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Digital Tool to Help Stop Newborn Phototherapy: A Prospective Study

Dennis T. Costakos, MD,, Mengyi Zha, MD, Lynn R. Dahlen, RN

Abstract

The present study evaluated end-user experience for effectiveness, efficiency, and satisfaction of a mobile application (app) to estimate the risk of rebound hyperbilirubinemia within 72 hours after initial phototherapy ends for infants at 35 weeks' gestation or longer and age younger than 14 days. This prospective parallel study was performed at one medical center. The 26 participants are neonatology and pediatric and family physicians, neonatal and family nurse practitioners, and family practice residents, who were asked to estimate the risk of rebound hyperbilirubinemia when phototherapy is stopped for a fictional newborn. Participants in Group 1 (no app) were compared with Group 2 (with app). Satisfaction measured from 1 (0%) to 7 (100%). Group 1 had fewer correct answers than Group 2 (38.5% vs. 84.6%; $P=.04$). The mean satisfaction score for Group 1 was 2, lower than the score for Group 2, 6.6 ($P<.001$). This provider-developed app is effective and receives high end-user satisfaction.

Keywords: jaundice; neonate; phototherapy; predictive; smartphone

“Every treatment has associated adverse events, however, and this includes phototherapy of newborns for hyperbilirubinemia. Phototherapy can disrupt breastfeeding and infant-mother bonding.”

Introduction

Worldwide, hyperbilirubinemia is a leading cause of neonatal morbidity and death.(1,2) The treatment goal of neonatal jaundice is the prevention of kernicterus, and newborn phototherapy is effective. Every treatment has associated adverse events, however, and this includes phototherapy of newborns for hyperbilirubinemia. Phototherapy can disrupt breastfeeding and infant-mother bonding. Hospitalization for phototherapy can be burdensome for families. Emerging evidence shows that DNA damage with phototherapy may cause melanocytic nevi and, potentially, infantile cancer.(3,4) Newborns who receive phototherapy have a small increased risk of childhood seizures, noted even after adjusting for bilirubin levels, at 4 per 1,000 excess risks over ten years.(5)

In a large study, Chang et al(6) investigated the timing of stopping first-time inpatient newborn phototherapy for late-preterm and term infants younger than 14 days. They reported that “34% of infants may have been able to discontinue inpatient phototherapy a day earlier with < 4% risk of rebound hyperbilirubinemia.”

In the United States and the United Kingdom, 6% to 9% of babies at 35 weeks' gestation or more are treated with phototherapy, but hyperbilirubinemia and the use of phototherapy are a global phenomenon. We believe that optimizing the length of initial inpatient phototherapy by doing an evidence-based estimate of bilirubin rebound is especially important not to over- or undertreat babies with phototherapy. Hence, estimation is important for the risk of rebound hyperbilirubinemia if phototherapy is discontinued to help decrease the need for over- or undertreatment.(7) This may be even more important during the time of coronavirus disease 2019 (COVID-19) because risk assessment of hyperbilirubinemia rebound has implications for hospital length of stay and readmission of babies.

Chang et al(6) evaluated a large cohort of 7,048 infants treated within patient phototherapy from a population of 105,808 infants from the Kaiser Permanente Northern California hospitals and addressed the timing for stopping phototherapy for babies at 35 weeks' gestation or more and before 14 days of age. The derived algorithm was based on the three clinical variables that best predicted the risk of rebound hyperbilirubinemia that would require further treatment within 72 hours if the initial phototherapy is stopped: the age when phototherapy is initiated, gestational age, and the American Academy of Pediatrics (AAP) threshold serum bilirubin (TSB) for phototherapy at the age when phototherapy is discontinued. The algorithm generates a score, corresponding to a percentage of risk of rebound. The score performed well, as evidenced by the receiver operating characteristics. Score = 15 (if gestational age is <38 weeks) – (7 × age [days at initiation]) – (4 × [AAP threshold TSB – infant's TSB at discontinuation of phototherapy]) + 50.

In our experience, we have found it cumbersome and time-consuming to calculate this score without a digital tool in real-time in the nurseries. Thus, we, as health care providers, developed a mobile application (app), with no malfunctions or crashes, to help clinicians perform this calculation. We created the app after a search for an available web-based or mobile app. We knew that Chang et al(6) recommended that a web-based calculator be created, but we did not find one in the Apple App Store or through Google (Alphabet Inc), and Bing (Microsoft Corp) searches. The purpose of the present study was to evaluate end-user experience for effectiveness, efficiency, and satisfaction of the app, which provides decision support and does the calculation to estimate the risk of rebound hyperbilirubinemia if phototherapy is stopped for infants born at 35 weeks' gestation or greater and before age 14 days.

Methods

The Mayo Clinic Institutional Review Board approved this minimal risk, prospective, parallel study. We invited pediatricians, neonatologists, neonatal, and family nurse practitioners, family physicians, and resident physicians and providers who worked for Mayo Clinic and made decisions about stopping phototherapy to participate in this study. For the study, they were asked to estimate the risk of rebound hyperbilirubinemia if phototherapy was stopped in a published, fictional newborn case.(8)

The fictional newborn is described as being born at 37 weeks'

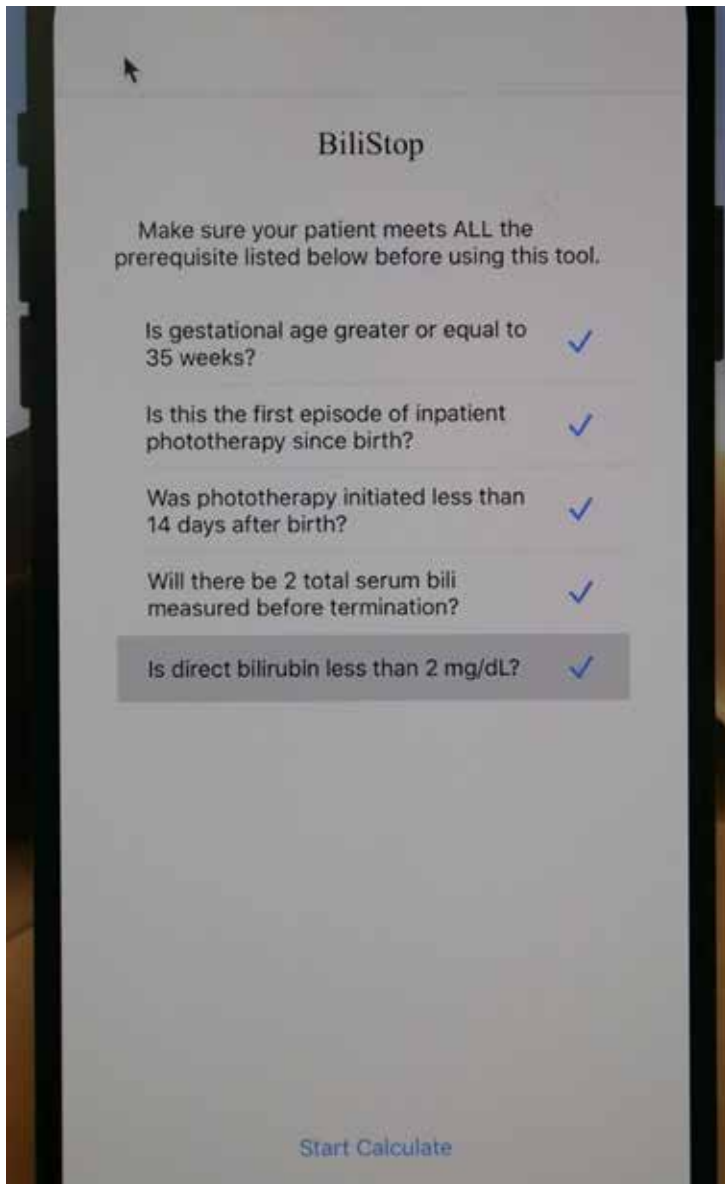


Figure 1. Screen 1 of the Application for the Fictional Published Patient. The display is a decision support checklist. Bili indicates bilirubin.

gestation and weighing 3,150 g. The infant is in the well nursery and receives phototherapy at 30 hours of age because of a TSB of 11 mg/dL. At 48 hours of age, the TSB is 10 mg/dL, and the mother is to be discharged from the hospital. No blood group incompatibility is known (mother has blood type A+). The infant is breastfeeding well, has had acceptable urine and stool output for age, and the mother believes her milk is coming in. Question 8 in the published article asks, "Of the following if phototherapy is discontinued at this time, the predicted risk of rebound hyperbilirubinemia to a concentration meeting the criteria for the reinitiation of phototherapy is CLOSEST to: A. 5%, B. 10%, C. 20%, or D. 40%?" The correct answer is D. Historically, the control respondents answered this question correctly 14% of the time.

In the present study, all-volunteer participants read a peer review paper about the phototherapy stop algorithm and viewed a brief (1 minute 52 seconds) video of the new app. The evaluated app was developed by two investigators (D.T.C. and M.Z.) in 2018 using Xcode (Apple Inc). The app has a user-friendly interface

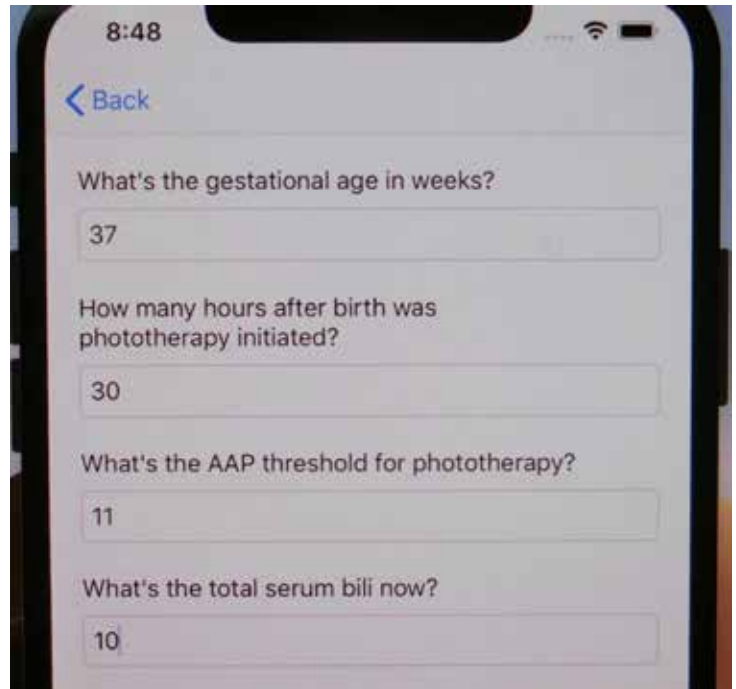


Figure 2. Screen 2 of the Application for the Fictional Published Patient. Patient-specific data are entered if all answers to screen 1 are yes. AAP indicates American Academy of Pediatrics; bili, bilirubin.

(i.e., what the user sees on the screen of a smartphone or digital tablet), and the user interacts by entering patient clinical data step by step as prompted by the app. A response (percentage risk of rebound admission) based on the algorithm published in the study by Chang et al(6) is generated for decision support.

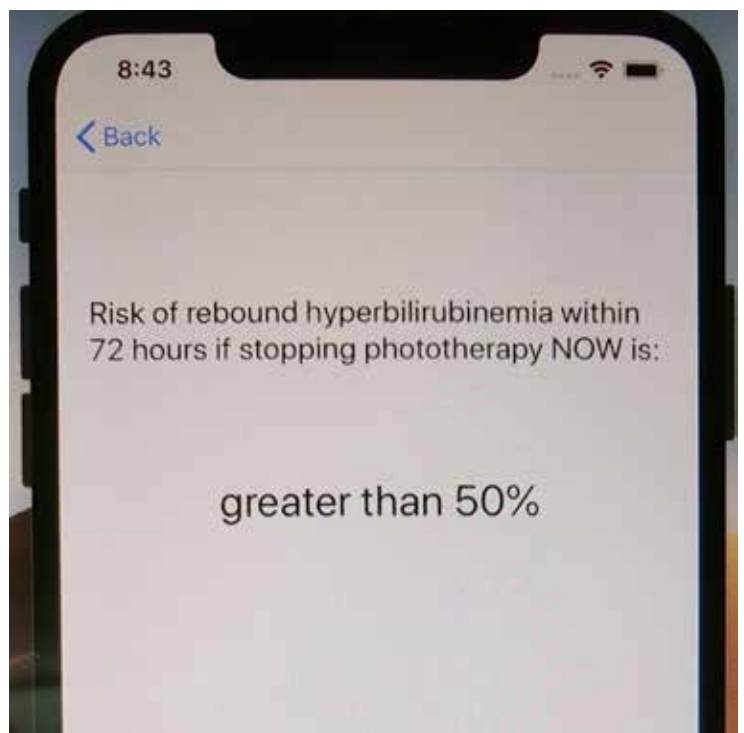


Figure 3. Screen 3 of the Application for the Fictional Published Patient. Display shows the percentage risk of rebound hyperbilirubinemia.

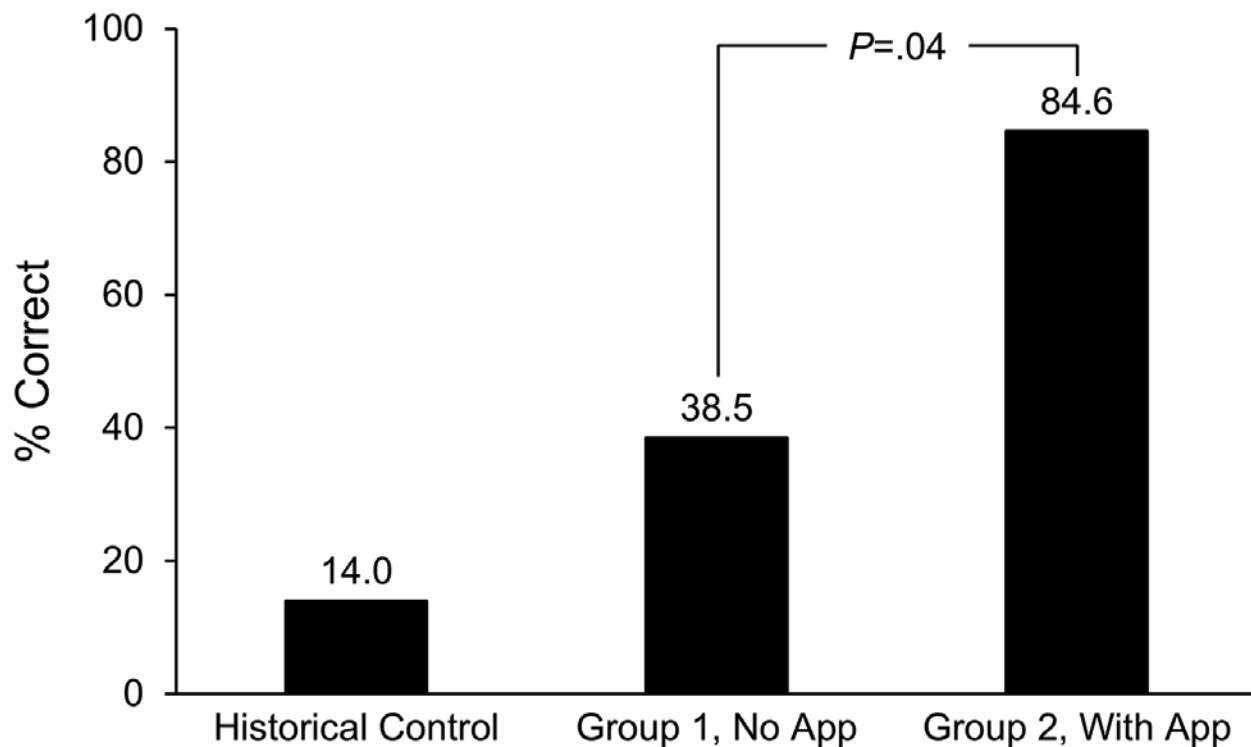


Figure 4. Correct Answers of Group 1 and Group 2 Compared With the Historical Control. Group 1 had no app and Group 2 had the app. P value calculated with Fisher exact test. App indicates application.

This app does not ask for the name, sex, or health record number of the patient. It does not identify the patient or the user, and no personal information is stored.

The first interaction of the app has the user confirm answers to 5 patient-related questions with the use of a quick checkoff list (Figure 1). The app user advances to the next screen if the answers to the checkoff list are “yes” and enters the answers for four additional questions (Figure 2), including a query about AAP’s threshold for initiating phototherapy. The AAP threshold is calculated with the free website (<https://www.bilitool.org> or <https://peditools.org/bili/>) in mg per dL or mmol per L. (The app does not provide linkage to either website.) These data are often readily available for the clinician and sometimes provided by nursing staff.

Additionally, clinicians commonly use hours as the unit for a newborn’s age. However, the algorithm by Chang et al(6) asks for fractional days as the input. This entry can create errors. For end-users, our app converts the more familiar and readily available unit of hours to the required unit of the algorithm, thereby reducing the risk of errors.

After the user has entered the data, the app displays a risk

percentage of rebound hyperbilirubinemia within 72 hours (Figure 3). This answer is generated quickly, 22 seconds from start to finish of all data.

In the present study, participants were entered sequentially. Control Group 1 were the odd-numbered participants, and Group 2, the even-numbered participants. The 2 groups differed only in that Group 2 used the app as a simulation on a laptop computer.

The groups were compared for the proportion of correct answers and time to the correct answer. No provider in the study had ever used this app. Provider satisfaction was measured on a Likert scale of 1 to 7 (1, 0% satisfaction; 7, 100% satisfaction).

In our statistical analysis, the *t*-test was used for continuous variables. χ^2 tests and Fisher exact tests were used for categorical variables. A *P* value less than or equal to .05 was considered statistically significant. Sample size calculations predicted that 20 volunteers would be needed for the study, with the assumption that the chance was 80% for missing the difference if Group 2 (with the app) answered correctly 90% of the time and Group 1 answered correctly 20% of the time.(9)

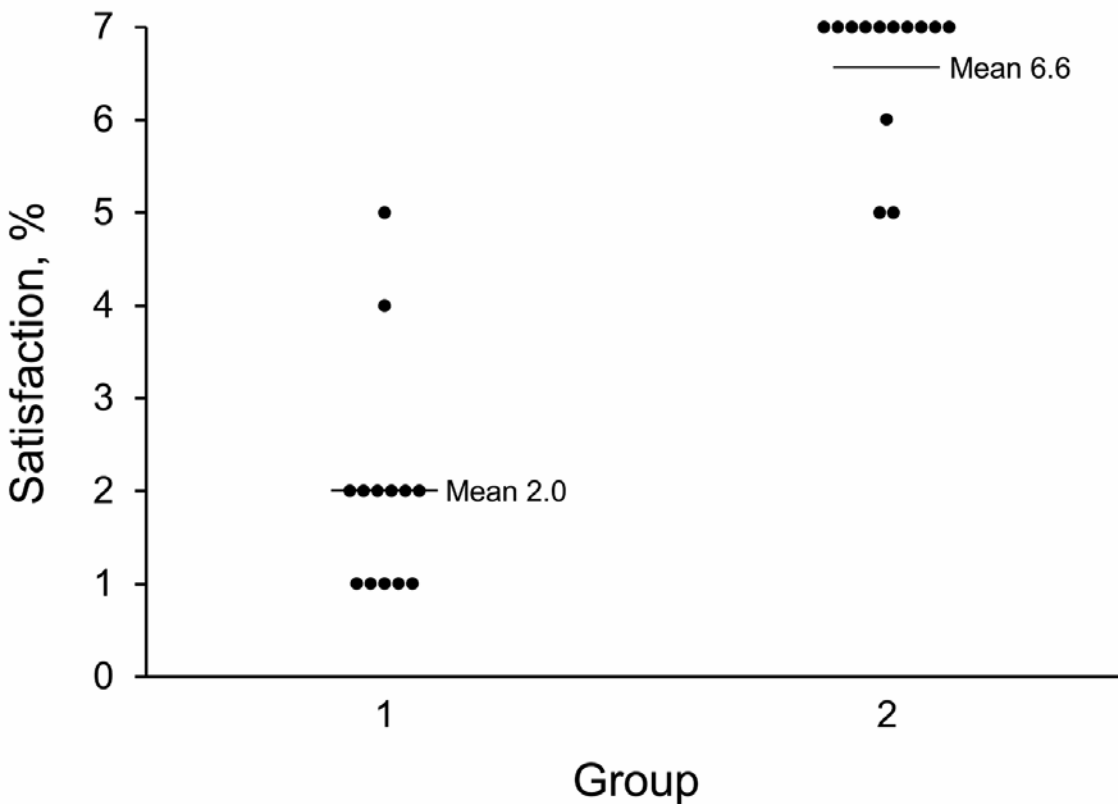


Figure 5. Satisfaction Scores of End Users. Group 1 (no application) compared with Group 2 (with application). A score of 7 equals 100%.

Results

Twenty-six volunteers (average work experience, 16.4 years) participated in the study. In Group 1, the average work experience was 18.7 years vs. 12.2 years in Group 2. This difference was not statistically significant ($P=.13$, t -test) (Table). Group 1 had proportionally fewer correct answers (Figure 4). Time to the correct answer was 6.67 minutes for Group 1 vs. 4.89 minutes for Group 2 ($P=.55$, t -test). The mean satisfaction score was 2 for Group 1 vs. 6.6 for Group 2 ($P<.001$) (Figure 5).

Table. Professional Roles of the 26 Volunteer Study Participants

Provider Role	Participants, No. (%)
Neonatologist	1 (4)
Neonatal nurse practitioner	5 (19)
Family nurse practitioner	1 (4)
Pediatrician	7 (27)
Family physician	7 (27)
Resident	5 (19)

Legends Discussion

The 100 most popular medical mobile apps, paid or free, in the Google and Apple stores cover 27 medical topics.(10) However, 44% of the apps did not provide the content's source in their provision of medical information to their target users. More than half of the apps did not provide general terms and conditions of use. Only 56% of the apps that collect user health data require the explicit consent of their users' precollection.(10)

In addition, because end users do not always have a privacy policy or context source, they must always wonder whether accuracy or effectiveness has been studied. The authors of 1 study tested the accuracy of 2 oxygen saturation, smartphone-integrated baby monitors not regulated by the US Food and Drug Administration (FDA) compared with an FDA-regulated pulse oximeter.(11) The authors reported that one monitor detected hypoxemia but performed inconsistently. The other monitor never detected hypoxemia and displayed pulse rates that were lower than a reference monitor. The authors of that study advise that physicians and parents should exercise caution when incorporating data from the smartphone-integrated consumer baby monitors

that they tested. This outcome is in contrast to a different study of smartphone apps and wearable devices for tracking physical activity data.(12) The investigators observed that many of the devices were accurate for tracking step counts.

We believe that good medical and health mobile apps will transform health care delivery. Similar to food in the United States, medical and health mobile apps might have a label that grades safety, evidence basis, and app interoperability in the future.(13) Therefore, in the development of our app, we focused its design on ease of use, prevention of errors, maintenance of user and patient privacy, and, most importantly, evidence-based conclusions and high end-user satisfaction.(14-16)

“In our experience, we have found it cumbersome and time-consuming to calculate this score without a digital tool in real-time in the nurseries. Thus, we, as health care providers, developed a mobile application (app), with no malfunctions or crashes, to help clinicians perform this calculation.”

In the present study of our app, we found that the number needed to treat (NNT) is 2.2 for one infant to benefit from its use.(17) In a cohort study of 204,485 infants, the NNT through the use of the Kaiser Permanente online early-onset sepsis calculator was 41 infants compared with the infants who received no antibiotics in the first 24 hours if their provider used the Kaiser sepsis app.(18) This was the primary question of that study. Its secondary question asked about a reduction in blood cultures in the first 24 hours. With the use of the Kaiser sepsis calculator, the NNT was ten infants. The providers who used our app had never seen the mobile app before. We speculate that if we allowed them to practice with our app, the proportion of correct answers could be close to 100%, thus decreasing the NNT even more. Our data showed that the use of the app did not improve the time to a correct answer significantly. However, familiarity with the app will likely change that outcome.

In 2020, we did find a free web-based rebound bilirubin calculator through the Bing search engine (<https://jscalculator.io/calc/68NNiFfS7iTMZhZY>). This free calculator is also based on the study by Chang et al(6) and uses the same algorithm. It worked well when answers were compared with the fictional patients to the mobile medical app that we created. However, no reminders (i.e., decision support) are provided that warn users

not to use the calculator for babies born at less than 35 weeks' gestation, that the baby in question should be age 14 days or less, and that this is the first time phototherapy is not reinitiated for the baby. In addition, physicians should make sure the privacy policy of the app is clear when they enter patient data into a mobile app.

“In our opinion, the next step for our app should be the integration of its use into electronic health records. Although mobile apps are a relatively new development in medicine and health, they are used more and more frequently in medical practice.”

In our opinion, the next step for our app should be the integration of its use into electronic health records. Although mobile apps are a relatively new development in medicine and health, they are used more and more frequently in medical practice. For instance, the Kaiser early-onset sepsis calculator is routinely used in the assessment of the risk of neonatal sepsis in many medical centers.(19-21) In fact, some centers have integrated it into electronic health records because it has helped reduce neonatal antibiotic treatment with no adverse events.(22) We believe our app also can benefit patients through its evidence-based design and our current study that found it effective with high end-user satisfaction. At the minimum, the provider is more efficient, and the digital tool should perform the math quicker, allowing easy checking. On many days, more than one baby on rounds will benefit in a busy newborn practice.(23)

We conclude that our mobile medical app and this study demonstrated that providers have an important role in transforming medical care with the leveraging of digital tools and data and in checking the quality of any medical software.(24) We were not surprised that—after about 5 months to make our mobile app, a year to design this study, the time to receive Mayo Clinic Institutional Review Board approval, and then the time to execute this study and interpret the study results—a separate physician-created, web-based bilirubin rebound calculator appeared online by a different group. This development indicates the importance of the algorithm in clinical practice.(22,25) The new digital tool we developed and tested as a mobile application was made available in the Apple store as BiliStop on June 12, 2020.

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Declaration of Conflicting Interests

DTC and MZ are the developers and owners of the new mobile medical app (BiliStop) discussed in this manuscript and studied. The authors acknowledge that they are the owners of the limited liability company Evergreen Bioinformatics, formed to allow further development of the mobile app by making it available to other health care providers

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Author Contributions

DTC: conceptualized and designed the study, coordinated and supervised data collection, participated in data collection and data analysis, and critically reviewed the manuscript for important intellectual content. Dr Costakos has approved the final manuscript as submitted and agrees to be accountable for all aspects of the work.

MZ: designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript. Dr Zha has approved the final manuscript as submitted and agrees to be accountable for all aspects of the work.

LRD: designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript. Ms. Dahlen has approved the final manuscript as submitted and agrees to be accountable for all aspects of the work.

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Federation for Medical Research, New Orleans, Louisiana, February 15, 2020, and published in abstract form: J Investig Med. 2020;68(2):656.

Potential Conflict of interest: Dennis T. Costakos MD and Mengyi Zha, MD, have intellectual property rights to the BiliStop as owners of Evergreen Bioinformatics LLC, one of the digital tools discussed in this paper. The BiliStop is sold in the Apple Inc. app store by Apple Inc. and Evergreen Bioinformatics LLC.

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- It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6: omega-3 fatty acid ratio of the product.

Contraindications

- Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders due to a potential effect on platelet aggregation, severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1000 mg/dL).

Please see Brief Summary of Prescribing Information for Omegaven on the reverse side.



OMEGAVEN (fish oil triglycerides) injectable emulsion, for intravenous use

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This brief summary does not include all the information needed to use Omegaven safely and effectively. Please see full prescribing information for Omegaven (fish oil triglycerides) injectable emulsion for intravenous use at www.fresenius-kabi.com/us.

INDICATIONS AND USAGE

Omegaven is indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC).

Limitations of Use:

Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients.

It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6: omega-3 fatty acid ratio of the product.

DOSAGE AND ADMINISTRATION

Prior to administration, correct severe fluid and electrolyte disorders and measure serum triglycerides to establish a baseline level. Initiate dosing in PN-dependent pediatric patients as soon as direct or conjugated bilirubin levels are 2 mg/dL or greater. The recommended daily dose (and the maximum dose) in pediatric patients is 1 g/kg/day. Administer Omegaven until direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires PN.

CONTRAINDICATIONS

Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders due to a potential effect on platelet aggregation, severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1,000 mg/dL).

