NEONATOLOGY TODAY

Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine

Volume 16 / Issue 9 | September 2021

Combining Probability Scores to Optimize Clinical Use of the NICHD Neonatal BPD Outcome Estimator
Rebekah M. Leigh, John B. C. Tan, Shirin R. DeGiorgio, Minha Cha, Chelsea Kent, Hung-Wen Yeh, Fu-Sheng Chou
.....Page 3

What do we know about COVID-19 Vaccines for Children?
Reese H. Clark, MD, Veeral N. Tolia, MD, Curtis B. Pickert, MD
.....Page 15

Fellows Column: Caloric Restricted Diets Anxiolytic Effect on Progeny
Landon Smith, OMS III
.....Page 24

Briefly Legal: Loss of Hand Secondary to a Percutaneous Arterial Line
Maureen E. Sims, M.D., Barry Schifrin, M.D,
.....Page 29

Gravens By Design: The Case of a NICU with Single-family Rooms: Design Recommendations to Support Family Engagement Behaviors
Herminia Machry, PhD, Robert White, MD, Sue Ann Barton, AIA, EDAC, LEED AP
.....Page 34

Machine Learning Workflow – Part 2
John B. C. Tan, PhD, Fu-Sheng Chou, MD, PhD
.....Page 46

Putting Baby Safety Month in The Infant Safe Sleep Context
Barb Himes, IBCLC, CD
.....Page 56

Academy of Neonatal Care: Local, Nationwide, Global!
Kelly Welton, BA, RRT-NPS
.....Page 62

The Importance of Data in an Exclusive Human Milk Diet: Key Concepts and Points of Consideration
Mitchell Goldstein, MD, MBA, CML
.....Page 69

30th Annual Course Jen-Tien Wung Respiratory Care of the Newborn: A Practical Approach October 9 & 10, 2021
Rakesh Sahni, MD
.....Page 74

Non-Invasive Ventilation (NIV): Failure is Not a Four-Letter Word
Rob Graham, R.R.T./N.R.C.P.
.....Page 77

Neonatal Intensive Care Unit Awareness Month
JaNeen Cross, DSW, MSW, MBA
.....Page 82

What Will It Take to Increase Maternal Vaccination Rates?
Michelle Winokur, DrPH, and the AfPA Governmental Affairs Team, Alliance for Patient Access (AfPA)
.....Page 94

I CAN Digitally Involved (I CANDI): Engage within Pediatric Healthcare, Science, Research, and Innovation
Amy Ohmer
.....Page 98

Inductive Processes, Heuristics, and Biases Modulated by High-Reliability Organizing (HRO) for COVID-19 and Disasters
Daved van Stralen, MD, FAAP, Thomas A. Mercer, RAdm, USN
.....Page 104

Medical News, Products & Information
Compiled and Reviewed by David Vasconcellos, MS IV
.....Page 119

Genetic Corner: Diaphragmatic Hernia in an Infant with a Type II Distal Deletion of 22q11.2 (LCR22E-F)
Robin Dawn Clark, MD
.....Page 131

Infant Health Matters
Susan Hepworth, Mitchell Goldstein, MD, MBA, CML
.....Page 138

Interim Guidance from the AAP for the Use of Pavalizumab Prophylaxis During the Delayed RSV Surge
Melanie Wielicka, MD, PhD
.....Page 145

Medico-Legal Forum: The Electronic Medical Record: Legal Issues to Consider Part I: Patient Care or Paper Care or Who Cares?
Gilbert I. Martin, MD
.....Page 149

Interpreting Umbilical Cord Blood Gases: Section 7: Fetal Circulatory Failure
Jeffrey Pomerance, MD, MPH
.....Page 155

Letter to the Editor: Winning the Race to the Bottom -- How to Get a Meaningful Product to Market
Will King, Mitchell Goldstein, MD, MBA, CML
.....Page 160

Academic True Open Model (ATOM)
.....Page 162

Upcoming Meetings, Subscriptions and Contact Information
.....Page 165

Editorial Board
.....Page 168

Policy on Animal and Human Research, Manuscript Submission
.....Page 170

Neonatology and the Arts
Herbert Vasquez, MD
.....Page 170

NICU Baby's Bill of Rights
NICU Parent Network
.....Page 171

Airborne
Nico Akiva Anderson
.....Page 172

The Canadian
Barbara Strobel-Dellger
.....Page 173

NEONATOLOGY TODAY

ISSN: 1932-7137 (Online), 1932-7129 (Print)
All editions of the Journal and associated manuscripts are available on-line:
www.NeonatologyToday.net
www.Twitter.com/NeoToday

NT

Loma Linda Publishing Company
A Delaware "not for profit" 501(c) 3 Corporation.
c/o Mitchell Goldstein, MD
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Combining Probability Scores to Optimize Clinical Use of the NICHD Neonatal BPD Outcome Estimator

Rebekah M. Leigh, John B. C. Tan, Shirin R. DeGiorgio, Minha Cha, Chelsea Kent, Hung-Wen Yeh, Fu-Sheng Chou

Abstract

Objective: Bronchopulmonary dysplasia (BPD) continues to prevail among very preterm infants. While NICHD BPD Outcome Estimator is easy to use, the clinical interpretation remains challenging. This study aims to optimize its use.

Study Design: A retrospective study was conducted with 469 infants born between 2015 and 2020. Data were entered into the Estimator to obtain probability scores. Trajectories of the probability scores were modeled using generalized additive modeling. The optimal cutoff number for predicting severe BPD or death was identified by a grid search from a range established by the original population distribution and the ROC curve.

Result: Combining probability scores from the severe and death categories and the no-BPD and mild categories may improve BPD outcome prediction. A cutoff of 21% combining outcome probabilities from severe and death categories is predictive of severe BPD or death.

Conclusion: Combining probability scores of different categories improves BPD outcome prediction.

Keywords

Bronchopulmonary dysplasia, Neonatal BPD Outcome Estimator, generalized additive modeling

"Among the survivors, bronchopulmonary dysplasia (BPD) is the most common respiratory complication of extreme prematurity (less than 28 weeks of gestation) and affects one-third or more of preterm infants (5). Despite improvement in other morbidities of extreme prematurity, the incidence of BPD remains high (6,7)."

Introduction

Preterm birth contributes significantly to both neonatal morbidity and mortality. Vast improvement in the preterm mortality rate due to advancements in neonatal care over the years has been at the expense of these infants who experience increased adverse outcomes such as respiratory illness, neurodevelopmental delay, and behavioral problems, among many others (1–4). Among the survivors, bronchopulmonary dysplasia (BPD) is the most common respiratory complication of extreme prematurity (less than 28 weeks of gestation) and affects one-third or more of preterm infants (5). Despite improvement in other morbidities of extreme prematurity, the incidence of BPD remains high (6,7).

BPD is a multifactorial disease that results from a vulnerable, underdeveloped lung experiencing injury, inflammation, and oxidative stress causing prolonged oxygen dependence, a lengthened hospital stay, and significant long-term pulmonary morbidities that may continue into adulthood (8–10). BPD occurs due to disrupted postnatal lung development with alveolar simplification and dysmorphic microvascular changes (11). The interruption of postnatal alveolarization decreases gas exchange in the lung and elevates the requirement for supplemental oxygen or mechanical ventilation, which can exacerbate the existing lung damage and inflammation (12). Due to the improvement in mortality rates of preterm neonates, the research focus for BPD has shifted to reducing the burden of the disease by promoting postnatal alveolarization and facilitating recovery through therapies such as optimized ventilation, surfactant replacement, caffeine, antioxidants, vitamin A, and corticosteroids (13–15).

"Corticosteroids, in particular, have shown numerous benefits in the de-escalation of respiratory support by reducing lung inflammation and improving the exchange rate of gases, although its role in BPD prevention is currently unclear (16,17). However, systemic corticosteroid use has also been associated with impaired neurodevelopment, cerebral palsy, increased risk of intestinal perforation with indomethacin exposure, and late-onset sepsis (18,19). "

Corticosteroids, in particular, have shown numerous benefits in the de-escalation of respiratory support by reducing lung inflammation and improving the exchange rate of gases, although its role in BPD prevention is currently unclear (16,17). However, systemic corticosteroid use has also been associated with impaired neurodevelopment, cerebral palsy, increased risk of intestinal perforation with indomethacin exposure, and late-onset sepsis (18,19). Given the potential for both benefit and harm, the prudent use of corticosteroids is suggested for infants when the severity risk of BPD is considerable (>50%) (20,21). One method to guide corticosteroid intervention is by using the Eunice Kennedy Shriver National Institute of Children Health and Human Development (NICHD) Neonatal BPD Outcome Estimator, developed in 2011, to quantify the risk (22). The model predicts four BPD outcomes (no BPD, mild, moderate, severe) or death based on demographic

variables and respiratory support for one postnatal day and is restricted by range limits for birth weight, gestational age, and race/ethnicity (only applicable for white, black, and Hispanic) (22). The Estimator is an easily accessible tool (23) for identifying infants with a risk of high severity BPD who may significantly benefit from postnatal corticosteroids.

A systematic review and meta-analysis showed that the Estimator is currently the best prediction tool for BPD (24). Yet, there is no clear consensus on how the Estimator should be used clinically. Recently, Baud et al. further validated the Estimator externally using a French cohort and attempted to optimize the model by introducing three additional variables - respiratory support at baseline, center effect, and multiple pregnancies (25). While the original and the modified models both provide plausible C statistics results, the evaluation of each model's accuracy, based on an optimal probability cutoff for each severity category, has not been extensively reported. Furthermore, Cuna et al. showed that a combined probability score of severe or death (> 37%) along with a no BPD probability score (< 3%) on postnatal day 14 was predictive of systemic corticosteroid administration, suggesting that the probability scores may be used independently or in combination (26). Since the study still did not provide a cutoff value for BPD outcome prediction, it remains unclear whether the severity category bearing the highest probability score should be considered the predicted BPD outcome or whether probability scores from different severity categories should be combined for clinical use.

"This study investigated how to translate the probabilities for each BPD category best to be clinically informative. We hypothesize that a comprehensive understanding of the probability trajectories for each BPD severity category is crucial to developing an optimal methodology for interpreting the results of the Estimator."

This study investigated how to translate the probabilities for each BPD category best to be clinically informative. We hypothesize that a comprehensive understanding of the probability trajectories for each BPD severity category is crucial to developing an optimal methodology for interpreting the results of the Estimator.

Subjects and Methods

Study population and data collection

This observational retrospective study was approved by Loma Linda University Institutional Review Board with a waiver for informed consent. Preterm infants included in the study were born at 30 weeks gestational age (GA) or less with a race/ethnicity designated as white, black, or Hispanic. All infants were admitted to the neonatal intensive care unit (NICU) at the Loma Linda University Children's Hospital between 2015 and 2020 with respiratory data available at postnatal days 1, 3, 7, 14, 21, and/or 28 and at 36 weeks' CGA for BPD outcome assessment. The categories of race/ethnicity and the discretization of the postnatal days are limitations set by the Estimator.

Demographic data including sex, race/ethnicity, birth weight, gestational age at birth, mortality before 36 weeks' CGA, as well as clinical data such as antenatal steroids, mode of delivery, postnatal steroids, and patent ductus arteriosus treatment, were collected with chart review. Notably, antenatal steroids were considered as administered if the mother received at least one dose prior to delivery. Additionally, we defined postnatal steroids (i.e., dexamethasone) as prescribed for BPD if given for a full 10-day course or more.

Other demographic information including birth GA, birth weight, sex, race/ethnicity, and respiratory data including ventilator type and oxygen fraction (FiO_2) on six postnatal days (1, 3, 7, 14, 21, and 28), when available, were obtained from the infants' medical charts. If a birth weight fell out of the range required by the Estimator (which differs for each GA), the closest weight suggested by the tool was used. Based on the options available in the Estimator, ventilator types were categorized into (1) high-frequency ventilation, which included high-frequency oscillator and high-frequency jet ventilator; (2) IMV/SIMV, which included conventional tidal ventilators; (3) continuous positive airway pressure (CPAP), which included regular CPAP or non-invasive positive pressure ventilation (NIPPV); (4) cannula/hood, which included either high-flow and low-flow nasal cannula. After entering the demographic and respiratory data into the Estimator, the probability scores for each BPD severity category were generated and recorded for the trajectory model development and validation.

BPD clinical outcome designation

The 2001 definition of BPD severity category was used to categorize respiratory outcomes, in which respiratory support of fewer than 28 days was defined as no BPD; respiratory support of more than 28 days with no need for respiratory support at 36 weeks CGA was defined as mild; respiratory support of more than 28 days with continued support at 36 weeks CGA by nasal cannula with FiO_2 < 30% was considered moderate, and respiratory support of more than 28 days with support at 36 weeks by nasal cannula with FiO_2 ≥ 30% or by positive pressure support was defined as severe BPD (13). Infants meeting the inclusion criteria but died before reaching 36 weeks CGA were included in the death category.

Severity probability score trajectory model development

Upon initial assessment of the probability score trajectories for each severity category, a non-linear trend was noted. Additionally, given repeated measurement of ventilator type and FiO2 across postnatal days of each infant, we utilized a generalized additive mixed modeling (GAMM) algorithm to model trajectories of the probability scores. In the initial model, we included the five severity categories of the outcome probabilities for each of the five clinical outcomes (*severity-by-outcome*, 25 levels) as fixed-effect; we also included a smoothed function of the *postnatal day* alongside its interaction with *severity-by-outcome*. In the subsequent models, the levels of the *severity-by-outcome* variable were reduced to 10 levels encompassing two severity categories for each of the five clinical outcomes or to 2 levels encompassing one severity category for dichotomized clinical outcome groups. The residual term distribution was assessed to ensure model adequacy. Generalized cross-validation was performed during the fitting process.

Table 1. Patient characteristics.

Variable \ BPD Group	No BPD/Mild/Moderate	Severe/Death	P value
Number of patients	220	249	-
Female	121 (55%)	100 (40.2%)	0.002
Race/ethnicity			0.44
White	51	46	
Black	41	47	
Hispanic	128	156	
Median gestational age	27 week 6 days	25 week 4 days	< 0.001
Mean birth weight	950 ± 186 grams	774 ± 186 grams	< 0.001
Death before 36 weeks CGA	0	53	<0.001
Antenatal steroids			0.29
Yes	202	218	
No	16	26	
Unknown	2	5	
C-section	157 (79%)	174 (70%)	0.80
Postnatal steroids	8	76	<0.001
Postnatal steroids ≤ 28 days of life	6	32	<0.001
Patent ductus arteriosus			
Medical treatment	26	31	0.95
Surgical Ligation	12	54	<0.001
Embolization	2	8	
Number of training data points	1,200	984	-
Number of testing data points	58	191	-

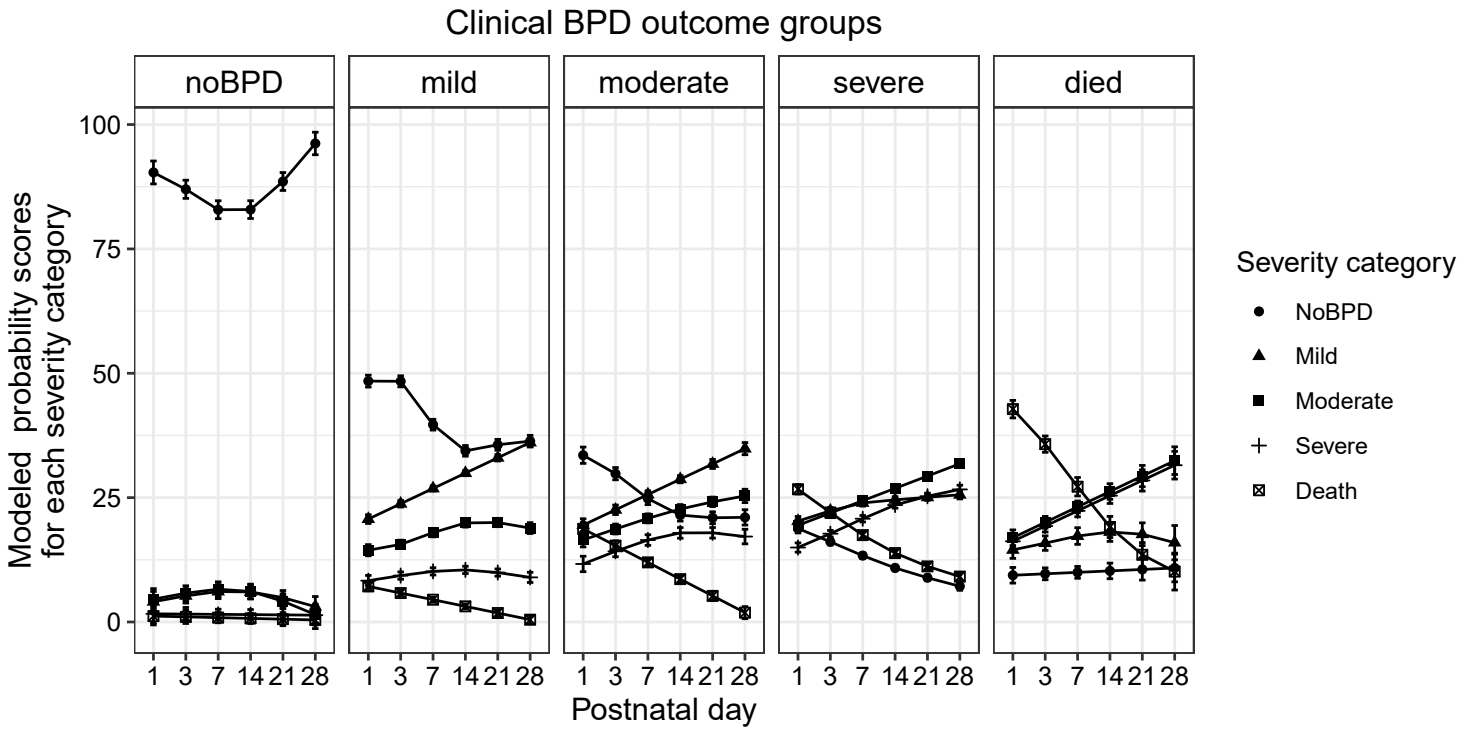

Figure 1. *Trajectories of probability scores of each severity category for each clinical BPD outcome group. A plot for the modeled trajectories of the probabilities of each severity category for each postnatal day stratified by clinical BPD outcome. Dots represent predicted values; error bars represent 95% confidence intervals.*

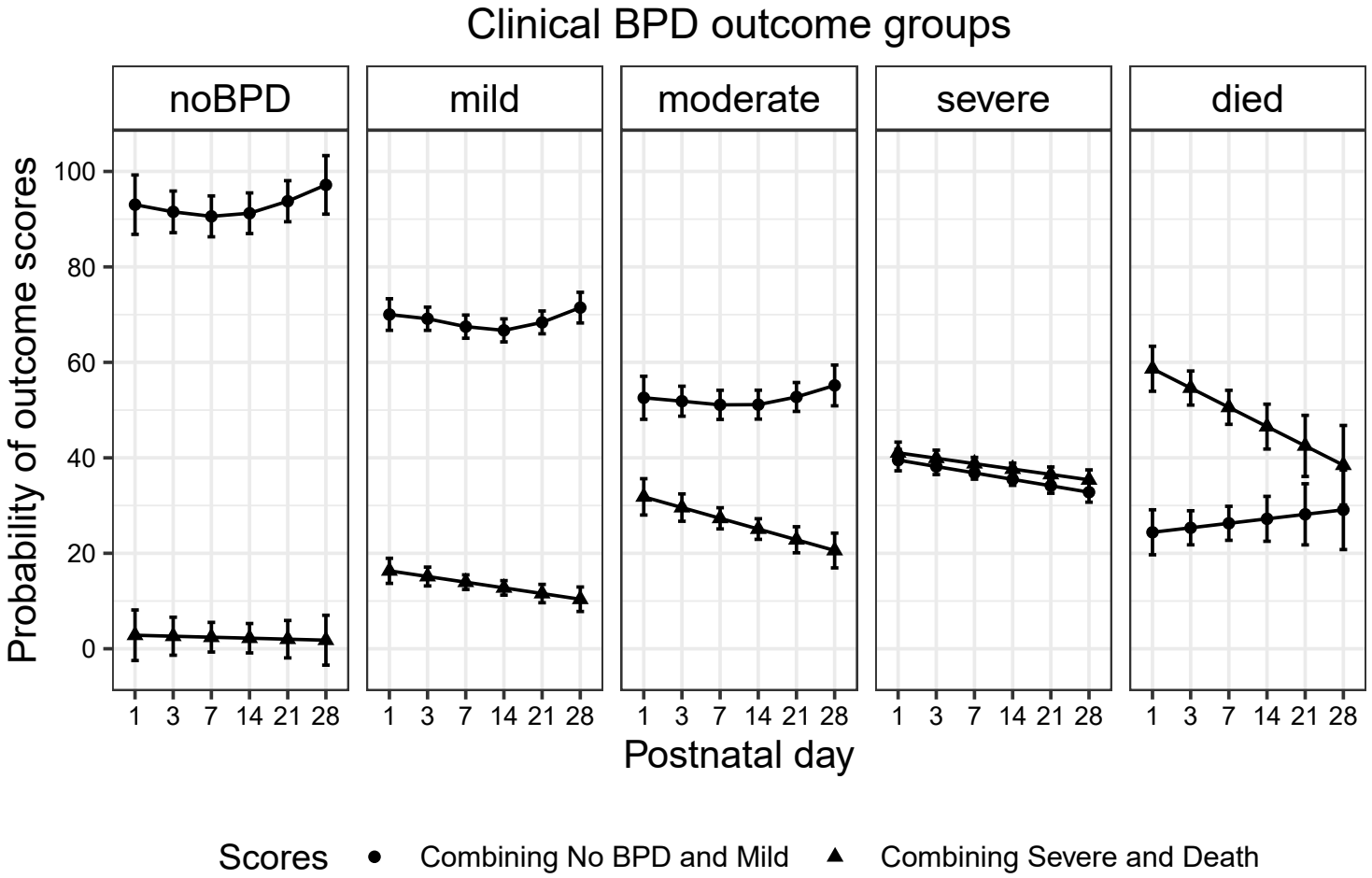

Figure 2*. Trajectories of combined probability scores for each clinical BPD outcome group. A plot for the modeled trajectories of the probabilities of each postnatal day stratified by clinical BPD outcome following combining the probability scores for no BPD and mild categories as well as severe illness and death categories. Dots represent predicted values; error bars represent 95% confidence intervals.*

