

NEONATOLOGY TODAY

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Advanced Specialty Pediatric Hospitals Position Statement

August 2, 2012: Nitric Oxide Use for Pulmonary Hypertension in Preterm Neonates

Don Null, MD

This statement was originally written to the United States Food and Drug Association in 2012. Despite increasing evidence to support the effectiveness of inhaled Nitric Oxide in premature infants with physiologic pulmonary hypertension, the use of iNO in this population is not routine. Dr. Null submitted this statement on behalf of the original authors of the document, which is included in this submission, along with the letter written by F. Sessions Cole.

The following national network of board-certified Neonatologists and Pediatric Intensivists recognize the administration and charge for inhaled Nitric Oxide (iNO) in neonates less than 34 weeks gestation in the treatment of pulmonary hypertension as both medically appropriate and a community standard of care practiced by Advanced Specialty Pediatric Hospitals across the United States. Insurance company refusal to reimburse for this standard of care reflects inappropriate application of labeling by the Food and Drug Administration (FDA).

"The following national network of board-certified Neonatologists and Pediatric Intensivists recognize the administration and charge for inhaled Nitric Oxide (iNO) in neonates less than 34 weeks gestation in the treatment of pulmonary hypertension as both medically appropriate and a community standard of care practiced by Advanced Specialty Pediatric Hospitals across the United States."

Our national network supports the FDA's labeling of inhaled Nitric Oxide as inappropriate for the treatment of lung disease in infants less than 34 weeks gestational age for bronchopulmonary lung disease. However, we do support the use of Nitric Oxide in neonates less than 34 weeks gestational age with severe respiratory failure with evidence of pulmonary hypertension that have shown no improvement with ventilation strategies. Additionally, we support the use of Nitric Oxide in patients who are older ex-premature infants with severe Chronic Lung Disease (CLD) that developed secondary pulmonary

hypertension. Pulmonary hypertension is a condition in which pulmonary artery blood pressure is abnormally high; this can dramatically increase the possibility of requiring heart and lung support via extracorporeal membrane oxygenation (ECMO). Our physician experts and leaders practice under extreme real-life circumstances. They are familiar with this deteriorating condition as they follow advances in technological science, research, clinical practice, and community standards of care when making clinical judgments to treat the patient. Medicine is based upon many diverse sources, and for neonates, these sources involve very few large clinical trials. The large clinical trial used as the basis for the FDA's labeling had gestational limitations inherent in their sampling, which included patients that were 34 weeks gestation and greater. This gestation age limitation was related to criteria for ECMO since one of the major outcome variables being tested was a reduction in the need for ECMO. But the most important outcome was the recognition that iNO is an effective therapy for pulmonary hypertension, and this is the basis for treating any infant with the diagnosis of pulmonary hypertension who is not responding to routine therapy regardless of their gestational or postnatal age. Community standards of care in medical practice evolve due to the extensive period required to methodically study patient groups and obtain regulatory approval.

"But the most important outcome was the recognition that iNO is an effective therapy for pulmonary hypertension, and this is the basis for treating any infant with the diagnosis of pulmonary hypertension who is not responding to routine therapy regardless of their gestational or postnatal age."

Per a review in the Cochrane Collaborative, the U.S and international use of pulse oximetry as "a tool that guides the anesthesiologists in the daily management of patients, in teaching situations, in emergencies and especially in caring for children" is in the absence of scientific evidence supporting such perioperative monitoring. (1) Despite requiring further scientific study, community standards of care are widely accepted and regarded as an integral part of making important medical decisions.

Based upon the National Institutes of Health (NIH) Consensus and utilizing state-of-the-science statements, this practice of utilizing Nitric Oxide on premature newborns is deemed appropriate based upon clinicians' judgment. (2) In rare clinical situations, Nitric Oxide "may have benefit in

infants <34 weeks' gestation." (2) The available evidence is equivocal and, therefore, does not suggest Nitric Oxide "either increases or decreases the risk of several short-term complications of prematurity." (2) In other words, the available early evidence involved a small number of very high-risk patients at high risk for mortality who are extremely difficult to study. This is why independent panelists and public representatives participating in the NIH Consensus conclude that the use of Nitric Oxide in premature infants "should be left to clinical discretion." (2)

"In association with the Child Health Corporation of America (CHCA), a consortium of free-standing pediatric hospitals, it is our position that the use of nitric oxide in infants of less than 34 weeks gestation with pulmonary hypertension is a community standard of practice."

Per the Agency for Healthcare Research and Quality under the U.S. Department of Health and Human Services, "we should not abandon the possibility that iNO may someday become a component of a treatment strategy for some preterm infants receiving respiratory support. Several factors contribute to our recommendation to continue the study of iNO: 1) our finding of a small but statistically significant difference in death or BPD at 36 weeks PMA, the common primary outcome variable of 73% of RCT conducted to-date; 2) the statistically significant finding of a diminished need for chronic pulmonary medication at one year corrected age, suggesting less severe lung disease in those treated with iNO, and 3) no studies have been powered to detect meaningful differences in infant functional outcome or quality of life with iNO treatment compared to standard therapy." (3) Future studies into premature birth in the U.S. and internationally will assist in providing a clearer strategy for the FDA to issue labeling changes.

In association with the Child Health Corporation of America (CHCA), a consortium of free-standing pediatric hospitals, it is our position that the use of nitric oxide in infants of less than 34 weeks gestation with pulmonary hypertension is a community standard of practice. We are a community of recognized leaders in providing the highest quality and excellence in pediatric medicine. We are committed to providing safety, quality performance, education, research, and child health advocacy joined with forward-thinking, ethics, and integrity in the vision of transforming healthcare.

In summary, Nitric Oxide use in preterm neonates with pulmonary hypertension is in accordance with 2011 NIH guidelines and not addressed in the current FDA labeling due to the lack of clinical studies. Furthermore, the use of Nitric Oxide in preterm neonates is a standard of practice at

free-standing pediatric hospitals across the country. Based on this community standard of practice, we use Nitric Oxide in a medically appropriate manner.

References:

1. Pedersen, T., et al., *Pulse oximetry for perioperative monitoring*. Cochrane Database of Systematic Reviews 2009, Issue 4. Art. No.:CD002013. DOI: 10.1002/14651858.CD002013.pub2
2. "NIH Consensus Development Conference Statement: Inhaled Nitric-Oxide Therapy for Premature Infants." *Journal of the American Academy of Pediatrics* 127.2 (2011): 363- 69. Web. September 28, 2011.
3. Allen MC., et al., *Inhaled Nitric Oxide in Preterm Infants*, Evidence Report/ Technology Assessment No. 195, (Prepared by Johns Hopkins University Evidence-based Practice Center under Contract No. 290-2007-10061-I). AHRQ Publication No. 11-E001. Rockville, MD: Agency for Healthcare Research and Quality. October 2010.

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3 August 2012

Mary Daymont, R.N., M.S.N., C.C.M.
Children's National Medical Center
Executive Director of Clinical Resource Management
111 Michigan Avenue NW
Washington, DC 20010

Dear Ms. Daymont:

As the Chairman of the Consensus Conference concerning use of inhaled nitric oxide in premature infants sponsored by the National Institutes of Health (Pediatr 2011;127:363), I oversaw and participated in a 2 year process of systematic data collection, review, and discussion. The conclusions of the conference included a specific acknowledgement of potential benefit of inhaled nitric oxide for clinical situations that included pulmonary hypertension or hypoplasia in premature infants (conclusion 2). This conclusion and the data upon which it is based were discussed in depth by the Committee. The data indicate that inhaled nitric oxide may be life saving in some populations of premature infants (e.g., infants with pulmonary hypertension), establish its use as a nationally recognized standard of practice, and demonstrate that inhaled nitric oxide should not be denied to any infant based on insurance coverage. Failure of insurance companies to cover the cost of use of inhaled nitric oxide in these clinical situations is inconsistent with current evidence, national practice standards, and with the Consensus Statement conclusions.

Yours truly,

A handwritten signature in black ink, appearing to read 'F. Sessions Cole'.

F. Sessions Cole, M.D.
Chairman, NIH Consensus Conference: Inhaled Nitric Oxide Therapy for Premature Infants
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Advanced Specialty Pediatric Hospitals
Position Statement August 2, 2012

Nitric Oxide Use for Pulmonary Hypertension in Pre-Term Neonates

The following national network of board certified Neonatologists and Pediatric Intensivists recognize the administration and charge for inhaled Nitric Oxide (iNO) in neonates less than 34 weeks gestation in treatment of pulmonary hypertension as both medically appropriate and a community standard of care practiced by Advanced Specialty Pediatric Hospitals across the United States. Insurance company refusal to reimburse for this standard of care reflects inappropriate application of labeling by the Food and Drug Administration (FDA).

Our national network supports the FDA's labeling of inhaled Nitric Oxide as inappropriate for the treatment of lung disease in infants less than 34 weeks gestational age for bronchopulmonary lung disease. However, we do support the use of Nitric Oxide in neonates less than 34 weeks gestational age with severe respiratory failure with evidence of pulmonary hypertension that have shown no improvement with ventilation strategies. Additionally, we support the use of Nitric Oxide in patients who are older ex-premature infants with severe Chronic Lung Disease (CLD) that developed secondary pulmonary hypertension. Pulmonary hypertension is a condition in which pulmonary artery blood pressure is abnormally high; this can dramatically increase the possibility of requiring heart and lung support via extracorporeal membrane oxygenation (ECMO). Our physician experts and leaders practice under extreme real-life circumstance. They are familiar with this deteriorating condition as they follow advances in technological science, research, clinical practice and community standards of care when making clinical judgments to treat the patient. Medicine is based upon many diverse sources and for neonates these sources involve very few large clinical trials. The large clinical trial used as the basis for the FDA's labeling had gestational limitations inherent in their sampling which included patients that were 34 weeks gestation and greater. This gestation age limitation was related to criteria for ECMO since one of the major outcome variables being tested was reduction in the need for ECMO. But the most important outcome was the recognition that iNO is an effective therapy for pulmonary hypertension and this is the basis for treating any infant with the diagnosis of pulmonary hypertension who is not responding to routine therapy regardless of their gestational or postnatal age. Community standards of care in medical practice evolve due to the extensive period required to methodically study patient groups and obtain regulatory approval. Per a review in the Cochrane Collaborative, the U.S and international use of pulse oximetry as "a tool that guides the anesthesiologists in the daily management of patients, in teaching situations, in emergencies, and especially in caring for children" is in absence of scientific evidence supporting such perioperative monitoring [1]. Despite requiring further scientific study, community standards of care are widely accepted and regarded as an integral part of making important medical decisions.

Based upon the National Institutes of Health (NIH) Consensus and utilizing state-of-the-science statements, this practice of utilizing Nitric Oxide on premature newborns is deemed appropriate based upon clinicians' judgment [2]. In rare clinical situations, Nitric Oxide "may have benefit in infants <34 weeks' gestation" [2]. The available evidence is equivocal and therefore, does not suggest Nitric Oxide "either increases or decreases the risk of several short-term complications

of prematurity” [2]. In other words, the available early evidence involved a small number of very high risk patients at high risk for mortality who are extremely difficult to study. This is why independent panelists and public representatives participating in the NIH Consensus conclude that use of Nitric Oxide in premature infants “should be left to clinical discretion” [2].

Per the Agency for Healthcare Research and Quality under the U.S. Department of Health and Human Services, “we should not abandon the possibility that iNO may someday become a component of a treatment strategy for some preterm infants receiving respiratory support. Several factors contribute to our recommendation to continue the study of iNO: 1) our finding of a small but statistically significant difference in death or BPD at 36 weeks PMA, the common primary outcome variable of 73% of RCT conducted to-date; 2) the statistically significant finding of a diminished need for chronic pulmonary medication at one year corrected age, suggesting less severe lung disease in those treated with iNO, and 3) no studies have been powered to detect meaningful differences in infant functional outcome or quality of life with iNO treatment compared to standard therapy” [3]. Future studies into premature birth in the U.S. and internationally will assist in providing clearer strategy for the FDA to issue labeling changes.

In association with the Child Health Corporation of America (CHCA), a consortium of free standing pediatric hospitals, it is our position that the use of nitric oxide in infants of less than 34 weeks gestation with pulmonary hypertension is a community standard of practice. We are a community of recognized leaders in providing the highest quality and excellence in pediatric medicine. We are committed to providing safety, quality performance, education, research and child health advocacy conjoined with forward-thinking, ethics and integrity in the vision of transforming healthcare.

In summary, Nitric Oxide use in preterm neonates with pulmonary hypertension is in accordance with 2011 NIH guidelines and not addressed in the current FDA labeling due to the lack of clinical studies. Furthermore the use of Nitric Oxide in preterm neonates is a standard of practice at free standing pediatric hospitals across the country. Based on this community standard of practice, we use Nitric Oxide in a medically appropriate manner.

1. Pedersen, T., et al., *Pulse oximetry for perioperative monitoring*. Cochrane Database of Systematic Reviews 2009, Issue 4. Art. No.:CD002013. DOI: 10.1002/14651858.CD002013.pub2
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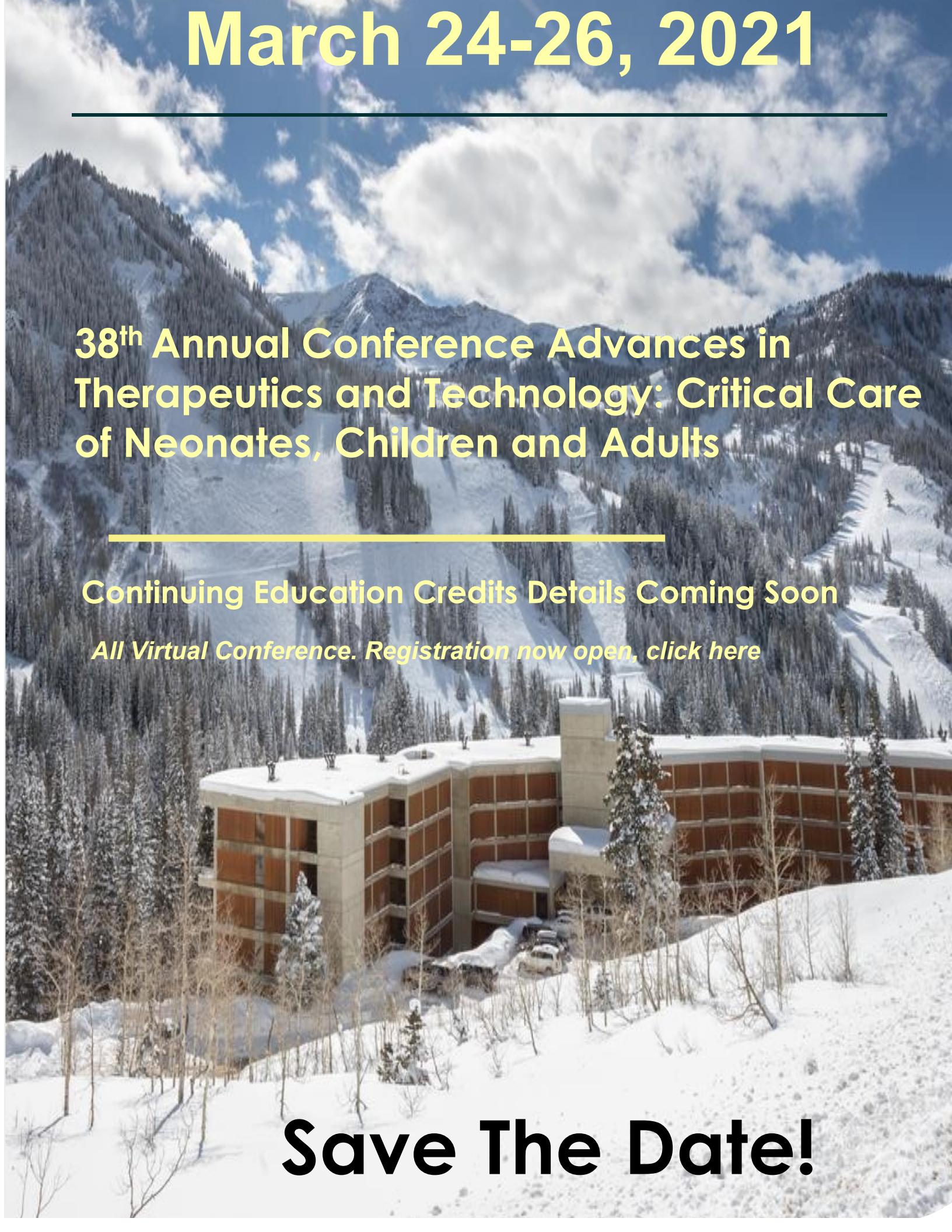
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Apnea in Term and Late Preterm Neonates Born to Coronavirus Infected Mothers

Jaimin Patel, MD, MSMI. Jagdish Desai, MD, MPH, Renjith-kumar Kalikkot Thekkeveedu, MD, Tasha N. Coleman, MD, Nilesh Dankhara, MBBS, Alisia C. Hankins, DNP, NNP-BC Mabolaji E. Famuyide, MD

Abstract:

We report three otherwise healthy neonates born to Coronavirus Disease-19 (COVID-19) positive mothers who developed apnea during birth admission but tested negative for COVID-19. We postulate that the apnea may be due to transplacental transmission of inflammatory cytokines. We strongly advise against early discharge in babies born to mothers with active COVID-19 infection.

Established Facts and Novel Insights:

Established Facts:

1. Limited data is available regarding the clinical presentation of infants born to COVID-19 positive mothers.
2. There is a paucity of data on false-negative rates of the COVID-19 RT-RNA PCR test in neonates.
3. There is no proven vertical transmission of COVID-19 infection to newborns. Inconsistent evidence exists regarding the Coronavirus's presence in amniotic fluid, placenta, umbilical cord blood, and breast milk samples.

Novel Insights:

1. Infants born to COVID-19 positive mothers may present with apnea despite testing negative for COVID-19. Close monitoring is needed.
2. There could be a cytokine storm released during maternal COVID-19 illness responsible for apnea, in the absence of viral transmission. Further studies are required to prove this hypothesis.

Keywords: Apnea; Neonate; COVID-19; Coronavirus; transmission; perinatal; cytokines

Abbreviations: BE=Base Excess, WBC=White blood cell, CRP=C-reactive protein, C-section=Cesarean section, SVD=Spontaneous vaginal delivery, CT=computed tomography, DOL=Day of life, NICU=Neonatal intensive care unit.

Introduction:

COVID-19 syndrome in pregnancy is often reported as mild to moderate in severity. (1, 2) The clinical presentation of COVID-19 syndrome in pregnancy is similar to that seen in non-pregnant adults. Coronavirus infection in pregnancy is associated with hospitalization and increased risk for intensive care unit admission and receipt of mechanical ventilation(3). Questions surrounding

perinatal care of mother and baby, such as clinical features in neonates, mode of transmission, particularly vertical transmission, delivery room care and isolation and timing of removal from isolation, and transmission through breast milk are still under scrutiny, and answers are evolving as more evidence is emerging. (4)

Variable clinical presentation of babies with a positive viral test for the COVID-19 infection is reported in the literature. (5-7) Most neonates born to mothers with COVID-19 infection are asymptomatic or only have mild symptoms. Lu et al. have reported fever, cough, and fatigue as the most common symptoms in neonates and children. (5) Nasal congestion, tachypnea, and reduced feeding have also been reported. (6) Respiratory symptoms may range from mild hypoxemia requiring oxygen therapy to respiratory failure requiring ventilatory support in neonates. Some patients may develop pneumonia, acute respiratory syndrome, and pneumothorax. (6)

"In our case series, we report a series of term and a late preterm neonate born to COVID-19 infected mothers who presented with apnea, bradycardia, and desaturation episodes during birth hospital admission."

Apnea is common in preterm infants; however, it is a rare clinical event in full-term infants, occurring at a rate of one per 1000. (8) Although the pathophysiology is not completely understood, intrauterine or perinatal inflammation may be an important factor. Pro-inflammatory cytokines, such as interleukin-1b (IL-1b), have been reported as triggers for central apnea and problems with respiratory control. (9) Common considerations when a full-term neonate presents with apnea in the delivery room or neonatal period include perinatal injury from hypoxia and ischemia, inflammation secondary to pneumonia or early-onset sepsis, central nervous system abnormalities including trauma, intracranial hemorrhage or seizures, and intrapartum maternal drug (e.g., narcotic or magnesium or general anesthesia) administration. (9)

In our case series, we report a series of term and a late preterm neonate born to COVID-19 infected mothers who presented with apnea, bradycardia, and desaturation episodes during birth hospital admission.

Case Report/Case Presentation

We describe the clinical presentation of three neonates born to

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COVID-19 positive mothers who became symptomatic during observation in-hospital after birth. The management of infants born to COVID-19 positive mothers in our institution is based on guidance from the American Academy of Pediatrics (AAP). Twenty-two mothers were admitted with COVID-19 positive status at the time of delivery from March 2020 to June 2020. Three (13.6%) of the 22 infants born to these mothers developed apnea of undetermined etiology during admission. Written informed consent was obtained from guardians regarding sharing information for scientific or teaching purposes, including research.

"Twenty-two mothers were admitted with COVID-19 positive status at the time of delivery from March 2020 to June 2020. Three (13.6%) of the 22 infants born to these mothers developed apnea of undetermined etiology during admission."

Neonate 1 was born to a 22-year-old Gravida 3, Term 2, Preterm 1, Abortion 0, Living 3 (G3P2I03) mother at 40 weeks of gestation via C-Section and presented with apnea at 26 hours of age. Neonate 2 was born to a 17-year-old G2P0010 mother at 35 weeks 6 days of gestation via C-Section and presented with apnea at 19 hours of age. Neonate 3 was born to a 28-year-old G2P2002 mother at 40 weeks of gestation via vaginal delivery and presented with apnea at 65 hours of age. All babies were discharged home spontaneously breathing in Room Air (RA). Table 1 provides a comprehensive description of the three dyads.

"Even in the absence of vertical transmission of the virus, the maternal illness may have detrimental effects on the fetus/neonate."

Discussion/Conclusion:

Clinical features in neonates born to mothers with COVID-19 infection vary. We present three neonates born at term/late preterm gestational age, who tested negative for Coronavirus via real-time polymerase chain reaction (RT-PCR), yet presented with apnea-

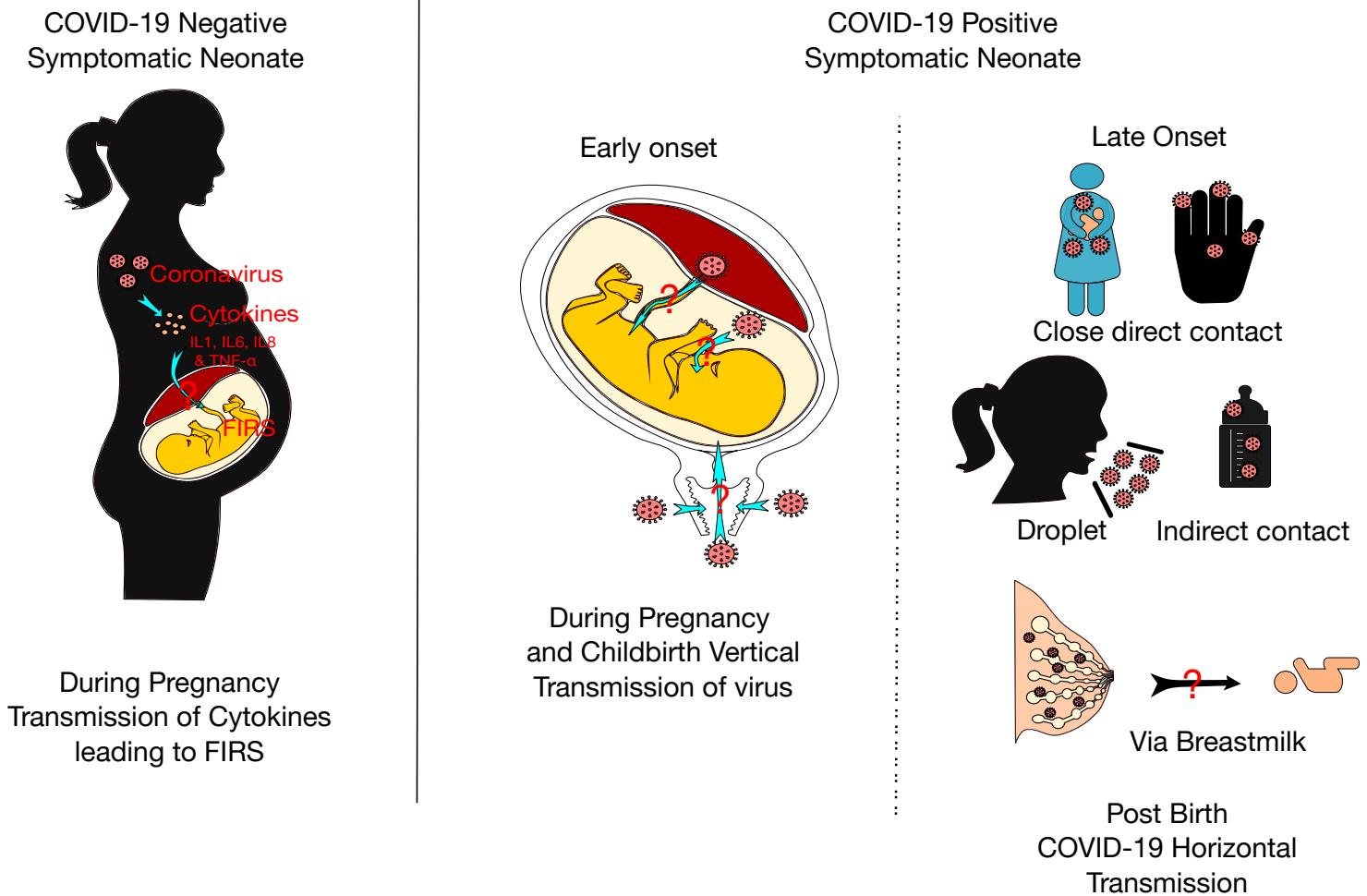


Figure 1: Symptomatic neonates born to mother with COVID-19 – possible pathophysiology and transmission modes.

Table 1: Maternal Characteristics

	Maternal Characteristics		
	Mother 1	Mother 2	Mother 3
Maternal age	22 year old	17 year old	28 year old
Pertinent History	G3P2103, shoulder dystocia in G1, history of preeclampsia	G2P0010, iron deficiency anemia, limited prenatal care	G2P2002, limited prenatal care
Symptoms and Mode of Diagnosis	Asymptomatic; Diagnosed by routine postpartum PCR*	Presented with fever, cough, shortness of breath; Diagnosed by PCR*	Fever noted postpartum; Diagnosed by PCR*
Time of Diagnosis in Relation to Delivery	1 day postpartum	1 day before delivery	Few hours postpartum
Race/Ethnicity	African American/Non-Hispanic	African American/Non-Hispanic	Other/Hispanic
Maternal Labs	WBC 7.1 on day of positive COVID-19 test, no differential or CRP available	WBC 6.5 on day of positive COVID-19 test Lymphocytes 10.5% on the day of COVID-19 positive test CRP 3.7/5.9 24 and 48 hours following positive COVID-19 test	WBC 4.6 on day of positive COVID-19 test Lymphocytes 10.3% and 9.5% on the day of COVID-19 positive test No CRP available
Placental Pathology	Not done	Yes; heavy mature placenta, laminar necrosis of membranes, increased villous fibrin deposition	Not done

Table 1: Clinical presentation of three neonates born to COVID-19 positive mothers. Footnote: *PCR= SARS-CoV-2 RNA RT-PCR

**Infant COVID-19 testing all by nasopharyngeal SARS-CoV-2 RNA RT-PCR

bradycardia-desaturation episodes, which are uncommon in this gestational age group. We hypothesize that this is due to the transplacental transfer of inflammatory cytokines from the mother to the baby.

The clinical presentation of symptomatic infants born to COVID-19 positive mothers can be broadly classified into three possible theoretical scenarios: (i) neonates who test negative for COVID-19 but are symptomatic possibly due to fetal inflammatory response syndrome from maternal inflammation and transplacental transfer of cytokines (ii) neonates who test positive immediately after birth (early-onset infection) due to possible vertical transmission (iii) neonates who test positive after discharged home and thus presented late (late-onset infection), due to possible horizontal transmission from infected caregivers (Figure 1).

The American Academy of Pediatrics Section on Neonatal-Perinatal Medicine (AAP SONPM) National Registry of Perinatal COVID-19 Infection (NPC-19) describes the majority of the reported deliveries as occurring vaginally (60%) at term or late preterm gestations with a median GA of 39 weeks (range of 15-45 weeks) to White (35%)/Non-Hispanic (50.3%) mothers. (10) At our center, deliveries for COVID-19 positive mothers have occurred mostly vaginally (58%) at term or late preterm gestations with a median GA of 39 weeks (range of 26-41 weeks) to predominantly Hispanic mothers (55%). Common symptoms reported in mothers were fever, cough, malaise/weakness, myalgia, dyspnea, sore throat,

diarrhea, and chest pain. (11-15) Laboratory features commonly reported include lymphocytopenia and elevated inflammatory markers such as CRP(16-18), abnormal LFT(19), and imaging findings consistent with pneumonia. (17, 19, 20) Severely affected patients may develop abnormalities of liver enzymes, acute renal failure, and coagulopathy-disseminated intravascular coagulation (DIC). (21, 22)

The consequences of COVID-19 infection early in pregnancy are largely unknown at this time. (23) Transmission of COVID-19 disease to the baby can occur intrauterine or during the peripartum and/or postpartum period. However, the chances of intrauterine infection remain low. (20, 23, 24) Placental changes like fibrin deposition and malperfusion have been reported(25), and there is evidence of Coronavirus being present and invading syncytiotrophoblast in the human placenta;(26, 27) although, the neonate in the same pregnancy tested negative for COVID-19. Multiple case reports suggest that viral tests for COVID-19 are negative in amniotic fluid and umbilical cord. (17, 23, 28) Several authors have also suggested that vertical transmission in utero is rare or did not occur (7, 11, 29, 30); however, in some cases, vertical transmission is suggested. (31) Dong et al. reported a case where a neonate born to a COVID-19 positive mother had elevated IgM antibodies at 2 hours. IgM antibodies are not transmitted to the fetus via the placenta, and hence its presence may suggest vertical transmission. (31) This infant also had elevated cytokines and AST, although repeated RT-PCR tests on nasopharyngeal swabs

Table 2: Infant Characteristics

Delivery Information			
	Infant 1	Infant 2	Infant 3
Gender	Female	Female	Male
Gestational age (GA)	40 weeks 0 days	35 weeks 6 days	40 weeks 1 day
Birthweight	2920 grams	2450 grams	3070 grams
Mode of delivery	C-Section	C-Section	SVD
Resuscitation Required at Delivery	None	Oral suctioning and CPAP	None
APGARs (at 1 and 5 minutes respectively)	8/9	8/9	8/9
Cord Blood Gas (pH/PCO ₂ /PaO ₂ /HCO ₃ /BE)	7.21/77/19/30.8/1	Not done	Not done
Duration of Maternal Exposure	26 hours	0 hours	12 hours
Infant's Clinical Presentation			
Age at Onset of Symptoms	29 hours	19 hours	65 hours
Infant Signs and Symptoms	Apnea and desaturations	Apnea and desaturations	Apnea and emesis
Highest Respiratory Support	2 Liters high flow nasal cannula	Continuous positive airway pressure at 5 cm H ₂ O	Continuous positive airway pressure at 5 cm H ₂ O
Pertinent diagnostics	Normal CT head Labs unremarkable	Normal chest x-ray and head ultrasound Labs unremarkable	Normal chest x-ray and head ultrasound Labs unremarkable
Timing of COVID-19 Testing**	DOL 1, 2, and 7	DOL 1, 2, 6, and 7	DOL 1,2, and 3
Testing Results	Negative	Negative	Negative
Days in NICU	9	11	7
Age at time of Discharge	10 days	13 days	9 days

remained negative. Zamaniyan et al. have also reported vertical transmission(32) in a neonate born to a COVID-19 positive mother. The amniotic fluid was positive for COVID-19, and this neonate developed a fever at birth. Although the infant's first nasopharyngeal and throat PCR tests, which were done at delivery, were negative, the second test done 24 hours later was positive, as were the third and fourth PCR tests done a week later.

Even in the absence of vertical transmission of the virus, the maternal illness may have detrimental effects on the fetus/neonate. Zhao et al. described a clinical entity called fetal inflammatory response syndrome (FIRS) from maternal COVID-19 infection in the absence of placenta infection with the virus. (33) The mother's immune response to infection promotes the fetal inflammatory response characterized by high levels of inflammatory cytokines in the placenta, such as IL-1, IL-6, IL-8, and TNF- α , even while negative for culture/PCR for microorganisms. These cytokines have

been shown to affect the central nervous system and circulatory system and tend to cause abnormal fetal morphology in animal models, including ventricular expansion and bleeding. (34-37) Similar inflammatory responses from other infections have been suggested to lead to long term neurodevelopmental and psychological abnormalities. (38) Therefore, proactive management of the cytokine storm in mothers with COVID-19 infection could mitigate its negative impact on fetal development.

Most of the babies delivered in our institution at \geq 35 weeks GA were asymptomatic throughout hospitalization (87%), a number comparable to data from the NPC-19 registry (84%)(10). Common symptoms reported in neonates born to COVID-19 positive mothers are respiratory distress (13-14%) (10, 39), fever (1-2%) (10, 24, 39), tachycardia (39), hypotonia, radiological findings of pneumonia (40), thrombocytopenia (39, 41), lymphocytopenia(40, 41) (24), disseminated intravascular coagulation (DIC) (39, 41), refus-

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al of feeding and feeding intolerance (39), vomiting (39), gastric bleeding(39), necrotizing enterocolitis, jejunal perforations (41), abnormal liver functions (39, 40), refractory shock(39). Chen et al. also reported elevated myocardial enzymes in a baby.(20) All these babies tested negative for the virus with RT PCR. Hence, it is difficult to attribute these symptoms solely to the viral infection. Apnea has not been separately reported in either the AAP registry or any other case series. There is a possibility that it might have been included with other respiratory symptoms and hence true incidence apnea is unknown in late preterm born to COVID-19 positive mothers is unknown.

There is a wide variation in neonatal testing suggested. This varies from nasopharyngeal, oropharyngeal, and rectal swabs at 24 to 48 hrs after birth (six swabs) on one end of the spectrum to no testing if asymptomatic on the other. (29) At our institution, we routinely test all neonates born to COVID-19 infected mothers 24 and 48 hours after birth. There is good data on the test's accuracy, but there is no data on the validity of the technique or timing of testing in neonates. Due to sample collection difficulty in neonates (strong gag reflex, small nasal passage, fear of going too far in the nasopharyngeal area) and possibly inadequate training, there is a high possibility of a high false-negative rate. The best time for sample collection after birth to detect vertical transmission remains controversial.(42) Early testing might be falsely negative due to a low viral load. All of the neonates in this series tested negative for SARS-CoV-2 at least three times; however, they were not tested for IgM and IgG for COVID-19. Apnea in these infants may also be associated with rhinovirus and other respiratory viruses, such as Respiratory Syncytial virus, metapneumovirus etc.; these were not tested in either mother or neonates as our focus was only on COVID-19 infection.

