regulation.

Evidence-Based Standards for Practice:

Infant-Family-Centered Developmental Care (IFCDC) is a neuroprotective model for the care of high-risk infants and families that seeks to ensure optimal conditions for development during the NICU stay and the transition home. The IFCDC standards and competencies (8) emerged from a model of care that has, at its core, the infant(s)/parent(s)/family member(s) as essential caregiving partners with medical professionals in an individualized approach to care where all participants in care recognize infants as competent interactors in their care. The 2024 revisions to these standards and competencies (in the process) now align with the European Standards of Care for Newborn Health (9) and the current recommendations from the World Health Organization (WHO) (10) for the care of preterm and low birthweight newborns by emphasizing non-separation of infant(s)/parent(s)/family as an essential, core component of IFCDC. These core components require a secure foundational context for implementation that includes: a) an organizational mission that utilizes systems thinking as a basis for evaluation and implementation of change, b) a commitment at all levels of the organization to principles and practices that demonstrate respect for diversity, equity, inclusion, and justice for all, and c) a shared mental model for individualized care that provides infant mental health, neuroprotection, and environmental supports.

Non-Separation to Enhance Baby's State Regulation:

Following the current IFCDC revisions, the sub-section of the standards that focuses on support for infant sleep and arousal now emphasizes non-separation, including skin-to-skin contact as early and for as long as possible, whenever the medical and social conditions of mother and baby permit. "Non-separation" in this context also refers to removing institutional barriers to parent-infant contact and close proximity from the earliest moments after birth. This addition to the standards goes beyond addressing the connection between sleep and arousal states and sensory aspects of the NICU environment (11). The call for non-separation recognizes the potential positive impact of an uninterrupted physical/emotional connection between the infant(s) and parent(s) on pain and stress (12) and physiologic and behavioral regulation, including states of sleep and arousal (13, 14). Immediate placement of the newborn to be in contact with the mother's skin while ensuring continuing medical stability of both mother and baby has been increasingly demonstrated to be not only possible (15) but potentially optimal for perinatal stabilization of the term dyad (16–18). Early, sustained physical proximity between baby and mother provides for mutual olfactory, tactile/kinesthetic, and auditory sensations, which contribute to physiologic and hormonal changes that, in turn, reinforce the emotional connection of the dyad (2, 19–22). From a practical standpoint, non-separation provides thermal regulation for the baby, which is particularly necessary in low-resource settings but has been demonstrated to

be beneficial even among very preterm babies in high-resource settings (23). A standard of immediate, continuous, skin-to-skin contact (15) is now strongly endorsed worldwide (10, 17) for the term, preterm, and low birthweight infants whenever possible. Earliest initiation" of STS contact for preterm and low birthweight infants is now accepted to be consistent with recommended perinatal care practices such as delayed cord-clamping, breast-crawl, and earliest provision of mother's own breastmilk, each of which have long been demonstrated to have positive relationships to physiologic and immunologic functioning, regulation of sleep and quiet alert states (24), breastfeeding success (25, 26), as well as short term and long-term social-emotional and developmental outcomes (27). Widstrom et al. (28) have provided detailed clinical recommendations for positioning healthy infants skin-to-skin on the mother's abdomen immediately after birth and for progressing mother and infant through nine stages of newborn behavior during this first skin-to-skin experience that includes a progression of increasing state regulation as the infant moves through wake and sleep states: 1. Birth cry, 2. Relaxation, 3. Awakening, 4. Active, 5. Resting, 6. Crawling, 7. Familiarization, 8. Suckling, 9. Sleeping. This practice is now recommended for preterm infants whenever medically possible to obtain some of the same benefits (10, 26). Immediate skin-to-skin contact offers parent(s) an opportunity to provide warmth, touch, and comfort to their newborn; these conditions facilitate their newborn's capacity to self-regulate their arousal and sleep states. Parental closeness, and skin-to-skin contact, in particular, affords the newborn the optimal environment to be soothed and obtain a quiet alert state, to gaze at faces, to actively move toward and engage the breast and/or suck on their fist, and to pull down to a sleep state. When it can be practiced immediately after birth, non-separation can be a profound shared experience with the potential for lasting physiologic and emotional benefits for babies and their parents.

"Earliest initiation" of STS contact for preterm and low birthweight infants is now accepted to be consistent with recommended perinatal care practices such as delayed cord-clamping, breast-crawl, and earliest provision of mother's own breastmilk, each of which have long been demonstrated to have positive relationships to physiologic and immunologic functioning, regulation of sleep and quiet alert states (24) , breastfeeding success (25, 26), as well as short term and long-term social-emotional and developmental outcomes (27)."

Non-separation may be an aspirational goal for families with complicated circumstances that prevent their prolonged presence at the bedside, such as the need to work or to care for other family members, as well as economic, cultural, and social-emotional factors. In the rare cases when close physical contact is not attainable immediately after birth or cannot be provided for sustained periods due to medical or family circumstances, non-separation can be practiced by the parent(s)/family as physical and social-emotional closeness through their active participation in individualized care, to the extent possible, which has known benefits to infant and family (29). Professional staff should use education and encouragement to empower parents in ways that maximize their participation, such as using technology (video conference software and hardware) for participation on rounds and education when physical distance cannot be avoided.

Essential to the implementation of non-separation as a core component of the IFCDC Standards is a shared mental model for individualized care between the obstetrical and neonatal teams. In this model, staff and parent(s)/family are educated in the known benefits of skin-to-skin contact, as well as safe transfer techniques and positioning to optimize airway maintenance for the baby and comfort for the mother/parent (30). Obstetrical and neonatal staff work in tandem to provide a safe, supportive environment for mother and baby to remain in skin-to-skin contact immediately after birth, performing only necessary observations and interventions. In contrast, the baby progresses through the initial stages described above, ultimately reaching a sleep state. For this shared mental model to be successfully implemented, staff and parent education must also include observation and recognition of infant sleep and arousal states.

"Obstetrical and neonatal staff work in tandem to provide a safe, supportive environment for mother and baby to remain in skin-to-skin contact immediately after birth, performing only necessary observations and interventions. In contrast, the baby progresses through the initial stages described above, ultimately reaching a sleep state. For this shared mental model to be successfully implemented, staff and parent education must also include observation and recognition of infant sleep and arousal states."

Application to Clinical Care:

Infant sleep and arousal states and other vital signs represent the infant's unique bio-behavioral communication of their responses to, and tolerance for, the conditions of care (19, 21, 31, 32). Optimally, ongoing assessment and documentation of sleep and arousal states, physiology, and behavior during the NICU stay are recorded in the electronic medical record (EMR) before, during,

and aftercare and should include the timing and context of care (i.e., infant location, if being held and by whom and for how long), infant position and positioning aids, and aspects of the environment (light, sound, furnishings). When this type of documentation is accessible to all team members via the EMR, it can be compared with concurrent vital signs and pain assessments within the caregiving context to inform team members of the infant's sensitivities, tolerances, and preferences for particular aspects of care. Recording these data in the EMR enables discussion by the team of such aspects of care as positioning and holding, feeding, participation in social interactions and scheduling of tests/interventions based on observed data. Trends in the infant's behavior can also be charted in the EMR and analyzed by the team. For example, documentation that an infant who was previously feeding eagerly but is now consistently lethargic and /or under-aroused for feedings may generate a team discussion on rounds where the parent(s)/family observations of their infant's behavior can be discussed. Modifications to the care schedule, the feeding plan, the environmental conditions, and the need for tests to assess for a medical source of the infant's lethargy may be considered, implemented, and followed up on. Consistent documentation of infant sleep and arousal during care and routine discussion of these observations on rounds demonstrates respect for contributions by all caregivers, particularly parent/family members, and brings the infant's voice to every team decision.

"When parent(s)/family members have participated actively in their infant's care throughout the NICU stay and have learned to recognize their infant's unique style of behavioral communication, they are more confident in their ability to support a healthy balance of sleep and arousal, which is the foundation for optimal feeding, interaction, and development (42)."

Hwang et al. (38) emphasize that physical presence is not sufficient for families to learn to support the development of healthy sleep patterns. Parents/families require education specific to this development area (IFCDC Sleep and Arousal Standard 5) (8). This, in turn, prepares them for a more successful transition home. Sleep, feeding, and behavioral regulation share a complex interaction, and difficulties with any or all of these components of development can be challenging to identify and resolve. However, they cannot be ignored since they are consistently among the primary concerns endorsed by families during the infant's transition home (39–41). Non-separation contributes to parents' understanding of their baby's arousal, sleep, feeding, and behavioral regulation. Healthcare workers' concerns about infant safety or the time required to support physical closeness between parent(s) and their baby have also been identified as barriers to implementation (33). Breaking down such barriers through staff and parent/family education and providing increased opportunities for family participation whenever possible should be a primary goal of the NICU (34, 35). Suppose parent(s)/family members face insurmountable barriers to non-separation. In that case, it is even more critical that they receive the necessary education to assess the behavioral communication of their infant(s) (36) and practice these skills in the NICU setting to facilitate competence and confidence in providing the individualized care their baby requires (37). When parent(s)/family members have participated actively in their infant's care throughout the NICU stay and have learned to recognize their infant's unique style of behavioral communication, they are more confident in their ability to support a healthy balance of sleep and arousal, which is the foundation for optimal feeding, interaction, and development (42).

Summary:

The emergence and regulation of sleep and arousal are foundational to later development and are impacted by early care by parents and intensive care staff. The IFCDC standards address the evidence that underpins essential aspects of care that support state and arousal development both in intensive care and as the baby transitions home. The parent's ability to understand and provide for the baby's state regulation is essential to laying that foundation, done best by not being separated from birth through the hospital stay. Non-separation, practiced early and often in the NICU, provides the best opportunity for families to be prepared to respond and adapt to the ongoing changes that are part of infant development once their baby is at home. Moreover, consistent participation as essential, valued members of the NICU care team prepares parent(s)/family members to partner with their baby's primary care providers following discharge to utilize necessary resources and to advocate for their baby's needs, ensure continuity of individualized care through the transition home.

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New Advances in the Prevention of RSV Infection

Angela Patterson, MD, Melissa Scala, MD

The National Perinatal Association (NPA) is an interdisciplinary organization that strives to be a leading voice for perinatal care in the United States. Our diverse membership is comprised of healthcare providers, parents & caregivers, educators, and service providers, all driven by their desire to give voice to and support babies and families at risk across the country.

Members of the NPA write a regular peer-reviewed column in Neonatology Today.

National Perinatal Association

Educate. Advocate. Integrate.

"Respiratory Syncytial Virus (RSV) is a common respiratory virus, infecting and reinfecting us many times over our lives. While RSV infection typically causes mild cold-type symptoms in older children and healthy adults, infants are especially vulnerable during their first two years of life."

Respiratory Syncytial Virus (RSV) is a common respiratory virus, infecting and reinfecting us many times over our lives. While RSV infection typically causes mild cold-type symptoms in older children and healthy adults, infants are especially vulnerable during their first two years of life. This is because RSV infection can be much more severe for infants whose immune systems are still maturing, particularly those who were born preterm or who have heart or lung issues. They may have difficulty breathing and feeding - requiring emergency room visits, hospitalization, and ICU care. In most places, RSV infections follow seasonal patterns, beginning in the fall and lasting until the spring each year. In most parts of the country, the season is underway!

"After a busy RSV season last year, new strategies are available now to help prevent RSV infection in infants. The FDA has approved a new RSV monoclonal antibody, nirsevimab, brand name Beyfortus™, which can provide protection or reduction in the severity of RSV infection."

After a busy RSV season last year, new strategies are available now to help prevent RSV infection in infants. The FDA has approved a new RSV monoclonal antibody, nirsevimab, brand name Beyfortus™, which can provide protection or reduction in the severity of RSV infection. The CDC has recommended this vaccine for all infants less than eight months of age during their first RSV season. It also recommends this vaccine for infants up to 24 months with certain medical conditions, including chronic lung and cardiac disease as well as immunodeficiency.

"Nirsevimab, similar to Synagis™, does not trigger the infant's immune system to make its own antibodies like most vaccines. Rather, it is a lab-made antibody that, when given by injection, targets and disables a protein that helps the virus infect cells."

Nirsevimab, similar to Synagis™, does not trigger the infant's immune system to make its own antibodies like most vaccines. Rather, it is a lab-made antibody that, when given by injection, targets and disables a protein that helps the virus infect cells. While Synagis™ lasts only 28 days, requiring monthly vaccination for optimum protection, nirsevimab lasts up to

5 months, meaning infants should require only one dose of nirsevimab if given during the RSV season. Your health care provider will administer either based on supply and availability. Although a one-time dose of nirsevimab may be preferable for most patients, monthly administration of Synagis™ is equally effective and should not be declined.

An additional way to protect infants from RSV is maternal vaccination (a vaccine for the pregnant person) with an RSV vaccine in the last trimester of pregnancy (preferably between 32-36 weeks). These vaccines trigger a maternal immune response and antibody production.

Antibodies cross the placenta and can protect babies from birth if given at least 14 days prior to delivery.

Preventive strategies - including good handwashing and isolation of known contacts with cough and cold-like symptoms - can help provide additional defense for adults and children.

All those who are pregnant or are parents of young infants are encouraged to speak to their healthcare providers about the best strategies to prevent RSV infection.

The National Perinatal Association RSV guidance supports vaccination during the last trimester of pregnancy and vaccination of infants who meet the criteria to reduce the impact of this common illness.

Vaccination of infants born during RSV season should be considered as early as just after delivery, prior to discharge from a healthcare facility if applicable, to minimize inequities that may exist in access to these innovations in prevention and protect ALL of our babies.

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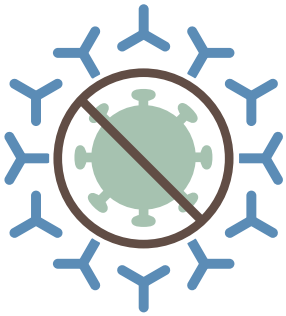
Protecting your baby and family from

Respiratory Viruses:



What parents need to know this RSV and flu season

Like COVID-19, RSV (Respiratory Syncytial Virus) and flu affect the lungs and can cause serious breathing problems for children and babies. Talk to your family about the risks.

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

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

The fewer germs your baby is exposed to, the less likely they are to get sick. Let people know you need their help to stay well. Limit visitors. Avoid crowds. Stay away from sick people.

Immunizations save lives. Stay up-to-date with your family's flu vaccinations and COVID-19 boosters. This helps our community stay safe by stopping the spread of deadly viruses.

Babies older than 6 months can get a flu shot and COVID-19 vaccinations. There is no vaccine for RSV, but monthly antibody shots during RSV season can help protect them.

WE CAN HELP PROTECT EACH OTHER.

National Perinatal Association

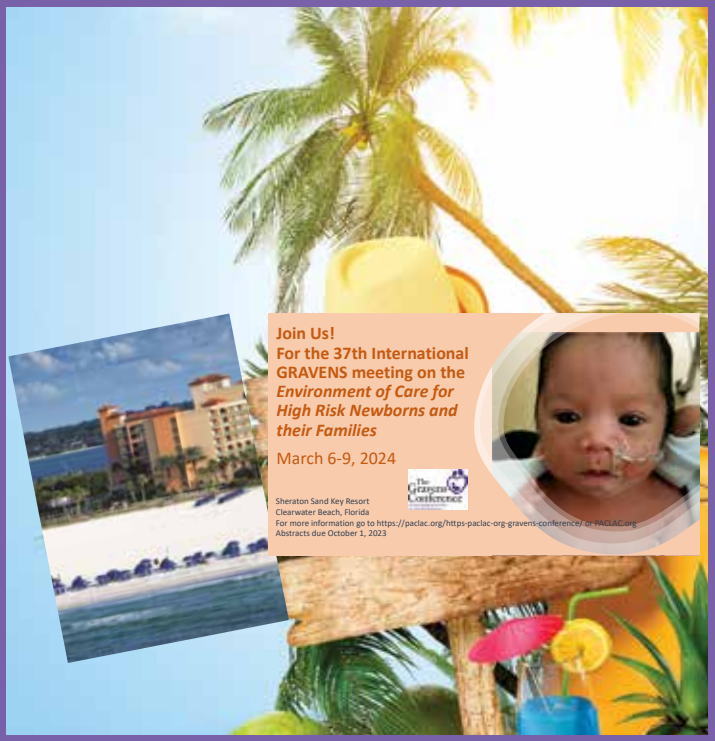
www.nationalperinatal.org/rsv

37th Annual Gravens Conference On The Environment Of Care For High Risk Newborns:

The Power of Voice: Using Your Voice for Babies, Families, Staff and Beyond

Attend Live, In Person Or Virtual

Wednesday - Saturday
March 6-9, 2024
Sheraton Sand Key Resort
1160 Gulf Boulevard
Clearwater Beach, FL 33767



WHY YOU SHOULD ATTEND

- Get updated on the most recent evidence for your work in supporting babies and families in intensive care.
- Have conversations with leaders in the field of developmentally supportive, family centered care and NICU design.
- Share your passion for optimizing the environment of care for babies, families and staff.
- Network with colleagues, family members and experts in the field who share similar ideas about supporting babies and families in intensive care.
- Take back ideas for change to your NICU policies and care practices.

GENERAL INFORMATION

Location

Sheraton Sand Key Resort
1160 Gulf Boulevard
Clearwater Beach, FL 33767
Hotel Phone: (727) 595-1611
www.sheratonsandkey.com

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

Refund Policy

Refund & Cancellation Policy: Cancellations must be requested in writing via email to gpakhanyan@paclac.org , and received by February 06, 2024 in order to receive a refund. A $100 cancellation fee will be assessed to cover administrative costs. There are no refunds for no-shows or for cancellations received after Feb. 06, 2024; however, substitutions are welcome without penalty. Eventbrite's fee is nonrefundable.

Conference Registration

We suggest you register early.

To register online, please go to:

Conference Registration, please register:
https://www.eventbrite.com/e/the-37th-annual-gravens-conference-tickets-668446410207?aff=oddtdtcreator

Or scan QR code

Conference Agenda

https://paclac.org/wp-content/uploads/2023/08/Gravens-Agenda-2024-1.pdf

Submit an abstract at:

https://event.fourwaves.com/gravensconference2024/pages

SHERATON SAND KEY RESORT

Accommodations

LOCATION: Sheraton Sand Key Resort
1160 Gulf Boulevard
Clearwater Beach, FL 33767
Hotel Phone: (727) 595-1611
www.sheratonsandkey.com

It is strongly advised that you make room reservations early.

Sheraton Sand Key Resort

A limited number of rooms have been reserved for this meeting at a special rate of $224 (plus tax). For reservations, call the hotel directly* at (727) 595-1611 (not the national sales office) and identify yourself as a participant of the Gravens Conference to receive the special group rate.

*If no one picks up at the local number, the call is automatically transferred to the national reservation line. The phone reps at the national reservations line will not know of the group and special rate. Continue to call the local number.

If you prefer to make online reservations,

Online Reservations

https://www.marriott.com/event-reservations/reservation-link.mi?id=1688650684784&key=GRP&app=resvlink

Book your group rate for Annual Gravens Conference (This will avoid the problems with reaching the national reservations line.)

The deadline to receive the group rate is February 4, 2024. This assumes the block has not sold out. If so, you will be quoted the standard rate, which is considerably higher than the group rate. The hotel sells out every year. Do not wait until the last minute. (The status of the pandemic will impact how quickly the room inventory sells out. Still, better to reserve the room in advance. You can always cancel, so long as it is within the allowable window.)

The hotel sells out every year.

Dress is casual throughout the conference. Please bring a jacket to the meeting rooms, as they are often cold. Physical distancing will be observed. Masks are optional.

The hotel has complimentary parking.

Airport & Ground Transportation

The two airports nearest the hotel are Tampa International Airport (TPA) and St. Petersburg/Clearwater airport (PIE). Both airports offer car rental.

Taxi fare from Tampa airport can exceed $60. Uber and Lyft average around $35 ish, before tips.

For more information on Tampa airport, visit https://www.tampaairport.com/guest-services and the St. Petersburg/Clearwater airport, visit http://www.fly2pie.com/

Diversity Scholarship Infomation

The Gravens Diversity, Equity, Inclusion, and Justice (DEIJ) Committee will provide travel awards to individuals from historically underrepresented groups (i.e., people from racially and ethnically diverse backgrounds, members of the LGBTQ+ population, individuals with cognitive disabilities, individuals with physical disabilities). Please contact Kelly McGlothen-Bell (mcglothen@uthscsa.edu) or Christie Lawrence (Christie_Lawrence@rush.edu) for questions regarding an application.

37TH ANNUAL GRAVENS CONFERENCE ON THE ENVIRONMENT OF CARE FOR HIGH RISK NEWBORNS

Conference Background

In a perfect world, there would be no need for a NICU. Yet our reality is that babies continue to be born too sick, too soon, and with medical conditions requiring hospitalization. Activities in the NICU have a profound impact on the babies, their families and the staff. What you do matters. Your work has the potential to impact a neonate's health outcome, as well as that of the family and staff in the NICU.

Since the 1980s, neonatal care providers have worked to mitigate the stress experienced by babies, parents and providers. Doing so has involved change and its inherent struggles, but eventually we have adapted our NICU culture, policies and approach. We strive to nurture the developmental needs of babies and the emotional and informational needs of their parents through evidence-based knowledge in neurodevelopmental science, developmental care, healthcare design, and family support. This work continues at The 37th Annual Gravens Conference.

Registration Fees

You will have access to recorded presentations after the conference is over.

