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Dexamethasone-Induced Bradycardia in a SARS-CoV-2 Positive Neonate with Bilateral Congenital Dacryocystoceles

Trevor B. Cabrera, MD

Abstract

We present a case of a term neonate perinatally infected with SARS-CoV-2 who developed asymptomatic transient bradycardia due to IV dexamethasone during treatment for bilateral congenital dacryocystoceles. While cases of steroid-induced bradycardia are reported in older children and adults, the incidence in neonates is unknown, given the relative paucity of use in this population. In addition, it is unclear if this effect may be compounded or complicated by acute infections with SARS-CoV-2. Neonates treated with steroids, especially in the setting of infections with SARS-CoV-2, should be monitored with telemetry for the development of bradycardia.

Keywords: Steroid-induced bradycardia, dexamethasone-induced bradycardia, COVID-19, SARS-CoV-2

"We present a neonate with congestion due to nasolacrimal duct obstructions from bilateral congenital dacryocystoceles in the setting of a perinatally acquired infection with SARS-CoV-2 that developed asymptomatic bradycardia after receiving IV dexamethasone."

Introduction

Bradycardia is an important finding in neonates due to the associated risk of increased mortality. While there are multiple associated etiologies, bradycardia has rarely been reported due to systemic corticosteroid use. Furthermore, bradycardia has been reported in individuals acutely infected with SARS-CoV-2. However, the concomitant occurrence and potential increased risk for developing bradycardia in neonates with known SARS-CoV-2 infections receiving systemic corticosteroids are unknown. We present a neonate with congestion due to nasolacrimal duct obstructions from bilateral congenital dacryocystoceles in the setting of a perinatally acquired infection with SARS-CoV-2 that developed asymptomatic bradycardia after receiving IV dexamethasone.

Case Presentation

The patient was a 5-day-old 3400g female born at 39 0/7 weeks gestation to a 38-year-old G1P0 mother who presented to our institution with a chief complaint of nasal congestion. The mother had an unremarkable prenatal course, and delivery was without complications. Prenatal labs were negative, including GBS.

However, on routine screening prior to induction, she had a positive SARS-CoV-2 PCR – the mother remained asymptomatic before and after delivery. The infant also had a positive SARS-CoV-2 PCR on day of life 1. On day of life three, the parents reported an episode of self-resolving perioral cyanosis. On day of life 4, she developed significant congestion with swelling and a bluish appearance of bilateral nasolacrimal duct sacs and was taken to an outside hospital, at which point repeat testing continued to be positive for SARS-CoV-2. She was recommended to perform nasolacrimal duct massages with warm compresses and sent home, but due to worsening congestion with decreased bottle feeding presented to our ED the following day.

On arrival to our ED, she was noted to have significant swelling near the medial canthus bilaterally with palpable firm cystic masses near the superior aspect of the nasolacrimal duct (Figure One) and was observed to have a drop in oxygen saturation to 85% during feeding. She was admitted to the Pediatric Hospitalist service, and Pediatric ENT and Pediatric Ophthalmology were consulted. Pediatric ENT performed a bedside flexible fiberoptic evaluation and noted bilateral dacryocystoceles with nasal obstruction. She was started on oxymetazoline, one drop per nostril every 12 hours, with mild improvement. On day of life 6, she was brought to the operating room by Pediatric Ophthalmology for lacrimal duct probing and received interoperative ophthalmic antibiotics as well as preoperative IV Dexamethasone 2mg (0.58mg/kg). She tolerated the procedure well and was noted to have improved nasal congestion immediately postoperatively. However, the following day, she had a recurrence of nasal congestion complicated by expiratory stridor and increased use of accessory muscles, so she was given IV Dexamethasone 2 mg approximately 18 hours after her preceding dose and a second flexible fiberoptic evaluation performed by ENT was concerning for near complete bilateral nasal obstruction from postoperative edema. She was given nasal saline drops and oxymetazoline to improve her congestion. However, approximately 3.5 hours after administration of systemic steroids, she was noted to develop persistent new-onset bradycardia while awake in the 70s with a nadir of 69 without associated desaturations.

"However, approximately 3.5 hours after administration of systemic steroids, she was noted to develop persistent newonset bradycardia while awake in the 70s with a nadir of 69 without associated desaturations."

Given the persistent bradycardia, she was transferred to the pediatric intensive care unit at which point a full work-up was performed, including complete blood count (CBC), blood culture, electrocardiogram (EKG), venous blood gas (VBG), comprehensive metabolic panel (CMP), elevated sedimentation rate (ESR), ferritin, d-dimer, pro-brain natriuretic peptide (pro-BNP), urinalysis with urine culture, head ultrasound, and chest

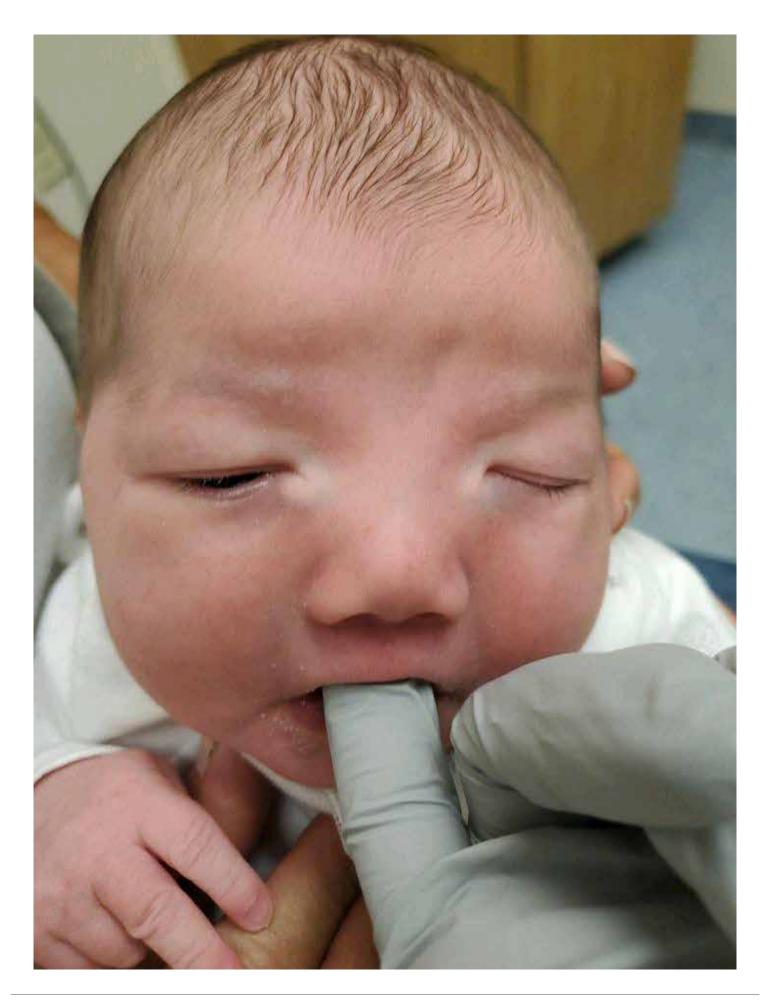




Figure 1: (Left) Preoperative bilateral dacryocystoceles; (above) One day postoperatively from probing of bilateral dacryocystoceles

and abdomen x-rays. Labs were only significant for ferritin of 872 and pro-BNP of 5429. The electrocardiogram showed sinus bradycardia. On day of life 8, pro-BNP had decreased without intervention to 3159, and an echocardiogram was performed, showing a small patent foramen ovale, normal LV function, normal proximal coronary arteries, and no pericardial effusion. Of note, her newborn state screens later returned as normal. Her bradycardia resolved without intervention within 12 hours from the onset, and she was transferred back to the Pediatric Hospitalist service for observation and then discharged at nine days of life in good condition.

"Her bradycardia resolved without intervention within 12 hours from the onset, and she was transferred back to the Pediatric Hospitalist service for observation and then discharged at nine days of life in good condition."

Discussion

We present the case of a term neonate found positive for SARS-CoV-2 at birth with nasolacrimal duct obstruction due to bilateral congenital dacryocystoceles that developed acute asymptomatic bradycardia suspected secondary to IV dexamethasone administration. This bradycardia was self-limited, occurring ~4 hours after systemic corticosteroid use and resolved within 12 hours from onset. Although referenced in general pediatric and adult literature, reports of steroid-associated bradycardia in neonates are rare, especially given the less common usage of systemic steroids in this population compared to older patients. Furthermore, its occurrence in SARS-CoV-2-positive neonates is unknown.

"Although referenced in general pediatric and adult literature, reports of steroid-associated bradycardia in neonates are rare, especially given the less common usage of systemic steroids in this population compared to older patients. Furthermore, its occurrence in SARS-CoV-2-positive neonates is unknown."

Bradycardia is a not uncommon yet concerning finding in neonates that may be due to multiple etiologies and warrants a thorough evaluation, given the high associated mortality. While more common in premature infants, the differential diagnosis in term newborns includes congenital heart block due to maternal systemic lupus erythematosus, sepsis, hypoxia, hypothermia, congenital hypothyroidism, congenital heart disease or congenital arrhythmias (e.g., Congenital Long QT Syndrome), central nervous system disturbances and electrolyte abnormalities (e.g., Hypoglycemia). A thorough evaluation of the above was performed in our infant and found negative, at which point the suspected

causal agent was thought to be IV dexamethasone.

Corticosteroids are known to have many acute and chronic adverse effects, most commonly: hypertension, electrolyte abnormalities (hyperglycemia, hypokalemia), behavioral changes, immune suppression with subsequently increased rates of infections, and sudden death (1,2). In the neonatal population, there are additional risks of spontaneous gastrointestinal perforation and the development of hypertrophic cardiomyopathy (3,4). While arrhythmias have been reported in the literature, a majority are associated with tachyarrhythmias as opposed to bradycardia. First reported in 1986, corticosteroid-induced bradycardia is a rare albeit not entirely unknown side effect seen in children and adults (1,5-11). Multiple case reports show this effect may occur after IV or PO administration with various agents, most notably in treating rheumatologic and oncologic conditions - particularly methylprednisolone and dexamethasone. The effect is mainly dose-dependent and may be questionably related to the speed of administration (e.g., IV bolus vs. drip). While the development of bradycardia has sometimes required pressor support in adults, it is generally asymptomatic in children. One case reported the development of asymptomatic bradycardia in a child treated with protocol-defined doses of IV methylprednisolone for multisystem inflammatory syndrome in children (a.k.a. MIS-c) (12).

In neonates, corticosteroids are sometimes used for bronchopulmonary dysplasia and hyaline membrane disease and to facilitate extubation (e.g., DART Protocol) (3,13). However, this protocol calls for a lower dose of dexamethasone of a cumulative 0.89mg/kg – our infant received a total of 1.15mg/kg within 24 hours. Limited case reports in the 1980s reported the development of persistent bradycardia in premature infants treated with dexamethasone at doses similar to that received by our14-16; however, these cases predate the era of SARS-CoV-2.

"The exact mechanism for corticosteroidinduced bradycardia is unknown; however, animal studies suggest direct effects on myocytes via alterations in cardiovascular sensitivity to catecholamines, along with acute electrolyte shifts accompanied by alterations in sodium and water physiology."

The exact mechanism for corticosteroid-induced bradycardia is unknown; however, animal studies suggest direct effects on myocytes via alterations in cardiovascular sensitivity to catecholamines, along with acute electrolyte shifts accompanied by alterations in sodium and water physiology. These changes are proposed to lead to an expansion of plasma volume with relative hypertension and activation of a baroreceptor response (1,2,5,6,8). However, these electrolyte changes are challenging to detect and generally tolerated by most infants without other underlying diseases. Furthermore, tracking of consistent elevation of blood pressure with simultaneous decreases in heart rate is difficult to obtain. In our patient, electrolytes, EKG, and echocardiogram were normal and blood pressure, while intermittently elevated, was difficult to correlate directly with the drop in heart rate.

Particularly of interest in our patient was an acute infection

with SARS-CoV-2. While her congestion was suspected mainly secondary to duct obstruction, it is difficult to determine if her symptoms or postoperative course were worsened by concomitant infection. Several studies have reported the presence of arrhythmias among individuals with SARS-CoV-2. While most reported are tachyarrhythmias, specifically sinus tachycardia or supraventricular tachycardias, relative bradycardia has been reported in adult literature to account for up to 12% of cardiac dysrhythmias, often as a marker of cardiovascular collapse (17-19).

Furthermore, increasing reports have noted an association between perinatal transmission of SARS-CoV-2 infection and bradycardia. In a study of 130 neonates in Jordan, sinus bradycardia was reported to occur in 18.8% of SARS-CoV-2 positive neonates as opposed to 1.8% of SARS-CoV-2 negative neonates; however, the time of exact occurrence of bradycardia was not reported. Bradycardia associated with acute SARS-CoV-2 infection has been thought to be multifactorial due to severe hypoxia, inflammatory damage of cardiac pacemaker cells, and exaggerated response to medications (20,21).

While it is difficult to conclude that an acute infection compounded our infant's response to IV corticosteroids with SARS-CoV-2, further studies should be undertaken to evaluate this risk. Presumably, viral damage of cardiomyocytes may predispose or exaggerate newborns' response to corticosteroid-associated bradycardia development.

"While it is difficult to conclude that an acute infection compounded our infant's response to IV corticosteroids with SARS-CoV-2, further studies should be undertaken to evaluate this risk. Presumably, viral damage of cardiomyocytes may predispose or exaggerate newborns' response to corticosteroid-associated bradycardia development."

Conclusion

We present the case of a newborn with significant nasal congestion due to bilateral congenital dacryocystoceles and acute infection with SARS-CoV-2 that developed asymptomatic self-limited bradycardia after the administration of IV dexamethasone. Bradycardia is suspected to be from corticosteroid use due to alterations in cardiovascular sensitivity, baroreceptor response, and electrolyte shifts, as well as in acute infections with SARS-CoV-2 due to cardiomyocyte damage and inflammation due to viral infiltration. The concomitant use of steroids in active SARS-CoV-2 infections may compound resultant bradycardia, and thus neonates should be monitored carefully with telemetry in these situations.

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Disclosures: None noted.

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Respiratory Syncytial Virus is a

Really Serious Virus

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

Coughing that gets worse and worse

Breathing that causes their ribcage to "cave-in"

Rapid breathing and wheezing

Bluish skin, lips, or fingertips

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

Call your doctor and meet them at the hospital.

If you baby isn't breathing call 911.





Thick yellow, green, or grey mucus







that clogs their nose and lungs, making it hard to breathe Fever that is higher than 101° Fahrenheit



which is especially dangerous for babies younger that 3 months



www.nationalperinatal.org/rsv



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 CLEANWASH 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





nicuparentnetwork.org nationalperinatal.org/skin-to-skin



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%	50.2% Breastfeeding	
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.



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Letters to the Editor

Letter to the Editor: "A
Comparison of Outcomes in
Conservative Versus Active
Treatment of Patent Ductus
Arteriosus in Two Neonatal
Intensive Care Units"

Dear Dr. Goldstein,

Thank you for your interesting publication of "A Comparison of Outcomes in Conservative Versus Active Treatment of Patent Ductus Arteriosus in Two Neonatal Intensive Care Units." We found the topic fascinating as we recently experienced two Patent Ductus Arteriosus (PDA) ligations in our NICU. Given how common neonates experience PDAs, we wanted to expand on this topic, emphasize the significance of the long-term and short-term effects of active and conservative management, and discuss how we can better make these vital decisions in neonatal care.

"We found the topic fascinating as we recently experienced two Patent Ductus Arteriosus (PDA) ligations in our NICU. Given how common neonates experience PDAs, we wanted to expand on this topic, emphasize the significance of the long-term and short-term effects of active and conservative management, and discuss how we can better make these vital decisions in neonatal care."

The degree of invasiveness when comparing treatment options should be considered when discussing the long-term outcomes of any intervention. As medical students, we had the opportunity to assist with a Patent Ductus Arteriosus ligation surgery and have witnessed first-hand the invasiveness of entering the thorax of a neonate. A neurodevelopmental delay is one standard used to assess the long-term outcomes of an invasive neonatal procedure. In a retrospective study on very low birth weight infants and PDA ligation, "...results suggest that surgical ligation for his PDA may not increase the risk for poor neurodevelopmental outcomes at corrected two years of age" (1). Other potential long-term adverse effects of PDA ligation include chronic lung disease, retinopathy of prematurity, and developmental delay (2). When deciding on PDA ligation as the treatment of choice, providers must consider and potentially develop systems to assess the susceptibility of patients to these adverse effects.

We find the statistical analysis of patients receiving conservative, as opposed to therapeutic and surgical management, to be valuable in discussing the efficacy of the intervention. In particular, we notice that birth weight and gestational age characteristics did not impact the clinical decision to provide treatment for PDA closure.

We want to take this a step further and discuss the importance of the size and turbulence of the patent ductus arteriosus on closure management. We state here that the size of the patent ductus arteriosus and its significance on hemodynamic stability have a different interpretation in various sources and is, therefore, not a uniformly agreed upon concept. Common measurements of PDA size include looking at the Left Atrium: Aorta ratio, with a standard cutoff of 1.4 (3). We also state that the complications of allowing hemodynamically large PDAs to persist and close naturally may impact various other components of the systemic vasculature, such as cerebral and/or renal blood flow. In a specific cohort of 87 premature neonates with PDA in the NICU, approximately 38% had a PDA of hemodynamic significance, all of whom received medical treatment (4). The study also found a statistically significant risk in the incidence of pulmonary hemorrhage in those with hemodynamically significant versus non-hemodynamically significant PDA (60.6% vs. 51.9%, p = 0.03).

"However, where do we, as doctors, draw the line at clinical significance? According to Conrad et al., finding that line in the sand is challenging. There is no universal scoring system for the severity of a PDA, making it challenging to facilitate comparisons in research, forcing physicians to make their own decisions despite possibly conflicting resources (5)"

This article's conclusion states that conservative management should be heavily considered when treating a PDA unless it is considered large and clinically significant. However, where do we, as doctors, draw the line at clinical significance? According to Conrad et al., finding that line in the sand is challenging. There is no universal scoring system for the severity of a PDA, making it challenging to facilitate comparisons in research, forcing physicians to make their own decisions despite possibly conflicting resources (5). Communication is vital throughout a medical team to successfully treat a patient. However, how can researchers and physicians communicate when there are no definite guidelines for the diagnoses they are discussing? Considering the severity of sequelae in PDAs discussed earlier in our letter, it is crucial to determine a universal scale for the best treatment plan for every patient.

"However, how can researchers and physicians communicate when there are no definite guidelines for the diagnoses they are discussing? Considering the severity of sequelae in PDAs discussed earlier in our letter, it is crucial to determine a universal scale for the best treatment plan for every patient."

Sincerely,

Victoria Hodsdon, OMS-III, Anthony Nazaryan, OMS-III, and Jayant Totlani, OMS-III

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Dear Drs. To Be Victoria Hodsdon, OMS-III, Anthony Nazaryan, OMS-III, and Jayant Totlani, OMS-III

Thank you for a well-thought-out discussion of the difficulty in dealing with the complications of a Patent Ductus Arteriosus (PDA). Certainly, no consensus exists on the right time to provide definitive therapy versus medical management or conservative observation. The difficulty is timing. Timing is everything. Certain PDAs may close on their own. Although there is no exact correlation, those who are small and of a younger gestation tend to be more affected by the symptomatology than those of an older gestation.

"The difficulty is timing. Timing is everything. Certain PDAs may close on their own. Although there is no exact correlation, those who are small and of a younger gestation tend to be more affected by the symptomatology than those of an older gestation."

Conservative management is usually best for those in whom the PDA will close on its own. However, we do not know which patients will, in fact, close. Consequently, many more patients are given prophylactic or treatment doses of Indomethacin or other medical management, including Ibuprofen and Acetaminophen, sometimes with significant morbidity and mortality. The occurrence of spontaneous intestinal perforation and, at times, nec-

rotizing enterocolitis has been associated with the use of these medications.

Surgical treatment is definitive but has its own set of risks. The long-term prognosis of babies who first received treatment and then ligation may be worse collectively than those who ligated without the "benefit" of medical treatment. Further, the delay associated with surgical intervention may be a risk for worse outcomes.

"Your comment regarding creating a standardized risk assessment tool is undoubtedly an approach to this problem; however, the validation of such an endeavor would be challenging and subject to local variation, which tends to occur with the management of the PDA."

Your comment regarding creating a standardized risk assessment tool is undoubtedly an approach to this problem; however, the validation of such an endeavor would be challenging and subject to local variation, which tends to occur with the management of the PDA.

Sincerely,

monamile.

Mitchell Goldstein, MD, MBA, CML

Editor in Chief



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Erratum (Neonatology Today January, 2023

Neonatology Today is not aware of the erratum affecting the January, 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.

NT

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

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

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Update: CORONAVIRUS COVID-19 According to data published in The Lancet Pregnancy and the risk of VERTICAL TRANSMISSION LOW National Perinatal Association

www.nationalperinatal.org

Should Infants
Be Separated from
Mothers with COVID-19?

FIRST DO NO HARM

SEPARATION may not prevent INFECTION.

SKIN to SKIN CARE supports newborns' physiology.

SEPARATION stresses parents and babies.





SEPARATION weakens immune protections.



SEPARATION

disrupts
breastfeeding
putting
babies'
health
at risk.

SEPARATING the DYAD

doubles providers' workload, burdening systems.



BASED ON THE ARTICLE:

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

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Fellow's Column: Three-Pronged Score to Monitor Weekly Postnatal Growth in Preterm Infants

Archana Bottu, MD Shabih Manzar, MD, MPH

"This brief report describes a threepronged scoring (TPS) system to monitor weekly postnatal growth in preterm infants. The TPS was developed by combining growth velocity (GV), weight gain ratio (WGR), and a delta z-score (D Z). A score of 3 is concerning, a score of 4-5 is reassuring, and a score of 6 is appropriate."

Acronyms and Abbreviations:

- GV Growth velocity
- WGR Weight gain ratio

ZSD –Z-score difference

Summary:

This brief report describes a three-pronged scoring (TPS) system to monitor weekly postnatal growth in preterm infants. The TPS was developed by combining growth velocity (GV), weight gain ratio (WGR), and a delta z-score (D Z). A score of 3 is concerning, a score of 4-5 is reassuring, and a score of 6 is appropriate. The TPS provides a model for developing clinical decision support.

Adequate growth is particularly important for preterm infants, monitored by weight, height, and head circumference plotted on growth charts. In this paper, we looked at growth pertaining to weight.

"Adequate growth is particularly important for preterm infants, monitored by weight, height, and head circumference plotted on growth charts. In this paper, we looked at growth pertaining to weight."

Three-Pronged Score (TPS)

Parameter	Score of 1	Score of 2
Growth Velocity	< 10 g/kg/day	10-15 g/kg/day
(g/kg/day)		
Weight Gain Ratio	< 0.5	>0.5
Z-score Difference	Negative	Positive

Minimum score 3, Maximum score 6

A score of 3 is concerning and needs action

A score of 4-5 is reassuring

A score of 6 is optimal/appropriate

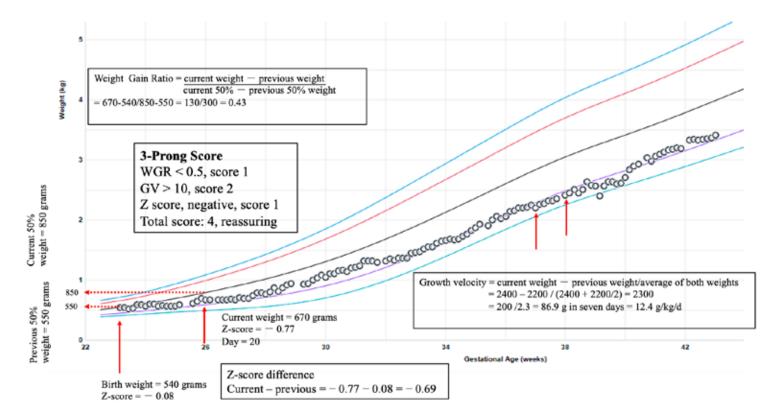


Figure 1 presents an example of calculating GV, WGR, and ZSD. Most of the studies on growth monitoring use Z-scores.(1) Rochow et al. (2) have shown that the inclusion of weight gain ratio (WGR) in addition to delta z-score (D Z) or the difference between z-scores (ZSD) is a better way to monitor postnatal growth. Growth velocity (GV) is the most common indicator to monitor growth.(3) The diagram below uses a three-pronged score, combining GV, WGR, and ZSD, to assess growth more thoroughly in a preterm infant. Example: Figure 1 presents an example of calculating GV, WGR, and ZSD.

"In conclusion, a three-pronged score may better evaluate weekly postnatal growth in preterm infants. This score could be used as a model for developing clinical decision support."

In conclusion, a three-pronged score may better evaluate weekly postnatal growth in preterm infants. This score could be used as a model for developing clinical decision support.

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- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
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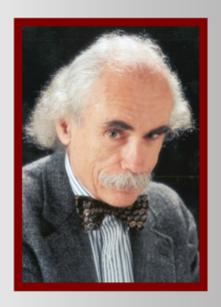
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TUESDAY, APRIL 25, 2023

UNIVERSITY
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9:00 a.m. - 4:30 p.m.



High-Reliability Organizing (HRO): Engagement Matters, Is Personal, and Initiates Enactment 1. The Color of Noise Impairs Cognition

Daved van Stralen, MD, FAAP

Sean D. McKay, Element Rescue, LLC

Thomas A. Mercer, RAdm, USN (Retired)

Abstract

The characteristics of abrupt crises are the elements that cause stress and fear. Stress impairs cognition, fear generates defensive behaviors, and existential threat drives aggressive behaviors. Nobody wants this; organizations expend effort to prevent or mitigate stress and fear. Unfortunately, these efforts promulgate and normalize belief in the inevitability of stress. Fear becomes normalized through situationally accepted behaviors such as anger and intimidation, creating the ecology of fear. These same stress responses, fear reactions, and amygdala reflexes drive engagement in the situation. Engagement mitigates and resolves the crisis. Engagement also modulates the stress responses, fear reactions, and amygdala reflexes that enable that engagement. Counterintuitively, stress-impaired cognition, fear-circuit behaviors, and amygdala-driven reflexive behaviors caused by the crisis are necessary for engagement in that crisis.

"Counterintuitively, stress-impaired cognition, fear-circuit behaviors, and amygdala-driven reflexive behaviors caused by the crisis are necessary for engagement in that crisis."

Introduction

Paramedics brought a pediatric motor vehicle collision victim into the trauma room. Staff became involved with the patient's care. The chief surgical resident for trauma entered, immediately calling out orders. Any miss brought a stiff rebuke from the chief resident. As the pediatric resident entered, the surgical resident demanded orders for specific drugs. The pediatric resident looked through a book and began calculating drug dosages. The surgical resident demanded a faster response. Everyone in the room worked rapidly, directing their attention toward the child rather than each other.

Later, the surgical resident ridiculed the pediatric resident for searching for drug doses in a book and using a calculator. The trauma residents were proud of their performance. What they saw was constant activity in response to their orders. One of the authors (DvS) had witnessed his first extensive resuscitation in a hospital and had a different view. The author observed the resuscitation team operating under the influence of fear.

The surgical resident did most of the talking, the tone tense, becoming louder as the resuscitation progressed. Communication only occurred from the chief resident to an individual. If people communicated at all, it was through eye contact and whispers.

Coordination was about *not* interfering with each other rather than working together. Information was only given to the surgical resident when requested and only for that specific request. Nothing was volunteered. All actions followed direct orders from the resident; there was little independent action to fix an immediate problem.

"It depends on whether we value a top-down or bottom-up approach, tight control, or self-organized action. Undoubtedly, there was order during the resuscitation, but it was likely from a more normative approach than a pragmatic one...it was a stunning exhibition of what would not happen during a medical emergency in a dangerous setting. No one becomes angry in public safety and military operations – that is the fastest way to lose control of the incident or situation."

Was this resuscitation style effective, or did it impair performance? It depends on whether we value a top-down or bottom-up approach, tight control, or self-organized action. Undoubtedly, there was order during the resuscitation, but it was likely from a more normative approach than a pragmatic one. For the author, it was a stunning exhibition of what would *not* happen during a medical emergency in a dangerous setting. No one becomes angry in public safety and military operations – that is the fastest way to lose control of the incident or situation.

The author participated in a surgical emergency with a widely respected attending at a different hospital. The surgeon called for a chest tube. As nurses brought the chest tube, the surgeon stated it would be placed in the OR. Shortly afterward, the surgeon demanded to know where the chest tube was. They brought it back to the bedside. The surgeon asked why they were not taking the child to the OR, where they would place the chest tube. Each movement occupied 2-3 nurses who left resuscitation duties to address the chest tube. Presented to a group of fire chiefs, the chiefs, thinking this was a fire captain at a major emergency, assumed that the captain was relieved of command and referred to the department's EAP stress program. This occurrence is not an isolated situation. Two authors (DvS and SDK) have received reports about anger from other highly respected surgeons during an operation. The individuals requested anonymity, but the similarity of the descriptions is striking.

Uncontrollability, particularly the *sense* of uncontrollability, is perhaps the most significant driver of action during an emergency.

The sense of uncontrollability can drive a person to act faster than the mind can think. In time-compressed states, responses are immediate and visible. An individual learns quickly what works and what does not. Such quick responses reinforce this type of thinking and whether specific behaviors work. Often called "experience," these behaviors readily incorporate into one's identity. This incorporation leads to respect from those with less experience. This thinking is unchallenged and immune from disconfirmation by being ingrained into organizational knowledge.

"Uncontrollability, particularly the sense of uncontrollability, is perhaps the most significant driver of action during an emergency. The sense of uncontrollability can drive a person to act faster than the mind can think. In time-compressed states, responses are immediate and visible. An individual learns quickly what works and what does not. Such quick responses reinforce this type of thinking and whether specific behaviors work. Often called "experience," these behaviors readily incorporate into one's identity. "

The belief too quickly forms that the stress of the situation impairs those who do not think fast. Their performance decreases as uncontrollability increases, an effect often described as the Yerkes-Dodson Curve (1). Increased stress impairs abstract thought to drive people toward concrete rules or to seek support and reassurance from nearby experts or leaders.

These approaches have become institutionalized to the degree that these behaviors have become beliefs – the expectation of performance decrements due to demands, as predicted by the Yerkes-Dodson curve. These beliefs and behaviors can also be observed in routine operations or informal leadership practices. Performance deficits from stress are expected and accepted.

What if we considered the debilitating effects of the stress-fear cascade as artifacts of the organization's culture and training? Individuals would terminate ongoing behaviors through the stress hypothalamic-pituitary-adrenal (HPA) axis while initiating attention-arousal behaviors through the locus coeruleus-norepinephrine (LC-NE) system. The system would support the modulation of stress-induced symptoms, fear circuitry behaviors, and amygdaladriven behaviors (2, 3).

Forcing functions and abrupt emergencies are part of life (4, 5), a routine part of the NICU. Rather than preventing, avoiding, or denying stress-induced symptoms and fear circuitry behaviors, we could recognize them for their utility. This recognition changes how we perceive and respond to the outlier and the salience, relevance, and meaning we give to information. Our decision approach is less linear and more reciprocal within the environment. Significantly, it means we change the logics we use to infer new information – constraining the use of classical logic that does not allow us to change the conclusion. We incorporate the more

natural modal and paraconsistent logic (6, 7).

This first in our series of articles that describe impairments to engagement focuses less on alternatives and solutions and more on articulating the problem. Articulating the problem makes solutions visible and achievable. Critically, it directs the individual toward internalizing solutions.

We believe every individual acts in a way that makes sense to them. "What you do every day is what you do in an emergency," Jim Denney, Capt., LAFD, Vietnam Veteran (two tours), USN, Seabees. We have an idiosyncratic approach to solving everyday conditions that emerge from the unique interactions of experience, education, training, support, and our way of thinking. One is not better than another, only different.

However, we caution against reliance on approaches developed in predictable white noise environments. Most likely, they have not been tested in complex or chaotic circumstances and may not support the engagement of forcing functions or abrupt crises. On the other hand, approaches that emerge from effectively engaging forcing functions or abrupt crises can, and do, translate to routine operations.

"Modulation of hormonal stress-induced cognitive disorders, fear circuitry behaviors, and amygdala-driven fear behavior allowed NICU staff to harness the inherent vices of stress. Through engagement, they converted stress and fear into strengths."

In this HRO series published in *Neonatology Today*, we have described the responses of Neonatologists and NICU staff in extreme circumstances (8-10). They *used their routine operations* to engage uncertainty and time compression during abrupt crises effectively. What happened was their application of routine operations in a self-organizing manner but with the inclusion of the environment into their condition (5). While their plans and initial expectations came from outside administrators who use the full field view, Neonatologists and NICU staff engaged as local groupings (Table 1). They did not "bend" or "break" the rules. They had found themselves in that liminal zone between the rules, where engagement matters (11-13). Modulation of hormonal stress-induced cognitive disorders, fear circuitry behaviors, and amygdala-driven fear behavior allowed NICU staff to harness the inherent vices of stress (14). Through engagement, they converted stress and fear into strengths (2, 15, 16).

We will encounter the 'different person,' one who does not respond as we expect. We do not criticize them, though we may critique their actions. We support them. One of the HRO values identified by two authors (DvS, TAM) is empathy (12, 17, 18). HROs work in challenging situations where people will fail, which could be us failing.

Never use malice or ignorance if stress or fear will fully explain the member's behavior.

White Noise Thought, Red Noise Experience

Autocorrelation describes how a system responds to its feedback. Human behavior is an example. Autocorrelation creates long-

period frequencies which carry greater power and hence more significant influence. This circumstance defines "red noise" from the longer red wavelengths in the electromagnetic light spectrum. Pink noise is midway between white and red noise (thus, "pink") and is characteristic of abrupt, catastrophic change. See Table 1.

Red and pink noise follow power distributions. Because they have a non-Gaussian distribution, statistical descriptions, and probability predictions do not apply. Increasing the amount of data will increase the variance, or spread, of the data. This spread creates more significant uncertainty in addition to the constantly changing situation. Frequent events have lower power in their power distributions, while infrequent, unpredictable events have greater power.

Red noise forcing functions and pink noise abrupt crises have the characteristics that cause stress and fear (Table 2).

If we follow the rules, then we succeed. However, a breach in the organization's structure and rules will allow energy dissipation (entropy) into the organization. These entropic changes demand an immediate response, or the breach will drive energy out of the organization, destabilizing vital structures. Identifying that breach and its causes assures the stability of operations going forward. This concept is the world as it is. That is, this is the world as a white noise environment.

However, when a system responds to itself internally, that is, when it has autocorrelations, the resulting fluctuations *support* stability. This stability can mask significant environmental fluctuations, giving the appearance of either a stable environment or a strong organization. The *non-HRO* executive or administrator then attributes stability and success to the organization and its "leadership."

Other missed causes of stability are long-period fluctuations that give the appearance of a stable environment, if not a stable world. Lost in sustained stability are the efforts of those who operate in

an HRO fashion or recognize the inevitability of a forcing function

William Corr, a fire captain and WWII US Navy Veteran, South Pacific, shared this observation with one of the authors (DvS), "When I came on the fire department in 1948, the job of the administration was to support the firefighter. Today [1976], the job of the firefighter is to support the administration."

"Autocorrelation creates long-period frequencies which carry greater power and hence more significant influence. This circumstance defines "red noise" from the longer red wavelengths in the electromagnetic light spectrum. Pink noise is midway between white and red noise (thus, "pink") and is characteristic of abrupt, catastrophic change."

Experience is the particulars and relations with meaning, values, and intention (21). Thinking is ongoing (22), contextual, and how we experience the environment and reach into and experience the environment (23). The engaged individual constantly thinks and makes judgments, using those judgments for the improvisation that directs self-organization (24) (22). This improvisation better describes the more accurate translation of René Descartes' dictum, *cogito ergo sum*, "I am *thinking*; therefore I exist" (22).