The NPC-19 Registry reports that 30% of infants born to a COVID-19 positive mother required some type of respiratory support at delivery. (10) The majority of the infants in this registry roomed in with the mother (50%), while 29% were admitted to a NICU and 21% monitored in the nursery. Fifty-eight percent of these infants were placed on contact/droplet/airborne isolation in a negative pressure room. (10) At the time of this report, our center separated all infants born to a COVID-19 positive mother and monitored in a negative pressure isolation room until two COVID-19 RT PCR tests from nasopharyngeal swabs obtained at 24 hours and 48 hours were negative and the infant cleared by infectious disease specialists. However, there is significant variability across the country regarding the location of care (separation versus rooming-in with mother) for term/late preterm asymptomatic neonates. The median hospital stay for term neonates in our institution was four days (range 4-11 days), similar to the NPC-19 registry mean hospital stay of 4.88 days (range of 0-80 days).(10) These practices are in line with the AAP interim guidance, which discourages early discharge and recommends that newborn discharge should be based on each center's usual criteria. (43, 44)

To date, apnea has not been reported in babies born to mothers with COVID-19 in term or late preterm infants. Apnea of prematurity is a commonly seen symptom in premature neonates, and apnea typically does not occur in full-term and near-term neonates. In our case series, we report apnea-bradycardia-desaturation episodes in near term /late preterm neonates born to mothers with COVID-19 infection. The AAP interim guidance discourages early discharge, which is traditionally defined as <48 h following

a vaginal birth and <96 h following cesarean delivery. This guidance recommends that newborn discharge should be based on each center's usual criteria. (43) These neonates presented with apnea between 19-65 hours after birth, which falls within the time frame for in-hospital newborn monitoring in the majority of newborn practices across the United States, depending on the route of delivery.

Due to the variability in the presentation of clinical features related to the fetal response to maternal inflammation from COVID-19 infection, we recommend closer monitoring, even when rooming-in, following birth admission, and strongly caution against early discharge. Further studies are needed to confirm the hypothesis of maternal cytokine storm during maternal illness as the cause of apnea in the absence of viral transmission.

"Apnea has not been separately reported in either the AAP registry or any other case series. There is a possibility that it might have been included with other respiratory symptoms and hence true incidence apnea is unknown in late preterm born to COVID-19 positive mothers is unknown."

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JP prepared figure 1 and wrote the first draft of the introduction and the discussion. RK contributed significantly to the discussion. TC, ND and AH collected data from patient charts. The table was prepared from that and revised multiple times based on feedback from other authors. JD coordinated task assignments and prepared Established Facts and Novel insights. MF contributed by revising all sections of manuscripts, contributed knowledge of national-level developments and registries. The final manuscript was prepared and circulated for approval by all authors before submission.

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Lily J. Lou, MD, FAAP

Dear All,

I hope you are all finding joy with those you love between all your hard-working hours as 2020 nears its end. How timely that the first COVID-19 vaccine is a gift to us in the holiday season.

The Advisory Committee on Immunization Practices (ACIP) met on Friday and Saturday (December 11th & 12th) to discuss and develop guidance on the Pfizer-BioNTech COVID-19 vaccine, the first COVID-19 vaccine to attain Emergency Use Authorization (EUA)—issued on December 10th.

Things continue to move rapidly, but here are a few key points about this first offering:

- ACIP voted to approve use in patients **16 years of age or older**.
- This is an **mRNA vaccine** (see box for descriptions of types).
- This vaccine requires **two doses**, 21 days apart. Immunity is estimated to be 52% after the first dose and 95% after the second dose. There is no data supporting the effectiveness if the second dose is with a different COVID vaccine, so the same manufacturer should be used to complete the series.
- **Prioritization** of vaccine access is a hot topic of discussion. Health care workers will receive the vaccine first, as will residents of long-term care facilities. Other 'essential' workers will follow.
- The issue of **pregnant and lactating mothers** is not settled
- Acetaminophen is recommended after vaccination in pregnant women to minimize risks to the fetus from significant fever. (This is different from the typical recommendation to avoid routine Tylenol with childhood immunization unless symptoms develop, as it may suppress the immune response and thus the effectiveness of the vaccine.)

For neonatologists, the last point is very important. Pregnant women are recognized to be at increased risk of death or serious disease with COVID-19, but they have not been included in vaccine trials. Some women have become pregnant during their trial participation, but this data is not yet released. The DART (developmental and reproductive toxicity) studies are slated to be released in late December. Pfizer stated that preliminary data showed no evidence of toxicity. Based on what we know about other coronavirus vaccine studies, "the overall complete consensus was that we don't see biological plausibility at this time for placental transfer of the mRNA and that we see that direct fetal exposure or the possibility of fetal inflammatory response is extremely unlikely," said Eckert, professor of obstetrics and gynecology at the UW-Seattle, and the ACOG representative to ACIP. "Clearly, we are waiting on the data."

Currently, there are three main types of COVID-19 vaccines under development. Here is a description from the CDC. A fourth type—inactivated virus—is not one of the front-runners at this point.

- **mRNA vaccines** contain material from the virus that causes COVID-19 that gives our cells instructions for how to make a harmless protein that is unique to the virus. After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies recognize that the protein should not be there and build T-lymphocytes and B-lymphocytes that will remember how to fight the virus that causes COVID-19 if we are infected in the future.
- **Protein subunit vaccines** include harmless pieces (proteins) of the virus that cause COVID-19 instead of the entire germ. Once vaccinated, our immune system recognizes that the proteins don't belong in the body and begins making T-lymphocytes and antibodies. If we are ever infected in the future, memory cells will recognize and fight the virus.
- **Vector vaccines** contain a weakened version of a live virus—a different virus than the one that causes COVID-19—that has genetic material from the virus that causes COVID-19 inserted in it (this is called a viral vector). Once the viral vector is inside our cells, the genetic material gives cells instructions to make a protein that is unique to the virus that causes COVID-19. Using these instructions, our cells make copies of the protein. This prompts our bodies to build T-lymphocytes and B-lymphocytes that will remember how to fight that virus if we are infected in the future.

Regarding breastfeeding mothers, a recent article (<https://pubmed.ncbi.nlm.nih.gov/32822495/>) showed a lack of transmission of the SARS-CoV-2 virus in breastmilk; however, other studies have demonstrated the presence of IgA against the virus. There is no data available yet regarding the transmission of vaccine components.

"Pregnant women are recognized to be at increased risk of death or serious disease with COVID-19, but they have not been included in vaccine trials. Some women have become pregnant during their trial participation, but this data is not yet released. The DART (developmental and reproductive toxicity) studies are slated to be released in late December."

“The strong recommendation is for pregnant and nursing women to undertake shared decision-making with their providers, based on local community risk and the individual's risk factors.”

The strong recommendation is for pregnant and nursing women to undertake **shared decision-making** with their providers, based on local community risk and the individual's risk factors. This may limit the liability of the manufacturer and is understandable with the paucity of data. Note that in the UK, the recommendation is for women who are pregnant (from 3 months prior to pregnancy to after delivery) to refrain from vaccination (<https://www.gov.uk/government/publications/covid-19-vaccination-women-of-child-bearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a-pregnancy-or-breastfeeding>).

For any provider engaging in shared decision-making with such patients (pregnant or lactating women, as well as immunocompromised patients, and perhaps teenagers), it is essential that good **documentation** is done, with a clear notation of the risks and benefits discussed and the rationale for giving or withholding the vaccine.

Questions about this important perinatal population notwithstanding, I am excited about the prospect of a COVID-19 vaccine. With proper recognition of the rapidity of its development, built on the shoulders of decades of coronavirus research, it will be important to keep up with the data as it evolves. This will be especially important as different types of vaccine become available, and as study populations are expanded to include broader age ranges and special groups.

Here are some references with more details on the recent vaccine guidance:

5. <https://www.medscape.com/viewarticle/942557>
6. https://www.fda.gov/media/144413/download?utm_medium=email&utm_source=govdelivery
7. <https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>

Thank you to all the vaccine scientists who labored to bring this to fruition, to all of the public health leaders and workers who will get the vaccine from the manufacturers to the people who need protection, and to all of the front line clinicians who continue to care for your patients and their families. With that, I will close and wish you a good week and a safe holiday season.

Warmly,
Lily

Disclosure: There are no reported conflicts.

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Necrotizing Enterocolitis Presented at birth in a Full-Term Baby Born to a Mother with Chorioamnionitis

Husam Salama MD, Alaa Al.fakharani MD, Salem K Mamoo

Abstract:

Necrotizing enterocolitis of newborn infants is an inflammatory disease affecting most commonly newborn infants born prematurely. This condition's main cause is yet unknown, but immature mucosa associated with the fast introduction of milk are the two major risk pillars. The optimum time of occurrence is between the two weeks of life, and week six depends on the gestation age. It is seldom to occur in full-term newborns and quite unusual to present at birth. The authors present a case where a full-term baby is born with evidence of necrotizing enterocolitis to a mother with chorioamnionitis and antiphospholipid syndrome.

Abbreviation:

aPL: Anti-phospholipid syndrome

CRP: C- reactive protein

FTN: Full-term newborn

NEC: Necrotizing enterocolitis

NICU: Neonatal intensive care

PI: Pneumatosis intestinalis

WBC: white blood cells

Keywords: chorioamnionitis, full-term newborn, NEC, maternal infection, pneumatosis intestinalis, Necrotizing enterocolitis

Case:

A 39 weeks gestation baby boy born by vacuum vaginal delivery. Mother is a gravida 3 para 0 with two previous abortions. Mother is on a regular subcutaneous low molecular weight heparin and oral aspirin as she has antiphospholipid syndrome. Mother was admitted two days before delivery with abdominal pain, abdominal wall tenderness, vomiting, nausea, tachycardia more than 100 beats/minute, high-grade fever as well as burning micturition. There was no prolonged rupture of the membrane. The mother's C-reactive protein was 69, and her WBC was (18.2^{10^9} L), mainly neutrophil. A 24 hours maternal blood culture grew gram-positive cocci in pairs and *Veillonella* species of anaerobic Gram-negative cocci. Maternal urine culture grew no organisms. Diagnosis of maternal chorioamnionitis was made, and intravenous antibiotics were initiated two days before delivery. At birth, the Baby's Apgar scores were 9 and 10 at the first and fifth minutes of age, and birth weight was 2.6 kilograms. The baby was admitted to a step-down unit for further evaluation. At one hour of age, the in-charge nurse observed a few blood spots in the stool, mild abdominal distension, tachypnea without increased work of breathing, and poor sucking. The abdominal examination revealed mild abdominal distension with mild erythema. The baby was jaundiced. The Baby's CBC was (4.6^{10^9} /L with neutropenia < 50%), CRP (108), blood culture grew no organisms after 72 hours, and the CSF study was normal. The abdominal x-ray showed a dilated and thickened bowel wall with a soap bubble appearance (Figure 1). The diagnosis of NEC was made. The baby started on intravenous antibiotics and continued nil by mouth and transferred to the NICU. Shortly after, the abdominal wall was getting more erythematous and spreading to the flanks, abdomen more distended, tender, and firm inconsis-

tency. Repeated abdominal x-ray after 8 hours (Figure 2) showed pneumatosis intestinalis (PI). At 24 hours of age, abdominal ultrasound showed mild ascites with dilated bowel loops, thickened bowel wall, and normal arterial blood supply with PI (Figure 3). By the fourth day of life, the baby's clinical condition was improving. The baby continued antibiotics for 14 days though feeding started at 14 days of age. On day 20 of age baby was on full feed and clinically stable. Before discharge, a routine repeat of abdominal



Figure 1b: Baby's abdomen at one hour of age, note the distension and bowel wall erythema

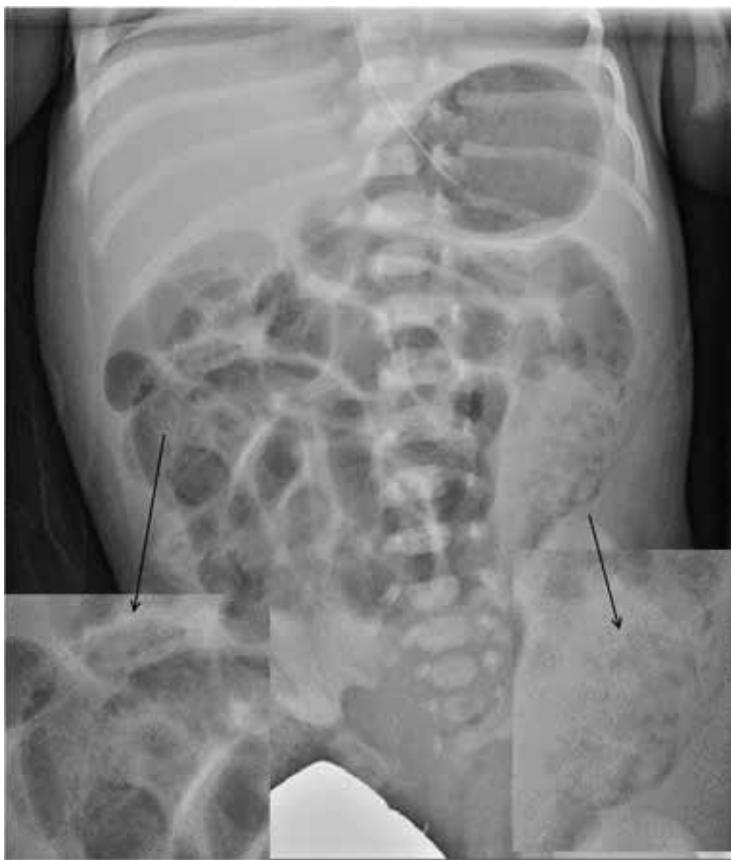


Figure 1a (one hour of age): Plane abdominal x-ray: note bubble soap appearance in the right upper and lower left quadrant.

x-ray (figure 3) showed significant bowel wall dilatation with significant stool retention. Contrast enema (figure 4) revealed a stricture of the proximal part of the rectum; the baby underwent successful surgical colostomy and was discharged home at 2 months of age.

Discussion:

Necrotizing enterocolitis is rare in full-term newborns. The main risk factors for NEC in FTN are listed in table 1. All will share one basic pathogenesis: mesenteric hypoxia and ischemia leading to intestinal mucosal necrosis. These risk factors should be allied with the early and fast introduction of milk. Rarely FTN will develop NEC before commencing the first feed; otherwise, as in this baby. This baby has established two maternal risk factors, chorioamnionitis, and antiphospholipid syndrome. Antiphospholipid syndrome is an acquired thrombophilia that causes blood clots and thrombi to form in the placenta. It is a recognized cause for recurrent abortion, stillbirth, IUGR, gestational hypertensive disorders, Fetal and neonatal thrombosis. More than 60% of newborns with aPL-related perinatal thrombosis had at least one additional risk factor identified, such as arterial and venous catheters, sepsis, asphyxia, and inherited thrombophilia. (1)

During the perinatal period, aPL may be present in 30% of newborns of affected mothers. Perinatal thrombosis and other aPL-related clinical manifestations are rare, while NEC is never reported as a complication. (2) In this case report, the x-ray was suggestive of soap bubble appearance and circular PI in the first x-ray while it became linear PI in the second x-ray with thickened and dilated bowel wall (Figures 1 &2). The presence of pneumatosis



Figure 2a: Plane abdominal x-ray (8 hours of age): note linear and circular PI in the right upper and lower left quadrant.

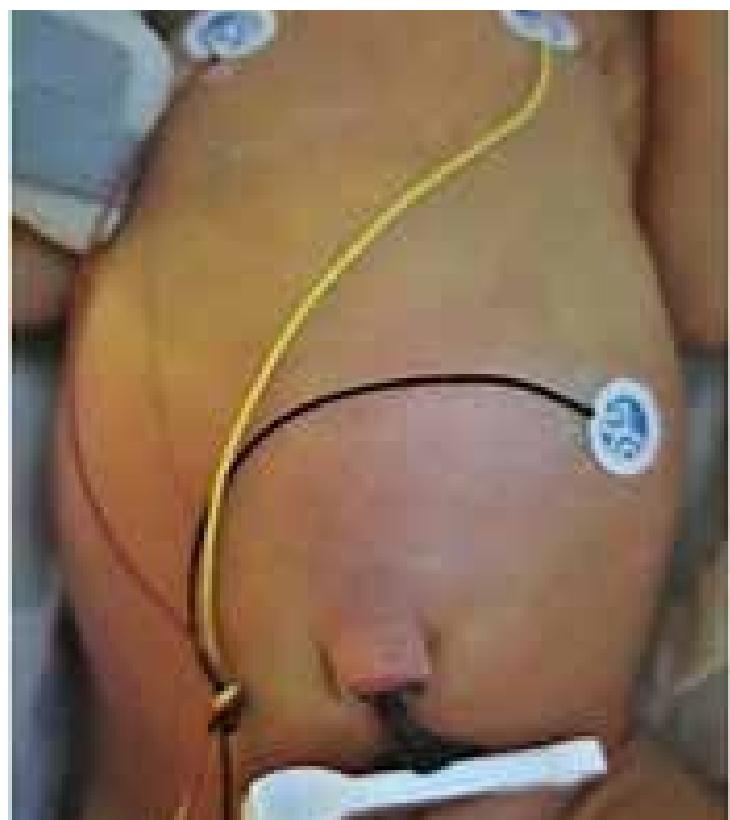


Figure 2b: Baby's abdomen, more distension, and more bowel wall erythema



Figure 3 Ultrasound at 24 hours of age: gas shadows within the mural wall. Dilated loops filled with fluid at left lower abdomen & free intraperitoneal fluid in between the bowel

intestinalis in both x-rays should support the diagnosis of NEC. Subsequent x-ray series showed no PI but a more thickened dilated bowel wall. According to Modified Bell's criteria of NEC, this case fits in stage 2B. (3)

Maternal Risk Factors:

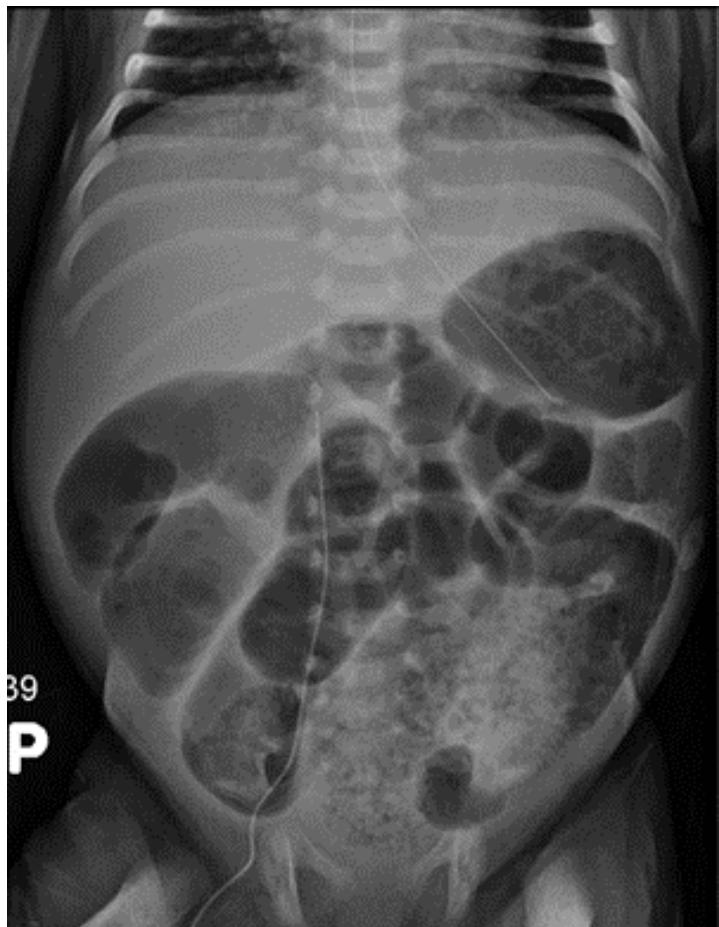


Figure 4a at 20 days of age: severe bowel wall distension

Maternal conditions that stimulate the fetal intestinal inflammatory cascade, such as pregnancy-induced hypertension, maternal infection, issues with placental blood flow, or recreational drug use (cocaine) with injury to the vasculature in the watershed areas may trigger mucosal damage process and NEC.(4-6). Histological chorioamnionitis and associated vasculitis increase the risk of an infant developing NEC 2.5-fold (odds ratio [OR] 2.6, $P = 0.02$). (7)

Intrapartum risk factors:

The major intrapartum risk factor is a hypoxic-ischemic insult to the fetus. (8) Though unlikely a major cause of NEC in the very preterm infant, hypoxia and ischemia modulate microvascular tone and vascular regulators such as endothelin and epidermal growth factor that play a role in the development of NEC. (9)

Incidence:

In a case-control study of 43 FTN who developed NEC, Wiswell et al. demonstrated that NEC in FTN accounted for 12% of NEC cases diagnosed in his center. At the onset, the median age was two days, and 18 infants developed NEC on the first day of life. Two (4.7%) of the 43 affected infants died. Only three of the full-term infants who subsequently developed NEC had entirely unremarkable courses before the onset of symptoms. Sick infants, those who are small for gestational age or require exchange transfusions, are at risk for NEC. The mortality rate in FTN is significantly less than those figures reported in the preterm age group. (11-15)

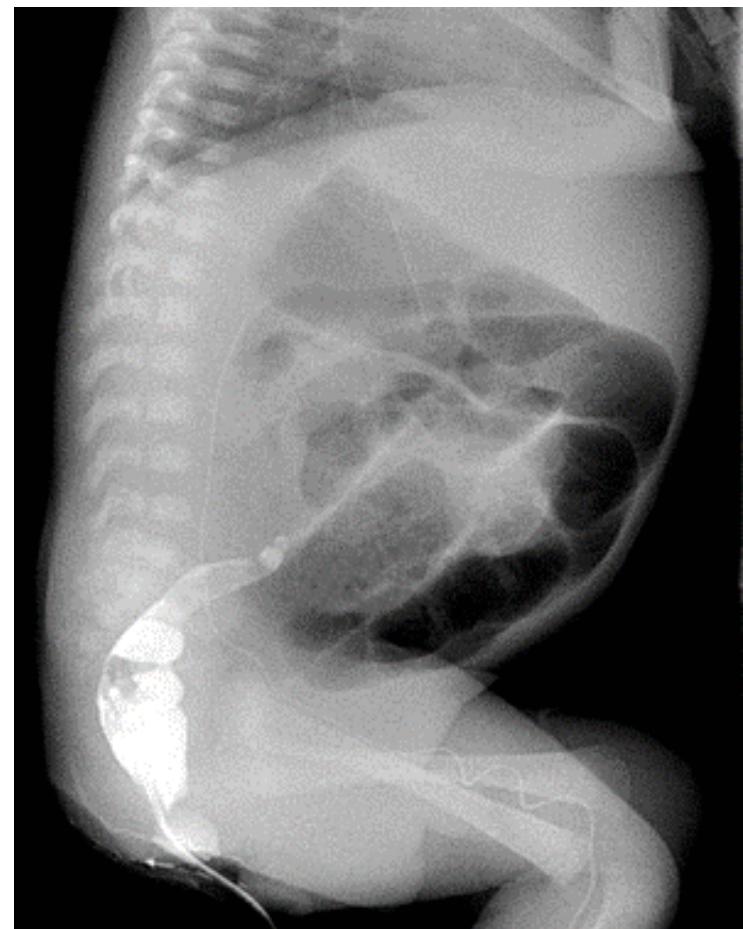


Figure 4b: Contrast study: note sigmoid colon stricture

In another case-control study, the incidence reported was as 0.16 to 0.71 per 1000 live births. (16) In China, NEC in FTN was reported as low as 0.44%, of which 20% were LBW. (17)

Diagnosis:

Radiology is considered the gold standard tool for the diagnosis of NEC. Often, infants with NEC do not have specific radiological findings. Frequently infants with NEC or those developing NEC manifest nonspecific metabolic or respiratory acidosis, thrombocytopenia, and neutropenia. The blood culture is positive in less than a third. (18,19) Some authors will distinguish FTN NEC from the true NEC seen in very preterm <32 weeks gestation infants and occurring during the second or third week of life. (21)

"PI is often detected by plain films of the abdomen early, which will be positive in approximately two-thirds of x-ray films, and its presence will last a short period then be replaced by a more thickened bowel wall as air is already absorbed."

Against this perspective, NEC is a state of pathology with clear criteria that do not include the newborn's gestation age. The hallmark of diagnosing NEC lies not only within the clinical condition but also within the radiological findings. Those are pneumatosis intestinalis, gas in the portal venous track of the liver, or the more serious pneumoperitoneum.

PI is often detected by plain films of the abdomen early, which will be positive in approximately two-thirds of x-ray films, and its presence will last a short period then be replaced by a more thickened bowel wall as air is already absorbed. Intramural gas tracks along the bowel wall can be either linear, which are usually submucosal, or rounded cystic "bubbly" collections, which are usually subserosal. Where they join, they may outline the circumferential margin of the bowel, creating rings (this circular pattern of PI favors a benign pathology, whereas the linear and bubbly lucencies can be associated with any, i.e., either benign or life-threatening causes). Radiological findings of ileus or thickened, dilated, and fixed loop are nonspecific, but a finding of intraluminal (PI) or portal gas, which is present in 50-75% of cases, are considered diagnostic. Shebrya et al. have shown that abdominal ultrasound is more sensitive than plain X-ray abdomen. (Figure 4). To date, serial KUB and cross-table lateral are the most often used studies to detect the subtle collection of free air in the abdomen. (22-26)

Table 1: risk factors of NEC in full-term infants.

1. Hypoxic-ischemic encephalopathy with early feeding
2. Placental insufficiency led to reversed diastolic
3. Maternal substance abuse (cocaine)
4. Maternal chorioamnionitis
5. Maternal hypertension.
6. Blood transfusion using old stored blood.
7. Exchange transfusion
8. Sepsis.
9. IUGR

10. Severe anemia
11. Gastroschisis, diaphragmatic hernia, and Hirschsprung disease
12. Polycythemia with hyperviscosity
13. Prolonged infusion of prostaglandin infusion

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Outstanding BC/BE Neonatologist Opportunities in Florida's Palm Beach County

Nicklaus Children's Health System and Nicklaus Children's Pediatric Specialists (NCPS), the health system's physician-led multispecialty group practice, have two exceptional opportunities for board-certified or board-eligible (BC/BE) fellowship-trained neonatologists with a minimum of three years of experience (preferred) for a new Level II NICU located on Florida's Treasure Coast in Palm Beach County.

Both positions will be part of a comprehensive perinatal and neonatal program for babies in a new Level II NICU. These roles present a unique and exciting opportunity for motivated candidates to flourish in a burgeoning market. Applicants should possess a passion for advocacy and improving care for all children. The BC/BE neonatologists will be responsible for attending deliveries, providing prenatal consultations to high-risk babies, resuscitating and stabilizing newborns in the delivery room, rounding on well babies, as well as provide leadership, oversight and supervision in the Level II nursery. Candidates should be proficient in newborn resuscitation, including neonatal intubation, umbilical line placement and peripheral cannulation, lumbar punctures, etc. Both roles offer salaries that are competitive and commensurate with experience. One of the two positions will have the additional responsibility of being the site director to provide leadership and direct quality and safety oversight of the program.

Nicklaus Children's neonatology program is consecutively ranked among the best in the nation by *U.S. News & World Report*. It was the first of its kind in South Florida and receives referrals of the most critically ill neonates from hospitals throughout Florida, Latin America and the Caribbean. The Level II NICU will be a part of the NCPS Section of Neonatology and the neonatologists will have access to the educational and professional development resources of Nicklaus Children's Health System.

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DFW

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).



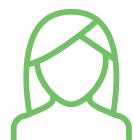
I was exposed to opioids.

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!

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Neonatal Abstinence Syndrome
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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 SSSESS PREFERENCES
- R EACH A DECISION
- E VALUATE THE DECISION



TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY



LONGITUDINAL DATA

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

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY

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

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Neonatology in Beirut, a Country Ravaged by a Financial, Political and Social Crisis

Carine Abi Gerges, MD

"While 2020 has been a difficult year for most people, Lebanon has been particularly hit hard by the turn of the decade. In October 2019, thousands took to the streets to demand the overthrow of a corrupt regime."

While 2020 has been a difficult year for most people, Lebanon has been particularly hit hard by the turn of the decade. In October 2019, thousands took to the streets to demand the overthrow of a corrupt regime. People protested for months while chanting '*Kellon yaane kellon*' (All of them means all of them) in reference to the entire ruling class. Political and civil unrest rocked the country against the backdrop of an unprecedented economic and financial crisis: the Lebanese pound plummeted in a free-fall, eventually losing over 80% of its value with local banks imposing strict restrictions on cash withdrawals preventing depositors from accessing both their savings and salaries. The Coronavirus pandemic made matters substantially worse. The final blow, however, was the Beirut Port explosion on August 4th, 2020. One of the largest non-nuclear blasts ever recorded, it left 150+ dead with 6,000+ injured, 300,000+ homeless, and many more forever scarred by the detonation of almost three kilotons of ammonium nitrate negligently stored in the heart of the capital. Three months later, someone has yet to be held accountable.

The health sector, buckling under the pressure, was not spared and is barely holding in this untenable situation. Not long ago, Lebanon was the medical capital of the Middle East. In Beirut alone, over ten hospitals are fully equipped with neonatal intensive care units (NICU), serving as a referral hub for rural areas and serving hundreds of thousands of patients. Among the 70,000 babies born in Lebanon annually, 12% (9,000) are born prematurely. Additionally, around 9,000 premature births have been recorded among Syrian refugees since 2015, amounting to a total of at least 18,000 documented premature births per year (10). All patients require appropriate financial health coverage to support their medical management, very costly for admitted neonates.

Prior to the financial crisis, less than half of Lebanese citizens

had private or semi-public health insurance plans while the remaining half paid out-of-pocket, partly relying on the Ministry of Public Health (MoPH). As an increasing number of previously insured families lost their jobs and consequently their insurance coverage due to the crisis, many more now resort to an already overwhelmed MoPH to cover their hospital fees. However, some hospitals refuse to admit MoPH-covered patients due to years of accumulated unpaid dues from the government. Soon, only the upper class will be able to afford the estimated \$30,000 in costs for the care of a premature baby (10).

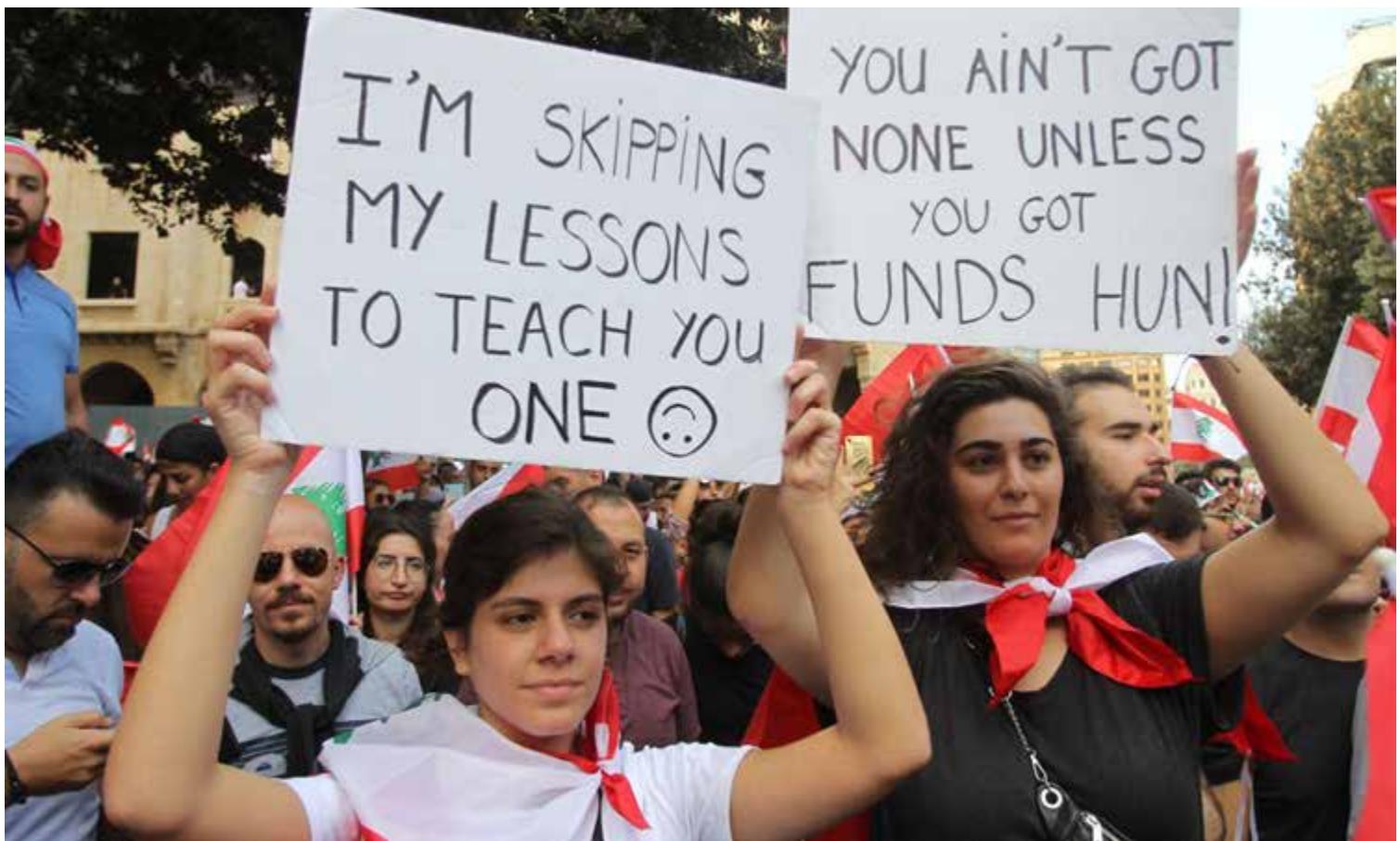
The cost of NICU hospitalization depends on whether the hospital is public or private, as well as the baby's condition. While most of Beirut's patients are admitted with frequently encountered cases such as prematurity, hyaline membrane disease, necrotizing enterocolitis, and neonatal sepsis, some infants transferred from peripheral hospitals require acute care for rare metabolic and genetic diseases. Although not studied in this specific context, rural areas have a higher prevalence of births with inborn errors of metabolism, likely due to more frequent consanguineous marriage. With the population in these areas being largely working-class, access to high-quality neonatal intensive care is particularly challenging, the crisis making it even worse. Dany al-Hamod, the director of the NICU at Saint George Hospital University Medical Center (SGHUMC), describes a substantial increase in the number of families unable to afford hospital bills recently, forcing them to run from one non-governmental organization (NGO) to another to gather funds to avoid having to move their child to different facilities, or worse.