WARNINGS AND PRECAUTIONS

- Risk of Death in Preterm Infants due to Pulmonary Lipid Accumulation: Deaths in preterm infants after infusion of soybean oil-based intravenous lipid emulsions have been reported in medical literature. Autopsy findings in these preterm infants included intravascular lipid accumulation in the lungs. The risk of pulmonary lipid accumulation with Omegaven is unknown. Preterm and small-for-gestational-age infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion. This risk due to poor lipid clearance should be considered when administering intravenous lipid emulsions. Monitor patients receiving Omegaven for signs and symptoms of pleural or pericardial effusion.
- Hypersensitivity Reactions: Omegaven contains fish oil and egg phospholipids, which may cause hypersensitivity reactions. Signs or symptoms of a hypersensitivity reaction may include: tachypnea, dyspnea, hypoxia, bronchospasm, tachycardia, hypotension, cyanosis, vomiting, nausea, headache, sweating, dizziness, altered mentation, flushing, rash, urticaria, erythema, fever, or chills. If a hypersensitivity reaction occurs, stop infusion of Omegaven immediately and initiate appropriate treatment and supportive measures.
- Risk of Infections: The risk of infection is increased in patients with malnutrition-associated immunosuppression, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other conditions or concomitant drugs. To decrease the risk of infectious complications, ensure aseptic technique in catheter placement and maintenance, as well as in the preparation and administration of Omegaven. Monitor for signs and symptoms of early infections including fever and chills, laboratory test results that might indicate infection (including leukocytosis and hyperglycemia), and frequently inspect the intravenous catheter insertion site for edema, redness, and discharge.
- Fat Overload Syndrome: A reduced or limited ability to metabolize lipids accompanied by prolonged plasma clearance may result in this syndrome, which is characterized by a sudden deterioration in the patient's condition including fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, hepatomegaly, deteriorating liver function, and central nervous system manifestations (e.g., coma).
- Refeeding Syndrome: Administering PN to severely malnourished patients may result in refeeding syndrome, which is characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, closely monitor severely malnourished patients and slowly increase their nutrient intake.
- Hypertriglyceridemia: Impaired lipid metabolism with hypertriglyceridemia may occur in conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome. Serum triglyceride levels greater than 1,000 mg/dL have been associated with an increased risk of pancreatitis. To evaluate the patient's capacity to metabolize and eliminate the infused lipid emulsion, measure serum triglycerides before the start of infusion (baseline value), and regularly throughout treatment. If hypertriglyceridemia (triglycerides greater than 250 mg/dL in neonates and infants or greater than 400 mg/dL in older children) develops, consider stopping the administration of Omegaven for 4 hours and obtain a repeat serum triglyceride level. Resume Omegaven based on new result as indicated.
- Aluminum Toxicity: Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Preterm infants are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Patients with impaired kidney function, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.
- Monitoring and Laboratory Tests: **Routine Monitoring:** Monitor serum triglycerides, fluid and electrolyte status, blood glucose, liver and kidney function, coagulation parameters, and complete blood count including platelets throughout treatment. **Essential Fatty Acids:** Monitoring patients for laboratory evidence of essential fatty acid deficiency (EFAD) is recommended. Laboratory tests are available to determine serum fatty acids levels. Reference values should be consulted to help determine adequacy of essential fatty acid status.
- Interference with Laboratory Tests: The lipids contained in Omegaven may interfere with some laboratory blood tests (e.g., hemoglobin, lactate dehydrogenase, bilirubin, and oxygen saturation) if blood is sampled before lipids have cleared from the bloodstream. Lipids are normally cleared after a period of 5 to 6 hours once the lipid infusion is stopped.

ADVERSE REACTIONS

The most common adverse drug reactions (>15%) are: vomiting, agitation, bradycardia, apnea and viral infection.

Clinical Trials Experience

The safety database for Omegaven reflects exposure in 189 pediatric patients (19 days to 15 years of age) treated for a median of 14 weeks (3 days to 8 years) in two clinical trials.

Adverse reactions that occurred in more than 5% of patients who received Omegaven and with a higher incidence than the comparator group are: vomiting, agitation, bradycardia, apnea, viral infection, erythema, rash, abscess, neutropenia, hypertonia and incision site erythema. Patients had a complicated medical and surgical history prior to receiving Omegaven treatment and the mortality was 13%. Underlying clinical conditions prior to the initiation of Omegaven therapy included prematurity, low birth weight, necrotizing enterocolitis, short bowel syndrome, ventilator dependence, coagulopathy, intraventricular hemorrhage, and sepsis.

Twelve (6%) Omegaven-treated patients were listed for liver transplantation (1 patient was listed 18 days before treatment, and 11 patients after a median of 42 days [range: 2 days to 8 months] of treatment); 9 (5%) received a transplant after a median of 121 days (range: 25 days to 6 months) of treatment, and 3 (2%) were taken off the waiting list because cholestasis resolved.

One hundred thirteen (60%) Omegaven-treated patients reached DBIL levels less than 2 mg/dL and AST or ALT levels less than 3 times the upper limit of normal, with median AST and ALT levels for Omegaven-treated patients at 89 and 65 U/L, respectively, by the end of the study.

Median hemoglobin levels and platelet counts for Omegaven-treated patients at baseline were 10.2 g/dL and $173 \times 10^9/L$, and by the end of the study these levels were 10.5 g/dL and $217 \times 10^9/L$, respectively. Adverse reactions associated with bleeding were experienced by 74 (39%) of Omegaven-treated patients.

Median glucose levels at baseline and the end of the study were 86 and 87 mg/dL for Omegaven-treated patients, respectively. Hyperglycemia was experienced by 13 (7%) Omegaven-treated patients.

Median triglyceride levels at baseline and the end of the study were 121 mg/dL and 72 mg/dL for Omegaven-treated patients respectively. Hypertriglyceridemia was experienced by 5 (3%) Omegaven-treated patients.

The triene:tetraene (Mead acid:arachidonic acid) ratio was used to monitor essential fatty acid status in Omegaven-treated patients only in Study 1 (n = 123). The median triene:tetraene ratio was 0.02 (interquartile range: 0.01 to 0.03) at both baseline and the end of the study. Blood samples for analysis may have been drawn while the lipid emulsion was being infused and patients received enteral or oral nutrition.

Postmarketing Experience

The following adverse reaction has been identified with use of Omegaven in another country. Life-threatening hemorrhage following a central venous catheter change was reported in a 9-month-old infant with intestinal failure who received PN with Omegaven as the sole lipid source; he had no prior history of bleeding, coagulopathy, or portal hypertension.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Prolonged bleeding time has been reported in patients taking antiplatelet agents or anticoagulants and oral omega-3 fatty acids. Periodically monitor bleeding time in patients receiving Omegaven and concomitant antiplatelet agents or anticoagulants.

USE IN SPECIFIC POPULATIONS

- Pregnancy: There are no available data on Omegaven use in pregnant women to establish a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with fish oil triglycerides. The estimated background risk of major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.
- Lactation: No data available regarding the presence of fish oil triglycerides from Omegaven in human milk, the effects on the breastfed infant, or the effects on milk production. Lactating women receiving oral omega-3 fatty acids have been shown to have higher levels of omega-3 fatty acids in their milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omegaven, and any potential adverse effects of Omegaven on the breastfed infant.
- Pediatric Use: The safety of Omegaven was established in 189 pediatric patients (19 days to 15 years of age). The most common adverse reactions in Omegaven-treated patients were vomiting, agitation, bradycardia, apnea and viral infection.
- Geriatric Use: Clinical trials of Omegaven did not include patients 65 years of age and older.

OVERDOSE

In the event of an overdose, fat overload syndrome may occur. Stop the infusion of Omegaven until triglyceride levels have normalized and any symptoms have abated. The effects are usually reversible by stopping the lipid infusion. If medically appropriate, further intervention may be indicated. Lipids are not dialyzable from serum.

REFERENCES:

1. Omegaven Prescribing Information, Fresenius Kabi USA, LLC. 2018.



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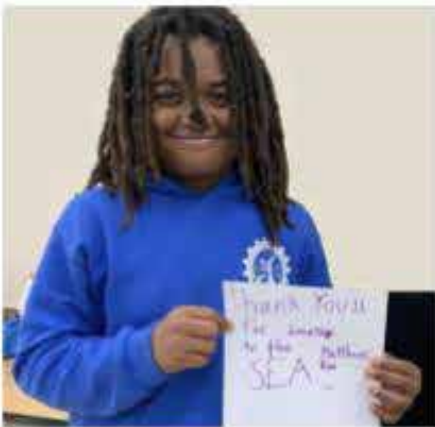
Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring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



A Life's Journey

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

Houchang D. Modanlou

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Fellow Column: Diagnostic Precision in Neonatal Medicine: Why Over Investigate?

Adil Khan, MD, Shabih Manzar, MD

Abbreviations:

CMV (cytomegalovirus), TORCH (Toxoplasmosis, others, rubella, C, Herpes), IUGR (intra

“Due to an increased reliance on the investigation, the art of clinical medicine is disrupted. The disruption in skill acquisition and critical thinking is concerning. A medical student’s journey from a clerkship to practice should be based on acquiring clinical skills and applying critical thinking. In the field of neonatology, it has been observed that the investigation is a rule rather than an exception.”

uterine growth restriction).

Introduction:

Neonatal patients are unique. They cannot express symptoms; however, a vigilant clinical examination may elicit signs that could be helpful in diagnosis. Due to an increased reliance on the investigation, the art of clinical medicine is disrupted. The disruption in skill acquisition and critical thinking is concerning. A medical student’s journey from a clerkship to practice should be based on acquiring clinical skills and applying critical thinking. In the field of neonatology, it has been observed that the investigation is a rule rather than an exception. Here we present an example of a neonate who was over investigated for thrombocytopenia.

Case study:

A newborn male infant was admitted to the nursery with an initial platelet count of 73, 000 K/uL. He was delivered via cesarean section at 38 weeks of gestation to a 34-year-old mother, gravida 4, Para 3103. The pregnancy was complicated by pregnancy-induced immune thrombocytopenia (ITP) for which she received a 10-day course of oral prednisolone. Her prenatal labs revealed a negative sickle cell screen, HIV, hepatitis B, and syphilis. She was rubella immune. Her blood group was O positive with negative antibodies. She had a past medical history of herpes simplex virus, treated with acyclovir. Upon delivery, the baby had a strong cry, he was dried, stimulated, and bulb suctioned. Apgar score was 8 and 9 at one and five minutes, respectively. His birth weight was 2375 grams (3.5%) and head circumference of 32.5 cm (16%). No signs of bleeding or bruises were noted. During rounds, a decision was made based on the clinical pathway to obtain an extensive workup to look for the reasons for low platelets. Although, this was a classic case of autoimmune thrombocytopenia, a TORCH titer, 3-daily urine CMV tests, and ultrasound of the head and abdomen were ordered. The natural resolution and course are depicted in Figure 1. What was the message given to the trainee?



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Figure

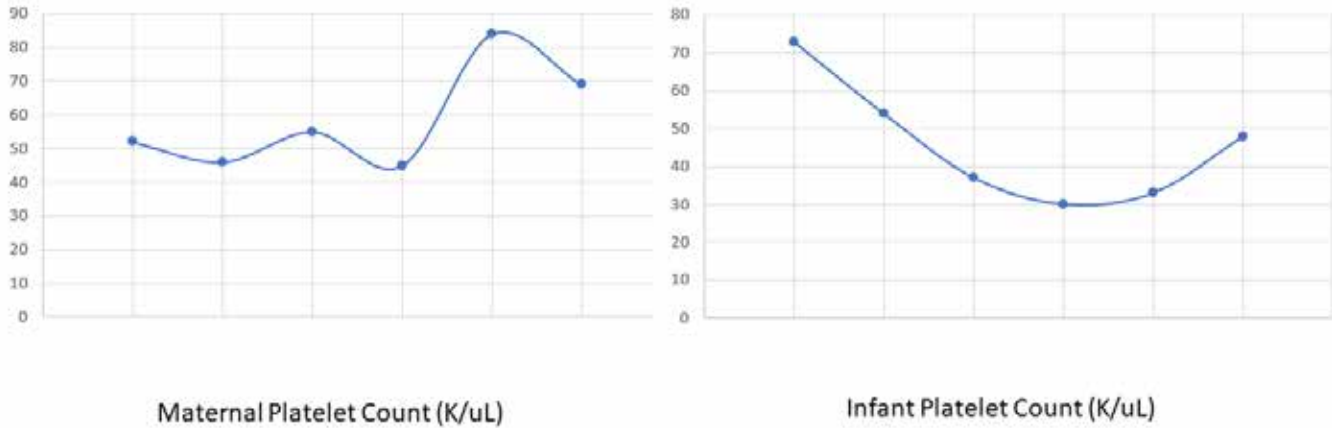


Figure 1: Maternal and Infant platelet count (K/uL) over time

Discussion:

Instead of following an approach of good history taking, developing a list of differential diagnoses, narrowing it out to the most likely diagnosis, and then investigating, the infant had multiple tests. In hospital practice, to minimize variation among practitioners' clinical pathways are often used. This approach has shown to contain costs and decrease the length of stay while maintaining clinical outcomes. (1) The downside of developing these algorithms is taking away the critical thinking process among medical students and young practitioners.

The best clinical decision refers to making a choice that maximizes effectiveness and minimizes harm. (2) A practitioner who is doubtful will end up maximizing the investigations. If a provider's decision-making has built-in subjectivity and lack of evidence and skills, this may result in variation and unpredictability. (3) To minimize these problems, using a decision tree could be a potential solution. (4)

As noted in the case, there was no indication for obtaining TORCH titers and urine CMV PCR. The infant was borderline small for gestational age (BW 3.5 %) with a head circumference of 16%. Maternal serology was negative for syphilis, and she was rubella immune. An infant with TORCH infection presents with symmetrical IUGR. CMV could be asymptomatic at birth, but in this case,

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Transform Your NICU

there was compelling evidence that TP was immune-mediated.

Now let us look at the multiple-choice question (MCQ) as an example (Appendix). All answers are correct, but with the knowledge and critical thinking, one can delineate to the best response. Similarly, the investigation should be tailored to the most likely diagnosis. A good history and clinical examination should eliminate the need for extensive investigation.

To conclude, as clinicians and medical educators, we should practice and teach our students the art of good history taking and to perform a complete physical examination. They should apply knowledge and critical thinking rather than jumping on extensive investigations. We should try to minimize the disruption in medical education and clinical practice.

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2. Aleem IS, Schemitsch EH, Hanson BP. What is a clinical decision analysis study? *Indian J Orthop*. 2008; 42:137-9.
3. Banning M.A review of clinical decision making: models and current research. *J Clin Nurs*. 2008; 17:187-95.
4. Bae JM. The clinical decision analysis using decision tree. *Epidemiol Health*. 2014;36: e2014025.

Appendix

A term newborn is noted to have a platelet count of 74 K/uL. Mother has a history of immune thrombocytopenia. The best next management step is:

- A) Obtain TORCH titer and urine CMV
- B) Obtain father's platelet antigen genotype
- C) Follow serial head ultrasound
- D) Follow serial platelet count
- E) Transfuse platelets for count < 50 K/uL

Correct Answer: D

In Practice: A, B, C, D, E (just in case, what if)

Early Neonatal thrombocytopenia (< 72 hours of life) could be due to intrauterine infection or immune-mediated. When the mother has ITP, the antibodies cross the placenta and destroy fetal platelet resulting in thrombocytopenia (TP). An infant born with a suspected infection should be checked for TORCH titer and urine CMV. However, isolated TP in the neonate is most likely immune-mediated. When maternal platelets are normal, alloimmune TP (NAIT) should be considered high in the list of differential diagnoses. When it comes to treatment, platelet transfusion is reserved for platelet count < 25 K/uL in well infants. Following serial head ultrasound is not logical. A screening HUS may be done, especially in NAIT. Decision pathways and management algorithms should be used as a guide; however, the investigation should not include all.

1. Del Vecchio A. Evaluation and management of thrombocytopenic neonates in the intensive care unit. *Early Hum Dev*. 2014;90 Suppl 2: S51-S55.

2. Curley A, Stanworth SJ, Willoughby K, et al. A Randomized Trial of Neonatal Platelet Transfusion Thresholds in Neonates. *N Engl J Med*. 2019;380: 242-251.

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Manzar has provided mentorship and has reviewed the manuscript.

NT

Fellow's Column is published monthly.

- Submission guidelines for "Fellow's Column":
- 2000 word limit not including references or title page. Exceptions will be made on a case by case basis
- QI/QA work, case studies, or a poster from a scientific meeting may be submitted..
- Submission should be from a resident, fellow, or NNP in training.
- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
- No more than 20 references.
- Please send your submissions to:

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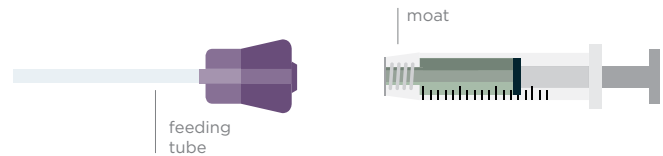


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SAFETY IN THE NICU

New tubes, new problems?

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DOSING ACCURACY

- The moat, or area around the syringe barrel, is difficult to clear. Medication can hide there, inadvertently increasing the delivered dose when the syringe and feeding tube are connected; patients may receive extra medication.

INFECTION RISK

- The moat design can increase risk for infection if residual breast milk or formula remains in the moat and transfers to the feeding tube.

WORKFLOW ISSUES

- Increased nursing workflow is seen with additional steps for clearing syringe moats, cleaning tube hubs, and using multiple connectors.

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First Candle Receives Grant from W.K. Kellogg Foundation to Address Racial Disparity in Infant Mortality Rates

Barb Himes, IBCLC



Saving babies. Supporting families.

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

Program Will Address Role of Implicit Bias in Safe Sleep Messaging

“This work is part of a larger set of First Candle goals aimed at addressing the impact of implicit bias, systemic racism and the social determinants of health on high rates of infant deaths among families of color.”

First Candle, the national non-profit committed to ending Sudden Unexpected Infant Deaths (SUID), has announced it is undertaking an initiative to collect input from communities of color to and share with the [American Academy of Pediatrics \(AAP\)](#) as it updates the [Safe Sleep Guidelines](#), for release in 2021. This work will be supported by a \$100,000 grant from the W.K. Kellogg Foundation, which will be directed to communities in Michigan.

This work is part of a larger set of First Candle goals aimed at addressing the [impact of implicit bias](#), systemic racism and the social determinants of health on high rates of infant deaths among families of color.

Sudden Infant Death Syndrome (SIDS) and accidental suffocation and strangulation in bed (ASSB) are classified under SUID and account for 3,600 infant deaths in the U.S. every year. The rate of SUID is more than twice as high for Black babies as white babies. ASSB has increased by 115% over the past decade and can be prevented by adopting the AAP Safe Sleep Guidelines. The guidelines include recommendations that families always place a baby alone in a crib or another surface designed for infants, on a firm, flat mattress in a supine position with nothing in the area including pillows, blankets, stuffed animals, fluffy bumpers or loose clothing.

According to First Candle, the risk of SIDS can be dramatically reduced by following these guidelines as well as breastfeeding for the first six months to a year of life, but these guidelines are not widely followed across all communities.

To better understand the issues surrounding adoption of the Safe Sleep Guidelines and to facilitate community-driven campaigns that eliminate the racial bias in messaging, First Candle will convene Community Task Forces in three states, including Michigan. The Task Forces will be comprised of parents, grandparents, in-home health care providers, social service agencies and doulas who will share their thoughts on the Safe Sleep Guidelines, the challenges and objections that exist in adopting them and the role systemic racism has played in accessing this life-saving information.

This information will be shared with the AAP as it develops the updated 2021 Safe Sleep Guidelines. Upon release of the new Guidelines, the Community Task Forces will create solutions-oriented education and outreach campaigns consistent with the lived experiences of the community to facilitate adoption of the revised Guidelines. Simultaneously, First Candle will continue the implicit bias training program, Straight Talk for Infant Safe Sleep, that it delivers to hospitals, health care providers and social service agencies to help foster dialogue between families and providers on safe sleep and breastfeeding.

“At First Candle we are committed to addressing the alarming rates of Black infant deaths from SUID, said First Candle CEO Allison Jacobson. “We want every baby to reach his or her first birth-



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

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org

day and the first step is eliminating racial disparity. We know the answers to the challenges of adopting the Safe Sleep Guidelines lie in the community and it's our job to listen, learn and support.

"We are proud to align with organizations such as Black Mothers' Breastfeeding Association, Black Mamas Matter and Moms Rising to end bias that exists within the healthcare system and save babies' lives. With the support of the W.K. Kellogg Foundation, we know we can finally drive down the number of infant deaths. We are incredibly grateful for this grant."

In addition to Michigan, Community Task Forces are being convened in Connecticut and Georgia.

References:

1. <http://www.aap.org/>
2. <https://firstcandle.org/aaps-infant-safe-sleep-recommendations/>
3. <https://firstcandle.org/straight-talk-for-infant-safe-sleep/>

Disclosure: The author is the Director of Education and Bereavement Services of First Candle, Inc., a Connecticut not for profit 501c3 corporation.

NT

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In January, heaven gained a new angel - Laura Reno.

Laura was a SIDS mom and a guiding force at First Candle.

She worked tirelessly to end SIDS and was a source of comfort for many of our bereaved families.

Laura will be greatly missed.



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Raising Global Awareness of RSV

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

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

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



Non-Invasive Ventilation Revisited

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.

In volume 14, issue 3, March 2019, I wrote on non-invasive ventilation (NIV). In that submission, the topic of suitable candidates for NIV was discussed. The sequelae resulting from not re-intubating when reaching failure criteria (or the failure to establish those criteria) was presented. The past sixteen months have provided me the time necessary to examine first hand the results of riding the NIV bandwagon. I suspected the ride had not been as smooth as had been suggested. My observations have given me ample food for thought and caused consternation amongst my colleagues as well.

“The past sixteen months have provided me the time necessary to examine first hand the results of riding the NIV bandwagon. I suspected the ride had not been as smooth as had been suggested. My observations have given me ample food for thought and caused consternation amongst my colleagues as well.”

I have previously suggested the success a facility has with NIV (as measured by chronic lung disease (CLD) outcomes), are likely to reflect how well invasive ventilation (IV) is practiced within that facility: if its clinicians are skilled at IV, then CLD outcome improvements will be less dramatic than they would be compared to those who are not as adept at IV. CLD outcomes in the unit in which I practice have been historically world-class. The adoption of NIV in our not-so-premature infants (i.e., >25 weeks gestation (GA)) was met with little resistance. The days of intubation based strictly

on GA were at that point already long past, and it made perfect sense to give these babies a chance. Things changed when NIV was used as a first-line mode for infants of less than 25 weeks GA.

If a baby is born active and breathing spontaneously, it is appropriate to use NIV to support the baby at least until vascular access is obtained; rapid sequence induction medication can then be given for intubation. It is also reasonable, in my opinion, to allow those babies, doing very well on NIV, to remain without an endotracheal tube (ETT). Here the proverbial devil is in the details; just what is “doing well”? If one’s definition is simply breathing spontaneously without regard to other factors like FiO_2 , bradycardia, and desaturation episodes, then one’s assessment is incomplete. Evidence of the adverse effects of high FiO_2 , particularly in the extremely premature lacking endogenous anti-oxidant protection, are well known. The consequences of remaining on NIV in high FiO_2 later in the infant’s course are also becoming clear: smooth muscle hypertrophy and hyperreactive airways, and poorer forced exhalation at one second (FEV1).¹ It is too early to draw firm conclusions, but it would appear that rates of intraventricular hemorrhage (IVH) and retinopathy of prematurity (ROP) have also increased in step with the increased and earlier use of NIV.

There is more to this equation than simply FiO_2 and NIV vs. IV. What mode of IV also plays a part, as does the equipment used to provide that mode, particularly with high-frequency oscillation. The disadvantages of the only oscillator currently available to US clinicians have been discussed in previous columns, and there is a myriad of differences in the approach to ventilation across NICUs worldwide. In Canada, as in the rest of the world, third-generation oscillators have been used now for over ten years, and second-generation machines for 15 or more years before that. These machines are fundamentally different from those used in the United States; however, all ventilation data gets dumped into the same pot; the results may thus be negatively skewed when examining oscillation.

While some units use high-frequency oscillation (HFO) or high-frequency jet ventilation (HFJV) as a first-line mode, many units do not. Indeed, many units do not have access to jet ventilation because the machine is not widely available outside the US and Canada. This is regrettable. I have a strong bias towards the use of HFO or HFJV (depending on the patient) as a first-line ventilation mode when intubation is required, and several units with particularly good outcomes do this, including the one in which I work. There are more that do not, and ventilation practices in many units are sub-optimal. Nevertheless, data from these units are dumped into the aforementioned pot, and the result is an average value comprised of a wide range of CLD outcomes. As NIV came into vogue, many units saw their CLD outcomes improve, which in turn made the average outcomes also improve. The NIV train left the station full of clinicians of all stripes eager to improve their outcomes; after all, who does not want better outcomes?

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About those outcomes...are they better, or are they worse? Yes. A year-to-year comparison does not allow for a concrete conclusion; however, the data I have observed is intriguing. In all age strata, CLD outcomes improved with one notable exception: 24 weeks GA. In this group, rates increased from approximately 30% to 58%.

24-week GA group may be secondary to increased use of NIV on these infants, combined with earlier extubations and subsequent maintenance on NIV in high FiO₂ and pressures.

Problems with NIV

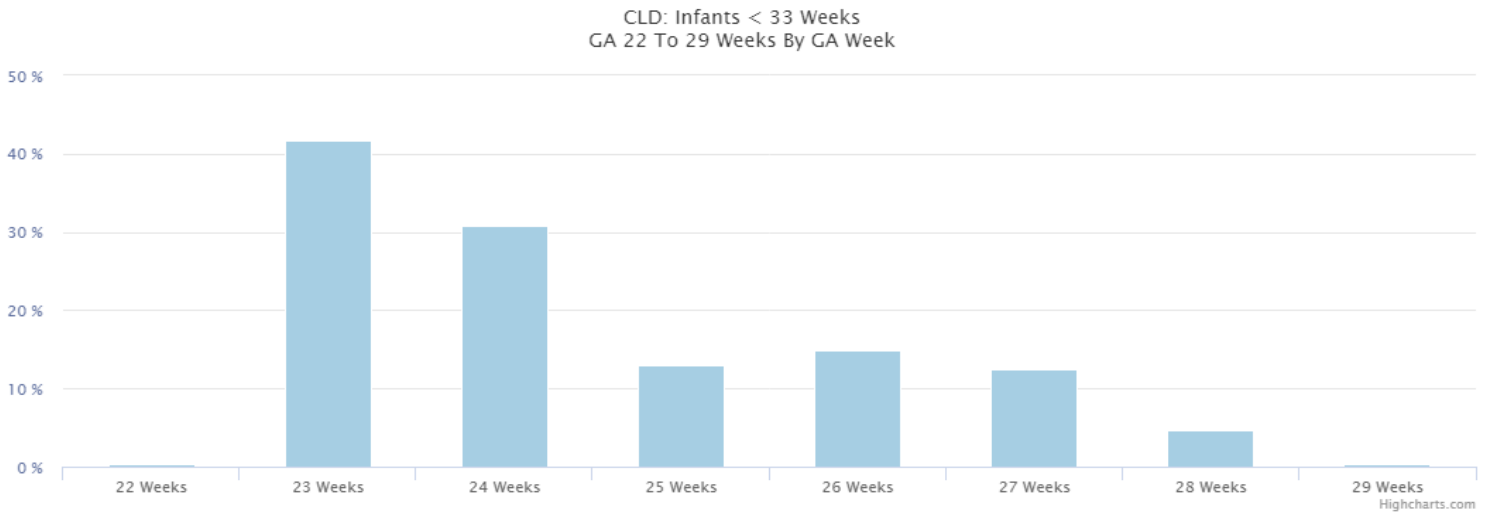


Figure 1: 2018 CLD outcomes (source blinded)

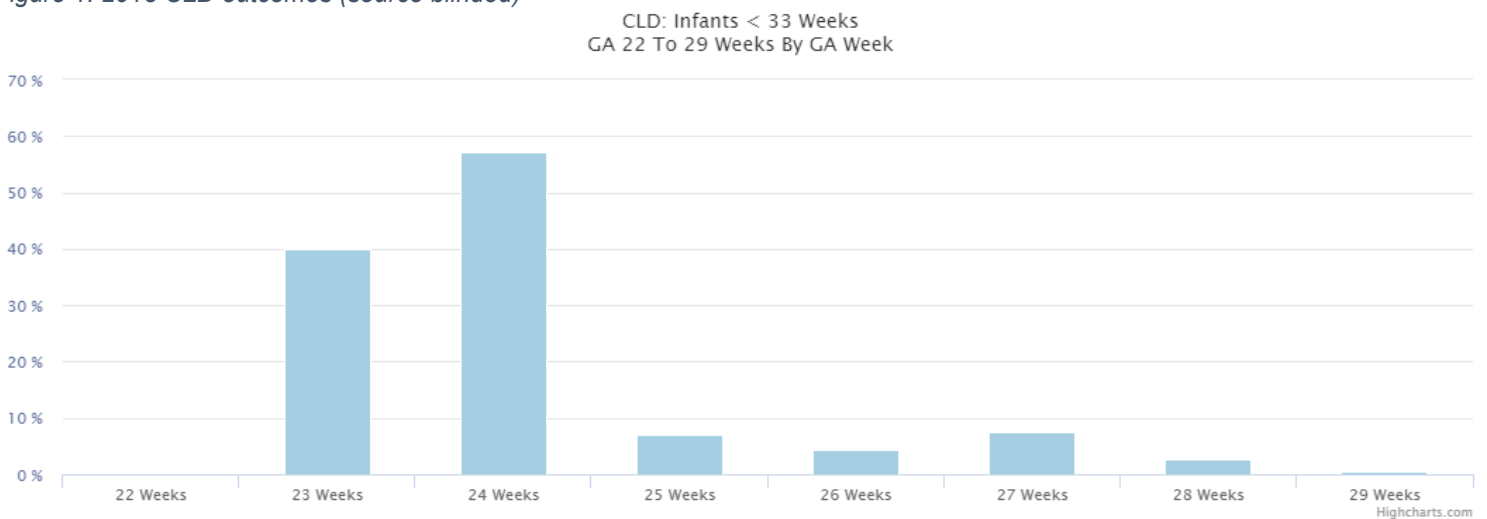


Figure 2: CLD outcomes 2019 (source blinded) Blue arrows indicate 2018 value

Why? It is almost unheard of to have a 23-week GA infant supported with NIV for any length of time. The CLD rate for these infants decreased insignificantly, while the rates in the 25-week GA group decreased from approximately 12% to 8%. This makes sense. At 25-weeks GA an infant is much more likely to tolerate NIV as the first intention, and they are also less likely to be managed with IV for an extended period. 24-week gestation infants are a much different animal. These infants are developmentally behind those at 25-weeks GA, and this must be considered when choosing respiratory support. As NIV has been used on lower and lower GA infants, the benefits have been mixed. In the ≥ 25-week GA group, the benefits seem clear: less CLD. It would appear from the limited data available to me that the increase in CLD in the

There are several ways to provide NIV, as well as modes within the realm of NIV, such as intermittent positive pressure and oscillation. Various devices exist from several manufacturers; nasal prongs, nasal masks, RAM[®] nasal cannulae, and others from companies such as Fisher Paykel. Each has its advantages and disadvantages, but the most egregious sequela is nasal septal damage, which follows these babies into childhood and beyond. This is most commonly related to the use of nasal prongs, although a nasal mask not carefully applied can also result in septal damage. Nasal masks are most commonly associated with skin breakdown on the bridge of the nose; in some cases, a distortion of facial features (the centre of the face being pushed in) results from having the mask applied very tightly in an attempt to maintain high pressures. Avoiding extubating from high IV support pressures can mitigate this. Adjunct barrier devices are also available, which help reduce injury **before** it happens. Alternately, “duoderm”[®] or similar products may be cut to size and used as a protective bar-

rier. Placing these barriers after the fact may exacerbate the injury as they may prevent them from drying out and healing.