Biological systems exist in a world of random, stochastic variation. These systems must maintain stability far from any equilibrium state

Table 1. Patterns and Characteristics of Noise (19)

Color	Structure	Variance	Distribution
White	No frequencies dominate Flattened spectrum Spectral density has equal amounts of all frequencies	Data <i>decreases</i> variance Forms Gaussian curve	Gaussian distribution Elements fiully independent No autocorrelation
Red	Low frequencies dominate Long period cycles	Data <i>increases</i> variance Forms power distribution	Power law distribution Elements <i>not</i> independent Mutual/reciprocal relations
Pink	Midpoint of red noise The slope lies <i>precisely</i> midway between white noise and brown (random) noise	Data continuously increases variance Distinguishes pink noise from reddened spectra	Power law distribution No well-defined long-term mean No well-defined value at a single point

Table 2. Characteristics of Noise and Fear Circuitry Traits

Red/Pink Noise	Characteristic	Challenge	Stress-Fear Cascade	Impairment	Engagement Function
Low frequencies (Red)	Slow variations, greater strength	Uncontrollability	Stress	Cognition	Thinking
()		Threat proximity	Fear	Distance	Defense
Abrupt change (Pink)	No single-point value	Unpredictability (Uncontrollability)	Stress	Cognition	Motor cognition
		Threat proximity	Fear	Distance	Defense
	Gaps	Existential threat	Amygdala	Survival	Modulation
Self-organizing	Novel properties	Novelty	Stress	Cognition	Motor cognition
3 0		Existential threat	Amygdala	Survival	Modulation
Power distribution Data increases variance		Uncertainty	Stress	Cognition	Information Motor cognition
Stochastic pro- cesses	Fluctuations	Uncontrollability	Stress	Cognition	Motor cognition
	Gaps	Threat proximity	Fear	Distance	Self-organizing
Power of incident	Gaps	Uncertainty	Stress	Cognition	Information Motor
		Uncontrollability	Stress	Cognition	cognition
		Threat proximity	Fear	Distance	Defense
		Existential threat	Amygdala	Survival	Modulation

or abrupt change. Long-period frequencies have greater power that forces the system to respond. The autocorrelations that generate these frequencies are part of any system with human behavior or open to the environment.

This realization also leads to the trope "Armies prepare to fight their last war, rather than their next war." Viewing wars as pink noise events or reddened noise-forcing functions, we can recognize that the years between wars are not white noise periods of peace. Instead, they are periods of attention to forcing functions and preparation for abrupt change. This understanding is an operational approach that keeps military forces prepared. For example, part of the effectiveness of the US Navy's response to the Mt. Pinatubo eruption was the operational preparedness of the fleet at Subic Bay fresh from operations in support of Desert Storm.

The observation about "fighting the last war" comes from those outside the system or focusing on logistics, strategy, and administration. These top-down specifications produce a broader, 'whole field view' useful for quantitative analysis (Table 3). The whole field view risks decontextualizing the knowledge and experience gained from war.

This approach, however, overlooks the bottom-up specifications of operations, tactics, human readiness, and experience—the qualitative characteristics that emerge from the activities of 'local groupings' (Table 3). Overlooked are the methods used to increase human and system capabilities. The contextualization of experience counterintuitively supports translating experience and capabilities into new and different contexts.

Table 3: Specifications of the Whole Field View and Local Groupings (20)

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

(25, 26). Multiple degrees of freedom within the system allows *internal* fluctuations to create the necessary 'nonequilibrium dynamical system' (27). In the HRO, the necessary degrees of freedom emerge from cognitive, affective, and behavioral approaches that form the basis of HRO. The result is an HRO-maintained nonequilibrium dynamical balance.

In these cognitive, affective, and behavioral domains, we can identify the impairments of engagement.

"Biological systems exist in a world of random, stochastic variation. These systems must maintain stability far from any equilibrium state. Multiple degrees of freedom within the system allows internal fluctuations to create the necessary 'nonequilibrium dynamical system'. In the HRO, the necessary degrees of freedom emerge from cognitive, affective, and behavioral approaches that form the basis of HRO. The result is an HRO-maintained nonequilibrium dynamical balance."

Stress, Fear, Amygdala

When faced with an abrupt change or approaching threat, our brain responds at the subcortical level to engage the situation. When modulated, this response generates effective engagement. Without modulation, however, hormonal stress-induced cognitive disorders, fear circuitry behaviors, and amygdala-driven fear behavior will co-opt the brain (2). This process can occur so insidiously that the individual does not notice it or considers such responses normal.

The ubiquity of these responses, often with immediate results, acts as operant conditioning that makes the behaviors seem natural if not desired. As a result, discussions usually focus on how they create dysfunction in everyone but the discussant. Stress, fear, and the amygdala have functions (2, 14, 28), arise from brain evolution as well as experience (2, 29), and can be separated into the motor and affective components (30). This division allows a less passionate discussion of stress, fear, and the amygdala.

The amygdala detects threats and then activates the sympatheticadrenal-medullary (SAM) axis and the hypothalamic-pituitaryadrenal (HPA) axis, orchestrating the stress, fear, and threat cascade responses in the brain and body (31, 32).

- Cognitive consequences direct inhibition of the prefrontal cortex and the executive functions
- Endocrine consequences secretion of corticotropinreleasing hormone (CRH) from the periventricular nucleus of the hypothalamus, CRH releases adrenocorticotropic hormone (ACTH) from the pituitary, ACTH stimulates the secretion of glucocorticoids from the adrenal cortex

 Autonomic consequences – the brainstem activates the sympathetic nervous system throughout the body

These are all responses mediated by neurochemicals. They can come on with incredible speed and, when accepted as simple neurochemical effects, can be interrupted almost as quickly.

"The amygdala detects threats and then activates the sympathetic-adrenal-medullary (SAM) axis and the hypothalamic-pituitary-adrenal (HPA) axis, orchestrating the stress, fear, and threat cascade responses in the brain and body."

Stress. Novelty, uncertainty, and uncontrollability, the domains of the executive functions, initiate the release of cortisol. Under stress, the brain "disarms" the executive functions to prevent the intrusion of abstractions and future thinking while limiting various memory systems. Even minor stress will impair executive functions (33).

Fear. An impending threat initiates fear circuitry behaviors below the level of awareness. Upon reaching awareness, the individual can augment or accelerate fear behaviors. Fear behaviors maintain a 'flight distance' from the threat, creating a safe distance ('fear flight'), or they create a safe distance should the threat breach the 'defense distance.' The individual will attack for self-defense and escape ('fear flight') (34).

Amygdala. Imminent danger or existential threat creates reflexive amygdala-driven fear behaviors from subcortical structures. Reflexive action arises from subcortical structures before identifying the threat (35). These behaviors include flight, fight, and freeze, occurring without particular order.

Stress-induced Cognitive Disorders

Stress impairs abstract thought and working memory. This confused state affects the ability to regulate thought, behavior, emotion, and flexibility of attention:

- Choke (expectations being observed).
- Impaired memory recall/enhanced procedural memory.
- Loss of abstract thought when prefrontal cortex and executive functions are impaired.
- Concrete thinking and reasoning due to loss of abstract abilities (amygdala impairs cortex).
- Rules are abstractions, therefore, challenging to recall and use.
- Failure of cognitive strategies: "Even quite mild acute uncontrollable stress can cause a rapid and dramatic loss of prefrontal cognitive abilities" (33).

Stress responses are from the amygdala and the neurochemical (cortisol) response to novelty, uncertainty, and uncontrollability. We must reset or change our learned approaches. Novelty, uncertainty, and uncontrollability disable abstract thought from focusing on context and action. *Without* stress responses, we would spend our spare time thinking of abstractions and theories.

Impairment of the prefrontal cortex constrains executive functions and abstract thought. Impairment of the hippocampus blocks

Table 4: Manifestations of Stress Conditions (36)

Defense	Initiation	Function	Mediator	Neurological Impairment	Manifestation
Stress	Novelty Uncertainty	Block Abstractions	Amygdala	Prefrontal Cortex	Impaired cognition
	Uncontrollability			Executive Functions	Concrete thinking
					Subjectively rational
					Objectively irrational
		Block Future Thinking	Cortisol	Memory Retrieval	Confusion
		Limit Memory			Blunted recall
					Constrained memory
Fear	Proximity	Defense	Ventromedial Prefrontal Cortex	Decision-making	Move to safety
			Periaqueductal		Offensive actions
		Escape	Gray	Flight	Defensive actions
				Fight	
Amygdala	Danger	Protection	Amygdala	Subcortical Reflexive Behaviors:	Anger, Frustration
		Survival		Freeze, Immobility	Plausible Avoidance
				Flight	Attentive Freeze
				Fight	Nausea
					Impeded Decision-making

memory retrieval except for procedural (habit or motor) memory, which is enhanced. The effect of *planned* motor activity on thought as motor cognition may explain why intentional movement can break the grip of cortisol on thinking (15, 28). Cortisol blocks memory retrieval in the prefrontal cortex and hippocampus (memory center), and the amygdala directly inhibits the prefrontal cortex.

- Novelty is processed in the right cerebral cortex, while the left cerebral cortex processes familiar perceptions.
- Uncertainty and ambiguity in decision-making occur in the ventromedial prefrontal cortex (vmPFC). The vmPFC is also involved with making decisions in uncertainty (37). See below.
- Uncontrollability or unpredictability is the stimulus for the HPA axis.

Uncontrollable stress releases cortisol to produce *stress responses*, generally related to failed memory recall. The primary memory systems affected are declarative memory for what is learned, episodic memory of experiences, and working memory for active problem-solving. Retained is procedural, or habit, memory, allowing the person to continue acting with practiced behaviors without losing time thinking and developing plans or actions.

A common belief about stress is that "during times of extreme stress, the brain takes the prefrontal cortex 'off-line' in favor of automated flight or fight responses." This consequent decrease in performance is attributed to the effects of the Yerkes-Dodson

"Impairment of the prefrontal cortex constrains executive functions and abstract thought. Impairment of the hippocampus blocks memory retrieval except for procedural (habit or motor) memory, which is enhanced. The effect of planned motor activity on thought as motor cognition may explain why intentional movement can break the grip of cortisol on thinking. Cortisol blocks memory retrieval in the prefrontal cortex and hippocampus (memory center), and the amygdala directly inhibits the prefrontal cortex."

Curve (1). This curve was identified through an artifact of research design and is now considered predictable, though it is partially

due to organizational design (14, 28). The cause is the belief in uncontrollability with stress-released cortisol block in memory retrieval in the prefrontal cortex and hippocampus (memory center) and the stress-induced amygdala directly inhibiting the prefrontal cortex.

"Now I know what you mean by [Bloom's Affective Domain of] affective knowledge," an emergency medicine physician once said to one of the authors [DvS] at an EMS medical meeting. The physician said he had been intubating an infant's airway and "realized how bad I'd look if I missed it. That pressure made it more difficult to intubate. My emotion began to get in the way." He told the author how his team had helped him and the duty he then felt toward them to place the tube successfully. The physician and author also talked about the criticisms they had heard about paramedics intubating children and how paramedics viewed the criticism since many paramedics had successfully intubated children in the past. In the EMS field, many people discuss the number of procedures necessary to maintain procedural skills; many believe that paramedics cannot reach the necessary number. The emergency medicine physician wondered how many failures in paramedic intubation may have occurred because of the pressure physicians and the system placed on EMTs (17).

Executive Functions

The brain integrates, from opposite ends, perception, hastily created plans, and motor activity. This integration is how we control our motor actions and think with motor cognition. The dorsolateral prefrontal cortex (DPFC) and the posterior parietal cortex (PPC) functionally cooperate during time-based contingencies between continuous perception and emerging motor action (38). The executive functions, acting hierarchically, coordinate temporary behavioral structures and "integrate actions with perceptions in the presence of novelty and complexity" (39).

There are specific roles for *motor attention* (impending motor action), *working memory* (sensory information for action that can be rapidly forgotten), and *inhibitory control* (interference, impulsive and reflexive behavior). These three elements produce the operational control and temporal organization of behaviors that characterize executive functions (38-40).

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The executive functions support motor attention, working memory, and inhibitory control:

- Motor attention prepares for impending motor action "memory of the future" (39).
- Working (short-term) memory allows changing sensory stimuli to mediate perception and action toward a goal in

- real-time (39).
- Inhibitory control and selective attention protect goal-directed behavior from interference, distracting information, and impulsive or reflexive behaviors (39); inhibit emotional memories (41, 42), well-established habits, and more easily processed intuitions (43).

Working memory allows one to remember events of the last several seconds or minutes and to prepare and plan "forward" in time for prospective, near-future motor acts. Working memory has the attribute of rapidly 'forgetting' information as motor actions evolve. During the action, we must release memories as we continually bring new things into memory. Working memory mediates perception and action in real-time (40).

Cognitive flexibility refers to the ability to shift between cognitive rules or modes of thought (44). Unrestrained neurological stress responses release almost pure bottom-up control to produce self-preserving behaviors. Cortisol and the amygdala continue suppressing executive functions, and a defense cascade follows (45).

The Hippocampus

The hippocampus creates context by identifying what is different. This context may be the mechanism for the brain moving toward abstractions versus contextualizing the circumstance – interpreting the situation similarly reduces stress (no novelty) and fear (distant threat).

The anterior (ventral) hippocampus identifies the change in context, and a significant change is signaled to areas in the cortex concerned with context and to the ventromedial prefrontal cortex (vmPFC). Uncertainty and ambiguity in decision-making occur in the vmPFC, which also incorporates contextual factors into decision-making. We maintain "flight distance" for safety, behaviorally or emotionally. The flight distance is an animal's security distance from a threat (34). Proximity measured in the hippocampus increases activity in the ventromedial prefrontal cortex (vmPFC) which connects to the amygdala to determine the motivational importance of the threat (37).

"The hippocampus creates context by identifying what is different. This context may be the mechanism for the brain moving toward abstractions versus contextualizing the circumstance – interpreting the situation similarly reduces stress (no novelty) and fear (distant threat)."

With active behavior or attentive processes, cells in the hippocampus fire in sequential order: cells focusing behind the person fire first, and cells focusing farther ahead of the person fire later. This sequence forms an ensemble representation of spatial trajectories near the individual. The *sequence* of approach plays a more active and complex role in information processing than encoding the experience (46).

The hippocampus is part of deliberative decision-making. Hippocampal disruption shifts decision systems away from deliberative planning systems. Transient disruptions of the hippocampus impair working memory (47). Stress also impairs

working memory.

Emotional Memory

During the experience of overwhelming, threatening circumstances, the individual may retain vivid memories (45) or experience memory retrieval deficits (48). In the hypervigilant state, a narrow range of stimuli may be sharply encoded (49). *Emotional memory* formation is closely linked to the amygdala and hippocampus (50), appearing to need timing with norepinephrine and cortisol release (42). During *dissociation*, on the other hand, the loss of context fragments the memory and impairs the encoding of the ongoing experience into memory. The dissociation of context and disrupted cortical integration prevent memory encoding (49).

Emotional memory is the only way an organism can learn from a single episode; what is learned is never extinguished. The amygdala processes highly arousing rewarding or aversive experiences to create persistent and vivid memories. Emotional memory is a form of episodic memory, a type of autobiographical memory from our lives. Once formed, emotional memory enhances the salience and priority of later stimuli. This system is the neurophysiology behind posttraumatic stress. *The trigger is from the past, but the response is in the present.*

A treating physician called one of the authors (DvS) by phone for advice while caring for a child with severe upper airway obstruction. After the author heard the child crying in the background, he recognized that the child was in far less danger than the team had surmised. The author used a rapid, visual respiratory exam (51) and described the use to the treating physician. The physician acknowledged that the previously administered therapy had achieved the desired effect.

The author drove to the hospital and helped the team complete the care for the child and start management. The treating physician then took the author into a private room, angry that the author had not immediately responded to the hospital; instead, the author "just talked on the phone." The author tried to explain, but the treating physician was too angry. Letting the person "empty their cup" is most effective. (It will get worse, better, or not change. If it worsens, they open up emotionally; if it gets better, they calm down and become lucid; if there is no change, it is instrumental anger. From the author's extensive experience, they do not become physical while vocal.) The physician's anger built to a crescendo, then the treating physician rapidly told the author of a personal experience in the military at a medical care facility with a critically injured sailor.

The corpsmen in assistance were worried that the sailor would die. The treating physician had called for helicopter transport, but the commanding physician at the main hospital refused, stating there was too much fog and the sailor could be cared for at the outlying facility. The treating physician remarked that helicopters had flown in worse fog and did not know why the commanding physician refused the transfer. The commanding physician would only talk on the phone.

The trigger for this anger was the author's initial action of talking by phone. The treating physician's response was to that commanding medical officer.

Fear Circuitry Behaviors

Threats that are proximal (static distance) or approaching (changing distance) will mobilize one to move toward safety or, if escape is not possible, to fight in self-defense (34). Fear circuitry behaviors are subjective cortical behaviors from the individual's spatial, temporal, or emotional distance from the threat (27-29). While fear reactions are a cortical response, they are triggered at

the subcortical level. It is initiated below awareness and monitored for distance and direction from the threat's approach – from behind, rapidly, or leaving in order of response.

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In humans, fear circuitry behaviors generally express the emotive components with impaired functional cognition and without the motor components (15, 35).

- Flight rapidly increases the distance between the organism and the threat, with cognition focused on reaching a safe place while creating distance.
- A fight engages solely intending to break free and escape from the threat.

Flight. The individual "flees" by increasing distance from the threat. This distancing can be the motor component when the individual physically leaves the situation, such as fetching equipment that is not immediately needed. The affective component appears as avoiding, discounting, ignoring the threat, or distracting talking, perhaps by asking for more information. Verbal maneuvers include denial, dismissiveness, or depreciation of disconfirming information (52).

Social distancing acts as either a threat or as support. The close physical proximity of a threatening person elicits the same reactions as any threat. Fear responses are also transmitted through social interactions. On the other hand, social support creates a protective factor against stress, reducing the hypothalamus—pituitary—adrenal axis responsiveness to social stress (53).

Social distance, favorable or unfavorable, is subjective, but the peripersonal (i.e., near body) space is not. This location is the space where intrusion by others elicits discomfort. This space is measurable in encoding the visual receptive fields involving the ventral intraparietal area (VIP) and a polysensory zone in the precentral gyrus (54). Responses are sensitive to nearby or approaching objects (55). The VIP connects to the amygdala and the PAG for defensive and aggressive behaviors (54). The neuropeptide oxytocin partly mediates social interaction and may also regulate fear (53).

will functionally switch the animal's repertoire of behaviors (58).

Fight. The fear attack is to push the threat away in order to flee. Separating the motor and emotional components leads to responding with anger (emotion component) without physical contact (motor component). We see this with emotional, verbal, offensive, or defensive protection.

Offensive protection prompts aggressive attacks to stop the spread of the problem. To achieve security or control, the person will use surprise, concentrated actions, fast tempo, and audacity. Blame, accusation, and personal attacks are standard methods.

Defensive protection focuses on the individual's safety, often moving to a place of psychological or physical safety (56). Demands *clearly* exceed capabilities, and risks become too great for the person to feel they can continue or survive. The person will not go near the threat or its source, whether it is abstract such as concepts or specific information, or concrete, such as the leader, an administrator, or a colleague. Because the individual will not sufficiently approach the situation, descriptions, correlations, or causations do not develop. As a result, individuals must rely on rationalizations and abstractions (for example, clichés and metaphors) to support and explain judgments, interpretations, and actions. The individual is less helpful in protecting others since they focus primarily on reducing risk to themselves. Deflection, excuses, justifications, and prophylactic self-blame are standard methods.

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Anatomic Location

The distant threat within the "flight distance" for physical, emotional, mental, or temporal threat increases activity in the *ventromedial prefrontal cortex* (vmPFC) which incorporates contextual factors into decision-making in uncertain, risky, ambiguous, or context-dependent conditions (37). The vmPFC connects to the amygdala to determine the motivational importance of, or degree of, the threat. The amygdala connects onward to the *bed nucleus of the stria terminalis* (BNST) to control a repertoire of behavioral defensive states (57).

Increasing proximity switches activity from the vmPFC to the midbrain *periaqueductal gray* (PAG) nucleus, a phylogenetically older part of the midbrain. This produces the subjective representation of threat and the degree to which it is felt. The PAG controls fast reflexive behaviors (e.g., fight, flight, or freeze) and fear-induced analgesia (55, 57). The PAG also coordinates behaviors essential to survival, including threat reflexes, rapid changes to subcortical behaviors, and startle posture corrections (57). Detection by the PAG of an approaching or receding threat

"Social distancing acts as either a threat or as support. The close physical proximity of a threatening person elicits the same reactions as any threat. Fear responses are also transmitted through social interactions. On the other hand, social support creates a protective factor against stress, reducing the hypothalamus—pituitary—adrenal axis responsiveness to social stress."

This movement from contextual decision-making under uncertainty in the vmPFC to reflexive decision-making from the PAG makes the fight or flight of the *fear reactions* appear the same as the fight or flight from *threat reflexes*.

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The PAG has different functions in its several dorsoventral and rostrocaudal divisions. Stimulation of the dorsoventral PAG promotes passive freezing while ventral stimulation promotes escape and other active coping behaviors (57). From nose to tail, active coping strategies shift from moderate to active defense;

then aggressive defense; then strong threat display and *non-opioid*-mediated analgesia; followed by vigorous escape when the enemy is near. When escape from an enemy is impossible, passive coping strategies disengage from the environment, and behaviors shift to freezing, then moderate to strong immobility with increasing proximity. Lastly, intense freezing with *opioid*-mediated analgesia occurs (59, 60).

Amygdala-driven Fear Behaviors

People do not generally recognize that anger is an amygdala-driven reflex. The unrecognized *fight* responses include anger and frustration. One of the authors (DvS) routinely queried staff, "What would make an attending angry with you?" Answers focused on errors or poor performance. After learning about stress, fear, and threat, the answers changed – "The attending is in a fear response or threat reflex." The subordinate's response is significant; becoming more careful or working harder does not decrease fear. Asking, "How can I help?" moves cognition from the amygdala to the prefrontal cortex.

"People do not generally recognize that anger is an amygdala-driven reflex. The unrecognized fight responses include anger and frustration... But anger works. The prevalence and pervasiveness of relaxed fight responses give the impression that anger is a normal, if not necessary, behavior in an urgent or emergency environment. For example, the immediate reactions observed using the fear responses of anger and force reinforce the belief in their effectiveness. The observed effectiveness, however, is an immediate change toward homeostasis at best."

But anger works. The prevalence and pervasiveness of relaxed fight responses give the impression that anger is a normal, if not necessary, behavior in an urgent or emergency environment. For example, the immediate reactions observed using the fear responses of anger and force reinforce the belief in their effectiveness. The observed effectiveness, however, is an immediate change toward homeostasis at best while impairing allostatic strengthening.

Amygdala-driven reflexes initiate behaviors for survival. This result is an adaptation to adverse or hostile environments. Perceptions of threat will trigger reflexes that operate below the level of consciousness (61).

Amygdala-driven behaviors operate below the level of consciousness where imperiling threat reflexes predominate (2, 61). Proximal, imminent danger initiates reflexive protective behaviors while maintaining our cognitive functions, differentiating threat reflexes from stress responses or fear reactions. Though commonly referred to as "fear responses," threat reflexes include the well-known fight, flight, and freeze reflexes and tonic immobility.

In humans, amygdala behaviors generally express the emotive components with functional cognition but without the motor components (15, 35).

- A fight engages to overcome the threat rather than escape the threat.
- Using cognitive abilities, flight increases the distance between the organism and the threat.
- Freeze (more accurately, "attentive freeze") is attentive or hypervigilant awareness with cessation of movement yet poised to act. It has two components: attentive awareness and poise for action. This allows information collection necessary for effective action while generating a faster response time.
- Tonic immobility, the parasympathetic nervous system, produces intense awareness with an inability to move.
 The initial response in many prey species is often accompanied by the evacuation of body contents to mimic carrion. More common in humans, it produces mild-to-severe nausea.

Tonic immobility. Of particular note, we have observed that tonic immobility is subtle, more commonly presenting as a "sick feeling in the pit of the stomach" or nausea. It is relieved when the threat is avoided, leading to inaction. The person maintains full awareness and consciousness (45, 62). The vagus nerve mediates many of the features of tonic immobility: bradycardia (slow heart rate), life-threatening arrhythmias, decrease in respiration, nausea and vomiting, urination, and defecation.

"For novices, nausea accompanies their first independent decision and, if unresolved, will inhibit future decisionmaking."

For novices, nausea accompanies their first independent decision and, if unresolved, will inhibit future decision-making. The individual does not necessarily become trapped in tonic immobility. Kozlowska et al.(45) described actions a Second World War Flying Officer would take when training pilots: he used a "firm voice devoid of fear to issue simple orders that the men had already learned and that were automatic: 'flaps,' 'raise the stick,' 'rudder.'

One of the authors (DvS) presented an invited lecture on decisionmaking to the Scottish Highland paramedics. The lights suddenly appeared during the presentation, and the slide projector was turned off. A gentleman announced that the lecture was over, and we were all to go home. Concerned that the lecture was too long, he asked the senior paramedics what had gone wrong. "Nothing," they said, "but could you finish your lecture early in the morning at a paramedic station?" The lecture would be recorded.

The following day, waiting at the paramedic station, the oncoming paramedic team told the author that he had become known throughout the Highlands overnight. It seemed that when a disagreement focused on a field situation, the medical director, inexperienced in the field, used anger to control the conversation. The author used neuroscience to describe what the field medics knew – anger is a sign of fear.

The night before, just after the author stated that anger is a sign of fear, the medical director stood up and walked out. The parking

attendant had been sent in to stop the presentation.

Anatomic Location

The amygdala detects conflict from acute threats or stressors, receiving exteroceptive stimuli (the external environment) and interoceptive stimuli (the body's internal environment). The amygdala activates the sympathetic-adrenal-medullary (SAM) axis for the proverbial "flight-or-fight" response and the hypothalamic-pituitary-adrenal (HPA) axis for the release of peripheral adrenal hormones, including cortisol (31). The brain, reacting from bottom-up reflexive and priming processes, prepares the body for survival.

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

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

Phenotypes of Fear

H. Stefan Bracha (2) differentiates fears having an evolutionary basis (brain-evolution-based) from fears we develop from experience (mode-of-acquisition-based). Evolution-based fears can be identified by the era they developed and their wild-type alleles, making them innate fears with which we are born. This allows us to distinguish functional stress and fear from affective disorders. That is, we can expect specific fears to be present in all of us during a crisis. We can also expect more idiosyncratic fears due to a person's family of origin and life experiences. We cannot know if someone has emotional memories or developed posttraumatic stress.

Some fears can become consolidated between innate fears and those from experiences. This "over-consolidation" can lead to the abrupt and unexpected appearance of situational cognitive distortions or disruptive behaviors. An example presented by Bracha is a clustering of phobias around blood, injections, and injuries. He posits that such a cluster consolidates a negative experience in a hospital, causing a phobia and a hardwired (innate) fear of seeing one's blood or a sharp object penetrating one's skin.

Some fear circuitry traits that had evolved have now outlived their usefulness (except in specific but uncommon circumstances). These include fear of separation, darkness, alligators, and crocodiles. Bracha divided these evolutionary fears into four eras:

- Mesozoic Era mammalian-wide evolved fear circuits
- Cenozoic Era simian-wide evolved fear circuits
- Mid and upper Paleolithic H. sapiens-wide evolved fear circuits
- Neolithic culture-bound-genome-specific (gene-culture coevolution-based) fear circuits

"What this means for us working with people during a crisis, the behaviors we observe have emergent, novel properties. The individual with unmodulated behaviors must be closely observed and supported during the event. They will need sense-giving and meaning-giving by the Neonatologist, or they may have a higher risk of avoidant behaviors as a means of coping post-trauma and are more likely to develop psychological distress."

Unfortunately, pediatricians have become familiar with the homicide or death rates within a household between married relatives (such as stepchildren) and blood relatives (biological children). As described by Bracha, "Throughout the mammalian class, intense fear of non-kin adult male conspecifics is widely documented in unweaned mammals" (2).

These behaviors are a form of phenotype, such as Panic Disorder or Dissociative-Conversive Spectrum, and are influenced by gene dosage of wild alleles. Endophenotypes are quantifiable heritable traits that are argued to index an individual's genetic liability to develop a given disease or disorder (63, 64).

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Situational Cognitive Distortions

It is often the situation that distorts our cognition. We do not live in a constant state of stress, fear, or amygdala-driven behaviors. Maladaptive stress and fear behaviors become normalized when we do not recognize how the situation distorts our thinking. We call these *situational cognitive distortions* because, absent stress or fear, the individual operates at a high level of cognition (3, 17, 52).

- Stress cognitive impairment
- Fear the creation of distance, drive to a safe place
- Amygdala existential protection

Situational cognitive distortions can develop from intrinsic sources, such as a supervisor pressuring somebody mentally, causing the impaired recall of information. This freeze response is common in the medical education method of "pimping," to ask a question that demonstrates a person does not know. It is like choking in sports. This quickly develops into ingrained responses of subordinates to the supervisor's presence while reinforcing the supervisor's belief in the poor performance of the individual.

Common cognitive distortions include (15, 35):

- Anger
- Frustration
- Avoidance
 - Complete or avoid tasks
 - Focus on inconsequential tasks
 - · Addressing easily accomplished tasks first
- Distractive comments
 - Responding to distractions
- Freeze ("attentive freeze")
- Actual cognitive or physical freezing
- Nausea and avoidance
 - · Urge to urinate or defecate
- Confusion
- Mental freeze
 - Inability to solve simple problems
 - Failure to recall knowledge
 - Impaired working memory

From our experiences and discussions with veterans from dangerous contexts, we have identified three salient situational cognitive distortions:

- Blocked recall
 - We ask an individual to recite the months of the year.
 Then we change the protocol to reciting the months in alphabetical order.
 - After reciting 3-4 months (and leaving out several), the individual finds it difficult to recall any month.
 - This demonstrates to the individual and witnesses the rapidity of cognitive freeze, a neurochemical. It has

- nothing to do with intellect or abilities.
- We provide an escape. Doing anything physical reverses the freeze immediately.
- Attentive freeze (threat freeze)
 - The individual experiences an abrupt threat and feels the freeze but is fully attentive to the surroundings. They will misinterpret this as being "frozen from fear" or tonic immobility.
 - By pointing out that they had focused attention to detail and the mental preparation for action, they appreciate that attentive freeze is a strength.
- Tonic immobility
 - In its milder form, it appears as active refusal or avoidance to make a decision. The individual feels a "knot in the stomach" or mild nausea. In more severe cases, they may vomit.
 - They do not discuss their intestinal discomfort, thinking it is unique to them and a sign of weakness, or they interpret the sensation as caused by the attending or leader.

"The emergency physician could not pronounce death by their medical staff bylaws if a heartbeat could be obtained through treatment. A second-year pediatric resident in the second week of her PICU rotation was part of the team. Not long after she left, she returned with the child, who was now stable on medication."

The director of an emergency department called the PICU to transfer an infant in repeated cardiac arrest. We could not place a fragile child in an ambulance with only three caregivers: a physician, a nurse, and a respiratory care practitioner. The emergency physician could not pronounce death by their medical staff bylaws if a heartbeat could be obtained through treatment. A second-year pediatric resident in the second week of her PICU rotation was part of the team. Not long after she left, she returned with the child, who was now stable on medication.

After her return, she approached one of the authors (DvS) to say, "They did the fear response you said they would do—they walked away when I came in." She added, "And I felt that freeze response in myself that you did to me last week." Asked what had happened, she said she checked the endotracheal tube *because* it was working. She elaborated that by physically checking something that was working well, she could bring herself out of the freeze response and resuscitate the infant. She achieved stable cardiac function after twenty minutes of treatment.

Was the earlier failure to achieve heart stability because of a lack of knowledge or from the influence of stress neurochemicals on the brain? An experienced emergency physician working with an experienced healthcare team responded to the stress of an infant undergoing cardiac arrest. Their response was neurochemical, situational cognitive distortions (17).

The Ecology of Fear

As a medical student and experienced fire paramedic entering the culture of medicine, one of the authors (DvS) found it odd that no one would discuss the circumstances of how an error could cause a fatal mistake, particularly for known incidents. How does one protect the patient without discussing experiences? Discussing such errors was common practice in the fire department – the year before the author arrived at his assigned firehouse, several firefighters had died from a building collapse. The incident was still a topic for discussion as a learning experience. LAFD at the time had a culture that could discuss these incidents for learning without criticizing or blaming participants.

When the Los Angeles City Fire Department experienced increased Rescue Ambulance collisions, the department sent Rescue Ambulance Drivers to the LAPD "Skid School" for training. One of the authors (DvS) attended this training. The focus was to increase the driver's capabilities. The final test was to drive fast within one's capabilities on a one-mile course, reaching speeds close to 100 mph. Then, drivers drove the course again, also for time. The second run used the siren. All students in the class passed the exam and wanted to know their times. The instructors would not give them their time – there was no set time for passing or failing. The driver failed if the driving time with the siren was faster than the time without the siren. The siren should not make someone drive faster. The instructors told the drivers, "If you are influenced by adrenaline, we don't want you."

Liability and malpractice continue to be issues that impair engagement, often framed in terms of safety or quality of care.

Without specifics and with frequent use and repetition, discussions of risk and liability become dissociated from bedside actions. The message is lost. Their influence no longer focuses on patient care, becoming generalizable fears instead. When no longer connected to specific risks, discussions of risk and liability lose relevance to patient care. However, they do gain immeasurable salience that influences the actions of healthcare providers – but not necessarily for patient care.

Administrators, regulators, and legal counsel have legitimate concerns about healthcare provider actions during uncertainty and time compression. The repetition of risks and liabilities readily develops an atmosphere of fear. Sadly, the providers who need support will scare themselves, *impairing* engagement. This process is the "ecology of fear." A different approach, described above by LAFD, is to increase capabilities, which will *enhance* engagement.

"In healthcare, we see the ecology of fear forming from the influence of error, litigation, and negligence, even in their absence."

Risk and liability can act like predators in an ecosystem. The direct killing of prey by a predator may have less influence on prey populations and even the landscape than the fear generated by the *absence* of a predator (69, 70). The ecology of fear describes predator-prey interactions in the absence of the predator (69). Not only do prey populations decrease, but the ensuing trophic cascade changes the landscape into a "landscape of fear" (71,

72). In the past two decades, fear has become a measurable element of ecology (72).

By analogy, the *fear* of failure, in the absence of failure or the threat itself, may significantly influence human behavior and culture more than actual failure (73). We can correct or recover from failure, but we cannot correct fear. Stress and fear are the individual's properties rather than the threat's properties.

In healthcare, we see the ecology of fear forming from the influence of error, litigation, and negligence, even in their absence.

- Fear of failure contributes to 'not acting' This is invisible and is readily assimilated into organizational knowledge (74).
- Fear of error contributes to behaviors that avoid actions or situations. The error can also become a faulty signal for the presence of failure (75).
- Fear of legal action, such as litigation, negligence, or malpractice, can become over-reliance on legal counsel with the undue influence of lawyers in providing medical care. Healthcare professionals may excessively document laboratory or radiologic studies, commonly called "legal medicine."
- Fear of discipline, such as for incomplete forms, leads to "euboxia," the practice of filling in blocks of information to ensure a completed form (17). Euboxia comes at the expense of an articulate description and can delay care as the individual seeks information necessary for the boxes but not medical care.

"Inadequate top-down modulation from executives, administrators, regulators, and legal counsel contributes to the ecology of fear. Repeated references to risk extend the span of control for this leadership. Such extended control, however, impairs engagement in the crises that the leaders hope to mitigate... These cognitions and behaviors can become normalized through bottom-up incorporation into the organization's culture. Because they are natural and produce swift results, they appear effective."

We can generally correct an error, but we can never correct a fear. In fact, like categorization and standardization (76), fear can be used to control people without the controller's presence. Administrators and regulators create categories and standards to avoid engaging the ill-structured problem. This permits the conversion of the ill-structured problem to the well-structured problem.

To control behavior, administrators, regulators, and, unfortunately, some leaders promulgate various fears. Such fear drives

subordinates' cognitive efforts and behaviors away from the illstructured problem. These are problems where no answer is predictably correct, an error has a function, and failure is a sign of quitting too soon.

Conclusion

The characteristics of forcing functions and abrupt crises create our ability to engage those crises.

- Stress-induced cognitive impairments "disarm" the executive functions to prevent intrusion of abstractions and future thinking while limiting various memory systems. Stress brings mental focus to the immediate circumstances.
- Fear circuitry behaviors, operating below the level of consciousness, keep us safe from threat. We can operate with safety. Distance can reduce stress, returning some of our cognitive functions.
- The amygdala operates at the subcortical level, identifying threats and initiating survival behaviors before we can recognize danger.

Without modulation, stress-induced cognitions become disorders, fear circuitry behaviors become disruptive, and amygdaladriven fear behaviors become dangerous. *Inadequate top-down modulation* from executives, administrators, regulators, and legal counsel contributes to the ecology of fear. Repeated references to risk extend the span of control for this leadership. Such extended control, however, impairs engagement in the crises that the leaders hope to mitigate. However, not only is engagement impaired at the level of local groupings but also impaired is the necessary close-in support from the full field view. Over time, there will be a widening of the operational gap between the central organizational authority and the operational line authority.