The situation is even more dire for refugees. Lebanon is host to the second-largest Syrian refugee population and third largest Palestinian refugee population in the world. This population has increased in the last few years, partly due to the influx of over 45,000 'twice-refugee' Palestinians, once settled in Syria, fleeing to Lebanon to escape the civil war (1). Unable to be employed as a result of their refugee status, most do not have access to either public or private health coverage. Instead, they depend



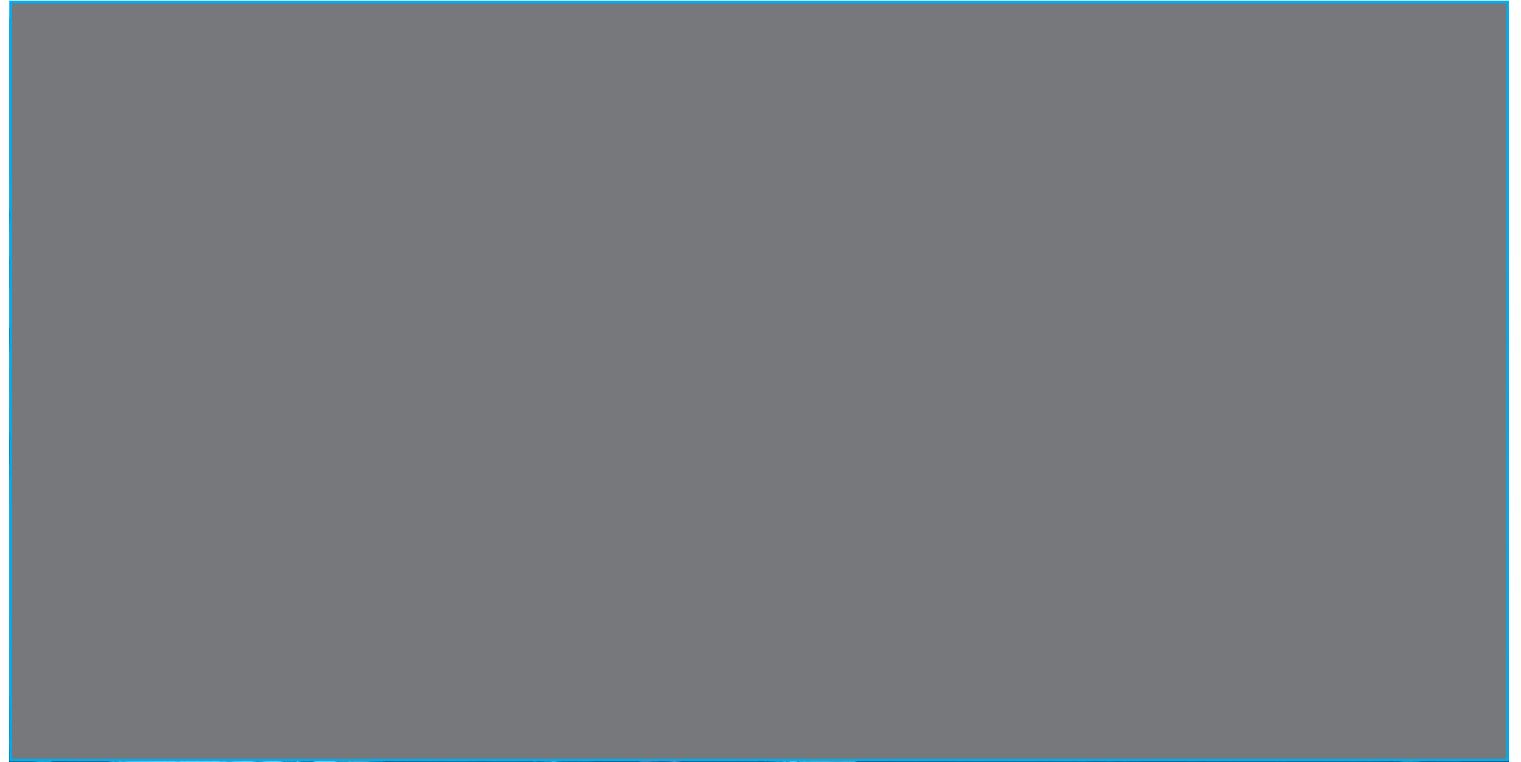
Empty fridges, reflecting the severity of the hyperinflation and the subsequent famine.

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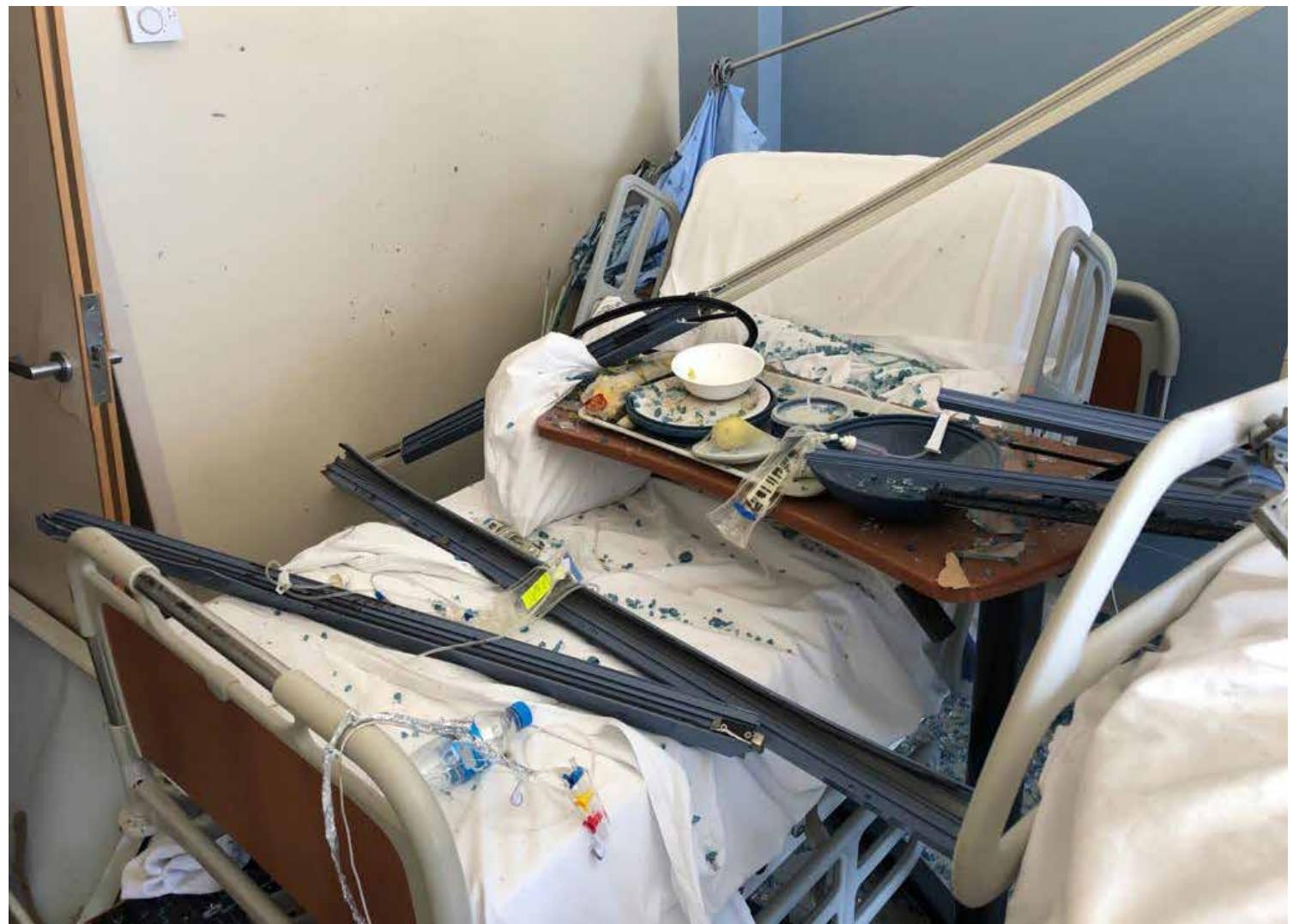


Above, below, and upper photo next page: protests and civil unrest that started over a year ago. Pictures represent young professionals or students taking the streets, AUBMC physicians joining those protests, medical students also joining (and wearing masks prior to 2020!). The last protest picture shows how "female-dominated" these protests were, led by strong women.





Pictures of a pediatric bed in SGHUMC, showing the extent of the damage done by the explosion





The picture of the man sitting next to the debris is that of Dr. Robert Sacy, next to the Karantina Hospital he built and invested in for the last 4 years only to see it blown away by the blast.

on humanitarian organizations to cover their healthcare needs, namely the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) and the United Nations High Commissioners for Refugees (UNHCR). These organizations have been essential to the survival of many newborns in this population, especially that they suffer a higher prevalence of neonatal complications due to inconsistent prenatal care, as well as higher rates of consanguinity (4). These organizations rely entirely on donations and grants, and their ability to cater to their

beneficiaries has been severely impacted after the donations they depended on contracted as a result of the ongoing global economic crisis. The severe financial situation that the UNRWA is currently facing threatens millions of refugees and further limits their already minimal healthcare access (9).

The Carlos Slim Center for Children in the Beirut Governmental University Hospital (BGUH - Karantina) was renovated in 2016 by the NGO ASSAMEH - Birth and Beyond through multiple local



Pictures of a pediatric ward in SGHUMC, showing additional damage done by the explosion

and international donations, building the first fully-equipped public NICU. This center's importance lies in its readiness to "care for those no one cares for." While only 70% of admitted children are eligible for MoPH-coverage (10), specialized care at this public hospital is provided indiscriminately. Since 2017, six babies found in trash bins and more than twenty-two "undocumented" children have been taken in and treated by the Karantina team (2). Adding fuel to the fire, this center was heavily damaged by the Beirut Port explosion, nearing total collapse. Inside their incubators, babies sheltered from the debris were evacuated within 3 hours. "An apocalypse — one minute was worse than 20 years of war," says Robert Sacy, head of the Pediatrics Department at the hospital and president of ASSAMEH – Birth and Beyond. What was once a haven for over 1,000 children per year has now been nearly razed to the ground. The remains of paintings of trees, suns, and smiles are now covered with blood on the few walls still standing. What was once joyful is now contaminated with death.

Making matters worse, a surge in the number of cases and ICUs at nearly full capacity, some project that the country might be heading towards an Italy-like scenario if serious long-term precautions measures are not implemented. The daily positivity rate fluctuates between 10 and 20%, and the death toll is 970+

since February 2020. The pandemic appears to be mostly affecting adults, with the case-fatality of children under nine years of age at 0.05% and only one recorded death (7). Although it has been speculated that neonates, due to their immature respiratory physiology and the immune system, might be at a higher risk for COVID-19 related complications, a review of the literature shows no increased risk of severe disease in infected neonates. Conversely, Martin Filho et al. raised concern about how a cytokine storm in pregnant mothers might increase the likelihood of poor neonatal neurodevelopmental outcomes (6). Associate professor of Neonatology at the American University of Beirut Medical Center (AUBMC), Lama Charafeddine, denied that the pandemic had had any noticeable immediate effects on the rate of perinatal complications or congenital malformations or infections. She did contend, however, that it is too early to draw any conclusions regarding this matter. While COVID-19 does not significantly affect the neonatal and pediatric population, Antoine Yazbeck, head of Neonatology at Serhal Hospital, reports a drop in the overall quality of care and staff morale due to increasing physician burnout. Indeed, as of early November, numbers from the doctors' syndicate and the order of nurses (5) show that a total of three doctors had died and seventeen admitted to intensive care units, with



"An apocalypse — one minute was worse than 20 years of war,' says Robert Sacy, head of the Pediatrics Department at the hospital and president of ASSAMEH – Birth and Beyond. What was once a haven for over 1,000 children per year has now been nearly razed to the ground. The remains of paintings of trees, suns, and smiles are now covered with blood on the few walls still standing. What was once joyful is now contaminated with death."

more than one hundred having been put under home quarantine and over 1,500 nurses having been infected. The pandemic has significantly affected the pediatric healthcare system's overall ca-

pacity, draining it in such that neonatal care is becoming severely compromised.

For physicians around the world, and particularly in Lebanon, working conditions have become increasingly difficult. "We see 4-5 kids per day, on a good day", reports Yazbeck, who has reported a ten-fold decrease in daily patient attendance to his clinic. Indeed, the pandemic has led many parents - those who have not migrated yet - to opt-out of vaccination programs and avoid routine follow-ups out of fear of exposure. Additionally, due to currency devaluation, consultation fees, still generally fixed at the same price in Lebanese pounds, are much less profitable to the physician (dropping from the equivalent of \$60/patient to less than \$12/patient) while still being largely unaffordable for the larger patient population. Maroun Matar, head of the Neonatology Department at Lebanese American University Medical Center (LAUMC), also describes an 80% decrease in his monthly income despite raising his clinic fees by 10% whilst food products and basic necessities witness an inflation rate of more than 400% (3) and half the population is now under the poverty line. Highly qualified and trained physicians, overworked and underpaid, have decided to immigrate for better opportunities abroad. Indeed, over 400 physicians have immigrated in the last couple of months, with more expected to follow suit (8). This has pushed government officials to seek

international aid to incentivize doctors to stay in the country by offering financial compensation (8). This exodus of physicians and the shortage of medications and medical equipment (hospital suppliers demanding to be paid in hard currency, largely unavailable on the market) has significantly reduced the quality of healthcare in Beirut, once a regional health hub in the Middle East.

"This exodus of physicians and the shortage of medications and medical equipment (hospital suppliers demanding to be paid in hard currency, largely unavailable on the market) has significantly reduced the quality of healthcare in Beirut, once a regional health hub in the Middle East."

It is crucial to bring to light the difficulties encountered by healthcare workers in developing countries to identify the various factors affecting the quality of care offered to patients. The pandemic has highlighted wide disparities and brought to the fore existing inequalities in developed countries, exposing the need to fill large healthcare delivery gaps to marginalized communities. In a country like Lebanon, shaken by financial precariousness, famine, civil unrest, a large explosion, a mass exodus, and a global pandemic, these disparities have become even more apparent and alarming. This eventful year has highlighted the lack of a national emergency preparedness plan, inadequate infection prevention and control practices, and the absence of an effective healthcare safety net for the uninsured in Lebanon. It is crucial to address these deficiencies for a better-equipped healthcare system in the face of the next blow in order to be able to, at least, give the newborns the gift of time.

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June 2020
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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.

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

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August 9, 1996 - April 3, 2010



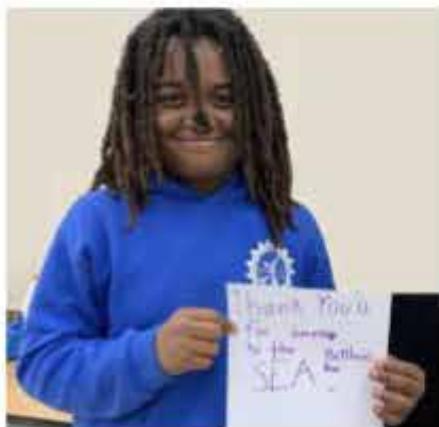
Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring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

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

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R and RStudio - The Basics

Fu-Sheng Chou, MD, PhD

Installing R and Rstudio:

R

As I mentioned in the previous post, R is open-source software maintained by a group of talents. R is freely available for download from multiple mirror sites (servers around the globe that host exactly the same files and data for the sake of convenience to the end-users). The most recent version is 4.0.3 ("Bunny-Wunnies Freak Out").

R is available for download [here](#). (1)

Installation in Windows and Mac environments are straightforward. Double-click on the downloaded file and the installation wizard will take you through the process. If you are using Linux, I assume you know the basics of command-line tools and can figure them out on your own.

"As I mentioned in the previous post, R is open-source software maintained by a group of talents. R is freely available for download from multiple mirror sites (servers around the globe that host exactly the same files and data for the sake of convenience to the end-users)."

Rstudio:

The next step is to install RStudio. RStudio comes in different flavors. There is a desktop version (RStudio Desktop) and a server version (RStudio Server). The latter version can be installed on a computer that runs the Linux operating system and allows users to log in remotely to use RStudio via a web browser. As a Delaware Public Benefit Corporation, RStudio always comes with an open-source version free for download. The paid Pro version provides advanced functionality and priority technical support. RStudio Desktop open-source, free version is quite sufficient to build web apps for personal or small-group use. The installation file can be downloaded [here](#). (2) Make sure you choose the one on the left side for RStudio Desktop Open-Source License. The website will detect your operating system directly and point you to the right version. The current stable version is 1.3. Version 1.4 is available for public preview.

After the file is downloaded, installation is also pretty straightforward on Windows or Mac. Just follow the installation wizard. Again, installing RStudio open-source on a machine running Linux can be tricky, but if you are using Linux, I am sure you can figure it out!

RStudio Cloud:

If you do not like the hassle of installing software on your personal computer, and you know you will always have a high-speed internet connection when you work on an R project, you may want to try RStudio Cloud offered by the RStudio company. Again, a free version provides 1 CPU and 1GB RAM per project for up to 15 projects in total. The free version should be sufficient for simple webApp development.

"Again, a free version provides 1 CPU and 1GB RAM per project for up to 15 projects in total. The free version should be sufficient for simple webApp development."

Navigating through the RStudio interface:

R is the programming language. RStudio is the integrated development environment (IDE) that accesses R to perform tasks. When you launch RStudio, R opens automatically in the background. In other words, all you need is to open RStudio, and you are ready to carry out all the coding tasks.

When you open RStudio, you see a window that is similar to Figure 1. There are three panels, one on the left and two on the right. The panel on the left defaults to a tab called "Console." This location is the place where all the codes are executed. The right upper panel defaults to the tab "Environment." This location is where all the "objects" that are created are listed. The right lower panel has multiple tabs, with "Files" being the default view. If you are using RStudio locally, the folders in the Files tab are the folders on your computer. If you use RStudio Cloud, the default view is the Project folder. Next to "Files," you have "Plots," where plots are displayed. Remember we said that R has a superb graphic engine for plotting! The next tab is "Packages," where all the installed packages are listed. The first one on top (in my R version) is "askpass," followed by "assertthat," and so on. The checkboxes left to the names of the packages can be clicked to "load" the library. Alternatively, you can also type **library(askpass)** in the Console to load the library you need. Next to the tab "Packages" is "Help," where all the resources are listed. The last tab is "Viewer," the tab that shows all the HTML rendering. For building webApps, you probably only need to access the "Files" tab.

There are numerous menu items and buttons in the RStudio IDE to improve coding efficiency. We will get to them when we need to. Interested readers may refer to the [RStudio IDE cheat sheet](#) for details. (3)

Install the shiny package:

Before we can dive in to make the first webApp, we need to install the package first. Type **install.packages("shiny")**. As you are

typing **install**, you should see hints displaying next to the cursor to guide you to the right "function." You can select the one you want and press ENTER.

"There are numerous menu items and buttons in the RStudio IDE to improve coding efficiency. We will get to them when we need to. Interested readers may refer to the RStudio IDE cheat sheet for details. (3)"

Let us pause for a second to dissect this "function" first. A "function" is a packaged task that you tell R to perform. All functions ideally should have their own unique names. In the above syntax, the name of the function is **install.packages**. Followed by the name is a set of parentheses needed for R to know that **install.packages** is a function to be executed. Inside the parentheses are "arguments" that the coders need to provide for the function to be executed meaningfully. In this case, if we do not provide the name of the package to be installed, R does not know what to do. Here we provided a character string **shiny**. A character string is a text; it is always labeled with quotation marks. Single or double quotations both work, in most cases.

One thing to point out is, if after pressing ENTER, you see a "+" sign showing up in the next line, and it looks like R is waiting for something to happen, usually, it is because there is a syntax error in the first line, or the syntax is not complete. For example, if you only provide a left-sided quotation mark, R thinks that the syntax is not complete and patiently waits for you to complete the syntax. In other words, R allows syntax entered on multiple lines.

The other thing to point out is, R is case-sensitive, so **install.packages("shiny")** is NOT equal to **install.packages("Shiny")**. R tells you that package 'Shiny' is not available for this version of R if you type in the latter.

It takes a few minutes to install the package, depending on your computer's speed and the internet speed.

Now, if you type **?install.packages()** in the Console, you will see that a document that describes the function **install.packages()** pulled up to the Help tab of the right lower panel. In the document, the top left corner has the name of the function, and the package that the function resides in is in curly brackets. The function **install.packages()** resides in the package called **utils**, which stands for **utilities**. Moving down, you can see the Description of the function, as well as Usage, which gives you all the arguments you can provide to R when executing the function. The first argument is **pkgs**, which stands for **packages**. R goes by the order inside the parentheses of a function if an argument's name is not specified. Therefore, **install.packages("shiny")** means the same as **install.packages(pkgs = "shiny")**. In Usage, you can see that the default answer for the argument **repos** is **getOption("repos")**, whatever that means. For installing packages, all you need is to provide the name of the package with quotation marks. That is all you need.

Summary:

In this post, we installed R and RStudio, went through a short introduction of the RStudio IDE interface, and installed the **shiny** package. We will start making our first webApp next month. Thanks for reading!

"In this post, we installed R and RStudio, went through a short introduction of the RStudio IDE interface, and installed the shiny package. We will start making our first webApp next month."

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

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

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

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

fu-sheng.chou@neonatologytoday.net

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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
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The Village Son



A Life's Journey

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

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Fellow Column:

Identification of a Solitary Posterior Cervical Cystic Hygroma: A Case-report

Bansari Patel, OSM, Nasser Hashem, OSM, Lakshan Fonseka, OSM, Kersti Bellardi, OSM, Mitchell Goldstein, MD

Abstract

Purpose: To report a case of a post-term neonate with an isolated cystic hygroma upon birth.

Methods: This is a retrospective case report followed by clinical observation, genetic testing, and surgical intervention.

Results: A post-term neonate was found with an isolated left parapharyngeal cystic hygroma with no incidence of concurrent genetic syndromes upon karyotyping and underwent surgical removal.

Discussion: Cystic hygromas are very commonly associated with genetic syndromes or maternal risk factors. If none exist, specific subtypes of cystic hygromas can also be inherited in an autosomal recessive fashion, a possibility that may need to be explored comprehensively.

“Cystic hygroma, also referred to as cystic or nuchal lymphangioma, is a congenital malformation of the lymphatic system resulting in a benign lesion composed of single or multiple cysts that can manifest anywhere in the body. (1)”

Introduction

Cystic hygroma, also referred to as cystic or nuchal lymphangioma, is a congenital malformation of the lymphatic system resulting in a benign lesion composed of single or multiple cysts that can manifest anywhere in the body. (1) These lymphatic malformations are most commonly found in the cervicofacial regions, particularly in the posterior cervical triangle. Approximately 20% occur in the axilla, and rarely the mediastinum, groin, and retroperitoneum. (1)

Cystic hygromas are thought to arise from maldevelopment or complete failure of the lymphatic system to communicate with the remainder of the lymphatic or venous circulation. (1) These isolated lymphatic sacs dilate from fluid retention and develop a cystic morphology due to the lack of venous outflow. They usually occur in the fetal population, with most lesions presenting by two years of age. The incidence is estimated to be 1 in 6,000 to 16,000 live births, with 50-65% apparent at birth, others manifesting later. (1)

The majority of prenatally diagnosed cystic hygromas are associated with aneuploidies, including Turner Syndrome, Noonan syndrome, trisomy 21, 18, and 13. (1) Isolated cystic hygroma can also be inherited as an autosomal recessive disorder. In addition to congenital development, these lymphatic malformations can arise as an isolated event or because of environmental etiologies, including substance abuse during pregnancy, vertical transmis-

sion of maternal viral infection, trauma, inflammation, or obstruction of lymphatic outflow. (1)

If sufficient in size, cystic hygromas can be visualized by abdominal ultrasound imaging at 8-10 weeks gestation. Detection in utero may indicate the need for further investigation, including amniocentesis to assess for genetic abnormalities and Fast Spin MRI to determine the extent of invasion into the surrounding fetal structures. (1) It is not uncommon for these lymphatic malformations to be discovered postnatally with negative intrapartum imaging. Management of cystic hygromas after birth include cytogenetic studies to rule out suspected chromosomal and genetic disorders. Imaging such as MRI or ultrasound can be advantageous in confirming the diagnosis as well as determining the size and infiltration of the lesion into surrounding neurovascular structures, which can fundamentally guide future management. (1) The standard care of treatment is surgical excision, attempting to remove the malformation in its entirety, sparing the surrounding structures. The cystic hygroma composition of microcystic lesions makes it challenging to remove due to its association with nearby tissues, with surgical excision rates up to 53%. (1) The exceptions to excision at the time of diagnosis include premature infants that are too small to completely identify crucial nerves, including the facial nerve encompassed by the lesion. (1) If no airway or vascular obstruction is present, surgical intervention can be delayed until 2 years of age especially if the lesion is located around the parotid gland or facial nerve. (1)

“The standard care of treatment is surgical excision, attempting to remove the malformation in its entirety, sparing the surrounding structures.”

Case Summary

The neonate is a post-term infant born at 40 weeks and 2 days gestation to a 33-year-old G4P3 Hispanic female with a blood type of O positive. Birth weight was 3250 grams (11-25th percentile), head circumference 35 cm (26-50th percentile), and length 48 cm (4-10th percentile). Except for being GBS positive, the mother of the baby had an uneventful pregnancy and a normal prenatal ultrasound exam. She received prenatal care and took prenatal vitamins throughout the pregnancy. At the time of delivery, the neonate presented in the transverse lie, indicating the need for a Cesarean section. APGAR score was 9 at both 1 and 5 minutes. The infant was active and crying upon delivery, with a large fluctuant neck mass on the left that warranted admission to the Neonatal Intensive Care Unit (NICU) for observation and evaluation.

On admission, the neonate's temperature was 36.1 C, heart rate of 164 beats per minute, respiratory rate of 49 breaths per minute,



Figure 1. Large fluctuant cystic hygroma located in posterior cervical triangle.

and blood pressure 63/27. Physical exam revealed a neck mass extending from below the left jaw to just inferior and slightly posterior to the left ear. No respiratory difficulties, murmurs, extremity deformations, or other abnormalities were found. The infant received ad lib feeds of expressed breast milk or Enfamil formula by mouth. Sepsis work-up included CBC, CRP, and blood cultures. CBC revealed WBC of 13.3, hemoglobin 18.1, hematocrit 52.8, and platelets 323. CRP was less than 0.4, and blood cultures were negative. Genetic testing was ordered to rule out chromosomal abnormalities and showed normal karyotype findings.

“Genetic testing was ordered to rule out chromosomal abnormalities and showed normal karyotype findings.”

The neck mass was evaluated by ultrasound the day after admission. The imaging revealed a complex cystic structure measuring 4.8 x 4.2 x 4.6 cm with low-level echoes and internal septations. Two days later, an MRI of the neck was performed and revealed a 4.9 x

7.9 x 5.2 cm trans-spatial cystic mass with a medially protruding component into the left parapharyngeal space. Internal septations and internal fluid-fluid levels suggested a large lymphatic malformation. A normal left parotid gland was not visualized. Due to the mass effect from the cystic mass, the left submandibular gland was displaced anteromedially. The infant underwent successful surgical resection of the neck mass one week later. The researchers acquired written parental informed consent before publishing this case study.

Discussion:

While many causes of cystic hygromas exist, they most commonly (about 62% percent of the time) manifest as part of a syndrome, including but not limited to Down, Turner's, and Noonan syndromes, especially if the hygromas form in utero early in the pregnancy. (1) However, this case proved to be different as the karyotype showed no associated anomalies in the neonate, as well as no early detection of the hygroma in utero, despite its presence and large size upon birth. As there were no maternal risk factors present during the pregnancy, such as alcohol abuse or viral infection, the case includes the possibility of a simple malformation of the lymphatics or an autosomal recessive inheritance of the hygroma.

Studies have shown that there may exist an autosomal recessive



Figure 2. Upper body coronal MRI with contrast showing with cystic hygroma located in the posterior cervical triangle.

inheritance pattern of a familial nuchal subtype of cystic hygromas, which manifest less commonly without any associated fetal defects in 20-40% of the cases. (2) Similarly, it may also be possible that cervicofacial cystic hygromas, the most common manifestation of hygromas, may also be familial in cases without any other associated defects. Thus, it may become necessary to study further the cases of isolated cervicofacial cystic hygromas in families.

Once a cystic hygroma presents, they are often monitored for any signs of complications, such as hemorrhage, respiratory distress, infection, dysphagia. During infancy, a challenge of cystic hygromas is that the course is often unpredictable, as it may grow and cause the aforementioned complications or even spontaneously regress.(1) If they are asymptomatic, no treatment is usually needed or performed. (1) However, if they continue to enlarge,



Figure 3. MRI with contrast showing lack of hygroma invasion into surrounding vasculature

they may lead to airway obstruction and necessitate intervention. (3) In other cases, parents may also want to remove the hygroma due to aesthetics or disfigurement.

Treatments currently used include surgical removal, drainage, sclerotherapy, or cauterization. (1) Aspiration is yet another form of treatment, but one that comes with a potential complication of necessary repetitive treatments or subsequent infection. (4) Sclerotherapy, a treatment that aims to shrink blood or lymphatic vessels via medications such as bleomycin, has become a popular choice for cystic hygromas due to its efficacy in eliminating the hygroma (5) but can potentially lead to complications such as discoloration of the skin, cellulitis, or rarely, an increase in the hygroma or a hard residual after shrinkage of the cysts, (1) In most cases, optimal treatment can be achieved by combining sclerotherapy with surgery or carrying out surgery alone. (1) Although surgery can also come with its own set of complications, such as facial nerve palsy or recurrence, many patients can be treated conservatively for complications and end with a good recovery. (6) However, in some instances, surgery may need to be delayed in instances of prior complications such as abscess formation, for which antibiotics would be administered and surgery delayed until 3 months. (1)

In this neonate, no complications such as respiratory distress or infection were perceived, and the decision to proceed to surgery was made. The neonate recovered well and was discharged without any further complications, with surgery proving to be a stable choice for treatment. However, as mentioned before, further evaluation and follow up would potentially be ideal for exploring the possibility of an inherited solitary cervicofacial cystic hygroma. The discovery of this inheritance pattern can lead to the development of further screening tools in utero, in addition to ones already established for cystic hygromas associated with genetic syndromes.

Conclusion:

This case presentation of a term neonate adds to the evidence for adequate surgical excision as a treatment for a cystic hygroma that was first identified after cesarean section, originally indicated for the transverse presentation. Though this case presented with a large cystic hygroma, the fact that it was not found prenatally is not particularly unusual. This case is an example of a good prognosis for cystic hygroma diagnosed after birth, as those found prenatally are more frequently associated with various malformation syndromes, karyotypic abnormalities, and various teratogenic agents. Furthermore, there may be a genetic basis for solitary cystic hygromas, potentiating the need for genetic testing for further exploration.

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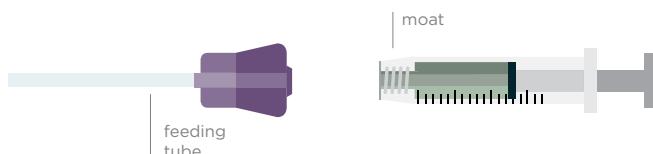


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SAFETY IN THE NICU

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While you're planning for 2021, don't forget to save the date for NEO: The Conference for Neonatology! We're going virtual this February to bring critical topics that influence the practice of neonatal medicine presented by leading experts in the field.

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The Year in Review and What Lies Ahead for First Candle

Alison Jacobson



Saving babies. Supporting families.

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

"This year has been like no other. For many parents who experienced a stillbirth or whose baby died from Sudden Unexpected Infant Death (SUID), First Candle was a much-needed source of comfort and hope when they were forced to remain isolated from friends and family."

This year has been like no other. For many parents who experienced a stillbirth or whose baby died from Sudden Unexpected Infant Death (SUID), First Candle was a much-needed source of comfort and hope when they were forced to remain isolated from friends and family.

These grief calls made us even more determined to expand our

Straight Talk for Infant Safe Sleep program because we know that practicing the safe sleep guidelines from the American Academy of Pediatrics (AAP) can prevent many of these deaths. While we could not do as many trainings in person, we developed an online curriculum, which was extremely successful. In addition to discussing the safe sleep guidelines, our Straight Talk curriculum continues to include techniques on individual self-reflection to raise awareness of potential bias across racial, socioeconomic and cultural lines and enable those who counsel families on maternal and infant health to assess their own perceptions and effect personal change.

And we have seen how our training makes a difference: 95% of Straight Talk participants reported gaining improved knowledge about safe sleep guidelines, recognizing their own implicit biases, and strengthening their ability to make them understandable and relevant to the families they work with.

We know that many families still either are not aware of the safe sleep guidelines, choose not to follow them, or have challenges in adopting these practices. We know that there is a great deal of misunderstanding and cultural differences about bed-sharing. Too often, we hear from moms, "I know what's best for my baby, and that includes sleeping with me." We have heard from dads who at times feel sidelined and want to be more involved in supporting their partners in breastfeeding and practicing safe sleep.

Sadly, we know that many SUID deaths are due to Accidental Suffocation and Strangulation in Bed (ASSB), and we are committed to engaging with care providers and families to identify safer sleep strategies. We are working to transform the way families receive information about safe sleep and are supported throughout their pregnancy and beyond when they are overwhelmed and exhausted caring for a new baby.

Community-based Outreach and Advocacy

In addition to our Straight Talk program, we are creating a grassroots campaign that will utilize community leaders to deliver the new safe sleep guidelines released by the AAP next year. The campaign will reflect the lived experiences of community members and include text-based messages, social media posts, and peer-to-peer interaction. The program will also include "Mama-vans" deployed into the community and staffed by public health nurses and safe sleep ambassadors to improve maternal and in-



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fant healthcare access.

At the national level, we are partnering with other national advocacy organizations, including Moms Rising, Black Mamas Matter, and Safe Kids, and supporting legislation such as the MOMS Act that will improve medical coverage postpartum and include doulas under Medicaid.

While this year has certainly been challenging, it has also been rewarding as we continue to expand our reach into communities around the country. We look forward to doing even more next year.

From all of us at First Candle, we wish you a happy, healthy, and safe holiday season.

"At the national level, we are partnering with other national advocacy organizations, including Moms Rising, Black Mamas Matter, and Safe Kids, and supporting legislation such as the MOMS Act that will improve medical coverage postpartum and include doulas under Medicaid."

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.

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

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The Survey says RSV

What you need to know about RSV

RSV stands for **Respiratory Syncytial Virus**

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See examples at nicuawareness.org and nationalperinatal.org/NICU_Awareness

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.

This project is a collaboration between



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Raising Global Awareness of RSV

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

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

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



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

A NICU Respiratory Therapist's Christmas Wish List

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.

"It is that time of year again, and while Christmas is typically thought of as for children, adults can dream of wished gifts under the tree. These gifts will not be found under any tree, but they represent the dreams of many an RRT."

It is that time of year again, and while Christmas is typically thought of as for children, adults can dream of wished gifts under the tree. These gifts will not be found under any tree, but they represent the dreams of many an RRT.

Fully integrated and automated saturation (SpO_2) monitoring and FiO_2 control

For over 70 years, we have known that too much oxygen is a major risk factor for retinopathy of prematurity. While the alarm limits and targeted SpO_2 ranges differ between NICUs, the reality is staffing issues mean that these targets are often exceeded, even with the most diligent monitoring. One bedside nurse or RRT cannot be in more than one place at a time, and unless a baby is assigned "one-to-one," their caregivers cannot be continuously at their bedsides. Too often, the results are alarm fatigue. This results in over-targeting or the adjustment of alarm limits outside targeted ranges. Histogram analysis of SpO_2 too often shows an inordinate amount of time with SpO_2 above 95%. The reliability of available monitors has significantly improved over the past decade, and automatic FiO_2 adjustment is available on some ventilators. To the best of my knowledge, this technology has not made it to the bedside in NICUs.

Universal availability of third-generation oscillators

Those who read this column regularly will know I am a proponent of high-frequency ventilation, and my first column (January 2019) addressed high-frequency oscillation with volume targeting. May the FDA grant the wishes of many American RRTs by approving at least one of these machines for American use.

"Those who read this column regularly will know I am a proponent of high-frequency ventilation, and my first column (January 2019) addressed high-frequency oscillation with volume targeting. May the FDA grant the wishes of many American RRTs by approving at least one of these machines for American use."

