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Impact of a Care Bundle on the Incidence of Necrotizing Enterocolitis in the Neonatal Intensive Care Unit Jerome P. Lee, MD, Winona K. Lee, MD, Chieko Kimata, PhD, MPH, MBA, Alyssa Honda, MD, Charles R. Macias Neal, MD, PhD .....Page 3	Despite COVID-19, Data Support Kangaroo Care Michelle Winokur, DrPH, and the AfPA Governmental Affairs Team, .....Page 81
Highlights of the 34th Annual Gravens Conference on the Environment of Care for the High-Risk Newborn and Satellite Conference on "Reimagining the NICU" Robert D. White, MD .....Page 17	I CAN Digitally Involved (iCANDI): Collaboration with the Pediatric Trials Network (PTN) Amy Ohmer .....Page 83
Reactivity in Shiny WebApps Fu-Sheng Chou, MD, PhD .....Page 26	Infection Control Policies in the NICU: Time for a review? Kelly Welton, RRT-NPS .....Page 86
Fellow Column: Objective Measures of Neonatal Pain Benjamin Shlomo, MD, Derek McCalla, MD .....Page 33	High-Reliability Organizing (HRO) in the COVID-19 Liminal Zone: Characteristics of Workers and Local Leaders Daved van Stralen, MD, FAAP, Thomas A. Mercer, RAdm, USN .....Page 90
First Candle Forming Public Health Advisory Committee to Address Health Inequities Barb Himes, IBCLC .....Page 39	Medical News, Products & Information Mitchell Goldstein, MD, David Vasconcellos, MSIII .....Page 110
From The National Perinatal Information Center: Maternal Mental Health Awareness Elizabeth Rochin, PhD, RN, NE-BC .....Page 42	The Genetics Corner: Pathogenic variants in DOCK6 mimic congenital viral infection in an SGA infant with VSD and intracranial calcifications Subhadra Ramanathan, Robin D. Clark, MD .....Page 124
Health Equity Column: Framing Birth Equity To Protect Black Maternal Health Outcomes Jenné Johns, MPH, Dawn Godbolt, Ph.D., .....Page 45	When Preterm Infants Struggle to Feed Erin Sundseth Ross, Ph.D., CCC-SLP .....Page 129
Who's on First? Split and Shared Services in the NICU Scott D. Duncan, MD, MHA .....Page 50	Clinical Pearl: What about Antibody Response and Transfer in Pregnant Women Who Have Had SARS-CoV-2 Infection Compared to those Receiving the Vaccine? Joseph R. Hageman, M.D., Mitchell Goldstein, M.D. .....Page 137
Will Artificial Intelligence Have a Place in the NICU? Are We There Yet, or Should We Be? Gilbert Martin, MD .....Page 53	Letters to the Editor: Pulse Oximeters Are Not Racist Mitchell Goldstein, MD responds to Joe Kiani .....Page 143
Neonatology Solutions Provides Resources to Ensure Fellows Can Still Define and Find Their Ideal Career Position Scott Snyder, MD, Amy Patel, MD .....Page 57	Erratum .....Page 146
The Role of Obstetricians and Neonatologists in Promoting COVID-19 Vaccination: Healthier Mothers and Infants Ricardo Peverini, M.D., Elba Fayard, M.D., Courtney Martin, MD, T. Allen Merritt, MD. .....Page 60	Academic True Open Model (ATOM) .....Page 147
Conventional Ventilation Lung Protective Strategies Rob Graham, R.R.T./N.R.C.P. .....Page 66	Upcoming Meetings, Subscriptions and Contact Information .....Page 149
"I Answered Obediently to 'She.'" Experiencing Pregnancy as a Nonbinary Person in the United States Cody Miller Pyke, JD, LLM .....Page 70	Editorial Board .....Page 152
	Policy on Animal and Human Research, Manuscript Submission .....Page 154
	Neonatology and the Arts - Herbert Vasquez, MD .....Page 154
	Flowers for Nico - Paula Whiteman, MD .....Page 155
	Ducks in DC - Mita Shah, MD .....Page 156



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# Impact of a Care Bundle on the Incidence of Necrotizing Enterocolitis in the Neonatal Intensive Care Unit

Jerome P. Lee, MD, Winona K. Lee, MD, Chieko Kimata, PhD, MPH, MBA, Alyssa Honda, MD, Charles R. Macías Neal, MD, PhD

## Abstract:

**Objective:** Evaluate the impact of a care bundle on the incidence of necrotizing enterocolitis (NEC) in the neonatal intensive care unit.

**Study Design:** Retrospective, single-center, population comparison of patients diagnosed with NEC before and after implementing a NEC care bundle utilizing standardized feeding protocol, donor milk program, transfusion protocol, early antibiotic protocol, and restricted indomethacin use.

**Result:** Incidence of NEC fell from 1.92 to 0.83% ( $P < 0.0001$ ). Incidence of NEC in the 23-27 weeks gestation group decreased from 14.21 to 6.09% ( $P = 0.0009$ ). In the 28-30 weeks gestation group, NEC incidence decreased from 5.56 to 2.10% ( $P = 0.0096$ ). Significant reduction of recurrent NEC and transfusion-associated NEC was observed.

**Conclusion:** Implementation of a NEC care bundle reduced NEC incidence, with the greatest impact seen in the most vulnerable preterm and very preterm infants.

## Introduction

Necrotizing enterocolitis (NEC) remains a devastating disease of the premature infant. When encountered in the neonatal intensive care unit (NICU), NEC carries a mortality rate of up to 44%, with significant long-term morbidity in survivors.<sup>(1)</sup> The incidence of NEC is highly variable and is dependent on gestational age and birth weight. Preterm and very preterm infants are at the highest risk for NEC. In a recent review by Battersby *et al.*, NEC occurred in 5-7% of infants born < 35 weeks gestation and in 5-22% of preterm infants with birth weight < 1000 grams.<sup>(2)</sup> Incidence of recurrent NEC has been reported to be 6-10%.<sup>(3,4)</sup>

NEC delays the establishment of full enteral nutrition, leads to poor growth, and increases the length of hospital stay with a concomitant increase in hospital costs. Providing optimal nutritional support to premature infants is vital to their survival, growth, and long-term neurodevelopmental outcomes.<sup>(5-7)</sup> Optimizing nutrition while minimizing the occurrence of NEC continues to be a major challenge in the NICU.

Following decades of basic research into the mechanism of this disease, the pathophysiology of NEC remains poorly understood. No single etiology has been shown to cause NEC, and no single preventative measure has been shown to eliminate NEC. As a result, various prevention strategies have been reported in attempts to limit its occurrence.<sup>(8-17)</sup> Of the prevention strategies studied, establishing a standardized feeding protocol and exclusive human milk feeds appears to have the greatest impact on decreasing the

incidence of NEC in the premature infant.

To enhance the care of the premature infant and improve outcomes, quality improvement initiatives in the NICU are now becoming standard practice worldwide. Quality initiatives dealing with complex disease processes, such as NEC, have demonstrated that care bundles when properly initiated, improve patient care and ultimately patient outcomes. As defined by the Institute for Healthcare Improvement, care bundles are a group or set of evidence-based practice protocols that, when followed consistently together, can improve patient care processes and patient outcomes more than the individual protocols alone.<sup>(18,19)</sup> In the NICU setting, care bundles have been shown to decrease the incidence of ventilator-associated pneumonia, central line-associated bloodstream infections, and nosocomial infections.<sup>(20-23)</sup> Recently, Talavera *et al.* reported a reduction in the incidence of NEC after the implementation of a quality improvement initiative that included early feedings with maternal breast milk (MBM), a feeding protocol, and limited use of ranitidine.<sup>(24)</sup>

***“A care bundle for NEC was developed and implemented for the level IIID NICU at Kapi‘olani Medical Center for Women and Children in an effort to decrease NEC and its associated morbidity and mortality, particularly in the most fragile ELBW population. The purpose of this study was to retrospectively analyze the incidence, severity, and mortality rate of NEC in our NICU population before and after implementation of the NEC care bundle.”***

A care bundle for NEC was developed and implemented for the level IIID NICU at Kapi‘olani Medical Center for Women and Children in an effort to decrease NEC and its associated morbidity and mortality, particularly in the most fragile ELBW population. The purpose of this study was to retrospectively analyze the incidence, severity, and mortality rate of NEC in our NICU population before and after implementation of a NEC care bundle.

## Methods

### *NEC care bundle*

In November 2007, we implemented a NEC care bundle in the NICU, the elements of which included: 1) a standardized feeding protocol; 2) initiation of a donor milk program; 3) a transfusion protocol; 4) a protocol to limit early empiric antibiotics, and 5) restriction of the use of indomethacin.

### *Standardized feeding protocol*

We developed a standardized feeding protocol that included all

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infants < 31 weeks gestation and any infant ≥ 31 weeks with any of the following risk factors: multiple gestation, congenital heart disease, perinatal asphyxia, intrauterine growth restriction, sepsis, and shock, gastroschisis, and polycythemia requiring partial exchange transfusion. The protocol included specific criteria for initiation and duration of trophic feedings, advancement of feedings, standard fortification practices, and use of parenteral nutrition.

We adopted a multidisciplinary approach with lactation consultants and nursing to establish early maternal breast milk feedings through maternal counseling and support. Education included information provided during the prenatal consult and an educational video on manual colostrum expression. An electric breast pump was provided to each mother. Lactation consultants were staffed to be available to the nursing mothers in the NICU 7 days a week.

#### Donor breast milk program

We also implemented a donor milk program that allowed infants to receive donated maternal breast milk (MBM) when the mother was unable to produce enough expressed MBM for her preterm infant. Donor breast milk (DBM) was obtained through a human milk bank licensed by the Human Milk Banking Association of North America. This assured supplementation of MBM feedings with a human milk alternative, reducing the use of preterm infant formula.

#### Packed red cell transfusion protocol

The packed red blood cell (PRBC) transfusion protocol included guidelines for PRBC transfusion based on infant age, need for respiratory support, and hemoglobin/hematocrit levels. Neonatologists agreed to not deviate from transfusion guidelines, limiting premature transfusion in VLBW infants while also not allowing hematocrits to become dangerously low. Transfusions were given in two 10 ml/kg aliquots, given 20-24 hours apart. Routine furosemide was not used. Feedings were decreased to trophic volumes during transfusion and advanced back to baseline volumes over 24-48 hours. Hemoglobin and hematocrit values were monitored weekly for infants up to 32 weeks post-conceptual age and every two weeks thereafter.

#### Antibiotic protocol

We modified our empiric antibiotic therapy practice by limiting

empiric treatment in non-septic appearing infants to 48 hours. A time-out note is documented for any use of antibiotics beyond 48 hours if the initial baby blood culture is negative. Previously, empiric antibiotic therapy was given for a minimum of 72 hours and up to a week for infants with a negative blood culture.

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***“We had inconsistent practice among our providers with the use of indomethacin for intraventricular hemorrhage (IVH) prophylaxis, patent ductus arteriosus (PDA) prophylaxis and PDA treatment. We stopped the practice of using indomethacin for IVH and PDA prophylaxis and transitioned to ibuprofen as first-line medical therapy for the symptomatic PDA.”***

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#### Indomethacin protocol

We had inconsistent practice among our providers with the use of indomethacin for intraventricular hemorrhage (IVH) prophylaxis, patent ductus arteriosus (PDA) prophylaxis and PDA treatment. We stopped the practice of using indomethacin for IVH and PDA prophylaxis and transitioned to ibuprofen as first-line medical therapy for the symptomatic PDA.

#### Study Design

After implementing our NEC care bundle, we conducted a 14 year retrospective population comparison study of two groups of patients diagnosed with NEC in the NICU at Kapi’olani Medical Center for Women and Children. The Pre-Bundle NEC group included infants born between 2004 and 2007 (4 year period). The Post-Bundle NEC group included infants born between 2008 and 2017 (10 year period). Infants were stratified into three categories,

**Table 1** Incidence of NEC in Pre-Bundle and Post-Bundle Cohorts in the NICU

	Pre-Bundle		Post-Bundle		P-value
	Frequency	%	Frequency	%	
<b>NEC Incidence</b>					
Total	54	1.92%	70	0.83%	<0.0001
23 to 27 week gestation	26	14.21%	33	6.09%	0.0009
28 to 30 week gestation	14	5.56%	14	2.10%	0.0096
≥31 week gestation	14	0.59%	23	0.32%	0.084
Recurrent NEC	9	16.67%	1	1.43%	0.0024
Transfusion related NEC	13	24.07%	5	7.14%	0.010
Surgical NEC	27	50.00%	29	41.43%	NS
Death related to NEC	14	26.92%	21	30.00%	NS

Abbreviations: NEC, necrotizing enterocolitis, NS, non-significant

**Table 2** Comparison of Pre-Bundle NEC and Post-Bundle NEC groups

<i>Characteristics</i>	<b>Pre-Bundle NEC</b>		<b>Post-Bundle NEC</b>		<i>P-value</i>
	N=54		N=70		
	<i>Mean/Freq.</i>	<i>( SD/% )</i>	<i>Mean/Freq.</i>	<i>( SD/% )</i>	
<u>Demographics</u>					
Gestation age at Birth (All)	28.61	( 3.87 )	29.16	( 4.65 )	NS
23 to 27 weeks	26	( 48.15% )	33	( 47.14% )	
28 to 30 weeks	14	( 25.93% )	14	( 20.00% )	NS
≥ 31 weeks	14	( 25.93% )	23	( 32.86% )	
Birth Weight (All)	1257.31	( 686.61 )	1391.14	( 931.54 )	NS
23 to 27 weeks	836.19	( 214.24 )	772.45	( 168.64 )	NS
28 to 30 weeks	1158.21	( 261.81 )	1044.71	( 361.40 )	NS
≥ 31 weeks	2138.50	( 750.79 )	2489.70	( 831.18 )	NS
Male Gender	32	59.26%	41	58.57%	NS
Days of life at NEC diagnosis	16.44	( 11.61 )	25.10	( 26.76 )	NS
<u>Prenatal factors</u>					
Cocaine/Methamphetamine use	3	5.56%	4	6.56%	NS
Tobacco use	9	16.98%	4	6.56%	NS
PIH/Preeclampsia/HTN	8	14.81%	14	22.95%	NS
Chorioamnionitis	6	11.11%	3	5.00%	NS
Indomethacin	4	7.41%	4	6.45%	NS
Betamethasone	36	66.67%	39	60.94%	NS
Fetal Distress	9	16.67%	11	18.33%	NS
Multiple gestation	16	29.63%	16	23.88%	NS
<u>Co-morbidities</u>					
Pneumothorax	4	7.41%	2	3.03%	NS
PDA	21	38.89%	34	50.75%	NS
PDA Ligation	10	18.52%	13	19.40%	NS
GI anomal	2	3.70%	12	17.91%	0.020
IVH	21	38.89%	21	31.82%	NS
IUGR/SGA	3	5.26%	11	16.92%	NS
CV Abnormalities	4	7.41%	4	6.25%	NS
<u>NEC Care Bundle interventions</u>					
Received trophic feeds	32	60.38%	48	72.73%	NS
Days of trophic feeds	3.38	( 2.42 )	4.59	( 2.73 )	NS
Types of trophic Feed					
MBM only	8	( 25.00% )	39	( 84.78% )	
MBM/DBM	0	( 0.00% )	5	( 10.87% )	
MBM/Formula	11	( 34.38% )	0	( 0.00% )	<0.0001
MBM/DBM/Formula	0	( 0.00% )	1	( 2.17% )	
Formula only	13	( 40.63% )	1	( 2.17% )	
Non-trophic Feeds	46	85.19%	54	83.08%	NS
Feeds Type					
MBM only	3	( 6.52% )	27	( 51.92% )	
MBM/DBM	0	( 0.00% )	3	( 5.77% )	
MBM/Formula	31	( 67.39% )	15	( 28.85% )	<0.0001
MBM/DBM/Formula	0	( 0.00% )	2	( 3.85% )	
Formula only	12	( 26.09% )	5	( 9.62% )	
PRBC	29	53.70%	36	51.43%	NS
Antibiotic use prior to NEC	38	70.37%	43	62.32%	NS
Days antibiotics, 1st week of life	3.20	( 2.27 )	3.23	( 2.63 )	NS
Indocin	22	40.74%	1	1.56%	<0.0001
<u>Other Interventions</u>					
Hydrocortisone	5	9.26%	7	11.29%	NS
Dexamethasone	2	3.70%	6	9.23%	NS
Epogen	14	25.93%	4	6.15%	0.0040
Ferrous sulfate	16	30.77%	16	24.24%	NS
Ranitidine	6	11.11%	4	6.45%	NS
Caffeine	23	42.59%	37	56.92%	NS
Dopamine	18	33.33%	18	27.69%	NS
Dobutamine	1	1.85%	3	4.76%	NS
Epinephrine	1	1.85%	4	6.35%	NS

Abbreviations: NEC, necrotizing enterocolitis, NS, non-significant, PIH, pregnancy induced hypertension, HTN, hypertension, PDA, patent ductus arteriosus, GI, gastrointestinal, IVH, intraventricular hemorrhage, IUGR, intrauterine growth restriction, SGA, small for gestation, CV, cardiovascular, MBM, maternal breast milk, DBM, donor breast milk, PRBC, packed red blood cells.

**Table 3** Comparison of Pre-Bundle NEC and Pre-Bundle Control groups

Total	Pre-Bundle NEC N=54		Pre-Bundle Control N=105		P-value (paired)
	Mean/Freq.	( SD/% )	Mean/Freq.	( SD/% )	
<u>Characteristics</u>					
<u>Demographics</u>					
Gestation age at Birth (All)	28.61	( 3.87 )	28.77	( 4.03 )	NS
23 to 27 weeks	26	( 48.15% )	48	( 45.71% )	
28 to 30 weeks	14	( 25.93% )	28	( 26.67% )	NS
≥ 31 weeks	14	( 25.93% )	29	( 27.62% )	
Male Gender	32	( 59.26% )	63	( 60.00% )	NS
<u>Prenatal factors</u>					
Cocaine/Methamphetamine use	3	( 5.56% )	6	( 5.71% )	NS
Tobacco use	9	( 16.98% )	12	( 11.43% )	NS
PIH/Preeclampsia/HTN	8	( 14.81% )	14	( 13.33% )	NS
Chorioamnionitis	6	( 11.11% )	5	( 4.76% )	NS
Indomethacin	4	( 7.41% )	6	( 5.71% )	NS
Betamethasone	36	( 66.67% )	67	( 63.81% )	NS
Fetal Distress	9	( 16.67% )	23	( 21.90% )	NS
Multiple gestation	16	( 29.63% )	24	( 22.86% )	NS
<u>Co-morbidities</u>					
Pneumothorax	4	( 7.41% )	2	( 1.90% )	NS
PDA	21	( 38.89% )	39	( 37.14% )	NS
PDA Ligation	10	( 18.52% )	12	( 11.43% )	NS
GI anomal	2	( 3.70% )	3	( 2.86% )	NS
IVH	21	( 38.89% )	24	( 22.86% )	0.034
IUGR/SGA	3	( 5.56% )	4	( 3.81% )	NS
CV Abnor	4	( 7.41% )	2	( 1.90% )	NS
<u>NEC Care Bundle interventions</u>					
Received trophic feeds	32	( 60.38% )	58	( 55.24% )	NS
Days of trophic feeds	3.38	( 2.42 )	3.66	( 3.14 )	NS
<u>Types of trophic Feed</u>					
MBM only	8	( 25.00% )	25	( 43.10% )	
MBM/DBM	0	( 0.00% )	0	( 0.00% )	
MBM/Formula	11	( 34.38% )	18	( 31.03% )	NS
MBM/DBM/Formula	0	( 0.00% )	0	( 0.00% )	
Formula only	13	( 40.63% )	15	( 25.86% )	
Non-trophic Feeds	46	( 85.19% )	94	( 89.52% )	NS
<u>Feeds Type</u>					
MBM only	3	( 6.52% )	11	( 11.70% )	
MBM/DBM	0	( 0.00% )	0	( 0.00% )	
MBM/Formula	31	( 67.39% )	66	( 70.21% )	NS
MBM/DBM/Formula	0	( 0.00% )	0	( 0.00% )	
Formula only	12	( 26.09% )	17	( 18.09% )	
PRBC	25	( 46.30% )	50	( 47.62% )	NS
Antibiotics	38	( 70.37% )	72	( 68.57% )	NS
Days antibiotics, 1st week of life	3.20	( 2.27 )	3.41	( 3.06 )	NS
Indocin	22	( 40.74% )	34	( 32.38% )	NS

Abbreviations: NEC, necrotizing enterocolitis, NS, non-significant, PIH, pregnancy induced hypertension, HTN, hypertension, PDA, patent ductus arteriosus, GI, gastrointestinal, IVH, intraventricular hemorrhage, IUGR, intrauterine growth restriction, SGA, small for gestation, CV, cardiovascular, MBM, maternal breast milk, DBM, donor breast milk, TPN, total parenteral nutrition, PRBC, packed red blood cells.

**Table 4** Comparison of Post-Bundle NEC and Post-Bundle Control groups

Total	Post-Bundle NEC N=70		Post-Bundle Control N=131		P-value (paired)
<i>Characteristics</i>	<i>Mean/Freq. ( SD/% )</i>		<i>Mean/Freq. ( SD/% )</i>		
<u>Demographics</u>					
Gestation age at Birth (All)	29.16	( 4.65 )	29.41	( 4.70 )	NS
23 to 27 weeks	33	( 47.14% )	62	( 47.33% )	
28 to 30 weeks	14	( 20.00% )	24	( 18.32% )	NS
≥ 31 weeks	23	( 32.86% )	45	( 34.35% )	
Male Gender	41	( 58.57% )	76	( 58.02% )	NS
<u>Prenatal factors</u>					
Cocaine/Methamphetamine use	4	( 6.56% )	5	( 4.59% )	NS
Tobacco use	4	( 6.56% )	4	( 3.74% )	NS
PIH/Preeclampsia/HTN	14	( 22.95% )	32	( 29.09% )	NS
Chorioamnionitis	3	( 5.00% )	11	( 10.09% )	NS
Indomethacin	4	( 6.45% )	5	( 4.63% )	NS
Betamethasone	39	( 60.94% )	70	( 63.06% )	NS
Fetal Distress	11	( 18.33% )	23	( 21.30% )	NS
Multiple gestation	16	( 23.88% )	17	( 15.32% )	NS
<u>Co-morbidities</u>					
Pneumothorax	2	( 3.03% )	4	( 3.48% )	NS
PDA	34	( 50.75% )	37	( 30.83% )	0.020
PDA Ligation	13	( 19.40% )	12	( 10.00% )	NS
GI anomal	12	( 17.91% )	18	( 15.65% )	NS
IVH	21	( 31.82 )	22	( 18.64% )	NS
IUGR/SGA	11	( 16.92% )	13	( 11.50% )	NS
CV Abnor	4	( 6.25% )	11	( 9.82% )	NS
<u>NEC Care Bundle interventions</u>					
Received trophic feeds	48	( 72.73% )	77	( 66.96% )	NS
Days of trophic feeds	4.59	( 2.73 )	5.03	( 2.61 )	NS
Types of trophic Feed					
MBM only	39	( 84.78% )	65	( 89.04% )	
MBM/DBM	5	( 10.87% )	6	( 8.22% )	
MBM/Formula	0	( 0.00% )	1	( 1.37% )	NS
MBM/DBM/Formula	1	( 2.17% )	0	( 0.00% )	
Formula only	1	( 2.17% )	1	( 1.37% )	
Non-trophic Feeds	54	( 83.08% )	107	( 92.24% )	NS
Feeds Type					
MBM only	27	( 51.92% )	37	( 37.37% )	
MBM/DBM	3	( 5.77% )	3	( 3.03% )	
MBM/Formula	15	( 28.85% )	29	( 29.29% )	0.032
MBM/DBM/Formula	2	( 3.85% )	24	( 24.24% )	
Formula only	5	( 9.62% )	6	( 6.06% )	
PRBC	36	( 51.43% )	50	( 39.37% )	NS
Antibiotics	43	( 62.32% )	70	( 54.69% )	NS
Days antibiotics, 1st week of life	3.23	( 2.63 )	2.24	( 2.62 )	0.0033
Indocin	1	( 1.56% )	7	( 5.93% )	NS

Abbreviations: NEC, necrotizing enterocolitis, NS, non-significant, PIH, pregnancy induced hypertension, HTN, hypertension, PDA, patent ductus arteriosus, GI, gastrointestinal, IVH, intraventricular hemorrhage, IUGR, intrauterine growth restriction, SGA, small for gestation, CV, cardiovascular, MBM, maternal breast milk, DBM, donor breast milk, TPN, total parenteral nutrition, PRBC, packed red blood cells.

<b>Table 5</b> Comparison of Pre-Bundle Control and Post-Bundle Control groups					
<i>Characteristics</i>	<b>Pre-Bundle Control</b>		<b>Post-Bundle Control</b>		<i>P-value</i>
	N=105		N=131		
	<i>Mean/Freq.</i>	<i>( SD/% )</i>	<i>Mean/Freq.</i>	<i>( SD/% )</i>	
<b><u>Demographics</u></b>					
Gestation age at Birth (All)	28.77	( 4.03 )	29.41	( 4.70 )	NS
23 to 27 weeks	48	( 45.71% )	62	( 47.33% )	
28 to 30 weeks	28	( 26.67% )	24	( 18.32% )	NS
≥ 31 weeks	29	( 27.62% )	45	( 34.35% )	
Birth Weight (All)	1346.81	( 741.52 )	1471.27	( 926.75 )	NS
23 to 27 weeks	808.49	( 208.83 )	833.48	( 173.86 )	NS
28 to 30 weeks	1264.79	( 284.44 )	1174.46	( 242.40 )	NS
≥ 31 weeks	2298.45	( 664.76 )	2508.29	( 862.47 )	NS
Male Gender	63	( 60.00% )	76	( 58.02% )	NS
<b><u>NEC Care Bundle interventions</u></b>					
Received trophic feeds	58	( 55.24% )	38	( 33.04% )	NS
Days of trophic feeds	3.66	( 3.14 )	5.03	( 2.61 )	0.0015
Types of trophic Feed					
MBM only	25	( 43.10% )	65	( 89.04% )	
MBM/DBM	0	( 0.00% )	6	( 8.22% )	
MBM/Formula	18	( 31.03% )	1	( 1.37% )	<0.0001
MBM/DBM/Formula	0	( 0.00% )	0	( 0.00% )	
Formula only	15	( 25.86% )	1	( 1.37% )	
Non-trophic Feeds	94	( 89.52% )	107	( 92.24% )	NS
Feeds Type					
MBM only	11	( 11.70% )	37	( 37.37% )	
MBM/DBM	0	( 0.00% )	3	( 3.03% )	
MBM/Formula	66	( 70.21% )	29	( 29.29% )	<0.0001
MBM/DBM/Formula	0	( 0.00% )	24	( 24.24% )	
Formula only	17	( 18.09% )	6	( 6.06% )	
PRBC	50	( 47.62% )	50	( 39.37% )	NS
Antibiotics	72	( 68.57% )	70	( 54.69% )	0.032
Days antibiotics, 1st week of life	3.41	( 3.06 )	2.24	( 2.62 )	0.0009
Indocin	34	( 32.38% )	7	( 5.93% )	<0.0001

Abbreviations: NEC, necrotizing enterocolitis, NS, non-significant, MBM, maternal breast milk, DBM, donor breast milk, PRBC, packed red blood cells.



23-27 weeks gestation, 28-30 weeks gestation, and  $\geq 31$  weeks gestation.

Infants were initially identified by a diagnosis of NEC in the problem list or discharge summary in the electronic medical record. From this initial search, we then limited the group to infants that completed at least 7 days NPO with antibiotic treatment. Infants diagnosed with spontaneous intestinal perforation were excluded. We also excluded patients that were transferred to our NICU with a preexisting diagnosis of NEC. Controls for each case were selected, matched with birth year, gestational age, and gender. The demographic and clinical data were summarized using descriptive statistics.

Institutional review board approval was obtained for access to the electronic medical records. Multiple clinical and demographic data were evaluated. Fischer's exact test, chi-square test, Kruskal-Wallis test, paired Wilcoxon signed-rank test, and exact conditional logistical regression were used for statistical analysis.

## Results

During the study period, 124 patients met the criteria for NEC diagnosis, and their charts were reviewed. There were 54 patients in the Pre-Bundle cohort and 70 patients in the Post-Bundle cohort. In addition, 236 patient charts were reviewed as NEC controls, 105 in the Pre-Bundle group and 131 in the Post-Bundle group. Each cohort was further classified into three age groups as assigned at birth: 23-27 weeks gestation, 28-30 weeks gestation, and  $\geq 31$  weeks gestation.

### Pre-Bundle NEC vs. Post-Bundle NEC

The incidence of NEC in the Pre-Bundle and Post-Bundle cohorts is displayed in Table 1. There was a 56.8% reduction in overall incidence of NEC in the Post-Bundle group compared to the Pre-Bundle group in our NICU. NEC incidence was 1.92% in the Pre-Bundle group and 0.83% in the Post-Bundle group ( $p$ -value  $< 0.0001$ ). This reduction in NEC was primarily seen in the 23-27 weeks and 28-30 weeks gestation groups. In the 23-27 weeks gestation group, there was a 57.1% reduction in the incidence (14.21 to 6.09%). The 28-30 weeks gestation group had a 62.2% reduction (5.56 to 2.10%). In the  $\geq 31$  weeks gestation age group, there was a trend in NEC reduction that was not statistically significant. There was a significant reduction (16.67 to 1.43%) of recurrent NEC in the Post-Bundle NEC group. There was a significant reduction in transfusion-associated NEC in the Post-Bundle group from 24.07 to 7.14%. We define transfusion-associated NEC as NEC occurring within 72 hours after initiation of a PRBC transfusion. There was no significant difference in the incidence of surgical NEC or deaths associated with NEC between the two historical cohorts.

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***“There were no significant differences in the incidence of IVH, intrauterine growth restriction (IUGR), small for gestational age (SGA), or other congenital or cardiac anomalies. In the Post-Bundle NEC group, there was a significant reduction in the use of indomethacin and erythropoietin.”***

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Table 2 compares demographic, maternal, and infant characteristics between Pre-Bundle and Post-Bundle NEC groups. There were no significant differences in gestational age at birth, birth weight, gender, or maternal conditions. In the Post-Bundle group, there was increased use of MBM and DBM and reduced preterm infant formula for both trophic and non-trophic feedings. Interestingly, the Post-Bundle NEC group had a higher incidence of gastrointestinal anomalies (17.91 vs. 3.70%) compared to the Pre-Bundle NEC group. There were no significant differences in the incidence of IVH, intrauterine growth restriction (IUGR), small for gestational age (SGA), or other congenital or cardiac anomalies. In the Post-Bundle NEC group, there was a significant reduction in the use of indomethacin and erythropoietin.

### NEC vs Control

Demographic, maternal, and infant characteristics comparing each NEC cohort with its respective control group are listed in Tables 3 and 4. There were no significant differences in gestational age at birth, gender, maternal conditions, or perinatal factors between the NEC and control groups in either the Pre-Bundle or Post-Bundle cohorts. There were no significant differences in the use of MBM, DBM, PRBC transfusions, or indomethacin use in either the Pre-Bundle or Post-Bundle cohorts.

There was a higher incidence of IVH ( $P = 0.034$ ) in the Pre-Bundle NEC group compared to Pre-Bundle Control. There was a higher incidence of PDA ( $P = 0.020$ ) in the Post-Bundle NEC group compared to Post-Bundle Control. There was also a significantly higher mean days of antibiotics during the first week of life in the Post-Bundle NEC group compared to the Post-Bundle Control ( $P = 0.003$ ).

### Pre-Bundle Control vs. Post-Bundle Control

The changes in practice before and after implementing the NEC care bundle are displayed in Table 5, which compares the Pre-Bundle and Post-Bundle control groups. There was no difference between the two groups with the implementation of trophic feeds. However, the duration of trophic feedings increased from mean of 3.66 to 5.03 days ( $P = 0.0015$ ). There was also a significant change in practice for the type of feeding given to patients, with increased use of MBM and DBM and reduction in the use of preterm infant formula. In the Post-Bundle control group, there was a significant reduction in the use of antibiotics 68.57 to 54.69% ( $P = 0.032$ ) as well as a reduction in the mean number of days of early empiric antibiotics in culture-negative infants, 3.06 to 2.24 days ( $P = 0.0009$ ).

There was a significant decrease in indomethacin from 32.38 to 5.93% ( $P < 0.0001$ ). We did not see a change in PRBC transfusions between the two control groups.

---

***“After implementing an NEC care bundle, there was a significant reduction in the incidence of NEC from 14.21 to 6.09% in our 23-27 weeks gestation infants and a reduction from 5.56 to 2.10% in our 28-30 weeks gestation infants.”***

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## Discussion

After implementing a NEC care bundle, there was a significant reduction in the incidence of NEC from 14.21 to 6.09% in our 23-27 weeks gestation infants and a reduction from 5.56 to 2.10% in

our 28-30 weeks gestation infants. In the ten-year Post-Bundle cohort, we had one patient with recurrent NEC, an incidence of 1.43%, compared to a recurrent NEC incidence of 16.67% in the Pre-Bundle group. We also saw a reduction in transfusion-associated NEC from 24.07% in the Pre-Bundle group to 7.14% in the Post-Bundle group.

When the NEC care bundle was implemented in our NICU, it was done in a stepwise approach over a 12 month period. Each intervention, when combined, had a cumulative effect that would not have been achieved were each component implemented alone. Although the use of protocols that decrease the incidence of NEC has been described previously, this is the first study, to our knowledge, that evaluates the impact of a NEC care bundle on both incidence and recurrence of NEC.

We suggest that several factors played a significant role in decreasing NEC incidence in our NICU. Implementation of a standardized feeding protocol eliminated variation in feeding practices within our group. In addition, using an exclusive human milk policy supported by the adoption of a donor human milk program virtually eliminated the use of preterm formula in our VLBW population. Implementation of a standardized transfusion protocol eliminated variation in transfusion practices, minimized unnecessary transfusions, and exposure to high-risk transfusions with severe anemia. Limiting empiric antibiotic therapy duration also impacted the unnecessary use of antibiotics in infants with low-risk factors and few clinical signs of sepsis at admission. Lastly, stopping the use of indomethacin in the NICU eliminated the associated risks for feeding and gastrointestinal complications without increasing PDA incidence or complications.

Previous studies support the importance of a standardized feeding protocol. Patole *et al.* concluded that the single most effective strategy to prevent NEC was implementing a standardized feeding regimen.(9) Standardized feeding regimens are beneficial since they decrease practice variations and increase awareness of potential feeding problems.(9) Our feeding protocol resulted in less variation in feeding advancements and fortification practices. Standardized feeding protocols have been found to be safe, resulting in the earlier achievement of full enteral feeds, reduced time on hyperalimentation therapy, better growth outcomes, and decreased length of stay.(25-27)

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***“Implementation of early empiric antibiotic treatment in preterm infants born for non-maternal reasons is a common practice because of this population’s immature immune system and risk for morbidity and mortality from early-onset sepsis. Duration of treatment is often based on individual practice and NICU policy as opposed to strong evidence-based practices.”***

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Our donor milk program was started to support infants whose mothers did not have enough MBM. It has been well documented that feeding preterm infants an exclusive human milk diet decreases NEC.(15,16,28-31) When there is insufficient MBM available, DBM is the preferred alternative for preventing NEC. A Cochrane meta-analysis review comparing formula milk versus donor milk

for feeding preterm infants showed a higher risk of developing NEC with formula-fed infants.(32)

Although controversial, several studies have described an association between PRBC transfusion and NEC.(2,33-35) The etiology of transfusion-associated NEC or gut injury remains unclear. The association may be related to the level of anemia,(2) inflammatory factors associated with transfusion, or a combination of both. It has been suggested that withholding feeds during the transfusion may be protective.(34) As an alternative to completely withholding enteral feedings during transfusions, we chose to provide trophic feedings during this time period. In large part, we adopted a transfusion protocol due to observations and experience with transfusion-associated NEC in our NICU. This decision was reinforced by the significant reduction in the number of transfusion-associated gastrointestinal and NEC events seen in our Post-Bundle NEC cohort.

Implementation of early empiric antibiotic treatment in preterm infants born for non-maternal reasons is a common practice because of this population’s immature immune system and risk for morbidity and mortality from early-onset sepsis. Duration of treatment is often based on individual practice and NICU policy as opposed to strong evidence-based practices. It is generally accepted that empiric antibiotics are safe, with perceived benefits outweighing potential risks. This is evident in the common practice of treating culture-negative sepsis.(36) However, emerging studies have reported that prolonged initial empiric antibiotic treatment (> 5 days) may be associated with adverse outcomes, including late-onset sepsis and death, and that each additional day of antibiotic use increases the risk of NEC.(37-39) Because of the increased morbidity associated with prolonged empiric antibiotic treatment, we reduced our use of early empiric treatment from 72 to 48 hours for infants with sterile culture results. To date, the use of any empiric antibiotics in our preterm population has decreased significantly as a result of these awareness practices.

In the NICU, indomethacin has been used both as prophylaxis for IVH and PDA and as a medical treatment for PDA closure. Studies report an increased risk of spontaneous perforation and NEC with prophylactic and therapeutic indomethacin use in preterm infants.(40,41) In a large retrospective study, O’Donovan *et al.* reported that indomethacin was not associated with an increased risk for NEC,(42) and although supported in a subsequent study, an increased risk for intestinal perforation with indomethacin was noted.(43) Prior to our NEC bundle, there was inconsistent practice using prophylactic indomethacin for IVH and PDA prophylaxis. With the NEC bundle implementation, routine use of prophylactic indomethacin was discontinued, and ibuprofen became the drug of choice for medical treatment of a symptomatic PDA. We did not see a significant change in PDA incidence or number of PDA ligations in the Pre-Bundle Control and Post-Bundle Control groups.

Our NEC care bundle was instrumental in decreasing the incidence and recurrence of NEC in a NICU with an already relatively low NEC rate. Balancing protocol-driven care for routine and common decisions with the autonomy for individualized care is important for physician buy-in and adherence to the care bundle. The strength of adherence to the NEC care bundle in our NICU is supported by the significant changes seen in the Pre-Bundle and Post-Bundle control group comparison results.

Limitations of our study should be noted. First and most importantly, we describe the implementation of a bundle specific to our NICU population. Generalization of this bundle to other NICU populations may not necessarily generate similar results. Secondly, our organization transitioned EMR systems between our Pre-Bundle and Post-Bundle study periods. As a result, there were missing or unavailable data for some analysis in the early Post-Bundle chart reviews. Finally, the protocols were introduced

stepwise to improve compliance, so the early Post-Bundle group did not reflect the full impact of all the protocols. We also did not measure the impact of each protocol individually. Future studies could evaluate the impact of each protocol separately.