Early Bird Full Conference In-Person Registration Early Bird Ends 1/22/2024	$725.00
Remote, in real time	$725.00
Full Time Students/Trainee Registration In-Person	$300.00
Group In-person Registration 3 and more	$650.00
Nurses/Allied Health Professionals In-person	$595.00
Nurses/Allied Health Professionals Remote in Time	$525.00
Single Day In-person Registration	$250.00
NICU Parent Registration In-person	$300.00
NICU Parent Registration Remote in Time	$300.00
Full Conference In-person 3/6-3/9	$800.00
Institutional Group Zoom Registration (10 Attendees)	$2,500.00
Institutional Group Zoom Registration (50 Attendees)	$10,000.00
International Low Income Country Zoom Registration	$85.00
International Zoom Registration	$250.00
Diversity Scholarship Participants	$300.00
Donation	

Course Objectives

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

Target Audience

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

Competencies to be addressed

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

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

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

Continuing Education

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

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

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

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

Certificate Policy:

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

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

Equal Opportunity & Accommodations for Disabilities:

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

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

Faculty

Andy Gomm, MSW

Brian Goldman, MD

Britt Pados

Carol Jaeger, DNP, RN, NNP-BC

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Robert White, MD
Mitchell Goldstein, MD, MBA, CML
Joy Browne, Ph.D, PCNS, IMH-E
Vincent C. Smith, MD MPH

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

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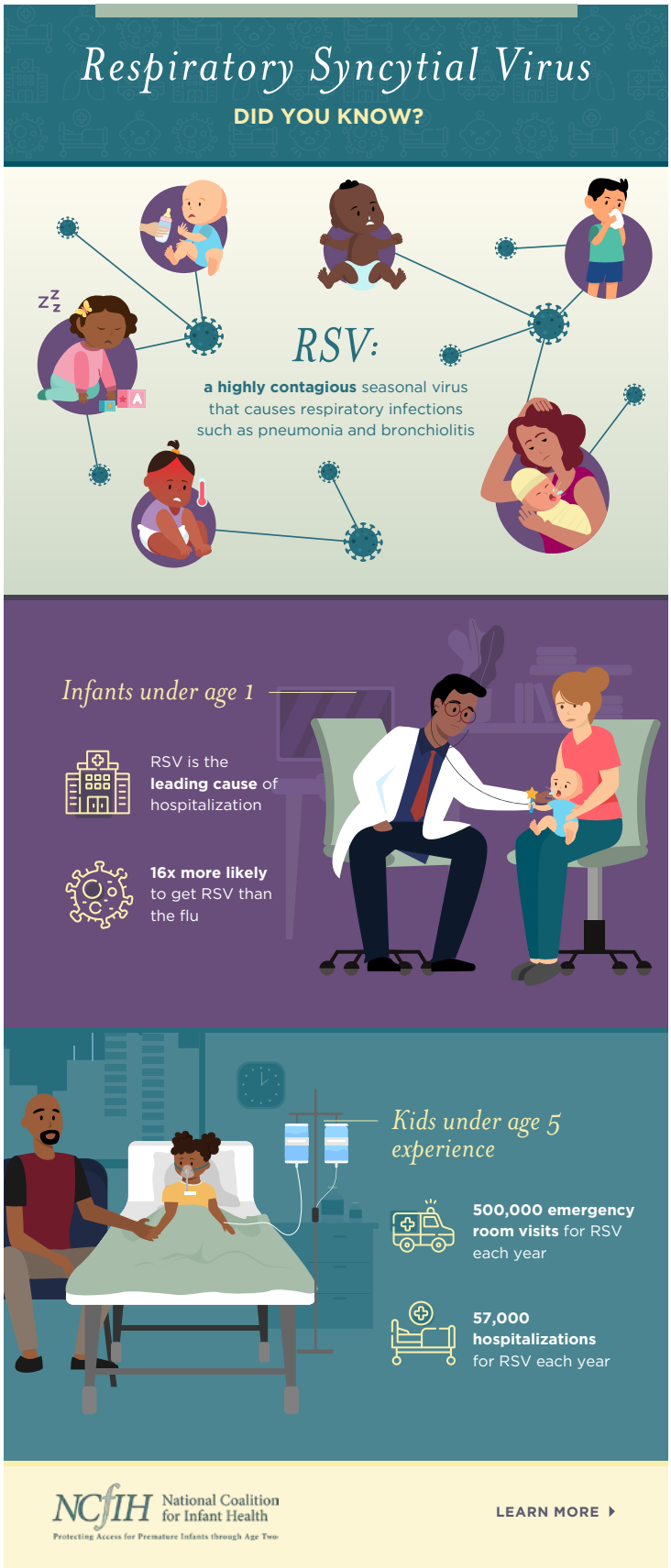
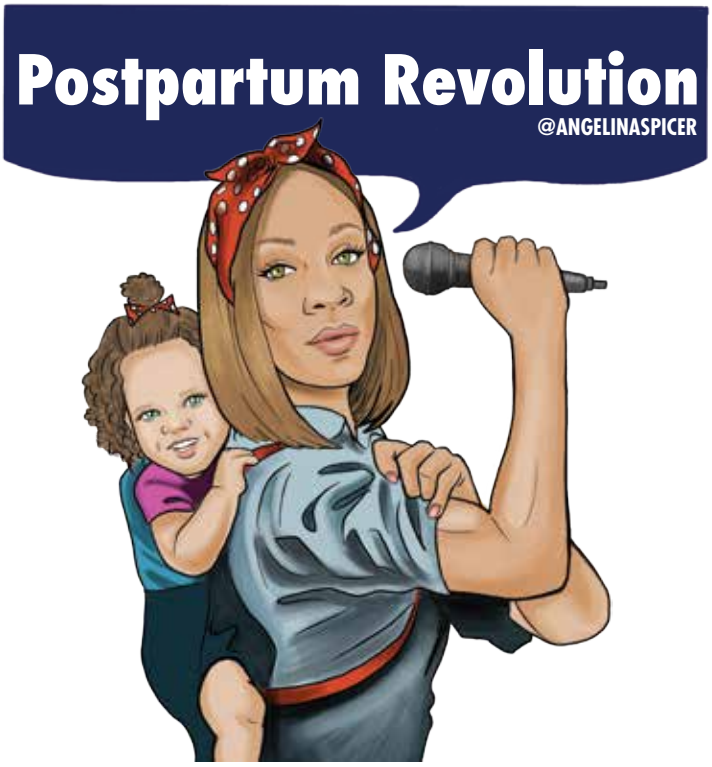


The Gap Baby: An RSV Story



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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

National Perinatal Association

Neonatology Today's Digital Presence

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

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

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

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

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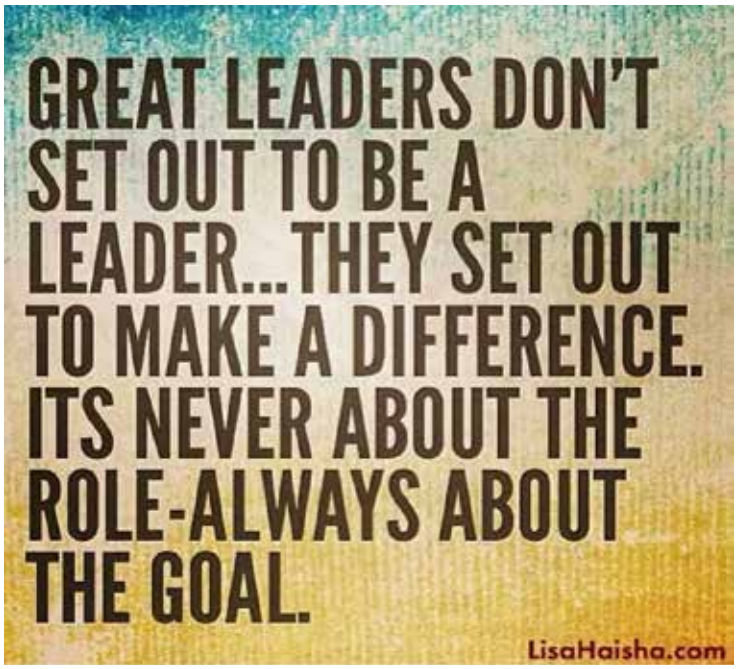
Respiratory Therapy Leadership, Part Two.

Kelly Lewis, BA, RRT-NPS



In this second installment on the topic of Leadership, I present to you another management conundrum. In case you missed last month's post, here is a quick recap:

The Respiratory Care Board in California changed the continuing education requirements to include courses in Leadership and communication and grant credit for attending certain upper-level meetings.

"The Respiratory Care Board in California changed the continuing education requirements to include courses in Leadership and communication and grant credit for attending certain upper-level meetings."

Here is this month's management/leadership challenge:

In a very busy 20-bed NICU, the BioMed tech is seen looking at all the clean ventilators in the equipment room. Asking if I can help her, she hands me a notepaper and says, "I need these two ventilators; they are overdue for preventive maintenance (PM)." We looked at the ID numbers on the clean vents, and none match. This means these two vents are likely on babies. I look through the rooms and find the two vents. They are on the two sickest babies in the unit.

""I need these two ventilators; they are overdue for preventive maintenance (PM)." We looked at the ID numbers on the clean vents, and none match. This means these two vents are likely on babies. I look through the rooms and find the two vents. They are on the two sickest babies in the unit."

The BioMed tech tells me that I have to change out the vents because her supervisor says they cannot go past PM dates. The machines need to go with her today. The Neonatologist said otherwise, as did I. I asked if any other NICU vents needed PM and promised that as soon as the babies were stable enough, I would call her to let her know she could take those ventilators. I'd even deliver the vent to her if she wanted. In a huff, she left. Later, I got a call from my Director: give BioMed the vents. I explained that these babies were not stable enough to tolerate being bagged right now. My Director explained that his colleague, the Director of BioMed, has deadlines to meet. I referred my Director to the Neonatologist. We left the babies on.

Fast forward to about two months later. I am the only RT in the unit and got called to a crash C-section on a 33-week gestation baby. I set up the ventilator and left it running to warm and humid the circuit. In the DR, the baby was fine, requiring only SiPap. We bring the baby back to the NICU room, and ….. wait a minute, er, where is the ventilator I set up - the one that was designated for this baby, a 33-week gestation C-section baby? I asked the shift lead, the nurses, and finally, my Director. No answers. After stabilizing the baby, I thought: "Noooooooooo.....". I placed a call to BioMed. She had indeed come and picked up a vent slated for use on a baby in the process of being born - a vent that was warming up and, technically, in my eyes, in use. The unit nurses were too busy

to notice that anything was amiss. What if that baby had been intubated and needed that vent? “That vent was due for PM, and you know we must stay on top of our PM deadlines,” Miss BioMed quipped. My Director had nothing to say about it, but the Neonatologist sure did. I do not think I can print that conversation here.

Discussion:

In terms of Leadership, what would you have done as a department director? As a NICU RT? As a neonatologist? What solutions could the RT and BioMed Director have devised to satisfy patient demand and equipment maintenance needs?

Disclosures: The authors have no disclosures

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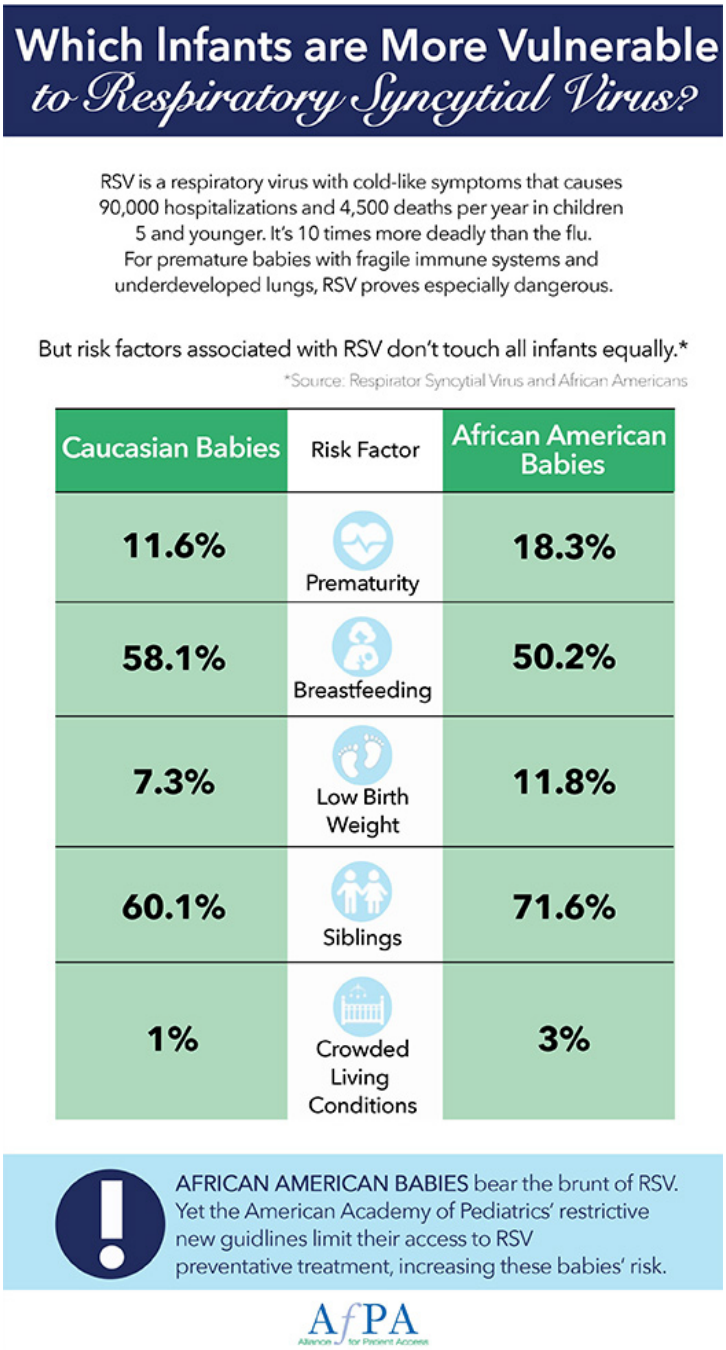

40th Advances in Neonatal and Pediatric Cardiorespiratory Care

Attend in person

Jan 31 - Feb 2, 2024

Location:
Hilton Los Angeles North/Glendale
Glendale, CA

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

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WHY YOU SHOULD ATTEND?

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- Learn how technology can help address health disparities in children.
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- Management of Post Discharge Bronchopulmonary Dysplasia associated Pulmonary Hypertension and pediatric patients with pulmonary hypertension.

GENERAL INFORMATION

Agenda

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

Location

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

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

Registration

We suggest you register early.

Online – To register online, please go to:

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

Conference Parking

Self Parking: $10.00

Valet Parking: $29.00

Transportation

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

UBER/LYFT: Estimate $10-$12.00

The nearest airports are:

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

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

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

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

Refunds

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

Hilton Los Angeles North/Glendale

Accommodations

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

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

It is strongly advised that you make room reservations early.

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

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

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

Faculty

COURSE DIRECTOR

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

FACULTY

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

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

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

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

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

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

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

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

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

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

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

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

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

Workshops

A. Functional Echocardiography

B. Lung US

C. aEEG /NIRS

D. Noninvasive Ventilation

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

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

DESCRIPTION

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

TARGET AUDIENCE

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

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

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

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

DISCLAIMERS:

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

GRIEVANCES:

Any grievances may be made to info@paclac.org

FEES

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

CONTINUING EDUCATION

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

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

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

CERTIFICATE POLICY:

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

COURSE OBJECTIVES

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

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

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

Practical Data Analytics for Innovation in Medicine:

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

Second Edition

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

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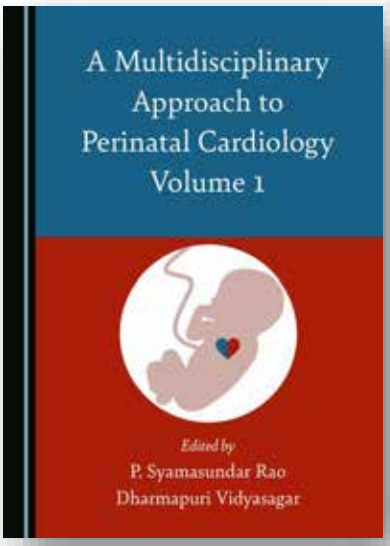
A Multidisciplinary Approach to Perinatal Cardiology *Volume 1*

Edited by P. Syamasundar Rao and Dharmapuri Vidyasagar



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£99.99

Book Description

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

About the Editors

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

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

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

My NICU Network
My Perinatal Network

National Perinatal Association + NICU Parent Network

Online L&D Staff Education Program

Caring for Pregnant Patients & Their Families:

Providing Psychosocial Support During Pregnancy, Labor and Delivery

WWW.MYPERINATALNETWORK.ORG

Continuing education credits provided by

pac-lac

About the Program

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

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

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

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

Program Objectives

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

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

PROGRAM CONTENT

COMMUNICATION SKILLS CEUs offered: 1

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

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

PERINATAL MOOD AND ANXIETY DISORDERS CEUs offered: 1

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

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

PROVIDING ANTEPARTUM SUPPORT CEUs offered: 1

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

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

PROVIDING INTRAPARTUM SUPPORT CEUs offered: 1

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

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

PROVIDING POSTPARTUM SUPPORT CEUs offered: 1

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

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

SUPPORTING STAFF AS THEY SUPPORT FAMILIES CEUs offered: 1

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

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

Cost

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

Contact help@myperinatalnetwork.org to learn more.

Faculty

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

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

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

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

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

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

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

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

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

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

Parent/Patient Contributers:

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

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

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

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

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

CANCELLATIONS AND REFUNDS

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

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

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

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

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

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

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

EVIDENCE

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

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

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

TRAUMA-INFORMED

Both parents and providers are confronting significant...

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

LONGITUDINAL DATA

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

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

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

Partnering for patient-centered care when it matters most.

nann.org nationalperinatal.org

National Association of Neonatal Nurses

National Perinatal Association

FREE ONLINE EDUCATION

Coping with COVID-19

A viral pandemic

A racial pandemic within a viral pandemic

Will mental illness be the next inevitable pandemic?

WWW.MYNICUNETWORK.ORG

and

National Perinatal Association
NICU Parent Network

Why Infant Deaths are Rising in 2023

Josie Cooper

The Alliance for Patient Access (allianceforpatientaccess.org), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of directors. Its physician leadership is supported by policy advocacy management and public affairs consultants. In 2012, AfPA established the Institute for Patient Access (IfPA), a related 501(c)(3) non-profit corporation. In keeping with its mission to promote a better understanding of the benefits of the physician-patient relationship in the provision of quality healthcare, IfPA sponsors policy research and educational programming.

AfPA | Alliance for Patient Access

IfPA | Institute for Patient Access

"The nation already struggles with a higher infant mortality rate than many other developed countries. Moreover, like other countries, the United States has recently charted higher rates of low birthweight and preterm births."

For the first time in two decades, infant mortality is on the rise in the United States.

The nation already struggles with a higher infant mortality rate than many other developed countries. Moreover, like other countries, the United States has recently charted higher rates of low birthweight and preterm births.

Nevertheless, new data from the CDC clearly illustrate the factors driving infant deaths – and give powerful clues about how to prevent them.

Infant Mortality Data:

Between 2021 and 2022, the United States saw a 3% climb in its infant mortality rate. That raises infant fatalities to 5.6 per 1,000 live births.

In a nation that welcomes 3.7 million babies each year, this means that more than 18,000 newborn lives were lost last year.

"A Black infant born in America is about twice as likely as a white infant to die in the first year of life. Native American infants and babies born before 37 weeks of gestation experienced the starkest change in mortality over the past few years."

Babies of color face a higher risk of death:

A Black infant born in America is about twice as likely as a white infant to die in the first year of life. Native American infants and babies born before 37 weeks of gestation experienced the starkest change in mortality over the past few years.

Reversing the Trend:

The CDC cites two primary causes of infant mortality: maternal complications and bacterial meningitis. However, the "cause of death" alone paints an incomplete picture. The factors driving changes in infant survival, especially the disparities in maternal and infant health, are complex and multifaceted.

Consider that Black, Alaskan Native, Native Hawaiian, and Native American women are far more likely than white women to face fetal death, preterm births, stillbirths, and low-birthweight babies. These same groups have higher rates of pregnancies for which they receive no prenatal care and have higher incidences of maternal mortality.

"Consider that Black, Alaskan Native, Native Hawaiian, and Native American women are far more likely than white women to face fetal death, preterm births, stillbirths, and low-birthweight babies. These same groups have higher rates of pregnancies for which they receive no prenatal care and have higher incidences of maternal mortality."

The trend suggests that lack of access to adequate prenatal care and interventions contributes to the rise in infant deaths. The COVID-19 pandemic, which reduced hospital visits and led some clinics to close, also deepened healthcare inequalities.

"The trend suggests that lack of access to adequate prenatal care and interventions contributes to the rise in infant deaths. The COVID-19 pandemic, which reduced hospital visits and led some clinics to close, also deepened healthcare inequalities."

Better access to care could not only save infants but also reduce pregnancy-related maternal death.

Reducing infant mortality, therefore, will require targeted policy interventions. Policymakers, healthcare professionals, and communities can unite around policy initiatives that bolster maternal and prenatal health services and education.

One example is the Black Maternal Health Momnibus Act of 2023, which aims to address the maternal health crisis in the United States. The legislation provides critical funding to address social determinants of health, enhance data collection processes, improve access to maternal mental health care, and promote maternal vaccinations to protect the health of moms and their babies.

"All expectant mothers, regardless of their demographic background, should have access to timely and comprehensive prenatal care. By prioritizing maternal health care and addressing disparities in access, policymakers, advocates, and providers can work toward a healthier, more equitable future for mothers and babies alike."

All expectant mothers, regardless of their demographic background, should have access to timely and comprehensive prenatal care. By prioritizing maternal health care and addressing disparities in access, policymakers, advocates, and providers can work toward a healthier, more equitable future for mothers and babies alike.

References:

1. https://time.com/6330531/us-infant-mortality-rate-increase/
2. https://thehill.com/policy/healthcare/4287207-infant-mortality-rises-first-time-20- years-cdc/
3. https://www.healthsystemtracker.org/chart-collection/infant-mortality-u-s-compare-countries/#item-the-u-s-infant-mortality-rate-has-improved-over-time
4. https://www.cdc.gov/mmwr/volumes/69/wr/mm6937a1.htm#:~:text=Fetal%20deaths%20in%20the%20United,%2Dgestation%20pregnancy%20(2).
5. https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/
6. https://www.cdc.gov/nchs/maternal-mortality

Disclosure: *Josie Cooper is executive director of the Alliance for Patient Access. This article was also published at healthpolicytoday.org.*

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Immunizing Yourself Against **COVID-19**

COVID-19 vaccines have been shown to:

- Lessen the severity of symptoms[1]
- Reduce disease transmission[3]
- Reduce risk of mortality[2]
- Make communities healthier and safer[4]

Understanding the Options

COVID-19 vaccines are available for children, adolescents and adults. There are 3 types to choose from.

mRNA VACCINES

New to market, but research has been ongoing since the 1990s.

HOW THEY WORK: **Instruct cells to make COVID-like proteins that trigger the immune system to fight the virus.**

PROTEIN SUBUNIT VACCINES

Used for three decades against the flu, whooping cough and hepatitis B.

Deliver harmless versions of the COVID protein that train the immune system to fight the virus.

VECTOR VACCINES

Used for decades against chickenpox, malaria and tuberculosis.

Use a modified virus, such as a common cold, to teach the body to fight off COVID.

COVID vaccines are recommended for everyone ages 6 months and older, and boosters for everyone ages 5 years and older, if eligible.[5]

Safe and Sound

COVID vaccines have been:

- **Thoroughly tested** through multi-phase trials with tens of thousands of participants[6]
- **Proven safe and effective** for adults as well as children[7]
- **Vetted and approved** by the US FDA and EMA and endorsed by the WHO[8-10]

Get Your Jab

Vaccines are available at your:

- **Doctor's office**
- **Neighborhood pharmacy**
- **Community health center**

Talk to your **health care provider** or **pharmacist** about which vaccine is right for you.

1. https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8782520/
3. https://www.nejm.org/doi/full/10.1056/nejmc2107717
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5. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
6. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-and-effectiveness
7. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-and-effectiveness
8. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
9. https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised
10. http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/WHO-EUA-qualified-covid-vaccines.pdf

GAfPA Global Alliance for Patient Access

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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

Limit Contact with Others

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

Provide Protective Immunity

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

Take Care of Yourself

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

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

WARNING

Never Put a Mask on Your Baby

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

If you are positive for COVID-19

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

We can help protect each other.

Learn more

www.nationalperinatal.org/COVID-19

National Perinatal Association

The Gap Baby: An RSV Story

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

The National Coalition for Infant Health advocates for:

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

www.infanthealth.org

iCAN's Inaugural Fundraiser Sets the Stage for Italy Summit, Expert Insights, and Spotlight on KIDS Chapters

Sabina Schmidt Goldstein-Becerra

Get involved today and Join the iCAN Parent Council!

"iCAN, or the International Children's Advisory Network, is committed to providing numerous opportunities for the pediatric community to come together and hear from the most crucial stakeholders in healthcare: the patients. Our organization empowers all pediatric patients worldwide by facilitating their active participation in innovation, research, and medicine. "

iCAN, or the International Children's Advisory Network, is committed to providing numerous opportunities for the pediatric community to come together and hear from the most crucial stakeholders in healthcare: the patients. Our organization empowers all pediatric patients worldwide by facilitating their active participation in innovation, research, and medicine. Whether you are a patient, family member, healthcare professional, or supporter of the cause, we welcome you to visit our website at www.iCAN.health to learn more about our mission, various programs, and initiatives. Join us to ensure that every child's voice is heard and that their unique experiences are taken into account to improve healthcare outcomes for all pediatric patients.

Ask the Experts' Insights: December Recap and Looking Forward for the New Year:

In our recent ATE on December 16, we chatted with Joe Kiani, Masimo's Founder, CEO, and Chairman. We thank Joe Kiani for sharing his thoughts on medical innovation and business. He stressed the importance of sticking to your principles in business and reminded us to stay determined. Our members asked him questions about his invention, the pulse oximeter, and got exclusive insights into how it works. You can check out the recorded session on our website for easy access.

"Our members asked him questions about his invention, the pulse oximeter, and got exclusive insights into how it works. You can check out the recorded session on our website for easy access."

January Topic: Empowering Hearts and Minds: Dr. Adam Starks on Child Welfare, Resilience, and Advocacy:

Looking ahead, mark your calendars for our upcoming Ask the Experts session on January 20 at 8 AM PST, 11 AM EST. We are excited to announce Dr. Adam Starks as our special guest.

"Dr. Adam Starks is an inspirational keynote speaker on various child welfare-related topics ranging from foster care, child mental health issues, and trauma-informed care. He is also an award-winning author of children's books Love Will Find Your Home, Love Makes The World Go Round, and his autobiography, Broken Child Mended Man."

Dr. Adam Starks is an inspirational keynote speaker on various child welfare-related topics ranging from foster care, child mental health issues, and trauma-informed care. He is also an award-winning author of children's books *Love Will Find Your Home*, *Love Makes The World Go Round*, and his autobiography, *Broken Child Mended Man*. After aging out of the Virginia foster care system, Dr. Starks earned a bachelor's degree from Eastern Mennonite University, an M.B.A. from Strayer University, and a Ph.D. in Organizational Leadership from Capella University. He is also the Founder and CEO of MNDYRR (mender), a supportive app that helps at-promise youth access social services and mental wellness resources. Dr. Starks' passion is child and family advocacy, serving on his local school board in Barbour County, Youth Advisory Board for World Vision KidReach, Hero's Haven Child Advocacy Center board member, and President of the West Virginia CASA Association board. Dr. Starks resides with his wife and three children in Philippi, West Virginia.

Do not miss this opportunity! Register for the event on January 20 with Dr. Adam Starks at icanresearch.org.

iCAN's Inaugural Fundraising Challenge: Join Us in Shaping Pediatric Healthcare!

- iCAN Challenge: Striving Towards Pediatric Healthcare Excellence
- Date: March 2, 2024
- Time: 24- Hour
- Location: Global

About the Event: Join us in our first-ever iCAN Challenge, a community-driven initiative for children living with rare or complex conditions, dedicated to fundraising for our 2024 Annual Research and Advocacy Summit in Bari, Italy. This event is a collective effort to help provide pediatric patients with a powerful voice in medicine, research, and innovation. Your participation will play a pivotal role in empowering young voices and advancing critical initiatives that will mold the future of pediatric healthcare.