A 2.0 jet adaptor.

This one is rather controversial. I admit to originally nixing the making of a 2.0 LifePort® adaptor, however further thought has changed my stance. It is becoming more common to resuscitate 22-week gestation infants, and high-frequency jet ventilation appears to offer the greatest hope for favourable respiratory outcomes for these babies. While the use of a 2.0 ETT should only be for a short time due to the virtual impossibility of suctioning effectively, it can bridge the gap between resuscitation and the placement of a 2.5 ETT once there has been some dilation. This has happened once in my practice.

Lower jet ventilator rates.

The physics of gas flow dictate that very tiny babies (and 2.0 ETTs) have inherently high resistance resulting in long time constants. While jet ventilation is the best tool available to mitigate gas trapping, it is often unavoidable, even at rates of 240.

An end to rib counting.

All too often, clinicians assess lung inflation by counting the number of ribs present on a chest film without assessing the quality of inflation. Haziness does not represent proper recruitment. Reducing PEEP in the face of gas trapping is catastrophic. High-

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frequency ventilation (HFV) favours more inflation to achieve an "open lung" than conventional ventilation does, i.e., 9-10 ribs (assuming the lung is well recruited) should not be considered hyperinflated when using HFV modes.

Core therapists.

There is an old saying: "jack of all trades, master of none." Many NICUs still rely on RRTs who rotate through other parts of the hospital. This is not a slight to those therapists. I believe the evidence shows that the units with the best outcomes have a core group of people managing ventilation. Given the steep learning curve, the complexity of ventilating premature infants, and their lungs' fragility, I believe strongly that these babies deserve their own RRTs. It takes at least a year of full-time work to achieve a measure of competency in the NICU. After all, you would not go to a pediatrician to manage your health as an adult; we recognize the value of sub-specialties in medicine in general; why not in mechanical ventilation? I personally would never attempt to manage an adult patient's ventilation without a full refresher/orientation to adult medicine.

RRT autonomy.

Having RRTs manage neonatal ventilation allows for closer monitoring and more timely response to changes in a baby's condition, coupled with a broad knowledge of respiratory physiology and the technology at use. Core therapists are more likely to have more autonomy in their practice by virtue of their experience.

Collegiality

Related to RRT autonomy, but on a broader scale. More involvement and sharing of best practices such as with the Vermont Oxford, Pedatrix, and Canadian Neonatal Network collaboratives can only improve the care we deliver. This also applies to inter-professional relationships within a given NICU.

Timely administration of antenatal steroids.

Nothing makes a NICU clinician's job harder than ventilating a baby whose mother has not received antenatal steroids. As the edge of viability inches down lower and lower, this becomes increasingly important. The evidence supporting antenatal steroids is overwhelming. Obstetricians, please practice accordingly.

Family integrated care.

All too often, parents are considered a nuisance in the NICU. This should never be the case, as parental involvement in a baby's care is vitally important from a developmental perspective and for better care overall. Nobody knows the baby better than parents. They can often see the cues of something going amiss before a clinician who may have never cared for their child. The best news? This one's free.

Lower nitric oxide (iNO) prices

While no one has been able to replicate Dr. Roberta Ballard's study on the use of iNO to prevent chronic lung disease, there are physiological reasons behind her success. It is also possible that discrepancies in ventilatory management and approaches may hinder reproducibility. In a socialised medical system such as the one I practice in Canada, costs must be considered when providing treatment. The current lack of evidence to support the use of

iNO in the premature population may in part be from its lack of usage and/or the relatively short duration of the treatment. Some babies present with initial pulmonary hypertension that may respond to iNO with a resulting decrease in ventilatory requirements(1). Published elsewhere in this journal is a letter urging more lenient guidelines for the use of iNO in the premature population.

Early treatment and timely availability of patent ductus arteriosus (PDA) ligation

A PDA invariably complicates the ventilatory management of a baby and has been implicated as a contributor to necrotizing enterocolitis(2), CLD, intraventricular hemorrhage, and death(3). The risk of ROP is also increased in the presence of a PDA (4,5). Delays in the surgical ligation of infants with PDA failing pharmacological treatment can only exacerbate these complications.

This raises the ongoing debate over the pharmacological treatment of PDA. There has been a fear of using indomethacin because of an increased risk of NEC; however, there is no increased NEC risk when used to treat PDA(6). Ibuprofen, on the other hand, is as effective as indomethacin and reduces the risk of NEC(7). If ventilation is a concern, one might elect to delay NSAID therapy in favour of steroid prophylaxis. I submit that if properly, gently ventilated, the risk of ROP and other PDA related sequelae outweigh the benefit of steroid prophylaxis. Acetaminophen has been shown to be effective in PDA treatment and can be used when NSAID therapy is contra-indicated, or steroid prophylaxis is a priority (8,9).

If ventilation is a concern, one might elect to delay NSAID therapy in favour of steroid prophylaxis. I submit that if properly, gently ventilated, the risk of ROP and other PDA related sequelae outweigh the benefit of steroid prophylaxis.

The problem at the bedside is that PDA presents as desaturation/labile FiO₂ especially if the SpO₂ sensor is not positioned at a pre-ductal site. The reaction is to increase FiO₂, which increases the PaO₂ of blood, reaching the eye and brain. That, in turn, increases the risks of both ROP and peri-ventricular bleeds through reperfusion injury(9). I might add the last reference is a course on the physiology of oxygen in the premature infant and pulse oximetry all in one.

Having said all this, the question of to treat or not to treat PDAs remains controversial at best and unanswered at worse. Studies have indicated interventions succeed in ductal closure but may not have any other benefit.(10) The latter studies do not appear to examine the risk of NEC independently.

I do not think Santa's sleigh has room for all of this, but one can hope. Every year new technology emerges that promises to give us better outcomes. All too often, it is we clinicians who are behind the curve.

A very Merry Christmas and Happy Holidays to all

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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.

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



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In Loving Memory

August 9, 1996 - April 3, 2010



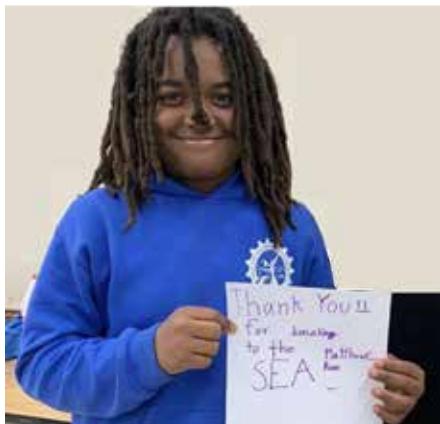
Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring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

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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.

Cheryl Ann Milford: A Tribute To Someone Who Gave So Much of Herself To Help So Many

Sage N. Saxton, Psy.D.

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*.



"Ms. Cheryl Ann Milford, Ed.S., gave tirelessly throughout her life to the fields of infant mental health, hospital staff support, and neonatology. This became abundantly clear during the recent annual National Perinatal Association Conference (held December 2-4, 2020)."

"My mom never let me forget that I was her first priority and the love of her life. But, I always knew that her (very close!) second priority was her work. For as long as I can remember, I've known that the babies, parents, and staff of every NICU she worked in were like a second family. I am so incredibly proud to be her daughter, and I hope I have even a fraction of the impact that she did."

"It is not so much what we have in this life that matters. It is what we do with what we have." – Fred Rogers.

Ms. Cheryl Ann Milford, Ed.S., gave tirelessly throughout her life to the fields of infant mental health, hospital staff support, and neonatology. This became abundantly clear during the recent annual National Perinatal Association Conference (held December 2-4, 2020). Many touching tributes and special memories were shared among conference participants. Some of those memories, among others, are shared here to honor the late, great Cheryl. Cheryl lived in Huntington Beach, California, with her beloved cairn terriers Nessa and Baxter. She passed away on February 29, 2020.

"Perhaps the only time we can truly recognize a huge contribution is when we are grieving the loss of all that Cheryl has given to us."

"Cheryl was like a second mother to me... she took people under her wing without ever expecting anything in return. She was the epitome of generosity and selflessness...it is undeniable that through her influence and love, she left this world brighter, kinder, and overall better than it was before she came."

Cheryl practiced as a neonatal psychologist for over 40 years. She spent 34 of those years providing psychological, neurodevelopmental, and infant mental health services in neonatal intensive care units (NICUs) and developmental follow-up clinics.

Cheryl graduated from high school in 1972, earned her B.A. in psychology (1976), M.A. in psychology (1977), and her Ed.S. in school psychology (1978) at Western Michigan University. She was certified as a School Psychologist in both Michigan and Pennsylvania and practiced as a school psychologist in the East De-

troit Public Schools until 1982. In 1983, her work in early childhood and infancy began, and she served as a psychologist and coordinator of the developmental follow-up program for St. Francis Hospital in Tulsa, Oklahoma. She was a Clinical Professor of Pediatrics at the University of California, Irvine Medical Center from 1985-1993, where she served as the Developmental Director of the HOPE clinic (which provided support for opiate exposed neonates and their families). She attended The Interdisciplinary Council on Developmental and Learning Disorders Graduate School to pursue her Ph.D. between 2011 and 2014. She was a licensed educational psychologist in the State of California until her untimely passing.

"Cheryl was a force. Her tenacious spirit and desire to help others made such a great difference in so many lives. Her legacy most certainly will carry on for generations to come"

"Cheryl was a force. Her tenacious spirit and desire to help others made such a great difference in so many lives. Her legacy most certainly will carry on for generations to come"
"You never had to wonder what she was thinking because she always told you, that is one of the many things I loved about her."

Cheryl was passionate about **neonatology**. She served as an expert witness in numerous medical malpractice and neonatal cases and a neonatal psychologist for Children's Hospital and Magee-Women's Hospital in Pittsburgh, PA. During her 21 years as a neonatal psychologist in Pittsburgh, PA, Cheryl chaired or co-chaired multiple committees focused on family-centered care, coordinated the neonatal follow-up clinic, and administered weekly NICU discharge rounds. She helped create and implement comprehensive developmental programs at both the NICU of

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Magee-Women's Hospital and the Children's Hospital of Pittsburgh.

"Your selfless giving to the "business" of advocacy and policy in the perinatal space put you as a leader and model to others."

Cheryl's **research** primarily focused on nursing practice environments and NICU outcome. She was Primary Investigator or Co-investigator on multiple studies and was involved in multiple trials examining the Magee Neonatal Feeding Assessment. She was interested in the impact of interventions in the NICU including adaptive car seat inserts, antidepressant use during pregnancy, music therapy, co-bedding, and delivery room resuscitation. Publications included multiple chapters, manuscripts, and internet contributions related to implementing family centered nursing care and promoting best practice in NICU follow-up settings.

"She was profoundly motivated to provide the best for those who were most at risk."

Cheryl was a leader in the **promotion of staff wellness**. Her independent practice: Cheryl Milford Consulting Innovative Service for the NICU, Infant Mental Health & Early Intervention Agencies and Professionals was created to reduce burnout among professionals in intensive and critical care units. She was proud of her program: Caring for the Caregiver: Supporting Optimal Mental Health for NICU Staff to be taught bedside to ensure optimal mental health for NICU staff. Components included self-care, staff support, developing a supportive staff culture in the NICU, and best practice.

"When she left clinical practice, and the opportunity came up to become more involved at NPA, she was thrilled... she felt like she had found "her people," professionals and advocates that shared her passion and love for improving the

lives of children and families."

"Cheryl is part of the DNA of NPA."

Never one to sit still, Cheryl became **Director of Development/Outreach for the National Perinatal Association (NPA)** in 2017. This role combined her passion for infants and young children, support for vulnerable families, and interest in creating a personal and professional connection with like-minded nonprofit and industrial partners. It is through the NPA that many of us first met our beloved Cheryl.

"She was an invaluable asset and a tireless worker, totally devoted."

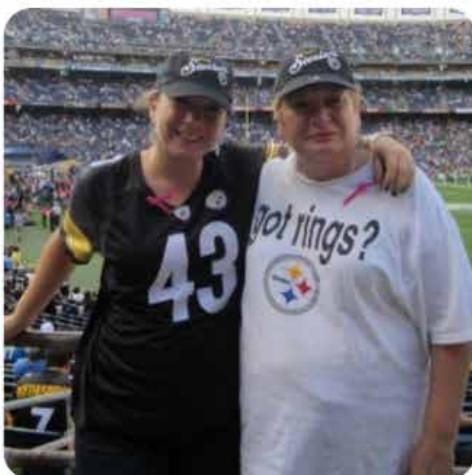
"She was the most cerebral down to earth intellect I've ever known." Cheryl was passionate about **education**. She served as an adjunct professor at Chatham University (2008-2016) and as a lecturer in Infant Mental Health through the University of Pittsburgh (2016-2018).

"She was a loving combination of friend, co-worker, drill sergeant, cheerleader, and wise sage advisor."

Cheryl volunteered her time to many national and international organizations, including the National Perinatal Association (NPA), Postpartum Support International (PSI), the World Association for Infant Mental Health, the California Association for Infant Mental Health, and the Pennsylvania Association for Infant Mental Health. She was both a founding member and past Vice-President of the Pennsylvania Association for Infant Mental Health.

"I am sure that her mentorship was one of the reasons that our membership of NICU psychologists has grown. Cheryl had experienced everything that could happen in the NICU."

"She was a mentor, friend, confidant, buddy, and my inspiration in so





many ways."

Cheryl was a mentor and friend to everyone fortunate enough to know her. Along with Dr. Michael Hynan, she provided structural expertise, guidance, and mentorship, for the newly reorganized National Network of NICU Psychologists.

Cheryl would say it is the little things that give life its richness and meaning. Thank you, Cheryl for the million little things you shared, the laughter, joy, and tears. Our lives are better because of you.

"You will always be remembered. You will always be treasured. You will always be loved."

On Behalf of the National Perinatal Association (NPA) and the National Network of NICU Psychologists (NNNP)

Conflict of Interest Disclosures: The author has no conflicts of interest to disclose.

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

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Note from the editor:

Cheryl meant so much to so many. I met Cheryl as a Fellow during my training at University of California, Irvine. She transcended traditionally boundaries, impacting so many families and perhaps, more than she even realized, clinicians as well. She made a huge impact on me and my approach to patient care. Cheryl was someone I could talk to who could relate to me at all levels of my career. She and I also worked together at Loma Linda Children's hospital and of course, the National Perinatal Association.

The last time we talked, at dinner, just before COVID times, she recounted the story of how Lou Gluck, MD, the Division Chair and renown academician, insisted on attending at the birth of her daughter. Somehow, what should have been routine was at once transformative. Cheryl knew how to tell a story. I wish I had the chance to sit with her and hear a few more.

As we look forward to new challenges in our field, we should not forget those who brought us to where we are today. Cheryl, may your memory always be honored by those whose lives you have touched.

*Mitchell Goldstein, MD
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SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS

DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing
the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA



EVIDENCE

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

PARTNERSHIP

What is the best
for this unique dyad?

SHARED DECISION-MAKING

- S**EEK PARTICIPATION
HELP EXPLORE OPTIONS
ASSESS PREFERENCES
REACH A DECISION
EVALUATE 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**



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NICU Awareness



Did You Know?

Most NICU babies have special needs that last longer than their NICU stay. Many will have special health and developmental needs that last a lifetime. But support is available.

Learn about the programs in your community. Seek out other families like yours. Then ask for help. Working together we can create a community where our children will grow and thrive.

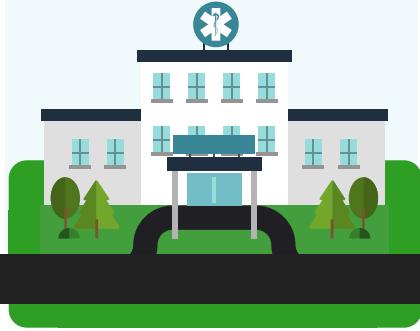
Special Health Needs

Babies who have had a NICU stay are more likely to need specialized care after they go home. **Timely follow-up care is important.**

NICU babies have a higher risk for re-hospitalization. So every medical appointment is important. Especially during cold and flu season when these babies are especially vulnerable to respiratory infections.

Who Can Help

- pediatricians
- neonatal therapists
- pulmonologists
- neurologists
- gastroenterologists
- cardiologists
- nutritionists
- CSHCN - Programs for Children with Special Health Care Needs



Special Developmental Needs

Any NICU stay can interrupt a baby's growth and development.

Needing specialized medical care often means that they are separated from their parents and from normal nurturing.

While most NICU graduates will meet all their milestones in the expected developmental progression, it is typical for them to be delayed. This is especially true for preterm infants who are still "catching up" and should be understood to be developing at their "adjusted age."

Who Can Help

- IBCLCs and lactation consultants
- Early Childhood Interventionists
- developmental pediatricians
- occupational therapists (OTs)
- physical therapists (PTs)
- speech therapists (SLPs)
- WIC - Special Supplemental Nutrition Program for Women, Infants, and Children
- social workers and case managers



Special Educational Needs

Every child has their own unique developmental needs and **every student has their own unique and special educational needs.**

Take advantage of the services and support that can meet your child where they are and help them reach their future educational goals.

Call your local school district to request a free educational evaluation. Learn about all the available programs and support.

Who Can Help

- Preschool Program for Children with Disabilities (PPCD)
- Special Education programs under the Individuals with Disabilities Education Act (IDEA)
- educational psychologists
- speech therapists (SLPs)
- occupational therapists (OTs)
- reading specialists



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The Gap Baby: An RSV Story



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



The National Coalition for Infant Health advocates for:

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

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Preventing RSV Should Not Be a Fight

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

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



Preventing COVID-19 is not the only fight parents may face this winter. They may also battle to shield their infant from a deadly respiratory syncytial virus. And their insurers may not be as cooperative as one would hope.

"RSV is the leading cause of hospitalizations among babies less than one-year-old."

(1) Among high-risk infants, the virus is associated with prolonged intensive care and mechanical ventilation. (2)"

RSV is the leading cause of hospitalizations among babies less than one-year-old. (1) Among high-risk infants, the virus is associated with prolonged intensive care and mechanical ventilation. (2) Preventive treatment, called palivizumab, decreases RSV-related hospitalizations and reduces infections by 55%. (3) Despite palivizumab's effectiveness, health insurers regularly deny access to the treatment.

In fact, a report card from the Institute for Patient Access shows commercial health plans reject 40% of prescriptions for infants born prematurely between 29 and 36 weeks' gestation. Under Medicaid, prescriptions are rejected for one in four of these infants. (4) The report card is based on nationwide claims data from January through December 2019. "Insurers often cover preventive treatment only for the most premature, those born before 29 weeks gestation," according to the report card. Even then, 25% of those severely premature babies have their palivizumab prescription rejected by a commercial insurance plan. (4)

"Health plans' denial of preventive RSV therapy may stem from controversial guidelines issued by the American Academy of Pediatrics."

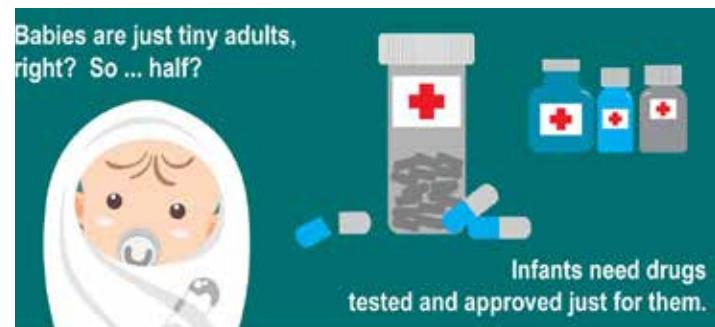
Health plans' denial of preventive RSV therapy may stem from controversial guidelines issued by the American Academy of Pediatrics.

In 2014, its Committee on Infectious Disease recommended limiting palivizumab to only severely premature infants born before 29 weeks gestation. This recommendation, however, is more limiting than the medication's FDA label. Palivizumab is indicated for three groups:

1. All babies with congenital heart disease
2. All premature infants born before 36 weeks gestation
3. Babies born before 32 weeks gestation with chronic lung disease

Health care providers understand the FDA label and prescribe palivizumab for infants who need it. Health insurers that deny access to the therapy do so against providers' medical judgment and knowledge of their patients' health.

Insurance denials leave babies vulnerable to contracting RSV, experiencing unnecessary hospitalization and susceptible to its long-term consequences. Meanwhile, parents are left reeling and



unsure of how to proceed. Health care providers can support parents in the fight for access to preventive treatment, up to and including appealing insurance denials.

Parents should never have to fight for treatment that keeps their babies healthy. But insurers' objections this winter make even less sense with hospitals strained from COVID-19 and ventilators scarce.

For almost a year, the nation has been focused on preventing the spread of coronavirus. While that is still important, let us not forego opportunities to protect vulnerable infants from RSV since a preventive treatment is available.

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Disclosure: The Alliance for Patient Access is affiliated with the Institute for Patient Access and the National Coalition for Infant Health, which supported the development of the RSV Report Card.

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info@allianceforpatientaccess.org

Still a Preemie?

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

But that's not every preemie's story.

Born between
34 and 36 weeks'
gestation?

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



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



Born preterm
at a "normal"
weight?

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

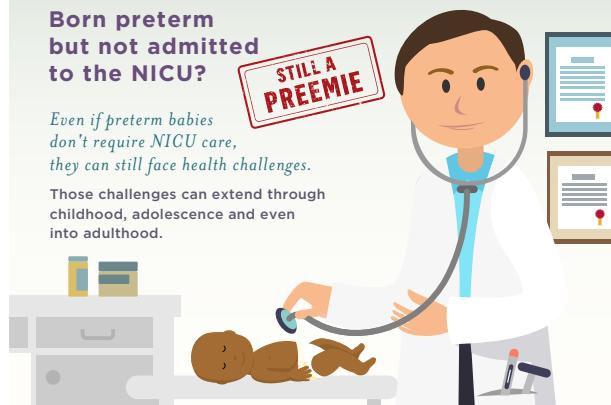
But because some health plans
determine coverage based on a
preemie's weight, families of
babies that weigh more may
face access barriers and
unmanageable medical bills.



Born preterm
but not admitted
to the NICU?

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

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



Some Preemies

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

All Preemies

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

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

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Ethics in Whole Genome Sequencing

Toni Lewis, MS

How much information is too much information?

The use of whole-genome sequencing (WGS) in diagnostic testing brings up the topic of secondary findings or incidental findings for many clinicians. Secondary findings are variants associated with a condition other than the one for which the patient is tested. For instance, if a newborn baby has a suspected illness detected on prenatal ultrasound and the infant is tested – would it be ethical for a clinician to disclose other medical conditions that the child may experience as an adult? The patient may not currently have any symptoms associated with the condition but may be at risk of developing it in the future.

Another example would be a three-year-old girl tested to identify the cause of her seizures and developmental delays. At the same time, through WGS, it is found that she has a BRCA1 variant that puts her at a higher risk of developing breast cancer years down the line. This information is not relevant to her current condition, but is it relevant for her future health?

This topic is particularly relevant for WGS because the entire DNA is sequenced, providing access to the individual's complete genomic information. This same level of access is not possible with more targeted single gene or panel tests.

The American College of Medical Genetics [published recommendations](#) to labs performing whole-exome and whole-genome sequencing. (1) They identified a list of 59 genes with known disease associations, for which there is some actionability. Labs commonly refer to this as ACMG59. Most of the genes are involved with cancer or cardiac conditions.

It is typical for labs to provide patients undergoing WES or WGS testing to opt into receiving findings in these genes. But other variants may also provide valuable, actionable information. An example is variants in the HFE gene, which can cause hereditary hemochromatosis, a disorder that causes the body to absorb too much iron from food. Excess iron is stored in organs like the liver, heart, and pancreas; it can lead to life-threatening conditions like liver disease, heart problems, and diabetes. If individuals know that they have hereditary hemochromatosis, these conditions can be avoided, but symptoms often do not appear until they are in their 40s.

Ethically, it is also a challenge, as some patients will want to know about conditions that they are at risk of developing, and others will not. This situation is why most labs provide the ability to opt-in or out of these types of findings. Explaining the types of findings that may be reported is an essential part of the consent process for genetic testing, which often involves a genetic counselor. But with what genes do you draw the line?

As a bigger picture, WGS provides a resource for life. Since the patient's entire DNA has been sequenced, it is possible to look at it for any number of reasons throughout the individual's lifetime.

Initial testing may be done to address a specific set of symptoms. If the individual develops different symptoms later in life, the sequence can be revisited to extract the information needed at that time.

“So how much information is too much information? How much should patients know early on, and how much should they learn when necessary? These questions must be answered individually for each patient as part of the consent process, within the context of the secondary findings policy of the lab performing the testing.”

So how much information is too much information? How much should patients know early on, and how much should they learn when necessary? These questions must be answered individually for each patient as part of the consent process, within the context of the secondary findings policy of the lab performing the testing.

References:

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3727274/>

Disclosure: Toni Lewis, MS, is a Field Genetic Counselor at Variantyx, a provider of highly specialized genetic testing to clinicians and their patients. Christine is responsible for overseeing clinical genomic interpretations and regulatory compliance for the clinical laboratory.

NT

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Welcome to iCAN

Amy Ohmer



"Founded in 2014 by Dr. Charlie Thompson, iCAN, a registered 501(c)3, has grown to represent children ages 8-18 on four continents in over 29 (including one virtual) chapters. This unprecedented growth results from the strong partnerships between the American Academy of Pediatrics, Georgia Tech, other academic institutions, and a large number of hospitals and other committed stakeholders."

Wrapping up the end of a very busy 2020, the International Children's Advisory Network, Inc. (iCAN), is proud to announce our year-end in review. Founded in 2014 by Dr. Charlie Thompson, iCAN, a registered 501(c)3, has grown to represent children ages 8-18 on four continents in over 29 (including one virtual) chapters. This unprecedented growth results from the strong partnerships between the American Academy of Pediatrics, Georgia Tech, other academic institutions, and a large number of hospitals and

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other committed stakeholders. Led by iCAN President and Chief Engineer of Pediatric Technologies at Georgia Tech, Ms. Leanne West, the goal remains unchanged. Shares Ms. West, "iCAN is here to ensure that every child, especially those living with rare, complicated, and chronic conditions, has a voice in medicine, technology, research, science, and innovation around the world. Through our global reach at iCAN, kids (and parents) can connect to share their experiences to better improve all facets of healthcare."

"Rounding out the fall, iCAN launched the "Ask the Experts" monthly virtual series hosted by Dr. Anthony Chang, Founder, AIMed and ISPI, and Chief Intelligence Officer, CHOC. This novel approach connects young patients to medical professionals, researchers, scientists, and other stakeholders to learn about innovation and opportunities within healthcare, science, and research."

In the spring, iCAN launched several exciting new initiatives such as the "Seal of Approval," a program designed to share when materials or programs are kid reviewed and kid-approved. This unique seal shows that kids have provided their special brand of feedback to make it easier for other kids to understand the content.

During the summer months, iCAN created an exciting program known as "Young Adult Professionals" to better support youth beyond 18 years old and who want to continue to stay connected through internship opportunities, advocacy, research, or other community endeavors. Launched in conjunction with the 2020 iCAN Advocacy and Research Summit, this program offers ongoing opportunities for furthering education.

Rounding out the fall, iCAN launched the "Ask the Experts" monthly virtual series hosted by Dr. Anthony Chang, Founder, AIMed and ISPI, and Chief Intelligence Officer, CHOC. This novel approach connects young patients to medical professionals, researchers, scientists, and other stakeholders to learn about innovation and opportunities within healthcare, science, and research.

Dr. Alison Parker and Dr. Tracy Scull, Research Scientists at innovation Research & Training (iRT), have created *DigiKnowIt News*, an interactive, multimedia website designed to educate children about pediatric clinical trials and help them when deciding whether or not to participate in a future clinical trial (<http://digiknowit.com/>). They were recently awarded a grant from the National In-

stitute of Nursing Research (NINR) to create a DigiKnowIt News version specifically for teenagers and their parents.

Youth and parents from iCAN have provided feedback on *DigiKnowIt News* throughout the development process. iCAN will be helping Drs. Parker and Scull to set up virtual Advisory Panels with iCAN teens and parents to get feedback on the teen version of *DigiKnowIt News*. This feedback will be used to create a new version of *DigiKnowIt News* that is relatable and useful to teens and their parents.

iCAN is already planning for the upcoming 2021 Research and Advocacy Summit in Lyon, France, from July 12th - 16th. Sponsorship is open, and we are seeking a call for papers to showcase the work being done to support pediatric innovation. All are invited to attend, and more details may be found at www.icanresearch.org

The author has no conflicts of interests to disclose.

NT



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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



Respiratory Syncytial Virus is a

Really Serious Virus

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

Coughing that gets worse and worse



Breathing that causes their ribcage to "cave-in"

Rapid breathing and wheezing



Bluish skin, lips, or fingertips

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

Call your doctor and meet them at the hospital.

If your baby isn't breathing call 911.



Thick yellow, green, or grey mucus

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

Fever that is higher than 101° Fahrenheit

which is especially dangerous for babies younger than 3 months



www.nationalperinatal.org/rsv

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RSV



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Protect vulnerable babies and children.



The Demise of Private Practice

Kenneth L. Saul, MD

Not long ago, when a preemie went home from their NICU, they could be referred to a host of private practices offering continuity with one doctor, availability every day, and open communication with the parents with that one doctor familiar with the particular complex case.

However, there are fewer and fewer private practices as economic pressures favor larger entities that have negotiated contracts with third-party payers. These contracts are paid double or triple what independent practices are paid, not to mention how much cheaper supplies can be bought for those larger entities. Because of this, large entities can offer nurses higher salaries and pay new doctors out of training more money. This all gradually erodes independent practices of their ability to stay in business.

Some private practices have attempted to renegotiate their third-party contracts by offering extended hours, cell phone access, weekend hours, suturing, blood draws, etc., in order to get better rates. However, I know of no cases where an independent practice has been offered anywhere close to large entity rates even with an equal or better quality of care and individualized service and follow through. This is true even with professional negotiating help.

In addition to this, most of the independent contracts offered have multiple codes that pay less than the cost on such items as breathing treatments, antibiotic injections, steroid injections, viral testing, and some vaccines.

“Some independent practices have responded to this stone wall by charging a concierge or administrative fee to the patient or balance billing the patient for items that are paid at less than the payer’s cost. They might also send patients to the more expensive ED or urgent care for these underpaid items.”

Some independent practices have responded to this stone wall by charging a concierge or administrative fee to the patient or balance billing the patient for items that are paid at less than the payer's cost. They might also send patients to the more expensive ED or urgent care for these underpaid items. The payers I have talked to insist it is illegal for a PPO provider to charge a concierge or administrative fee or balance bill. They insist that paying \$5 for a \$40 cost item is still a covered benefit that can only be billed to the health plan. I contend that insurance companies should have

an obligation to pay reasonable and customary fees for services, and they argue that they only have an obligation to pay usual and customary charges where they decide what is usual.

“The result of all this is the obvious erosion of independent practice, with new doctors preferring to work salaried positions for large business entities rather than being their own boss. If this is what the recent graduates want,”

The result of all this is the obvious erosion of independent practice, with new doctors preferring to work salaried positions for large business entities rather than being their own boss. If this is what the recent graduates want, it is their choice, but what about equal pay for equal work or antitrust rules? The Academy of Pediatrics and the CMA are always there to fight for Medi-Cal and CCS causes as well as a huge number of great social causes. However, we also need them to lobby for a level playing field and the preservation of independent practices. By doing so, they can also combat the skyrocketing of overall healthcare costs caused by this unequal payment system.

Disclosure: The author is a pediatrician in private practice.

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- **The Lancet:** COVID-19 and pregnancy
- **MotherToBaby:** Coronaviruses
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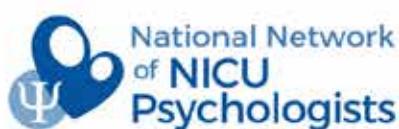
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Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

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

Teach families how to protect



their babies from respiratory infections

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



Use your best clinical judgement



when prescribing RSV prophylaxis

Tell insurers what families need



and provide the supporting evidence

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

Survey Says: RSV

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

Hospitalization

Lifelong health complications

Death

for infants and young children



ACCORDING TO A NATIONAL SURVEY,

Specialty Health Care Providers say:

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

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

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



But Parents are Unprepared.

Only 18% know "a lot" about RSV

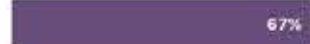
Only 22% consider themselves "very well" prepared to prevent RSV

RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:



"More concerned" about their child contracting the disease



Likely to ask their doctor about RSV



 National Coalition for Infant Health

Promoting better health for infants through age two
www.infanthealth.org

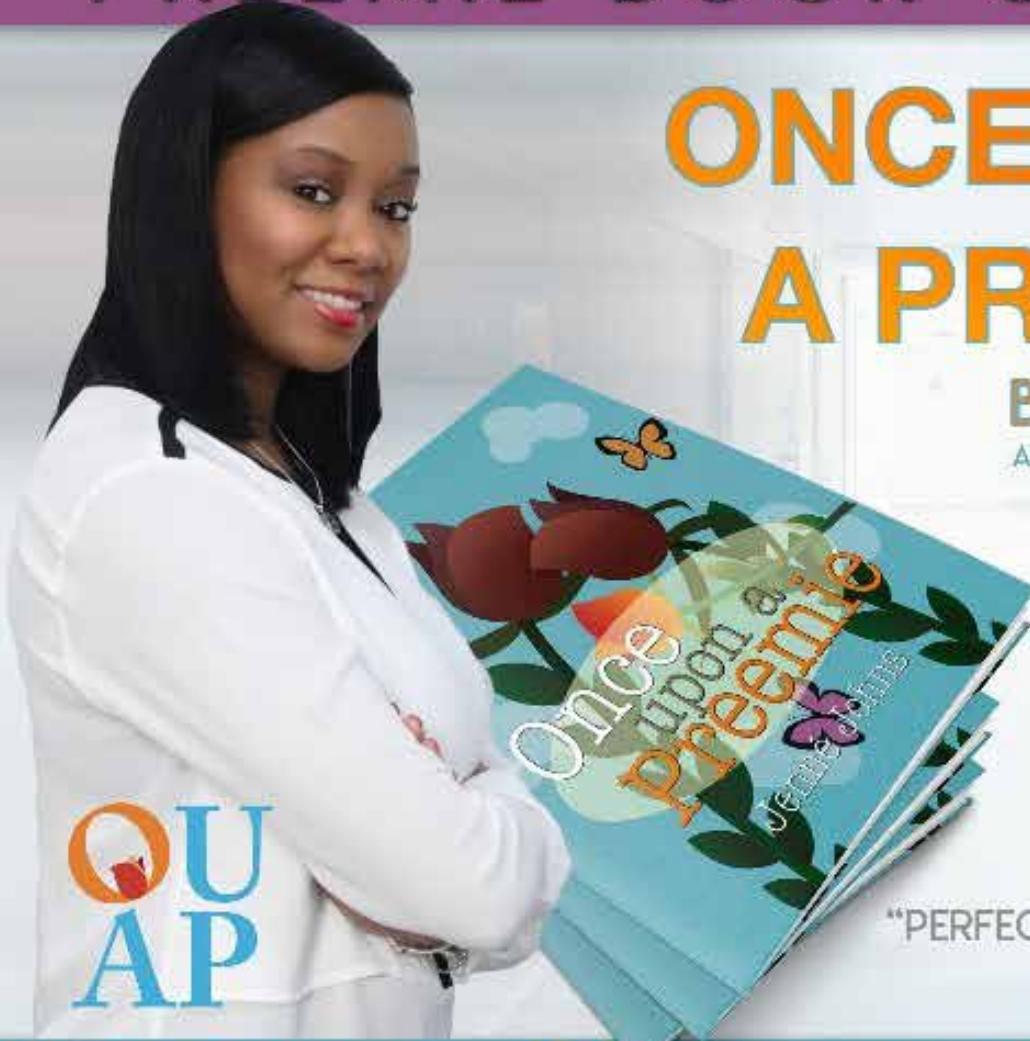
Learn More about RSV at
www.infantHealth.org/RSV

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ONCE UPON A PREEMIE

BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE



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"PERFECT FOR PREEMIE FAMILIES"

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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 16% 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:

65%

"More concerned" about their child contracting the disease

67%

Likely to ask their doctor about RSV



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



Salting Newborns, the Skin Barrier from Antiquity to Today

Eugene L. Mahmoud, MD

Although salting of newborns has been a practice claimed to be part of indigenous culture from antiquity up to the present day, it is a practice not well understood. The purpose of this article is to look at the existing evidence for the use of salting newborns down through time in order to help us understand how this agent and other agents are used to protect the newborn skin against foreign agents and damage after birth.