These cognitions and behaviors can become normalized through bottom-up incorporation into the organization's culture. Because they are natural and produce swift results, they appear effective. This normalization creates unrecognized stress responses, unrecognized fear reactions, and situational cognitive distortions. The result is impaired immediate engagement of early heralds of failure and covert, compensated system failure.

"Seeing the problem as a puzzle rather than as mysteries to investigate is simpler. Stress and fear impede the engagement of mysteries. We can use Adrian Wolfberg's concept of Full Spectrum Analysis (77) when unimpeded. We can then extend Neonatology into new areas and the mystery of the next infant's illness."

Recognition of the inherent vices of stress and threat can move individuals and organizations toward effective modulation. Gaining the ability to operate in uncertainty and time compression permits the use of greater resources, widening the spectrum of available information. A great limitation to problem-solving is our mental limits on ourselves and each other. Seeing the problem as a puzzle rather than as mysteries to investigate is simpler.

Stress and fear impede the engagement of mysteries. We can use Adrian Wolfberg's concept of Full Spectrum Analysis (77) when unimpeded. We can then extend Neonatology into new areas and the mystery of the next infant's illness.

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INFANT AND FAMILY-CENTERED DEVELOPMENTAL CARE (IFCDC)

STANDARDS AND SAMPLE RECOMMENDATIONS FOR INFANTS IN THE INTENSIVE CARE UNIT





- 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 $\underline{\text{team}}$ and treated as essential partners in decision-making and care of
- 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
- Does the feeding management plan demonstrate a feeding & nutrition continuum from in-hospital care through the transition to home & home care?



WANT TO KNOW MORE ABOUT THE STANDARDS AND RECOMMENDATIONS? VISIT: HTTPS://NICUDESIGN.ND.EDU/NICU-CARE-STANDARDS/

@CONSENSUS PANEL ON INFANT AND FAMILY-CENTERED DEVELOPMENTAL CARE 2022

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
- more than 20 seconds
- · Use alcoholbased sanitizers



• Wear a face mask when out

Limit Contact

- 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
 - 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



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

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Breifly Legal: The Battle of the Experts— and Beyond

Barry S. Schifrin, MD, Maureen Sims, MD

"Increasingly in the area of malpractice litigation involving perinatal injury to the child, the deliberations go beyond the opinions of the experts to challenges to the bases of obstetrical care and the relationship of obstetrical events to the subsequent outcome."

Increasingly in the area of malpractice litigation involving perinatal injury to the child, the deliberations go beyond the opinions of the experts to challenges to the bases of obstetrical care and the relationship of obstetrical events to the subsequent outcome. The comportment of the experts in lawsuits is governed by Federal Rule 702, which was created to codify standards for evidence and opinions presented by expert witnesses in legal proceedings. It states that a witness becomes "qualified" as an "expert" based on his / her knowledge, skill, experience, training, or education. This specialized knowledge, considered beyond the normal knowledge of the judge or jury, assists them in understanding the scientific or technical issues involved in the case. What makes the qualification so important is that the expert witness, unlike other witnesses, may provide testimony as an opinion. However, the expert's opinions must be based on sufficient facts or data and be the product of reliable principles and methods that the expert has meaningfully applied to the facts of the case.

"Most states have adopted or modified Federal Rule 702, including those portions covering expert testimony. These guidelines are governed by the Frye or Daubert Standard in individual states."

Most states have adopted or modified Federal Rule 702, including those portions covering expert testimony. These guidelines are governed by the Frye or Daubert Standard in individual states.

The Frye standard was based on a century-old 1923 court ruling (Frye v. United States) rejecting using lie detectors to discern

"truth." At that time, the Court reasoned that there was insufficient general acceptance of the technology and offered guidelines for determining the admissibility of scientific examinations on determining when there is, "... experimental testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." In a trial alleging medical negligence, for example, the judge had to decide if a meaningful proportion of the relevant scientific community generally accepted the procedure, technique, or principles in question.

"In [the decision of Daubert v. Merrell Dow Pharmaceuticals, Inc.], the Court held that while the federal standard includes general acceptance (from Frye), it also looks at the more fundamental science and its application."

While this principle is still used as a benchmark for the admissibility of evidence in certain states, it has been supplanted by the Daubert rule established by the Supreme Court in 1993 in the case of Daubert v. Merrell Dow Pharmaceuticals, Inc. In that decision, the Court held that while the federal standard includes general acceptance (from Frye), it also looks at the more fundamental science and its application. In addition, the Daubert ruling made trial judges the "gatekeepers" of the admissibility of evidence and the acceptance of the opinions of an expert witness in their courtrooms. In this role, the judge should consider:

- What is the basic theory, and has it been tested?
- Are there standards controlling the technique?
- Has the theory or technique been subjected to peer review and publication?
- What is the known or potential error rate?
- Is there general acceptance of the theory?
- Has the expert adequately accounted for alternative explanations?
- Has the expert unjustifiably extrapolated from an accepted premise to an unfounded conclusion?

The Daubert court also ruled that concerns over questionable evidence or conclusions by the opposing expert could be scrutinized by opposing counsel through the presentation of contrary evidence

and pointed cross-examination of the expert. A "Daubert challenge" is made to request the Court to exclude certain testimony. The motion is made in limine, i.e., the deliberations are conducted outside the presence of the jury and decided by the judge. If conducted during the trial, the format creates the potential of a "trial within a trial" and demands careful instructions to the jury on the burden of proof. Thus, the admissibility of evidence may determine the case's outcome or even whether the case can be brought to Court. If the challenger prevails, the testimony is forbidden, and the case may be dismissed. The evidence may be presented if the challenger does not prevail but is subject to cross-examination. The decision to dismiss the challenge does not decide the outcome of the trial, only the matters that may be presented at trial. A Daubert challenge by the defense has a secondary gain in that in countering the challenge, the plaintiff's side will have disclosed the arguments made at trial.

"While being a physician may be sufficient to qualify as an expert in any particular case, it is usually insufficient to offer authoritative opinions on specialized issues that are commonplace during medico-legal cases alleging substandard care in Obstetrics."

While being a physician may be sufficient to qualify as an expert in any particular case, it is usually insufficient to offer authoritative opinions on specialized issues that are commonplace during medico-legal cases alleging substandard care in Obstetrics. In these cases, a medical expert's credibility and qualification in brain-damaged children usually require considerable relevant experience. Research and publications are helpful, but so are common sense and the ability to communicate.

The case presentation below and the deliberations of a judge in a Daubert motion in limine before trial are designed to highlight the contemporary dispute over the role of mechanical factors during labor and delivery in the causation of perinatal injury and to illustrate the tortuous path some cases take, even before they get to trial.

"The patient is a 29 y/o primigravida who got pregnant while taking various medications for migraines and associated depression."

Facts of the case:

The patient is a 29 y/o primigravida who got pregnant while taking various medications for migraines and associated depression. During her pregnancy, she stated that she had asked her obstetrician if she was too small and if she should just have a cesarean section. She was 5 feet tall, "on a good day," and her pre-pregnant weight was 105 lbs. In discussing the options for delivery with

her obstetrician, she commented that she was not committed to a "natural birth;" her most important concern was the baby's health. Her prenatal course was unremarkable.

"At 40 3/7 weeks' gestation, the patient was admitted to the hospital late afternoon for elective labor induction. An external monitor demonstrated a reassuring pattern with a stable baseline rate, intermittent accelerations, and absent decelerations with occasional contractions."

At 40 3/7 weeks' gestation, the patient was admitted to the hospital late afternoon for elective labor induction. An external monitor demonstrated a reassuring pattern with a stable baseline rate, intermittent accelerations, and absent decelerations with occasional contractions. A cervical exam reveals she is 1 cm dilated, 75% effaced at -1 station. After several hours of observation, Cervidil 10 mg is inserted vaginally. About 12 hours later, she was feeling cramps, and the Cervidil was removed. Oxytocin was started at 2 mU/min and increased progressively to 12 mU/min. Nubain 10 mg IV/ and Phenergan 6.25 mg were administered three hours later for pain. Twenty hours after admission, the cervix is only 3 cm dilated, 0 station, 85% effaced, and an epidural is begun with Fentanyl/bupivacaine 0.125%. At 24 hours, the patient is 6 cm dilated, 90% effaced, and -1 station. Because of excessive uterine activity, decreased maternal blood pressure, and late decelerations in response to the epidural, the Oxytocin is reduced to 6 mU/min, and ephedrine and oxygen are administered with relief of both the hypotension and the fetal decelerations.

"At 24 hours, the patient is 6 cm dilated, 90% effaced, and -1 station. Because of excessive uterine activity, decreased maternal blood pressure, and late decelerations in response to the epidural, the Oxytocin is reduced to 6 mU/min, and ephedrine and oxygen are administered with relief of both the hypotension and the fetal decelerations."

Over the next several hours, progress to 8 cm of dilatation is very slow. Membranes rupture spontaneously, revealing a moderate amount of clear fluid. Despite the slow progress and evidence of excessive uterine activity, Oxytocin is again increased up to '14 mU/min, and at 27 hours, the patient is feeling rectal pressure. Examination reveals the cervix to be 8 cm dilated, +1 station, with moderate contractions every 3-4 minutes. In response to decelerations, the Oxytocin is reduced to 7 mU/min, and 02 is administered and remains with an IV bolus.

"It has taken 5 hours to go from 8 cm to full dilatation – an interval that usually requires less than 2 hours."

An IUPC is inserted, and the Oxytocin progressively increases to 16 mU/min. For increasing pain, the patient receives several boluses of epidural anesthesia, and a fetal scalp electrode is applied 32 hours after admission. Ninety minutes later, the cervix is fully dilated with the head at +2 station - It has taken 5 hours to go from 8 cm to full dilatation - an interval that usually requires less than 2 hours. The patient is feeling increased pressure. With the onset of pushing, repetitive decelerations begin. After 2 hours of effort, the patient stops pushing. She is complaining of back pain and lower abdominal cramping. She is encouraged to resume pushing and take deep breaths during breaks in the contractions. With continued pushing, the FHR pattern deteriorates with decreased variability, multiple late and variable decelerations, and fetal tachycardia to 170 bpm. The physician is summoned to the delivery room when the decision is made to perform a vacuumassisted delivery (VAD), and the scalp electrode and IUPC are discontinued. With the head still at +3 station, the vacuum is placed, and traction is applied. Within 4 minutes, there have been four pulls with the vacuum and three pop-offs. An episiotomy is performed, the vacuum is reapplied, and the fetus is delivered. The indication for delivery was "maternal exhaustion" and "nonreassuring fetal heart rate tracing."

"An EEG confirmed the presence of seizure activity, and a CT scan on that day revealed a skull fracture to the right parietal bone at the level of the lambdoid suture and evidence of bilateral ischemic infarcts...On follow-up, in addition to diplegia, the infant showed developmental delay with obvious physical, speech, and cognitive deficits requiring physical, occupational, and speech therapies."

The female infant weighs 3095 grams and receives Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. There is obvious bruising and marked caput and molding of the head. The HC was 32.5 cm. (<10th %ile) the length was 51.5 cm. (There was no follow-up measurement of the HC. She was initially sent to the normal newborn nursery, but on DOL 2, she was found to have decreased alertness, episodes of cyanosis, apnea, and seizures. An EEG confirmed the presence of seizure activity, and a CT scan on that day revealed a skull fracture to the right parietal bone at the level

of the lambdoid suture and evidence of bilateral ischemic infarcts. Phenobarbital was prescribed. A thrombophilia workup was negative. On follow-up, in addition to diplegia, the infant showed developmental delay with obvious physical, speech, and cognitive deficits requiring physical, occupational, and speech therapies.

The allegations

The failure to properly assess the feasibility of safe vaginal delivery

At no time during the labor did any provider consider an alternative to vaginal delivery, given the very protracted labor and the patient's small stature? This required an assessment of the pelvis, an estimate of the fetal weight, and an ongoing evaluation of the progress in cervical dilatation and descent of the presenting part. Pelvic size and estimation of fetal weight were not performed.

Failure to appreciate the abnormality of labor.

The patient made slow progress from 3 cm to 6 cm. From 6 cm to 8 cm, an interval that should have taken from 1 to 2 hours took 4 hours. She then made no progress for the next 5 hours – an arrest of labor in the active phase, from 8 cm to full dilatation, required 4 hours, an interval that should have taken about 1 hour (a protracted active phase). She was fully dilated for about 2 hours before her labor was abbreviated by a traumatic VAD despite the fetal head at +3 station. The labor abnormalities included the protracted active phase, arrest of the active phase, and protracted descent (and/or arrest of descent) in the 2nd stage of labor. The progress in descent is quite slow, and the true head was likely considerably higher in the birth canal than appreciated at the time of vacuum application, with a likely malposition of the fetal head, probably OP, suspected based on considerable back pain and rectal pressure.

"The caregivers should have recognized and responded to the excessive uterine activity and stopped the Oxytocin or at least refused to increase it further. They should also have notified the physician concerning the excessive uterine activity, the intermittent decelerations, and the lack of progress."

The failure to maintain proper surveillance of uterine activity, The failure to properly and safely conduct the administration of Oxytocin, and the failure to timely recognize and respond to excessive uterine activity.

Increases in Oxytocin were contraindicated in light of the already excessive uterine activity, including the coupling of contractions and uterine hypertonus by IUPC. Efforts to diminish the effect of Oxytocin were insufficient as excessive uterine activity continued. The caregivers should have recognized and responded to the excessive uterine activity and stopped the Oxytocin or at least refused to increase it further. They should also have notified the physician concerning the excessive uterine activity, the intermittent decelerations, and the lack of progress.

The failure to timely recognize and respond to abnormal FHR patterns

The initial FHR started as reactive with absent decelerations. When combined with normal amniotic fluid volume, fetal growth, and behavior, these features bespeak both normal fetal responsiveness and the absent threat of hypoxia or ischemia. Over time, the baseline variability becomes flat with multiple decelerations, and changes in baseline rate and variability were not recognized or responded to appropriately by the moderation of pushing and reduction of Oxytocin.

"The required assessments of the patient at 8 cm of dilatation would have revealed the constellation of a mother of very short stature, quite prolonged labor with protracted active phase and an arrest of labor in the face of ruptured membranes, excessive uterine activity, high dosage of Oxytocin and malposition of the fetal head."

Failure to timely perform an atraumatic cesarean section.

The required assessments of the patient at 8 cm of dilatation would have revealed the constellation of a mother of very short stature, quite prolonged labor with protracted active phase and an arrest of labor in the face of ruptured membranes, excessive uterine activity, high dosage of Oxytocin and malposition of the fetal head. Under these circumstances, safe vaginal delivery was reasonably unlikely, and a cesarean section was required by the standards of care and would have resulted in a fetus free from a neurologic handicap. It also would have avoided the trauma and ischemia related to the prolonged non-progressive labor, excessive forces upon the fetal head, and traumatic delivery.

Failure to follow proper guidelines in the selection of patients and the use of vacuum devices

There was no assessment of the true station, the position of the presenting part, or the amount of molding or caput. The fetal head was noted to be at +3 station, but given the likely malposition of the head and the amount of molding and caput (confirmed at delivery), and the difficulty in effecting vacuum delivery, despite the mother's "pushing well," the true station of the fetal head was likely considerably higher in the pelvis than believed by the obstetrician.

From the outset, the likelihood of successful operative delivery was markedly diminished and preparations for cesarean section had to be made simultaneously in the event of failure. The vacuum delivery should not have been attempted without assessment of the several problems with the true station and position of the presenting part, as detailed above. It is highly improbable that there was true descent of the fetal head with each pull of the vacuum as required by the standard of care. The inappropri-

ate operative delivery having been undertaken should have been abandoned with the failure of the first attempt. Failing to have the option for cesarean necessitated multiple attempts at vacuum and dramatically increased the risk of harm – exaggerated under the circumstances annotated above.

"From the outset, the likelihood of successful operative delivery was markedly diminished and preparations for cesarean section had to be made simultaneously in the event of failure."

Causation:

With regard to the neurological well-being of the fetus, the initial normal FHR patterns, combined with normal amniotic fluid volume, fetal growth, and behavior, bespeak both a normal fetal responsiveness and an absent threat of hypoxia or ischemia. Over time, there are changes in the baseline rate, variability, and the appearance of significant decelerations. Further, there is no clinical or radiological evidence of an earlier injury or some metabolic or genetic basis for injury. Nor is there evidence of significant umbilical acidemia or immediate depression in the newborn. The variable decelerations represent cerebral ischemia from impaired cerebral blood flow, not systemic hypoxia. {Ball, 1992 #21140} The traumatic efforts at vacuum delivery most likely provide the final blow to a baby set up for injury by severely protracted labor, with excessive uterine activity, including hypertonus and abnormalities of the fetal heart rate pattern.

The Daubert challenge:*

The review by the judge first produced a summary of the arguments

"The Defendants and their experts made a Daubert motion in limine that any evidence regarding the Plaintiffs' causation theory, including the testimony of its witnesses, be excluded. Should the challenge prevail, the lawsuit would not go to trial."

The Defendants and their experts made a Daubert motion in limine that any evidence regarding the Plaintiffs' *causation* theory, including the testimony of its witnesses, be excluded. Should the challenge prevail, the lawsuit would not go to trial. In their motion, the defendants contended that Plaintiffs' theory that the baby's injuries were caused by mechanical forces acting on the fetal head had repeatedly been rejected by the obstetrics and medical communities as "junk science" and that none of the Plaintiffs' experts has a scientifically reliable basis to support the theory.

Plaintiff's experts opined that the physician's use of a vacuum extraction caused complications, leading to the baby suffering a perinatal stroke due to compression forces acting on the fetal head. Defendants argue that such a theory is inadmissible under Evidence Code 702 because it (1) has not been tested; (2) has not been subjected to peer review; (3) has no known or potential rate of error; and (4) perhaps most importantly, has gained **no general acceptance whatsoever** in the obstetrics and/or medical communities." Further, they argued that no Plaintiff expert could point out a single instance in which the theory has been tested and/or peer-reviewed in their expert reports. The experts agree that no controlled studies have tested (or could ethically test) the theory.

"Further, they argued that no Plaintiff expert could point out a single instance in which the theory has been tested and/ or peer-reviewed in their expert reports. The experts agree that no controlled studies have tested (or could ethically test) the theory"

Defendants' experts further testified that an article on which the plaintiff's expert relied during his deposition to support the theory (1) was not peer-reviewed in a journal accepted in the relevant medical and scientific communities and that the American College of Obstetrics and Gynecologists ("ACOG") has consistently rejected the head compression theory as unreliable and that it does not "reflect the generally accepted standard of care in the field of obstetrics."

Defendants also refer to several cases from other states which have precluded evidence of this theory from being introduced. Indeed, in a case in the state court of Georgia, the ACOG filed an amicus brief in support of a similar motion made to preclude the admission of the theory, which motion the Georgia court ultimately granted. Defendants, however, omitted the far more prevalent acceptance of the theory by many other courts.

"In response, the Plaintiffs contend that the causation theory that the baby suffered mechanical trauma during the patient's prolonged labor when the physician 'applied a vacuum extractor using multiple pulls after multiple pop-offs on a malpositioned fetal head resulting in a skull fracture, physical signs of trauma and a focal ischemic stroke.""

In response, the Plaintiffs contend that the causation theory that the baby suffered mechanical trauma during the patient's prolonged labor when the physician "applied a vacuum extractor using multiple pulls after multiple pop-offs on a malpositioned fetal head resulting in a skull fracture, physical signs of trauma and a focal ischemic stroke."

"Plaintiffs assert that their experts' causation testimony is admissible under Evidence code 702(C) as other State courts have found "scientific support and scientific bases for the concept and theory that forces acting on the fetal head have the potential to cause ischemic injuries." "

Plaintiffs assert that their experts' causation testimony is admissible under Evidence code 702(C) as other State courts have found "scientific support and scientific bases for the concept and theory that forces acting on the fetal head have the potential to cause ischemic injuries."

Indeed, in many previous cases, the courts overruled motions from defendants seeking to exclude expert opinions that "trauma from abnormally excessive contractions caused decreased blood flow and oxygenation to the fetal brain resulting in brain injuries."

"Plaintiffs further claim that under Evidence code 702(C) analysis, a flexible inquiry determines whether the principles and methodology used to conclude are reliable."

Plaintiffs further claim that under Evidence code 702(C) analysis, a flexible inquiry determines whether the principles and methodology used to conclude are reliable. First, the Plaintiffs argue that their causation theory has been studied and tested to the extent ethically possible. For instance, the plaintiff's experts based their opinions on data and research from within their field and animal studies that tested fetal trauma and compression that they extrapolated to humans. Second, the Plaintiffs contend that "disruption of fetal cerebral circulation, infarction and stroke due to skull compression caused by excessive uterine activity and traumatic delivery" has been discussed and recognized in peer-reviewed literature. Additionally, such peer review is not necessary for an opinion to be admissible.

Third, Plaintiffs assert that State law does not require a rate of error for expert opinion testimony to be admissible as long as there is literature that includes a quantitative analysis of the background principles and methods used by the expert to reach his or her opinion.

Fourth, the Plaintiffs argue that the methods and principles used to reach the expert opinions that birth trauma is a cause of perinatal stroke have been generally accepted.

"In reply, Defendants contend that there is no methodologically sound evidence to support Plaintiffs' experts' opinions that mechanical forces to the fetal head during labor and delivery 'can cause sufficient disruption of cerebral blood flow in the fetus to cause hypoxic-ischemic injury and focal ischemic stroke."

In reply, Defendants contend that there is no methodologically sound evidence to support Plaintiffs' experts' opinions that mechanical forces to the fetal head during labor and delivery "can cause sufficient disruption of cerebral blood flow in the fetus to cause hypoxic-ischemic injury and focal ischemic stroke." According to Defendants, the only methodically sound scientific evidence is that mechanical labor and delivery forces can cause a global/ watershed injury, not a focal ischemic stroke. Defendants reassert that Plaintiffs cannot meet any of the four requirements under Evidence code 702(C), meaning that the expert opinions are not admissible.

"Defendants reiterate that the Plaintiffs' causation theory has not been generally accepted, and their theory has not been tested. Specifically, Defendants contend that any studies relating to testing on sheep are not applicable because Plaintiffs have not established that humans are sufficiently similar to the tested animal (sheep)."

Defendants emphasize that the Plaintiffs' experts' causation theory extrapolates opinions based on the opinions of others, though these other opinions do not fit the Plaintiffs' experts' causation theory. In making this argument, Defendants rely upon the case of Valentine v. PPG Industries, Inc., 158 Ohio App.3d 615, 2004-Ohio-4521, 821 N.E.2d 580 (4th Dist.), which held that expert opinions that a specific type of brain cancer was caused by exposure to certain chemicals were not admissible because the experts extrapolated their opinions from studies that did not deal with specific cancer. Defendants also contend that the Second District Court of Appeals holds that experts "cannot extrapolate a causation opinion from the studies and publications of others if ... those studies and publications do not reach the expert's conclusions and/or provide a scien-

tifically reliable methodology for reaching the expert's conclusions." Additionally, Defendants state that a number of the publications relied upon by Plaintiffs do not support their specific causation theory and that Plaintiffs cannot meet their burden of proof to establish the admissibility of the expert testimony. Defendants reiterate that the Plaintiffs' causation theory has not been generally accepted, and their theory has not been tested. Specifically, Defendants contend that any studies relating to testing on sheep are not applicable because Plaintiffs have not established that humans are sufficiently similar to the tested animal (sheep).

The judge then offered an opinion about the prevailing law and its analysis

A. Legal Standards

Pursuant to Evidence code 702 (C), a witness may testify as an expert if all of the following apply:

- (A) The witness' testimony either relates to matters beyond the knowledge or experience possessed by lay persons or dispels a misconception among lay persons;
- (B) The witness is qualified as an expert by specialized knowledge, skill, experience, training, or education regarding the subject matter of the testimony;
- (C) The witness' testimony is based on reliable scientific, technical, or other specialized information. Evidence code702.(C).

"The parties agree that the Defendants' challenge to the Plaintiffs' expert opinions on causation is raised solely under Evidence code 702(C). "In determining whether the opinion of an expert is reliable under Evidence code 702(C), a trial court examines whether the expert's conclusion is based on scientifically valid principles and methods.""

The parties agree that the Defendants' challenge to the Plaintiffs' expert opinions on causation is raised solely under Evidence code 702(C). "In determining whether the opinion of an expert is reliable under Evidence code 702(C), a trial court examines whether the expert's conclusion is based on scientifically valid principles and methods." The trial court is not tasked with determining whether the expert's ultimate conclusions are correct. To determine reliability, a court is to consider several factors: "(1) whether the theory or technique has been tested, (2) whether it has been subjected to peer review, (3) whether there is a known or potential rate of error, and (4) whether the methodology has gained general acceptance."

These factors aid in determining reliability and are meant to be flexible. When an expert draws inferences from bodies of work or extrapolates, this must be done in accordance with scientific principles and methods. If the Court determines that there is "too great an analytic gap between the data and the opinion proffered," the opinion has no place in evidence. The determination of whether the expert opinion testimony is admissible is within the trial court's discretion, and the decision will not be disturbed absent abuse of discretion.

B. Analysis

1. Whether the theory or technique has been tested

The Court finds that Plaintiffs' experts' causation theory opinions have been tested. The causation theory is that increased intracranial pressure caused by mechanical forces, trauma during the baby's labor and delivery, and degrees of fetal hypoxia caused the baby's injuries. The theory that mechanical factors and excessive uterine activity cause hypoxic-ischemic cerebral injury has been tested and explained in medical literature and has been tested in animal studies. For example, Towner (2) et al. concluded that the "rate of intracranial hemorrhage is higher among infants delivered by vacuum extraction, forceps, or cesarean section during labor than among infants delivered spontaneously or by elective cesarean section. Plaintiffs provide several other journal articles summarizing various forms of testing performed after birth and reviews of trauma in hindsight, which have also tested the Plaintiffs' experts' causation theory that mechanical factors, along with excessive uterine activity, cause hypoxic-ischemic cerebral injury. The experts may base their opinions on a review of such professional literature.

"The Court finds that Plaintiffs' experts' causation theory opinions have been tested. The causation theory is that increased intracranial pressure caused by mechanical forces, trauma during the baby's labor and delivery, and degrees of fetal hypoxia caused the baby's injuries."

Plaintiffs rightly argue that the articles only address post-birth reviews and/or testing, as it would be unethical to test human fetuses before birth to determine whether mechanical factors, along with excessive uterine activity, can cause hypoxic-ischemic cerebral injury. Similar testing has been done on animals. Animal studies may be admissible to prove causation in humans if good grounds exist to extrapolate from animals to humans.

In the case at bar, the Plaintiffs provided examples of research performed on animals (3) in which pressure exerted on the skulls of lamb fetuses showed that the compression "of the fetal head by an externally applied force caused severe cerebral ischemia due to a marked reduction in cerebral blood flow." A similar study was conducted on monkey fetuses in the late 1960s in which the fetuses were subjected to asphyctic compromise. (4) The results showed that seven of the ten fetuses "exhibited mild to moderate degrees of brain swelling." Both the animals (sheep and monkeys) and this baby were fetuses who suffered from the same

injury: pressure exerted on the skull during birth. In 1971, Myers (5) stated that in monkey fetuses, the "eventual long-term, static lesions closely compare to the lesions of human perinatal injury or cerebral palsy."

"It is not too great of an analytic gap for an expert to agree that mechanical forces, trauma during labor and delivery, and degrees of fetal hypoxia caused the baby's injuries. Thus, the Court finds that the literature and animal studies have tested the Plaintiffs' causation theory."

Defendants, though, argue that the Plaintiffs' experts' causation theory has not been tested because there is "too great of an analytic gap between the conclusions from the journal articles and animal test results and the expert conclusions." The Defendants contend that the opinion does not fit the Plaintiffs' case because the specific causation theory has not been tested. In considering this argument, the Court was persuaded by the opinion of a Judge in a similar case in this state who held that it is "not 'too great an analytic gap' in this case as Plaintiffs' have proffered literature to support the theory that pressure to the fetal head can produce injury." As in other cases, the Plaintiffs, in this case, have presented literature that the forces of labor, including mechanical forces used in labor and excessive uterine activity, can cause injury and have presented test results indicating that pressure to the fetal brain can cause severe cerebral ischemia by a marked reduction in cerebral blood flow. It is not too great of an analytic gap for an expert to agree that mechanical forces, trauma during labor and delivery, and degrees of fetal hypoxia caused the baby's injuries. Thus, the Court finds that the literature and animal studies have tested the Plaintiffs' causation theory.

2. Whether the theory or methodology has been subjected to peer review

The Court finds that Plaintiffs' experts' causation theory has been subjected to peer review. In this case, the Plaintiffs have submitted peer-reviewed publications and journal articles discussing labor forces that contribute to the type of injury the baby sustained. In making this determination, the Court did not focus on whether this causation opinion was correct or whether the opinion would satisfy the Plaintiffs' burden of proof at trial. If the evidence is questionable or confusing, it should not be excluded "since the experts' opinions would be subject to cross-examination and the credibility of their conclusions left to the trier of fact." Even if the theories which have been peer-reviewed have a contradictory conclusion, the theory should not be excluded, especially since it is the process of the peer review and not the conclusions that the Court must consider. Additionally, based on the above reasoning, the Court finds that it is not too great of an analytic gap for an expert to reach an opinion that increased intracranial pressure caused by mechanical forces and trauma during the baby's labor and delivery, along with degrees of fetal hypoxia, caused the baby's injuries. As such, the Court finds that Plaintiffs' causation theory has been subjected to peer review.

3. Whether there is a known potential rate of error

The parties do not dispute that there is not a known potential rate of error associated with the Plaintiffs' causation theory. A lack of a known error rate is not "fatal to the methodology's reliability because no one of the Daubert factors is dispositive of the inquiry, as the factors should be applied flexibly. Thus, the Court finds that Plaintiffs' causation theory is not unreliable based on the lack of a known potential rate of error.

"It is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [that] are the traditional and appropriate means of attacking shaky but admissible evidence.""

4. Whether the methodology has gained general acceptance

The Court finds that the methodology used to reach the experts' opinions has gained general acceptance. Defendants assert that the theory is at odds with the generally accepted cause of neonatal injuries being asphyxia or oxygen deprivation. Defendants also contend that there is a lack of general acceptance since ACOG has rejected the causation theory. Plaintiffs have provided many journal articles that support the general causation theory that brain injury can occur due to excessive intrauterine pressure and forces of mechanical extraction. For instance, in an article by Kumar entitled "Contralateral Cerebral Infarction Following Vacuum Extraction" (6), the authors summarized that "[m]echanical birth trauma has been recognized as a direct cause of intracranial arterial injury leading to ischemic or hemorrhagic stroke in the newborn." Further, it is unnecessary that scientific opinions "enjoy 'general acceptance' in the relevant scientific community to satisfy the reliability requirement of Evidence code 702." "Even if an expert's opinion has neither gained general acceptance by the scientific community nor has been the subject of peer review, these are not prerequisites to admissibility under Daubert"). It is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [that] are the traditional and appropriate means of attacking shaky but admissible evidence." Additionally, based on the above reasoning, the Court finds that it is not too great of an analytic gap for an expert to reach an opinion that increased intracranial pressure caused by mechanical forces and trauma during labor and delivery, along with degrees of fetal hypoxia, caused the baby's injuries. Accordingly, the Court finds that Plaintiffs' causation methodology has gained general acceptance, and even if it had not, this is not a prerequisite to its admissibility.

"The Court OVERRULED the Defendants' Motion in Limine to Exclude Testimony Regarding Plaintiffs' Causation Theory."

The Ruling and its impact

The Court **OVERRULED the** Defendants' Motion in Limine to Exclude Testimony Regarding Plaintiffs' Causation Theory. Shortly thereafter, their case was settled.

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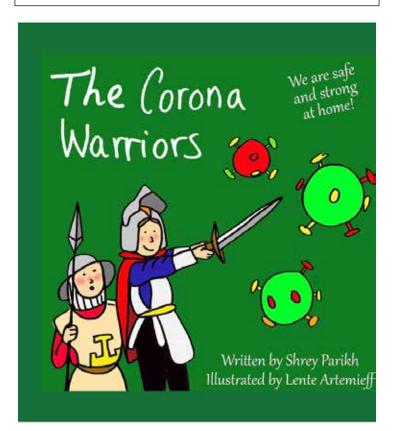
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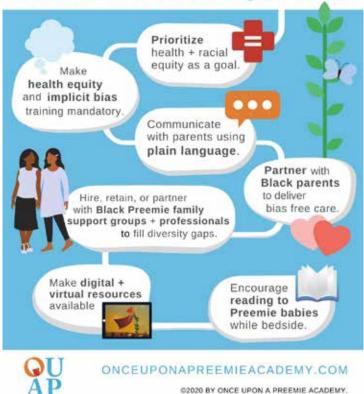
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Gravens By Design: New NICU Design Standards are Approved

Robert White, MD

The Recommended Standards for Newborn ICU Design has been a guideline for NICU planners and regulators for more than 30 years as NICU design has evolved to keep pace with striking changes in NICU care practices, family engagement, and technology. The 10th edition of these standards was recently approved and presented at the Gravens Conference; they will be published in a supplement to the Journal of Perinatology in late 2023.

"The Recommended Standards for Newborn ICU Design has been a guideline for NICU planners and regulators for more than 30 years as NICU design has evolved to keep pace with striking changes in NICU care practices, family engagement, and technology. The 10th edition of these standards was recently approved and presented at the Gravens Conference; they will be published in a supplement to the Journal of Perinatology in late 2023."

The most substantive change to the Standards is the specification of couplet care rooms in NICUs located in hospitals with a delivery service:

"Any hospital that offers both an obstetrical delivery service and neonatal intensive care shall include an adequate number of couplet care rooms equipped to provide both intensive care for the newborn and postpartum care for the mother in the same room or suite. This requirement does not apply to mothers who require specialized care after delivery, such as treatment for unstable hypertension or respiratory failure, or to infants who require care, such as ECMO or isolation, that cannot be provided in a conventional NICU room.

"Rooms to be used for couplet care should be appropriately sized and equipped for care of both the mother and her NICU baby, but depending on the functional program, could also be used for twin newborns, a healthy baby/mother couplet, or a pediatric patient."

Many recently-constructed or renovated NICUs have successfully incorporated couplet care rooms into their design with positive results on outcomes and parental satisfaction. This change creates considerable operational challenges that have been successfully addressed, resulting in mothers not being subject-

ed to the trauma of separation from their babies in the critical days immediately after birth.

"The use of color is an essential aspect of good design; research has documented overt and subliminal effects on families and caregivers alike, but this has often been overlooked."

The use of color is an essential aspect of good design; research has documented overt and subliminal effects on families and caregivers alike, but this has often been overlooked. The new Standards address this topic:

"Color choices shall reflect local culture and climate and be modifiable (through colored light and accessory options) when possible.

"Color preference is impacted by culture, climate, and length of stay in a space. Ideally, some pieces of the environment are chromatically interchangeable and can be modified by the families or staff."

"Views of nature shall be provided in the unit in at least one space that is accessible to all families and one space that is accessible to all staff. If direct physical access to the outdoors is not available, simulated access to nature shall be provided in at least one space that is accessible to all families and one space that is accessible to all staff."

Access to nature is also more clearly specified in the new Standards:

"Views of nature shall be provided in the unit in at least one space that is accessible to all families and one space that is accessible to all staff. If direct physical access to the outdoors is not available, simulated access to nature shall be provided in at least one space that is accessible to all families and one space that is accessible to all staff." Standards for the size and specifications of patient and treatment rooms have been updated. For single-family (private) rooms:

"Each room shall be designed to allow visual and speech privacy for the infant and family, including for skin-toskin contact, breastfeeding, and pumping."

For specialized infant care spaces or rooms:

"Infant care space designed to accommodate specialized bedside procedures that require additional space for equipment, staff, and other needs shall have a minimum clear floor area of 225 square feet (21 square meters) per infant in multi-bed rooms and 300 square feet (27.9 square meters) in single-bed rooms (e.g., extracorporeal membrane oxygenation, or ECMO, space-intensive bedside surgical procedures that require higher minimum space standards for staff and equipment)."