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**“This decreased incidence of NEC was attained after implementing an NEC care bundle that centered on a standardized feeding protocol that relied primarily on a human milk-based diet, along with protocols for PRBC transfusions, the use of empiric antibiotics, and indomethacin.”**

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### Conclusion

Implementation of a NEC care bundle decreased NEC incidence in our NICU population, with the greatest impact seen in the most vulnerable preterm and very preterm infants. Incidence of recurrent NEC and transfusion-associated NEC were significantly decreased. This decreased incidence of NEC was attained after implementing a NEC care bundle that centered on a standardized feeding protocol that relied primarily on a human milk-based diet, along with protocols for PRBC transfusions, the use of empiric antibiotics, and indomethacin.

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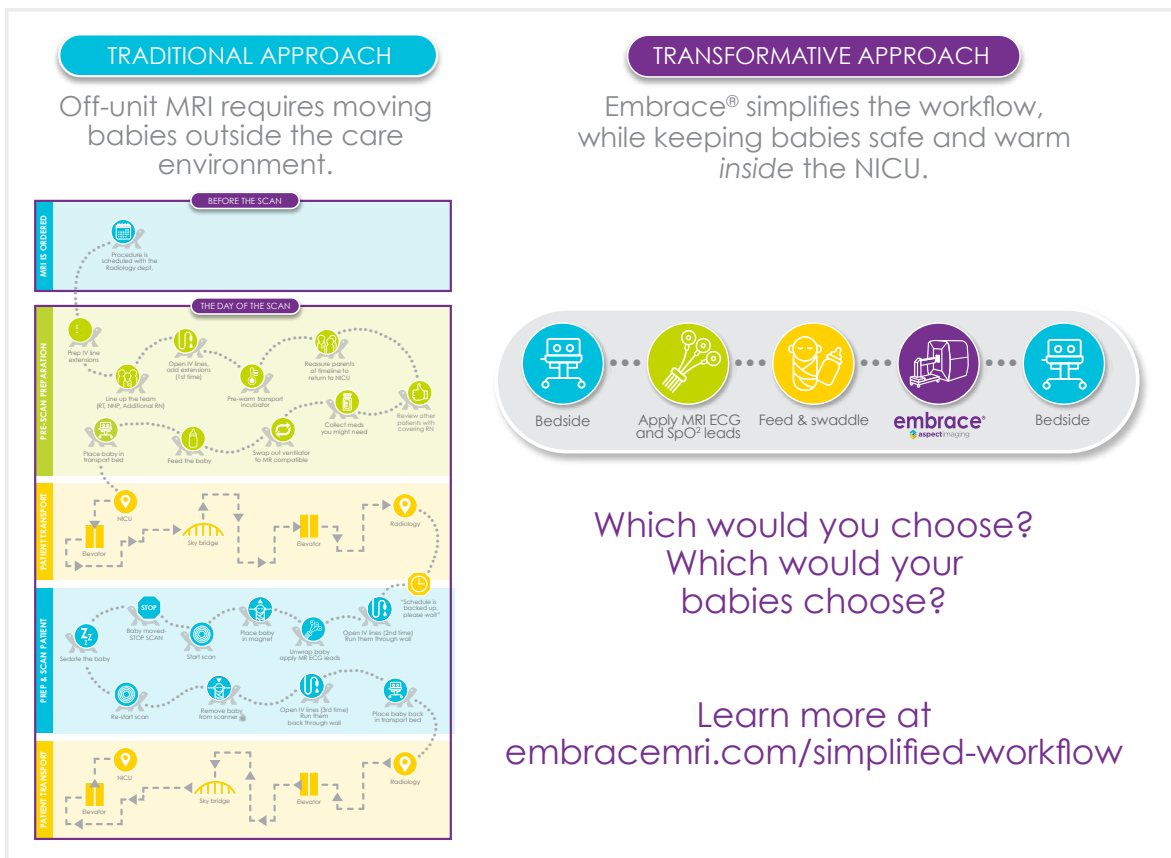


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# Highlights of the 34<sup>th</sup> Annual Gravens Conference on the Environment of Care for the High-Risk Newborn and Satellite Conference on "Reimagining the NICU"

Robert D. White, MD

*"The 34th annual Gravens Conference was held virtually this March, bringing scientists, clinicians, and advocates together to discuss the environment of care of the high-risk newborn"*

The 34<sup>th</sup> annual Gravens Conference was held virtually this March, bringing scientists, clinicians, and advocates together to discuss the environment of care of the high-risk newborn. As in the past, presentations focused on the biology of the newborn brain and developmentally supportive care, care and support of the baby's family, and new directions in NICU design and operation.

## Biology of the Newborn Brain and Developmental Care

Dr. Regina Sullivan (NYU) reviewed infant attachment as described in both the animal and human literature. She discussed the intimate feedback mechanisms that develop between an infant and caregiver and how stressful settings can permanently affect brain structure and biochemistry. Dr. Gretchen Lawhon (Philadelphia) showed the continued influence of the environment on newborn brains as they transition from the NICU to home. Dr. Samantha Butler (Boston Children's) then described a QI project for implementing developmental care in a Cardiac ICU. Several abstracts were presented that continued to build evidence on the value of kangaroo care to both baby and parent.

## Integration of the Family into NICU Care

Dr. Lee Gettler (Notre Dame) reviewed a growing body of evidence that substantive changes occur in hormone levels of new fathers and that these can be influenced by early intimate contact with their newborn infants, with a long-term impact on their commitment to parenting. DeWayne Pursley (Beth Israel Deaconess) provided extensive evidence of racial disparities in health care and how those strongly influence newborn outcomes. Julian and Shante Nixon (NICU parents, South Carolina) gave a face to these statistics, recounting their experience with inequities they experienced as African-American parents in the NICU. Betsy Pilon, founder and executive director of Hope for HIE, presented the many resources now available to families of babies with hypoxic-ischemic encephalopathy. Several abstract presentations described the impact of COVID restrictions on family interaction with their babies in the NICU, and we heard about a unique program

that provides housing for high-risk pregnant women in a Native American population.

## Design and Operational Considerations in the NICU

Two new NICUs were described; Dr. David Paul presented the NICU at Christiana Care in Newark, Delaware and Dr. John Wimmer presented the NICU at Cone Health in Greenville, NC. Both units incorporated single-family rooms and couplet care rooms into their design then did post-occupancy evaluations that showed very high acceptance of this new model of care among both families and caregivers. Dr. Whitney Gray (International WELL Building Institute) and Dr. Mardelle Shepley (Cornell) reviewed the WELL Building Standards and related them to NICU design and operation in ways that can improve air, water, light, and sound quality to the benefit of occupants and the community. Technological advances utilizing artificial intelligence in the NICU were proposed by Dr. Jim Gray and Joanna Celenza (Dartmouth), and Bridget Davern (Minnesota) with a subsequent workshop that focused on new ways to support communication with parents. A team from Lurie Childrens' (Chicago) also presented a workshop that described their program to engage families via telemedicine.

*"Technological advances utilizing artificial intelligence in the NICU were proposed by Dr. Jim Gray and Joanna Celenza (Dartmouth), and Bridget Davern (Minnesota) with a subsequent workshop that focused on new ways to support communication with parents."*

## Reimagining the NICU

A special feature of Gravens this year was a post-conference seminar sponsored by the Sextant Foundation that brought clinicians and parents together with hospital planners and designers to imagine what the NICU of the future might look like. Several multidisciplinary teams spent one day identifying many needs, including balancing the family's need for privacy while avoiding isolation, the challenges new designs place on caregivers, and the need for developmentally appropriate stimuli for babies while simultaneously reducing noxious stimuli. There was also a desire to create additional support space for families and caregivers. A

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second day was focused on potential solutions, which fell into four categories:

- Creation of a “community space” at the heart of the NICU as a gathering place for families and a central staging area for caregivers, distinct from the long hallways typical in current hospital design
- Room designs that could adapt to the needs of the baby and the family, allowing a more personalized experience
- Use of technology to deliver patient information, parent education, and a home-like atmosphere
- Operational changes that enhanced family support and the environment of care for the infant

This project is ongoing; the third day of prototype development will occur in mid-May, then the prototypes will be presented at the 2022 Gravens Conference to solicit input from all attendees. After that session, suggested changes to the next edition of the Recommended Standards for NICU Design will be summarized along with subsequent proposals for changes to the FGI Guidelines that

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***“This project is ongoing; the third day of prototype development will occur in mid-May, then the prototypes will be presented at the 2022 Gravens Conference to solicit input from all attendees. After that session, suggested changes to the next edition of the Recommended Standards for NICU Design will be summarized along with subsequent proposals for changes to the FGI Guidelines that are used by most states for their hospital building codes.”***

---

are used by most states for their hospital building codes.

All the 2021 Gravens presentations are available for viewing now through September 30; register at <https://health.usf.edu/public-health/chiles/gravens-conference/registration>. The 35<sup>th</sup> Gravens Conference on the Environment of the High-Risk Newborn is planned for March 9-12 in Clearwater Beach, Florida.

*Disclosures: The author has no relevant disclosures*

**NT**

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**SHARED DECISION-MAKING**  
PROTECTS PARENTS + BABIES COVID-19

**INFORMED PROVIDERS**  
S eek participation  
H elp explore options  
A ssess preferences  
R each a decision  
E valuate the decision

**CARE DELIVERY REQUIRES PARTNERSHIP**

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NANN  
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**newly validated**

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

7- Module Online Course in NICU Staff Education

National Perinatal Association and NICU Parent Network  
[mynicunetwork.org](http://mynicunetwork.org)

# COVID-19

## STOP THE SPREAD AT HOME

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

### HYGIENE TIPS

#### MOUTH

- Wear a face mask or face shield.
- If in car, wear mask & put windows down.
- NO cloth face masks for children younger than 2yrs.
- Avoid kissing

#### EYES

- Wear protective eye gear (glasses)

#### HANDS

- ALWAYS wash your hands

#### CLOTHING

- Wear a jacket when dealing with infected.
- DO NOT share clothing, sheets, or pillows.

### SELF ISOLATION

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



6 FT

Practice social distancing

### KITCHEN

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



#STOPTHESPREAD

Stop the Spread at HOME

Miora



TRACK COVID-19 NEAR YOU BY VISITING COVIDNEARYOU.ORG

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# COVID-19

## DETENER LA PROPAGACION EN CASA

Qué hacer cuando usted o un ser querido está infectado.

### CONSEJOS DE HIGIENE

#### BOCA

- Use una mascarilla o careta
- Si está en el automóvil, use una máscara y baje las ventanillas
- NO mascarillas de tela para niños menores de 2 años.
- Evitar besos

#### OJOS

- Use equipo de protección para los ojos (lentes)

#### MANOS

- SIEMPRE lávate las manos

#### ROPA

- Use una chaqueta cuando se trata de infectados.
- NO comparta ropa, sábanas o almohadas.

### ASLAMIENTO

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



6 FT

Practica el distanciamiento social

### COCINA

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



#STOPTHESPREAD

Detén la propagacion en CASA

Miora



### PROTEGER

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



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

Visitar Miora.org

Tráido por Miora en asociación con United2Care



## Ways to Manage Covid 19 @ Home

### Household

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

### Sick

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

## Maneras de manejar COVID-19 en casa


### Hogar

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

### Enfermo

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

NOT



We've had a great year of Neonatology Grand Rounds webinars! Missed one? Access them online for free.

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*presented by Karen F. Watters, MB, BCh, BAO, MPH*  
Wed., April 7, 2021 • 4:00pm EDT



**Newborn Glycemic Management - From the Endocrinologist Point of View**

*presented by Paul Thornton, M.D.*  
Wed., May 5, 2021 • 4:00pm EDT

*Webinar topics and speakers subject to change.*

For more information and to register: [mednax.com/NEOGR2021](https://mednax.com/NEOGR2021)



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# PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

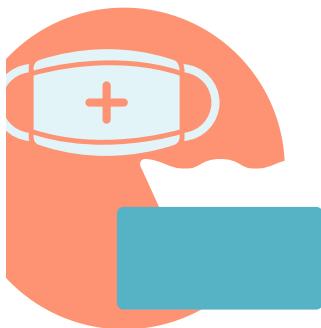
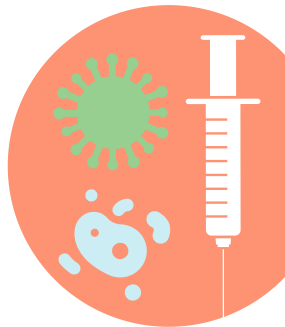
flu coronavirus  
pertussis RSV



**WASH YOUR HANDS** often with soap and water for 20+ seconds. Dry well.

SOAP

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



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

**USE A HAND SANITIZER THAT IS 60%+ ALCOHOL.**



**STAY AWAY FROM SICK PEOPLE** Stay at home to protect vulnerable babies and children. Avoid crowds when out.



[nicuparentnetwork.org](http://nicuparentnetwork.org)  
[nationalperinatal.org](http://nationalperinatal.org)



# 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

SHARED DECISION-MAKING

What is the best for this unique dyad?

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



## TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY

## LONGITUDINAL DATA

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

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY



NEW DATA EMERGE DAILY.

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

Partnering for patient-centered care when it matters most.



National Association of Neonatal Nurses

[nann.org](http://nann.org)



[nationalperinatal.org](http://nationalperinatal.org)

## NICU-NET

NICU-NET is a private and moderated forum for neonatology professionals. Membership is available to physicians, nurses, and other caregivers in neonatal and perinatal medicine. Conference announcements and other news of interest to members may be posted here. Please do not post messages with identifiable patient information of any kind. Vendor posts and messages of a commercial nature will be deleted.

To post to the list, send email to

[nicu-net@nicu-net.org](mailto:nicu-net@nicu-net.org)

To subscribe or unsubscribe, send an email to [nicu-net-request@nicu-net.org](mailto:nicu-net-request@nicu-net.org) with one of the following commands in the subject line:

join - Join this mailing list.

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Rather than joining by email, if you would like more granular control over your subscription (frequency of digests, vacation holds, etc.), you can navigate to <https://nicu-net.org/mailman3/lists/nicu-net.nicu-net.org/>, create a username and password, and set, view, or modify your subscription settings.

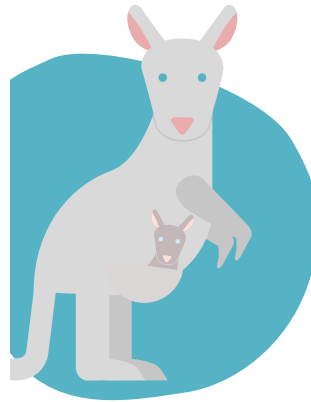
Message archives from the U. of Washington NICU-NET (1994-2003) and Yahoo Groups NICU-NET (2003-2019) are available on Google Drive. You can download them using this link: <https://drive.google.com/drive/folders/1MoPTrDjzmGbsZIKqY9MczihApWaFbREK?usp=sharing>

To contact the list owners, use the following email address:

[nicu-net-owner@nicu-net.org](mailto:nicu-net-owner@nicu-net.org)

## SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



### GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

### GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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



### PUT ON FRESH CLOTHES

change into a clean gown or shirt.

### IF COVID-19 + WEAR A MASK

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



[nicuparentnetwork.org](http://nicuparentnetwork.org)

[nationalperinatal.org/skin-to-skin](http://nationalperinatal.org/skin-to-skin)





COMING SPRING 2021

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Babies are just tiny adults,  
right? So ... half?



Infants need drugs  
tested and approved just for them.

NATIONAL PERINATAL ASSOCIATION


# CORONAVIRUS

COVID-19

RELIABLE  
RESOURCES:

- CDC: 2019 Novel Coronavirus
- The Lancet: COVID-19 and pregnancy
- MotherToBaby: Coronaviruses
- WHO: Emerging respiratory viruses

STAY INFORMED.



[www.nationalperinatal.org](http://www.nationalperinatal.org)



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

# *In Loving Memory*

*August 9, 1996 - April 3, 2010*



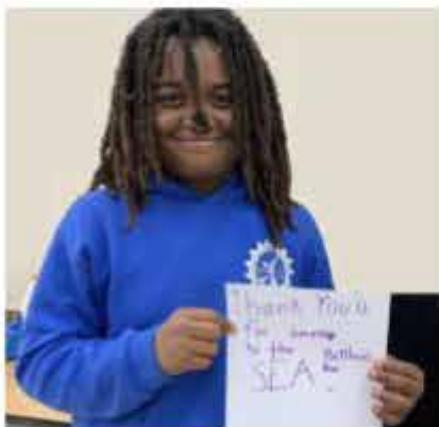
Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring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

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

Please visit [emilyshane.org](http://emilyshane.org)

## **Sponsor a Child in the SEA Program**

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



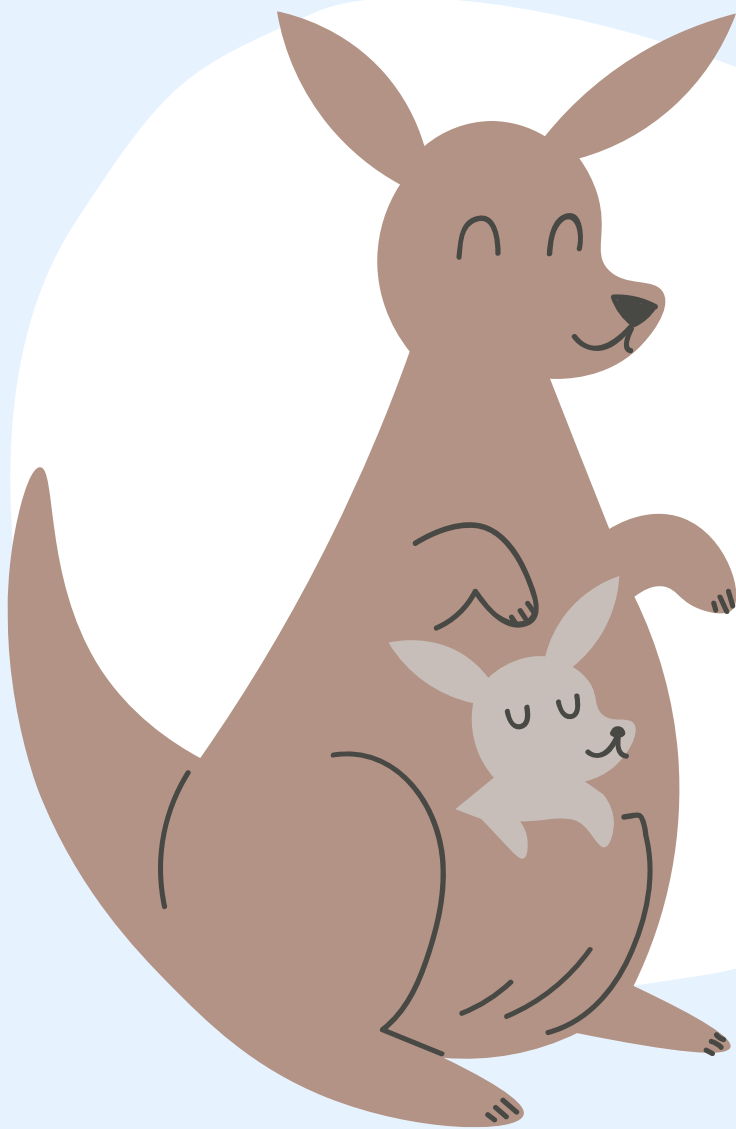
1 session_____	\$15
1 week _____	\$30
1 month_____	\$120
1 semester_____	\$540
1 year_____	\$1,080
Middle School_____	\$3,240

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



MAY 15

KANGAROO CARE AWARENESS DAY



Every  
moment  
spent  
skin-to-skin  
is time  
spent

- bonding
- healing
- growing

# KANGAROO CARE

#THESNUGGLEISREAL

[kangaroo.care](http://kangaroo.care)

[nicuparentnetwork.org](http://nicuparentnetwork.org)

[nationalperinatal.org/skin-to-skin](http://nationalperinatal.org/skin-to-skin)



# Reactivity in Shiny WebApps

*Fu-Sheng Chou, MD, PhD*

Reactivity is the heart and soul of Shiny WebApps. It allows the WebApps to respond to user input with immediate response. There are three components in a reactivity system:

1. Reactive source
2. Reactive conductor
3. Reactive endpoint

In a simple one-to-one reactivity system, the reactive conductor can be left out of a reactivity system's design. However, in more sophisticated WebApps with multiple sources and endpoints, the design of one or multiple reactive conductors will allow computation to be more efficient and make the reactivity system work more seamlessly.

## Reactive source and endpoint

Figure 1A illustrates the simplest form of a reactivity system, where an input corresponds to an output. For example, scoring of each neonatal abstinence syndrome (NAS) items (as input) results in reporting of total scores (as output). Another example would be inputting bilirubin levels and hours of life, resulting in the output of the risk category. In a more sophisticated reactivity system, values of one or multiple variables provided by the user enter a statistic model to calculate a predicted value as a reactive endpoint for output (Figure 1B).

***“One can make an analogy of reactivity to the autosave function of Google Doc documents. Many readers likely have a Google account and have used Google Doc at least once in the past. Different from saving word processing documents in Microsoft Word, where a “Save” button is clicked to save the changes to the document, in the modern-day Google Doc, the document is saved as soon as the document is modified, without the need to hit “Save.” That is Reactivity.”***

One can make an analogy of reactivity to the *autosave* function of Google Doc documents. Many readers likely have a Google account and have used Google Doc at least once in the past. Different from saving word processing documents in Microsoft Word, where a “Save” button is clicked to save the changes to the document, in the modern-day Google Doc, the document is saved as soon as the document is modified, without the need to hit “Save.” That is *Reactivity*. Of course, in the Shiny WebApp, the flexibility still exists to build a button to trigger the flow from input to output (such as the SEARCH button of [Neonatology Today's new website](#)), but the use of a reactivity system provides the opportunity to

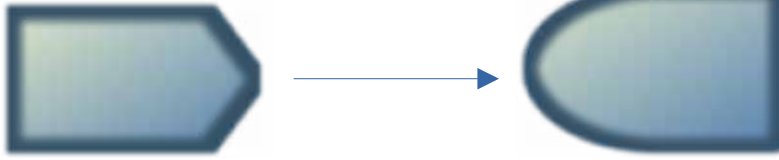
assess the output dynamically. This access is particularly useful when the input is a continuous numeric variable or a multi-level categorical variable. With reactivity, data presentation is no longer static constrained in a tabular or a 2-dimensional figure format but now has a “depth.”

The [NAS WebApp](#) has the simplest form of reactivity. As you can see, when an option for an item is clicked, The Total Score (at the top) is updated immediately to reflect the selection. Another example is the PAST ISSUES box of [Neonatology Today's new website](#). When the Year pull-down menu is updated, the Month list is updated immediately (the Month list options are dynamic in accordance to which year is selected: when 2021 is selected, the Month list only displays January and February, but when 2020 is selected, the Month list has all months available for selection. Similarly, changes in year and month result in automatic updates of the table of contents resulting from reactivity.

***“It is relatively easy to conceptualize in a one-to-one or multiple-to-one reactivity system. Nonetheless, the system can handle much more sophisticated situations. There can be one-to-multiple or multiple-to-multiple reactivity systems, with one source going out to multiple endpoints and each endpoint receiving input from multiple sources, sort of like neuronal connections in the brain.”***

## Reactivity Conductor

It is relatively easy to conceptualize in a one-to-one or multiple-to-one reactivity system. Nonetheless, the system can handle much more sophisticated situations. There can be one-to-multiple or multiple-to-multiple reactivity systems, with one source going out to multiple endpoints and each endpoint receiving input from multiple sources, sort of like neuronal connections in the brain. In such a case, designing the flow to include one or multiple reactivity conductors as the information relay station is helpful (Figure 2A). It may seem redundant to have a conductor between the source and the endpoint if data stored in the input source is transferred to the endpoint without any modification. However, in a case where the input source is fed into a very complex statistical algorithm that takes minutes or even hours to run, having a reactivity conductor to store the output from the very complex statistical calculation will make computation much more efficient. Why so? Let us say we developed a statistical model that predicts the probability of successful extubation based on 15 variables. The calculation takes 5 min. The endpoints are multiple, including 1) displaying the probability, 2) calculating the sensitivity and specificity of the model, and 3) plotting the receiver's operating characteristic (ROC) curve. It would probably be wise to have the calculation performed once (takes 5 min), store the predicted values, and render the outputs based on the stored values instead of performing a calculation

**A****Reactive Source(s)****Reactive endpoint**

Scoring each item:

- ✓ High-pitched cry
- ✓ Sleep
- ✓ Moro reflex
- ✓ Tremor
- ✓ ...

NAS total score

**B****Reactive Source(s)****Statistical model****Reactive endpoint**

every time an output requests the predicted values (takes 15 min). The *reactivity conductor* is the object that stores the values; in other words, the conductor reacts to the input, the value stored in the conductor is constantly monitored for an update. The endpoints then monitor the conductor for further updates (Figure 2B). In this case, the *conductor* is a mediator, which can be treated as an output (to the input sources) and an input (to the endpoints).

**How does reactivity work?**

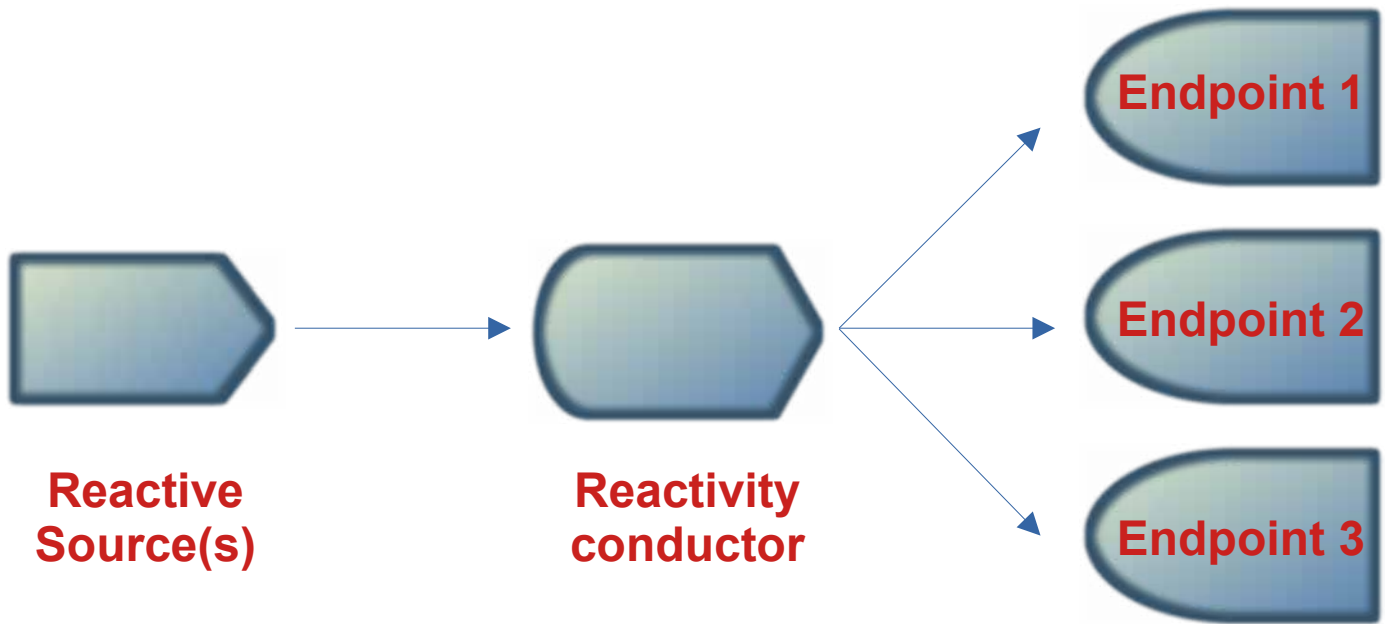
In the previous section, we hinted at how reactivity works. First, the arrows' direction in Figure 1 and Figure 2 is easy for humans to understand, but it is not how reactivity works behind the scene. Rather than passively waiting for input sources to send out a notice to the conductor or the output endpoint upon update of an input source, the receiving endpoints constantly check the computer memory to see if any upstream variable contributes to the output endpoints is updated. The upstream variables can be the input sources or the reactivity conductors. There is a computer science approach to the monitoring task, so it does not exhaust the computing power quickly. We, as end-users, probably do not need to know all the details.

**In practical terms**

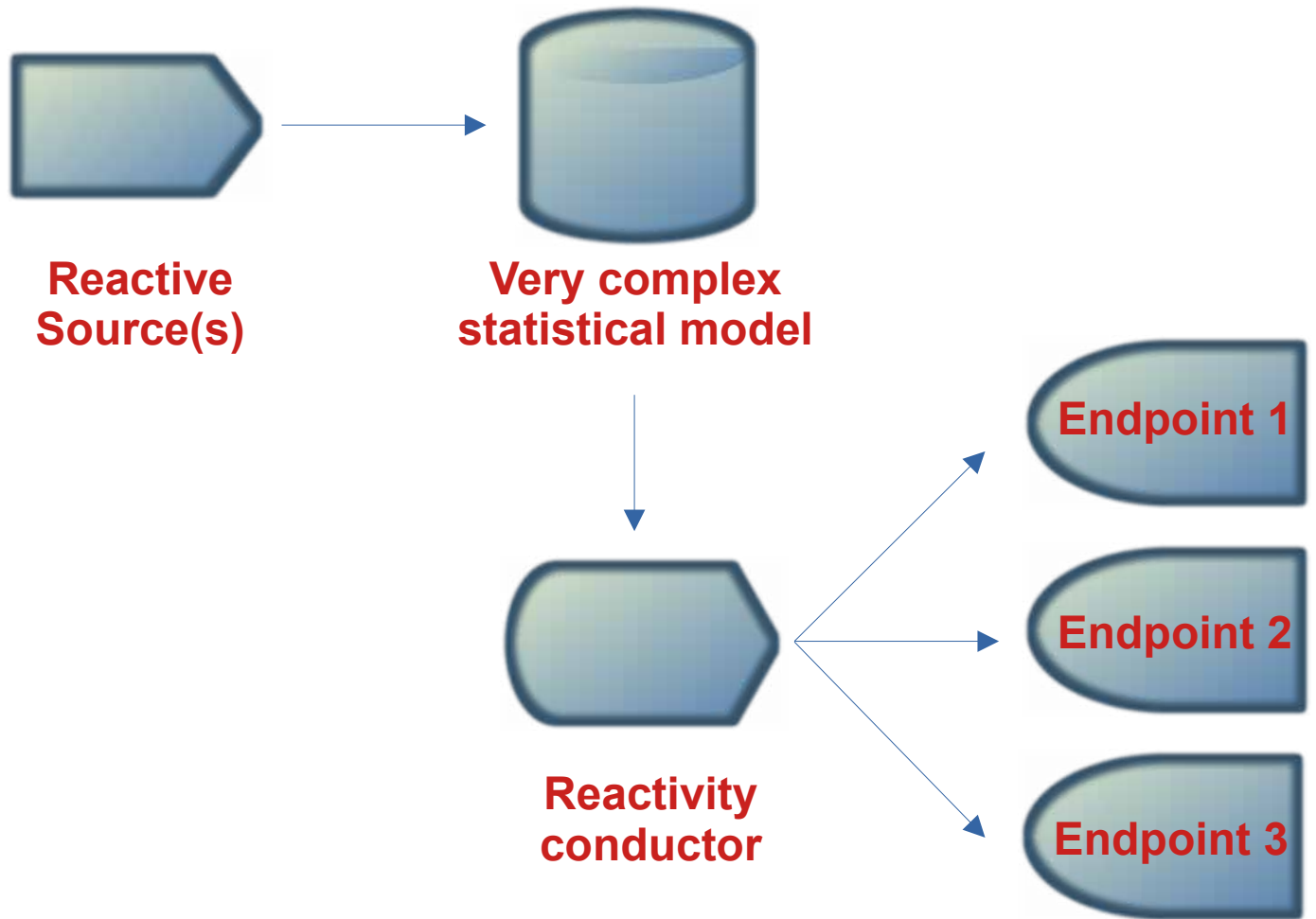
In our NAS example, because of the reactive nature of the `renderUI()` function, it constantly monitors whether input values are changed. If so, the user interface, which displays the total score value, will be re-rendered to provide the updated total sum to the variable *total* in the output:

```
server <- function(input, output) {
  output$total <- renderUI({
    score = as.numeric(input$high_pitch_cry) +
      as.numeric(input$sleep) +
      as.numeric(input$moro) +
      as.numeric(input$tremor) +
      as.numeric(input$stone) +
      .....
  })
}
```

**A**



**B**



Therefore, the users do not have to click a button to tell the system to re-calculate the total score; it automatically does the job. As one can imagine, the accuracy of the information provided by the input source is critical. One has to choose the correct answer for each NAS item because the total score is updated immediately without a security check. It is like stepping away from working on a manuscript in Google Docs, and your cat jumps onto the computer and decides to walk on the keyboard. You are left with extra random symbols on the document, or even worse, a paragraph is completely deleted. Google Doc does not know it is the cat walking, not human typing, so all the changes are saved. In the old days, when all the changes were not saved in document history, it was an absolute nightmare. The true story, thanks to my lovely cat Aimee.

**“Google Doc does not know it is the cat walking, not human typing, so all the changes are saved. In the old days, when all the changes were not saved in document history, it was an absolute nightmare. The true story, thanks to my lovely cat Aimee.”**

One last thing to point out is that the *Shiny* package comes with a function called `reactiveValues()` which functions similarly to the `list()` function we introduced in the January 2021 article, (1) except it allows the values stored in each element to be monitored “reactively.” Let us say you decide to treat the NAS score as a reactive conductor because you want the output to be the management plan (for example, if the total score is  $> 12$ , you want the endpoint to be displaying the unit protocol for NAS pharmacological treatment). In such a case, a reactive list using the `reactiveValues()` function (see below where we created an element named *NAS* within the reactive list named *myReactiveValues*) can be created to store the total score value. The `observeEvent()` function can then be used to monitor any update on the value stored in `myReactiveValues$NAS` to produce the endpoint. In the example below, you can see that `observeEvent()` has two arguments: the first one is the reactive conductor to monitor, and the second is the *expression* flanked by curly brackets. Note that the first argument can also be an input value, meaning that `observeEvent()` can monitor the input source too.

```
server <- function(input, output) {
  myReactiveValues <- reactiveValues(NAS = NA)
  myReactiveValues$NAS <-
    score = as.numeric(input$high_pitch_cry) +
    as.numeric(input$sleep) +
    as.numeric(input$moro) +
    .....
  observeEvent(myReactiveValues$NAS, {
    if (myReactiveValues$NAS > 12) {
      display the protocol for NAS pharmacological
      treatment
    }
  })
}
```

## Summary

In this article, we discussed what reactivity is and how it works. We introduced a couple of functions to store and monitor reactive values. Reactivity systems should hopefully make the WebApps more responsive to the users. However, if user input verification is critical to your app, building a security checkpoint (a button, a message dialog, etc.) may not be a bad idea either.

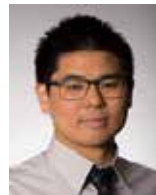
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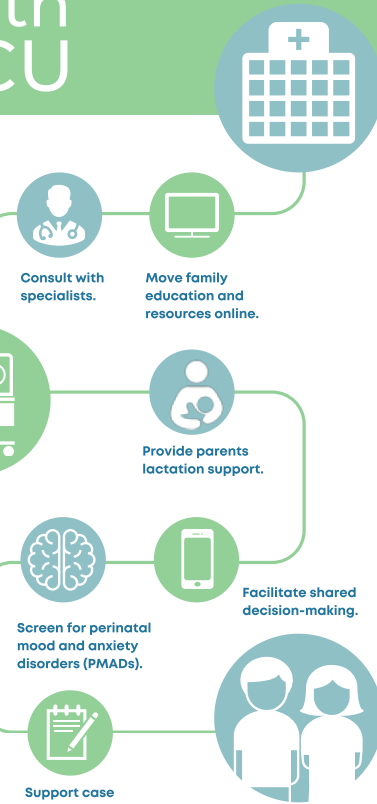
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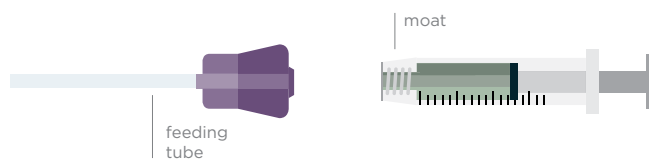
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# Fellow Column: Objective Measures of Neonatal Pain

Benjamin Shlomo, MD, Derek McCalla, MD

## Introduction:

Pain is a recurring concern for pediatric physicians that is particularly complicated in the neonatal patient who cannot verbally articulate even the amount of pain.

**Discussion:** Per interviews with the nursing staff of both the PICU and wards, the Loma Linda University Children's Hospital measures pediatric pain in one of three ways, depending on patient competency: Older children are asked to self-rate their pain on the 1-10 scale, also known as a "Visual Analog Scale" (VAS). Verbal but less mature patients are shown the Wong-Baker (WB) faces (1) and asked to select the nearest representation of their pain. Research has shown that child Wong-Baker ratings correlate to their VAS ratings and that neither WB nor VAS ratings correlate to a Fear Scale, suggesting both measure pain rather than fear (2); Finally, the pain level of nonverbal children are judged by the nursing staff according to the FLACC scale (3). FLACC uses third-party observation of the Face (grimacing), Leg (position), Activity (level), Cry, and Consolability on a 0-2 scale for each of the five criteria. FLACC has been incorporated directly into the LLU Epic EMR flowsheets.

Third-party ratings of pain may be unreliable. For example, in one study of 63 emergency department patients from 4 to 7 years of age, self-reported ratings on a scale similar to WB (the Smiley Analog Scale) did not correlate with physicians' ratings of their pain and only very slightly correlated with parent's ratings of their children's pain (4).

It has been argued that the patient's sense of his or her pain should be "the primary source of information since it is more accurate than the observation of others" (5). However, in the field of psychology, self-report is often considered the least reliable form of data-gathering: "Although self-report measures are easy to obtain and inexpensive, they are notoriously inflated and inaccurate..." (6). "Why would the researcher trust what people say about themselves?" (7). Indeed, in studies of adults, the intensity of pain complained of often did not match the intensity of the pain stimulus delivered (8), and a quality improvement plan that routinely measured pain as "the 5th vital sign" did not appear to improve quality of pain management (9). A questionnaire of long-term elderly care nurses showed they were more likely to trust their physical exam findings of facial expressions of pain than patients' descriptions, and the more experienced the RN, the less they trusted self-reported pain (10).

Ironically, although self-report is considered unreliable, proposed objective modalities for measuring pain (including FLACC) are judged by how strongly they correlate to it. Then why bother examining or applying objective measures of pain? One advantage to objective measurement is to counterbalance biases that might influence physicians' subjective evaluations, such as towards race, gender, spoken language, etc. (11). Another purpose could be to distinguish genuine pain from faked pain, such as when a patient may have social rather than medical reasons for wanting to stay in the hospital (12). Alternatively, one could detect when a patient was masking the degree of suffering, such as in a child who believes they will go home faster if they lie about not being hurt (13). Finally, preverbal or nonverbal patients, including the entire neonatal population, cannot describe symptoms for the doctor, so objective pain measures would help guide therapy.