It is apparent from ancient times that the health of newborns was closely connected to the ability of the skin barrier to protect from objects and agents of illness. Midwives and elderly female relatives helped transmit the benefits believed in salting babies, which included protection from putrefaction, hygiene, morals, warding off evils, preventing a bad smell, and preventing sweating. The Bible in the Book of Ezekiel (King James Version) Chapter 16 Verse 4 portrays the use of salting newborns at birth as a metaphor that compares Jerusalem to an abandoned child:

"And as for thy nativity, in the day thou wast born thy navel was not cut, neither wast thou washed in water to supple thee; thou wast not salted at all, nor swaddled at all".

Dioscorides, Galen, and Soranus of Ephesus are three great physicians from the Greco-Roman Era of Medicine who were aware of the cleansing properties of salt. Dioscorides (40 – 90 A.D.) wrote an encyclopedia, *Materia Medica*, that was used for centuries after his death. During this time in the care of the newborn, regimens for the care of newborns, as well as older children, were included in the medical texts of Gynecology. While Galen recommended that newborns be treated almost like hams being cured to harden the skin, Soranus cautioned against salt entering the eyes or mouth, as it may produce ulceration, severe inflammation, or suffocation. And much salt should not be besprinkled, for by too great pungency the physique, which is still tender and very weak, is corroded, nor with little, since the surface is not rendered sufficiently firm.

"The rise of the Islamic Civilization in the Middle Ages produced many outstanding physicians, who were influenced by the medicine of Galen and Soranus."

The rise of the Islamic Civilization in the Middle Ages produced many outstanding physicians, who were influenced by the medicine of Galen and Soranus. The Three Outstanding Physicians known during the Islamic Civilization were Aboo Bakr Muhammad ibn Zakariyyah al-Razi (Rhazes) (865-925), 'Ali ibn al-'Abbas al-Majusi (Haly Abbas) (d. 994), and Abu 'Ali al-Husayn ibn 'Abd Allah ibn Sīnā (Avicenna) (980-1037).

In his medical textbook, 'Al Mansour,' dedicated to a prince, Al Rhazes, speaks of neonatal care without explicitly stating the sub-

stances with which the newborn should be sprinkled or anointed. The baby's ears should be sucked as he is being born and after. Beware that the milk does not enter [the ears] during nursing. The newborn's palate must be rubbed with honey, and it is necessary to clean his nose by rubbing it with hot water and oil and wiping it. You must also rub and anoint him, stretch out his members in [the appropriate] directions, swaddle him and settle the parts of his head, the forehead, and nose. With these cares, the child is protected against a large number of diseases. And Al Majusi, in his book, 'The Complete Art of Medicine,' on 'The Regimen of the Baby's Bodies', in Chapter 20 of Volume Two, Article One, starts by mentioning:

'However, when a child is born, it should be sprinkled on him with powdered salt and roses reduced to strengthen the skin by it against the air'.

He then goes on to mention other substances applied to the body and the washing of the baby. Whereas, Avicenna who was by far the most prestigious source in Arabo-Islamic medicine and the well-known Arabic physician in Europe, his book, 'The Canon of Medicine' says on Childbirth and the Care of the Skin:

'The face and the body of the newborn should be bathed in salt-water to harden the skin and set the features. The best salt for this purpose is the One, which contains a small quantity of seeds of Indian hemp, costus root, fumitory, fenugreek, and origanum. The saline bath could be safely repeated if the body is found to be still dry or covered with secretions.'

"It is the story of contact and cultural exchange across countries and creeds, affecting caliphs, kings, courtiers, courtesans, and the common crowd. In addition to being fascinating in its own right, medieval Islamic medicine is also important because of its influence on Europe, where it formed the roots from which modern Western medicine arose."

Forcada's study from Spain offers a full and careful historical study of the practice.

The medical tradition that developed in the lands of Islam during the medieval period has, like few others, influenced the fates and fortunes of countless human beings. It is the story of contact and cultural exchange across countries and creeds, affecting caliphs, kings, courtiers, courtesans, and the common crowd. In addition to being fascinating in its own right, medieval Islamic medicine is also important because of its influence on Europe, where it formed the roots from which modern Western medicine arose. The earlier Graeco-Roman scholarly medical literature was the stem from

which much Islamic medicine grew, just as, several centuries later, Islamic medicine was to be the core of late medieval and early European medical education. As will be seen in the following, Islamic medicine was a venue for innovation and change.

Depending on the country and climate, some recommended that the infants should be washed, as soon as they are born, with fenugreek water and barley flour; others suggested that to the salt should be added myrtle, rose, laurel leaves, pistachio tree leaves, costus or malabathron, either separately or mixed one another. It was necessary to employ these samples according to the temperaments of the countries which are hot, it may be cold regarding the infant's temperament, and that those which are cold, it may be hot regarding the infant's temperament. He who thinks that only salt suffices for achieving a balanced temperament will think that salt is enough. As for what is mixed in the water with which the infant is bathed, one must follow the very same method. The method of adding what the physicians think best is according to a particular climate, as well as the oral tradition of midwives and old women that carried forth these methods. For this reason, the country must have its own method and custom whose inhabitants follow. All this suggests a fairly consistent picture of a widely dispersed practice which is ill-understood, yet which persists in any case.

During the middle of the 12th century, Spain's Ibn Zuhr was the only voice raised against the application of salt on newborns,

"The infant's body is like fresh cheese because his members have soft bones and. The midwife must correct what needs to be corrected with extreme care and patience. If she bathes the child, she must do so with lukewarm and sweet water, as long as he resists and avoiding that the air should damage his body."

Ibn Zuhr's opinion was that salt burns them and possibly makes them sleepless when they cannot endure the pain, and insomnia makes them weak. He says:

"I think that salt is not convenient for his body, and it seems that there are other things for the same purpose better than salt, such as acorn oil. This has the same effect of hardening, but it neither burns nor causes insomnia."

This innovation of change stems not from a systematic empirical search, nor an a priori rereading of Greek sources along Aristotelian lines. It is a simple amendment suggested either by experience, common sense, and deduction or by all these factors conjointly, just like many other criticisms and innovations which frequently appear in Arabo-Islamic medical sources. Since Galen's recommendation indicated that one should administer astringent and cleansing substances to the newborn's skin, Ibn Zuhr might have thought that acorn oil was preferable because it does not irritate. Also, other astringents were used, such as henna. Because of this, an ointment with acorn oil became a regular feature of treatises on Obstetrics and Newborn Care written leading to the Renaissance of Spain and Europe.

Different methods of salting are still used in today's Turkey as well as other parts of the world such as the Middle East, India, China. This practice is performed with the assumption that it would (a) avoid the bad smell of the body sweat from the newborn, (b) decrease sweating, (c) strengthen the muscles and bones, (d) prevent infections, and (e) ensure that injuries would heal fast. Also, it is believed to deter supernatural beings and evils; salt is tradi-

tionally used with the assumption that it would not bring disease and death. Skincare practices during the immediate neonatal period and in infancy can affect the maturation and function of the epidermal barrier.

"Some studies have revealed in the literature that an extensive amount of salt may cause absorption of sodium through the skin and thus epidermolysis and hypernatremia, which is a life-threatening disease with symptoms of dry or burnt-like skin. "

Some studies have revealed in the literature that an extensive amount of salt may cause absorption of sodium through the skin and thus epidermolysis and hypernatremia, which is a life-threatening disease with symptoms of dry or burnt-like skin. In many cases of salting in which the newborn babies were brought to hospitals, it has been observed that numerous medically dangerous conditions such as hypernatremia, renal failure as a complication of hypernatremia, dehydration, neonatal convulsion, skin lesions, hyperbilirubinemia, intracranial bleeding, and even death can occur. Gangrene cases have also been observed among newborn babies due to salting. Even though the salting practice is not common in the United States and urban areas of developed countries, the Emergency Room Department and Urgent Care Centers should be aware of salting practice and its results while in their evaluation of the newborn.

The normal anatomy of the skin consists of a complex of a multi-functional organ that interfaces with the organism and the environment.

Forming from the embryonic ectoderm, the epidermis contains appendages of hair follicles, sweat glands, and sebaceous glands. The main bulk-forming the dermis is derived from the embryonic mesoderm and consists of collagen embedded in a hydrated matrix of glycosaminoglycans. In addition, the epidermis is composed of multiple cell types.

1. The stratum basale, is for keratinocyte proliferation and epidermal renewal.
2. The stratum spinosum consists of tightly packed keratinocytes linked by desmosomal connections.
3. The stratum granulosum is responsible for barrier lipid synthesis and corneocyte production by programmed cell death.
4. The anucleated outermost layer, the stratum corneum, which forms the interface with the environment is lacking or diminished in the Very Low Birthweight Newborn.

Research supports the hypothesis that vernix caseosa (a product of sebaceous secretions) participates in regionally "waterproofing" the skin surface.

After birth, the skin must immediately perform multiple functions vital to the survival of the organism.

The functions include the production of sweat, which is important

for thermoregulation and bacterial homeostasis. And the acid mantle is important for production of a natural moisturizing factor, as well as hydrolysis of triglycerides and lactate generation.

It is important to understand the “barrier function of skin” which mainly resides within the stratum corneum layer of the epidermis. It consists of the keratinocytes (constituted by proteins and lipids) embedded in a lipid rich matrix, consisting of cholesterol, ceramides and fatty acids. Another class of lipids also, is secreted at the surface of the epidermis which when in contact with the environment, interacts with water forming a hydrophilic film which is important for maintaining the moisture content and sensorial attributes of the skin. The lipid fraction of this hydrophilic film can penetrate in the upper layer of the epidermis merging with the epidermal barrier and also contributing to its functions. This is extremely important when considering what cleanser to apply on the newborn skin. Another important developmental variation of the infant skin is the “acid mantle” or the functional capacity of the skin to form a surface pH of less than 5. There is close association between the skin surface pH and its microbial flora, because an increased skin pH from acidic to neutral can cause a transient increase in the total number of skin bacteria and a shift in the species present. Therefore, it is important to maintain this acid mantle on the baby’s skin.

Today the Association of Women’s Health, Obstetric and Neonatal Nurses and the National Association of Neonatal Nurses (AWHONN/NANN) have evaluated the skin condition of the newborn based on the dryness, erythema, and skin breakdown. Those newborns who did present with these findings did benefit in each three (3) conditions from guideline-based therapy, such as emollients. As the skin of the newborn is susceptible and sensitive to trauma and infection and requires special care, all soaps, cleansers, powder and synthetics, should be used with proper indications and cautious judgement with evidence-based recommendations for the care of newborn skin that should be integrated into the routine practice.

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Coding Question for Neonatology Today: December 2020

Kate Peterson Stanley, MD

Yesterday, your neonatology colleague, Dr. Smith, admitted via transfer from a referral hospital a newborn 24-week, 550-gram infant delivered by cesarean section secondary to maternal pre-eclampsia. The infant has respiratory failure due to RDS and is on mechanical ventilation. Dr. Smith made daily rounds earlier and has reported a global daily critical care code 99469. You are the attending physician on-call and are notified by nursing staff during the evening sign-out that the infant is hypotensive. Bedside exam shows a poorly perfused infant requiring increased oxygen support. After initiating a sepsis evaluation and antibiotic therapy, you obtain a CXR, which shows severe RDS. You recently completed a training program in point of care ultrasound and received privileges at your institution to use this tool. You perform a limited ultrasound evaluation, including five standard views (parasternal long- and short-axis, apical four-chamber, subcostal, and inferior vena cava views) of the infant's cardiac structure and function. Results show normal cardiac structure, including cardiac valves and inflow/outflow tracts. However, there is poor right ventricular cardiac function, elevated pulmonary pressures, and a moderate PDA with right to left shunting, and you decide to begin inotropic therapy. The total time for your evaluation is 45 minutes. In addition to documenting the infant's change in status in a progress note, you write a separate report describing the normal and abnormal echocardiographic findings in all five views. The echocardiographic images are recorded and stored in the hospital's Picture Archiving and Communications System (PACs).

In addition to the global daily critical care code, 99469, reported by Dr. Smith, the correct CPT codes are:

- A. Evaluation and management of a critically ill patient, first 30-74 minutes: 99291
Limited/Follow up transthoracic echocardiography: 93308
- B. Limited/follow up transthoracic echocardiography: 93308
- C. Evaluation and management of a critically ill patient, first 30-74 minutes: 99291
Complete, transthoracic echocardiography: 93306
- D. Complete, transthoracic echocardiography: 93306

"In addition to documenting the infant's change in status in a progress note, you write a separate report describing the normal and abnormal echocardiographic findings in all five views. The echocardiographic images are recorded and stored in the hospital's Picture Archiving and Communications System (PACs)."



Correct Answer: B. Limited/Follow up transthoracic echocardiography: 93308

The use of point of care ultrasound (POCUS) is increasing in many NICUs to guide procedures and assist with clinical diagnosis and management. Competently trained providers may code and be reimbursed for their expertise when using this tool. Specific CPT codes vary depending on the anatomical region evaluated and whether the device is used during a specific procedure, such as thoracentesis. Three conditions are required when billing for POCUS: 1) the organ or anatomical area should be thoroughly evaluated, 2) the ultrasound findings are documented in a report within the medical record, and 3) the images are recorded and permanently archived according to local, state and federal regulations. In this specific scenario, the provider performed a limited evaluation of the infant's cardiac structure and function, documented the findings in a report, and stored the images in the hospital's PACs. Images can be retrieved as needed for clinical review, quality assurance, payer audits, or medical liability issues. Since this was a limited cardiac echocardiogram, the correct CPT code is 93308. Limited transthoracic echocardiography is defined as a follow-up or limited study that does not provide a complete evaluation of cardiac structures. Instead, it uses two-dimensional views to answer a clinical question or evaluate a specific structure(s).

In contrast, a complete transthoracic echocardiogram includes multiple two-dimensional views that evaluate the heart's entire structure with appropriate measurements, including the left and right atria, left and right ventricles, the aortic, mitral, and tricuspid valves, the pericardium and adjacent parts of the aorta. Both codes may include M-mode imaging if performed. If a structure cannot be identified or measured, the reason for lack of visualization should be documented in the record (e.g., technical, patient instability).

A: Incorrect: Although the limited/follow-up echocardiography CPT code is correct, the medical provider should not bill for providing additional hourly critical care. The bedside care performed and the echocardiogram are included in the global daily neonatal critical care code, 99469. In this scenario, your colleague, Dr. Smith, made daily rounds and entered the global daily care code.

C: Incorrect: The provider did not perform a complete transthoracic echocardiogram, which includes evaluating the entire structure of the heart and parts of the aorta and associated measurements. The bedside care performed and the echocardiogram are included in the global neonatal critical care admission code. In this scenario, your colleague, Dr. Smith, made daily rounds and entered the global daily care code.

D: Incorrect: The provider did not perform a complete transthoracic echocardiogram, which includes evaluating the entire structure of the heart and parts of the aorta and associated measurements.

ICD-10 codes would include:

Associated with CPT code 93308:

P29.0 Neonatal cardiac failure

Q25.0 Patent ductus arteriosus

P29.3 Persistent pulmonary hypertension of the newborn

Associated with CPT code 99469:

P22.0 Respiratory Distress Syndrome

P07.02 Extremely low birth weight newborn, 500-749 grams

P07.23 Extreme immaturity of newborn, gestational age 24 completed weeks

P29.0 Neonatal cardiac failure

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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!

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From The National Perinatal Information Center: Narrowing the Gap in Perinatal and Neonatal Disparities: The Race and Ethnicity Dashboard

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.



"In June 2020, the National Perinatal Information Center presented information on the importance of race and ethnicity reporting, particularly surrounding perinatal and neonatal outcomes. To understand outcomes necessitates the understanding of the communities that are cared for and the potential gaps that exist in quality care."

In June 2020, the National Perinatal Information Center presented information on the importance of race and ethnicity reporting, particularly surrounding perinatal and neonatal outcomes. To understand outcomes necessitates the understanding of the communities that are cared for and the potential gaps that exist in quality care.

Racial and ethnic disparities continue to generate widespread interest and concern, particularly among maternal morbidity and mortality researchers. Maternal outcome disparities, particularly maternal mortality, warrant immediate attention and focus on assuring a standardized care approach, rigorous quality assessment, and rapid cycle improvement. The wide variation in obstetrical outcomes across hospitals, poor overall performance on perinatal indicators, and the persistent racial and ethnic disparities in obstetric and perinatal outcomes require innovative remedies that tackle these challenges together(1). In 2019, expert obstetric disparities researcher Dr. Elizabeth Howell recommended the fol-

lowing eight (8) steps(2) for narrowing gaps in maternal outcome disparities:

- ✓ Enhance team communication
- ✓ Address implicit bias
- ✓ Implement a race and disparities dashboard
- ✓ Perform enhanced severe maternal morbidity and severe maternal mortality reviews
- ✓ Standardize care in Perinatal settings
- ✓ Promote a culture of equity
- ✓ Develop new models for Respectful Care
- ✓ Engage key stakeholders (internal and external)

"The efforts of utilizing a race and disparities dashboard illustrate hospital or system overall results and stratify these measures by race and ethnicity to understand and quantify the disparities that exist locally within a hospital or system."

The efforts of utilizing a race and disparities dashboard illustrate hospital or system overall results and stratify these measures by race and ethnicity to understand and quantify the disparities that exist locally within a hospital or system. Such dashboards are an important snapshot of performance, and the data contained therein can then be measured over time to monitor local quality improvement efforts(3). Dedicated and coordinated inpatient team efforts to reduce disparities, including documentation of race and ethnicity at the time of admission, must be a priority for those serving our communities. Earlier discussions included the importance of assuring self-reporting of race and ethnicity to enhance the quality and accuracy of that reporting.

With as few as 14% of healthcare organizations using patient data to assess variation in care and outcomes(4), it is imperative that race and ethnicity reporting be incorporated in all quality improvement projects and those whose voices are most likely to be impacted involved in the development and execution of those improvement programs.

In November 2020, the National Perinatal Information Center deployed a Race and Ethnicity Dashboard with all quarterly reporting, with both maternal and newborn outcomes, a routine component of the quarterly data package received by hospitals going forward. The goal of this reporting is to serve as an adjunct to diversity and inclusion programs, as well as to serve as a catalyst for discussion related to quality improvement/patient experience initiatives within racial and diversity lenses.

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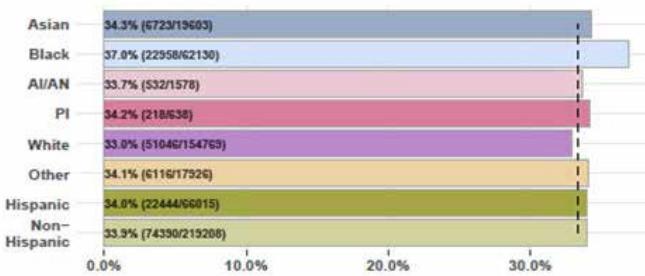
4/01/2019 – 3/31/2021

Total Deliveries: n = 290,288

Rates as a Percent of Discharges within each Race/Ethnicity Category

Cesarean Section

NPIC DB = 33.9%



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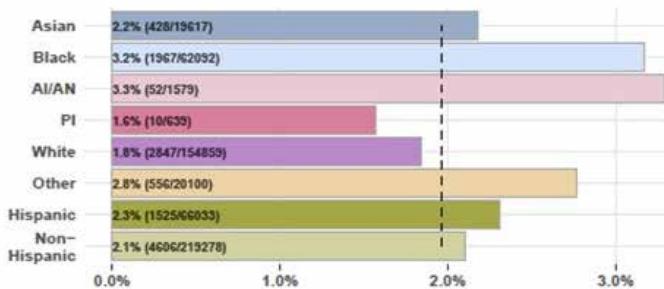
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Rates as a Percent of Discharges within each Race/Ethnicity Category

Severe Maternal Morbidity¹ (SMM): Overall

NPIC DB = 2.2%



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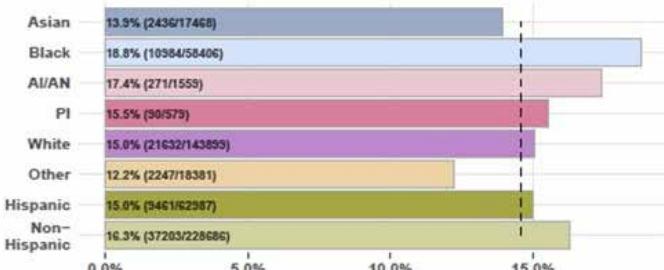
4/01/2019 – 3/31/2021

Total Neonates: n = 303,095

Rates as a Percent of Discharges within each Race/Ethnicity Category

Special Care Discharges (% of Neonates)

NPIC DB = 15.9%



The penultimate goal of quality improvement initiatives in obstetric, perinatal and neonatal programs is the **elimination** of preventable maternal and neonatal morbidity and mortality. Understanding the issues of systemic racism and implicit bias on outcomes must be an integral component of any patient safety program. Coupling race and ethnicity data and patient outcomes creates a much more robust and transparent vantage point of where vulnerabilities exist in patient care.

“Understanding the issues of systemic racism and implicit bias on outcomes must be an integral component of any patient safety program. Coupling race and ethnicity data and patient outcomes creates a much more robust and transparent vantage point of where vulnerabilities exist in patient care.”

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Health Equity Column: More Than A Moment: Dismantling Racism

Jenné Johns, MPH



In this month's Health Equity Column, I welcome the readers of Neonatology Today to journey with me, as we take a deeper look into health and racial equity issues plaguing our society and impacting Black NICU and Preemie families. As we move to the end of 2020, a year with inequitable outcomes associated with COVID-19, civil unrest, and rising rates of maternal-infant morbidity and mor-

tality rates for Black families, racism is at the core. According to the American Public Health Association, racism is now deemed a public health crisis that must be systematically addressed and dismantled to eliminate health outcomes disparities. This month, I have interviewed Deidre McDaniel, MSW, LCSW, maternal and child health expert with front line NICU and policy/systems change expertise to share insights on addressing health and racial equity in neonatal care.

"According to the American Public Health Association, racism is now deemed a public health crisis that must be systematically addressed and dismantled to eliminate health outcomes disparities."

Question 1: What is your definition of health equity?

My definition of health equity is when health outcomes and life expectancy are not defined by race and when people of color are valued within healthcare systems and able to operate with the autonomy to determine and engage in the care that we receive.

Question 2: What are your organizational priorities for addressing health and racial equity in neonatal care?

Health Equity Resources & Strategies (HERS) provides training and technical assistance on how to implement equitable quality improvement initiatives, develop strategies for clinical-community collaborations in service delivery, and conducts research and advocacy to eliminate disparities in birth outcomes.

Question 3: What personal and professional experiences led you to focus on health equity in neonatal care?

I learned very early on in my social work career that the best way to address health inequities was to develop strategies that shifted the organizational culture. During my tenure as a neonatal intensive care unit social worker, I witnessed firsthand the impact

of inequitable treatment among families of color. Equity cannot operate within the bubble of one unit; it must be instilled within the entire hospital system. Once I started to provide staff training, serving on NICU Quality Improvement Committees, and engaging in patient advocacy and began to see changes, I enlisted NICU Leadership to continue to foster these strategies across units and within their Leadership Team meetings. In hindsight, I realize that at the time, I did not have the language to adequately name the work that I was embarking on but what I did know is that I was witnessing unfair treatment and needed to do something about it. Those experiences and many others continue to fuel my passion and growth personally and professionally to continue to advocate for and elevate the voices of women of color. My research focuses on anti-racist healthcare practices through collaborative, participatory research. It is important to engage the community as leaders in their care and to provide spaces and opportunities for their voices to be heard and respected.

"My research focuses on anti-racist healthcare practices through collaborative, participatory research. It is important to engage the community as leaders in their care and to provide spaces and opportunities for their voices to be heard and respected."

Question 4: What is your call to action for the industry as we seek to eliminate health and racial inequities in neonatal care?

Actively work to dismantle racism. Racist policies and practices are embedded in the history of medical practice and are prevalent in medical care today. Organizations such as the American Medical Association and the Centers for Disease Control have cited racism as a "threat" to public health. Therefore, if you are working to eliminate health and racial inequities, you must acknowledge and address the role of racism in medical education and service delivery and be committed to its eradication.

Disclosure: The authors have no disclosures.

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About the Author: Deidre McDaniel, MSW, LCSW:



President & Founder

Health Equity Resources & Strategies

Deidre McDaniel, MSW, LCSW is the President and Founder of Health Equity Resources & Strategies (HERS). With over 20 years of experience in maternal & child health, Ms. McDaniel provides guidance to state agencies, healthcare systems, and public/private organizations on how to successfully implement and sustain equitable quality improvement projects to address disparities in maternal morbidity and mortality. Ms. McDaniel's research focuses on anti-racist healthcare practices and eliminating disparities in birth outcomes for African American women. Ms. McDaniel is a Doctoral Fellow at Morgan State University and a Maternal & Child Health Subject Matter Expert with the National Healthy Start Association and has dedicated her career to improving the health and well-being of African American women and children.

About the Author: Jenné Johns, MPH:



President, Once Upon A Preemie www.onceuponapreemie.com
Founder, Once Upon A Preemie Academy www.onceuponapreemieacademy.com

Jenné Johns, MPH is President of Once Upon A Preemie, Founder of Once Upon A Preemie Academy, mother of a micropreemie, author, speaker, advocate, and national senior health equity leader. Once Upon A Preemie is a non-profit organization with a two-part mission: 1.) to donate Once Upon A Preemie books to NICU families in under resourced communities, and 2.) lead virtual health and racial ethnic training programs and solutions to the neonatal and perinatal community through the Once Upon A Preemie Academy. Jenné provides speaking, strategic planning and consultation services for fortune 500 companies focused on preemie parent needs from a cultural lens and reading as a tool for growth, development, and bonding. Jenné is also a national senior health equity thought leader and has led solutions-oriented health equity and quality improvement portfolios for the nations' largest health insurance and managed care companies.

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Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Statement from NIH and BARDA on the FDA Emergency Use Authorization of the Moderna COVID-19 Vaccine

The second of two COVID-19 vaccines has received emergency use authorization from the FDA.

Friday, December 18, 2020

Today, the U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) to Moderna, Inc., a biotechnology company based in Cambridge, Massachusetts, for its COVID-19 vaccine, which was co-developed with scientists at the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID). This innovative and monumental partnership has enabled NIH and Moderna to develop a safe and effective COVID-19 vaccine within the span of a year that will be manufactured and distributed across the U.S. The vaccine, called mRNA-1273, is a messenger RNA (mRNA) vaccine against COVID-19 encoding a prefusion stabilized form of the spike protein of SARS-CoV-2, co-developed by investigators from Moderna and NIAID's Vaccine Research Center. The approach to stabilize the coronavirus spike protein, called S-2P, was developed by NIAID scientists and their collaborators at Scripps Research, Dartmouth College and the University of Texas at Austin. NIAID supported the early development of the mRNA-1273 vaccine, and worked with Biomedical Advanced Research and Development Authority (BARDA) scientists to support the mid- and late-stages of clinical development, with BARDA leading government support of the scale-up of manufacturing and regulatory pathway to EUA. The mRNA-1273 vaccine is the second COVID-19 vaccine in the United States to be granted an EUA. NIH Director Francis S. Collins, M.D., Ph.D., NIAID Director Anthony S. Fauci, M.D., and BARDA Director Gary Disbrow, Ph.D. released the following statements:

"It has been less than a year since the world first learned of SARS-CoV-2 and the terrible disease it can cause. To have not one but two safe and highly effective COVID-19 vaccines ready for deployment to the American public is truly a remarkable scientific achievement, and a significant step toward ending the pandemic that has caused so much suffering. The partnership to develop the mRNA-1273 vaccine is a prime example of the tremendous good that can be accomplished when the public and private sec-

tors work together to address a serious public health problem. It is through the dedicated efforts of our federal scientists and their collaborators at Moderna and in academia, the clinical staff who conducted the vaccine's rigorous clinical trials, and the tens of thousands of study participants who selflessly rolled up their sleeves, that another safe and highly effective vaccine to protect against COVID-19 will soon be rolled out to the American public." – NIH Director Francis S. Collins, M.D., Ph.D.

"Several years before SARS-CoV-2 entered the public consciousness, NIAID scientists were working with Moderna to develop vaccines for other coronaviruses. That existing scientific foundation is what enabled both partners to move quickly to develop the mRNA-1273 vaccine candidate against the novel SARS-CoV-2 coronavirus. NIAID conducted the initial Phase 1 testing of the vaccine and, with the support of BARDA and other Operation Warp Speed partners, played a central role in its large-scale clinical trial. Throughout each stage of clinical testing, the Moderna vaccine proved to be safe and highly effective at preventing symptomatic COVID-19. In a study of more than 30,000 people, it demonstrated 94% efficacy, and subsequent analyses have revealed that the vaccine induces a durable immune response. There is much we still do not know about SARS-CoV-2 and COVID-19. However, we do know that this vaccine is safe and can prevent symptomatic COVID-19 and severe disease. It is my hope that all Americans will protect themselves by getting vaccinated when the vaccine becomes available to them. That is how our country will begin to heal and move forward." – NIAID Director Anthony S. Fauci, M.D.

"Today stands as a reminder of what can be accomplished when people come together to reach a common goal. We are working with a constant sense of urgency to bring vaccines, therapeutics and diagnostics to bear to end the crisis. As partners in Operation Warp Speed, NIAID and BARDA scientists collaborated with Moderna, adding BARDA's expertise in late-stage clinical trials, scale-up manufacturing and regulatory requirements. By collaborating, we were able to complete these steps in parallel and accelerate the development of a safe and effective vaccine. While we celebrate today's accomplishment, we recognize that there is still much work to do to ensure every American who wants a

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COVID-19 vaccine receives one. Every American has been touched in some way by this virus, and so we will continue to push forward. With continued collaboration and investment in scientific research, health security, and innovative public-private partnerships, we can achieve a safer, more prepared world.” – BARDA Director Gary Disbrow, Ph.D.

Francis Collins, M.D., is Director of the National Institutes of Health in Bethesda, Maryland.

Anthony S. Fauci, M.D., is Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.

Gary Disbrow, Ph.D., is Director of the Biomedical Advanced Research and Development Authority (BARDA), in the HHS Office of the Assistant Secretary for Preparedness and Response.

Explore how we got to today: To learn more about the various milestones in the development of the NIH/Moderna vaccine and the robust portfolio of COVID-19 vaccines, visit [BARDA's COVID-19 Response Timeline](#).

About Operation Warp Speed: OWS is a partnership among components of the Department of Health and Human Services and the Department of Defense, engaging with private firms and other federal agencies, and coordinating among existing HHS-wide efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.

About HHS, ASPR, and BARDA: HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of [medical countermeasures](#) – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, BARDA-supported products have achieved [56 FDA approvals, licensures or clearances](#). To learn more about BARDA [COVID-19 Portfolio](#) and [BARDA's COVID-19 Response](#), visit [www.medicalcountermeasures.gov](#)

About the National Institute of Allergy and Infectious Diseases: NIAID conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the [NIAID website](#).

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ing the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit [www.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

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

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zo624@gmail.com

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NT

Cataract surgery in infancy increases glaucoma risk

NIH-funded clinical trial shows risk is similar whether or not a cloudy lens is replaced with a lens implant. Study suggests lifelong monitoring is crucial to preventing glaucoma-related vision loss.

Thursday, December 17, 2020

Children who undergo cataract surgery as infants have a 22% risk of glaucoma 10

years later, whether or not they receive an intraocular lens implant. The findings come from the National Eye Institute (NEI)-funded Infant Aphakic Treatment Study, which today published 10-year follow-up results in JAMA Ophthalmology. NEI is part of the National Institutes of Health.

"These findings underscore the need for long-term glaucoma surveillance among infant cataract surgery patients. They also provide some measure of assurance that it is not necessary to place an intraocular lens at the time of cataract surgery," said Michael F. Chiang, M.D., director of NEI.

"The results challenge the notion that replacing the child's lens with an implanted one protects the child from developing glaucoma, a belief among some pediatric ophthalmology surgeons," said the trial's principal investigator, Scott R. Lambert, M.D., professor of ophthalmology at Stanford University, Palo Alto, California.

At the time of cataract removal, the 114 study participants (ages 1-6 months) had been born with cataract in one eye. In the operating room, the infants were randomly assigned to receive an artificial lens implant or go without a lens, a condition called aphakia.

Annually, fewer than 2,500 children in the U.S. are born with cataract, a clouding of the eye's lens. Surgery is used to remove and replace the cloudy lens. To allow the



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child's eye to focus light properly following removal of the cataract, an intraocular lens implant may be placed at surgery, or the eye may be left aphakic, and a contact lens (or glasses, if both eyes have had a cataract removed) may be used to provide the needed correction.

"I tell patients' parents that implanting a lens in the infant's eye is like buying your child's wedding shoes when they're an infant. It is hard to predict what final power the intraocular lens should have, without knowing how that eye will grow over the years, so placing a lens at the time of cataract removal in an infant involves estimation, and may not turn out to be correct. Hence the eye may end up needing strong glasses or even replacement of the original lens implant," said the lead author on the paper, Sharon F. Freedman, M.D., a pediatric glaucoma specialist at Duke University, Durham, North Carolina.

Children who undergo cataract removal have an increased risk of glaucoma, a sight-threatening condition that damages the optic nerve—the connection between the eye and brain. Scientists speculate that surgery to remove the cataract interferes with the maturation of how fluid flows out of the infant's eye leading to increased eye pressure and optic nerve damage in some of these eyes.

Among the 110 children who were available for re-examination at 10 years, 25 eyes (24%) had developed glaucoma, and 21 eyes (20%) were glaucoma suspects due to elevated eye pressure. However, visual acuity was similar among those eyes that developed glaucoma compared to those eyes that had not. The researchers found no evidence of glaucoma-related eye damage, assessed by imaging of the optic nerve head to measure the retinal nerve fiber layer thickness.

The investigators attribute the absence of glaucoma-related eye damage to close patient monitoring, as any sign of glaucoma was aggressively treated.

While the lifetime glaucoma risk trajectory for patients who have cataract removal

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as infants remains unknown, this study found that the risk of glaucoma after cataract removal rose from 9% at 1 year, to 17% at 5 years, and to 22% at 10 years.