"Join us in our first-ever iCAN Challenge, a community-driven initiative for children living with rare or complex conditions, dedicated to fundraising for our 2024 Annual Research and Advocacy Summit in Bari, Italy. This event is a collective effort to help provide pediatric patients with a powerful voice in medicine, research, and innovation."

How to Get Started:

1. Get your team together and choose a fun challenge.*
2. Set a fundraising goal; we suggest aiming for $2500.
3. Decide whether you want to do the challenge as a group or if each member can do it independently.
4. If you do it together, make sure everyone wears iCAN gear if they have it!
5. Hand out forms to each team member to show to people and ask for donations.
6. Encourage members, parents, and team leaders to find sponsors, individually or as a group, if someone feels shy.
7. Use Zeffy to collect money after the event – download the app or visit the website, and donors will receive a donation

email automatically.

8. Have a blast during the event and take lots of pictures!
9. Send the pictures to abbyclark@icanresearch.org so iCAN can share them.
10. iCAN will keep the funds in an account for your chapter to help cover expenses for kids attending the Summit.

Start brainstorming and decide on your challenge, as we will be sending out a link in January for your team/chapter to begin fund-raising for the Summit.

*Participating in the iCAN Challenge is easy and adaptable to all ages and abilities.

To celebrate our 10th annual year, we encourage you to take on challenges based on the number 10.

"Here are some inspiring ideas: Bake 10 cakes, read 10 books, complete 10 sketches, pick up 10 pieces of litter, do 10 good deeds, plant 10 trees, run or walk 10 blocks, bike 10 miles, knit 10 things, dance 10 dances, decorate 10 rocks, or swim 10 laps. The challenge is up to you!"

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Spotlight on our iCAN KIDS:

KIDS Bari Adds New Chapter Members!

Expanding its footprint in Bari, Italy, KIDS Bari joyously welcomes an influx of new members to its growing chapter. We are thrilled to witness the remarkable expansion as Bari diligently fosters connections between healthcare professionals and the children they serve. This marks the beginning of an exciting journey, and we commend KIDS Bari for its dedicated efforts to impact the well-being of the community's youth positively. Bravo, KIDS Bari, for paving the way to a brighter and healthier future!

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Huiyun's Artistic Insight into Clinical Research:

We spotlight Huiyun, a talented member of our KIDS Chapter at Walter Peyton. Huiyun recently contributed an exceptional piece of art to our Anthology, created in collaboration with Duke.

Her artwork skillfully captures the intricacies of clinical research, providing a visual journey through the process. Huiyun's ability to express her keen interest in the subject is genuinely remarkable.

As she prepares to apply to college for fall admission, we extend our best wishes to Huiyun. May she successfully embark on her journey toward fulfilling her dreams of delving deeper into research. We are proud to have such dedicated and creative individuals like Huiyun in our iCAN community!

iCAN Opportunities:

Upcoming Events: Mark Your Calendar!

1. Ask the Experts - January 20th, 8 AM PST, 11 AM EST:

   Please save the date for our upcoming Ask the Expert session on January 20, featuring Dr. Adam Starks, Founder & CEO of MNDYRR Technologies, Inc. This insightful session promises to provide valuable expertise and perspectives.

2. Ask the Experts- February 24th, 8 AM PST, 11 AM EST:

   "Global Perspectives on Healthcare Regulation: A Dialogue Between Dr. Martine Dehlinger Kremer and Victor Garcia"

"Our upcoming 2024 summit is set to unfold in the picturesque city of Bari, Italy, from July 15 to 19th! The anticipation among our enthusiastic young participants is palpable as they eagerly await this remarkable event. However, to make it truly unforgettable, we need your support!"

Exciting News: iCAN's 2024 Summit in Bari, Italy!

Our upcoming 2024 summit is set to unfold in the picturesque city of Bari, Italy, from July 15 to 19th! The anticipation among our enthusiastic young participants is palpable as they eagerly await this remarkable event. However, to make it truly unforgettable, we need your support!

Our annual Summit is a transformative platform for nurturing innovation, compassion, and collaboration in pediatric healthcare among youth.

"Thank you for considering this opportunity to support the next generation of healthcare leaders. Your generosity and dedication are deeply valued. Let us unite in Bari, Italy, to create a summit experience that empowers young minds for years to come!"

If you believe in the power of education and inspiration, we invite you to participate in this life-changing event. You can contribute in two meaningful ways:

1. Sponsor the 2024 Summit: Your sponsorship plays a pivotal role in the seamless organization of the Summit. Your generous support ensures an impactful experience for all attendees.

2. Sponsor a Child to Attend: Your sponsorship directly impacts a child's life, granting them the chance to attend the Summit in Bari. Covering travel, accommodation, and participation – your support offers a world of learning and empowerment.

Together, we shape a brighter future for pediatric healthcare by

nurturing the potential of our young members. Regardless of size, your contribution makes a significant difference in fostering innovative advancements.

Thank you for considering this opportunity to support the next generation of healthcare leaders. Your generosity and dedication are deeply valued. Let us unite in Bari, Italy, to create a summit experience that empowers young minds for years to come!

Disclosures: *There are no reported disclosures*

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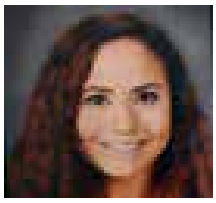

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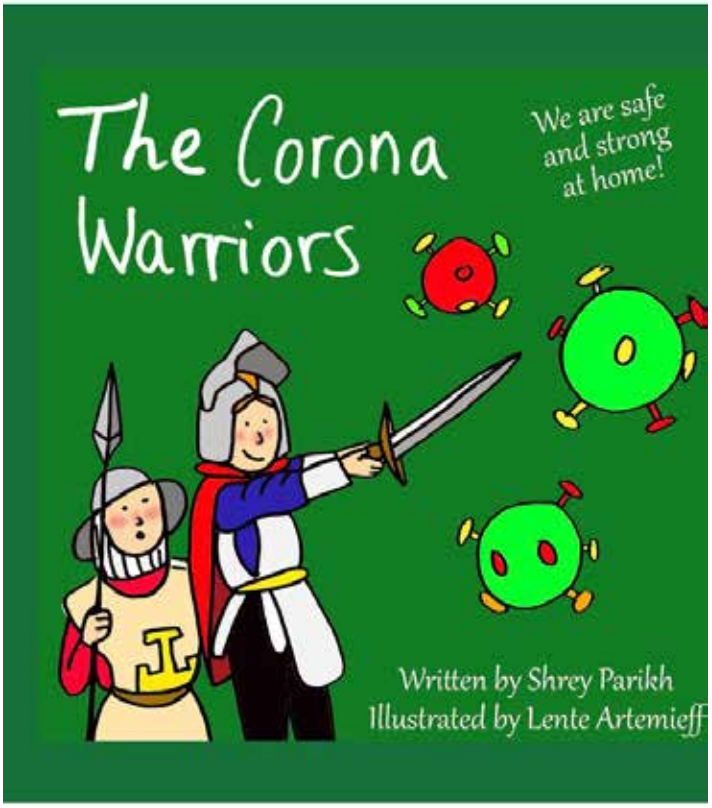
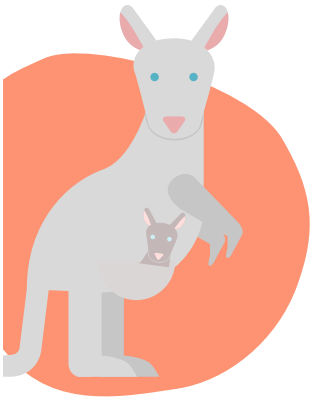


SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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

National Perinatal Association

nicuparentnetwork.org

nationalperinatal.org/skin-to-skin

Your Pregnancy and Substance Use

4 Things you can do to improve your health and lower your risk for complications

Get Prenatal Care

Start early. Go to all your visits. Empower yourself with information so you can make smart decisions. Build relationships with providers who understand Substance Use Disorders (SUDs) and know how to help. Partner with them to reach your goals. But remember, you do not need to be abstinent from substance use to get care. Go now.

Reduce Your Use

There are simple things you can do to limit the harm substances might do.

- Use fewer substances
- Use smaller amounts
- Use less often
- Learn how to use safer

Reducing or quitting smoking is a good place to start. Set your goals, then ask for help.
One of the best things you can do is to stop using alcohol. We know that even small amounts are risky. And when combined with benzos and opioids, alcohol can kill.

Use Medications for Opioid Use Disorder (MOUD) if you are opioid dependent

Methadone and Buprenorphine (Subutex® or Suboxone®) are the "Standard of Care" during pregnancy because they:

- Eliminate the risks of illicit use
- Reduce your risk for relapse
- Can be a positive step towards recovery

Take Good Care of Yourself

You deserve a healthy pregnancy & childbirth.

- Eat healthy and take your prenatal vitamins
- Find the right balance of rest and exercise
- Surround yourself with people who care

Your Health Matters

Academy of Perinatal Harm Reduction

www.perinatalharmreduction.org | www.nationalperinatal.org

National Perinatal Association

Education. Anytime, Anywhere.

Academy of Neonatal Care

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

www.AcademyofNeonatalCare.org.

Keeping Your Baby Safe
from respiratory infections

RSV
COVID-19
colds
flu

How to protect your little ones from germs and viruses

This year is an especially dangerous cold and flu season - especially for vulnerable infants and children. Fortunately, there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

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

Limit Contact with Others

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

Provide Protective Immunity

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

Take Care of Yourself

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

Get Immunized

Vaccinations save lives. Protecting your baby from COVID-19, flu and pertussis lowers their risks for complications from respiratory infections.

WARNING

Never Put a Mask on Your Baby

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

If you feel sick or are positive for COVID-19

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

We can help protect each other.
www.nationalperinatal.org/rsv

National Perinatal Association

PROTECT YOUR FAMILY FROM

RESPIRATORY VIRUSES

flu coronavirus pertussis RSV

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

www.nationalperinatal.org

FREE RESOURCES FOR YOUR NICU

Coping During COVID-19

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

BONDING WITH YOUR BABY

HELPING CHILDREN AND FAMILIES COPE

CAREGIVERS NEED CARE TOO

National Network of NICU Psychologists

nationalperinatal.org/psychologists

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

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

Identify babies at greatest risk

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

Teach families how to protect

their babies from respiratory infections

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

Use your best clinical judgement

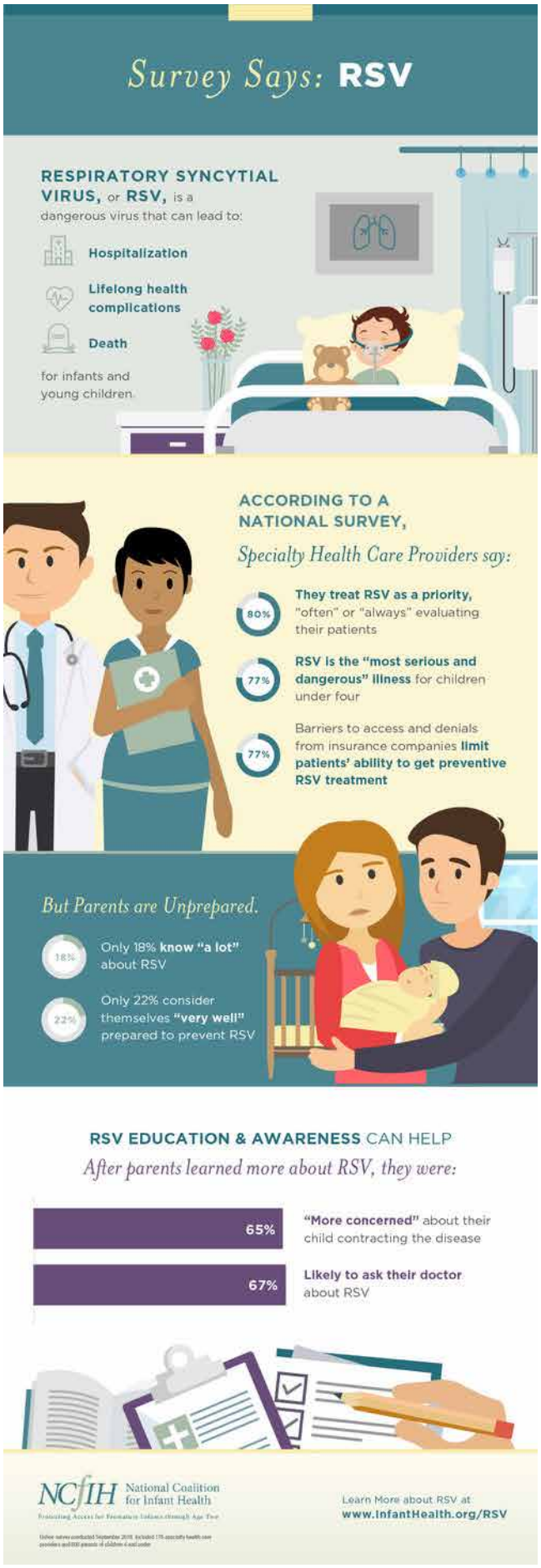
when prescribing RSV prophylaxis

Tell insurers what families need

and provide the supporting evidence

National Perinatal Association

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



Peer Reviewed

Briefly Legal: The Classification of Fetal Heart Rate Patterns, Time for a Change?

Barry S. Schifrin, MD; Maureen Sims, MD

"I speak truth, not so much as I would, but as much as I dare; and I dare a little the more as I grow older."— Michel de Montaigne

Introduction:

In 1964, long before the introduction of fetal monitoring, John Pratt, in an article entitled "Strong Inference," asked why certain systematic methods of scientific thinking may produce much more rapid progress than others. He thought several scientific specialties progressed rapidly while others, including medicine, progressed much more slowly. (1)

"Electronic fetal monitoring (EFM) is the most common obstetrical procedure in the United States; it is used annually by upward of 3.8 million individuals in labor. The ubiquity of EFM ultimately boils down to the need to assess the ability of the fetus to tolerate the hypoxemic, ischemic, and mechanical stresses of labor imposed by loss of amniotic fluid, contractions, and maternal pushing, which may be superimposed on problems of the mother including infection, or problems intrinsic to the fetus or placenta."

In a contemporary article on Clinical Quality Measures in Obstetrics, the authors trace the limited results of numerous efforts to enhance the quality of obstetrical care, including the withdrawal of many indicators of quality once considered necessary. None of the indicators involved the response to FHR patterns. (2)

In attempting to glean wisdom and direction from these widely spaced communications, we offer comments here on the recent "Systematic Review" of the ACOG classification of FHR patterns during labor (Review) and its consequences for the outcome of babies, for the conduct of labor, and in the adjudication of allegations of obstetrical negligence when accountability for injury is sought. (3)

Electronic fetal monitoring (EFM) is the most common obstetrical procedure in the United States; it is used annually by upward of 3.8 million individuals in labor. (4, 5) The ubiquity of EFM ultimately boils down to the need to assess the ability of the fetus to tolerate the hypoxemic, ischemic, and mechanical stresses of labor imposed by loss of amniotic fluid, contractions, and maternal pushing, which may be superimposed on problems of the mother including infection, or problems intrinsic to the fetus or placenta. (6–9) There seems to be no reliable alternative to defining the wellbeing of the individual fetus given the limitations of both intermittent auscultation and newer modalities including fetal pulse oximetry and fetal ST-segment analysis. (10–12)

EFM is not without its limitations. These include significant intra- and interobserver variability (using current terminology) and increased operative deliveries. (13–15) Beyond this, there is widespread disagreement on both its value in terms of improved outcome, as well as the basic glossary of terms related not only to FHR patterns and uterine contractions but to definitions of the feasibility of safe vaginal delivery. (6, 16)

"EFM is not without its limitations. These include significant intra- and interobserver variability (using current terminology) and increased operative deliveries. Beyond this, there is widespread disagreement on both its value in terms of improved outcome, as well as the basic glossary of terms related not only to FHR patterns and uterine contractions but to definitions of the feasibility of safe vaginal delivery."

The ubiquity and longevity of EFM notwithstanding, we are now engaged in a broad debate over the value of EFM, especially as it applies to the nomenclature, the management guidelines, and deliberations in courts and other tribunals. (17–22) In 1991, Freeman opined that EFM was a "modality that is difficult to learn, difficult to interpret. It has become a major factor in obstetrical litigation, where its inexact nature confuses attorneys and lay juries." (23) Beyond litigation, the interpretation of FHR patterns has continued to "befuddle obstetric care providers" as well. (24) Indeed, more than 50 years after its introduction, the level of befuddlement has contributed to calls for the technique to be abandoned clinically and in the courtroom. (20–22)

"In 1991, Freeman opined that EFM was a "modality that is difficult to learn, difficult to interpret. It has become a major factor in obstetrical litigation, where its inexact nature confuses attorneys and lay juries."

The publication of the 3-tier (Category I–III) interpretive and management schema by the American College of Obstetricians & Gynecologists followed a consensus workshop. (25, 26, 6) It is difficult to argue now or then that the publication of these 3-tier guidelines by the ACOG in 2009 and 2010 would improve the problems associated with EFM, improve outcome statistics, or the sense of community on labor and delivery (26–29)

The Category System:

The review attempted to evaluate the rate of adverse neonatal or maternal outcomes in parturients at term according to FHR Categories I–III within 30 to 120 minutes of delivery. The authors reviewed 671 articles but accepted only three disparate, observational studies of term infants reporting outcomes of interest for their analysis. These three reports (two from the US, one from Italy) included 47,648 singletons at 37 weeks gestation: 27.0% of deliveries had CAT I tracings, 72.9% had CAT II tracings, and 0.1% had CAT III tracings. (30–32) It is troubling in several respects that one of the studies, thought by the authors to be of poor quality, contributed more than 80% of the data but had no CAT III tracings. (30)

"The review attempted to evaluate the rate of adverse neonatal or maternal outcomes in parturients at term according to FHR Categories I–III within 30 to 120 minutes of delivery... It is troubling...that one of the studies, thought by the authors to be of poor quality, contributed more than 80% of the data but had no CAT III tracings."

Adverse outcomes were based on ***either*** an Apgar score <7 at 5 minutes or umbilical artery pH (UApH) <7.00. Secondary outcomes included several neonatal and maternal outcomes considered adverse. The incidence of an Apgar score <7 at 5 minutes was significantly higher among CAT II deliveries (OR 1.56; 95% CI 1.23–1.99) than CAT III tracings (OR 14.46; 95% CI 2.77–75.39). The incidence of UApH <7.00 was similar among CAT I and CAT II tracings (0.08% vs 0.24%; OR 2.85; 95% CI 0.41–19.55) but was significantly more common with CAT III tracings (31.04%; OR 161.56; 95% CI 25.18–1036.42. Although the incidence was low, hypoxic-ischemic encephalopathy (HIE) occurred with a similar frequency with CATs I and II (0 vs 0.81%; OR 5.86; 95% CI 0.75–45.89) but was significantly more common among those with CAT III tracings (0 vs 18.97%; OR 61.43; 95% CI 7.49–503.50).

"The incidence of an Apgar score <7 at 5 minutes was significantly higher among CAT II deliveries than CAT III tracings. The incidence of UApH <7.00 was similar among CAT I and CAT II tracings but was significantly more common with CAT III tracings. Although the incidence was low, hypoxic-ischemic encephalopathy (HIE) occurred with a similar frequency with CATs I and II but was significantly more common among those with CAT III tracings"

Cesarean delivery occurred with similar frequency with CAT I (13.41%) and CAT II tracings (11.92%) (OR 0.87; 95% CI 0.72–1.05) but was significantly more common among those with CAT III tracings (14.28%) (OR 3.97; 95% CI 1.62–9.75). Unspoken in the presentation of the cesarean section data is the lack of discussion of the timing in the labor of the appearance of the abnormal pattern or its relationship and the feasibility of safe vaginal delivery. (33) Should the FHR abnormality deserving of intervention be found in the 1st stage of labor, vaginal delivery is either not an option or the duration of abnormality is prolonged in the effort to achieve vaginal delivery. In the 2nd stage of labor, operative vaginal delivery may be a reasonable option—avoiding a cesarean section, but again potentially increasing the exposure to a deteriorating FHR pattern.

In addition to those limitations mentioned above, the Category system offers no insight into the source of the abnormal tracing. Thus, decelerations related to maternal hypotension, excessive uterine activity, and fetal growth restriction are not differentiated from those related to impaired umbilical or cerebral blood flow or those related to maternal or fetal infection. The system does not acknowledge a pattern of neurological injury (34), although an ACOG monograph states that if a pattern goes from CAT I to CAT III and the fetus suffers a neurological injury, that injury may be ascribed to the events of labor and delivery. (35) The Category system offers no comments related to the response

(recovery) from the contraction-induced deceleration, likely the most important information to be gleaned in the analysis of FHR patterns. (36) Given these physiological limitations, there can be little surprise that efforts to ameliorate abnormal patterns appear to be of limited value in preventing adverse short- or long-term outcomes. (37, 38) There is an apparent lack of benefit to the increase in cesarean section rate. (5, 39, 25, 40)

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The limitations of the Category system notwithstanding, the authors justify their systematic review, arguing that no previous comprehensive review provides an extensive overview of the differences in the adverse neonatal-maternal outcomes among the different categories. Previous reviews of EFM in the context of intermittent auscultation, amnioinfusion, supplemental oxygen, tocolytics, or deceleration areas related to CAT II patterns do not satisfy these requirements. (41–45, 32)

The authors of the Review aver that they have addressed these shortcomings by including all non-anomalous singletons who reached 37 weeks' gestation with deliveries after labor across two different countries. In addition, they contacted the authors of the publications that met the inclusion criteria to obtain data on several secondary outcomes that were unavailable in the initial publications. The authors further claim that by linking the three categories with the incidence of a low Apgar score at 5 minutes and neonatal acidosis, the co-primary outcomes of the review, they achieve an objective assessment of fetal wellbeing. (46, 47)

These efforts notwithstanding, the frequency of the 3 Categories varied significantly among the studies. Overall, almost three-quarters of FHR patterns in labor were characterized as CAT II and only 0.1% were classified as CAT III. (see below). Some of the secondary adverse neonatal outcomes—treatment for sepsis, HIE, and death within 27 days of birth—increased significantly with increasing Category, but others (*e.g.*, ventilation for 6 hours and neonatal seizures) did not. The rate of cesarean delivery also varied among the three groups, but the rate of postpartum hemorrhage or transfusion did not vary significantly. The maternal characteristics, the proportion of complicated pregnancies, study design, the experience and familiarity with FHR patterns among the physicians and nurses who interpreted and responded to the FHR patterns, and the outcomes that were investigated and how they were defined were all varied across the three studies. In both reports from the United States, (30, 32) the FHR patterns were interpreted by registered nurses. None of the studies were randomized. The small number of cases in one of the included studies (31) and the heterogeneity in the definition of outcomes and some of the assigned categories represent significant limitations of the review.

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In addition, several secondary outcomes were assessed by using the outcomes of only one study. (32) Given the limitations of the data and the limited questions posed by the authors, they caution that the associations, despite their biological plausibility, do not establish causation. They conjecture that the considerable variation in the Categories in these studies resulted from plausible but indeterminable features, including (3):

1. the baseline maternal characteristics
2. antecedent risk factors associated with abnormalities in the FHRTs (e.g., oligohydramnios or intrauterine growth restriction)
3. the intrapartum management of abnormal fetal tracing (e.g., amnioinfusion or oxygen supplementation)
4. the intrapartum complications (e.g., chorioamnionitis or abruption),
5. the interobserver variability in FHRT interpretation

6. the threshold that prompted cesarean or operative vaginal delivery

The Category classification truncates the assessment of uterine activity and ignores the evolution of FHR patterns or uses the individual fetus as its physiological control. It imposes arbitrary definitions of tachycardia and bradycardia and downplays the information contained in the recovery of decelerations. There is no recognition of the importance of fetal behavior or the potential for the prospective identification of fetal neurological injury or intracranial hemorrhage. (34, 48) There is no attempt to evaluate the contraction frequency, strength, and duration linked with adverse outcomes. (44) Nor do they call attention to the need for a more comprehensive assessment of uterine activity than ACOG promulgating the term "tachysystole." Is a Category I pattern with tachysystole still Category I?

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As mentioned above, the CAT system is predicated on the presumed relationship between FHR features and UApH, not the relationship to Apgar score or long-term outcome. Consider this notion and numerous other studies considering Apgar score <7 at 5 minutes **or** UApH <7 as equivalent markers of adverse outcomes. (49) In such a calculus, babies with low Apgar scores but normal UApH values are considered equivalent to vigorous babies with very low UApH values. The risk of adverse outcomes in these two exemplars is quite different. The authors do not compare the Categories according to any combination of these outcome parameters.