*"Alternatively, one could detect when a patient was masking the degree of suffering, such as in a child who believes they will go home faster if they lie about not being hurt (46). Finally, preverbal or nonverbal patients, including the entire neonatal population, cannot describe symptoms for the doctor, so objective pain measures would help guide therapy."*

Vital signs have traditionally been suggested as possible measurements of pain. In one study of 120 adult ICU patients, heart rate and respiratory rates increased, and SpO<sub>2</sub> decreased in correlation with pain scores (by either VAS or "Behavioral Pain Scale" if unconscious) (14). Another study of almost 1.5 million children found heart rate and respiratory rates were higher in acute ER presentations than the upper normal standards of APLS and PALS. (15).

Acute pain leads to generalized sympathetic nerve activity, which raises BP. (16). Increased BP can cause a pain-relieving and possibly stress-relieving effect due to increased endorphin release (17). However, evidence shows that high BP reduces pain sensory thresholds (18,19), making the detection of acute pain by BP changes in chronic hypertension more complicated than in normotensive patients.

Tachycardia is also frequently used as a sign of pain in many observational scales, but not all research confirms the relationship. In one study of acute pain in 10,617 adult ER visits, "heart rate and self-reported pain were correlated among whites, but the association was modest. ...Among blacks, there was no statistical difference in heart rate across all pain scores." (20).

Various modalities have been used to reverse-engineer neuroimaging patterns that correlate with pain, including fMRI, PET, NIRS (near-infrared spectroscopy), EEG, and MEG (magnetoencephalography). However, aside from radiation exposures, such imaging is typically too expensive and time-consuming for routine daily pain-monitoring (21). In the neonatal population, imaging would be further limited by the need to obtain sedation to keep the patient from moving too much for the scan.

Neuroendocrine hormones have been proposed as markers of pain (22), but studies have shown variable results. For example, procedural pain did not raise plasma cortisol levels or catecholamines in adult intensive care patients after cardiac surgery (23).

Salivary amylase has also been shown to increase with self-report with WB faces pain scale in children (24). However, again, research data has been mixed. Another study in Neonates showed no definite changes in salivary biomarkers (Salivary cortisol (sCgA) or salivary amylase (sAA)) detected before and after heel lancing (25).

"Facial expression is perhaps the biggest determinant and most

consistent cue in judging pain in children...even above cry...Literature reviews report over 20 behavioral/observational scales, all of which essentially have some component of facial expression" (26).

Research interpreting facial expressions relies on the theory that such expressions have consistent meanings. Prior to the 1960s, most sociologists believed that human emotions were specific to individual cultures, which explained why some languages had words for unique emotions (for example, the Italian word for the specific pride at one's achievement "fiero") (27). Conversely, Charles Darwin wrote the first book on Evolutionary Psychology, *The Expression of Emotions in Man and the Animals*, arguing that emotional displays were innate and evolved as part of natural selection and shared among humans and other species (28). For instance, the expression of fear opens one's eyes to observe better while signaling to the pack that a predator is nearby, while the expression of disgust wrinkles the nose to limit the inhalation of toxic substances.

In 1963, a psychologist named Paul Ekman took photographs of Caucasian graduate students posing the emotional expressions as described by Darwin and demonstrated that naïve subjects universally identified the expressions consistently. But what if that were a function of cross-cultural sharing through travel or television? Ekman researched the Fore tribe of Papua New Guinea, a society that had almost no contact with the outside world, as well as no reflective surfaces or clean water, and therefore had never seen their own faces. The Fore, too, correctly identified—through a translator—the same images of Caucasians posing emotional facial expressions, demonstrating that facial signaling was universal among humans (29). Later research confirmed this finding, for instance, showing that congenitally blind winners and losers in Paralympic Judo exhibit the same expressions for pride and shame, respectively, as those sighted competitors in Olympic Judo (30).

The next step was developing an objective system for studying expressions. After 8 years of work, Ekman and Dr. Wallace Friesen published the Facial Action Coding System. The functional unit of FACS is an "Action Unit," a muscle group that contracts at different intensities, rated by suffixes of "a" ("trace") to "e" ("maximum") to alter a subject's expression. FACS itself makes no judgments about the meaning of the expressions observed (31). It takes a human approximately 100 hours to learn how to code photographs or videos into FACS units by visual changes alone; however, modern research now includes computer programs that auto-code video (32). FACS has since been adapted to the human infant (33) and various animal (34,35) physiology.

Neonatal research using FACS has led to a variety of discoveries, for example, that newborns who have never tasted anything before still have distinct facial expressions for sweet, sour, and bitter tastes (36), but the most relevant research to this essay is the facial expression of Pain.

A study of 117 adults with chronic low back at a tertiary care clinic asked to pose for 6-second videos at baseline, on the exam, while hiding the effect of painful movement, and while posing pain showed that there was a universal facial expression of pain. The face of pain specifically consists of AU4 (eyebrow lowerer with vertical glabella wrinkling), AU6 (cheek raiser/crow's feet wrinkler), AU7 (eyelid tightener/squinting), AU10 (upper lip raiser), AU25 (mouth opener), and AU43 (upper eyelid closer). Adults were able to produce all of those same action units when faking/posing pain at statistically significant levels above baseline, whereas when hiding/masking/suppressing true pain, only AU25 (mouth opening) and AU43 (upper eyelid closing) appeared more often than baseline (37). Note that many studies include AU9 (the levator labii superioris alaeque nasi muscle strands) instead of or in ad-

dition to the anatomically adjacent AU10 (levator labii superioris caput infraorbitalis muscle strands) (38); either AU is interchangeably part of the universal facial expression for disgust when symmetrical, and contempt when asymmetrical (39).

A sister study using the same dataset as (37) showed that judges were able to distinguish genuine pain faces from baseline expressions but, relative to genuine pain faces, attributed more pain to faked faces and less pain to suppressed ones." In judging the intensity of observed pain, judges' opinions correlated only with AU6 and AU43. In self-reporting of Pain intensity, the subjects' opinions correlated only with AU6. Warning of deception did not improve discrimination but led to a more conservative or non-empathic judging. "Facial information consistently was assigned greater weight" than verbal claims (40).

In another study of adult pain induced by electric shock, cold, pressure, and ischemia, researchers found that all 4 modalities produced the same universal facial expression of pain (38). Later investigations have shown the same expression for acute (41) as chronic pain. Similar findings confirming the same universal facial expression of pain was found in automated coding of 57 neonates during heelstick, with no differences by gender or ethnicity (42). Pain can have different intensities and different time courses, but it always looks the same unless the patient is suppressing or faking.



Fig. 1: An example of automated coding of the facial expression of pain. From Schiavenato, M. "Evaluating Neonatal Facial Pain Expression: Is There A Primal Face Of Pain?" (2007). Electronic Theses and Dissertations, 2004-2019;3337. <https://stars.library.ucf.edu/etd/3337> (used with permission of the author)

"Faked expressions of pain in [8-12-year-old] children were found to show more frequent and more intense facial actions compared to their genuine pain expression...suppressed expressions, however, showed no differences from baseline...Parents correctly identified the four conditions significantly more frequently than would be expected by chance. They were generally quite successful at detecting faked pain...children are capable of controlling their facial expressions of pain when instructed to do so. However, they are better able to hide their pain than to fake it" (40). Infant pain expressions show more consistent research outcomes than

similar investigations of adult faces (43), "leading one to believe that exposure, experience, and normal human development may lead to modulation of the facial display." (42). Therefore, the suggestion is that using facial expressions to measure pain would be particularly reliable in neonates compared to older children because babies have not yet learned the social actions of hiding or faking their hurt.

Research involving FACS in pediatrics has shown a good correlation with other measures of pain. Facial coding of muscles of pain expression in infants post-surgery correlates with the nurse reports used to direct morphine administration (44). Computer-automated coding of ongoing pain in 5-17-year-old post-laparoscopic appendectomy patients' chronic pain demonstrated a higher correlation with child self-ratings (on a VAS-equivalent 0-10 scale) than with nurses' ratings and performed similarly to parent ratings. Automated coding performed similarly to nurses for pain induced by palpation. (45).

The physician's task is to synthesize the subjective and objective measures to make a clinical judgment about pain and its management. Facial expressions of pain correlate with self-reporting and require no special equipment other than direct observation. Comparing subjective pain to objective pain could help bridge the gap for patients and physicians when forming pain goals.



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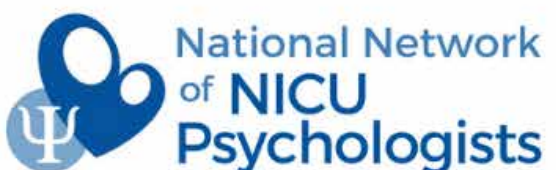
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# First Candle Forming Public Health Advisory Committee to Address Health Inequities

Barb Himes, IBCLC



Saving babies. Supporting families.

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

***"We have previously shared information with Neonatology Today readers about our work to lower the rates of sleep-related infant deaths in the U.S., first as a charter participant in the 1994 national Back to Sleep (now Safe to Sleep) campaign, which contributed to a 50% reduction in the SIDS rate, and our ongoing educational outreach to professionals and families."***

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reduction in the SIDS rate, and our ongoing educational outreach to professionals and families.

At the core of this has been the set of safe sleep guidelines developed by the American Academy of Pediatrics (AAP), which continues to be updated and which forms the foundation of our own Straight Talk for Infant Safe Sleep training program targeted to health care professionals who provide maternal and infant health services to families.

Through our work, we have come face to face with the complexities that affect parents' adoption of the guidelines, with the perseverance required to create long-term change in health behaviors; and the larger challenges within the health care system that families depend on for maternal and infant health. We have seen that a thread running through all of this is implicit bias and its impact on maternal and infant health and mortality in the U.S.

Presenting evidence-based safe sleep guidelines is not enough; the context in which it is conveyed to health care professionals and families has a direct bearing on how it is received, accepted, or rejected.

Through our Straight Talk for Infant Safe Sleep, we have been helping health care professionals identify implicit bias and learn how to address it. In Straight Talk and our overall organizational work, we look at bias in the many forms it takes, from gender to socioeconomic, from bedside manner to race, from small interpersonal behaviors to institutional practices.

But there is always more to be done. Today the rate of SUID among black infants is three times higher than for whites, and for Hispanic babies, it is twice as high. And while the AAP guidelines recommend regular prenatal care for pregnant women, maternal health in communities of Color is threatened by health inequities resulting from structural racism in health care, lack of access to quality prenatal and postpartum care, and racial stress. These can contribute to low birth weight, pre-term birth and birth complications, all infant death risk factors.

Therefore, we are expanding our efforts and are developing a standing Public Health Advisory Committee of health care professionals and advocates to constructively address the racial disparity, health inequity, and implicit bias in maternal and infant health practices and their impacts on sleep-related infant mortality. This committee will also help us ensure that our educational outreach messages and materials work effectively in the real world that families experience.

This volunteer committee will include leaders ranging from health care and public health outreach professionals to national maternal justice advocacy organizations and policymakers. Founding members include First Candle board members Andrew Rubenstein, MD, Chair, Obstetrics and Gynecology for the Dignity Health Medical Group at Saint Joseph's Hospital and Medical Center in Phoenix; and John Ciannella, MD,



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***“ This volunteer committee will include leaders ranging from health care and public health outreach professionals to national maternal justice advocacy organizations and policymakers.”***

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Dr. Rubenstein considers “the formation of this diverse, multi-disciplinary advisory committee paramount to drive changes within the health-care models and address the disparities in maternal and child health.”

Another member is Dauline Singletary, MPH, Public Health Educator at Wake County Health in Durham, North Carolina, and a Doula, who notes that “working in public health, we all see that the racial and health inequities in Black and brown communities are much higher than that of white communities, and developing a committee that focuses on the needs and providing the resources not only promotes health babies but healthy families.”

The committee-in-formation is also expected to include representatives from organizations focused on inequities in maternal morbidity rates as well, and to look at premature and low birth weight births, where infants have a four times greater risk of SIDS.

This committee formation complements our recent increased public outreach around family perceptions of the AAP safe sleep guidelines. We have been convening community task forces in Georgia, Connecticut, and Michigan, comprised of parents, extended family, in-home health care providers, social service agencies, and doulas, to learn their thoughts on the guidelines and the challenges in adopting them, as well as the role systemic racism plays.

The findings are being shared with the AAP as it develops the updated safe sleep guidelines, scheduled to be released later in 2021. The community task force participants will then have the opportunity to be involved in framing how the revised guidelines are communicated to

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***“The committee-in-formation is also expected to include representatives from organizations focused on inequities in maternal morbidity rates as well, and to look at premature and low birth weight births, where infants have a four times greater risk of SIDS. ”***

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their specific communities.

We want every baby to reach his or her first birthday and beyond. Health inequities imperil this, but the answers lie within the relationship between health care providers and families, and we feel it is our job to listen, learn and provide both leadership and support.

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### About First Candle

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





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# From The National Perinatal Information Center: Maternal Mental Health Awareness

Elizabeth Rochin, PhD, RN, NE-BC

The National Perinatal Information Center (NPIC) is driven by data, collaboration and research to strengthen, connect and empower our shared purpose of improving patient care.

For over 30 years, NPIC has worked with hospitals, public and private entities, patient safety organizations, insurers and researchers to collect and interpret the data that drives better outcomes for mothers and newborns.



*“May is Maternal Mental Health Month, which provides an opportunity for providers, patients, communities, and activists to engage in discussion and dialogue about the importance of recognizing maternal mental health as an unmet public health need.”*

*“I couldn’t bring myself to tell my doctors or nurses, or the doctors and nurses in the NICU about the way I was feeling. I was already that “bipolar patient.” I had used opiates for a few years to cope with the pain that depression brought with the disease. I could feel myself becoming more and more depressed and desperate for help, but thought that if I asked for help, my baby would be taken away from me. My bipolar disorder had haunted me for most of my adult life, had labeled me, and now with a new baby, had no one to reach out to. Each time I left the NICU, I thought it would be the last time I would see my baby. That feeling was so traumatic, and even though my baby is now 1 year old, I still relive that fear every day.” –A.R., during a postpartum interview*

## Overview

May is Maternal Mental Health Month, which provides an opportunity for providers, patients, communities, and activists to engage in discussion and dialogue about the importance of recognizing maternal mental health as an unmet public health need. Compound this maternal mental health need with the public health crisis of racism (1) and a stark picture emerges of women and birthing people in need of tremendous support. Many facets must be addressed within maternal mental health—access to care, transportation, stigma, insurance coverage, stable housing, to name a few. An area of concern that has been identified is that of opioid use disorder during pregnancy. A greater prevalence of comorbid psychiatric disorders, physical and sexual abuse, intimate partner violence, and chronic pain disorders likely contribute to disproportionate rates of opioid use and misuse (2) in women and particularly women during pregnancy. As opioid use among pregnant women has increased, the rate of infants in the United States experiencing opioid withdrawal after birth, known as neonatal abstinence syndrome (NAS) or, more recently, neonatal opioid withdrawal syndrome (NOWS), has grown nearly fivefold over the past decade (3). From 2000 to 2016, the incidence of NOWS increased from 1.2 to 8.8 per 1000 hospital births, with West Virginia reporting the highest rate of NOWS at 33.4 per 1000 hospital births (4). Much of this information is not new, and in fact, most hospitals across the country have been supporting these families and babies for years.

*“The National Perinatal Information Center has been tracking deliveries with substance use disorder for some time, with the rates steadily increasing year over year since 2016. However, during this same time, there has been a small, consistent decrease in inborns with neonatal abstinence syndrome (NAS) within the NPIC Perinatal Center Database (PCDB).”*

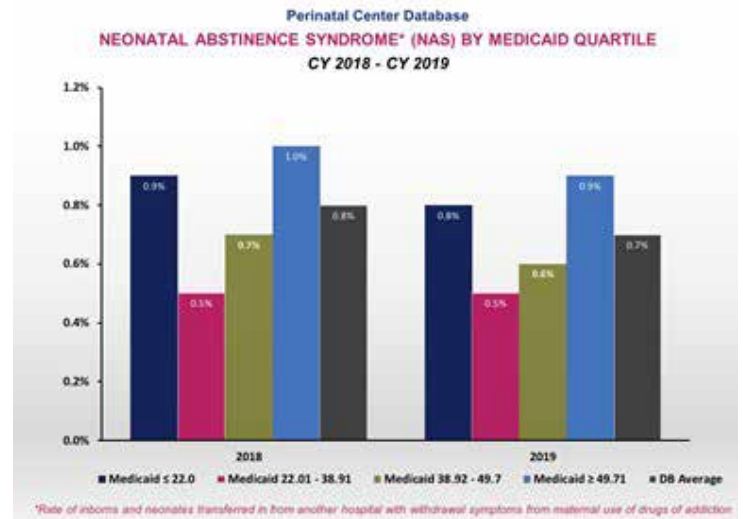
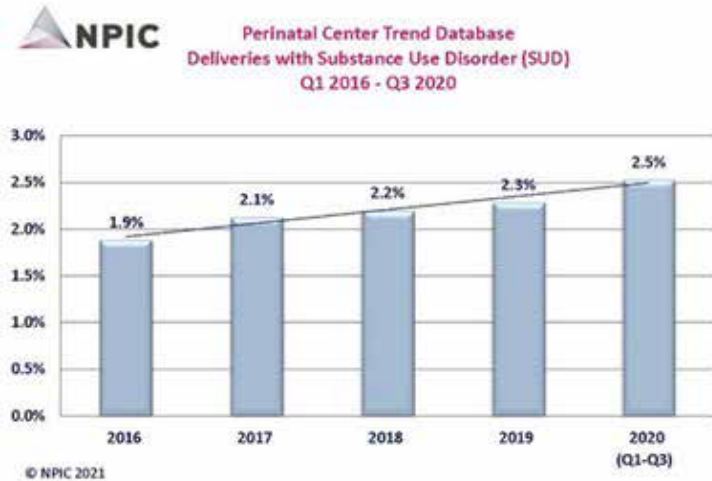
The National Perinatal Information Center has been tracking deliveries with substance use disorder for some time, with the rates steadily increasing year over year since 2016. However, during

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this same time, there has been a small, consistent decrease in inborns with neonatal abstinence syndrome (NAS) within the NPIC Perinatal Center Database (PCDB). Reasons for this may include the specificity of ICD-10 codes used for NAS versus opioid exposure, non-billable F codes within ICD-10 that include specificity related to neonatal exposure, and utilization of non-billable Z codes that do not roll up into billing.

tion, such as a NICU or transitional nursery.



## Discussion

Maternal mental health directly impacts the outcomes of a newborn. Perinatal mood disorders are some of the most identified maternal mental health concerns and are associated with increased risks of maternal and infant mortality and morbidity and are recognized as a significant patient safety issue (5). In addition to perinatal mood disorders, other mental health diagnoses must be appreciated, including pre-existing psychiatric illnesses (major depression, bipolar disorder, schizophrenia, etc.) that often are underreported and undertreated due to stigma and fear of reporting. During the month of May, certain elements of maternal mental health must be recognized and addressed:

NPIC also provides additional outcome metrics, such as diagnosis code grouped by Medicaid quartile. As described, NAS is found with more frequency within the highest Medicaid quartile (> 49.71) than any other Medicaid quartile in the NPIC Perinatal Center Database. Providing foundational and population health data to support key initiatives such as NAS and substance use disorder may amplify those areas of greatest resource need within an organiza-

- 1) **Destigmatize mental illness:** Stigma is a complex phenomenon that has three different types: public, self, and institutional<sup>6</sup>. Self-stigma develops from shame, blame, and internalization of mental illness, which is most often fueled by public and institutional stigma. Supporting women and birthing people experiencing maternal mental health illness, and reducing shame and self-blame, is critical in achieving treatment regimens and continued engagement with healthcare providers.
- 2) **Screening women for mental health during the postpartum period:** NICUs across the United States have begun to engage in various forms of screening and intervention to reduce stress and depressive symptoms in mothers during admission. In many cases, maternal mental health concerns remain under-identified and undertreated during a NICU stay, which can have deleterious effects on the offspring, both in short-term outcomes while in the NICU as well as long-term neurodevelopmental and behavioral outcomes (7). Mendelson et al. (6) performed a systematic review and meta-analysis of NICU programs designed to evaluate for postpartum depression and anxiety and found it increasingly important to evaluate maternal mental health during NICU admissions to assure engagement and understanding of treatment and discharge plans.
- 3) **Disparities in maternal mental health treatment:** Overall, Black women are 3-4 times more likely to die during childbirth or within the first year after delivery. In-

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ingly, studies describe inequity in mental health screening, identification, and treatment for women of color and other vulnerable populations. Sidebottom (8) and colleagues described their study's findings in which African American, Asian, and non-white women were less likely to be screened for postpartum depression than their white counterparts. This study also revealed that women insured by Medicaid and other state programs were less likely to be screened than those with private insurance.

This May, it is essential that we create space to discuss maternal mental health and develop sustainable treatment and well-being strategies. Whether that be in a prenatal visit, admission to Labor and Delivery, during a NICU visit, or in the community, as a nation, we must be prepared to destigmatize maternal mental health and assure a compassionate course of treatment for women who continue to suffer in silence.

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# Health Equity Column: Framing Birth Equity To Protect Black Maternal Health Outcomes

Jenné Johns, MPH, Dawn Godbolt, Ph.D.



This April marks two important national campaigns that shine a light on inequities in the United States. First is National Minority Health Month, led by the HHS Office of Minority Health. Second is Black Maternal Health Week (April 11<sup>th</sup>-17<sup>th</sup>) led by the Black Mommas Matter Alliance. This is a global awareness-raising week to address systemic and systematic inequities within the Black Maternal

Health crisis while leading advocacy and community engagement opportunities to advance improvements to protect and keep Black mothers and infants alive. These movements require the perinatal and neonatal healthcare community to address the most pressing challenges facing communities of color at the most vulnerable yet deserving time of life- childbearing, childbirthing, and infant rearing. Yet, this opportunity is unequal and unjust for many women in this country due to factors surrounding policy, systems, and institutional bias within healthcare. In this interview, I am honored to share highlights of my interview with a leading policy, advocacy, and community engagement organization, the National Birth Equity Collaborative, led by my colleague and industry mentor, Dr. Joia Crear Perry. She has a lifelong passion and commitment to improving birth outcomes for Black mothers and infants. I'm equally honored to introduce the readers of Neonatology Today to NBEC's Policy Director, Dr. Dawn Godbolt, who is paving the way to ensure the voices and stories of Black mothers and infants are reflected in the necessary and imperative policy and legislative changes required to protect all Black birthing families. Including the equity needs of Black families in the NICU. Through our interview, as you learn about the equity-focused maternal health initiatives led by Dr. Perry, Dr. Godbolt, and the amazing women at NBEC, I encourage you to leverage these resources within your respective institutions and to support the closing of racial and ethnic disparities in perinatal and neonatal health outcomes based on the birth equity framework.

*"I'm equally honored to introduce the readers of Neonatology Today to NBEC's Policy Director, Dr. Dawn Godbolt, who is paving the way to ensure the voices and stories of Black mothers and infants are reflected in the necessary and imperative policy and legislative changes required to protect all Black birthing families."*

What is the National Birth Equity Collaborative?

The National Birth Equity Collaborative (NBEC) was established in 2015 by Dr. Joia Crear Perry, MD, FACOG, and is a Black women-led organization that creates solutions that optimize Black maternal and infant health through training, policy advocacy, research, and community-centered collaboration. NBEC is a space where the sexual and reproductive health and wellbeing of Black women is centered in the fight to expand health equity by applying a reproductive justice framework to every aspect of our work. We believe in the value of Black lives, and as such, we work to build solutions to the maternal health crisis that shifts the narrative of blame to one that acknowledges systemic racism as the root cause of maternal health disparities.

**What is "Birth Equity," and why was this definition created?**

The term birth equity was coined by NBEC founder and President Dr. Joia Crear-Perry. **Birth equity is the assurance of the conditions of optimal births for all people with a willingness to address racial and social inequities in a sustained effort.** Birth equity is critical to understanding the various ways systemic oppression like racism, classism, and gender oppression can all impact birth outcomes. A birth equity framework works to create a structure where all people can birth safely. Birth equity is rooted in the reproductive justice framework: the human right to maintain personal bodily autonomy, have children, not have children, and parent the children we have in safe and sustainable communities.

*"A birth equity framework works to create a structure where all people can birth safely. Birth equity is rooted in the reproductive justice framework: the human right to maintain personal bodily autonomy, have children, not have children, and parent the children we have in safe and sustainable communities."*

**Who are the members of NBEC, and what geographies do you serve?**

NBEC is composed of Black and Brown maternal health experts who serve as thought leaders in the maternal health space. We work to build community through sisterhood across the country

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and internationally with our work.

- NBEC's Research and Strategy team provides the data and analysis needed to advance birth equity.
- The Training, Evaluation, and Practice team provides technical assistance to programs and systems interested in unpacking the manifestations of racism within their organizations.
- The Policy Shop manages and promotes NBEC's Federal, State, and Local policy and advocacy priorities. The Policy Shop uses a reproductive justice lens to make recommendations to elected officials, key stakeholders, and community-based advocacy groups in an effort to advance birth equity through policy, practice, and programs.
- The Global Birth Equity Team is responsible for NBEC's global projects, advocacy, and partnerships, as well as internal community care for staff members. The team helms initiatives centered on learning from Black women globally, unpacking the harms of the family planning framework, and addressing the impact of climate change and environmental racism on sexual and reproductive health.
- The Birth Equity Scholars program is designed to train and mentor Black and brown doctoral students in the field.
- The Administrative and Finance teams keep us going like a well-oiled machine, manages our interns, and leads our community engagement initiatives.

### **What personal and professional experiences led you to your leadership role with NBEC?**

As a Black woman in the United States, maternal health outcomes are deeply personal to me. From the earliest age, I understood that something was fundamentally wrong with American society. While working on my Ph.D., my study of sexual and reproductive health led me to identify maternal health as my passion. There is something gut-wrenching about the fact that Black mommies and babies die at such an alarmingly high rate in comparison to our white counterparts. When unpacking the data and analyzing the power structures that influence the Black maternal health crisis, I knew I needed to be a part of the solution. My role at the NBEC comes with the knowledge that I am advocating for myself and my sisters across the country and around the world every day.

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*“When unpacking the data and analyzing the power structures that influence the Black maternal health crisis, I knew I needed to be a part of the solution. My role at the NBEC comes with the knowledge that I am advocating for myself and my sisters across the country and around the world everyday.”*

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### **Describe Black Maternal Health Week and the imperative for advancing health outcomes for Black and Brown birthing women.**

Black Maternal Health Week was founded and led by the Black Mamas Matter Alliance (BMMA), of which NBEC is a kindred partner and Dr. Joia Crear-Perry is an advisory committee member. It is a week of awareness, activism, and community building seeking to amplify the voices of Black mamas and uplift reproductive justice. This week also provides a national platform for Black-led organizations advancing efforts on maternal health, birth, and reproductive justice and seeks to really amplify community-based solutions. It's also important to note that BMMA terms “Black Mamas” to represent the full diversity of lived experiences, including all birthing people and all people of African descent across the diaspora.

### **What is NBEC's call to action for Black Maternal Health Week?**

NBEC is participating in a range of activities during Black Maternal Health Week! On Monday, April 12<sup>th</sup>, we are co-hosting an event with Rep. Lauren Underwood (IL-14), Rep. Alma Adams (NC-12), and leaders in the Reproductive Justice space to introduce the Vanguard of maternal health and, later in the day, our State and Local Policy Analyst will be a featured panelist in a Twitter Town Hall designed to connect audiences and experts to gain insight on the current maternal health space. On Tuesday, April 13<sup>th</sup>, we are partnering with the Institute of Women's Studies (IWES) to host a maternal yoga session, and in partnership with the Commonwealth Fund and Tara Health Foundation, Dr. Joia Crear-Perry will be on the panel to address how philanthropy and organizations can shift culture and improve healthcare conditions. Wednesday, April 14<sup>th</sup>, NBEC's Federal Policy Team will be participating in a live fireside chat with Black Maternal Health Policymakers and experts to provide details on the Black Maternal Health Momnibus Act of 2021. On Thursday, April 15<sup>th</sup>, we will be live on Instagram for a candid conversation about Black Women, COVID-19, Fibroids, and Infertility. And on Friday, April 16<sup>th</sup>, we're rounding out the week by hosting a workshop about liberating voice and vagina. We are really looking forward to BMHW 2021 and hope everyone will tune in!

We are also rolling out many products and deliverables related to our work at NBEC, so keep an eye out on our website!

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*“NBEC's mission and vision are to optimize Black maternal and infant health so that all Black mothers and babies thrive. This means every step along the way from prenatal to postpartum care.”*

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### **What does NBEC mean to the field of neonatology at this time?**

NBEC's mission and vision are to optimize Black maternal and infant health so that all Black mothers and babies thrive. This means every step along the way from prenatal to postpartum care. We seek to address systemic factors that contribute to why Black babies may be born premature, but we also work to ensure that the

quality and standard of care the baby receives in the NICU is high quality, accessible and addresses structural and social determinants impacting the baby's health outcomes.

#### How can we learn more about NBEC?

You can visit our website [www.birthequity.org](http://www.birthequity.org) or follow us on social media @birthequity!

*Disclosure: The authors have no disclosures.*

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Organization: National Birth Equity Collaborative

Dawn Godbolt, Ph.D is the Policy Director at the National Birth Equity Collaborative where she works to improve maternal health disparities through federal policy levers. She sits on the National Quality Forum's Maternal Mortality and Morbidity Committee and chairs the Equitable Maternal Health Coalition policy working group. Prior to joining NBEC, Dr. Godbolt was the Senior Manager for Maternal Health initiatives at the National Partnership for Women & Families. Dr. Godbolt holds a PhD in Sociology from Florida State University, and has completed a fellowship with the OpEd Project to develop her voice as a thought leader.

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## About National Minority Health Month

Celebrated every year in April, National Minority Health Month:

- Builds awareness about the disproportionate burden of premature death and illness in minority populations.
- Encourages action through health education, early detection and control of disease complications.

The origin of National Minority Health Month is in the 1915 establishment of National Negro Health Week by Booker T. Washington. In 2002, National Minority Health Month received support from the U.S. Congress with a concurrent resolution (H. Con. Res. 388) that “a National Minority Health and Health Disparities Month should be established to promote educational efforts on the health problems currently facing minorities and other health disparity populations.” The resolution encouraged “all health organizations and Americans to conduct appropriate programs and activities to promote healthfulness in minority and other health disparity communities.”



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# Who's on First? Split and Shared Services in the NICU

Scott D. Duncan, MD, MHA

The baseball analogy is appropriate in neonatology, as the provision of neonatal care is a team sport, including, but not limited to, physicians, advanced practice providers, nursing, nutritionists, pharmacists, respiratory therapists, speech therapists, physical therapists, and social workers. In many instances, the neonatologist's role has undergone significant modifications, with an increasing role of advanced practice providers, as well as a reduction in trainee rotations and restrictions on work hours.

***“In many instances, the neonatologist’s role has undergone significant modifications, with an increasing role of advanced practice providers, as well as a reduction in trainee rotations and restrictions on work hours.”***

## Scenario

In the batter's box, the delivery team attends the delivery of a 32-week gestation infant due to maternal gestational diabetes and pre-eclampsia. The delivery team includes two nurses, a respiratory therapist, and a neonatal nurse practitioner (NNP) as the team leader. In the delivery room, the infant requires intubation and positive pressure ventilation. The infant is admitted to the NICU on a ventilator. By 30 minutes of age, the infant demonstrates increasing respiratory distress, hypercarbia, and the CXR reveals severe RDS. The NNP orders surfactant therapy.

While making rounds with the fellow and resident team, the neonatologist asks the NNP about the patient. The NNP gives the neonatologist a verbal report and completes the electronic medical record's history and physical (EMR). Following rounds, the neonatologist examines the infant and places a macro-based attestation used for resident documentation on the H&P, co-signs the note, and uses the charge capture feature on the EMR to place a 99468 code for the date of admission.

## A Strikeout

**Strike One** – The neonatologist provided limited services in the assessment and care plan.

**Strike Two** – A NNP is not a trainee, and Physician at Teaching Hospital (PATH) guidelines do not apply for documentation and attestations.

**Strike Three** – The service for the day is an initial critical care charge, and split/shared services are prohibited with critical care delivery.

## Discussion

In this Scenario, the neonatologist made multiple errors as related to split/shared services and supervision. A split/shared service is an encounter where a physician and the NNP from the same group and same specialty each personally perform a portion of an Evaluation and Management (E/M) visit. As applied to in-patient neonatology, the split/shared E/M rule applies only to selected E/M visits such as these in the hospital settings:

- hospital admissions (CPT® codes 99221-99223)
- subsequent hospital visits (CPT® Codes 99231-99233)
- discharge management (CPT® Codes 99238-99239).

In the case of critical care, split/shared services are not allowed. The guidance provided by the US Department of Health and Human Services states, “Critical care services are reflective of the care and management of a critically ill or critically injured patient by an individual physician or qualified non-physician practitioner for the specified reportable period of time. Unlike other E/M services where a split/shared service is allowed, the critical care service reported shall reflect the evaluation, treatment, and management of a patient by an individual physician or qualified non-physician practitioner [NPP] and shall not be representative of combined service between a physician and a qualified NPP.” (1)

Appropriate documentation must substantiate the nature of the admission. Per the recommendations of the AAP Committee on Coding and Nomenclature, (2) the medical record documentation should include:

- Documentation of the critical status of the infant
- Documentation of the bedside direction and supervision of all aspects of care
- Review of pertinent historical information and verification of significant physical findings through a medically indicated, focused patient examination
- Documentation of all services provided by members of the care team and discussion and direction of the ongoing therapy and plan of care for the patient
- Additional documentation of any major change in a patient course requiring significant hands-on intervention by the reporting provider.

***“Split/shared services may be utilized for E/M services, hospital admissions, subsequent hospital visits, and discharge, as noted above. In these instances”***

Split/shared services may be utilized for E/M services, hospital admissions, subsequent hospital visits, and discharge, as noted above. In these instances, the providers should each document their portion of the service provided. Charges may be placed using the following rules: (3)

- When the physician provides any face-to-face portion of the encounter, use either provider's NPI
- When the physician does not provide a face-to-face encounter, use the NNP's NPI.

Note, there is no guidance for split/shared services for intensive care charges (CPT® codes 99477-99480). Best advice – if using a physician NPI for billing, ensure that the documentation clearly demonstrates that the physician took ownership of the patient.

## Revised Scenario – a pinch hitter

At the plate, the delivery team attends the delivery of an infant of 32-week gestation due to maternal gestational diabetes and pre-

eclampsia. The delivery team includes two nurses, a respiratory therapist, and a neonatal nurse practitioner (NNP) as the team leader. In the DR, the infant requires PPV and intubation. The infant is brought to the NICU on assisted ventilation. By 30 minutes of age, the infant demonstrates increasing respiratory distress, hypercarbia, and the CXR reveals severe RDS.

While making rounds with the fellow and resident team, the neonatologist asks the NNP about the patient. The NNP gives the neonatologist a verbal report, and the neonatologist leads the rounding team to the patient's bedside, where a complete examination is performed. The neonatologist orders surfactant replacement, and following rounds completes a history and physical, including the assessment and plan, in the EMR, independent of documentation by the NNP. The neonatologist uses the charge capture feature on the EMR to place a 99468 charge for the date of admission.

**A Home Run!**

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# Keeping Your Baby Safe

during the COVID-19 pandemic

## How to protect your little one from germs and viruses

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

### Here's what you can do...

#### Wash Your Hands

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



#### Limit Contact with Others

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



#### Provide Protective Immunity

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



#### Take Care of Yourself

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



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

**WARNING**

#### Never Put a Mask on Your Baby

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



#### If you are positive for COVID-19

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



We can help protect each other.

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# Will Artificial Intelligence Have a Place in the NICU? Are We There yet, or Should We Be?

Gilbert Martin, MD

Artificial Intelligence (AI) is machine-oriented, in contrast with natural intelligence, which is humanistic. This concept promotes computerization that mimics the natural intelligence demonstrated by humans.

***“Artificial Intelligence (AI) is machine-oriented, in contrast with natural intelligence, which is humanistic. This concept promotes computerization that mimics the natural intelligence demonstrated by humans.”***

First described by John McCarthy (1927-2001), the use, or sometimes misuse, has become a significant part of everyday life. The field began in 1956 where after a short period, computers were defeating humans in checkers, solving word problems, and predicting mathematical models. Basically, an algorithm is designed to make decisions that have previously been the responsibility of the physician.

Research in AI includes both objective and subjective components. The objective relationships include statistical methods, probabilities, data mining, and logistics. However, subjectively can algorithms be developed that deal with ethical issues, policies, symbolism, and logic?

There are pros and cons when incorporating artificial intelligence into the healthcare arena. Since the algorithms inputted are well researched, there is a decreased chance for errors to occur. If the data input and the algorithm are robust enough, the time involved in making a clinical decision will be shortened. Also, the artificial intelligence system, unlike the “human variety,” does not fatigue. In the NICU, information can be voluminous and complex. Algorithms can focus and simplify decisions. The cost of implementing such a program can be high, but if we shortened the time to diagnosis and targeted care, the cost-benefit ratio will be positive. Despite more comprehensive input of data and information, the dependency on human decision-making remains essential. Finally, the algorithms and their machinery are not creative, and frequently protocols and guidelines cannot adapt to a changing situation. The answer is to use both machine learning (algorithmic) and human interaction.

However, this type of automation has been present throughout history. The industrial revolution was just the beginning. In today's world, the assembly line facility often has more robotics than human interaction. AI will inevitably achieve more sophistication and intelligence than is demonstrated by humans today.

The automobile industry demonstrates an example of this type

of progress. We now have self-driving cars that can accelerate or decelerate, change lanes, turn on lights, and use braking intelligently to prevent accidents. Would you be comfortable in a self-driving car?

If utilized correctly, there can be a convergence of human and artificial intelligence, improving morbidity, mortality, productivity, and even workflow. Intelligence is created, but do these machines function intelligently? There is expert knowledge, commonsense knowledge, inferential knowledge, and default reasoning. Can the machine be perceptive, recognize sentiment or engage in reasoning? These are questions that remain at present and will become more complicated in the future.

So.....can artificial intelligence become part of the daily NICU environment?

As data in the NICU becomes increasingly comprehensive, there is a need for a mechanism to analyze, interpret and respond to this information. The machine learning models use an extensive amount of input data to predict therapeutic interventions. Unfortunately, one weakness is that no explanations deal with any logic based on these decisions since the recommendations are based upon the type of algorithm used.