"Any child who has had a cataract removed needs to be seen by an eye care provider once a year at a minimum," said Freedman. "Any child diagnosed with glaucoma or above-normal intraocular pressure without signs of ocular damage — what we called glaucoma suspect — should be monitored every four to six months depending upon the stability of the condition and the health of the eye."

At 10 years, 40% of the followed children had developed the diagnosis of glaucoma or glaucoma suspect. A glaucoma suspect is an eye that has above normal eye pressure or another feature suspicious but not diagnostic of glaucoma.

The findings also confirm that the timing of cataract surgery is a balancing act: Whereas surgery at younger ages increases glaucoma risk, delaying surgery

increases risk of amblyopia, a leading cause of visual impairment in children that results when cataract in one eye causes the brain to ignore signals from that eye and favor the other eye.

Future studies of glaucoma following cataract surgery in children will benefit from groundwork by the Infant Aphakic Treatment Study. Freedman said collaboration among the 12 study centers defined diagnostic standards for pediatric glaucoma and glaucoma suspect and criteria for glaucoma-related adverse events. "This cohort began the process leading to an international classification of childhood glaucoma in 2013 that is used around the world today," she said.

Investigators at Emory University, Harvard University, Duke University, Indiana University, Vanderbilt University, Medical University of South Carolina, University of Minnesota, Cleveland Clinic, Baylor University, Oregon Health and Science University, Miami Children's Hospital, and University of Texas Southwestern



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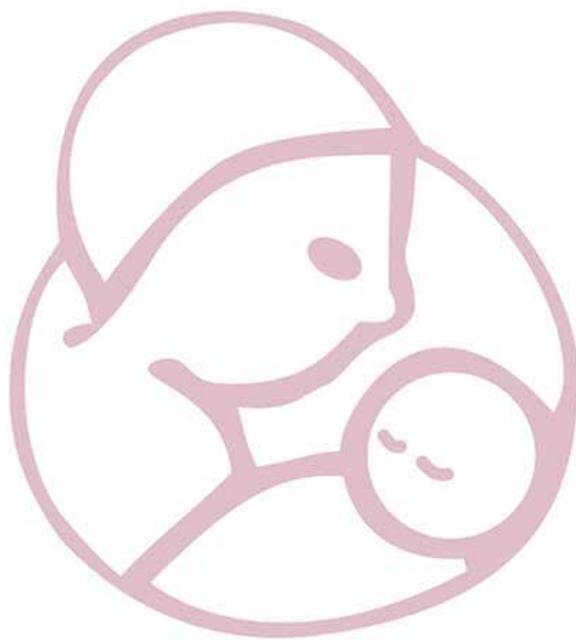
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helped lead the trial. NEI funding includes grants UG1EY013287, UG1EY013272, UG1EY025553, and P30EY026877. The clinicaltrial.gov identifier is NCT00212134.

NEI leads the federal government's research on the visual system and eye diseases. NEI supports basic and clinical science programs to develop sight-saving treatments and address special needs of people with vision loss. For more information, visit <https://www.nei.nih.gov>.

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Institute/Center
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NT

NIH observational study of coronavirus infection and multi-system inflammatory syndrome in children begins

NIH anticipates a large cross sectional study under the auspices of the Pediatric Research Immune Network on SARS-CoV-2 and MIS-C (PRISM).

Wednesday, December 16, 2020

An observational study has launched to evaluate the short- and long-term health outcomes of SARS-CoV-2 infection in children, including multisystem inflammatory syndrome in children (MIS-C), and to characterize the immunologic pathways associated with different disease presentations and outcomes. SARS-CoV-2 is the virus that causes COVID-19. The study, called the Pediatric Research Immune Network on SARS-CoV-2 and MIS-C (PRISM), will enroll at least 250 children and young adults ages 20 years or younger from diverse racial and ethnic backgrounds at approximately 20 sites nationwide. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is sponsoring and funding the study. The PRISM study is part of a research effort led by NIH's National Heart, Lung, and Blood Institute and Eunice Kennedy Shriver National Institute of Child Health and Human Development to understand MIS-C.

Although SARS-CoV-2 infection usually causes either no illness or only mild illness in children, some children become seriously ill at the time of infection, while others who initially have no symptoms later develop MIS-C. MIS-C is a life-threatening condition marked by severe inflammation of one or more parts of the body, including the heart, lungs, kidneys, brain, skin, eyes and gastrointestinal organs. The syndrome typically

begins several weeks after SARS-CoV-2 exposure and disproportionately affects Black and Hispanic children.

"It is critical that we learn how to prevent and treat this rare but very serious syndrome in children," said NIAID Director Anthony S. Fauci, M.D. "Information gathered through the PRISM study may ultimately help clinicians diagnose and treat MIS-C as well as predict which children are susceptible to the disease."

The PRISM study aims to fill gaps in understanding of the clinical spectrum of COVID-19 in children and young adults, the long-term outcomes of SARS-CoV-2 infection in these populations, and the underlying immunologic basis of MIS-C. It is led by clinical protocol chair Steven A. Webber, M.B.Ch.B., M.R.C.P., chair of the department of pediatrics in Monroe Carell Jr. Children's Hospital at Vanderbilt in Nashville, Tennessee.

The PRISM study team is enrolling children and young adult volunteers with detectable SARS-CoV-2 in respiratory samples, with symptoms of MIS-C, or both. Participants will be followed for at least one year.

The study has two main goals. The first is to determine the proportion of children who die, are re-hospitalized after an initial hospital admission, or have major health complications due to SARS-CoV-2 at six and 12 months after initial presentation with COVID-19, MIS-C, or both. The second is to determine the immunologic mechanisms and characteristics associated with different forms of MIS-C and COVID-19 in children. Results are expected in mid-2022.

More information about the PRISM study is available at ClinicalTrials.gov under study identifier [NCT04588363](#).

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[Laura Leifman](#)

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NT

NIH Statement on World AIDS Day 2020

We reflect both on the remarkable progress that has been made against HIV as well as the considerable challenges that remain.

Tuesday, December 1, 2020

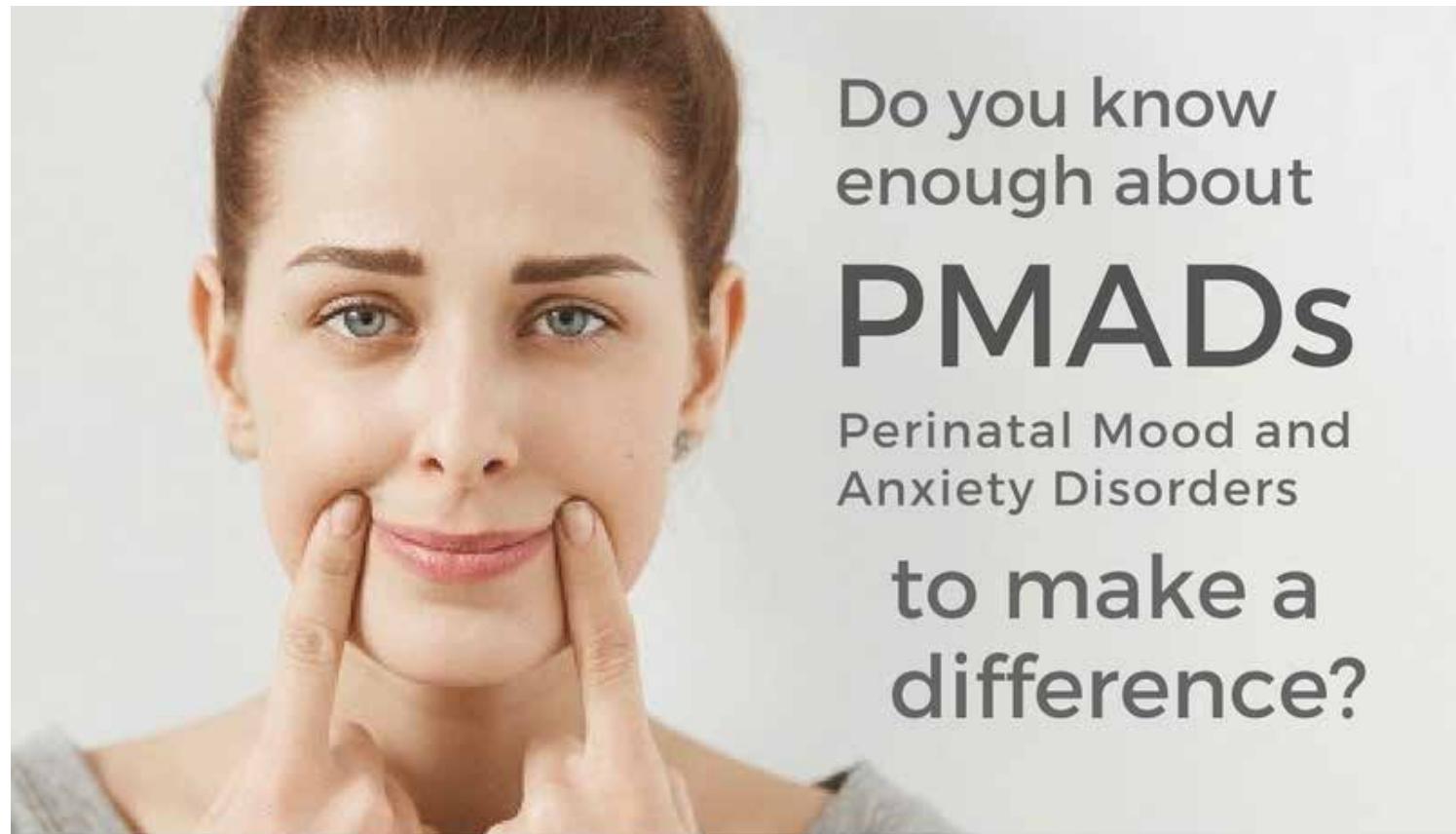
Today on World AIDS Day, we reflect both on the remarkable progress that has been made against HIV as well as the considerable challenges that remain. We now have highly effective HIV treatment and prevention methods, and work is underway to address the remaining challenges in delivering these tools to the people who need them most, as well as to develop new interventions. The National Institutes of Health continues to advance rigorous, innovative research to prevent new HIV transmissions and improve the health of people with HIV worldwide.

This year the coronavirus disease 2019 (COVID-19) pandemic is creating great

concern and uncertainty for people everywhere, including those affected by HIV. Notably, lessons we learned from involving affected communities in HIV research planning and implementation are informing our response to this new pandemic. NIH also is leveraging its HIV research infrastructure and expertise to conduct critical clinical trials evaluating investigational vaccines and monoclonal antibodies for COVID-19 prevention, as well as a variety of potential COVID-19 therapeutics.

In the face of the challenges posed by COVID-19, our work to address HIV has not slowed, reflecting the U.S. Government theme for this year's World AIDS Day—[Ending the HIV Epidemic: Resilience and Impact](#) — and the theme for NIH's observance — [Science and Community: Working Together to Prepare for the Unexpected](#). We applaud the resilience of the HIV clinical trial participants, researchers, health care professionals, advocates and other members of the global community who are continuing their work to advance HIV research.

If current HIV treatment and prevention

A close-up photograph of a woman with light brown hair pulled back, smiling warmly at the camera. Her hands are gently resting on her cheeks, framing her face. The background is a soft, out-of-focus light color.

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methods could be optimally implemented, an end to the HIV epidemic is feasible. This year, NIH [awarded approximately \\$10 million](#) to support implementation science research to advance the goals of the Ending the HIV Epidemic: A Plan for America initiative, which aims to reduce new HIV diagnoses in the United States by at least 90% by 2030.

Achieving a durable end to the HIV pandemic also will require continued development of new and improved HIV prevention and treatment tools that are safe, effective, scalable and desirable to diverse global populations. In a landmark advance this year, two large-scale clinical trials found that a long-acting form of the antiretroviral drug cabotegravir injected once every eight weeks was safe and more effective than daily oral pre-exposure prophylaxis at preventing HIV acquisition among [cis-gender women](#) and [cisgender men and transgender women who have sex with men](#). These results mark the first time a systemic, long-acting form of HIV prevention has been conclusively demonstrated to be highly effective.

Other forms of long-acting HIV prevention modalities under investigation include intravaginal rings, implants and antibodies. The adoption of a [positive scientific opinion on the dapivirine vaginal ring](#) by the European Medicines Agency this year and subsequent prequalification by the World Health Organization marked pivotal steps toward expanding HIV prevention choices for women. If approved by regulatory agencies, the monthly ring would provide women in developing countries with a discreet long-acting HIV prevention option that they control.

Development of a safe and effective HIV vaccine remains a top priority, and notably, certain platforms used to [develop COVID-19 vaccine candidates](#) employed the structural biology techniques used in HIV vaccinology. Two ongoing clinical trials for HIV vaccines, Imbokodo and Mosaico, are evaluating an experimental HIV vaccine regimen designed to protect against

a wide variety of global HIV strains. Results expected soon from two other clinical trials, evaluating intravenous infusions of a broadly neutralizing antibody for HIV prevention, will provide key insights for further development of antibody-based HIV prevention tools and ultimately a vaccine.

Thanks to extraordinary advances in antiretroviral therapy, many people with HIV can control the virus by taking just one pill each day. However, adhering to daily pills can be challenging. Researchers therefore are pursuing long-acting treatments that would allow a person with HIV to keep the virus suppressed without daily medication, as well as strategies to completely eradicate HIV from the body.

A few exceptional clinical scenarios have provided proof that HIV can be cured, including that of [Timothy Ray Brown](#). Brown was widely recognized as the first person cured of HIV and for inspiring and advocating for scientists and communities worldwide to advance HIV cure research. Sadly, he died of leukemia in September 2020; however, his legacy lives on in the robust [HIV cure](#) agenda that researchers are pursuing today.

Even when HIV is well-controlled with treatment, people living with the virus are at heightened risk for co-infections and comorbidities. Tuberculosis remains the leading cause of death globally for people with HIV. Researchers recently reported that a [new four-month treatment regimen](#) is as safe and effective as the standard six-month regimen for drug-susceptible tuberculosis, a finding that has the potential to offer an additional tuberculosis treatment option that may be more convenient.

People with HIV also are more likely to experience noninfectious comorbidities such as heart disease, kidney disease and certain cancers. In order to successfully address these comorbidities, a robust research agenda is required to better understand how these conditions develop

and to evaluate appropriate treatments. In this regard, the global REPRIEVE clinical trial that is focused on HIV and heart disease is teaching us about the many [long-term health effects of HIV](#). The trial recently began gathering data to assess the impact of COVID-19 on people with HIV.

As we reflect today on our progress, we also look forward to new HIV research advances. To guide these efforts, NIH, through the Office of AIDS Research, recently released a 5-year [strategic plan for HIV and HIV-related research](#). Yesterday, NIAID named the [four HIV clinical trials](#) networks that will conduct innovative clinical research in the United States and internationally over the next seven years to accelerate progress against the pandemic.

It is essential to work closely with communities and advocates to develop HIV prevention and treatment strategies that suit the diverse needs, preferences and desires of people with or at risk for HIV worldwide. It also is critical that we continue efforts to nurture the next generation of HIV investigators and ensure that [diverse voices are represented](#). Together, we can identify the optimal strategies to improve the health of those with HIV, prevent new cases, and ultimately, end the pandemic.

NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the [NIAID website](#).

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NT

Commonly used antibiotic shows promise for combating Zika infections

NIH preclinical study suggests FDA-approved tetracycline-based antibiotics may slow infection and reduce neurological problems.

Tuesday, November 24, 2020

In 2015, hundreds of children were born with brain deformities resulting from a global outbreak of Zika virus infections. Recently, National Institutes of Health researchers used a variety of advanced drug screening techniques to test out more than 10,000 compounds in search of a cure. To their surprise, they found that the widely used antibiotic methacycline was effective at preventing brain infections and reducing neurological problems associated with the virus in mice. In addition, they found that drugs originally designed to combat Alzheimer's disease and inflammation may also help fight infections.

"Around the world, the Zika outbreak produced devastating, long-term neurological problems for many children and their families. Although the infections are down, the threat remains," said Avindra Nath, M.D., senior investigator at the NIH's [National Institute of Neurological Disorders and Stroke](#) (NINDS) and a senior author of the study published in [PNAS](#). "We hope these promis-

ing results are a good first step to preparing the world for combating the next potential outbreak."

The study was a collaboration between scientists on Dr. Nath's team and researchers in laboratories led by Anton Simeonov, Ph.D., scientific director at the NIH's [National Center for Advancing Translational Sciences](#) (NCATS) and Radhakrishnan Padmanabhan, Ph.D., Professor of Microbiology & Immunology, [Georgetown University Medical Center](#), Washington, D.C.

The [Zika virus](#) is primarily spread by the *Aedes aegypti* mosquito. In 2015 and 2016, at least 60 countries reported infections. Some of these countries also reported a high incidence of infected mothers giving birth to babies born with abnormally small heads resulting from a developmental brain disorder called fetal [microcephaly](#). In some adults, infections were the cause of several neurological disorders including [Guillain-Barré syndrome](#), [encephalitis](#), and [myelitis](#). Although many scientists have tried, they have yet to discover an effective treatment or vaccination against the virus.

In this study, the researchers looked for drugs that prevent the virus from reproducing by blocking the activity of a protein called NS2B-NS3 Zika virus protease. The Zika virus is a protein capsule that carries long strings of RNA-encoded instructions for manufacturing more viral proteins. During an infection, the virus injects the RNA into a cell, resulting in the production of these proteins, which are strung together, side-by-side, like the parts in a plastic model airplane kit. The NS2B-NS3 protease then snaps off each protein, all of which are critical for assembling new viral particles.

"Proteases act like scissors. Blocking protease activity is an effective strategy for counteracting many viruses," said Rachel Abrams, Ph.D., an organic chemist in Dr. Nath's lab and the study leader. "We wanted to look as far and wide as possible for drugs that could prevent the protease from snipping the Zika virus polyprotein into its active pieces."

To find candidates, Dr. Abrams worked with scientists on Dr. Simeonov's and Dr. Padmanabhan's teams to create assays, or tests, for assessing the ability of drugs to block NS2B-NS3 Zika virus protease activity in plates containing hundreds of tiny test tubes. Each assay was tailored to a different screening, or sifting, technique. They then

used these assays to simultaneously try out thousands of candidates stored in three separate libraries.

One preliminary screen of 2,000 compounds suggested that commonly used, tetracycline-based antibiotic drugs, like methacycline, may be effective at blocking the protease.

Meanwhile, a large-scale screen of more than 10,000 compounds helped identify an investigational anti-inflammatory medicine, called MK-591, and a failed anti-Alzheimer's disease drug, called JNJ-404 as potential candidates. A virtual screen of over 130,000 compounds was also used to help spot candidates. For this, the researchers fed the other screening results into a computer and then used artificial intelligence-based programs to learn what makes a compound good at blocking NS2B-NS3 Zika virus protease activity.

"These results show that taking advantage of the latest technological advances can help researchers find treatments that can be repurposed to fight other diseases," said Dr. Simeonov.

The Zika virus is known to preferentially infect stem cells in the brain. Scientists suspect this is the reason why infections cause more harm to newborn babies than to adults. Experiments on neural stem cells grown in petri dishes indicated that all three drugs identified in this study may counteract these problems. Treating the cells with methacycline, MK-591, or JNJ-404 reduced Zika virus infections.

Because tetracyclines are U.S. Food and Drug Administration-approved drugs that are known to cross the placenta of pregnant women, the researchers focused on methacycline and found that it may reduce some neurodevelopmental problems caused by the Zika virus. For instance, Zika-infected newborn mice that were treated with methacycline had better balance and could turn over more easily than ones that were given a placebo. Brain examinations suggested this was because the antibiotic reduced infections and neural damage. Nevertheless, the antibiotics did not completely counteract harm caused by the Zika virus. The weight of mice infected with the virus was lower than control mice regardless of whether the mice were treated with methacycline.

"These results suggest that tetracycline-based antibiotics may at least be effective at

preventing the neurological problems associated with Zika virus infections," said Dr. Abrams. "Given that they are widely used, we hope that we can rapidly test their potential in clinical trials."

Article:

Abrams, R.P.M., Yasgar, A. et al., Therapeutic Candidates for the Zika Virus Identified by a High Throughput Screen for Zika Protease Inhibitors. PNAS, November 23, 2020 DOI: [10.1073/pnas.2005463117](https://doi.org/10.1073/pnas.2005463117).

These studies were supported by [NIH Intramural Research Programs](#) at [NINDS](#) and [NCATS \(TR000291\)](#) and an NIH grant ([AI109185](#)).

For more information:

medlineplus.gov/zikavirus.html

www.cdc.gov/zika/index.html

www.ninds.nih.gov/Disorders/All-Disorders/Microcephaly-Information-Page

<https://www.ninds.nih.gov/Disorders/All-Disorders/Guillain-Barr%C3%A9-Syndrome-Information-Page>

www.ninds.nih.gov/Disorders/All-Disorders/Meningitis-and-Encephalitis-Information-Page

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NINDS (<https://www.ninds.nih.gov>) is the nation's leading funder of research on the brain and nervous system. The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease.

About the National Center for Advancing Translational Sciences (NCATS): NCATS conducts and supports research on the science and operation of translation — the process by which interventions to improve health are developed and implemented — to allow more treatments to get to more patients more quickly. For more information about how NCATS helps shorten the journey from scientific observation to clinical intervention, visit ncats.nih.gov.

About the National Institute of Allergy and Infectious Diseases: NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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NT

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

Consider the following:

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



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

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

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

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

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



Visit www.GrahamsFoundation.org to learn more.

[National Institute of Neurological Disorders and Stroke \(NINDS\)](#)

[National Center for Advancing Translational Sciences \(NCATS\)](#)

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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.

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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We can help protect each other.

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www.nationalperinatal.org/COVID-19

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis

RSV



WASH YOUR HANDS

often with soap and warm water.



GET VACCINATED

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



COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.



USE AN ALCOHOL-BASED HAND SANITIZER.



STAY AWAY FROM SICK PEOPLE

Avoid crowds. Protect vulnerable babies and children.

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NIH expands research to improve COVID-19 testing among underserved and vulnerable populations

Research designed to rapidly implement testing strategies in populations disproportionately affected by COVID-19.

Friday, November 20, 2020

WHAT:

The National Institutes of Health has awarded nearly \$45 million to expand the research network of the [Rapid Acceleration of Diagnostics Underserved Populations \(RADx-UP\) program](#), adding 20 institutions and seven states and territories. RADx-UP aims to enable and enhance COVID-19 testing of populations disproportionately affected by the disease, including African Americans, American Indians/Alaskan Natives, Latinos/Latinas, Native Hawaiians, older adults, pregnant women and those who are homeless or incarcerated. This second round of awards brings the total investment in the RADx-UP program to more than \$283 million at 55 institutions across 33 states and territories and the Cherokee Nation.

These new grants bolster two critical components of the RADx-UP program to address testing hesitancy among underserved and/or vulnerable populations:

- Research on the 1) cultural, ethical, social, behavioral, historical, economic and contextual factors associated with COVID-19 testing; 2) attitudes, expectations and preferences for testing and how test results influence ability and willingness to get tested; 3) interpersonal, institutional (e.g., health system), community and policy factors that affect access to COVID-19 testing.
- A collaborative network of community-engagement projects with established programs that have adequate capacity, infrastructure and relationships with underserved communities. This effort will strengthen available data on disparities in infection rates and disease progression and outcomes and improve understanding of differences in testing access and uptake patterns.

The initial round of awards [announced](#) on Sept. 30, 2020 also includes a coordination and data collection center at Duke University, Durham, North Carolina.

WHO:

Co-chairs of the RADx-UP Governance Committee are available for interviews:

- Richard J. Hodes, M.D., director of the National Institute on Aging
- Eliseo J. Pérez-Stable, M.D., director of the National Institute on Minority Health and Health Disparities
- Tara A. Schwetz, Ph.D., NIH Associate Deputy Director.

About the Rapid Acceleration of Diagnostics (RADxSM) initiative: The RADx initiative was launched on April 29, 2020, to speed innovation in the development, commercialization and implementation of technologies for COVID-19 testing. The initiative has four programs: RADx Tech, RADx Advanced Technology Platforms, RADx Underserved Populations and RADx Radical. It leverages the existing NIH Point-of-Care Technology Research Network. The RADx initiative partners with federal agencies, including the Office of the Assistant Secretary of Health, Department of Defense, the Biomedical Advanced Research and Development Authority, and U.S. Food and Drug Administration. Learn more about the RADx initiative and its programs: <https://www.nih.gov/radx>.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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





Protecting Access for Premature Infants through Age Two

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



The National Coalition for Infant Health advocates for:

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

www.infanthealth.org

Why PREMATURE INFANTS Need Access to an EXCLUSIVE HUMAN MILK DIET



In the United States, more than **1 IN 10 BABIES ARE BORN PREMATURE**. Very low birthweight babies are born severely premature, weighing less than 1,250 grams.



VERY LOW BIRTHWEIGHT BABIES

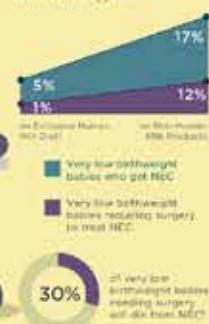
are at risk for Necrotizing Enterocolitis (NEC), which:

- Damages intestinal tissue
- Causes distended abdomen, infection, low blood pressure and shock
- Threatens infant's life



NEC occurrence increases when a preemie consumes non-human milk products.

What that happens:



HOW TO HELP PREVENT NEC: EXCLUSIVE HUMAN MILK DIET

What is an Exclusive Human Milk Diet?



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

Why Is An Exclusive Human Milk Diet Important?

An Exclusive Human Milk Diet gives premature infants the best chance to be healthy and reduces the risk of NEC and other complications.

When a very low birthweight baby can access an EXCLUSIVE HUMAN MILK DIET:



HUMAN MILK = MEDICINE

Human milk offers many benefits providing the best nutrition for your baby. Any amount of human milk you help return is beneficial. Talk to your care team about your baby's specific nutrition needs and resources available to help you achieve your goals.

[LEARN MORE](#)

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

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Genetics Corner: Risk of Epilepsy in an Asymptomatic Infant with Prenatally Diagnosed Tuberous Sclerosis

Robin Dawn Clark, MD and Subhadra Ramaanthan, MSc, MS

Case History:

A healthy 10-month old male infant who had been prenatally diagnosed with tuberous sclerosis (TSC) was referred for a genetic consultation. The diagnosis of TSC in this child was made prenatally via gene testing on a chorionic villus sample by a maternal-fetal medicine consultant. Fetal hydronephrosis was briefly noted on an ultrasound exam at ~20 weeks gestation, but there were no other signs of TSC in the fetus. The mother herself reported polycystic ovarian syndrome and chronic emesis but denied teratogenic exposures, diabetes, or other illnesses during her pregnancy. The baby was born at term by NSVD without complications and received routine newborn care. Birth weight and birth length were 7 lbs 14 oz. and 20.5 inches, respectively. He passed his newborn hearing screen. He was discharged with his mother.

Since birth, this infant has been healthy and developing normally. He has not had any imaging studies or specialist evaluations to date. At the genetic clinic visit, his mother voiced concern about his risk for seizures after his upcoming MMR vaccination because his father, who also had TSC, had a seizure after his MMR vaccination as an infant.

The physical examination revealed a well-nourished, well-developed, alert, nondysmorphic male infant in no distress. He had one hypomelanotic macule on his right forearm. His neurologic examination was normal. He was socially engaged, vocal, and moved all extremities symmetrically. He demonstrated good muscle mass, strength, and tone.

Developmental history:

The patient met age-appropriate developmental milestones. He sat alone at 5-6 months of age and is almost standing unassisted at ten months. He said his first word at eight months of age and had a vocabulary of 3 words at ten months.

Family and social history:

The patient is the only child born to his parents. The patient's father, in his 30s, was diagnosed at age 30 with tuberous sclerosis as an incidental finding when he had a brain MRI for another indication. He has facial angiofibromas, migraine headaches, benign brain tumors, and a history of learning difficulties in school. He had a seizure with fever as an infant after receiving his MMR vaccine, but he has had no seizures since age 2. A pathogenic variant in *TSC1* was identified in the patient's father: c.2006_2007insTTTAGGTTGCCTTT (p.Leu669Phefs*60).

The paternal grandmother and her mother are also affected by TSC. The paternal grandmother underwent genetic testing for tuberous sclerosis after the patient's father was diagnosed with TSC, and she has the same pathogenic variant. She has angiofibromas and brain and kidney tumors. She had "convulsions" when she was younger. The paternal great-grandmother had been clinically diagnosed with tuberous sclerosis in the past but had not had genetic testing. She has unspecified kidney issues.

Assessment and counseling:

This infant has a tuberous sclerosis complex (TSC) based on his family history, physical exam, and prenatal genetic test results. The hypomelanotic macule on his forearm is one of the earliest indicators of TSC and, in this patient, it is the sole manifestation of TSC at presentation. After an uneventful delivery, this infant was asymptomatic and went home with his mother without further interventions until ten months of age when he presented for an outpatient genetic consultation.

Although prenatal diagnosis provided the opportunity for early intervention in this case, the opportunity was missed, possibly because the fact that he was asymptomatic was overly reassuring to his family and his medical providers. Preventive management has an important role in the neonatal care plan of all affected newborns with TSC, even if asymptomatic. His mother's concern for seizure risk following routine immunizations motivated us to focus on the risk of epilepsy in TSC for this report and highlight preventive interventions appropriate at the time of diagnosis for all newborns with TSC.

Background:

TSC (OMIM 191100) is an autosomal dominant disorder caused by excessive activation of the mTOR signaling pathway by heterozygous inactivating pathogenic variants in either *TSC1* or *TSC2*. It occurs in approximately 1 in 6000 births and is inherited from an affected parent in about one-third of cases. In the other approximately two-thirds of cases, the responsible gene variants occur as *de novo* events. The penetrance of TSC is thought to be 100%, which means that all individuals with pathogenic variants express the disorder to varying degrees. However, the phenotype of TSC can be highly variable, even among affected members of the same family, so the disease does *not* "run true." Although no genotype-phenotype correlations regarding specific pathogenic variants in *TSC1* have been reported, pathogenic variants in *TSC1* are generally associated with a milder phenotype than pathogenic variants in *TSC2*.

In TSC, hamartomas develop in many organs: brain, heart, skin, kidneys, and lungs but the most severe manifestations are neurologic. The prevalence of intellectual disability is 40-70%, and severe or profound disability is reported in 30-45% of patients. There is a strong association between mental handicap and epilepsy. Early-onset epilepsy, especially infantile spasms, is strongly linked to severe intellectual disability in TSC.

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Epilepsy and neurodevelopmental comorbidities

Patients with TSC are at high risk of developing epilepsy. Seizures occur in about 80% of TSC infants, usually in the first year of life. Rapid treatment is important because seizures, especially uncontrolled seizures, increase the risk for TSC-associated neuropsychiatric disorders (TAND) such as intellectual disability/developmental delay and autism. Unfortunately, in approximately 65% of those patients with TSC who develop epilepsy, seizures are severe and drug-resistant. Because mTOR activation can cause increased neuroexcitability and seizures, mTOR inhibitors have been studied for their antiepileptic therapeutic effect with positive results. The EXamining everolimus In a Study of Tuberous sclerosis 3 (EXIST-3) trial demonstrated decreased seizure frequency with the mTOR inhibitor everolimus in TSC-related refractory seizures in subjects aged 2-65 years old (French *et al.* 2016). Attention has now become focused on preventing epilepsy in at-risk infants with TSC by initiating treatment before clinical seizures are evident, and evidence is accumulating that this is beneficial.

“Vigabatrin is the most effective first-line monotherapy for TSC-associated infantile spasms and/or focal seizures in the first year of life (Curatolo *et al.*, 2018).”

Vigabatrin is the most effective first-line monotherapy for TSC-associated infantile spasms and/or focal seizures in the first year of life (Curatolo *et al.*, 2018). It has also been shown to be effective as a preventive therapy. In 2011, Joswiak and colleagues demonstrated that vigabatrin, when initiated before the onset of seizures in at-risk infants with TSC, reduced the severity of their epilepsy and their risk of intellectual disability. In their study, a standard therapy group ($n=31$) received antiepileptic treatment early but after the onset of seizures. A preventive therapy group ($n=14$) was treated when active epileptic discharges were seen on EEG but before the onset of clinical seizures. At 24 months of age, the developmental delay was significantly more frequent and severe in the standard versus the preventive group (48% vs. 14%; $p=0.031$; mean IQ score 68.7 vs. 92.3; $p<0.05$). The preventive group had a higher ratio of seizure-free children (93% vs. 35%; $p=0.004$), a lower incidence of drug-resistant epilepsy (7% vs. 42%; $p=0.021$), and lower numbers who required polytherapy (21% vs. 55%; 0.039). These authors concluded, “preventative antiepileptic treatment of infants with tuberous sclerosis complex and high risk of epilepsy markedly improves their neurodevelopmental outcome and reduces the incidence of drug-resistant seizures.”

Wu and colleagues (Wu *et al.*, 2019) used serial routine 1 hour awake and sleep video EEGs as a biomarker for epileptogen-

esis in at-risk infants with TSC. They studied 40 seizure-naïve infants who had TSC, aged seven months or younger, following them until two years of age with video EEGs at baseline, every six weeks until six months, every three months until 12 months, then every six months until 24 months of age. They found that interictal epileptiform discharges (IEDs) on EEG predicted clinical seizures by age 2 with a positive predictive value of 77.3% and a sensitivity of 85%. Among the 32 infants who completed the study, 20 developed seizures, and 17 of these had persistent IEDs on multiple EEGs. In contrast, among the 12 infants who did not develop seizures, only 5 had IEDs on a single EEG that later resolved. The EEG changes preceded the onset of clinical seizures by a mean of 3.6 months. By demonstrating significant developmental decline only in the infants with ongoing seizures but not in infants who never developed seizures or whose seizures were controlled, these authors also showed that “decline in developmental outcome in infants with TSC is clearly linked to the persistence of seizures.”

Most recently, the international EPISTOP clinical trial (Kotulska *et al.*, 2020) compared the effectiveness of vigabatrin as a preventive therapy (after EEG evidence of epileptic activity) versus its use as conventional antiepileptic treatment (after the onset of clinical seizures) in TSC infants. Among 94 infants with TSC, aged four months or less, and without seizure history who participated in EEG surveillance, 54 were eligible for preventive treatment with vigabatrin in either a randomized arm or an open-label arm of the study. Of these, 25 had preventive treatment at the time of abnormal EEG, and 25 had no preventive treatment at the time of abnormal EEG. The median time from birth to the first clinical seizure was about four times longer with preventive treatment than conventional treatment (614 days vs. 124 days). Patients in the preventive treatment group were about three times more likely to remain free of clinical seizures over the study period (46% vs. 15%, $p=0.011$). The preventive treatment group had a lower median proportion of days with seizures (17% vs. 62%, $p=0.022$) and less frequent drug-resistant epilepsy (31% vs. 77%, OR=0.15) than the conventional treatment group. None of the patients who received preventive treatment developed infantile spasms, whereas 10 of 25 patients on conventional therapy did. Importantly, there were no adverse events related to preventive treatment. The authors support the use of serial video-EEG monitoring “beginning at the time of diagnosis of TSC in infants and the immediate initiation of antiepileptic treatment with vigabatrin at the onset of epileptogenic activity.”

We communicated this recommendation to the patient's pediatrician and family in the hope that an EEG could be performed prior to the patient's upcoming MMR vaccination. The patient was referred to the Pediatric Neurology service for brain MRI and further follow up.