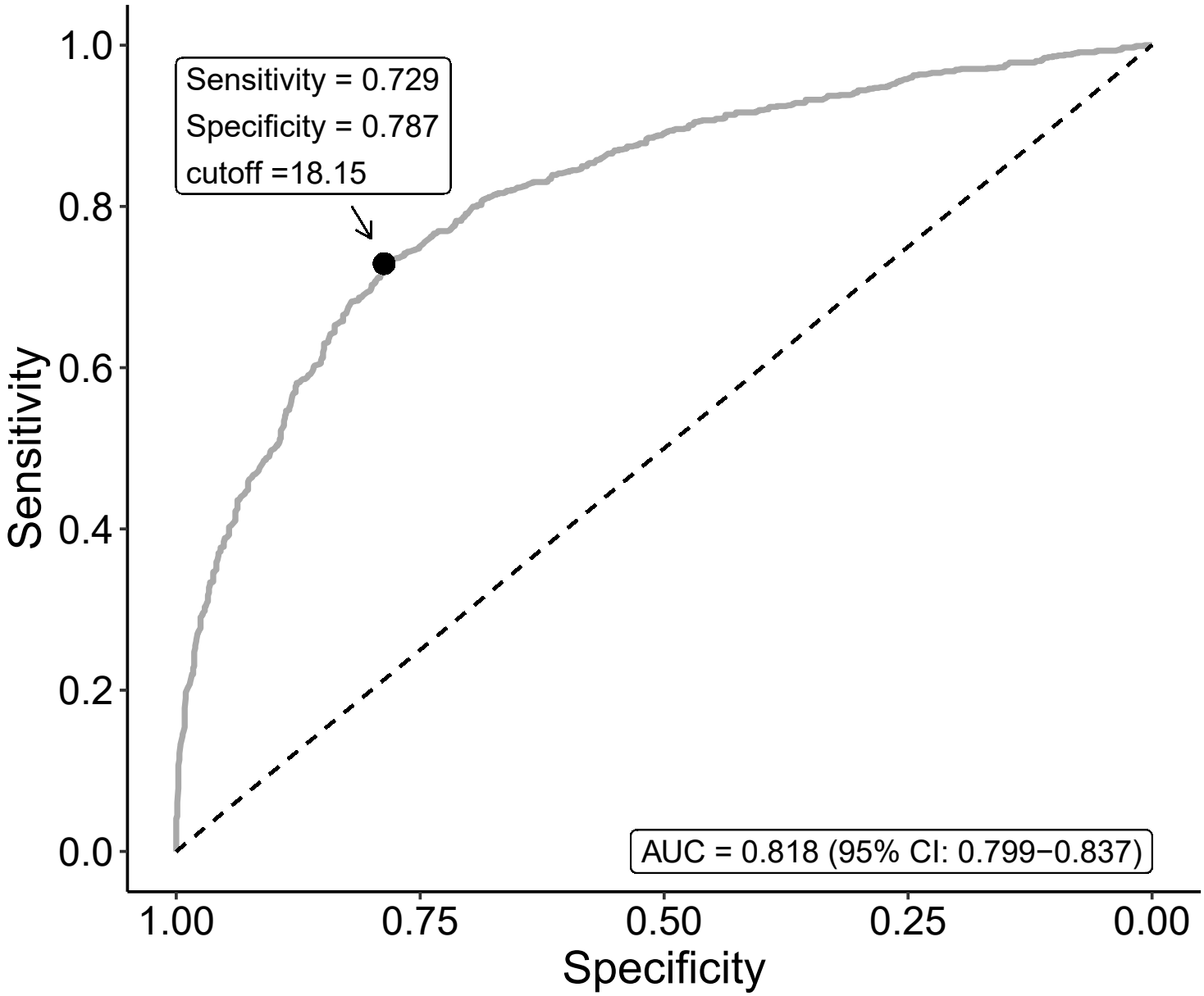

Figure 3. A receiver's operating characteristic curve shows the BPD outcome's predictability using combined probability scores of severe disease and death. The curve showed the relationship between sensitivity and specificity using various cutoff points for the combined probability scores. The area under the curve (AUC) was 0.818 (95% confidence interval: 0.799-0.837). A Youden's J statistics showed a cutoff of 18.15 provides the most balanced sensitivity and specificity.

The final model equation is as follows:

Probability score = severity-by-outcome + smoothed(postnatal day, by = severity-by-outcome)

Statistical analysis and performance assessment

Descriptive statistics were performed to characterize the patient population. Student's *t*-test or Wilcoxon rank-sum test was used for continuous variables, and *chi*-squared test was used for the categorical variables.

For binary outcome prediction, a confusion matrix was used. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated. Additionally, the area under the receiver's operating characteristic (auROC) curve was calculated to assess the predictability of respiratory outcome using combined probabilities from the Estimator.

All statistical analyses were performed in R 4.1.0 using RStudio 1.4 (27). The GAMM models were developed using the *gamm4* package (28). Codes are available upon request.

Results

Infant characteristics

We identified 469 infants from 2015 to 2020, meeting inclusion criteria with a total of 2,433 respiratory data points (infants born at outside hospitals may not have respiratory data prior to transfer for probability score calculation). Detailed patient characteristics are available in Table 1. Out of the 469 infants, 220 with no BPD, mild, or moderate were categorized as "non-severe," whereas the other 249 infants were categorized in the "severe" group. Fifty-five percent of the infants in the non-severe group were female,

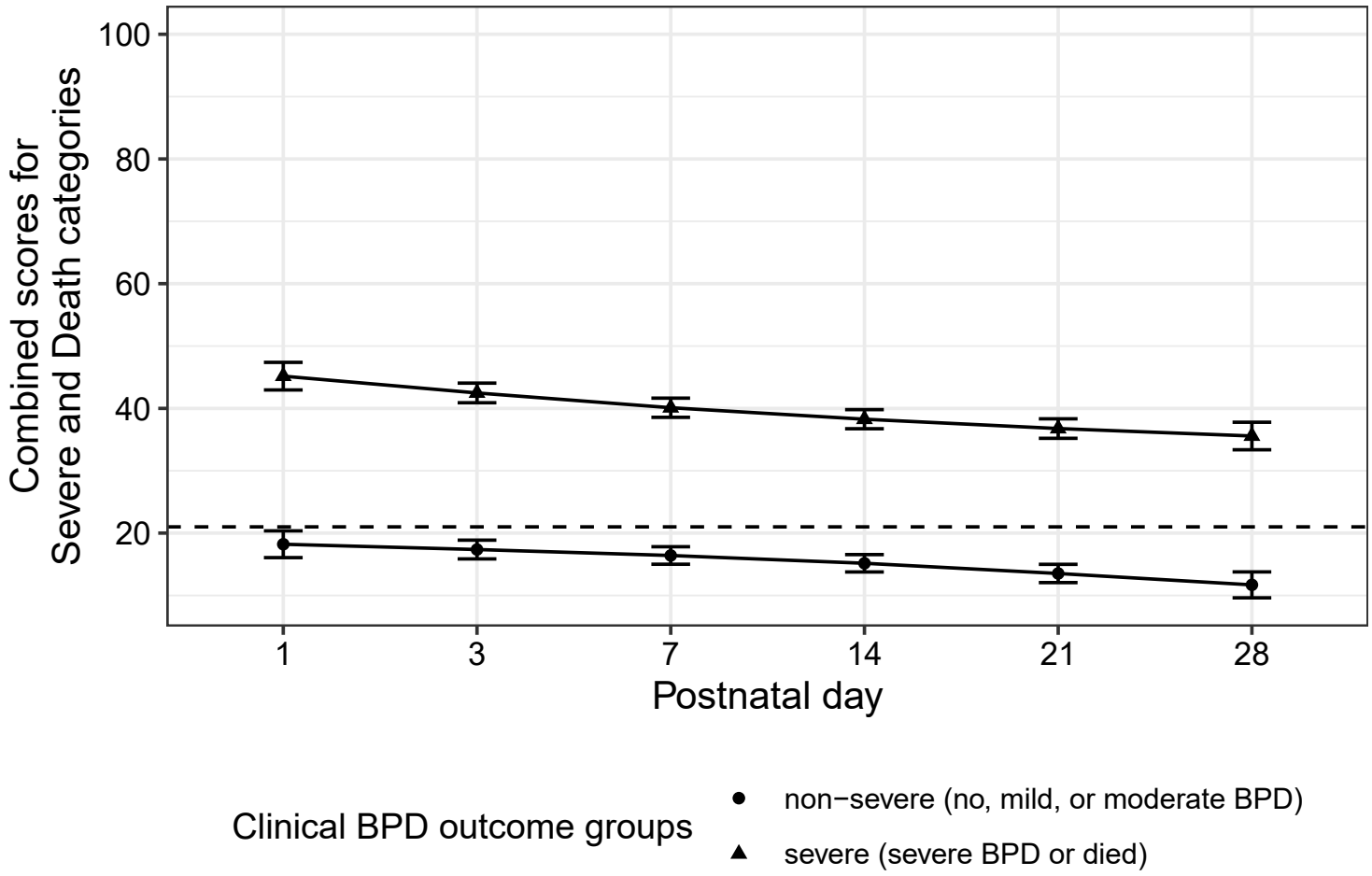

Figure 4. Trajectories of combined probability scores for dichotomized clinical BPD outcome groups. A plot for the modeled trajectories of the probabilities of each postnatal day following combining the probability scores for severe and death categories and dichotomizing the clinical BPD outcome groups into the non-severe (no, mild or moderate BPD outcome) group and the severe (severe BPD or died before 36 weeks' corrected gestational age) group. Dots represent predicted values; error bars represent 95% confidence intervals. The horizontal dashed line represents the cutoff number of 21.

compared to 40% in the severe group. The mean GA in the non-severe group was 27 weeks 5 days ± 1 week 6 days, compared to 25 weeks 6 days ± 1 week 6 days in the severe group (p<0.001, Table 1).

Additionally, the mean birth weight was 950 ± 186 grams in the non-severe group, compared to 774 ± 186 grams in the severe group (p<0.001). There was no significant difference between the rate of antenatal steroids and the mode of delivery between the two groups. Infants in the severe group were significantly more likely to receive corticosteroid intervention and invasive intervention for patent ductus arteriosus (PDA). Demographic and clinical comparisons are available in Table 1.

Performance of the Estimator using the highest score of the probability of an outcome for BPD outcome prediction

We first assessed the Estimator's performance by using the maximum probability scores to predict BPD severity. The prediction was assigned by the severity category with the highest probability of outcome score. A five-by-five confusion matrix was constructed (Table 2) and showed a poor correlation between clinical BPD outcome and predicted outcome, with an overall accuracy rate of 29%.

Generalized additive modeling of the trajectories of the probability of outcome scores

All 2,433 sets of probability score data from 469 infants, including 31, 125, 64, 189, and 60 infants in the no BPD, mild, moderate, severe, and death group, respectively, were used to develop the trajectory model. The modeled trajectories for each respiratory outcome group are shown in Figure 1. Each column represents a clinical BPD outcome or death. Every curve in each clinical outcome represents a trajectory of the probabilities for one severity category over time. The no BPD clinical outcome group showed a distinct predicted probability curve for the no BPD severity category with predicted values all above 80. However, in the clinical outcome groups of mild, moderate, severe, and death, the trajectories for each severity category demonstrated increasing overlapping as the clinical outcome severity increased. The modeled trajectories of the outcome probabilities confirmed that using the highest probability score to predict clinical BPD outcome is inadequate other than for the no-BPD group.

Combining probability of outcome scores from different severity

Clinical outcome / Predicted outcome	No BPD	Mild	Moderate	Severe	Death
No BPD	175	386	108	127	17
Mild	1	276	119	311	16
Moderate	1	42	57	265	19
Severe	0	7	33	149	19
Death	0	16	37	188	64

Table 2. Comparison between actual clinical and predicted BPD outcome using the NICHD BPD Outcome Estimator probability scores. The numbers shown in the table are the numbers of patients in each corresponding outcome category.

categories

Infants with severe BPD or who died before 36 weeks' CGA had a higher likelihood of needing invasive treatment for PDA and were more likely to receive systemic corticosteroid treatment, representing infants on the worse end of the spectrum in terms of the respiratory outcome at 36 weeks' CGA. On the other hand, infants with no BPD or mild did not require any respiratory support at 36 weeks' CGA, representing the better end of the spectrum in terms of respiratory outcome. Based on these clinical features, we combined probability scores for severe BPD and death into one score and scores for no BPD and mild into another score, followed by repeating the trajectory modeling of the new combined scores (Figure 2). The predicted trajectories of combined probability scores showed a significantly improved distinction both across the five clinical BPD outcome groups and across the scoring groups (no BPD + mild vs. severe BPD + death). This approach of combining the probability scores represents a better model for predicting clinical BPD outcomes.

Identifying the optimal cutoff threshold to maximize prediction

Infants predicted to have severe BPD or death are the target population for early interventions, such as providing an aggressive nutrition program, vitamin A injections, and/or systemic corticosteroid administration. The population used for the model development of the Estimator included 26% of infants, approximately, that had severe BPD or death before 36 weeks' CGA (22). If the distribution of the clinical outcome in our cohort was similar to the distribution of the population used to develop the model, a combined score (severe + death) of 26 would likely be an ideal cutoff. Due to the much higher percentage (53%, 249 out of 469) of infants in our cohort's severe and death clinical outcome categories, we require a lower cutoff threshold. To further identify the optimal cutoff, the outcome probabilities for both severe BPD and death severity categories were combined, and a ROC curve was generated by comparing the combined probabilities with clinical BPD outcomes of either severe or death (Figure 3). The ROC curve showed an auROC of 0.818 (95% CI: 0.799-0.837). The optimal cutoff based on Youden's J statistic was 18% (29). To maximize sensitivity, specificity, PPV, NPV, and accuracy altogether, we performed a grid search between 18 and 26 as cutoff scores for each postnatal day using probability data from 80% of randomly selected infants. The clinical BPD outcome was dichotomized into a non-severe (no, mild, or moderate BPD) group and a severe (severe BPD or death before 36 weeks' CGA) group. After incorporating all postnatal days, we identified a combined score of 21 as the most optimal cutoff score, giving an overall accuracy of approximately 75%. The performance was comparable using data from the remaining 20% of the infants. The complete characterization of the prediction performance is shown in Table 3. For a visual depiction, Figure 4 showed the trajectories of the combined probability of outcome scores for severe BPD and death for dichotomized clinical outcome groups comparing infants with non-severe (no BPD, mild, or moderate) disease vs. infants with severe disease (severe BPD or death before 36 weeks' CGA).

Discussion

In this report, we systematically assessed the probability scores calculated by the NICHD BPD Outcome Estimator in 469 very preterm infants. Our analysis suggested that individual probability scores may not be adequate in prediction, but combining probabilities and trending combined probability scores over time may be more informative to clinicians. Using our regional cohort, we further demonstrated that a summed score from the severe and death categories of more than 21 accurately predicted a dichotomized clinical BPD outcome in 75-80% of infants.

Evidence suggests a developmental origin of BPD (30). Using respiratory data in the first 28 days of postnatal life can be viewed as one way to assess the potential reversibility of the impact of antenatal factors on BPD development and the need for interventions to alter the trajectory of BPD pathology early on in life.

A common goal for BPD Estimator use is to assist clinicians in determining whether systemic corticosteroid administration is justifiable. Studies have shown that systemic corticosteroid use in a group of infants, along with 50% requiring oxygen therapy at 36 weeks CGA, showed a clinical benefit by reducing mortality or cerebral palsy (31). This cutoff number is similar to the percentage (approximately 46%) of infants in the moderate, severe, or death outcome categories used to develop the models for the Estimator. In this study, the most optimal cutoff number assessed by the ROC curve (18%) was much lower than the percentage of

Postnatal day / Parameter	Day 1	Day 3	Day 7	Day 14	Day 21	Day 28
Exploratory dataset for grid search						
Sensitivity	0.764	0.740	0.730	0.755	0.691	0.710
Specificity	0.741	0.742	0.750	0.738	0.807	0.831
Positive Predictive Value	0.750	0.720	0.720	0.717	0.755	0.793
Negative Predictive Value	0.755	0.761	0.759	0.774	0.751	0.759
Accuracy	0.752	0.741	0.741	0.746	0.753	0.774
Validation dataset						
Sensitivity	0.805	0.825	0.833	0.884	0.810	0.744
Specificity	0.641	0.675	0.800	0.700	0.800	0.800
Positive Predictive Value	0.702	0.717	0.814	0.760	0.810	0.800
Negative Predictive Value	0.758	0.794	0.821	0.848	0.800	0.744
Accuracy	0.725	0.750	0.817	0.795	0.805	0.771

Table 3. Assessing performance of combined probability scores for BPD severity prediction. Performance of the NICHD Neonatal BPD Outcome Estimator using combined scores of the severe and death categories with a cutoff number of 21, above which predictive of a severe (positive) disease outcome and below which predictive or a non-severe (negative) disease outcome. The actual clinical outcome was dichotomized into the severe (severe BPD or death before 36 weeks' corrected gestational age) group and the non-severe (no, mild or moderate BPD) group for comparison.

infants in the severe and death outcome categories (26%) used to develop the Estimator, suggesting that the Estimator may underestimate the severity of BPD in infants in our cohort. In other words, our findings suggest that the infants admitted to our NICU may require higher acuity care and prolonged respiratory support compared to the cohort used to develop and validate the Estimator. We must also acknowledge that our findings may suggest room for improvement in our neonatal respiratory management approaches. One possible improvement would be to develop a geographically localized cutoff number to improve predictability. Baud et al. found a significant influence of a center-related effect in their efforts to improve the predictability of the Estimator (25). Unfortunately, this regional effect becomes diluted in a large cohort.

We recently modeled postnatal weight and weight z-score trajectories of extremely preterm infants using GAM to faithfully summarize weight gain at various stages of development in the NICU (32). Here, we adopted a similar approach and modeled trajectories of outcome probabilities using our institutional data. Trajectory analysis using a mixed modeling approach with interaction terms allows for a better understanding of interrelationships in the overall direction of the propagation of the probability scores across the clinical outcome groups in one model. Unfortunately, the trajectories across various clinical outcome groups, especially in the mild, moderate, and severe BPD groups, was that the relationship among trajectories within each clinical outcome group was resemblant across clinical outcome groups. These findings confirm that using the probability scores directly from the Estimator would not be feasible. A recent report comparing various grouping strategies also suggested that the grouping strategy used for the Estimator may not be clinically informative (33). In this report, the most optimal grouping strategy did not support a correlation between respiratory support needs for more than 28 days and BPD development. Furthermore, respiratory support modality, rather than FiO_2, demonstrated a better correlation with BPD outcome.

Multiple antenatal and postnatal non-respiratory factors have been shown to play a significant role in the respiratory outcome and BPD (25,30). The original Estimator does not incorporate these risk factors into the prediction models developed for a single postnatal day. The Estimator only accounts for two respiratory variables: ventilator type and the fraction of inspired oxygen which may change over time. This approach to predictive model development makes the disadvantageous presumption that all factors contributing to BPD development, known or unknown, can be summarized by these two respiratory variables. This assumption inevitably leads to prediction error when these two respiratory factors cannot encapsulate other contributing factors. For example, infants affected by intrauterine growth restriction may perform su-

perior to those born at the same GA. Yet, they frequently require prolonged respiratory support beyond 36 weeks CGA and are more likely to be diagnosed with BPD (34). On the other hand, significant events (systemic corticosteroid administration, late-onset sepsis, stage 3 necrotizing enterocolitis, among others) that usually occur after 28 postnatal days may alter the trajectory of respiratory support and change the respiratory outcome at 36 weeks CGA. This illustrates why a model that considers these events would improve predictability (25). Future work may focus on incorporating antenatal exposure variables and postnatal comorbidity variables to assess which variables may improve prediction accuracy. Such effort will aid clinical decision-making and provide greater insight and understanding into how non-respiratory factors may affect respiratory outcomes.

Using the new grading system for BPD, a recent report using the Vermont Oxford Network data found a positive correlation between the grades and adverse respiratory outcomes such as supplemental oxygen use after hospital discharge and tracheostomy (35). Moreover, the study also showed that most of the non-respiratory comorbidities of extreme prematurity were associated with mechanical ventilator use at 36 weeks CGA (Grade 3). Future work could include developing prediction tools for outcomes stratified by respiratory support type at a predefined postnatal age and/or for long-term respiratory outcomes beyond infancy.

Limitations

The study is limited by a lack of prospective and external validation. Additionally, the intrinsic limitations of the Estimator, including low temporal resolution (6 time points out of 28 days), the use of only two respiratory variables, and the lack of non-respiratory factors that may impact the respiratory outcomes in the model are also inherited as limitations to this study.

Conclusion

In this study, we found that the NICHD Outcome Estimator was prone to underestimating the respiratory severity of our preterm infants. A longitudinal approach based on non-linear modeling of the severity probability score trajectories was proposed, which significantly improved prediction accuracy. Our study emphasizes the crucial role of longitudinal assessment of the respiratory trajectory. Future work may include incorporating more detailed respiratory data alongside antenatal and postnatal non-respiratory comorbidity data to improve respiratory outcome prediction further.

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Funding

Not applicable

Author contribution

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Minha Cha	Collect data, critically review the initial manuscript
Chelsea Kent	Collect data, critically review the initial manuscript
Hung-Wen Yeh	Interpret data and critically review the initial manuscript
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Disclosures: The authors declared no conflict of interest related to this manuscript.