***“ The machine learning models use an extensive amount of input data to predict therapeutic interventions. Unfortunately, one weakness is that no explanations deal with any logic based on these decisions since the recommendations are based upon the type of algorithm used.”***

In 2019 Masino et al. investigated a machine learning model which could recognize infant sepsis before it became clinically suspected. A prediction model was developed utilizing the electronic medical record to predict general applicability. They identified 30 features obtained from the NICU Sepsis Registry known or suspected of infant sepsis. Using a “logistic regression model,” researchers identified infant sepsis hours before clinical symptoms. The machine models evaluated in this study produced a numeric output that interpreted the probability of sepsis. (1) In the United States, a neonatal sepsis risk calculator designed by Kaiser Permanente is a multivariate model which assesses the probability of early onset of sepsis using maternal risk factors algorithms and the infant's clinical appearance after birth. (2) The Kaiser Permanente early-onset sepsis calculator's sensitivity compared with the National Institute for Health and Care Excellence (NICE) guidelines have been evaluated by Pettinger KJ et al., who believe that a large proportion of early-onset sepsis cases were “missed” by the calculator. (3) The Heart Rate Observation system or HeRO is a monitoring technology that incorporates an algorithm that detects changes in the infant's heartbeat which can be an early sign

of infection. This concept can be considered a form of AI. (4)

Since the whole concept of AI depends on the development of frameworks or algorithms, can we program these algorithms to avoid pitfalls? We are looking for a method to make better decisions. Since the algorithm itself is developed by humans, shouldn't we be concerned about bias? Since AI's predictions are a reflection of input information, there must be an accurate representation of patient demographics. For example, are there enough males in the data set? Are minority populations included? An algorithm can be designed for a do not resuscitate order. However, there are morality issues with such an order, and will the algorithm which is designed be able to assist the healthcare team in making important, life-changing decisions? Someone needs to monitor the bias, which can be overwhelming, and make certain that the program is working efficiently within some structured guidelines. However, to date, these guidelines have not evolved significantly. In addition, another benefit of the use of AI is decreasing medical costs since the goal is a more accurate diagnosis and a more organized and accepted treatment plan.

Since respiratory disease is at the forefront of essential neonatal care, consider the following scenario concerning ventilator management in the newborn.

A 3850-gram male infant is delivered emergently after a clinical history of abruptio placenta. The baby's Apgar score is 1 (5), 2 (10), 3 (15). A cord arterial blood gas is 6.95 with a pCO<sub>2</sub> of 31 and a base deficit of -18. The baby is resuscitated, admitted to the NICU, and placed on a ventilator. The ventilator has been inputted with ten algorithms that represent data collected with everyday ventilator-associated events. The physician and respiratory therapist set parameters for the amount of oxygen, respiratory rate, peak inspiratory pressure, PEEP, compliance, inspiratory, and expiratory time. The neonatologist and respiratory therapist allow the computerized ventilator's AI to make adjustments in ventilator settings depending upon the algorithms' data.

Is this scenario futuristic? Is it reliable? Will the artificial intelligence algorithm adjust these settings and modify lung compliance, oxygenation, and other parameters?

Previously I would have thought that a similar patient that is presented above needed to have active input from the medical, respiratory therapy, and nursing personnel to make all therapeutic decisions

A second example that neonatologists often encounter is the interpretation of imaging studies. The following patient illustrates this point.

A 28 day old late preterm infant with a history of perinatal asphyxia is recovering in a NICU step-down area. At three days of age, the baby developed a grade III intraventricular hemorrhage (on head ultrasound examination) and has been recovering. Over the last week, the patient demonstrated increase tone, and an MRI was

performed. On clinical rounds, the neonatal team was evaluating the MRI images. An artificial intelligence database suggested signal abnormalities which included the deep nuclear grey matter and not the watershed area. These findings allowed the neonatologist to offer a more accurate prognosis to the parents based upon a more extensive database. (5)

A third scenario that is timely involves the following patient.

An 1850 gram male infant is born by cesarean section to a Covid positive mother who has a temperature of 101F and is tachypneic at delivery. The baby was admitted to the NICU for prematurity. Due to the maternal history of symptomatic Covid-19, her information was entered into the hospital's infectious disease database to determine the newborn's care and treatment. This database is constantly updated with current guidelines (CDC), and the artificial intelligence algorithm suggests the need for isolation (negative pressure), nutritional support (including breastfeeding), and visitation guidelines.

Information regarding Covid-19 continues to be presented and modified as new scientific data emerges. A cohesive approach based upon factual material is essential for a successful outcome. (6)

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***“Artificial Intelligence will have an increasing role in administering medical care. It will eventually enter the Kingdom of the NICU. When this occurs, will the number of needed personnel (neonatologist, respiratory therapist, and nursing) decrease? What will be the impact of artificial intelligence on the future role of the physician? (7)”***

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Artificial Intelligence will have an increasing role in administering medical care. It will eventually enter the Kingdom of the NICU. When this occurs, will the number of needed personnel (neonatologist, respiratory therapist, and nursing) decrease? What will be the impact of artificial intelligence on the future role of the physician? (7) The real question revolves around the displacement of particular physician's specialties. Will algorithms help radiologists or pathologists become more effective? Imagine a court proceeding where a defendant physician is asked why a specific therapeutic approach was utilized. In the past, the answer would be, "I choose this approach due to my personal experience and understanding of the literature on this topic." In the future, will the answer be, "I choose this approach due to the healthcare data using interactive systems which exceed the capacity of any human

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in making finite decisions”?

I predict that there will shortly be a curriculum added to medical school education dealing with artificial intelligence. We will utilize data in order to make decisions which we believe are robust. The machine intelligence used for this process at some point in time will surpass human interaction.

For now, I still am hesitant about getting into a self-driving car. Am I too cautious? Am I old-fashioned? Am I not progressive enough?

Are you?

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work with your medical team to create a plan

## GET CLEAN WASH YOUR HANDS, ARMS, and CHEST

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



## PUT ON FRESH CLOTHES

change into a clean gown or shirt.



## IF COVID-19 + WEAR A MASK

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



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# Neonatology Solutions Provides Resources to Ensure Fellows Can Still Define and Find Their Ideal Career Position

Scott Snyder, MD, Amy Patel, MD



We at [Neonatology Solutions](#) remain acutely aware of the challenges fellows face as they complete their training and navigate their future career path in an increasingly virtual world. To gain a deeper perspective, we sat down (virtually, of course) with Dr. Amy Patel, a first-year fellow at Columbia University Irving Medical Center, to hear how COVID-19 has changed the training process and how Neonatology Solutions has provided resources to ensure fellows can still define and find their ideal career position following fellowship:

**Neonatology Solutions:** So, you're completing your first year of fellowship in the middle of a pandemic, which is certainly an incredibly unique and challenging situation. What have been the biggest barriers to the usual educational process that we are all used to in medicine?

**Dr. Patel:** Well, with regards to our educational materials, a lot of the format has changed from the traditional bedside educational opportunities and traditional conference setting to more virtual set-ups. So everything from noon conference to other didactic sessions are almost all Zoom-based. When I teach residents now, I appreciate the flexibility and convenience that webinar platforms have provided, but I do think it has taken away from some of the insights and shared mental model that one would try to foster during these types of discussions. And while we all do our very best to teach effectively, reassure families and staff, there is now an impersonal component to doing so much of this over phone or video. And that's just a function of the pandemic. I really feel for our families who at baseline already have many challenges and barriers while having a baby in NICU. There are just so many more layers now that make it incredibly hard for both families and staff.

**Neonatology Solutions:** How do you see all these changes impacting your ultimate job search?

**Dr. Patel:** So throughout the years I've been fortunate to have many colleagues and friends with whom I've trained who are now early career attendings. They've given me great practical advice along the way, sharing lessons they learned. I also feel I've definitely benefitted from my bicoastal training. I started my training in California and am now in New York; because of this I feel fortunate to have met many leaders in our field with whom I can continue to pursue my research interests. I'm grateful that I've had such strong mentors very early on and I've known that I've wanted to do neonatology since my 4th year of medical school. I'd be remiss to not mention one mentor in particular who's been a fierce advocate since my intern year and shares many of my interests in global health, research and quality improvement, Dr. Priscilla Joe!

I also have sought out online resources, websites, and blogs such as Kevin MD, the White Coat Investor, and Neonatology Solutions. These resources have empowered me to think about the job search and my financial planning much earlier than I think I otherwise would have. I'm already reading about contracts and terms so that I can put my best foot forward and advocate for myself and my career. To that end, I've really come to appreciate the transparency of websites such as Neonatology Solutions. Coding, physician contracts, managing credentials...these are often not covered extensively in fellowship since there is so much medicine to learn.

**Neonatology Solutions:** How did you hear about Neonatology Solutions? What aspects of the site have been most helpful?

**Dr. Patel:** Well, I read a lot, whether about different practice models, physician lifestyles, career planning, etc. In researching different topics within our field, I came across your website which had so many of these elements concisely summarized. The NICU Directory has been really helpful since I have been in so many different places. I can appreciate how one's geographical preference can change over time, and fellows and trainees can have different preferences. This gives them a tool to compare and contrast different practice settings. I like that I can quickly search by State and NICU Level because, at least right out of training, I want to be at a busy Level III or IV NICU. I haven't looked at specific job postings at this point since I'm still in my first fellowship year, but I love that so many positions are compiled here.

Speaking specifically about the Career Planning section, I do appreciate the stepwise approach that is provided. While I haven't gone through the interview process yet, some of my colleagues who have become attendings in the last couple years have said that they felt unprepared going about negotiating a contract, and even just understanding what some of the different terms in the contract even mean. There's good information on the website to help fellows learn about these aspects of the job search.

**Neonatology Solutions:** What new features or content can Neonatology Solutions incorporate to further support fellows in their training and job search efforts?

**Dr. Patel:** Some of the areas I feel I don't have a good knowledge base of right now are things like billing and coding. By the time I approach my final year of fellowship, I want to be sure I understand this well. In the meantime, I plan to continue to share awareness of the Neonatology Solutions website and the resources it provides to my fellow colleagues.

We wish to express our appreciation to Dr. Patel for spending time to not only share ideas on how to improve our services, but for sharing her current efforts and challenges in long-term career planning, on behalf of Neonatology fellows across the U.S. We hope her perspective sheds some light for others and we want to ensure all Neonatology fellows know there is a dedicated resource to help with their ongoing career success.



Skip To: 2nd Year 3rd Year



## 6 Steps to Success

**Step 1**  
Applying the Right Timeline

**Step 2**  
Defining Your Ideal Position

**Step 3**  
Finding the Right Practice

**Step 4**  
Preparing for Your Interview

**Step 5**  
Reviewing Your Job Offer

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- [6 Steps of Career Planning](#)
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Our gratitude also goes to Columbia University for allowing Dr. Patel to participate in this interview and publication.

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# The Role of Obstetricians and Neonatologists in Promoting COVID-19 Vaccination: Healthier Mothers and Infants

Ricardo Peverini, M.D., Elba Fayard, M.D., Courtney Martin, MD, T. Allen Merritt, MD.

The COVID-19 pandemic has had a profound impact on health-care systems and pregnancy outcomes. The adverse effects on maternal and neonatal health have not been limited to morbidity and mortality caused directly by SARS-CoV-19, but also in disruption of prenatal care and fear of attending health care facilities that may have affected maternal well-being and their babies. (1) Rates of stillbirth and preterm birth have changed substantially during pandemic worldwide. (2) A global systematic review found increased maternal mortality and stillbirths, increased ruptured ectopic pregnancies, and maternal stress during the pandemic compared to data prior to the pandemic, including the U.S., Canada, and the UK, as well as in moderate-income countries. These disparities are most significant in low resource settings. (3)

***“A global systematic review found increased maternal mortality and stillbirths, increased ruptured ectopic pregnancies, and maternal stress during the pandemic compared to data prior to the pandemic, including the U.S., Canada, and the UK, as well as in moderate-income countries. These disparities are most significant in low resource settings. (3)”***

In the US, as of 3/1/21, 73,600 COVID-19 infections and 80 maternal deaths have occurred in pregnant women. (4) SARS-CoV-2 infection is more severe in pregnant women compared to non-pregnant women with an increased risk of hospitalization, intensive care unit admission, and death. (5) However, despite their increased risk, pregnant and lactating women were not eligible included in the initial COVID-19 vaccine trials. However, about 15,000 incidentally pregnant women received either the Pfizer/BioNTech or Moderna vaccines during the initial clinical trials, and “no red flags” were identified in terms of adverse events. (6)

Although these safety and efficacy trials did not intend to enroll pregnant women because of heightened safety concerns, (7-9) pregnant women (primarily healthcare workers) received the vaccine. These concerns for enrolling pregnant or lactating women were heightened due to the novelty of vaccines utilizing mRNA to deliver SARS-CoV-2 Spike to stimulate the immune system. (10) While infection with wild type SARS-CoV-2 produced antibody responses in mothers with the placental transfer of IgA and IgG to the fetus and newborn, it was unclear whether the mRNA spike protein in novel vaccines would stimulate an identical or similar immunologic response with maternal antibodies transferred to their newborns and via breastmilk.

Recently Gray et al. (11) reported data from 84 pregnant, 31 lactating, and 16 non-pregnant women (mostly healthcare workers) at two medical centers regarding their responses to either Pfizer/BioNTech or Moderna mRNA vaccines to deliver SARS-CoV-2 spike antigens to the maternal immune system. Those enrolled were primarily White, non-Hispanic women. Some had reported prior SARS-CoV-2 infection (2 pregnant, 2 lactating, and 1 non-pregnant). The gestational age at vaccination was 23.2 weeks (mean), with 11 women receiving their first dose in the first, 39 during the second, and 34 in the third trimester. Notably, adverse effects during the first dose were minimal, with vaccine-related pyrexia noted in 32 pregnant and 50% non-pregnant women. Thirteen women delivered during the study (one at 35 weeks) and cord blood was available for only some of the newborns delivered. Maternal IgM, IgG, and IgA responses to the Spike receptor-binding domain (RBD) and S1 segment of S and S2 of S were measured. The immune response was robust and did not differ amongst pregnant or lactating women. Robust IgM and IgA responses were found with less IgG. In all groups and by two weeks after the second dose, IgG was the dominant induced serum antibody for pregnant, lactating, and non-pregnant women. mRNA vaccination resulted in the induction of antibodies in the sera of vaccinated mothers; however, IgG levels were predominantly induced in breast milk compared to maternal serum.

***“In all groups and by two weeks after the second dose, IgG was the dominant induced serum antibody for pregnant, lactating, and non-pregnant women. mRNA vaccination resulted in the induction of antibodies in the sera of vaccinated mothers; however, IgG levels were predominantly induced in breast milk compared to maternal serum.”***

Further maternal IgG crossed the placenta to providing immunity to the newborn in 10/10 umbilical cord blood after maternal vaccination.; however, neutralizing antibodies were lower in the cord than the maternal sera. A second dose boost augmented IgG levels in maternal sera, translating to the enhanced transfer of IgG to the neonate through the placenta and via breastmilk. While IgA dominates the antibody transferred from natural COVID-19, it is unknown whether IgG or IgA is more important for neonatal protection. These small study results provide strong evidence that COVID-19 mRNA vaccines induce similar humoral immunity in pregnant and lactating women than seen in non-pregnant. (11)

A recent study reported by Pearl et al. also showed robust secretion of SARS-CoV-2 specific IgA and IgG antibodies in breast milk for six weeks after vaccination in 84 lactating subjects. IgA secretion was evident as early as two weeks after vaccination, followed by a spike in IgG after four weeks (a week after the second vaccine). (12) A few other studies have shown similar findings in

women infected with COVID Antibodies found in the breastmilk of these women showed strong neutralizing effects, suggesting a potential protective effect against infection in the infant. (13)

Vaccination during pregnancy must show evidence of maternal and fetal benefits and not have adverse effects on pregnancy outcomes. Shimabukuro presented data on adverse events among pregnant and non-pregnant women receiving the vaccination and has established a Vaccine Adverse Event Reporting System (VAERS) at the CDC. VAERs serve as an early warning system to detect possible safety issues with US vaccines. (14) Among the 56,567 receiving the Moderna vaccine and 48,196 receiving the Pfizer-BioNTech vaccine, reports of 6,081 (6%) serious adverse events were reported, including headaches and pyrexia chills, pain, fatigue, nausea, dizziness, injection site pain, pain in the extremity, and dyspnea. Among 154 vaccine-associated adverse events among pregnant women with mean maternal age of 33 (range 16-51 years) with 51% receiving vaccine during the first-trimester pregnancy or neonatal specific conditions were reported in 27%, with spontaneous abortion/miscarriage occurring in 29 but at a rate no different than among non-vaccinated pregnant women and three women developed premature rupture of membranes (data through February 16, 2021). Compared to the US population, PPROM affects 2-4% of the singleton pregnancy population, versus 1.9% in the VAERS reporting. (15) Most reports (73%) reports of vaccine-associated adverse events among pregnant women involved non-pregnancy-specific adverse events (e.g., local and systemic reactions). (16)

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***“Based on these new findings and other information, the American College of Obstetrics and Gynecologists have revised their recommendations regarding COVID-19 effective March 24, 2021. They now recommend that COVID-19 vaccines should not be withheld from pregnant individuals and COVID-19 should be offered to lactating individuals similar to non-lactating individuals.”***

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Based on these new findings and other information, the American College of Obstetrics and Gynecologists have revised their recommendations regarding COVID-19 effective March 24 2021. They now recommend that COVID-19 vaccines should not be withheld from pregnant individuals and COVID-19 should be offered to lactating individuals similar to non-lactating individuals. Further, ACOG recommends a conversation regarding the use of vaccines under an emergency authorization, but such a conversation should not be a barrier to vaccine access on a timely basis.” Furthermore, it is imperative women have a conversation with their providers to consider “the risk and potential severity of maternal disease, including the severity of maternal disease, including the effects of disease on the fetus and newborn” with viral activity in their community and the safety of the vaccine for the pregnant patient and the fetus. These conversations or vaccine counseling visits must not be a barrier or requirement to receive the vaccination. The two series of mRNA vaccine injections recommended for mRNA vaccines require that other vaccines such as Ddap and

influenza be deferred for 14 days after completing the COVID -19 vaccination period (i.e., five or six weeks after initiation). There is no need to avoid initiation or discontinue breastfeeding in women who receive COVID-19 vaccination for women who choose to breastfeed. Racial and ethnic disparities in health care delivery and outcomes have been reported from COVID-19 epicenters finding increased morbidity and mortality above the general population. In New York City, Latinx women were disproportionately represented among those affected by SARS-CoV-2 infections compared to white women. Latinx women also differed significantly in the borough of residence, insurance type, and household crowding, suggesting that variations in the urban environment and insurance-associated inequities play a more significant role than socioeconomic status alone in the observed disparities related to SARS-CoV-2 infection in an obstetric population. (17)

The need for health equity has been emphasized, especially in communities of color and where inequities have existed in vaccination distribution, especially in communities with Black and Latinx populations. (17) To meet this health inequity recognizing a disproportionate number of COVID-19 infections among African Americans due to structural racism and adverse social determinants of health, Loma Linda University School of Medicine mobilized a “three-tiered approach” by leveraging their relationships with other religious organizations dedicated to confronting issues of bias and promoting health within the Black communities within San Bernardino County, California.

They worked with pastors, coordinated educational webinars about COVID-19 vaccinations, distributed registration materials, and created appointment lists for community members before attending a vaccination clinic. Because attendance at large vaccination sites was disproportionately low among some ethnic groups (Blacks and Latinx), Loma Linda University mobilized health leaders in the Black community, including physicians, pharmacists, and Black faith leaders, to broaden access and receptiveness for vaccination participation. Further, mobile vaccination clinics were held at a primarily Black church parking lot to offer a familiar atmosphere for vaccinations. (16) In addition, researchers at Loma Linda’s School of Public health have encouraged finding ways to leverage technologies to get to those highly vulnerable populations for vaccinations.

Issues to be considered when counseling pregnant persons include data from among Latinx communities; vaccine hesitancy has been attributed to social disadvantage, disease misinformation, immigration fears, and healthcare access challenges. Many Latinx community members believed that the threat was “over-exaggerated;” therefore, some protective measures were dismissed. These concerns were coupled with fear of unemployment and eviction, inability to self-protect from COVID-19, reluctance to seek health care if uninsured or undocumented, and, among those undocumented, fear of deportation seriously increased their risk of acquiring COVID-19 and the disproportionate risk of hospitalization and death. Within the health care system, social isolation and loneliness, language difficulties, and hospital discharge with insufficient information or clinical follow-up compounded mistrust of public health efforts. Latinx COVID-19 advocates and faith and Hispanic community resiliency offered some resiliency to public health messaging. However, Latinx individuals need more effective public health messaging to reduce testing and vaccination fears and improve vaccine access. (18) The Catholic Diocese has an extensive reach into the Latinx community (particularly undocumented, farmworkers, and migrant workers). In San Bernardino and Riverside counties, Loma Linda faculty collaborated with the Diocese to provide vaccination sites and improve access. Messaging comes from the priests in Spanish supporting vaccination, emphasizing types of public health messaging shown to be most effective (personal communication).

The Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine, and the American Academy of Pediatrics have each issued guidance supporting offering the COVID-19 vaccine to pregnant women. Combining both Obstetricians' and Neonatologists' efforts coupled with religious organizations that reach minority women will have a greater combined impact to increase vaccinations in pregnant women. Vaccine compliance to protect both mothers and infants should be encouraged now with the added benefit of transferring maternal antibodies to her infants and quite possibly protecting both mothers and their infants from COVID-19 variants. (18)

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**“We contend that prospective mothers should be encouraged to carefully consider the benefits of vaccination on their health and the health of their newborn. Breastfeeding should be encouraged now with the added benefit of transferring maternal antibodies to her infants and quite possibly protecting both her and her infant from COVID-19 variants. (17)”**

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#### **Why are Obstetricians and Neonatologist responses to COVID-19 immunizations so critically important for mothers and infants?**

We contend that prospective mothers should be encouraged to carefully consider the benefits of vaccination on their health and the health of their newborn. Breastfeeding should be encouraged now with the added benefit of transferring maternal antibodies to her infants and quite possibly protecting both her and her infant from COVID-19 variants. (19)

1. **An essential role for neonatologists and pediatricians is to ask about COVID-19 vaccination status during the evaluation of newborns.**
2. **Removing barriers to vaccine access, mobilizing communities with leaders, and especially faith leaders with local access using mobile clinics in community settings will increase the likelihood of healthier mothers and their infants.**
3. **It is the mission of Obstetricians and Neonatologists to promote healthier mothers and infants. It is a moral obligation to protect mothers and their infants from COVID-19 by encouraging vaccination among all women of reproductive age in our society for their well-being and that of their babies.**

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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 5<sup>th</sup> 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](http://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.





# The Survey says RSV



What you need to know about RSV

**RSV** stands for **Respiratory Syncytial Virus**

RSV is a **Really Serious Virus**

**WHEN IS RSV SEASON?**

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

Protect babies and families this RSV season  
**Educate. Advocate. Integrate.**


National Perinatal Association

Consult the CDC's RSV Census Regional Trends to learn more [www.cdc.gov/rsv/census/regional-trends-surveillance.html](http://www.cdc.gov/rsv/census/regional-trends-surveillance.html)

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- 3 Recognize NICU Staff**  
Let them know the difference they are making in our babies' lives. Write a note, send an email, or deliver a gift to show them that you appreciate them.
- 4 Share Your Story**  
Most people have never heard of a NICU before. Let others know about the extraordinary care that NICUs provide.
- 5 Join Our Community**  
Get involved. Become a member of our organizations and share your talents.

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[www.nicuawareness.org](http://www.nicuawareness.org)

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# Conventional Ventilation Lung Protective Strategies

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.*

*“Regular readers of this column will be aware of my preference for high-frequency ventilation (HFV) for lung protection. Indeed, I have not routinely used conventional ventilation (CV) for over 15 years.”*

Regular readers of this column will be aware of my preference for high-frequency ventilation (HFV) for lung protection. Indeed, I have not routinely used conventional ventilation (CV) for over 15 years. That being said, I realize there are many units that either do not have access to HFV or only use these modes as “rescue therapy.”

Years before HFV was available to me as a clinician, CV was the only option for my patients. Initially, only basic IMV ventilators were available, and it was not until the 1990s that patient synchronized modes were introduced. Virtually all intubated babies were started at a respiratory rate of 40-60, peak inspiratory pressure (PIP) of 20, inspiratory time (Ti) of 0.4 seconds, and PEEP of 5. The rate was decreased before PIP; neither PEEP nor Ti was virtually ever changed. Unfortunately, one size does not fit all.

The first of these modes was synchronized intermittent mandatory ventilation (SIMV). The first attempts at synchronization used abdominal sensors and did not work very well (in fact, we had no success with them whatsoever). Only when flow sensors arrived on the scene did synchronization become reliable, and more modes quickly became available, such as assist-control (A/C) and then pressure support. (PS). A flow sensor inline allowed clinicians to monitor delivered tidal volumes (VT) and eventually led to volume-targeted ventilation, commonly referred to as volume guarantee (VG). As well, flow triggering became the norm, being much more sensitive than pressure triggering.

Historically, ventilation was adjusted based on the amount of chest excursion. Seeing how much volume was actually being delivered was a revelation. It was soon realized that high VTs were being delivered even at relatively low pressures, and “adequate” chest excursion was a crude estimate, often delivered very high (and damaging) VT. Before VG was introduced, volumes were targeted manually, often at 5-6 ml/kg. While this volume is acceptable in the older infant population, decreasing gestation age calls for decreasing VT since usable lung volume decreases and little volume is required to damage conducting airways. It was not long before the unit where I practice began using a fairly standard 4 ml/kg target.

*“Twenty-five years after its introduction, SIMV is still used in some units. As I near retirement age, it occurs to me that it is also time for SIMV to be retired as a standard mode.”*

Twenty-five years after its introduction, SIMV is still used in some units. As I near retirement age, it occurs to me that it is also time for SIMV to be retired as a standard mode. As the rate increases, the synchronicity of SIMV decreases. Once a rate of 40 is reached, there is little “window” time for the machine to synchronize, and breath stacking may occur. A/C provides more stable VT (when VG is not used), decreases work of breathing, and better facilitates weaning. (1)

PS provides even better synchronization because the delivered breath is terminated based on flow. (1) Thus, the infant is afforded more control of their breathing, and the lung is better protected because it is the infant that decides when they've had enough VT. A caveat when switching to PS from A/C is that mean airway pressure (MAP) is decreased. As a result, an increase in PEEP may be required to maintain optimal lung inflation. (2)

Using the VG adjunct provides the highest level of lung protection; however, this too comes with a caveat: the lung must be adequately recruited. If lung recruitment is only at 50%, then a “protective” VT of 4 ml/kg is really 8 ml/kg and is not protective at all. It has taken a long time for clinicians to recognize this and adjust PEEP levels accordingly. Nevertheless, “PEEPophobia” is still a widespread malady and is the antithesis to lung-protective ventilation in any mode.

In the extremely small/premature infant, it stands to reason that VT should also be small. If forced to use CV in this population,

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I prefer to use 3 ml/kg, shorter Ti (when using A/C), and higher rates. Ti is adjusted using flow graphics to minimize breath holding at end inspiration. This, at least in theory, should reduce gas trapping and volutrauma. Again, adequate functional residual capacity (FRC) must be maintained, and lower Ti and accompanying lower PIP required with lower VT may require higher PEEP. Longer Ti may be used with PS since the baby controls breath termination, and a longer Ti allows the baby to draw a larger breath if desired.

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***“An important consideration when using ventilators with flow sensors is the quality of the signal provided to the machine. Contacts on the flow sensor and/or the flow sensor cable can corrode or have poor connections, providing inaccurate measurements (a problem with hot wire anemometer sensors).”***

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An important consideration when using ventilators with flow sensors is the quality of the signal provided to the machine. Contacts on the flow sensor and/or the flow sensor cable can corrode or have poor connections, providing inaccurate measurements (a problem with hot wire anemometer sensors). Sensors may calibrate successfully but still measure inaccurately. Water accumulation may also interfere with accurate flow measurement regardless of the device. Cables on hotwire anemometers should not be positioned dependently; similarly, pressure lines from a pneumotachometer should also be positioned in an upright orientation. Once again, the quality of the flow graphic is related to the quality of the signal. Be suspicious if a machine is consistently using full PIP to deliver the set VT, which may indicate a poor signal. If pressing the cable into the flow sensor results in lower PIP and a better flow graphic, it indicates either the flow sensor or the cable (or both) should be changed. Any signal dampening will also reduce trigger sensitivity, thus increasing work of breathing and asynchrony.

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***“Even the most sophisticated ventilators can still be fooled by the accumulation of water in the circuit. Water sloshing back and forth can cause auto-triggering and should be suspected if an infant’s respiratory rate is consistently high.”***

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Even the most sophisticated ventilators can still be fooled by the accumulation of water in the circuit. Water sloshing back and forth can cause auto-triggering and should be suspected if an infant’s respiratory rate is consistently high.

Perhaps one of the most controversial lung-protective strategies is permissive hypercapnia. While widely used, what constitutes permissive hypercapnia is a matter of debate. PaCO<sub>2</sub> of 45 -55 mmHg is widely cited, but much higher levels are often allowed. Low CO<sub>2</sub> is associated with reduced cerebral blood flow, while

high CO<sub>2</sub> results in cerebral vasodilation and may promote vessel leakage, resulting in brain injury. Hypercapnia also impairs cerebral blood flow regulation. (3)

Just how high or low PaCO<sub>2</sub> must be to result in damage depends on several factors. Rapid changes in PaCO<sub>2</sub> are inadvisable as it stands to reason reperfusion injury may result similar to that following hyperoxia. Gestational age likely also plays a part with more premature infants being more susceptible to injury, particularly during the critical first 72 hours. For instance, a term or near-term infant can rapidly drop their PaCO<sub>2</sub> during a crying fit with no discernable effect. I have personally ventilated infants with severe compensated respiratory acidosis (PaCO<sub>2</sub> > 80 mmHg) and regularly allow PaCO<sub>2</sub> to rise into the 70s. This practice has not appeared to result in neurological sequelae based on rates of interventricular hemorrhage or periventricular leukomalacia. I believe the key here is a gradual increase in PaCO<sub>2</sub>, allowing for pH compensation and avoidance of high or low levels during the first week of life, particularly in the micro-prem. Nevertheless, severe hypercapnia has been linked to white matter injury, and clinicians should proceed with caution until the risk-benefit ratio is better established. There is no question that maintaining “normal” CO<sub>2</sub> levels by increasing mechanical ventilation results in further lung damage.

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***“The current shift towards early extubation and non-invasive support (and avoidance of intubation entirely) is likely to result in improved outcomes, particularly in units where HFV is not routinely used.”***

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The current shift towards early extubation and non-invasive support (and avoidance of intubation entirely) is likely to result in improved outcomes, particularly in units where HFV is not routinely used. As discussed in a previous column, this may not be the case in the sub-25-week gestation strata. (4)

In summary, if using CV in the premature population, lung damage may be reduced by using low volumes with volume-targeted ventilation, using fully synchronous modes such as PS or A/C, optimizing PEEP, avoidance of over-ventilation/hypocapnia, judicious permissive hypercapnia, and extubation at the earliest opportunity. As with any mode of respiratory support, avoidance of high FiO<sub>2</sub> is also advisable.

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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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## National Perinatal Association PERINATAL MENTAL HEALTH

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# "I Answered Obediently to 'She.'"

## Experiencing Pregnancy as a Nonbinary Person in the United States

Cody Miller Pyke, JD, LLM

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*.



**"This year the chosen theme focused on the 4th Trimester and the various areas of vulnerability for parents and infants during this time, as well as the resources available for support."**

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In Summer 2020, Morgan McCarter(\*) discovered something incredible. They were pregnant. Not "they," as in "Morgan and Morgan's partner," but "they"—the singular third-person pronoun(1) for Morgan, a non-binary person living in the United States. Morgan was both delighted and concerned. The pregnancy was planned, but they worried about the emotional toll of what they already suspected would be a highly gendered experience. Their anxiety was further deepened because they are not fully 'out' to the world or their biological family as a non-binary person. "I am not open to my family, nor am I really in a place emotionally to explain [my gender] to others. Basically, I am only openly myself in queer spaces or with those few people that I know are safe to be open with."

Transgender, non-binary, and gender-expansive (TGE) people are not novel, nor are they a rarity. Estimates report that 1 in 6 members of Generation Z identify as LGBTQ+, (2) and this generation is already well into reproductive age. (3) For many TGE individuals, the experience of being misgendered—being referred to by pronouns or gendered terms which conflict with one's gender identity—is traumatic and contributes to psychological distress. (4) Despite the known harmful effects of misgendering TGE patients, multiple studies have shown that medical education on transgender health is desperately lacking in the United States and Canada. (5) Worse still, one study reported that "26% of transgender individuals experienced discrimination in the health care system due to their gender identity and 52% were unable to obtain health service due to financial issues." (6)

Morgan was fortunate to have health insurance and access to healthcare. However, what should have been an affirming prenatal experience of their first pregnancy was overshadowed by family and health professionals misgendering them and propagating unnecessarily gendered stereotypes.

"Birth classes were very gendered... [Everyone's] obsession with the baby's 'gender,' even when I decided not to find out the sex until birth... 'choose blue for boy or pink for girl!' It is difficult to face the dissonance of wanting to appreciate your family for their love, [but also] feel unheard when you say things like 'It's sex, not gender,' 'gender doesn't have a color' [and] 'my

child will be able to wear what they want to.'"

The dissonance was not only external. Like many TGE individuals who become pregnant, the physiology of pregnancy also triggered Morgan's gender dysphoria. "I struggled a lot with both the physical and emotional aspects of pregnancy. [As my body changed,] I had many small breakdowns about what I can only describe as 'body horror' [which] I needed to face [because of] both my own intrinsic feelings and the extrinsic reactions [to my body] of the society around me. It was lucky that [because of the pandemic] I wasn't seeing very many people anyways."

Morgan's interactions with health professionals during labor and delivery were also mixed. Speaking of the staff at the birth center where delivery was to occur, Morgan described their midwife as "trauma-informed and also respectful of their pronouns," and their doula as "also very respectful." Unfortunately, at nearly 2 feet in length and more than 10 pounds, Morgan's baby was large—especially for a primigravid parent. After an induced trial of labor at the birth center, Morgan was ultimately transferred to a hospital for a Cesarean section.

By the time they arrived at the hospital, Morgan described themselves as "desperate" and that this desperation "overrode" their concerns about their own body and what effects surgical interventions may have on their dysphoria. "I did not bring up my gender identity [in the hospital]. I answered obediently to 'she' and 'her' and terms like 'mother.' I even referred to myself as such." Morgan felt "bizarre" and now only had their partner and the birth center doula who knew their gender identity. The hospital staff was professional and compassionate, but none stopped to ask about Morgan's gender identity, pronouns, or their history of trauma. All simply assumed they were a self-identifying woman with no reservations of how their body was to be discussed and treated. "The worst were the lactation specialists pushing for breastfeeding. The pressure to make me breastfeed made me feel sick because I was still unsure of [how I felt about breastfeeding]. One [lactation specialist] pushed me so hard. She told me that it *should hurt* and that she *didn't care* that my nipples were scabbing over."

Despite taking home a healthy newborn,

Morgan's troubles continued at home. "My relationship with breastfeeding still feels a bit abusive even now. People in my life take breastfeeding for granted and don't understand my struggles with breastfeeding—even my partner who knows about my dysphoria. It is all just a continuation of the assigned-female-at-birth experience of my life... [where I'm unable] to assert autonomy over my body and mind. [Being treated this way] was one of the main reasons why I was staunchly against having children for a long time."

To date, Morgan and their partner are doing well and absolutely in love with their new baby. Nonetheless, when asked what they wished more health professionals knew about non-binary gestational parents, Morgan had this to say: "Just, everything. Be informed. Be aware. Have pronouns and gender identity be a part of the paperwork—and give more options than just male/female. People don't want to have to take extra steps to explain or justify themselves."

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(\* ) The patient interviewee's name has been changed for privacy reasons. Details on the birth are also kept appropriately vague for privacy.

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

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# COPING WITH COVID-19

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



Provide culturally-informed and respectful care.

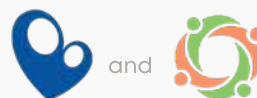
TELL PARENTS HOW YOU WILL KEEP THEM AND THEIR BABIES SAFE DURING THEIR NICU STAY.



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



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# 2020 SONPM

# Virtual Awards Ceremony



**Thursday  
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12:30PM PT

1:30PM MT

**2:30PM CT**

3:30PM ET

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## Join Ceremony Here

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**2:30PM- Intro & Update from the Chair**

**2:40PM- Intro to Merenstein Lecture-**

2020 Merenstein Lecture: "Moral Status and Justice Considerations in the NICU"

Mark Mercurio, MD, FAAP

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**3:05PM- Intro to 2020 Fanaroff Education Award-**

2020 Education awardee- Bill Benitz, MD, FAAP

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**3:15 PM- Intro to 2020 Landmark Award-**

2020 Landmark awardee - Tom Wiswell, MD, FAAP

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**3:25PM- Intro to Thomas Cone History Lecture-**

2020 Cone History Lecture: "Seventy-five years of Progress in Neonatal Sepsis: The Cha-cha Hypothesis"

Rich Polin, MD, FAAP

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**3:50PM- Intro to 2020 Virginia Apgar Award-**

2020 Apgar awardee- Betty Vohr, MD, FAAP

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**4:05PM- Closing**

Presenters: Lily Lou, MD, FAAP; Mark Hudak, MD, FAAP;  
David Stevenson, MD, FAAP; Bill OH, MD, FAAP

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- Make **digital + virtual resources** available.
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# SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS

DURING COVID-19

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



## TRAUMA-INFORMED

Both parents and providers  
are confronting significant...

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

## LONGITUDINAL DATA

We need to understand more about outcomes for mothers  
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- **MENTAL HEALTH**
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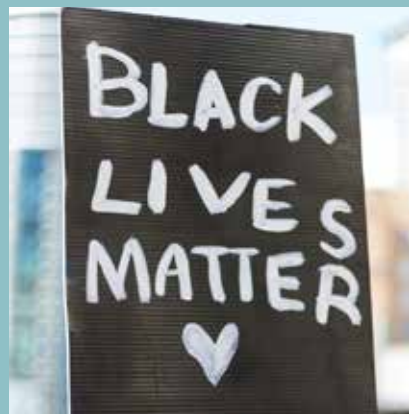


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A racial pandemic within a viral pandemic



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# Keeping Your Baby Safe

during the COVID-19 pandemic

## How to protect your little one from germs and viruses

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

### Here's what you can do...

#### Wash Your Hands

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



#### Limit Contact with Others

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



#### Provide Protective Immunity

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



#### Take Care of Yourself

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



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



**WARNING**

#### Never Put a Mask on Your Baby

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



#### If you are positive for COVID-19

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

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# Despite COVID-19, Data Support Kangaroo Care

Michelle Winokur, DrPH, and the AfPA Governmental Affairs Team, Alliance for Patient Access (AfPA)

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



According to a global survey, more than 85% of neonatal health care personnel feared for their own health while working during COVID-19. (1) Inadequate or erratic availability of personal protective equipment, such as masks and gloves, was chief among providers' anxieties. Staff shortages and longer shifts increased providers' stress.