The sum of current evidence is rapidly changing the standard of care for infants with TSC. Neonatal practitioners have an important role in advancing the health of these babies by ordering serial EEGs and advocating for preventive therapy, if needed, with



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vigabatrin when epileptogenic activity is present.

"The sum of current evidence is rapidly changing the standard of care for infants with TSC. Neonatal practitioners have an important role in advancing the health of these babies by ordering serial EEGs and advocating for preventive therapy, if needed, with vigabatrin when epileptogenic activity is present."

Practical applications:

1. Recognize the important role you have as a neonatal care provider in improving the lives of infants with tuberous sclerosis complex
2. Consult a pediatric neurologist whenever a newborn infant has TSC, even when the baby is asymptomatic, to initiate EEG surveillance, brain imaging and create a treatment plan
3. Anticipate that clinical seizures will develop in the first year of life in most infants with TSC.
4. Understand that early and close video EEG monitoring provide a biomarker for seizure susceptibility in TSC, and early treatment based on EEG monitoring significantly improves the neurodevelopmental outcome of young children with epilepsy.
5. Order EEG surveillance in infants with TSC prior to the onset of seizures to identify and treat early epileptiform changes
6. Recognize that antiepileptic treatment with vigabatrin begun prior to the onset of clinical seizures in infants with TSC improves neurologic outcome more than the same therapy initiated after the onset of seizures.

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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.



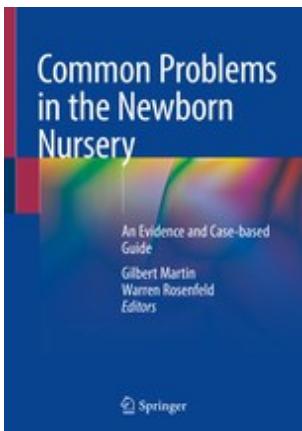
My potential is limitless.

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



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



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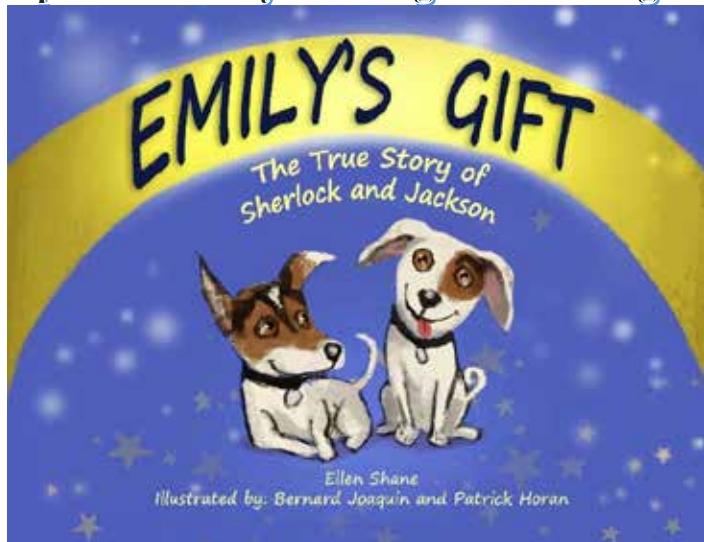
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Benefits of an Exclusive Human Milk Diet (EHMD) for Premature Infants

Laura Madlinger Lewis, OTD, OTR/L, CNT



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.

"The benefits of breastmilk for preterm infants are very well established. However, when infants are born prematurely and miss all or part of the third trimester, they receive less vital nutrients via the placenta."

Does your unit have goals to provide an exclusive human milk diet (EHMD) for preterm infants? Why should neonatal therapists play a role in advocating for EHMD and supporting families as they work alongside the team to help accomplish this? What does the evidence say?

The benefits of breastmilk for preterm infants are very well established. However, when infants are born prematurely and miss all or part of the third trimester, they receive less vital nutrients via the placenta. Preterm infants have low mineral stores and often



require fortification of breastmilk and/or pasteurized donor milk. Many NICUs utilize fortifier derived from cow's milk, and others use human-based milk fortifier (as part of the EHMD). Is there a difference?

"There is also a large body of evidence that illustrates the positive effects of breastmilk on infant neurodevelopment. However, there has been concern regarding the neurodevelopmental outcomes for preterm infants fed EHMD,"

What are the health benefits of EHMD for very low birthweight (1,250 grams and below) preterm infants?

Several studies demonstrate improved morbidity and mortality for these very preterm infants who are fed an EHMD over cow's milk-derived fortifier. A recent meta-analysis published in the summer of 2020 identified three studies directly comparing human milk-based vs. cow milk-based fortifiers where the base milk diet was all human milk. One study was a randomized trial that compared EHMD and cow's milk-derived fortifier, and two additional studies provided raw data to the authors as subgroup analyses of a randomized controlled trial and a quasi-experimental study (1). This study found that infants fed EHMD had significantly less: NEC, ROP, PDA, and feeding interruption.

Are there differences in neurodevelopmental outcomes for preterm infants fed EHMD?

A recent retrospective observational study found a correlation with decreased incidence of grade III or IV IVH and PVL for extremely low birthweight infants fed EHMD compared to infants fed formula or mother's milk fortified with bovine fortifier. It should be noted that more infants in the EHMD group received antenatal steroids, but after correcting for antenatal steroid use, the significant differ-

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.

ence remained (3).

There is also a large body of evidence that illustrates the positive effects of breastmilk on infant neurodevelopment. However, there has been concern regarding the neurodevelopmental outcomes for preterm infants fed EHMD, as there are associations between EHMD and extrauterine growth restriction (weight <10th % at discharge). One study published recently in Breastfeeding Medicine may dispel some of the concern. This prospective cohort study included 44 ELBW infants who were fed an exclusive human milk diet until 34 weeks, 36% of whom weighed <10th percentile at NICU discharge. They were tested using the Bayley Scales of Infant Development 3rd Edition at age 2. The study found that there were no statistically significant differences in communication, motor, or cognitive scores between the growth restricted and non-growth restricted groups. Researchers then suggest that there could be a neuroprotective element of EHMD in the ELBW population (2).

"They found that implementing the standardized feeding protocol, which included earlier fortification of maternal milk was associated with improved growth and had no effect on NEC. (5)"

So...What about growth?

One study sought to compare post-discharge growth, adiposity, and metabolic outcomes of AGA versus SGA premature infants fed EHMD. SGA premature infants who received EHMD exhibited greater catch-up growth without increased adiposity or elevated insulin resistance compared with AGA infants at age 2. This study suggests that being fed an EHMD may actually improve body composition and metabolic outcomes for SGA infants in the long term. (4)

Since growth has been shown to be less for infants fed EHMD, another research group sought to determine how to best optimize growth for these infants. This was a retrospective study that looked at growth (weight, length, and head circumference gain velocities from birth to discharge) in infants <1250g before and after the implementation of a standardized feeding protocol for EHMD. They found that implementing the standardized feeding protocol, which included earlier fortification of maternal milk was associated with improved growth and had no effect on NEC. (5)

What are the financial implications of using EHMD?

At first glance, using a human-derived milk fortifier may seem to increase healthcare expenditure. However, when considering the clinical benefits, it may be cost-saving over time. Researchers conducted an economic analysis of EHMD compared to the standard practice of care, which includes the use of cow's milk-based products when needed. Their analysis revealed that using EHMD saves \$16,309 USD per infant, given the improved clinical outcomes (6). Evidence also exists for the financial benefit of EHMD in Canada and Europe.

Final Thoughts

A growing body of evidence supports the use of EHMD for preterm infants. Neonatal therapists can have an important role in advocating for its use as part of a multidisciplinary team.

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The Preemie Parent's SURVIVAL GUIDE to the NICU

By

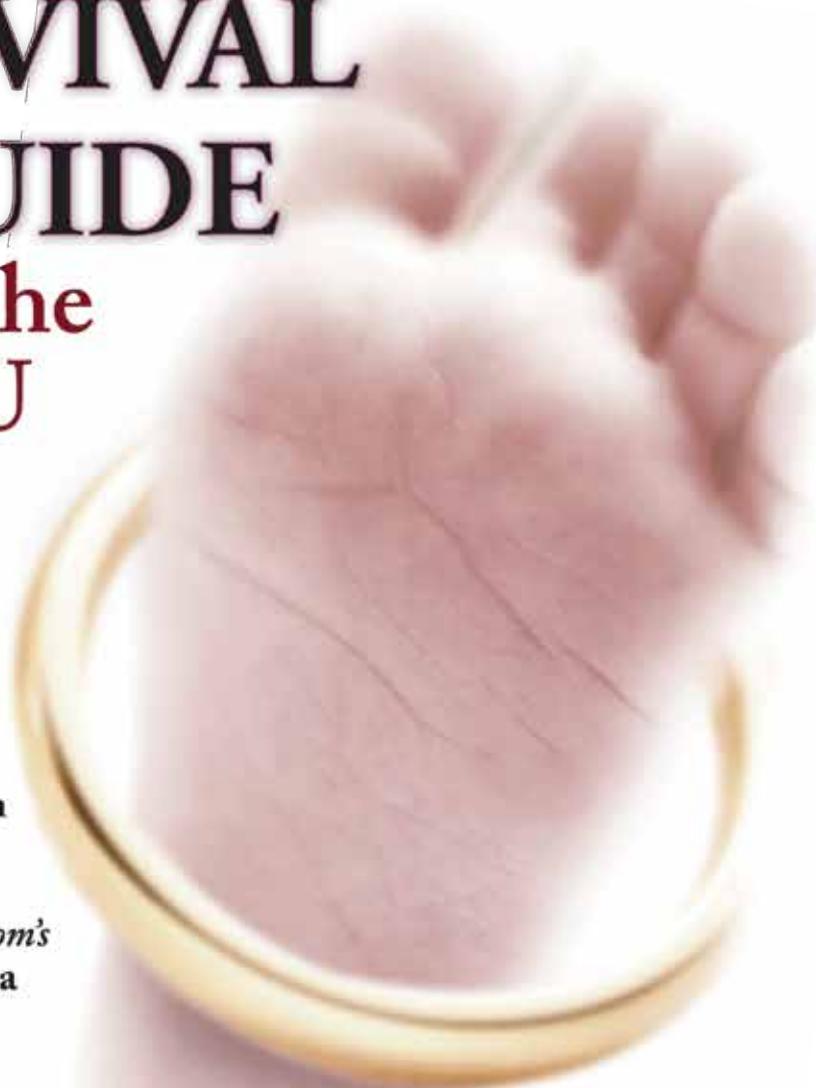
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second edition

**HOW TO
MAINTAIN YOUR SANITY
& CREATE A NEW NORMAL**

National Statistics

Respiratory Syncytial Virus



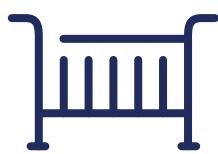
About Respiratory Syncytial Virus

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.¹ 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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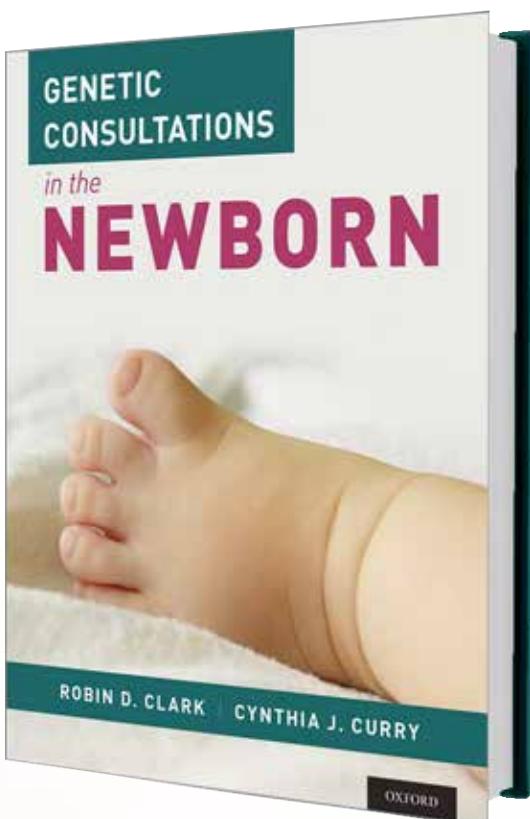
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RSV AWARENESS:

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

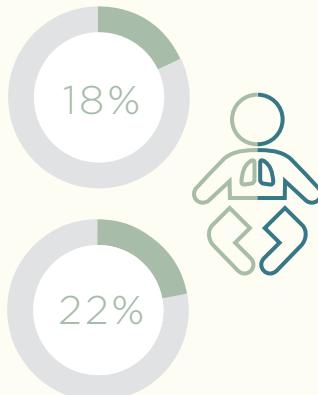
Parents of children age four and under report that understanding of RSV is lacking. That leaves them less than fully prepared to prevent their young children from catching the virus.

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 The Coronavirus Vaccine for Pregnant Women?

Sherri Sadler NNP, Joseph R. Hageman, MD, Mitchell Goldstein, MD

The Coronavirus 19 pandemic continues, and investigators from all over the world are working hard to characterize the short and long-term effects of COVID-19 infection/disease in adults, children, pregnant women, their fetuses, and newborn infants. This data is available to clinicians daily via the World Wide Web (www) as discussed in our last two clinical pearls with help from data scientists Tatiana Anderson and Kelty Allen (1,2). Now that the coronavirus (SARS-CoV-2) vaccine is becoming available, recommendations about the administration of the vaccine for pregnant women are being made by maternal-fetal medicine specialists (3-6).

"Now that the coronavirus (or SARS-CoV-2) vaccine is becoming available, recommendations about administering the vaccine for pregnant women are being made by maternal-fetal medicine specialists (3-6)."

This is the recommendation from the Society for Maternal-Fetal Medicine (SMFM) in their statement from 12/1/2020 regarding vaccination in pregnancy (3-6), which I learned about during our most recent Illinois Perinatal Quality Collaborative (ILPQC) COVID-19 Zoom webinar:

"Despite the categorization of pregnancy as a high-risk condition for severe COVID-19, hospitalization, and mortality, pregnancy remains an exclusion for participation in vaccine trials. The Society for Maternal-Fetal Medicine (SMFM) and other leading organizations, including the National Academy of Medicine, have consistently advocated for the inclusion of pregnant and lactating women in vaccination trials, particularly when the following criteria are met: (1) pregnancy poses increased susceptibility to or severity of a disease; (2) the best approach to protecting the infant is through passive placental antibody transfer, which provides the most efficient and direct protection to the newborn before an infant can be vaccinated, and (3) there is an active outbreak. Ultimately, the existing practice of "protection by exclusion" is harmful and has been characterized as clinical experimentation on pregnant women, as vaccines are distributed and administered without the safeguards of research protocols in place. Furthermore, there is no biological plausibility for the exclusion of lactating women from these trials.

In general, SMFM strongly recommends that pregnant women have access to COVID-19 vaccines in all phases of future vaccine campaigns and that she and her healthcare professional engage in shared decision-making regarding her receipt of the vaccine. Counseling should balance available data on vaccine safety, risks to pregnant women from SARS-CoV-2 infection, and a woman's individual

risk for infection and severe disease. As data emerge, counseling will likely shift, as some vaccines may be more suitable for pregnant women. **mRNA vaccines**, which are likely to be the first vaccines available, do not contain a live virus but rather induce humoral and cellular immune response through the use of viral mRNA. Healthcare professionals should also counsel their patients that the theoretical risk of fetal harm from mRNA vaccines is extremely low.

"Healthcare professionals should also counsel their patients that the theoretical risk of fetal harm from mRNA vaccines is very low."

SMFM recommends that healthcare workers, who are considered prioritized for vaccination, be offered the vaccine if pregnant. A report by the National Academies of Sciences, Engineering, and Medicine entitled Framework for Equitable Allocation of COVID-19 Vaccine recommends that high-risk workers in health facilities or first responders should be among the first to receive the vaccine. Although pregnant women are not explicitly targeted in this framework, pregnant and lactating women who are otherwise eligible should be offered the vaccine" (3-6).

These vaccines employ novel next-generation platforms consisting of either vaccine expression from the nucleic acid construct, as in the mRNA-based Moderna and Pfizer vaccines, or using a viral-vector, as in AstraZeneca's vaccine. AstraZeneca's use of a viral-vector is similar to the mechanism used in the Ebola vaccine, which is the only regulated vaccine using these next-generation



platforms. The Ebola vaccine has been administered during pregnancy and thus far has an acceptable safety profile (7-9).

"AstraZeneca's use of a viral-vector is similar to the mechanism used in the Ebola vaccine, which is the only regulated vaccine using these next-generation platforms. The Ebola vaccine has been administered during pregnancy and thus far has an acceptable safety profile (7-9)."

Several important points are emphasized from the information in this statement and other available clinical research and recommendations:

1. Pregnant women are now included in the high-risk group of severe SARS-CoV-2 disease.
2. The exclusion of pregnant women in the COVID-19 vaccine trials is a problem as it relates to having vaccine tested, data analyzed, and efficacy and safety established for the pregnant population.
3. Data from other vaccines produced with mRNA viral material suggests this type of vaccine is safe for administration to pregnant women. The theoretical risk to the fetus is very low.
4. The passive antibody transplacental transfer is the best way to protect the newborn infant before the infant can also be immunized. At this time, infants have also not been included in vaccine trials.
5. In addition, lasting immunity is not known at this time. But the importance of protection at the height of this pandemic is crucial.

It is also widely known that a single dose of the seasonal inactivated influenza vaccine given during pregnancy will induce maternal seroconversion and seroprotection, lessen the severity of any illness, decrease the risk for poor obstetric outcomes, and lower rates of influenza-like illness among newborns (10). The same may be able to be said of the COVID-19 vaccines' benefit to mother and fetus.

With the availability of more data, it is clear that maternal complications are common in pregnant women infected with SARS-CoV-2. Most commonly is pneumonia; however other reported complications include premature rupture of membranes (PROM), preterm deliveries, fetal distress, increased cesarean deliveries, gestational hypertension, diabetes, pre-eclampsia, placenta previa, oligohydramnios, polyhydramnios, hypothyroidism, and abnormal umbilical cord. Fetal complications include preterm birth, fetal distress, intrauterine growth retardation, stillbirth, neonatal death, and neonatal asphyxia (11). These complications during pregnancy can and do lead to future complications for the mother and unborn child.

Including pregnant women in the study of and administering the

COVID-19 vaccine when the vaccine is available is likely to prevent future illness and associated morbidities.

Following SMFM recommendations, appeals to NIH and the US food and drug administration have been made to reverse the exclusion of pregnant from their ongoing trials, and pregnant women should have the same autonomy that other adults have in participation in trials for COVID therapeutics and vaccines. As stated above, this population is underrepresented and needed to establish efficacy and safety data (12).

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Keeping Your Baby Safe

How to protect your little one from germs and viruses

The 2020 cold and flu season is going to be especially dangerous for vulnerable infants and their families. But there are things you can do to be safer.

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.
- Wear a face mask when out.
- Stay at least 6 feet apart 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 serious illnesses lowers their risk for complications from RSV and COVID-19.

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 respiratory viruses from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

We can help protect each other.

Learn more: www.nationalperinatal.org/COVID-19

99nicu

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.

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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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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 PREEMIES

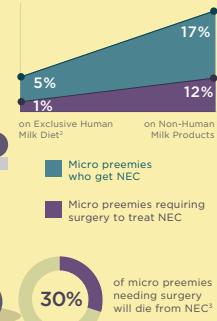
are at risk for Necrotizing Enterocolitis (NEC), which:

- 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:



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

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Protecting infants for perinatal infants through age two

- *Hull AB, et al. "Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet." *Breastfeeding Medicine* DOI: 10.1089/bfm.2019.0114
†Alvarez SA, et al. "Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products." *Breastfeeding Medicine* July/August 2014; 9(8): 281-285
‡Hull MA, et al. "Morbidity and management of surgical necrotizing enterocolitis in very low birth weight newborns." *Journal of Pediatric Surgery* 2010; 45(10): 2230-2234
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Pandemic COVID-19, the High-Reliability Organization (HRO), and the Ecology of Fear

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Abstract:

COVID-19 has changed the social, financial, and political environments for healthcare. Healthcare organizations have abruptly changed operations for a new environment due to pervasive threats to the organization, patients, and healthcare professionals. While the direct, infectious presence of COVID-19 as a threat would seem to cause the greatest stress to the healthcare system, perhaps the absence of the threat may cause more severe and wide-ranging problems. Ecological studies demonstrate a greater decrease in prey populations from the predator's absence due to an "ecology of fear." By analogy, organizations share these trait responses and can develop an organizational culture of stress or stress. HRO describes functional traits for effective operations in environments of severe threat.

"The tendency to discuss stress and fear as responses to threat may have misled us to diminish people's feelings, reasoning, and behaviors when the threat is absent. When nearby and visible, we can discuss measures to avoid attack and how to reduce psychological effects.."

Introduction:

The tendency to discuss stress and fear as responses to threat may have misled us to diminish people's feelings, reasoning, and behaviors when the threat is absent. When nearby and visible, we can discuss measures to avoid attack and how to reduce psychological effects. The absence of threat, however, creates a pervasive unease that requires a response. The functional stress responses, fear reactions, and threat reflexes (1) work well to direct reason and action toward the threat. Without a target, however, these behaviors become misdirected and maladaptive.

Predators reduce prey populations to a greater extent by the absence of the predator rather than direct predation. The "ecology of fear" describes predator-prey interactions in the absence of the predator (2). Not only do prey populations decrease, but the ensuing trophic cascade changes the landscape to become a "landscape of fear" (3, 4).

COVID-19 has changed the social, financial, and political environments for healthcare, creating a new landscape. Healthcare organizations have abruptly changed operations for this new environment. While the direct, infectious presence of COVID-19 as a threat seems the greatest challenge, perhaps the absence of the threat may cause more severe and wide-ranging problems.

This paper will translate the ecology of fear through analogy to understand HRO as a culture for fear. By their absence, threats create an environment containing fear that interferes with operations. HRO, as a verb, actively responds to the waxing and waning of threats while continuing operations in a normal manner. This combination of the environment with threat and continuous actions in response to the threat forms a culture that resists the stresses and fears or succumbs. HRO describes the functions not only to resist but to grow.

"This paper will translate the ecology of fear through analogy to understand HRO as a culture for fear. By their absence, threats create an environment containing fear that interferes with operations. HRO, as a verb, actively responds to the waxing and waning of threats while continuing operations in a normal manner."

The Ecology of Fear:

The direct killing of prey by a predator may have less influence on prey populations, and even the landscape, than the fear generated by the absence of a predator (2, 5). In the past two decades, fear has become a measurable element of ecology (6). By analogy, the fear of failure, in the absence of failure or the threat itself, may have a greater influence on human behavior and culture than actual failure (7). We will discuss this by analogy with mammalian ecosystems because of similar structures in predator-enemy-threat, prey-employees-organizations, and environmental stochasticity.

The fear of large carnivores changes the behavior of smaller carnivores and herbivores, which in turn alters the vegetation and landscape. For example, impala avoid woody areas due to predation by large carnivores. Experimental thinning of vegetation on the African savanna creates a safer environment that impala will enter

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to consume preferred, less-thorny Acacia trees. With the loss of competition, the thornier Acacia trees then become predominant. Grazing by larger herbivores, such as elephants, giraffes, eland, and oryx, that are not nearly as threatened by large carnivores, did not contribute to this change (8). The reintroduction of wolves in Yellowstone National Park changed the patterns of willow and cottonwood growth. Vegetation grew taller with significantly decreased growth of new vegetation that occurred where terrain features limited visibility or impeded escape by elk (9). The ecology of fear does not rely solely on the death of prey or the physical presence of predators. Introducing the sound of a large carnivore predator (dog in this study) into the environment of a smaller carnivore (raccoon in this study), compared to a non-predator (harbor seal in this study), had a significant influence on raccoon intertidal prey (10).

"We use the term "stress" to encompass the organism's response to demands greater than a routine that marshal functional behavioral, metabolic, and neurobiological capabilities."

We use the term “stress” to encompass the organism’s response to demands greater than a routine that marshal functional behavioral, metabolic, and neurobiological capabilities. The “ecology of fear” includes the “stress response” of the hypothalamic-pituitary-adrenal (HPA) axis that releases glucocorticosteroids into the bloodstream and “fear reactions” that maintain a safe distance from a predator or other threat (11). The utility of the neuroanatomic and functional attributes helps interpret field studies that measure stress response through HPA activation and assess fear reactions through vigilance and maintenance of the “flight distance,” a measurable distance that maintains safety (12).

In the wild, there is no risk-free environment. The absence of a predator does not mean the absence of risk; the lack of a threat perceived by the prey does not mean the absence of threat. To the prey, predation risk and the associated costs of antipredator

defenses are an activity cost (13), while novelty, uncertainty, and uncontrollability are the fundamental causes of stress (14, 15). Increased vigilance when threats are predictable and controllable decreases food intake. Stress responses when threats are unpredictable and uncontrollable release systemic glucocorticoids, increase vigilance, change feeding locations, and reduce fecundity (2, 5).

Post-traumatic stress disorder (PTSD), through the *stress response* of HPA activation and *fear reactions* of vigilance and behavior changes, can link prey stress from predation with human stress. Animals in laboratory studies demonstrate ‘sustained psychological stress’ comparable to PTSD (16). However, various prey species in the wild have different HPA activation responses to persistent high predation risk. There is no HPA activation when lemmings or voles interact with weasels or when elk interact with wolves. There is, however, HPA activation when snowshoe hares or ground squirrels interact with predators (17).

On the other hand, wild animals develop persistent *fear reactions* similar to those observed in laboratory animals. Both groups demonstrate enduring effects on behavior such as hypervigilance and time spent in immobility and vigilance. Neuronal activation as enduring or immediate effects also meets the criteria for the animal model of PTSD (18). Predator exposure can lead to behavioral change that interferes with foraging over weeks to months (19).

Fear of Disease:

The ecology of fear can also develop from disease. The perception of predators elicits fear reactions for self-protection and to maintain a safe distance. Pathogens, on the other hand, elicit disease avoidance through disgust and fear, preventing contact with contagious objects (20). For example, disease-relevant invertebrates elicit greater fear and disgust relative to disease-irrelevant invertebrates (21).

Disgust for pathogen avoidance appears to be a conserved survival behavior. In tadpoles, chemical and/or vibrational cues released from cercariae induce hyperactivity with a movement away from the source (22). In their review, Jason Rohr, et al. (22) offered: tree frogs laying eggs use chemosensory detection to avoid pools containing trematode-infected snails, rainbow trout avoid cataract-causing trematode cercariae, and some vertebrates use defecation and foraging strategies to reduce fecal-oral parasitic

Table 1: Stress conditions

Condition	Cause	Characteristics	Effects	Resolution
Stress	Novelty Uncertainty Uncontrollability	Objective Neurochemical release	Impaired declarative & working memory Impaired cognition	Perception of control
Fear	Proximity	Subjective Feeling	Maintain distance	Reframe
Threat	Existential harm	Objective Behaviors	Fight, anger Flight, avoid Freeze, vigilance Tonic immobility, nausea Dissociation	Conditioning

infection.

Human Stress-Fear-Threat Cascade in an Ecology of Fear

We will present fear ecology by analogy using the close alignment of the ecology of fear and the stress-fear-threat cascade (11). The functions of stress in the ecology of fear are listed in Table 1. From (11)

"We can discuss fear ecology by analogy with mammalian ecosystems due to similar predator-enemy-threat, prey-employees-organizations, and environmental stochasticity. As in mammalian ecologies of fear, the stress HPA system is activated, vigilance increases vigilance, and behaviors change toward self-protection."

We can discuss fear ecology by analogy with mammalian ecosystems due to similar predator-enemy-threat, prey-employees-organizations, and environmental stochasticity. As in mammalian ecologies of fear, the stress HPA system is activated, vigilance increases vigilance, and behaviors change toward self-protection. In more constrained human societies (compared to wild animal communities), the ecology of fear initiates the stress-fear-threat cascade manifested through distinct human behaviors (11). In the HRO, human performance strengthens the cascade's functions, while in the non-HRO, an ecology of fear leads to a rapidly malfunctioning cascade and performance deterioration. The manifestations of stress are listed in Table 2.

The fear of failure, rather than failure itself, itself, may have a greater influence on human behavior and culture than actual failure (7). We can correct or recover from failure, but we cannot cor-

rect a fear. We will discuss this by analogy with mammalian ecosystems because of similar structures in predator-enemy-threat, prey-employees-organizations, and environmental stochasticity. The ecology of fear activates the stress HPA system, increases vigilance, and changes behaviors toward self-protection.

Paraphrasing a previous paragraph, stress is a property of the individual rather than a property of the threat. An HRO environment is not a risk-free environment. The absence of a threat does not mean the absence of risk. Hazard and threat-risk and the associated costs of reliability and safety defenses are an activity cost accepted by individuals and the organization. Safety behaviors and programs focus on unrecognized threats and hazards, the more insidious harm to operations. Novelty, uncertainty, and uncontrollability are the fundamental causes of stress. Individuals accept the duty, and organizations develop the structure for vigilance for and response to discrepancies and disruptions.,

We focus in this paper on stress responses and fear reactions, pervasive in the ecology of fear. We defer discussion of threat reflexes, which are an immediate response to an existential threat.

Stress responses functionally narrow cognition for focus on threats from abrupt contingencies and happenstance. However, even with mild stress, the amygdala will impair the executive functions and the prefrontal cortex (23). Increased stress response strength further impairs the prefrontal cortex and judgment, but imperceptibly so since we use our judgment to judge our judgment. The stress hormone cortisol impairs memory retrieval, interfering with cognitive capacity and memory consolidation, impeding allostatic learning. While close colleagues can recognize this in real-time, all participants become affected in the ecology of fear, decreasing the quality of collective judgment. Unrecognized threats and hazards will unpredictably, and likely unnoticed, damage operations.

Fear reactions functionally maintain a safe distance from the threat, giving a better perspective while also reducing the likelihood of existential harm. The individual can achieve distance from threat through diminishment, offensive protection, and defensive protection (11). The diminishment of the concerns of others about the threat increases the cognitive distance from the threat. More insidious is to question, devalue information, or impede information flow (24).

Table 2: Manifestations of stress conditions

Condition	Mediator	Neurological Action	Manifestation
Stress	Amygdala	Impaired prefrontal cortex Impaired executive functions	Loss of cognition Subjectively rational Objectively irrational;
	Cortisol	Impaired memory retrieval	Confusion Blunted recall
Fear	Ventromedial Prefrontal cortex Periaqueductal Gray	Self-defense	Move to safety Offensive actions Defensive actions
Threat	Amygdala	Self-protection	Anger, frustration Plausible avoidance Attentive freeze Impeded decision-making

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

Defensive protection focuses on the individual's safety, often moving to a place of psychological or physical safety (25). Demands clearly exceed capabilities, and risks become too great for them to feel they can continue or survive. The person will not go near the threat or its source, whether abstract, such as concepts or specific information, or concrete, such as the leader, an administrator, or a colleague. Because the individual will not sufficiently approach the situation, descriptions, correlations, or causations do not develop. As a result, individuals must rely on rationalizations and abstractions (for example, clichés and metaphors) to support and explain judgments, interpretations, and actions. The individual is less useful to protect others since the person becomes focused primarily to reduce risk to themselves. Deflection, excuses, justifications, and prophylactic self-blame are standard methods.

"The person will not go near the threat or its source, whether abstract, such as concepts or specific information, or concrete, such as the leader, an administrator, or a colleague. Because the individual will not sufficiently approach the situation, descriptions, correlations, or causations do not develop."

Embedded in fear reactions in the ecology of human and organizational fear are offensive and defensive acts to protect the person's ego. The unrecognized threat to ego is possibly the most dangerous situation in the ecology of fear.

A Virus Ecology of Fear:

A pandemic virus-as-predator might create an ecology of fear within a society, observed Raymond Novaco, University of California, Irvine (personal communication).

Ebola Virus Disease (EVD)

Gregg Mitman (26) described the fear surrounding the EVD as having its own ecology that needed to be understood. The EVD epidemic demonstrated the effects of the ecology of fear when fear of a disease combines with prejudice (US) and painful history (Africa). Western attitudes associate equatorial Africa with deadly tropical diseases, generating irrational fears about the pathogenesis and infectious nature of the Ebola virus, an RNA virus (26, 27).

Incomplete information and historical distrust in authorities, particularly western authorities, contribute to rumors that will naturally emerge during an evolving event. Constrained health literacy contributes to resistance against effective healthcare principles. People in western countries then dismiss reasoned rumors and well-founded resistance as simple ignorance and superstition (28). Some US school officials and college admissions programs

banned students or rejected applicants from African nations, even as far as 1,700 miles from the exposed region (27).

The social fabric expected to hold society together began to tear. Caring for the sick and dead within Sierra Leone, Liberia, and Guinea would bring sickness and death (28). Fears stigmatized survivors. In the US, shunning behavior was directed against healthcare providers close to hospitalized quarantined patients (27).

The fear of creating an EVD fear ecology may have originated from the fear of an unknown infection in a land with a long history of exploitation by western nations (26-28).

Suspicion of healthcare workers and response teams was less a rejection of western medicine than re-experiencing "sub-standard and heavy-handed provision" of care in the past (27). The EVD epidemic occurred in an area with a history of "European and West African slave traders, white missionaries, and Liberian soldiers recently sent to conquer the interior" and painful memories of past medical encounters in West Africa (26). This history and exploitation by western countries contributed to fear and conspiracy theories (27).

The severity of EVD, with limited knowledge about transmissibility and effective treatment, made EVD an accessible vehicle for politics, with response teams becoming deeply politicized (28). The consequences of politicizing fear and prejudice in the historical background of abuse and marginalization lead to violent anger. The consequent Ebola ecology of fear may explain violent fatal attacks on healthcare providers and volunteers (27, 28).

COVID-19

A previously unidentified coronavirus, also an RNA virus from a geographic and cultural region dissimilar to the US, led to a worldwide pandemic. The social response to COVID-19 is quite similar to the response to EVD, though on a larger, more pervasive, and intense scale.

"The consequences of politicizing fear and prejudice in the historical background of abuse and marginalization lead to violent anger."

Though pathogens tend to elicit disease avoidance, the present human and social response to COVID-19 bears more semblance to the fear reactions elicited by predators. We can appreciate COVID-19 fear ecology through an analogy using the close alignment of the ecology of fear, the stress-fear-threat cascade (11), and the recent experience with EVD.

Ecology of fear and the recent experience with EVD describes some of our current problems with a virus that, as stated by Mitman (26), has its own ecology that needs to be understood. The current COVID-19 pandemic combines prejudice and painful history, complicates, and confounds our best efforts to achieve a successful resolution. Attitudes associated with "the other not like us" and incomplete information about an evolving disease generates

irrational fears and further misinformation.

Incomplete information and distrust in authorities and scientific experts during an evolving event contribute to rumors that naturally emerge from confusion and uncertainty. People reduce the stress of novelty by anchoring information to what they believe—gaining a sense of autonomy, even if in conflict with prudent healthcare or public health principles, brings predictability and controllability. Finding the familiar in the novel, seeking certainty even if contrived, and controlling one's behaviors and beliefs will reduce the causes of stress – novelty, uncertainty, and uncontrollability (14, 15).

Constrained health literacy, almost an endemic problem, contributes to resistance against effective healthcare principles. Dismissing non-medical beliefs increases the resistance to prudent and effective public health measures.

The social fabric that we expect will hold society together has begun to tear as in West Africa during the EVD epidemic. Fears stigmatize those with whom we disagree. Shunning behavior becomes directed against healthcare providers and public health officials.