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What do we know about COVID-19 Vaccines for Children?

Reese H. Clark, MD, Veeral N. Tolia, MD, Curtis B. Pickert, MD

Introduction

Our goal is to review the current literature on the safety and efficacy of COVID-19 vaccines in children, some of which will be out of date before the end of the month. There is still much to be learned about vaccines to prevent COVID-19 in children.

The accumulating data in adults is encouraging. Authorized mRNA vaccines are highly effective in preventing SARS-CoV-2 infection and severe disease when administered in real-world conditions. Vaccines attenuated the viral RNA load, risk of febrile symptoms, and duration of illness among those who had breakthrough infection despite vaccination. (1)

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Why are safe, effective vaccines for children needed?

1. Protect children from acute infections with COVID-19 and reduce the risk of Multisystem Inflammatory Syndrome in children (MIS-C).
2. Facilitate in-person learning and socialization and promote mental health support for recovery from the ill effects of social isolation.
3. Contribute to herd immunity.
4. Improve access to all forms of care. Shelter-in-place orders have been associated with declines in outpatient pediatric visits and fewer vaccine doses administered, leaving children at risk for vaccine-preventable diseases. Establishing herd immunity can improve access to all forms of care (spiritual, mental, health, and physical) and all vaccines.

What is known

1. There are at least two distinctively different COVID-related diseases in children: an acute illness that is similar, but not the same, as that seen in adults, and MIS-C. There is also increasing evidence that children can have persistent symptoms (Long COVID) following testing positive for COVID-19.
2. While it is rare, children can become critically ill and die with COVID-19.
3. Vaccines elicit an immune response to the components that make up the vaccine, and the immune response is different in children than in adults.
4. The BNT162b2 (Pfizer–BioNTech) vaccine in adolescents between 12 to 15 years was at least 75% (lower 95% confidence limit) effective in preventing Covid-19 cases with an onset of 7 or more days after dose 2. Currently, this is the only vaccine with FDA emergency authorization for children.
5. Common adverse events (e.g., local injection reactions, headache, fatigue, muscle aches, and fever) resolve without treatment and are not serious.

What is not known

1. Duration of protection for any vaccine in any age group
2. The immune response to COVID-19 is different in children; it will be important to understand that to define the pathophysiology of MIS-C.
3. How well do vaccines prevent people from spreading COVID-19 to others?
4. How effective vaccines are for preventing new variants of the virus that causes COVID-19.
5. Why states chose different ways to define the term "child," variable definitions created different denominators in reported rates, creating confusion when rates of disease or adverse events in "children" are reported. Children population cohorts are variably defined as <18 years old or <21 years old.
6. What rare serious adverse events are truly related to vaccination and when to anticipate their occurrence in relation to receiving the vaccine (first vs. the second dose).
7. How the Delta Variant of SARS-CoV-2 changes the risk of infectivity, long and short-term disease in children?
8. Nothing in medicine is 100 percent safe and effective. Never say "always works" or "never hurts." Our job as clinicians is to weigh the risks and benefits, often without perfect knowledge of efficacy or safety.

Context/prevalence/incidence/severity of disease in children

There are two distinctively different COVID-related diseases in

children; an acute illness that is similar, but not the same, as that seen in adults, and MIS-C. CDC defines children as under 21 years old. The incubation period for acute infection with SARS-CoV-2 in children is 2-14 days with an average of 6 days. The signs and symptoms of acute COVID-19 in children are like influenza, streptococcal pharyngitis, and allergic rhinitis. The lack of specificity of signs or symptoms and the significant proportion of asymptomatic infections make symptom-based screening for identification of SARS-CoV-2 in children particularly challenging. (2)

"The lack of specificity of signs or symptoms and the significant proportion of asymptomatic infections make symptom-based screening for identification of SARS-CoV-2 in children particularly challenging. (2)"

In "Children and COVID-19: State-Level Data Report," the definition of a "child" case is based on varying ages (0-14, 0-17, 0-18, 0-19, and 0-20 years) reported across different states. Summary data from the AAP report shows that of children tested, 5%-35% test positive for COVID-19. As of September 2, 5 million children have tested positive for COVID-19. There were 251,781 cases added 8/26/21-9/2/21, five times the number of cases reported during weeks in July. Children now represent 15.1% of all COVID-19 cases reported since the beginning of the pandemic. From 8/12/21-8/19/21, children represented 22.4% (180,175/806,003) of the weekly reported cases. 251,781 child COVID-19 cases were reported the past week from 8/26/21-9/2/21, and children represented 26.8% (251,781/939,470) of the weekly reported cases. (3) COVID-19–associated hospitalization rates among children and adolescents rose nearly five-fold from late June to mid-August 2021. (4)

When infected, children generally remain asymptomatic or develop mild disease. Between 0.2 and 1.9 percent of children with COVID-19 require hospitalization, and 1 in 3 children hospitalized with COVID-19 in the United States are admitted to the intensive care unit. (1) Mortality in children with critical disease has been reported to be 3.8%. (5,6)

The CDC reports 412 COVID-related deaths in children 0-17 years old in 2020 and 2021 through September 2, 2021. (7) Child deaths due to COVID-19 are rare and generally occur in children with comorbidities. The most common reported comorbidities are chronic lung disease (including asthma), cardiovascular disease, and immune suppression. In studies from the United States, an underlying medical condition was noted in 77% of hospitalized children, in contrast with 12% of those not hospitalized. (8)

Since mid-May 2020, the CDC has tracked case reports of MIS-C (children <21 years old), a rare but serious condition associated with COVID-19. As of August 27, 2021, there were 4661 total cases of MIS-C and 41 deaths in children meeting the case definition. (9) *The median age of patients with MIS-C is nine years. Half of the children with MIS-C are between the ages of 5 and 13 years.* Sixty-two percent of the reported patients with race/ethnicity information available occurred in Hispanic children or Latino (n=1,280) or Black, Non-Hispanic (n=1,077 cases). Ninety-nine percent of patients had a positive test result for SARS CoV-2. The remaining 1% of patients had contact with someone with COVID-19. Sixty percent of reported patients were male. (9)

Of 394 *PICU* patients with Coronavirus Disease, 171 (43.4%) had MIS-C. Children with MIS-C were more likely younger (2–12 years vs adolescents; $p < 0.01$), Black (35.6% vs 21.9%; $p < 0.01$), more likely to present with fever/abdominal pain than cough/dyspnea ($p < 0.01$), and less likely to have comorbidities (33.3% vs 61.9%; $p < 0.01$) compared with those without MIS-C. Inflammatory marker levels, use of inotropes/vasopressors, corticosteroids, and anticoagulants were higher in MIS-C ($p <0.01$). Overall mortality was 3.8% (15/394), with no difference in the two groups. Diagnosis of MIS-C in children was associated with a longer duration of hospitalization as compared to non-MIS-C in children (7.5 d [interquartile range, 5–11] vs. 5.3 d [interquartile range, 3–11 d]; $p < 0.01$). (5)

There are emerging reports of long COVID-19 in children. Symptoms range from cough and shortness of breath to fatigue, headache, palpitations, chest pain, joint pain, physical limitations, depression, and insomnia. Data from the United Kingdom Coronavirus Infection Survey found that 13% of children under the age of 11 and 15% of children ages 12 to 16 years continued to have at least one symptom five weeks after testing positive for COVID-19. (10)

"During the pandemic, parents with children ages 5-12 reported their children showed elevated symptoms of depression (4%), anxiety (6%), and psychological stress (9%); and experienced overall worsened mental or emotional health (22%)."

Mental health impact of impact on children

During the pandemic, parents with children ages 5-12 reported their children showed elevated symptoms of depression (4%), anxiety (6%), and psychological stress (9%); and experienced overall worsened mental or emotional health (22%). More than 25% of high school students reported worsening emotional and cognitive health, and over 20% of parents with children ages 5-12 reported similar worsening conditions for their children. (11)

Relevant data with respect to the population of children included in the BNT162b2 (Pfizer–BioNTech) trial

"BNT162b2 (Pfizer–BioNTech) is a Covid-19 vaccine containing *nucleoside-modified messenger RNA encoding the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike glycoprotein.* In healthy adults, two 30-µg doses of BNT162b2 elicited high neutralizing titers and robust, antigen-specific CD4+ and CD8+ T-cell responses against SARS-CoV-2. In phase 2–3 part of an *ongoing global* clinical trial in people 16 years of age or

older, BNT162b2 had a favorable safety profile characterized by transient mild-to-moderate injection-site pain, fatigue, and headache and was 95% effective in preventing Covid-19 from 7 days after dose 2. Based on these findings, BNT162b2 received emergency use authorization from the Food and Drug Administration (FDA) on December 11, 2020, for Covid-19 prevention in persons 16 years of age or older. *On May 10, 2021, the emergency use authorization was expanded to include persons 12 years of age or older based on data reported to the FDA." (12,13) On August 23, 2021, the FDA approved the first COVID-19 vaccine. The Pfizer-BioNTech COVID-19 Vaccine is approved to prevent COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals. (14)*

FDA Evaluation of Effectiveness Data

The effectiveness data to support the EUA in adolescents down to 12 years of age is based on immunogenicity and analysis of COVID-19 cases. The immune response to the vaccine in 190 participants, 12 through 15 years of age, was compared to the immune response of 170 participants, 16 through 25 years of age. (13) The immune response (based on Serum Neutralization Assay) was greater in adolescents than in young adults.

An analysis of cases of COVID-19 occurring among participants, 12 through 15 years of age, seven days after the second dose was also conducted. In this analysis, among participants without evidence of prior infection with SARS-CoV-2, no cases of COVID-19 occurred among 1,005 vaccine recipients, and 16 (1.6%) cases of COVID-19 occurred among 978 placebo recipients; the vaccine was 100% effective in preventing COVID-19. (12) The observed vaccine efficacy was 100% (95% CI, 75.3 to 100). There are limited data to address whether the vaccine can prevent transmission of the virus from person to person. At this time, data are not available to determine how long the vaccine will provide protection.

FDA Evaluation of Available Safety Data in Adolescence 12-15 (13)

Phase 1/2/3 of the Pfizer-BioNTech COVID-19 Vaccine trials have enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. *Of 2,260, 1,131 adolescent participants received the vaccine, and 1,129 received a saline placebo. More than half of the participants were followed for safety for at least two months following the second dose.*

Adverse events in children 12-15 years of age.

Common side effects in the adolescent clinical trial participants were pain at the injection site, tiredness, headache, chills, muscle pain, fever, and joint pain. Symptoms typically lasted 1-3 days. More adolescents reported side effects after the second dose than after the first dose.

Serious Adverse Events (SAEs) in children 12-15 years of age.

The frequency of SAEs was low among all participants; five serious adverse events (0.4%) were reported among vaccine recipients and two (0.2%) among placebo recipients, with no statistically significant difference in frequency observed between the two groups. None of the SAEs were considered related to the vaccine.

Ongoing Safety Monitoring

Pfizer Inc. and vaccination providers must report the following to the Vaccine Adverse Event Reporting System for Pfizer-BioNTech COVID-19 Vaccine: all vaccine administration errors, serious adverse events, cases of MIS-C, and cases of COVID-19 that result in hospitalization or death.

"As of July 16, 2021, approximately 8.9 million US adolescents aged 12–17 years had received the Pfizer-BioNTech COVID-19 vaccine."

As of July 16, 2021, approximately 8.9 million US adolescents aged 12–17 years had received the Pfizer-BioNTech COVID-19 vaccine.

Summary of population-based methods for identifying adverse events in children who are eligible to receive a vaccine (15)

There are two reporting systems.

1. *Vaccine Adverse Event Reporting System (VAERS)* is a passive vaccine safety surveillance system comanaged by CDC and FDA that monitors adverse events after vaccination. Under COVID-19 vaccine emergency use authorization requirements, health care providers must report certain adverse events after vaccination to VAERS, including death. VAERS reports are classified as serious if any of the following are reported: hospitalization or prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death. Reports of serious adverse events receive follow-up to obtain additional information, including medical records; for reports of death, death certificates and autopsy reports are obtained, if available. *CDC physicians reviewed available information for each decedent to form an impression about the cause of death.*
2. *V-Safe.* The CDC established V-Safe, a voluntary smartphone-based active safety surveillance system, to monitor adverse events after COVID-19 vaccination. Adolescents who receive a COVID-19 vaccine are eligible to enroll in V-Safe, through self-enrollment or as a dependent of a parent or guardian and receive scheduled text reminders about online health surveys. Health surveys sent in the first week after vaccination include questions about local injection sites, systemic reactions, and health impacts. *If a report indicated medical attention was sought, VAERS staff members contacted the reporter and encouraged completion of a VAERS report, if indicated.*

VAERS data summary adolescents aged 12–17 years (15)

VAERS received and processed 9,246 reports of adverse events for adolescents aged 12–17 years who received the Pfizer-BioNTech vaccine from December 14, 2020–July 16, 2021. Overall, 8,383 (90.7%) VAERS reports were for non-serious events, and 863 (9.3%) for serious events. Among the 863 serious conditions and diagnostic findings, the common reports were chest pain 487/863 (56.4%), increased troponin levels 360/863 (41.7%),

myocarditis 348/863 (40.3%), and increased c-reactive protein 264/863 (30.6%). (15)

CDC reviewed 14 reports of death after vaccination. Among the decedents, four were aged 12–15 years, and ten were aged 16–17 years. CDC physicians reviewed all death reports; impressions regarding the cause of death were pulmonary embolism (two), suicide (two), intracranial hemorrhage (two), heart failure (one), hemophagocytic lymphohistiocytosis and disseminated Mycobacterium chelonae infection (one), and unknown or pending further records (six). No reports of death to VAERS were determined to be the result of myocarditis. Two cases of severe myocarditis have been reported in adults. (16)

Limitation of VAERS

VAERS is a passive surveillance system and is subject to underreporting and reporting biases. Data in VAERS is not validated. The precise percent of the 8.9 million US adolescents aged 12–17 years who received the Pfizer-BioNTech vaccine and subsequently had an SAE cannot be known because research quality data on each patient who receives a vaccine is not captured. *The denominator used in the tables is not all vaccinated patients; instead, it is the 9,246 adolescents with adverse events who were reported to VAERS. The data reported above only describe the characteristics and demographics of events. (14)*

V-Safe data summary adolescents aged 12–17 years (15)

"During December 14, 2020–July 16, 2021, V-Safe enrolled 66,350 adolescents aged 16–17 years who received the Pfizer-BioNTech vaccine." (15) After the Pfizer-BioNTech vaccine was authorized for adolescents aged 12–15 years (beginning May 10, 2021), V-Safe enrolled 62,709 adolescents in this age group. Less than 1% of adolescents aged 12–17 years required medical care in the week after receiving either dose; 56 adolescents (0.04%) were hospitalized.

"The Vaccine Adverse Event Reporting System (VAERS) had received 1226 (0.000038%) preliminary reports of myocarditis and pericarditis after about 300 million doses of the Pfizer and Moderna vaccines up to June 11, 2021. There were 233 (0.006427%) cases of myocarditis or pericarditis after 3,625,574 second doses administered to men aged 18-24."

Limitation of V-Safe

Approximately 129,000 US adolescents aged 12–17 years voluntarily enrolled in V-Safe after Pfizer-BioNTech vaccination. Voluntary reporting may represent a selected population who are willing to report health care data on themselves. Therefore, V-Safe data might not be generalizable to the overall vaccinated adolescent population. Rates of adverse events could be over-reported. It is reassuring that the CDC V-Safe reported local (63.4%) and systemic (48.9%) reactions with a frequency similar to that reported in preauthorization clinical trials.

Adult and teen myocarditis/pericarditis reports

The Vaccine Adverse Event Reporting System (VAERS) had received 1226 (0.000038%) preliminary reports of myocarditis and pericarditis after about 300 million doses of the Pfizer and Moderna vaccines up to June 11, 2021. There were 233 (0.006427%) cases of myocarditis or pericarditis after 3,625,574 second doses administered to men aged 18-24. Based on population cohort studies, 2 to 25 cases would have been expected. After 5,237,262 doses administered to women in this age group, 27 (0.000516%) cases were reported; 2 to 18 would have been predicted. A similar pattern of risk was seen in children 12-17 years old. (17) The crude reporting rates of myocarditis or pericarditis decreased with increasing age as did the gender differences.

In Israel, 275 (0.0055%) cases of myocarditis were reported between December 2020 and May 2021 among more than five million vaccinated people. Most of the cases were in men aged 16-19, usually after the second dose. In most cases, myocarditis took the form of a mild illness that lasted a few days. (18)

The United States military administered more than 2.8 million doses of mRNA COVID-19 between January 1 and April 30, 2021. Twenty-three male military members patients (median [range] age, 25 [20-51] years) presented with marked chest pain within four days after receipt of an mRNA COVID-19 vaccine. All were previously healthy and physically fit. Seven received the BNT162b2-mRNA vaccine (Pfizer–BioNTech), and 16 received the mRNA-1273 vaccine (Moderna). Twenty patients had symptom onset following the second dose. Testing did not identify other etiologies for myocarditis, including acute COVID-19, infections, ischemic injury, or underlying autoimmune conditions. All patients received brief supportive care and were recovered or recovering at the time of this report. While the number of myocarditis cases was small, the number was higher than expected among male military members. (19)

Joint statement on vaccines and myocarditis or pericarditis. (20)

An exceedingly small number of people will experience myocarditis or pericarditis after vaccination. Importantly, most cases are mild for the young people who do, and individuals often recover independently or with minimal treatment. *Myocarditis and pericarditis are more common if one gets COVID-19, and the risks to the heart from COVID-19 infection can be more severe.*

Adult data on other serious adverse events

Anaphylaxis after COVID-19 vaccination is rare and occurred in approximately 2 to 5 people per million vaccinated in the United States based on events reported to VAERS. (21) This kind of allergic reaction almost always occurs within 30 minutes after vaccination.

Safety monitoring of the J&J/Janssen vaccine suggests a rare risk of a serious adverse event called "thrombosis with thrombocytopenia syndrome (TTS)," which may be associated with the J&J/Janssen vaccine. Most reports of this serious condition have been in adult women younger than 50 years old. It is estimated that one person in 318,750 vaccinated people is at risk for this disease.

"As of June 30, 2021, approximately 141 million second mRNA

COVID-19 vaccine doses had been administered in the United States to persons aged ≥18 years. Within VAERS, 497 reports of myocarditis after the second mRNA COVID-19 vaccine dose were received for persons aged ≥18 years. The reporting rate of myocarditis overall among adults was 3.5 cases per million second doses of mRNA COVID-19 vaccine administered. *In subgroup analyses by age and sex, the reported rate was highest among males aged 18–29 years (24.3 cases per million mRNA COVID-19 vaccine second doses administered). (22)"*

CDC conclusion (23,24)

The Advisory Committee on Immunization Practices conducted a risk-benefit assessment and continues to recommend the Pfizer-BioNTech COVID-19 vaccine for all persons aged ≥12 years.

AAP recommendations (25)

The AAP recommends COVID-19 vaccination for all children and adolescents 12 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age.

After full approval of the Pfizer-BioNTech COVID-19 vaccine, *the AAP released a statement strongly discouraging the off-label use of this vaccine in children 11 years old and younger.* Clinical trials for the COVID-19 vaccine in children ages 11 years old and younger are actively enrolling patients to evaluate the safety and efficacy of the COVID-19 vaccine in this age group. (26,27)

"As of June 11, 2021, the FDA endorsed only the Pfizer-BioNTech vaccine for emergency use in 12- to 17-year-olds. Moderna applied Thursday, June 10, 2021, for authorization for its shot in adolescents aged 12 to 15. No vaccine is authorized or approved for younger children."

Vaccines available as of August 23, 2021

As of June 11, 2021, the FDA endorsed only the Pfizer-BioNTech vaccine for emergency use in 12- to 17-year-olds. Moderna applied Thursday, June 10, 2021, for authorization for its shot in adolescents aged 12 to 15. No vaccine is authorized or approved for younger children.

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Funding Source: None.

Financial Disclosure: The authors have indicated they have no financial relationships relevant to this article to disclose.

Conflict of Interest: The authors have indicated they have no potential conflict of interest relevant to this article to disclose.

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Fellows Column: Caloric Restricted Diets Anxiolytic Effect on Progeny

Landon Smith, OMS III

Anxiety disorders are the most common mental disorder in the United States. More than $42 billion is spent by the United States every year on anxiety disorders (1). With such extensive resources devoted to anxiety disorders each year, research is vital to find a cost-effective, successful form of treatment. Although the use of antianxiety medications has proven to help combat the effects of an anxiety disorder, there may be a more straightforward, cost-effective way to ameliorate anxiety. Environmental factors such as dieting may be the answer to a multibillion-dollar problem. A review of several studies shows the effects of caloric restriction on increasing anxiolytic behavior and that paternal caloric restriction has been shown to ameliorate anxiety in their progeny. DNA methylation may be the reason for the increase in anxiolytic behavior, but further research is needed to establish the mechanism for why caloric restriction ameliorates anxiety.

" A review of several studies shows the effects of caloric restriction on increasing anxiolytic behavior and that paternal caloric restriction has been shown to ameliorate anxiety in their progeny. DNA methylation may be the reason for the increase in anxiolytic behavior, but further research is needed to establish the mechanism for why caloric restriction ameliorates anxiety."

In order to determine if the caloric restriction is indeed lowering anxiety, it is vital to understand the neurocircuitry of anxiety. The neurocircuitry of anxiety has been well diagrammed and has shown a few brain regions that play a significant role in the anxiety response. The hypothalamic–pituitary–adrenal axis has been shown to have a significant role in the anxiety neurocircuitry (2). The hormones involved in anxiety are a key component of assessing the effectiveness of treatment options for anxiety. The corticotropin-releasing factor is a peptide hormone heavily involved in the stress response (3). Its principal function is the stimulus of the pituitary to induce the production of Adrenocorticotropic hormone. Corticotropin-releasing factor is released from the hypothalamus and sent to the pituitary. Upon stimulation, the pituitary releases Adrenocorticotropic hormone into the bloodstream, which then travels to the adrenal gland to stimulate the release of cortisol. Cortisol is released to respond to stress and facilitates increased blood glucose levels to provide more energy for the body's consumption. This mechanism that the body uses is well understood as the hypothalamic-pituitary-adrenal axis (HPA-axis) (4-6). With an emphasis on the HPA-axis, we can now discuss the experiments performed showing amelioration in the anxiety response.