For NICU Magnetic Resonance Imaging (MRI) Room:

Where provided, an in-NICU-specific, self-shielded MRI room shall meet the following minimum requirements:

- Room size shall be a minimum of 250 square ft (23.2 square meters)
- Floor weight capacity shall be a minimum of 13,000 lbs (5,897 kilograms)

"Usability testing," the stage of mockup and simulations following the initial design and prior to preparation of final construction documents, was first introduced to the Standards in the 9th edition and updated and expanded for the 10th edition. Virtual simulation techniques have become much more refined in the past few years such that repeated, iterative simulations can considerably enhance a single time-intensive and expensive mockup. The updated standard now specifies that all users—including families—should be involved in these simulations and that color and lighting schemes should also be tested.

"Virtual simulation techniques have become much more refined in the past few years such that repeated, iterative simulations can considerably enhance a single time-intensive and expensive mockup. The updated standard now specifies that all users - including families - should be involved in these simulations and that color and lighting schemes should also be tested."

Additional articles related to these recommendations and other aspects of NICU design will appear in the upcoming supplement in the Journal of Perinatology to support those planning a major renovation or new construction for their NICU soon. The current

version of the Recommended Standards can be found at https://nicudesign.nd.edu/

Disclosure: The author has no conflicts of interest

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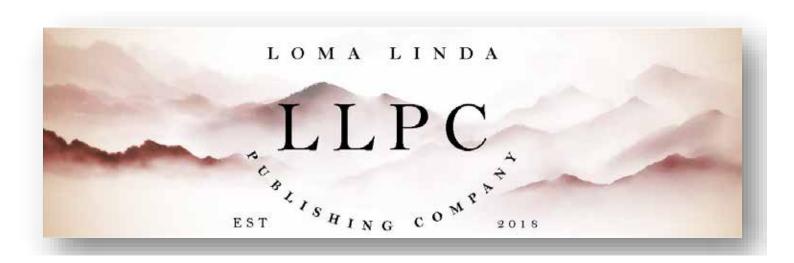
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NT Behind the Scenes: Lesia Cartelli Discusses Angel Faces, "Head Up. Wings Out!"

Kimberly Hillyer, DNP, NNP-BC



The following is an amended transcript for Neonatology Today Media between Dr. Kimberly Hillyer and Lesia Cartelli, author of *The Heart of Fire*. The interview took place on August 24, 2022.

Lesia Cartelli is the chief executive officer of Angel Faces. She founded Angel Faces in 2003 after launching and directing multiple aftercare programs for burn and trauma patients.

Angel Faces' motto is "Head Up, Wings Out!" They aim to provide ongoing support through education and healing retreats, empowering girls and young women with burn/trauma injuries. Their work was a mini-documentary that won an EMMY. Cartelli was selected as "Hero of the Week" by People Magazine and featured on CNN's "Human Factor" with Dr. Sanjay Gupta. She has received many prestigious awards for her leadership and inspiration, including the "Heart of a Woman" Award on the Dr. Phil Show. She has also been one of San Diego Magazine's Women of the Year finalists.

"Cartelli was selected as "Hero of the Week" by People Magazine and featured on CNN's "Human Factor" with Dr. Sanjay Gupta. She has received many prestigious awards for her leadership and inspiration, including the "Heart of a Woman" Award on the Dr. Phil Show."

**The next scheduled retreat will be in Wolfeboro, New Hampshire, in June 2023.

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<u>Dr. Kimberly Hillyer:</u> Hello and thank you for joining us on today's segment of Neonatology Today. I am your host, Kimberly Hillyer, a Neonatal Nurse Practitioner with Loma Linda University Health publication team, and I'm here today with Lesia.

How are you doing, Lesia?

Lesia Cartelli: I'm doing great. Really good.

<u>Dr. Kimberly Hillyer:</u> I'm glad to hear that, and thank you so much for joining us.

I was really inspired by your biography, the current book that you have out, "The Heart of Fire." I really wanted to talk to you about your information that you have regarding the book, the service that you are doing out for the community, and really hear about your story. Your story is a very emotional story, and I'm hoping that you might be able to tell my audience a little bit about that story.

Lesia Cartelli: Yes, sure, and it really is when the piece of my life, the path, really opened up to where I'm at today, many decades later. When I was nine years old, I was in a natural gas explosion as a child at my grandparent's home. They'd been smelling gas for a few days, and we arrived for dinner on a Sunday afternoon. There were nine of us in the house. Gas had seeped in, hit an ignition point, and the house exploded. I was trapped in the basement.

"I had sustained burns over half of my body at nine years old; half your body that total that TBSA (total body surface area) 50-60% is huge. Full-thickness burns, so I was transported to Children's in Detroit. This was 1969, so treatments were very barbaric."

I had sustained burns over half of my body at nine years old; half your body that total that TBSA (total body surface area) 50-60% is huge. Full-thickness burns, so I was transported to Children's in Detroit. This was 1969, so treatments were very barbaric. Burns were pretty much still being, as horrific as they were, it was a long process in that hospital. Coming out months later and carrying the weight of not only the trauma of what happened to my family losing everything. Thankfully, no lives were lost, but we really lost that foundation of our family that my grandparents were the really strong, steady link within the family. And so, being literally blown to pieces and not a spoon left. So, coming out of that, we all fumbled. My whole family didn't know how to handle that grief and that loss. And here I am now, ten years old, with severe scars over my face and my body. I launched into a series of years of struggling to find purpose. Struggling to transform that pain into something good.

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You know, I knew that I didn't survive that fire just to survive the fire. I had to get to a place where I didn't want to waste the pain that I had gone through and my family had gone through because of being severely injured as a child. There's that whole sense of adolescence where you're going back into the hospital. You have more grafts, you have more surgeries, you have contractures, you have all these pieces that go into having a severe burn injury, and with each one presented more hurdles. Going back to school, the staring, the questions, the unwanted questions—it's very difficult on the whole entire family.

"You have more grafts, you have more surgeries, you have contractures, you have all these pieces that go into having a severe burn injury, and with each one presented more hurdles. Going back to school, the staring, the questions, the unwanted questions, it's very difficult on the whole entire family."

<u>Dr. Kimberly Hillyer:</u> Now, as you talk about just the adolescent part, I think almost everyone can connect to just the normal difficulties and struggles of going through adolescence. Then you have the additional burden of having to explain, like you said, what's going on with your appearance. How do you find the courage to talk about something that's so painful? Because I'm sure questions were asked by classmates and teachers.

"You handle it on different days depending on how...or I handle it on different days, depending on how I felt. Some days I would put my head down and scurry away. Some days I would give quick answers, "I was in a fire." And some days, I would cry."

<u>Lesia Cartelli:</u> Oh, and strangers. You handle it on different days depending on how...or I handle it on different days, depending on how I felt. Some days I would put my head down and scurry away. Some days I would give quick answers, "I was in a fire." And some days, I would cry. It really would depend on how I wanted to be treated that day.

I really...Kimberly, I had an epiphany in 5th grade. It is what really started to make me think about what? When I treat myself with some self-love and grace, which is a tall order for a 5th-grader, right?

Dr. Kimberly Hillyer: Very much.

Lesia Cartelli: But if I could accept myself and love myself, so

would other people. But if I was separate from myself then and felt like a victim, I was treated like a victim. If I acted strong and I acted tough, then more people would gravitate to me in a positive manner. So, it was really about the choice because when I acted like a victim, I was treated like a victim. I saw this in 5th grade with another student.

"But if I was separate from myself then and felt like a victim, I was treated like a victim. If I acted strong and I acted tough, then more people would gravitate to me in a positive manner. So, it was really about the choice because when I acted like a victim, I was treated like a victim."

I had started school at this public school and didn't know anybody. It was in the middle of the year, which was the worst. My family had moved from Detroit to Florida, so I was waiting to get into this Catholic school, and they hadn't had room for me yet. So, my family put me in this 5th-grade class at a public school in January. I come in, and not only do I look very different with all these scars, but it's in the middle of school the year. Everyone's got established friendships, and I don't. So, for the first three days, I was pretty quiet, observing. On the fourth day, this girl came in who had been out sick. She came in, and she apparently was the one that the class was always bullying. And she walked in, and the class came alive. They were throwing erasers and pencils when the teacher would turn their back or leave the room, and they would unleash on this girl, Rose. And Rose would turn around and leash back. I thought, OK, she's feeding that. And where's my responsibility? Because they're not treating me like that...So, I really learned that when you feed into that victim and the anger, that's what you're going to get back because I would go the other route and be happy and pretend, I was happy and be funny and friendly even though I was dying inside. But it got me through.

Dr. Kimberly Hillyer: You had to first learn about self-love. Then you learned that, basically, what you put out in the universe is also what you will perceive. When do you get to the step of finding that purpose?

Lesia Cartelli: It came, it came decades later, really came in my young 30s. I talked about it in my book. I had gotten my real estate license and was trying to get a job here in Southern California. This broker, I was interviewing every day with him. He would say to me, "Come back tomorrow; I want to interview you again and have you meet so and so." He would go through this process.

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For detailed information regarding application forms and guidelines, fees/scholarships, and upcoming retreat visit angelfaces.com

Angel Faces (est. 2003) provides intensive educational and healing retreats and ongoing support for girls and young women with burn/trauma injuries. To inspire and empower so that they reach their optimum potential and develop meaningful relationships for themselves, their families, and their communities

After four and five days, Kimberly, I'm running out of interview clothes. You know what I mean? I'm running out of openings and closings. I'm just like, let's cut to the chase here. I got a phone call on that fourth night from a woman who was in the office. She said, "the broker you're interviewing with is my roommate, and he will never hire you. He can't get past your scars. He's hoping that every day he brings you back that you're just going to get so worn down, you're just going to move on and go somewhere else because he doesn't have the heart to tell you." And that was, that was a huge epiphany for me! I'm like, why am I going to sell real estate? I need to...I need to help people and make that transition. Like, what do other teenage girls do, what do other women do who have disfigurements and scars and trauma, and what do they do? I've made it this far into my 30s, jumping ahead a little bit; that's when I started Angel Faces.

Dr. Kimberly Hillyer: So, I can imagine, with today's technology, that it is much easier to connect with that community and the community that you're building today through Angel Faces. What was it like for you back in the 80s and 90s as you were finding yourself, growing towards that purpose that you find a little bit later on? Were you able to find a community or build a community to grow from?

Lesia Cartelli: Not that it had anything to do with trauma or burns or injuries. I worked retail, so my life was not shallow, but you know, pretty adventuresome and carefree, and paycheck to paycheck. I can remember going in that period of time, in my early 30s, when I couldn't get that real estate job. I had a doctor friend say to me, my sister was a nurse, I was at her house at a little party, and he said, "You know, we can do this procedure on your face." And I said, "my face?" And he said, "Yeah, that would make your face look better." I said, well, I'll go get a second opinion.

So, I went to UCSD to the Head of Plastics there to get a second opinion. He said to me, "Lesia, your face is beautiful. We'll talk about that in a minute." He said, "I'm astonished at your recovery from your accident as a child. Why aren't you helping burn children in the world?" I remember sitting on the edge of the table in the exam room, dangling my feet and saying to him, you mean there's burn children in the world? I mean, that's how removed I was from that whole world. And he said, "Yes, there are several hundreds, thousands of children with burn injuries in the world who need you." And that's when my wheels started going. I think I need to switch gears.

Dr. Kimberly Hillyer: Now. I remember this transformation in you and seeing that light bulb moment, and it really was something

angel faces Young Women's Regional Retreat, Wolfeboro, NH

Facial Design















Head Up, Wings Out!

that inspired me because sometimes. As you said, you get so focused on that narrow vision, and sometimes just the day-to-day life gets to you. But you were still open. You were open to this physician talking to you about the rest of the world, the community that people may not be aware of. So, you decided to bring awareness to it through Angel Faces and to really help build a community for these young ladies. Can you tell me a little bit about Angel Faces and how you try to help them through the same trauma that you went through?

"They come to us, and we're giving them a toolbox of all the methods that I found helpful to me over the years. Surviving through those traumatic years of adolescence and in my 20s was just as traumatic. We give them everything and let them pick."

Lesia Cartelli: So, we're a small nonprofit, Kimberly, but we're very mighty, and our reach goes wide. We're about the depth of healing from trauma, not the breadth of it. We run retreats that are very intensive. They're a week long, and the girls come from various trauma centers and burn centers. We get referrals from CPS, Child Protective Services, and schools from across the board, and of course, burn centers too. They come to us, and we're giving them a toolbox of all the methods that I found helpful to me over the years. Surviving through those traumatic years of adolescence and in my 20s was just as traumatic. We give them everything and let them pick.

The main thread is getting them to tell their story to us in a non-judgment way because we know what happens to the child, happens to the whole family. But the family and the parents and the mothers are so wounded themselves from shame and guilt. Even if they weren't anywhere near what happened, as my mother was not near us, she was en route and had arrived after the explosion. So, the child I have found with my girls, they tell the story that they have never been really allowed to tell. From their eyes, because what happens is they start protecting the family, right? Their childhood has been robbed, and they grow up really quick. They've got to be strong. So, when they get to us, they can lay down that social armor. They can lay down that protective armor that have to stay on within their family.

So, we get through the grief and loss. We're all led by licensed professionals, and the mental health professionals really start to unfold with them over a period of time at the retreat. What happened? How did it happen? Then we start to put together back the story in a healing manner. We do a big forgiveness piece. Were they write a letter of forgiveness, and we talk a lot about forgiveness. We do a lot of role-playing on staring and role-playing on unwanted questions. Like you're in Walmart, and the lady is following you around with some sort of barrage of questions. How do you handle that? How does your mother handle that? How does your sister, who you're with, handle it? How do you handle

your family handling them? So, there's methods and tools that we teach. To help them embrace all that with grace, not with anger, not with shouting back, and there's a way to disarm those situations. We use art therapy too. The girls sometimes they don't have the words to describe the shame or describe what they're feeling. But boy, when we weave in that art project into the theme. Wow. It really is pretty magnificent. We have fun, too, at our retreats in New Hampshire; we do paddleboarding and hiking and lots of great stuff in the afternoon. Mornings are mostly sessions we do corrective cosmetics. But I have to correct myself because the girls reminded me a few years back. That there's nothing to correct.

Dr. Kimberly Hillyer: No. Beautiful.

<u>Lesia Cartelli:</u> That is facial design. So now we call it facial design, which a team of makeup artists in the field of corrective cosmetics come in and really teach the girls. Maybe how to draw that eyebrow on that was burned off or just give some symmetry.

<u>Dr. Kimberly Hillyer:</u> To highlight what is beautiful inside and out. I love the way that the girls were able to, kind of have you do a course correction with that scene. It just shows the resilience that they have in this and the growth and the strength that they have in these retreats.

"It's really beautiful to watch because, in the beginning of my opening, I always say to them, your trauma is a gift. There are gifts in this trauma that will change the course of your life, and they're like, this isn't a gift. I'm missing a hand, and I'm missing fingers, this is horrible. But, over time they find that gift."

Lesia Cartelli: It's really beautiful to watch because, in the beginning of my opening, I always say to them, your trauma is a gift. There are gifts in this trauma that will change the course of your life, and they're like, this isn't a gift. I'm missing a hand, and I'm missing fingers, this is horrible. But, over time they find that gift. They'll say to me, "Why did this happen to me?" And I say, "Why not you? And what are you going to do about it now? How are you going to build? How are you going to impact? How are you going to transform that pain into something beautiful?" You didn't get this far to get this far, right?

<u>Dr. Kimberly Hillyer:</u> That's correct. Now you transformed your pain into something beautiful, not just with the work that you do with the girls, but you found a way to share your story, not just one-on-one, but with the world. So going back to your book. There's bits and pieces in which you find why your title, "The Heart of Fire," was created, but can you tell me in the audience why did you choose that title?

<u>Lesia Cartelli:</u> Because. Because the fire inside of me burns hotter and stronger than any fire that tried to destroy me. Right.

Dr. Kimberly Hillyer: That's powerful, and that is truly correct. I

think your readers will definitely get that, and especially when they see you battling that fear of the fire. Can you tell me a bit about how you battled that fear of a fire and were able to overcome?

"I wanted to be free of fire. I wanted to be free of the fear I had of fire. It wasn't a crippling fear, but it stunned me a little. I'd go get gas in my car, and I would just hesitate and make sure nobody was smoking around the pumps."

Lesia Cartelli: You mean literally, literally? But yeah, so I am. I was in the middle of running these burn camps. And I remember standing there, and there was this little boy, and he was up on this ropes course, and I was shouting at him. "Don't be afraid. Just embrace your fear." And I thought, well, you know you can't tell somebody something when you're not doing it yourself, right? I mean, the other day, I was on my husband because his office was dirty, and then I woke up in the morning with my office is filthy and disorganized. So, I got up, and I cleaned my office, and then I went to him, and I go, now I can say it again.

I wanted to be free of fire. I wanted to be free of the fear I had of fire. It wasn't a crippling fear, but it stunned me a little. I'd go get gas in my car, and I would just hesitate and make sure nobody was smoking around the pumps. I go through this little checklist in my head. Don't be on your cell phone at the gas pump because rumor has it; it's going to explode. And all this. I would never live in a house with natural gas. It always had to be one of those switches or no fireplace at all or wait till Frank came over to light my BBQ. Little things like that. And then I thought, this is crazy. I want to go back into a fire. I want to face my fear head-on. I'm going to pull the dragon out from underneath the bed, the monster. I just want to go back to that and face the angels that had rescued me out of that basement.

"And then I thought, this is crazy. I want to go back into a fire. I want to face my fear head-on. I'm going to pull the dragon out from underneath the bed, the monster. I just want to go back to that and face the angels that had rescued me out of that basement."

<u>**Dr. Kimberly Hillyer:**</u> And by finding the courage and the strength to do that, you actually did find love through that as well.

<u>Lesia Cartelli:</u> Found love, and I married the love. Two years later and it was something I didn't ever think was going to happen. I was in survival mode most of my life. Yeah, so I married the fire-fighter who took me back into the controlled burn. To teach me about fire so I wasn't afraid of it, that I understood it as a woman,

not a scared child.

Dr. Kimberly Hillyer: So you able to after facing your fear, after finding love through facing your fear. Are you able to come to a point in your life in which you say through this trauma, I've been able to find peace?

Lesia Cartelli: Oh, yes, because it strengthened my faith. It really strengthened my faith in being able to serve for a good reason. Really gave me a sense of going back, and as horrific as it was, as painful as it was, I don't know how my life would be not having that accident. I know it's brought me some incredibly beautiful people in my life. It's brought in me incredible richness for appreciation. You know, would I love flawless skin? Yeah. Wouldn't anybody. But it really forced me to dig down deeper to find the meaning of all life.

<u>Dr. Kimberly Hillyer:</u> Now, you talk about some of the people you've encountered. I know that you've also encountered people that have been able to help you build this organization. Can you tell me about how you're able to connect with these people and how you're able to bring your story to life?

Lesia Cartelli: You know, that's pure magic, and I just laugh about it because it's...I don't laugh because I also worry; oh my God. How am I going to pay the bills? It is because I have to raise the money, not only hold the girl's hands, but I raised the money as well. And yeah, there's times over the last 19 years. So, for 19 years, I've had Angel Faces, which is kind of unheard of these days for a nonprofit that is small and mighty, you know? When I get a little nervous, I go, God, I really need a donor to come in.

"Really gave me a sense of going back, and as horrific as it was, as painful as it was, I don't know how my life would be not having that accident. I know it's brought me some incredibly beautiful people in my life. It's brought in me incredible richness for appreciation. You know, would I love flawless skin? Yeah. Wouldn't anybody. But it really forced me to dig down deeper to find the meaning of all life."

The weirdest thing happens, my phone rings, or I'll get a random donation that's anonymous. I'm not very good at raising money. People say I am very good at it, but I don't feel it because I never want people to run out of the room when they see me and go, oh my God, she's just going to ask me for money. You know? Here she comes. But I think the key for me is to stay open because you never know. What's going to happen? You never know who's standing next to you that happens to know somebody who has a traumatic injury that feels compelled. You just never know. I think, I have to believe in what I'm doing wholeheartedly for that magic to continue.

<u>Dr. Kimberly Hillyer:</u> I can't imagine anyone not hearing your story, reading your book, and not, you know, feeling a movement in their heart. If they do feel that movement in listening to you today, how could someone participate and donate and help you and your organization?

Lesia Cartelli: You know, donations are always welcome. I'm always looking for partnerships with corporations that can help fund our retreats. Through our website, you can go on and find me that way; there are many different opportunities. I was telling somebody yesterday I don't have a lot of time to cultivate these long relationships, and I don't have a big development office. I just have to say, let's get to the part where you write us the check because I have work to do, and it's just that way. Sometimes I look at these big foundations. I'm like, how did they do it? Yeah, but the cord of where the funding comes into who it reaches is really short. And that's what I like about what we're doing is you can see the impact.

Dr. Kimberly Hillyer: It's small steps for sure, and the impact that you're making, especially for these young women at the retreats. At the other things that you're doing for individuals who will read your book. It's truly magnificent. Your retreat, I know that you'll have one going on soon. If someone, a physician, or someone listening to us today had an individual that they were treating. How can they help connect them with you and your community?

Lesia Cartelli: So yeah, we have a retreat coming up in Knoxville, TN. The first week in October, October 5 through the 9th (2022). We still have some spots open as of this morning. So, for the physicians, if you're treating somebody, a woman between the ages of 17 and 29 with a traumatic injury does not have to be on the face, can be anywhere significant on the body, 20 or 30%, TBSA or if it's a significant scarring on the face, but a smaller TBSA then go to our website, complete the application process and then they'll be in our system. We'll contact them, they just need to get themselves to Knoxville, and we will cover the retreat. We cover food, transportation, and everything. It can be a pretty life-changing opportunity for the patient because it's really a buffet of everything from healing modalities on grief and loss, yoga, exercise, nutrition, and how to find that self-love back.

<u>**Dr. Kimberly Hillyer:**</u> As you go to these retreats, build these opportunities for these young ladies to find their way back. Find their purpose. How does this continue to affect your spirit?

"What keeps you going? You give all that. What keeps you going? It's when the women and the girls go home, and they take what we've done and what we've taught them, and they make an impact. That's what makes me excited and engaged."

Lesia Cartelli: Somebody just asked me that yesterday...What fills you up? What keeps you going? You give all that. What keeps you going? It's when the women and the girls go home, and they take what we've done and what we've taught them, and they make an impact. That's what makes me excited and engaged. I

get these beautiful, flowery letters and all this gratitude, but it's the action that I like to see when they go home and apply for college or leave the bad, toxic, abusive relationship or make a better life. That's what gets me going. I'm like, OK, all this is [not] for naught.

<u>Dr. Kimberly Hillyer:</u> In your book, you go through all the different aspects of your story, and I'm sure that there's maybe a small part of the story that maybe you weren't able to fit into your book, but you still felt was a monumental moment in your life. Is there something that just didn't quite make it into your book that you felt was still a point for you?

"One of them was the fireman that rescued me out of the house that I had met him many decades later for the first time. That was powerful meeting him. That was really because he was this little old man by then, and it was such a beautiful full circle for both of us."

Lesia Cartelli: It's such a good question, Kimberly. It's such a good question. Yeah, there's several which has prompted me to write a second book, which I'm working on now. One of them was the fireman that rescued me out of the house that I had met him many decades later for the first time. That was powerful meeting him. That was really because he was this little old man by then, and it was such a beautiful full circle for both of us. It was funny, like we were in the car, and the Detroit Fire Department pulled up behind me. I was told that he was one of the guys on the call. I wasn't told that he was the one who got me. My head went into a kind of time warp. I see the Chief step out from behind the wheel, and he's 40 years old, and he's in all his regalia. I'm like, oh wow, there he is, and they're like, no. The door opened, and the passenger came out, this little man with this University of Michigan hat on and his U of M jacket. He shuffled up to me. That was a powerful moment. Yeah, it was powerful.

Dr. Kimberly Hillyer: I can't wait to read. I'm sure, as you said, there are moments that you just can't fit into one book that you know you'll be continuing to work on with your next book. So, I can't wait to read that and to see as your story continues to unfold.

Lesia Cartelli: Thank you.

<u>Dr. Kimberly Hillyer:</u> Now, I know you have a website, but would you go ahead and give our audience the website and the information for you and your organization?

Lesia Cartelli: Yes so, the website is angelfaces.com. We are a 501c(3) nonprofit organization going into our 20th year. I know, it's pretty exciting. Who would have thought? I'm still crying over the fireman story. Is that crazy? He's passed on now.

So angelfaces.com, and they can find out anything that they want about the retreats. They can watch video clips. We've done a lot of research that has been accepted by the American Burn Association. They can look at our research data from there, and all the outcomes are pretty impressive. They can find me through there.



Dr. Kimberly Hillyer: Then you have your own website as well.

Leisa Cartelli: Yes, I have my own website because I do a lot of speaking. That's lesiacartelli.com. So, you can find a little bit out about me personally and professionally through my own website, as well as Angel Faces.

"I can just imagine that the girls' lives that you were touching they're going to be feeling the same way about you, your organization, and what you're doing because even though the fireman physically saves you, you're saving these women emotionally and mentally."

Dr. Kimberly Hillyer: You still have the tears coming down. I can just imagine that the girls' lives that you were touching they're going to be feeling the same way about you, your organization, and what you're doing because even though the fireman physically saves you, you're saving these women emotionally and mentally. As you said, it takes time for those scars to heal, and they go through multiple procedures or surgeries sometimes, but sometimes the hardest thing to touch is that emotional and mental healing aspect.

Lesia Cartelli: And really for them to know that it takes time and a whole lot of gentle self-talk, a whole lot of gentle grace with yourself and the people around you. It took me years to get to a place where I just felt really good gratitude that I'm able to do this work. That I am fulfilled enough to do this work, that donors step up and allow me to do this work. I tell the girls, I'm one beggar telling another beggar where the bread is. As long as I'm sustained in our funding, I'll keep doing it.

Dr. Kimberly Hillyer: Well, you said it multiple times throughout our conversation today. Finding that grace with one another, I think, really does open the heart. Opens the heart to respond to each other on this human level that pours love, and sometimes that love happens to build into a donation, and sometimes the love is the personal love, and aspect that you get from meeting your husband. So glad you were able to just not just face your fears but to have this moment of strength, and that will continue to be around with you through the love that you built with your husband, who's a firefighter.

<u>Lesia Cartelli:</u> You know, isn't that great and then he went on to become a chief and then retired. So, it's just a fun full circle.

There's something that I want to say that I think is important for your listeners. I cover this in the retreat. I think this is a good platform to make this point to your listeners and your readers that one of the pieces that we do at the retreat is to teach the girls and the women that they are not the only one injured. That they may have sustained a physical injury, but around them, there is a whole group of people that maybe witnessed it, that see you as a different person now. That loved you and now has angst and pain for what you're going through. There are the frontline workers,

the emergency, the firefighters, the police officers who were on that call who saw what happened. Not only the family, but the first responders, the nurses, and the doctors that are impacted. To try and get them to see beyond their own woe is me. Have compassion for the people around them who are equally, sometimes more affected, particularly with the parents who feel helpless.

I really try and get them to get to a place where they have gratitude for their nurses, and their doctors, and their police officers, and their firefighters, and the people who care for them and got them back on their feet. Angel Faces gets the accolades because we come in at the 11th hour when they've been discharged. You've put them all back together, and we come in and work on their spirit. They go, oh, like a little duckling that's been imprinted, right. But I want them to know that there needs to be a shared gratitude with the medical centers and with those first responders. That they're not the only ones that are injured, and you could see their little light bulbs going off in their head. Going, oh yeah, the nurses, the doctors, the technicians, the people that helped clean their room, their hospital rooms, the custodians, and the maintenance people—everyone's affected.

"Angel Faces gets the accolades because we come in at the 11th hour when they've been discharged. You've put them all back together, and we come in and work on their spirit. They go, oh, like a little duckling that's been imprinted, right. But I want them to know that there needs to be a shared gratitude with the medical centers and with those first responders. That they're not the only ones that are injured, and you could see their little light bulbs going off in their head."

<u>Dr. Kimberly Hillyer:</u> Yeah. I know before you were saying, back in the 70's, that there wasn't as much treatment, and you had to go to Detroit. I've heard the long-term aspects of treatment for some of these individuals that have a large amount of their surface area that has sustained burns. The amount of time that it takes with the nurses and the doctors, like you said, trying to physically put some of those pieces back together.

Lesia Cartelli: Yeah, it's a long process. You know, when you have a heart attack, you get repaired, and then you go in for some PT and some OT. You get things back together, and you're done. As long as you eat healthy and stay away from salt. But with a burn injury, you go back constantly for more surgery and more releases, more skin grafts because the skin is constantly contracted during and not tightening and changing. So, it really is a long process.

<u>Dr. Kimberly Hillyer:</u> Well, it's a process that I'm so glad that your organization helps these young ladies through after they continue to work with us in healthcare. Filling, bringing that physical pro-

cess through. Then you're able to bring the mental and emotional support for them. So, I'm glad that they're imprinting on you like little ducklings because that really is what brings that resilience, that self-love that you talked about. That courage that we talked about gives them that purpose that then builds for them, for their families, and for all souls that touched their lives, even strangers.

" I tell the girls that when they walk into a room, people are going to stare anyway. They're all going to look up, and they're going to look over. So why not give them something beautiful and strong to look at? Why not be that teacher and show your resilience and put your girls out, put your shoulders back and your head up, and smile at them?"

Lesia Cartelli: Strangers. I tell the girls that when they walk into a room, people are going to stare anyway. They're all going to look up, and they're going to look over. So why not give them something beautiful and strong to look at? Why not be that teacher and show your resilience and put your girls out, put your shoulders back and your head up, and smile at them? You know, and pretty soon, the scarring will go away, and they'll start to see your light.

<u>**Dr. Kimberly Hillyer:**</u> See the light shining through the eyes? Because that's what's being focused on.

<u>Lesia Cartelli:</u> Yes, and we role play that, and boy, is it really interesting to watch the behavior and the response of people.

Dr. Kimberly Hillyer: Well, Lisa, I'm so glad that you've spent this time talking to me. I want to remind our audience about your book, which I know I found on Amazon. I'm sure it's also in all the other bookstores that still exist today. Brick and mortar still there.

Lesia Cartelli: Yeah, right? I think they are.

<u>Dr. Kimberly Hillyer:</u> Yeah, at least Barnes and Nobles, because I just went there.

Lesia Cartelli: There you go. Uh-huh.

<u>Dr. Kimberly Hillyer:</u> So want them to go ahead and pick up your book, "The Heart of Fire" and then soon maybe we'll have a second book. Do you have a publication date yet or still in the writing process?

Lesia Cartelli: I'm still in the writing process. You know, they say it takes three weeks to write a book and three years to edit, right?

<u>Dr. Kimberly Hillyer:</u> I can only imagine. Your heart pours into those pages, and then you have someone coming back and ripping it apart. Having you add and mix this and remixing it, you're like, wait, I did tell my story.

Lesia Cartelli: But I wanted that fireman in there, and they were like, no. Save it for book two. I'm like, OK, yeah. But it's a fun

process.

<u>**Dr. Kimberly Hillyer:**</u> I'm so excited for this next journey for you with this. With the book, the second book and that you continue to grow and have purpose and strength in what you do with these young ladies that have gone through so much.

Lesia Cartelli: Thank you and thank you so much, Kimberly, for giving me this time and this platform to tell my story and share the girls' journey. I am really grateful, and keep doing what you're doing up there, and take care of those patients. It just makes the world a better place every day.

"Thank you and thank you so much, Kimberly, for giving me this time and this platform to tell my story and share the girls' journey. I am really grateful, and keep doing what you're doing up there, and take care of those patients. It just makes the world a better place every day."

Dr. Kimberly Hillyer: Thank you, thank you so much.

We want to thank our audience for joining us on today's episode of Neonatology Today Media.

Lesia Cartelli: Thank you, thank you so much.

NT



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



Title: NT News Anchor and Editor

Title: Neonatal Nurse Practitioner & News Anchor, Editor for Neonatology Today

Organization: Loma Linda University Health Children's Hospital

Neonatology Today in partnership with Loma Linda University Publishing Company.

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

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

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

About the Author: Lesia Stockall Cantrelli



Lesia Stockall Cartelli is a sought-after speaker and author. She is the founder and chief executive officer of Angel Faces - a national nonprofit providing healing retreats and ongoing support to adolescent girls and young women with severe burn/trauma injuries. Cartelli endured serious burn injuries at the age of nine in a natural gas explosion. Her grandparents' home was destroyed yet her spirit survived.

For the past 30 years, Cartelli has launched and directed aftercare programs for burn and trauma patients. In 2003, she founded Angel Faces. Resiliency and courage motivated Cartelli to face her fear of fire at age 33. She suited up in firefighting gear and entered a burning building known as a "control burn." Her fear conquered, she married the fire captain who led her into the fire to face her fears.

Cartelli transformed her pain into a life of passion and purpose. Thousands have been deeply impacted through her programs and her talks. She inspires all who are in her path. Cartelli was selected as "Hero of the Week" by People Magazine, featured on CNN's "Human Factor" with Dr. Sanjay Gupta, HLN, ABC NEWS 20/20, MSN, PBS, and other national media. She has received many prestigious awards for her leadership and inspiration including the "Heart of a Woman" Award on the Dr. Phil Show and an EMMY for Angel Faces mini documentary. San Diego Magazine's Women of the Year, finalist.

Cartelli is often interviewed on Doctor Radio and Sirius Radio and has been written about by the Associated Press, Reader's Digest, Woman's World and many other national and international publications. She is a dynamic, captivating, nationally-known motivational speaker.

Her book, Heart of Fire is available through Amazon.

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COVID-19

HYGIENE TIPS

EYES LOTHING

SELF ISOLATION



BATHROOM Sanitize EVERYTHING



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



sicker, DON'T WAIT

Miora



Los enfermos deben estar separados del hogar. Habitación con ventan preferida Airear la habitación 3x al día ar la habitación 3x

6 FT

MANOS

ROPA

COVID-19

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

BAÑO

SIGUIR

COVID-19 VISTAR



PROTEGER

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



AISLAMIENTO

CONSEJOS DE HIGIENE



#STOPTHESPREAD

Maneras de manajer COVID-19 en casa

Detén la

en Casa

Miora

propagacion

COCINA







Enfermo

Ways to Manage Covid 19 @ Home

Spread at

HOME

VIIORA

KITCHEN

se SEPARATE utens

#STOPTHESPREAD

Household

Stay 6 feet apart from others at all times.

Gargle with antiseptic mouthwash in the morning and evening.

Wash hands 10-12x a day, before each neal for at least 20 seconds.

Wear protective clothing (jacket, gloves, mask) that can be remove after being around infected.

idows/doors) where pos Do not share towels, blankets, p with sick.

Wear protective covering over mouth and eyes (mas AMD shield/goggles/glasses) when near others. (Do not put masks on children under 2 years old)

Sick

Keep water and sanitation products in room.

5. Keep plastic garbage bag in room.

6. Protect pets - don't cuddle

7. Notify contacts in last 10 days.

8. Don't wait! Call dector if symptoms get worse.

Hogar

todo memento. Use una cubierta protectora sobre la boca y la máscara para los ojos Y el protector / gafas / anteojos cuando esté cerca de otras personas. No ponga máscaras a niños menores de 2 años

Hacer gárgaras tedas las mañanas y noches con productos de enjuague bocal antiséptico que contienen alcohol.

Mantéga Buena ventilacion en toda la casa. Abra las ventanas y puertas cuando sea posible. Ne compartá toallas, cobijas, y almohadas con personas que esten infectados.

7. Llame al 211 para obtener servi de entrego gratuitos.

Aislese permanecindo en una habitación separada con ballo separado. No vayas a espacios compartidos

3. Ventile la habitacion con aire fresco por lo menos 3 veces al dia.

Mantenga agua y productes de saneamiento en la habitacion.

Mantenga una belsa de basura en la habitación.

6. Proteja a las mascotas, no las abrace.

8. No espere! Si se siente peor l'Iame a su medico.

WEAR A MASK

When we all

PROTECT PARENTS + BABIES

wear masks... We protect parents and

babies.



∆@egs

Perinatal

USA UNA MASCARILLA

PROTEGER A LOS PADRES Y BEBÉS

Cuando todos usamos mascarillas ...

Protegemos a los padres y los bebés.





Fragile Infant Forums for Implementation of IFCDC Standards:

The Infant as Baby as a Competent Interactor

Joy V. Browne, Ph.D., PCNS, IMH-E



"The baby communicates physiologically and with their state of arousal and motor skills. These interaction components are present in fetal life and at birth, regardless of the baby's gestational age."