Suspicion of healthcare workers and response teams may be less a rejection of medical practice than re-experiencing impersonal, “sub-standard, and heavy-handed provision” of care by the healthcare community. In some communities and minority groups, painful memories of denied or limited medical care remain in the collective memory. One author (DvS) reminds healthcare staff before and after discussions for limitation or withdrawal of medical care for a child of a minority that a family member or friend likely had medical care denied or limited because of race. That experience will be at the forefront of their mind as we discuss limiting medical care for defined ethical reasons. This is personal to them rather than the larger issue of healthcare equity.

COVID-19 had a confusing presentation with a wide range of severity, the facility of its spread, and a misleading mortality rate. Combined with the initially limited knowledge about transmissibility and effective treatment, COVID-19 became an accessible vehicle for politics.

Viewing the COVID-19 or EVD responses as an ecology of fear reveals the similarities of the fear environment created by the viruses. Because the predator is not physically present, viruses can act like a predator. But an ecology of fear was likely already present. People can treat abstractions as a concrete rendering of a predator, allowing them to respond to abstractions like error, failure, liability, even someone's fear, as they would a predator. Alfred North Whitehead (29) warned against this “fallacy of misplaced concreteness,” mistaking the abstract for the concrete.

“Fears stigmatize those with whom we disagree. Shunning behavior becomes directed against healthcare providers and public health officials.”

When created from abstractions, the ecology of fear forms an environment with mutual threats, but the importance or degree of

mutual threats is not equally shared. Error, failure, and liability as abstractions of mutual threat create or influence a fear environment, but the fear is not equally distributed. Employees, managers, supervisors, administrators, regulators, and executives also create a fear environment. Any abstraction considered a predator, along with the ecology of fear, creates a fear environment. Culture as the social response to the environment can effectively extend a group into a fear environment, or the culture can generate avoidance or withdrawal. HRO, as a culture, extends the organization into an ecology of fear (30).

Stress As A Culture:

Cultures function within an environment and are continued through shared social knowledge. Stress and the ecology of fear can influence cultures toward homeostasis and protection against change or generate allostasis and strength through change. Stress can predominate in the organization's operational environment, or stress can become a form of acquired knowledge to interpret experience and generate behavior. We can describe cultures, regardless of the model used, with the same characteristics: an *environment* in which the culture developed, *behaviors* useful in the environment, and some are norms specific to a culture, beliefs as invariant values or adaptive attitudes, and some artifact or technology shaping the culture. Rules and procedures form the artifacts in many organizations.

Cultural ecology is the “ways in which culture change is induced by adaptation to the environment” (31). The environment, even the ecology of fear, influences human adaptation but does not determine adaptation. Steward's (31) primary arguments were that (1) cultures in similar environments might have similar adaptations; (2) all adaptations are short-lived and are continually adjusting to changing environments, and (3) changes in culture can elaborate on an existing culture or can result in the creation of entirely new ones.

Culture is the knowledge acquired and shared and how knowledge is used to interpret experience and generate behavior (32). As people learn their culture, they acquire new ways to interpret experience

Sources of social knowledge include social learning by observation of other people (33). These individuals may be found within the organization or during other social interactions. Social learning also occurs through movies and television. The author (DvS) noted a change in behavior from bystanders during fire rescue ambulance responses. People stood closer and watched rather than becoming involved and helping, questions became directed toward what paramedics should do rather than concern about the patient's condition, and expectations for specific actions and behaviors began to appear. Colleagues pointed the author to a television show, *Emergency!*, which showed these behaviors. Perhaps the realistic portrayal of physician, nurse, and paramedic relationships and interactions facilitated the transfer from what people watched on television to what they saw when paramedics were on scene. The realistic interactions were by design. Ronald Stewart, the medical advisor to the show, broke with the tradition of vetting physician roles by the AMA that maintains a physician's distance from nurses and ancillary staff. Stewart had designed paramedic education and operations in Los Angeles County to drive discussion between physicians, nurses, and paramedics. He wanted the realism of that approach in the show (personal com-

munication).

Unfortunately, the social learning of some stress behaviors through movie and television representations has become common. Character-driven movies with introspective lead characters, such as the 1953 Western movie *Shane* where the gunfighter shows gentle, controlled strength, have been replaced with action, retribution, and vengeance movies. Maladaptive and dysfunctional responses to abrupt contingencies have become more acceptable and the norm in some areas. Early in medical school, one author (DvS) encountered the belief that to learn stress; one had to be placed under stress, "sink or swim." When queried for the source of the belief, it was how the military trained recruits. Because none of the respondents had military service, the next query was how one would know. The consistent answer, "It's in the movies." Hollywood clichés of emotional bonding in the military may also influence soldiers and social scientists (34) as well as healthcare professionals. Influenced by movies and television, the environment becomes distorted as unsafe while maladaptive behaviors become accepted that further distort the environment.

"Social learning also occurs through movies and television. The author (DvS) noted a change in behavior from bystanders during fire rescue ambulance responses. People stood closer and watched rather than becoming involved and helping, questions became directed toward what paramedics should do rather than concern about the patient's condition, and expectations for specific actions and behaviors began to appear."

Stress and fear are attack vectors aimed at the individual or organization but can readily become attack vectors for organizational failure when error becomes identified as a threat (7). Organizations may use threat and stress responses for compliance and obedience and to support directive or authoritarian leadership styles. Paradoxically, while stress as a concept brings comprehension, it robs the individual of the sense of controllability. Stress, fear, and threat then become affective experiences, constructing an environment built from subjective stress and nearly independent of objective threats. That is, rather than engaging in a situation, individuals evaluate threat as risk, judging whether to engage. Threat and stress become the environment and ecology of fear. For example, faced with an explosive device or a burning train inside a tunnel, a prudent individual might weigh the risk and benefits of rescue. Yet, when queried about civilians trapped near an explosive device, a San Bernardino City (California) Police Sergeant, with that experience, immediately remarked the officers would continue extrication (as they had done with some criticism from outside), "We won't leave someone alone." When asked why the fire rescue team would approach a burning train within a tunnel, a French Division Chief, Bouches du Rhone Fire Department

(France), answered, "The French people expect us to come to their aid." Yet, in healthcare, concern for liability informs the working environment and the possibility of "doing harm" informs the practice environment.

Stress as a functional property of the individual (1, 11), rather than a property of the predator or threat, allows us to discuss stress responses, fear reactions, and threat reflexes as situational functions. Rather than missed as part of the environment, stress becomes visible as acquired social knowledge, contributing to the maintenance of culture. Stress, fear, and threat are knowledge: the salience and meaning of stimuli, the interpretation of events, information flow and communication, and interactions between leader and subordinate. To evaluate stress as social knowledge, we ask, "How do people in the culture use or respond to stress?" The HRO uses threat and stress responses as drivers to increase capability toward engagement. Others may use threat and stress responses to avoid a threat, reduce risk, or enforce compliance.

We can now see culture in terms of interactions with a small-scale environment, a process operating as the social group continually adapts to the environment (31). This "cultural ecology" represents the "ways in which culture change is induced by adaptation to the environment" (31). Threat or a predator, as an independent component of the environment, then informs the cultural response of stress and fear and the cultural response becomes social knowledge shared with members of the organization. The characteristics of an HRO begin to degrade.

The HRO uses threat and stress responses as drivers to learn, inform leadership styles (35, 36), team formation, and foster collegiality. As acquired cultural knowledge, stress informs the detection and response to threats and identifies and modulates stress responses. Rather than forming around stress when engaging adversity or entering an adverse environment, the HRO leverages stress into safety and reliability (7).

A culture of stress debilitates people and weakens organizational responses. A culture for stress strengthens the individual. It is the individual who believes in themselves who decides to move forward and engage. HRO is a culture for stress.

Organizational Response To Fear:

Nobel laureate Niko Tinbergen, writing "Every animal has to cope in numerous ways with a hostile, at least uncooperative environment," posited that it is behavior that gives the animal the ability to cope and survive (35). Measurable antipredator behaviors in the ecology of fear when the predator is absent include vigilance, sociality, location, and feeding (when and where). Decision-making by prey includes trade-offs between the risk of predation, the benefits of the activity, and the ability for antipredator behavior (5, 13). Patterns of defenses differ if the risk is unpredictable, uncontrollable, variable, and defense costs are high (5).

Proactive defenses have the greatest effectiveness when risks are predictable and controllable. Reactive defenses are more effective and reliable with increasingly unpredictable or uncontrollable risk. When risks are consistently high or if defensive costs are low, then fixed constitutive defenses, such as spines, become effective. More often, risks will vary by location or over time, and defenses carry costs (5). Vigilance in the absence of the predator, a defense cost, sustains the stress response with chronically elevated glucocorticoid levels and reduced reproduction (2, 16).

Inducible antipredator responses allow the selection of antipredator behaviors with variable expression, increased behaviors for elevated risks, and decreased expression as the risk abates (5).

In organizational terms, proactive, fixed constitutive defenses make sense for their effectiveness and lower cost, becoming a normative stance from an external, fixed reference frame. On the other hand, the pragmatic frame corresponds to the adaptive expression of behaviors selected by the individual at the point of contact (30). A fundamental problem lies in the interpretation of error. During a risky episode, behaviors will likely deviate from rules. From the normative stance, these deviations signal the possibility of error, while from the pragmatic stance, these deviations may be considered an error, though the pragmatist sees adaptability and finds utility in the information generated. Notions of high reliability make a big deal of this difference. Control operators, like those in a nuclear power facility, prevent failure. Deviation from rules signals potential failure. Like wildland firefighters, emergency responders respond to failure, and tight adherence to rules signals potential failure (36).

"A culture of stress debilitates people and weakens organizational responses. A culture for stress strengthens the individual. It is the individual who believes in themselves who decides to move forward and engage. HRO is a culture for stress."

Adaptive expression of behaviors for defense also performs well with competing objectives, where one objective appears to threaten another objective. Neonatologists work toward goals with varying time horizons generating varied temporal perspectives: how does resuscitation affect maternal bonding, social development of the family, and organ development after NICU discharge? Neonatologists routinely work with multiple, conflicting objectives, varying timelines, and limited and imperfect information. Despite this variability, neonatologists share a drive to achieve the same end-state – bonding of infant and family in the best possible physiological condition. For example, a review of multiple national COVID-19 treatment guidelines from various nations showed similarities in treatment. All national groups, however, produced their guidelines for the same, shared end-state (37). Variability creates stability in an uncertain world.

This notion that behavior contributes to failure by way of error leads organizations to constrain adaptive behaviors increasingly during a crisis. The mistranslation of error from a method to correct heuristic bias (38) and identify the limits of operations and performance (the “performance” or “operational envelope”) has turned an error into an early herald of failure (7). But it is the contextual expression of behaviors, utilizing reciprocal feedback, and correcting errors that generate improvisation (39), even under life-threat (40). Perhaps the gap between the different logics of theory and practice (41) informs this mistranslation. The scientific logic for theory creates mental objects, abstractions not “found” through

inquiry but inference (42). In an ecology of fear, we cannot accept these inferred abstractions as concrete representations (29). Representational logic underlies scientific theory while the operator is immersed in the ecology of fear where entities and events continuously and constantly change. Operators in this engaged practice use practical rationality to form a logic of practice, a logic that is not well worked out (43).

Following a year engaged in a “behavior versus concepts” controversy with experts and specialists from multiple industries, the author (DvS) received the following note of encouragement from Karl Weick: “John Dewey agrees with your emphasis on behavior” followed by this quotation:

John Dewey insisted that inquiry is always a behavioral response of a reflective organism to its environing conditions....inquiry belongs to “action or behavior, which takes place in the world, not just within the mind or within consciousness....Inquiry, just as much as walking or eating, is what Dewey termed an “outdoor fact.” (42).

Defensive measures protect the organization from damage due to direct attack and also protect routine operations from distractions. Karl Weick (personal communication) once described how his motivation for “sensitivity to operations” came from studies that demonstrated failure when a disruption had distracted the organization from their routine operations. It would appear prudent to cancel or defer risky studies that do not have an immediate benefit for a neonate in the NICU. Risks, however, may have a window of treatment before irreversible damage occurs. For example, the mechanism of damage to incompletely developed organs is similar to Acute Radiation Syndrome (ARS): the pathogen is hidden (ionizing radiation/cellular damage from hypoxia), the damage is delayed, and the disease is untreatable. The problem of fissile material causing ARS contributed directly to the development of safety culture in the nuclear power industry (44). Retinal cells of the premature neonate provide several examples. Drugs that may damage a small percentage of vision cells may cost an adult only a small percentage of cells with limited effect on vision. For a premature infant, those damaged cells represent a logarithmic growth of vision. For Retinopathy of Prematurity, Candace Frazier (45) identified methods for monitoring ROP that limit exposure to COVID-19 through membranes around the eye through the use of telemedicine and ultra-widefield imaging.

In the ecology of fear, the influence of the predator is through its absence. For an HRO, the influences of threats are through their absence, less of a measurable probability and more of the ease, or possibility, for abrupt change. The five characteristics of HRO (46) initiate action against threat or adversity. *Preoccupation with failure* describes vigilance toward absent threats; *reluctance to simplify* acknowledges the latent presence of threats before they become visible; *sensitivity to operations* guarantees continued operations of the organization for logistic support to exigencies; *commitment to resilience* ensures engaging the problem, decomposing objectives as needed; and *deference to expertise* entrains resources into the engagement.

Organizations maintain vigilance for outliers in operational terms, treating them as early heralds of attack rather than random, independent events that can be disregarded. Engagement initiates sensemaking by generating information and creating structure through action (30). Enactment driven by the organization’s cul-

ture changes the environment from an ecology of fear and generates allostatic stability through change.

"As a continuous process, doing in emergencies what is done every day, the organization responds to, recovers from and incorporates minor insults and major disruptions while moving forward. Rather than returning to the pre-crisis state, this form of resilience generates dynamic stability and strength through change."

Conclusion:

Stress describes the organism's response to novelty, uncertainty, or uncontrollability (14, 15). Fear describes the response to the proximity of a threat (12, 47). We limit our discussion of threat reflexes reacting to existential threat (48, 49) because stress responses and fear reactions can be sustained in the absence of a threat (16, 18, 19) while the direct, personal closeness of existential threat triggers threat reflexes that more quickly resolve.

The functional value of stress can become dysfunctional without adaptive neuromodulation (1). Functionally, stress describes the stress responses to constrain reason and thought fear reactions to keep the threat at a safe distance, and threat reflexes for existential survival (11). Stress responses can be "linked to mere thoughts" (50), and fear responses can be generated by the absence of a predator (2, 5).

In the larger, environmental context, stress and fear can shape an ecology of fear (2), which then informs human culture into a culture of fear or culture for fear. HRO describes the characteristics (46) and attributes (30, 38), allowing an organization to continue operations during severe disruptions or extend operations into a volatile, threatening environment.

Acknowledging the function of stress and the survival value of behaviors, the organization can produce distinct proactive, constitutive defenses for predictable and controllable risks, even for consistently high risks. Planning becomes focused and substantive. On the other hand, for unpredictable or uncontrollable risks, or risks that vary with time and place, reactive defenses may prove more effective and reliable. When defense carries costs, the organization can plan for actions expressed for situations heralding system dysfunctions, evoked by early heralds, acting before problems begin entraining resources.

An outlier becomes noticed as the beginning of unwanted processes for further inquiry rather than a random, independent event that can be readily disregarded. Error then becomes a tool, in effect an artifact that informs the organization's culture, a marker for the boundaries of the operational envelope, indicators for a changing environment, revealing novel or unexpected elements.

In an environment of disruption, an ecology of fear, the adaptive organization supports vigilance for early heralds of failure. Not

preoccupied at the expense of other duties, but vigilance as sensitivity to operations, maintaining operations during disruption while also resolving the disruption. Engage what initially appears simple but through inquiry revealing more complex salient elements. The increased granularity brings out relevant, local expertise for more effective actions. As a continuous process, doing in emergencies what is done every day, the organization responds to, recovers from and incorporates minor insults and major disruptions while moving forward. Rather than returning to the pre-crisis state, this form of resilience generates dynamic stability and strength through change. This is HRO; rather than responding to the future, the organization prepares for the future through daily operations.

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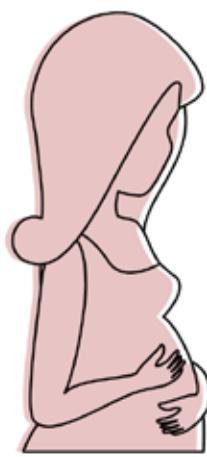
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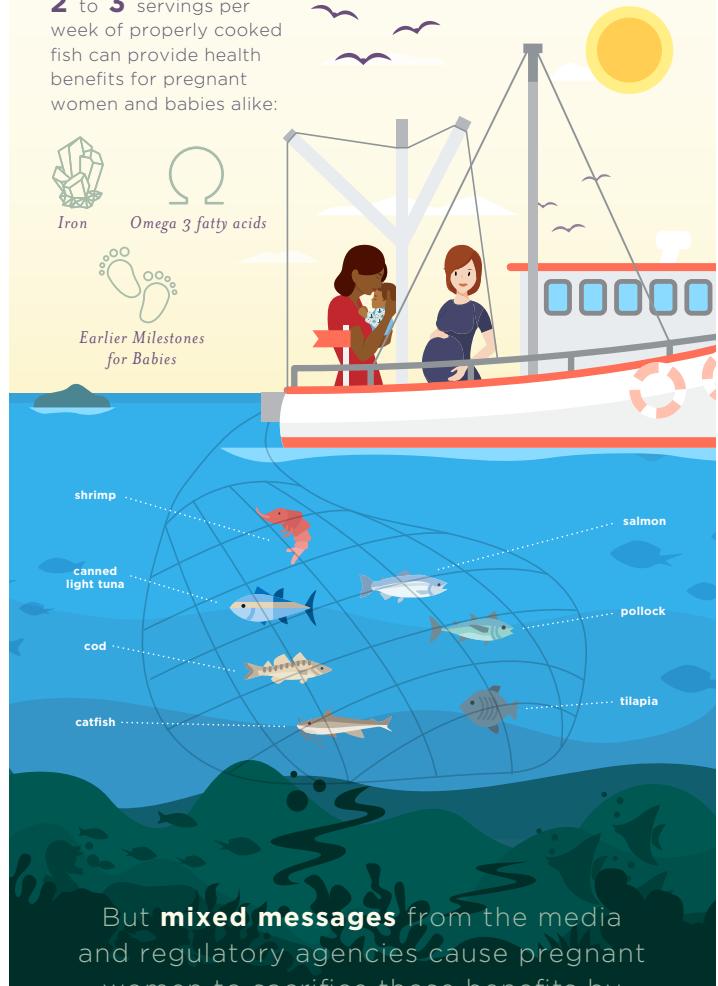
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Letters to the Editor

Letter to the Editor

Postnatal Steroids in Non-ventilated Preterm infants

Bronchopulmonary dysplasia (BPD) is a disease of infants born prematurely. The incidence is inversely proportional to the gestation age. Basing on the severity and per the National Institute of Health (NIH) consensus, it is defined as mild, moderate, and severe. (1) The prevention and treatment of BPD remain a challenge. The variation in the management depends upon the three phenotypic disease components; moderate-severe parenchymal disease, pulmonary hypertension, or large airway disease. (2)

"The prevention and treatment of BPD remain a challenge. The variation in the management depends upon the three phenotypic disease components; moderate-severe parenchymal disease, pulmonary hypertension, or large airway disease. (2)"

Recently, Hansen et al. (3) described a guideline for the use of dexamethasone in the preterm infant \leq 30 weeks at birth and \leq 30 days of life with developing BPD by using the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) BPD estimate calculator. (4) They suggested using

dexamethasone for a BPD/ death score of \geq 35% on ventilated preterm infants. The question that remained unanswered is: what about the non-ventilated preterm infant \leq 30 weeks at birth and \leq 30 days of life with a probability of severe BPD and/or death of \geq 35%?

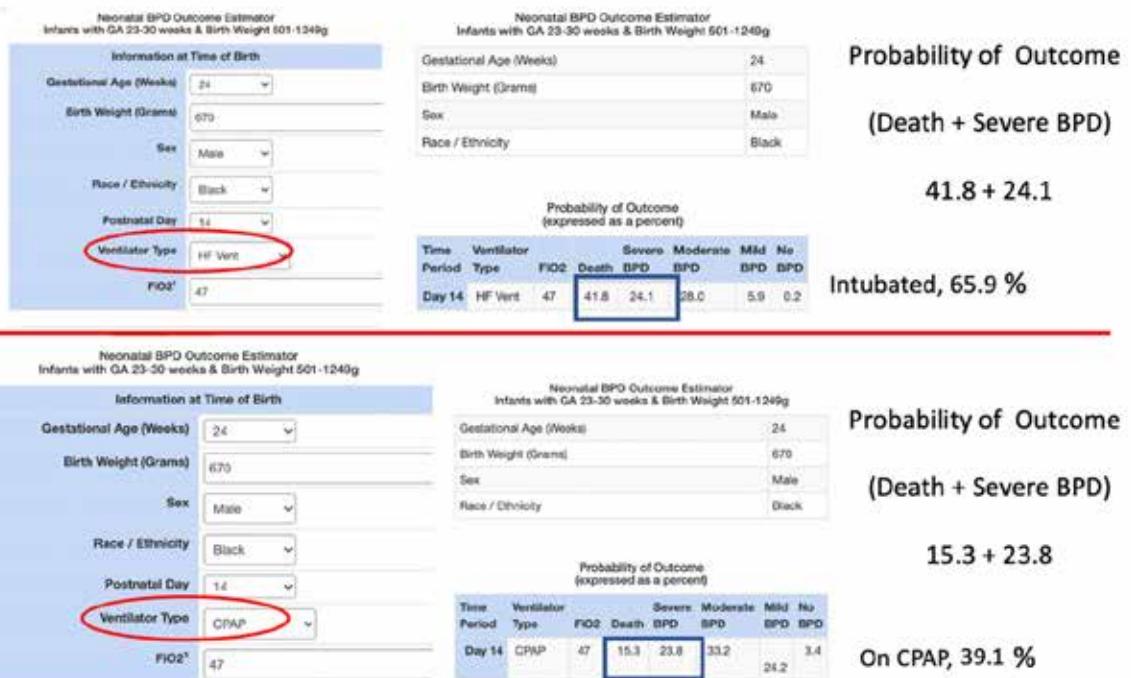
With the advent of non-invasive ventilator strategies, preterm infants are extubated earlier. Nasal continuous positive airway pressure (NCPAP) is a useful method for providing respiratory support after extubation. Similarly, the use of nasal intermittent positive pressure ventilation (NIPPV) had been shown to reduce the incidence of extubation failure and the need for re-intubation. (5)

With the increased use of non-invasive ventilation, we would have a 'high-risk group' of non-intubated preterm infants \leq 30 weeks at birth and \leq 30 days of life that might have a probability of severe BPD and/or death of \geq 35%. For example, based on the NICHD BPD estimate calculator, a preterm infant on NCPAP at 14-day of life, weighing 670 grams at birth, born at 24-week gestation, still has a 39.1 % probability of developing BPD and/or death combined as compared to the same infant on the ventilator (Figure). Using Hansen et al. (4) current study guidelines and cut-off of 35%, should we consider using a 7-10 days course of low-dose dexamethasone in this specific group of non-ventilated high-risk preterm infants?

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Figure



<https://neonatal.rti.org/index.cfm?fuseaction=BPDCalculator.start>

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Sincerely,

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Dear Dr. Manzar,

Bronchopulmonary Dysplasia (BPD) has been fought with issues since the term was first described in preterm babies born at 28 weeks gestation or greater with chronic lung disease (CLD). (1) Although first used to describe CLD that was primarily a result of an increased interest in ventilating a population whose physiology was neither wholly understood nor compatible with the ventilators of the day, BPD developed into a term that was used to describe a clinical oxygen requirement and not a distinctive lung pathology. (1) These "so-called" oxygen challenge tests are appropriate in determining whether oxygen is indeed required but do little to define the actual lung disease that qualified the oxygen requirement in the first place. Moreover, with increased attention towards oxygen saturation targeting, one must remember that even conventional pulse oximetry did not exist when BPD was first defined. (2)

Decadron is another issue. Certainly, Decadron, a potent glucocorticoid, is a leading choice to prevent brain edema brought on

by neurological trauma in older patients. It provides enhanced access across the blood-brain barrier when compared to other steroids and is particularly effective in preventing the ramifications of brain swelling and subsequent herniation. However, a frequent aspect of treatment 25 years ago, Decadron use all but disappeared because of the negative consequences associated with the "scorched earth" doses commonly used during that era. Subsequently, BPD rates increased. Antenatal steroids improved the statistics considerably, but it is only comparatively recently that we have seen Decadron's resurgence, albeit at lower doses and shorter intervals. (3, 4)

"So at this point, we are using a potent therapeutic capable of crossing the blood-brain barrier to treat a disease with myriad etiologies based on a clinical perception now possible because of advances in monitoring that were not attainable when the disease was originally defined."

So at this point, we are using a potent therapeutic capable of crossing the blood-brain barrier to treat a disease with myriad etiologies based on a clinical perception now possible because of advances in monitoring that were not attainable when the disease was originally defined. Worse still, numerous benchmarks for good patient care have centered on BPD rates and the need for oxygen at discharge. These benchmarks are thought to be associated with improved clinical care and, thus, supposed better outcomes.

What was once a metric designed to highlight best of breed ventilator management is now clearly a tool that can be applied post-haste to redefine the care we provide. So while the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) BPD estimate calculator may provide guidance regarding the risk of development of BPD, (5) we must now go one step further. How can we possibly address whether the provision of nasal ventilation with oxygen presents more toxicity than the alternative, using a mode that was not even on the horizon when BPD was defined; pulse oximetry, developed; and Decadron, first prescribed to treat babies with chronic lung disease?

With increasing attention to resuscitating smaller babies than thought possible fifty years ago and using even more novel therapeutics, is it fair to still use the term BPD as a catch-all for chronic lung disease in a population we could not have even envisioned saving when the term was first defined? (6) Moreover, do we still see considerable "BPD" in the original index population? (1, 5)

While recent work from Harmon et al. suggests that the use of steroids in at-risk populations prior to day of life 50 will reduce the

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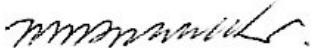
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risk of "severe" BPD, (5) unfortunately, the more important answer is still a question. Why are we still using an archaic term to guide our treatment of a clinical entity related to the original disease in name only?

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Sincerely,



Mitchell Goldstein, MD

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Erratum (Neonatology Today November, 2020)

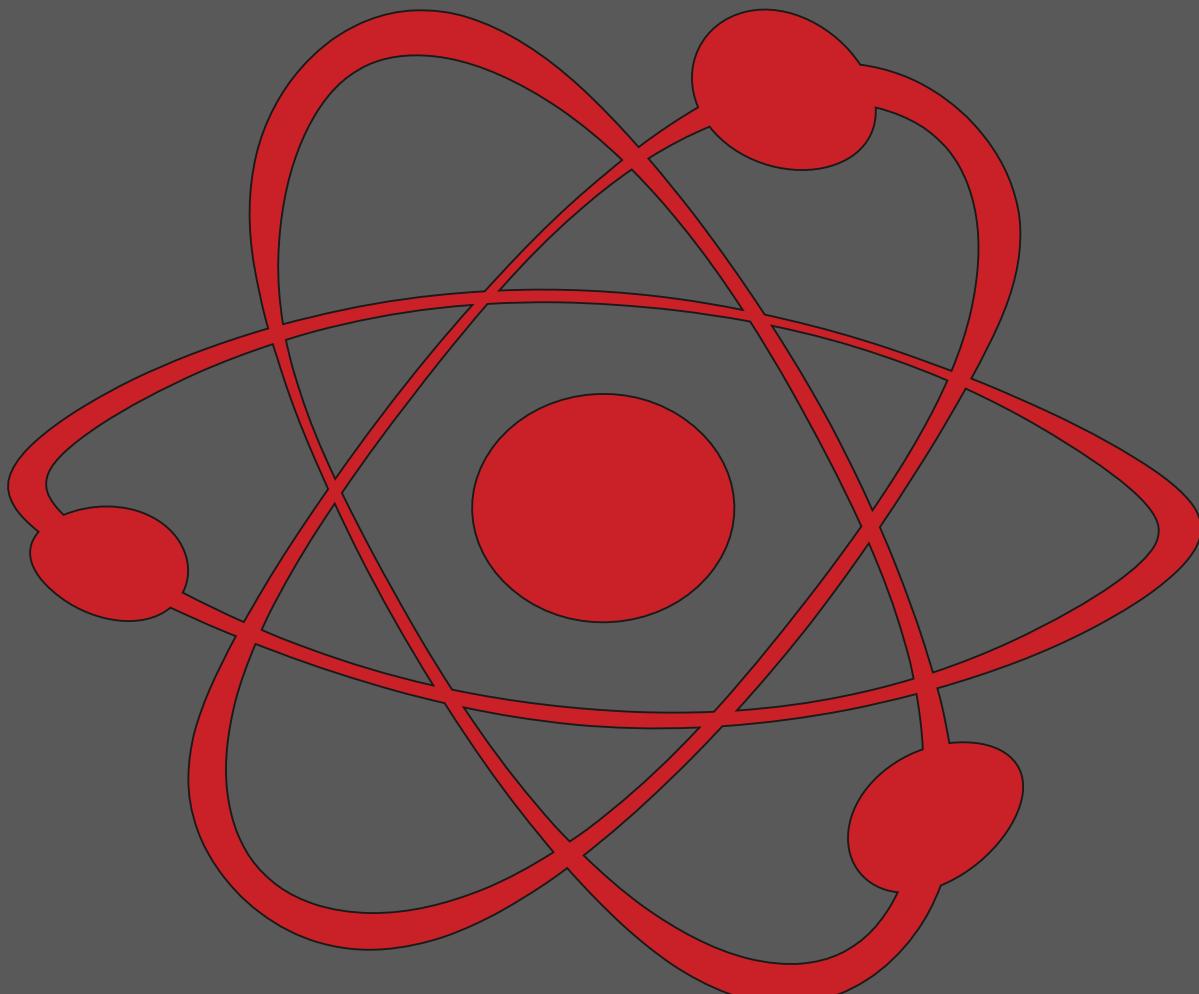
Neonatology Today has identified no erratum affecting the November, 2020 edition.

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

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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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Will your PRETERM INFANT need EARLY INTERVENTION services?

Preterm infants are:

- 2x** more likely to have developmental delays
- 5x** more likely to have learning challenges
- 1 in 3** preterm infants will require support services at school

Early intervention can help preterm infants:

- Enhance language and communication skills
- Build more effective learning techniques
- Process social and emotional situations
- Address physical challenges
- Prevent mild difficulties from developing into major problems

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

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

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

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

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

Las nuevas mamás necesitan acceso a la detección y tratamiento para LA DEPRESIÓN POSPARTO

1 DE CADA 7 MADRES AFRONTA LA DEPRESIÓN POSPARTO, experimentando

- Llanto incontrolable
- Sueño interrumpido
- Ansiedad
- Desplazamientos en los patrones de alimentación
- Ideas de hacerse daño a sí mismas o al bebé
- Distanciamiento de amigos y familiares

Sin embargo, sólo el 15% recibe tratamiento¹

LA DEPRESIÓN POSTPARTO NO TRATADA PUEDE AFECTAR:

- El sueño, la alimentación y el comportamiento del bebé a medida que crece²
- La salud de la madre
- La capacidad para cuidar de un bebé y sus hermanos

PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

- Financiar los esfuerzos de despitaje 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 posparto^{3,4}
- Conectar a las mamás con una organización de apoyo

¹ American Psychological Association. Available at: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>
² National Institute of Mental Health. Available at: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology 2018; 38: 629–636 doi:10.1038/jp.2018.147
⁴ Prevalence and risk factors for postpartum depression among women with preterm and low birth-weight infants: a systematic review. Vigod SN, Villegas L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

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

Upcoming Medical Meetings

NEO: The Conference in Neonatology
February 15-19, 2021
Virtual
[https://mednax.swoogo.com/
NEO2021](https://mednax.swoogo.com/NEO2021)

The 34th Annual Gravens Conference
March 3, 4, 10, and 17, 2021
Virtual
[https://health.usf.edu/publichealth/
chiles/gravens-conference](https://health.usf.edu/publichealth/chiles/gravens-conference)

37th Annual Advances in Therapeutics and Technology Conference
March 24 -26, 2021
Virtual
[https://paclac.org/advances-in-care-
conference/](https://paclac.org/advances-in-care-conference/)

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/)

22nd 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>

44th Annual Conference on Neonatal Perinatal Medicine
June 17 - 21, 2021
AAP District VIII Section on Neonatal-Perinatal Medicine
<https://nm2020.district8sonpm.org/>

Innovations in Neonatal Care
Location: Santa Fe, New Mexico
August 9 - 11, 2021
Mednax
[http://www.innovationsconference.
com/](http://www.innovationsconference.com/)

42nd Conference on Pediatric Health Care.
Phase 1:
March 10-13 (Orlando, FL)
Phase 2:
March 24-27 (Virtual)
NAPNAP
[https://www.napnap.org/national-
conference/](https://www.napnap.org/national-conference/)

Location: Austin, Texas
For up to date Meeting Information, visit NeonatologyToday.net and click on the events tab.

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With over 900 beds in four hospitals, we operate some of the largest clinical programs in the nation. We also offer the only Level I Regional Trauma Center and Children's Hospital in the Inland Empire servicing the largest county in the US. We lead in many areas of excellence; pediatrics, cardiac services, cancer treatment and research, mental health, chemical dependency, and other essential clinical disciplines. All this adds up to endless possibilities for our patients and for you.

The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children's Hospital is committed to providing high-quality, family-centered care with our highly skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill infants and a new Tiny Baby Program focusing on improving survival and outcomes of extremely low birth weight infants (<1000g at birth). As one of the only level 3 tertiary centers in Southern California, we are equipped to provide the highest level of care for the most complex disorders. We have subspecialists in all medical and surgical areas that are available at all times and are supported by hospital staff with technical, laboratory, and service expertise.

At Loma Linda University Health, we combine the healing power of faith with the practices of modern medicine. We consist of a University, a Medical Center with four hospitals, and a Physicians Group. These resources have helped us become one of the best health systems in the nation.

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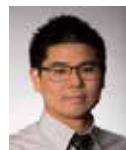
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Neonatology and the Arts

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 from Paula White, MD who shares a stunning image of Cherry Blossoms. Our Bird for this month is a White Ibis with purple flowers in the background provided by Dr. Tinsley.

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1. Manuscripts are solicited by members of the Editorial Board or may be submitted by readers or other interested parties. Neonatology Today welcomes the submission of all academic manuscripts including randomized control trials, case reports, guidelines, best practice analysis, QI/QA, conference abstracts, and other important works. All content is subject to peer review.

2. All material should be emailed to:

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3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication. There is no charge for your manuscript to be published. NT does maintain a copyright of your published manuscript.

4. The title page should contain a brief title and full names of all authors, their professional degrees, their institutional affiliations, and any conflict of interest relevant to the manuscript. The principal author should be identified as the first author. Contact information for the principal author including phone number, fax number, e-mail address, and mailing address should be included.

5. A brief biographical sketch (very short paragraph) of the principal author including current position and academic titles as well as fellowship status in professional societies should be included. A picture of the principal (corresponding) author and supporting authors should be submitted if available.

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 10,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard "NLM" format (APA 7th may also be used). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

9. Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main file after the references. Captions should be brief.

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