The role of dieting in increasing quality of life has been demonstrated. Two studies focused on the physiological changes that intermittent fasting and caloric restriction have on the body. Intermittent fasting has been shown to decrease anxiety through anti-inflammatory pathways (7). Calorie restriction (CR), as previously stated, has been seen to ameliorate numerous diseases outcomes as well as the overall standard of living. Calorie Restriction is defined as lowering the average food intake by a percentage. Many of the studies cut the caloric intake of the experimental group by 25% and 50%. One study reported that when placed on a calorie restriction diet, adolescent mice demonstrated an increase in cerebral blood flow and blood-brain barrier function compared to the controls (3). With age, calorie-restrictive diets were shown to decelerate the steady decline of the cerebral blood flow typically seen in adult mice. Age has been shown to result in a decline in many homeostatic functions. The continued cerebral blood flow allowed for the continued normal function of the hippocampus and frontal cortex. With the normal function of the hippocampus and frontal cortex, the rats demonstrated preserved memory and learning and reduced anxiety. They reported that correlations between vascular integrity, cognitive functions, and mental health induced by calorie restriction in aging mice were significant and that calorie-restrictive diets demonstrated an increase in all of the previously mentioned parameters (8). Further research has demonstrated that caloric restriction delays age-related methylation drift (9). This study and others show that calorie restriction can increase lifespan and ameliorate disease outcomes (10).

Understanding the potential that caloric restriction has for increasing the quality of life leads to learning its effects, specifically anxiety. Its effects on anxiolytic-like effects have been observed. One study subjected rats to 1 of 4 dietary regimens: control, 25% of the controls food amount (CR25%), 50% of the controls food amount (CR50%), and an acute episode of calorie restriction, which was an experimental group given the same size meal as the control, once every three days. They then tested them in the anxiety test known as the open field test. In the open field test, the CR25% and CR50% groups made more central zone entries than the control and Acute groups, demonstrating a distinct increase in anxiolytic behavior.

"One epigenetic factor is DNA methylation. DNA methylation is a unique tool used by our body to affect the expression of DNA. Methylation can change the activity of a DNA segment without changing the sequence. DNA methylation occurs on the cytosine of a guanine-cytosine dinucleotide (12). These methylation results are permanent and can be passed on from one DNA strand to each of its daughter strands."

Moreover, both calorie-restricted groups explored the central zone more than the control group in the initial 5 min of the test (11. Calorie-restricted mice consistently demonstrated a significant decrease in anxiety behavior compared to the controls. They reported that calorie-restricted diets did increase anxiolytic behavior; however, the mechanism of how it works to do so is still unknown. This research is evidence for a calorie-restricted diet's ability to decrease anxiety in mice and shows promise for further investigation into the mechanism of how such behavior changes occur.

One epigenetic factor is DNA methylation. DNA methylation is a unique tool used by our body to affect the expression of DNA. Methylation can change the activity of a DNA segment without changing the sequence. DNA methylation occurs on the cytosine of a guanine-cytosine dinucleotide (12). These methylation results are permanent and can be passed on from one DNA strand to each of its daughter strands. The potential for differences in DNA methylation sites as a possible epigenetic factor affecting anxiety disorder was assessed.

"If differences in DNA methylation sites are shown in those that display the anxiety disorder phenotype instead of those that do not, then there is potential for that being the mechanism of how anxiety can be ameliorated. Researchers have seen that even minimal traumatic brain injury has shown a decrease in DNA methylation and an increase in the anxiety phenotype (13)."

If differences in DNA methylation sites are shown in those that display the anxiety disorder phenotype instead of those that do not, then there is potential for that being the mechanism of how anxiety can be ameliorated. Researchers have seen that even minimal traumatic brain injury has shown a decrease in DNA methylation and an increase in the anxiety phenotype (13). One study examined the amygdala, a fundamental brain structure in the fear response (14), of mice that demonstrated a low behavioral response to novel situations and displayed high fearfulness, anxiety, and diminished sociability and sexual motivation. They compared the methylation of these mice to high novelty responders. In comparison with the high novelty responders, they found that the DNA methyltransferase protein levels were similar, but 793 differentially methylated genomic sites. They then decided to test the hypothesis that increasing the methylation of the low responding mice would decrease the anxiety phenotype. After changing the food of the low responders to an increased dietary methyl donor content diet, they saw a significant decrease in the anxiety phenotype of the mice (15).

Another study showed that prenatal caloric restriction enhances DNA methylation in the offspring. Specific nuclear protein DNA complex formation was associated with prenatal calorie restriction-induced reduction of placental glut3 expression and thereby transplacental glucose transport. This research provided therapeutic interventions for reversing fetal growth restriction (16) and demonstrated that paternal caloric restriction was able to increase DNA methylation in the progeny. Although they were not looking specifically at anxiety and the changes in DNA methylation, we were able to connect the two studies to see that there could be a potential for DNA methylation, given that caloric restriction decreases anxiety behaviors in mice.

The potential mechanisms by which anxiety exists and can be ameliorated are complex. These anxiolytic phenotypes may be passed on to the next generation. There is some evidence that shows that maternal diets can affect the behavior of the offspring. One study showed that sleep homeostasis was affected by the maternal diet (17). Prenatal calorie restriction has been shown to have a wide range of effects on progeny. A recent study done by Dr. Nowacka-Woszuks group showed that paternal caloric restriction could alter the lipid metabolism in their progeny (18). Because of this evidence, Further research into the potential for paternal caloric restriction to eliminate the anxiety phenotype merits attention. This concept is illustrated by the research done by Govic et al. His group showed that Paternal Caloric restriction prior to conception had altered anxiety-like behavior in adult progeny. Adult male rats were exposed to 25% calorie restriction or glucocorticoid elevation for six weeks prior to breeding. Elevated plus maze, open field, and predator odor were assessed in the adult male offspring. Plasma concentrations of corticotrophin-releasing hormone, adrenocorticotropic hormone, and serum leptin were measured in both parents and offspring. Only the calorie restriction induced anxiolytic behavior in the elevated plus-maze.

Moreover, calorie-restricted offspring demonstrated an anxiolytic-like profile in the elevated plus-maze and open field, but no alteration to predator odor induced defensiveness compared to control. This study showed that calorie restriction in paternal mice increases anxiolytic behavior in their adult male offspring. The mechanism as to how this increase in anxiolytic behavior occurred is unknown, but they concluded that there might be some support of an epigenetic factor leading to the decrease in progeny anxiety behavior (19)

"The potential mechanisms by which anxiety exists and can be ameliorated are complex. These anxiolytic phenotypes may be passed on to the next generation. There is some evidence that shows that maternal diets can affect the behavior of the offspring."

In conclusion, Caloric restriction may be a simple solution to a huge problem in the United States. Compelling research provides evidence that caloric restriction decreases anxiety. The brains of those with anxiety disorders have been shown to display differences in DNA methylation. Caloric restriction has been shown to alter DNA methylation, and although this has not yet been shown to be the mechanism of how caloric restriction works in ameliorating anxiety, there is enough evidence to merit research as a potential mechanism. Another potential area for research is how paternal caloric restriction decreases the anxiety phenotype in their progeny. These studies and subsequent investigations may help us develop novel therapeutic techniques for the many who suffer from anxiety disorders and may be the solution to the multi-billion-dollar problem we face today.

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Disclosure: The author of this paper does not have any conflicts of interest to report.

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Maureen E. Sims, M.D., Barry Schifrin, M.D,

Features of the Case

Identical, concordant female twins were delivered at 24 4/7 weeks gestation to a 33-year-old G8P4 woman who ruptured membranes ten days prior to going into preterm labor. A full course of antenatal steroids and antibiotics had been administered before the delivery. Twin A had Apgar scores of 4^{1}, $5^{5,}$ and $6^{10,}$ and twin B had Apgar scores of 3^{1}, $4^{5,}$ and 6^{10}. The twins had normal physical examinations, and both were placed on conventional ventilators with low settings, each having received one dose of surfactant. Twin A was transferred to a hospital with a higher level of care on day seven because of constipation. She remained stable, was discharged when full feeds were achieved and has developed normally.

"Twin B, weighing 689-grams, had remained at the birthing hospital. She developed a hemodynamically significant patent ductus arteriosus (PDA) at 48 hours, for which she received one course of indomethacin."

Twin B, weighing 689-grams, had remained at the birthing hospital. She developed a hemodynamically significant patent ductus arteriosus (PDA) at 48 hours, for which she received one course of indomethacin. A percutaneous central catheter was placed on day 10 to supplement her enteral nutrition.

She remained stable until day **26** when she developed multiple episodes of desaturation associated with a weight gain of 105-grams in the preceding 24-hours. She was placed NPO and observed. The next day, she required increasing inspired oxygen and was placed on the high-frequency oscillatory ventilator. After the Allen Test was passed, several attempts to place a percutaneous arterial catheter (PAL) were made. ***There was no description of the number of punctures or the side on which the attempts were made.*** A complete blood count (CBC) showed a hematocrit (hct) of 28%, a white blood count (WBC) of 5 u/L, a platelet count of 204 u/L, and a chest radiograph showed diffuse haziness. With a presumptive diagnosis of sepsis, blood cultures were drawn, and the baby was started on vancomycin, cefotaxime, and gentamicin. Her abdominal girth was increasing. Her blood gases showed a mixed acidosis with pHs ranging from 7.03-7.13. Her diastolic blood pressures (BP) were in the teens, and her heart rate was persistently >200 bpm. She was given two transfusions of packed red blood cells and multiple boluses of normal saline as well as increasing dosages of dopamine and eventually epinephrine in an effort to stabilize her BP. No echocardiogram was obtained. Later in the night, a PAL was successfully placed in the right radial artery to monitor BPs and sample blood gases continually. There was no documentation of the Allen Test being performed. The waveform was normal. Her abdominal girth continued to increase.

"In the early morning on day 28, the PAL waveform appeared normal. The right upper extremity was noted to be pink, mottled, warm, and to have a capillary refill <3 seconds, but no comment was forthcoming about the hand."

In the early morning on day 28, the PAL waveform appeared normal. The right upper extremity was noted to be pink, mottled, warm, and to have a capillary refill <3 seconds, but no comment was forthcoming about the hand. ***However, there was a checkmark in the hospital form signifying that the right had was "mottled" but lacked any further description, and the physician was not notified about the mottling.*** For the following 6 hours, there was no further documentation of either the PAL waveform or the appearance of the hand. In the deposition, ***the night nurse explained that she did not document the findings but was sure she had evaluated them as per her usual practice – and assumes that she had found them normal.*** In the morning, 9 hours after the PAL was placed, the oncoming nurse noted that the arterial waveform was dampened and that the right extremity was pink, mottled, and cool - but she did not notify the physician. ***The nurse stated in her deposition that she knew these findings were abnormal but did not report them to the neonatologist because she was very busy with this critically ill baby. She could not remember if the whole right extremity was mottled and cool or just the right hand.*** **Both night and the morning nurses affirmed that whenever a PAL was in place, the nursing policy was to check the waveform, evaluate the hand hourly, and report any abnormal findings to the physician immediately.** Within an hour, the hand became white. At this point, the nurse informed the neonatologist about the earlier dampened waveform and the cool, pale hand and added that the waveform was now flat. Neither BPs nor blood draws had been possible from the PAL for several hours prior to the morning shift. ***In his deposition, the treating neonatologist stated that he ordered the nurse to flush the catheter, loosen the dressing, and apply a warm compress. The plaintiff neonatologist agreed that loosening the tape was potentially helpful, and repositioning the hand was sometimes effective, but warming the hand, however, was contraindicated.***

Further, any attempts at aspiration to draw out clots could be useful, but irrigation should be extremely gentle lest forceful entry release clots, obstruct flow, and compromise the hand even further. Other maneuvers, including elevating the right arm, applying warm compresses to the opposite (left) arm to

attempt reflex vasodilatation, and trying nitroglycerin, have a varying success rate but have little risk. Most critically, since the purpose of the PAL was for blood sampling and BP monitoring, neither of which had been possible for several hours, the PAL should have been removed hours earlier when it stopped functioning. When evidence of a pale, cold hand became present, the PAL should have been discontinued immediately.

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As the various maneuvers failed to re-establish circulation in the hand, the nurse contacted the neonatologist on several occasions. In each instance, ***the neonatologist directed the nurse to continue to observe. The plaintiff neonatologist contended that had the proper assessments been performed before the morning nurse arrived, the PAL would have been removed when the waveform was damped if positioning or readjusting the tape did not improve it. Mottling of the hand made it more urgent; a cool, white hand demanded immediate removal.***

Two and a half hours after the morning nurse assumed care of the baby, the neonatologist ordered the PAL to be removed. As a curious aside, ***in her deposition, the mother related that about 2 months after the incident, an unknown individual had sent her a letter stating that the neonatologist was being adamant about leaving the PAL despite multiple nursing requests to have it removed. The post-marked, handwritten, but unsigned letter was produced at her deposition.***

The baby was transferred to a center with a higher level of care because of her abdominal distension. She was hypotensive, tachycardic, massively edematous, had a tense distended abdomen and a pulseless white hand. Her chest radiograph showed white-out, and her abdominal radiograph showed a homogeneously opacified abdomen with air present only in the stomach. She had an exploratory laparotomy for presumed perforation secondary to necrotizing enterocolitis, but the intraperitoneal contents were normal except for massive ascites. Her cardiac ultrasound showed a huge PDA, which was ligated soon after the abdominal surgery. All blood cultures were negative. The thinking of the physicians at the receiving hospital was that the hypotension at the referral hospital was secondary to the PDA; subsequently, the baby developed heart failure as the attempt was made to normalize her BP with multiple fluid boluses. The massive volumes of fluid to increase her blood pressure additionally compressed her inferior vena cava as increasing ascites developed, thereby limiting venous return to the heart. Her right hand was amputated at a month of age. ***The plaintiff neonatologist agreed and pointed that this further underscored the need for the cardiac ultrasound to evaluate the PDA at the birthing hospital.***

The birthing hospital and the neonatologist were sued. **The plaintiffs alleged: 1) that the nurses failed to assess hourly the color, perfusion, and temperature of the hand and the waveform of the PAL as required by their own standards. 2) the nurses failed to notify the physician timely about the abnormal findings and failed to summon the physician. Further, the plaintiffs alleged that the physician failed to timely remove the PAL when the hand was cold and pale. When the physician did not order the PAL to be removed immediately, the nurses needed to advocate for the baby by going up the chain of command by first discussing the issue with the neonatologist, and if that failed, then informing the supervising nurse could be accomplished very quickly, or informing the physician that it was unacceptable to leave the PAL in place under the circumstances. As a last resort, the nurse should have discontinued the PAL and then explained why it was necessary to her supervisors and the physician who was resisting.**

"As a last resort, the nurse should have discontinued the PAL and then explained why it was necessary to her supervisors and the physician who was resisting."

The case was settled before trial.

Discussion

For over 40 years, peripheral arterial catheter insertion has been indispensable in newborn intensive care despite the risk of both short- and long-term complications. Complications include thromboembolism, vasospasm, infection, iatrogenic blood loss, peripheral nerve damage, rarely pseudoaneurysm, and arteriovenous fistula. The overall risk of ischemic injury secondary to radial or ulnar artery catheterization is approximately 5%. Precautions during the insertion, vigilance in the maintenance of catheters, removal as soon as medically feasible, and prompt discontinuation when signs of compromise develop reduce the risk of complications. The radial and posterior tibial arteries are the primary sites for cannulation. Because of the potential risk of ischemic injury to the entire hand or arm, the ulnar, brachial, and axillary arteries generally are used for cannulation only if arterial access at the primary site is unsuccessful.

Monitoring the extremities frequently, especially the tips of the fingers or toes, for signs of vascular compromise is crucial. Studies of Doppler flow of radial artery by Hack et al. showed complete occlusion in 63% of infants with radial artery catheterization. Further, blood flow to the site distal to the cannulation site depended on adequate collateral circulation. Blood flow in the radial artery did resume within 1-29 days after catheter removal.

The Allen Test is routinely used to demonstrate collateral circulation in the catheterized extremity. Although inter-observer variability exists with the Allen test, it is routinely used to demonstrate

collateral circulation.

Evaluation of the waveform is useful in determining how well the PAL is functioning (Figure). Flattening of the curve can be caused by obstruction of the catheter from clot formation, or from the catheter being pushed against the arterial wall, or from bent tubing. If an obstruction is suspected, the catheter should be gently aspirated. If no resistance is encountered and the catheter allows sampling, a 1 ml flush may be given.

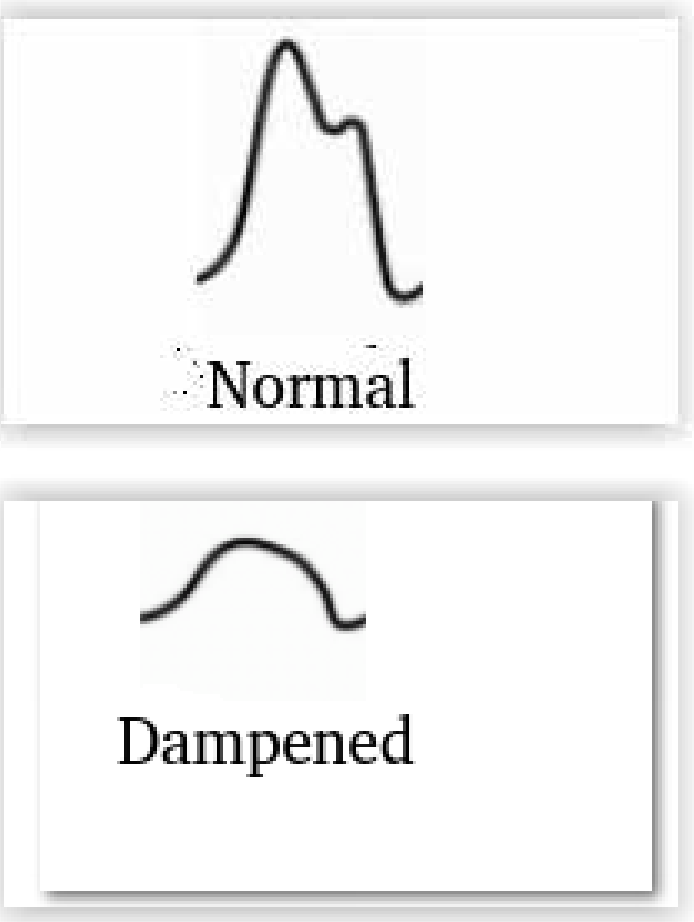

Figure – Arterial waveform from PAL catheter illustrating:
A. *Normal arterial waveform*
B. *Dampened arterial waveform*

Although there are multiple case reports of ischemic injury with peripherally inserted arterial catheters, very limited data is available on their use in extremely low birth weight infants. When peripheral ischemia is recognized immediately, and appropriate action is taken, permanent loss of digits is generally avoided. Topical nitroglycerin has been found to be effective in restoring perfusion in a few cases in which radial artery catheterization resulted in compromised hands. As stated, immediate removal of the catheter at the earliest signs of ischemia is essential to prevent ensuing tissue loss.

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Disclosures: The authors have indicated no conflicts of interest.

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- **E** VALUATE THE DECISION

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Peer Reviewed

Gravens By Design: The Case of a NICU with Single-family Rooms: Design Recommendations to Support Family Engagement Behaviors

Herminia Machry, PhD, Robert White, MD, Sue Ann Barton, AIA, EDAC, LEED AP

"In NICU environments, evidence shows that while the presence and wellbeing of family members are very important, their active involvement in communication with staff, decision-making, and direct contributions to care is also critical for the development of newborns (3,4)."

Introduction

Saving very low birth weight, preterm, and underdeveloped infants is undoubtedly the primary premise in the neonatal intensive care unit (NICU). Towards this goal, care contributions from family members are integral to facilitate infants' developmental care and vital to support the care continuum at home, after NICU discharge (1,2). In NICU environments, evidence shows that while the presence and wellbeing of family members are very important, their active involvement in communication with staff, decision-making, and direct contributions to care is also critical for the development of newborns (3,4). In a process known as family engagement, healthcare organizations are currently motivated to help reduce NICU length of stay and hospital readmissions by promoting a care partnership between family and staff in the NICU (5). Family Engagement builds on the family-centered care philosophy to activate patients' families as caregivers (6). It is particularly relevant in neonatal care settings due to the great extent to which sick infants rely on their parents during treatment.

The design of NICUs has morphed to include families, initially with the open bay design – room shared by multiple infants with bedside chairs for parents – and more recently with the Single-family Room (SFR) design model – private rooms for each family, sometimes including other shared family support spaces(7). In the post-occupancy evaluation of a NICU solely composed of single-family rooms, this study builds on previous research recognizing the current trend of SFRs based on their positive impact on both infant and family outcomes at the NICU(8-10). We share findings and recommendations around the design of the SFR design model from studying the case of a NICU using SFRs and family support rooms to promote family engagement.

Design as a Resource to Support Family Engagement

Evidence-based design research shows that the built environment impacts human behavior and health outcomes in healthcare settings (11), such as family engagement. Best practice design in NICUs has been generally guided by clinical evidence, addressing the needs of underdeveloped premature infants in terms of individualized and supportive developmental care, focusing on infant care and parents as infant's support of care (staff and parents care-partners). While the contemporary NICU environment has always been driven by intense medical technology and multidisciplinary staff supervision, individualized developmental care was the first step towards evidence-based design in the NICU, fundamentally defining the ideal environment for infant development as a 'womb-like environment, with controlled lighting, temperature and acoustic conditions(12). Expanding the focus from the illness to the infant's context, supportive developmental care followed by addressing infants' need for parental care as it relates to natural nutrition (breast-milk feeding), touch stimuli (e.g., skin-to-skin care), and sound stimuli (e.g., maternal voice), which closely simulate womb-like conditions while also promoting infant sleep and reducing infant agitation(13,14).