Foundations of what we know about the baby as a competent interactor

For humans, life is dependent on interaction with others for survival, nurturing, and social exchanges. At birth, a baby's interaction is primarily dependent on sensory and physiologic exchange in concert with the mother or another essential caregiving person, which we now refer to as the m(other). Each member of the dyad brings their competence to the development of their own exceptional culturally appropriate relationship. These essential initial dyadic interactions lay a foundation for early development and beginning vocal and gestural communication. Also embedded in these early interactions is a rich emotional exchange that lays a foundation for attachment and bonding.

No longer is the baby considered a "tabula rasa" or "white paper, void of all characters," whose mind is developed primarily through

experience after birth. Those were the views of followers of John Locke, whose philosophical stance continued through the 20th century (1). We now know the baby comes well prepared with observable behaviors that signal the need for interaction with their familiar m(other). The baby communicates physiologically and with their state of arousal and motor skills. These interaction components are present in fetal life and at birth, regardless of the baby's gestational age. They can indicate recognition and responsiveness to their mother's taste, smell, sound, movement, and face. They even come with familiarity and responsiveness to the mother's language and her community (2-5).

In the early 1970s, the work of T. Berry Brazelton and colleagues introduced the Newborn Behavioral Assessment Scale (NBAS), which described the many communicative behaviors of newborn babies, recognizing that they emerge from utero with a rich repertoire of organized behavior (6, 7). He emphasized that each baby has an individual temperament and ways of communicating right from birth. These observations and the development of the structured assessment (NBAS) articulated the behavioral repertoire of newborns and emphasized how babies strive to interact with their caregivers.

One of Brazelton's protégés, Dr. Heidelise Als, further articulated the baby's striving to connect with their m(other) through responsive changes in their behavior during interactions (8). Her observations were extended to babies born preterm, where she described a vast, intricate, readily observable, and measurable catalog of behaviors. She developed insights into understanding the baby's behavior that can be interpreted as a striving toward developmental goals and social reciprocity. (9, 10) The behavioral repertoire that she described has laid a foundation for an evidence-based program of interpreting the "voice of the newborn" or, to put another way, the baby as a competent interactor (www.nidcap.org).

"Various intervention studies now use behavior to measure their impact on the baby--measuring the baby's behavioral responses to the environment, physical interaction with caregivers, and social bids."

Based on Brazelton and Als's seminal work on communication, we can ask the baby about their developmental capacity and experiences. Other neurobehavioral assessments have been since developed, which evaluate the baby's preferences and competence in the face of responding to social bids, reflex elicitation, and holding. Various intervention studies now use behavior to measure their impact on the baby--measuring the baby's

behavioral responses to the environment, physical interaction with caregivers, and social bids (11-14). For example, several pain scales are based on observing behavioral responses in their faces, body, and physiological signs. (15, 16) Responses to therapies such as massage or music also depend on understanding the baby's interaction or withdrawal behavior as indicators of the baby's preferences. (17, 18) Using observations of the baby's behavioral communication and resulting interpretation of the baby's experience can and should be used with parents to demonstrate how best to understand their baby.(19)

"With the constraints of separation from the mother and experiencing multiple interactions with unfamiliar caregivers, i.e., "someone," the qualities of the baby as the competent interactor are often undetected."

Relationship development—the baby's role as a competent interaction partner

Recent research provides a major focus on the efforts of the parent/caregiver to provide physical and verbal communication in interactions with their baby. (20-22) As active communicators, babies "hold their own" in interactions with their caregivers. They strive to engage in conversations through their physiologic behavior, movement, arousal, and sleep states. They are competent communicators and strive to interact with their caregivers in a meaningful dialogue. However, the baby's communication efforts are often not recognized and responded to. To demonstrate, when we attempt to converse with someone whose language is unfamiliar, we may avoid listening or misunderstand what they are trying to say.

"The shift in intensive care to singlefamily rooms and "couplet care" is an important return to assuring that the baby and m(other) are together to develop their unique interaction and coregulatory relationship."

Babies have a unique way of communicating their need for interaction, social exchange, and development, which their interactors may not understand correctly. Should that person not have received training in babies' unique behavioral language, they may not notice and respond to the subtle communication efforts of a baby. In particular, it is likely to happen with fragile babies whose behaviors are not as straightforward as if they were robust communicators. Even with specific training, many professionals may not recognize the subtle attempts at communication if they are in a busy intensive care unit where the baby may be overwhelmed and unable to communicate effectively. Addition-

ally, medical procedures take precedence in an intensive care unit, and professionals may not make a point of becoming fluent communicators with babies.

The mother as an active member of the interaction dyad

It is a given that human infants cannot survive without the protective nurturing of the mother. An early quote by Donald Winnicott is often cited to demonstrate that concept: "There is no such thing as a baby, there is only a baby and someone." (23) However, the separation of early born and medically fragile babies have relegated physiologic nurturing to machines, medicines, and revolving caregivers. The m(other) is often unavailable to the baby, as has been experienced in many intensive care units during the recent pandemic. (24-27) With the constraints of separation from the mother and experiencing multiple interactions with unfamiliar caregivers, i.e., "someone," the qualities of the baby as the competent interactor are often undetected. Too often, the baby is relegated to an "observer" rather than an "active participant" role during routine interactions and activities in the intensive care unit.

"What about the baby'? It provides an opportunity to focus and reflect on what the baby is saying through their behavior; what they are requesting, what makes them comfortable, how they are striving towards their developmental goal, what bothers them, what exhausts them, what invigorates or energizes them, and most importantly, how do they participate in their care?"

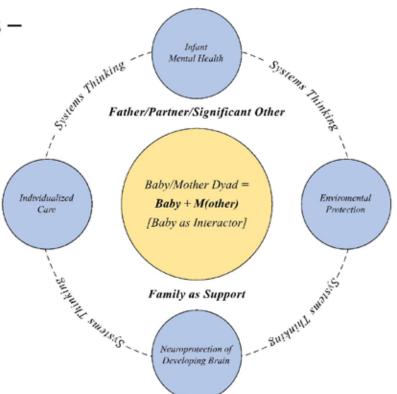
Under stressful conditions such as intensive care, sensitive interactions between m(others) and their baby are affected, creating challenges to developing an attachment relationship. (28-30) Parents who find themselves in very stressful and potentially traumatic environments and circumstances need supportive interventions in order for them to develop a nurturing relationship with their babies. Policies to keep m(others) with their baby after birth through single-family rooms, couplet care, kangaroo m(other) care, and encouragement to be present are essential to support the baby and m(other) as competent interactors. The shift in intensive care to single-family rooms and "couplet care" is an important return to assuring that the baby and m(other) are together to develop their unique interaction and co-regulatory relationship. (31-34)

Research has emphasized the benefit of seeing the baby and m(other) as a co-regulatory unit both physiologically and socially and should be treated as such during hospitalization. (35-37) Care should be taken to provide for the support of the m(other) and emphasize how to help them understand the communication attempts that the baby offers.

Recognizing the baby as the core focus of caregiving in inten-

IFCDC Principles – Concept Model

- Systems thinking in complex adaptive system
- Individualized care
- · Family involvement
- Environmental protection
- Neuroprotection of developing brain
- · Infant mental health
- Baby as a competent communicator &interactor
- Diversity, equity, and inclusion (DEI)



Consensus Committee on Infant Family Centered Developmental Care. Gravens Conference Workshop: Recommended Standards, Competencies and Best Practices for Infant and Family Centered Care in the Intensive Care Unit. 2017, 2020.

Figure 1

sive care

A well-understood question used in the field of Infant Mental Health and exemplifies how babies have been neglected in our professional interactions with families is to ask, "What about the baby"? It provides an opportunity to focus and reflect on what the baby is saying through their behavior; what they are requesting, what makes them comfortable, how they are striving towards their developmental goal, what bothers them, what exhausts them, what invigorates or energizes them, and most importantly, how do they participate in their care?

In the recently available evidence-based Standards, Competencies, and Best Practices in Infant and Family-Centered Developmental Care(38), a model has been developed to demonstrate the basic principles of Infant and Family-Centered Developmental Care (IFCDC) (Figure 1).

"One of the most rewarding aspects of regulation is that the baby is becoming a social interactor. So, supporting regulation in these areas is essential for later development."

The central "anchor" for the model is the inseparable coregulated baby and m(other). In this relationship, the baby should be given as much validation as an active interactor as is the m(other). The model emphasizes that the baby has individual strengths, vulnerabilities, and strivings toward relationships and is a competent interactor within the caregiving environment. As the core focus of IFCDC, the baby needs his or her efforts to communicate to be heard, understood, valued, and complimented.

Supporting the infant's efforts to be a competent interactor

Provide regulatory support: A baby's primary developmental goal is to become regulated in the face of their family environment and relationships. (36, 39) During the first few weeks and months, regulation is the foundation for what babies are working hard to achieve. As they develop, they become more stable in their physiologic functions, such as breathing, color changes, bowel movements, and temperature control, which are essential for later development. Reflexes present at birth become more volitional. Regulation of sleep states and becoming more predictable in their sleep cycles emerges. Coming to alertness for interaction for more extended periods is also a primary developmental goal that requires regulation of all the other foundational systems. One of the most rewarding aspects of regulation is that the baby is becoming a social interactor. So, supporting regulation in these areas is essential for later development.

Professionals need to know what regulation in these areas looks like, why understanding the behavior is essential, and how to

help the baby become more regulated in the face of the environment and caregiving. Often dysregulation occurs during social interactions, which may be too overwhelming to the baby and may be misinterpreted by the caregiver. Should professionals or parents not understand their baby's regulatory needs, they may not know how to respond to dysregulation and instead resort to other overwhelming sensory inputs that they feel will help with regulation.

Relationships: Babies and their m(other) should be supported to be together from birth with few extraordinary exceptions. The familiarity of the m(other)'s body, voice, movement, and sensory organization promotes regulation in the baby so that they become competent interactors. Emerging relationships can be enhanced through understanding what the baby is saying and responding according to what they say.

Human relationships are unique in that we typically communicate face-to-face and eye-to-eye. Removing barriers and distortions to seeing and holding the baby eye-to-eye and face-to-face will go a long way to allow the baby to develop regulated interactions and an emotional connection. (40) Recent research demonstrates that when the m(other) talks, sings, or reads to the baby, the baby strives to interact with her by becoming alert, changing their breathing, and calming. During kangaroo m(other) care, the baby also often attempts to come to alertness and look at the m(other) 's face. The Family Nurture Intervention (FNI) program encourages the m(other) to use emotional language and share emotions to develop an emotional connection while touching and holding skin to skin in the NICU. (40, 41) These studies have demonstrated improvement in the baby's behavior and brain organization and a reduction in m(other)s' depression. (42-44)

For professionals who provide caregiving, watching the subtle and not-so-subtle physiologic, motor, and state behavioral responsiveness to language, caregiving, or other therapeutic interventions will assist the baby in feeling "heard." Professional-to-baby

communication will be facilitated by observing, understanding, and responding to the baby's behavioral language.

Reflection: An essential component of seeing the baby as a competent interactor is to reflect on the baby's experience and the parents' experience. In order to have a thoughtful perspective on a baby's experience, parents and professionals can take the time to routinely sit to watch the baby and identify what the baby is communicating in response to the environment, caregiving, procedures, or when they are sleeping. Taking the time to imagine what the baby is feeling and responding to every breath, movement, and color change will give a window to the baby's experience.

"All babies deserve to be heard, understood, and responded to appropriately. What is needed to have a 'conversation' with the competent baby interactors in your unit? It is powerful to be heard and responded to, even if the language is not verbal but behavioral. The resulting conversations will reward you, the parents, and the baby."

Parents typically have insights and reflections about their baby's communication and can help the professional to know the individual responses that might not be readily visible. As parents are the most familiar and invested people in their baby's lives, they will have essential insights into how their baby communicates.

Final thoughts on the baby as a competent interactor.

Some suggestions to help with understanding the baby as a competent communicator and interactor.

- Sit undisturbed and watch the baby for a while. Note what happens when there is sound, activity, caregiving. How does the baby respond?
- As yourself what the baby is telling you about his or her experience with caregiving, the environment, the procedures?
- When you interact with a baby, ask yourself what the baby's experience of being a competent social partner is and how did you know?
- As your self if you can identify what the baby is telling you about their developmental or social interaction goal.
- Watch an interaction between the baby and their m(other) and another time
 with a staff member. See if you can tell what is the baby's experience was
 like when with the mother, when with the staff, and when they are alone.

Babies each come to us with their own unique behavioral "lanquage" and, when supported, can be effective communicators and competent interactors. When we do not know the baby's language, it is hard to understand them and to respond in a supportive way. Without focusing on or accurately interpreting what the baby has to say, we risk not understanding their experience. Miscommunication often results in missed opportunities for meaningful and robust development. The baby whose behavioral communication is ignored, bypassed, or talked over during conversations may begin to understand that their attempts to tell of their experience are not essential. After so many attempts at being heard, learned helplessness may ensue, and the baby may "give up" on being an effective interactor. Imagine an adult with a visual deficit has a medical appointment, and the driver accompanying the adult is talked to rather than themselves. Or when in rounds, nurses are asked how the baby is doing without acknowledging that the m(other) is there and knows best what is going on with her baby, so the baby might feel that their communication is not valued or heard.

All babies deserve to be heard, understood, and responded to appropriately. What is needed to have a "conversation" with the competent baby interactors in your unit? It is powerful to be heard and responded to, even if the language is not verbal but behavioral. The resulting conversations will reward you, the parents, and the baby.

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Moral Distress In the NICU - Their Pain is Our Pain

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.

"Since the very first units specialising in the care of premature infants opened, those have questioned what is done to them. Today is no different. Constantly pushing the boundaries of viability has only exacerbated the problem."

Since the very first units specialising in the care of premature infants opened, those have questioned what is done to them. Today is no different. Constantly pushing the boundaries of viability has only exacerbated the problem.

At the beginning of my nearly 34-year career in the NICU, resuscitation was offered at 25 weeks postmenstrual age (PMA), discouraged at 24 weeks PMA, and was not offered at 23 weeks PMA or if weight was <500 grams. Reasons for this were the equipment limitations, the belief that the pulmonary system was incapable of supporting respiration, and the small chance of survival, making any lifesaving measures futile. In cases where resuscitation was offered below 25 weeks, PMA survival was reported to be 8% at 23, 16% at 24, and 53% at 25 weeks PMA By 26 weeks, PMA survival increased to 63%, and 72% by 27 weeks PMA (1).

Data comparison between 1982-1985 vs. 1985-1988 showed no improvement in survival (20%) despite more aggressive treatment and technological advances. What did "improve" was the mean time to death once transferred to NICU, increasing over 10-fold (1). Perhaps this is where the seeds of caregiver moral distress were first sown.

By 1993 significant improvements in the treatment/care of these

infants are borne out by the statistics. No infants resuscitated at 22 weeks PMA survived, but at 23 weeks, survival increased to 15%. At 24 and 25 weeks, that rate was 21% and 69%, respectively, and overall survival increased to 39% (2). While the overall survival rate was significantly higher, excluding 22-week PMA infants (29 infants), survival increased to 50% in the 23 – 25-week PMA cohort.

Aside from the routine adoption of surfactant replacement, improvements in mechanical ventilation were undoubtedly a major driving force behind increased survival rates. With the introduction of microprocessors, ventilator technological improvements accelerated during the '90s. Genuine, reliable synchronisation, volume monitoring, and later volume targeting, plus greater monitoring capability, were added to the clinician's repertoire. In contrast, before the '90s, most babies were ventilated with non-synchronized intermittent mandatory ventilation (IMV), and earlier attempts to provide synchronisation (in the author's experience) were unreliable. By the late '90s, with the notable exception of the US, a new generation of ventilators could offer both conventional ventilation (CV) and high-frequency oscillatory ventilation (HFO). This facilitated the increased adoption of HFO first as a "rescue" strategy and later as a first-line mode of ventilation.

"By the late '90s, with the notable exception of the US, a new generation of ventilators could offer both conventional ventilation (CV) and high-frequency oscillatory ventilation (HFO). This facilitated the increased adoption of HFO first as a "rescue" strategy and later as a first-line mode of ventilation."

Improvements in pulmonary outcomes resulted in resuscitation being routinely offered to infants below 25 weeks PMA, first at 24 weeks, then at 23 weeks. Herein lies the source of uneasiness felt by many bedside caregivers. Patient acuity and length of stay increase with declining PMA. For the caregiver, this results in more exposure to all the unpleasantness stemming from the interventions necessary for the baby's care. Follow-up analysis of survivors post-discharge revealed that acuity and length of stay notwithstanding, outcomes were very similar between 23-25 weeks PMA babies.

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One analysis showed that while death at 23 weeks PMA was significantly higher than at 24 or 25 weeks PMA (44.2% vs 31.6% and 12.1%, respectively), this was not the case for minor or major morbidity nor survival without morbidity. Surprisingly, those born at 23 weeks PMA were *least* likely to suffer any morbidity and *most* likely to suffer no morbidity at all (3). Buoyed by these numbers, neonatology set its sights on the 22-week PMA infant. For better or worse, this is where we are today.

"Surprisingly, those born at 23 weeks PMA were least likely to suffer any morbidity and most likely to suffer no morbidity at all (3). Buoyed by these numbers, neonatology set its sights on the 22-week PMA infant."

Survival statistics at 22 weeks PMA vary widely and are influenced by several factors. Between ≈20 and ≈70 % live to 1 year of age, with odds declining significantly with lower birth weight. Exposure to antenatal steroids improves survival, and centres that liaise with the obstetrical team have the best outcomes (4).

It is likely that when presented with this data, many bedside caregivers would be suspect; caregivers have a long history of underestimating survivability and overestimating incidence of morbidity. Two things are of note: pediatricians and neonatologists are likely to be more optimistic than bedside caregivers (RN etc.), and these perceptions were worse in 2020 than in 2010 (5).

Why would there be a discrepancy in perception between those at the bedside and physicians who typically spend very little time there? Furthermore, why would those perceptions be worse now than ten years ago? A deep dive into the complex psyche of caring for critically ill premature babies sheds some light.

"Surveys of beside nurses and residents show marked differences in feelings depending on the scenario. Moral distress is higher amongst those working in outborn facilities than inborn ones, and increases as the gestation age of the patient decreases."

Surveys of beside nurses and residents show marked differences in feelings depending on the scenario. Moral distress is higher amongst those working in outborn facilities than inborn ones, and increases as the gestation age of the patient decreases. Tying in with the generally pessimistic attitude described above, those with less knowledge of actual outcomes are most likely to feel distressed (6). In having said that, there is more to feelings of moral distress than a lack of knowledge, and this reference indicates a reverse effect among medical residents.

Moral distress increases with acuity and decreasing PMA, as does the continuation of aggressive treatment in situations caregivers perceive as futile. It is challenging to measure feelings, but it is prudent to address their source. It is the hallmark of cognitive behavioural therapy. Let us examine some possible sources.

A bedside nurse is a witness to everything a baby goes through and the anguish of parents. They may feel powerless to alleviate it. Next to the parents, the bedside nurse is arguably the strongest advocate for the baby. Not being heard is a source of angst in and of itself. Many caregivers are female and of childbearing age if not mothers themselves. Women are known to be more empathic than men (7), and motherhood increases their capacity for empathy (8). When a mother tells you, "I feel your pain," it may be true. This has implications in the NICU since they may be susceptible to their patient's pain. When concerns are voiced, they are often met with "get used to it; this is the new normal" or dismissed altogether. If feelings are dismissed without acknowledgment or discussion, the person's perceived value with those feelings is diminished, and the whole team suffers as a result.

"Bearing witness to ongoing pain (real or perceived) has a cumulative effect that can result in PTSD, similar to first responders. The magnitude of this must not be ignored. Since the resuscitation of 22-week PMA infants has become routine, I have seen nurses leave or retire early or go off on stress leave."

A bedside nurse may form bonds with both patients and parents. Bearing witness to ongoing pain (real or perceived) has a cumulative effect that can result in PTSD, similar to first responders. The magnitude of this must not be ignored. Since the resuscitation of 22-week PMA infants has become routine, I have seen nurses leave or retire early or go off on stress leave. All too often, when asked why the answer is, "I cannot be part of this anymore." With 20% survival, a bedside nurse sees only pain and suffering for 80% for the survival of 20%. "Is it worth it" is an unpopular but valid question -- one whose answer may be yes or no depending on the individual's experience and perception.

There is no shortage of places to work for nurses seeking escape from the challenges of the NICU. The mental well-being of bedside staff must be addressed. A 15-minute de-brief just does not cut it. Increased acuity will undoubtedly lead to faster burnout for those not suffering moral distress.

For the patient in the NICU, there is no escaping a degree of pain. Some neonatologists are reluctant to provide sedation and analgesia due to uncertainty regarding long-term effects in the premature population. When they do, it may be inadequate. There is good reason to be cautious. There has been insufficient research into the drugs used for sedation to validate their use in the premature population, particularly the micro-premature. Midazolam is widely used outside the NICU, but flags have been raised regarding its

safety, namely slower growth of the hippocampus (9), and in 2017 a Cochrane review concluded there was insufficient evidence to support the use of midazolam in the premature population (10). Recently dexmedetomidine, a drug with anxiolytic, sedative, and analgesic effects but without causing respiratory depression, has been used in the NICU. To date, it appears safe, and while not established in the preterm population, there is evidence it is neuroprotective (11). Still, long-term data is lacking.

"Kangaroo care (KC) has been shown to significantly reduce a baby's stress level along with a host of other benefits (12) and is, without a doubt, the safest, most cost-effective therapy employed in the NICU. When it comes to infant comfort, KC should be a first-line therapy."

Kangaroo care (KC) has been shown to significantly reduce a baby's stress level along with a host of other benefits (12) and is, without a doubt, the safest, most cost-effective therapy employed in the NICU. When it comes to infant comfort, KC should be a first-line therapy. I practice offering KC to any infant stable enough to do so, including babies on high-frequency jet ventilation. It is a bit of work, but it is worth it.

Many factors adversely affect the developing brain; pain has been shown to alter brain structure (13), which is also true in premature infants (14). Morphine is one of the oldest analgesics and is still widely used in the NICU. Evidence suggests it may not be the best choice as it alters the developing brain (15). Fentanyl is now being used increasingly as a first-line analgesic. Its lack of cardiovascular depressive effects is instrumental in the preterm population. Its ability to produce chest-wall rigidity if given too quickly is well known, but it also has enormous patient-to-patient variability regarding elimination half-life (317 -1266 minutes c.f. 222 in the adult). Tolerance may also develop (16). In my experience, fentanyl tolerance can develop quickly in some babies. (Perhaps this is more reflective of lower half-life than tolerance.) I recall one infant under my care whose heart rate would jump when the incubator door opened even though he received fentanyl at an adult anesthetic dose. In my opinion, it is crucial to assess the effect of an analgesic, not just give it.

Recent follow-up data on premature infant exposure to fentanyl is somewhat reassuring. "Higher cumulative dose was associated with lower composite motor scores on bivariate analysis... cumulative fentanyl dose was not associated with MACB-2 (17) scores on multiple linear regression" (18). Since infants experiencing more pain are likely to receive more fentanyl, it is hard to determine which is responsible for the results.

This logic brings us to the proverbial elephant in the room: cost. The cost of a day in the NICU in the US may exceed \$3500 (all figures in 2008 dollars), and bills at discharge are routinely over \$1 million. Of the 12 most costly procedures in the US, only intestinal transplantation costs more, and barely at that (19). The smallest, most premature babies spend the most time in hospital, thus cost-

ing the most for which to provide care. While the total expenditure is a tiny percentage of the US spending on healthcare, it was about \$26 billion in 2008 (20). As resuscitation of 22-week PMA infants becomes increasingly common, are insurance companies going to balk at the cost, or worse, deny coverage?

That figure does not reflect the cost of sometimes life-long postdischarge care, and caregivers are acutely aware of what life holds for these babies and their families. However, one cannot decide what quality of life is for another person, and it is impossible not to empathise with them, even if our perception of their happiness is inaccurate. In 2021 post-discharge costs were over \$25 billion annually in the US. Those costs may relegate many to a lifetime of poverty, doubly punishing since poverty in and of itself is a risk factor for preterm birth (21). Caregivers are not unaware of the burden their patients may impose on society.

"While placing a price on human life is anathema to healthcare professionals, it is the de facto reality many face daily and one which insurance companies impose regularly. Whether this money could be better spent is a legitimate, even ethical, question."

While placing a price on human life is anathema to healthcare professionals, it is the de facto reality many face daily and one which insurance companies impose regularly. Whether this money could be better spent is a legitimate, even ethical, question. The US system is far too focused on catching the proverbial horses rather than keeping the barn door shut. This context is perhaps inevitable in a system focused on profit as the outcome. In countries with government-funded healthcare systems, the NICU is considered a "black hole" for money and must compete for resources with other programs.

That is not to say that money spent in NICU is not well spent; indeed, quite the opposite. A neonatologist I work with once told me that NICU provides greater value for money than anywhere else in the system. If that is true, preventing NICU admission must provide even more value.

The rate of preterm birth in the US in 2010 was 12 per 100 live births and 10.5 per 100 live births in 2021, a slight year-over-year increase. By comparison, even 10.5 is higher than the 2010 rates in the rest of the G-7 countries (21,22). Money spent reducing factors contributing to premature birth is not only a good investment but also morally imperative.

Moral distress is not going away, but we can choose to reduce it. I firmly believe that all life deserves a chance, but with one caveat: recognise the futility and stop. We once recognised the futility of resuscitating a 23-week PMA baby; we must now recognise that continuing treatment on a dying 22-week PMA infant is not care. It is cruelty.

Since nurses are the ones who spend the most time in direct con-

tact with babies and their families, this column has focused on the nursing profession. That is not to say other team members do not face the same moral dilemmas, perhaps most of all respiratory therapists.

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

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

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New Amsterdam and Martin Luther King-Drew Hospital

Kelly Welton, BA, RRT-NPS

I recently got sorta-kinda hooked on the Netflix show New Amsterdam.

With their technical errors and impractical equipment setups, medical shows typically make me a little nuts.

Although the series has yet to show a NICU scene (I am in season 1), and the show is technically weak, the underlying script of working in a public hospital serving all patient populations rings true.

The story reminds me very closely of the tale of Martin Luther King-Drew hospital in Los Angeles, CA.

"Closed for various reasons, I still wonder if anyone outside the medical community ever really 'got it' as to why King-Drew had so many problems. Bad nurses and RTs? Lazy staff, that took too many shortcuts? Poor management? I do not believe it was any of these things."

Closed for various reasons, I still wonder if anyone outside the medical community ever really 'got it' as to why King-Drew had so many problems. Bad nurses and RTs? Lazy staff, that took too many shortcuts? Poor management? I do not believe it was any of these things. It is reported that King/Drew failed a Federal inspection due to "serious health and safety violations and poor record of patient care."

I am no MBA but have been in healthcare in various roles for 40 years now.

If, in retrospect, we perform a modern-day 'Root Cause Analysis," we can cite 100 reasons why King-Drew had to close: wrong medications given, ED patients in the waiting room decompensating fast and not being admitted, inpatients neglected for hours – the list goes on.

But no one went deep enough into the 'roots':

Exhausted staff, overcrowded units, mistrust of hospitals and medical staff, and care costs -- moreover, the biggest question is: Why are the majority of public hospitals that serve the poor too small for the said patient population?

Back at New Amsterdam's hospital, Medical Director Max Good-

win gets himself in a pinch every episode because he puts the patients first. He is in trouble with his boss, his wife, his doctor, and with his health. All because his character has devoted his life to the patients. So Many Patients.

"Exhausted staff, overcrowded units, mistrust of hospitals and medical staff, and care costs -- moreover, the biggest question is: Why are the majority of public hospitals that serve the poor too small for the said patient population?"

Patients that needed care yesterday. Patients simply cannot be prioritized; they all need to be attended to right now. Patients that need beds, lots of beds, in a hospital only built to accommodate half as many.

I am again reminded of my NICU transport days. I went to several hospitals over the years to pick up sick babies and bring them to a higher level of care. Arriving in NICUs built to accommodate 20 babies, with 30 babies in the unit. At least with isolettes, you can move them over and make room for one more (or 10) in a crowded unit. But that practice compromises care because there are only so many oxygen, air, and electrical outlets. And ventilators. And IV machines. And RTs. and Nurses. And space for all the machines and the people who run them. The hospital likely did not budget to provide for 150% of its capacity. And that is how mistakes are made. By merely having two hands and two feet. And 12 hours.

"But that practice compromises care because there are only so many oxygen, air, and electrical outlets. And ventilators. And IV machines. And RTs. and Nurses. And space for all the machines and the people who run them. The hospital likely did not budget to provide for 150% of its capacity. And that is how mistakes are made. By merely having two hands and two feet. And 12 hours."

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But that is where we are. Patients large and small compete for beds and sometimes urgent medical attention. And supplies.

If we really drill down to the root cause, why do these patients need so much care? If we could eradicate the human destruction of other humans and the human destruction of self with drugs, food, or smoking, would that make enough room for the unfortunate sick? Or seemingly random occurrences of preterm births?

Perhaps when we get past the mechanical issues of management and budgets and focus on why these hospitals that serve the poor and undereducated public are not big enough to accommodate the said public, we can make a real impact on their care. They need a lot of care, education, direction, counseling, and an expectation of accountability.

"Perhaps when we get past the mechanical issues of management and budgets and focus on why these hospitals that serve the poor and undereducated public are not big enough to accommodate the said public, we can make a real impact on their care. They need a lot of care, education, direction, counseling, and an expectation of accountability."

I once had a job with multiple tasks competing for the number one priority for attention in a day.

Given that I am human, I could only be in one place at a time.

Fixing a non-working ABG machine in the ICU took precedence over running a STAT gas because we had 7 ABG machines in a huge hospital that all needed to be up and running at all times. Sure, I could have left the broken machine to draw the gas and run to the other side of the hospital to run it, but the priority was to have all machines working 24/7.

In the same way, three patients cannot fit into one bed. One RT or RN cannot tend to 3 critically ill babies simultaneously. One RT or RN cannot attend three crash C sections simultaneously.

The most amazing point about Martin Luther King-Drew hospital was this:

"When plans emerged to close King-Drew, a public hearing at an auditorium across from the hospital prompted a spirited, daylong protest by well over 1,000 people, who gathered to send a powerful message to the Los Angeles County Board of Supervisors. They would rather have a lousy hospital than no hospital."

Were they really guilty of neglecting patients? Or: simply not being able to handle the impossible?

When plans emerged to close King-Drew, a public hearing at an auditorium across from the hospital prompted a spirited, daylong protest by well over 1,000 people, who gathered to send a powerful message to the Los Angeles County Board of Supervisors. They would rather have a lousy hospital than no hospital.

References:

. New Amsterdam is an American medical drama television series based on the book <u>Twelve Patients: Life and Death</u> at Bellevue Hospital by author Eric Manheimer.

Disclosures: The author is President of the Academy of Neonatal Care, A Delaware 501 C (3) not for profit corporation.

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NPA's statement: BLACK LIVES MATTER



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Jonathan R. Swanson, MD, MSc

Associate Professor of Pediatrics University of Virginia Children's Hospital Charlottesville VA



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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

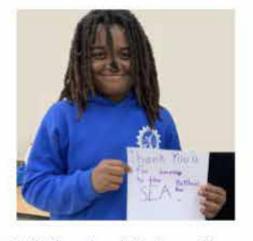


Each year, the Emily Shane Foundation SEA(Successful Educational Achievement)
Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring 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 <u>emilyshane.org</u>

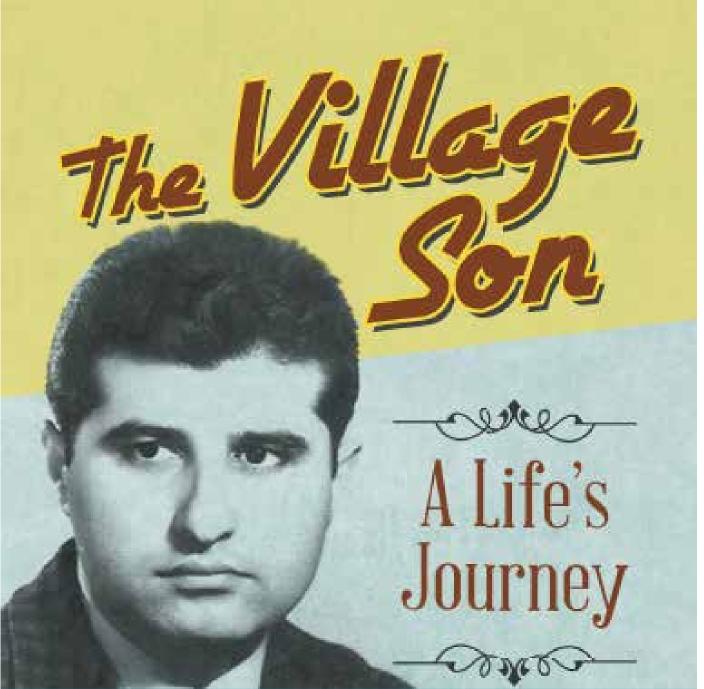
Sponsor a Child in the SEA Program

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

he Emily Shane Foundation is a 501(c)3 nonprofit charity, Tax id # 27-3789582. Our flagship SEA (Successful Educational Achievement) rogram 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.



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

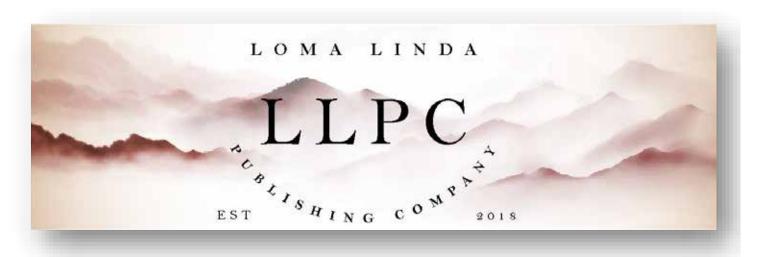
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Straight Talk for Infant
Safe Sleep program to
your hospital so that
everyone is up to date
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- Caregivers Need Care Too

Finding the Way Forward to Improved Infant Product Safety

Alison Jacobson



Saving babies. Supporting families.

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

"Last month's International Consumer Product Health and Safety Organization (ICPHSO) annual conference brought up an issue that has a direct bearing on infant health and is one that our organization is aware of as it works to end sleep-related infant death."

Last month's International Consumer Product Health and Safety Organization (ICPHSO) annual conference brought up an issue that has a direct bearing on infant health and is one that our organization is aware of as it works to end sleep-related infant death.

ICPHSO members represent U.S. and global government agen-

cies, manufacturers, importers, retailers, trade associations, certification/testing laboratories, law firms, consultants, academia, health educators, standards writing organizations, media, consumer advocacy groups, and others involved in the consumer product safety community. Members meet annually to exchange ideas, share information, and address health and safety concerns affecting all consumers.

"This panel discussion included manufacturers, advocates, and the U.S. Consumer Product Safety Commission (CPSC). The discussions focused on how to improve collaboration among the various constituents, what other players need to be involved, and current obstacles to collaboration and how they can be eliminated."

I was particularly interested in Enhancing Safety Through Collaboration and Communication. This panel discussion included manufacturers, advocates, and the U.S. Consumer Product Safety Commission (CPSC). The discussions focused on how to improve collaboration among the various constituents, what other players need to be involved, and current obstacles to collaboration and how they can be eliminated.

As a key player in efforts to align various stakeholders toward reducing rates of Sudden Unexpected Infant Death (SUID), First Candle has been engaged in dialogue with regulators and juvenile product manufacturers. What we have seen, and what was pointed out by the panel, is that trust and transparency seem to be missing between these two groups.

The CPSC works to reduce the risk of injuries and deaths from consumer products by developing voluntary standards with industry; issuing and enforcing mandatory standards; banning consumer products if no standard would adequately protect the public;



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

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org informing and educating consumers through media, state and local governments and private organizations; and by responding to consumer inquiries.

"Manufacturers share the same goal of creating safe products that support parents' needs in caring for their babies. Advocates and non-profit organizations also play a key role, bringing the voice of parents and consumers to the table."

Manufacturers share the same goal of creating safe products that support parents' needs in caring for their babies. Advocates and non-profit organizations also play a key role, bringing the voice of parents and consumers to the table. Many times these parents have lost a baby to a tragedy associated with a product.

While all three constituencies want the same goal – safe products for infants – the mistrust between them hinders progress. Manufacturers, in some cases, have been cast as the bad guy by advocates and regulators, and manufacturers believe regulators are not being transparent regarding sharing data on research and incidents.