***“According to a global survey, more than 85% of neonatal health care personnel feared for their own health while working during COVID-19. (1) Inadequate or erratic availability of personal protective equipment, such as masks and gloves, was chief among providers' anxieties. Staff shortages and longer shifts increased providers' stress.”***

***“The worst-case scenario, assuming 100% transmission, could result in 1,950 neonatal deaths, they found. (3) In contrast, they estimated more than 125,000 newborn lives would be saved if kangaroo care was practiced universally.”***

Now, details about how those sentiments have changed the practice of maternal and neonatal medicine are coming to light.

According to the survey, two-thirds of healthcare providers would not support “kangaroo care” with mothers who had a positive or unknown COVID-19 status. The technique involves prolonged skin-to-skin contact and exclusive breastfeeding. It is an evidence-based best practice for small and sick newborns. World Health Organization guidelines strongly recommend initiating kangaroo care for all newborns weighing 2,000 grams or less as soon as the baby is clinically stable. (2)

Instead of following this guidance, however, some health care providers separated babies from their mothers to reduce COVID-19 exposure. In separating babies from their mothers, health care providers inadvertently traded one risk for another, more serious one.

A team of researchers from the WHO, London School of Hygiene & Tropical Medicine, and the University of California San Francisco modeled scenarios in which a COVID-19-infected mother would transmit the virus to her infant. The worst-case scenario, assuming 100% transmission, could result in 1,950 neonatal deaths, they found. (3) In contrast, they estimated more than 125,000 newborn lives would be saved if kangaroo care was practiced universally.

Study authors concluded infants had at least a 65-fold increase in death risk by *not* doing kangaroo care. The risk of virus transmission, they cautioned, cannot be mitigated completely, although “infection prevention and control practices have been shown to reduce that risk considerably.”

In short, COVID-19 separation policies have harmed newborns. Warned the authors: “Since the start of the COVID-19 pandemic ... coverage and quality of maternal and neonatal care has deteriorated.”

It behooves babies – and their mothers – for health systems to reevaluate precautionary policies that curtail parental closeness on account of coronavirus exposure. Kangaroo care, even if the mother is COVID-19 positive, is in the baby's best interest. Models have shown the benefits of kangaroo care far outweigh the risk of COVID-19 mortality.

As the world starts to look toward a life beyond COVID-19, patients, providers, and policymakers would do well to keep the pandemic's lessons top of mind. Deterring from long-standing, evidence-based care does not often turn out well, even when it is driven by the best of intentions.

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# Still a Premie?

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

But that's not every premie's story.

## Born between 34 and 36 weeks' gestation?

**STILL A PREMIE**

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

- Jaundice
- Feeding issues
- Respiratory problems

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

## Born preterm at a "normal" weight?

**STILL A PREMIE**

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

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

## Born preterm but not admitted to the NICU?

**STILL A PREMIE**

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

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

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

**NCJH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
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# I CAN Digitally Involved (iCANDI): Collaboration with the Pediatric Trials Network (PTN)

Amy Ohmer



*“Spring has sprung and with that is the launch of new and exciting kid-friendly initiatives at the International Children's Research Network, Inc. (iCAN). Starting with a new approach to discussing clinical research trials, iCAN completed a collaboration with the Pediatric Trials Network (PTN) in which a 13-year old youth member, Kenneth, from the KIDS Ohio chapter shared his perspective for a lay summary”*

Spring has sprung and with that is the launch of new and exciting kid-friendly initiatives at the International Children's Research Network, Inc. (iCAN). Starting with a new approach to discussing clinical research trials, iCAN completed a collaboration with the Pediatric Trials Network (PTN) in which a 13-year old youth member, Kenneth, from the KIDS Ohio chapter shared his perspective for a lay summary. This unique project helped create a kid-friendly short video designed to educate other children (and their families) about the safety and effectiveness of pediatric medicine.

Next, iCAN participated in the latest AIMed series to spotlight

Medical Devices and pediatrics. Sharing the wisdom of 15-year-old Imaan, a member of the KIDS CT chapter, the AIMED series host, Dr. Anthony Chang, CHOC, was treated to a better understanding of what it is like to wear an insulin pump and a continuous glucose monitor as a young person. The theme of Medical Device discussion continued. During the month, iCAN's President Leanne West and Director Amy Ohmer participated in a community engagement session with MDUFA (FDA) for sharing support to create a better understanding of pediatric devices and how to help kids. This promises to be an important spotlight during the year as more understanding of pediatric medical device innovation is shared worldwide. In partnership with Boston Children's Hospital, connecting in May, KIDS Barcelona will be hosting a Hackathon. This event is designed to draw out creativity from the community to help support new pediatric medical innovation. All iCAN Chapters have been invited to serve as judges to help narrow down the finalists. We are confident this will be a terrific event. Details on our news page at [www.icanresearch.org](http://www.icanresearch.org)

*“ In partnership with Boston Children's Hospital, connecting in May, KIDS Barcelona will be hosting a Hackathon. This event is designed to draw out creativity from the community to help support new pediatric medical innovation.”*

iCAN youth members participated globally through several surveys designed to capture feedback on clinical research trial design and helped create new iCAN Youth Member recruitment flyers. For our organization, it is vital to ensure that the kid's voice is infused everywhere, so almost everything is reviewed by kids. In completion, all of the finalized work with feedback incorporated was given the "iCAN Seal of Approval". Going forward, if you see

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the seal, you can rest assured that it was "kid reviewed - kid approved"

Additionally, iCAN summit planning (to be held July 12th - July 16th, 2021) is happily underway. Dr. Sharon Smith, CT Children's Hospital, is creating a session to help youth members understand steps to a diagnosis by doctors. The session aptly named "What Doctors Want You To Know" will be part of the weekly summit events. Furthermore, iCAN and Sing Me A Story kicked off a new and exciting musical collaboration for a global group of six lucky youth members living with rare, complicated, and chronic medical conditions. In a wonderful alignment with iCAN to support youth in providing opportunities to share children's voices, Sing Me A Story's mission is to serve deserving families in need through sharing stories of children combined with the power of music. Sing Me A Story connects professional singer-songwriters with each youth member and family to understand who the child is, what they like, such as hobbies, families, pets, vacations, or other important parts of life for the child. Once the story is shared, the singer-songwriter team sets the words to music, creating a lasting memory for a lifetime. The summit will feature the final musical creations of young people from KIDS Bari, KIDS Virtual, KIDS Albania, and KIDS Houston, and our newly created Young Adult Professionals.

Looking ahead, we invite all summit participants to send in a Chapter Poster - a culmination of work done throughout the year to support their local chapters. The Summit Poster Session is also open to other interested community members that might like to showcase their original abstracts to the iCAN Community. The Poster Session and all other open projects are available on the 'FOR KIDS' tab on the homepage. As a reminder, if any interested kids are not involved in an iCAN chapter but would like to participate, iCAN offers a Virtual Chapter to accommodate any child, anywhere in the world. There is no cost to create a chapter or for a child to participate as iCAN is supported through sponsoring partnerships. If you would like to sponsor a child, a chapter, or our summit, please contact us by email [info@icanresearch.org](mailto:info@icanresearch.org) or visit [www.icanresearch.org](http://www.icanresearch.org)

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*The author has no conflicts of interests to disclose.*

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## OPIOIDS and NAS

When reporting on mothers, babies, and substance use

# LANGUAGE MATTERS



### I am not an addict.

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



### I was exposed to opioids.

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



### NAS is a temporary and treatable condition.

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



### My mother may have a SUD.

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

### My potential is limitless.

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



Learn more about  
Neonatal Abstinence Syndrome  
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Respiratory Syncytial Virus is a

# Really Serious Virus

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

Coughing that gets worse and worse



Breathing that causes their ribcage to "cave-in"

Rapid breathing and wheezing



Bluish skin, lips, or fingertips

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

Call your doctor and meet them at the hospital.

If your baby isn't breathing call 911.



Thick yellow, green, or grey mucus



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

Fever that is higher than 101° Fahrenheit



which is especially dangerous for babies younger than 3 months

 National Perinatal Association

[www.nationalperinatal.org/rsv](http://www.nationalperinatal.org/rsv)

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis

RSV



SOAP

**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](http://www.nationalperinatal.org)

 National Perinatal Association

# Infection Control Policies in the NICU: Time for a review?

Kelly Welton, RRT-NPS

It is every NICU manager's worst nightmare: That your NICU has to close down because of an outbreak or a high rate of infection with the same pathogen. But ask any RT or RN who works at more than one NICU: policies vary from facility to facility.

As a Respiratory Therapist, it seems like we get blamed for every infection, there is. In many hospitals, the RT workload is divided very differently from the way nurses do it. Not many nurses have a couple of patients in one unit and other patients in another unit. It is just not done that way. Depending on the hospital, many RT's are given half a patient load in one unit and half a load in another area. RT's may have several patients on the general floors, for example, and 2 babies on HFNC in the NICU because that is how the workload points add up. But as you're going to see in a minute, it does not make much sense to do that.

All who enter the NICU must do what first? Some NICUs require a 3 minute surgical scrub upon entry, and some NICUs only require handwashing with soap or use of an alcohol-based rub. Let's consider ALL the people that do enter the NICU. There are doctors, not just the neonatologists but specialists such as eye doctors and surgeons. If your hospital is a teaching hospital, there may be residents that rotate through, not just for neonatology but surgical and pediatric cardiology residents. Physical therapists and Occupational therapists work with the babies on feeding, swallowing, and developmental care. Hearing professionals come in to screen the babies. Imaging people come in to do x-rays and ECHOs. Although most nurses work in one unit, some nurses may float to other units. But when nurses float, they are usually there for the whole shift, not jumping back and forth between 2 units. How about parents, foster parents, siblings, and grandparents. What does *your* facility require to enter the NICU?

***“Although most nurses work in one unit, some nurses may float to other units. But when nurses float, they are usually there for the whole shift, not jumping back and forth between 2 units. How about parents, foster parents, siblings, and grandparents. What does your facility require to enter the NICU?”***

After a visitor or staff member has done the initial wash or scrub, this seems to be where the rules change for everyone. Although family members will only visit their child or children, these fragile babies with immature immune capabilities may need to be better protected from their own parents. If mom and dad are able to hold their baby, is that a risk to the baby? What about Mom or Dad's

hair? Staff are made to pull our hair back, yet parents' hair can drag all over a baby and their warmer. Most adults are well-colonized nasally with several different bacteria and then allowed skin-to-skin right under their nose. What should the true standard be?

In term neonates, skin infections due to staph aureus, both MRSA and MSSA are most commonly found on the umbilical stump and on the groin. NICU staff and parents are said to be staph aureus nasal carriers. Neonates can handle being colonized but not overloaded. In very low birthweight or less than 1500 gram infants, the gram-positive organisms cause 70% of the infections, the majority being with coagulase-negative staph, which affects the skin and mucous membranes. Gram-negative pathogens cause 20% of infections: E Coli, Klebsiella, Pseudomonas, Enterobacter, and Serratia. The remaining 10% are fungal, usually candida Albicans. Infection is generally facilitated by multiple invasive procedures that very low birth weight infants undergo, such as UAC's, UVC's, other lines, endotracheal intubation, and nasogastric tubes. This is all from a study done by Dr. Brenda Tesini, who does a lot of infectious disease studies. Let us pause and think: if it is mostly invasive procedures causing these infections, where are pathogens coming from, and how are they being transmitted? Let's go back to the gram-positive pathogens. We know that gram-positive organisms are on our hands and in our nose. As for the gram negatives, E Coli generally comes from the gut, so for example, if somebody changes a diaper and does not wash their hands well afterward or does not remove their gloves and gel before going on to the next task. Klebsiella is usually found in urine and gets transferred the same way – a quick diaper change, no hand hygiene, then touching the baby again. Pseudomonas is typically from water as it likes warm and moist environments but can also be found in urine. Pseudomonas infections often get blamed on the humidifier or ventilator circuits, but there is often to be a good explanation of how it got there. Enterobacter can come from a UTI and also from a perforated bowel. Serratia is generally passed from hand-to-hand contact. The candida or fungal infections can come from an overgrowth caused by steroids or antibiotics. By killing both the good and the bad bacteria, the candida overgrows and can be passed to other babies.

What are some other factors that might cause a virus or bacteria to be transmitted from staff to baby or parent to baby? We encourage kangaroo care for mom and dad for the baby to spend some skin-to-skin time. Because we know that many pathogens normally live on our skin, could that be a cause of hospital-acquired infection? Are the parents required to wipe down with some CHG bath cloth first? When the eye doctor comes in to examine the baby, does he or she have a mask on? They get right up there with the scope looking into the baby's eyes, and even if the baby is intubated, could there be a risk of passing colonized pathogens to the baby? Respiratory therapists document ETT placement every 2 hours, requiring a very close look at those tiny endotracheal tubes to see the ETT depth at the lip or the gum. Nurses must document NG tube placement, also requiring a close look. Is a mask required to do those tasks?

Upon reviewing the current Center for Disease Control recom-

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recommendations for NICU's, the only thing that stood out was a recommendation to perform active surveillance testing for Staph Aureus and MRSA colonization in NICU patients when there is an increased incidence of infection or in an outbreak setting. Current precautions for most NICUs are contact isolation when a baby is known to have an infection. Otherwise, it is hand hygiene and standard precautions only. Standard precautions essentially boil down to "Do what you need to do to protect yourself and prevent the spread of infection." Hand washing and use gloves when you know you're going to be handling something dirty. Should there possibly be a new class of precautions such as NICU precautions? What would that look like?

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***"If a baby does end up in contact isolation, there is often a flyer or poster on the door or curtain. Are the instructions clear for visitors and family?"***

---

If a baby does end up in contact isolation, there is often a flyer or poster on the door or curtain. Are the instructions clear for visitors and family? Contact isolation requires dedicated or disposable equipment and clean and disinfect equipment before use on another person. Do all visiting MDs, OTs, and imaging people follow this? Who is monitoring? Moreover, back to the initial entry scrub: Should it be mandatory every time they come in? For example, some people come in at the start of their shift, do a 3-minute surgical scrub, and wash or gel in between patients. They leave to go to lunch, they are on their phone, they're in the cafeteria, they're handling stuff, they're talking with friends, and they come back into the NICU and then hand wash. Should they do another 3-minute scrub? What about personnel who come in and treat patients and then leave to go take care of other patients in another unit? Think PT, OT, even RT. This has been the basis for some confusion for some time. Should they do a 3-minute scrub also every time they come in the unit? What about the gowning procedure? For example, somebody who has a split load, a few patients on the adult floors, and 3 NICU babies. They start their day on the adult floors in their scrubs, then they come into the NICU, do a 3-minute scrub, and put a gown on. Does that adequately protect the babies from what is on their scrubs? Or, what if they do the opposite - what if that therapist starts out seeing the babies in the NICU and then goes up to the adult floor? If they come in and if it is mandated, they put on NICU issued scrubs and see their babies and wash in between, and then they put a gown on when they go up to the adult floors, the idea being to keep their scrubs clean and take that gown off when they come back to NICU. Assuming they have no isolation patients upon the adult floors, is that good enough? Furthermore, if they did, many hospitals will insist that if standard precautions are being followed, there is no risk. However, how many times, [yes raise your hand], have you gone in to see a patient, Neo, peds, or adult, and on the first round, the patient is clean, and you follow standard precautions. And the next time you go back to see those patients, one of them is now in isolation -- suddenly, there is a yellow cart by the door and a big sign. You have already exposed other patients and been exposed yourself to whatever this now-isolation patient has. Is it that effective to wear a gown as a barrier to your scrubs, take care of non-NICU patients, and take that gown off and go back into the NICU?

VAP – According to a meta-analysis done by a group of doctors in Switzerland, "Ventilator-associated pneumonia (VAP) is defined as a nosocomial lower airway infection, i.e., pneumonia in intubated patients with onset after 48 hours or more of invasive

mechanical ventilation<sup>1</sup> (1). VAP is usually caused by airway colonization by potential pathogens, which disseminate due to inadequate immune response of the newborn's immature immune system. Sources of airway colonization can be the patient's own flora, i.e., bacterial overgrowth in oral secretions, reflux, and aspiration of gastric fluid, or the patient's environment with its caretakers and equipment (2, 3). It also states, "There is a high diagnostic inconsistency and a low reliability of interpretation of chest x-rays regarding VAP." Meaning, if a baby is initially intubated and the CXR looks OK, and then 48 hours later, the CXR looks worse, that would be a presumed VAP. Because of the cost of VAP, even though it is difficult to define, diagnose, and treat, all hospitals have implemented a VAP bundle of some sort, usually requiring elevated head of bed, 24 or 48-hour change of inline suction catheters, no use of saline to suction, no changing or breaking a ventilator circuit unless necessary.

Infection cost to hospitals. In 2009 and 2010, various studies were published that said the hospital-acquired infection could cost as much as \$14,000 to \$18,000 extra over what it would have been had the patient not gotten an HAI. However, that is from 2001 data. According to inflation, it is now 20 years later, so in today's dollars, that cost is estimated at \$20,000 per patient incident. Let us do some general math: if you have 200 NICU admissions per year on average, and half of those babies are affected by an HAI, at an extra \$20,000, that is \$2 million in unnecessary treatments and unnecessary charges. Had we just been able to prevent the HAI, we could have avoided the risks of antibiotics, the extra ICU days, and the stress on the parents of an extended NICU stay. And just keep that number in your head for a minute because we are going to come back to that.

What are the risk factors for a hospital-acquired infection? The risk is inversely proportional to the baby's gestational age, in addition to the number of lines the baby will need and the number of other-human exposures the baby will have.

The question is, is it time for a new NICU infection control protocol? Have best practices been identified worldwide? Say what you will about Facebook; here is a poll that I did in one of the Respiratory Therapy groups asking what the current infection control practice in your NICU is? The most common response at the time was: RT only has patients in the NICU no matter how slow it is. In other words, no mixing of loads, no assigning some patients that are adults or peds, and then some patients in NICU. That got the most votes, and that is a good thing. The second most popular option was in the "other" category, but only three people left comments and explanations. One says, "our charge is the only NICU RT that would see other patients. Our staff providing direct care only have NICU babies". That is good. The second commenter said, "What we practice is not what I feel is best" [mixed loads].

The third person says, "If we don't have full staffing, they short staff the NICU instead of making a split assignment." That does not seem fair, but it has been responsible for staffing and scheduling. It can become quite the balancing act, and it looks like this hospital has decided on no mixing of patient populations. The third most popular answer was: if an RT has a patient load outside of the NICU, the RT can wear a cover gown in the NICU. I read that as they wear whatever they wear outside of NICU and then put a cover gown on to protect the babies when they come in NICU. One more vote says an RT with a mixed load must change into NICU-issued scrubs and use a cover gown to see patients outside of NICU. There was no absolute consistency as far as, should a non-designated RT or other staff put a gown on to come into NICU? Or, should they put a gown on when leaving NICU after seeing babies see other patients?

If we are going to improve NICU infection control policies, what would be considered extreme versus necessary? What does the

evidence say about NICU visitors of any kind? Should we wear masks if we will be getting close to the baby? Should everybody that comes into the NICU wear NICU only scrubs? What is the current best practice with cover gowns, bodysuits, and generally protecting the babies from the things we pick up and carry on our clothing? What if you come to work in the NICU, change into NICU scrubs, do the three-minute wash, and then you get a call to go down to the ER to help out with a 30 weeker that popped out by surprise. Do you put a cover gown on to protect your scrubs while you go down to see this 30 weeker? When you come back to NICU, should you change scrubs again? How well do we clean our stethoscopes in between patients? How well does the ophthalmologist clean his equipment between babies? Who wipes down equipment after use and gets equipment ready for the next patient?

VAP and HAI numbers in the NICU must be reviewed to make a difference. Random surveillance must be done. I have long fought to get hooks at the doorway of every baby's bed to try to get people with lab coats, jackets, hoodies, sweaters, etc. to hang it up outside of the baby's room so they can keep an eye on it and everything that's in their pockets. Would that be a sound infection control measure to add at your hospital? Remember, at \$20,000 now per incident, depending on the number of admissions you have, whether it is \$1,000,000 or \$2 million a year would it be worth it for the hospital to hire an extra RT or two to avoid mixing loads? Or have you dedicated NICU PTs and OTs? If you could show that hiring more staff would save the hospital money, would you speak up?

I teach my students always to make it a point for people to see them hand wash and then gel, see them cleaning their stethoscope between babies, see them put their hair up or a cap on, and then wash or gel, not the other way around. No one likes to get blamed for spreading infection, but perhaps it is time for a more effective global policy as a starting point.

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# High-Reliability Organizing (HRO) in the COVID-19 Liminal Zone: Characteristics of Workers and Local Leaders

Daved van Stralen, MD, FAAP, Thomas A. Mercer, RAdm, USN

## Abstract

*HRO has become better studied, producing concepts that bring clarity to its structure and function. Reliability, safety, and resilience, as concepts, do not carry the same immediacy of a fellow worker in danger or bringing a novice into the workforce in a way that that novice may save you. Reviewing how workers did their jobs while ensuring their own safety reveals elements of HRO that are at risk of becoming lost. We reviewed the experiences of WWII heavy bomber crews, high-rise ironworkers, underground miners, prison chaplains, fire rescue ambulance crews, and Vietnam aerial combat aviators. From their experience, we describe a VUCA-2T environment (Volatility, Uncertainty, Complexity, Ambiguity-Threat, Time Compression). Workers pass through, if not caught up in, a liminal zone. The common themes across work domains include suppressing fear, trust, helping the novice, protecting your partner, recognizing fear in fellow workers, and local leadership. Perhaps the organization's response to liminality differentiates management by high reliability organizing from conventional organization management.*

*“Too much difference from what the physician knows, too much discrepancy from what is expected, a disrupted response to treatment, or any abrupt change, and the neonatologist must figure something out. That figuring forms the basis of High-Reliability Organizing.”*

## Introduction

Arriving at a resuscitation, the neonatologist looks for the familiar and what is different. Drawing upon knowledge and experience, the physician begins treating the neonate. Too much difference from what the physician knows, too much discrepancy from what is expected, a disrupted response to treatment, or any abrupt change, and the neonatologist must figure something out. That figuring forms the basis of High-Reliability Organizing.

This figuring out seems more reliable coming from scientific evidence using the best practices identified by experts. Concepts, categories, standards, and rules create norms for decisions and action (1), comforting us that we are doing the right thing. That is until an abrupt change jumps us into a different situation. Or

the novelty or uncertainty of the situation keeps us from clearly identifying a specific treatment. Inability to control events or the people around us brings frustration. Failed response to treatment brings death perilously near. The drive to act rapidly becomes disorienting. The individual impulsively takes any option that appears better (2). From within the situation, all decisions are rational, and all actions are reasonable. On the outside, things look different.

Stress responses reduce distraction to create focused attention and allow our learned responses – the “tried but true.” Fear reactions keep us a safe distance from the threat to create a comfortable area to work. Threat reflexes initiate action to create engagement before we can fully recognize the danger (3, 4). On the other hand, unmodulated stress responses inhibit memory retrieval and constrain thinking. Unmodulated fear reactions misdirect our behaviors toward offensive and defensive protective actions. Unmodulated threat reflexes focus on self-protection, paradoxically increasing failure (4).

*“The HRO, on the other hand, investigates failure as a result of impaired stress capacity, fear management, of threat disruptions. The HRO re-evaluates leadership and systemic decision migration, early engagement, and support to the individual operating within the trajectory.”*

Unmodulated behaviors experienced as organized suites and structured ensembles become expected, even normal. We perceive them as cultural traits. Unrecognized unmodulated behaviors too easily escalate toward cascading failure (3). Failure appeared inevitable. Failure explained by events or “the system.” Failure ascribed to human error or shortcoming (5). The HRO, on the other hand, investigates failure as a result of impaired stress capacity, fear management, of threat disruptions. The HRO re-evaluates leadership and systemic decision migration, early engagement, and support to the individual operating within the trajectory.

A concern for leaders in an HRO is an undue emphasis on the normative stance at the expense of the pragmatic stance (6, 7). This emphasis impairs the “organizing” component of HRO and can remain covert in an untested system. HRO, conventional organization management, and all manner of reliability, safety, and resilience programs perform well in stable environments. What differ-

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entiate HRO from other programs is its origins within dangerous contexts, the capability to modulate abrupt disruptions, horizontal translation between industries, vertical translation within an organization, and, most significantly, the ability to extend an organization into uncertain or treacherous environments.

We can learn from industries operating in dangerous environments, but not through studies conducted in a controlled laboratory (8, 9). Laboratory research constrains the subject's ability to respond, which does not represent the real-world environment. Neither can a researcher mimic a live-or-die circumstance (8). Field research incorporates the heterogeneity of populations and practices, group expertise, and the spaces and concepts created by science (10). Field experience identifies gaps between theory and practice (11), the effect of granular, local influences, manifestations of stress and fear, and the local effects of threats (6).

Concepts and linear inference (scientific logic) generate the ability to predict. To predict is to prepare, thus creating a safe margin for organizational managers. To know the concept is to know the properties, thus creating a knowledge system. But predictions for stochastic environments or human behaviors, whether individual or collective, misleads planners at a fixed reference point and participants within the flux of events. Prediction for HROs is literally a matter of life or death; inaccurate models can kill (9).

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***“To predict is to prepare, thus creating a safe margin for organizational managers. To know the concept is to know the properties, thus creating a knowledge system. But predictions for stochastic environments or human behaviors, whether individual or collective, misleads planners at a fixed reference point and participants within the flux of events.”***

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This article introduces into the HRO literature academic research that objectively described the field environment and presented the experience of individuals. We evaluated for consequential influence from concepts (1, 12, 13). Mental and emotional balance, trust, and neuromodulation are learned skills. They can be readily learned within the milieu of operations.

We describe the environment that necessitates neuromodulation of stress, fear, and threat; HRO as a quality that emerged from adaptive beliefs and behaviors; and social cognition and prosocial behaviors as HRO characteristics.

### **The Environment**

We can readily understand the function of stress, fear, and threat behaviors within the context of danger, yet we more commonly experience the behaviors in a liminal zone. The military concept of "VUCA" to describe threats to national security (14, 15) and the anthropological experience of liminality as a transition (16) have entered the lexicon of business, public safety, and healthcare. The incomplete translation of VUCA, liminality, and HRO theory into the practice of reliability and safety comes with the loss of nuance and missed, subtle cues within the environment (6). Unrecognized is the loss of neuromodulation as a skill and methods for its ac-

quisition.

*VUCA: Volatile, Uncertain, Complex, Ambiguous*

In 1995, US Army researchers working in the Carlisle (Pennsylvania) Barracks, US Army War College, described the global environment developed at the end of the Cold War as VUCA: *volatile, uncertain, complex, and ambiguous* (14, 15).

- *Volatility* comes from the rapid and abrupt change in events.
- *Uncertainty* describes the lack of precise knowledge about the situation, our need to obtain more information, the unavailability of the necessary information.
- *Complexity* refers to the large number of interconnected and changing parts that come together to create the situation.
- *Ambiguity* describes how multiple interpretations, causes, or outcomes may be possible for one situation.

*VUCA-2T: VUCA with Threat and Time Compression*

VUCA is a *military* concept. Military professionals carry the implicit assumption that they work in a dangerous and lethal environment of "going in harm's way" (per John Paul Jones). Consequently, the concept of threat is not translated into civilian applications (17). On the other hand, the author (DvS) had included time compression into the element of volatility as the quality of instability (17, 18). A special group in SOCOM (Special Operations Command) used "VUCAT" but found the element of time compression to have such importance it should stand alone (Sean McKay, personal communication). We now use VUCA-2T though the group uses VUCA-T<sup>2</sup> (19).

- *Threat* impairs cognition and decision-making.
- *Time compression* describes the limitations on acquiring information, deciding, or acting before consequential changes in circumstances. Time compression is not a quality of time-dependence or time-limitation.

A threat more often takes place out of sight of the public. People then reject or misunderstand how threat formed HRO and how it makes a program stronger. Threat acts as a motivating condition to generate a set of beliefs and behaviors from within the ranks of workers and relatively independent of the organization or regulatory agencies (20). This form of informal subculture is an adaptation to operate in a hazardous environment. Without discussion of threat, we lose many HRO elements and misunderstand HRO characteristics.

We incorporated well-understood experiences for threats, such as military operations and high-rise ironwork, and some that people may not be fully aware of the threats such as underground mining, prison chaplain, and fire department rescue ambulance work.

Underground mining is dangerous and geographically, physically, and socially isolated. Mines operate in unpopulated, rural areas away from major population centers, emergency rescue teams, and medical care. Mining in some areas has a social and occupational stigma attached to isolation manifested in defensive group solidarity. Miners work underground in small groups, physically separated from, and unable to communicate with, other workgroups. "For the miner, danger requires a response. It is a common, day-to-day, potentially lethal occurrence" (20)

A prison is built on the tendency of inmates to harm others. However, prisons must allow inmates to practice their own religion, including access to a religious or spiritual advisor. Prison chaplains work in this dangerous context to meet the pastoral needs of inmates. However, they must maintain vigilance for their own safety as inmates, even the inmate they counsel, may intend harm to the chaplain. Prison chaplains work as treatment staff within a correctional facility, occupying a liminal social space between corrections officers and inmates (21). This also creates an HRO-type of subculture.

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***“It is a bit discomfiting when we find ourselves in a space we do not belong, or that is meant for passage. The discomfort arises from the loss of context but also when the discomfort triggers the sympathetic nervous system.”***

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### *Liminality*

It is a bit discomfiting when we find ourselves in a space we do not belong, or that is meant for passage. The discomfort arises from the loss of context but also when the discomfort triggers the sympathetic nervous system. The triggered behaviors for stress, fear, and threat do not belong in the absence of danger, yet the trigger continues to incite these internal responses. The liminal zone described in anthropology is that space between a world we know and a world we do not, where our old rules do not apply, and we have not learned the new rules (16). In this area of experience, we must engage the situation to leave, yet we do not know what works (1).

The liminal zone challenges us as individuals but also for planning, leadership, and organizational science. These are temporary spaces where we either do not belong or that were created to pass through. We do not have context. We cannot rely on learned concepts, policies, or rules (1). We may have entered a liminal space as a neonatologist approaching an active resuscitation, or we may have space thrust upon us when a neonate abruptly deteriorates. Liminal zones also expose us to other, quite different, experiences such as a physically hostile parent or a NICU damaged from an earthquake or hurricane.

Liminal zones are not continuous with routine operations or with each other. Abrupt changes disrupt operations. Our treatments may abruptly disrupt the disease process and the neonate's physiology. Such a sequence of experiences creates the more common "punctuated experience" of resuscitation that necessitates constant evaluation and re-evaluation rather than sensemaking guiding us from the immediate past to the immediate future. "HRO is a trajectory of engagement that fuses now with the experience of then into simultaneous inquiry and redescription," Karl Weick (personal communication). Karl Weick describes the repeated presentation of abrupt changes as "punctuated sensemaking" (personal communication). Every action is a failure, and every action creates an unrelated or disconnected experience.

We would rely on our knowledge and experience, except we do not know what will work or what results we can reach. This is the "practice of reliability" to engage an uncertain problem within the liminal zone (1). Through engagement, we work to increase our chance of success while also decreasing the effect of failure. We

simultaneously react to events while preventing events. This practice of reliability is an extension of our team into the liminal space at a local level and the extension of the art and science of neonatology at a larger level of analysis. This is how neonatologists and neonatology have gained life.

While this may describe common experiences, it does not describe how VUCA-2T or the liminal zone places demands on the brain's survival system. Nor how those demands affect our thinking and behavior. It is your brain that tells you that your brain is working well. Healthcare professionals in emergency and critical care believe what their brain tells them. They believe they have healthy stress, fear, and threat response for disagreements, abrupt disruptions, and danger. Thus, unmodulated cognitive functions remain unrecognized and even appear logical. "I had to yell/stare/intimidate to make the team act." Maladaptive and dangerous stress-fear-threat reactions then enter the culture and become accepted, even though lethal.

The liminal experience shapes the HRO by shaping the individual. Experience describes the changes within an individual due to the environment (1). The liminal zone's more severe environment has a profound effect on the individual, sometimes as a larger number of small liminal experiences or fewer but more severe incidents. What makes High-Reliability Organizing is not the number or severity of liminal experiences but learning how to perform in the liminal zone. These are lessons learned firsthand for prison chaplains rather than by instruction, such as an inmate who uses trust to manipulate the chaplain. Liminal experiences have three functions for chaplains (21):

- a rite of passage for chaplains that proves their mettle and demonstrates an ability to navigate these situations;
- teaching to be proactive for assessing potential problems with inmates and engage early rather than allowing them to escalate;
- providing up-to-date "lesson stories" to be shared.

Engagement of a liminal experience, rather than passive endurance, change the cognitive domain and the affective domain. Perhaps the differentiation of trust, risk, and danger between pragmatic and normative stances (6) lies in the lexicon of liminality.

WWII American bomber crews arriving in the theater of operations were insecure and defensive. In action, they were overly self-assured though some were particularly diffident (22). About their tenth raid [the airmen had entered and remained in liminality]:

the man had experienced fear and by now knew that he could deal with it; he found that care and skill and coolness in the pilot and crew had a real bearing upon the question of his return; he saw that his crew and his airplane could withstand catastrophe; he developed an "esprit de corps" regarding his squadron, and was now really part of it. He developed for the first time a sense of his responsibility to his mates and to formation. At this stage... the men were effective, careful, fighting men, quiet and cool on the ground and in the air. They attained a sort of tranquility despite their anxiety. *They had very little need for defensive mechanisms of any sort to deceive themselves or anyone else.* [Authors' emphasis.] They talked easily and quietly (22).

### **Neuromodulation of stress, fear, and threat**

Drive the course as fast as you can in the police car. Two runs. Then we learn if we passed the LAPD "skid school" for high-speed

driving. For the second run, we used the siren. All of us, fire department rescue ambulance drivers, had passed. We asked what the failing time would be. "There isn't one. If you drove faster with the siren, that means you are run by adrenaline. We don't want you" (DvS, personal experience).

### *Manage your fear*

A second-year pediatric resident felt her mind freeze. As the critical care transport physician, she walked up to the head of an infant in cardiac arrest. The referring team left when they saw her enter the emergency department. They had been unable to achieve a sustainable heart rhythm. Her mind froze; she couldn't think. That is the report she gave one of the authors (DvS) when she returned to the PICU. She said it was a familiar sensation as the author had earlier given her an exercise to recite the months of the year alphabetically. The exercise demonstrates how quickly cortisol impairs memory retrieval. Inability to think in a crisis is a neurochemical effect, not a measure of cognitive ability or intellect. She checked the endotracheal tube "because it was working." She could immediately think and then stabilized the infant in 20 minutes. Voluntary, directed movement can counter cortisol-mediated freeze.

One paradox of fear is managing fear through the act of not showing fear. This is not the same as not showing fear through denial of the threat or false bravado. This comes from the acceptance of fear by all participants with the realization that showing fear impairs performance (personal experience and observation of the authors; (21, 23, 24). A major norm in mining is to not become victim to your own emotions, "don't get excited," "play it cool" (23). Described by a journeyman high-rise ironworker, "One must accept danger and fear without allowing it to control or adversely affect your behavior" (24). For the prison chaplain, one state code of ethics includes, "I will be constantly mindful. To the best of my ability, I will remain calm in the face of danger" (21).

Those with personal experience have learned that suppression of the fear response reduces the effects of fear. They each learn methods to neuromodulate during their routine dangerous tasks. Experienced veterans also learn how the expression of fear alone spreads the fear response to others. In mining, one can express frustration through an emotional outburst, but there is a limit that the outburst must not pass (23). For the prison chaplain, recognizing the threat from being alone in a prison yard enhances alertness, yet they also recognize sustained levels of alertness negatively affect thinking, generate paranoia, and create cynicism and skepticism for people's intentions (21).

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***“One paradox of fear is managing fear through the act of not showing fear. This is not the same as not showing fear through denial of the threat or false bravado.”***

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### *One piece of information*

The engine stopped. He was flying a small Pacer airplane up the mountains toward a pass in an area with a big valley surrounded by mountains. Going up the mountain when ~~with~~ the engine went out. The only way to land was going up the hill. He thought about what to do. He figured he could dive downward. Then, while he still had flying speed, he would turn up to land uphill toward the

end of the valley.

On another flight, he was flying at night when the engine stopped. It was out of gas; he had no gauges, had no instruments, and had no lights. He began a descent into a forest, planning for the trees to break the landing. One hundred feet above the trees, quickly coming into view, he saw a field. He lowered the landing gear to slow his airspeed and went for the field. The landing gear, not fully deployed, caused the plane to swerve as it crashed.

The 3G force was what kept him thinking. In a small plane, he had been told the cockpit could handle a landing with a force of 3Gs. Knowing he would be safe no matter what happened, he was able to figure out a solution.

Both crashes occurred in the early 1950s. In 2018, he learned how a person could neuromodulate thinking when in danger. That is when he understood how he could think clearly while his plane was about to crash into a mountain pass or into trees at night. One piece of information, safety at 3Gs, was enough for him to think clearly.

Charles Aldridge, personal communication to the author (DvS).

You are part of your equipment. Feelings are powerful and influence thinking, behavior, and body functions. That was the message given to airmen in preparation for the emotional stresses of combat in WWII (25). While anger and fear emerge in many forms, what counts is its direction toward destructive or constructive effects. *"Fear must be clearly related to its real cause, and that relationship must be maintained, because you can't attack a problem if you don't know what the problem is,"* David G. Wright, Captain, Medical Corps, USAF (25).

### *A subculture for dangerous contexts*

"The requirement for reciprocity applies to most social exchanges and is especially pronounced during occasions of danger or accidents. Miners know that they can count on other miners to be available and lend assistance during their moments of peril. They also know they are expected to and will return a similar favor to another miner someday in the future" (23).

HRO was codified from the Nimitz class nuclear aircraft carriers. The system called HRO emerged from 1) the experience of 35 years of naval aviation warfare, 2) Captains with both aerial combat and complex ship handling experience and nuclear propulsion training, and 3) the high technical knowledge and professionalism of the nuclear-trained crew (7). What is easily missed is how HRO developed from routine operations in the liminal zone.

The liminal zone more than distinguishes HRO from other approaches for safety, reliability, and resilience. Liminality also distinguishes operational organizing from administrative organizing, leadership at the operational level from executive leadership, and operations within the trajectory of events from observation and operations at a fixed point. Most significant, liminality underscores the necessity to have neuromodulation of stress, fear, and threat integrated into the organization.

Entering a VUCA-2T environment or a liminal zone, we shift our orientation from routine work to short-term objectives. From a distance, it appears to make sense to have training and plans in place. The expert following the rules performs poorly (26, 27) and has plans for everything to have plans for nothing. The HRO organizes differently because, despite best intentions, "What you do in an emergency is what you do every day," Jim Denney, EMS

Captain, LAFD, US Navy Seabee Vietnam Veteran. This article introduces methods for individuals and small groups to develop daily operations that rapidly expand for emergencies.