"Expanding the focus from the illness to the infant's context, supportive developmental care followed by addressing infants' need for parental care as it relates to natural nutrition (breast-milk feeding), touch stimuli (e.g., skin-to-skin care), and sound stimuli (e.g., maternal voice), which closely simulate womb-like conditions while also promoting infant sleep and reducing infant agitation(13,14)."

Family involvement became an important principle in infant care. Parents were gradually incorporated as part of the NICU environment in response to empirical findings of the benefits of breast-milk feeding and skin-to-skin care to premature infants (15,16). NICU design led to the open bay configuration as a temporary best practice, allowing parents to stay at the infant bedside (7). The open bay, however, raised concerns about infection control,

privacy, and confidentiality (17), thus provoking discussions in the literature about private rooms (SFRs) being an adequate design strategy for NICUs(18). In the last 25 years, multiple NICUs have been built following the SFR design model, which is likely to become prevalent in the United States, investing extensive resources in planning and construction. This study helps validate this investment by contributing to the expansion and refinement of current family-focused design recommendations about the SFR model in neonatal ICUs, evaluating a NICU intentionally designed to apply the SFR design model as an effort to improve family engagement.

Methods

We used a qualitative approach to examine a NICU fully embodying the SFR Design model, investigating how different built environment aspects of the unit influence behaviors across four family engagement concepts – family presence, family care, family information exchanges, and family caregiving. We adapted the family involvement model developed by Olding and colleagues(19) to look at behavioral patterns and outcomes across these family engagement concepts, measuring them through the characteristics of all behaviors in which family members are involved during their experiences in the unit. Behavioral characteristics included the type of action or interaction related to family engagement concepts (e.g., daily activities like eating and drinking, and interactions like medical rounds, infant care training, infant feeding, and skin-to-skin care), the type of people involved (e.g., mother, father, nurse, physician), and the number, location, position and movement of people and physical elements during actions/interactions. The built environment was measured by physical characteristics affecting family engagement behaviors at both unit and room levels, including the overall NICU layout (physical arrangement of spaces in the unit), the physical proximity and visibility between spaces, and the physical characteristics within spaces used by families.

Setting

The case study is a level III NICU located at a Children's Hospital in the Midwestern US. It applies a family-centered care model that includes 24h family access with overnight stay and an active family engagement program, which involves various types of family engagement actions and interactions. As depicted in Figure 1, the unit offers two types of SFRs (SFR and Couplet-care SFR), all with adjacent private bathrooms and multiple family support spaces (family-dedicated waiting areas, meeting room, lounge, garden, and atrium).

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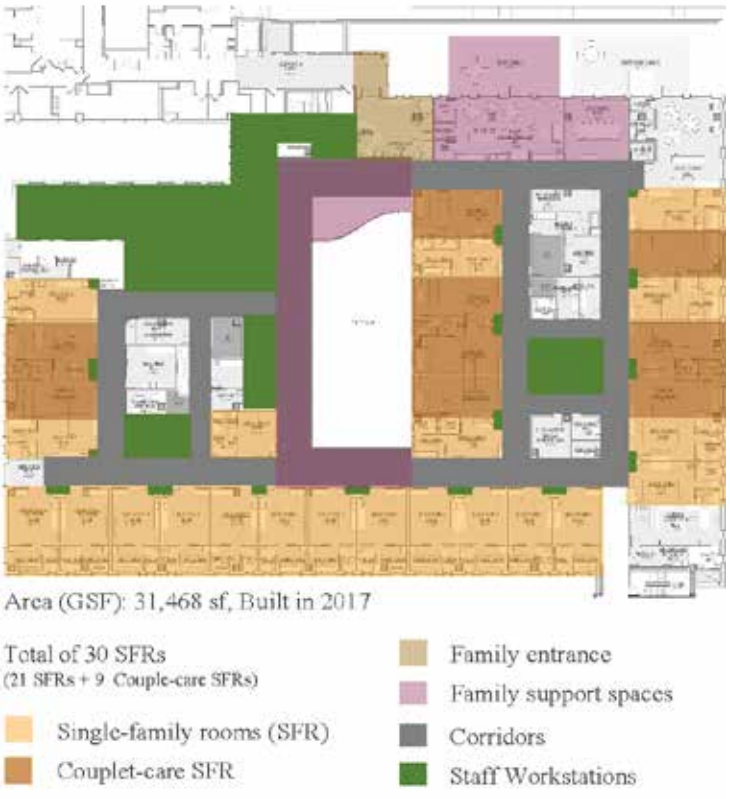

Figure 1: Floor plan of the SFR NICU.

Design Process with Family Participation

Integrating families to participate in infant care was a central focus in the design development of this NICU. Integrated design events with hands-on participation by staff and families were held to develop concepts improving infant, family, and staff-related outcomes and experiences at the unit. Kids and families provided valuable input on many fronts, from the check-in process to the color palettes and environmental graphics developed for the interior design concepts. Mock-up-based design sessions focused on family and staff spaces, where multidisciplinary teams tested layout and equipment needs within the SFR. Refinement of the design was achieved through simulation exercises, where clinical care scenarios were enacted with parents and staff acting in prescribed roles.

Design Intentions for Family Engagement

Design sessions resulted in many design decisions intended to encourage and support family engagement. The vision was to create an environment that would provide family accommodation and amenity spaces across the unit and inside patient rooms to facilitate early mother-infant bonding, which is historically limited during the first days of the infant's life in the NICU. The layout of the unit was organized into two neighborhoods around a central courtyard garden overlooking a treehouse to foster a welcoming arrival and provide daylight and natural views for every patient room. A family lounge was located next to the family arrival space and offered families a shared kitchen, eating and activity areas, and direct access to an outdoor garden terrace to provide respite, reduce stress and improve optimism.

Two innovative room prototypes were developed: an enhanced

SFR (with a window and private toilet with shower) and the Couplet-care SFR. Informed by insights from conversations with NICU leadership at the Karolinska Institute in Sweden, the design of the SFR included these resources. Interview responses were transcribed verbatim and thematically analyzed with an observational, survey, and physical data.

Summary of Findings

Data from 109 hours of field observations (154 observation logs), 24 semi-structured interviews (9 families and 15 staff members), and 14 responded surveys (29% response rate) amounted to 517 initial codes related to family engagement behavioral outcomes, and 135 codes about built environment factors impacting family engagement behaviors.

The SFR was the space where most types of actions/interactions occurred. Patterns associating spaces with actions/interactions at the unit showed that while families were using the SFR for most family engagement interactions, support spaces were being used when families prepared their food and drinks, worked on the artwork, and engaged in childcare, distracting their other kids. Family caregiving interactions were unsurprisingly found only in the SFR, whereas family care and information exchanges were associated with both SFRs and the meeting room. The meeting room was utilized for interactions related to family-staff communication and education requiring more people and family focus (e.g., CPR and safe car seat training), where families mainly reported meeting each other in the unit (they met during classes). Staff workstations, on the other hand, were rarely mentioned by families but sometimes mentioned by staff or observed in use when a parent briefly left the SFR to look for staff in areas close to their room; when families greeted staff at the front desk (family access/waiting room); and when family members visited staff in their private offices (e.g., lactation room or social worker office), which were located in corridors connecting SFRs to the family arrival space. Corridors and the family arrival space, in turn, were associated with family-to-family and family-to-staff socialization.

"Observations and interviews helped consolidate functional zones in the SFR (Figure 2). During data collection, families were usually sitting at the kangaroo chair or family bed during all actions and interactions."

Observations and interviews helped consolidate functional zones in the SFR (Figure 2). During data collection, families were usually sitting at the kangaroo chair or family bed during all actions and interactions. The staff were usually at the computer area next to the infant bed. Other room areas were either transition areas or areas occasionally shared by staff and family for infant care activities. Family and staff worked together around the information board (information board zone) and at the counter and sink area (feeding care zone), where activities pertained to warming, cleaning, storing, and staging infant milk supplies. Family-staff collaboration also happened on direct infant care activities like holding and cleaning the infant around the infant bed (namely infant zone). It included a "trash zone" (e.g., for dispensing dirty diapers) conveniently accessed by both the inside and the outside of the room.

Built environment characteristics at both room and unit levels emerged as factors impacting family engagement behavioral outcomes. The unit's layout was arranged, so that family support spaces were close to the family entrance and the meeting room, which staff and family perceived as convenient and easily accessible during their flow between activities. Positive feedback came from having family classes within close proximity to infants and having easy access to toys at the family lounge to distract kids accompanying parents during class. Staff perceived the physical proximity between staff offices and the family entrance as supportive to family-staff face-to-face communication, which occurred through informal family visits to these offices. On the other hand, the family thought that the physical proximity between SFRs and staff workstations facilitated their access to staff.

Figure 2: Floor plan and photos illustrating functional zones in a typical SFR.

The family mentioned the visibility between spaces as supportive to their comfort and reassurance, respectively in the form of window views into the atrium and window views between the SFR and staff workstations near their room. Additionally, the "kid-friendly" aesthetics (artwork and signage), as well as the "vibrant" and "uplifting" wall

colors found in corridors and SFRs, were perceived by both family and staff as supportive to family comfort (See Figure 3).

At the room level, the presence of the SFR and the couplet-care SFR was unanimously perceived by family and staff as a supporting factor to family prolonged presence at the bedside, family privacy and comfort, and daily living activities, which include childcare. These private rooms were also perceived as supportive to family-staff communication, family education, and caregiving interactions. Conversely, staff sometimes associated the SFR with family seclusion and potential sleep disruptions caused by staff's constant in-and-out flow. This, however, may have been affected by other factors related to family and staff individual attitudes and by staff's dual and somewhat conflicting role of being a care provider to both family and infants, at the same time and environment.

The size of the SFR (average area of 350 square feet) was perceived by family and staff as "more than enough" for their actions and interactions in the room. SFR layout was perceived by staff as even conducive to infection control education due to the sink and vertical headwalls used to demarcate 'clean' and 'dirty' areas in the room. Horizontal surfaces, in turn, were described as insufficient in some SFRs and taken by staff as helpful to maintain clean areas (e.g., countertops, where infant milk is prepared) free of family's potentially contaminated personal items. Furthermore, decorations (e.g., Christmas tree), lighting, and sources of distractions in the SFR (e.g., TV) were perceived by family and staff as supporting family comfort (TVs and decorations acting as "connections to the outside world") and caregiving (lights tailored to moments of family-infant bonding).

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Figure 3: Photos illustrating aesthetics and visibility factors mentioned by study participants.

Staff and family consistently perceived the information board as a supportive communication interface between family and staff. In contrast, infant milk-related equipment (e.g., milk refrigerator and warmer) were perceived as supportive to family caregiving due to their autonomy and ownership of infant feeding activities. Both family and staff agreed that SFR family zone doors and curtains supported family privacy, and therefore their visual comfort during daily living and caregiving activities. However, the glass material found on family zone and bathroom doors sometimes hindered privacy and family sleep due to light borrowed from the rest of the room. Also, multiple study participants mentioned the lack of ergonomic comfort provided by the family bed, which hindered family sleep comfort and was perceived as one of the reasons why families sometimes may prefer to sleep at the nearby outsourced lodging facility.

Characteristics of the interior of family support spaces also emerged as impacting family presence at the NICU and family behaviors related to daily living and information exchanges. While

data demonstrated the family lounge being used and appreciated, observations showed that the room is mainly used for quick in-and-out daily living activities where families mostly occupied the kitchen area or used the restroom accessed through the room. Unscheduled and informal socialization between families was rarely observed in the room. The presence of the meeting room, on the other hand, was perceived by staff as supporting family-to-family socialization and family discharge education, where features such as storage and equipment (e.g., car-seat replica) supported teaching ergonomics.

Design Recommendations for Family Engagement in the NICU

While contemporary NICU design guidelines (20,21) suggest room size and zoning standards (e.g. family, patient, and staff zone distinctions inside the SFR), as well as the inclusion of specific types of spaces in the NICU (e.g., library and family lounge), empirical data provided by this study support recommendation of NICU design for family engagement that are more evidence-based. First and foremost, our findings support adopting the SFR NICU design model as a resource to support family engagement. Potential challenges presented by the presence of the SFR to family seclusion may be mitigated with shared and adequately sized family support spaces with activities inside the unit rather than outside, and in close proximity and easy accessibility to SFRs, as to support family-to-family and family-staff informal interactions within infant proximity. We also recommend the integration of private bathrooms adjacent to SFRs and inpatient mother accommodations in the room (couplet-care) to facilitate the family's prolonged bedside presence and wellbeing. Additionally, we found the deployment of bright colors and infant-like decorations across the unit to be successful.

More specific design recommendations relate to interior design features of SFRs and family support rooms. In the SFR, the room layout should translate to a spatial hierarchy that facilitates different locations of privacy-sensitive family behaviors observed in the room. While family zone doors and curtains contribute to shielding families during activities conducted away from infants (e.g., getting dressed and pumping breast milk), other activities like breastfeeding and skin-to-skin care may need additional elements to protect them visually at the bedside while also securing staff-to-infant supervision. This may be challenging but alleviated by additional shields or by layout or shape changes in the room. The physical arrangement of the room should also afford direct visibility between family, staff, and infant, and between family, staff, and information displays, facilitating family-infant supervision, family-staff communication, and information access and awareness for family members. In the family zone, family presence can be increased by providing more comfortable beds, sources of positive distractions, family storage, and space for artwork and decorations. Moreover, providing enough sitting in the SFR is likely to facilitate interactions with staff at eye level when family members are using the kangaroo chair.

Due to different levels of privacy needed during social interactions occurring in family support rooms, layout flexibility is also recommended in the design of NICU spaces with a shared kitchen, living room, and play areas. This can be achieved by providing mobile furniture and vertical partitions that can adapt to different group sizes involved in social interactions and to different levels of personal space desired by family members. Spatial hierarchy can be created by furniture or wall positioning to allow for different activities and people to coexist in these shared spaces (e.g., children coexisting with adults, family events coexisting with daily living activities), affording choice for families according to their preferred interaction in the room (e.g., alone time versus socialization). Aiming for balancing family-infant proximity and an increased sense of community in the NICU, findings from this study also recommend sources of distraction in family support rooms, such as TVs and childcare distractions, therefore supporting family respite, socialization, and childcare.

"By evaluating the design of an SFR NICU designed to promote family engagement, this research was able to show the combined impact of unit layout and aesthetics, SFRs, and family support rooms on family presence, care, information exchanges, and caregiving, from the perspectives of both family and staff. We demonstrated how SFR affords privacy as a key environmental quality to facilitate family presence, wellbeing, in-depth family-staff interactions, and intimate family-infant interactions."

Conclusions

By evaluating the design of an SFR NICU designed to promote family engagement, this research was able to show the combined impact of unit layout and aesthetics, SFRs, and family support rooms on family presence, care, information exchanges, and caregiving, from the perspectives of both family and staff. We demonstrated how SFR affords privacy as a key environmental quality to facilitate family presence, wellbeing, in-depth family-staff interactions, and intimate family-infant interactions. This study helps guide future NICU projects by providing them empirical rather than best practice design recommendations. This study adds to the body of knowledge around NICU design by emphasizing and exploring in-depth the perspective of family needs, thereby contributing to existing best practices literature such as the FGI Guidelines and the Journal of Perinatology Recommended Standards for Newborn ICU Design.

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Conflict of Interest Disclosure: ZGF Architects funded data collection costs for this research

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COVID-19

STOP THE SPREAD AT HOME

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

HYGIENE TIPS

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

EYES
Wear protective eye gear (glasses)

HANDS
ALWAYS wash your hands

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

BATHROOM

- Sanitize EVERYTHING.
- Clean after every use.
- Patient gargle Listerine every morning & night.

PROTECT

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

If you are feeling sicker, DON'T WAIT. Call your doctor immediately.

SELF ISOLATION

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

6 FT

Practice social distancing

KITCHEN

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

TRACK COVID-19 NEAR YOU BY VISITING COVIDNEARYOU.ORG

#STOPTHESPREAD

MIORA

Visit Miora.org

Brought to by Miora in partnership with United2Care

COVID-19

DETENER LA PROPAGACIÓN EN CASA

Qué hacer cuando usted o un ser querido está infectado.

CONSEJOS DE HIGIENE

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

OJOS
Use equipo de protección para los ojos (lentes)

MANOS
SIEMPRE lávate las manos

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

BAÑO

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

PROTEGER

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

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

AISLAMIENTO

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

6 FT

Practica el distanciamiento social

COCINA

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

SIGUIR COVID-19 VISTAR COVIDNEARYOU.ORG

#STOPTHESPREAD

MIORA

Visitar Miora.org

Traído por Miora en asociación con United2Care

Ways to Manage Covid 19 @ Home

Household

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

Stop the Spread at HOME

MIORA

Sick

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

Maneras de manajer COVID-19 en casa

Hogar

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

Detén la propagacion en casa

MIORA

Enfermo

1. Aíslese permanecindo en una habitación separada con baño separado. No vayas a espacios compartidos
2. Si no se puede aislarse crea un separador de ambiente con una sabana.
3. Ventile la habitacion con aire fresco por lo menos 3 veces al día.
4. Mantenga agua y productos de saneamiento en la habitacion.
5. Mantenga una bolsa de basura en la habitación.
6. Proteja a las mascotas, no las abrace.
7. Notifique a todos los contactos de los últimos 10 días.
8. No espere! Si se siente peor llame a su medico.

PROTECT YOUR FAMILY FROM

RESPIRATORY VIRUSES

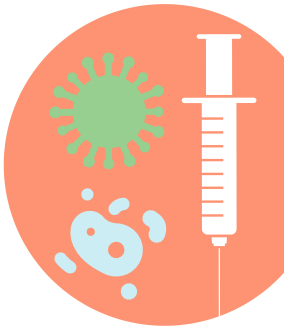
flu coronavirus pertussis RSV

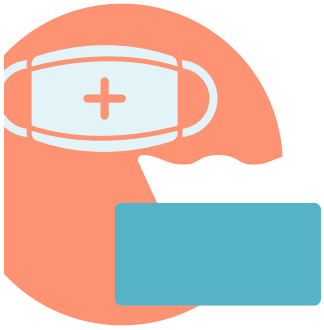
WASH YOUR HANDS

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

GET VACCINATED

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





COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.

USE A HAND SANITIZER THAT IS 60%+ ALCOHOL.

STAY AWAY FROM SICK PEOPLE

Stay at home to protect vulnerable babies and children. Avoid crouds when out.

National Perinatal Association

nicuparentnetwork.org
nationalperinatal.org

NPN NICU PARENT NETWORK

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

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing...

Risk of horizontal infection

Risks of separation and trauma

EVIDENCE

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

PARTNERSHIP

SHARED DECISION-MAKING

What is the best for this unique dyad?

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

TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY

LONGITUDINAL DATA

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

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY

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

Partnering for patient-centered care when it matters most.

National Association of Neonatal Nurses
nann.org

National Perinatal Association
nationalperinatal.org

NICU-NET

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

To post to the list, send email to

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join - Join this mailing list.

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

Message archives from the U. of Washington NICU-NET (1994-2003) and Yahoo Groups NICU-NET (2003-2019) are available on Google Drive. You can download them using this link: https://drive.google.com/drive/folders/1MoPTrDjzmGbsZlKqY9MczihApWaFbREK?usp=sharing

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

nicu-net-owner@nicu-net.org

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

In Loving Memory

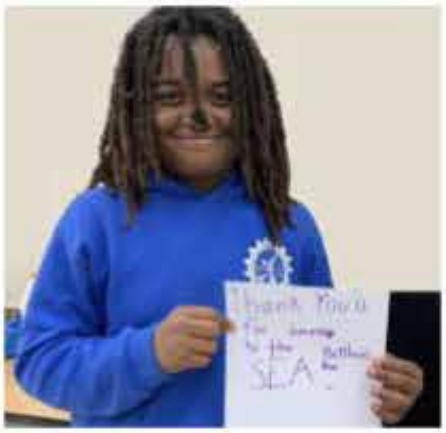
August 9, 1996 - April 3, 2010

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

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

Sponsor a Child in the SEA Program

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



1 session	$15
1 week	$30
1 month	$120
1 semester	$540
1 year	$1,080
Middle School	$3,240

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

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National Perinatal Association

Machine Learning Workflow – Part 2

John B. C. Tan, PhD, Fu-Sheng Chou, MD, PhD

Last month, we discussed data preparation and processing. We introduced some terminology in data processing that you may encounter when reviewing or reading articles. Specifically, we discussed eliminating variables with zero or near-zero variance; we also briefly discussed ways to handle missing values. The most important and at the same time awkward terminology to keep in mind is, in the world of machine learning, variables are called "features"!

"This month, we will discuss more in-depth steps to take after initial data processing and the actual learning steps. Before we begin, we would like to point out that some minor changes were made to the machine learning flow chart (Figure 1) to align with the industry-level standard for machine learning in healthcare."

This month, we will discuss more in-depth steps to take after initial data processing and the actual learning steps. Before we begin, we would like to point out that some minor changes were made to the machine learning flow chart (Figure 1) to align with the industry-level standard for machine learning in healthcare. In this revised flow chart, internal validation refers to using institutional datasets (training and testing) for data validation. External validation indicates taking data from a different environment (extramural, multi-center, etc.) to validate the model further. On the other hand, prospective validation means further validation of the model using prospectively collected new data. We will discuss this in more detail later.

Considerations in splitting data for model development

Now you have collected all the raw data and gone through the painful processing steps to put all the data into a nice tidy format. You may have data from one NICU for one year or data across multiple years from multiple NICUs that are all managed under the same protocol by the same group of neonatologists. Now the question is, do we use all of the data for model development? A short answer is NO. A typical approach is to split the data 80:20 and take the larger portion for model development. But how do we decide how to split the data?