Infants may be switched over to the RAM® canulae when nasal septal erosion or other skin breakdown is noted. Clinical experience would seem to indicate this device is less likely to result in septal damage (although it is possible) and may be used to “give the nose a break.” The biggest problem with RAM® is pressure delivery. There are varying estimates of how much pressure is delivered at a given setting with this device. In clinical practice, I find increasing the set CPAP pressure by 2-3 cmH₂O seems to compensate. Accordingly, I set the pressure to a level that meets the needs of the baby. When reporting, the type of device used is stated since the team are aware of the differences between RAM® canulae and nasal prongs or masks. Should a baby require a backup rate, the RAM is not ideal, although the utility of NIV with a rate is a subject of debate. (The exception to this might be NI-high frequency jet ventilation, coined “NINJA” (see Volume 14 Issue 5).

“Alternating between nasal prongs and nasal mask helps to reduce the incidence of injury, as may gentle massaging of the baby’s nose when off during routine care if tolerated. If a baby tolerates brief periods off NIV support “cycling” time off, while also contentious, may also give the nose a rest.”

Alternating between nasal prongs and nasal mask helps to reduce the incidence of injury, as may gentle massaging of the baby’s nose when off during routine care if tolerated. If a baby tolerates brief periods off NIV support “cycling” time off, while also contentious, may also give the nose a rest. The best predictor of nasal damage is time on NIV support, although it can occur very quickly, sometimes in a matter of hours.² Obviously, the earlier a baby is extubated and supported with NIV, the greater the risk of damage is. Another option is to change the NIV mode to high flow as early

as possible, although as with RAM® the pressure delivered is unknown, and flow rates are set clinically (within reason) to meet the baby’s needs. Some use the “Wilkinson formula” to set high flow rates.² (It is worth noting that Dr. Wilkinson does not use these formulae.)

Last but not least is the problem of “CPAP belly”; as NIV pressure increases, so does the amount of air that finds its way into the stomach and bowel. As gastric/intestinal air increases, the space available for ventilation decreases. In addition, the air in the stomach may contribute to feeding intolerance and reflux, repeated X-rays, and septic workups to investigate the (perhaps obvious to the bedside caregivers) reason a baby is not doing well. Maintaining a gastric tube vented to air is *de rigueur*. The length of that tube is also important. I often see babies on continuous feeds with the extension tubing vented. The increased resistance posed by that extension makes venting it to air moot.

IVH and ROP

That premature infants will have apnea and/or bradycardia (with or without accompanying oxygen desaturation) episodes is a forgone conclusion. These events are less common when an infant’s respiratory needs are fully met (i.e., IV); however, they are far more common when NIV is used. The solution? If a manual inspiration button is available, it may be used to give a gentle reminder to the baby that breathing is not optional. If that button is not available (with bubble CPAP, for instance), the only choice is gentle stimulation to trigger breathing and increase heart rate. The availability of a manual inspiration button notwithstanding, more vigorous stimulation may be required. Stimulation, particularly in the first 72 hours of life, may activate the “fight or flight” response. While this accomplishes the caregiver’s goal, it also causes a spike in blood pressure and cerebral blood flow; this is a setup for a bleed. Oxygen desaturation prompts the bedside caregiver to increase FiO₂, therefore increasing saturation (SpO₂) to within an acceptable range. This acceptable range is invariably overshoot before FiO₂ is returned to the baby’s normal baseline. Worse, if the FiO₂ is left up (for instance, when the bedside caregiver is called to attend to another patient), re-perfusion injury or prolonged hypoxia is the result.

Conclusion

As with any therapy, risk/benefit must be assessed, and NIV patients should be selected appropriately. I would suggest NIV not be used in babies under 25-weeks GA except under exceptional circumstances. This does not mean a baby <25-weeks GA cannot be supported with NIV temporarily while vascular access is obtained. It may also be neuro-protective to support the 25-week GA infant with carefully monitored, lung-protective NIV for the first 72 hours to decrease the amount of stimulation the infant receives during this critical period. Avoiding extubating from high support pressures and ensuring properly sized nasal prongs (they should fit snugly into the nares without putting pressure on the nasal tissue) are the best ways to mitigate nasal and facial damage.

NIV has likely saved many babies from CLD, and it has earned its place as a proven mode of respiratory support, particularly in the ≥25-week GA strata. The success of NIV is directly related to GA,

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rising quickly as GA increases. Where once all infants <30 weeks GA would be intubated “for prematurity,” it is now unusual to find a ≥27-week GA infant receiving IV for any length of time. With the advent of minimally invasive surfactant therapy (MIST), it is now unusual to see these infants intubated at all, and it would appear that this too may have a positive effect on CLD outcomes.

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- 1 <https://www.nejm.org/doi/full/10.1056/NEJMoa1700827>
- 2 <https://pubmed.ncbi.nlm.nih.gov/19176303/>
- 3 *Wilkinson formulae for CPAP using high flow:*
 CPAP 5: 3.9 x weight in kg
 CPAP 6: 4.8 x weight in kg
 CPAP 7: 5.7 x weight in kg
 CPAP 8: 6.6 x weight in kg

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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- **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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Open letter to Black Moms: Why they should all be Breastfeeding

Shalea Cotton BSN, RN, CLC,
Tiffany Moore, RN, PhD

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

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

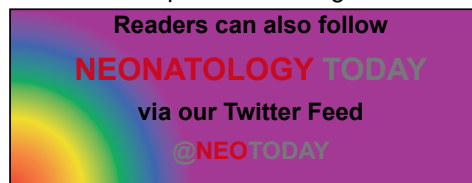


Educate. Advocate. Integrate.

Is breastfeeding considered a “white thing”?

When we look back at history, African slaves gave birth to their children only for them to be taken from their hands as they were forced to breastfeed their slave masters’ babies the very breastmilk designed for their own. Society has made it easy to think that since slavery was abolished, we should put topics and truths as such behind us; however, this logic neglects the idea that traumatic experiences can become generational.

Generational health practices, especially those involving maternal-child health care, are powerful in the black community. The mimicking of behaviors such as breastfeeding was a practice not often seen and therefore not passed down generation to



generation. If a young woman does not see her mother or any woman in her family or community breastfeed, likely, she will not have the knowledge, experience, or confidence to breastfeed her children. Interventions that improve breastfeeding beliefs and behaviors should include those

“If a young woman does not see her mother or any woman in her family or community breastfeed, likely, she will not have the knowledge, experience, or confidence to breastfeed her children.”

who promote self-efficacy (Reno, 2018).

The breastmilk of African slaves and subsequently, that of their descendants, was enough to sustain the livelihood of white children; why is it not thought to be enough for black babies today?

According to the Centers for Disease Control and Prevention (CDC) (2019), black infants are the least likely to be breastfed, more specifically 15% less likely than white infants. Why is this disparity important? Black infants are at higher risk for infant mortality. In 2017, African American infants held the highest mortality rate of 10.97 deaths per 1,000 births compared to a rate of 4.67 in white infants. Black

infants more than double white infants in the cause of death related to sudden infant death syndrome known as SIDS (Ely & Driscoll, 2019). Some of the many benefits of breastfeeding for infants include a reduction in the risk of death from SIDS, and conditions such as asthma and obesity. The act of nursing does so much more than provide nutrition. It also provides the first constructs of immunity, and comfort for the growth, development, and health of the infant. Statistics by the CDC (2019) suggest the implications of having lower breastfeeding rates increase medical costs \$3 billion a year in the United States. Experts suggest that increasing breastfeeding in black mothers can reduce infant mortality by nearly half.

With known data that suggests that black infants can benefit greatly from breastfeeding, why hasn’t there been an increase in rates?

There are a number of barriers that contribute to the disparities in breastfeeding amongst black mothers and families in the United States. A large majority of the black communities across the states are contained in impoverished neighborhoods where unhealthy living conditions and exposure to risky health behaviors are plenty. In black neighborhoods, more often than not, you are able to easily spot a liquor store on every third corner, in addition to an abundance of fast-food restaurants. There are a number of factors to touch on when considering the unhealthy conditions of the “ghetto” which make black families at much higher risks for morbidity and mortality. We must consider systematic oppression and socioeconomic setbacks when discussing health promotion and in-

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tervention for these communities.

Black women are returning to work at much faster timeframes in order to provide for their families. If breastfeeding was not successfully established, a formula might be easier to use. Or perhaps she could not afford a breast pump making it difficult to maintain supply while at work. It is also possible that her work does not provide the space or time to pump or store breastmilk. Passing laws for breastfeeding in the workplace as well as in public places is essential for women to have successful breastfeeding experi-

“Passing laws for breastfeeding in the workplace as well as in public places is essential for women to have successful breastfeeding experiences and further adds to breastfeeding normalcy, recognized as a necessary act of health that can function within everyday life (Johnson, Kirk, & Muzik, 2015).”

ences and further adds to breastfeeding normalcy, recognized as a necessary act of health that can function within everyday life (Johnson, Kirk, & Muzik, 2015).

To have a mother, aunts, grandmother, neighbors, and friends who never breastfed, where does the support for a black mother on a breastfeeding journey come from? Did her health providers present breastfeeding as an option?

Healthcare professionals need to be cognizant of avoiding assumptions and presenting education on breastfeeding without bias. It can be argued that breastfeeding should be discussed during the early prenatal appointments as opposed to the third trimester or after delivery. The way words and images are added to a message reflects the way it will be perceived. If a nurse were to ask, “what do you know about breastfeeding?”; instead of “are you going to breastfeed?” (Johnson, Kirk, Rosenblum, & Muzik, 2015); it can change the direction of the conversation completely and open the door for positive thoughts and questions. Postpartum support is very important, as well. Imagine this scenario. A mother, who has never breastfed and has not seen anyone in her family breastfeed attempting to breastfeed, is struggling and on the verge of giving up. What will happen if a nurse says, “formula won’t kill the baby.” This is where language and wording are important; for a married upper-middle-class white family with limitless access to health resources, the formula may not hurt, but for a black infant of a low-income family who is at twice the risk for mortality, the formula has that much greater potential of being harmful.

So, where do we go from here?

Many urban areas that are in the most need of health resources for breastfeeding do not have neighborhood clinics or facilities that house lactation support. The location of where resources are places should be accessible. Communities, as described above, could greatly benefit from lactation home visits or one on one

counseling. In addition to accessibility, tools and resources must also have affordability, such as free breast pumps for Medicaid eligible families, for example. The involvement of the community must be strong. Creating partnerships within the community and with leaders and stakeholders, such as those in churches, daycares or schools, or the local library and educational programs, is necessary to expand knowledge and support (Johnson et al., 2015a).

In a population of people who were stripped of the confidence to breastfeed for generations, we must act to promote and uplift in a number of different methods to bridge a connection between the identification as a black person with the healthy behavior of breastfeeding. Advertisements, billboards, commercials, product designs, magazine and journal photos, etc., are all ways to help reframe the imagery of breastfeeding to not being an only “white thing.” There is an underlying mistrust of providers given the history of mistreatment; therefore, cultural representation holds extreme importance in interventions designed to transform a health behavior of a specific community. Expanding the number of black lactation professionals, nurses, doctors, etc. is one way to respond to the needs of the community, also creating strong peer groups. By taking advantage of the technological advances of the world, the use of social media platforms and virtual services such as telehealth can be used to bring black women together in support of each other and not only inform but aid in building assurance for breastfeeding longevity.

Considering the current events of the COVID-19 crisis, think about the uproar of sold-out toilet paper and Lysol. If there were an extreme shortage of infant formula, how many infants who are already at risk would starve? In third world countries where there is extreme poverty or constant war, breastfeeding may be the only way to keep the life of an infant sustained.

Breastfeeding is enough and has always been enough. The month of August is dedicated to Breastfeeding Awareness, and for the last seven years, the last week in August has been coined



Black Breastfeeding Week. This year's theme is "revive, restore, reclaim" (Black Breastfeeding Week, n.d.). August 25th to 31st deserves much-needed support and recognition and is another tool to spread knowledge and seek improvements in breastfeeding success in black communities.

Breastfeeding is the most natural form of nutrition and should be normalcy for all women, especially those groups who are at the most risk for morbidity and mortality. It is of vital importance that we continue to work to first ground ourselves with a full understanding of the detriment that slavery and the continued oppression and injustices toward black citizens of America have caused, and second, actively restore equality and eliminate disparities.

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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 that 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)
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- speech therapists (SLPs)
- occupational therapists (OTs)
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- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
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COVID-19 Update: The Rise of Telemedicine - Benefiting Patients and Providers

Gavin Clingham, JD, Director of Public Policy, 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.



Healthcare insurers, patients, and providers have all been quick to incorporate telemedicine into their routines, another sign of how COVID-19 is changing healthcare delivery.

“COVID-19 has made accessing in-person care more difficult, some areas have restricted travel, some sites of care have been limited, and some patients fear risks of exposure when seeking routine and even emergency care.”

COVID-19 has made accessing in-person care more difficult, some areas have restricted travel, some sites of care have been limited, and some patients fear risks of exposure when seeking routine and even emergency care. But health care professionals know that a missed diagnosis or delayed or skipped treatments

can be just as harmful to patients' health.

As a result, healthcare insurers, led by Medicare and private insurers, rapidly expanded access to telemedicine temporarily to meet this need. Can telemedicine work for pediatric patients as well?

Appropriate Telemedicine Services for Pediatric Patients

Telemedicine can cover any number of services and types of visits regardless of a patient's age. Many insurers already cover telemedicine for behavioral health needs among the pediatric population. Telemedicine might also be appropriate for common medical conditions that are already diagnosed based on an image or phone call from the patients. Services delivered in this manner can, for example, be used for assessment, diagnosis, intervention, consultation, and supervision across any distance.

Examples of services where a video visit can provide you with enough information to diagnose are common rashes or prescribing antibiotics for conjunctivitis. Telehealth can also be useful for follow-up visits after a recent in-person appointment or prescribing prescription refills.

Telemedicine will not be able to meet all healthcare needs but is an exciting option that healthcare providers and patients should explore.

Coverage and Reimbursement Policies

Providers must remain aware that telemedicine coverage policies vary widely. In addition to private health insurers' policies, the Centers for Medicare and Medicaid Services (CMS) has been encouraging states to expand coverage through both Medicaid and the Children's Health Insurance Program (CHIP). To help answer questions, CMS released a [State Medicaid & CHIP Telehealth Toolkit](#) to urge States to implement the flexibilities that they have and to make it easier for them to apply for waivers if necessary.

CMS makes clear that States have a great deal of flexibility with respect to covering Medicaid and CHIP services provided via telehealth. States have the option to determine whether (or not) to utilize telehealth; what types of services to cover; where in the state it can be utilized; how it is implemented; what types of practitioners or providers may deliver services via telehealth, as long as such practitioners or providers are "recognized" and qualified according to Medicaid federal and state statute and regulation; and reimbursement rates.

Importantly, CMS makes clear that States are not required to submit a state plan amendment (SPA) to pay for services delivered via telehealth if payments for services furnished via telehealth are made in the same manner as when the service is furnished in a face-to-face setting.

Healthcare providers need to understand the differing rules for their state and private insurance programs so that they can take full advantage of new flexibilities.

Privacy Concerns

All telemedicine comes with new privacy concerns based on the technology used. Providers are encouraged to use HIPAA compliant technology as it will be the standard of care going forward. Treating pediatric patients means compliance with other legal requirements, including the Children's Online Privacy Protection Act (COPPA). This law helps ensure any personal information gathered from children under 13 online is adequately protected and subject to parental consent.

Conclusion

COVID-19 has caused ripple effects throughout the healthcare system. Increased access to reimbursement for telemedicine visits is one development that has many excited. While much of the flexibility is limited to the duration of the declared Public Health Emergency, efforts are underway to continue coverage past that date.

“COVID-19 has caused ripple effects throughout the healthcare system. Increased access to reimbursement for telemedicine visits is one development that has many excited. While much of the flexibility is limited to the duration of the declared Public Health Emergency, efforts are underway to continue coverage past that date..”

Telemedicine for pediatrics has different benefits and challenges than telemedicine for other populations. Experience from healthcare providers and their patients about what did and did not work in pediatrics will be important in informing the telemedicine policies that continue forward.

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

Infants need drugs tested and approved just for them.

Centers for Clinical Trials Analysis | **NCJIH** National Coalition for Infant Health | Protecting Access for Premature Infants through Age Two

Still a Premie?

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

But that's not every premie's story.

Born between 34 and 36 weeks' gestation? **STILL A PREMIE**

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

- Jaundice
- Feeding issues
- Respiratory problems

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

Born preterm at a "normal" weight? **STILL A PREMIE**

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

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

Born preterm but not admitted to the NICU? **STILL A PREMIE**

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

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

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

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

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CORONAVIRUS

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RELIABLE RESOURCES:

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

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Respiratory Syncytial Virus is a

Really Serious Virus

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

Coughing that gets worse and worse



Breathing that causes their ribcage to "cave-in"

Rapid breathing and wheezing



Bluish skin, lips, or fingertips

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

Call your doctor and meet them at the hospital.

If your baby isn't breathing call 911.



Thick yellow, green, or grey mucus



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

Fever that is higher than 101° Fahrenheit



which is especially dangerous for babies younger than 3 months

 National Perinatal Association

www.nationalperinatal.org/rsv

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu

coronavirus

pertussis

RSV



SOAP

WASH YOUR HANDS

often with soap and warm water.

GET VACCINATED

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



COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.

USE AN ALCOHOL-BASED HAND SANITIZER.



STAY AWAY FROM SICK PEOPLE

Avoid crowds. Protect vulnerable babies and children.

www.nationalperinatal.org

 National Perinatal Association

A Teen-Led, Volunteer-based NICU Reading Program: A Model for Supporting Family Reading and Family Integrated Care

Benjamin Olshin, Howard Cohen, MD

Introduction:

NICU babies are at high risk of neurodevelopmental impairment for multiple reasons, including prematurity, critical illness, and family emotional and economic stressors associated with hospitalization in the NICU. (1) Care in single-patient-room NICUs can compound the issues of sensory deprivation and contribute to speech and language deficits in NICU graduates. (2) Reading aloud with babies creates and strengthens neural connections that “promote ... social-emotional development...and language and literacy skills during this critical period of early brain and child development.” (3) Providing parents and other caregivers books and encouraging them to read to their infants in the NICU is a low-cost intervention to increase infants’ speech and language interactions. Parent reading with their baby in the NICU supports family integrated care and bonding (4) and improves the NICU experience.

“The NICU Reading Program is a collaboration between teen volunteers and NICU providers, consisting of four discrete components - Admit Reading Packets, One-on-one Book Rounds, a Family Shared Reading Library, and literacy events and celebrations.”

Babies With Books (BWB) NICU Reading Program:

BWB, a teen-led volunteer organization, began its first NICU Reading Program at Randall Children’s Hospital (RCH) in 2017. The NICU Reading Program is a collaboration between teen volunteers and NICU providers, consisting of four discrete components - Admit Reading Packets, One-on-one Book Rounds, a Family Shared Reading Library, and literacy events and celebrations. Admit Reading Packets contain a book, bookmark, and information on how and why to read aloud with babies beginning in the NICU. Teens source and assemble these admit packets, which are given by healthcare providers to each infant at NICU admission. One-on-one Book Rounds encourage and reinforce NICU reading. During book rounds, teen volunteers meet weekly

with NICU families to talk with them about how to read with their infant and why reading aloud to their babies beginning in the NICU is important. Some of this information was developed in collaboration with Reach Out And Read® (ROR). Families are offered their choice of 3 books from a mobile book cart to read with their infant, keep in the NICU, and bring home at NICU discharge. The Family Shared Reading Library is a library located outside of the NICU (ex. in the NICU lobby or lounge) stocked with donated, gently used books. Literacy Events & Celebrations include NICU read-a-thons, book nooks at NICU reunions, and other literacy promoting events that engage families in shared reading. In BWB’s first NICU read-a-thon at RCH, 45% of families participated, and all surveyed staff and families expressed high satisfaction. BWB has also hosted a “book nook” program at the RCH NICU reunion, during which we provided more than 200 donated books to NICU graduates and their siblings and read stories with them. Through this NICU Reading Program, BWB has served more than 850 NICU babies at RCH.

“We recommend books by a wide range of authors that engage and represent the diversity of the NICU patient population. Funding is through generous foundation grants as well as individual and corporate donations.”



Readers can also follow
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Books used in the Reading Program include a variety of high contrast board books, children's stories, and "I love you" type books. Only new books are used with babies. Donated, gently used books may be used in the Family Shared Library and in "book nooks" at NICU reunions for NICU families and graduates. Books are available in multiple languages, and picture books are available for families whose primary language is not represented and for non-reading families. We recommend books by a wide range of authors that engage and represent the diversity of the NICU patient population. Funding is through generous foundation grants as well as individual and corporate donations. We receive donated books from a local book bank and a used bookstore.

Like all hospital-based programs, BWB has been impacted by the COVID-19 pandemic. The BWB teens have continued to source and assemble admit reading packets but do so offsite and deliver these to the hospital where they are stored for at least 72 hours prior to being given to NICU families. To assemble and deliver admit packets, volunteers must be symptom-free, wear masks, and adhere to strict hand hygiene. One-on-one volunteer-led book rounds have been paused during COVID-19 but can be performed by personnel with continued access to the NICU. Shared Family Reading Libraries are not recommended during COVID-19. Read-a-thons remain a great way to support infants and families and build NICU morale during COVID-19.

Conclusion:

By engaging motivated, passionate, and creative teen volunteers in our BWB Reading Program, we provide valuable service to NICU babies and families with limited burden and cost to healthcare providers and hospitals.

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The authors have no conflicts of interests to disclose.

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Join our multi-site NICU Read-a-thon September 14-24, 2020! This September 14-24 2020, BWB is organizing an international, multi-site NICU read-a-thon. To register for it, please complete this short form: <https://forms.gle/YgrzqfVi2yYp-wPeZ6>. By registering, our team will also provide you with information on how to organize and implement a read-a-thon including downloadable family and healthcare provider information sheets, reading tracking sheets/raffle tickets, bookmarks, prize suggestions, and more! We have also created a NICU Reading Program process guide to help you start or expand your NICU Reading Program. Request the guide here: <https://forms.gle/wj6uYXfyKZydXQZw5>. Visit us at babieswithbooks.org and email us at babieswithbooks@gmail.com.

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

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



Identify babies at greatest risk



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

Teach families how to protect



their babies from respiratory infections

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



Use your best clinical judgement



when prescribing RSV prophylaxis

Tell insurers what families need



and provide the supporting evidence



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

Survey Says: RSV

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children



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

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



But Parents are Unprepared.

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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

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



NCJIH National Coalition for Infant Health
Preventing RSV in Preterm Infants through Age Five

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BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE



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Humanity Beyond Borders

Boris Schmidt Goldstein

Within the Middle East, many nations are war-ravaged, thus limiting available healthcare. Not only has the need for medical treatment surged with the outbreak of COVID-19, but many medical centers throughout the Middle East are neither equipped with sufficient technology nor comprised of well-trained personnel in order to assist with life-threatening operations and treatments. However, there is one anomaly in the war-torn region- Israel. Since the nation's establishment in 1948, the highly-acclaimed Sheba Medical Center has played a large role in facilitating healthcare. It began as the first military hospital in order to treat casualties from the 1948 Arab-Israeli War, which was prompted by the Israeli Declaration of Independence and the resulting outrage from its Arab neighbors. The war lasted for nine months. After 1953, the military hospital was converted to a civilian hospital. Since then, Sheba Medical Center has had prominent influence within the Middle East and facilitates medical research in many areas, greatly shaping modern medicine. Newsweek ranks the medical center as the ninth-best hospital in the world, alongside other notable hospitals such as Mayo Clinic and Toronto General Hospital (1). Sheba has recorded 200,000 ER visits and over 2,000,000 patients treated annually both domestically and internationally (2). Many of their emergency visits are provided to international patients, primarily within the Middle East.

“However, Operation Good Neighbor’s running of aid through southern Syria came to a halt after Syrian President Bashar al-Assad’s forces defeated the Free Syrian Army in the 2018 Southern Syria offensive (3).”

A large percentage of these patients are children from the Palestinian Authority, which lacks sufficient neonatal care units. The Palestinian Authority processes and transfers thousands of patients in order to obtain urgent hospitalization, primarily for critical operations. Israel, despite rivalries, continues to provide aid to its Arab neighbors enabling medical access for civilians for humanitarian causes. A notable example that exemplified Israel's international assistance to those deprived of proper healthcare was Operation Good Neighbor, which began administering medical aid through the Israeli Defense Forces to those affected by the Syrian Civil War. Over 110 operations were performed on patients brought to Israel through the Golan Heights, where northern Israel borders Syria. Many of these operations provided aid to children and admitted them to hospitals within the region. However, Operation Good Neighbor's running of aid through southern Syria came to a halt after Syrian President Bashar al-Assad's forces defeated the Free Syrian Army in the 2018 Southern Syria offensive (3).

Within just the past months, two emergent neonatal intensive care

cases from the neighboring region outside of Israel required transfer to Sheba Medical Center. The first involved the child of a Syrian refugee currently living in Cyprus. The 10-day-old baby was flown into Israel through special coordination between the Cypriot and Israeli government so that the infant could undergo the first of three surgeries for his rare congenital heart defect, hypoplastic left heart syndrome (4). HLHS disrupts normal blood flow and greatly impacts the left side of the heart, preventing it from properly pumping oxygen-rich blood to the rest of the body. Without treatment, it is fatal. HLHS is considered a critical CHD as it requires the affected infant to undergo the initial operation promptly after birth (5). The baby successfully underwent the first of the three scheduled surgeries, the Norwood procedure. The Norwood procedure creates an artificial aorta connected to the right ventricle of the heart and creates a conduit to supply the pulmonary arteries with sufficient blood flow. This surgery is the most challenging of the three procedures, and both oxygen-rich and oxygen-poor blood still mix in the heart following the operation. After the infant's recovery, he will return to Cyprus and be expected to return in 6 months to take the next step in the process with the Bi-directional Glenn Shunt procedure, which will lower the workload of the right ventricle by enabling the returning blood flow to redirect to the lungs. The infant will then return back to Sheba Medical Center 18 months after the second operation to finalize the repair with the Fontan procedure, which will also correct the mixing of oxygen-rich and oxygen-poor blood. This is the first emergency surgery since the initial outbreak of coronavirus. Similar cases involving HLHS were transferred urgently to Israel before the pandemic from other countries within the region where relations are not normalized with Israel, such as Syria and Iraq.

“ Palestinian Authority President Mahmoud Abbas recently decided to halt any mutual agreements with Israel and to withdraw from any cooperation between the two governments due to Israeli Prime Minister Benjamin Netanyahu’s decision to apply Israeli sovereignty over regions of the West Bank.”

However, while the region depends on Israel for its healthcare, new issues are evident. Palestinian Authority President Mahmoud Abbas recently decided to halt any mutual agreements with Israel and to withdraw from any cooperation between the two governments due to Israeli Prime Minister Benjamin Netanyahu's decision to apply Israeli sovereignty over regions of the West Bank. This area comprises most of the Area C set by the Oslo Accords, where Israel holds military and civil control (6). This geopolitical obstacle will most likely hinder the delivery of Israel's healthcare,

especially to the children of Gaza.

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In the second instance of a neonatal emergency within the region, a 8-month-old's planned heart surgery for his life-threatening cardiac condition was delayed due to this halt in coordination from the Palestinian Authority. The procedure was promptly rescheduled through activism by humanitarian groups in the region, but the baby died three days before the rescheduled date (7). This infant had already received treatment from Sheba Medical Center at 1-month and was denied transfer due to the strained political relations between the two governments. If this issue remains prominent, many Palestinians will be affected as Palestinian hospitals are not able to facilitate aid because of insufficient resources, limited technology, and lack of specialized medical personnel.