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***“The liminal zone more than distinguishes HRO from other approaches for safety, reliability, and resilience. Liminality also distinguishes operational organizing from administrative organizing, leadership at the operational level from executive leadership, and operations within the trajectory of events from observation and operations at a fixed point. ”***

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To "manage your fear" refers to the affective response, not to disregard the threat. Experienced workers accept the threat's reality, which means they teach the novice how to work around the threat.

#### *From daily to emergency*

Accurate observation and description will reframe the situation from imagination to actionable concreteness. The prison chaplains' experience being observant reduced their stress working in prisons and aided their vigilance for things "not right." As a result, they experienced less complacency, a well-known danger in prison work (21).

Along with accuracy in observation is accuracy with the lexicon. A primary step Ron Stewart (founding president of the National Association of EMS Physicians) took when creating the paramedic program in Los Angeles County was accurate medical terminology and descriptions (personal observation, DvS). Manifestations of this step influenced information gathered in the field, communication with physicians and hospital personnel, and medical thought processes. The author continued this method by creating a PICU, critical care transport program, and subacute care programs. The prison chaplains changed negative words, like "riot," to neutralize the lingering feelings of negative feeling. They could remain cautious without becoming overwhelmingly paranoid or too fearful to work (21).

A final comment on accurate observations and how they influence our thinking, adrenaline does not cross the blood-brain barrier. There is no adrenaline in brain tissue because adrenaline does not cross the blood-brain barrier (26).

#### *Human safety systems*

The human stress system evolved to support an effective response against an acute physical life threat, assisting immediate escape and survival (27-29). Neuromodulation of this rescue system, part of the sympathetic nervous system, allows harmony with the growth system, or parasympathetic nervous system, for adaptation to various circumstances.

Neuromodulation allows the stress-fear-threat system to balance our human response to the level of demand. In this way, we reduce our reactions when called for resuscitation and find the neonate responded to initial treatment, and we accelerate our reac-

tions when the neonate we are treating deteriorates abruptly.

Without neuromodulation, the stress-fear-threat system contributes to unrecognized, normalized, instrumental, and even institutionalized maladaptive behaviors. These behaviors come in suites of related behaviors common to humans and ensembles of behaviors developed within individuals from instrumental experience (3). A shared threat, such as fear of malpractice, error, or a leadership style, creates the ecology of fear, further normalizing maladaptive behaviors that contribute to a culture of fear. The strength of the stress-fear-threat system is lost.

Stress, fear, and threat motivate engagement, maintain a safe working distance, and focus attention toward action (3, 4). Military and public safety operations rely on the neuromodulation of stress responses, fear reactions, and threat reflexes.

One author (DvS) has educated staff for neuromodulation during the development of a PICU, subacute care facilities, and several EMS education programs. However, the wrong education substance (teaching and content) makes good people and organizations vulnerable to compensated but covert failure. They will not recognize or identify the proximity of failure because the system continues to operate. Operations will continue through failure until there is an abrupt, severe disruption with unexpected catastrophic failure.

#### **HRO emerging from adaptive beliefs and behaviors**

This material comes from observations written within a dangerous context before extramural regulations circumscribed behaviors or concepts became established that would influence interpretation. This is the material experienced veterans shared with novices.

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***“Without neuromodulation, the stress-fear-threat system contributes to unrecognized, normalized, instrumental, and even institutionalized maladaptive behaviors. ”***

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It seems intuitive, if not prudent, to select personalities for high-risk work. At the least, we would want training designed for work in confusing environments with rapid, abrupt change. These industries – WWII heavy bombing, US Marine Corps recruit training, high-rise ironwork, hard rock mining, prison chaplain – trained the novice to the job and allowed the intensity of danger to reinforce what was learned. One psychiatrist joined a B-17 crew "to a distant target in enemy-occupied Europe." He observed a crew of diverse personality types in action, everyone wounded, the plane badly damaged and flying alone, with successful return to England in doubt (22):

"It was striking that the emergency did not tend to increase the differences in the reaction patterns of the differing personalities; rather they came to act in much more similar fashion than usual...The reduction of all personality types to a common reaction pattern appears to be a matter deserving contemplation."

A second difficulty arises when incorporating bona fide experience into any safety, reliability, or resilience model: the inability to compare liminal experience and engagement to established

laboratory or field studies. The academician seeks to generalize research findings across many settings, seemingly unidirectional from laboratory settings and peacetime to operational, live-or-die, *in extremis* situations (30). Observers outside the liminal experience or who use a fixed frame of reference (6) rely on a deduction to categories using linear inference to place new information into known concepts (1).

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***“It seems intuitive, if not prudent, to select personalities for high-risk work. At the least, we would want training designed for work in confusing environments with rapid, abrupt change.”***

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While translating between these environments seems counterintuitive, we argue in this paper that migration of the model to one of the human-circumstance interactions will illuminate the similarities and elucidate the mechanisms. There is a gap between observations in combat and laboratory studies(30), theory and practice (11), discrete concepts and continuous perceptions (31), and

abstractions and concreteness (Karl Weick, personal communication). Engagement in the liminal zone melds both sides of the gap (6) to bring an understanding of HRO to those outside live-or-die experience.

#### *Functional nature of the subculture*

The subculture that develops for hazardous work – the rules, beliefs, attitudes, and values – reduces the expected mental stress. As a subculture isolated from the general population, those who work in dangerous contexts constrain each other to safety norms (20).

Ironworkers will "binge" each other, harassment meant to reinforce boundaries and mental control of emotions (32). Miners constantly assumed that how a miner worked could avoid accidents and that recognizing and coping with potentially dangerous situations could be learned. They always respected a dangerous situation. They did not bend or ignore rules (20). Clergy build their culture with trust, yet clergy working in prisons, *prison chaplains*, learn to "watch out" when they work in prisons. They must apply their pastoral skills in an institution not built on trust, where the worst can happen, with inmates having tendencies to harm others (21).

#### *Leadership*

Organization management reaches its limits at the ambiguous, moving boundaries of liminal zones and deadly contexts (6, 30, 33). The May 1996 Mount Everest climbing disaster illustrates the unrecognized risk inexperienced people generate when they *knowingly* cross the liminal zone threshold or enter a dangerous

context (33, 34). We are well-served to remember the chemistry lab mantra – "hot glass looks like cold glass." A dangerous mountain looks like a safe mountain. A miseducated organization looks like an HRO.

Leadership for high altitude mountain climbing developed from experienced participants. As climbing became settled, novices and outsiders began high altitude climbing. May 1998, a low-pressure weather system passed over Mount Everest. This was the equivalent of abruptly gaining several thousand feet, a deadly occurrence at that altitude for the climbers. The environment looked the same. The threat was not visible to inexperienced sojourners on the climb and was disregarded by some experienced leaders (33). Eight climbers died.

What works in a stable, predictable environment also works in the liminal zone and dangerous contexts. However, the longer it works, the stronger the belief that outsiders and inexperienced leaders have in their leadership and management abilities. What becomes lost is the unique knowledge and experience necessary for liminal zones, dangerous contexts, abrupt changes, and punctuated events. Designs and the normative stance work...until they don't. In the subsequent chaos, "if you don't have it, it doesn't exist" (a common firefighter sentiment).

Operators engage within the turbulence and trajectory of events, generating information and knowledge for lessons learned (1, 6). A fixed-point reference frame outside the flux of events has a broader view with less confusing nuance. Concepts neatly and rapidly coalesce, partly for the purposes of organization management and sometimes for the needs of distant regulators and customers. The speed, putative strength, and familiarity of these accounts drive them to dominance. Lost are the experienced hidden voices that captured ephemeral lessons learned (34). As the baseline shifts (35), the subculture *for* dangerous contexts drifts, looking more and more like the dominant culture.

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***“The May 1996 Mount Everest climbing disaster illustrates the unrecognized risk inexperienced people generate when they knowingly cross the liminal zone threshold or enter a dangerous context (33, 34).”***

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Leadership in dangerous contexts and the liminal zone is local, an ephemeral nature rapidly shifting between those with local information and those with knowledge for action (personal observation of the authors; (36)). This type of leadership supports self-organization during the event and the necessary improvisation to generate solutions (18). It naturally arises during the experience of lethal threat (interviews by the authors; (36)).

In mining, the shift boss worries that the inexperienced miner will most likely be injured. For novices, accidents were due to ignorance. Miners have a uniform belief that guidance and experience make a good and safe miner. It is the shift boss's responsibility and experienced miners to teach and mentor new workers (23).

The United States Marine Corps uses social learning theory (37) during recruit training for socialization and to model desired behaviors. The drill instructor facilitates this enculturation (38, 39).

*Fear is not weakness*

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Fear is taken for granted. You can have fear yet continue to work and be accepted by your colleagues. There are no cowards. Withdrawing from a dangerous situation does not diminish one's reputation in mining (23) or ironwork (24). Miners and ironworkers respect others' fears and limitations without testing their courage (23, 24).

Military and public safety operators also accept an individual's fear, yet they must follow through to engage the problem despite an elevated probability of death [personal experience of the authors; interviews with San Bernardino City Police officers and Bouches du Rhone (France) fire officers; (38)].

Fear is the only natural reaction to the inescapable threats of combat. It is common to everyone.

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***“Leadership in dangerous contexts and the liminal zone is local, an ephemeral nature rapidly shifting between those with local information and those with knowledge for action (personal observation of the authors; (36)). This type of leadership supports self-organization during the event and the necessary improvisation to generate solutions (18).”***

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"The whole physiologic reaction of your body to fear is to prepare your body for action. You are prepared to respond to threat with vigorous action. When you cannot respond, you still have the sensations *necessary for response*" (25). That is the quandary of fear and anger, your body has prepared you to respond. But you cannot.

#### *Help the new member*

Uncontrolled fear responses impair performance not only in dangerous situations but also can create a dangerous situation. Both novice and newly hired veterans are at risk. The novice is gaining experience in a new discipline while the newly hired is learning a new team. Both individuals operate in a liminal zone.

Not possessing the requisite knowledge and skill results in poor performance and injury. The focus on training and the apprentice period is to develop qualified members. Miners believed it is the duty of the veteran miner to guide and teach the novice miner. The new miner would learn to work in a way to avoid accidents, recognize potential danger, and learn how to respond to such situations (23). Journeyman ironworkers told apprentices how to act by having them think out their tasks and make sure their coworkers do the same. The journeyman would present situations, even if it was not the job of the apprentice. The apprentice would then give interpretations of the proper actions as "part of the process of sharing this perspective about fear and threatening coworkers" (24). The US Marine Corps sees recruit training as developmental and positive despite the high personal demands. Drill Instructors **were** are present to help, not harass the recruit (38-40).

In ironwork, apprentices cannot appear incompetent because they can inadvertently cause serious problems. Asking questions

can be a sign of incompetence, just as not asking questions could be. The apprentice ironworker dilemma is the dilemma of a novice nurse, resident, or attending physician in the NICU – how to learn without revealing ignorance (32).

Prison chaplains are taught that awareness can help control risks and prevent problems. Abrupt social disruptions erupt from resentments nurtured over long periods. Alert officers and veteran chaplains notice the subtle warning signs. The vigilance of prison chaplains for subtle changes in human behavior is much the same as an experienced leader in an HRO – "anticipate risk in order to control it effectively," and "chaplains assumed the existence of risk, even in the absence of evidence of a clear threat" (21).

There **was** no effort in these dangerous industries to scare or test the novice's mettle with situations or horrible stories of death (23, 24, 38). Rather, veterans were supportive. In the mines, a new miner would be greeted with comments along the lines of: "First time in a mine? Don't worry; it ain't that bad. You'll do all right" (23). The experienced veteran gives meaning to the feeling of fear and stress.

Every state and facility corrections training for prison chaplains has a strong focus on the threats from inmates, often in the first section of the training session. Training includes how to negotiate risky situations when the prison chaplain is alone, including being taken as a hostage (21).

To increase stress capacity and performance in US Marine Corps recruits, successful drill instructors in the 1970s set the tone of the social environment in training. These drill instructors, nearly all Vietnam veterans, were significantly more job-involved, held higher internal control expectations, were significantly less impatient and less prone to anger, were lower in physiological arousal, and emphasized self-control of emotions. They also had more realistic job expectations and greater empathy for recruits (40). Their beliefs, expectations, and attitudes influenced the recruits' self-appraisals and expectations (41). Drill instructors with low-attrition units used reward contingencies to internalize locus of control. Even recruits who had had negative or failed experiences in life, such as failure, rejection, and emotional disruption, developed the belief that success will result from their own efforts (39, 42). Recruit training increased recruits' stress capacity by increasing training demands and from drill instructors who developed the recruits' capability for effective performance under stress conditions (43).

#### *Stress for stress*

"Just how does cortisol help you learn?!" Joe Martin, Battalion Chief, LAFD (retired), asked his training captains in the drill tower. The captains had incorporated into training activities for gratuitous stress. Some of the captains believed that a recruit learned to deal with stress by being stressed, while others believed they needed to keep the recruits from believing they are smarter than average. Martin understood that stress to the degree of cortisol release impairs learning and memory formation. Haas (24, 32) and Fitzpatrick (20, 23) described the support experienced workers gave to the novices in ironwork and mining, respectively.

This is not a rare belief. When one of the authors (DvS) observed this frequently in medical education, the individual taught this way because the military used the techniques. None of the respondents had served in the military – they said they had learned from the movies. In the 1970s, the Marine Corps did have a period when drill instructors believed the only way to produce good Marines was with high stress and a heavy-handed approach (39, 40). No scientific evidence supports the belief that intentionally



imposed stress increases the student's capabilities. Conformity is not discipline. The Marine Corps changed its program (38).

In the HRO, stress has no utilitarian value. Stress is not used for education, training, emphasis, behavioral modification or control, or bullying. Rather, the HRO considers stress from the organization to be a systemic failure, removing the necessary freedom to act early in response to a discrepancy or disruption. Stress, fear, or threat behaviors in an individual are more serious as they have several causes. These behaviors must not be allowed to affect the behaviors of others.

#### *Stories teach and share*

In the mid-1970s, Angel Dust (phencyclidine or PCP) initially arrived in the area where one author (DvS) served on a fire rescue ambulance (RA). PCP's effects as a dissociative anesthetic caused violent behavior and hallucinations in some victims. The RA crews would call the police for "officer needs help," which resulted in a tumultuous scene, increasing the possibility of injuries and arrests. Passing along stories of what worked created a body of knowledge that, within six months, the crew of the RA could manage a PCP response without assistance. Within an HRO, stories have a privileged role in generating and diffusing knowledge.

Workers in dangerous industries use stories to teach and for socialization (17). Stories bridge the gap between the tacit and the explicit. Stories as anecdotes deliver social knowledge to maintain or change a culture. Stories carry values and tacit social knowledge, allowing knowledge to be demonstrated and learned without the need to make formal presentations of ethics or to specify in detail the proper behavior. We share lessons we have learned from unique or novel situations. Stories can impress on the novice the effects of poor decision-making skills and the need for vigilance against the early signs of a crisis.

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***"In the HRO, stress has no utilitarian value. Stress is not used for education, training, emphasis, behavioral modification or control, or bullying. Rather, the HRO considers stress from the organization to be a systemic failure, removing the necessary freedom to act early in response to a discrepancy or disruption."***

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In mining, stories commonly focus on the most common event rather than fires or cave-ins that the miner cannot prevent. Often these stories tell of the new miner floundering until an experienced miner rescues and guides the new miner. This reflects the "uniform belief that a man needed the guidance and wisdom of an experienced miner to become a good miner" (23). For example, a journeyman ironworker told some ironworker apprentices on a bridge who had his hat on backward. When a wind gust blew the hat off, he reached out to grab it, lost his balance, and fell 100 feet into the water. In one story, even if apocryphal, the journeyman instructs the apprentices of the problem of wind and rain to put their safety first, then worry about their clothing and equipment later (24).

In dangerous contexts, stories teach without the need for direct

exposure to a threat. An "incident story," not to be mistaken for the "war story," gives a concrete example of a situation and its solution. Incident stories always incorporate a principle. Prison chaplains learn about their surroundings, inmate behavior, specific troubles, precautions, and solutions from incident stories. More general stories provide lessons for general threats, acting more like cautionary tales that apply to everyone (21).

Rather than teaching thinking and performance, some people use stories to describe prohibitions and warnings. These stories tell the novice what to do or not do rather than how to perform. This difference, prohibition versus performance, is nuanced but relevant to the HRO. A "cautionary tale" stops curiosity, associated with a strong will, masquerading as an educational tale to control behavior. Such stories create a "pedagogy of fear" (44) that contributes to the ecology of fear (45) found in many organizations and industries.

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Stories also have a neurological function. Novices tend to tell stories to process their immediate personal experiences. Experienced veterans often integrate both inner and outer realities, which produces understanding and is a central component of wisdom (46). Narratives are well-crafted anecdotes that describe the experience and the underlying principle. Such stories are ordered sequentially yet understood as a whole. Narratives require various structures in the brain, including conscious memory, knowledge, sensations, feelings, and behaviors. In this way, narratives integrate neural systems in the brain and socialize us into a culture (46).

The experienced veteran helps interpret the novice's stories and has a duty to share stories with the novice for guidance.

#### *Protect your partner*

"Look out for the other man" (23). "You never do anything without first making sure that your partner's all right" (24). Amid a heated discussion between several fire officer colleagues and the author (DvS), an RCP (respiratory care practitioner) interjected, "I thought you were friends. Why are you fighting?" One officer (Joe Martin, Battalion Chief, LAFD, retired) had worked with the author on the fire department rescue ambulance in a high drug and gang area. Martin responded, "We're sparring. You don't want your partner to go out without knowing his weaknesses or making him stronger, do you?" The RCP had not thought in terms of entering a dangerous social environment alone.

Among ironworks, preventing misunderstandings during a crisis while "running the steel" requires a "sparring match of social ges-

tures." This teaches the ironworkers how each will respond when the need to communicate freely, curtly, and, at times, forcefully occurs during a crisis (24). A threat to anyone is a threat to everyone.

"Looking after one's partner is the strongest and most immediate requirement and is adhered to even when there is conflict between partners" (20).

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***"Stories also have a neurological function. Novices tend to tell stories to process their immediate personal experiences. Experienced veterans often integrate both inner and outer realities, which produces understanding and is a central component of wisdom (46)."***

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Neonatologists are aroused by the distress of the babies, their parents, and NICU staff. Empathy is this vicarious sharing of another person's internal state. For ironworkers, empathy and their perspective of fear drive workers to watch out for each other. Ironworkers protect others from any situation that increases the common danger (24) while miners share tasks and warn others of dangerous situations (23). Workers can have strong opinions, but they come together against occupational threats. Empathy is one of five HRO values identified by the authors (dignity, honesty, humility, empathy, and duty) (17). HROs work in tough situations where people are going to fail, and it could be any of us doing the failing—"There but for the grace of God go I."

#### *Recognize fear in your partner*

The resuscitation of a child began accelerating. The author (DvS) asked a nearby nurse for assistance. The newly hired nurse peering into the room begged off to take routine vital signs in the adjacent room. The author then asked if the nurse could prepare a dopamine infusion, and he returned to the resuscitation. Within a few minutes, the nurse entered the room, set the dopamine infusion on a table, and joined the team. Acceptance of the initial response and voluntary movement modulated the nurse's affect and influenced cognition, resolving the fear response.

A major norm in mining is to respect the fears of others. It is not a sign of weakness to withdraw. You do not test a miner's masculinity or courage as there are no cowards in mining (23). During a wildland firefighting staff ride, participants discussed cutting a fire line on an extremely steep ridge. Several Hot Shot Crews declined the request. The main question for discussion centered around the crew that cut the line – did the crew have greater experience which enabled a successful cut, or did their lesser experience place them in harm's way? (Personal observation, DvS). [A staff ride is an on-site, structured study of an incident.]

We more commonly think of fear as incapacitating. While that does happen, insidious and more common is the individual who performs in a state of unrecognized fear. Miners protect the greenhorn who lacks experience and knowledge and provide on-the-spot instruction (23). Ironworkers, working more independently, watch for the worker who is afraid. Such workers are unpredictable and can cause serious accidents (24).

Whether workers in dangerous contexts avoid or instruct a fearful worker, the reasons are the same: "Ignorance and lack of skill

resulted in injuries" (23). A fearful worker will not act correctly, may act rashly, will put self-protection over group protection, places priority on his emotions, and neglects or avoids his responsibilities (24). The novice will flounder without the "guidance and wisdom" of experienced miners (23). Prosocial empathy increases group affinity and reduces stress responses and fear reactions through oxytocin systems (47-49).

#### *Trust*

One author (DvS), as a rookie on a fire department rescue ambulance, had called for a fire company to assist. The senior captain approached and asked what was needed. Believing his captain should decide, the author began to describe the situation. The captain cut him off and simply wanted to know what was needed. With that request, the author understood that his descriptions and requests would be accepted "as is" and acted upon. At that moment, the author understood the imperative for accurate descriptions and the gravity of every decision. The captain, William J. Corr, became his mentor, quoted in many of the author's publications.

Trust afforded colleagues is a determinant of the level of danger operators can accept (personal experience of the authors; (24, 32)). Trust in the operational domain is transactional between two people, similar to trust in the business domain. *Keiretsu*, a component of lean systems, describes how Toyota used trust to develop mutual benefit in partnerships to coordinate productivity and support long-term relationships with suppliers (50). Having high levels of trust is crucial for the transfer of tacit knowledge in the lean system (51). But trust in the liminal zone differs from trust in the business sense. The transactions can occur in moments and may or may not carry a moral equivalent. We trust a person to the extent of their capability. On the other hand, our trust may abruptly change as described by a US Army Combat Medic and Vietnam Veteran (personal communication), "I trust you until I see you putting yourself first." This comment distinguishes trust in the lexicon of liminal operators from that of the business community.

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***"We more commonly think of fear as incapacitating. While that does happen, insidious and more common is the individual who performs in a state of unrecognized fear. "***

---

Trust in prisons provides a good example of the utilitarian use of trust. The environment is constructed for distrust, and staff are taught not to trust (21, 52); trusting colleagues is the same as other dangerous contexts. However, continual treatment of inmates without trust creates worse problems working with inmates (52) and is counter to a prison chaplain's ministry (21). When we use trust as a tool and appreciate the myriad of reasons why people

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cannot be trusted, we begin to accept the firefighter's situational statement about trust, "I trust myself, so I can trust you."

Trust as consistency in performance or a character trait can be cultivated—the US Marine Corps formally cultivates character starting with recruit training (38). Civilian organizations are unable to cultivate trust and character in the same way. Members who work in dangerous contexts may "assay" for a person's ability to perform in the liminal zone in a manner that stresses its importance, teaches how to trust, and identifies those less trustworthy.

Firefighters and ironworkers in the 1970s tested trust or harassment or "binging," respectively. One author (DvS), assigned as a rookie to a busy fire department RA, noticed the firefighters would target a new transfer for harassment. His partner explained they would see what it takes to make the new firefighter "pop his cork," that is, to become infuriated rapidly. They would then know what made the firefighter angry and what the anger looked like. During an emergency, they would leave each other alone yet maintain vigilance for triggers and early signs of anger in each other. Should either occur, the other firefighters would engage in protecting the susceptible firefighter. Ironworkers used binging to test self-control under pressure. Ironworkers who lose control during binging will likely be worse in an emergency (32).

Rather than trust as an HRO value, the authors use *honesty* – what someone says represents the circumstances (17). Trust is a transaction that can be influenced by bias and experience.

## Conclusion

The "figuring out mechanism" for VUCA-2T and the liminal zone makes the HRO. We found the elements of figuring out had developed in several domains without the formal introduction of HRO concepts. These are domains where a threat is immediate and personal: WWII heavy bomber crews, ironworkers, hard rock or underground miners, prison chaplains, fire rescue ambulance crews, and Vietnam aerial combat aviators. HRO emerged from adaptive beliefs and behaviors found in these social groups.

These domains had traits of HRO, yet they developed outside the concepts of HRO. One of the authors (TAM) had invited Karlene Roberts to study the crew of his ship, the USS Carl Vinson. Roberts described the crew's performance in the first article that coined the term "High-Reliability Organizing" (53). Roberts had submitted a research paper for publication describing the work of one of the other authors (DvS) developing a PICU (54). Roberts and Bea

described the development without the label HRO because the PICU was developed before the codification of HRO (Karlene Roberts, personal communication, DvS).

These HRO traits reflect the workers' focus to help each other get the job done while working around danger. Keeping calm during daily work ensured they were calm during an emergency. All workers learned to engage discrepancies and disruptions. They also learned to identify and engage events earlier during the covert but compensated phase of failure. At some point in their experience, early engagement becomes prevention.

The amalgamation of response and prevention for routine operations expanded with little change to form emergency operations. In every emergency, responders identify and prevent further disruption ~~with~~ while simultaneously responding to control the emergency. This nature of HRO, at this level of analysis, facilitates the translation of HRO to diverse industries and throughout the hierarchy of an organization.

It can be viewed as a liminal rite of passage; the novice passes from the civilian world to a new "HRO" subculture. Experienced veterans are vital to this passage. A threatening, disorienting experience creates the feeling of vulnerability. No one wants that to happen to them again. Cognitive and affective fragmentation will resolve. Immediately after an incident, the individual becomes susceptible to dysfunctional coping mechanisms, maladaptive beliefs and behaviors, or harmful principles and concepts. In the HRO, the experienced veteran models effective, adaptive beliefs and behaviors necessary for the job.

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***"Trust is a transaction that can be influenced by bias and experience."***

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HRO is leadership, and leadership sustains High-Reliability Organizing. Hidden voices within the HRO tether the dominant account. During a crisis, ephemeral leadership anchors operations by rapidly and locally addressing discrepancies and disruptions. Minimal impairment on operations continues the organization's core work, work necessary to support the emergency response. This approach, to work with stress, fear, and threat, is learned by modeling leaders' beliefs and behaviors.

Help the new member control fear responses, identify danger, and become trustworthy. You are teaching the novice to protect you, which is to "protect your partner." This form of empathy is one of the five HRO values identified by the authors. HRO empathy leads to rapid, nonjudgmental support for colleagues and facilitates learning when everyone accepts, "That could happen to me."

Stress has no utilitarian purpose in dangerous contexts. Fear, as an instructive construct, teaches the novice what to look for and how to respond. In no situation do these domains working in dangerous contexts use stress or fear to interfere with thinking and acting. Informative stories teach safety and reliability. "Pedagogy of fear" stories create an ecology of fear (45). Modulated emotions, incorporation of fear, trust, and empathy emerge from the



rite of passage into the liminal zone. These traits do not appear without the modeling of leaders. In an HRO, every person is a leader.

Perhaps the organization's response to liminality differentiates management by high reliability organizing from conventional organization management.

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- R EACH A DECISION
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# Respiratory Syncytial Virus:

## How you can advocate for babies this RSV season

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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](http://www.nationalperinatal.org/rsv)

## Survey Says: RSV

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children



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

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



But Parents are Unprepared.

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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

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



NCJIH National Coalition for Infant Health

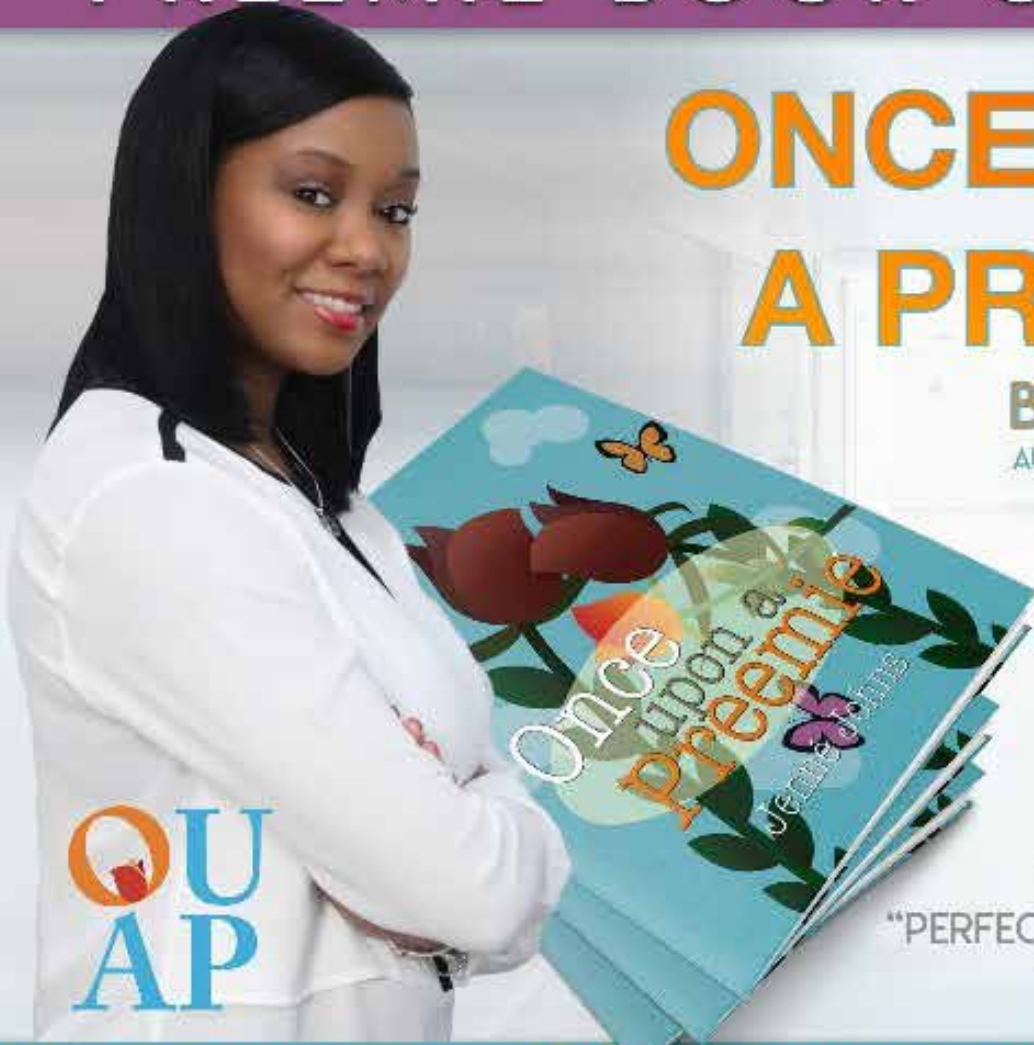
Learn More about RSV at [www.infanthealth.org/rsv](http://www.infanthealth.org/rsv)

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## ONCE UPON A PREEMIE

BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE



OU  
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## Survey Says: RSV

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

-  Hospitalization
  -  Lifelong health complications
  -  Death
- for infants and young children



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

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



*But Parents are Unprepared.*

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



**RSV EDUCATION & AWARENESS CAN HELP**

*After parents learned more about RSV, they were:*



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## OPIOIDS and NAS

When reporting on mothers, babies, and substance use

## LANGUAGE MATTERS



**I am not an addict.**

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



**I was exposed to opioids.**

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



**NAS is a temporary and treatable condition.**

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



**My mother may have a SUD.**

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

**My potential is limitless.**

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



Learn more about Neonatal Abstinence Syndrome at [www.nationalperinatal.org](http://www.nationalperinatal.org)



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



Eunice Kennedy Shriver National Institute  
of Child Health and Human Development



# Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief and David Vasconcellos, MSIII

## NIH, DC government form partnership to reduce sleep-related infant deaths

Wednesday, March 24, 2021

*Three-year partnership will develop D.C. project for infant safe sleep education and outreach.*

The National Institutes of Health and the District of Columbia government are teaming up to raise awareness among District parents and caregivers about how to reduce the risk of sudden infant death syndrome (SIDS) and other sleep-related causes of infant death, such as accidental suffocation.

Although many U.S. states and territories have seen decreases in sleep-related infant deaths over the last few years, the District's Office of the Chief Medical Examiner [reported an increase in these deaths between 2014 and 2018 \(pdf\)](#). Sleep-related causes of death include SIDS — the sudden, unexplained death of an infant younger than 1 year of age that does not have a known cause, even after a full investigation — or [suffocation, overlay, or other deaths from an unsafe sleep environment](#).

The [Safe to Sleep campaign](#), led by the NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), will work with the District of Columbia Office of the Chief Medical Examiner, the Thrive by Five DC initiative and other D.C. groups to understand information or service gaps related to safe infant sleep and determine how those gaps contribute to deaths and risks for families in the District. The collaboration, known as the D.C. Safe Sleep Education and Outreach Project, will then develop and implement the outreach and awareness campaign to inform D.C. parents and caregivers about how they can bridge these gaps.

"By combining science with safe sleep practices and tailoring safe sleep messages and activities to area parents and caregivers, this new collaboration has the potential to save infant lives," said Diana W. Bianchi, M.D., NICHD Director. "We are excited to work with our colleagues in the District of Columbia government and other local groups to help babies and families thrive."

"Every parent or caregiver wants their child to have the best start in life," said Dr. Francisco J. Diaz, Chief Medical Examiner for the

District. "The D.C. Safe Sleep Education and Outreach Project will provide families with valuable information on how to provide the safest possible sleeping environment for their infants, helping to reduce sleep-related deaths in the District and providing opportunities for each child to have a strong start."

"I am excited about this collaboration and the partnerships it is sparking to move us toward sustainable solutions and more positive outcomes for our babies. Together with families, we can make sure our babies have everything they need to thrive, and that includes safe sleep environments and practices," said Dr. Faith Gibson Hubbard, Executive Director of Thrive by Five.

NICHD and collaborators, including the American Academy of Pediatrics (AAP) and the Centers for Disease Control and Prevention (CDC), launched the Safe to Sleep® campaign as the [Back to Sleep campaign in 1994](#) to raise awareness among caregivers and healthcare providers about ways to reduce the risk of SIDS. The collaborators expanded the campaign to Safe to Sleep® in 2012 to focus on reducing risks for other sleep-related causes of infant death, such as suffocation.

The campaign translates safe infant sleep recommendations from the AAP into messages, educational resources, and outreach materials for lay and provider audiences. Key messages include always placing infants on their backs to sleep, using a firm and flat sleep surface such as a mattress in a safety-approved crib, and breastfeeding.

[Recent research findings](#) jointly published by NICHD, CDC, and the Health Resources and Services Administration suggest that other safe sleep behaviors, such as keeping loose bedding and soft objects out of baby's sleep area and room sharing with parents instead of bed sharing are not as well known. As a result, parents and caregivers may unknowingly be creating an unsafe sleep environment and putting their babies at risk.

With guidance and technical support from NICHD, the Office of the Chief Medical Examiner, Thrive by Five DC and other partners will assess the District's existing infant mortality data and safe sleep education and resources to determine if additional support

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systems or communications are needed to ensure that parents and caregivers make optimal choices related to safe infant sleep. Through focus groups and online surveys, they will identify any barriers to safe sleep practices among area residents and develop interventions to address those barriers. They will also identify and test safe sleep messages and materials, emphasizing the needs of and feedback from communities with the highest number of infant sleep-related deaths.

After testing is complete, these messages will provide the basis for the campaign, which will be a comprehensive outreach effort that will include community events, local media and community faith leaders, public service announcements, and media outreach. Dr. Diaz's office notes that the D.C.-focused project will likely launch in late 2021.

**About the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD):** NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. For more information, visit <https://www.nichd.nih.gov>.

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

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

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

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- Invitation for special programming by the Section at the AAP's National Conference.
- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

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children. If you have any questions, please feel free to contact:

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*The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit [www.aap.org](http://www.aap.org). Reporters can access the meeting program and other relevant meeting information through the AAP meeting website at <http://www.aapexperience.org/>*

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## NIH-funded COVID-19 testing initiative aims to safely return children to in-person school

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Thursday, April 15, 2021

*New RADx-UP research effort combines*

*testing and safety measures in underserved populations.*

The National Institutes of Health is awarding up to \$33 million over two years to fund projects at 10 institutions across eight states to build evidence on safely returning students, teachers and support staff to in-person school in areas with vulnerable and underserved populations. This funding was made available by the American Rescue Plan. Known as the Safe Return to School Diagnostic Testing Initiative, the [awards](#) are part of the NIH Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) program, which aims to increase COVID-19 testing access and uptake for vulnerable and underserved populations. Projects will combine frequent COVID-19 testing with proven safety measures to reduce the spread of the SARS-CoV-2 virus.

“Many children have inequitable access to reliable virtual learning, and it is important they are able to participate safely in person while also maintaining the health and safety of the of the school and general communities,” said Eliseo J. Pérez-Stable, M.D., director of NIH’s National Institute on Minority Health and Health Disparities and co-chair of the RADx-UP program. “Establishing frequent COVID-19 testing protocols for schools in vulnerable and underserved communities is essential to the safe return to school effort, and these projects will inform decision makers on the best strategies to accomplish this.”

Although many schools are offering both in-person and virtual learning options, some students face barriers to attending school remotely. For example, children may lack access to computer equipment and internet connectivity or may not have family members who can assist them with virtual learning. Moreover, without in-person schooling, many children forego school-based meals, speech or occupational therapy and after school programs. These barriers often disproportionately affect minorities, socially and economically disadvantaged children, and children with medical complexities and/or developmental disabilities.

Participating early childhood education and kindergarten through 12 schools include public, chartered, special education, and pediatric complex care that serve children in urban, rural and tribal communities. Attendance ranges from 50 to 3,500 children and populations are racially and ethnically diverse, including African Americans, American Indians/Alaska Natives, Latinos/Latinas, and Asian Americans. Schools were also selected for being in a school district with at least 50% of students receiving free or reduced-price lunch.

Some projects will involve at-home COVID-19 testing, while others will use pooled, in-school testing approaches. Study participants will receive either molecular or antigen tests, which can detect SARS-CoV-2 infection in samples from nasal swabs or saliva. Researchers will obtain parental consent prior to administering the diagnostic tests to children.

“These awards will foster the development of comprehensive programs to meet the challenge of safely returning children to in-person schooling, particularly for children who are vulnerable to COVID-19 or who are at risk for significant disparities in access to testing,” said Diana W. Bianchi, M.D., director of NIH’s *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), which is managing the initiative.

In the coming months, the RADx-UP program will make additional awards, pending availability of funds, to expand the initiative across more locations.

RADx-UP<sup>SM</sup> is a registered service mark of the Department of Health and Human Services.

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Institute/Center

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Contact

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## Most differences in DNA binding compounds found at birth in children conceived by IVF not seen in early childhood

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Wednesday, April 14, 2021

*NIH study results bolster previous studies finding no growth, development differences with IVF.*

Compared to newborns conceived traditionally, newborns conceived through *in vitro* fertilization (IVF) are more likely to have certain chemical modifications to their DNA, according to a study by researchers at the National Institutes of Health. The changes involve DNA methylation — the binding of compounds known as methyl groups to DNA — which can alter gene

activity. Only one of the modifications was seen by the time the children were 9 years old.

The study was conducted by Edwina Yeung, Ph.D., and colleagues in NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). Previous studies by the research team found no differences in [growth](#) and [development](#) for this group.