Random split

This is the most straightforward way of doing the split. All the data

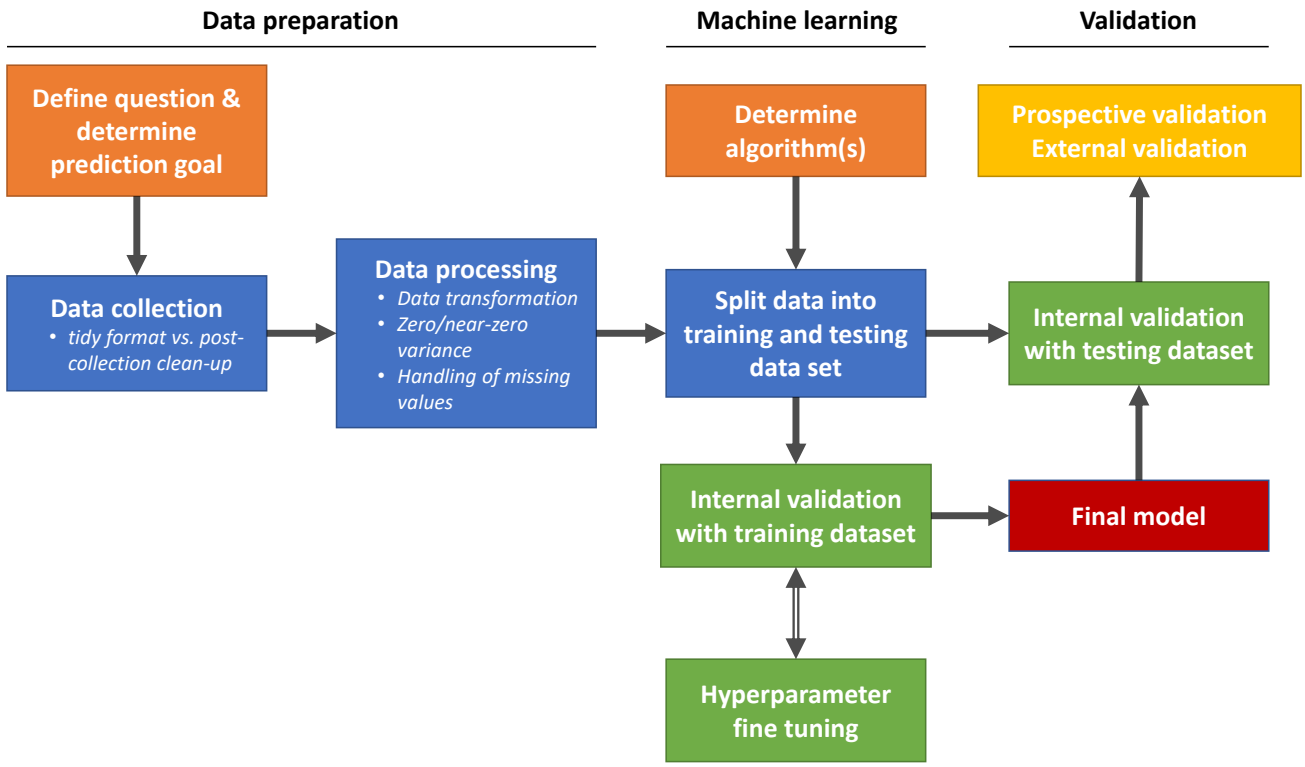

Figure 1.

are lined up and randomly split into two groups based on the outcome feature we would like to predict. Classic machine learning algorithms cannot consider repeated measures, like what mixed modeling can provide. Therefore, features such as year, location, or patient ID, intended to address repeated measurement in the data may become an issue for future prediction, as those features need to be supplied in future data, which may sometimes become awkward. For example, if one includes data from the year 2010 to 2015 for modeling, and a categorical feature "Year" was included in the training dataset. Now, you have a set of data from 2021 that you would like to supply to predict the outcome. You would then supply 2021 for the feature Year, but it would not make sense to the model. This is because 2021 was never observed during model development as a possible value for feature Year. It would also not make sense to treat Year as a continuous data type.

"When multiple years of data are involved, it usually means that the study is retrospective in nature, which is typical for machine learning projects, in healthcare, or anywhere else, as one of the intrinsic nature of prediction is 'to learn from the past.'"

Spatial split

When data are obtained from more than one NICU, one can either randomly take data from all NICUs for model development and use the remaining data for validation or take data from some designated NICUs for model development, then validate the model using data from the remaining NICUs. The first approach is like what we just discussed in the *Random split* section. It is intuitive and makes perfect sense. On the other hand, the second approach may be appealing for several reasons:

1. Logistic considerations:

   If each NICU requires an independent ethics review (IRB) process, it will take a long time to get all applications reviewed and approved from all institutes. It would also lengthen the time needed to gather raw data from all NICUs for processing and randomization. This may not be feasible from a project development and funding standpoint. One may consider taking data from 1 or 2 NICUs to establish the data organization and processing pipeline and use these data for model development. Findings obtained from this process may be turned into a grant proposal to secure more resources for model fine-tuning and external validation.

2. **Clinical practice comparison:**

   In clinical protocol (the flowcharts with the boxes and the arrows that we, at some point, have all been involved in developing) implementation, we tend to test the protocol in one unit for a defined period of time. This allows us to fine-tune the protocol to address any obstacles that may be encountered during implementation. After successful implementation in a confined environment, we would then expand it to other units. There may be additional obstacles that are NICU-specific that need to be further fine-tuned. We can take a similar approach to machine learning model development. After all, one common goal of developing prediction models is to allow the machine (the algorithms) to tease out the hidden patterns in the data to inform the relationship between the features and the outcome. We can take data from 1 or 2 NICUs to develop a prediction model. We investigated the model well to understand the essential features that the machine had learned using a chosen algorithm. We can then try to validate the model using data from a separate environment and assess whether the model still holds. We may also develop two models using data from two different sources and compare the list of important features between the two models. Either way, such an approach provides an opportunity for us to understand the difference in practice between locations.

3. Identification of essential predictive features:

   Careful selection of features for model development is key to successful model development. Features that are specific to one NICU may not be applicable to another NICU. For example, if one NICU only uses a high-frequency jet ventilator (HFJV) for rescue, and the other NICU only uses a high-frequency oscillator (HFO) for rescue, including a feature of whether HFJV is used to train a model using data from the first NICU is not going to result in a generalizable model. If we perform careful feature selection and develop a generalizable model for another NICU, we know these features will be critical to all practices.

Temporal split

When multiple years of data are involved, it usually means that the study is retrospective in nature, which is typical for machine learning projects, in healthcare, or anywhere else, as one of the intrinsic nature of prediction is "to learn from the past." We typically include multi-year data for different reasons: we may not have enough data from just one year. Also, we may include a specific period because of protocol change or because a new initiative was started to improve care for a specific patient population. Comparisons between epochs in traditional statistical analysis are sometimes made for retrospective data because there was no good control group for the clinical question, or the clinical question was geared towards understanding how clinical outcomes evolve over time. There are a few considerations when it comes to splitting the data based on time:

1. Evolvement in clinical practice:
   It is essential to know whether the clinical practice has evolved during the period data were collected. For example, our NICU used to use HFO as a mode of ventilation for extremely low gestational age newborns (ELGANs), but the practice has moved away from it, and now HFJV is almost exclusively used for this population if a high-frequency mode of ventilation is needed. Having a feature that indicates the use of HFO would yield a near-zero answer in the more recent cohort and lead to significant errors in the model. On the other hand, if two features were included, one for HFO use, and the other for HFJV use, the model may then provide an opportunity to assess the difference between HFO and HFJV in predicting the outcome of interest. However, the conclusion may be misleading if the temporal effect is substantial since the differences may be due to time rather than the ventilation method. It is vital to take into account changes over time to reduce confounding as much as possible.

Table 1. Supervised learning algorithms and their strength and weakness

	Use	Principle	Strength	Weakness
Support vector machine	Classification, regression	A "maximum distance" approach to creating a hyperplane which provides the largest separation between outcome classes in a high-dimensional space	1. High number of features 2. Less likely to overfit 3. Small training dataset 4. Fast	1. High demand for computing power and computer memory 2. Difficult to interpret the relationship between input features and output.
Naïve Bayes Classifiers	Classification	Based on Bayes' probability theorem. All features are presumed to be independent of others.	1. Fast 2. Can tolerate a high number of features 3. Does not require a massive number of training data	1. Less accurate, especially with a low number of features (low-dimensional data) 2. The assumption of total independence of all features
k-nearest neighbor	Classification, regression	Use a decision boundary based on the hyperparameter *k* to determine the class of unknown data points, e.g., if *k*=5 and 3 out of 5 neighbors are *positive*, then the unknown is assigned as *positive*.	1. Simple to interpret 2. Good for data that has no prior knowledge about its distribution	1. Not suitable for data with a high number of features (high dimensional data) 2. Cannot tolerate missing values 3. Likely to overfit with high-dimensional data
Random forest	Classification, regression	A decision-tree-based approach with nodes and branches by "planting" a predetermined number of trees to avoid overfitting and high sensitivity to subtle changes in the training data. Handles missing values differently than single decision trees and does not prune the trees.	1. Easily explainable and excellent graphic representation 2. Tolerate missing values by conducting imputation or taking a proximity-based measure 3. High performance	1. High demand for computing power 2. Slow
Panelized regression	Classification, regression	In addition to linear regression, penalizing features to shrink large coefficients (Ridge) or drop less important features (LASSO) Elastic net regression is a mixture of ridge or LASSO regression, and in theory, is superior to either regression alone	1. Address overfitting issue with linear regression to provide better generalizability 2. Fast	1. Does not tolerate missing data 2. Not useful in data with a non-linear relationship

2. <u>The temporal feature:</u>
To reiterate, it is not advisable to include the temporal feature in the data for modeling, as including a temporal feature that is not recurring (e.g., the year is not recurring, the season is recurring) will make the prediction or future events impossible. It is also important to be cautious when including features that are highly correlated with time, as it may give a false impression about the importance of the feature. Readers interested in temporal effects may wish to read more on the concept of time-series forecasting.

Choosing machine learning algorithms

In the past articles, we introduced supervised vs. unsupervised algorithms and linear vs. non-linear algorithms. As most of what we try to accomplish involve predicting the outcome, we typically deal with supervised learning. When choosing algorithms, it is essential to consider sample size, missing values and how they are handled, and the feature size. For example, a support vector machine can tolerate a smaller sample size and high-dimensional (a lot of feature numbers) data. On the other hand, a random forest cannot tolerate missing values and cannot extrapolate. The ad-

vantages and disadvantages of some of the common algorithms are listed in Table 1. While this article does not intend to provide an exhaustive list of all the strengths and weaknesses of all available models, we advise the readers to conduct online searches on the characteristics of algorithms they encounter to understand better the suitability of the algorithm for the clinical questions. It is also essential to discuss which algorithm(s) to choose to build the prediction model with the machine learning engineer. Key aspects to ask include:

1. Handling of dimensionality (high vs. low number of features)
2. Classification vs. regression
3. Training data size
4. Missing value tolerance
5. Real-time modeling (training time) and computational costs
6. Tendency for overfitting
7. Accuracy

"Finally, the metrics for performance assessment are also something to discuss with the machine learning engineer and will be discussed in a later article."

Finally, the metrics for performance assessment are also something to discuss with the machine learning engineer and will be discussed in a later article. Sometimes it may be desirable to trial different algorithms empirically, and that is okay. Machine learning projects are, after all, not hypothesis-driven studies. A predetermined analytic approach, the required sample size for adequate statistical power, and power analysis are usually not considered. The ultimate goal is to create the best model that gives the best prediction performance.

Author contribution: Drs. Tan and Chou contributed equally to this manuscript.

Disclosure: The authors identify no conflict of interest

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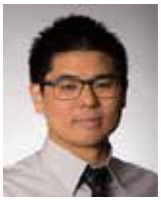

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Neonatology Today's Digital Presence

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

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

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

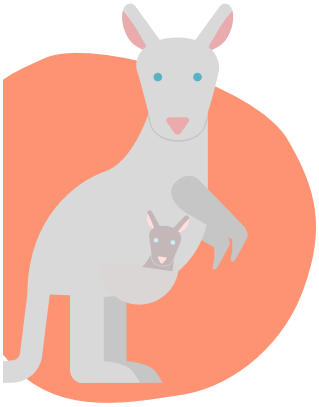
Neonatology Today will continue to promote our Academic True Open Model (ATOM), never a charge to publish and never a charge to subscribe.

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

fu-sheng.chou@neonatologytoday.net

SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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

National Perinatal Association

nicuparentnetwork.org

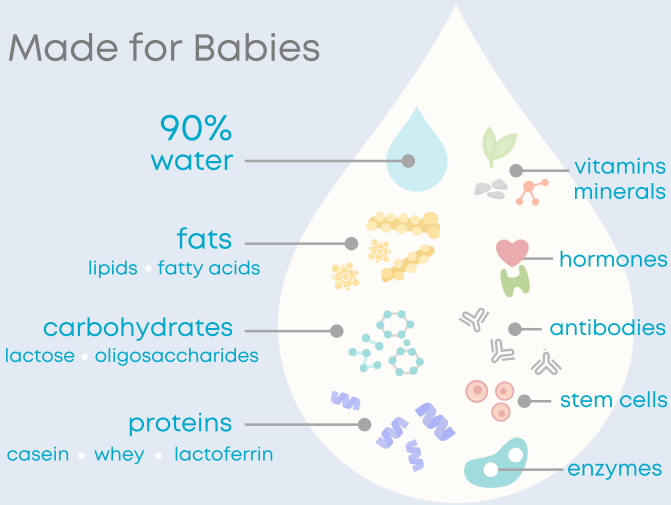
NPN NICU PARENT NETWORK

nationalperinatal.org/skin-to-skin

The Composition of BREAST MILK

200+ components

Made for Babies



Breast Milk is Living Tissue

National Perinatal Association

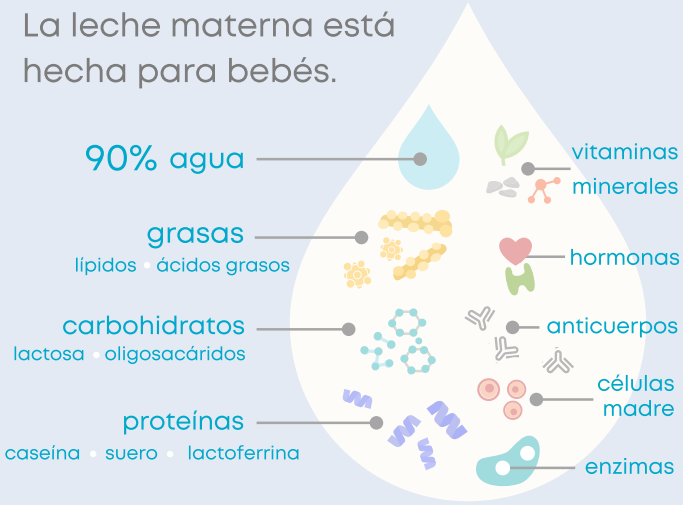
Educate. Advocate. Integrate.

nationalperinatal.org/feeding_our_babies

La composición de la LECHE MATERNA

200+ componentes

La leche materna está hecha para bebés.



La leche materna es tejido vivo.

National Perinatal Association

Educate. Advocate. Integrate.

nationalperinatal.org/feeding_our_babies

The Village Son

A Life's Journey

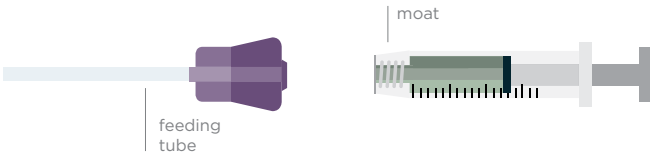
Iranian village to a university professor in the United States of America in this memoir. As a boy, his unruly behavior was sedated by scholastic challenges as a remedy. At age twelve, he left home for junior high school in a provincial capital. At first, a lack of self-esteem led him to stumble, but 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

SAFETY IN THE NICU

New tubes, new problems?

A new tubing design meant to eliminate tubing misconnections has introduced new challenges for the NICU population. Pediatric providers must deliver medication in small volumes to tiny patients with high levels of accuracy. The new tubing design, known as ENFit®, could present dosing accuracy and workflow challenges.



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.

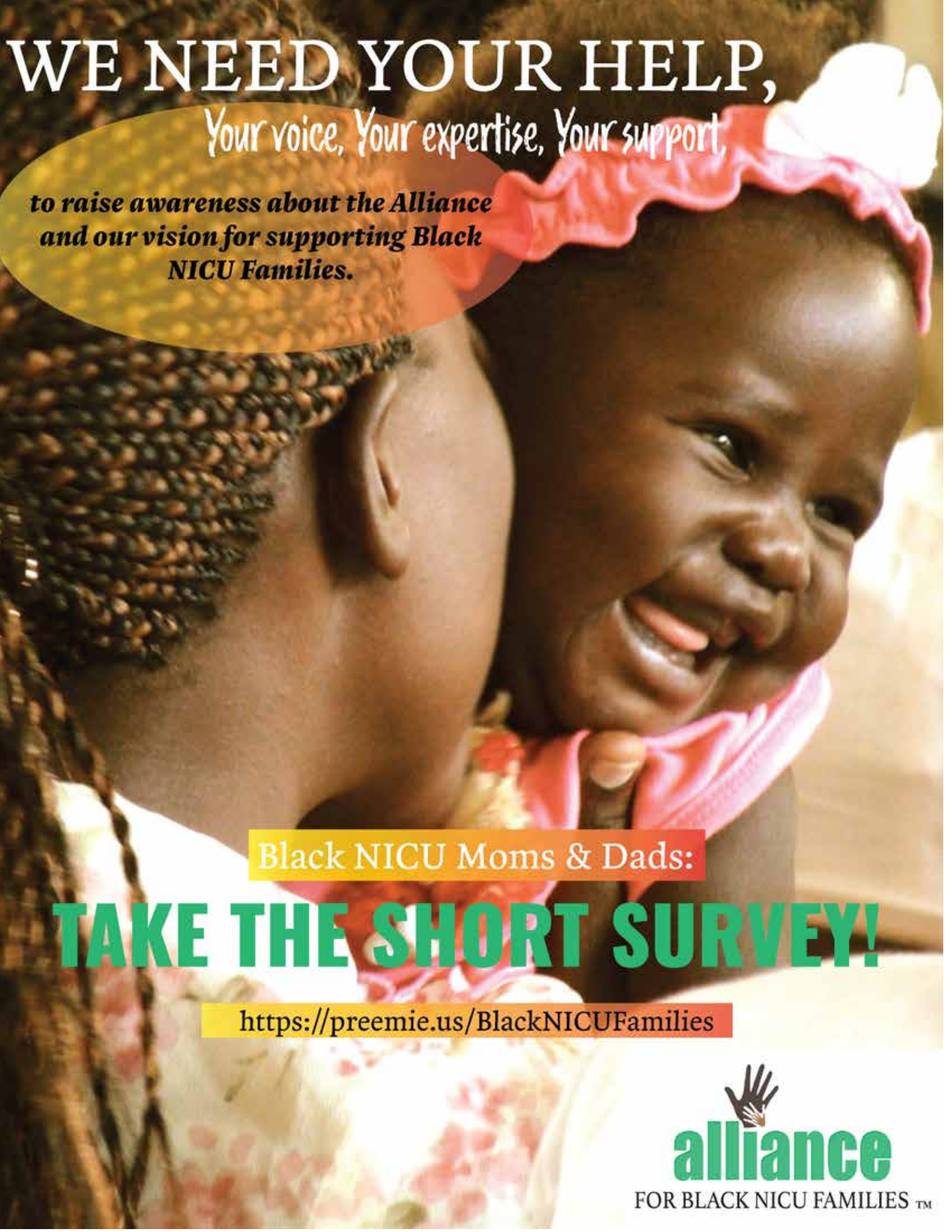
WORKFLOW ISSUES

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

Improved standards are important to protect patients from the dangers of tubing misconnections. But we must avoid mitigating existing risks by creating new ones.

Individual hospitals should consider all factors impacting their NICU patients before adopting a new tubing design.

ENFit® is a registered trademark of GEDSA


WE NEED YOUR HELP,
Your voice, Your expertise, Your support,
to raise awareness about the Alliance and our vision for supporting Black NICU Families.
Black NICU Moms & Dads:
TAKE THE SHORT SURVEY!
https://preemie.us/BlackNICUFamilies
alliance
FOR BLACK NICU FAMILIES ™

Putting Baby Safety Month in The Infant Safe Sleep Context

Barb Himes, IBCLC, CD

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.

"September is Baby Safety Month, a reminder of the choices and challenges facing parents, extended families, and caregivers in creating both waking and sleeping safe environments for infants."

September is Baby Safety Month, a reminder of the choices and challenges facing parents, extended families, and caregivers in creating both waking and sleeping safe environments for infants. Sponsored annually by the Juvenile Product Manufacturers Association, Baby Safety Month is a time to focus on the prevention of accidents and the prevention of accidental suffocation and strangulation in bed (ASSB), a sleep-related infant death.

While the rate of Sudden Infant Death Syndrome (SIDS), another sleep-related infant death, has been falling, the number of babies dying from ASSB has risen from 4.38 per 100,000 live births in 1997 to 25.5 in 2019. From 1999 to 2015 alone, SIDS rates decreased 35.8%, and ASSB rates increased 183.8%, a sobering statistic. (1)

Accidental suffocation is now the most common cause of injury deaths for babies in the United States under one year old, with 82% being attributable to ASSB. The majority of these cases were due to soft bedding and occurred most often in an adult bed. (2)

This information underscores the need to address the causes of ASSB deaths – which are preventable -- and to counsel families on what to do when mother and baby leave the hospital.