Umbilical cord gases may be normal even with severe fetal compromise. When blood has not been flowing efficiently through the umbilical arteries because of occlusion of the umbilical cord or a drop in fetal blood pressure (heart failure), the blood gases of the umbilical arteries at birth may be normal despite the delivery of a lifeless baby. (50) The arterial gases at birth reflect the fetal status before the occlusion or the critical drop in blood pressure. In some instances, e.g., fetal stroke, birth trauma, or acute fetal hemorrhage, the injury may develop rapidly and not be reflected in umbilical cord gases.

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The Apgar scoring system was designed to identify infants who need immediate intervention, not as a tool to reflect or sort out fetal adversities. **Low** scores are never secondary to a metabolic, genetic or prenatal condition but rather reflect intrapartum events. Nevertheless, in defense of inappropriate labor and delivery management, prenatal or a yet unknown genetic disease is put forth in an attempt to defend poor intrapartum management. On the other hand, defense attorneys often use high Apgar scores to dismiss adverse intrapartum events. This is especially common in cases where the fetus experiences head trauma; with head trauma without systemic hypoxia and ischemia, babies will be quite vigorous at birth. Since the hypoxia and ischemia that are experienced in this scenario are regional (limited to the brain) and do not involve the cardiovascular system, the baby appears robust at birth; only hours or days later, as the cytotoxic edema develops, do they develop symptoms of poor feeding, apnea or seizures. Upon further evaluation, they are found to have subdural and retinal hemorrhages and, at times, major changes in head circumference. (51, 52)

The CAT II classification, officially, is "indeterminate;" the patterns satisfy neither the criteria of Categories I or III. This paradigm denies physiological and pedagogical insights. CAT II patterns represent disparate combinations of either decelerations with normal or abnormal baseline features without decelerations. The breadth of the physiological and pathological conditions may present with a CAT II tracing (cord compression, head compression, placental insufficiency, medication effects, prematurity, fetal sleep cycles, existing injury, anomaly, etc.). For example, a tracing with variable decelerations that recover promptly to a stable baseline rate and moderate variability (transient, tolerable cord or head compression) is in the same Category as a tracing with a baseline tachycardia with minimal variability, with absent decelerations (anomaly, drug effect, neurological injury, etc). It seems unreasonable to consider that the metabolic status or the tissue oxygen reserve of each CAT II fetus or the time to decompensation or recovery is the same in each instance. Thus, the presence of a "CAT II" pattern may reflect a normal, healthy, resilient fetus but excludes neither fetal acidosis nor neurological injury. (53–56, 29)

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Combining these disparate features and etiologies into a single classification and offering vague guidelines for their management, including "continued surveillance and reevaluation," (25, 17) appears to have created an unsatisfying "conundrum" for those providers trying to decide what the ubiquitous CAT II tracing means, how to respond, how to counsel patients and defend against the allegation of negligence when there is an adverse outcome. How does one teach, communicate, or use a management recommendation based on CAT II? Published approaches have proven successful. (57) The authors of the Review comment that the incidence of CAT III pattern in their study varies from zero to 9.9%, a differential unlikely to reflect a difference in patients or fetal condition. This improbable range of CAT III tracings is likely related to: 1) an understandable reluctance to identify CAT III tracings—a common problem in malpractice cases, or 2) the understandable confusion imposed by the requirement that CAT III patterns have "absent variability when the technology (using Doppler ultrasonic transducers) does not permit a reliable differentiation of absent and diminished variability. Similarly, tracing interpretation is significantly affected by fetal monitor chart speed concerning variability, accelerations, and decelerations. (58) Ultimately, there is no evidence that the distinction between decreased and absent variability is clinically meaningful; irrespective, it is considered a critical feature of the designation of CAT III.

A sub-analysis of the CAT III in 52 cases led the authors to conclude that the generalizability of the association between CAT III tracings and adverse neonatal outcomes is questionable. They are further unable to comment on whether intrauterine resuscitative measures for the prevention of the development of CAT III, including cesarean delivery done earlier, would reduce neonatal morbidity. (59) Nor could they exclude the Hawthorne effect (improved outcomes derived from clinicians' awareness that their performance was being observed) on the designation of the Category and the associated outcomes. (32, 60, 61)

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We understand that decelerations in the mature fetus represent impaired blood flow. It may represent impaired uteroplacental blood flow without direct impediment to fetal circulation or direct impairment of the umbilical or cerebral circulations. The deceleration, however, only points to the mechanism of the insult; the fetus' ability to deal with that insult is measured by the impact of the deceleration on the baseline rate and variability during the recovery. (36)

The most prominent missing data in the review is understanding the FHR tracing when the patient is admitted for surveillance. Because the three reports included in the analysis focused narrowly either on the last 30 or 120 minutes of labor, the authors could not comment on the FHR patterns before these periods. It is difficult to make sense of these statistics or understand the benefits of intervention without first knowing the Category of the tracing on admission and its evolution throughout labor, including the effect of pushing in the 2nd stage of labor. (62, 63) An adverse outcome with a Category III tracing is understandable. The adverse outcome is likely unpreventable if the tracing is Category III on admission. (64)

Let us set out to create a "perfect," physiologically understandable, teachable classification of FHR patterns. The most superficial

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assessment begins with the notion that tracings either show decelerations or not. In addition, they either have normal baseline features (a stable HR, in the normal range with normal variability) or not (unstable rate, bradycardia, tachycardia, altered variability). Thus, as a minimum, we have a 4-part classification. A fifth classification might be applied to the agonal pattern where, in addition to absent variability and unclassifiable decelerations, there is an unstable, falling baseline FHR. A sixth classification might be applied to fetal arrhythmias, which can sometimes be found. There would be no plausible physiological basis for a 3-tier classification in analyzing FHR responses to uterine contractions. Beginning with the minimum 4-tier classification, it becomes possible to assign pathophysiological explanations as we trace the evolution of patterns. It enables us to focus on restoring normal homeostasis or timely intervention rather than the need to satisfy some elusive level of fetal acidemia before injury has occurred.

If this scenario were "perfect," *the initially normal fetus* would reveal reliable evidence of early compromise, corrective measures would be undertaken promptly, and the fetus would either return to homeostasis or be delivered expeditiously unharmed. If such a system existed, there would be no relationship between evidence of compromise and the outcome because all preventable adverse outcomes were indeed prevented by timely intervention. On the other hand, if the test were worthless, with no correlation between the test results and the outcome, there would again be no relationship between the indicators of distress and the outcome.

The finding of a significant correlation between certain surveillance features and adverse outcomes provides information that the test is not "perfect," as defined above. Under the circumstances where the normal fetus starts with a reassuring pattern (Category I) that evolves to a certain Category II or III tracing and an adverse outcome, in most instances, this often represents a clinical failure—the failure to timely interrupt the deleterious effects of contractions, or pushing, or alteration in the maternal condition. This may develop because the signs were not acted on promptly, or the trajectory of deterioration was not appreciated. There is no evidence that FHR patterns during labor will fail to detect abnormalities in the availability of oxygen or impediments to the heart or brain perfusion early, before the appearance of acidemia. In the rare case, the injury (stroke) in the form of the sudden, unpredictable transition from CAT I to CAT III may occur so quickly as to preclude timely intervention, even with assiduous care. (34)

Why has EFM failed to live up to its expectations? (61, 62) Part of the answer seems to lie in the promulgation of the Category system, a system that permits "allowable" acidosis to develop before responding, in the hopes that the response is sufficiently timely to avoid injury when we do not know the trajectory of deterioration.

Rigorous studies did not accompany the introduction of the FHR CAT system. A greater deficiency was the failure to understand the provenance of intrapartum fetal injury based on the assessment of both immediate and long-term outcomes, not just injury associated with a very low pH. Although ACOG guidelines accept the evolution of CAT I to CAT III as confirmation of an intrapartum injury, most babies injured during labor had CAT II, not CAT III FHR patterns. (54) The majority of these are not acidemic at birth. The measurement of UApH is simple to obtain. We fall back on it as a measure of outcome because no measurements of greater relevance, such as fetal blood pressure or cerebral perfusion, are available. FHR patterns, correctly interpreted, provide information about these parameters. (67)

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However, if the test of EFM's value rests with the correlation with pH or base deficit (BD) at the time of birth and not with meaningful immediate (requirements for resuscitation, etc) and long-term outcome (cerebral palsy, seizures, ASD, etc), then the wrong question is being asked. On the other hand, if EFM has no preventive value except to increase the cesarean section rate, what can be the justification for EFM or intermittent auscultation?

We must remove the notion of waiting for presumed acidosis before intervention. The monitor should be used as an instrument of preventive care rather than one geared to rescuing the fetus from a hostile, presumably acidemic environment. (68) Intervention

based on the provenance of the alterations must begin earlier with the expectation of converting the CAT II to a CAT I tracing. (24) In this recommendation, ensuring adequate fetal reserve at the outset of monitoring is essential. Additional measures include the avoidance of excessive uterine activity with the informed use of oxytocin, irrespective of FHR pattern, and titrating the use of the mother's expulsive efforts according to the response of the fetus. These should be considered as primary instruments to prevent or improve abnormal FHR patterns and minimize the need for urgent intervention. Interestingly, the need for urgent intervention in a patient undergoing a trial of labor is not a measure of the quality of obstetrical care in any of the monitored indicators of obstetrical quality. (69)

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It would seem that these modest initiatives must be taken early, and their trajectory assessed with each contraction. Withholding intervention until the pattern reaches CAT III determines fetal acidemia is more important than a normal fetal outcome. The fact that most CAT III tracings are not acidotic is irrelevant. The pattern reflects a lack of fetal homeostasis from which the fetus does indeed deserve rescue.

The review's authors concluded that "although the incidence of an Apgar score <7 at 5 minutes and umbilical artery pH <7.00 increased significantly with increasing FHR CAT, about 98% of newborns with CAT II tracings do not have ***these*** adverse outcomes. This argument, presumably to sustain the use of the Category system, parallels an argument to tolerate prolonged pushing in the 2nd stage of labor despite the increased risks of seizures and HIE (70). This raises another issue potentially impacting the interpretation of the data: the relationship of outcome to the duration of any abnormal FHR pattern. A European, multicenter, randomized controlled trial study compared the effects of "moderate" versus "intensive" pushing in ***nulliparas*** in the 2nd stage of labor with an epidural and a "normal" FHR pattern. Irrespective of the outcome of the study, the standard of care required that the *midwife* call an obstetrician ***after 30 minutes of pushing*** to discuss operative delivery (71)

It can come as no surprise that the review ultimately concludes that the 3-tiered FHR tracing interpretation system provides "***an approximate, but imprecise,*** measurement of neonatal prognosis." In addition to the limited, if any, according to some, benefit of this classification of FHR patterns on outcome statistics and its apparent impact on the induction of an increased rate of cesarean sections discussed above, we must consider the impact on the allegation of malpractice based on the interpretation of the EFM tracing. This ubiquitous concern appears in many articles on EFM and in the majority of medico-legal allegations of preventable fetal injury worldwide. (72, 73) Finding FHR Categories "approximate, but imprecise" potentially undermines their probative evidence in the courtroom, a benefit to the defense—at the expense of understanding accountability for the preventability of fetal harm.

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Why have the authors of the review not called for the abandonment of this flawed, unphysiological approach to fetal surveillance? We seem to have been "befuddled" for way too long; we need to make better use and stronger inferences from the data that we do have. There seems to be no better way to reduce allegations of negligence than to improve outcomes.

Keywords: EFM, Classification of FHR patterns, fetal distress,

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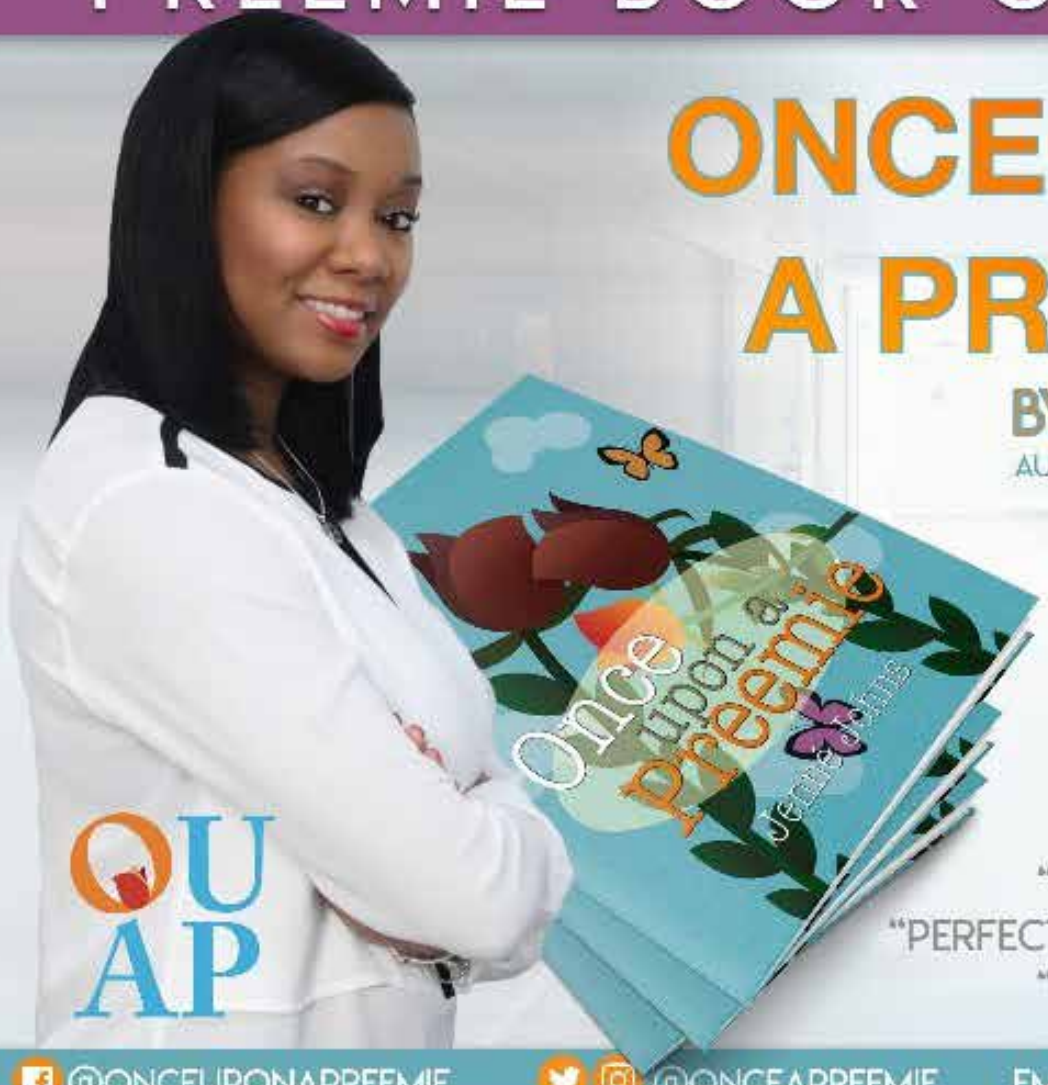

ONCE UPON A PREEMIE

BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE

QUAP

"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.

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STILL A PREEMIE

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

Jaundice | Feeding issues | Respiratory problems

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Born preterm at a "normal" weight?

STILL A PREEMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREEMIE

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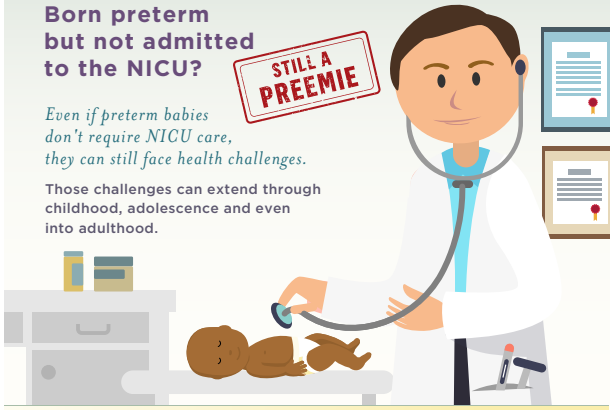
Those challenges can extend through childhood, adolescence and even into adulthood.



Some Preemies

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

All Preemies

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

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OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

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

I was exposed to opioids.

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Compiled and Reviewed by Sandeep Lankireddy, BA, OMS IV

Notes from the Field: Undiagnosed Tuberculosis During Pregnancy Resulting in a Neonatal Death — United States, 2021

NEWS PROVIDED BY

Center for Disease Control and Prevention

by Kathryn Miele, MD; R. Bryan Rock, MD; Sylvia M. LaCourse, MD; David Ashkin, MD; Lisa Y. Armitige, MD; William Pomputius, MD; Neela D. Goswami, MD

December 8, 2023

In 2022, the World Health Organization reported 10.6 million new cases of tuberculosis (TB) globally. One third of these new cases were reported in women; however, pregnancy status was not included in these data.* CDC recently added pregnancy status to national TB reporting in the United States; however, because the number of U.S. TB cases during pregnancy is presumed to be low, adverse effects of TB on pregnancy and postpartum outcomes are likely not well characterized.† A 2017 meta-analysis of 13 studies that included approximately 123,000 pregnancies from several countries found that TB disease during pregnancy was associated with increased odds of maternal morbidity and mortality, including hospital admission, anemia of pregnancy, cesarean birth, miscarriage, preterm birth, low birthweight, and neonatal TB (1). TB diagnosis during pregnancy might be delayed because of overlap in symptoms of TB with those of pregnancy, as well as clinician reluctance to use chest radiography during pregnancy.§ Perinatal TB is a life-threatening illness, with a congenital and neonatal TB mortality rate of approximately 50% (2), highlighting the importance of diagnosing and treating TB before and during pregnancy. This report describes a case of fatal neonatal TB after successful in vitro fertilization in 2021.

Investigation and Outcomes

The infant's mother underwent in vitro fertilization for infertility in her home country of India, which accounted for 27% of global TB incidence in 2022¶; she returned to the United States 1 month before delivery. During U.S. prenatal visits, she experienced insufficient weight gain, hyperemesis, and chronic cough, which was attributed to gastroesophageal reflux disease. Results for standard pregnancy laboratory tests were normal; no test for TB infection was performed. The mother experienced premature rupture of membranes at 33 weeks' gestation followed by an uncomplicated spontaneous vaginal delivery of a healthy-appearing newborn and a normal-appearing placenta.

The newborn had 1- and 5-minute Apgar scores of 7 of 10 and 9 of 10, respectively, and weighed 5 lbs 6.7 oz (2,460 g) (90th percentile for gestational age). After receiving inpatient care for prematurity, the newborn was discharged home on the 14th day of life. However, shortly after hospital discharge, the infant developed labored breathing, became progressively ill, and was readmitted 4 days later (the 18th day of life) in septic shock, which was managed with endotracheal intubation and admission to an intensive care unit. Chest radiography demonstrated overall ground-glass–appearing infiltrates, suggesting inflammation, and loss of lung volume. On the basis of these findings, the mother's chronic cough, and her origin from a country with high TB incidence, pulmonary TB was suspected. The infant's gastric aspirate samples contained acid-fast bacilli on smear microscopy (an indicator of pulmonary TB) and grew Mycobacterium tuberculosis in culture.

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TB treatment** was commenced on the 22nd day of life. Initially, the infant's condition improved, but 12 days after the diagnosis of TB, a pneumothorax was identified in the context of sudden respiratory deterioration. Respiratory treatments were not effective, and in alignment with the family's wishes, support was withdrawn with institution of comfort measures. The infant died on the 42nd day of life of TB-related respiratory failure.

The mother's chest radiograph demonstrated bilateral reticular nodular opacities. Acid-fast bacilli were identified on sputum smear microscopy, and a sputum sample tested positive for M. tuberculosis by polymerase chain reaction; a sputum culture was also positive. The mother recovered while completing a full course of treatment for drug-susceptible pulmonary TB, the same treatment that would have been recommended if a diagnosis had occurred during pregnancy. The only other household contact was determined not to have TB disease or latent TB infection after evaluation. This activity was reviewed by CDC, deemed research not involving human subjects, and was conducted consistent with applicable federal law and CDC policy.††

Preliminary Conclusions and Actions

Although TB disease typically affects the lungs, it can involve any system, including the reproductive system, which can be affected in the absence of pulmonary findings (3). TB of the female reproductive system can cause infertility, pain, a pelvic mass, or menstrual disorders (3). Diagnosis requires a high index of suspicion for TB when a person from a country with endemic TB experiences genitourinary symptoms, including infertility. In India, TB is considered the likely cause of infertility in nearly one quarter (24.2%) of women with infertility (3). The sensitivity of chest radiography in detecting disease is 10%–75% in genitourinary TB (4). Ascertaining a diagnosis of TB during a female infertility evaluation should include consideration of pelvic organ imaging and specimen collection via laparoscopy and endometrial biopsy for acid-fast bacilli smear microscopy, polymerase chain reaction and culture for M. tuberculosis, and histology (4).

The fatal case reported here might have been avoided by TB prevention or TB treatment during the infertility evaluation or during pregnancy. This case underscores the importance of considering TB during an evaluation of women with infertility or a history of infertility if they are from a country with endemic TB. To reduce TB-associated morbidity and mortality, including congenital and neonatal TB, all persons, including those who are pregnant, should be considered for TB evaluation by assessing risk factors for TB infection (e.g., current or previous residence in a high TB-incidence country, a homeless shelter, or correctional facility) and risk factors for progression to TB disease if TB infection is present (e.g., diabetes, HIV infection, or substance use disorder)§§ (5) (Box).

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For all references and/or figures please visit source at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7249a4.htm

NT

Improved Outcomes for Very Preterm Infants

NEWS PROVIDED BY

American Academy of Pediatrics

by Julia Evans, MD, Pediatrics Resident, University of Virginia

December 6, 2023

Editor's Note: Dr. Julie Evans (she/her) is a resident physician in pediatrics at the University of Virginia. She is interested in general pediatrics and global health. – Rachel Y. Moon, MD, Associate Editor, Digital Media, Pediatrics

"Preterm," "very preterm," "early term," and "term" are all words we use to describe how long the gestation (pregnancy) has been when a baby is born. Very preterm infants are those who are born before 28 weeks' gestation.

Unsurprisingly, when a baby is born very preterm, many morbidities (diseases that can cause long term consequences) and even mortality (death) are more common. Dr. Jeffrey D. Horbar, MD, and colleagues from the University of Vermont analyzed data from the Vermont Oxford Network for 447,396 very preterm infants at 888 US hospitals to describe trends over time in outcomes for these infants in their article entitled, "Trends in Mortality and Morbidities for Infants Born 24 to 28 Weeks in the US: 1997-2021," which is being early released this week in Pediatrics (10.1542/peds.2023-064153).

This study included very preterm infants born at 24–28 weeks' gestation who weighed 401 to 1500 grams (0.88–3.3 pounds) at birth. The authors examined trends in mortality and the following morbidities: late onset sepsis, necrotizing enterocolitis (NEC), chronic lung disease (CLD), intraventricular hemorrhage (IVH), and retinopathy of prematurity (ROP). In addition, the authors looked at the category of death or morbidity, which was defined as an infant dying or having at least one of the morbidities above.

The authors found that from 1997 to 2021:

- Rate of mortality decreased (18.1% to 12.4%)
- Rate of late onset sepsis decreased (32.4% to 13.4%)
- Rate of NEC decreased (10% to 6.8%)
- Rate of CLD increased (33.4% to 43.3%)
- Rate of severe IVH decreased (11.8% to 10.7%)
- Rate of severe ROP decreased (14.8% to 9.3%)

The overall rate of death or morbidity also decreased from 65.4% to 57.6%.

However, when the authors analyzed the data by clustering years in smaller groups, they discovered that improvements in mortality and morbidity have slowed, stalled, or even reversed in recent years. Nearly all of the morbidities had rapid improvement early on, with slower or no improvement in more recent years. The authors speculate that the early improvements observed may have been due to quality improvement by neonatal care teams and the start of effective therapies that are now being used for most infants. The authors propose that we may have reached the limit of effectiveness of available therapies such as antenatal steroids, surfactant administration, and non-invasive ventilation.

In order to regain the pace of improvement seen in the earlier years of this study, the authors propose a 3-pronged strategy:

- Research to develop new therapies
- Quality improvement to optimize effectiveness of available interventions
- Commitment to follow through addressing social determinants of health

Regardless of subspecialty, most pediatricians care for children who were born very preterm, and this article will remind all of us of how far treatment for these smallest infants has progressed over the past few decades.

NT

FDA Raises Concerns About Probiotic Products Sold for Use in Hospitalized Preterm Infants

NEWS PROVIDED BY

U.S. Food & Drug Administration

Content current as of October 26, 2023

Warning Letters Issued to Two Companies for Illegally Selling Probiotic Products to Treat Diseases in Preterm Infants

As part of the U.S. Food and Drug Administration's commitment to protecting public health, the agency is advising the public, including healthcare providers, of the possible risks that products containing live bacteria or yeast, which are commonly called probiotics, pose to preterm infants in hospital settings. The agency recently sent a letter to healthcare providers warning them about this topic and has issued two warning letters to companies for illegally selling their products for use in treating or preventing certain diseases in preterm infants.