"However, the voice missing from the conversation is that of the public health professionals and community organizations who regularly engage with families. For this reason, we are continuing to expand our Let's Talk Community Chats, a program that allows us to hear from these groups."

However, the voice missing from the conversation is that of the public health professionals and community organizations who regularly engage with families. For this reason, we are continuing to expand our <u>Let's Talk Community Chats</u>, a program that allows us to hear from these groups. (1)

We believe these components need to work together:

- Manufacturers and advocates can reach families, informing them on the proper use of products.
- Regulators have the data to help manufacturers continue to innovate and create even safer products.
- Community organizations are the on-the-ground conduits to receiving and delivering messages and meeting families where they are located.

I was encouraged that this panel happened. We will only move the needle in reducing the SUID rates by providing families with safe

products that help them create a safe sleep environment. This requires a unified effort by all stakeholders, who can and should work together to make this happen.

References:

1. https://firstcandle.org/lets-talk-community-chats/

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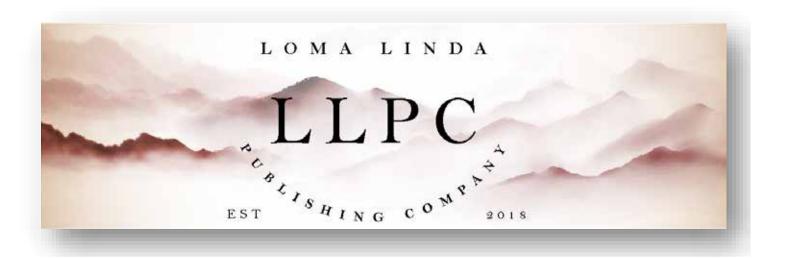
As we indicated last month, we look forward to a number of new features as well.

- 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.
- 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
- 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.

If there are any questions about the new website, please email Dr. Chou directly at:

fu-sheng.chou@neonatologytoday.net



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

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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



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 in

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.



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.



Support families and NICU staff as they grieve. Stay current with best practices in pallitative 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.

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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



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



PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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





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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.

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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 upto-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.





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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.





A Global Mortality Database for Children with RSV Infection



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 <u>emilyshane.org</u>

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.

National Perinatal Association Incoming President Chavis Patterson

Chavis A. Patterson, PhD

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.



Educate. Advocate. Integrate.

"I am honored to serve as President-Elect of the National Perinatal Association. I look forward to continuing the work of Drs. Viveka Prakash-Zawisza and Jerry Ballas as NPA continues to grow and evolve"

I am honored to serve as President-Elect of the National Perinatal Association. I look forward to continuing the work of Drs. Viveka Prakash-Zawisza and Jerry Ballas as NPA continues to grow and evolve.

A little about me: I am a licensed Clini-

cal Psychologist whose work focuses on stressors that put children, couples, and families at risk for future difficulties. I received my master's and doctoral degrees from the American University in Washington D.C. and completed my internship at the Philadelphia Child Guidance Center. I have worked with families and their adolescent children at Temple University's Center for Research on Adolescent Drug Abuse, Congreso de Latinos Unidos, and the NorthEast Treatment Centers in Philadelphia. I have conducted parenting classes and presented nationally and internationally on topics such as family and parental relationships, coping with a chronic illness, and non-medical alternatives to pain management. I have also provided psychosocial training for staff caring for children with chronic illnesses.

"I have conducted parenting classes and presented nationally and internationally on topics such as family and parental relationships, coping with a chronic illness, and non-medical alternatives to pain management."

I am the Director of Psychosocial Services of the Newborn / Infant Intensive Care Unit (N/IICU) at the Children's Hospital of Philadelphia (CHOP). I am responsible for overseeing the provision of expert psychosocial care to the families as they cope with the complexities of having a child in a Neonatal Intensive Care Unit (NICU). Partnering with the interdisciplinary team, I am an administrative leader, educator, and researcher. With a courtesy faculty appointment at Drexel University, I collaborate on research projects relevant to parental mental health and functioning, as well as NICU staff support and provide mentor-

ship to graduate students in psychology. I am also an Associate Professor in the Department of Psychiatry at the University of Pennsylvania School of Medicine. In this role, I supervise students and fellows entering the neonatology arena as part of a psychosocial services team.

"When I began my career in NICU psychology in 2010, I had the pleasure of meeting some of the pioneers in the NICU world. I met with Drs. Heidi Als and Gretchen Lawhone to learn about their work in NICUs with NIDCAP (the Newborn Individualized Developmental Care and Assessment Program)."

When I began my career in NICU psychology in 2010, I had the pleasure of meeting some of the pioneers in the NICU world. I met with Drs. Heidi Als and Gretchen Lawhone to learn about their work in NICUs with NIDCAP (the Newborn Individualized Developmental Care and Assessment Program). I also had the pleasure of meeting Dr. Mike Hynan. Dr. Hynan introduced me to the National Perinatal Association and discussed his desire to explore psychosocial support in NICUs nationwide. In 2011, he gathered a few psychologists associated with NICUs, and we began to have monthly calls to share our work experience and ideas. As a result of those early calls and with the support of Dr. Hynan, Drs. Steve Lassen, Carrie Piazza-Waggoner, Pam Geller, and I organized the beginnings of what has now grown into the National Network of Neonatal Psychologists (NNNP) and the Neonatology Special Interest Group in Division 54 of the American Psychological Association. I was also fortunate to be invited by Dr. Hynan and Dr. Sue Hall to participate in creating the Interdisciplinary Recommendations for the Psychosocial Support of NICU Parents published in the *Journal of Perinatology*.

I look forward to continuing to partner with NNNP and the Neonatology SIG (recently renamed the Young Pediatrics SIG) to increase awareness and extend the work of psychologists in NICUs.

"In addition to my role in the N/IICU at CHOP, I serve on the Department of Pediatrics Diversity Council and Diversity Fellowship Committee at CHOP. I am a member of the North American Society of Psychosocial Obstetrics and Gynecology, the Marcé Society of North America, the Society of Pediatric Psychology, and the Association of Black Psychologists, Delaware Valley Chapter."

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In the past, I have served as the Director of Programs and conference co-chair for NPA. I was a board member for Dragonfly Forest, an overnight camp for children with life-threatening illnesses, and Graham's Foundation, an organization offering support, advocacy, and research to improve outcomes for preemies and their families. I am also a past president and board member of the Association of Black Psychologists, Delaware Valley Chapter.

"I look forward to using my past experiences and current associations to assist in the growth of our organization, helping to raise the visibility of critical issues in the field of perinatal care and continuing to contribute to developing standards of care and best practices to inform the field."

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

NT

Corresponding Author



Chavis A. Patterson, Ph.D. Assistant Professor of Clinical Psychiatry Children's Hospital of Philadelphia Division of Neonatology, 2 Main, Room 2NW59A 3401 Civic Center Boulevard Philadelphia, PA 19104

Email: PattersonC1@email.chop.edu

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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.

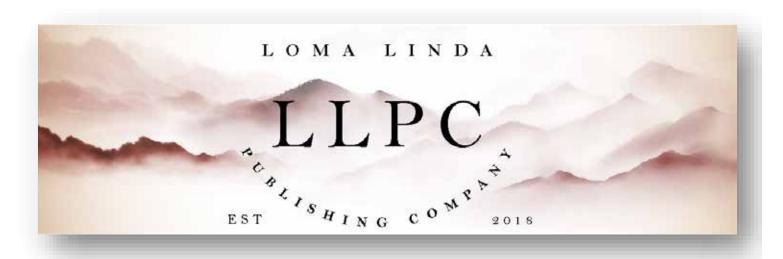


Babies older than 6 months can get a flu shot and COVID-19 vaccinations. There is no vaccine for RSV, but monthly antibody shots during RSV season can help protect them.



WE CAN HELP PROTECT EACH OTHER.

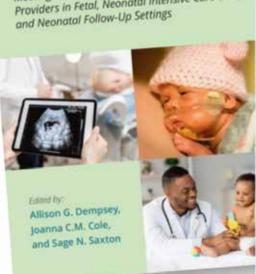






Education, Resources, and Support for Perinatal Mental Health Professionals

Behavioral Health
Services with High-Risk
Infants & Families
Meeting the Needs of Patients, Families, and
Providers in Fetal, Neonatal Intensive Care Unit,
and Neonatal Follow-Up Settings



We are pleased to announce the Publication of this NEW Essential Resource

Behavioral Health Services with High-Risk Infants and Families

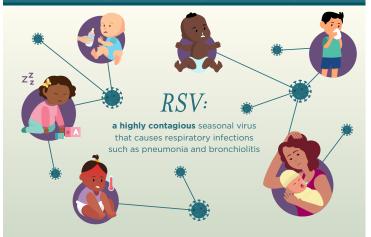
Meeting the Needs of Patients, Families, and Providers in Fetal, Neonatal Intensive Care Unit, and Neonatal Follow-Up Settings

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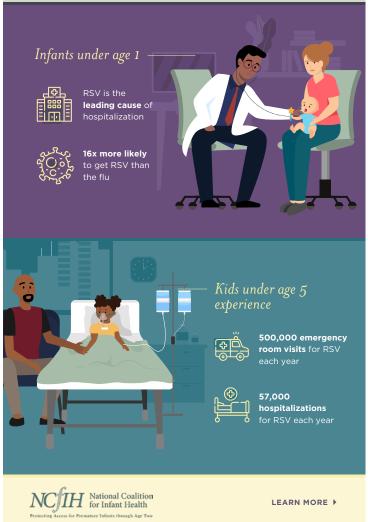
NATIONALPERINATAL.ORG/PSYCHOLOGISTS

Respiratory Syncytial Virus



The Gap Baby: An RSV Story







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Family Centered Care Taskforce: Using Technology to Improve Discharge Preparation and NICU Parent Satisfaction

Malathi Balasundaram, MD

The Family-Centered Care Taskforce offers educational webinars every other month focusing on integrating NICU families into their infant's care. The March webinar focused on improving home transition and discharge education. To strengthen FCC in your NICU, join the listserv by scanning the QR code or clicking here. Visit our website to view previous webinar recordings and resources.



Readiness for discharge from a neonatal intensive care unit (NICU) requires both the clinical stability of the infant and the parental ability to care for the infant at home. After days, weeks, or months in the NICU with full-time support from NICU staff, families can feel overwhelmed by the amount of education needed for discharge and often express distress about their ability to assume total care of their infant. Families feeling inadequately prepared for discharge with their high-risk infant contributes to poor infant outcomes, heightened family anxiety, and increased healthcare utilization after discharge. Quality of discharge teaching has proved to be the strongest predictor of discharge readiness.

"High-risk infants hospitalized in the NICU often receive life-saving interventions during a critical development period when their brain is susceptible to positive and negative environmental factors. This time is particularly challenging for families."

We implemented a discharge education improvement process as a part of a family-centered care program (FCCP) quality improvement work in 2017 at El Camino Health (ECH) NICU. ECH is a not-for-profit acute care hospital in Santa Clara County, California. The 20-bed, community-level 3 NICU has approximately 4200 newborn deliveries and 450 NICU admissions per year. The ECH NICU can care for infants from 23 weeks gestational age (GA) and those infants with severe or complex illnesses.

We aimed to improve the % of parents who selected "prepared for discharge," top box score (a response that reflects the highest possible rating, from a baseline of 47% in 2017. We used technology to improve the consistency of discharge teaching, starting on admission rather than waiting until the last few days of hospitalization. Our ECH FCCP formed a Comprehensive Discharge Teaching Taskforce (CDTT) to explore ways to improve our discharge process and increase parental feelings of preparedness and satisfaction. The CDTT comprised neonatologists, nurses, unit administrative support, the NICU clinical nurse specialist, the NICU nurse manager, and members of our family advisory board (FAB).

"Our ECH FCCP formed a Comprehensive Discharge Teaching Taskforce (CDTT) to explore ways to improve our discharge process and increase parental feelings of preparedness and satisfaction. The CDTT comprised neonatologists, nurses, unit administrative support, the NICU clinical nurse specialist, the NICU nurse manager, and members of our family advisory board (FAB)."

Intervention 1: e-Book Discharge Education

Our initial process improvement was to move all education content to an electronic format for parents. In 2017, the CDTT wrote unit-specific education topics and created videos of staff demonstrating hands-on skills such as mixing formulas, medication administration, and bulb suction use. We converted the educational content into an e-book via the iBooks Author application (iBooks is a registered trademark of Apple Inc, Cupertino, California). The e-book had an easy-to-navigate table of contents and options to bookmark topics parents needed to review. The e-book was uploaded onto three tablets donated by former NICU parents. Parents could use our tablets during their time in the NICU to review the discharge education content in the e-book at their own pace.

CDTT developed a paper discharge teaching checklist to match the education content in the e-book and electronic health record (EHR) (figure1). Upon NICU admission, the checklist was placed at the bedside. We did not include hospital readmissions or shortstay babies as the discharge education content was deemed too

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

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extensive for parental review during a short NICU stay. This initial process was developed to provide consistent educational material, allow families to review information conveniently, and start education earlier in their NICU stay.

Intervention 2: e-Book Improvements

Based on qualitative feedback from nurses during the intervention, we recognized that readmitted families often needed consistent and in-depth discharge teaching due to truncated, rushed discharge preparation during their birth admission. We also found that nurses primarily focused on breastfeeding education with short-stay infants, so other education topics should have been included or done at the last minute. Therefore, during intervention 2, we included readmitted infants and infants with a length of stay of less than 48 hours, placing a paper discharge checklist at their bedside and encouraging parents to review the e-book discharge education. In addition, to facilitate ease of access to discharge education, we published the content on the hospital website for parents to access from home even after discharge. Staff and phy-

sicians provided the website link to parents in written discharge instructions.

"Based on qualitative feedback from nurses during the intervention, we recognized that readmitted families often needed consistent and in-depth discharge teaching due to truncated, rushed discharge preparation during their birth admission."

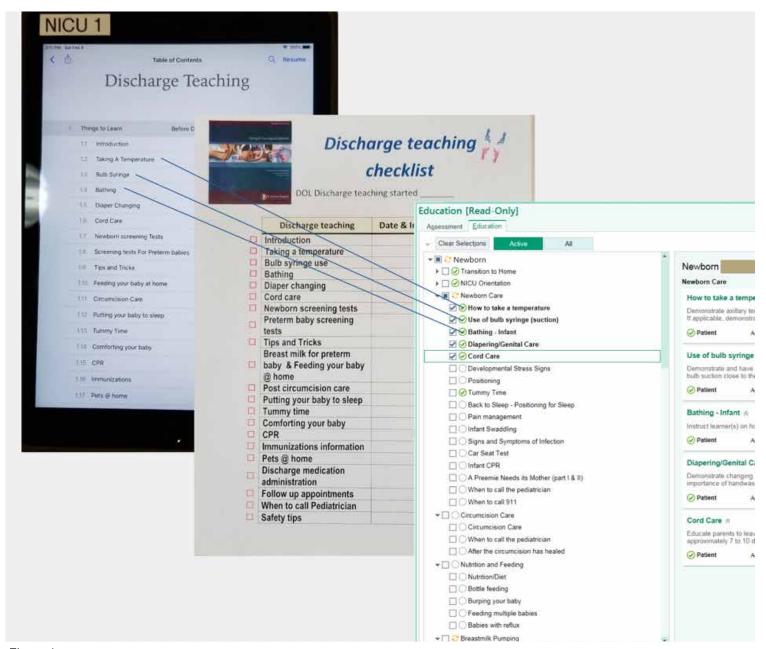


Figure 1:

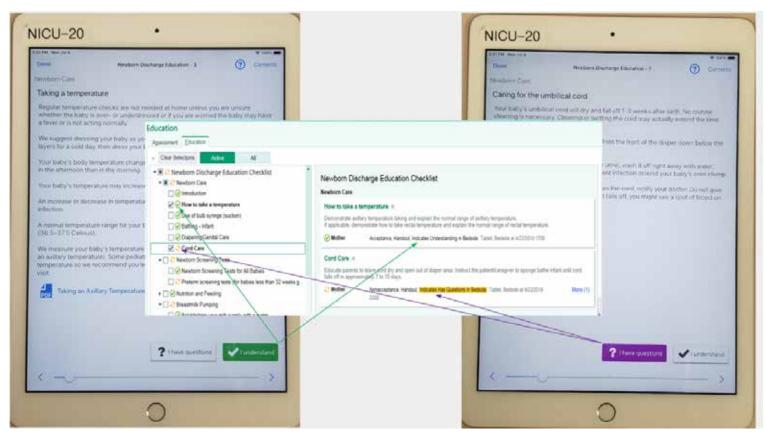


Figure 2:

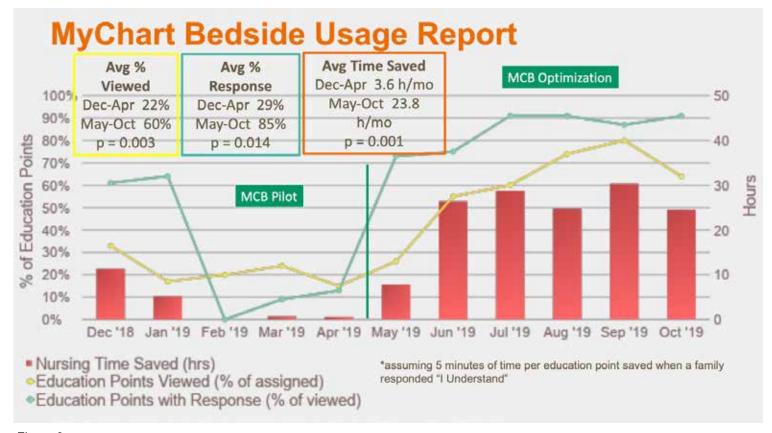
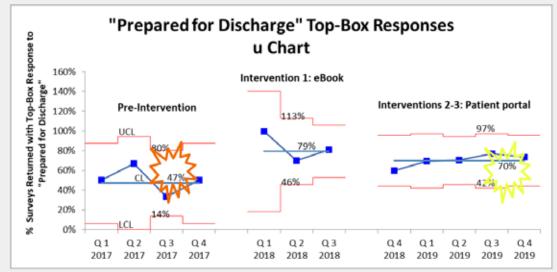


Figure 3:

Post Discharge Survey: "Prepared for Discharge"

Relative 50% improvement!



Top box analysis (percentage of responses that reflect the highest possible rating) of parent responses to patient satisfaction survey question regarding preparation for discharge from NICU

Figure 1: Intervention 3: Integration of the e-Book into the EHR Patient Portal

In November 2018, the ECH NICU was chosen as a pilot unit for our hospital's MyChart Bedside implementation, which gave us an unexpected opportunity to further expand our QI work by transferring our e-book to the inpatient portal. Our EHR, Epic Systems Corporation (Verona, Wisconsin), has education modules built into both the inpatient portal (MyChart Bedside) and an outpatient portal (MyChart). MyChart Bedside (MCB) allows patients to view parts of their EHR online during an inpatient hospitalization. Once MCB was launched, IT provided 20 iPads (one for each bed). Parents could also use their devices from home and scan the QR code from EPIC for full access. In addition to reviewing education, NICU families could view their infants' vital signs, medications, laboratory results, and treatment teams in MCB.

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Intervention 4: Optimization of My Chart Bedside

In previous interventions, nurses manually assigned the discharge education in EHR, which was found to be inefficient. With the help

of an EPIC physician builder and IT analyst, we automated the assignment process using Best Practice Advisory (BPA). Parents reviewed the information on the iPad on their own time and checked a box to indicate whether they "understood" or "had questions." These indications flowed directly into the EHR so nurses could see them (Figure 2). Nurses reviewed this information regularly and encouraged parents to complete their education. In this intervention, we also translated the materials into Spanish and ensured parents received the appropriate language education materials.

Intervention 5: Families and Nurses' Response

We reached out to 159 families through our post-discharge follow-up phone calls. 92% of the families liked this education system; comments included: "it was very informative, simple, smooth, easy to follow," "I enjoyed the streamlined discharge process," and "it was a good refresher for experienced families." Nurses shared that the training and education on MCB improved the workflow for families on the day of discharge and made teaching easier for parents as they had seen content previously and could ask better-informed questions. Nurses also liked the consistency of teaching content and how easy it was to keep track.

Results:

We improved the percentage of families engaging with discharge educational materials in MCB from 29% during intervention 3 to 85% during the optimization phase. Assuming 5 minutes of nursing time per education point saved when a family responded, "I understand," we saved an average of 24 hrs/month of nursing time during intervention 4 (Figure 3). While this program is not designed to replace bedside teaching, allowing families to explore content beforehand reduces confusion and ensures that time spent with the family is individualized to their needs and questions. We also improved the % of parents who selected "prepared for discharge," Top box score (a response that reflects the highest

possible rating), from 42 % in 2017 to 70% in 2019 (Figure 4) and, not shown, further enhanced the % to 78% in 2022.

Discussion:

Families received consistent information that began early in their NICU stay, indicated they felt better prepared for discharge, and had the opportunity to ask questions. Nurses saved time and felt that families were more consistently provided with the right tools to transition home successfully. The FCC team created a yearly refresher orientation checklist and continues to provide one on one orientation to new staff and rotating trainees. Additionally, the program content is easy to update based on feedback/changes in the unit as needed. While implementing this project, we encountered a few challenges: physicians' time commitment in writing the eBook, formatting, uploading, and building EHR best practice advisory, and IT concerns about losing iPads.

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Conclusion:

Our goal is for families to feel well supported during their NICU journey and to better prepare them for discharge by delivering clear, concise, and consistent information. We recognize the importance of discharge readiness and guiding families through discharge preparation, starting at the time of NICU admission. We have learned much about using technology to support families and enhance discharge education. We anticipate more NICUs creating multidisciplinary teams and using patient portals for family education.

Acknowledgments:

Dr. Kari McCallie (EPIC Physician Builder), ECH FCC Team, ECH NICU staff. ECH IT Department, ECH Marketing Department, Stanford ECH Neonatologists. ECH NICU Family Advisory Board (now called Family Partnership Council). Caroline Toney-Noland for reviewing this article. You can review our detailed original publication at https://pubmed.ncbi.nlm.nih.gov/33534225/.

Disclosures: No conflicts have been identified.

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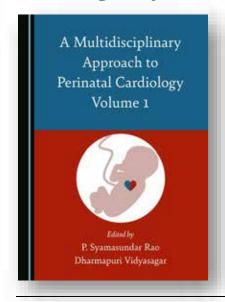
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A Multidisciplinary Approach to Perinatal Cardiology *Volume 1*

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.

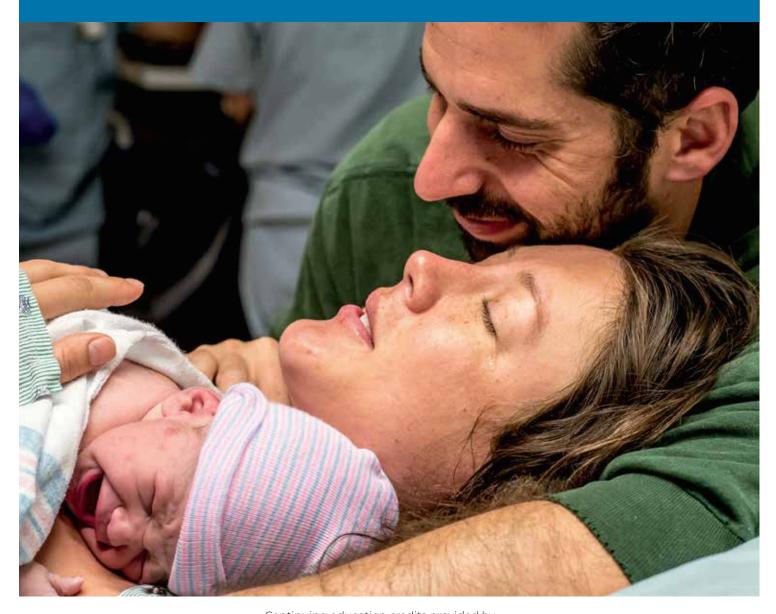


Online L&D Staff Education Program

Caring for Pregnant Patients & Their Families:

Providing Psychosocial Support During Pregnancy, Labor and Delivery

WWW.MYPERINATALNETWORK.ORG





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

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Former NICU and Developmental psychologist, in memoriam.

Karen Saxer, CNM, MSN

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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.

Follow us online at @MyNICUNetwork





SHARED DECISION-MAKING 'PROTECTS MOTHERS + INFANTS

DURING COVID-19



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
F 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.





Coping COVID-19





A viral pandemic

A racial pandemic within a viral pandemic









Will mental illness be the next inevitable pandemic?

WWW.MYNICUNETWORK.ORG



National Network of NICU Psychologists

FREE for our NICU COMMUNITY

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







Download at www.nationalperinatal.org/psychologists

newly validated

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

7- Module Online Course in NICU Staff Education



National Perinatal Association PERINATAL SUBSTANCE USE

nationalperinatal.org/position www.nationalperinatal.org/Substance_Use



Why do women wait?

The threats of discrimination, incarceration, loss of parental rights, and loss of personal autonomy are powerful deterrents to seeking appropriate perinatal care.

Educate. Advocate. Integrate.

Readers can also follow

NEONATOLOGY

via our Twitter Feed

@NEOTODAY





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

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

FDA Grants Priority Review to Drug for Depressive Disorders

Michelle Winokur, DrPH

The Alliance for Patient Access, 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 policyminded 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 di[1]rectors. Its physician leadership is supported by policy advocacy management and public affairs consultants.

In 2012, AfPA established the Institute for Patient Access, a related 501(c)(3) non-profit corporation. The Institute for Patient Access is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. In furtherance of its mission, IfPA produces educational materials and programming designed to promote informed discussion about patient access to approved therapies and appropriate clinical care.

Visit allianceforpatientaccess.org and instituteforpatientaccess.org to learn more about each organization.





"The bleakness and challenges associated with depression are long-standing problems newly complicated by the pandemic."

The bleakness and challenges associated with depression are long-standing problems newly complicated by the pandemic.

However, doctors and hospitals currently overwhelmed by those seeking help might soon have a new tool to support people experiencing major depressive disorder and new mothers experiencing postpartum depression.

"The FDA recently granted zuranolone priority review. The status is reserved for medicines that, if approved, would significantly improve the effectiveness of treatment, diagnosis, or prevention of a serious condition."

Two-Week Treatment

The FDA recently granted <u>zuranolone</u> priority review. The status is reserved for medicines that, if approved, would significantly improve the effectiveness of treatment, diagnosis, or prevention of a serious condition. Under the priority review system, the FDA is scheduled to act on the application for this drug in early August. (1)

Zuranolone is being evaluated as a rapid-acting, 14-day oral treatment for adults with postpartum depression or major depressive disorder. Its reported ability to relieve symptoms in two weeks makes it a potentially game-changing option, as current medications can take several months to show results.

The drug itself is a neuroactive steroid. In people with depression, it works by rebalancing deregulated neuronal networks to help reset brain function. Zuranolone targets brain networks responsible for mood, arousal, behavior, and cognition, among other functions.

"While there is a wide variety of depression treatments available, most clinicians are welcoming of new treatment options. Different mental health patients with the same diagnosis frequently do not respond well to the same medications."

While there is a wide variety of depression treatments available, most clinicians are welcoming of new <u>treatment options</u>. Different mental health patients with the same diagnosis frequently do not respond well to the same medications. (2)

An Increasing Burden

Rates of depressive disorders tripled early in the pandemic and continue to rise. It is estimated that 21 million adults in America experienced at least one major depressive episode in 2020, with nearly 14 million diagnosed with major depressive disorder.

Moreover, as many as one in seven new mothers in the U.S. experiences postpartum depression, totaling more than half a million

cases annually. Like the country's maternal mortality and infant death rates, the condition disproportionately affects women of color. Postpartum depression adds stress to women's – and whole families' – lives at a time that is already stressful. In severe cases, it can leave mothers unable to care for themselves, their new babies, or their families.

"Postpartum depression adds stress to women's – and whole families' – lives at a time that is already stressful. In severe cases, it can leave mothers unable to care for themselves, their new babies, or their families."

The impact of both conditions makes a strong case for expanding treatment options. Hopefully, zuranolone will be a step in that direction.

References:

- https://investor.sagerx.com/news-releases/news-releasedetails/sage-therapeutics-and-biogen-announce-fda-accepts-filing-new
- 2. https://healthpolicytoday.org/2022/08/10/open-to-new-options-for-treating-depression/

Michelle Winokur, DrPH, is the Executive Director of the Institute for Patient Access. This article was also published at healthpolicytoday.org.

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Corresponding Author

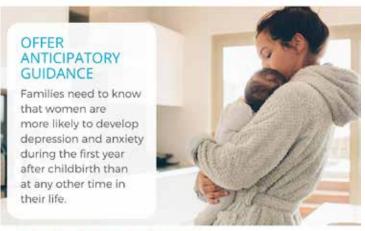


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National Perinatal Association PERINATAL MENTAL HEALTH

nationalperinatal.org/position www.nationalperinatal.org/mental_health



Educate. Advocate. Integrate.





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

www.99nicu.org

Immunizing Yourself Against COVID-19

COVID-19 vaccines have been shown to:

- Lessen the severity of symptoms¹
- Reduce disease transmission³
- Reduce risk of mortality²
- Make communities healthier and safer⁴



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.



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



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.

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

the immune system to the virus.

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 participants⁶



Proven safe and effective

for adults as well as children⁷



Vetted and approved by the US FDA and EMA and endorsed by the WHO⁸⁻¹⁰

Get Your Jab

Vaccines are available at your:



Doctor's office



Neighborhood pharmacy



Community health center

- https://www.mayoclinic.org/diseases-conditions/coronavirus/symptomscauses/syc-20479963
- 2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8782520/
- https://www.nejm.org/doi/full/10.1056/nejmc2107717
 https://royalsocietypublishing.org/doi/full/10.1098/rsif.2020.0683
- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim considerations-us.html
- considerations-us.ntml

 6. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-andeffectiveness
- https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-andaffectiveness
- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- 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
- http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/WH0-EUA-qualified-covid-vaccines.pdf



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





Save the Date! May 25, 2023

26th Annual Conference Quality of Life for Families XXVI pac-lac

Keynote Speaker: Dr. Diana Ramos California Surgeon General

Where: Hilton Los Angeles North/Glendale

100 West Glenoaks Blvd,

Glendale, CA 91202





You can attend In-Person or Hybrid





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www. Congenital Cardiology Today. com

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 alcoholbased sanitizers.

Limit Contact with Others

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



Provide Protective Immunity

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



Take Care of Yourself

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



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



WARNING

Never Put a Mask on Your Baby

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

If you are positive for COVID-19

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

We can help protect each other.

Learn more

www.nationalperinatal.org/COVID-19



The Gap Baby: An RSV Story



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



The National Coalition for Infant Health advocates for:

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

www.infanthealth.org

iCAN: Happy Spring from The International Children's Advisory Network! "Empowering Pediatric Patients Worldwide"

Abby Clark



International Children's Advisory Network

Get involved today and Join the iCAN Parent Council!

Spring has Sprung! The International Children's Advisory Network, Inc. is ushering in the warmer weather by hosting many new opportunities for those in the pediatric patient community to get involved. If you are new to iCAN, please visit our website at **www.iCAN.health** to learn more about how to get involved in our mission of making sure every child can share their voice.iCAN is looking for sponsors and donations for our 2023 Summit Presented by Jumo Health!

We will partner with our sister organization, the International Society for Pediatric Innovation (iSPI). This annual event allows our members to learn from one another's unique experiences as kids who live with chronic and/or rare conditions and network with leading healthcare professionals. In turn, the iCAN Summit affords the scientific community direct engagement with children, young adults, and families so that they may learn about the importance and value of the pediatric patient voice in research, medicine, and





Mark Your Calendars! iCAN's Annual Advocacy and Research Summit presented by Jumo Health is July 14 - 15, 2023 in San Diego, California

innovation. Registration opens soon!

Learn More:

https://www.icanresearch.org/summit

Sponsor a child to attend the iCAN Summit! A good portion of iCAN's funding goes to annually sending kids to the Summit. We have youth from around the world who would love to get to San Diego this Summer!

Learn How to Support iCAN Youth:

"Sponsor a child to attend the iCAN Summit! A good portion of iCAN's funding goes to annually sending kids to the Summit. We have youth from around the world who would love to get to San Diego this Summer!"

https://www.icanresearch.org/donate

They are an engaged group of young people interested in a medical career. They meet monthly and are provided with access to internship, speaking, and research opportunities. If you know a young person, please have them apply!

Apply Here:

https://www.icanresearch.org/councils-committees





Help Support a Child \$1,000

Help Our Youth Share Their Story

Did you know that iCAN has a Young Adult Professionals Program?

Do you have internships or additional engagement opportunities? Our YAP program is full of bright, unique individuals who often have personal experiences with chronic or rare conditions. We are happy to post those opportunities on our website and send them to our vast network.

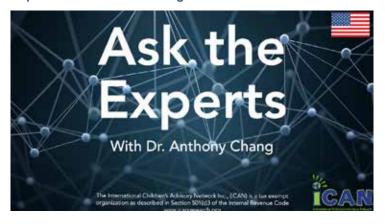
Please contact iCAN at abbyclark@icanresearch.org for more information.

"iCAN's Parent Council is recruiting members to join. The iCAN Parent Council is an engaged group of parents and caregivers dedicated to supporting youth initiatives throughout iCAN."

iCAN's Parent Council is recruiting members to join. The iCAN Parent Council is an engaged group of parents and caregivers dedicated to supporting youth initiatives throughout iCAN. A member of the Parent Council does not have to have a child who is an iCAN Youth Member. This group is for all!

Join Here:

https://www.icanresearch.org/councils-committees



Do not miss iCAN's next session of *Ask the Experts*! Mark your calendar for April 15, 2023, at 10:00 a.m.EST. All are welcome to attend, and kids of all ages are invited to join. We welcome all doctors, researchers, and community leaders to join us. We are always looking for experts to speak to our kids, so if you are interested, please email iCAN! To join this fun and free event.

Please register:

www.icanresearch.org/events.



If you want to create a project or initiate a new chapter, please contact Abby Clark at abbyclark@icanresearch.org to start to-day. It is FREE to start a Chapter. To learn more,

Check Out

https://www.icanresearch.org/chapters.

Disclosure: The author has no conflicts of interests to disclose.

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NEONATOLOGY TODAY

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to be held July 10-14th in Southern California







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Join Us In-Person for 2023

Kids - Make Your Summer Count!

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







SHARED DECISION-MAKING **PROTECTS**

MOTHERS + INFANTS

DURING COVID-19

KEEPING **MOTHERS** + INFANTS TOGETHER



Means balancing...



EVIDENCE

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

PARTNERSHIP

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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

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





www.perinatalharmreduction.org | www.nationalperinatal.org

Education. Anytime, Anywhere.

Academy of Neonatal Care



The Academy of Neonatal Care serves to educate Respiratory Therapists, Nurses, and Doctors in current and best practices in Neonatal ICU care. We prepare RTs 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

www.AcademyofNeonatalCare.org.

something for you at:

Keeping Your Baby Safe



from respiratory infections

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

WARNING

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



COVID-19

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



PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis

RSV



WASH YOUR HANDS

often with soap and warm water.

GET VACCINATED

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





COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.

USE AN ALCOHOL-BASED HAND SANITIZER.