Annually, there are thousands of permits given to Palestinian infants in order to undergo treatment at Israeli neonatal care units. However, with the straining of relations recently, an entire generation of infants may be deprived of proper healthcare.

“Annually, there are thousands of permits given to Palestinian infants in order to undergo treatment at Israeli neonatal care units. However, with the straining of relations recently, an entire generation of infants may be deprived of proper healthcare.”

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The Brett Tashman Foundation is a 501(c)(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to TheBrettTashmanFoundation.org or phone (909) 981-1530.

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After parents learned more about RSV, they were:



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OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS



I am not an addict.

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



I was exposed to opioids.

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



NAS is a temporary and treatable condition.

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



My mother may have a SUD.

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

My potential is limitless.

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



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



Judge Rules ICE Must Free Migrant Children, but what about their Parents?

Rebecca Leff, Medical Student

Approximately 5,500 [migrant children](#) were separated from their parents by the [Trump Administration](#). And these are just the children we are aware of. Long before the Trump administration instigated the Zero Tolerance immigration policy in 2018, officials had already begun separating children from their parents as part of a so-named pilot program conducted in the El Paso, Texas, region, which then extended along the border. As late as May 29, 2020, a [review](#) conducted by the U.S. Customs and Border Protection (CBP) Office of Field Operations (OFO) in response to congressional requests, identified an additional 60 asylum-seeking families separated at 11 ports of entry between May and June 2018, far greater than the seven such separations originally claimed. We are only beginning to understand the extent of the devastating toll separation has taken on immigrants and asylum seekers families. Reunification is complex, hinging on such determinants as when a child was separated if they are labeled as plaintiffs in a class-action lawsuit against the Trump Administration, and where the children's parents are currently located.

“Reunification is complex, hinging on such determinants as when a child was separated if they are labeled as plaintiffs in a class-action lawsuit against the Trump Administration, and where the children’s parents are currently located.”

And then, amid this chaos, a global pandemic struck. Despite a binding [2009 internal directive](#) to do so, ICE refused to release children from detention centers. Not only are families in these centers unable to practice the evidence-based social distancing that states and federal government agencies have promoted throughout this pandemic, but they often [lack access](#) to masks as well as hand washing and cleaning supplies: basic necessities that are critical in the face of an unprecedented viral pandemic. The crime for which they are paying with their lives: having nowhere else to go.

This leads us to June 26, 2020, when Judge Dolly M. Gee of the U.S. District Court for the Central District of California [ordered the release of all children](#) who have been held for more than 20 days in detention centers run by Immigration and Customs Enforcement. As of June 8, there were 124 children in ICE custody, according to the ruling. As a medical trainee in my final year of medical school who has worked with immigrant and asylee children and families, I was encouraged by the [order to release these children](#). I recognized how critical this order is to protect the health and wellbeing of children. I recognized that without this order, children and their families might die. While children are less likely to become

severely ill than older adults, there are subpopulations of children with [increased risk](#), among them children with asthma or other underlying health conditions. For children in detention centers, this risk was not theoretical. Children and parents have [already tested positive](#) for the coronavirus at a family detention center in Karnes City, Texas, and others have known exposure to COVID-19 at a family facility in Dilley, Texas.

“But there is a catch. ICE may be required to release the children, but the parents’ release is up to their discretion. There is some concern amongst advocates that ICE will force parents to separate from their children to comply with Judge Gee’s order.”

But there is a catch. ICE may be required to release the children, but the parents’ release is up to their discretion. There is some concern amongst advocates that ICE will force parents to separate from their children to comply with Judge Gee’s order. This is unacceptable. Such a policy would ignore the overwhelming [evidence of harm from separating children](#) from their parents that has been articulated by multiple American medical societies, including the [American Pediatric Association](#), who represents pediatricians across the United States. Family separation can affect irreparable harm to children and is an act from which many families may never convalesce. Multiple courts have even ruled the practice [unconstitutional](#).

“While we advocate for all children in this crisis, we must realize that these children are disproportionately vulnerable. The impetus of this moment of change must be applied to these children who need our voices now.”

We, as a society, have seen over these past weeks what our voices can achieve. Voices from Minnesota to Los Angeles, calling for an end to police brutality and racial discrimination, resulted in [police reforms](#) swiftly taking hold across the nation. The sheer brutality of the fate of George Floyd forced us to examine injustice. So too, must the sheer brutality of the act of separating a child from his or her family, force us to examine injustice. While we advocate for all children in this crisis, we must realize that these children are disproportionately vulnerable. The impetus of this moment of change must be applied to these children who need our voices now.

I implore ICE to release children in conjunction with the June 26, 2020 ruling by Judge Gee responsibly with their parents or to a suitable guardian. And I implore you to raise your voice to affect a positive change in these children's lives. Children should be released from ICE detention with their parents immediately. Families belong together.

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Health Equity Column: Addressing Health and Racial Equity Requires Continuous Training

Jenné Johns, MPH



As a follow up to my inaugural article, *Preemie Parent Perspective: Addressing Health Equity and Cultural Competency in the NICU*. I want to introduce the Health Equity Column. The views and opinions expressed in this column are my own, as both an African American Micropreemie Mom, and National Senior Health Equity Leader. 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. In this months' column, we will examine the important role of continuous health and racial equity training for the neonatal and perinatal medical community.

Over the last few months' I have silently and emotionally witnessed the impact of two global pandemics: COVID-19 and its associated health, social, economic and political disparities, and the civil unrest of racism and police brutality in the United States. The surge of lives lost due to both pandemics requires us as a nation to address the value we place on each and every human life from a health, safety, and racial justice lens.

“As the pandemic ramps down and stay-at-home orders expire, continued federal relief may be forthcoming. Access and support for pediatric care must be included.”

Historically in the United States, health and racial disparities were examined and addressed as intellectual, theoretical, quality improvement, and research exercises. These efforts yielded a plethora of government and philanthropic sponsored research grants, scholarly journal articles, intellectually agreed-upon theoretical frameworks. At best, it produced a few evidence-based clinical guidelines and best practices connecting quality improvement and health disparities. However, if we examine overall health and healthcare outcomes in premature birth rates and the survival rates of Black mothers and infants pre, during, and post-delivery, and the treatment of these families in the United States, these early exercises do not match the desired equitable health outcomes.

Recently, we have seen a wave of institutions committing to making large financial investments in the Black Lives Matters Global Movement with some designations to the Black Maternal Health Movement. Even though I believe this is a step in the right direction, our Black mothers and infants deserve more. In order for the financial commitments to match the much-needed health outcomes we desire including equitable maternal health outcomes, reduction in premature birth rates among Black infants, and drastic improvements in the survival rates of Black mothers and in-

fants); it is equally imperative for our healthcare systems and its professionals to commit to continuous health and racial equity education and training that includes addressing the role of implicit bias when delivering care.

“Despite healthcare institutions being encouraged to complete annual cultural competency training as recommended in the National Culturally and Linguistically Appropriate Services (CLAS) Standards, it is only a start for the general healthcare community.”

Despite healthcare institutions being encouraged to complete annual cultural competency training as recommended in the National Culturally and Linguistically Appropriate Services (CLAS) Standards, it is only a start for the general healthcare community. CLAS Standard # 4 is to: “Educate and train governance, leadership, and workforce in culturally and linguistically appropriate policies and practices on an ongoing basis.” If this education and training CLAS provision is not monitored and recorded on a routine basis by healthcare institutions or regulatory and accreditation bodies, we will miss the opportunity to hold ourselves accountable as a healthcare community to deliver the high quality and equitable care, that is imperative for the neonatal and perinatal medical community. I believe it is time to pair annual CLAS training with continuous and routine Health and Racial Equity Training. This pairing is where we begin to see our commitment to training and organizational change match the equitable delivery of care for Black NICU and Preemie families.

As referenced in the June edition of *Neonatology Today*, *Once Upon A Preemie Academy* is a first of its kind to offer a virtual training program focused on health and racial equity training for all NICU and Preemie professionals. In order for this training program to support the education and training needs of the neonatal and perinatal medical community, we must collectively expand our health and racial equity journey together. We are seeking your help by:

1. Visiting our website and joining the listserv for important registration updates

Readers can also follow

NEONATOLOGY TODAY

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2. Increasing awareness about this training program with the NICU/Preemie Professional Community
3. Advocating for continuous health and racial equity training within your own institution
4. Consider sponsoring members of your team to attend our training program- see sponsorship prospectus on the adjoining page
5. Share your challenges, solutions, and success stories with us as we welcome your experiences to inform our training content.

We are all in this together, and together we will take a stand against racial disparities in the neonatal and perinatal communities.

For more information about the Once Upon A Preemie Academy, please visit: <https://onceuponapreemieac.wixsite.com/website>

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Respiratory Syncytial Virus:

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

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Use your best clinical judgement



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and provide the supporting evidence



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



ONCE UPON A PREEMIE ACADEMY



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Our virtual training program will launch this fall and offer four in-depth, live, one-hour educational experiences packed with case studies, parent and healthcare professional testimonials, and opportunities for Q & A.

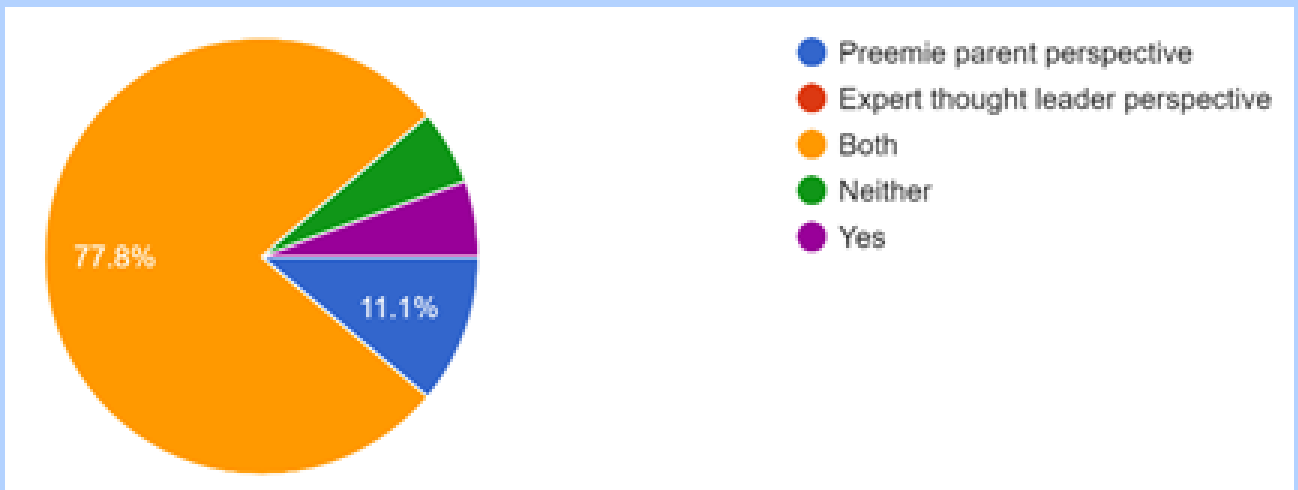
Training topics include:

- A Primer on Health Equity, Birth Equity, Social Determinants of Health, and Implicit Bias;
- Challenges, Opportunities, and Solutions for Addressing Health Equity, Racial Equity, and Implicit Bias in the NICU and Beyond;
- Preemie Parents As Partners for Delivering Equitable Health Care;
- Black Women's Mental and Emotional Health Needs Pre, During, and Post NICU

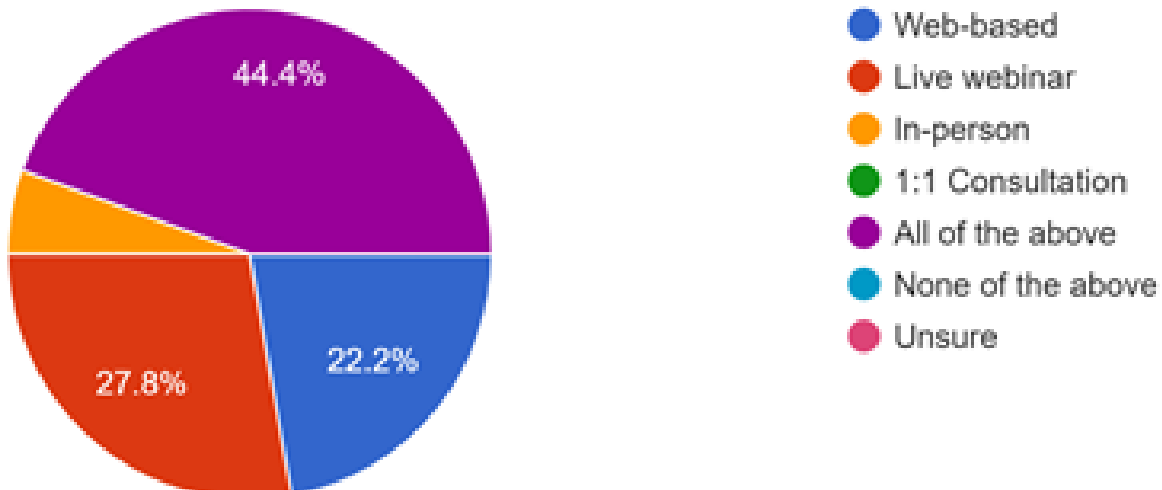
Industry Insights:

We commissioned a national survey to gather insights on the current and future NICU/Preemie health equity training environment. We heard from leaders in NICU nursing, non-profit, health insurance, academia, and parent advocacy. Here's what they had to say!

- Nearly 80% prefer a training from both a preemie parent and thought leader perspective!*



- 50% prefer either web-based and or live*



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Abnormalities of Growth and ICD-10 Coding

Scott D. Duncan, MD, MHA

International Classification of Diseases (I.C.D.) has evolved across decades, emerging from a death registry to a statistical classification system recognized within international healthcare systems. In the United States, the I.C.D. is used to statistically map mortality, health conditions, patient outcomes, and reimbursement. While most historians would recognize Jacques Bertillon, Chief of Statistics for the City of Paris, as the father of the modern I.C.D. system, attempts at disease classification extend as far back as the 15th century, and includes British epidemiologist William Farr's classification for statistical purposes, appearing in the *First Annual Report of the Registrar - General of Births, Deaths, and Marriages* in England, 1837-38.^{1,2} By 1893, Bertillon presented his classification system, focusing on anatomical sites, which was published as the *International List of Causes of Death*.¹ The I.C.D. system has been revised and/or expanded to include causes of death, illnesses, and injuries. A list of revisions may be found in Table 1.

“While the I.C.D. system introduced prematurity as a cause of death as early as ICD-1, ICD-7 introduced specific conditions with and without mention of immaturity.³ ICD-9 introduced three general categories of related to fetal growth and gestation including 1) slow fetal growth and fetal malnutrition, 2) disorders relating to short gestation and low birthweight and 3) disorder relating to long gestation and high birthweight.⁴”

While the I.C.D. system introduced prematurity as a cause of death as early as ICD-1, ICD-7 introduced specific conditions with and without mention of immaturity.³ ICD-9 introduced three general categories of related to fetal growth and gestation including 1) slow fetal growth and fetal malnutrition, 2) disorders relating to short gestation and low birthweight and 3) disorder relating to long gestation and high birthweight.⁴ Within the group of infants demonstrating slow fetal growth and fetal malnutrition, subcategories included light for dates infants without mention of malnutrition (i.e., infants underweight for gestational age, light for dates infants with signs of fetal malnutrition (i.e., infants underweight for gestation age and showing signs of malnutrition), fetal malnutrition without mention of light for dates (i.e., infants who are not underweight for gestational age, but are showing signs of malnutrition), and a category labelled fetal growth retardation, unspecified, which applies to intrauterine growth retarded infants. Within the category of disorders relating to short gestation and low birthweight, ICD-9 included subcategories of disorders relating to extreme immaturity of the infant, defined as a birthweight of less than 1,000 grams, but included birthweight exceeding 1,000 grams. ICD-9 also introduced a subcategory of preterm infants, defined as a birthweight of 1,000-2,500 grams, but included birthweights ranging from less

than 1,000 grams to greater than 2,500 grams. Gestational age was introduced, with stratification from less than 24 weeks gestational age to 37 or more weeks gestational age, meant to be coded with birthweight, as appropriate. Those infants with long gestation and high birth weights were divided into infants with a birthweight of 4,500 grams or more, large for gestation, born between 40-42 weeks or over 42 weeks.

With I.C.D. 10 came a reorganization of the classifications, while providing room for expansion, without disturbing the code structure. Within the area of fetal growth and gestation, ICD-10 better defined these subcategories, while maintaining the general categories noted previously. Found within the alphanumeric chapter "P," "Certain conditions originating in the perinatal period," P05-P08 encompasses the diagnosis of the newborn related to the length of gestation and fetal growth.⁵ The general categories described in ICD-9 are found within P05, P07, and P08, respectively. The subcategories in P05 include P05.0X, newborn light for gestational age including birthweight less than 10th percentile but length above 10th percentile, subdivided by birthweight; P05.1X, newborn small for gestational age with birthweight and length both below 10th percentile for gestational age, subdivided by birthweight; P05.2 newborn affected by fetal malnutrition not light or small for gestational age, and P05.9 newborn affected by slow intrauterine growth, i.e., IUGR.

Table 1
I.C.D. Revisions³

Name	Revision	Year	In Use
International List of Causes of Death	First	1900	1900-1909
ILCD	Second	1909	1910-1920
ILCD	Third	1920	1921-1929
ILCD	Fourth	1929	1930-1938
ILCD	Fifth	1938	1939-1948
International Classification of Diseases, Injuries, and Causes of Death	Sixth	1948	1949-1957
ICD	Seventh	1955	1958-1967
ICD	Eighth	1965	1968-1978
ICD	Ninth	1975	1979-1994
ICD	Tenth	1989	1995-present

Subcategories found within P07 include those related to short gestation and low birthweight. ICD-10 corrects the birthweight stratification, with codes P07.0X those infants of extremely low birthweight, 999 grams or less, regardless of gestational age, and P07.1X those newborns with a birth weight of 1,000-2,499 grams, regardless of gestational age and both sets excluding codes found in P05. P07.2X and P07.3X refer to extremely immature newborn (less than 23 weeks to 27 weeks) and the premature newborn (28

weeks to 36 weeks), respectively.

P08 maintains the subcategories of exceptionally large newborn (P08.0, birthweight 4,500 grams or more, excluding I.D.M.), other heavy for gestational age newborn (P08.1, Large for Gestational Age, usually 4,000-4,499 grams, excluding I.D.M.) and the post-term newborn (P08.21 40-42 weeks) or prolonged gestation newborn (P08.22, gestation over 42 weeks).

In I.C.D. coding for the neonatologist, birthweight and gestational age remain an important distinction, as several E.M.R. data dictionaries mistakenly connect birthweight and gestational age together under a single code, for example, the infant described as "prematurity 500-749 grams, 25-26 complete weeks" as P07.02. When both birth weight and gestational age are available, proper I.C.D. coding dictates that both should be coded, with birthweight coded in sequence before gestational age. Further, the provider should be able to distinguish the proper codes for the infant that is small for gestation by weight, weight, and length, or of low birthweight regardless of gestational age.

Reimbursement in neonatology is based upon proper documentation, supporting the Current Procedural Terminology (CPT®) and International Classification of Disease, Tenth Revision, Clinical Modification codes. Many practices required the neonatologist and/or advanced practice provider (APP) to select the correct diagnosis, which may impact payments to the provider and health-care system. The neonatal care practitioner should have knowledge of correct diagnosis coding, selecting the correct code(s) for the neonate.

Questions

1. A 24 3/7 weeks gestational age male neonate with a birthweight of 650 grams and a length of 31 cm is admitted to the NICU. The correct ICD-10 code(s) for this patient would include:
 - A. P05.02
 - B. P07.02
 - C. P07.23
 - D. P05.12

The correct answers are B and C.

P07.02 represents an extremely low birthweight infant of 500-749 grams.

P07.23 represents an extremely immature infant of 24 completed weeks gestation

2. A 24 3/7 weeks gestational age male neonate with a birthweight of 490 grams and a length of 29.5 cm is admitted to the NICU. The correct ICD-10 code(s) for this patient would include:
 - A. P05.01
 - B. P07.01
 - C. P07.23
 - D. P05.11



The correct answers are A and C.

P05.01 represents light for dates infant with a weight of less than 500 grams, less than the 10th percentile, but a length above the 10th percentile.

P07.23 represents an extremely immature infant of 24 completed weeks gestation

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Retractions: Failure of the Peer Review Process?

Gilbert Martin, MD

Many years ago (March 1991), I wrote an editorial for the Journal of Perinatology entitled: Peer Review: Guerir Quelquefois Soulager Souvent, Consoler Toujours. This quotation thought to be from medieval times has had many definitions but basically is defined as “to cure sometimes, to relieve often, to comfort always.” In my monograph, I referenced David Horrobin (1939-2003), who was a longtime critic of the anonymous peer review system. In an article discussing the philosophical basis of peer review, he was concerned about the peer review system stifling creativity and innovation (1). He believed that the true aim of the peer review was the same as medicine: To cure sometimes, to relieve often, to comfort always.

“The number of articles retracted has increased in recent years. Research integrity has been questioned, and misconduct is often emphasized. It remains a question of whether the peer-review process has become flawed and too lenient.”

As physicians interested in an academic career, we are taught early that we had to “publish or perish.” This is an aphorism which puts pressure on academics to publish in scholarly journals as a condition for employment and career advancement. When our applications for employment or advanced ranking are reviewed, the bibliography is always scrutinized and can be the basis of success or failure.

“Peer-review functions as a mechanism to support quality, to provide a fertile breeding ground for dissension and improvement in the “final product.” This peer review assists the editorial board of a journal to decide whether or not the submission can be accepted, accepted with revisions, or rejected. Therefore this process needs to be objective and complete.”

In the last few months with a great emphasis on needed information on Covid-19, there have been several retracted articles, but most noteworthy, these pieces were retracted from The New England Journal of Medicine and the Lancet, two of

the most respected international publications

The number of articles retracted has increased in recent years. Research integrity has been questioned, and misconduct is often emphasized. It remains a question of whether the peer-review process has become flawed and too lenient. Are more cases occurring, or with the benefit of computerization, are we able to become justifiably more critical? It is difficult not to plagiarize minimally, and journal editors now have “plagiarism-detecting software” at their disposal.

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- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
- **Clear, science-based nutrition guidelines** for pregnant and breastfeeding mothers
- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

www.infanthealth.org

Peer-review functions as a mechanism to support quality, to provide a fertile breeding ground for dissension and improvement in the “final product.” This peer review assists the editorial board of a journal to decide whether or not the submission can be accepted, accepted with revisions, or rejected. Therefore this process needs to be objective and complete. After this degree of scrutiny, there should be no place for retraction of an article if the process was satisfied.

In the early days of peer-review, the material was sent to anonymous reviewers, and a generous amount of time was allowed for this review. In today’s world, there are always comments by the reviewers, which can go back and forth between author and reviewer. In fact, some journals encourage the submitting authors to suggest reviewers for their material

Am I surprised that retractions can occur?. Not at all..... for in order to present information to the public quickly, which can be important for health-care professionals, short-cuts and impediments to the full process are roadblocks to objectivity.

The retraction of an article from a well- established, well respected medical journal should be considered a failure of the peer-review process. Journal editors must use reviewers who have credentials, are free of bias and can offer objective opinions

One approach may be to use checklists and algorithms to make the process simpler. Questions with yes or no answers such as “Is the material well-organized?”; “are the facts accurate?”; “is the information up to date?”; and “is the style clear, informative, and readable?” will immediately simplify and shorten the entire process

“In the early days of peer-review, the material was sent to anonymous reviewers, and a generous amount of time was allowed for this review. In today’s world, there are always comments by the reviewers, which can go back and forth between author and reviewer. In fact, some journals encourage the submitting authors to suggest reviewers for their material”

I hope that when I am asked to review an article, I am chosen because of my expertise in the field and not a colleague (friend or foe?). I often chuckle when the letter from the editor asks that I complete my review in a short period of time. The shorter the period of time allowed often results in an inferior review.

In the future, the Guidelines for Contributing Author’s page may end up as an instruction manual. There will be confusion, frustration, and the work necessary to produce a manuscript will increase. Perhaps, then, the number of submissions will decrease, the workload to the referees will lessen, and the entire process will be improved.

References:

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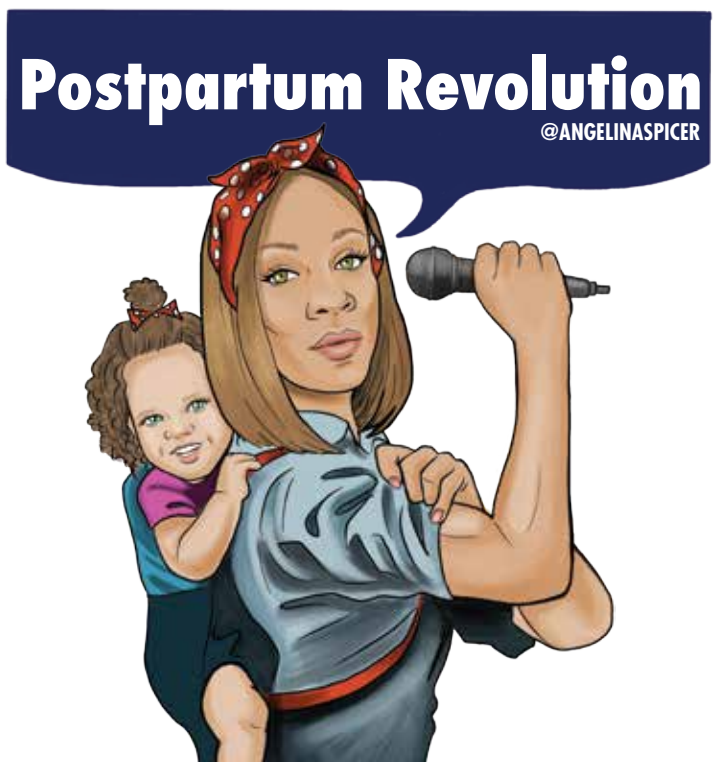
Disclosure: Dr. Martin indicates no relevant disclosure.

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From The National Perinatal Information Center: Chronic Disease and Maternal Health: Impact of Maternal Health upon NICU Admissions

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.



Maternal health has been a focus of countless discussions in the past several years, particularly as the rate of maternal morbidity and mortality in the United States has continued to rise. Multiple factors have been shown to contribute to maternal morbidity and mortality, including inadequate access to care, poor assessment of chronic illness risk by obstetric and women's health providers, and lack of financial resources for women seeking care (Centers for Disease Control, 2017). However, chronic illness has also been shown to play a significant role in maternal morbidity. Among patient factors, the increasing prevalence of chronic diseases, such as hypertension, diabetes and obesity among pregnant women (and among women of childbearing age), contributed significantly to the increase in the maternal mortality rate (Agrawal, 2015).

“Among patient factors, the increasing prevalence of chronic diseases, such as hypertension, diabetes and obesity among pregnant women (and among women of childbearing age), contributed significantly to the increase in the maternal mortality rate (Agrawal, 2015).”

The National Perinatal Information Center (NPIC) routinely captures information surrounding chronic illness, including patients with coded comorbidities such as diabetes, hypertension and obesity. For the time period of 2018 – 2019, NPIC reviewed 658,465 MDC-14 Obstetric discharge records, and 572,277 linked Mother/Baby discharge records to assess impact of these conditions on an obstetric population. What is important to note is that the rate of diabetes, hypertension and obesity in this national database tends to have no improvement over the time period of 2018-2019, and in fact shows slow to moderate increases over time:

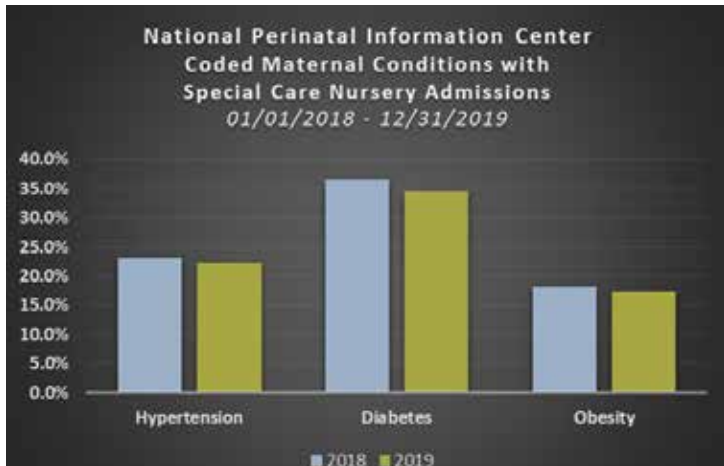
Important to note are these conditions within the conversation of COVID-19. Pre-existing comorbidities within the obstetric population have been described in the literature during the COVID-19 pandemic (Breslin et al, 2020; Chow et al 2020; Blitz et al, 2020). The most common pre-existing comorbidities described in the COVID-19 literature are obesity, diabetes, hypertension, and pulmonary involvement, such as asthma. There continues to be emphasis and interest in how existing comorbidities may impact the severity and outcomes of COVID-19 within the obstetric population. NPIC will be following this information closely in 2020 and into 2021 for trends that may yield additional value to perinatal care, particularly for its role in fetal and neonatal outcomes.