Probiotic products contain live organisms such as bacteria or yeast and are commonly marketed as foods, including as dietary supplements. The FDA is concerned as these products can be dangerous for preterm infants and are being illegally sold to treat or prevent diseases in preterm infants in hospital settings, such as to reduce the risk of necrotizing enterocolitis. Preterm infants who are administered a probiotic product are at risk of invasive, potentially fatal disease, or infection, caused by the bacteria or yeast contained in the probiotics.

The FDA is aware that certain probiotic products used in hospital settings to prevent necrotizing enterocolitis have contributed to invasive disease, including one infant death in 2023, and have been associated with more than two dozen other reported adverse events in the United States since 2018. The agency is also concerned about and is investigating reports that these products may have contributed to additional adverse events, including death, and is working to obtain the proper evidence and medical records, where possible. Any death or adverse event in an infant following the use of a probiotic product is very concerning, and the FDA is actively working with healthcare providers to better understand the link between the probiotic products used and the adverse events in preterm infants reported by these institutions.

Importantly, the FDA has not approved any probiotic product for use as a drug or biological product in infants of any age. Unapproved, unlicensed probiotics that are used to treat or prevent a disease or condition in preterm infants have not undergone the agency's thorough premarket evaluation for safety and effectiveness. Further, they have not been evaluated for compliance with the agency's rigorous manufacturing and testing standards for drugs and biological products, including testing for other organisms. For these products to be lawfully marketed as drugs and biological products, the FDA requires approval of a Biologics License Application to ensure they have been appropriately evaluated. In the absence of an approved product, healthcare providers who administer products containing live bacteria or yeast to treat, mitigate, cure or prevent a disease or condition are required to submit an Investigational New Drug application to the agency to ensure the investigational use of an unapproved product is conducted with the appropriate safeguards.

"Adverse events in any infant following the use of a probiotic are a concern to the FDA. We especially want to make clear that products containing live microorganisms may present serious risks to preterm infants in hospital settings," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Bio-

logics Evaluation and Research. "With today's message, we want to warn parents, caregivers and healthcare providers that if these products are used for the prevention or treatment of disease, they have not undergone the agency's rigorous premarket process to evaluate their safety, effectiveness and quality for these medical uses."

The agency is committed to ensuring that any violations and safety issues presented by these products are addressed by their manufacturers. The agency issued a warning letter to Abbott Laboratories on Oct. 24, 2023, for its product, Similac Probiotic Tri-Blend, which contains B. infantis (Bb-02), S. thermophilus (TH-4) and B. lactis (BB-12). Of note, this product is not an infant formula and is not related to the previous issues the agency has noted with powdered infant formula manufactured by Abbott Nutrition. Abbott has agreed to discontinue sales of its Similac Probiotic Tri-Blend product and is working with the FDA to take additional corrective actions.

The warning letter notes the company sells the probiotic product for use in hospital settings for preterm infants. Based on the intended uses on the company's websites and Abbott's marketing materials, the product is an unapproved new drug and an unlicensed biological product being sold in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act. Additionally, the product is an adulterated dietary supplement under the FD&C Act because, when intended for consumption by preterm infants, the Bb-02 and TH-4 ingredients have not met the applicable safety requirements.

The agency also recently issued a warning letter to Infinant Health, Inc (formerly Evolve BioSystems Inc.) regarding its probiotic product, Evivo with MCT Oil, an unapproved and unlicensed product sold for use in treating or preventing disease in preterm infants, in violation of the FD&C Act and the Public Health Service Act. The product was intended to be added to food for preterm infants and as such was also found to be an adulterated food under the FD&C Act. This product has since been voluntarily recalled and is no longer available in the U.S.

"Protecting public health, especially of the most vulnerable populations such as preterm infants, is one of the highest priorities for the FDA," said Jim Jones, the FDA's Deputy Commissioner for Human Foods. "We are encouraging all involved in the care of preterm infants, including parents, caregivers and healthcare providers, to be aware of the possible risks associated with the administration of probiotic products to preterm infants in hospital settings. The FDA continues to investigate these incidents and is committed to using our available resources and authorities to identify and address potentially unsafe products in the market."

The FDA understands there are conflicting data in the literature on the safety and effectiveness of probiotics for the prevention of necrotizing enterocolitis, and that the study of the use of probiotics has been complicated by several factors, including the use of different probiotics in different trials. Because of the potential for harm posed by these products in highly vulnerable individuals, such as preterm infants, the agency urges the industry, clinical and research funding communities to focus on high quality clinical trials with products meeting quality criteria to provide definitive evidence to inform the use of these products by healthcare providers and,

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where appropriate, to support applications for drugs and biological products for use in infants of any age.

The agency continues to carefully review and investigate adverse event reports for probiotics. To inform the agency's surveillance efforts, and to better understand these issues to help protect public health, the FDA encourages healthcare providers and caregivers to report adverse events following use of probiotics to the manufacturer, the FDA's MedWatch program and CFSAN's Adverse Event Reporting System. Caregivers may also speak with their healthcare provider regarding concerns or questions with these products.

NT

Frequency of Children Diagnosed with Perinatal Hepatitis C, United States, 2018–2020

NEWS PROVIDED BY

Center for Disease Control and Prevention

by Suzanne M. Newton et al.

Abstract

We describe hepatitis C testing of 47 (2%) of 2,266 children diagnosed with perinatal hepatitis C who were exposed during 2018–2020 in 7 jurisdictions in the United States. Expected frequency of perinatal transmission is 5.8%, indicating only one third of the cases in this cohort were reported to public health authorities.

Hepatitis C virus (HCV) can be transmitted perinatally (1). Rates of acute HCV infection have increased recently (2), but few children perinatally exposed to HCV are tested and referred to care (3). As of November 2023, the Centers for Disease Control and Prevention recommends testing of all perinatally exposed infants for detection of HCV RNA at age 2–6 months, which is earlier than previous recommendations of ≥18 months of age for HCV antibody testing (4). There may be advantages to performing HCV RNA testing earlier, before children might become lost to follow-up (5). A prior analysis found only 16% of children perinatally exposed to hepatitis C in Philadelphia, Pennsylvania, USA, received HCV testing (6). Limited data are available from larger surveillance cohorts about current testing patterns of children perinatally exposed to HCV.

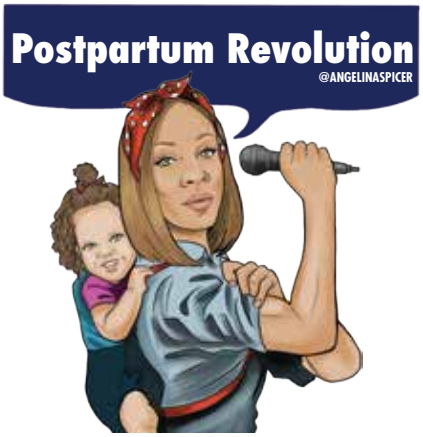
Positive HCV test results are nationally notifiable in the United States, but negative HCV test results are not. To identify potential gaps in testing and surveillance, we used positive HCV test results to describe testing and frequency of children diagnosed with perinatal hepatitis C during 2018–2020 compared with the expected frequency of perinatal transmission in 7 US jurisdictions. This activity was deemed as public health surveillance and not research at Centers for Disease Control and Prevention, thus exempt from institutional review board review.

We assembled a retrospective cohort from surveillance data of pregnant women. The exposure of interest was prenatal exposure to HCV, and perinatal hepatitis C was the outcome. The Surveillance for Emerging Threats to Pregnant People and Infants Network conducts surveillance of pregnant women with HCV infection and their children (7). As of September 9, 2022, seven US jurisdictions (Georgia, Los Angeles County, Massachusetts, New York City, New York State, Pennsylvania, Tennessee) had contributed data on persons with HCV RNA detected during or within 1 year before pregnancy who had no evidence of treatment or clearance and who had live births during January 1, 2018–October 9, 2020. Children were determined to have perinatal hepatitis C if HCV RNA was detected or they had a reactive HCV antibody test during the recommended window (RNA at ≥2 months of age or antibody at ≥18 months of age) (4). Collection of data is ongoing to provide a complete picture of testing practices, including distinguishing those who were not tested from those who tested negative. We determined the expected number of children with perinatal hepatitis C by estimating 5.8% (95% CI 4.2%–7.8%) of live births exposed to HCV from included jurisdictions on the basis of a published estimate (1).

A total of 2,266 children were born to pregnant women with hepatitis C during the surveillance period (Figure). Among those children, 408 (18%) were tested for HCV infection within the recommended window and 19 (1%) outside it. Forty-seven children (2%) had perinatal hepatitis C. Median age at initial positive test was 18.6 months. Perinatal HCV infection was detected at <18 months of age for 17 (36%) children and ≥18 months of age for 30 (64%) (Table). Of the 47 children with perinatal hepatitis C, 18 (38%) had a reactive HCV antibody test and HCV RNA detected on the same day, likely reflecting reflex laboratory testing.

The expected number (1) of children with perinatal hepatitis C by 20 months of age was 131 (95% CI 95–176), suggesting there were an additional 84 children with unidentified perinatal hepatitis C in this cohort. Therefore, only 36% (47/131) of children by 20 months of age who were expected to have perinatal hepatitis C within our cohort were reported to public health authorities. Potential reasons for this discrepancy include loss to follow-up (e.g., patients did not attend follow-up appointments), lack of awareness of the need for testing, delayed testing or testing too early, not completing ordered tests (8), or lack of reporting positive tests to health departments.

Limitations of this report include the fact that negative tests are not uniformly reportable across the jurisdictions we studied. However, medical record abstraction is ongoing to be able to describe testing practices, including those who were not tested or tested negative. In addition, the number of children included in this analysis may be underestimated if confirmatory testing occurred outside of the jurisdiction for the pregnant person or they were lost to follow-up before delivery. Last, although 5.8% is a pooled estimate for risk of verti-



cal HCV infection, underlying differences between the prior study population and the population included in this analysis could affect risk (1).

This report identified more positive infants than a previous study (36% vs. 16%) (6), but both indicate that most children perinatally exposed to hepatitis C are not tested for infection. Understanding testing patterns among children with perinatal HCV exposure and current gaps in perinatal HCV testing and surveillance will help serve as a baseline for improving testing and surveillance to identify children with perinatal hepatitis C, connect them to the appropriate care, and move toward hepatitis C elimination.

Ms. Newton is an epidemiologist with the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention, Atlanta, Georgia. Her main areas of study include infections during pregnancy and short- and long-term impact to the child.

For references, figures, and acknowledgements please visit source at: https://wwwnc.cdc.gov/eid/article/30/1/23-0315_article

Early-Onset Infection Caused by Escherichia coli Sequence Type 1193 in Late Preterm and Full-Term Neonates

NEWS PROVIDED BY

Center for Disease Control and Prevention

Abstract

Using whole-genome sequencing, we characterized Escherichia coli strains causing early-onset sepsis (EOS) in 32 neonatal cases from a 2019–2021 prospective multicenter study in France and compared them to E. coli strains collected from vaginal swab specimens from women in third-trimester gestation. We observed no major differences in phylogenetic groups or virulence profiles between the 2 collections. However, sequence type (ST) analysis showed the presence of 6/32 (19%) ST1193 strains causing EOS, the same frequency as in the highly virulent clonal group ST95. Three ST1193 strains caused meningitis, and 3 harbored extended-spectrum β-lactamase. No ST1193 strains were isolated from vaginal swab specimens. Emerging ST1193 appears to be highly prevalent, virulent, and antimicrobial resistant in neonates. However, the physiopathology of EOS caused by ST1193 has not yet been elucidated. Clinicians should be aware of the possible presence of E. coli ST1193 in prenatal and neonatal contexts and provide appropriate monitoring and treatment.

Extraintestinal pathogenic Escherichia coli and Streptococcus agalactiae are bacterial pathogens that commonly cause early-onset neonatal sepsis (EOS) in industrialized countries. EOS is confirmed by a blood or cerebrospinal fluid culture positive for the causative pathogen <72 hours after birth. EOS incidence is ≈1/1,000 live births (1,2); 10% of cases are complicated by meningitis, which can lead to neurologic sequelae in up to 50% and death in 10% of cases in industrialized countries (3).

EOS caused by S. agalactiae can be prevented by peripartum antimicrobial prophylaxis but not EOS caused by E. coli. E. coli strains that cause neonatal meningitis have been well characterized, but E. coli strains that cause EOS less so (4,5). Neonatal meningitis E. coli strains belong mainly to phylogenetic group B2/sequence type complex (STc) 95 (6) and are frequently O18:K1, O1:K1, O83:K1, or O45S88:K1 serotypes (7,8). Most STc95 strains are distributed worldwide and still largely susceptible to antimicrobials (9). However, other strains that can cause EOS, notably in preterm neonates, might be resistant to probabilistic antimicrobial therapy. In a recent study in Israel (10), maternal carriage rates of extended-spectrum β-lactamase (ESBL)–producing E. coli were 17.5% for mothers and 12.9% for preterm neonates; in China, ESBL accounted for up to 48% of E. coli infections in neonates (11).

Characterizing E. coli strains that cause EOS would constitute a critical first step towards better understanding the pathophysiology of this condition and developing potential preventive strategies. We conducted a prospective study covering a large area in France to estimate annual incidence and pathogen distribution of EOS in neonates born at ≥34 weeks of gestation during 2019–2021 (12). In total, we recorded 107 cases of bacteremia including 35 caused

by E. coli, 15 (incidence 0.89/1,000 births) in late-preterm and 20 (0.06/1,000 births) in full-term infants. We prospectively recorded data on maternal and infant demographics, maternal antimicrobial therapy, peripartum antimicrobial prophylaxis, and outcomes (12). We aimed to use whole-genome sequencing (WGS) to characterize E. coli strains that caused EOS in cases from this prospective study and stratify results according to these data. In addition, we determined to compare those strains to E. coli strains obtained from cultures from vaginal swabs collected to screen for S. agalactiae carriage at 34–38 weeks of gestation from woman with newborns who had no history of EOS. The ethics committee institutional review board (Ramsay Santé Recherche & Enseignement, IRB00010835) authorized the study (12).

Methods

Bacterial Strains

We recorded 35 cases of EOS caused by E. coli during a prospective study in 81 maternity wards of the Ile de France area during 2019–2021 (12). Thirty-two E. coli isolates were sent to the National Reference Center in Robert-Debré Hospital to be further characterized. For comparison with the isolates from the Ile de France study, we included 50 E. coli isolates obtained from cultures from vaginal swabs collected from 4 maternity wards to screen pregnant woman for S. agalactiae carriage at 34–38 weeks of gestation. We found healthy vaginal carriage (HVC) among all; that is, none of the infants of the pregnant women from the S. agalactiae screening developed EOS caused by E. coli.

Antimicrobial Susceptibility Testing and Phenotypic Characterization

We determined antimicrobial susceptibility of the E. coli strains using disk diffusion on Mueller-Hinton agar plates (bioMérieux, https://www.biomerieux.comExternal Link), as recommended by Comité de l'Antibiogramme de la Société Française de Microbiologie (https://www.sfm-microbiologie.orgExternal Link) guidelines. We defined ESBL production by synergy between clavulanic acid and >1 extended-spectrum cephalosporin or aztreonam.

Molecular Characterization

We performed WGS on 82 isolates, 32 described elsewhere (12) and 50 from the HVC/S. agalactiae screening. We extracted bacterial genomic DNA using the DNeasy UltraClean Microbial Kit (QIAGEN, https://www.qiagen.comExternal Link) and prepared libraries using Nextera Flex/DNA Prep library kits (Illumina, https://www.illumina.comExternal Link) as specified by the manufacturers. We performed sequencing using 2 × 150 bp MiniSeq technology (Illumina) and assembled models using SPAdes (https://github.com/ablab/spadesExternal Link). We estimated quality of sequencing data using standard metrics, including N50 and mean coverage (Appendix). We determined phylogenetic groups, serotypes, fimH type, sequence type (ST), and STcs (which regroup all STs of <1 allele difference), whole-genome multilocus sequence typing (MLST), and hierarchical clustering of core genome MLST using Enterobase (https://enterobase.warwick.ac.ukExternal Link) (13). We used the Center for Genomic Epidemiology website (https://genomicepidemiology.orgExternal Link) to search for resistance and virulence genes. We also used a local BLAST with a collection of virulence genes as described elsewhere (14). We used Fisher exact analysis for statistical comparisons among groups.

Results

Bacterial Collection and Demographic and Clinical Features of Patients

We studied 82 E. coli isolates. Birth locations of the neonates within Ile de France were diverse (30 different locations among 32 EOS case-patients). Babies were delivered at full term (≥37 weeks of gestation) in 59% (19/32) and preterm (<37 weeks of gestation) in 41% (13/32) of cases. In 6 (31%) cases from the full-term group and 7 cases (54%) from the preterm group, mothers received antimicrobial treatment <3 days before labor. We observed 6 cases of meningitis, 3 each from the full-term and preterm neonate groups (Table 1).

Diversity and Phylogenetics of EOS and HVC E. coli Strain Collections

Five of 7 major E. coli phylogroups—A, B1, B2, D, and F, but not C or E—were represented in similar proportions in both the Ile de France study and vaginal swab collections (p>0.05). The exceptions to this trend were phylogroup A being more common in vaginal swab (22%) than EOS (9.4%) isolates and group B2 more common in EOS (65.6%) than vaginal swab (48%) isolates (Figure 1). Among the 3 most frequent ST/STc variants in our study, STc10 (phylogroup A) was present in more HVC strains, whereas ST95 and STc14 (phylogroup B2) were more common in EOS strains. The imbalance was striking for STc14, which was present in 25% of EOS strains but only 4% of HVC strains (p = 0.01) (Figure 2). STc14 isolates included 6 ST1193, 2 ST14, and 2 ST404. Of note, the 6 ST1193 isolates were found exclusively in the EOS collection.

Virulence and Antimicrobial Resistance

We observed no significant difference in distribution of virulence factors between the EOS and HVC strain collections, except for genes encoding the K1 capsule, which were present significantly more in the EOS collection (Appendix Table 1). In contrast, antimicrobial resistance differed markedly between collections (Figure 3). Aminopenicillin resistance was ≈2 times higher among EOS (65.6%) than HVC (34%) collection strains (p = 0.007); ESBL was present in 12.5% of EOS and 8% of HVC strains (p>0.05). Resistance to fluoroquinolone and gentamicin were also more common among EOS strains (Figure 3).

We examined the distribution of phylogenetic groups and ST/STc frequency among EOS strains stratified by gestational term of newborns. Differences in rates of B2 phylogroup strains in the 2 subpopulations (69% in preterm, 63% in full-term neonates) were not statistically significant (Figure 4). STc14 (ST14/ST1193) was >2 times as frequent in the preterm (38.5%) as the full-term subpopulation (15.8%), but the difference was not statistically significant (p>0.05). Distribution of ST95, the second most frequent ST, was similar between preterm

(15.4%) and full-term (21.1%) subpopulations (Figure 5). There were more mothers with STc14 E. coli isolates (5/13 [38.5%]) among those who received antimicrobial therapy <3 days before delivery than those who did not (3/19 [15.8%]) (p>0.05) (Figure 6). In contrast, there were fewer ST95 isolates among mothers receiving prenatal antimicrobial therapy (1/13 [7.69%]) than those receiving no therapy (5/19 [26.32%]) (p>0.05).

Main Features of EOS Caused by ST1193 E. coli and Characterization of Isolates

All 6 ST1193 EOS strains were isolated from different maternity hospitals. Half (3/6) of neonates with ST1193 EOS were born at full term. Three neonates had meningitis, 2 full-term and 1 preterm. Four (67%) mothers with ST1193 strains received prenatal antimicrobial therapy compared with 9 (35%) for the non-ST1193 strains (p>0.05) (Table 1; Figure 6). All strains were resistant to fluoroquinolones, 3 were resistant to azithromycin, and 3 others harbored an ESBL phenotype (Table 2). All strains were lactose nonfermenters (data not shown).

We assessed presence of putative virulence factors among the 6 ST1193 isolates (Table 2; Appendix Table 2) and identified presence of factors with a significant difference (p<0.05) among ST1193 compared with non-ST1193 strains: adherence protein Iha, colicin Ia immunity protein Imm, major pilin subunit PapA_F43, plasmid-encoded enterotoxin SenB, serine protease Sat, vacuolating autotransporter toxin Vat, and Type 1 fimbrin D-mannose specific adhesion 64.

Three strains harbored ESBL phenotypes contained the β-lactamase–encoding genes blaCTX-M-15 and blaOXA-1 associated with the aac(6')-Ib-cr genes, and 3/6 strains harbored the mph(A) gene (macrolide 2′-phosphotransferase), which inactivates macrolides, reinforcing observed phenotypic resistance to azithromycin. None of the non-ST1193 strains carried that gene. One strain was resistant only to fluoroquinolones (Table 2). All strains had different hierarchical cluster 10 (HC10) but the same HC20 (571), whereas ribosomal MLST (rMLST) split the strains into 2 main populations: rMLST 33503, which regroups the 3 ESBL-producing strains, and rMLST 1674, which contains 2 less-resistant isolates.

Discussion

In our study, we used WGS to characterize E. coli strains causing EOS from a prospective multicenter study in France (12) and compared them to E. coli strains obtained from vaginal samples from pregnant women at 34–38 weeks of gestation. Although we observed no major differences between the EOS study and vaginal sample collections in distribution of phylogroups or virulence factors except the K1 antigen, we identified emerging ST1193 strains as major causes of EOS. Three isolates of the ST1193 clonal group caused meningitis, and half harbored an ESBL. E. coli ST1193 thus appears to be the most virulent and antimicrobial-resistant E. coli group that causes EOS.

Among major phylogroups, B2 and, to a lesser extent, D are associated with extraintestinal infections, whereas A and B1 are most associated with commensal strains or intestinal infections (15). We also observed predominance of B2 strains in our EOS population, regardless of the term of birth of the newborns. Although the proportion of phylogroup A strains was higher in the HVC than the EOS population, B2 strains largely predominated in the HVC collection, as reported in previous studies (16,17). However, sequence typing enabled a finer comparison between the 2 collections. Among the HVC strains, phylogroup A/STc10 (ST10, ST13795, ST6826, and ST13957) was predominant but was rarely observed among the EOS patients, in which ST95 and STc14 (notably ST14 and ST1193) were largely predominant. The high frequency of ST95 was expected because of its virulence in neonates, notably those with neonatal meningitis, which is well known worldwide (6,18). Of note, ST95 was second most common among HVC strains, suggesting its capacity to colonize the vagina, at least temporarily. Five of 6 mothers with EOS caused by ST95 received no prepartum antimicrobials. In contrast, ST14 and ST1193 strains were frequently associated with women receiving prepartum antimicrobials (5/8), and those strains were not present among HVC patients, suggesting the vaginal environment might inhibit the presence of ST14 and ST1193 strains. Of note, that STc14 but not ST95 was more prevalent among preterm neonates with EOS and 3/6 infections caused by ST1193 strains occurred in preterm newborns. It might be that ST1193 strains are less virulent than ST95 strains commonly found in full-term neonates. However, almost all women with preterm newborns received antimicrobial drugs, which might favor the selection of resistant strains, such as ST1193.

ST1193 was identified within STc14 approximately 25 years ago; its prevalence in extraintestinal infections could become a public health burden (19–21). One study observed an increased rate of ST1193 causing bloodstream infections, mostly in elderly patients in Canada during 2016–2018 (22). In an analysis of the population structure of 218 ESBL–producing E. coli in urinary tract infections in febrile children in France during 2014–2017, we noted prevalence of ST1193 rose from 0% to 9% (23). Large epidemiologic studies of ST1193 prevalence in neonatal infection have only recently been conducted. In 2 studies, ST1193 was shown to be a major cause of neonatal sepsis; however, because the definition of EOS in those studies differed from ours, data are difficult to compare (11,24). The finding of a worrying percentage of ST1193 among EOS patients (19%) in our study population indicates that in the future that ST should be closely monitored using microbiologic detection.

One epidemiologic study of intracranial infections in neonates caused by E. coli (25) found ST1193 to be the most prevalent ST (28%). All 8 ST1193 isolates caused late-onset infections, although none caused EOS. Only 1 recent case of early-onset meningitis caused by E. coli ST1193 has been reported, but cases of meningitis caused by ST1193 occurring >72 hours after birth were described in another study (24,26). The recent case occurred in a late-preterm neonate with a history of prolonged rupture of the membrane with prepartum and peripartum antimicrobial drugs administered, as in most of our cases.

Given that 3/6 ST1193 strains caused neonatal meningitis, such strains were shown to have high invasive disease potential in newborns. Several virulence factors and genetic determinants have been shown to be involved in the pathophysiology of neonatal meningitis, such as capsule K1, siderophore salmochelin, plasmid pS88, and invasin IbeA (27). Of note, among these determinants, only the K1 capsule was present in the ST1193 strains. Several virulence factors (Iha, Imm, plasmid-encoded enterotoxin SenB, Sat) were present in all ST1193 strains, with a significant p value (p<0.05) compared with non-ST1193 (Appendix Table 2) strains, and were present in >85% of ST1193 strains in the large collection of 1 study (28). Therefore, without in vivo study, it is difficult to determine the specific roles of these key factors in the invasiveness of ST1193 in cerebrospinal fluid.