STAY AWAY FROM SICK PEOPLE

Avoid crowds. Protect vulnerable babies and children.



www.nationalperinatal.org

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





nationalperinatal.org/psychologists

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

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



Identify babies at greatest risk



including those with CLD, BPD, CF, and heart conditions Teach families how to protect



their babies from respiratory infections

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



Use your best clinical judgement



when prescribing RSV prophylaxis

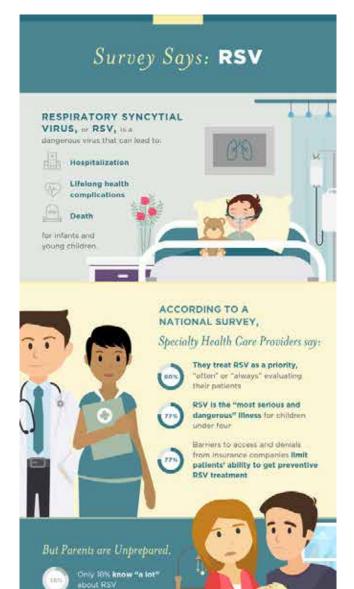
Tell insurers what families need



and provide the supporting evidence



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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

65% "More c. child co

themselves "very well" prepared to prevent RSV

"More concerned" about their child contracting the disease

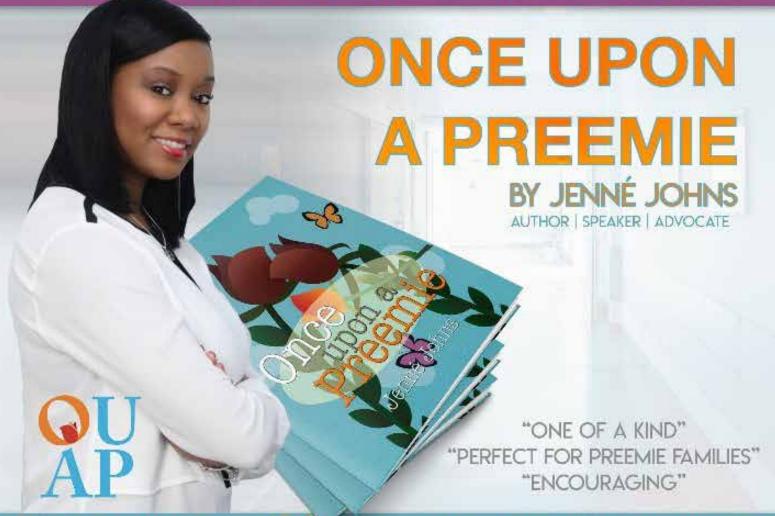
Likely to ask their doctor about RSV



NCIH National Coolinion
For Infant Health

Learn More about REV at www.infantHealth.org/RSV

PREEMIE BOOK ON SALE



MONCEUPONAPREEMIE



EMAIL: HI@ONCEUPONAPREEMIE

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

SPEAKING ENGAGEMENTS

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





MEDIA APPEARANCES



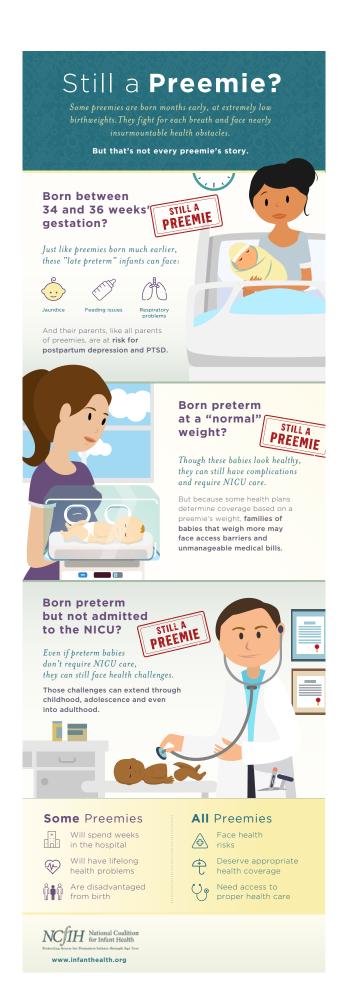












OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS



I am not an addict.

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



I was exposed to opioids.

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



NAS is a temporary and treatable condition.

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



My mother may have a SUD.

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



I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you

invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as



well as any of my peers!

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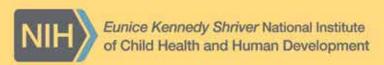
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Medical News, Products & Information

Compiled and Reviewed by Saba Saleem, BS, OMS 4

Oral Azithromycin During Labor Fails to Stop Neonatal Sepsis, Death — Some secondary benefits seen in West African trial, however

March 7, 2023

Giving azithromycin to mothers during labor did not reduce the incidence of neonatal sepsis or mortality, a randomized trial conducted in Gambia and Burkina Faso found.

Of nearly 12,000 live births in the two West African nations, the primary outcome of neonatal sepsis or mortality at 28 days was a similar 2.0% with intrapartum oral azithromycin and 1.9% with placebo (OR 1.06, 95% CI 0.80-1.38, *P*=0.70), Anna Roca, PhD, of MRC Unit The Gambia at the London School of Hygiene & Tropical Medicine in Fajara, Gambia, and colleagues reported.

Evaluated separately, the rates of neonatal mortality and sepsis were identical in the two study groups, at 0.8% and 1.3%, respectively, according to the findings in *JAMA*.

Fewer cases of culture-confirmed sepsis were identified among newborns in the azithromycin group (13 vs 24 in the placebo group), though this difference was not significant. Gram-positive *Staphylococcus aureus* was the most commonly isolated bacterium (two cases in the azithromycin group and six in the placebo group), while gram-negative bacteria made up 59.5% of the confirmed cases.

"It is unclear why the effect of intrapartum azithromycin on *S. aureus* carriage and noninvasive disease did not translate into a reduction in neonatal sepsis or neonatal mortality,» Roca and co-authors wrote.

"It may be that sepsis and bacteriologically confirmed sepsis are caused by different pathogens, with gram-negative bacteria, viruses, and/or fungus being more prevalent causes of clinical sepsis," they continued. "An alternative explanation is that a decrease in sepsis caused by some etiologies is balanced by an increase in other etiologies."

Among secondary outcomes in the newborns, the azithromycin group had a significantly lower incidence of clinical skin infections (0.8% vs 1.7% in the placebo group) and less use of antibiotics (6.2% vs 7.8%, *P*<0.001 for both), as well as a significantly lower odds of any infection (3% vs 4.4%).

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In mothers, the azithromycin-treated group experienced a lower incidence of mastitis (0.3% vs 0.5% in the placebo group) and puerperal fever (0.1% vs 0.3%, *P*=0.04 for both), results "consistent with a <u>trial of azithromycin in cesarean deliveries</u> conducted in the U.S. that found that azithromycin reduced severe maternal infections by half," the authors noted.

Mothers in the current study (<u>PregnAnZI-2</u>) also experienced a significantly lower odds of any infection with the broad-spectrum macrolide (0.4% vs 0.7% with placebo).

"Early evaluations of mass drug administration campaigns to control trachoma in sub-Saharan Africa suggested that azithromycin reduced carriage of bacteria other than Chlamydia trachomatis and significantly reduced childhood mortality," wrote Roca and colleagues in their introduction.

"A subsequent large-scale cluster-randomized trial in sub-Saharan Africa found that mass azithromycin administration reduced mortality in children younger than 5 years, with a stronger effect in infants younger than 6 months," the team continued. «A recent proof-of-concept trial found that oral azithromycin administered during labor reduced carriage of gram-positive bacteria during the subsequent 4 weeks, and a post hoc analysis found reduced mild to moderate disease in both birthing parents and newborns."

More recently, the randomized A-PLUS trial -- conducted in low- and middle-income countries across Asia, Africa, and Latin America -- showed that a single dose of azithromycin given to mothers during vaginal birth significantly reduced the risk for maternal sepsis or death versus placebo (1.6% vs 2.4%). However, the intervention made no difference on the incidence of stillbirth or neonatal death or sepsis.

"Mortality in the neonatal period remains a stubborn problem," wrote Stephanie Schrag, DPhil, of the CDC, and Cynthia Whitney, MD, MPH, of Emory University, both in Atlanta, in an accompanying editorial. "Evidence suggests complications of labor and delivery play a major role in deaths in the first hours after birth, and that preterm delivery and infections also each cause approximately one-third of deaths in the first week of life."

In the current trial, other factors besides sepsis may have affected the mortality rates, they noted. "Deaths were attributed to delivery complications (birth asphyxia) in both sites, and sudden death and aspiration were commonly cited as causes of death in The Gambia."





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Despite any benefit the antibiotic might have provided for some secondary endpoints, Schrag and Whitney warned that antibiotic intervention should be approached with "caution," as they "can lead to serious adverse events, such as prolongation of the cardiac QT interval and sudden death reported among a subset of susceptible persons taking azithromycin."

Moreover, antibiotic resistance and growing evidence that antibiotics may disrupt the maternal and newborn microbiome must also be considered. Thus, although the current trial results are "discouraging," said Schrag and Whitney, several other ongoing efforts hold promise to move the field forward.

From October 2017 to May 2021, PregnAnZI-2 randomized 11,983 pregnancies in Gambia (55%) and Burkina Faso (45%) in a 1:1 ratio to the intervention or placebo.

Overall, 11,783 live births met criteria for the primary analysis (neonatal deaths due to asphyxia, low birth weight, and severe congenital malformations were excluded).

Of the 5,889 in the azithromycin group, the combined primary endpoint occurred in 115 newborns, with 79 cases of sepsis and 47 deaths. Of the 5,984 live births in the placebo group, a primary endpoint event occurred in 111 newborns, with 78 cases of sepsis and 45 deaths.

There were eight maternal deaths in the intervention group and six in the placebo group.

Limitations cited by Roca's group included the low proportion of microbiology-confirmed neonatal sepsis; as a result, easyto-grow bacteria such as *S. aureus* may have been over-represented.

The study authors also highlighted "striking differences" in early-onset sepsis between participants in Gambia and Burkina Faso, which suggests some cases were missed in the latter due to travel distance to the study health facility. In addition, late-onset sepsis may have been missed in Gambia "because C-reactive protein was measured qualitatively and could not meet the trial criterion of 40 mg/L."

Disclosures

The study was funded by a grant from the U.K. Research and Innovation under the Joint Global Health Trial Scheme (JGHT), the Medical Research Council Unit The Gambia at the London School of Hygiene and Tropical Medicine, and the Bill & Melinda Gates Foundation.

Roca reported receiving grants from JGHT, the U.K. Department for International Development, and the Bill & Melinda Gates Foundation. Co-authors reported grants from those sources, as well as from the

Medical Research Council that supported the Burkina Faso study; one co-author reported employment from GSK.

The editorialists had nothing to disclose.

Primary Source

JAMA

Source Reference: Roca A, et al "Effect of intrapartum azithromycin vs placebo on neonatal sepsis and death: a randomized clinical trial" JAMA 2023; DOI: 10.1001/jama.2022.24388.

Secondary Source

JAMA

Source Reference: Shrag SJ, Whitney CG "Still looking for a simple, effective prevention measure for neonatal sepsis in high-mortality settings" JAMA 2023; DOI: 10.1001/jama.2022.24139.

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MedPage Today

By Ingrid Hein

NT

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Maternal Preconception Hepatitis B Virus Infection and Risk of Congenital Heart Diseases in Offspring Among Chinese Women Aged 20 to 49 Years

March 13, 2023

Key Points

Question

What is the association between maternal preconception hepatitis B virus (HBV) infection and congenital heart diseases (CHDs) in offspring?

Findings

In this matched cohort study including 3 690 427 participants, increased CHD risks in offspring were observed among women with preconception previous HBV infection.

Meaning

In this study, maternal preconception previous HBV infection, which might affect the formation of the ovum, was associated with risk of CHDs in offspring.

Abstract

Importance

Maternal hepatitis B virus (HBV) infection during early pregnancy has been related to congenital heart diseases (CHDs) in offspring. However, no study to date has evaluated the association of maternal preconception HBV infection with CHDs in offspring.

Objectives

To explore the association of maternal preconception HBV infection with CHDs in

offspring.

Design, Setting, and Participants

This retrospective cohort study used nearest-neighbor (1:4) propensity score matching of 2013 to 2019 data from the National Free Preconception Checkup Project (NFPCP), a national free health service for childbearing-aged women who plan to conceive throughout mainland China. Women aged 20 to 49 years who got pregnant within 1 year after preconception examination were included, and those with multiple births were excluded. Data were analyzed from September to December 2022.

Exposures

Maternal preconception HBV infection statuses, including uninfected, previous, and new infection.

Main Outcomes and Measures

The main outcome was CHDs, which were prospectively collected from the birth defect registration card of the NFPCP. Logistic regression with robust error variances was used to estimate the association between maternal preconception HBV infection status and CHD risk in offspring, after adjusting for confounding variables.

Results

After matching with a 1:4 ratio, there were 3 690 427 participants included in the final analysis, where 738 945 women were infected with HBV, including 393 332 women with previous infection and 345 613 women with new infection. Approximately 0.03% (800 of 2 951 482) of women uninfected with HBV preconception and women newly infected with HBV carried an infant with CHDs, whereas 0.04% (141 of 393 332) of women with HBV infection prior to pregnancy carried an infant with CHDs. After multivariable adjustment, women with HBV infection prior to pregnancy had a higher risk of CHDs in offspring compared with women who were uninfected (adjusted relative risk ratio [aRR], 1.23; 95% CI, 1.02-1.49). Moreover, compared with couples who were uninfected with HBV prior to pregnancy (680 of 2 610 968 [0.026%]),

previously infected women with uninfected men (93 of 252 919 [0.037%]) or previously infected men with uninfected women (43 of 95 735 [0.045%]) had a higher incidence of CHDs in offspring and were significantly associated with a higher risk of CHDs in offspring (previously infected women with uninfected men: aRR, 1.36; 95% CI, 1.09-1.69; previously infected men with uninfected women: aRR, 1.51; 95% CI, 1.09-2.09) with multivariable adjustment, while no significant association was observed between maternal new HBV infection and CHDs in offspring.

Conclusions and Relevance

In this matched retrospective cohort study, maternal preconception previous HBV infection was significantly associated with CHDs in offspring. Moreover, among women with HBV-uninfected husbands, significantly increased risk of CHDs was also observed in previously infected women prior to pregnancy. Consequently, HBV screening and getting HBV vaccination-induced immunity for couples prior to pregnancy are indispensable, and those with previous HBV infection prior to pregnancy should also be taken seriously to decrease the CHDs risk in offspring.

SOURCE JAMA

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JAMA PEDIATRICS

Hanbin Wu, MS^{1,2}; Ying Yang, PhD^{1,2,3}; Jiajing Jia, PhD^{1,2,4,5}; et al

NT

Plasma Biomarkers of Brain Injury & Evolving Encephalopathy in HIE Neonates

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March 22, 2023

The following is a summary of "Plasma Biomarkers of Evolving Encephalopathy and Brain Injury in Neonates with Hypoxic-Ischemic Encephalopathy," published in the JANUARY 2023 issue of *Pediatrics* by Li. et al.

For a study, researchers sought to investigate the correlation between a group of potential plasma biomarkers and two aspects of evolving encephalopathy in neonates with moderate-to-severe hypoxic-ischemic encephalopathy (HIE): death or severe brain injury on MRI, and impaired cerebral pressure autoregulation.

The patients received therapeutic hypothermia (TH) and were continuously monitored using blood pressure and nearinfrared spectroscopy. The hemoglobin volume phase (HVP) index was used to assess cerebral pressure autoregulation, and Tau, glial fibrillary acidic protein, and neurogranin were measured in serial blood samples. The MRI results were evaluated using National Institutes of Child Health and Human Development scores. The relationships between the candidate biomarkers and death or severe brain injury on MRI (defined as a National Institutes of Child Health and Human Development score of ≥ 2B) and autoregulation were analyzed using bivariate and adjusted logistic regression models.

The findings showed that 62 patients had elevated Tau levels on days 2-3 of TH, which was linked to death or severe injury on MRI (aOR: 1.06, 95% CI: 1.03-1.09; aOR: 1.04, 95% CI: 1.01-1.06, respectively). Additionally, higher Tau levels were linked to poorer autoregulation (higher HVP index) on the same day (P = .022).

The study concluded that high levels of Tau in plasma were associated with death or severe brain injury on MRI and impaired cerebral pressure autoregulation in neonates with HIE, necessitating further extensive research to validate Tau as a biomarker of brain injury in neonates with HIE.

Reference: jpeds.com/article/S0022-3476(22)00675-8/fulltext

SOURCE PHYSICIAN'S WEEKLY NEWS PROVIDED BY

PHYSICIAN'S WEEKLY

NT

Increasing Disparities in Sudden Unexpected Infant Deaths Reflect Societal Failures

March 13, 2023

The coronavirus disease 2019 (COVID-19) pandemic and the subsequent preventive measures (physical distancing, mask use, and staying at home) have been associated with changes in the rates of many health outcomes. Some of these, such as a steep decline in viral illnesses, are not surprising. Others, such as an increase in fatal motor vehicle accidents, may be more unanticipated, as a complicated interaction of factors and root causes may be at play.

In their analysis comparing sudden infant death syndrome (SIDS) and sudden unexpected infant death (SUID) rates before and during the COVID-19 pandemic, Shapiro-Mendoza and colleagues from the US Centers for Disease Control and Prevention noted that, although overall US infant mortality continued its steady decline through 2020, the overall rate of SUID (which includes SIDS, accidental suffocation and strangulation in bed, and ill-defined cause of death) did not; it remained unchanged from 2015 to 2020.3 Additionally, in 2020 there was a rise in SIDS rates and an increase in the SUID rate for those who identified as being non-Hispanic Black.

We agree with the authors that, given that the overall SUID rate over this same period is stable, the variations in SIDS rates likely reflect shifting diagnostic criteria rather than a true rise. However, these diagnostic shifts highlight the need for increased uniformity in SUID investigations and cause of death certification. Without standardization of certification of deaths, it becomes almost impossible to track true trends in the subcategories of SUID, which

in turn limits our ability to better understand the pathophysiology of these deaths and to develop targeted educational interventions.

More concerning from these data are the overall rise in SUID deaths between 2019 and 2020 among infants born to non-Hispanic Black families. As the authors note, this rise further increases the already existing disparities in these deaths, with the rate among infants born to non-Hispanic Black families now 2.3-fold higher than the general population and 2.8-fold higher than infants born to non-Hispanic white families. Although there were also disparities in COVID-19 infection rates,4 since few SUIDs were associated with a COVID-19 diagnosis, infection with the virus per se does not explain the increased rate. Rather, these disparities are likely multifactorial, reflecting poverty levels, lack of access to prenatal and well-child care, and education regarding safe sleep and other practices, including the feeding of human milk, which can reduce the risk of SUID, and social norms related to these practices that vary between communities. Although small-scale intervention studies to provide education to new parents have shown promise in their ability to decrease these disparities, 5 as with most inequities, to make a truly large difference in the rates of sleep-related deaths, as a society we need to address the underlying causes. Shapiro-Mendoza's Although does not stratify data by socioeconomic non-Hispanic characteristics, Black Americans are more than twice as likely as non-Hispanic white Americans to live in poverty,6 and among families with children, homelessness is 50% more likely among those who identify as non-Hispanic Black. Our societal failures to address these issues not only result in limited access to health care and education, but also in many families not having a stable, safe place for their infants to sleep.

In contrast to many middle- and high-income countries, the United States lacks large-scale support for families, including but not limited to lactation assistance to increase human milk feeding rates, home visiting programs to support families in





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their home and help identify and address unsafe sleep conditions, and support for maternal mental health, particularly in the postpartum period. Our lack of guaranteed paid family leave means that parents may be forced to stop human milk feeding before they would like, parents are more desperate for nighttime sleep and thus, may turn to less safe sleep practices, and infants are often cared for by a variety of caregivers, not all of whom are adequately educated on safe sleep practices. Additionally, during the pandemic, many of the limited resources available to families, such as physician offices, Special Supplemental Nutrition Program for Women Infants and Children, home visiting programs, and mental health organizations stopped or drastically curtailed in-person visits. This may have decreased the quality and quantity of support and eliminated in-person modeling of best practices for these families. All of these factors potentially contributed to the increased rate of SUID seen in 2020 for non-Hispanic Black infants.

These latest data about the SUID rates during the first year of the COVID-19 pandemic reflect our societal failures. The United States has one of the highest SUID rates for all middle- and high-income countries that track these deaths, and the findings regarding increasing disparities sound the alarm about the need for interventions that look beyond individual counseling and toward community- and society-level solutions. All infants deserve a better start in life than we in the United States are providing to them now.

Dr. Carlin made substantial contributions to the conception and design of this commentary and drafted the initial manuscript; Drs Hauck and Moon made substantial

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contributions to the conception and design of this commentary and revised the commentary critically for important intellectual content; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

COMPANION PAPER: A companion to this article can be found online at http://www.pediatrics.org/cgi/doi/10.1542/peds.2022-058820.

Competing Interests

CONFLICT OF INTEREST DISCLO- SURES: The authors have indicated they have no potential conflicts of interest to disclose.

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Released: Thursday 12/13/2018 12:32 PM, updated Saturday 3/16/2019 08:38, Sunday 11/17/2019 and Friday 11/20/2020

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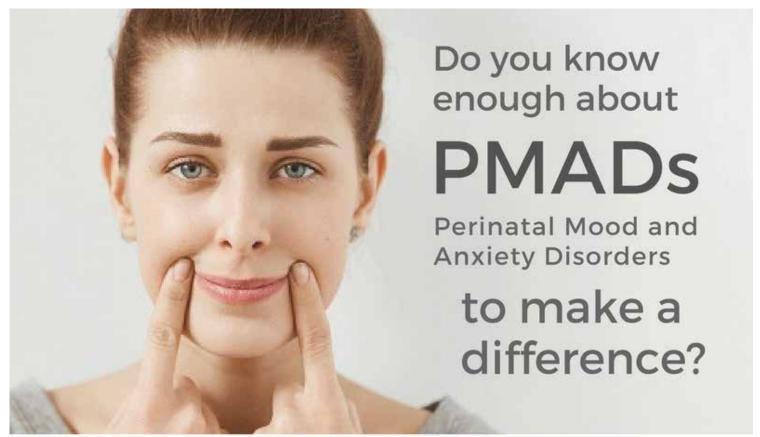
Thank you for all that you do on behalf of children. If you have any questions, please feel free to contact:

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NT

Target product profile for aerosolized surfactant therapy in neonates with respiratory distress syndrome in low- and middle-income countries

March 14, 2023

Overview

Treatment with surfactant improves the survival rate of neonates with respiratory distress syndrome, particularly preterm infants. However, surfactant is usually administered by endotracheal intubation and generally only in level-3 (tertiary) neonatal

intensive care units. Recent improvements in aerosolization technology have raised the possibility that aerosolized surfactant could now be given in wider range of settings, including resource-poor settings. Consequently, the World Health Organization has developed a target product profile for product developers that describes the optimal and minimal characteristics of an aerosolized surfactant for treating neonates with respiratory distress syndrome in low- and middle-income countries. This target product profile is now available on the World Health Organization website as listed below.

Access the target product profile via the repository

Other World Health Organization target product profiles

SOURCE WHO

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World Health Organization

NT

Autism Prevalence Higher, According to Data from 11 ADDM Communities

Second report highlights disruptions in early autism detection at the start of the COVID-19 pandemic

Press Release

Embargoed Until: March 23, 2023; 1:00 p.m. ET

Contact: Media Relations

(404) 639-3286

One in 36 (2.8%) 8-year-old children have been identified with autism spectrum disorder (ASD), according to an analysis published today in CDC's Morbidity and Mortality Weekly Report (MMWR). The new findings are higher than the previous 2018 estimate that found a prevalence of 1 in 44 (2.3%). The data come from 11 communities in the Autism and Developmental Disabilities Monitoring (ADDM) Network and are not representative of the entire United States.

A second report on 4-year-old children in the same 11 communities highlights the impact of COVID-19, showing disruptions in progress in early autism detection. In the early months of the pandemic, 4-year-old children were less likely to have an evaluation or be identified with ASD than 8-year-old children when they were the same age. This coincides with the interruptions in childcare and healthcare services during the COVID-19 pandemic.

"Disruptions due to the pandemic in the timely evaluation of children and delays in connecting children to the services and support they need could have long-lasting effects," said Karen Remley, M.D., director of CDC's National Center on Birth Defects and Developmental Disabilities. "The data in this report can help communities better understand how the pandemic impacted early identification of autism in young children and anticipate future needs as these children get older."

Shifting demographics among children identified with autism

ASD prevalence among Asian, Black, and Hispanic children was at least 30% higher in 2020 than 2018, and ASD prevalence among White children was 14.6% higher than in 2018. For the first time, the percentage of 8-year-old Asian or Pacific Islander (3.3%) Hispanic (3.2%) and Black (2.9%), children identified with autism was higher than among 8-year-old White children (2.4%). This is the opposite of racial and ethnic differences observed in previous ADDM reports for 8-year-olds. These shifts may reflect improved screening, awareness, and access to services among historically underserved groups.

Additionally, disparities for co-occurring

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intellectual disability have persisted. A higher percentage of Black children with autism were identified with intellectual disability compared with White, Hispanic, or Asian or Pacific Islander children with autism. These differences could relate in part to access to services that diagnose and support children with autism.

Overall, autism prevalence within the ADDM sites was nearly four times higher for boys than girls. Still, this is the first ADDM report in which the prevalence of autism among 8-year-old girls has exceeded 1%.

Community differences in autism prevalence

Autism prevalence in the 11 ADDM communities ranged from 1 in 43 (2.3%) children in Maryland to 1 in 22 (4.5%) in California. These variations could be due to how communities are identifying children with autism. The variability across ADDM Network sites offers an opportunity to compare local policies and models for delivering diagnostic and intervention services that could enhance autism identification and provide more comprehensive support to people with autism.

Autism and Developmental Disabilities Monitoring Network

Established in 2000, the ADDM Network is the only network to track the number and characteristics of children with autism and other developmental disabilities in multiple communities throughout the United States. It provides estimates of the prevalence and characteristics of autism among 8-year-old and 4-year-old children in 11 communities in Arizona, Arkansas, California, Georgia, Maryland, Minnesota, Missouri, New Jersey, Tennessee, Utah, and Wisconsin.

Tools for parents, healthcare providers, early childhood educators and caregivers

CDC's "Learn the Signs. Act Early." program provides free resources in English, Spanish, and other languages to monitor children's development starting at 2 months of age. CDC's *Milestone Tracker* mobile app can help parents and caregivers track their child's development and share the information with their healthcare providers. For more information visit www.cdc.gov/ActEarly.

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NT

Whooping cough vaccination during pregnancy benefits US infants

NEWS PROVIDED BY

CDC Newsroom Release

February 6, 2023

A <u>CDC</u> study <u>published</u> today provides further evidence that Tdap vaccination during pregnancy helps protect newborns from whooping cough during their first two months of life, when they are most vulnerable to the disease.

Whooping cough, or pertussis, is highly contagious and can be especially serious for infants who aren't old enough to be vaccinated. CDC scientists tracked reports of infant whooping cough cases between January 1, 2000, and December 31, 2019. They found an association between reduced rates of whooping cough in newborns younger than two months old and Tdap vaccination during pregnancy. These findings further support CDC's recommendation for Tdap vaccination during weeks 27–36 of each pregnancy.

"Getting Tdap during pregnancy offers infants the best protection before they are old enough to receive their whooping cough vaccines," said Dr. José R. Romero, Director of CDC's National Center for Immunization and Respiratory Diseases. "This protection is critical because those first few months are when infants are most likely to have serious complications, be hospitalized or die if they get whooping cough."

The new study is the first time researchers have looked at U.S. population level trends in infant whooping cough cases since this

maternal vaccination strategy began in 2011. Newborn whooping cough rates decreased significantly since the introduction of maternal Tdap vaccination. When given during the third trimester of pregnancy, Tdap vaccination prevents more than three in four cases of whooping cough in infants younger than two months old.

"Everyone who is pregnant should feel confident in knowing that the Tdap vaccine is safe and effective," said Dr. Linda Eckert, American College of Obstetricians and Gynecologists' liaison to CDC's Advisory Committee on Immunization Practices. "Knowing that Tdap vaccination during pregnancy protects nine in 10 babies from being hospitalized with whooping cough, I strongly recommend this vaccine to all my pregnant patients for their peace of mind and for their family's health and well-being."

Women should get vaccinated during the third trimester of each pregnancy to boost their antibodies and pass those antibodies on to their infants. All people in close contact with infants should be up to date with their whooping cough vaccines.

CDC and partners are working to increase Tdap vaccination during pregnancy, which dropped during the COVID-19 pandemic. Visit the CDC whooping cough website for more information.

Contact: Media Relations (404) 639-3286

SOURCE CDC

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FDA and CDC Response to the Florida Surgeon General

Press Release

March 10, 2023

Contact: Media Relations

(404) 639-3286

Original Letter [PDF – 321 KB]

Joseph A. Ladapo, M.D., Ph.D.

State Surgeon General

Florida Department of Health

4052 Bald Cypress Way, Bin A-00 Tallahassee, FL 32399-1701

Sent Via Electronic Mail Only

Dear Dr. Ladapo,

Thank you for your letter regarding CO-VID-19 vaccine safety. We appreciate this opportunity to address your questions and we would like to correct the associated misinterpretations and misinformation about the data from the Vaccine AdverseEvent Reporting System (VAERS), in the spirit of transparency and supporting and serving the health of our nation.

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) continue to diligently monitor a variety of data sources to identify any potential risks of the vaccines and to ensure that information is available to the public. That said, focusing on adverse events in the absence of causal association and without the perspective of countervailing benefits is a great disservice to both individuals and public health. Like every other medical intervention. there are adverse effects from vaccination. Serious adverse events from COVID-19 vaccines are rare and are far outweighed by the benefits of these vaccines for every age group.

The claim that the increase of VAERS reports of life-threatening conditions reported from Florida and elsewhere represents an increase of risk caused by the COVID-19 vaccines is incorrect, misleading and could be harmful to the American public. The FDA-approved and FDA-authorized COVID-19 vaccines have met FDA's rigorous scientific and regulatory standards for safety and effectiveness and these vaccines continue to be recommended for use by CDC for all people six months of age and older. Both FDA and CDC have continued to collect outcome data from multiple sources that demonstrate the clear benefit of COVID-19 vaccines in preventing death, serious illness, and hospitalization from SARS- CoV-2 infection, along with indicating a modest benefit in the prevention of infection and transmission that wanes over time, even as new variants have emerged. Additional benefits include a reduced risk of known complications from SARS-CoV-2 infection, including post-COVID conditions, COVID-19-associated stroke and heart disease, and COVID-19-induced venous thromboembolism.

Reports of adverse events to VAERS following vaccination do not mean that a vaccine caused the event. Since December 2020, almost 270 million people have received more than 670 million doses of COVID-19 vaccines in the U.S., with over 50 million people having received the updated bivalent vaccine. The Emergency Use Authorizations (EUAs) for the COVID-19 Vaccines require sponsors and vaccine providers to report certain adverse events through VAERS, so more reports should be expected. Recent concerns about increased reports of cardiovascular events provide an instructive example of the need to do further analysis when increased reporting of an event occurs. Despite increased reports of these events, when the concern was examined in detail by cardiovascular experts, the risk of stroke and heart attack was actually *lower* in people who had been vaccinated, not higher.

FDA and CDC physicians continuously screen and analyze VAERS data for possible safety concerns related to the CO-VID-19 vaccines. For signals identified in VAERS, physicians from FDA and CDC screen individual reports, inclusive of comprehensive medical record review. Most reports do not represent adverse events caused by the vaccine and instead represent a pre-existing condition that preceded vaccination or an underlying medical condition that precipitated the event.

Adverse events must be compared to background rates in the population. This VAERS review methodology allows for successful identification of rare adverse reactions related to specific COVID-19

vaccines (e.g., Guillain-Barré Syndrome, thrombosis with thrombocytopenia syndrome, and immune thrombocytopenia following use of the Janssen COVID-19 Vaccine or myocarditis, pericarditis and anaphylaxis following use of the Pfizer-BioNTech and Moderna COVID-19 vaccines). Information about these adverse reactions is included in the fact sheets for healthcare providers administering vaccine and vaccine recipients and caregivers. FDA and CDC also continue to post summaries of the key safety monitoring findings and present the data publicly at regularly scheduled advisory committee meetings.

In addition to VAERS, FDA and CDC utilize complementary active surveillance systems to monitor the safety of COVID-19 vaccines. Active surveillance involves proactively obtaining and rapidly analyzing information occurring in millions of individuals recorded in large healthcare data systems to verify safety signals identified through passive surveillance or to detect additional safety signals that may not have been reported as adverse events to passive surveillance systems. FDA is conducting active surveillance using the Sentinel BEST (Biologics Effectiveness and Safety) System and collaborating with the Center for Medicare and Medicaid Services (CMS) and Department of Veterans Affairs (VA). These efforts complement those of CDC's Vaccine Safety Datalink (VSD) and the v-safe textbased monitoring system for conducting surveillance of adverse events, as well as the Clinical Immunization Safety Assessment (CISA) Project. FDA and CDC are also collaborating with other non-federal partners, including state and local health departments.

Based on available information for the COVID-19 vaccines that are authorized or approved in the United States, the known and potential benefits of these vaccines clearly outweigh their known and potential risks. Additionally, not only is there no evidence of increased





risk of death following mRNA vaccines, but available data have shown quite the opposite: that being up to date on vaccinations saves lives compared to individuals who did not get vaccinated. Multiple well conducted, peer-reviewed. published studies here and here demonstrate that the risk of death, serious illness and hospitalization is higher for unvaccinated individuals for every age group. Because we are not the only country in the world using COVID-19 vaccines, we also benefit from the experience of other countries. More than 13 billion doses of COVID-19 vaccines have been given around the world, including hundreds of millions of doses of mRNA vaccines and hundreds of millions of doses to children. Consistent with our data, these multiple international partners have robust monitoring for both safety and effectiveness. They find little evidence of widespread adverse events, also detect rare events as we do, and conclude that the benefits of the vaccines generally far outstrip their risks.

While many studies could be cited, a retrospective cohort study using the CDC's Vaccine Safety Datalink found no increased risk of death for the mRNA and Janssen vaccines across age, sex. and race/ethnicity groups. They found that crude non-COVID-19 mortality rates among COVID-19 vaccine recipients were lower than those among unvaccinated comparators. Another study using mathematical modeling estimated that the vaccines saved an estimated 14 million lives from COVID-19 in 185 countries and territories between December 8, 2020, and December 8, 2021. Vaccination is also associated with a reduction of postacute sequelae of COVID-19. The data supporting the benefits of the COVID-19 vaccines have been critically reviewed and accepted by the medical and public health community, including state and local public health agencies and academic and professional organizations.

The most recent estimate is that those who are up to date on their vaccination status have a 9.8 fold lower risk of dying from COVID-19 than those who are unvaccinated and 2.4 fold lower risk of dying from Covid-19 than those who were vaccinated but had not received the updated, bivalent vaccine. Roughly 90% of deaths from COVID-19, as carefully classified by the CDC, in recent months have occurred among those who

were not up to date on their vaccines. Furthermore, as stated above, emerging reports indicate a possible reduction in the risk of post-COVID conditions in vaccinated people who survive an infection.

As the leading public health official in state, you are likely aware that seniors in Florida are under-vaccinated, with just 29% of seniors having received an updated bivalent vaccine, compared to the national average of 41% coverage in seniors. It is the job of public health officials around the country to protect the lives of the populations they serve, particularly the vulnerable. Fueling vaccine hesitancy undermines this effort.

We agree that communication between patients and their health care providers is critical, and fully support clear, accurate communication about the benefits and risks of medical products. It is inaccurate to suggest that the federal government will "retaliate" against any health care provider for communicating with their patients about the benefits and risks of a particular medical product.

Over the course of the pandemic, FDA and CDC have held numerous public meetings to discuss the safety and effectiveness of the COVID-19 vaccines where detailed safety data are shared with outside experts and public comment is encouraged. Further, FDA publishes the full regulatory action package containing hundreds of pages summarizing clinical studies and review for each COVID-19 approval on FDA's website (see "COVID-19 Vaccines Authorized for Emergency Use or FDA Approved") and CDC publishes an extensive amount of information on their clinical use in Interim Clinical Considerations. Complete information about both benefits and risks helps health care providers better care for their patients.

Unfortunately, the misinformation about COVID-19 vaccine safety has caused some Americans to avoid getting the vaccines they need to be up to date. This has led to unnecessary death, severe illness and hospitalization. These tragic outcomes not only have a devastating effect on individuals and their families, but they also create a tremendous strain on our healthcare systems and clinicians, potentially compromising care for other patients.

We stand firmly behind the safety and effectiveness of the mRNA COVID-19 vaccines, which are fully supported by the

available scientific data. Staying up to date on vaccination is the best way to reduce the risks of death and serious illness or hospitalization from COVID-19. Misleading people by overstating the risks, or emphasizing the risks without acknowledging the overwhelming benefits, unnecessarily causes vaccine hesitation and puts people at risk of death or serious illness that could have been prevented by timely vaccination.

Sincerely,

Robert M. Califf, MD

Commissioner
U.S. Food and Drug Administration

Rochelle P. Walensky, MD, MPH

Director

Centers for Disease Control and Prevention

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Genetics Corner: The Alternate "Backdoor" Steroidogenesis Pathway in the Placenta Links Hypospadias, Early IUGR, and Severe Placental Dysfunction

Dev Priya Singhvi, MBBS, BSc, Robin D. Clark, MD

Case Summary

A premature male infant of 36w1d gestation was referred for a genetics consultation because of penoscrotal hypospadias and bifid scrotum (Figure 1).