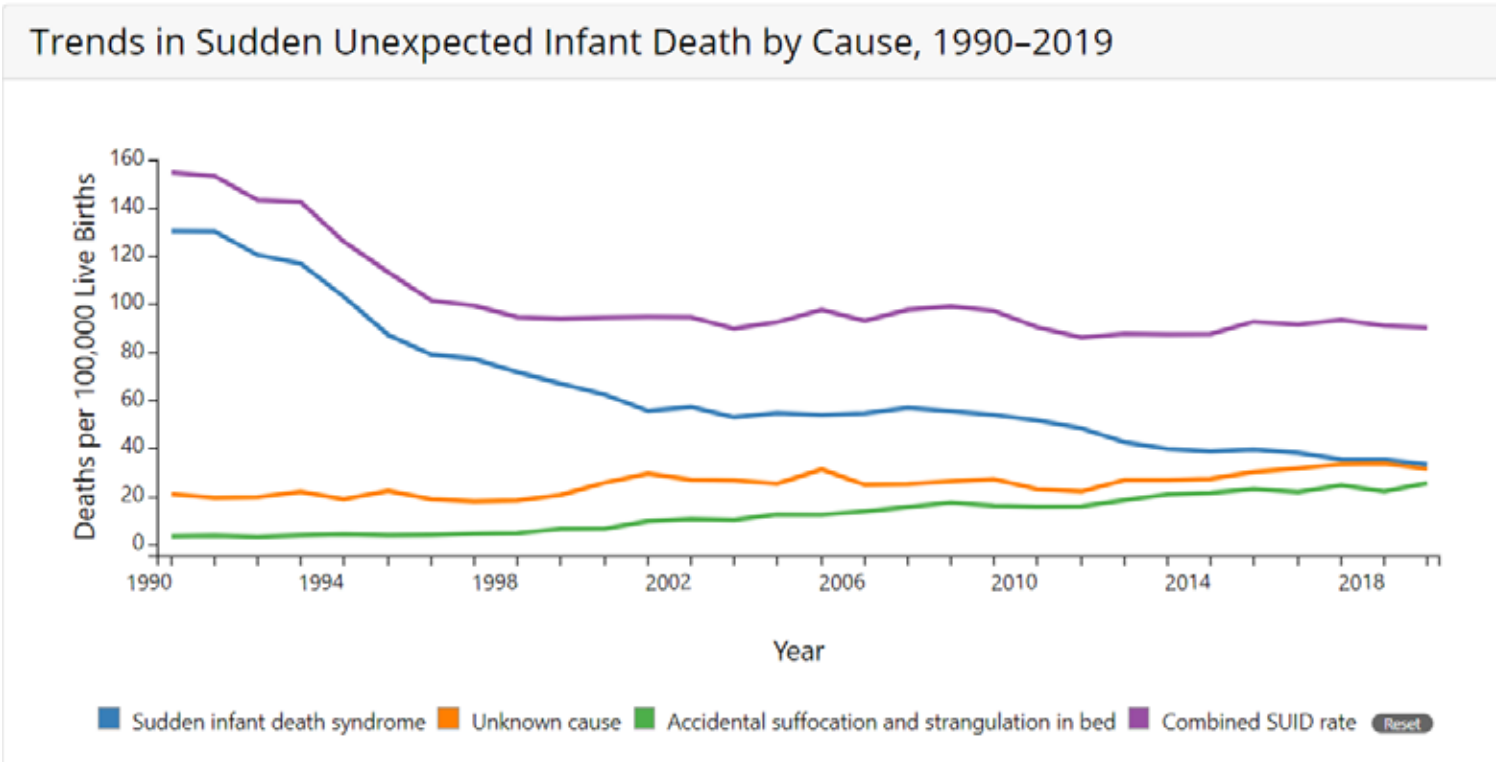
"Accidental suffocation is now the most common cause of injury deaths for babies in the United States under one year old, with 82% being attributable to ASSB. The majority of these cases were due to soft bedding and occurred most often in an adult bed. (2)"

Health Care Providers: A Critical Source

Health care providers, particularly in NICUs, have an opportunity to educate families about safe sleep practices to undertake when they take their baby home. They are in a position to help new parents learn about the American Academy of Pediatrics' 2016 safe sleep guidelines and also to help them understand that there will be differences between what they may see practiced in the NICU and what should be done at home.

As reported in the July 2021 issue of Pediatrics, it is important for health care professionals to prepare families on how they can maintain their infant in a safe home sleep environment. (3) NICU infant needs may call for non-supine positioning, a practice that should be converted as soon as medically feasible (and well prior to hospital discharge) to sleep practices that are safe and appropriate for the home environment.

This includes compliance with the 2016 guidelines by placing in-



Source: https://www.cdc.gov/sids/data.htm

fants at home on a flat, firm sleep surface, such as a crib or bassinet, covered by a fitted sheet with no other bedding. Soft bedding and loose objects can cause airway obstruction and therefore increase the risk of rebreathing, SIDS, and suffocation. If bedding and positioners have been prescribed for developmentally sensitive care, they should nonetheless be removed from the sleep environment.

Safe sleep practices also extend to maternal and infant health through maternal adherence to keeping wellness visits and to gaining the benefits of breastfeeding and skin-to-skin contact. It is understood that safe sleep counsel will differ for non-NICU infants and NICU infants and that there may be individual considerations such as monitoring for Sudden Unexpected Postnatal Collapse (SUPC), depending upon maternal, infant, and birthing characteristics. (4)

New parents should be learning about infant safe sleep practices and concepts at multiple touchpoints: during prenatal care, in the hospital setting, and at well-child check-ups. Giving parents the chance to understand and discuss infant safe sleep and breastfeeding practices increases the likelihood they will become part of their parenting framework.

NICU nurses play a pivotal role in helping parents transition to home care, and during the time before babies are discharged from the NICU, nurses have a critical opportunity to help parents hear and see by demonstration how to help their baby sleep safely at home. NICU staff are a trusted resource for parents who may not realize what they need to know.

At First Candle, we often hear from parents who have lost their baby to ASSB that they did not know about the dangers of having a blanket or stuffed animal in the crib or having their baby in bed with them. This is why we are increasing our efforts to educate all care providers on the importance of creating a safe sleep environment and why we value the role that neonatology health care providers can play in parent education and baby safety.

"At First Candle, we often hear from parents who have lost their baby to ASSB that they did not know about the dangers of having a blanket or stuffed animal in the crib or having their baby in bed with them. "

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4. *https://www.jognn.org/article/S0884-2175(20)30080-0/fulltext*

Disclosure: The author is an International Board Certified Lacta-

tion Consultant, Certified Doula, and the Director of Education and Bereavement Services of First Candle, Inc., a Connecticut-based not for profit 501(c)3 corporation.

NT

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www.firstcandle.org

About First Candle

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

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Neonatologist Opportunity
Davenport, Iowa

Looking to make a change? We have the total package…

The Department of Pediatrics at the University of Illinois College of Medicine and OSF Healthcare are partnering with Genesis Medical Center-Davenport and currently seeking a board certified Neonatologist. Genesis Medical Center-Davenport is a Level II nursery with roughly 1,700 deliveries/year. An excellent benefits package is available including vacations, sick time, malpractice coverage, CME, health and life insurance and retirement plan.

Genesis Medical Center-Davenport is a licensed 502 bed facility, which offers a wide range of inpatient and outpatient medical services. Specifically, the NICU is a 20 bed unit, which consists of ten private rooms and three open bays. The NICU functions as a Level II intensive care nursery. The NICU is equipped to stabilize and manage neonates with acute and chronic illness. It is equipped with emergency and resuscitative equipment including:

- Cardiac and apnea monitors with capabilities for trending/monitoring pulse oximetry
- Non-invasive and invasive blood pressure monitoring
- Oxygen therapy (ventilators, CPAP, bag/mask, high flow nasal cannula, RAM cannula and nasal cannula)
- Warmer units
- Isolettes
- Neonatal instruments for insertion of UAC/UVC lines, PICC lines and chest tubes

The Quad Cities (made up of 5 cities, including Davenport Iowa), representing roughly 400,000 people, is the largest metropolitan area on the Mississippi River between Minneapolis and St. Louis. It is three hours west of Chicago and two and a half hours east of Des Moines, Iowa. The area has recently been ranked as a "best place to live" and is known for safe neighborhoods, short commute times and a reasonable cost of living. The community is fortunate to have excellent schools (in the Quad Cities and surrounding areas), the Niabi Zoo, museums, fine arts, a local festival scene, minor league baseball and hockey, and many seasonal outdoor activities. The John Deere Classic, PGA Tour event, and the Bix 7 road race bring in people from all over the world every summer. The Quad Cities International airport located in Moline, IL connects our community to almost a dozen other cities in the US.

Please contact or send CV to:
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Email: stacey.e.morin@osfhealthcare.org
Web: www.osfhealthcare.org

OSF HealthCare Children's Hospital of Illinois

GENESIS

Neonatal Nurse Practitioner Opportunity

Davenport, Iowa

Looking to make a change? We have the total package…

The Department of Pediatrics at the University of Illinois College of Medicine and OSF Healthcare are partnering with Genesis Medical Center-Davenport to provide neonatology coverage in Davenport, Iowa. Genesis Medical Center-Davenport is a Level II nursery with roughly 1,700 deliveries/year. An excellent benefits package is available including vacations, sick time, malpractice coverage, CME, health and life insurance and retirement plan.

Reporting to the Medical Director of the Neonatal Intensive Care Unit, and according to professional nursing standards of care, performs a variety of advanced nursing diagnostic and therapeutic procedures for the high risk neonates in the critical care setting at Genesis Healthcare—Davenport (Davenport, IA). Demonstrates the knowledge and skills necessary to provide patient care that is appropriate to the ages of the patients served.

Genesis Medical Center-Davenport is a licensed 502 bed facility, which offers a wide range of inpatient and outpatient medical services. Specifically, the NICU is a 20 bed unit, which consists of ten private rooms and three open bays. The NICU functions as a Level II intensive care nursery. The NICU is equipped to stabilize and manage neonates with acute and chronic illness. It is equipped with emergency and resuscitative equipment

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OSF HealthCare Children's Hospital of Illinois

GENESIS

Academy of Neonatal Care: Local, Nationwide, Global!

Kelly Welton, BA, RRT-NPS

"This was necessitated by the closure of several venues where live training was to take place, and now, with the Delta surge, it is happening again. While we are happy this NICU training is now available to anyone in the USA, expanding the training means one thing: we need to go worldwide!"

We previously wrote about the next generation of RT's from a local (Southern California) standpoint. Recently, a 3-day live program was approved by the AARC as an online course. This was necessitated by the closure of several venues where live training was to take place, and now, with the Delta surge, it is happening again. While we are happy this NICU training is now available to anyone in the USA, expanding the training means one thing: we need to go worldwide!

NICUs exist worldwide, and many countries' health systems are continually studying, publishing, and generally improving neonatal care worldwide.

Online and distance learning has been around for some time now, and Covid has elevated our online experience by requiring faster, better platforms to learn and test.

Meetings that previously required travel to see how another country handles a certain disease process now can be accessed from home, often at any convenient hour. Significantly as travel is restricted and likely will be for many more months, we cannot let that slow down our continual improvement of patient care.

Have you ever wondered how another country handles RDS babies? How does another health system in a country without sophisticated implements deal with 24-week premature babies? How does a country thousands of miles away with minimal resources handle the treatment of pneumonia?

Here in the US, we like to think we have the best health system in the world. The most advanced technology. Look at global NICU survival rate statistics, and we are close to the top.

What if we could train, via distance learning, healthcare personnel from around the world? Starting with the basics, let each learner decide how far they want to go with their education. A learner's health system or availability of equipment and supplies may dictate their scope, but let it be that and not the fact that they have no one to teach them one-on-one.

Such a program exists via AcademyofNeonatalCare.org.

Even training in basic foundational NICU care would be helpful to many in countries where there are no RT's, only specialists who learn primarily on the job.

Practical information, such as clustering care and assessment

Technical, such as how to set up NIV and optimize settings for the baby

How- to such as surfactant administration and screening for congenital heart disease

Best practices, such as management of apneas and bradycardias

All of these aspects of care could be pooled with worldwide input to determine new Best Practices and elevate the care of newborns everywhere, not just in developed countries.

"All of these aspects of care could be pooled with worldwide input to determine new Best Practices and elevate the care of newborns everywhere, not just in developed countries."

In our live classes, we discover how vital actual hands-on time is to practice with new equipment until a level of proficiency and competency is reached. Until a NICU student has a way to do so, online programs that allow the learner to review the modules as many times as desired and at times that are convenient for them can help them transfer the knowledge to an actual baby when the time comes.

We look forward to enrolling NICU students from every part of the world in hopes of not just expanding their knowledge but expanding their minds to create systems and processes from any tools, equipment, or resources they have, whether limited or abundant.

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

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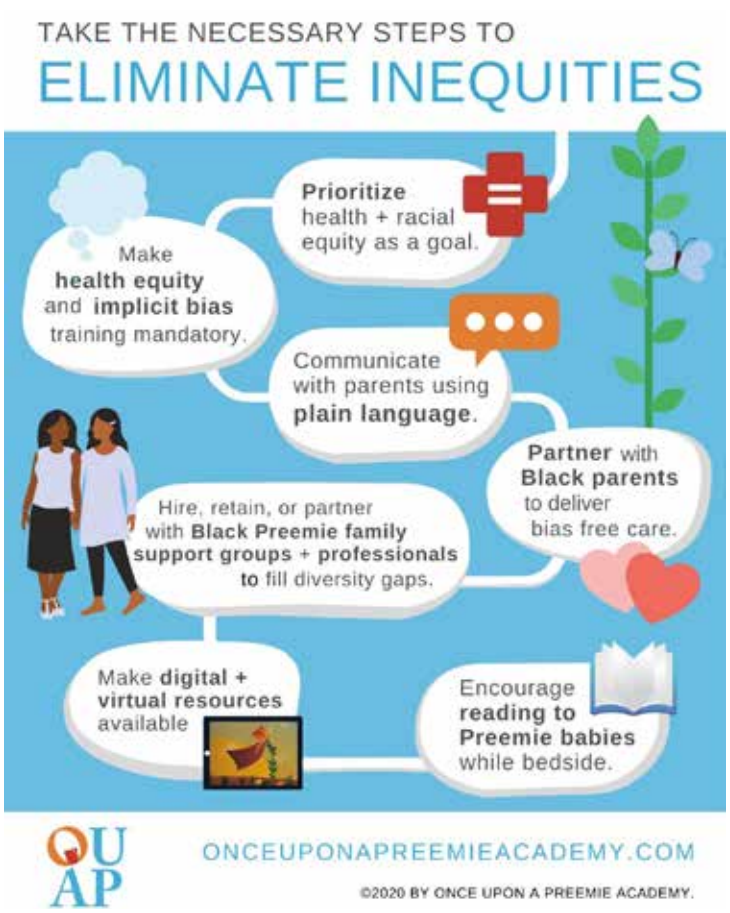


Chief, Division of Neonatology
Project New Born Distinguished Chair in Neonatology
University of Miami Miller School of Medicine
Medical Director, Newborn Services, Jackson Health System

On behalf of the Department of Pediatrics at the University of Miami Miller School of Medicine (UMMSOM), Jackson Health System (JHS), and Holtz Children's Hospital, CareerPhysician, LLC, the national leader in academic pediatric leadership recruitment, has initiated an international search to identify a transformational leader to serve as the next UMMSOM Chief of the Division of Neonatology, and Medical Director of Newborn Services for JHS.

- The incoming Chief will have the opportunity to continue the renowned legacy of the program and the responsibility of establishing and implementing a strategic plan that will guide the division into the future. Eligible applicants shall be at the academic rank of Associate Professor or Professor, board-certified in Neonatology, and hold or be eligible for an unrestricted medical license in the state of Florida.

Opportunity Highlights:

- Dr. Eduardo Bancalari, an international thought leader in Neonatology who has led the division for the past 45-years, has initiated a succession plan and will be stepping down with the naming, transition, and onboarding of his successor. Given the scale and scope of the program and its strong national and international reputation, we believe this opening to be among the premier leadership opportunities currently available in Neonatology.
- The Division has grown to 26 faculty, in addition to administrative and research team members, as well as well as a prestigious and well-respected neonatal fellowship program.
- The incoming leader will also serve as Director of Project: New Born, a nonprofit philanthropic organization supported by the Jackson Foundation.
- JHS hospitals have approximately 7,000 deliveries annually, with the division providing full-time coverage in the Newborn Special Care Center at Holtz Children's Hospital and in two neonatal units at Jackson North and Jackson South hospitals. Division faculty also provide educational support to developing clinical programs in Haiti, the Dominican Republic, and throughout Latin America.
- With 126 beds, the Newborn Special Care Center is one of 11 Regional Perinatal Intensive Care Centers designated by the State of Florida, and is the only Level 4 birthing hospital in Miami-Dade County, a community of 2.8 million people. Of the NICU's 126 beds, 66 are Level IV ICU stations and 60 are Level II/III stations.
- As the only academic Neonatology program in the South Florida region, the division's basic and translational science research interests are comprehensive, with long standing intra and extramural funding.
- As part of the Total Rewards benefits package, University of Miami faculty, staff, and their eligible dependents can receive tuition remission for undergraduate and most graduate degree programs.
- Miami is known as the top ranked healthiest city in the United States, where you will enjoy no state taxes, weather that is never cold, endless recreational pursuits, and world-class amenities!

For more details about this opportunity, or if you would like to recommend an individual(s) who exemplifies the qualities we are seeking in a candidate, please contact Marcel Barbey at marcel@careerphysician.com, or at 817-707-9034. All interactions will remain confidential, and no inquiries will be made without the consent of the applicant.

The University of Miami is an AA/EOE/ADA employer that seeks applicants who add to our culture of diversity and inclusion.

COPING WITH COVID-19

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

Provide culturally-informed and respectful care.

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

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

myNICUnetwork.org

and

National Perinatal Association
NICU Parent Network

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

TOP 10

RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

SUPPORT 4 NICU PARENTS

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

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

1 PROMOTE PARTICIPATION

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

Welcome!

2 LEAD IN DEVELOPMENTAL CARE

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

3 FACILITATE PEER SUPPORT

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

4 ADDRESS MENTAL HEALTH

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

5 SCREEN EARLY AND OFTEN

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

6 OFFER PALLIATIVE & BEREAVEMENT CARE

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

7 PLAN FOR THE TRANSITION HOME

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

8 FOLLOW UP

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

9 SUPPORT NICU CARE GIVERS

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

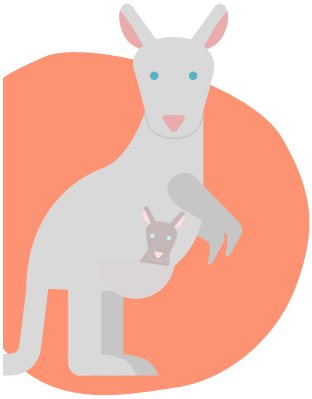
10 HELP US HEAL

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

SUPPORT4NICUPARENTS.ORG

SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

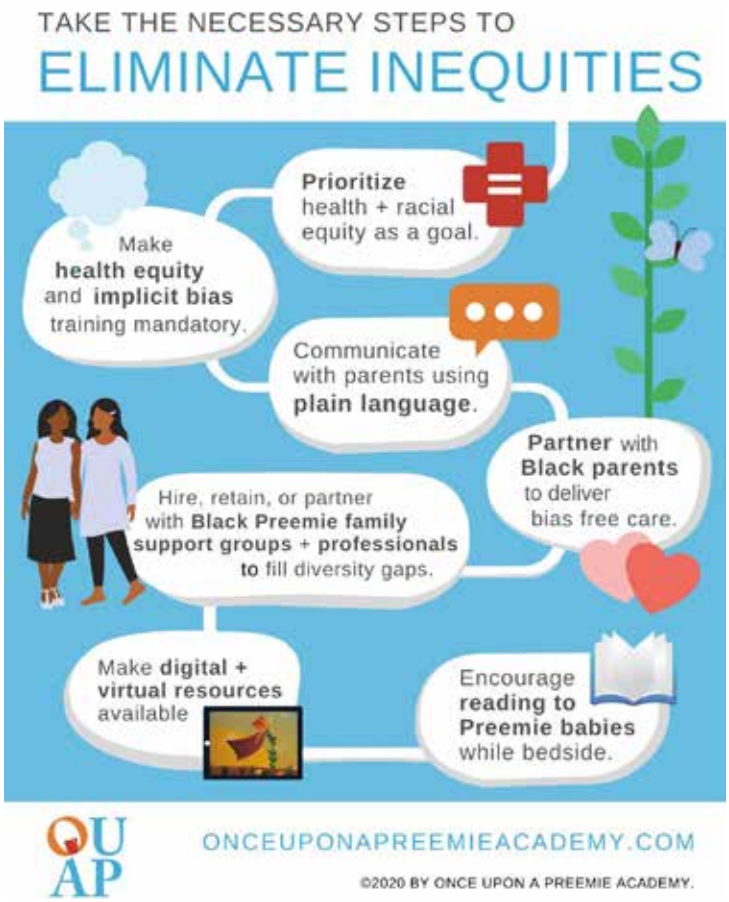
and ask others to hold your baby when you can't be there

National Perinatal Association

nicuparentnetwork.org

NPN NICU PARENT NETWORK

nationalperinatal.org/skin-to-skin


TAKE THE NECESSARY STEPS TO
ELIMINATE INEQUITIES
Prioritize health + racial equity as a goal.
Make health equity and implicit bias training mandatory.
Communicate with parents using plain language.
Partner with Black parents to deliver bias free care.
Hire, retain, or partner with Black Preemie family support groups + professionals to fill diversity gaps.
Make digital + virtual resources available
Encourage reading to Preemie babies while bedside.
QUAP
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Keeping Your Baby Safe
during the COVID-19 pandemic
How to protect your little one from germs and viruses
Even though there are some things we don't know about COVID-19 yet, there are many more things that we do know. We know that there are proven protective measures that we can take to stay healthy.
Here's what you can do...
Wash Your Hands
This is the single, most important thing you can do to stop the spread of viruses.
Use soap.
Wash for more than 20 seconds.
Use alcohol-based sanitizers.
Limit Contact with Others
Stay home when you can.
Stay 6 feet apart when out.
Wear a face mask when out.
Change your clothes when you get home.
Tell others what you're doing to stay safe.
Provide Protective Immunity
Hold baby skin-to-skin.
Give them your breast milk.
Stay current with your family's immunizations.
DONATE
Take Care of Yourself
Stay connected with your family and friends.
Sleep when you can.
Drink more water and eat healthy foods.
Seek mental health support.
Immunizations Vaccinations save lives. Protecting your baby from flu and pertussis lowers their risks for complications from coronavirus.
WARNING
Never Put a Mask on Your Baby
Because babies have smaller airways, a mask makes it hard for them to breathe.
Masks pose a risk of strangulation and suffocation.
A baby can't remove their mask if they're suffocating.
If you are positive for COVID-19
Wash with soap and water and put on fresh clothes before holding or feeding your baby.
Wear a mask to help stop the virus from spreading.
Watch out for symptoms like fever, confusion, or trouble breathing.
Ask for help caring for your baby and yourself while you recover.
We can help protect each other.
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The Importance of Data in an Exclusive Human Milk Diet: Key Concepts and Points of Consideration

Mitchell Goldstein, MD, MBA, CML

"Data is a term that is not hard to define but is difficult to describe. We recognize data for what it is but fail to understand how to interpret it. In the interest of qualifying data and preserving effort, more rigorous challenges to data are often put aside to qualify or validate the effort."