Except for consistency of fluoroquinolone resistance and carrying the fimH64 allele, which characterized all ST1193 E. coli strains described in previous studies, multiple plasmid-borne resistance genes have been reported but are inconsistently associated with ST1193 (19,28,29). No isolates harbored the same phenotypic antimicrobial resistance pattern, highlighting their diversity. The co-occurrence of blaCTX-M-15/blaOXA-1/aac(6′)-Ib-cr, which we observed in 3/6 of EOS strains, has been frequently described, initially in ST131 but also more recently in emerging lineages of ST1193 (30). Half of our strains, similar to findings from other studies (28), carried the mphA resistance gene and had a high azithromycin MIC (>32 mg/L) (data not shown), which might have contributed to the emergence of ST1193 given that azithromycin is among the most-prescribed antimicrobial drugs worldwide among adult outpatients (31).

As of May 2023, sequences of 2,031 E. coli ST1193 strains from all over the world are available in Enterobase (13). Of those, 80% belong to HC20 571, as did our strains, and most (82%) harbor rMLST 1674, whereas rMLST 33503 is found in only 8%. Hierarchical clustering analysis did not suggest the presence of a particular clone in our collection. Distribution of rMLSTs was notably different: half of our ST1193 strains belonged to rMLST 33503. Whether this subgroup is emerging or has specific invasive disease potential in neonates has yet to be determined.

Among its strengths, our prospective epidemiologic study, conducted in a large area of France, estimated annual incidence and pathogen distribution in EOS patients (12) and documented the unique molecular and phenotypic characteristics of the strains in our study. We were limited by the small number of patients; results, especially implication of ST1193 in infections in very preterm neonates, need to be confirmed in larger study populations.

In conclusion, our findings suggest that ST1193 is emerging as a major E. coli pathogen that can cause EOS and early-onset neonatal meningitis in full-term and late-preterm newborns and might surpass ST95 in incidence and causing illness because of its potential virulence combined with its resistance to multiple antimicrobials. Pediatricians and microbiologists should be aware of the public health threat from E. coli ST1193 and the benefits of prepartum/peripartum EOS treatment with effective antimicrobials. Isolating ST1193 E. coli strains in the neonatal context (from mother, newborn, or both) will require careful, sustained clinical monitoring of newborns. It might also require implementing measures to limit spread, especially in neonatal wards. On the basis of microbiologic evidence, ST1193 should be suspected when 3 properties are all present: high resistance to ciprofloxacin, K1 capsule, and non–lactose-fermenting colonies, each of which can easily be tested for in a microbiology laboratory. Further studies should help to define the genetic determinants of ST1193 virulence in neonates and confirm and subsequently explain its inability or weak ability to colonize the vagina. Clinicians need to be aware of the possible presence of E. coli ST1193 in prenatal and neonatal contexts and provide appropriate monitoring and treatment.

For references, figures, and acknowledgements please visit source at: https://wwwnc.cdc.gov/eid/article/30/1/23-0851_article

NT

Are Transcutaneous Bilirubin Measurements Reliable During or After Phototherapy?

NEWS PROVIDED BY

American Academy of Pediatrics

by Rachel Y. Moon, MD, Associate Editor, Digital Media, Pediatrics

November 27. 2023

We see a lot of newborns in our practice—and so we do a lot of transcutaneous bilirubin (TCB) measurements. It's much less traumatic for the infant and parents when we can just touch the skin with the bilirubinometer than it is for us to get blood from the infant for a total serum bilirubin (TSB).

One of the times when we cannot use TCB measurements is when the infant is receiving or has recently received phototherapy for hyperbilirubinemia, because there is concern that the TCB measurements are unreliable.

But is that actually true?

This week, an article being early released in Pediatrics by Dr. Lisa ten Kate and colleagues from 4 institutions in Suriname and the Netherlands entitled, "Transcutaneous Bilirubin Accuracy Before, During, and After Phototherapy: A Meta-Analysis," tackles this question (10.1542/peds.2023-062335).

The authors reviewed the literature and conducted a meta-analysis of studies that compared TCB and TSB before, during, and after phototherapy.

For those who are not as familiar with phototherapy, it involves shining bright lights on the infant. The phototherapy works by converting unconjugated bilirubin into a form that is water-soluble and can be removed from the body in the urine and stool. For phototherapy to be maximally effective, as much of the infant's skin as possible should be exposed to the light. So generally, only the infant's eyes and perhaps the genital area are covered.

The authors found that use of the TCB was reasonably reliable before and during phototherapy, but there were not enough data to determine the reliability of the TCB after phototherapy. The authors also noted that for TCB to be most reliable during phototherapy, it should be measured on covered skin—which I assume means skin that is not exposed to phototherapy. They mention the forehead as most reliable, and the forehead between the eyes would have been covered during phototherapy.

It is helpful to know that forehead TCB measurements before and during phototherapy are reliable. However, until we have more data, we still need to rely on TSB measurements after phototherapy.

NT

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We want as many children to come to the summit as possible. However, attending the Summit is not always possible for our families who often experience financial hardships. So iCAN pays for lodging, most food, and a transportation stipend in addition to summit activities. As more youth join iCAN, we need your help more than ever! Your tax-deductible donation of $1,000 will help bring a child to the Summit, to make it possible for that child to share their voice, and to interact with medical professionals and other kids like them. We will acknowledge you as an individual donor or you may dedicate the donation in honor of a loved one, as you wish.

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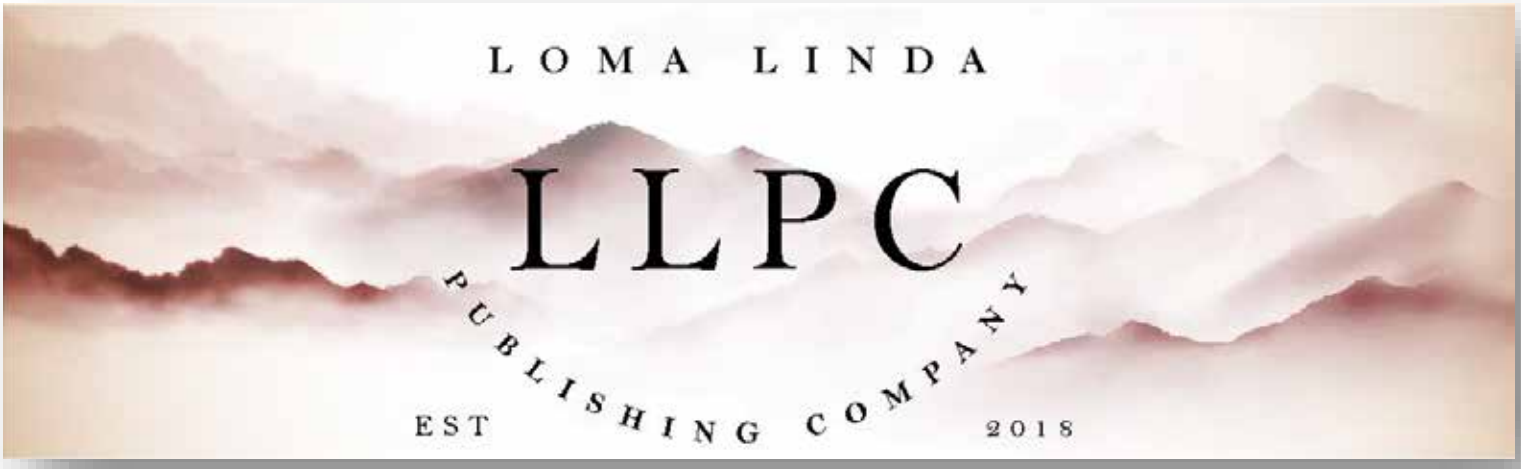


Peer Reviewed

Genetics Corner: A New Case of Rubinstein-Taybi Syndrome with a Novel Variant in the CREBBP Gene Detected through Whole Exome Sequencing

Hua Wang, M.D., Ph.D., Ann Ly, GC, MSc.

Abstract:

Rubinstein-Taybi syndrome (RSTS), an autosomal-dominant neurodevelopmental disorder affecting 1 in 125,000 newborns, is characterized by intellectual disability, growth retardation, facial dysmorphisms, and skeletal abnormalities. RSTS results from mutations in epigenetic machinery genes: CREBBP (~60%) or its homologous EP300 (~10%). Up to 30% of patients lack identified causative mutations, complicating early diagnosis due to phenotypic overlap with other syndromes. Here, we report a new RSTS case in an infant with atypical presentation. Whole-exome sequencing at 20 months revealed a de novo heterozygous pathogenic variant in CREBBP, c.6067C>T (p.Gln2023), establishing the diagnosis. This case introduces a new CREBBP gene variant, illustrating the broad clinical spectrum of Mendelian disorders of the epigenetic apparatus. High WES diagnostic rates emphasize its utility in cases with challenging phenotypes spanning distinct syndromes.*

"Rubinstein-Taybi syndrome (RSTS), an autosomal-dominant neurodevelopmental disorder affecting 1 in 125,000 newborns, is characterized by intellectual disability, growth retardation, facial dysmorphisms, and skeletal abnormalities."

Introduction:

Rubinstein-Taybi syndrome (RSTS, OMIM 180849, 613684) is an exceptionally rare autosomal dominant genetic disorder, with an estimated prevalence of one case per 125,000 live births (1). Initially documented in 1963 by Rubinstein, a pediatrician, and Taybi, a radiologist, RSTS is a rare neurodevelopmental multisystem malformation syndrome characterized by developmental delay and intellectual disability (DD/ID), growth retardation, skeletal anomalies (such as broad/short thumbs and/or big toes), and distinctive facial features (e.g., downslanting palpebral fissures, broad nasal bridge, low hanging columella) (2). Individuals with RSTS may also exhibit a diverse range of anomalies and malformations, including cardiac and genitourinary abnormalities, recurrent infections, feeding difficulties, constipation, and hearing loss (3). Typically occurring sporadically, RSTS is linked to loss-of-function mutations in the homologous genes cAMP-response element binding protein (CREB)-binding protein (CREBBP) and EA1 binding protein p300 (EP300) in 50–75% of cases (4). The phenotypic overlap between RSTS and other Mendelian conditions often complicates the clinical diagnosis of RSTS (5). This report presents a newly identified case of RSTS with novel variants presented with an atypical clinical presentation, diagnosed through whole exome sequencing.

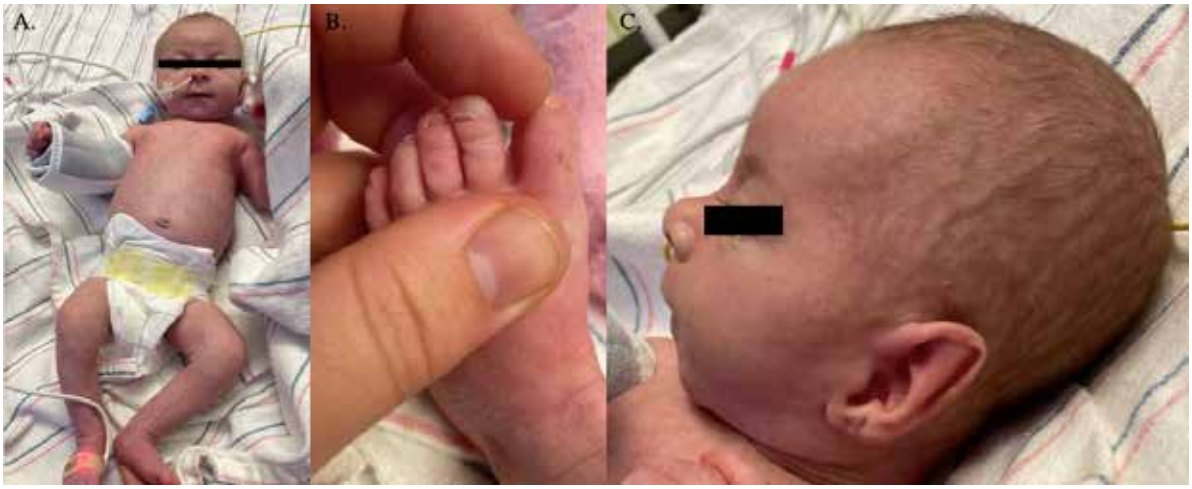
Case Description:

A 41-day-old female with a personal medical history of laryngomalacia and failure to thrive was admitted to LLUCH in January 2022 for acute respiratory failure. After admission, she was also found to have microtia, webbed toes, an aberrant right subclavian artery, and a patent ductus arteriosus. She was born full term at 39 weeks and 1-day gestation to a 39-year-old G3P2 mother via normal spontaneous delivery without complications. She passed her cardiac and hearing screens and was appropriate, though slightly small, for gestational age with a birth weight of 2.778 kg (15th %ile) and a birth length of 19.02" (33rd %ile). She had been conceived by *in vitro* fertilization. During the pregnancy, her mother did have a COVID-19 infection requiring hospitalization for a week. Otherwise, there were no other reports of preeclampsia, diabetes, or other exposures. Prenatal ultrasounds and screens were unremarkable. Both parents were healthy and had no physical abnormalities; the family history was not contributory.

"A 41-day-old female with a personal medical history of laryngomalacia and failure to thrive was admitted to LLUCH in January 2022 for acute respiratory failure. After admission, she was also found to have microtia, webbed toes, an aberrant right subclavian artery, and a patent ductus arteriosus...On physical examination, slight hypertelorism, a broad and high nasal bridge, uplifting earlobes with pits, and bilateral webbed toes were noted."

On physical examination, slight hypertelorism, a broad and high nasal bridge, uplifting earlobes with pits, and bilateral webbed

Figure 1: Patient's (A) full front profile (note the slight hypertelorism and broad and high nasal bridge), (B) webbed toes, and (C) uplifting earlobes with pits during her admission in January 2022, when she was 1.5 months old.

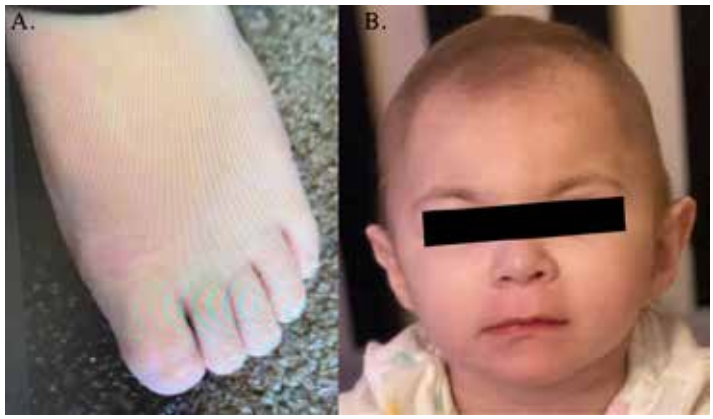


toes were noted lorism, a broad and high nasal bridge, uplifting earlobes with pits, and bilateral webbed toes were noted (Figure 1). Abdominal ultrasound was normal. A sleep study had found central sleep apnea. A head ultrasound found lenticulostriate vasculopathy of uncertain clinical significance and was otherwise normal. Given the heart defect and otherwise non-specific features, a chromosomal microarray was ordered and returned negative for chromosomal microdeletions and microduplications.

At eight months old, she returned to Genetics in the outpatient setting in August 2022. In between her discharge in January and this appointment, she had several admissions due to complications from her laryngomalacia, feeding intolerance, and Chiari malformation. Her suboccipital craniectomy the previous month was reported to improve her sleep apnea. She still had plagiocephaly and a bump on her forehead. At this stage, she was also noted to experience developmental delays. She was beginning to hold her head up and could not sit independently. She could roll over from her back to her stomach but not vice versa. Physical examination also noted epicanthal folds. Her parents consented to trio whole exome sequencing (WES); the blood was collected at 20 months old, which provided the diagnosis of Rubenstein-Taybi syndrome. He returned at 22 months old to discuss the WES result with her family. Her developmental delays persisted. She was still unable to walk or talk. She could stand with support at 18 months and sit independently at 14 or 15 months. She also lacked fine motor skills. As a result, she was a client of the Early Intervention program at the Inland Regional Center and received occupational and feeding therapy. New physical exam

"A head ultrasound found lenticulostriate vasculopathy of uncertain clinical significance and was otherwise normal. Given the heart defect and otherwise non-specific features, a chromosomal microarray was ordered and returned negative for chromosomal microdeletions and microduplications."

Figure 2: (A) Broad hallux and (B) low-hanging columella identified at 22 months old.



"...she had several admissions due to complications from her laryngomalacia, feeding intolerance, and Chiari malformation. Her suboccipital craniectomy the previous month was reported to improve her sleep apnea. She still had plagiocephaly and a bump on her forehead. At this stage, she was also noted to experience developmental delays...Physical examination also noted epicanthal folds. Her parents consented to trio whole exome sequencing (WES); the blood was collected at 20 months old, which provided the diagnosis of Rubenstein-Taybi syndrome."

findings included low-hanging columella, and broad halluces become apparent (Figure 2).

"Whole exome sequencing (WES) was performed at 20 months. WES identified a de novo heterozygous pathogenic variant in the CREBBP gene, c.6067C>T (p.Gln2023). This pathogenic variant has not been previously reported, is not listed in ClinVar, and is absent from control population databases. This variant occurs in the last exon of the CREBBP gene (exon 31 or 31 total exons)."*

Genetic Testing:

The initial chromosome microarray performed soon after birth was negative. Whole exome sequencing (WES) was performed at 20 months. WES identified a *de novo* heterozygous pathogenic variant in the *CREBBP* gene, c.6067C>T (p.Gln2023*). This pathogenic variant has not been previously reported, is not listed in ClinVar, and is absent from control population databases. This variant occurs in the last exon of the *CREBBP* gene (exon 31 or 31 total exons). It is predicted to cause premature protein truncation, though expected to escape nonsense-mediated decay due to its location in the last exon of the gene. It is predicted to delete approximately 18% of the protein, including the functional *CREB*-binding domain. Other truncating variants in this gene, including those further downstream of this variant, have also been associated with disease.

Discussion:

Here, we present a new case of Rubinstein-Taybi syndrome (RSTS) characterized by atypical manifestations during infancy (see Table 1 for the comparison of the typical features with our case). The conclusive diagnosis was established through whole exome sequencing conducted at 20 months of age. This underscores the challenging nature of RSTS diagnosis, given the considerable variability in phenotypes and genotypes, as

Table 1: the typical features of RSTS1 (4) and our patient's features.

Features of RSTS (incidence %)	Patient's clinical features
Typical facial features (100%)	Microtia, hypertelorism, broad and high nasal bridge, uplifting earlobes with pits, epicanthal folds, low-hanging columella
Intellectual disability (~100%)	Global developmental delay
Cryptorchidism (78–100%)	—
Microcephaly (35–94%)	Microcephaly
Broad thumbs/halluces (96%)	Broad halluces, webbed toes
Speech delay (90%)	Speech delay
Recurrent respiratory infections (75%)	—
Delayed bone age (74%)	—
Constipation (40–74%)	Constipation
Talon cusps (73%)	—
Gastroesophageal reflux (68%)	Gastroesophageal reflux disease
EEG abnormalities (57–66%)	—
Renal anomalies (52%)	—
Refractive defects, glaucoma, retinopathy (>50%)	—
Congenital heart defects (24–38%)	Aberrant right subclavian artery, patent ductus arteriosus
Seizures (25%)	—
Keloids (24%)	—
Deafness (24%)	—
Growth retardation (21%)	Initial failure to thrive
Malignant tumors (3–10%)	—
Spinal cord tethering (<5%)	—
Other	Sleep apnea, laryngomalacia, feeding intolerance, Chiari malformation, strabismus, astigmatism

documented by Spena et al. in 2015(3). Furthermore, our case highlights those phenotypic changes, particularly those emerging during growth, were only discerned through clinical re-evaluation prompted by the results of whole exome sequencing (5). This underscores the significance of whole exome sequencing as a reliable and expeditious diagnostic tool for suspected genetic diseases, as emphasized by Yu et al. in 2019 (6).

"The CREBBP gene is one of the most frequently reported genetic contributors to Rubinstein-Taybi syndrome (RSTS). Presently, approximately 500 pathogenic variants have been documented within CREBBP, constituting the identified etiology in 50–60% of all RSTS cases, whereas mutations in EP300 (OMIM 602700) account for only 5% of cases. The mutation spectrum encompasses diverse types, with 80.2% attributed to point mutations. Truncating mutations predominate among point mutations, comprising 55.2%, followed by large rearrangements (18.8%), missense mutations (16.8%), and splice mutations (9.2%). Notably, CREBBP lacks distinct hotspot mutation sites, with the mutation spectrum distributed across all 31 exons."

CREBBP Gene Mutations

The CREBBP gene is one of the most frequently reported genetic contributors to Rubinstein-Taybi syndrome (RSTS). Presently, approximately 500 pathogenic variants have been documented within CREBBP, constituting the identified etiology in 50–60% of all RSTS cases, whereas mutations in EP300 (OMIM 602700) account for only 5% of cases (7). The mutation spectrum encompasses diverse types, with 80.2% attributed to point mutations. Truncating mutations predominate among point mutations, comprising 55.2%, followed by large rearrangements (18.8%), missense mutations (16.8%), and splice mutations (9.2%). Notably, CREBBP lacks distinct hotspot mutation sites, with the mutation spectrum distributed across all 31 exons. Despite this distribution, recurrent mutations have been identified, with approximately 52% of missense mutations concentrated within the histone acetyltransferase (HAT domain) region (8). The genetic etiology remains unidentified in up to 30% of cases where clinical symptoms strongly suggest RSTS (9). This may be attributed to undetected genetic variants, underscoring the complexity of the genetic landscape associated with Rubinstein-Taybi syndrome.

Disease pathogenesis:

The CREBBP gene, located on 16p13.2, and its counterpart, the E1A binding protein p300 (EP300), situated on 22q13.2, are integral players in fundamental cellular processes such as DNA repair, cell growth, differentiation, apoptosis, and tumor suppression. Acting as transcriptional co-activators across diverse signaling pathways, they significantly influence normal fetal development (7). Deletion or mutation of a single copy of the CREBBP gene leads to a consequential reduction in CREBBP protein production, compromising antenatal and postnatal developmental processes. Beyond developmental implications, CREBBP's involvement in multiple signaling pathways heightens RSTS patients' risk of developing both non-cancerous and cancerous tumors, including leukemia and lymphoma (10). This underscores the intricate interplay between genetic mutations and the potential for tumorigenesis in individuals affected by RSTS.

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Genotype and phenotype correlation:

Establishing a conclusive genotype–phenotype correlation in Rubinstein-Taybi syndrome (RSTS) has proven challenging (11). Recent studies, however, offer valuable insights into the roles of the CREBBP and EP300 genes in neural cell and brain development, particularly in regulating precursor cell migration and neuronal plasticity (12). RSTS is categorized into two types based on the associated mutation spectrum: RSTS1 (OMIM#180849), linked to the CREBBP mutation spectrum, and RSTS2 (OMIM#613684), associated with the EP300 mutation spectrum. The classic phenotype resulting from CREBBP gene deletions or truncating mutations manifests as intellectual disability, broad thumbs, and distinctive facial dysmorphism. Notably, the severity of symptoms is more pronounced in cases of CREBBP mutations compared

to EP300 mutations (13). A severe phenotype of RSTS1, known as the chromosome 16p 13.3 contiguous deletion syndrome, results from large deletions encompassing the CREBBP gene and adjacent 3' genes, including DNASE1 and TRAP1(14). This severe form often presents with profound mental retardation, life-threatening infections, systemic complications, and other classic features. Notably, pathogenic variants in CREBBP exons 30 and 31 have been associated with Menke-Hennekam syndrome (15). Although Menke-Hennekam shares similarities such as developmental delay, intellectual disability, feeding difficulties, autistic behavior, recurrent upper airway infections, hearing impairment, short stature, microcephaly, and facial dysmorphism, it differs from Rubenstein-Taybi in specific facial features and the absence of classic broad/angulated thumbs or halluces observed in RSTS patients. Despite these classifications, emerging evidence suggests a lack of significant correlation between phenotype and mutation type, location, or deletion size for either CREBBP or EP300 genes in RSTS patients (16). This underscores the intricate nature of the relationship between genotype and phenotype in the context of Rubinstein-Taybi syndrome.