Figure 1. Incomplete masculinization of the male genitalia in a small for gestational age infant with a small placenta.

"Birth weight was 1630 g (0.36 percentile), birth length 16.93" (3.74 percentile), and birth head circumference 31 cm (11.75 percentile) based on Fenton Preterm growth chart, consistent with asymmetric IUGR. Maternal placental pathology demonstrated a small 216 g placenta (less than the third percentile)."

He was born to a 42-year-old Asian-American G2T1P0A1L1 mother with PCOS, conceived by IVF with ICSI and single embryo transfer. NIPT test result was low risk and male sex. Fetal growth restriction was identified at 13–14 weeks gestation by fetal ultrasound, with estimated fetal weight less than the first percentile, two-vessel umbilical cord, and abdominal circumference at the first

percentile. The mother reported a prior history of smoking 13 years before conception. Her chronic hypertension and superimposed preeclampsia without severe features did not respond to Labetalol and Procardia. Labor was induced for those indications, but an emergency cesarean section was performed due to recurrent variable decelerations, minimal/absent variability, and failure to descend. APGAR scores were 1, 5, and 7 at 1, 5, and 10 minutes, respectively. The baby required vigorous stimulation, positive pressure ventilation, and transfer to the NICU.

"The infant's anomalies were confined to his genitalia: penoscrotal hypospadias and bifid scrotum. Both testes were palpable in the scrotum. A renal ultrasound was normal, as were chromosome analysis and microarray."

Birth weight was 1630 g (0.36 percentile), birth length 16.93" (3.74 percentile), and birth head circumference 31 cm (11.75 percentile) based on Fenton Preterm growth chart, consistent with asymmetric IUGR. Maternal placental pathology demonstrated a small 216 g placenta (less than the third percentile; the third percentile for 36 wk male placenta is 392 grams). (1) Placental histology revealed focally circummarginate (10%), marginal insertion (90%), focally disrupted cotyledons, and focal adherent hemorrhage. The infant's anomalies were confined to his genitalia: penoscrotal hypospadias and bifid scrotum. Both testes were palpable in the scrotum. A renal ultrasound was normal, as were chromosome analysis and microarray. He fed slowly but was otherwise well. He was growing poorly at a follow-up visit at 12 weeks of age.

"The mother is Asian with ancestry from Cambodia/Vietnam/China, and the father is English/Caucasian."

Family history was negative for genital anomalies, birth defects, developmental delay, intellectual disability, early infant deaths/ sudden deaths, multiple miscarriages, or early onset cancers. The mother is Asian with ancestry from Cambodia/Vietnam/China, and the father is English/Caucasian. Parental consanguinity was denied.

Assessment

Hypospadias is a common disorder reported in 1 in 250 male births. It is caused by incomplete development of the penis between 8–14 weeks gestation. The urethral opening, normally at the distal tip of

the penis, is proximally placed on the ventral surface of the phallus. Hypospadias is classified into three subgroups. The mildest, first-degree hypospadias, occurs when the urethral opening is located at the glans or corona; second-degree hypospadias occurs when the urethral meatus is on the shaft of the penis; and the most severe, third-degree hypospadias, occurs when the urethra opens in the penoscrotal region, scrotum, or perineum. (2)

"The etiology of hypospadias is heterogeneous. It may be isolated or syndromic, encompassing endocrine (e.g., 5-alpha reductase deficiency or androgen insensitivity syndrome), genetic (e.g., Smith-Lemli-Opitz syndrome), environmental (e.g., use of pesticides/endocrine-disrupting chemicals), and most commonly idiopathic or multifactorial causes."

The etiology of hypospadias is heterogeneous. It may be isolated or syndromic, encompassing endocrine (e.g., 5-alpha reductase deficiency or androgen insensitivity syndrome), genetic (e.g., Smith-Lemli-Opitz syndrome), environmental (e.g., use of pesticides/endocrine-disrupting chemicals), and most commonly idiopathic or multifactorial causes.

"The association of hypospadias, especially the more severe third-degree form, with early and severe IUGR, SGA, IVF, maternal hypertension, and placental insufficiency/dysfunction has been well documented in the medical literature. The incidence of hypospadias in SGA infants admitted to the NICU is >10 times higher than that reported for the general population."

The association of hypospadias, especially the more severe third-degree form, with early and severe IUGR, SGA, IVF, maternal hypertension, and placental insufficiency/dysfunction has been well documented in the medical literature. (3-5) The incidence of hypospadias in SGA infants admitted to the NICU is >10 times higher than that reported for the general population (5). A retrospective case-controlled study in Shanghai, China, compared male infants with hypospadias (n=97) and infants without birth defects (n=42147) between January 2015 and December 2019. These authors identified several perinatal risk factors for hypospadias in their cohort, including hypertensive disorders of pregnancy. (6) In a population-based cohort of 388,422 Danish

singleton boys born between 1997-2008, Arendt et al. studied the association between placental weight and cryptorchidism and hypospadias. Boys with placental weight in the lowest decile (<10th %ile) had almost twice the rate of hypospadias (HR 1.97) as boys whose placentas were in the reference decile (50-59.9th %ile). (7)

Normal development of the penis from the genital tubercle depends on two androgen-producing pathways. The canonical androgenic pathway in the testis is best known, which produces testosterone from androstenedione. The second pathway is the less wellknown, alternative ("backdoor") pathway in which the placenta produces 5α-dihydrotestosterone (DHT) from androsterone (8). Plasma and tissue levels of endogenous steroids in secondtrimester human fetuses show that androsterone is the principal "backdoor" androgen in the male fetal circulation and that DHT is undetectable (<1 ng/mL) during that time in gestation. These "backdoor androgens" are synthesized primarily in the placenta and fetal liver and derive from placental progesterone. Notably, maternal progesterone levels are reduced in IUGR pregnancies suggesting that placental steroidogenesis is affected. These findings shed light on the relationship between placental insufficiency, incomplete masculinization of the male genitalia, and early growth restriction. (9,10) Placental steroidogenesis is now understood to play a critical role in early male genital development.

"These 'backdoor androgens' are synthesized primarily in the placenta and fetal liver and derive from placental progesterone. Notably, maternal progesterone levels are reduced in IUGR pregnancies suggesting that placental steroidogenesis is affected. These findings shed light on the relationship between placental insufficiency, incomplete masculinization of the male genitalia, and early growth restriction. Placental steroidogenesis is now understood to play a critical role in early male genital development."

Practical applications:

- 1. Many risk factors for hypospadias implicate a causative role in early placental dysfunction: early and severe fetal growth restriction, maternal hypertension, preeclampsia, IVF, and small placental size.
- Seek a history of maternal hypertension, preeclampsia, and IVF and evaluate the placental size and histology in small for gestational age infants with hypospadias.
- 3. Recognize that placental progesterone is the necessary

precursor for "backdoor" androgen production, which is critical for the normal development of male genitalia.

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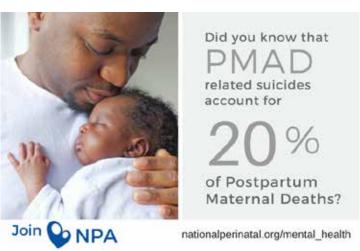


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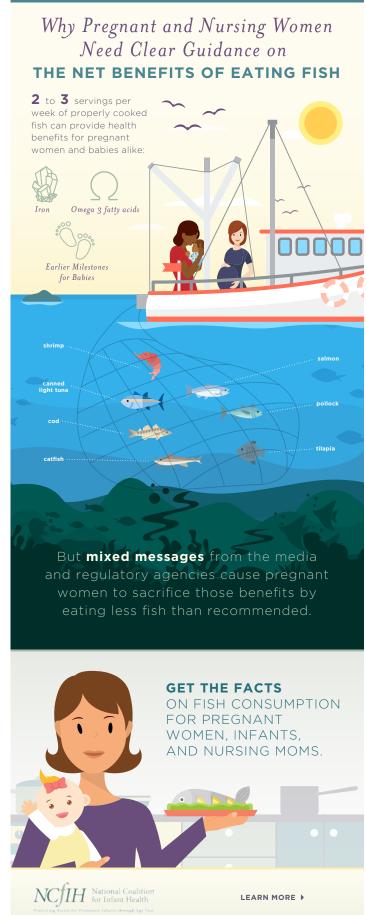
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Medical-Legal Forum: Case Debrief: Blagden Versus McMillin - A Phone Consult Is Enough to Establish Physician-Patient Relationship

Jonathan M. Fanaroff, MD, JD, Gilbert I. Martin, MD

The first element a plaintiff must prove in order to establish medical malpractice is that the physician had a "duty" towards the patient. Black's Law Dictionary defines duty as "a legal obligation owed or due to another, and that needs to be satisfied." Generally, this is done by showing a physician-patient relationship and is not a controversial issue. Clearly, a neonatologist on service caring for a baby in the NICU has a physician-patient relationship. If that neonatologist is out of town and another one is covering, it would be very difficult to establish a duty of care. Duty is, however, a "threshold" issue, meaning if there is no duty to the patient, there is no negligence.

"Clearly, a neonatologist on service caring for a baby in the NICU has a physician-patient relationship. If that neonatologist is out of town and another one is covering, it would be very difficult to establish a duty of care. Duty is, however, a "threshold" issue, meaning if there is no duty to the patient, there is no negligence."

There are more complex questions about when a duty exists regarding situations such as telephone advice. Can you be held liable for a patient you have never met being treated by a different attending? The answer will depend on a number of factors, including the circumstances involved and the specificity of the advice given. If the consulting physician generates a bill, it would be very difficult to argue that there was no relationship. The converse, however, is not true, meaning that a duty may be established even if the patient was never billed.

The question of whether a telephone consultation between an Emergency Department (ED) physician and an on-call physician is enough to create a physician-patient relationship was recently addressed by the Fourth District Appellate Court of Illinois in the case of *Blagden v. McMillin, MD* 2023 IL App (4th) 220238. ED attending Dr. McMillin in the Graham Hospital Emergency Department saw and evaluated Dennis Blagden. While he thought the patient was primarily having a muscular issue, he also noted an elevated white count. He called to discuss Mr. Blagden with Dr. Krock, the on-call Internal Medicine physician, who had admitting privileges, to discuss the patient. Ultimately, the patient was not admitted, discharged home, and three days later came back to the ED critically ill with a spinal epidural abscess from which he unfor-

tunately died. His family sued Dr. Krock for malpractice because he did not rule out an infectious process and did not admit and treat Mr. Blagden. Dr. Krock's defense was that he did not have a physician-patient relationship with this patient. The trial judge agreed, stating, "[t]here was no direction here, there was just confirmation, and I think that's an important distinction." Dr. Krock was dismissed from the case, and the plaintiffs appealed.

"While it was a "collaborative" decision whether to admit, the ultimate decision was by Dr. Krock. At the same time, he noted that only the ED physician was actually looking at the patient."

When deposed about this case, Dr. Krock did not recall this particular patient but testified that when called from the ED, "[t]ypically the decision to admit has already been made" and that deciding whether to admit was "not typically our role, but yes sometimes we'll do that." He also agreed that he could refuse an admission, although he had never done so. While it was a "collaborative" decision whether to admit, the ultimate decision was by Dr. Krock. At the same time, he noted that only the ED physician was actually looking at the patient.

Dr. McMillin testified that he had discussed whether or not to admit with Dr. Krock and that Dr. Krock did not believe that the patient needed to be admitted.

"In a decision released on January 26, 2023, the Appellate Court reversed the trial court and found that a physician-patient relationship existed between Dennis Blagden and Dr. Krock."

In a decision released on January 26, 2023, the Appellate Court reversed the trial court and found that a physician-patient relationship existed between Dennis Blagden and Dr. Krock. The Court cited seven "undisputed" facts that Dr. Krock was:

- 1) The on-call physician based on a contractual obligation
- 2) Compensated for being on-call
- 3) Consulted specifically for medical advice for Mr. Blagden's benefit concerning admission
- Given specific information about Mr. Blagden's history, symptoms, and test results

- Considered the information and collaborated on the decision to discharge
- Ultimately responsible for the decision concerning whether to admit
- 7) Decided admission was not necessary and discharge with follow-up was appropriate

Note that this decision does not find Dr. Krock liable for malpractice in this case or that his decision to discharge was inappropriate. It simply means that a duty exists, and the case can continue. He may or may not be found liable. The States generally regulate medical malpractice. It should be stressed that this case was decided by an Appellate Court based on Illinois law and is being used in this article for educational purposes. It certainly should not be relied upon as legal advice. There are, however, lessons that can be learned.

"While this case involved an adult patient, it has relevance for neonatologists since we are often consulted over the phone by Pediatricians, Family Physicians, and Emergency Room Physicians. Additionally, we need to be careful about "curbside consults" as specific information and advice may lead to establishing a physician-patient relationship."

While this case involved an adult patient, it has relevance for neonatologists since we are often consulted over the phone by Pediatricians, Family Physicians, and Emergency Room Physicians. Additionally, we need to be careful about "curbside consults" as specific information and advice may lead to establishing a physician-patient relationship. This does not mean that informal conversations between physicians are not important and, indeed, encouraged. When in doubt, however, request a formal consultation or the information needed to provide the most appropriate advice.

Disclosure: There are no reported conflicts.

NT

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Translated by Phyllis Aronoff and Howard Scott



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



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VACCINES

PREVENTIVE MONOCLONAL ANTIBODIES

Introduce antibodies that are ready to

Teach the body to create antibodies that fight off a specific disease.

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.



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.



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



RSV COVID-19

Both can provide tailored protection from a variety of diseases.

Yes



Both vaccines and preventive monoclonal antibodies undergo extensive testing for safety and efficacy.

Preventive Monoclonal Antibodies

Vaccines and

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



NPA's statement: BLACK LIVES MATTER





The Indirect Impact of **RSV**



Susan Hepworth, Suzanne Staebler, DNP, APRN, NNP-BC, FAANP, FAAN, Mitchell Goldstein, MD, MBA, CML

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

RESULTS

of providers agreed

that parents need

more information

RESULTS



FINANCIAL BURDEN

More than 3/3 of parents said the costs of RSV posed a

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 PSV

(%)

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

TREATMENT CHALLENGES

PARENT EDUCATION & AWARENESS

Nearly 1/3

routine care.

86%

of providers said

they include RSV

education as part of

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

48%

99%

about RSV

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.



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.



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.

Emily's RSV Story

Susan Hepworth, Mitchell Goldstein, MD, MBA, CML



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.

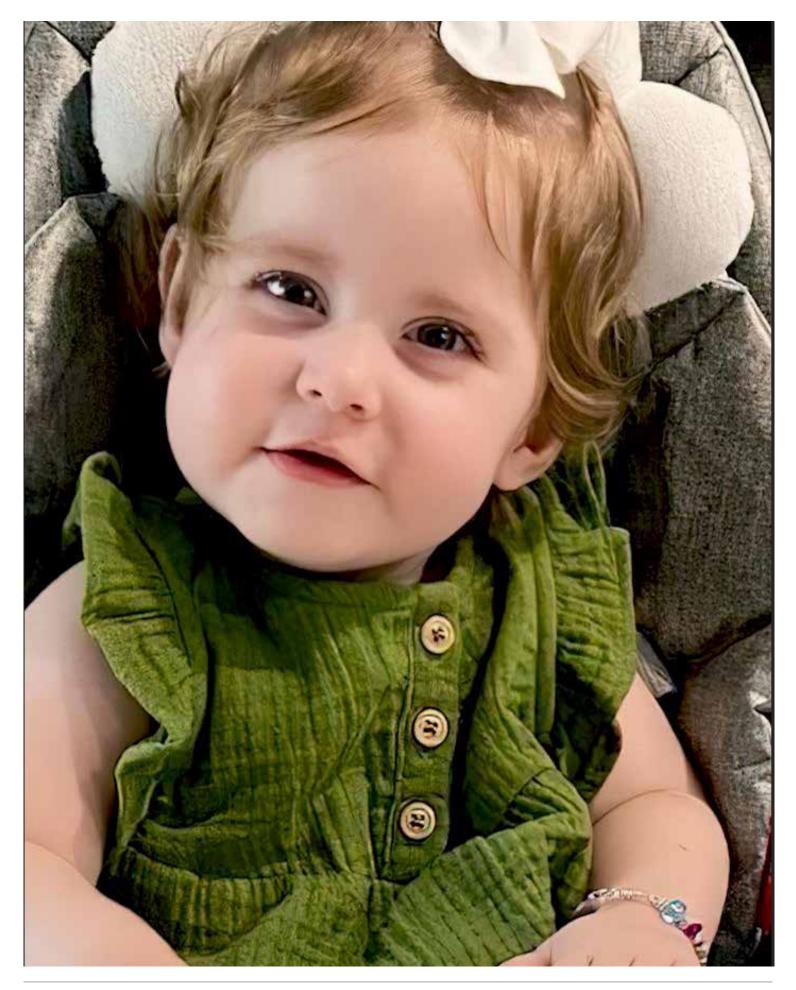
On February 22, the coalition released a new video, <u>Emily's RSV Story</u>. Emily Lang lost her daughter to RSV in November 2021. Her way of grieving – as she explains it – is to advocate for greater awareness about RSV in hopes that other families will not have to endure what she did. Emily is incredibly brave, and we are so grateful for her willingness to share Presley's story to help other families understand how serious RSV can be.

The text from the video follows. Please feel free to share this video with your networks.



"On February 22, the coalition released a new video, Emily's RSV Story."





daughter, trying to keep her going.

"This is Presley's bunny. It has a G tube and oxygen because she had a G tube and oxygen. She loved her bunnies. I'm Emily Lang. I am the mother of Presley Meeks, who passed away on November 26, 2021."



This is Presley's bunny. It has a G tube and oxygen because she had a G tube and oxygen. She loved her bunnies. I'm Emily Lang. I am the mother of Presley Meeks, who passed away on November 26, 2021. When Presley first got sick. It was fast. We know that she had a chest compression where it was like her lungs were going inside her ribs. And, that's how we know that something was definitely wrong. We actually rushed to the hospital, and I said, "My baby is not breathing." Okay? She was at 56%, her oxygen levels. They tested her for rhinovirus, RSV, and COVID. And at that point, they determined it was RSV. One of my friend's babies actually gave Presley it [RSV]. They were having a play date. And, her baby was, of course, playing with Presley's toys. And Presley touched her toys.

She was on a bunch of different machines. It was one day, she was on a normal ventilator. And then next day, we had to put her on a different ventilator. And then, at night, we'd have to be on this ventilator. And they were doing everything possible to keep her going. One morning I woke up, and I noticed there were about two new machines in the room, and I was like, What's going on? And the nurse, I looked over at the nurse, and she was begging my

"And I called my parents, and I said, "you guys need to get here soon." Like, she's not okay. She's not going to make it. We need to let her go. On November 26, Presley passed away peacefully in my arms. Grief, it comes in a wave."

And I called my parents, and I said, "you guys need to get here soon." Like, she's not okay. She's not going to make it. We need to let her go. On November 26, Presley passed away peacefully in my arms. Grief, it comes in a wave.



"My way of grieving is to advocate and to spread awareness of RSV. I just feel like it's important for people to know because I didn't know what RSV really was until I went through having to lose my daughter."

Some days I'm okay. And some days, I struggle a lot. My way of grieving is to advocate and to spread awareness of RSV. I just feel like it's important for people to know because I didn't know what RSV really was until I went through having to lose my daughter.

Disclosure: No relevant disclosures noted

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National Coalition for Infant Health Values (SANE)

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

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

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

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

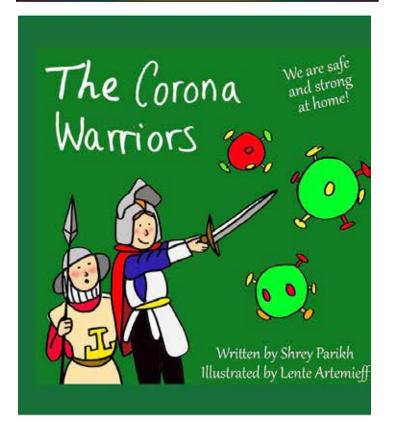
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The Signs & Symptoms of RSV RESPIRATORY SYNCYTIAL VIRUS

Know the Signs & Symptoms of RSV



Cough



Runny Nose



Struggling to Breathe (breastbone sinks inward when breathing)



Difficulty Eating



Lethargy



Wheezing

RESPIRATORY SYNCYTIAL VIRUS

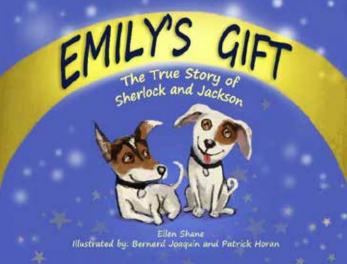
is a highly contagious seasonal virus that can lead to hospitalization for some babies and young children.

Know the Signs.



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Purchases of this engaging **true story** provide disadvantaged middle school students, risking academic failure, the opportunity to attain their best personal and academic potential.

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You can provide both reading entertainment for younger children, and make a difference in the lives of the disadvantaged middle schoolers we support.

Sales support our nonprofit charity's SEA Program. You can make a difference for these children!

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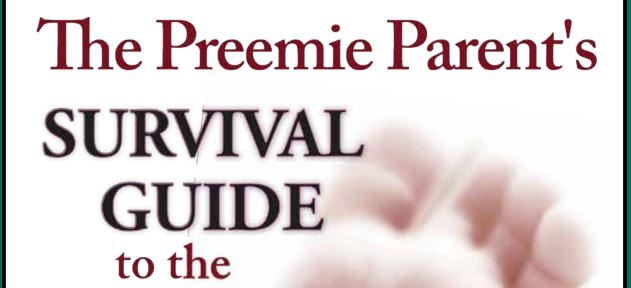
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The Emily Shane Foundation is a 501(c)3 nonprofit charity. Our flagship SEA (Successful Educational Achievement) Program is a unique educational initiative that provides essential mentoring/tutoring to disadvantaged middle school children across Los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

For more information, please visit emilyshane.org.



By

NICU

little man's Nicole Conn

&

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Deb Discenza

with

Medical Editor Alan R. Spitzer, M.D.



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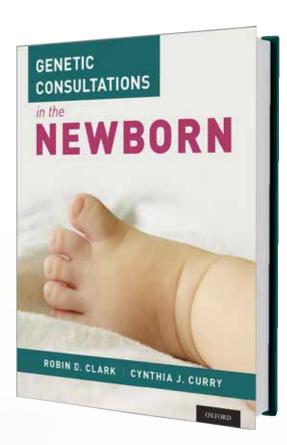


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Clinical Pearl: Maternal COVID-19 Infections

Pyone David, MD, MSW

"COVID-19 was initially seen as an adult problem, thankfully sparing children at the pandemic's beginning. That mindset has changed, especially as pediatricians worldwide faced the "tripledemic" this respiratory season."

As the third year of the COVID-19 pandemic persists, I have reflected on both the progress and limitations. Like many pediatric trainees during the beginning of the pandemic, I faced the difficulty of managing a condition with relatively little published data in the neonatal population. COVID-19 was initially seen as an adult problem, thankfully sparing children at the pandemic's beginning. That mindset has changed, especially as pediatricians worldwide faced the "tripledemic" this respiratory season.

With the initial paucity of research, the American Academy of Pediatrics (AAP) guidance on infants born to mothers with suspected or confirmed COVID-19, published on April 2, 2020, was celebrated, carefully studied, and adhered to in my hospital's nursery and NICU. Utilizing published reports from China describing deliveries from pregnant women with COVID-19 and their neonatal outcomes, the members of the AAP Section on Neonatal-Perinatal Medicine, Committee on Infectious Disease, and Committee on the Fetus and Newborn combined this information with current Centers for Disease Control and Prevention to come up with its recommendations (1). The recommendations for safety precautions, isolation, testing, discharge, and visitation are similar in the most current iteration published November 10, 2022 (1-2).

Some of the most controversial recommendations have been reversed as additional studies emerged. In the original guidance, separation of the newborn from the mother was recommended even if there was no other medical indication (1). Although the studies at that time had not detected the virus in breast milk, it was also recommended that mothers express milk and have not infected caregivers feed the baby directly out of an abundance of precaution (1). These two recommendations were highly controversial and impacted families' early bonding periods. Based upon new research showing no significant association with neonatal infection risks, the new AAP guidance now recommends rooming in with precautions and breastfeeding when medically appropriate (2).

As greater attention and research were focused on neonatal outcomes, some concerning associations have been seen in the lit-

erature. Maternal COVID-19 infection has been found to be associated with an increased risk of numerous complications for infants, especially if infection occurs near the delivery date. These complications include increased risk of fetal demise, preterm birth, NICU admission, respiratory conditions, and mortality (3-6). Specific respiratory concerns for neonates include respiratory distress syndrome, pneumonia/bronchiolitis, apnea of prematurity, bronchopulmonary dysplasia, transient tachypnea of the newborn, and meconium aspiration (6).

The exact pathophysiology related to the relationship between maternal COVID-19 and neonatal complications is still being investigated. However, COVID-19 is associated with maternal systemic inflammatory response and placental inflammation. These maternal issues may contribute to preterm birth, fetal growth restriction, and risk of fetal demise (3).

"Preventing COVID-19 infections during pregnancy to mitigate these impacts remains challenging. Vaccine hesitancy, especially among pregnant women, remains despite the scientific research completed (7). The lockdowns and strict social distancing are part of a bygone period."

Preventing COVID-19 infections during pregnancy to mitigate these impacts remains challenging. Vaccine hesitancy, especially among pregnant women, remains despite the scientific research completed (7). The lockdowns and strict social distancing are part of a bygone period.

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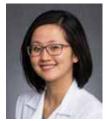
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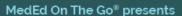
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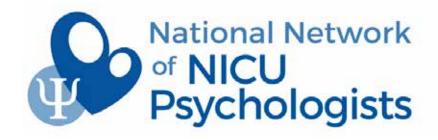
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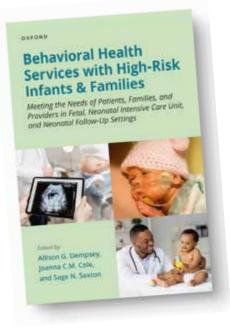
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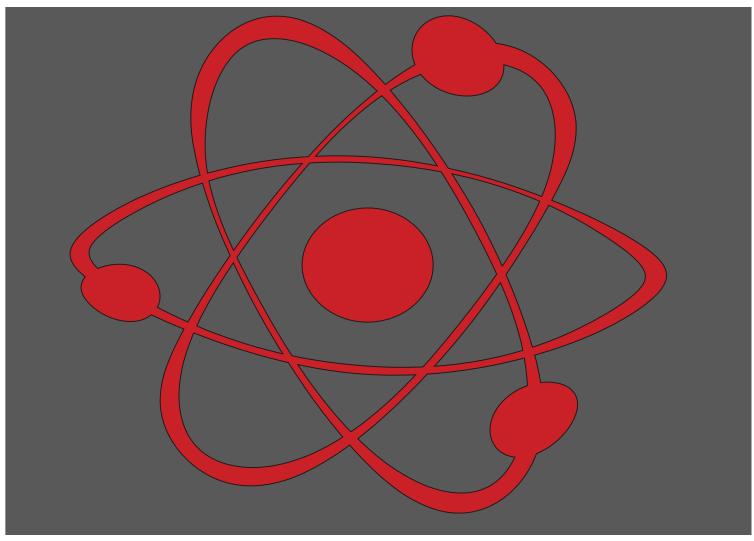
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The Emily Shane Foundation Annual Spring Gala Fundraiser Wings Over Malibu Thursday, April 27, 2023 from 6:30 – 8 PM

The Emily Shane Foundation, a 501(c) 3 nonprofit charity based in Malibu, CA, currently serves the Malibu, Oxnard, Thousand Oaks, Santa Monica, Westchester, Culver City, South Los Angeles, and Pico Rivera communities. This school year, we commenced at a new site in Watts. The foundation was created in honor of Emily Rose Shane, following her tragic murder on April 3rd, 2010. She was 13 years old and in eighth grade (middle school).

Our foundation's SEA (Successful Educational Achievement) Program empowers underserved, disadvantaged middle schoolers by providing them with essential academic tutoring and mentorship. The SEA Program serves those identified as being at risk of failure and who could not otherwise afford this essential after-school support. Our objective is to enable these children to be successful students, so they can achieve their goals and dreams. Participants are guided on a path toward success in school and life. The foundation's "Pass it Forward" motto encourages kindness and social consciousness, as each SEA Program participant is encouraged to perform one good deed for every session with their mentor/tutor.

The need for SEA has always been significant. However, as a result of the pandemic, it has only increased. Our comprehensive program includes a mentorship component and a focus on organizational and study skills, offering a complete approach for our students to attain success in the classroom. The SEA Program truly makes a difference in a child's life. Our students face challenges such as being below grade level in one or more subjects; others cope with English language struggles and their academic challenges are often coupled with both home-life and/or social issues.

We are excited to announce our annual spring gala fundraiser, Wings Over Malibu, to take place the evening of April 27, 2023, directly over the waves in the lovely Ocean Room at Duke's Restaurant in Malibu. This event provides the opportunity for those who support our work to learn firsthand of the incredible impact of our SEA Program. Highlights include a live auction, an online silent auction, exclusive wines presented by The Narcissist Wine Company, hearty appetizers, members of the Malibu Middle and High School Orchestras serenading our guests, a featured SEA Program student sharing their experience in the program, and more!

For more information, requests for sponsorship, or donations, please contact us by sending an email to this address: <u>info@emilyshane.org</u>. If you are mailing a donation, please send it to: 2893 Searidge St., Malibu, CA 90265. We must receive all donations by Friday, April 14th, 2023.

Thank you so much for your consideration,

Ellen Shane Executive Director The Emily Shane Foundation www.emilyshane.org

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40th Advances in Neonatal and Pediatric Cardiorespiratory Care

You can attend In-Person or Virtual



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Attractions Distances are displayed to the nearest 0.1 mile and kilometer.

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Americana at Brand - 2 km / 1.2 mi
Griffith Park - 3.3 km / 2.1 mi
Los Angeles Zoo - 5.3 km / 3.3 mi
Walt Disney Studios - 7.9 km / 4.9 mi
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 Santa Monica Pier -26 mi Venice Beach - 28 mi

The nearest airports are:

Hollywood Burbank Airport (BUR) - 12.8 km / 8 mi Los Angeles Intl. (LAX) - 43.5 km / 27 mi 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





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 NÍCU and Surgical services
- Maternity services and delivery center
- 24/7 coverage by NNP team and Fellows
- Competitive employee benefit packages



For more information, please contact:

Karin Colunga, MSN, RN, PNP-BC Director of Advanced Practice Nursing kecolunga@llu.edu | 909-558-4486

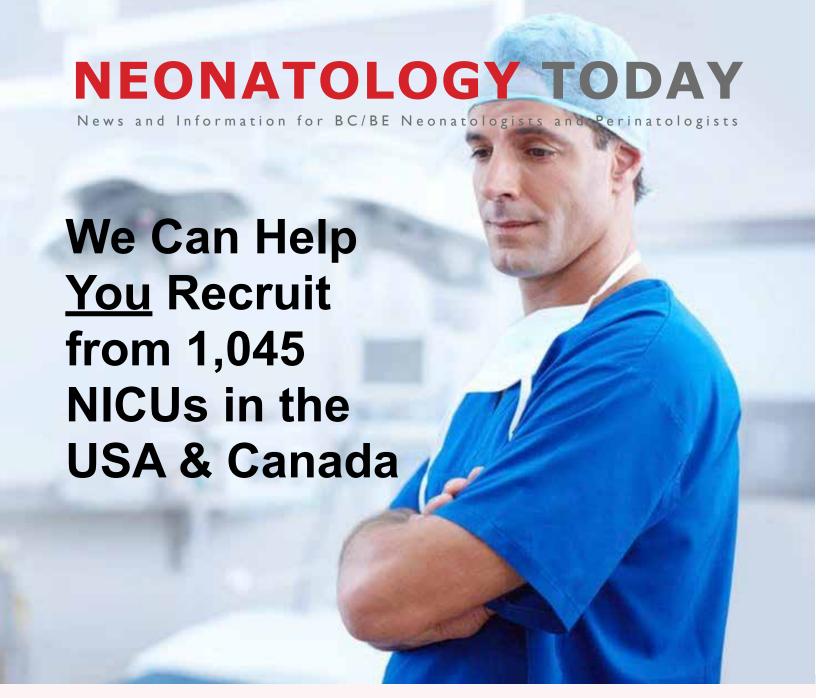








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For more information, contact:

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+1 (302) 313-9984 or

Melissa.LaMarca@neonatologytoday.net

NEONATOLOGY TODAY

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

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PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis





WASH YOUR HANDS

often with soap and warm water.



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





COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.







STAY AWAY FROM SICK PEOPLE

Avoid crowds. Protect vulnerable babies and children.



www.nationalperinatal.org

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.

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Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one the next tolast page as well as photographs of birds on rear cover.. For this edition, we have a Psychedelic Seahorse by Dr. Paula Whiteman and a Pelican in Flight by Dr. Larry Tinsley.



Mita Shah, MD, Neonatal Intensive Care Medical Director Queen of the Valley Campus Emanate Health, West Covina, CA

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Manuscript Submission: Instructions to Authors

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



1- THE RIGHT TO ADVOCACY

My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical records, and prognosis, so they celebrate my achievements and support me when things get challenging.

2- THE RIGHT TO MY PARENTS' CARE

In order to meet my unique needs, my parents need to learn about my developmental needs. Be patient with them and teach them well. Make sure hospital policies and protocols, including visiting hours and rounding, are as inclusive as possible.

3- THE RIGHT TO BOND WITH MY FAMILY

Bonding is crucial for my sleep and neuroprotection. Encourage my parents to practice skin-to-skin contact as soon as and as often as possible and to read, sing, and talk to me each time they visit.

4- THE RIGHT TO NEUROPROTECTIVE CARE

Protect me from things that startle, stress, or overwhelm me and my brain. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time and faster than it ever will again. The way I am cared for today will help my brain when I grow up. Connect me with my parents for the best opportunities to help my brain develop.

5- The Right to be Nourished

Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Also, let my parents know that donor milk may be an option for me.

6- The Right to Personhood

Address me by my name when possible, communicate with me before touching me, and if I or one of my siblings pass away while in the NICU, continue referring to us as multiples (twin/triplets/quads, and more). It is important to acknowledge our lives.

7- THE RIGHT TO CONFIDENT AND COMPETENT CARE GIVING

The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help educate them about my unique needs, development, diagnoses, and more.

8- THE RIGHT TO FAMILY-CENTERED CARE

Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9- THE RIGHT TO HEALTHY AND SUPPORTED PARENTS

My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my parents about resources such as peer-to-peer support programs, support groups, and counseling, which can help reduce PMAD, PPD, PTSD, anxiety and depression, and more.

10- THE RIGHT TO INCLUSION AND BELONGING

Celebrate my family's diversity and mine; including our religion, race, and culture. Ensure that my parents, grandparents, and siblings feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

Presented by:



NICU Parent Network

NICU PARENT NETWORK Visit nicuparentnetwork.org to identify national, state, and local NICU family support programs.

* The information provided on the NICU Baby's Bill of Rights does not, and is not intended to, constitute legal or medical advice.

Always consult with your NICU care team for all matters concerning the care of your baby.

NANT 13 - Call for Abstracts

Presented by the National Association of Neonatal Therapists (NANT)

Conference Dates:

Main Conference: April 14-15, 2023 Pre-Conference: April 13

Location: Tucson, AZ USA*

*Barring any restrictions to the contrary, NANT 13 is scheduled to be held in- person. However, in the event such restrictions occur, the event will be hosted online including all accepted sessions/posters.

The theme for NANT 13 is *Inspiring Competence & Confidence*.

NANT and our Members aim to deliver best practices for NICU babies and parents all over the world. This advanced practice area requires a high level of competence, fueled by interprofessional collaboration and research.

Competence is not finite—it is an ongoing commitment to the pursuit of scientific knowledge and skill proficiency. We never arrive or are experts in all areas of practice. We rely on each other and use our unique professional lenses and experiences to advance the field of neonatal therapy.

We are calling upon you to share your research and clinical expertise. What can you contribute to the standard of care? How can you fill the gaps in neonatal therapy competency?

NANT intends to develop attendees' confidence to serve, lead, and implement collaboratively. We seek the right individuals, research, and tools to make that happen.

Sharing your valuable work in this internationally attended conference is a powerful way to inspire new levels of competence and confidence in this specialty.

We invite you to submit an abstract to present an oral or poster presentation at NANT 13.

Click here to submit an abstract.

Abstract Submission Deadline: Monday, August 15, 2022