“The most common pre-existing comorbidities described in the COVID-19 literature are obesity, diabetes, hypertension, and pulmonary involvement, such as asthma. There continues to be emphasis and interest in how existing comorbidities may impact the severity and outcomes of COVID-19 within the obstetric population.”

With the emphasis on pre-existing comorbidities and chronic illness, it is important to address how these coded diagnoses impact NICU admissions. During this time period of 2018 - 2019, there have been small improvements in coded maternal conditions with a subsequent NICU admission:

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

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Chronic maternal illness will continue to require a multidisciplinary team approach that includes obstetrical expertise, as well as maternal-fetal medicine, key subspecialists who can advise on chronic illness superimposed on pregnancy and neonatologists familiar with the impact of maternal chronic illness on the fetus and newborn.

“Chronic maternal illness will continue to require a multidisciplinary team approach that includes obstetrical expertise, as well as maternal-fetal medicine, key subspecialists who can advise on chronic illness superimposed on pregnancy and neonatologists familiar with the impact of maternal chronic illness on the fetus and newborn.”

Mothers who find themselves with newborns admitted to the NICU may have barriers to participating in the care of their newborn: reliable transportation, availability of nutritious food, secure housing, environmental stressors. Add to those the presence of maternal chronic illness, and the care paradigm shifts to caring for both sick newborn and sick mother. These mothers and newborns may face many obstacles in their care that compound already present barriers to care. These obstacles may include disjointed health care systems with policies that vary between sites and locations, disjointed communication between providers in multiple systems, a lack of coordination in patient management, and the absence

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of policies and procedures that facilitate coordination of care, or lack of care coordination necessary for community care handoff (Agency for Healthcare Research and Quality, 2018).

Populations that are at greatest risk to lack of primary and preconception care are those who continue to suffer from implicit, unconscious and systemic bias, including:

- 1) Black and Brown women;
- 2) Transgender women;
- 3) Morbidly obese women;
- 4) Undocumented women;
- 5) Women with history of trauma;
- 6) Women lacking insurance or ability to pay for care;
- 7) Women with history of Opioid Use Disorder;
- 8) Incarcerated women

COVID-19 has brought to light already existing barriers to care, and simply magnified them. Access to primary care has never been more readily available, and at the same time, never more difficult to acquire for at-risk populations.

From a perinatal standpoint, it is imperative that primary care and preconception care receive the attention and funding they deserve to assure optimal outcomes for mothers and newborns. The costs of care related to undervalued and underfunded primary care in rural, urban and community environments will continue to result in maternal chronic illness that can potentially be avoided by effective and coordinated management between providers and their community counterparts.

The National Perinatal Information Center will continue to engage in the conversation of population health and its impact on perinatology, neonatology and the well-being of the smallest of patients within our healthcare community.

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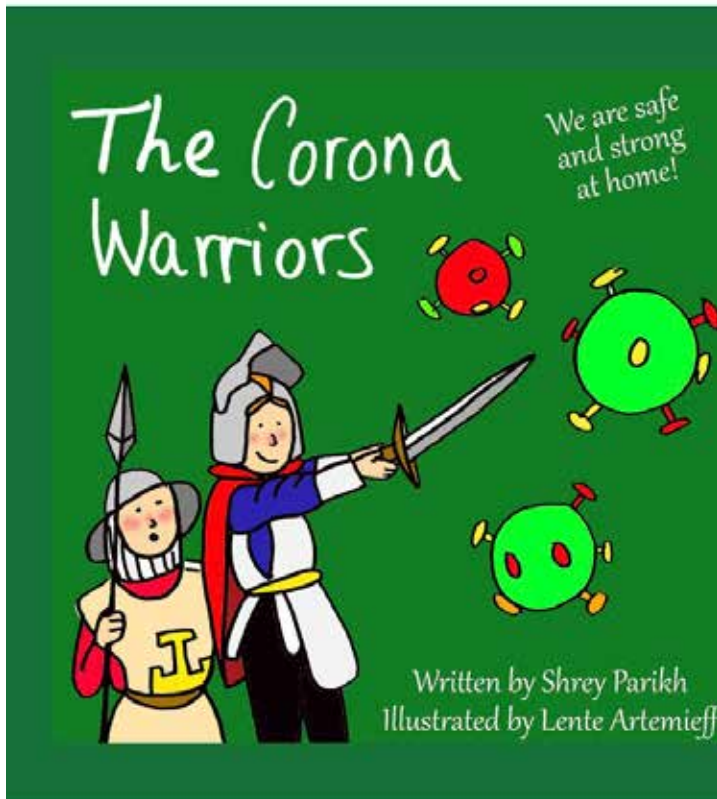
The author has no conflicts of interests to disclose.

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Will your **PRETERM INFANT** need *EARLY INTERVENTION* services?

Preterm infants are:

- 2x** more likely to have developmental delays
- 5x** more likely to have learning challenges

1 in 3 preterm infants will require support services at school

Early intervention can help preterm infants:

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

Early diagnosis could qualify babies for their state's **early intervention services...** ...but many parents are **unaware.**

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

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

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

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

Neonatology Solutions NICU Directory: Happy First Birthday, Neonatology Solutions!

Scott Snyder, MD



Neonatology Solutions is one year old this August! On August 12, 2019, we launched our website with the mission to better serve neonatology fellows embarking on their career search. Our goal to help fellows find their ideal position came from the many years of offering career planning workshops, panel discussions, and on-site visits. While these face to face sessions were fun and invaluable, we knew even then that we were providing information for only the small number of fellows in attendance. Having a continuously available, online resource was the goal when we launched, and this has become even more relevant now in the era of pandemic-limited travel.

“ While these face to face sessions were fun and invaluable, we knew even then that we were providing information for only the small number of fellows in attendance. Having a continuously available, online resource was the goal when we launched, and this has become even more relevant now in the era of pandemic-limited travel.”

Since our launch, we have been able to provide:

- a career planning guide, including a timeline, tools to help determine your ideal position, explanations of practice types, interview and negotiation tools, salary and compensation data, and onboarding considerations (photo below) [https://](https://neonatologysolutions.com/career-planning/)

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NEONATOLOGY TODAY

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subscription page**

neonatologysolutions.com/career-planning/ [neonatologysolutions.com]

- a comprehensive list of neonatology conferences (remember when we used to go to those?). As many of these have rescheduled or moved to virtual formats, we have done our best to keep this list current and accurate (photo below) <https://neonatologysolutions.com/upcoming-neonatology-conferences/> [neonatologysolutions.com]
- a fledgling repository of locally developed NICU clinical guidelines (photo below) <https://neonatologysolutions.com/clinical-guidelines/> [neonatologysolutions.com]
- and one of our crowning achievements: a comprehensive NICU directory which includes information on all Level 2-4 NICUs in the U.S, including State and AAP District summaries, and listings of available job postings (photo below) <https://neonatologysolutions.com/explore-nicus-and-programs/> [neonatologysolutions.com]

“In March, like the rest of the world, we pivoted our work to help support healthcare providers who were learning their way through the SARS-CoV-2 pandemic. Neonatology Solutions provided free and open access to national and international links, tools, websites, articles, and data repositories that we found helpful in our local preparations for our NICUs.”

In March, like the rest of the world, we pivoted our work to help support healthcare providers who were learning their way through the SARS-CoV-2 pandemic. Neonatology Solutions provided free and open access to national and international links, tools, websites, articles, and data repositories that we found helpful in our local preparations for our NICUs. In the same spirit of information sharing from organizations around the globe that have allowed us to develop our local protocols, we continue to share these guidelines, pathways, and algorithms in the hopes that they may help others. Our COVID Resources page has also proven to be a quick, easily accessible reference point for our staff and providers to get critical, time-sensitive information at their fingertips without cumbersome firewalls, passwords, or login requirements. <https://neonatologysolutions.com/covid-19-resources/> [neonatologysolutions.com]

Here are just a few highlights of what we have built into the website in our first year:

6 Steps to Success



Step 1

Applying the Right Timeline



Step 2

Defining Your Ideal Position



Step 3

Finding the Right Practice



Step 4

Preparing for Your Interview



Step 5

Reviewing Your Job Offer



Step 6

Starting with Your New Practice

- Data on **1,373** NICUs, including website links, Level, Bed number, Medical Director, practice size, fellowship programs, community and livability info, and more
- **Dozens** of thought-provoking questions to consider as you define and refine your ideal position, as well as questions you will likely be asked during your interviews
- Links to **186** currently open positions for Neonatologists
- More than **35** evidence-based clinical pathways, algorithms, protocols, and guidelines covering nutrition, respiratory support, infectious diseases (including COVID-19), neurodevelopment, and more
- Dates and locations (including a map-based search feature) for more than **92** Neonatal-focused national and international educational conferences

COVID-19

FREE for our NICU COMMUNITY

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



Clinical Protocols, Pathways, Guidelines, & Algorithms







We know how hard it is to find implemented, adopted, and proven practice guidelines.

Despite the countless hours that expert teams have spent building these tools, sharing them with others is exceedingly difficult, so we all continually reinvent the wheel. Neonatology Solutions helps by providing a repository of different team standardization approaches for you to explore, modify, and adopt.

Have a standardized approach you wish to share??

[Upload your file here](#) and we will post it for you!

[CLICK HERE FOR COVID-19 CLINICAL GUIDELINES.](#)

 <p>Feeding & Nutrition</p>	 <p>GI / Hepatic</p>	 <p>Respiratory</p>
 <p>Cardiovascular</p>	 <p>Neuro</p>	 <p>Infectious Disease</p>

We still have more to accomplish! Our goals for the coming year include:

- Development of an interactive Practice Assessment tool to assist in comparing job opportunities
- Providing financial planning references and resources for new and practicing Neos
- Expanding our career search platform and job listings to support NICU Hospitalists and NNPs

NEONATOLOGY TODAY is interested in publishing manuscripts from Neonatologists, Fellows, NNPs and those involved in caring for neonates on case studies, research results, hospital news, meeting announcements, and other pertinent topics.
Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com



Upcoming Neonatology Conferences

Fellowship is about growing your knowledge AND your network. You can do both as you attend conferences around the country. Plan to start in your 1st year and continue throughout your training. We know you're busy and likely broke, but make it happen if you can!

There are dozens of opportunities to attend conferences. Try to find some in the region where you hope to practice to increase the likelihood of making connections.



Click on map marker for conference details.



Conference Calendar

[Add Your Conference Here!](#)

Skip To: [September](#) [October](#) [November](#) [2021](#) [INTERNATIONAL](#)

2020



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

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org



COVID-19 Obstetric, Neonatal, and NICU Guidelines



[COVID-19 OB Universal Testing Algorithm](#)

updated 7/23/20

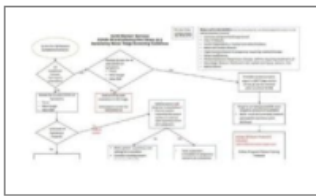
Provides a pathway for testing asymptomatic obstetric patients across all inpatient and outpatient settings.



[Maternal & Infant Testing/Isolation Post-COVID Recovery](#)

updated 7/21/20

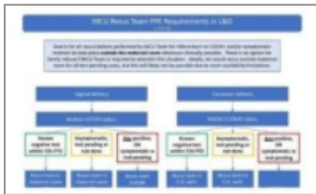
For laboring mothers with a history of COVID-19 from which they have recovered, this provides recommendations regarding testing and isolation of both the laboring mother and her infant, based on the latest CDC guidance.



[COVID-19 OB Protocol](#)

updated 7/27/20

Provides guidelines, protocols, and pathways for:
 Ambulatory Nurse Triage Screening Guidelines
 Inpatient and Outpatient Testing Protocols
 Intra/Postpartum and Antepartum Guidelines
 Neonatal Stabilization for Infants Born to + Patient
 Management of Asymptomatic Newborns



[COVID-19 NICU Resus Team PPE Requirements](#)

updated 7/17/20

Provides a pathway with PPE guidance for NICU resuscitation teams in both vaginal and Cesarean delivery settings.



[COVID-19 Newborn Transport from DR to NICU](#)

updated 7/17/20

Provides a pathway with PPE guidance for transporting a newborn from the delivery room to the NICU for COVID PUI infants.

- Creation of an online forum for providers and staff to share objective experiences and reviews of NICU equipment such as monitors, ventilators, point-of-care devices (ultrasound, lab, etc.), video laryngoscopes, etc.
- Once travel restrictions allow, reinvigorating on-site career planning workshops for fellowship programs

teams, and families do what they do best...care for tiny precious lives.

It has been an exciting first year! Appreciation and credit go to our Advisory Panel, who has guided and influenced so much of our direction. We are grateful to all who have helped and supported us as we continue to develop a comprehensive, free resource for our profession. Thank you to our current 7,778 users, and welcome to the new daily visitors to our site!

“ We are grateful to all who have helped and supported us as we continue to develop a comprehensive, free resource for our profession. Thank you to our current 7,778 users, and welcome to the new daily visitors to our site! ”

At Neonatology Solutions, our goal is to help providers, clinical

NICU Directory

NICU Level: ▾

Hospital Type: ▾

Children's Hospital: ▾

State: ▾

AAP District (View map here): ▾

City Size: ▾

Currently Hiring Fellowship Program VON Member

Hospital

RESET

RESULTS: 1373 NICUs

Click on map marker for NICU information.



Gratefully,

Scott and Celinda Snyder

References:

1. <https://neonatologysolutions.com/explore-nicus-and-programs/>

The author is a principal of Neonatology Solutions, LLC.

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 Founder
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Nurses: parents trust you.

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

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

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



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Got milk? Human milk based fortifiers improve health outcomes for the smallest premature babies

Researchers compare traditional cows milk based fortifiers with human milk based alternative.

August 12, 2020

Contact: Brian Consiglio, 573-882-9144, consigliob@missouri.edu

Columbia, Mo. – More than 380,000 babies are born prematurely in the United States each year, according to the March of Dimes. “Preemies” can be severely underweight babies and struggle to get the nutrients they need from breast milk alone, so neonatal intensive care units provide an additional milk fortifier, either in the form of cow’s milk or manufactured from donor breast milk, to keep them healthy.

Now, a new research study from the University of Missouri and University College in London suggests that using a human-based milk fortifier has better health outcomes for severely underweight, premature babies compared to traditional, cow-based milk fortifiers.

This is a photo of Dr. Jan Sherman



Jan Sherman, a professor in the MU Sinclair School of Nursing, collaborated with Alan Lucas, a professor at University College in London, to perform a meta-analysis on various studies involving more than 450 severely underweight, premature babies in the United States, Canada and Austria who received either traditional cow-based milk fortifiers or human-based milk fortifiers.

By comparing their health outcomes, they found that the babies who were fed cow milk fortifiers were more than three times as likely to develop necrotizing enterocolitis, a life-threatening intestine disease, and

more than twice as likely to develop retinopathy of prematurity, an eye disorder that can lead to blindness.

“Everyone wants what’s best for these underweight, premature babies, and choosing the best type of milk fortifiers for feeding can help lead to improved health outcomes,” said Sherman. “Nearly half of neonatal intensive care units in the United States, including the one at MU Children’s Hospital, are already using human-based milk fortifiers. If we can reduce these cases of necrotizing enterocolitis, if we can preserve their eye sight and reduce the risk of infection, that will benefit the babies’ health in the long term.”

Neonatal intensive care units can use this research in evaluating the nutritional supplements they give to severely underweight, premature babies, who have a higher risk of death or disease than babies born after a full nine-month pregnancy.

“Our research is geared toward better understanding if we can avoid cow’s milk fortifiers while still feeding premature infants well,” said Lucas. “The most current evidence suggests that a diet with entirely human milk and enriched feeds manufactured from donated human milk will meet the nutritional needs of the baby without the potential negative health effects that can come with a cow milk fortifier.”

This is a photo of Dr. Alan Lucas.

Alan Lucas is a professor at University College in London.

“Safety of Cow’s Milk-Derived Fortifiers Used with an All-Human Milk Base Diet in Very Low Birthweight Preterm Infants” was recently published in *Neonatology Today*. Other authors include Maushumi Assad of the Beth Israel Deaconess Medical Center, John Boscardin of UC San Francisco and Steven Abrams of University of Texas, Austin.



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The National Urea Cycle Disorders Foundation



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

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THE FIFTH ANNUAL BRETT TASHMAN GOLF TOURNAMENT AND LUNCHEON

Dear Friends,

Due to COVID-19, the foundation's golf tournament and luncheon scheduled for July 18, 2020 has been cancelled.

Please remember the foundation's mission is to find a cure for DSRCT. It is a cancer that takes the lives of young adults and children. Accordingly, the foundation's research at the University of North Carolina Children's Hospital must continue and be supported.

So, please make your gift using the DONATE button below.

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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, and Sunday 11/17/2019 1020

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

- Connect with other AAP members who share your interests in improving effective drug therapies and devices in children.
- Receive the SOATT newsletter containing AAP and Section news.
- Access the Section's Website and Collaboration page – with current happenings and opportunities to get involved.
- Network with other pediatricians, pharmacists, and other health care providers to be stronger advocates for children.

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

AAP members can join SOATT for free. To activate your SOATT membership as an AAP member, please complete a short application at <http://membership.aap.org/Application/AddSectionChapterCouncil>.

The Section also accepts affiliate members (those holding masters or doctoral degrees or the equivalent in pharmacy or other health science concentrations that contribute toward the discovery and advancement of pediatrics and who do not otherwise qualify for membership in the AAP). Membership application for affiliates: <http://shop.aap.org/aap-membership/> then click on "Other Allied Health Providers" at the bottom of the page.

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

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Dedicated to the Health of All Children

###

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

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NIH study suggests opioid use linked to pregnancy loss, lower chance of conception

NIH study may help explain why opioid users have higher morbidity and increased difficulty becoming pregnant.

Tuesday, August 18, 2020

Newly-Validated Online NICU Staff Education



Transform Your NICU

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

based on the "Interdisciplinary Recommendations for Psychosocial Support for NICU Parents."

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- National Perinatal Association
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Opioid use among women trying to conceive may be associated with a lower chance of pregnancy, suggests a National Institutes of Health study. Moreover, opioid use in early pregnancy may be associated with a greater chance of pregnancy loss. The study appears in *Epidemiology*.

“Our findings indicate that women who are pregnant or planning a pregnancy should, along with their physicians, consider the potential effects opioids may have on their ability to conceive or sustain a pregnancy,” said Kerry Flannagan, Ph.D., the primary author of the study and a postdoctoral researcher in the Division of Intramural Population Health Research at NIH’s Eunice Kennedy Shriver National Institute of Child Health and Human Development.

According to the authors, much of the research on prescription opioid use has focused on the effects of drug dependency. Little information exists on non-habitual, periodic opioid use around the time of conception and early in pregnancy.

The researchers analyzed data from the Effects of Aspirin in Gestation and Reproduction (EAGeR) trial, which investigated low-dose aspirin as a treatment to prevent pregnancy loss. Participants were women from 18 to 40 years old with a history of one or two pregnancy losses. Women were followed for six monthly cycles if they did not get pregnant and throughout pregnancy if they did. The women provided urine samples, which were analyzed for various prescription opioids.

Of the 1,228 women in the study, 226 (18%) had used opioids while trying to conceive and 33 (5%) of 685 women who became pregnant had used opioids in early pregnancy. None tested positive for methadone or buprenorphine, typically used to treat opioid dependence.

Opioid use before conception was associated with a 29% lower chance of achieving pregnancy during a given monthly cycle, compared to women who had not

used opioids. Among the women who became pregnant, those who used opioids around the time of conception were 1.5 times as likely to have a miscarriage as women who had not. Women who used opioids in the first four weeks of pregnancy were more than twice as likely to have a miscarriage. Women who used opioids in weeks four through eight of pregnancy were 2.5 times as likely to have a miscarriage.

The authors called for additional research on how opioid use affects fertility and early pregnancy. They added that until more is known, patients and physicians should evaluate the potential risks and benefits of opioids for pain management among women who are pregnant or may become pregnant, including those undergoing assisted reproduction procedures that may involve opioid treatment to manage pain.

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

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](http://www.nih.gov).

NIH...Turning Discovery Into Health®

References

Flannagan, KS et al. Is opioid use safe in women trying to conceive? *Epidemiology*. 2020.

###

[Eunice Kennedy Shriver National Institute of Child Health and Human Development \(NICHD\)](http://www.nichd.nih.gov)

Contact

[Robert Bock or Meredith Daly](mailto:Robert.Bock@nih.gov)
[301-496-5133](tel:3014965133)

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NIH-funded project seeks to identify children at risk for MIS-C

Research effort will develop tests to predict severe COVID-19-linked illness.

Friday, August 7, 2020

The National Institutes of Health has announced research funding to encourage the development of approaches that identify children at high risk for developing Multi-system Inflammatory Syndrome in Children (MIS-C), thought to be a severe complication of COVID-19. Up to \$20 million will be awarded to successful research proposals over four years.

Most children exposed to or infected with SARS-CoV-2, the virus that causes CO-



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VID-19, develop only a mild form of the illness. However, others go on to develop MIS-C (link is external), a severe, sometimes fatal, inflammation of organs and tissues, including the heart, lungs, kidneys, brain, skin and eyes. The new effort seeks to encourage studies of genetic, immune, viral, environmental, and other factors that influence how severe a case of COVID-19 will be and the chances of developing to MIS-C.

"We urgently need methods to distinguish children at high risk for MIS-C from those unlikely to experience major ill effects from the virus, so that we can develop early interventions to improve their outcomes," said Diana W. Bianchi, M.D., director of NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

The NICHD-led project, called Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL klds), is part of NIH's Rapid Acceleration of Diagnostics (RADx) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. PreVAIL klds aims to encourage development of cutting-edge approaches for understanding the underlying factors influencing the spectrum of conditions that may occur in children and youth infected with the SARS-CoV-2 virus. These range from no symptoms at all to fever and cough, abdominal pain and diarrhea, and inflammation of the coronary arteries. The goal of the initiative is to understand the range of symptoms of COVID-19 and the factors leading to MIS-C.

Studies funded through PreVAIL klds will evaluate genes and other biomarkers in COVID-19 pediatric cases, as well as examine how the virus interacts with its host and how the immune system responds. Researchers will rely on artificial intelligence and machine learning to sort and categorize the data they acquire to understand the disease patterns they uncover.

Other NIH components providing funding for PreVAIL klds are the NIH Office of the Director; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infec-



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tious Diseases; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute on Drug Abuse; National Institute of Minority Health and Health Disparities; and Fogarty International Center.

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

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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Reference:
Emergency awards: RADx-rad Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL klds). 2020. <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-023.html>.

###

Institute/Center
[Eunice Kennedy Shriver National Institute of Child Health and Human Development \(NICHD\)](https://www.nih.gov/eunice-kennedy-shriver-national-institute-of-child-health-and-human-development)

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[301-496-5133](tel:3014965133)

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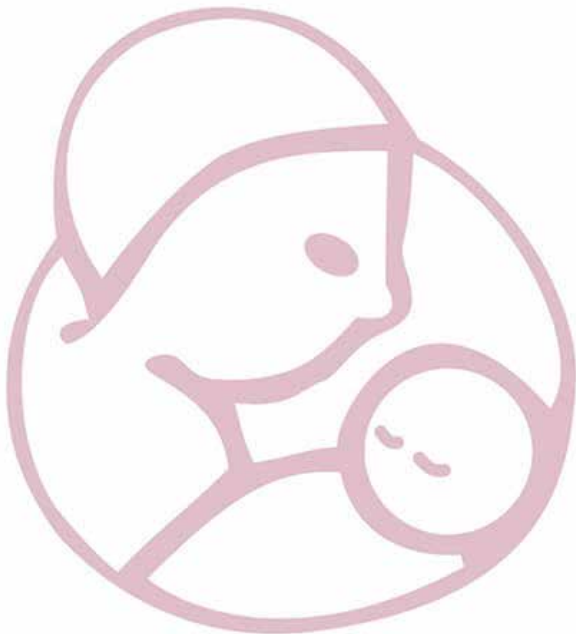
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New tool compares rates of severe pregnancy complications across U.S. hospitals

A new tool characterizes severe maternal complications.

Media Advisory

Thursday, August 6, 2020

What

NIH-funded researchers have developed a new system(link is external) for classifying severe maternal morbidity — life-threatening complications associated with childbirth — across U.S. hospitals. The system relies on patient discharge data to compare rates of severe maternal morbidity between different hospitals and different groups of patients. The study was led by Stephanie A. Leonard, Ph.D., of the Stanford University School of Medicine and appears in the journal *Obstetrics & Gynecology*. Funding was provided in part by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and National Institute of Nursing Research.

In the United States, rates of severe maternal morbidity are rising(link is external) for all women and are worse among racial and ethnic minorities. Researchers studying severe maternal morbidity lack reliable ways to compare rates between groups with different underlying health statuses. According to the study authors, the new scoring system offers an advantage over current approaches. It also relies on U.S. patient discharge data, which is more readily available than electronic health records.

The study team developed and validated their tool using patient discharge data for all 919,546 live births in licensed hospitals in California from 2016 to 2017. The

new system also evaluates a woman's risk for severe birth complications independent of her risk from blood transfusions alone, which tend to be less severe than other complications. These two categories match how the Centers for Disease Control and Prevention and other public health professionals track maternal morbidity. With the new tool, scores range from 1 to 59 for severe maternal morbidity and 1 to 36 for non-transfusion severe maternal morbidity. The study team hopes that the new system will aid maternal health research and efforts to improve maternal health across the country.

Who

Juanita J. Chinn, Ph.D., of the NICHD Population Dynamics Branch is available for comment.

Article

Leonard, SA, et al. An expanded obstetric comorbidity scoring system for predicting severe maternal morbidity. *Obstetrics & Gynecology* DOI: 10.1097/AOG.0000000000004022 (2020)

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

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NIH harnesses AI for COVID-19 diagnosis, treatment, and monitoring

AI helps identify more serious disease states, providing a more rapid diagnostic evaluation. Collaborative network to enlist medical imaging and clinical data sciences to reveal unique features of COVID-19.

Wednesday, August 5, 2020

The National Institutes of Health has launched the Medical Imaging and Data Resource Center (MIDRC), an ambitious effort that will harness the power of artificial intelligence and medical imaging to fight COVID-19. The multi-institutional collaboration, led by the National Institute of Biomedical Imaging and Bioengineering (NIBIB), part of NIH, will create new tools that physicians can use for early detection and personalized therapies for COVID-19 patients.

"This program is particularly exciting because it will give us new ways to rapidly turn scientific findings into practical imaging tools that benefit COVID-19 patients," said Bruce J. Tromberg, Ph.D., NIBIB Director. "It unites

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leaders in medical imaging and artificial intelligence from academia, professional societies, industry, and government to take on this important challenge.”

The features of infected lungs and hearts seen on medical images can help assess disease severity, predict response to treatment, and improve patient outcomes. However, a major challenge is to rapidly and accurately identify these signatures and evaluate this information in combination with many other clinical symptoms and tests. The MIDRC goals are to lead the development and implementation of new diagnostics, including machine learning algorithms, that will allow rapid and accurate assessment of disease status and help physicians optimize patient treatment.

“This effort will gather a large repository of COVID-19 chest images,” explained Guoying Liu, Ph.D., the NIBIB scientific program lead on this effort, “allowing researchers to evaluate both lung and cardiac tissue data, ask critical research questions, and develop predictive COVID-19 imaging signatures that can be delivered to healthcare providers.”

Maryellen L. Giger, PhD, the A.N. Pritzker Professor of Radiology, Committee on Medical Physics at the University of Chicago, is leading the effort, which includes co-Investigators Etta Pisano, MD, and Michael Tilkin, MS, from the American College of Radiology (ACR), Curtis Langlotz, MD, PhD, and Adam Flanders, MD, representing the Radiological Society of North America (RSNA), and Paul Kinahan, PhD, from the American Association of Physicists in Medicine (AAPM).


“This major initiative responds to the international imaging community’s expressed unmet need for a secure technological network to enable the development and ethical application of artificial intelligence to make the best medical decisions for COVID-19 patients,” added Krishna Kandarpa, M.D., Ph.D., director of research sciences and strategic directions at NIBIB. “Eventually, the approaches developed could benefit other conditions as well.”

The MIDRC will facilitate rapid and flexible collection, analysis, and dissemination of imaging and associated clinical data. Collabora-

tion among the ACR, RSNA, and AAPM is based on each organization’s unique and complementary expertise within the medical imaging community, and each organization’s dedication to imaging data quality, security, access, and sustainability.

About the National Institute of Biomedical Imaging and Bioengineering (NIBIB): NIBIB’s mission is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating engineering and physical science with biology and medicine to advance our understanding of disease and its prevention, detection, diagnosis, and treatment. NIBIB supports emerging technology research and development within its internal laboratories and through grants, collaborations, and training. More information is available at the NIBIB website <https://www.nibib.nih.gov>.

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



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NIH researchers generate complete human X chromosome sequence

The accomplishment opens a new era in genomics research.

Tuesday, July 14, 2020

Researchers at the National Human Genome Research Institute (NHGRI), part of the National Institutes of Health, have produced the first end-to-end DNA sequence of a human chromosome. The results, [published today](#) in Nature, show that generating a precise, base-by-base sequence of a human chromosome is now possible, and will enable researchers to produce a complete sequence of the human genome.

“This accomplishment begins a new era in genomics research,” said Eric Green, M.D., Ph.D., NHGRI director. “The ability to gen-

erate truly complete sequences of chromosomes and genomes is a technical feat that will help us gain a comprehensive understanding of genome function and inform the use of genomic information in medical care.”