Management:

The approach to managing individuals with Rubinstein-Taybi syndrome (RSTS) is tailored to the specific presenting abnormalities. With over 90% of affected individuals surviving into adulthood and achieving varying degrees of independence in self-care and communication, life expectancy is generally normal. However, it may be compromised in individuals with RSTS who are prone to infections or have severe congenital heart defects, underscoring the importance of promptly addressing these complications. Behavioral disorders, mood swings, and obsessive-compulsive disorders may emerge as individuals with RSTS transition to adulthood. Simultaneously, ongoing research explores therapeutic strategies targeting the molecular pathology of RSTS, with many interventions currently in the preclinical testing phase. Given the irreversible nature of most genetic mutations and the high reversibility of epigenetic modifications, therapeutic targeting and modulation of altered epigenetic components in RSTS present a promising avenue for future treatment modalities (4).

Conclusions:

Rubenstein-Taybi Syndrome represents a rare genetic disorder characterized by distinctive physical attributes, growth impediments, and intellectual disabilities. The diagnostic intricacy arises from shared clinical features with multiple syndromes and the dynamic phenotype evolution during growth, posing challenges for early detection. A pivotal tool in achieving diagnostic precision is whole exome sequencing. In this context, the identification of the genetic variant in the presented case contributes to the molecular elucidation of RSTS. This report enhances the collective understanding of RSTS and broadens the spectrum of genetic variants associated with the intricate complexity of the CREBBP gene in this disorder.

Practical Applications:

- Rubinstein–Taybi syndrome (RSTS) is an autosomal-dominant neurodevelopmental disease characterized by intellectual disability, growth retardation, facial dysmorphisms and skeletal abnormalities.
- The diagnostic intricacy arises from shared clinical features with multiple syndromes and the dynamic phenotype evolution during growth, posing challenges for early detection.
- Whole exome sequencing plays a critical role in confirming a definitive diagnosis.
- Managing individuals with Rubinstein-Taybi syndrome is tailored to the specific presenting abnormalities.

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Medical Coding: New phone, Who Dis? Telemedicine at the End of the Public Health Emergency

Kara Wong Ramsey, MD

"Telemedicine services, a real-time interaction between a physician or other health practitioner and a patient located at a distant site, have become increasingly more widespread since the COVID-19 pandemic. During the COVID-19 public health emergency, Centers for Medicare and Medicaid Services (CMS) emergency waivers increased flexibility for healthcare providers to offer telemedicine services"

Telemedicine services, a real-time interaction between a physician or other health practitioner and a patient located at a distant site, have become increasingly more widespread since the COVID-19 pandemic. During the COVID-19 public health emergency, Centers for Medicare and Medicaid Services (CMS) emergency waivers increased flexibility for healthcare providers to offer telemedicine services. This was accomplished by expanding the coverage of audio-video synchronous telemedicine to incorporate more Current Procedural Terminology (CPT®) services, including critical care and other inpatient services, and place of service (POS) codes to account for the receipt of telehealth in a patient's home. CMS waivers also now allow for coverage of certain CPT® services felt appropriate for audio-only telemedicine without video and include services such as behavioral health-related services and physical/occupational therapist services. Although the public health emergency is over, these waivers will be extended to at least December 2024.

"There are several important aspects to remember when billing for telemedicine services. The same CPT® for an equivalent face-to-face encounter should be used. For neonatologists, common scenarios for using telemedicine may include outpatient office visits for prenatal consultations or NICU follow-up clinic visits."

There are several important aspects to remember when billing for telemedicine services. The same CPT® for an equivalent face-to-face encounter should be used. For neonatologists, common scenarios for using telemedicine may include outpatient office visits for prenatal consultations or NICU follow-up clinic visits. The time spent or complexity of the telemedicine interaction must be sufficient to meet the key components or requirements of evaluation and management CPT® codes used when the same service is rendered face-to-face. When telemedicine services provide the CPT® services, an appropriate modifier should be added. Modifier 95 is used for synchronous audio-video services. Modifier 93 is used for audio-only visits (including telephone) when applicable. Additionally, the place of service code should be reported for the distant site (where the patient is located) and the originating site (where the provider is located). Codes for the distant site include 02 for telehealth provided in a place other than the patient's home or 10 for telehealth provided in the patient's home.

"When telemedicine services provide the CPT® services, an appropriate modifier should be added. Modifier 95 is used for synchronous audio-video services. Modifier 93 is used for audio-only visits (including telephone) when applicable. Additionally, the place of service code should be reported for the distant site (where the patient is located) and the originating site (where the provider is located)."

Question:

You have a scheduled outpatient prenatal consult visit via telemedicine on a secured 2-way audio video conferencing platform for a 24-year-old G1P0 woman at 34 weeks gestation with a fetus with gastroschisis, as requested by her primary Ob-Gyn. You spend 10 minutes reviewing her medical chart. Your MA confirms the patient's consent for telehealth services over the phone before you connect via your telemedicine platform for 5 minutes. You spend 15 minutes reviewing with the patient the plan for NICU admission after delivery with silo placement, central line placement, surgical repair, and anticipated NICU stay while gradually advancing feeds and weaning off of TPN according to your unit protocol and answer her questions. You additionally spend another 10 minutes completing your documentation of the consultation and another 10 minutes coordinating care with your multidisciplinary NICU regarding this anticipated NICU admission.

Which CPT® Code and Modifier would you use?

A. 99242 initial outpatient consult, 20-29 minutes

B. 99243 initial outpatient consult, 30-39 minutes

C. 99244 initial outpatient consult, 40-54 minutes

D. 99245 initial outpatient consult, 55 minutes

E. Modifier 93 audio-only telemedicine

F. Modifier 95 audio video telemedicine

Answer: C (CPT® 99244 initial outpatient consult 40-54 minutes) and F (modifier 95 audio video telemedicine)

This vignette presented a new outpatient office consultation, with the proper outpatient office visit CPT® code based on time spent (sum of both face-to-face and non to face to face time, including preparation work) and modifier to reflect the use of synchronous audio-visual telemedicine.

To ensure proper reimbursement, in addition to including the required elements to substantiate your chosen CPT® code (such as the reason for consultation and the name of the requesting physician for a consulting service), your documentation of a telemedicine encounter must include the following elements.

"To ensure proper reimbursement, in addition to including the required elements to substantiate your chosen CPT® code (such as the reason for consultation and the name of the requesting physician for a consulting service), your documentation of a telemedicine encounter must include the following elements."

Patient consent:

You need to document that the patient gave you verbal or written consent for the telehealth encounter. This can be done by either the provider or another staff member, as done by the MA in this scenario.

Time of visit:

While you may count the time you spent preparing for the encounter, face-to-face time, documentation, and care coordination, you may not count the time that other staff members spent during the encounter. Therefore, similar to an in-person visit, you cannot count the 5 minutes the MA spent in consenting and preparing for the telehealth encounter.

Originating and distant site:

Your documentation should list the originating site (where the provider is located) and the distant site (where the patient is located). Your POS codes should also reflect these locations.

Name of the telemedicine platform used:

The telemedicine platform used must comply with Health Insurance Portability and Accountability Act (HIPAA) Rules and follow HIPAA business associate agreements to ensure adequate protection of patient privacy.

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Disclosures: *Dr. Wong Ramsey is a Fellow of the American Academy of Pediatrics and a member of the Coding Committee of the Section on Neonatal-Perinatal Medicine since 2020.*

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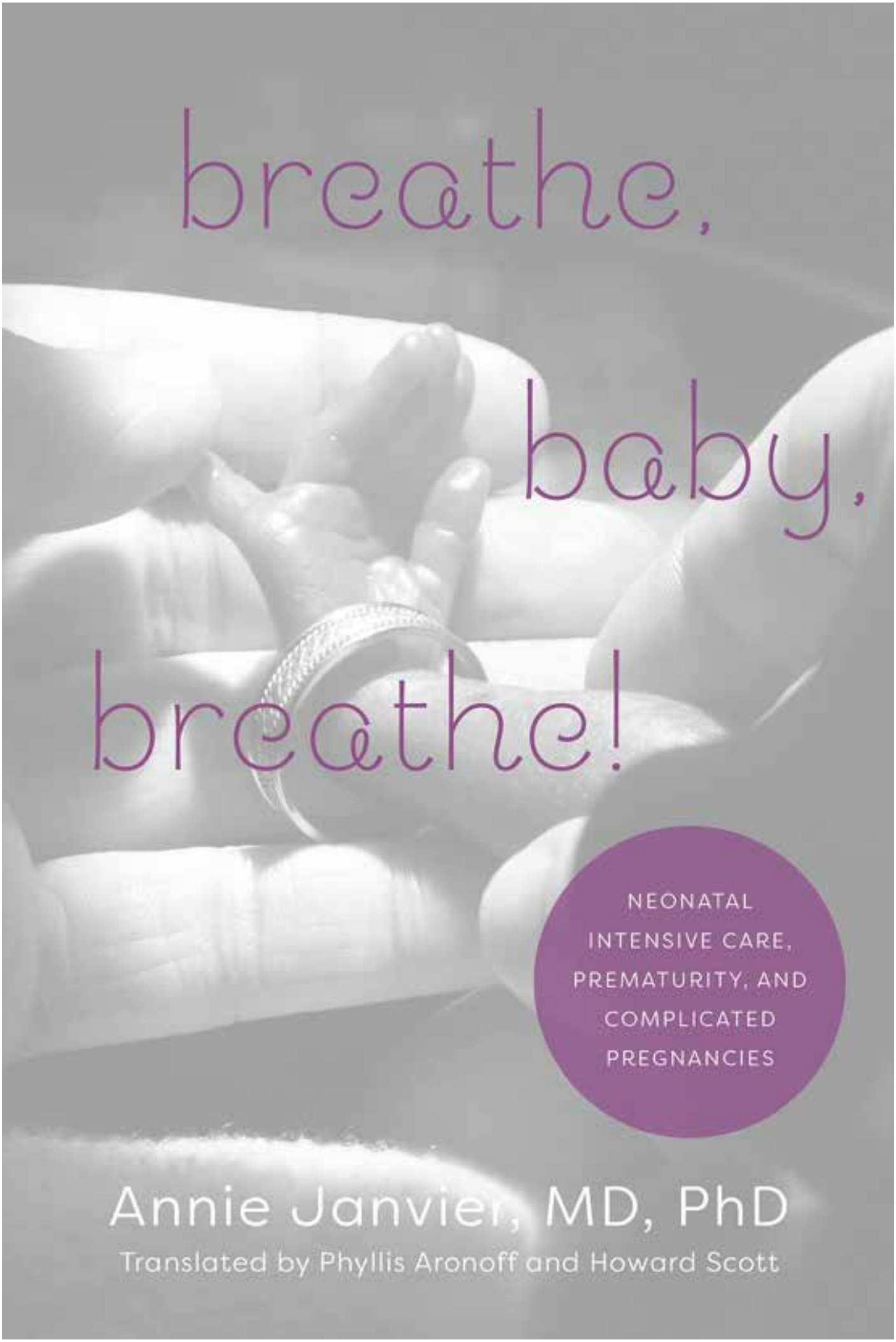
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NEONATAL INTENSIVE CARE, PREMATURITY, AND COMPLICATED PREGNANCIES
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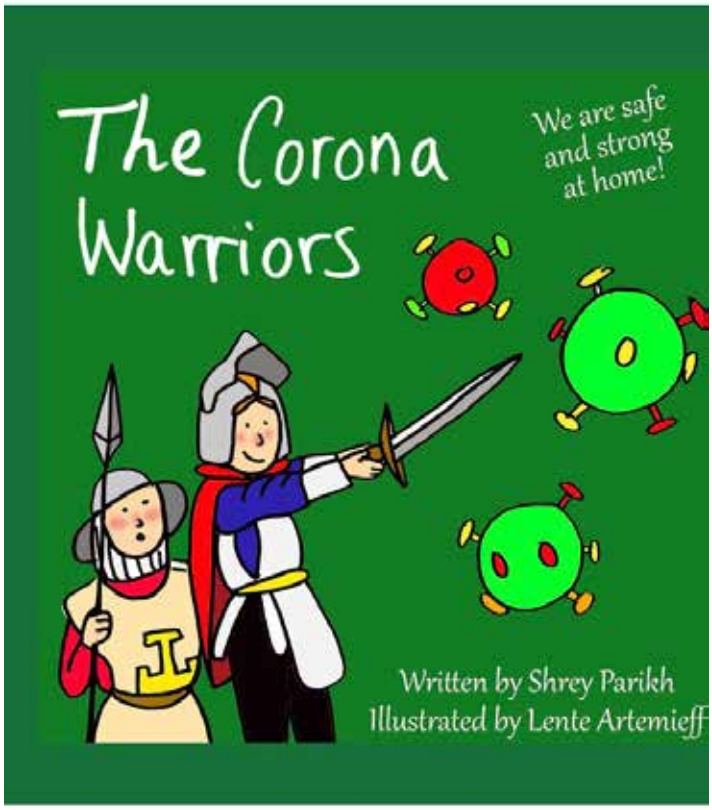

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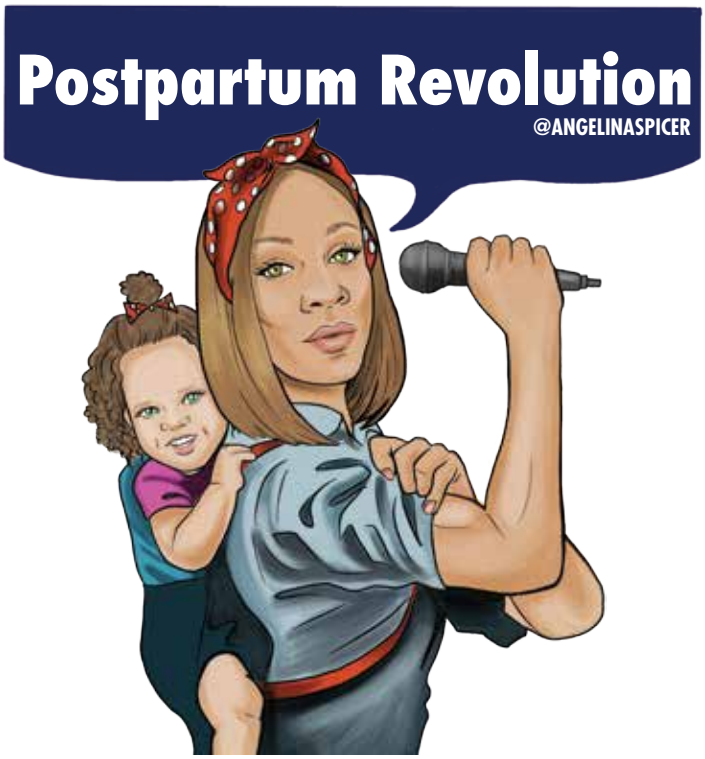

Vaccines and Preventive Monoclonal Antibodies

WHAT'S THE DIFFERENCE?

The Importance of Immunization

Vaccines and preventive monoclonal antibodies are two different types of immunization. While they function differently, they both serve the same purpose: protecting people from serious illnesses and diseases.

Different Technology, Same Protective Value

AfPA

https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work#:~:text=Vaccines%20contain%20weakened%20or%20inactive,rather%20than%20the%20antigen%20itself.

https://static1.squarespace.com/static/5523fcf7e4b0fef011e668e6/t/62445afd0134140ff954f3f6/1648646910485/NCIIH_Monoclonal+Antibodies+Inclusion+in+the+VFC+Program_Position+Paper_Mar+2022.pdf

VACCINES		PREVENTIVE MONOCLONAL ANTIBODIES
Teach the body to create antibodies that fight off a specific disease.		Introduce antibodies that are ready to ward off disease in the body.
By introducing an inactive piece of a disease or proteins that look like the disease, they trigger an immune response, training the body to create antibodies that defeat the disease.	**How does it work?**	Instead of teaching the body to create antibodies and defenses, they provide antibodies that are readily available.
Both support the immune system's defenses.		
Many vaccines are readily and easily available. The technology behind vaccines has been around for decades.	**What are the benefits?**	Preventive monoclonal antibodies can provide protection for diseases where there isn't an existing vaccine or there isn't an existing vaccine for certain patient groups.
Both protect against disease and provide a public health benefit by decreasing the burden of disease.		
Polio Measles COVID-19 And more	**What can this immunization protect against?**	RSV COVID-19
Both can provide tailored protection from a variety of diseases.		
Yes	**Is it safe?**	Yes

Both vaccines and preventive monoclonal antibodies undergo extensive testing for safety and efficacy.

READ NPA's statement: BLACK LIVES MATTER

Family-Centered Care Taskforce November 2023 Webinar Summary

Morgan Kowalski, Malathi Balasundaram, MD, Vargabi Ghei, MD

"The Family-Centered Care Taskforce stands as a pioneering force, being the FIRST international, multicenter, collaborative initiative solely dedicated to quality improvement in family-centered care. The Taskforce employs a small group model and large group webinars, enabling effective communication and facilitating change across various healthcare settings."

The Family-Centered Care Taskforce stands as a pioneering force, being the FIRST international, multicenter, collaborative initiative solely dedicated to quality improvement in family-centered care. The Taskforce employs a small group model and large group webinars, enabling effective communication and facilitating change across various healthcare settings. By sharing evidence-based practices and critical family perspectives during webinars and promoting accountability through small groups, we are creating a forward movement to close the healthcare gap. We are sharing our 11th webinar summary below; you can listen to complete recordings on the website www.fcctaskforce.org.

Helping Parents Cope in the NICU with Annie Janvier, MD, PhD

Annie Janvier, MD, PhD, is a Professor of Pediatrics and Clinical Ethics at Universite de Montreal and a Neonatologist and Clinical Ethicist at CHU Sainte-Justine. She shared her experience as a NICU mom of a 24-weeker and as a Neonatologist implementing Family-Integrated Care (FICare) in her unit. Annie's presentation shed light on the complexity of implementing FICare and the ethics of FiCare, emphasizing her finding that to succeed, providers must first master the basics. This includes learning and using the infant's first name, using parent or family caregivers' preferred name, sitting eye-to-eye with parents and family caregivers to make introductions, answer questions, ask parents how they are doing, and always explain the 'why' behind your organization.

"She shared her experience as a NICU mom of a 24-weeker and as a Neonatologist implementing Family-Integrated Care (FICare) in her unit. Annie's presentation shed light on the complexity of implementing FICare and the ethics of FiCare, emphasizing her finding that to succeed, providers must first master the basics."

Annie explains that the NICU experience can be traumatic and celebratory during a relatively short time; therefore, we must meet parents where they are at and keep care models flexible when putting FICare practices in place. Often, parents in the NICU do not feel they are truly parents, let alone good parents, given the highly specialized continuous medical care their infant is receiving. She offers twelve tips on ways to decrease guilt, empower and bolster confidence in parents and family caregivers, for example, by explaining skin-to-skin care in a nuanced way that includes

a caveat that parents may not feel comfortable doing it initially or addressing the guilt that many mothers feel about preterm birth. Using the sentence "some parents..... other parents" can help in these circumstances ("some parents feel anxious when they first do skin-to-skin while other parents feel this is a very positive experience. We will be with you to ensure this experience becomes positive for you").

"For example, while most physicians supported the development of FICare practices, some parents expressed hesitance about doing some more medical interventions, for example, tube feedings, presenting at rounds, and being present during resuscitations. For those parents, these were not things they saw parents doing, and they preferred to have other roles."

Lastly, Annie presented an article including the results of a FICare questionnaire administered in her unit. The survey results illustrate some barriers units may face in implementing FICare. For example, while most physicians supported the development of FICare practices, some parents expressed hesitance about doing some more medical interventions, for example, tube feedings, presenting at rounds, and being present during resuscitations. For those parents, these were not things they saw parents doing, and they preferred to have other roles. The "some parents... other parents" is a good way to ask parents about their preferences in these situations without causing harm and additional guilt. Ultimately, the survey results showed that FICare should not be felt by parents as "imposed" but instead offered in a way that helps parents based on their individual needs during their unique NICU journey.

Next Level FCC: How FICare Can Benefit US NICUs with Linda S. Franck, RN, PhD, FRCPCH, FAAN (she/her)

Linda S. Franck, RN, PhD, FRCPCH, FAAN, is a Professor and Jack & Elaine Koehn Endowed Chair in Pediatric Nursing at the University of California San Francisco Department of Family Health Care Nursing. She investigated the implementation of the Family-Integrated Care (FICare) model of NICU care delivery in US NICUs. FICare is based on Family-Centered Care (FCC) principles and includes providing a structured, parent-co-designed program of NICU care and encourages parents to become primary caregivers and full partners in care planning/caregiving for their infant. Key components of the FICare model that make it distinct from other parent support interventions include NICU staff training in working with parents (e.g., teaching, coaching, shared decision-making), parent participation in clinical rounds, peer parent mentorship, group education and psychosocial support for parents, and greater involvement of parents in caregiving for their infant. Some FICare models include parent-designed FICare app technology to increase parental access to information and support.

"Families in the study received either routine FCC or FICare. Compared to the FCC group, the FICare group infants exhibited a lower rate of nosocomial infections and mothers who experienced higher NICU-related stress and had reduced depression and PTSD symptoms after NICU discharge."

Linda shared the results of a clinical trial of FICare in three different California NICUs with 253 patients 33 weeks and under. Families in the study received either routine FCC or FICare. Compared to the FCC group, the FICare group infants exhibited a lower rate of nosocomial infections and mothers who experienced higher NICU-related stress and had reduced depression and PTSD symptoms after NICU discharge. FICare components of participation in rounds, having a parent mentor, and group classes were associated with positive outcomes. Although there were no differences in outcomes specifically related to using the FICare app, it may have reinforced or increased access to other FICare content, such as education and support materials and preparation for parental participation in rounds. For more information about applying the FICare model to your NICU, check out https://familyintegratedcare.com/.

Disclosure: The authors have no disclosures.

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The Signs & Symptoms of RSV

RESPIRATORY SYNCYTIAL VIRUS

Know the Signs & Symptoms of RSV

- Cough
- Runny Nose
- Struggling to Breathe *(breastbone sinks inward when breathing)*
- Difficulty Eating
- Lethargy
- Wheezing

RESPIRATORY SYNCYTIAL VIRUS
is a highly contagious seasonal virus that can lead to hospitalization for some babies and young children.

Know the Signs.

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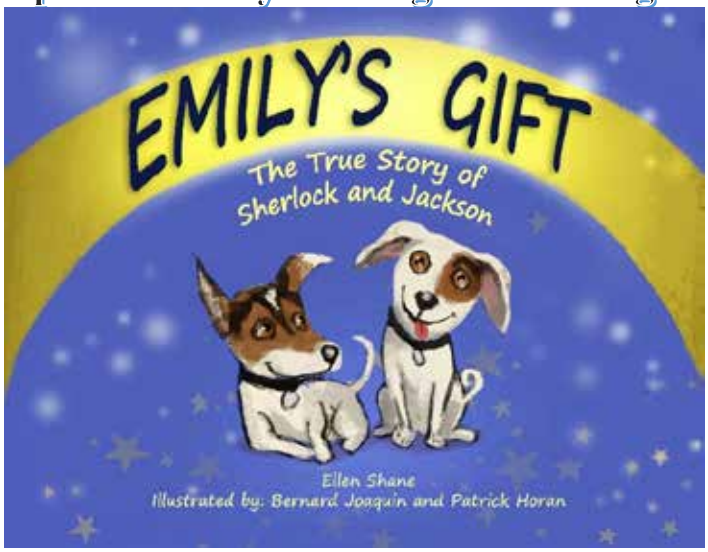
"Emily's Gift" can be purchased by clicking on the image of the cover below.