“Our study found only small differences in DNA methylation at birth and these were not seen in early childhood,” Dr. Yeung said. “When considered along with our previous studies finding no differences in children’s growth and development, our current study should be reassuring to couples who have conceived with fertility treatments and to those considering these methods.”

IVF consists of collecting eggs and sperm, fertilizing the eggs in a lab, and then transferring the resulting embryo or embryos into the uterus. Another technique, intracytoplasmic sperm injection (ICSI), consists of injecting a sperm cell directly into the

egg before placing the resulting embryo into the uterus.

Methylation changes were not associated with two other fertility treatments, ovulation induction (drug treatment to release the egg from the ovary) and intrauterine insemination (insertion of semen directly into the uterus).

According to a [national report in 2018](#)([link is external](#)), almost 75,000 IVF-conceived infants (2.0% of all infants) were born in the United States. Of these, approximately 76% were conceived with ICSI. Another study found that 3 to 7% of births resulted from ovulation induction and intrauterine insemination.

When [methyl groups are added](#) to a gene, the gene is switched off and does not produce a protein. Methyl groups are added and removed from DNA throughout life, as genes are alternately switched on and off. Changes in methylation may occur in any step of IVF. These include exposure to hormones needed to bring the eggs to maturity so they can be collected or exposure to the culture medium in



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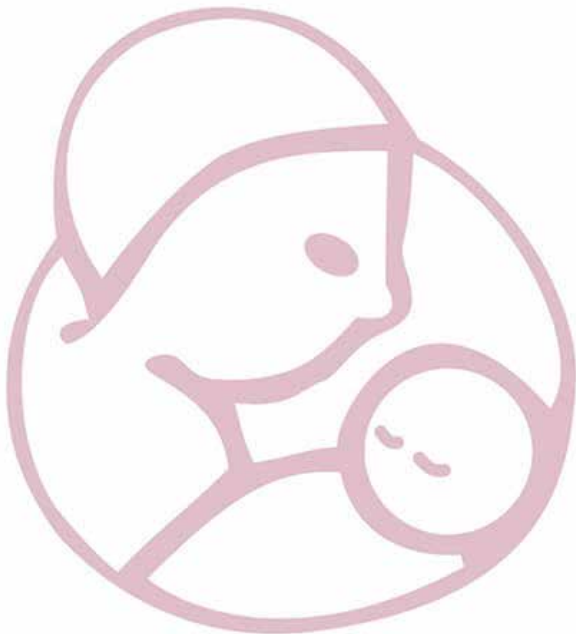
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which the eggs are fertilized and embryos develop.

Previous studies have found associations between IVF and certain rare disorders. However, many of these studies were small and their results inconsistent. Also, many of the studies were conducted before ICSI was in widespread use.

For the [current study](#), researchers evaluated data on DNA methylation differences in children beginning at birth and when they were 8 to 10 years old. The children were born in New York State from 2008 to 2010 and more than 70% of IVF birth were with ICSI.

Of the newborns, 157 were conceived with fertility treatments and 520 were conceived without treatments. Newborns conceived with IVF were more likely to have lower methylation levels in some parts of their DNA. The researchers did not find any methylation changes for newborns conceived by ovulation induction or intrauterine insemination.

Among the 152 children who provided DNA samples at 8 to 10 years old, 23 were conceived with IVF and 34 with ovulation induction or intrauterine insemination. For children conceived with IVF, lower methylation levels were seen for only one region, in the *GNAS* gene, which has been found in some previous studies but not others.

The study authors called for more research on how variations in fertility treatments could contribute to methylation differences in children, such as variations in the medium used to culture embryos.

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#### References

Yeung, EH, et al. [Conception by fertility treatment and offspring deoxyribonucleic acid methylation](#). *Fertility & Sterility* (2021)

###

#### Institute/Center

[Eunice Kennedy Shriver National Institute of Child Health and Human Development \(NICHD\)](#)

#### Contact

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## NIH scientists develop breath test for methylmalonic acidemia

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Monday, April 5, 2021

*Breath test for methylmalonic acidemia measures disease severity and success of liver transplantation for patients.*

Researchers at the National Institutes of Health have developed a breath test that measures how well patients with methylmalonic acidemia (MMA) respond to receiving liver or combined liver and kidney transplantation. Researchers also used the test to assess the severity of the disease in people and help determine if they

would benefit from surgical or experimental genomic therapies that target the liver. The study results were published in *Genetics in Medicine*. Scientists at the National Human Genome Research Institute (NHGRI) led the project team, with collaborators from the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Mental Health.

MMA is a rare genomic disease that impairs the body's ability to metabolize certain proteins and fats. This causes toxic substances to build up, which may result in kidney disease, pancreatitis, movement disorders, intellectual impairments, complications in many organs, and, in severe cases, death. One in 80,000 children born in the United States are diagnosed with MMA during newborn screenings. Currently, MMA is incurable, but people with MMA manage their symptoms through dietary restrictions and vitamin supplements. In extreme cases, patients receive liver or combined liver and kidney transplants, which help restore normal levels of metabolic proteins.

"Vast fluctuations in metabolic substances in the bodies of patients make it difficult for us to tell if treatments like genome editing and transplants are likely to be successful," said Charles P. Venditti, M.D., Ph.D., senior author and senior investigator in the NHGRI Medical Genomics and Metabolic Genetics Branch. "Instead of looking at levels, we decided to measure metabolism itself."

One form of MMA is caused by mutations in the methylmalonyl-CoA mutase gene (*MMUT*), which encodes for the MMUT protein. People with this form of MMA have a deficiency in the MMUT protein, which plays a pivotal part in metabolism. The protein is involved in the biological steps that help break down food, fats, cholesterol and amino acids.

MMUT helps break down food into a chemical byproduct called propionate, which is followed by an integral process involved in metabolism called oxidation. Through oxidation, a healthy body converts propionate into energy and carbon dioxide, which is



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exhaled, but that process is faulty for people with MMA.

Because MMUT protein function is compromised in people with MMA, Venditti and his team chose to assess how well the MMUT protein helped break down propionate in both patients who did and not receive treatment. The researchers believed this would act as a proxy for how much oxidation was happening in a patient's body.

"We wanted to measure exhaled carbon dioxide because we planned to use a breath test to track oxidation of propionate in a non-invasive way," said Irini Manoli, M.D., Ph.D., co-author and associate investigator in the NHGRI Medical Genomics and Metabolic Genetics Branch. "The trick was to somehow 'mark' the carbon dioxide so we could see which patients are unable to oxidize propionate because of a faulty MMUT protein."

Usually, the carbon dioxide we exhale as a result of propionate breaking down in the body contains a lighter, more common form of carbon, carbon 12. But because carbon dioxide that contains carbon 12 is

released by several metabolic processes in the human body, simply measuring carbon dioxide exhaled by MMA patients would not show how well MMUT helped oxidize propionate.

To detect if the MMUT protein was functioning properly, researchers gave patients a dose of the heavier, less abundant version of carbon — carbon 13 — via a commercially available food additive.

The team recruited 57 study participants, including 19 MMA patients who had received transplants (liver, kidney or both) and 16 healthy volunteers. Researchers gave participants a dose of the food additive containing carbon 13 via a drink or through a feeding tube, and then collected their breath samples after a two-minute wait.

The researchers measured how much of the exhaled carbon dioxide contained the usual carbon 12 compared to added carbon 13. As hypothesized, MMA patients who did not receive any treatment had lower levels of carbon 13 than healthy volunteers. By contrast, MMA patients with liver transplants had higher levels of carbon 13,


similar to the healthy volunteers. This result indicated that the MMUT protein was helping oxidize the carbon 13 molecules by bonding with inhaled oxygen molecules.

Higher levels of carbon 13 oxidation also correlated with better clinical outcomes, such as improved cognition and slower decline in kidney function.

Currently, the test is only available for use at the NIH Clinical Center; however, the researchers hope it will soon be broadly adopted for clinical and research use.

"Our next goal is to see if this specialized breath test can detect increase in carbon 13 propionate oxidation after gene, mRNA or genome editing therapies," Venditti said. "This way, we can also use this test to measure how effective these treatments are in restoring MMUT function."

NHGRI is one of the 27 institutes and centers at the National Institutes of Health. The NHGRI Extramural Research Program supports grants for research, and training and career development at sites nationwide. Additional information about NHGRI can be found at <https://www.genome.gov>.



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Manoli, I., Pass, A.R., Harrington, E.A. et al. 1-13C-propionate breath testing as a surrogate endpoint to assess efficacy of liver-directed therapies in methylmalonic acidemia (MMA). *Genet Med* (2021). <https://doi.org/10.1038/s41436-021-01143-8>(link is external)

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NT

## Younger age of first cannabis use or prescription drug misuse is associated with faster development of substance use disorders

Monday, March 29, 2021

*Substance use disorders are associated*

*with age of first use of cannabis.*

A new study shows that in the time after first trying cannabis or first misusing prescription drugs, the percentages of young people who develop the corresponding substance use disorder are higher among adolescents (ages 12-17) than young adults (ages 18-25). In addition, 30% of young adults develop a heroin use disorder and 25% develop a methamphetamine use disorder a year after first using heroin or methamphetamine. These findings, published in *JAMA Pediatrics*, emphasize the vulnerability of young people to developing substance use disorders.

The study was led by researchers at the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health.

"We know that young people are more vulnerable to developing substance use disorders, but knowledge is limited on how the prevalence of specific substance use disorders varies by time since first substance use or misuse among adolescents and young adults in the United States," said Dr. Nora Volkow, M.D., NIDA Director and a lead author of the analysis. "Though not everyone who uses a drug will develop addiction, adolescents may develop addiction to substances faster than young adults. This study provides further evidence that delaying substance exposure until the brain is more fully developed may lower risk for developing a substance use disorder."

To conduct this study, NIDA researchers analyzed data from the nationally representative 2015 to 2018 [National Surveys on Drug Use and Health](#)(link is external) conducted by the Substance Abuse and Mental Health Services Administration.

The researchers examined the proportion, or prevalence, of adolescents (ages 12-17) and young adults (ages 18-25) who had a substance use disorder in the past year (i.e., past-year substance use disorder) at various intervals since the first time they used or misused one of nine different drugs: tobacco, alcohol, cannabis, cocaine, methamphetamine, heroin, and

prescription drugs (opioids, stimulants, and tranquilizers used non-medically). The researchers evaluated past-year substance use disorders at four timepoints since first drug use: fewer than or equal to 12 months, more than 12 through 24 months, more than 24 through 36 months, and more than 36 months.

The researchers found that the prevalence of past-year cannabis use disorder was higher for adolescents than young adults at all examined time frames since first use of the drug. For example, within 12 months since first cannabis use, 10.7% of adolescents had cannabis use disorder versus 6.4% of young adults.

Similarly, for the non-medical use of prescription drugs (opioids, stimulants, and tranquilizers), the researchers found a greater prevalence of past-year substance use disorders among adolescents than young adults at all examined time frames since first use. For example, within 12 months since first misuse of prescription drugs:

- 11.2% of adolescents had prescription opioid use disorder versus 6.9% of young adults.
- 13.9% of adolescents had prescription stimulant use disorder versus 3.9% of young adults.
- 11.2% of adolescents had prescription tranquilizer use disorder versus 4.7% of young adults.

For alcohol and tobacco, adolescents and young adults had similar prevalence of past-year substance use disorders within 12 months of initiation, but that prevalence was higher for young adults in the subsequent time periods examined.

Estimates of cocaine, methamphetamine, and heroin use among adolescents were too small to report. However, approximately one-third of young adults developed a heroin use disorder (30.9%) and one-quarter of young adults developed a methamphetamine use disorder (24.8%) within one year after trying that drug for the first time.

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The data excluded individuals who were incarcerated and individuals experiencing homelessness who are not living in shelters, possibly underestimating the prevalence of substance use disorders across the findings, authors noted.

“Research has shown that brain development continues into a person’s 20s, and that age of drug initiation is a very important risk factor for developing addiction,” said Emily B. Einstein, Ph.D., chief of NIDA’s Science Policy Branch and a co-author of the study. “This underscores the importance of drug use prevention and screening for substance use or misuse among adolescents and young adults. Offering timely treatment and support to young people who need it must be a public health priority.”

**About the National Institute on Drug Abuse (NIDA):** NIDA is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world’s research on the health aspects of drug use and addiction. The Institute carries out a large variety of programs to inform policy, improve practice, and advance addiction science. For more information about NIDA and its programs, visit <https://www.drugabuse.gov/>.

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NT

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## Moderate daily caffeine intake during pregnancy may lead to smaller birth size

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Thursday, March 25, 2021

*Smaller birth size and Caffeine may be linked.*

Pregnant women who consumed the caffeine equivalent of as little as half a cup of coffee a day on average had slightly smaller babies than pregnant women who did not consume caffeinated beverages, according to a study by researchers at the National Institutes of Health. The researchers found corresponding reductions in size and lean body mass for infants whose mothers consumed below the [200 milligrams of caffeine per day\(link is external\)](#) — about two cups of coffee — believed to increase risks to the fetus. Smaller birth size can place infants at higher risk of obesity, heart disease and diabetes later in life.

The researchers were led by Katherine L. Grantz, M.D., M.S., of the Division of Intramural Population Health Research at NIH’s *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The study appears in *JAMA Network Open*.

“Until we learn more, our results suggest it might be prudent to limit or forego caffeine-containing beverages during pregnancy,” Dr. Grantz said. “It’s also a good idea for women to consult their physicians about caffeine consumption during pregnancy.”

Previous studies have linked high caffeine consumption (more than 200 milligrams of caffeine per day) during pregnancy to infants being small for their gestational age (stage of pregnancy) or at risk for intrauterine growth restriction—being in the lowest 10th percentile for infants of the same gestational age. However, studies on moderate daily caffeine consumption (200 milligrams or less) during pregnancy have produced mixed results. Some have found similar elevated risks for low birth weight and other poor birth outcomes, while others have found no such links. The current study authors noted that many of the earlier studies did not account for other factors

that could influence infant birth size, such as variation in caffeine content of different beverages and maternal smoking during pregnancy.

For their study, the authors analyzed data on more than 2,000 racially and ethnically diverse women at 12 clinical sites who were enrolled from 8 to 13 weeks of pregnancy. The women were non-smokers and did not have any health problems before pregnancy. From weeks 10 to 13 of pregnancy, the women provided a blood sample that was later analyzed for caffeine and paraxanthine, a compound produced when caffeine is broken down in the body. The women also reported their daily consumption of caffeinated beverages (coffee, tea, soda and energy drinks) for the past week—once when they enrolled and periodically throughout their pregnancies.


Compared to infants born to women with no or minimal blood levels of caffeine, infants born to women who had the highest blood levels of caffeine at enrollment were an average of 84 grams lighter at birth (about 3 ounces), were .44 centimeters shorter (about .17 inches), and had head circumferences .28 centimeters smaller (about .11 inches).

Based on the women’s own estimates of the beverages they drank, women who consumed about 50 milligrams of caffeine a day (equivalent to a half cup of coffee) had infants 66 grams (about 2.3 ounces) lighter than infants born to non-caffeine consumers. Similarly, infants born to the caffeine consumers also had thigh circumferences .32 centimeters smaller (about .13 inches).

The researchers noted that caffeine is believed to cause blood vessels in the uterus and placenta to constrict, which could reduce the blood supply to the fetus and inhibit growth. Similarly, researchers believe caffeine could potentially disrupt fetal stress hormones, putting infants at risk for rapid weight gain after birth and for later life obesity, heart disease and diabetes.

The authors concluded that their findings suggest that even moderate caffeine consumption may be associated with decreased growth of the fetus.

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NT

## Graduates of comprehensive preschool program less likely to be obese in adulthood, NIH-funded study finds

Monday, March 22, 2021

*Such programs could lead to improvements in body mass index later in life.*

#### What

Children in high-poverty neighborhoods who participated in a comprehensive preschool program that provided parents with health and educational services and job training had a lower body mass index (BMI) in their late 30s than a similar group who participated in the usual early childhood programs, according to a study funded by the National Institutes of Health. The study authors concluded that comprehensive, school-based early childhood programs could lead to improvements in body mass index later in life. The study was conducted by Arthur J. Reynolds, Ph.D., of the University of Minnesota, and colleagues. It appears in *JAMA Pediatrics*.

Funding was provided by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

Of the study participants, nearly 700 had attended the Child-Par-

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

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

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



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ent Center preschool program, which enrolled children in high-poverty, majority Black neighborhoods in Chicago. Offering small classes and intensive instruction in school readiness skills, the program also provides parents with job and parenting skills training, educational classes, and social services. The children were provided with healthy meals and learned how to make healthy

# Keeping Your Baby Safe

during the COVID-19 pandemic

## How to protect your little one from germs and viruses

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

Here's what you can do...

### Wash Your Hands

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



### Limit Contact with Others

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



### Provide Protective Immunity

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



### Take Care of Yourself

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



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

**WARNING**

### Never Put a Mask on Your Baby

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



### If you are positive for COVID-19

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



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food choices. Compared to a similar group of more than 350 people who had not attended the program, participants showed a 3.2% reduction in BMI at 37 years of age. Women participants had a 7.5% reduction in BMI. Women also were 27% less likely to be obese compared to women who had not attended the program. The researchers found no significant differences in obesity rates among men who took part in the study, as the men in both groups had a low obesity rate.

Previous studies of the program's graduates have found that, as adults, they have higher rates of [educational attainment](#) and [household income](#) than adults of the same background who did not partake in the program.

**Who**

James A. Griffin, Ph.D., chief of the NICHD Child Development and Behavior Branch, is available for comment.

**Article**

Reynolds, AJ, et al. A comprehensive, multisystemic early childhood program and obesity at age 37 years. *JAMA Pediatrics*. 2021.

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**COVID-19**

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- Bonding with Your Baby
- Caregivers Need Care Too

# The Genetics Corner: Pathogenic variants in *DOCK6* mimic congenital viral infection in an SGA infant with VSD and intracranial calcifications

Subhadra Ramanathan, Robin D. Clark, MD

## Case Summary:

This baby girl was born to an 18-year old primigravida at 35 weeks three days' gestation by planned induction of labor for oligohydramnios and IUGR. Fetal ultrasound examination revealed a single umbilical artery and a VSD. Mother had irritable bowel syndrome with abdominal pain and vomiting during pregnancy treated with amitriptyline, omeprazole (Prilosec), ondansetron HCl (Zofran) until two months gestation. She denied teratogenic exposures. Apgar scores were 7 and 9. Birth weight 1925g (9<sup>th</sup> %ile), length 40.1 cm (<3<sup>rd</sup> %ile), head circumference 30 cm (11<sup>th</sup> %ile). The placenta was small (266 grams, < 3<sup>rd</sup> %ile) with mild decidual arteriopathy but no infarctions or significant inflammatory changes.

The initial physical exam revealed mild micrognathia, a loud 2/6 holosystolic murmur, bilateral sandal gaps between the first and second toes, and a deep groove on the plantar surface of each foot. She had a high-pitched shrill cry and unusual posturing of the extremities: wrists flexed, and hands were held above the shoulders, ankles crossed, with generalized hypertonia and clonus at the ankles.

There was a large perimembranous type VSD with a left ventricle to right atrial shunt and a persistent superior vena cava on echocardiogram. The brain MRI revealed "mildly enlarged lateral ventricular bodies and atria with periventricular subependymal foci of T1 shortening suggesting calcification and scattered subarachnoid hemorrhage versus areas cortical calcification. Findings are consistent with intrauterine TORCH infection." A dilated eye exam by the ophthalmology consultant was normal. Chromosome microarray, Zika and TORCH titers, serum PCR for Zika, and urine PCR for CMV were negative.

The family history was significant for VSD and atrial fibrillation in the paternal grandmother, paternal great grandfather, and paternal great uncle (paternal grandmother's brother). The father had ADHD and bipolar disorder.

Because of the baby's abnormal neuro exam and CNS calcifications, the initial plan to order a cardiac gene panel was changed to a whole-exome sequencing test (Baylor). This test revealed two likely pathogenic variants in *DOCK6*, the gene responsible for the autosomal recessive Adams-Oliver syndrome 2 (OMIM 614219). The infant had two variants that caused premature truncation of the gene product: a novel variant c.3737\_3738del (p.S1246Cfs\*2) and c.1987C>T (p.Q663\*).

At a return outpatient visit a four months of age, the VSD appeared to be closing spontaneously. The baby was less irritable, and her resting tone was normal without unusual posturing of the extremities. She had an area of scalp alopecia that had not been appreciated during the newborn exam. There were no digital anomalies except mild syndactyly of toes 2 and 3 and the previously noted sandal gap.

The mother provided an additional family history that the father also had an area of scalp alopecia at the vertex.

## Discussion:

This child, who was small for gestational age, had features that

suggested a congenital viral infection: a septal heart defect, an abnormal neurological examination, and intracranial calcifications. When viral titers and PCR tests were negative, whole-exome sequencing revealed two likely pathogenic variants in *DOCK6*. This gene is responsible for the autosomal recessive condition, Adams-Oliver syndrome 2 (AOS2, OMIM 614219).

Adams and Oliver described their eponymous syndrome in 1945 (AOS, OMIM 100300) as a phenotype comprised primarily of aplasia cutis congenita (ACC) and transverse terminal defects of the limbs. AOS is now considered a heterogeneous disorder with at least six responsible genes: AOS1, 3, 5, and 6 are autosomal dominant, and AOS2 and AOS4 are autosomal recessive traits.

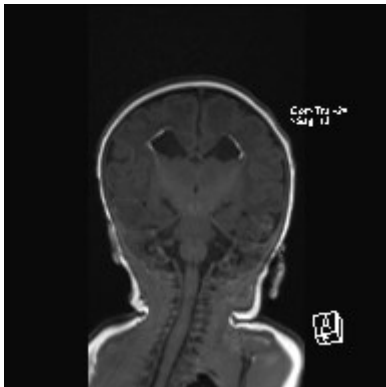
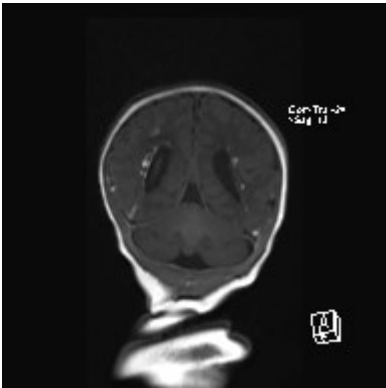
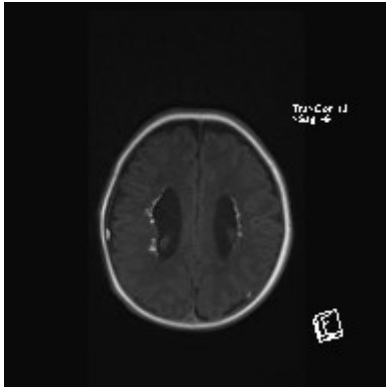
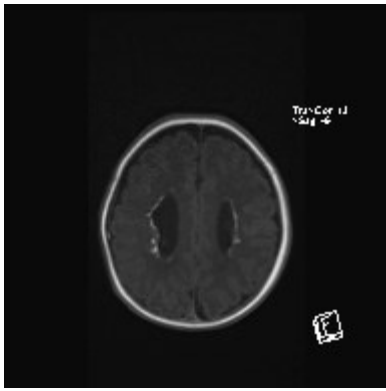
***“AOS was initially thought to be a disorder of vascular neogenesis, but evidence now points to genes that impair the actin cytoskeleton's formation.”***

AOS was initially thought to be a disorder of vascular neogenesis, but evidence now points to genes that impair the actin cytoskeleton's formation. *DOCK6*, the dedicator of cytokinesis 6 gene, encodes an atypical guanidine exchange factor (GEF) known to activate two members of the Rho GTPase family of signaling proteins: Cdc42 and Rac1. Both Cdc42 and Rac1 induce actin polymerization in the cytoskeleton. Shaheen *et al.* (2011) have shown that the *DOCK6* mRNA expression profile is consistent with the AOS2 phenotype with expression in the distal developing limb bud in the mouse. Inactivating mutations in *DOCK6* are likely to impair actin-cytoskeleton organization, but the mechanism of action responsible for alopecia, cardiac defects, and intracranial calcifications has not been elucidated.

In AOS, the ACC is usually in the midline, parietal or occipital region of the scalp. Structures underlying these skin defects (skull bones, meninges, sinus) may also be involved. The transverse terminal limb defects are typically limb truncation defects affecting the distal phalanges or entire digits (true ectrodactyly). Syndactyly, most commonly of second and third toes, can also be seen. Interestingly, this child has an uncommon and milder presentation of the limb defects associated with AOS, but not all patients with AOS have transverse limb defects (Dudoignon *et al.* 2020). To complicate matters, our patient's scalp defect was initially missed, so none of the classic features of AOS were evident that would have suggested the diagnosis.

The clinical features of AOS are highly variable and include cardio-

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vascular malformations, brain abnormalities, and vascular defects such as cutis marmorata and dilated scalp veins. Our patient is one of the about 20% of patients with AOS who have congenital heart defects, including septal defects (Snape *et al.* 2008). Dudoignon and colleagues (2020) reviewed the clinical features of 29 patients with AOS, including three with variants in *DOCK6*, and their patient nine who had intrauterine growth retardation, intracranial calcifications, and cardiac anomalies (valvulopathy) was similar to our patient.

Sukalo *et al.* (2015) described ten patients with biallelic pathogenic variants in *DOCK6* and abnormal structural brain anomalies. The most common CNS anomalies were ventriculomegaly, periventricular leukomalacia, calcifications, and hypoplasia or atrophy of the corpus callosum. They described developmental delay and seizures. Ocular findings associated with AOS2 include optic nerve hypoplasia, microphthalmia, retinal detachment. Sukalo and colleagues conclude that *DOCK6* mutations are "strongly associated with structural brain abnormalities, ocular anomalies, and intellectual disability, thus suggesting that *DOCK6*-linked disease represents a variant of AOS with a particularly poor prognosis."

Both parents should be tested specifically for these two *DOCK6* variants in order to establish the phase of the variants as *cis* or *trans*: when the phase is *cis*, both variants are inherited from the same parent, whereas *in trans*, the variants are inherited on separate chromosomes, one from each parent. Parental testing will

establish the biallelic nature of these variants in this patient and allow informed counseling regarding recurrence risks for future offspring born to these parents.

#### Practical Applications:

1. Select gene testing that is appropriate to the patient. Whole exome sequencing was the better option and more appropriate than a cardiac gene panel for this infant with a congenital cardiac anomaly who also had poor overall growth and evidence of major CNS anomalies.
2. Consider a genetic etiology for the small for gestational age infant with intracranial calcifications when congenital infections such as TORCH and Zika have been ruled out.
3. Examine each infant carefully for minor anomalies, in this case, alopecia of the scalp, which was initially missed.
  - a. Minor anomalies can define the phenotype and guide testing choices.
  - b. Had we identified the infant's scalp defect prior to ordering gene testing, we might have chosen a more focused and less costly gene panel that was specific for Adams-Oliver syndrome.
4. Examine the parents and ask for information about even seemingly minor anomalies.

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Disclosures: The authors have no relevant disclosures.

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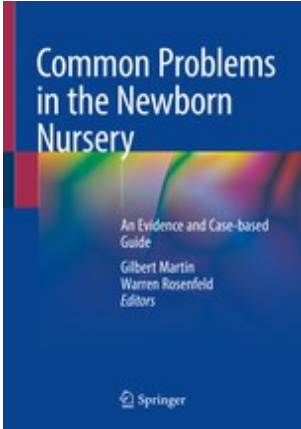
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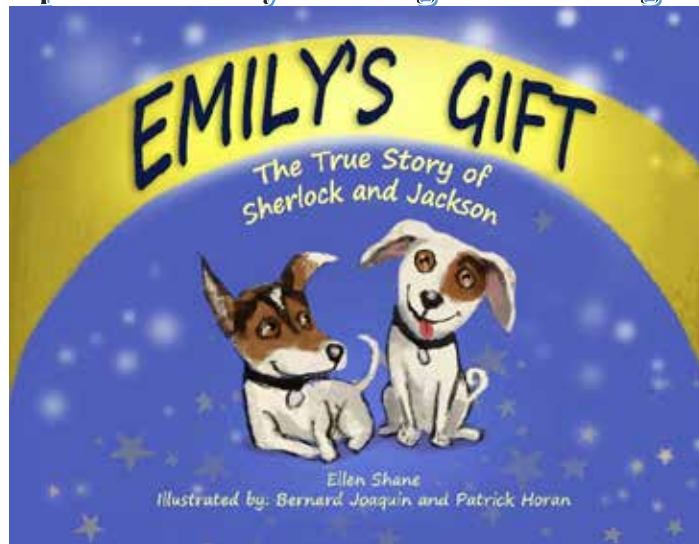
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## When Preterm Infants Struggle to Feed

Erin Sundseth Ross, Ph.D., CCC-SLP



*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.*

Working in the NICU, I have observed a wide range of challenges affecting late preterm infants. But perhaps the most concerning is difficulty eating.

Late preterm babies, born between 34 and 37 weeks gestation, may look as healthy as term babies. Yet, they lack the physical maturity and developmental skills needed for their tiny bodies to function properly. They may have underdeveloped lungs, low muscle tone, difficulty regulating their body temperature – and feeding issues.

Late preterm babies may experience similar challenges as early preterm babies. They may look bigger or healthier than fragile preemies born earlier, but these late-preterm infants are struggling too. And these feeding problems may continue after the baby goes home. Preterm babies often are not interested in eat-

ing and may avoid eating foods that are higher in nutrition, such as vegetables.

Feeding is a learned ability, not a function of the body such as breathing. Furthermore, for late preterm infants, learning the skill of feeding is critical. Only with proper feeding skills can a preterm infant continue maturing and developing. Lack of optimal nutrition, on the other hand, can lead to a downward health spiral.

Perhaps that is why feeding challenges are particularly stressful for the parents of late preterm babies. They agonize – and understandably so – about their little one's struggle. Mounting stress and concern can cause a hyper-focus on intake and food. This may lead to force-feeding, which can have adverse effects on the baby.

---

***“The babies in this study receive exclusive human milk diets. The milk is from their own mother or pasteurized donor human milk. All babies in the study also receive a human-milk-based fortifier to provide the additional calories and protein they need.”***

---

NICU staff are committed to helping infants and families facing feeding challenges. The necessary tools, however, are not always available. Educational information, **questionnaires**, specialists, and early intervention services can make a significant difference. However, these solutions are not always readily accessible or affordable.



Developmental delays are hard to identify. Many insurance providers refuse to cover the cost of feeding therapy, arguing that not enough “research” exists to justify coverage for the intervention. That is why recognizing infant feeding challenges as a critical developmental delay is so important.

Through increased awareness, research and education, and improved health plan coverage, we can bring about changes that help preterm infants master the most fundamental skills – feeding.

*Disclosure: The author has no relevant disclosures.*

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Erin Sundseth Ross, Ph.D., CCC-SLP, iF  
ounder of Feeding Fundamentals, LLC.

**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.

**OPIOIDS and NAS**

When reporting on mothers, babies, and substance use

**LANGUAGE MATTERS**



**I am not an addict.**

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



**I was exposed to opioids.**

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



**NAS is a temporary and treatable condition.**

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



**My mother may have a SUD.**

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

**My potential is limitless.**

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



Learn more about Neonatal Abstinence Syndrome at [www.nationalperinatal.org](http://www.nationalperinatal.org)



# The Premie Parent's SURVIVAL GUIDE to the NICU

By

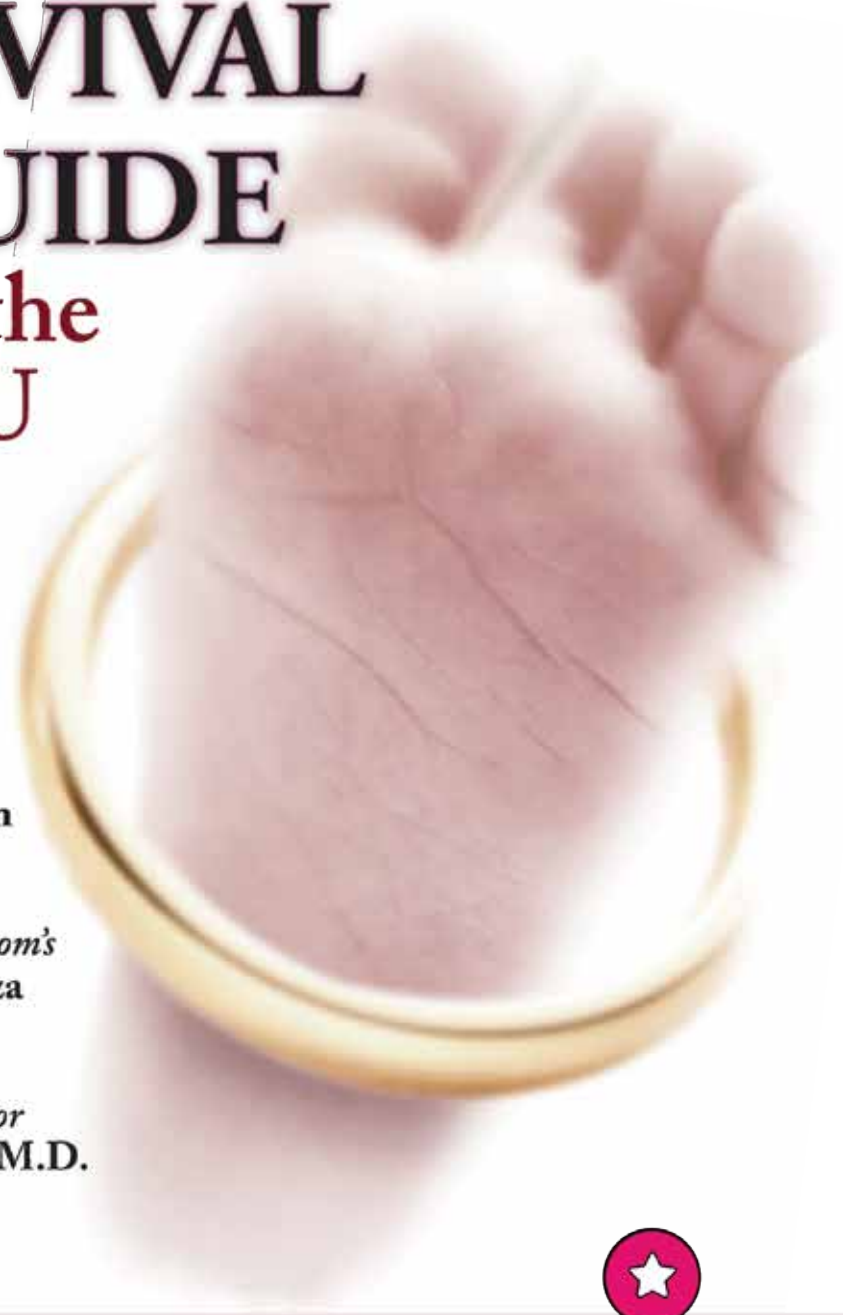
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second edition



# National Statistics

## Respiratory Syncytial Virus



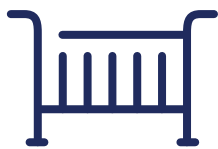
### About Respiratory Syncytial Virus

Respiratory syncytial virus, or RSV, is a contagious seasonal respiratory virus that can cause bronchiolitis and pneumonia. It is also the leading cause of hospitalization in babies less than one year old.<sup>1</sup> RSV can be deadly for premature infants and at-risk infants with congenital heart disease or chronic lung disease.

Preventive treatment called palivizumab can protect infants from RSV, but national claims data shows certain babies aren't getting access to this FDA-indicated therapy.

### National Health Plan Coverage & Access

A national data supplier provided palivizumab claims for Medicaid and commercial health plans across the nation from January 2019 through December 2019.



#### "Gap" Babies

Commercial Plans Denied

**40%**

Medicaid: **25%**

Health plans deny 40% of palivizumab prescriptions for premature infants born between 29 and 36 weeks gestation.



#### "In-Guidance" Babies

Commercial Plans Denied

**25%**

Medicaid: **14%**

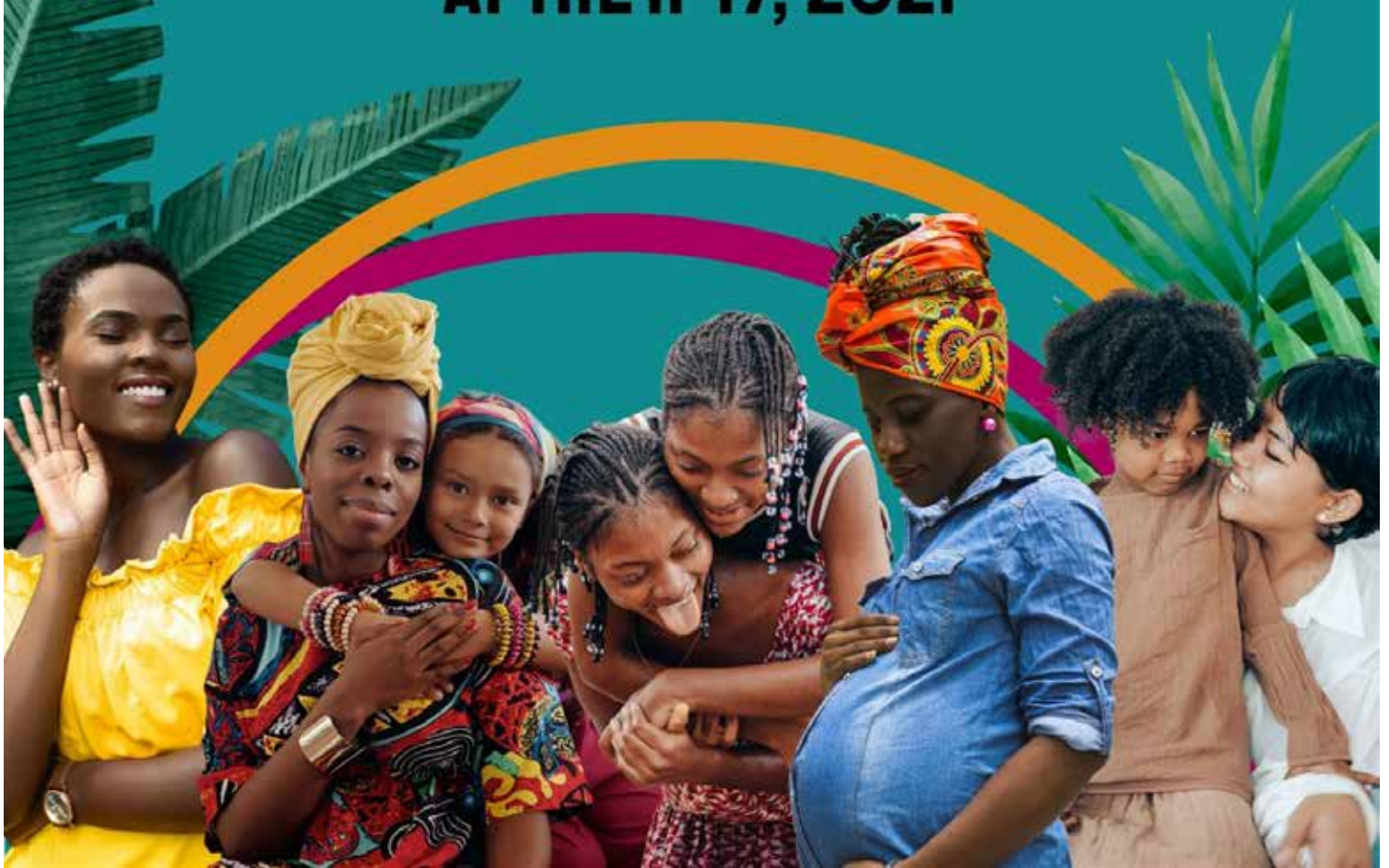
One in every four prescriptions is denied for infants who should qualify for coverage under standard insurance policies.