After nearly two decades of improvements, the reference sequence of the human genome is the most accurate and complete vertebrate genome sequence ever produced. However, there are hundreds of gaps or missing DNA sequences that are unknown.

These gaps most often contain repetitive DNA segments that are exceptionally difficult to sequence, and yet these repetitive segments include genes and other functional elements that may be relevant to human health and disease.

Because a human genome is incredibly long, consisting of about 6 billion bases, DNA sequencing machines cannot read all the bases at once. Instead, researchers chop the genome into smaller pieces, then analyze each piece to yield sequences of a few hundred bases at a time. Those smaller DNA sequences must then be put back together.

Senior author Adam Phillippy, Ph.D., at National Human Genome Research Institute (NHGRI) compared this issue to solving a puzzle.

“Imagine having to reconstruct a jigsaw puzzle. If you are working with smaller pieces, each contains less context for figuring out where it came from, especially in parts of the puzzle without any unique clues, like a blue sky,” he said. “The same is true for sequencing the human genome. Until now, the pieces were too small, and there was no way to put the hardest parts of the genome puzzle together.”

Of the 24 human chromosomes (including X and Y), study authors Phillippy and Karen Miga, Ph.D., at the University of California, Santa Cruz, chose to complete the X chromosome sequence first, due to its link with [a myriad of disease](#), including hemophilia, chronic granulomatous disease and Duch-

enne muscular dystrophy.

Humans have two sets of chromosomes, one set from each parent. For example, biologically female humans inherit two X chromosomes, one from their mother and one from their father. However, those two X chromosomes are not identical and will contain many differences in their DNA sequences.

In this study, researchers did not sequence the X chromosome from a normal human cell. Instead, they used a special cell type – one that has two identical X chromosomes. Such a cell provides more DNA for sequencing than a male cell, which has only a single copy of an X chromosome. It also avoids sequence differences encountered when analyzing two X chromosomes of a typical female cell.

The authors and their colleagues capitalized on new technologies that can sequence long segments of DNA. Instead of preparing and analyzing small pieces of DNA, they used a method that leaves DNA molecules largely intact. These large DNA molecules were then analyzed by two different instruments, each of which generates very long DNA sequences – something previous instruments could not accomplish.

After analyzing the human X chromosome in this fashion, Phillippy and his team used their newly developed computer program to assemble the many segments of generated sequence. Miga’s group led the effort to close the largest remaining sequence gap on the X chromosome, the roughly 3 million bases of repetitive DNA found at the middle portion of the chromosome, called the centromere.

There is no “gold standard” for researchers to critically evaluate the accuracy of assembling such highly repetitive DNA sequences. To help confirm the validity of the generated sequence, Miga and her collaborators performed a number of validation steps.

“We have never actually seen these sequences before in our genome, and do not have many tools to test if the predictions we



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are making are correct. This is why it is so important to have specialists in the genomics community weigh in and ensure the final product is high-quality," Miga said.

The effort is part of a broader initiative by the Telomere-to-Telomere (T2T) consortium, partially funded by NHGRI. The consortium aims to generate a more complete reference sequence of the human genome.

The T2T consortium is continuing its efforts with the remaining human chromosomes, aiming to generate a complete human genome sequence in 2020.

"We don't yet know what we'll find in the newly uncovered sequences. It is the exciting unknown of discovery. This is the era of complete genome sequences, and we are embracing it wholeheartedly," Phillippy said.

Potential challenges remain. Chromosomes 1 and 9, for example, have repetitive DNA segments that are much larger than the ones encountered on the X chromosome.

"We know these previously uncharted sites in our genome are very different among individuals, but it is important to start figuring out how these differences contribute to human biology and disease," Miga said. Both Phillippy and Miga agree that enhancing sequencing methods will continue to create new opportunities in human genetics and genomics.

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

Note: This release was amended to add additional information on July 23, 2020

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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[National Human Genome Research Institute \(NHGRI\)](#)

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NT

Updated Isolation Guidance Does Not Imply Immunity to COVID-19

Isolation does not confer immunity.

Media Statement
For Immediate Release: Friday, August 14, 2020
Contact: Media Relations
(404) 639-3286

On August 3, 2020, CDC updated its isolation guidance based on the latest science about COVID-19 showing that people can continue to test positive for up to 3 months after diagnosis and not be infectious to others. Contrary to media reporting today, this science does not imply a person is immune to reinfection with SARS-CoV-2, the virus that causes COVID-19, in the 3 months following infection. The latest data simply suggests that retesting someone in the 3 months following initial infection is not necessary unless that person is exhibiting the symptoms of COVID-19 and the symptoms cannot be associated with another illness.

People with COVID-19 should be isolated for at least 10 days after symptom onset and until 24 hours after their fever subsides without the use of fever-reducing medications.

There have been more than 15 international and U.S.-based studies recently published looking at length of infection, duration of viral shed, asymptomatic spread and risk of spread among various patient groups. Researchers have found that the amount of live virus in the nose and throat drops significantly soon after COVID-19 symptoms develop. Additionally, the duration of infectiousness in most people with COVID-19 is no longer than 10 days after symptoms begin and no

longer than 20 days in people with severe illness or those who are severely immunocompromised.

CDC will continue to closely monitor the evolving science for information that would warrant reconsideration of these recommendations.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES 

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

NT



UPDATE: AAPGlobalCOVIDSeries: Promoting Early Childhood Development Globally in the Time of COVID-19 - August 25th - Register Now!

Case Study Provides Evidence of Intrauterine Transmission of SARS-CoV-2 from Mother to Infant

* UPDATE: Please use the password 1234 when registering for this webinar event.

Dear Section on Neonatal Perinatal Medicine members,

Please join us for our next installment of the AAP's webinar series, *Global Health Practice in the time of COVID: Finding Effectiveness in Your Personal & Professional World*, on Wednesday, August 25th.

Promoting Early Childhood Development Globally in the Time of COVID-19
Tuesday, August 25, 2020 (12:00pm ET|1600 UTC)

This webinar, with experts from the Sesame Workshop, LEGO Foundation, Conrad N. Hilton Foundation, Ummeed Child Development Center, and AAP, will address the impact of COVID on early childhood development (ECD) programs and provide tangible ways to promote ECD during the pandemic.

Sponsored by the AAP, the AAP Section on Global Health, Ummeed Child Development Center, and Conrad N. Hilton Foundation

Speakers:

Jill Popp, PhD
Senior Researcher, LEGO Foundation

Roopa Srinivasan, MBBS, DNB
Director, Developmental Pediatrics & Head, Clinical Services, Ummeed Child Development Center

Deborah M. Rodríguez García, MS
Education Manager, Humanitarian Programs, Sesame Workshop

Lisa Bohmer, MPH
Senior Program Officer, International Programs, Conrad N. Hilton Foundation

Moderator:
V. Fan Tait, MD, FAAP
Chief Medical Officer, American Academy of Pediatrics

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

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



Visit www.GrahamsFoundation.org to learn more.

Note: This free webinar will be recorded and posted online for those unable to attend the live event. Please register if you would like to have the link emailed to you once it is available. For those able to join, please enter password 1234 when prompted on the day of the webinar.

Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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



Limit Contact with Others

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



Provide Protective Immunity

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



Take Care of Yourself

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



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

WARNING

Never Put a Mask on Your Baby

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



If you are positive for COVID-19

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



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GET VACCINATED

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



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Join the conversation online using the hashtag #AAPGlobalCOVID-Series.

Questions ? E-mail: sogh@aap.org.

A link to the recording of this session will be shared with the registrants.

NT



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Update: **CORONAVIRUS COVID-19**

According to the data in The Lancet, even when mothers were infected

No virus was detected in:

- NASOPHARYNGEAL SWABS OF THE BABY
- AMNIOTIC FLUID
- CORD BLOOD
- BREASTMILK

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#AAPGlobalCOVIDSeries

Promoting Early Childhood Development Globally in the Time of COVID-19

August 25, 2020 | 12p ET/1600 UTC



Jill Popp, PhD
Senior Researcher,
LEGO Foundation



Roopa Srinivasan, MBBS, DNB
Director, Developmental Pediatrics & Head, Clinical Services
Ummeed Child Development Center



Deborah M. Rodríguez García, MS
Education Manager,
Humanitarian Programs
Sesame Workshop



Lisa Bohmer, MPH
Senior Program Officer,
International Programs
Conrad N. Hilton Foundation



Fan Tait, MD, FAAP
Moderator
Chief Medical Officer
American Academy of Pediatrics

This session is brought to you by the American Academy of Pediatrics, AAP Section on Global Health, Ummeed Child Development Center, and Conrad N. Hilton Foundation.



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- **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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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 infants' lives

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

When that happens:

5%	17%
1%	12%

Very low birthweight babies who get NEC

Very low birthweight babies requiring surgery to treat NEC

30% of very low birthweight babies requiring surgery will die from NEC

HOW TO HELP PREVENT NEC: EXCLUSIVE HUMAN MILK DIET

What is an Exclusive Human Milk Diet?

NO cow's milk NO sheep's milk NO goat's milk NO formula

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

Why is An Exclusive Human Milk Diet important?

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

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

Mortality is reduced by 36%

Feeding intolerance decreases

Chances of NEC are reduced by 37%

HUMAN MILK = MEDICINE

NEC is a life-threatening condition that can be prevented. All the babies that babies need. A tiny amount of human milk your baby needs to be healthy. Talk to your care team about your baby's specific human milk needs and request support to find your healthy way.

LEARN MORE

The Genetics Corner: HNF1B-Related Bilateral Cystic Kidney Disease in an Infant and his Asymptomatic Mother

Robin Dawn Clark MD

Case History:

A 5-year old boy with end-stage renal disease presented for a genetic evaluation with his foster mother.

Bilateral cystic kidneys were identified prenatally at the 20-week fetal anatomy ultrasound scan in an otherwise uncomplicated pregnancy. An amniocentesis was offered and declined. Parental renal ultrasound exams were recommended. Polycystic kidneys were identified in the asymptomatic and healthy 22-year old G2P1 mother. A male infant was born at 34 weeks gestation by emergency C-section. He was in the NICU at another facility for a month and then institutionalized at a chronic care facility for his first three years of life. At age 3, he was discharged to a foster family. At age 5, when he presented to us for genetic evaluation, he had chronic kidney disease, stage V, treated with nightly peritoneal dialysis, and he was fed by gastrostomy tube. He was being evaluated for diabetes mellitus due to high glucose levels.

“At age 5, when he presented to us for genetic evaluation, he had chronic kidney disease, stage V, treated with nightly peritoneal dialysis, and he was fed by gastrostomy tube. He was being evaluated for diabetes mellitus due to high glucose levels.”

Parents are of African American ancestry. Consanguinity was denied. In addition to his biological mother, several other maternal family members had chronic renal disease, which followed an autosomal dominant pattern of inheritance. A maternal uncle in his early 30s had a polycystic kidney disorder, but he did not require dialysis. The maternal grandfather had polycystic kidney disease that required dialysis. He died at age 63 of pancreatic cancer. A maternal great uncle had renal failure that required dialysis.

The physical exam was pertinent for poor growth: weight: 18.9 kg, 48%ile, Z= -0.06, height: 111 cm, 52%ile, Z= 0.05, head circumference: 49 cm, 3.92%ile, Z= -1.76. No significant dysmorphic features were noted.

Echocardiogram, bone age, and chromosome microarray were normal. Laboratory studies revealed an elevated hemoglobin A_{1c}, 6.4 (reference range: 4.8-5.95). A gene panel was ordered (Autosomal Dominant Polycystic Kidney Disease Panel: *PKD1*, *PKD2*, *PKHD1*, *HNF1B*, *DNAJB11*, *DZIP1L*, *GANAB*) that identified a pathogenic heterozygous variant in *HNF1B* that led to a prema-

turally truncated protein: c.826C>T, p.Arg276*. This established his diagnosis as autosomal dominant *HNF1B*-related renal disease at age 5.

Discussion:

Background on CAKUT

The prevalence of congenital anomalies of the kidney and urinary tract, referred to as CAKUT, ranges from 3-6 per 1,000 births. This heterogeneous group of anomalies includes a wide range of conditions: renal agenesis, hypodysplasia, multicystic dysplastic kidney, horseshoe or ectopic kidney, anomalies of the collecting system (ureteropelvic junction obstruction, posterior urethral valve, hydroureter, duplicated collecting system) and bladder (vesicoureteral reflux, ureterocele). CAKUT is the most common cause of end-stage renal disease in childhood, accounting for over 40% of all children who require renal replacement therapy. More than two-thirds of CAKUT patients progress to ESRD as adults.

“CAKUT is the most common cause of end-stage renal disease in childhood, accounting for over 40% of all children who require renal replacement therapy. More than two-thirds of CAKUT patients progress to ESRD as adults.”

Is a prenatal diagnosis of CAKUT reliable?

Although in our patient, the prenatal diagnosis of bilateral renal cystic disease was confirmed postnatally, that is not always the case. A prenatal ultrasound examination is not as reliable as a postnatal ultrasound for the diagnosis of CAKUT. Prenatal US exams produce both false negative and false positive CAKUT diagnoses. The positive predictive value and sensitivity of prenatal US for the detection of CAKUT can be calculated from data published by Li *et al.* (2019), who determined the true incidence of CAKUT in a series of neonates who were screened with both prenatal and postnatal ultrasonography (US). Although this work was published in Chinese, an English-language abstract provides enough data to perform these calculations. The authors found CAKUT on postnatal US in 3.1% of their study group (82/2655). Although 44 neonates in the sample were prenatally diagnosed with CAKUT, only 35 of these were true positives (TP), with a confirmed postnatal diagnosis of CAKUT. The predictive value of a positive prenatal US diagnosis of CAKUT in this sample was 79.5% (TP/TP+FP; 35/44).

Further, among the 2611 neonates who had a normal prenatal

ultrasound exam, 1.8% had a CAKUT on the postnatal US, yielding 47 infants with CAKUT after a falsely negative, normal prenatal US (FN; false negatives; 47). These false negatives represent more than half of their total of 82 confirmed CAKUT cases. In this study, the sensitivity of prenatal US for detecting CAKUT was 42.7% (TP/TP+FN; 35/35+47). This data suggest that all prenatal CAKUT diagnoses should be confirmed with postnatal imaging and that a normal prenatal US does not rule out a renal anomaly.

Should we screen asymptomatic first-degree relatives for CAKUT?

CAKUT is often familial, even when the family history does not reflect it. The frequency of familial CAKUT ranges from 7-50%. Bulum *et al.* (2013) studied the family histories of 218 index patients with CAKUT in Ankara, Turkey, and identified 72 affected individuals in 50 families (22.9%) who were known to have a CAKUT. These authors also performed ultrasound exams in 504 asymptomatic first-degree relatives of 180 of their index patients with CAKUT and identified a CAKUT in 116 (23%) individuals from 87 families (48.3%). When both family histories and ultrasound results in asymptomatic first-degree relatives were considered together, 129/504 first-degree relatives (25.6%) in 92/180 families (51.1%) had a CAKUT. Consanguinity was reported in 24.8% of these index patients. The rate of autosomal recessive traits would be expected to be higher in the consanguineous families, but two affected children were born to unaffected parents in only ten families (5.6%).

In India, Manoharan *et al.* (2020) identified a familial clustering of CAKUT among 7.9% of 270 asymptomatic first-degree relatives of 138 index cases. In another study, from Istanbul, Turkey, Gok *et al.* (2020) found familial CAKUT in 14.4% (21/145 families) of 412 asymptomatic first-degree relatives of 145 index patients with CAKUT. The risk for familial CAKUT was higher among patients with renal agenesis. Among 5 index cases with renal agenesis, 3 had an affected asymptomatic first-degree relative. The type of anomaly was comparable between the index cases and affected first-degree relatives in 11/21 CAKUT families (51%). In 6 of the 21 affected families, CAKUT was diagnosed only in siblings, suggesting an autosomal recessive disorder. Familial CAKUT was present in 13.8% of the consanguineous families (4/29) and 14.6% of the non-consanguineous families (17/116). In this study, consanguinity contributed little to the risk of familial CAKUT, probably because of the predominance of autosomal dominant disorders.

These and other studies suggest that US screening of asymptomatic first-degree relatives of individuals with CAKUT may be reasonable. However, there are no official guidelines on screening family members because the cost-effectiveness of this strategy has not been established. Such a cost-benefit analysis should determine the relative efficacy of family screening based on the type of anomaly and for unilateral vs. bilateral CAKUT. We know that genetic testing has a higher yield in patients with bilateral CAKUT, and it is reasonable to wonder whether familial screening might be more cost-effective in these patients as well.

What are the features of *HNF1B*-associated Renal Cysts and Diabetes syndrome?

Although many genes contribute to the risk for familial CAKUT, variants in the hepatocyte nuclear factor 1 beta, *HNF1B*, are the

most common monogenic cause of developmental renal disease, responsible for 5-15% of cases. Both pathogenic variants in gene sequence and large deletions of chromosome 17q12 that include this gene can cause Renal Cysts and Diabetes (RCAD) syndrome, also referred to as Maturity Onset Diabetes of the Young, Type 5 (MODY5; OMIM 137920). The renal disease in RCAD syndrome is highly variable and ranges from a small or single kidney, horseshoe kidney, hyperuricemic nephropathy to renal cysts. Of these, renal cysts were the most common, present in 19/23 patients, in the series reported by Edghill *et al.* (2006). Eleven of 23 patients in this cohort had diabetes, which is typically diagnosed before age 25 years. Two (9%) had genital tract malformations: uterus didelphys with a single ovary and hemi-uterus, respectively, whereas another female mutation carrier had unexplained primary infertility. The *HNF1B*-associated disease is a multisystem disease that can include pancreatic hypoplasia, genital tract malformations (vaginal aplasia, rudimentary uterus), early-onset gout, abnormal liver function, and hypomagnesemia. Autism and cognitive impairment may occur in individuals with 17q12 deletion. Our patient has early evidence of hyperglycemia, suggesting that he may be developing diabetes associated with this disorder in childhood.

Do bilateral CAKUT increase the yield of genetic testing?

Bilateral renal anomalies increase the likelihood of finding a gene mutation. Ishiwa *et al.* (2019) performed a retrospective analysis of 66 patients with CAKUT who underwent gene analysis. Of these, 21.2% (14/66) had detectable pathogenic variants in *HNF1B* (7/14), *PAX2* (Renal coloboma syndrome, 4/14), *EYA1* (Branchio-oto-renal syndrome, 1/14) *CHD7* (CHARGE syndrome, 1/14) and *EP300* (Rubinstein-Taybi syndrome, 1/14). Bilateral renal lesions were significantly more likely to have a detectable gene variant, 32.5% (13/40; $p=0.02$). An *HNF1B* variant was identified in 7/14 patients, all of whom had bilateral hypodysplastic, polycystic or multicystic kidneys. Of these, 2/7 had point mutations in *HNF1B*, and 5/7 had 17q12 deletion syndrome, illustrating the value of chromosome microarray in the evaluation of CAKUT.

Patients with CAKUT who are diagnosed in the newborn period are in a unique position to have an early genetic diagnosis, which allows their medical providers to anticipate complications and better manage their disease and to provide genetic counseling and testing for at-risk relatives. Our patient did not have genetic testing during the newborn period. This missed opportunity delayed his diagnosis for 5 years.

Practical Applications:

1. When an infant has a CAKUT, take a detailed family history for renal disease, diabetes, and other anomalies
2. Consider renal US screening in asymptomatic first-degree relatives of infants with CAKUT, especially the baby bilateral involvement with at least one multicystic or polycystic kidney.
3. Search for other anomalies (eye, ear, cardiac, limb, genital) to determine if CAKUT is isolated or syndromic and choose genetic tests accordingly.
4. Order genetic testing during the newborn period whenever possible and especially when CAKUT is bilateral. Order chromosome microarray (for 17q12 deletion). When CAKUT

is apparently isolated or nonsyndromic but bilateral, choose a gene panel that includes *HNF1B*

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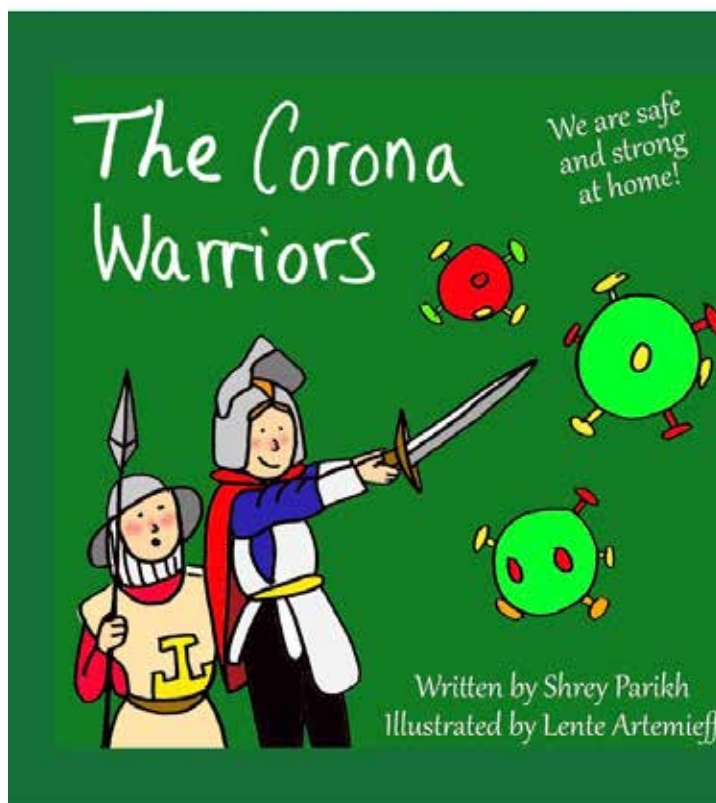
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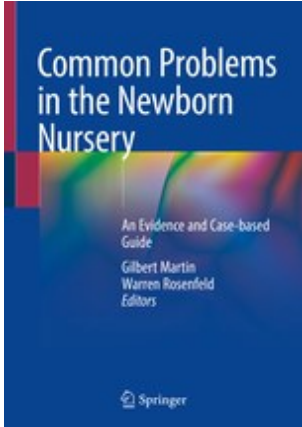
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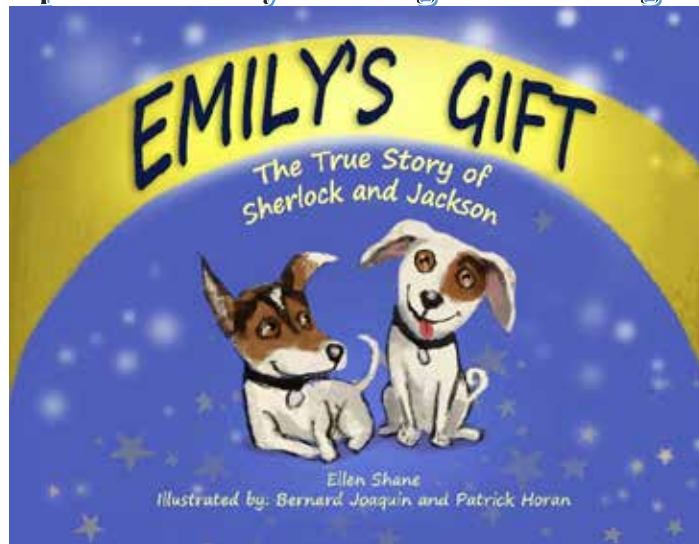
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2020 Infant Health Steering Committee Meeting Held Virtually

Mitchell Goldstein, M.D., Susan Hepworth



The National Coalition for Infant Health is a collaborative of more than 180 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCfIH prioritizes safety of this vulnerable population and access to approved therapies.

On July 23, 2020, the National Coalition for Infant Health held its 2020 steering committee meeting. Originally scheduled as an on-site event to coincide with the Pediatric Academic Society meeting in San Diego, difficulties secondary to the COVID 19 pandemic

forced rescheduling the steering committee meeting as a "Zoom" conference call.

The National Coalition for Infant Health (NCfIH) is a multidisciplinary coalition of over 200 organizations within the Neonatal, Pediatric, and Perinatal fields focusing on protecting access for

"Join health care providers, parents, regulators, policy makers and advocates for the 2020 Infant Health Policy Summit on September 10. This year's summit will be held virtually because, in spite of the current public health situation, we must continue the important dialogue about issues facing the infant health community and their families."



— 2020 —



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Questions? Charlie Husser chusser@allianceforpatientaccess.org

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2019 SUMMIT HIGHLIGHTS

Infants through age two.

The National Coalition for Infant Health Advocates for:

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

The National Coalition for Infant Health promotes a SANE approach to the care of premature infants:

- **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.

A volunteer steering committee supports the National Coalition for Infant Health, all of whom contribute significantly to the lives of premature infants through work and parenting. Steering committee members represent national nonprofits, academic institutions, and parent organizations, and they provide leadership as well as help to mobilize partners in the field of prematurity.

Following initiation of the Zoom Webinar and "Welcome and Introductions," Susan Hepworth, Executive Director, National Coalition for Infant Health, presented the National Coalition for Infant Health 2020 Year Plan. Steering Committee Member Advocacy Updates were provided by Melinda Elliott, MD, Medical Director, Prolacta Bioscience, Cathy Jackson, Senior Director, Patient Engagement and Advocacy, Mallinckrodt Pharmaceuticals, Dana Harkin, Director of Patient Advocacy, Sobi, Inc., May Lee Tjoa, MD, Director of Medical Affairs, Momenta Pharmaceuticals, and Victoria Niklas, MD, MA, FAAP, Global Medical Unit Head- Rare Diseases Therapeutic Area, Takeda.

A discussion of the plans for the 2020 Infant Health Policy Summit Planning Session followed. Join health care providers, parents, regulators, policy makers and advocates for the 2020 Infant Health Policy Summit on September 10. This year's summit will be held virtually because, in spite of the current public health situation, we must continue the important dialogue about issues facing the infant health community and their families. Registration for the meeting can be accessed on our website (<http://www.infanthealth.org/summit>).

The meeting adjourned with a virtual group picture.

The National Coalition welcomes those interested in our activities as well as organizations interested in protecting access for premature infants through age two to visit our website www.infanthealth.org.

Disclosures: The authors do not have any relevant disclosures.

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National Coalition for Infant Health Values (SANE)

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

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

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

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

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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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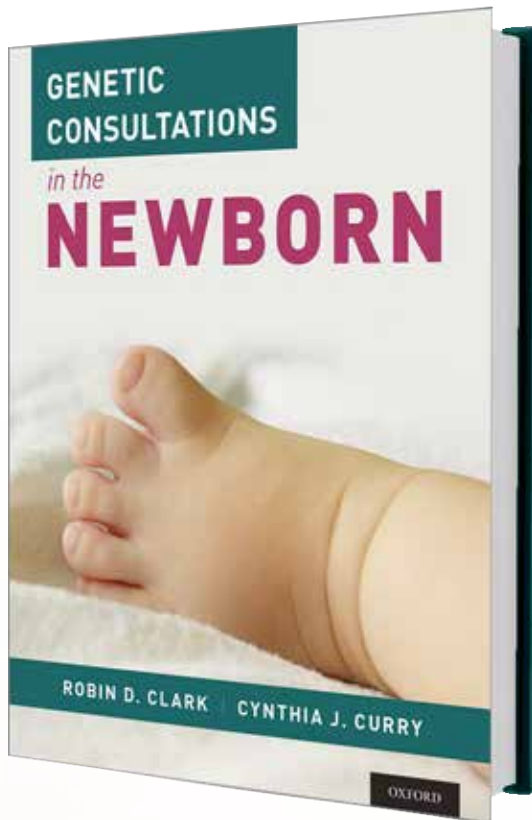


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RSV AWARENESS:

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

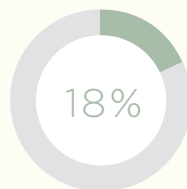
Preparedness

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.

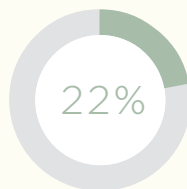
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

PARENTS

Only 18% said parents know “a lot” about RSV, reflecting an awareness level that’s roughly half that of the flu

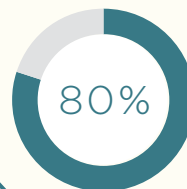


Only 22% of parents consider themselves “very well prepared” to prevent RSV.

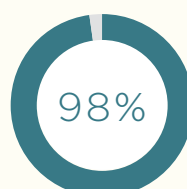


SPECIALTY HEALTH CARE PROVIDERS

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:

Management of a Symptomatic COVID-19 Positive Pregnant Woman and Her Newborn Infant

Jaclyn Eisenberg, MD, Poj Lysouvakon, MD, FAAP, Joseph R. Hageman, MD

Case Presentation

KM is a male newborn of 39 5/7 weeks' gestational age born to a 31yo G4P3013 mother. Maternal history is significant for sickle cell trait, psoriasis, which was untreated during this pregnancy, and latent tuberculosis, which was treated three years ago. She received adequate prenatal care, and her prenatal labs were unremarkable: O+, antibody negative, HIV negative, RPR non-reactive, rubella immune, gonorrhea negative, chlamydia negative, hepatitis B surface antigen-negative, GBS negative. The pregnancy was complicated by COVID-19 diagnosed 12 days prior to delivery with a positive test when the patient's mother developed cough and fatigue. She had been in self-quarantine at home for 12 days prior to delivery and was cleared by her primary care physician (PCP) given her lack of fever and greater than ten days since the onset of symptoms.