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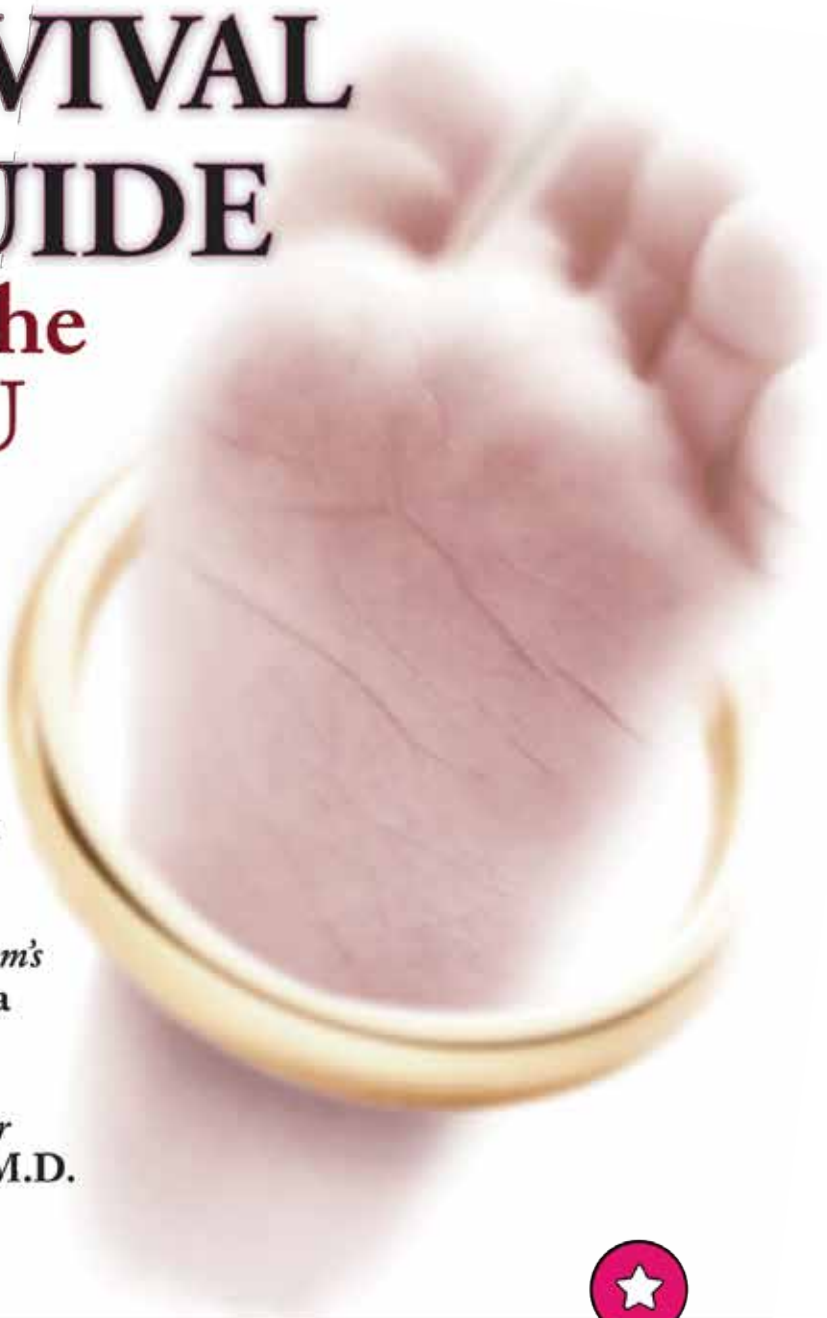
For more information, please visit emilyshane.org.

The Preemie Parent's SURVIVAL GUIDE to the NICU



By

little man's
Nicole Conn

&

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with

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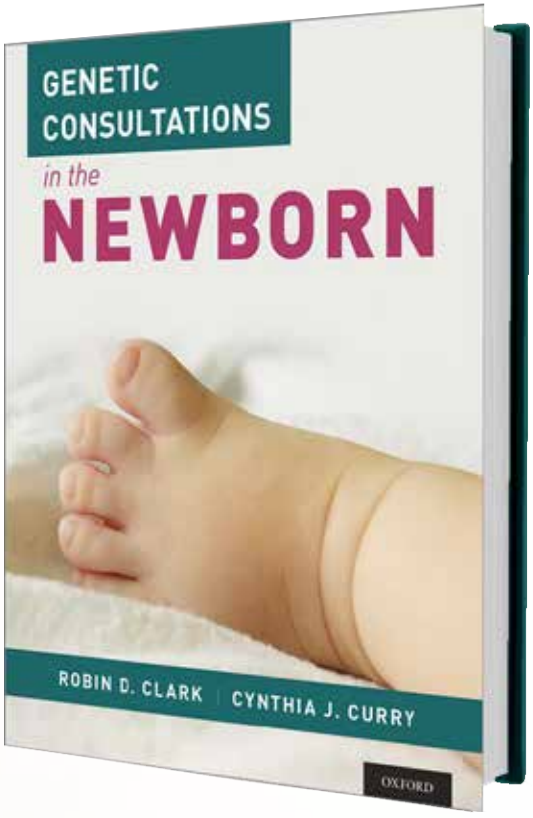

Robin D. Clark | Cynthia J. Curry

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- Organized by symptom and system, enriched with more than 250 photography and clinical pearls derived from authors' decades of clinical practice
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- OMIM numbers for each condition situate authors' practical guidance in the broader genetics literature, connecting readers to the most up-to-date references

Comprising of more than 60 chapters organized by system and symptom, *Genetic Consultations in the Newborn* facilitates fast, expert navigation from recognition to management in syndromes that manifest during the newborn period. Richly illustrated and packed with pearls of practical wisdom from the authors' decades of practice, it empowers readers to recognize the outward signs and symptoms crucial for an effective diagnosis.

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National Perinatal Association

May 15-17

in Anaheim California

Clinical Pearl: Fentanyl Exposure Syndrome

Walid Hussain, MD, Joseph R. Hageman, MD, Mitchell Goldstein, MD, MBA, CML, Robin D. Clark, MD

"Physicians say there may be a novel genetic syndrome among infants born to mothers who use fentanyl after a group of babies was found to have physical features such as cleft palate, small head and body size, drooping eyelids, undersized lower jaws, foot abnormalities, malformed thumbs, and male genital irregularities."

Fentanyl Exposure May Be Linked to a Novel Syndrome. Physicians say there may be a novel genetic syndrome among infants born to mothers who use fentanyl after a group of babies was found to have physical features such as cleft palate, small head and body size, drooping eyelids, undersized lower jaws, foot abnormalities, malformed thumbs, and male genital irregularities. Genetic counselor Erin Wadman and colleagues reported on the potential syndrome in the journal Genetics in Medicine Open, and researchers say more research is needed to establish if there is a connection.

Full Story: HealthDay News (12/5) (1)

"Genetic counselor Erin Wadman and colleagues reported on the potential syndrome in the journal Genetics in Medicine Open, and researchers say more research is needed to establish if there is a connection."

There has been so much discussion about a substance use disorder with exposure to fentanyl in different forms, such as fentanyl patches, that I was not surprised when I was reviewing today's summaries of the literature for ideas for writing this month's Clinical Pearl for *Neonatology Today* and I came across a summary of an article of a novel syndrome in newborn infants who have been exposed to fentanyl prenatally (2).

This group of 10 newborns included six babies from Nemours Children's Hospital from Wilmington, DE, and another four newborns from other centers around the country, including one from Loma Linda (1). The six newborns were microcephalic, growth restricted (short stature), and had several congenital malformations, including cleft palate, talipes equinovarus or rocker bottom feet, and hypospadias or a chordee (2). They also had broad thumbs, single palmar crease, and a mild 2,3 toe syndactyly (2). For the five with magnetic resonance imaging, a hypoplastic corpus callosum was also evident in 3 of 5 babies (2). Of the ten newborns, 7 had exome sequencing, all considered non-diagnostic (2).

"Interestingly, this group's growth and physical features were suggestive of Smith-Lemli-Opitz Syndrome but not diagnostic (2). Because of these similarities, biochemical metabolic studies of cholesterol metabolism (7-DHC or 8-DHC) were performed and were considered elevated initially in 7 of 8 patients, then normalized in follow-up studies in 6 of 6 babies (2)."

Interestingly, this group's growth and physical features were suggestive of Smith-Lemli-Opitz Syndrome but not diagnostic (2). Because of these similarities, biochemical metabolic studies of cholesterol metabolism (7-DHC or 8-DHC) were performed and were considered elevated initially in 7 of 8 patients, then normalized in follow-up studies in 6 of 6 babies (2).

These clinical findings in this group of newborns whose mothers had used fentanyl and other opioid substances prenatally, but especially fentanyl, were evaluated by geneticists and felt to be consistent with a new syndrome secondary to prenatal fentanyl exposure (1). The authors also discussed the importance of further studies to confirm this new syndrome.

References:

1. https://www.healthday.com/health-news/child-health/new-syndrome-may-be-affecting-babies-exposed-to-fentanyl

2. Wadman E, Fernandes E, Muss C, et al. A novel syndrome associated with prenatal fentanyl exposure. *Genetics in Medicine Open 2023;1,100834.*

Disclosures: The authors have no disclosures

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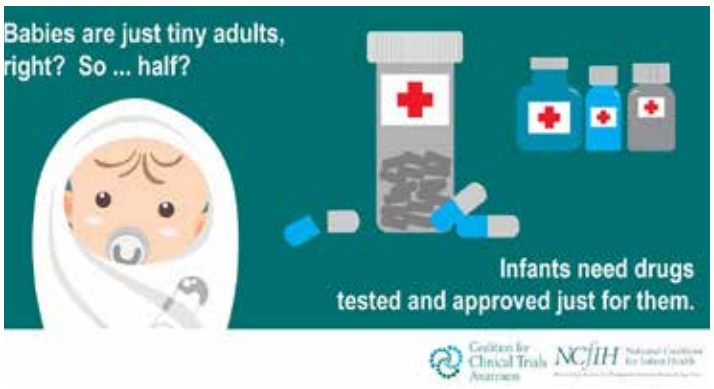

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Clinical Pearls are published monthly.

Submission guidelines for "Clinical Pearls":

1250 word limit not including references or title page.

May begin with a brief case summary or example.

Summarize the pearl for emphasis.

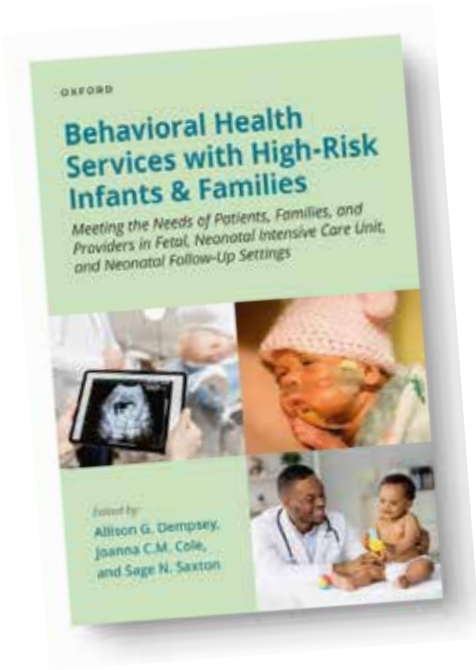
No more than 7 references.

Please send your submissions to:

jhageman@peds.bsd.uchicago.edu

National Network of NICU Psychologists

Education, Resources, and Support for Perinatal Mental Health Professionals



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National Perinatal Association

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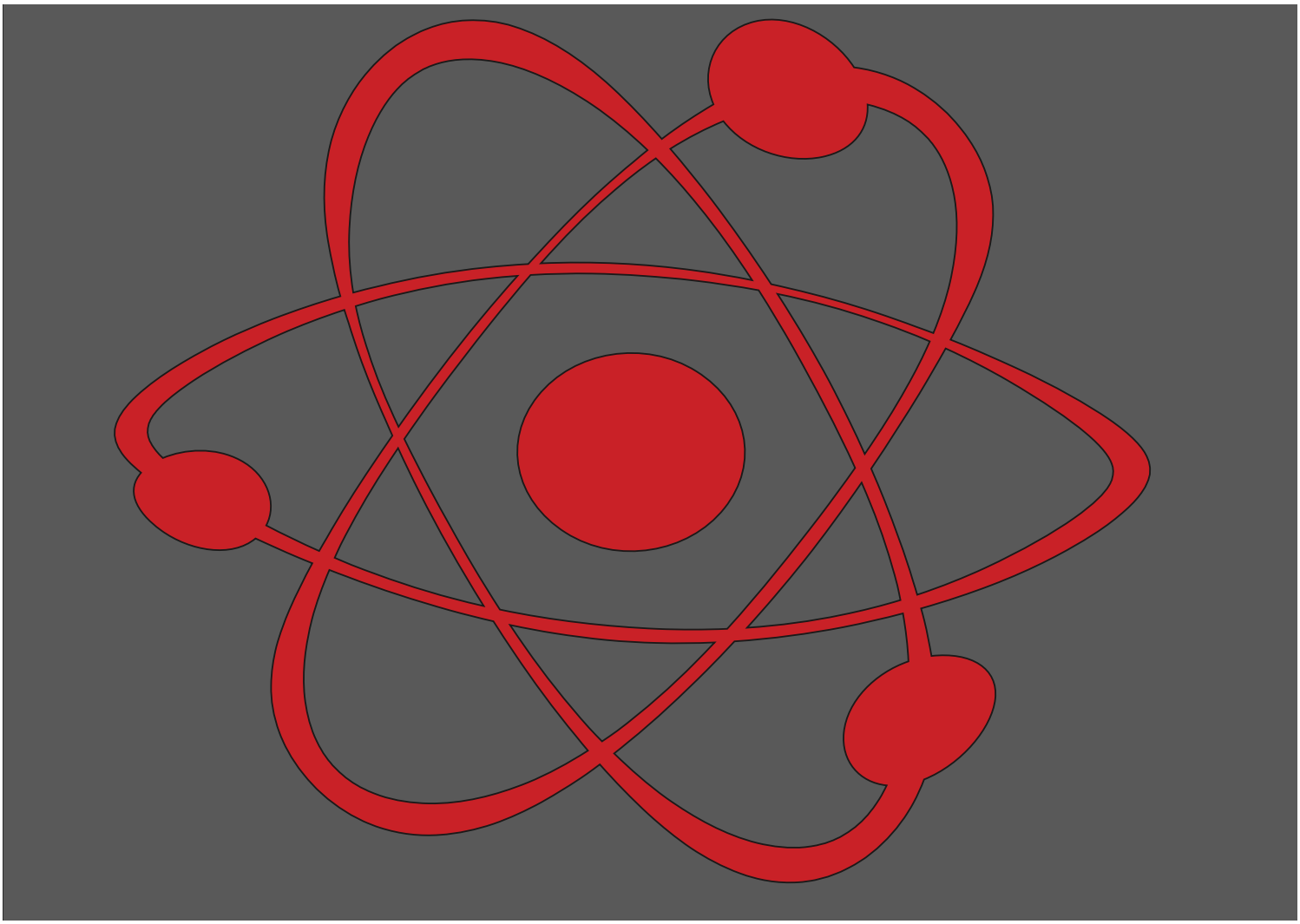

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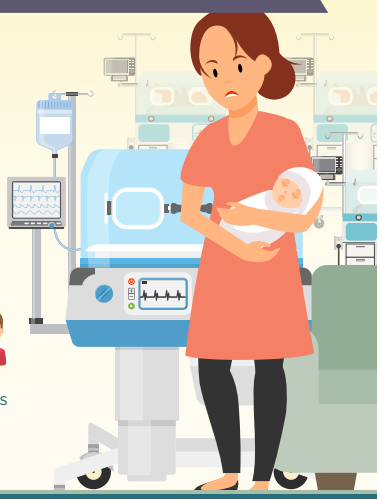
Will your PRETERM INFANT *need* EARLY INTERVENTION *services?*

Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges

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

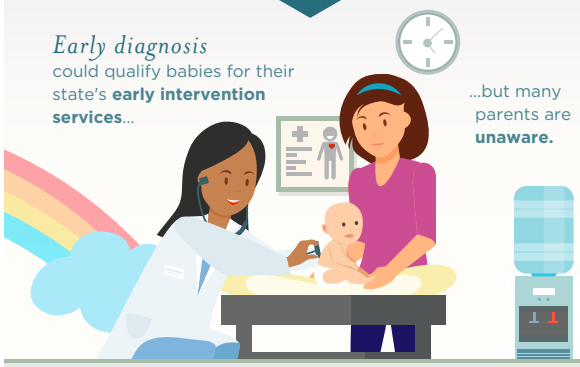


Early intervention can help preterm infants:

- Enhance language and communication skills
- Build more effective learning techniques
- Process social and emotional situations
- Address physical challenges
- Prevent mild difficulties from developing into major problems

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

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



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

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

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

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

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

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

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

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

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

- *La salud de la madre*
- *El sueño, la alimentación y el comportamiento del bebé a medida que crece*[2]
- *La capacidad para cuidar de un bebé y sus hermanos*

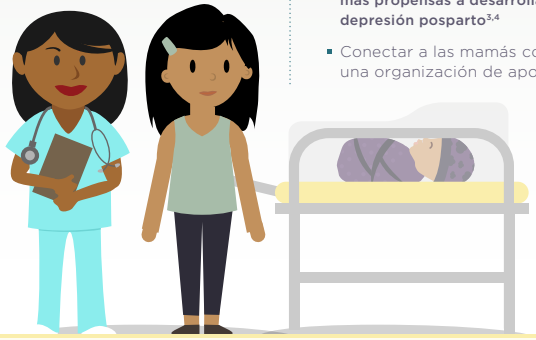
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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

LOS HOSPITALES PUEDEN:

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



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Protecting Access for Premature Infants through Age Two

www.infanthealth.org

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

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

[3] Journal of Perinatology (2015) 35, 529–536; doi:10.1038/jp.2015.147.

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

Upcoming Medical Meetings

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
January 31-February 2, 2024
Hilton Los Angeles North/Glendale
100 West Glenoaks Blvd.
Glendate, CA 91202
https://paclac.org/advances-in-care-conference/

NEO: The Conference for Neonatology
Feb 21 – Feb 23, 2024
Las Vegas, NV
https://www.pediatrix.com/for-clinicians/neo-conference

Mednax: Specialty Review in Neonatology
Feb 19 – Feb 24, 2024
Las Vegas, NV
https://www.pediatrix.com/for-clinicians/specialty-review-conference

2024 Gravens Conference: The Power of Voice: Using Your Voice for Babies, Family, Staff and Beyond
March 6-9, 2024
Sheraton Sand Key Resort
Clearwater Beach, FL
https://paclac.org/https-paclac-org-gravens-conference/

14th annual National Association of Neonatal Therapists (NANT) Conference in
Miramar Beach, Florida,
April 11th - 13th, 2024
https://nantconference.com/early-notification/

PAS 2024
Toronto, Canada
May 2-6, 2024
https://www.pas-meeting.org/

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

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Nickelodeon Animation Studio - 7.9 km / 4.9 mi
Warner Brothers Studio - 8.2 km / 5.1 mi
Greek Theatre - 9.9 km / 6.1 mi
Descanso Gardens - 9.9 km / 6.2 mi
Hollywood Boulevard - 10.3 km / 6.4 mi
Universal Studios Hollywood - 10.9 km / 6.8 mi
Rose Bowl Stadium - 11.2 km / 7 mi
Pasadena Convention Center - 11.6 km / 7.2 mi

Other Attractions

Disneyland – 35 mi
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Venice Beach - 28 mi

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Ontario International Airport- 45 mi
Long Beach Airport- 35 mi

Clinical Trial Center (Full-Time, Day Shift) - Research Coordinator

The Loma Linda University Health's Clinical Trial Center is actively seeking and recruiting top clinical research coordinator talent.

Our mission is to participate in Jesus Christ's ministry, bringing health, healing, and wholeness to humanity by Creating a supportive faculty practice framework that allows Loma Linda University School of Medicine physicians and surgeons to educate, conduct research, and deliver quality health care with optimum efficiency, deploying a motivated and competent workforce trained in customer service and whole-person care principles and providing safe, seamless and satisfying health care encounters for patients while upholding the highest standards of fiscal integrity and clinical ethics. Our core values are compassion, integrity, humility, excellence, justice, teamwork, and wholeness.

Able to read, write and speak with professional quality; use computer and software programs necessary to the position, e.g., Word, Excel, PowerPoint, Access; operate/troubleshoot basic office equipment required for the position. Able to relate and communicate positively, effectively, and professionally with others; provide leadership; be assertive and consistent in enforcing policies; work calmly and respond courteously when under pressure; lead, supervise, teach, and collaborate; accept direction. Able to communicate effectively in English in person, in writing, and on the telephone; think critically; work independently; perform basic math and statistical functions; manage multiple assignments; compose written material; work well under pressure; problem solve; organize and prioritize workload; recall information with accuracy; pay close attention to detail. Must have documented successful research administration experience focused on managing clinical trials function. Able to distinguish colors as necessary; hear sufficiently for general conversation in person and on the telephone; identify and distinguish various sounds associated with the workplace; see adequately to read computer screens and written documents necessary to the position. Active California Registered Nurse (RN) licensure preferred. Valid Driver's License required at time of hire.

The Clinical Trial Center is actively involved in many multi-center global pediatric trials, which span different Phases of research to advance health care in children. Please reach out to Jaclyn Lopez at 909-558-5830 or JANLopez@llu.edu with further interest. We would love to discuss the exciting research coordinator opportunities at our Clinical Trials Center.

Additional Information

- Organization: Loma Linda University Health Care
- Employee Status: Regular
- Schedule: Full-time
- Shift: Day Job
- Days of Week: Sunday, Monday, Tuesday, Wednesday, Thursday, Friday, Saturday

LOMA LINDA UNIVERSITY

Loma Linda University Children's Hospital is hiring Neonatal Nurse Practitioners

Children's Hospital, centrally located in Southern California, has earned Magnet Recognition as part of the American Nurses Credentialing Center's (ANCC) Program.

We are looking for experienced or new graduate Neonatal Nurse Practitioners (NNPs) who are excited to join a cohesive team that practices in a collaborative, fast-paced, high-acuity setting.

- Full-time and part-time positions available
- Level IV, 84-bed Neonatal Intensive Care Unit (NICU)
- Regional referral center encompassing Tiny Baby unit, ECMO, Cardiac ICU, Neuro NICU and Surgical services
- Maternity services and delivery center
- 24/7 coverage by NNP team and Fellows
- Competitive employee benefit packages

*Offering a **sign-on bonus** with relocation reimbursement for full-time, direct applicants who meet requirements.

For more information, please contact:

Karin Colunga, MSN, RN, PNP-BC
Director of Advanced Practice Nursing
kecolunga@llu.edu | 909-558-4486

BEST CHILDREN'S HOSPITALS U.S.News & World Report NEONATOLOGY 2022-23

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For more information, contact:

Melissa LaMarca

+1 (302) 313-9984 or

Melissa.LaMarca@neonatologytoday.net

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Neonatology Today's Policy on Animal and Human Research

Neonatology Today's policies ensure the protection and responsible use of animals and humans in all research articles under consideration. Authors are encouraged to follow the guidelines developed by the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3R), International Committee of Medical Journal Editors, and the Guide for the Care and Use of Laboratory Animals and U.S. Public Health Service's Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Authors are expected to demonstrate to their institutional review board or suitable proxy that ethical standards are met. If there is doubt whether research conducted was in accordance with ethical standards, then there must be verification that the institutional review body approved the uncertain aspects. Research not following these policies on participating animal and human subjects may be rejected. Researchers have a moral obligation towards the humane treatment of animals and ethical considerations for humans participating in research and are expected to consider their welfare when designing studies.

https://www.nc3rs.org.uk/arrive-guidelines

http://www.icmje.org

https://olaw.nih.gov/policies-laws/phs-policy.htm

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Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on the next to last page as well as photographs of birds on rear cover. For this edition, our art was again graciously provided by Colleen Kraft, MD. It is a work called "Landscape" done by her son Tim. Our Bird is "Migrating" from my collection.

Mita Shah, MD,
Neonatal Intensive Care Medical Director
Queen of the Valley Campus
Emanate Health, West Covina, CA

NT

Manuscript Submission: Instructions to Authors

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

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

3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication. There is no charge for your manuscript to be published. NT does maintain a copyright of your published manuscript.

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

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

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 10,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard "NLM" format (APA 7th is no longer acceptable). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

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

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

11. NT recommends reading Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals from ICMJE prior to submission if there is any question regarding the appropriateness of a manuscript. NT follows Principles of Transparency and Best Practice in Scholarly Publishing(a joint statement by COPE, DOAJ, WAME, and OASPA). Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

NICU Baby's Bill of Rights

1- The Right to Advocacy
My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical records, and prognosis, so they celebrate my achievements and support me when things get challenging.

2- The Right to My Parents' Care
In order to meet my unique needs, my parents need to learn about my developmental needs. Be patient with them and teach them well. Make sure hospital policies and protocols, including visiting hours and rounding, are as inclusive as possible.

3- The Right to Bond with My Family
Bonding is crucial for my sleep and neuroprotection. Encourage my parents to practice skin-to-skin contact as soon as and as often as possible and to read, sing, and talk to me each time they visit.

4- The Right to Neuroprotective Care
Protect me from things that startle, stress, or overwhelm me and my brain. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time and faster than it ever will again. The way I am cared for today will help my brain when I grow up. Connect me with my parents for the best opportunities to help my brain develop.

5- The Right to be Nourished
Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Also, let my parents know that donor milk may be an option for me.

6- The Right to Personhood
Address me by my name when possible, communicate with me before touching me, and if I or one of my siblings pass away while in the NICU, continue referring to us as multiples (twin/triplets/quads, and more). It is important to acknowledge our lives.

7- The Right to Confident and Competent Care Giving
The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help educate them about my unique needs, development, diagnoses, and more.

8- The Right to Family-Centered Care
Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9- The Right to Healthy and Supported Parents
My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my parents about resources such as peer-to-peer support programs, support groups, and counseling, which can help reduce PMAD, PPD, PTSD, anxiety and depression, and more.

10- The Right to Inclusion and Belonging
Celebrate my family's diversity and mine; including our religion, race, and culture. Ensure that my parents, grandparents, and siblings feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

Presented by:

NPN
NICU PARENT NETWORK

NICU Parent Network

Visit nicuparentnetwork.org to identify national, state, and local NICU family support programs.

*** The information provided on the NICU Baby's Bill of Rights does not, and is not intended to, constitute legal or medical advice. Always consult with your NICU care team for all matters concerning the care of your baby.**