This includes severely premature infants born before 29 weeks gestation, babies born before 32 weeks gestation who have chronic lung disease, and babies born with congenital heart disease.

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people from  
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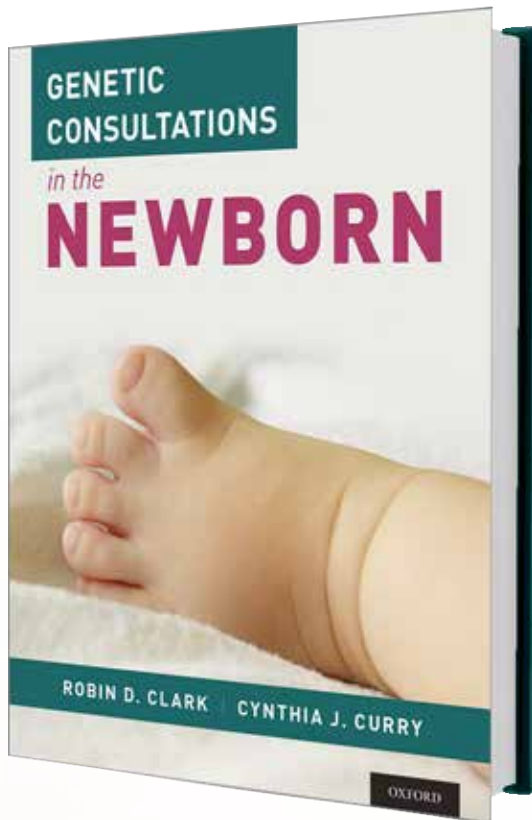
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OXFORD

# RSV AWARENESS:

## *A National Poll of Parents & Health Care Providers*

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

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

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

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

## KEY FINDINGS

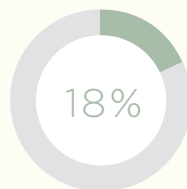
### *Preparedness*

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

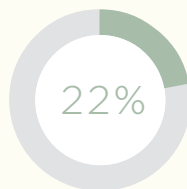
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

#### PARENTS

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

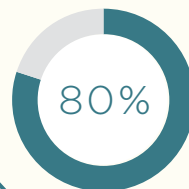


**Only 22% of parents consider themselves “very well prepared” to prevent RSV.**

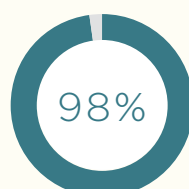


#### SPECIALTY HEALTH CARE PROVIDERS

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



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





## Clinical Pearl:

# What about Antibody Response and Transfer in Pregnant Women Who Have Had SARS-CoV-2 Infection Compared to those Receiving the Vaccine?

Joseph R. Hageman, M.D., Mitchell Goldstein, M.D.

***“Dr. Borders summarized that pregnant women who received the vaccine had comparable vaccine-related side effects compared with non-pregnant women who were vaccinated. There were no untoward effects on the fetus in this group of pregnant women who received the COVID-19 vaccine as per the American College of Gynecology Practice Advisory (1).”***

Our daughter and her family have had SARS-CoV-2 infection and have recovered. She is now 31 weeks pregnant, and it has been over 90 days since they were symptomatic. She and her husband have received the Moderna COVID-19 vaccine is being offered at a local pharmacy after she called her obstetrician, who gave her a note stating that it is safe for her to get the vaccine. She had a sore arm and some nausea, fatigue, body aches, and a mild headache after her first vaccine. After the second vaccine, she had fatigue and mild nausea intermittently for about 24 hours (personal communication, K. Jakobs, 04/13/2021). What are the data? In a recent Illinois Perinatal Quality Collaborative COVID-19 informational update coordinated by Dr. Ann Borders, Maternal-Fetal Medicine (MFM) obstetrician from the NorthShore University HealthSystem, data on over 77,960 pregnant women who received either the Pfizer or Moderna vaccine were presented from the vSafe website (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>). Dr. Borders summarized that pregnant women who received the vaccine had comparable vaccine-related side effects compared with non-pregnant women who were vaccinated. There were no untoward effects on the fetus in this group of pregnant women who received the COVID-19 vaccine as per the American College of Gynecology Practice Advisory (1). A summary of studies in animals receiving a [Moderna, Pfizer-BioNTech](#) COVID-19 vaccine before or during pregnancy found no safety concerns (2).

However, what data are available for pregnant women who have had clinical COVID-19 infection, then recover and receive the vaccine? To my knowledge, I have not seen any follow-up data re antibody responses in pregnant women who have had SARS-CoV-2 infection, recovered, and then received the COVID-19 vaccine. One small study by Saadat and colleagues followed health care workers who have had COVID-19 infection, then received the COVID-19 vaccine; 70-88% of workers were women (3). Health care workers who were previously infected with SARS-CoV-2 had higher antibody titers that started peaking at seven days post vaccine and achieved higher titers and neutralization in 14 days compared with antibody-negative volunteers (3). The workers received ei-

ther the Pfizer-BioNTech or Moderna vaccine (3).

In a study by Flannery and colleagues, maternal IgM and IgG were measured in pregnant women with SARS-CoV-2 infection. Cord blood was also collected from the newborn infants, and IgM and IgG were also assayed. Cord IgG was detected in 72 of 83 babies (87%) born to mothers who had and recovered from SARS-CoV-2 infection (5). The placental transfer ratio of maternal IgG exceeds 1.0 in this study (5). Also, in this group of mothers, 50 of 83 (60%) were clinically asymptomatic during their SARS-CoV-2 infections (5).

***“In a study by Flannery and colleagues, maternal IgM and IgG were measured in pregnant women with SARS-CoV-2 infection. Cord blood was also collected from the newborn infants, and IgM and IgG were also assayed. Cord IgG was detected in 72 of 83 babies (87%) born to mothers who had and recovered from SARS-CoV-2 infection (5).”***



Gilbert and Rudnick described a term infant born to a COVID-19 naïve mother who had received a single dose of Moderna mRNA vaccine for SARS-CoV-2 three weeks prior to delivery. Antibodies (IgG) to the S-protein of SARS-CoV-2 were detected in the cord blood from this infant (4).

---

***“The vaccine-induced immune responses were equivalent in pregnant and lactating vs. non-pregnant women (6). The responses were higher than that in pregnant women with SARS-CoV-2 infection as well (6).”***

---

Finally, in a cohort study, Gray and co-investigators measured IgG, IgA, IgM in a group of 84 pregnant, 31 lactating, and 16 non-pregnant women following Pfizer-BioNTech or Moderna mRNA vaccination and compared the titers with pregnant women with native infection (6). They also measured IgG in cord blood in 10 babies, breastmilk at baseline, second vaccine dose, 2-6 weeks post second vaccine, and delivery (6). The vaccine-induced immune responses were equivalent in pregnant and lactating vs. non-pregnant women (6). The responses were higher than that in pregnant women with SARS-CoV-2 infection as well (6).

ACOG and SMFM recommend pregnant women talk with their obstetrician and make an informed decision on whether to receive one of the vaccines. However, their recommendation is to receive the vaccine. It appears that transplacental antibody transfer (IgG) following maternal SARS-CoV-2 infection or following mRNA vaccination is significant for their infants in the studies thus far. In an editorial by Munoz, what is not clear is whether this IgG transplacental transfer is clinically protective if the newborn becomes clinically ill with SARS-CoV-2 infection (7).

---

***“Although most neonatal patients and younger pediatric patients have mild disease, as the virus mutates, the extent to which younger patients are affected or develop MIS-C may increase dramatically. Only by decreasing the spread in those eligible for vaccination can we hope to decrease the likelihood of a more virulent strain developing.”***

---

Regardless of whether the transplacental transfer is sufficient to prevent neonatal disease, the window of opportunity is perhaps closing. With different variants of SARS-CoV-2 evolving and the

specter of spike protein configuration changes decreasing the effectiveness of the present vaccination options, increasing the rate of vaccination of those at most risk now appears logical. Although most neonatal patients and younger pediatric patients have mild disease, as the virus mutates, the extent to which younger patients are affected or develop MIS-C may increase dramatically. Only by decreasing the spread in those eligible for vaccination can we hope to decrease the likelihood of a more virulent strain developing.

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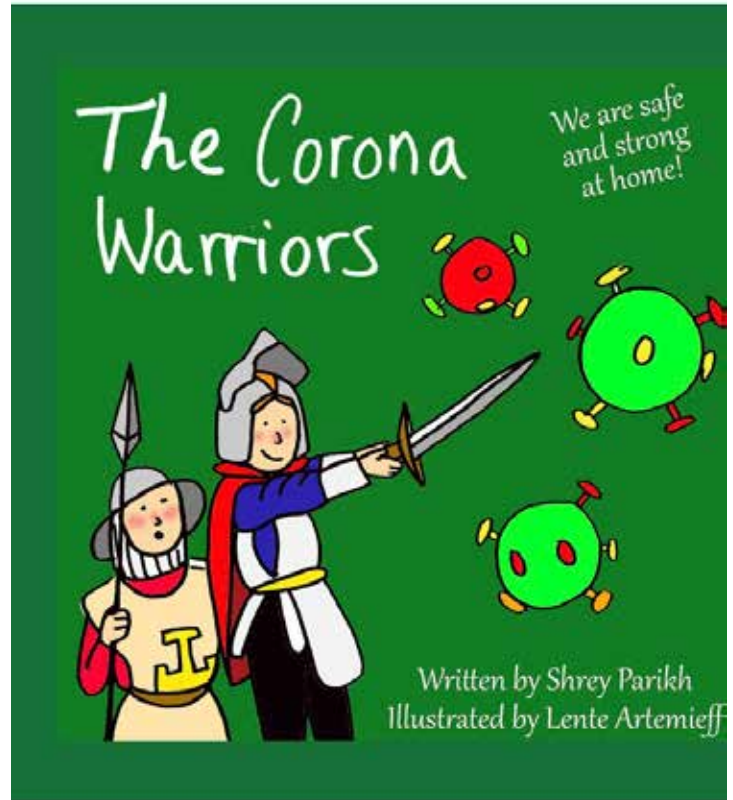
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When reporting on mothers, babies, and substance use

# 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.



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

### My potential is limitless.

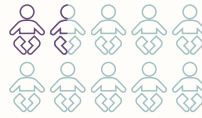
I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!



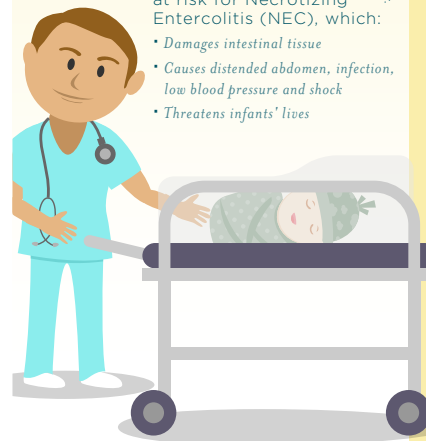
Learn more about Neonatal Abstinence Syndrome at [www.nationalperinatal.org](http://www.nationalperinatal.org)



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



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

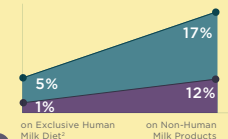


**MICRO PREMIES** are at risk for Necrotizing Enterocolitis (NEC), which:

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

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

When that happens:



30% of micro preemies needing surgery will die from NEC†

## HOW TO HELP PREVENT NEC: EXCLUSIVE HUMAN MILK DIET

What is an Exclusive Human Milk Diet?



NO cow's milk



NO sheep's milk



NO goat's milk



NO formula



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

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

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

When a micro preemie can access an EXCLUSIVE HUMAN MILK DIET:



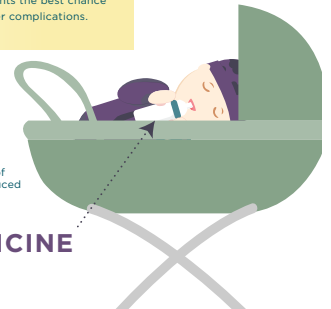
Mortality is reduced by **75%**\*



Feeding intolerance decreases\*



Chances of NEC are reduced by **77%**\*



HUMAN MILK = MEDICINE

LEARN MORE ▶

**NCFIH** National Coalition for Infant Health  
Promoting the best for Perinatal Infants through Age 100

\* Hair AB, et al. "Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet." *Breastfeeding Medicine* 2015; 10:108-116. DOI: 10.1089/bfm.2015.0124

\* Abrams SA, et al. "Greater Mortality and Morbidity in Extremely Premature Infants Fed a Diet Containing Cow Milk Protein Products." *Breastfeeding Medicine* July/August 2014; 9(6): 281-285

\* Hall SA, et al. "Mortality and management of surgical necrotizing enterocolitis in very low birth weight neonates: a prospective cohort study." *J Am Coll Surg*. 2014 Jun;218(6):1148-55.

\* Assad M, Elliott MJ and Abraham JH. "Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet." *Journal of Perinatology* advance online publication 12 November 2015; DOI: 10.1097/jp.2015.1169

# SUPPORTING KANGAROO CARE



SKIN-TO-SKIN CARE DURING  
**COVID-19**



## GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical  
team to create a plan

## GET CLEAN WASH YOUR HANDS, ARMS, and CHEST

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



## PUT ON FRESH CLOTHES

change into a clean  
gown or shirt.

## IF COVID-19 + WEAR A MASK

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



[nicuawareness.org](http://nicuawareness.org)  
[nationalperinatal.org/NICU\\_Awareness](http://nationalperinatal.org/NICU_Awareness)  
[projectsweetpeas.com](http://projectsweetpeas.com)  
[nationalperinatal.org/skin-to-skin](http://nationalperinatal.org/skin-to-skin)

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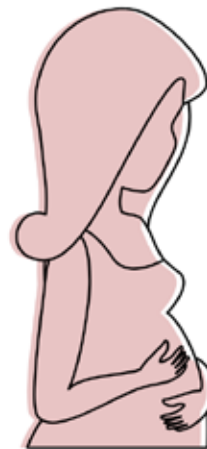
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subscription page

# 99nicu

NATIONAL PERINATAL ASSOCIATION

## Update: CORONAVIRUS COVID-19



According to data  
published in The Lancet

Pregnancy  
and the risk of  
**VERTICAL  
TRANSMISSION**

**LOW**



[www.nationalperinatal.org](http://www.nationalperinatal.org)

Time is precious, just like your patients.





## Why Pregnant and Nursing Women Need Clear Guidance on THE NET BENEFITS OF EATING FISH

**2 to 3** servings per week of properly cooked fish can provide health benefits for pregnant women and babies alike:



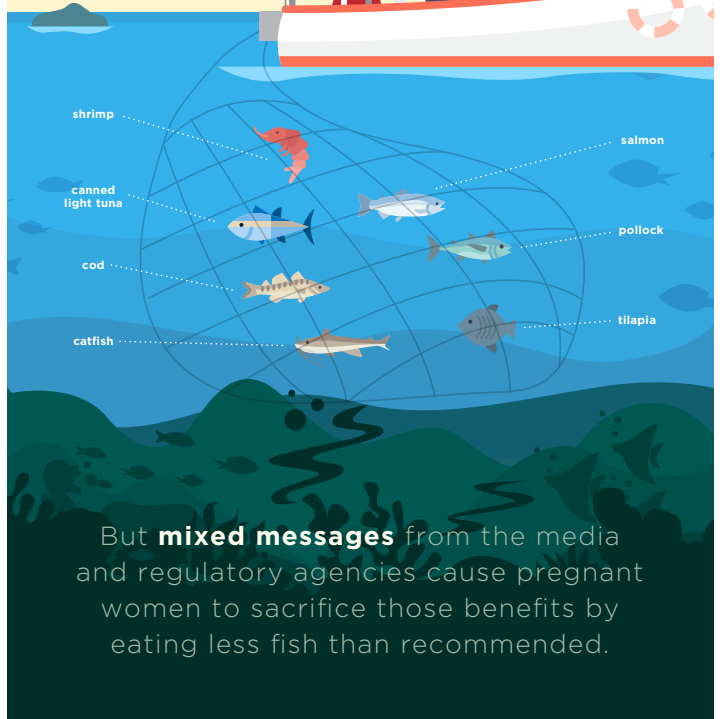
Iron



Omega 3 fatty acids



Earlier Milestones for Babies



But **mixed messages** from the media and regulatory agencies cause pregnant women to sacrifice those benefits by eating less fish than recommended.



Did you know that  
**PMAD**  
related suicides  
account for

**20%**

of Postpartum  
Maternal Deaths?

Join  **NPA**

[nationalperinatal.org/mental\\_health](http://nationalperinatal.org/mental_health)

**Support the  
Open Letter**



**Breastfeeding  
Innovations  
Team**



**GET THE FACTS**  
ON FISH CONSUMPTION  
FOR PREGNANT  
WOMEN, INFANTS,  
AND NURSING MOMS.

**NCfIH** National Coalition  
for Infant Health

Protecting Access for Premature Infants through Age Two

**LEARN MORE** ▶

## Letters to the Editor

### Pulse Oximeters Are Not Racist

As the Founder and CEO of Masimo, I co-invented the modern-day measure-through motion and low perfusion pulse oximeter (SET® Pulse Oximeter) and have spent my life in pursuit of data-based solutions throughout healthcare, most prominently in monitoring patients via pulse oximetry.

The December 17, 2020 *New England Journal of Medicine* article, “Racial Bias in Pulse Oximetry Measurement,” is correct that black patients have been a challenge for conventional pulse oximetry, resulting in the overestimation of arterial blood oxygen saturation. When I started Masimo in 1989, this is a variable we worked to address with our SET® Pulse Oximeter by making sure to have an equal number of dark-skinned and light-skinned people represented in our calibration studies. However, I do not believe that the whole picture has been painted here, leaving room for some to create an inaccurate narrative with potentially lethal consequences.

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***“When I started Masimo in 1989, this is a variable we worked to address with our SET® Pulse Oximeter by making sure to have an equal number of dark-skinned and light-skinned people represented in our calibration studies.”***

---

For context, multiple studies over the years have examined this issue and reported a bias between -1.6% to +3.9% between different brands of pulse oximeters. A 2017 study of infants with hypoxemia comparing Masimo and Medtronic pulse oximeters found an overall bias with black infants of 0.8% for Masimo devices and 3.9% for Medtronic devices.(1) The authors concluded at the time that there was “no significant difference in systematic bias based on skin pigment for either oximeter.”

Given that the University of Michigan study, published as a letter to the editor in *The New England Journal of Medicine*, had many more subjects than the previous studies, I wondered if maybe we had not noticed the bias because the sample sizes in the previous studies were smaller. Therefore, we did a further review of our internal data—which covers over 2,000 subjects with more than 1,000 dark-skinned people (more than the number of subjects in the Michigan study)—and found a 0.3% difference between the groups across an oxygen saturation range of 70-100%, and a 0.25% in the more limited pulse oximetry range the Michigan study focused on. Applying the statistical test used in the Michigan letter to our internal data, we found a difference between dark and light-skinned subjects of 1%, whereas that same test applied in the Michigan study found a 325% difference.

Although we recorded skin color for all of the subjects in our validation dataset (using the Massey-Martin pigmentation scale), most subjects did not report ethnicity. To expand our analysis, we also compared just those black and white subjects who *had* reported ethnicity—394 subjects, 200 black and 194 Caucasian, a similar ratio as in our overall dataset—and found a similar bias, 0.4%, between the two groups.

Given that our bias was so much less than that of the Michigan

study, we questioned what could be the cause of the disparity between the results presented by the University of Michigan authors and all the data we had seen in the past two decades?

We came up with several hypotheses, and here are some of them:

Sickle-cell disease is one potential confounder. The sickle-cell trait affects nearly 10% of the black population. Sickle-cell disease has been shown to cause significant errors between invasive CO-Oximeter and noninvasive pulse oximeter measurements.(2) If sickle-cell patients were not excluded in the Michigan study, that alone could account for most of the difference between what we have seen and what Michigan reported. The question is, did the Michigan study account for this?

---

***“MetHb not only causes huge errors in pulse oximetry, including biasing pulse oximetry readings but also can kill the patient if it’s not detected and treated immediately.(6) Did the Michigan study account for this?”***

---

An additional error source for pulse oximetry is the presence of high carboxyhemoglobin (COHb) and methemoglobin (MetHb) in the blood. (3, 4) The Michigan researchers briefly discussed COHb but did not discuss if they excluded patients with high MetHb. There are over 40 drugs commonly given in hospitals that unfortunately can elevate MetHb to dangerous levels. One of them, hydroxychloroquine (which has been recently used on COVID-19 patients), has been shown to elevate MetHb in black patients dramatically. (5) MetHb not only causes huge errors in pulse oximetry, including biasing pulse oximetry readings but also can kill the patient if it’s not detected and treated immediately.(6) Did the Michigan study account for this?

Another confounder could be tissue damage and poor circulation, which afflicts black people more than any other racial or ethnic group and can also negatively affect the accuracy of the pulse oximetry readings. (7, 8) So again, did the Michigan study account for this?

In addition, to speak of pulse oximeters as though they are all the same in accuracy and reliability is wrong. While the University of Michigan has been our customer for many years, and we have to assume the pulse oximeters they used in their study are ours, we are not certain that they were. It is important that researchers report the brand and version of the pulse oximeters and sensors they used. For example, the data shown in Figure 1 in the Michigan study exhibit a very large spread, which is inconsistent with many independent peer-reviewed studies of Masimo SET® pulse oximeter accuracy over the past decades.(9) These inaccuracies are usually associated with conventional pulse oximeters, or worse, the cheap knock-off finger-clip pulse oximeters that are sold at local pharmacies.

Another confounder is the unacceptably large delay between pulse oximetry readings and invasive blood sampling, during which a patient’s oxygen saturation may be changing. In our internal studies, care is taken to record pulse oximetry measurements simultaneously with invasive blood samples. The Michigan study did not have that critical control, and up to 10 minutes passed between the two measurements—even though the oxygen saturation of sick patients can change dramatically in 10 seconds.

While I do not know if these potential sources of error are the confounders that created such a large bias between black and white patients in the Michigan study, I do believe that the Michigan study should prompt further investigations, with the goal of removing systematic sources of error from the data collection to uncover any true source of pulse oximetry bias.

What these publications did is regretful:

- With very little explanation and underlying data, the Michigan authors sent in their findings.
- The *New England Journal of Medicine* published their findings seemingly without asking for the kind of data that you expect in a scientific journal.
- The *Boston Review* and the *New York Times* rushed to give the purported bias in a pulse oximeter a racist narrative.

We need to go back to our meritocracy and not let the acts of some badly behaved people change who we are. Yes, we have a race issue in our country—one that I believe we, as individual citizens, need to do everything in our power to fix. My family and I, along with our friends and colleagues, marched for Black Lives Matter. We seek opportunities to stand up for justice and peace everywhere we can. We join every other citizen who understands the brilliance of action out of kindness. When it comes to developing products and running our company, we stick with data and science done by the best people, no matter their beliefs, race, sex, or sexual orientation.

In the pursuit of science and patient safety, we will further test our hypotheses about the source of the high pulse oximetry bias on black patients in the Michigan study and will report our findings in the near future. We have been in touch with the Michigan researchers and hope to work with them as well as any other committed researchers toward helping to ensure the health and safety of ALL humankind.

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9. *Published clinical studies on Masimo SET® can be found at <http://www.masimo.com>*.

Thank you and kind regards,

Joe Kiani

Founder and CEO, Masimo

*This manuscript was originally published in the Orange County Business Journal, reprinted with permission.*

Dear Mr. Kiani

The concept that a technology as vital as pulse oximeter could be racist is beyond comprehension. Although darker skin pigmentation may present more challenges, the medical device industry is a challenging space. There are tight, at times overwhelming regulations, a requirement for superior accuracy, and a steep curve to achieve clinical relevancy. It is unusual and disruptive when a company comes to market with a technology that fundamentally changes the way clinical outcomes are measured (1).

However, such was the case in 1989, when Joe (Masi) Kiani and Mohammed (Mo) Diab set out to build a better pulse oximeter, a device that measures oxygen saturation in blood non-invasively. Both were electrical engineers who had previously worked with early models of pulse oximetry that employed conventional measurement technology to assess these values (2). In certain patients, these devices were unreliable. Where there were high motion and low perfusion, the oximeters became less reliable, leading to the inappropriate titration of oxygen and other therapeutic misadventures. Working out of Mr. Kiani's garage, Masimo came together. As opposed to working from a top-down perspective and striving for incremental improvements in standard metrics, Masimo strove to revolutionize the way oximetry was measured (2). Conventional oximetry works by measuring a "ratio of ratios," comparing the moving components of red light to nonmoving components in the numerator to the moving components of infrared light to nonmoving components in the denominator. Motion causes an additional signal to be present in both the numerator and the denominator, overwhelming oxygen saturation measurement. Poor perfusion decreases the amplitude of both the numerator and denominator to the point that the signal became hard to read. Darker pigmentation affects light absorption. Without appropriate calibration for skin coloration, improvements in a technology that read through motion and low perfusion would be limited at best. With their training in algorithms and mathematical modeling, Masimo used these technological implementations to improve upon conventional oximetry and introduce real-time modeling of physiological change.

In the early 1990s, the technology was ready for clinical testing. However, when Masimo approached clinicians, they found that many of these clinicians regarded this innovation as a technology in search of a problem. Pulse oximetry was considered a mature technology. In well adults and children, pulse oximetry worked "good enough" to provide an estimate of clinical wellbeing. By many, it was referred to as a "fair weather" friend. Not thought to be as robust or accurate as invasive blood monitoring of oxygen levels, physicians, in particular, regarded this technology as one that provided an adjunct to care (2). Working through extensive contacts, Masimo continued to approach clinicians about doing studies using this novel signal extraction technology or SET in their patients. One physician presented them with a unique challenge (3). As a trainee in Neonatal-Perinatal medicine at a local university medical center, he had seen the devastating effects of relying upon conventional pulse oximetry in these most at-risk babies. Pulse oximetry was unreliable in over 90% of these patients. Small preterm infants of every race were subject to oxygen concentrations that resulted in long-term eye problems



and even blindness (4). Some were kept on ventilators much longer because of concerns regarding whether they were getting adequate oxygen to provide growth and development. This "budding" neonatologist had called the oximeter company that provided the conventional oximetry technology to the hospital and was told, "You should be glad it works at all." The technology was not designed for monitoring small preterm babies regardless of their race and had not been validated for this use. What followed was research by this physician and others that demonstrated the importance of SET in these patients. In numerous studies, it was shown to be superior to conventional oximetry (2). Not only did the technology read through motion, low perfusion with more accuracy than thought possible but it also read through different pigmentations. Neonates are not only difficult to monitor because of their physiology but because of the changes in their pigmentation. Over the course of these initial studies, Masimo algorithms were adapted not only to skin parameters immediately after birth but also to changes that occurred over days and weeks that followed. The attention to detail was not based on what was expedient but what was right for those neonates most at risk. Indeed, the initial prototype oximeters were referred to as the "Stork."

At this point, the technology was software only. Masimo had to find medical device manufacturers in the hardware space who would install their software and use it in their installations. By not having to support a hardware base, Masimo figured that it would focus its efforts on the technological end and rely on other more established organizations to provide the distribution network.

What they found was very much different from what they had hoped for in their initial marketing efforts. Manufacturers of conventional oximetry were not interested in their technology. They took exception to the thought that the software product produced by this start-up could improve upon their offerings. They commissioned competing studies and argued that SET's technological improvements including those that addressed the issue of darker pigmentation were only applicable in special circumstances. Some signed non-disclosure agreements but then, despite initial praise of the benefits, rejected the technology as one that did not meet their specifications for various reasons. One day, one of the competing firms called Joe Kiani and offered him a million dollars for exclusive technology rights. The sum would have covered most of the corporation's increasing debt and would have potentially allowed Masimo technology to be used in subsequent products made by the competitor. Mr. Kiani vetted the proposal to several clinicians, including some of his original advocates. The competitor was trying to acquire the technology in order to "shelf" it. The investigation into the other competitors' acquired technologies demonstrated that they were not ultimately developed into products to improve patient outcomes. In situations where an existing manufacturing facility was acquired, the plant was closed within a short period of time. It was more profitable for this competitor to market using their existing patents and kill innovative technology to challenge the *status quo*. Patient outcomes were secondary to profit. Mr. Kiani turned the offer down (1, 2).

Not having a hardware base impeded further progress. Further improvements in software were technology and sensor-specific. The conventional oximeters and their Masimo had outgrown the original target. They would ultimately have to manufacture a hardware device and transition from a company that provided a software component to a medical device manufacturer. Masimo cared enough to do the right thing even when it would have been expedient to pursue a different path.

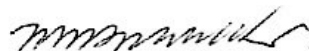
Over the intervening years, the technology received considerable attention; not only was Masimo able to demonstrate improved accuracy, precision, and outcomes in all patients, but the use

of the equipment had actually saved the life of a newborn with complex congenital heart disease (2, 5). Masimo technology could measure not only those patients who were subject to routine neonatal problems but also those at *extremis* and most at risk of disparity. Masimo did not take shortcuts, it did not develop a technology that worked only for adults or only those individuals with lighter skin. Masimo looked first at the most challenging problems in neonates before moving on to older patients. On the strengths of these metrics, Masimo rose to the challenge and monitored though motion, perfusion and disparity (1). For Masimo, Black Lives have always mattered.

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Sincerely,



Mitchell Goldstein, MD

Editor in Chief



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**Erratum (Neonatology Today March, 2021)**

Neonatology Today is not aware of any erratum affecting the March, 2021 edition.

Corrections can be sent directly to [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com). The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from [www.neonatologytoday.net](http://www.neonatologytoday.net).

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


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

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

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

\*Source: Respirator Syncytial Virus and African Americans

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



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



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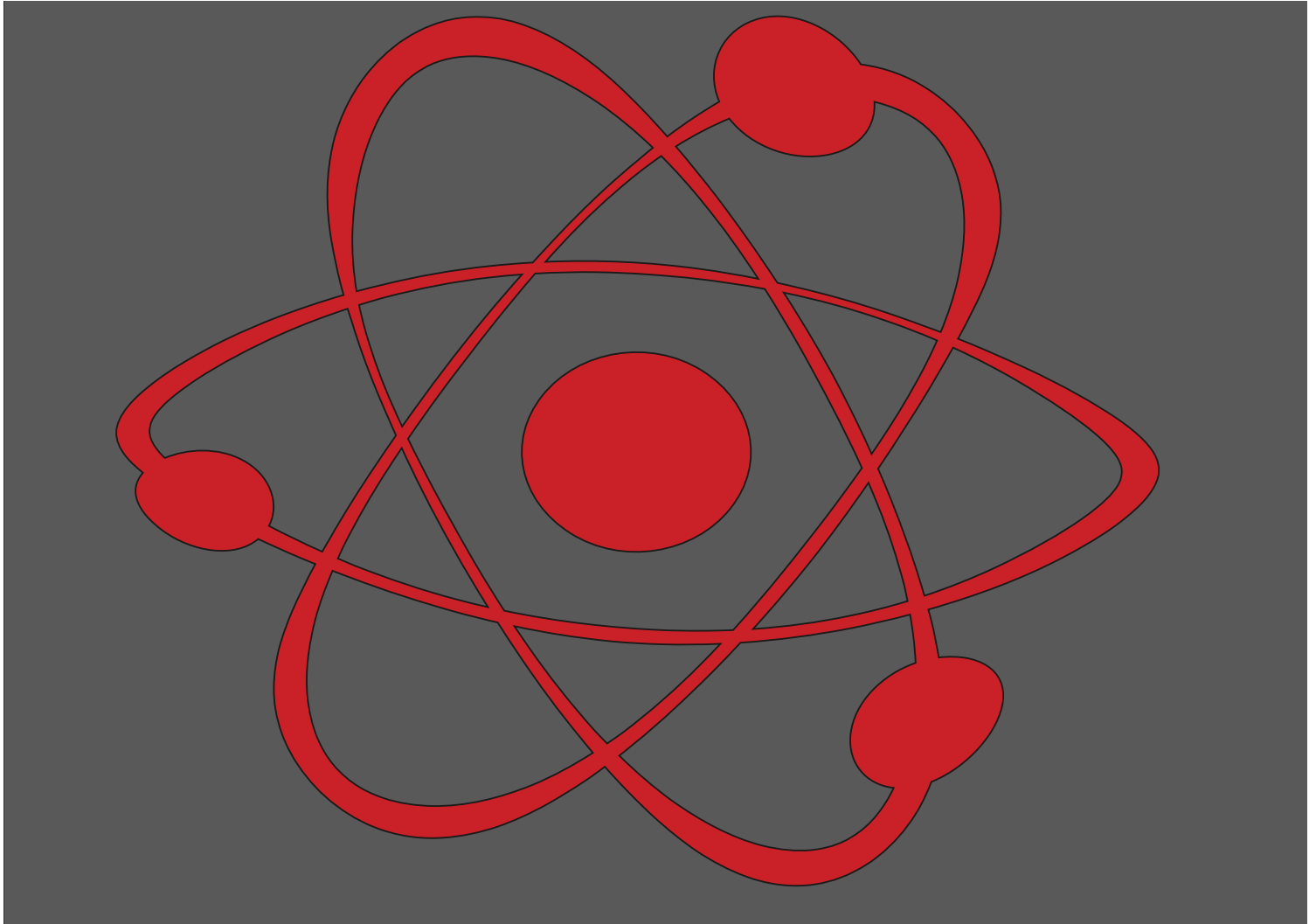
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Will your **PRETERM INFANT** need **EARLY INTERVENTION** services?

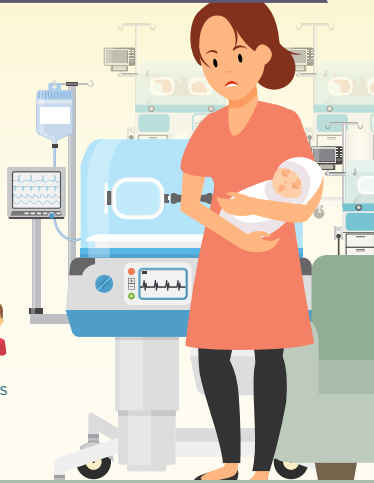
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Process social and emotional situations



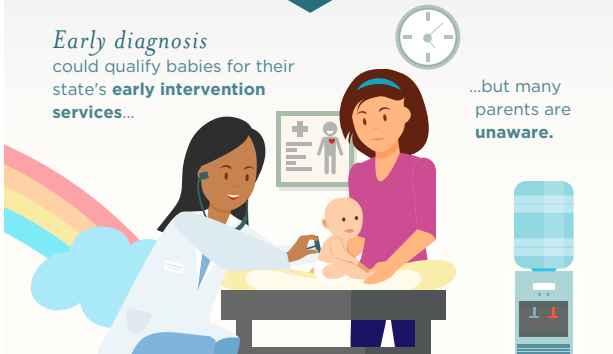
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Prevent mild difficulties from developing into major problems

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

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



**NCFIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
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Visit [CDC.gov](http://CDC.gov) to find contact information for your state's early intervention program.

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



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



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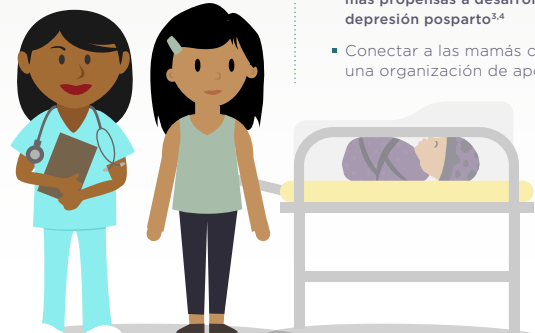
**LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:**

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



**LOS HOSPITALES PUEDEN:**

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



**NCFIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

<sup>1</sup> American Psychological Association. Accessed on: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>

<sup>2</sup> National Institute of Mental Health. Accessed on: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>

<sup>3</sup> Journal of Perinatology (2015) 35, 529–536. doi:10.1097/01.jp.0000000000.00000

<sup>4</sup> Prevalence and risk factors for postpartum depression among women with problem and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

## Upcoming Medical Meetings

Annual Neonatal and Pediatric  
Airborne Transport Conference  
May 5 - 7, 2021  
International Biomedical  
Austin, Texas  
[https://www.int-bio.com/events-  
news/airborne-conference/](https://www.int-bio.com/events-news/airborne-conference/)

Pediatric Academic Society Virtual  
Meeting  
Phase 1: April 30 - May 4, 2021  
Phase 2: May 10 - June 4, 2021  
[https://www.pas-meeting.org/  
pas2021-virtual/](https://www.pas-meeting.org/pas2021-virtual/)

22<sup>nd</sup> Annual International Perinatal  
Bereavement Conference (IPBC)  
May 12 - 15, 2021  
Pregnancy Death and Infant Loss  
Alliance (PLIDA)  
Chicago, Illinois  
<https://www.plida.org/ipbc-2021>

44<sup>th</sup> Annual Conference on Neonatal  
Perinatal Medicine  
June 17 - 21, 2021  
AAP District VIII Section on  
Neonatal-Perinatal Medicine  
<https://nm2020.district8sonpm.org/>

42<sup>nd</sup> Conference on Pediatric Health  
Care.  
Phase 1:  
March 10-13 (Orlando, FI)  
Phase 2:  
March 24-27 (Virtual)  
NAPNAP  
[https://www.napnap.org/national-  
conference/](https://www.napnap.org/national-conference/)

NEO: The Conference for  
Neonatology  
Feb 23-25, 2022  
San Diego, CA  
[www.neoconference.com](http://www.neoconference.com)

Specialty Review in Neonatology  
Feb 21-26, 2022  
San Diego, CA  
[www.specialtyreview.com](http://www.specialtyreview.com)

*For up to date Meeting  
Information, visit  
[NeonatologyToday.net](http://NeonatologyToday.net) and click  
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## NEONATOLOGY TODAY

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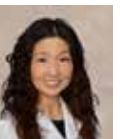
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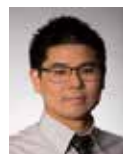


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## Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one page as well as photographs of birds on another. This month's original artwork is again provided by Paula White-man, MD, entitled "Flowers for Nico." Our Bird for this month is provided by Mita Shah, MD who provides us with "Ducks in DC."

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

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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<sup>th</sup> may also be used). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

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