The patient's mother presented to labor and delivery with leaking fluid, frequent and regular contractions, and good fetal movement. She continued to have cough and congestion, and given her history of a positive SARS-CoV-2 test; she was enrolled in the institution's "PUI" pathway. She was placed on special respiratory precautions and was tested again for SARS-CoV-2, which resulted in a positive screen 7 hours after admission.

Our patient was delivered by cesarean section after a failed trial of labor after cesarean (TOLAC) secondary to failure to descend and fetal intolerance of labor with deep variable decelerations. The rupture of membranes was 14 hours prior to delivery with clear fluid. The NICU team was present for the delivery and donned full PPE, including N95 masks, gowns, and eye protection per hospital guidelines, given the positive COVID status. They reported that the infant cried spontaneously at birth and assigned APGAR scores of 9 and 9 at one and five minutes. Cord gases were within the normal range.

“Hospital policy at the time recommended the separation of infants from SARS CoV-2 positive mothers after delivery.”

Hospital policy at the time recommended the separation of infants from SARS CoV-2 positive mothers after delivery. Infants are monitored in isolation rooms in the NICU during their hospital stays, and breast milk expression is encouraged. This patient's mother initially planned to separate from her infant but later refused separation, and the infant roomed in with her. We recommended that she wear a mask at all times, keep the patient at least 6 feet from her except during feeds, and practice hand hy-

giene prior to all encounters with the infant. We encouraged the mother to give her newborn pumped breastmilk. For COVID-positive parents who choose to breastfeed directly, we recommend that they be masked and gowned (except for the exposed breast) and to practice good hand and skin hygiene.

KM had an unremarkable hospital stay. He received intramuscular vitamin K, erythromycin eye ointment, and hepatitis B vaccine. He passed a CCHD screen but failed his hearing screen bilaterally and was referred for repeat testing as an outpatient as well as CMV screening with his PCP. He had a circumcision on postnatal day of life 1, which he tolerated well. Discharge bilirubin was in the low intermediate risk zone. His physical examination was normal, and he had normal vital signs during his hospitalization.

“We encouraged the mother to give her newborn pumped breastmilk. For COVID-positive parents who choose to breastfeed directly, we recommend that they be masked and gowned (except for the exposed breast) and to practice good hand and skin hygiene.”

Per hospital protocol, KM was tested for SARS-CoV-2 at 24 hours after birth with a negative result. He was discharged home on day 3 with a prolonged hospital stay due to maternal observation. She experienced peripartum hypoxia for several hours requiring supplemental oxygen with a normal chest radiograph and normal post-partum course after discontinuation of oxygen. She was discharged home on Lovenox[®]. At the time of discharge, KM had lost 3% of his birthweight and was taking PO formula well with normal stools and voids.

He was discharged home with his mother, where he will live with his father and two older siblings. Our hospital guideline recommended continuing separation of KM from his mother at home while she is symptomatic as well as good hand hygiene.

Of note, KM had an abnormal newborn screen, which was positive for amino acid disorders. The repeat screen was negative. He has been seen regularly by his pediatrician, who reports that he is doing well without any sequelae from his mother's infection.

Discussion

The management of the mother and infant at the University of Chicago is consistent with guidelines published by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics at present (1,2). That is to say, the AAP Guidelines, which recommended the separation of COVID-19 positive mother and her infant, have just been revised such that mother and infant do not need to be separated as long as mother

and her infant are clinically stable (1,2). Here is a summary of the revised AAP rooming-in recommendations:

Rooming-in recommendations

The AAP offers the following guidance for rooming-in:

- Follow the usual practice of the birth center.
- Mothers with confirmed or suspected COVID-19 should maintain a *reasonable distance* from their infants when possible. While performing hands-on care, mothers should wear a mask and use hand hygiene. An isolette may facilitate distancing and provide added protection; take care to latch isolette doors properly to prevent infant falls.
- Health care workers should wear gowns, gloves, standard procedural masks, and eye protection when providing care for well infants. When this care is provided in the same room as a mother with COVID-19, health care workers may opt to use N95 respirators instead of standard procedural masks, if available.
- Mothers who are acutely ill may not feel up to providing all care for their babies. They might need to be temporarily separated or have the infant cared for by another, healthy caregiver in the room.
- Noninfected partners or other family members present during the birth hospitalization should use masks and hand hygiene when delivering hands-on care to the baby.

As outlined in an editorial by Gupta and colleagues, the management of pregnant women with COVID-19 and their newborns continues to evolve (3). Perlman et al. present a prospective initiative of mothers admitted to labor and delivery with universal testing, with 31 of 326 (9.5%) mothers testing positive for COVID-19 (4). Of these mothers, 15/31 (48%) were asymptomatic, and 16/31 (52%) were symptomatic (4). All of their newborn infants were

also tested and were negative (4). Twenty-nine newborns roomed in with their mothers, were breastfed as per their mother's choice, and were discharged with their mothers at one to two days of age. Two premature infants were admitted to the Neonatal intensive care unit and managed with continuous positive airway pressure (CPAP) and were not intubated. They were testing serially and remained negative, as well (4). The authors outline their preparation precautions for delivery, delivery room management, and transportation of infants as well as precautions in the NICU (4).

It is clear that the preparation, precautions, and management of pregnant women and their newborn infants will continue to evolve with more clinical experience. In a new editorial published in JAMA Pediatrics, Yanhong and colleagues from Australia emphasize this as well and discuss aspects of the management, breastfeeding recommendations, and state the evidence for vertical transmission of COVID-19 from mother to infant is "not convincing" (5). Thus far, I think investigators around the world also agree (2,5). They also discuss the need for large mother-infant dyad cohorts to further clarify the natural history of COVID-19 infection and long term outcomes (5).

"It is clear that the preparation, precautions, and management of pregnant women and their newborn infants will continue to evolve with more clinical experience."

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NT





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published in The Lancet

Because of the risk of
developing severe
pneumonia, pregnant
women and newborn
babies should be
considered key
at-risk populations.



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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.

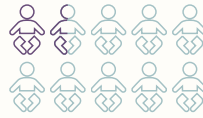
I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!



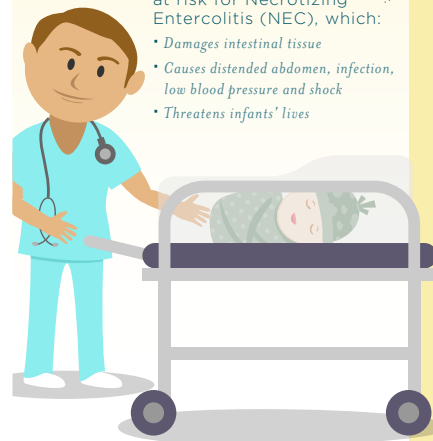
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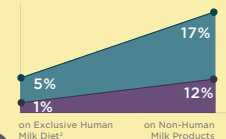


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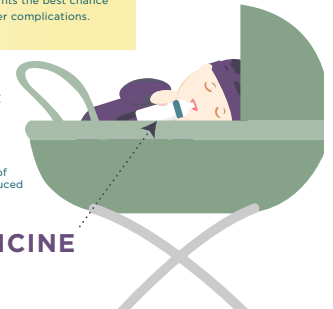


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Pragmatic Leadership Practices in Dangerous Contexts: High-Reliability Organizing (HRO) for Pandemic COVID-19

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Thomas A. Mercer, RAdm, USN (retired)

Abstract

The threat of COVID-19 to professionals has become personal. Professionals in neonatal healthcare can acquire infection and unknowingly become a vector, infecting babies, and their colleagues. A pragmatic stance of leadership, derived from leadership in extremis, communicates to subordinates that leaders have their immediate well-being in mind while engaging in demanding situations. Effective leadership for ill-structured problems embedded in the environment has distinct characteristics such as modeling cognitive and affective skills (attitudes and the contingent value of information) and the ability to modulate emotional states. Pragmatic leaders effectively increase subordinates' collective stress capacity for, and leverage individual capabilities during, in extremis circumstances. This paper describes pragmatic leadership characteristics and practices derived from experience, primary sciences, and High Reliability Organizations (HRO).

Introduction

The threat of COVID-19 to professionals has become personal. A deadly infection acquired in the community or NICU, unknowingly becoming a vector infecting babies and their colleagues, and interference with decision-making and routine behaviors. Inadequate protective material demanded healthcare professionals improvise with locally-available resources, much like the fire department adage for improvisation, "if you don't have it, it doesn't exist." Premature infants, however, do not have the compensation capacity, makeshift material, nor the physiological reserve to survive while neonatologists determine an effective treatment. During COVID-19, neonatologists faced the dual challenge of identifying and treating a previously unencountered disease while protecting themselves and others from contracting a highly infectious virus. As such, COVID-19 is an undefined and ill-structured problem that necessitates error probing.

Healthcare leaders directing medical care now must incorporate leadership principles and practices that support and protect subordinates in a manner previously unheard of in the NICU. A pragmatic stance of leadership, derived from leadership *in extremis*, communicates to subordinates that their leaders have their immediate well-being in mind while engaging in new situations.

High-Reliability Situations (HRS) present disrupted structure and logic to the individual. We cannot know if an error is occurring, if we discovered a discrepancy, or if we are experiencing a new disruption to our operations. We cannot know if our hesitation to en-

gage is not an error. "Look before you leap" may cause a serious error during cascading events. A threat, an uncontrollability, and the weight of demands initiate reflexive behaviors and involuntary release of neurochemicals that, though inevitable, need not be sustained. The pragmatic leader accepts the duty to increase the stress capacity, sense of controllability, and operational capability of subordinates in order to engage the HRS.

The cultural response to pandemic COVID-19 and the effect of the virus on healthcare systems revealed the effects of unrecognized fear on routine and emergency operations. Stress, as demands exceeding our abilities, is natural, expected, and leads to strength through change (allostasis). Stress responses from uncontrollability and fear reactions or sustained threat reflexes, unfortunately, have become normalized into programs expected to encounter the HRS.

"The cultural response to pandemic COVID-19 and the effect of the virus on healthcare systems revealed the effects of unrecognized fear on routine and emergency operations. Stress, as demands exceeding our abilities, is natural, expected, and leads to strength through change (allostasis)."

These circumstances disrupt care, induce unrecognized fear responses, discussed later in this article, and challenge leadership. Information for decisions is limited, uncertain, and ambiguous. Time for decisions is constrained. Unrecognized fear and sustained threat reflexes influence decisions-in-the-moment, making plausible short-term personal concerns. It is just such situations where a leader models decision making for the good of the community, a virtue, rather than self, a vice (Aristotle 2011 1140b5-7).

Phronesis – prudence or practical wisdom – is acquired by both practice and observation: practice creates the experience, while observation of elders who model this virtue leads to *phronesis* (Ryan 2014). Leaders stimulate people to act on their own in an interface with their environment. Practical wisdom is the capacity to choose appropriate goals and successfully devise means to reach them (Halverson 2004). Practical wisdom relies on the dynamic interaction between perception, experience, and character. It offers an insightful vision of what is proximately and ultimately

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good for people, organizations, and businesses. Phronesis, as prudence, is the first of Aristotle's four Cardinal Virtues (Prudence, Justice, Temperance, and Fortitude).

Leadership models developed in safe, stable environments do not generalize well in dangerous circumstances where leaders and followers must *personally* face dynamic and unpredictable situations, actively avoid death, and consider outcomes that include life-threatening disease or psychological injury (Kolditz 2006; Campbell, Hannah, and Matthews 2010). The sense of uncontrollability and existential threat results in stress responses and fear reactions that go unrecognized, impairing human performance and interaction (van Stralen, Byrum, Inozu 2017 269-73). Increasing stress capacity, a distinct yet inadequately developed leadership dimension in civilian leadership models, is fundamental to pragmatic HRO leadership. In this article, we will adapt the leadership characteristics of leadership *in extremis* and the leadership characteristics missed by the early HRO researchers into leadership for routine operations.

“The pragmatic leader gives meaning to the adage ‘Safety through operations and operations through safety.’”

The HRO pragmatic leader increases in subordinates 1) operational and decision-making, *capabilities*, 2) methods to discover, acquire, and maintain a functional sense of *controllability*, and 3) stress *capacity*. The leader models values, attitudes, practical wisdom, conflicted decision-making, and modulation of stress and fear responses. Below, we describe 1) management of unrecognized stress and unrecognized fear, and 2) the elements and characteristics of leadership *in extremis*.

Unrecognized stress, unrecognized fear

Mild uncontrollable stress, even the sense of uncontrollability, initiates a stress response sufficient to impair cognition (Arnsten 2009). The amygdala directly impairs the executive functions, and cortisol release impairs memory recall for declarative memory (knowledge), episodic memory (experience), and working memory. Cortisol enhances procedural memory (habits and skills). Left unrecognized, the individual's abrupt inability to recall or process necessary information increases the sense of uncontrollability, mimicking an unqualified individual. A controlled physical act resolves the problem. Working memory manages 7-9 chunks of information at a time, readily occupied by system demands, rigorously mandated protocols, and fear of causing harm. We call this “unrecognized stress” when amygdala activation and cortisol-mediated stress responses become accepted as normal, expected responses rather than avoidable, serious, but recoverable performance deficits.

Maladaptive fear behaviors include protective behaviors, that is, protective of ego and reputation, and the threat reflexes. Defensive protection occurs when the individual is outside of the situation, not engaging the problem, and unfamiliar with local or immediate correlations and causations. Defensive, protective actions, directed toward saving what has not already been harmed, shift attention away from the individual's actions through deflection,

excuses, justification, and “prophylactic” self-blame. Offensive protection develops within or upon entering the problem space. Offensive protective actions, to stop the spread of problems, shift attention toward the actions of others by attacking colleagues, blaming others, and making accusations. *Instrumental anger*, a distinct form of offensive protection, brings secondary gain for the individual. Instrumental anger, and the similar instrumental use of stress and fear, are manipulations independent of any context. Recognizing fear reactions as neurochemical responses allows the normative leader to reframe circumstances to gain the perception of controllability, reduce stress responses, and focus on the person's capabilities, system resources, re-evaluate demands, or decompose objectives for attainability.

“ This led to a single level of analysis rather than a macroscopic view providing multiple levels of analysis. The initial data collection and research did not identify the effect of command and leadership on the organizational structure and culture of the carrier.”

Asking residents for reasons an attending physician would become angry with them, the single common answer is that the resident made a serious mistake. They would respond by working harder. We then discussed anger as the fear fight response without the motor component. Working harder does not resolve the fear. Rather, requesting a directed action or asking, “How can I help?” moves the brain activity out of the amygdala and can resolve the anger. As reflexes, we cannot prevent the appearance of a fight, flight, or freeze, but we can modulate both motor and emotion components of the reflex to prevent sustained uncontrolled behaviors (McConnell and van Stralen 1997; Bracha 2004; van Stralen, Byrum, and Inozu 2017 285-87).

The pragmatic leader readily identifies threat reflexes and interrupts the cycle. Tonic immobility (“playing dead”), common though unrecognized, is the vagal induced “sick” feeling in the stomach (alarm bradycardia in mammals and birds) hindering decisions and actions (Alboni and Alboni 2014). Flight presents as plausible avoidance, distraction, intense review of information, or leaving to obtain equipment or information. Freeze (hypervigilance) maintains attention in preparation to act, but thinking and acting are “on hold.” The leader can interrupt the threat reflex, returning the person to the team, by prompting the executive functions (ask “How can I help you?”) or assigning a simple task to perform (shift to a dopamine pathway or network). In the first moments of resuscitation, a nearby nurse could not assist because of routine tasks for another patient. One of the authors (DvS) then asked the nurse to prepare a dopamine infusion, readily accomplished, and brought to the room. The author then asked the nurse for another task which the nurse undertook. Fifteen minutes into the resuscitation, the nurse asked about administering the infusion. It had not been needed. The flight response (plausible avoidance) rapidly resolved because performing a familiar task gave a sense of controllability, and the familiar task was possible because cortisol-

induced stress enhances procedural (skill) memory.

“The flight response (plausible avoidance) rapidly resolved because performing a familiar task gave a sense of controllability, and the familiar task was possible because cortisol-induced stress enhances procedural (skill) memory.”

Stress Capacity

Pragmatic leaders increase the stress capacity of subordinates by increasing demands while increasing their capacity to perform. The objective is to develop increased capability and a sense of controllability, frame experiences as challenges rather than threats, and distinguish between demands and expectations (Fisher, Hutchings, and Sarros 2010; Geraci et al. 2011; Sweeney, Matthews, and Lester 2011; van Stralen, Byrum, and Inozu 2017 pages 283-4). Context influences subordinates. Framing experiences as challenges for growth also frame the environment (Sweeney and Matthews 2011), and subordinates develop the capability for effective performance under stress conditions (Novaco et al. 1979).

The leader models the necessary attitudes and behaviors, openly discusses capabilities, core values, and shared purpose, and gives meaning to the efforts of subordinates. Attitudes *influence* behavior, are generalizable, and less specific, making them adaptive to varying contexts. Attitudes represent predispositions in favor of or against an element (Banaji and Heiphetz 2010, 350). For example, three years after graduating from medical school, Thomas Peebles joined the lab of Nobel Laureate John Enders to work on isolating the measles virus. Enders observed no success and removed Peebles from the project, but Peebles continued working on his own time. Peebles then isolated the measles virus used in the measles vaccine (Enders and Peebles 1954). Peebles was a US Navy aviator who flew B-24 Liberators in the South Pacific, receiving his crew's respect for his courage and leadership. He attributed his success to perseverance and a “failure to be bound by preconceived ideas” (Maugh 2010). Perseverance, courage, and acceptance of the novel are attitudes also found in naval aviators.

Pragmatic leaders treat all subordinates fairly, independent of the leader's feeling or judgment toward the subordinate. It is not uncommon, if not accepted, for a leader to marginalize subordinates through nonverbal cues and obtuse comments. Subordinates will notice a colleague who has become marginalized by the leader and, even if others do not favor the subordinate, the leader's actions negatively affect group performance. Actions by the leader are what create trust. Trust was a central factor in defining the characteristics of leading in combat during the Vietnam War (Fisher, Hutchings, and Sarros 2010).

Controllability

Controllability not only averts the cortisol-mediated memory impairment (cortisol released due to *uncontrollable* stress), it is also the objective for first actions. That is, through sensing (*not* sense-

making), the individual identifies an action to take, observes the response to the action, then acts on that information (McConnell and van Stralen 1997; van Stralen, Byrum, and Inozu 2017 183-4). The goal is to identify any point of controllability.

Leadership can instruct subordinates in methods to identify controllability during crises. One of the authors (DvS) sent a PGY2 pediatric resident to stabilize and transport an infant actively being resuscitated in the emergency department (ED) of a local major medical center. The pediatric resident later described the hyper-vigilant freeze response that came over her, she could not think. After the sensation started, she checked the endotracheal tube to see if it was working. It was working before checking, but it was the physical activity she wanted, and it was that physical activity that broke the freeze. The transport resident successfully resuscitated the infant within 20 minutes and returned with the child to the PICU (van Stralen, Byrum, and Inozu 237-8).

Expectations and demands

On the tactical level, during an emergency or crisis, we can too easily confuse expectations with demands. (The military refers to demands as constraints and limitations: what you must and cannot do.) Demands are objective, have a practical pathway that can be developed, a clearly identified end state, and can be described in concrete terms without abstractions, metaphors, or the use of clichés. Demands are the priority for the pragmatic HRO stance. Expectations, on the other hand, are subjective, vague, even nebulous, and are more often described in the abstract or through metaphors. Expectations may appear concrete and objective, but they lack the practicality of developing a path from the situation to the end state. Demands are more likely to be independent of the context and person, have objective markers to show progress, and have measurable endpoints. Expectations more likely come from desire or imperfect knowledge and depend on the strength of personal or group beliefs. Expectations too readily replace or become confused with demands. Striving for an expectation frames the situation or problem improperly, creates uncontrollability, generates gratuitous stress, impairs individual and team performance, and builds toward traumatic stress. A demand we cannot reach because of efforts and resources directed toward an expectation is a preventable tragedy.

Cognitive Appraisal and Traumatic Stress

Operations in a demanding, life-or-death environment, whether the NICU, public safety, or military operations, create two trajectories for psychological health: resilience or traumatic stress (Geraci et al. 2011). While there are numerous contributing factors, the NICU attending's use of leadership in dangerous contexts can decrease the likelihood of the traumatic stress trajectory and enhance the likelihood of the resilience trajectory. Cognitively appraising experiences and training as threatening, by the subordinate, contributes to later poor psychological health and impaired resilience (Geraci et al. 2011). Collegiate athletes also show similar differences when they appraise experience as a threat versus a challenge, the latter is a problem solver's perspective. Leadership is not restricted to organizational line authority, allowing the neonatologist to influence the cognitive appraisal of events by NICU staff and the families of patients. Using the same methods military leadership *in extremis* uses with soldiers (Geraci et al. 2011; Sweeney and Matthews 2011; Sweeney, Matthews, and Lester 2011), the neonatologist can reduce the incidence of post-

traumatic stress and contribute to post-traumatic growth in staff and families (Aftyka et al. 2017; Rodríguez-Rey et al. 2017; Wu et al. 2019; Aftyka, Rozalska, and Milanowska 2020). Post-traumatic growth is the psychological, emotional, and spiritual growth found after extreme traumatic experiences (Tedeschi and Calhoun 2004; Calhoun and Tedeschi 2014)

The trajectory begins with the first independent decision a subordinate makes and is repeated with the first decision the subordinate makes that others will rely on. Gastric distress due to the tonic immobility reflex induces avoidance of decisions. Recognizing this, and with some risk to his professional reputation, one of the authors (DvS) routinely compelled staff to make their first final decision in front of him, this is the decision the team would act on without review, even for medications administered “as needed.” Discussions ensued to identify and correct a decision that didn’t work and the presentation of a “decision box”: what would happen if we gave too much or not enough, or acted too soon or too late? Identifying a “box” within which it was safe to decide and act, while identifying the dangers of over or under treating, supported initiative on the part of the subordinate.

“The trajectory begins with the first independent decision a subordinate makes and is repeated with the first decision the subordinate makes that others will rely on.”

“Leaders of HRO systems, under no existential threat themselves in treating patients, can become normative, procedural, and algorithmic. This does not work well in a room with a contagious COVID-19 patient or pre-symptomatic staff. This new threat happens all the time in a military fight zone or during operations by Special Operations Forces. With the pragmatic leadership stance, I imagine, all personnel will be much calmer because information and authority will flow among them much easier.” Errol van Stralen, Ancora Education.

Elements of pragmatic leadership

The pragmatic stance is not about the leader entering a difficult environment, but how the leader’s behavior influences the well-being of subordinates, so they not only enter the environment but effectively perform (Kolditz 2006). Working the problem from within the situation, sharing threats and uncertainty as a participant, defines the pragmatic leadership stance. The ill-structured problem is a natural system that becomes ordered from internal processes, a self-organizing system. The team, and leader, must enter the system, becoming part of the internal processes that generate order. We cannot organize the situation and use commands and rules to resolve ill-structured problems from the outside as is possible with context-independent, well-structured problems.

The problem situation

The pragmatic leadership stance prepares subordinates to engage undefined and ill-structured problems, interact with processes internal to the system, then share experiences with others to

make the HRO stronger. The leader guides engagement through participation and closes the gaps between discrete concepts, continuous perceptions (Weick 2011), and between theory and practice (Zundel and Kokkalis. 2010; van Stralen 2020).

Leadership from the pragmatic stance, the foundation of HRO, is directional and developmental. *The directional component carries a team into an environment* characterized by disorder or randomness, lack of identifiable structure, instability, and unpredictability. The developmental component moves the novice toward decision-making that is less influenced by unrecognized fear. To identify the necessary leadership characteristics for the pragmatic stance, we look to *leadership in extremis* or *leadership in dangerous contexts*, a type of leadership in organizations with a long history of dangerous operations. Leadership skills in these organizations include use of contingent principles, context-dependent information, affective and cognitive thought processes (Palmer, Hannah, and Sosnowik 2011; van Stralen et al. 2017 82-87), and development of “swift trust” as groups rapidly form then dissolve to reform later or elsewhere (Meyerson, Weick, and Kramer 1996).

Leader-Leader; Leader-Follower

We expect, in the pragmatic stance, to develop “leader-leaders” (van Stralen, Byrum, and Inozu 2017). Staff in the NICU must immediately engage any disruption and investigate any discrepancy, not delaying for contact with the neonatologist. When a novel, unexpected event occurs, we expect someone to engage in some manner. In the pragmatic stance, people lead the problem until they are relieved.

Followership is the *capacity* to follow. We acknowledge that some executives, administrators, and managers consider followership the *willingness* to follow, but that view brings focus on conformity, obedience, and submission. Few, if any, traits are unique to followers in the pragmatic stance that are not also found in leaders. What may appear as bad followership may actually be good leadership for a problem when observed from a different point of view.

“Staff in the NICU must immediately engage any disruption and investigate any discrepancy, not delaying for contact with the neonatologist. When a novel, unexpected event occurs, we expect someone to engage in some manner.”

Elements of pragmatic leadership stance

Distributed Knowledge

An emergency creates its own, unstable environment which contains new, evolving information. Teamwork develops as an emergent property, a stabilizing structure, to facilitate shared sense-making (Maitlis and Christianson 2014; Dixon et al. 2017; van Stralen, Byrum, and Inozu 2017 396). Information changes with time, and what happens at any moment will continually influence what happens next, sequentially, and reciprocally (Dixon et al. 2017; van Stralen, Byrum, and Inozu 2017 396). The rapidity of

these developments, and the stabilizing effect of the team, occur before the leader arrives, a characteristic of dangerous contexts. When team members believe they are less competent than the leader, they will also have less influence on each other, impairing efforts to achieve high performance. Team members who can influence the leader and each other perform better in the absence of leadership (Ramthun and Matkin 2014).

Reciprocal Influence and Trust

The greatest distinction between healthcare and those working in an *in extremis* environment is the acceptance of trust. One of the authors (DvS) assumed care of an infant experiencing abrupt, severe upper airway obstruction. The surgeons requested an examination before intubation, if possible. Notified of the severe obstruction, the resident surgeon resisted responding. Only after speaking with the chief of service did the surgeons respond. The same author, as a paramedic, responded to a house for an assault victim, a juvenile with an intellectual disability. The assailant in the room threatened to shoot the paramedics if they continued treating the child. The assailant left the house to get a gun with everyone in the house running out. The author called fire dispatch, saying, "A kid said he's going to shoot us." The dispatcher replied, simply, "We'll get you the help you need." The author left the house to prevent the assailant from returning. A helicopter arrived at low altitude, six police cars arrived together, smoke from the brakes filling the street, followed by more. A fire engine arrived, its brakes adding to the smoke. A battalion chief arrived. (The police did apprehend the assailant.) This is the difference between high trust and low trust, between operating routinely in a stable environment and operating in an unsafe environment.

"When team members believe they are less competent than the leader, they will also have less influence on each other, impairing efforts to achieve high performance. Team members who can influence the leader and each other perform better in the absence of leadership (Ramthun and Matkin 2014)."

Trust is often considered a transaction, often dependent, unfortunately on the "other" person, the outsider, or the new member. Drawing from one of the author's (DvS) experiences from winter mountaineering, and unaccompanied rescue ambulance responses in drug and gang areas, he learned that one never enters a situation where you cannot extricate both yourself and your partner. That is trust in yourself for the capability to help others and yourself. The reason is that you might be the one who needs extrication. A fire department phrase, "If you don't trust me, you can't be trusted."

The goal is for trust to initiate reciprocity, maturing to mutual influence, culminating in shared leadership. Along the way, detection of weak signals, sorting out noise, and the flow of information dramatically improve with earlier detection of the covert, compensated phase of a process. Inductive processes extend HRO into

adverse or hostile environments. Inductive processes depend on accurate description of observable phenomena, the very thing trusted subordinates, communicating through reciprocity, will generate and be supportive of "deference to expertise." Blind spots become visible, information removes uncertainty, and meaning resolves the ambiguity. The meaning of the vignette about US Navy SEALs becomes clear. "All personnel will be much calmer because information and authority will flow among them much easier."

Studies of leadership *in extremis*, from the Vietnam War to the present, found that trust and mutual influence are the keys to shared leadership (Fisher Hutchings, and Sarros 2010; Ramthun and Matkin 2014). Trust and reciprocity form the basis of collective sense-making in dangerous contexts (Baran and Scott 2010; Campbell, Hannah, and Matthews 2010; Dixon et al. 2017). Similarly, in firefighting, shifting events may suggest to individuals that hazards are unfolding or developing, but contextual ambiguity ensures that the nature and essential significance of these hazards are frequently open to multiple and conflicting interpretations. Such leadership (i.e., collective sense-making) results from the ongoing, reciprocal interactions among all the team participants in the situation, regardless of their formal organizational rank or authority.

The evidence from leadership *in extremis* studies shows that, when the leader adjusts plans based on information submitted by a subordinate, it creates greater trust in the leader, increased sharing of information, and increased communication to the leader. Mutual interdependence, rather than trust in the leader, can explain how leaders may earn subordinate trust, and be perceived as credible. Proactive solicitation of suggestions demonstrates there is no one right answer or perspective, encouraging divergent thinking (Barton et al. 2015).

The team becomes structured through internal, self-organizing processes driven by mutual framing, distributed knowledge, a common threat, and shared sense-making/sense giving. Military veterans describe the importance of mutual influence on performance *in extremis*, the mutual influence acting as a multidirectional pattern of reciprocal leadership, enabling team members to lead each other to achieve common objectives (Ramthun and Matkin 2014). For polar explorers, this reciprocal influence makes the team highly effective while the leader maintains a strong influence (Karrasch, Levine, and Kolditz 2011). The leader who seeks perspectives, encouraging the sharing of information, models on how to engage ambiguous situations (Barton et al. 2015). Leadership in dangerous contexts, then, becomes a collective undertaking, with influence fluidly moving to the site it is needed, while team members gain a common, and increasingly accurate understanding, of the situation (Campbell, Hannah, and Matthews 2010; Fisher, Hutchings, and Sarros 2010). Through reciprocal influence, the leader gains a sense of how members think and

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their motivation (Karrasch, Levine, and Kolditz 2011).

Reciprocal influence toward resuscitating an infant, as a form of altruism, is associated with reward processing in the brain and is related to resilience (Charney 2003). Leadership becomes an emergent property with sustained social cooperation in dangerous contexts, with different leaders emerging serially based on expertise and knowledge. The serial emergence of leaders provides “leader sustainability” (Ramthun and Matkin 2014).

Framing

Self-awareness allows leaders to frame experiences as challenges to increase growth (Sweeney and Matthews 2011). How the leader frames the situation guides followers, whether it is worthy of greater vigilance and exploration, and the leader’s behavior will model engagement as a problem-solving strategy (Barton et al. 2015). Framing selects and calls attention to particular aspects of reality, allowing us to filter information, give meaning to perceptions, organize experience, and guides actions. We then create basic cognitive structures that guide our perception of reality. A leadership process used by firefighters continually adjusts their framing in dangerous contexts to not only maintain awareness of their surroundings through continual interaction but also to continuously keep themselves poised for a shift of action as the situ-

“Leadership becomes an emergent property with sustained social cooperation in dangerous contexts, with different leaders emerging serially based on expertise and knowledge. The serial emergence of leaders provides “leader sustainability” (Ramthun and Matkin 2014).”

ation evolves (Baran and Scott 2010). The subordinate’s framing supports common sense-making and sense-giving reciprocity with the leader, particularly in an *in extremis* situation (Dixon et al. 2017). Framing, as a learned personal and social skill for *in extremis* situations, should then come from the neonatologist.

In the flux of a neonatal emergency, the frame rapidly changes, yet no one participant can experience another’s frame. When the frame changes, what rules also change, and which rules remain? (This is the *frame problem* from artificial intelligence.) “The first inchoate ‘sense’ that a leader and his command may be *in extremis* triggers a sense-making/sense-giving cycle,” continually refining or revising both (Dixon et al. 2017). Team members and the leader engage in sense-making/sense-giving as interactive, iterative, recursive, intertwined, and overlapping parts of a single process. Each action, rapid shifts in contingencies, and unexpected disruptions change some of the rules. More than group interaction, it is through shared cognition and visual communication (Baran and Scott 2010; Dixon et al. 2017; van Stralen et al. 2017 104) that the team generates a frame that, while dynamically changing, becomes an increasingly accurate representation of events.

Conflicting objectives

Bill Corr, Captain, LAFD, and a South Pacific WWII US Navy veteran, and his firefighter took advantage of a fence and low roof to rapidly gain access in order to cut a ventilation hole at a house fire. The arriving Battalion Chief called out, “Corr! Don’t you know it’s department policy to always have a ladder when you’re on the roof?!” Capt Corr shouted back, “Isn’t it also department policy to put out the fire?!”

During an emergency, we maintain a dynamic balance between opposing principles, simultaneously increase the chance of success while decreasing the possibility of failure. There will be times we lose synchrony, and we disagree on principles to use or actions to take. Active, reciprocal involvement of the leader during routine operations supports decision making when ambiguity and equipoise worsen the conflicting objectives and solutions typical of the ill-structured problem. For example, in order to win the ‘hearts and minds’ of villagers, soldiers will give up their safety to patrol on foot, exposing themselves to improvised explosive devices leading to personnel losses by bombs and shootings. The “show friendliness” makes contact easier with the local population versus increased protection that damages relationships with the local population (Vogelaar, Van den Berg, and Kolditz, 2010). “Short feedback” favors force protection over civilian contact while “delayed feedback” or “indirect feedback” favors closer contact with civilians. Short feedback protects in the immediate environment, similar to short feedback (“error”) in resuscitation – it uncovers threat and reveals the boundary of the safe operational envelope. “Long feedback” contributes to growth, accumulates over time, and is unnoticed in the heat of the emergency. “Indirect feedback,” as a form of wisdom and teaching, employs immediate actions to put in place ideas or structures that benefit a later group. “Delayed feedback,” a hallmark of neonatology, protects nascent tissues, the effect which cannot be known for years.

The pragmatic leader, aware of these distinctions, guides the team through actions that will produce effects on a variety of timelines.

“The captain then said, “There are a thousand things happening on the scene. You can only see a hundred. You can only act on ten. I may see a different hundred. I may act on a different ten. That doesn’t mean I’m better than you; only that I’m different.” Even if engaged side by side, people experience different forms of sense-making in unexpected events.”

Conclusion

The pragmatic leadership stance increases the mental and psychological capabilities of staff. The qualities of the HRO pragmatic leader enable the smooth implementation of HRO and support identification and engagement of early heralds of failure. The neonatologist, using the pragmatic leadership stance, can improve performance and effective operations while reducing uncontrol-

lable stress in the NICU for the benefit of the babies, families, and staff.

How the leader responds to errors and failures demonstrates internalization of these leadership characteristics. The following vignettes also reveal the long-term growth the pragmatic leader initiates.

A senior physician at a university medical center believed the critical care fellows should have a deep appreciation for the responsibilities they have providing care. If the fellow made an error that contributed to a child's death, the attending expected the fellow to cry. If the fellow did not cry, the attending personally counseled the fellow, believing that all fellows should cry at least once during training. If the fellow still did not cry, the attending believed the fellow had no feelings for the children.

One of the authors (DvS), working on a fire rescue ambulance, managed a motor vehicle collision with the unconscious victim trapped in the car. Because of miscommunications and misjudgments, the responding fire apparatus did not have the necessary extrication tools, delaying transportation of the patient to the hospital. The patient died that evening. That evening, the fire captain thanked the author for his efforts, telling him he was *the* most qualified rescue ambulance driver the fire department had at the time of the call and that the department would support him and everything he did. Then he opened a discussion of what could be done differently, developing reasons for each decision point. The captain concluded by restating the author was *the* most qualified rescue ambulance driver the department had for the call so that the department would stand behind the driver and his actions.

The captain then said, "There are a thousand things happening on the scene. You can only see a hundred. You can only act on ten. I may see a different hundred. I may act on a different ten. That doesn't mean I'm better than you; only that I'm different." Even if engaged side by side, people experience different forms of sense-making in unexpected events.

"This remains, to me, one of your more powerful, rich experiences. One can dwell on its implications for a long time." Karl Weick, personal communication.

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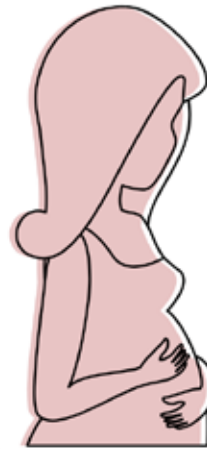
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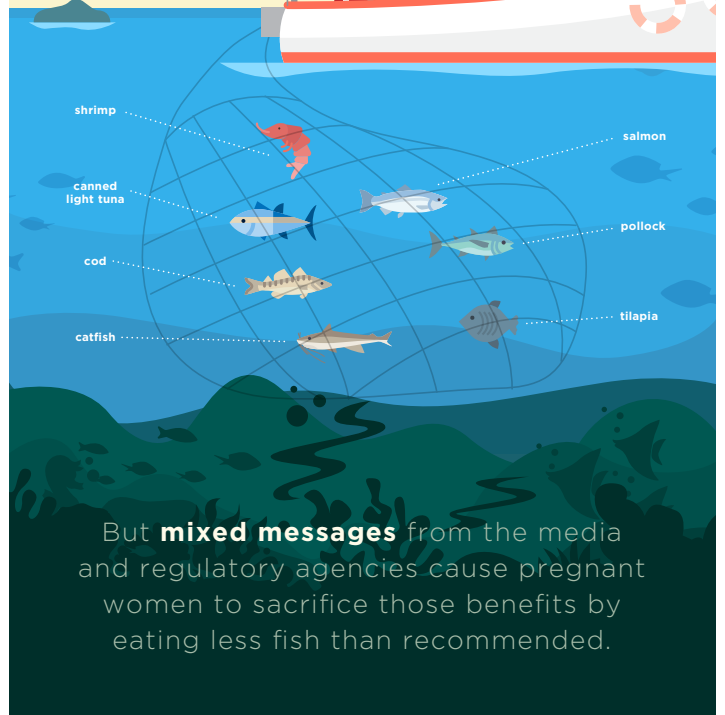
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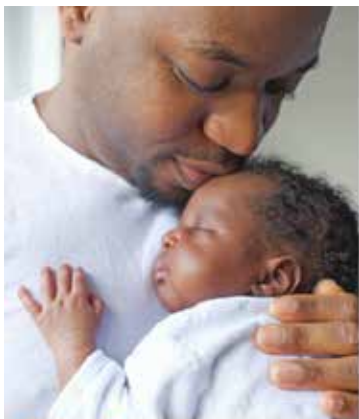
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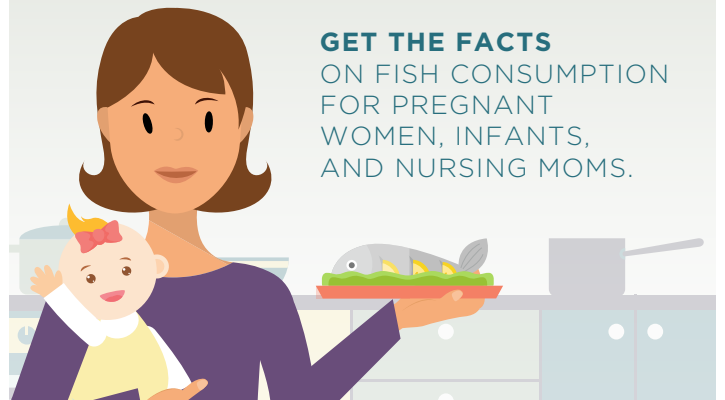
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Letters to the Editor

The following email "chain" is part of a dialogue between a prominent professional organization and Neonatology Today. Per the request of that organization, identifying characteristics of the conversation have been redacted. Although subscriptions to NT are free, the journal is not in the public domain. We have since improved the language describing our position.

MG

Dear Dr. D,

We have completed our review of your below 2 requests; unfortunately, the Organization's Copyright Policy prohibits granting permission to use any material in any Open Access publications/systems, so we must deny both requests. If you have any questions, please feel free to contact us. Thank you

Sincerely,

J

Dear J,

Thank you for returning my call today. For clarification, Neonatology Today is not an open access journal. Our most recent publication can be found [here](#). Our copyright statement is on page 1. Our ATOM publication position is referenced on page 131. Additional information regarding use and permissions can be found on page 139 on the right hand side of the page. We are truly an academic based journal and eschew the predatory practices of certain other publications. We are not for profit and have a worldwide circulation of 15,000.

I would be happy to answer any further questions that you might have.

Regards,

MG

Dr. G & Dr. D,

I have just come from our Legal review meeting and there was one more question that came up. The team reviewed the material that you sent, Dr. Goldstein, but then they ask me to find out what, exactly, in your policies prevent readers from re-using the material in your newsletter. We were not able to determine that from the 3 areas of the newsletter that we reviewed.

The organization must do whatever it takes to protect their ma-

terial; I am sure that you both can understand that. Any further information that you can provide will be most helpful. Thank you

Sincerely,

J

Dear J,

On page 1, in the lower left hand corner, it clearly states that all rights are reserved. They are not placed in the public domain as with many "open access" journals. On page 139, subpoint 10, "10. Only manuscripts that have not been published previously will be considered for publication except under special circumstances. Prior publication must be disclosed on submission. Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today." As we are a Delaware corporation, we would protect our copyright to the extent that the law allows in the state of Delaware.

Regards,

MG

Thank you, Dr. G ,

Legal is going to approve this usage; however, I have no idea what this item is, or where it is located. Dr. D , would you be so kind to provide the location or a link to the material you are wanting to use?

Sincerely,

J

Dear J

Would you mind if we used this exchange in our "letter to the editor" section? We have had this issue before and have resolved it in much the same manner but think that it would be important to our readers to understand our position on copyright.

Regards,

MG

I can run this by the legal team, for their OK.

However, would it be better to add a permanent line that answers the questions that some have about your definition or category of "open access"? For instance, adding the open access license

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type, i.e. BY-NC-ND?

Sincerely,

J

Dear J

I understand your point but we have deliberately tried to make the journal accessible but secure in terms of copyright. Although this is the traditional model, a discussion like this would go a long way towards making this point clear to our readers and those considering submission of a manuscript.

Regards,

MG

Dr. G,

Legal is fine with you using our exchange in your "letter to the editor" section, as long as my name nor the organization's name, is included.

One other point that I wish to share with you that confused the issue for us was the Manuscript Instructions to the Authors statement in #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 (i.e., open access). There is no charge for your manuscript to be published under open access".

It might behoove you to add something at these points to explain that this is not the anything goes "open access".

And, finally, I have attached the permission agreement for you/ Dr. D.

If you have any questions, please feel free to contact us. Thank you, and thank you for your patience, as we worked through the definitions and process.

Sincerely,

J

Dear J,

I think that you are right. This segment is confusing. We were referring to our ATOM model which neither charges for manuscripts to be published nor subscriptions but does not invalidate our copyright. We will wordsmith the language so that this is more clear.

Regards,

MG



Sincerely,

Mitchell Goldstein, MD

Editor in Chief

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Introducing Fu-Sheng Chou, MD, PhD our New Senior Associate Editor, Director of Neonatology Today's Digital Enterprise



Dr. Fu-Sheng Chou received his medical degree from National Taiwan University. He then completed a PhD in Cancer and Cell Biology from the University of Cincinnati. Afterwards, he completed his Pediatric Residency

at the University of Kansas Medical Center, followed by a Neonatal-Perinatal Medicine Fellowship at Boston Children's Hospital / Harvard Medical School.

Dr. Chou did his PhD thesis with Dr. James C. Mulloy, PhD, at Cincinnati Children's Hospital Medical Center. Dr. Chou's thesis work was to delineate the role of a survival signal in promoting self-renewal of pre-leukemia hematopoietic stem cells expressing AML1-ETO, a fusion gene product resulting from t(8;21). Prior to joining the Neonatology division at Loma Linda University as an Assistant Professor in the School of Medicine, Dr. Chou spent three years at Children's Mercy-Kansas City / University of Kansas Medical Center, where he studied the impact of intrauterine growth restriction (IUGR) on fetal neural stem cells. Dr. Chou developed profound interest in data science while he was studying the molecular mechanisms underlying cell-cycle effect of IUGR on fetal neural stem cells using RNA sequencing and transcriptome analysis.

Dr. Chou is a neonatologist and a stem cell biologist by training, as well as a self-taught data scientist. Dr. Chou's primary clinical and research interests are in areas related to IUGR and extreme prematurity. Dr. Chou's research experiences span across multiple research domains, from preclinical disease modeling to transcriptome analysis and big data-driven risk factor analysis and predictive modeling. By taking a data science approach, Dr. Chou's current main focus is on identifying ways to better quantify risks of adverse cardiometabolic and neurodevelopmental outcomes associated with IUGR and extreme prematurity.

Dr. Chou is a rare breed. In addition to core basic science, data science, and clinical skills, he has web technology capabilities that transcend simple web design. Dr. Chou is currently working on designing Neonatology Today's new web presence, which he will supervise. We anticipate that this interface will help us meet the metric for ultimate inclusion in the National Library of Medicine Database (Pub-Med). Please find a preview of our new interface just to the right of this column.

We welcome Dr. Chou and his innovation to the Neonatology Today Team and look forward to the new innovations that our association will bring. Beyond that, he's a great guy with a terrific personality.

Dr. Chou, great to have you on board!



The screenshot displays the Neonatology Today website interface. At the top, it features the journal title "NEONATOLOGY TODAY" in large red and black letters, with the subtitle "Peer Reviewed Research, News, and Information in Neonatal and Perinatal Medicine" below it. The date "SUNDAY AUGUST 16, 2020" is shown, along with a search icon and a "SUBSCRIBE" button. The main content area is divided into several sections: "About the journal" (describing the journal's scope and mission), "Current Issue" (highlighting the July 2020 issue with a featured article on cow's milk-derived fortifiers), "Archive" (allowing users to browse past issues by year and month), "Events" (listing upcoming training courses), and "Sponsors" (a placeholder for advertising). A banner for BCPAP ventilation is also visible. The "Editors' Corner" section introduces Mitchell Goldstein, MD FAAP, as the Editor-in-Chief. The "Authors' artwork" section features a photograph of a bird.

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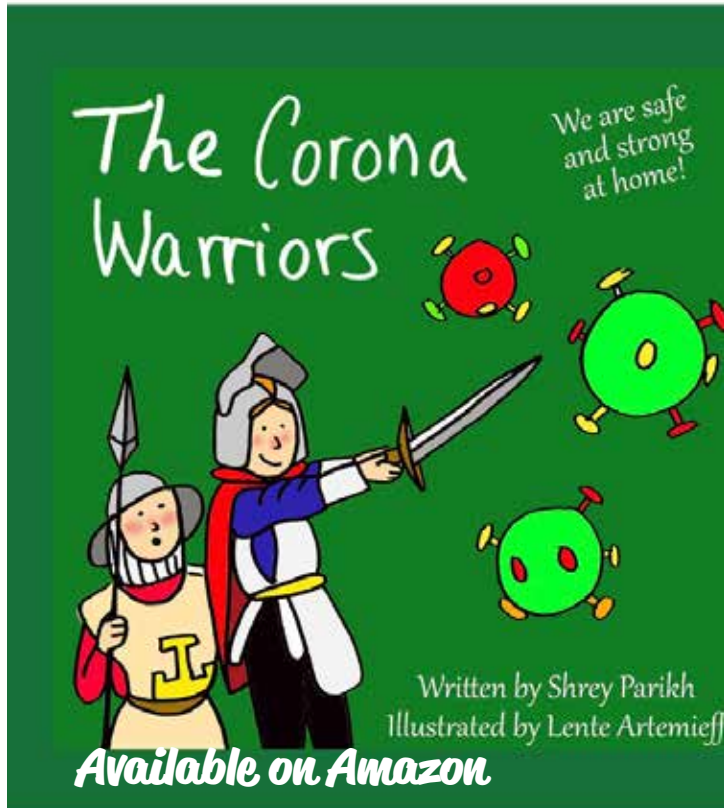
Which Infants are More Vulnerable to Respiratory Syncytial Virus?

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%



Erratum (Neonatology Today July, 2020)

Neonatology Today has identified no erratum affecting the July, 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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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.

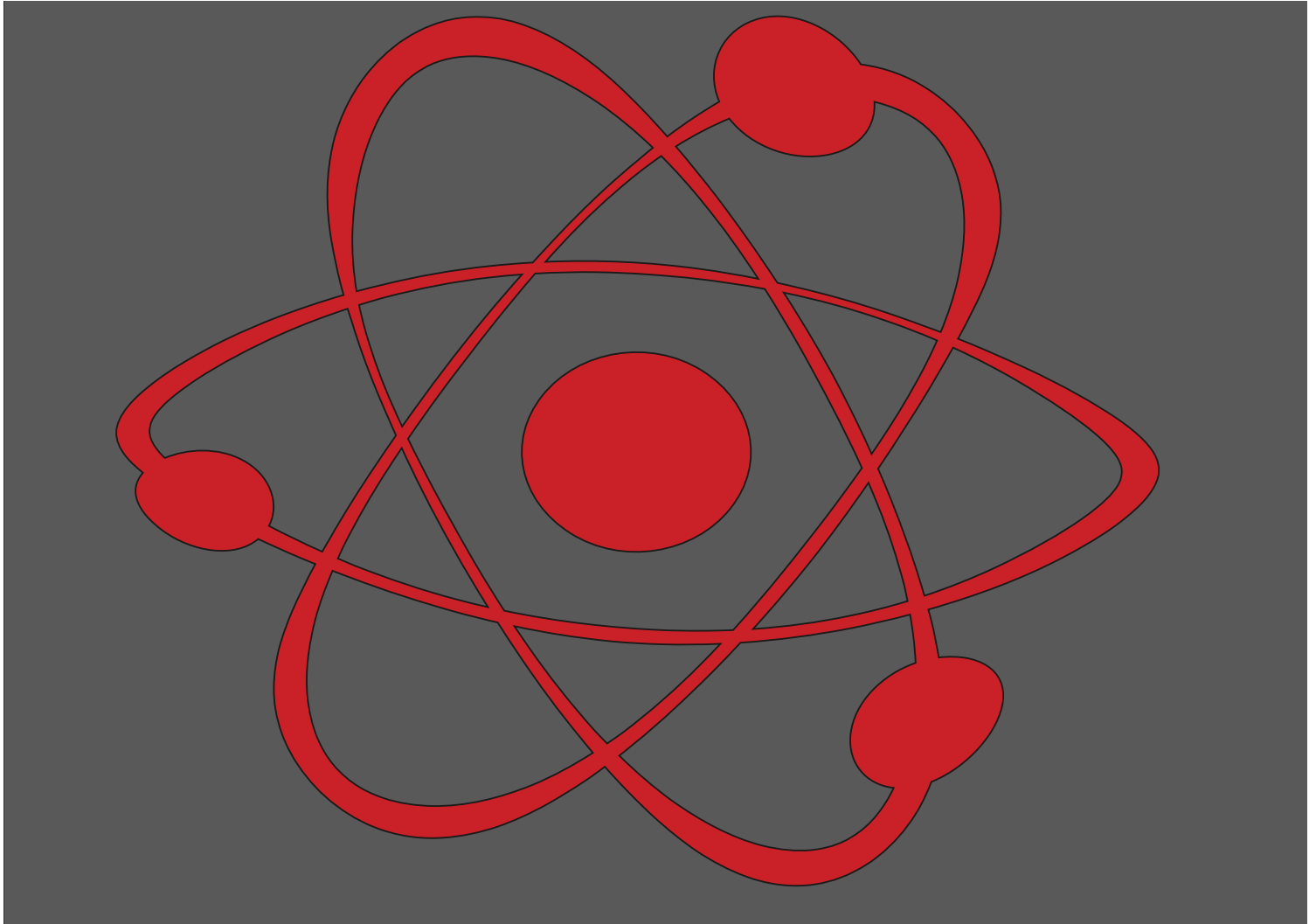
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Will your **PRETERM INFANT** need **EARLY INTERVENTION** services?

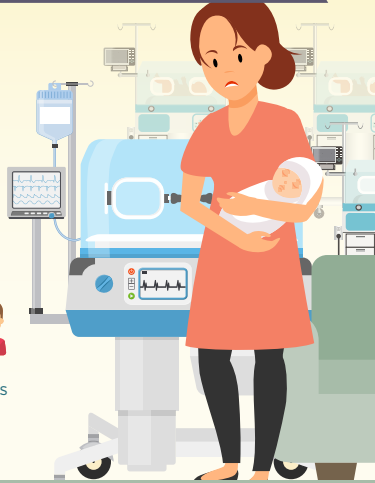
Preterm infants are:

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



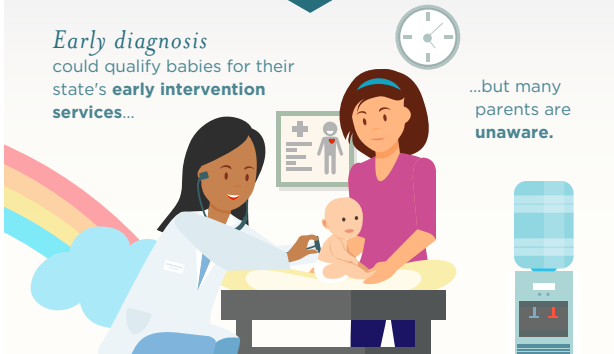
Address physical challenges



Prevent mild difficulties from developing into major problems

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

...but many parents are **unaware**.



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

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



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

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

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



1 DE CADA 7 MADRES AFRONTA LA DEPRESIÓN POSPARTO, experimentando



Sin embargo, sólo el **15%** recibe tratamiento!

LA DEPRESIÓN POSTPARTO **NO TRATADA PUEDE AFECTAR:**

El sueño, la alimentación y el comportamiento del bebé a medida que crece?



La salud de la madre
La capacidad para cuidar de un bebé y sus hermanos

PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO



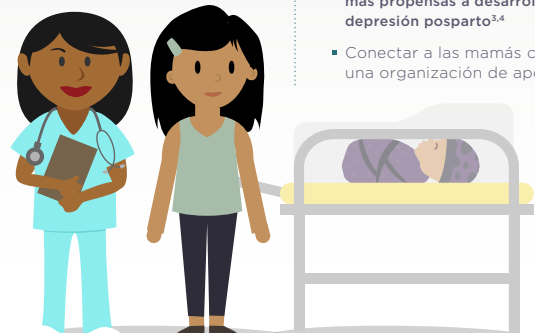
LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

- Financiar los esfuerzos de despistaje y diagnóstico
- Proteger el acceso al tratamiento



LOS HOSPITALES PUEDEN:

- Capacitar a los profesionales de la salud para proporcionar apoyo psicosocial a las familias... **Especialmente aquellas con bebés prematuros, que son 40% más propensas a desarrollar depresión posparto**^{3,4}
- Conectar a las mamás con una organización de apoyo



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

¹ American Psychological Association. Accessed on: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>

² National Institute of Mental Health. Accessed on: <https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>

³ Journal of Perinatology (2015) 35, 529–536. doi:10.1097/JP.0000000000000147

⁴ Prevalence and risk factors for postpartum depression among women with problem and low-birth-weight infants: a systematic review. Vigod SN, Villages L, Dennis CL. *PLoS ONE* 2010 Apr; 11(7):1540-50.

Upcoming Medical Meetings

9TH ICCN International Conference on
Clinical Neonatology
September 3 - 4, 2020
Turin, Italy
[https://www.mcscientificevents.eu/
iccn/](https://www.mcscientificevents.eu/iccn/)

8th Annual Fall Conference on
Current Concepts in Neonatal Care
September 23 - 26, 2020
Napa, California
[https://www.emedevents.com/c/
medical-conferences-2020/8th-
annual-fall-conference-on-current-
concepts-in-neonatal-care](https://www.emedevents.com/c/medical-conferences-2020/8th-annual-fall-conference-on-current-concepts-in-neonatal-care)

PDA Symposium 2020
October 9 - 10, 2020
Location: Las Vegas, NV
<https://pdasymposium.org/>

AAP National Conference &
Exhibition
October 18 - 20, 2020
American Academy of Pediatrics
San Diego, California
<https://aapexperience.org/>

4th Annual NeoHeart
October 28 - 30, 2020
New York, New York
[https://neoheartsociety.org/
conference2020/](https://neoheartsociety.org/conference2020/)

International Conference on
Neonatology and Perinatology
November 5 - 6, 2020
Cape Town, South Africa
[https://waset.org/neonatology-
and-perinatology-conference-in-
november-2020-in-cape-town](https://waset.org/neonatology-and-perinatology-conference-in-november-2020-in-cape-town)

Miami Neonatology 2020: 44th
International Conference
live interactive online conference
November 16-20, 2020
University of Miami Miller School of
Medicine
Miami Beach, Florida
[http://pediatrics.med.miami.edu/
neonatology/international-neonatal-
conference/](http://pediatrics.med.miami.edu/neonatology/international-neonatal-conference/)

Perinatal Care and the 4th Trimester:
Redefining Care
National Perinatal Association
Aurora, Colorado
[http://www.nationalperinatal.
org/2020conference](http://www.nationalperinatal.org/2020conference)

Hot Topics in Neonatology
December 6 - 9, 2020
Organization: Nemours
National Harbor, Maryland
[http://www.hottopicsonneonatology.
org/](http://www.hottopicsonneonatology.org/)

*For up to date Meeting
Information, visit
[NeonatologyToday.net](http://www.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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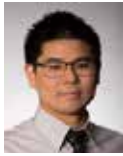
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Neonatology and the Arts

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 announce an expanded presence of the arts within Neonatology Today. We will 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 Whiteman, MD who has graced Neonatology Today with an another amazing graphic. Our bird of the month is provided by Dr. Mita Shah.



Herbert Vasquez, MD, Associate Neonatologist, Queen of the Valley Campus Emanate Health, West Covina, CA

VasquezH1@gmail.com

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Manuscript Submission: Instructions to Authors

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

2. All material should be emailed to: LomaLindaPublishingCompany@gmail.com in a Microsoft Word, Open Office, or XML format for the textual material and separate files (tif, eps, jpg, gif, ai, psd, or pdf) for each figure. Preferred formats are ai, psd, or pdf. tif and jpg images should have sufficient resolution so as not to have visible pixilation for the intended dimension. In general, if acceptable for publication, submissions will be published within 3 months.

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

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

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

6. An abstract may be submitted.

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

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

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

10. Only manuscripts that have not been published previously will be considered for publication except under special circumstances. Prior publication must be disclosed on submission. Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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