Data is a term that is not hard to define but is difficult to describe. We recognize data for what it is but fail to understand how to interpret it. In the interest of qualifying data and preserving effort, more rigorous challenges to data are often put aside to qualify or validate the effort. Such is the case with the study of human milk. Although a study could be found to support just about any conclusion one is seeking, when reviewed in toto an exclusive human milk diet (EHMD) defined as mother's milk and/or pasteurized donor milk plus a human milk-based fortifier has proved to be best for babies time and time again. (1-5) Not all donor milk is created equal, however, and relying on pasteurized donor milk studies to draw conclusions about donor milk sterilized by other means is not appropriate. Any inference that pasteurization is a form of sterilization is incorrect. (6)

The importance of appropriate data analysis

Although statistics do not really lie, they can be manipulated to mask the truth, especially if the most meaningful benchmark for the data analysis is not applied. For example, setting an appropriate endpoint and studying an appropriate sample size are both critically important.

A power analysis for an appropriate metric should be performed. (7) Whether that metric focuses on increases in lean body mass, improved immunological wellbeing, or reduction in NEC, clinically meaningful differences must be defined. Studying a vast number of points is not a viable solution to this problem but will invariably qualify even the most numerically similar samples as smaller and smaller differences are deemed significant. (8) Yes, quantity is important, but this quantity must be qualified by a study design that supports realistic conclusions.

In Neonatology, the provisioning of an exclusive human milk diet has been demonstrated as superior in numerous trials. Although data exist for various means to improve clinical outcomes, increase growth velocity, and improve other aspects of newborn health, few interventions compare with human milk. (1-5)

When analyzed appropriately, the totality of the data strongly support the use of an EHMD

To date, roughly fifty studies provide evidence of the overwhelming success of EHMD in providing solid metrics of health quality improvement in an at-risk population defined by higher risks for morbidity and mortality.

The quality and quantity of these data are critically important, as is the sheer preponderance of the evidence, be it different centers or different protocols. If all these studies have similar outcomes, this is not by chance. That being said, studies that look at a range of human milk supplementation or supplementation that varies according to the availability of mom's own milk can be called into question. For there to be equipoise, bias in thought and bias in the sample must be avoided. The statistical methodology must be appropriate for the data. Specifically, it is inappropriate to use multiple T-tests to study the differences between different points of comparison in a study. By chance, certain comparisons may show up positive, despite the lack of true statistical significance. (9) A Bonferroni correction can help provide clarity and adjust for the multiple comparison problem, but other statistical methods may provide a better and more thorough analysis. Post hoc testing can help define where differences in data exist but looking at outcomes other than the primary endpoint may be problematic, (10) particularly those that have not been pre-defined. (11) Lack of statistical power may lead to incorrect conclusions, but overpowered studies may invariably find a "statistically" significant finding with no clinical utility. (12)

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In planned comparisons, the data uniformly favors an exclusive human milk diet. The data support that EHMD is the standard for premature infants less than 1,250 grams. Data demonstrate a 77% reduction in NEC and meaningful reductions in many other common comorbidities (Sepsis, ROP, BPD, along with feeding intolerance, TPN, and length of stay). (13, 14)

What is more, the use of human milk has long been associated with other advantages, including reduced risk of diarrhea, leukemia, otitis media, viral respiratory tract disease, as well as certain metabolic disease processes, including type II diabetes and childhood obesity. (15-18) Neurodevelopmental studies and those that look at the quantification of white and grey brain matter suggest a definitive effect.

Additionally, the maternal benefits of breastfeeding cannot be ignored. Breastfeeding has been associated with decreased risk of type II diabetes, more rapid return to prepartum weight, decreased cardiovascular disease, modulation of hypertension, and reduced risk of metabolic syndrome. (19, 20) A reduced risk of breast and ovarian cancer has been demonstrated in those women who have breastfed. Even autoimmune disease processes may be mediated by breastfeeding. (21, 22)

The cost of using bovine and other breastmilk substitutes reaches into the billions of dollars annually in the United States. (17, 23, 24) Society is effectively subsidizing disparate outcomes in our most at-risk infants. Understanding the demographics of this situation is crucial. With the breastfeeding rates lowest in African American and Latinx families, these patterns worsen existing disparities. (25, 26) Inequities in access to resources to improve breastfeeding rates and lack of support in these communities for baby-friendly practices create boundaries that are often insurmountable for those most at risk.

"The cost of using bovine and other breastmilk substitutes reaches into the billions of dollars annually in the United States. (17, 23, 24) Society is effectively subsidizing disparate outcomes in our most at-risk infants."

It is not appropriate to extrapolate data from pasteurized human milk studies to human milk sterilized by a different process.

The handling, the testing, and the processing of human milk are all critical to its makeup. Milk that is not processed appropriately is not equivalent to milk, that is. Protein, fat, vitamin, mineral, and micronutrient content and HMOs can be altered significantly if the integrity in processing is compromised. In particular, retort sterilization methods can produce results that may be suitable for canned tuna but not for a product as vulnerable as human milk. (27) Arguably, while a product made from the process may have a limitless shelf life, the process destroys the entire biologic value of human milk. There is a fundamental lack of data for retort sterilization. (28) How can this be acceptable? It is an experiment at best. Certain providers are selling an ill-defined product without relevant data -- A false narrative. At some point, it is crucial to demonstrate that human milk is still functionally human. Scientific rigor is meaningless if processing renders the product less than what it is claimed to be. (29)

No discussion about human donor milk is complete without at least a mention of safety. Although there is not a clear FDA qualification as to what constitutes and what is required for EHMD safety, it goes without saying that whether donor milk comes from a for- or not-for-profit model, the risks are still the same. Risks associated with pathogens and adulterants are not different between products made by milk banks of the two business models, as the only distinction between the two is merely their tax filing status. (30) Both for-profit and not-for-profit entities still have expenses and must pay their employees, provide safety screening, and ensure that adequate testing is in place to provide a safe final product. Both for-profit and not-for-profit milk banks are collecting human bodily fluid from a person outside of their direct proximity and control. The chance that a donor may inadvertently leave her child's daycare with milk belonging to someone else is not different between business models. The prescription drugs that donors are prescribed are not different, nor is the risk of exposure to harmful pathogens. Rigorous donor screening is not enough; the milk itself must be tested to ensure it is safe for the fragile infants it is destined to feed. (30-33)

The slightest error could be harmful or fatal for premature babies in Neonatal Intensive Care Units (NICUs). The possible long-term effects are myriad. These errors, when compounded, may mean the difference between an outcome that results in a baby that has a chance to reach a high potential and one that leads to developmental delay, multiple subspecialty appointments, increased risk of chronic disease, and growth failure. (34) Preemie parents, often feeling helpless and overwhelmed, place their faith and their child's life in the hands of physicians, nurses, and other hospital providers, doing everything humanly possible to ensure the best outcome for the baby. These clinicians must use the most scientifically sound information available to them. Knowledge of this information requires intense scrutiny of the literature and an understanding of how to interpret the findings for the best possible outcomes. For the healthcare team, every decision is made with the utmost care. Anecdotal reports have no place in this evaluation. Instead, evidence-based randomized control trials, other well-controlled data, and knowledge of the best information available must dictate best practice. That care often includes the use of human donor milk and human donor milk-derived products, including fortifiers. (13, 35)

"Anecdotal reports have no place in this evaluation. Instead, evidence-based randomized control trials, other well-controlled data, and knowledge of the best information available must dictate best practice. That care often includes the use of human donor milk and human donor milk-derived products, including fortifiers. (13, 35)"

When analyzing studies, several questions must be asked:

1. Who is in the population? Preterm babies? Term babies?

2. What is being compared? Human milk to cow milk? Traditional Pasteurization methods to those that are less well known or studied?
3. Is the term exclusive human milk diet truly exclusively human milk, or just human milk as a base with cow milk-based fortification?
4. Where is the study taking place? In the NICU? In the normal nursery? In a home environment?
5. Is this a randomized control study, a cohort study, a case report, or case series?
6. If this is a randomized control study, did a research board approve the study?
7. Is the study adequately powered? Is the sample size sufficient to make the comparison? Did patients drop out of the study? Were there enough patients at the end of the study to make an adequate comparison?
8. Do the statistics support a clinically relevant endpoint? Or is the endpoint trivial?
9. What are the implications for practice? Findings in term infants or more mature preterm infants may not be relevant to those at the margins of viability.
10. What is the feasibility of implementing these findings in other populations? Are the conclusions generalizable to broader clinical arenas?
11. What about cost? Will spending more upfront produce economies of scale, decrease morbidity or mortality, or decrease the length of hospitalization?
12. Are there long-term outcome data? Many therapies are too new to be looked at retrospectively, but where data exists, it should not be ignored.

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Disclosures: There are no relevant disclosures identified.

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Raising Global Awareness of RSV

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

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

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

RSV GOLD

A Global Mortality Database for Children with RSV Infection

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

30th Annual Course Jen-Tien Wung Respiratory Care of the Newborn: A Practical Approach October 9 & 10, 2021

Rakesh Sahni, MD

Program Description and Objectives

The use of nasal continuous positive airway pressure (CPAP) as the initial mode of respiratory support in critically ill very low birth weight infants is associated with a lower incidence of chronic lung disease. Evidence also supports the role of nasal CPAP in facilitating weaning from mechanical ventilation and reducing lung injury. However, nasal CPAP success rates are widely variable and may be attributable to how well it is utilized. With a recent renewed interest in bubble nasal CPAP, it is essential to evaluate strategies for success that may depend on using correct CPAP devices, attention to detail, and caregiver experience. This unique program will share the successful bubble nasal CPAP experience at the Morgan Stanley Children's Hospital of New York, Columbia University Medical Center, and discuss the rationale, practical aspects, and strategies for replicating success with bubble CPAP use. These management protocols have been practiced successfully for more than forty-five years and have been shown to reduce chronic lung disease without increasing morbidity and mortality.

"This two-day course will cover virtually all aspects of neonatal respiratory care, including kinder, gentler mechanical ventilation, neurally adjusted ventilator assist, high-frequency ventilation, non-invasive modes of respiratory support, oxygen targeting, one-lung ventilation, surfactant therapy, inhaled nitric oxide therapy, and the use of laryngeal mask airway."

This two-day course will cover virtually all aspects of neonatal respiratory care, including kinder, gentler mechanical ventilation, neurally adjusted ventilator assist, high-frequency ventilation, non-invasive modes of respiratory support, oxygen targeting, one-lung ventilation, surfactant therapy, inhaled nitric oxide therapy, and the use of laryngeal mask airway. Participants will become familiar with the application and pitfalls of bubble nasal prong continuous positive airway pressure (CPAP) therapy and ventilatory strategies in infants with respiratory distress. We will also address strategies for CPAP success from a nursing perspective, clinical care of patients with RDS, persistent pulmonary hypertension in term and preterm infants, pulmonary hypertension in infants with chronic lung disease, and fetal surgery. In addition, innovations in monitoring during neonatal intensive care, golden hour management, screening for congenital heart disease, comfort care, point of care sonography, and 'Pearls in Neonatology' will be discussed. The conference will include didactic presentations and videos. The virtual platform will provide an interactive experience for participants with live-streamed educational sessions and live Q&A. The main learning objectives of the conference are that at the conclusion of this conference, participants will be able to recognize the rationale for using bubble nasal CPAP, familiarize themselves with practical aspects of effective bubble CPAP use, identify strategies for replicating and evaluating success with bubble nasal CPAP and other respiratory care practices at their own institutions. This CME activity will be evaluated for its impact on knowledge/competence with the completion of evaluation forms at the end of the conference.

This conference is intended for the entire neonatal critical care team: physicians, nurses, nurse practitioners, respiratory therapists, physician assistants, and other allied health professionals practicing in the neonatal intensive care arena interested in improving respiratory care outcomes in neonates. Attendance by complete physician-nurse-respiratory therapist teams is strongly recommended and encouraged.

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Disclosures: There are no relevant disclosures identified.

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NT

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Did you know that more than half of the babies admitted to NICUs were not born prematurely? See our fact sheets.

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3 Recognize NICU Staff
Let them know the difference they are making in our babies' lives. Write a note, send an email, or deliver a gift to show them that you appreciate them.

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Most people have never heard of a NICU before. Let others know about the extraordinary care that NICUs provide.

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Non-Invasive Ventilation (NIV): Failure is Not a Four-Letter Word

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.

"Not so long ago, premature babies were intubated and ventilated strictly based on gestational age (GA) and not a clinical condition. Many of these babies ended up with chronic lung disease (CLD) that could have likely been avoided had they not been intubated."

NIV may be the most substantial change in neonatal ventilation since neonatal ventilators were invented. Before ventilators, NIV was the only respiratory support available to clinicians caring for neonates. As the saying goes, "everything old is new again." The concept may be old, but the practice is quite clearly here to stay. That is not a bad thing. Not so long ago, premature babies were intubated and ventilated strictly based on gestational age (GA) and not a clinical condition. Many of these babies ended up with chronic lung disease (CLD) that could have likely been avoided had they not been intubated.

The tools available to clinicians have changed considerably during neonatology's relatively short life. While bubble CPAP and nasopharyngeal tubes (NPTs) were once the only NIV game in town, today we have a myriad of equipment and modalities at our disposal as well as different interfaces (I confess to being fondly reminiscent of NPTs).

In addition to having a greater selection of equipment to choose from, we now also have several NIV modes available. I have used non-invasive positive pressure ventilation (NIPPV) in my practice since I started as a respiratory therapist over 32 years ago. Back in the day, it was referred to as "NPT puffs," and pressures were set by occluding the circuit and adjusting accordingly, and standard settings were a peak inspiratory pressure (PIP) of 12 cmH_2O and a PEEP of 5 cmH_2O at a rate of 12. The practice was laughed at by other NICUs in Toronto, but fast forward to today, and its use is commonplace, albeit with different interfaces.

Without leak compensation and adaptive flow, older machines delivered considerably less pressure than was set. Combined with the low PEEP/CPAP level, this undoubtedly resulted in many failures and subsequent intubation/reintubation. A major difference today is that newer ventilators are more adept at maintaining and delivering pressure than those of old, and pressures are set while the baby is connected; thus, the baby receives what is dialed in.

Other NIV modalities include high flow (HF) and non-invasive high-frequency oscillation (NIHFO), and both of these modes have been used extensively over the last decade or so. The latter may improve the odds of successful extubations (1). I have previously written on non-invasive high-frequency jet ventilation (coined "NINJA"), and while some research has been done on the topic (2,3), it has not (as of yet) seen utilisation in the clinical setting. Until the FDA approval of 3rd generation ventilators with NIHFO capability, this is the only high-frequency NIV mode currently available to American clinicians.

"The newest adjunct to NIV is the use of neurally adjusted ventilatory assist (NIV-NAVA), which allows for synchronization of NIPPV as well as assessment of the adequacy of CPAP level through diaphragmatic tone."

The newest adjunct to NIV is the use of neurally adjusted ventilatory assist (NIV-NAVA), which allows for synchronization of NIPPV as well as assessment of the adequacy of CPAP level through diaphragmatic tone. NIV-NAVA shows great promise in facilitating successful extubation and more efficient NIV, possibly by decreasing work of breathing (WOB) and by decreasing the amount of gastric air in NIPPV through synchronization (4). It is rapidly gaining favour for the provision of NIV.

Technical improvements in NIV have undoubtedly increased the likelihood of success, while the patients we place on NIV have gotten ever smaller. Simultaneously, "ETTphobia" threatens to overtake "PEEPaphobia" as the dominant malady in NICUs as NIV has been taken up with religious fervor around the world. This is not a problem when NIV is used judiciously on appropriate patients who indeed do not require intubation and are best served by an NIV modality; the problem arises when it is not.

As a practicing bedside clinician, I have always believed in treating the patient, not the numbers. NIV can and should be considered even for a tiny baby should that baby's respiratory drive be sufficient and oxygen requirements low enough, but as much thought should be put into failure criteria as is put into the selection of respiratory support. Like an emotional investor who watches their money disappear when the value of the stock they "believe in" plummets into oblivion, too many clinicians stubbornly refuse to intubate a baby who is telling them loudly and clearly in the only language available to them that they are failing. What is that language? There are several dialects: FiO2, apnea, bradycardia, and WOB.

FiO_2

July's NT column discussed O_2 and O_2 toxicity and how they relate to gestational age and endogenous antioxidant protection (or lack thereof). The relative lack of antioxidant protection in the micropremature infant is well known. What is now becoming clearer are the consequences of long-term exposure to increased levels of O_2: impaired pulmonary function later in life and structural lung abnormalities (5), not to mention retinal damage. This effect appears to be a combination of O_2 concentration and time, and it has been suggested that cumulative O_2 exposure during the first 72 hours of life is predictive of "respiratory symptoms and respiratory-related health service and medication use during infancy in a dose-dependent manner" (5).

"While high FiO2 is detrimental over the long term, it is wise to avoid it during the first 72 hours of ventilatory management as much as possible."

While high FiO_2 is detrimental over the long term, it is wise to avoid it during the first 72 hours of ventilatory management as much as possible. I maintain that the closest one can manage a baby to 21% O_2, the better.

Finally, increasing O_2 requirements are usually an indication that the lungs are de-recruiting. Ignored, this may progress to total collapse with associated atelectrauma and resulting inflammatory cascade.

Apnea and/or Bradycardia

Apneic and bradycardic episodes are de rigueur in the premature infant even with adequate "caffeination." NIPPV or NIHFO may mitigate the severity of spells but come with the risk of increasing gastric air. The changes in SpO_2 and cerebral blood flow associated with these episodes can contribute to the development of ROP and cerebral bleeds, particularly during the first 72 hours of life. An infant requiring frequent stimulation and adjustments in FiO_2 during this period may be better off being intubated and ventilated with a lung-protective strategy until this risk period is over.

WOB

The smallest babies will generally display a degree of WOB, and because their chest walls lack rigidity, some degree of intercostal indrawing is usually evident. In and of itself, this is not of great importance unless quite severe; however, when the chest wall significantly retracts, this represents a problem. This may appear to be more severe than is actually the case in the presence of a pectus excavatum, as the concave chest gives the appearance of retraction even at rest. Severe indrawing is evidence of high airway resistance and/or low pulmonary compliance. It may be accompanied by expiratory grunting, the infant's physiological response to maintain airway patency on expiration. This demonstrates the need for greater support than is being provided to the baby.

Tachypnea is often cited as evidence that an infant is experiencing increased WOB. Faster breathing clearly requires more energy but smaller babies (just like smaller animals) tend to have faster respiratory rates than larger ones. In isolation, mild tachypnea is not concerning; however, in combination with other clinical observations such as retractions and increasing FiO_2, it is. Tachypnea can be a sign of insufficient recruitment since insufficient functional residual capacity (FRC) results in decreased pulmonary compliance. In this case, drawing smaller breaths at a faster rate requires less energy than breathing at a slower rate with larger tidal volumes. Note that as compliance deteriorates, further grunting may ensue, and respiratory rate may decrease as the collapsing lung increases airway resistance (Ra/w) which, in turn, requires longer expiratory time.

"Tachypnea can be a sign of insufficient recruitment since insufficient functional residual capacity (FRC) results in decreased pulmonary compliance."

Modes and Devices

Stand Alone NIV Devices

Bubble CPAP (BCPAP)

The bubbling from bubble (BCPAP) produces a high frequency, low amplitude oscillation, and noise that may explain its history of reliability and successful use. Even with this relatively ancient, simple modality, some factors influence both the frequency and amplitude of the bubble BCPAP, such as the flow rate, the diameter of the submerged tube and the diameter of the BCPAP bottle (6). Changing the underwater portion of the circuit also has implications with a "J" shape improving oscillatory amplitude and consistency (7), and the noise generated by the bubbling water itself may also be implicated as a contributing factor to the mode's success (8). BCPAP may be used with virtually any NIV interface that will fit.

Stand Alone NIV devices

The first commercial device that provided CPAP was the "Aladdin®" from Hamilton Medical, later renamed the Infant Flow System®. This device came with proprietary securement hats, nasal prongs, and mask interfaces. A fluidic flip in the interface was purported to reduce WOB by reducing expiratory resistance though some question the validity of the evidence supporting this. Later models (called SiPAP®) included providing bi-level pressure at an adjustable rate and inspiratory time. Later, an interface for synchronization was added; however, it did not work very well in practice. The Achilles heel of this system was its "safety" pressure limit. Once a system pressure of 12cmH_2O was reached, it would dump **all** pressure for a few seconds. This happened more frequently as support pressures increased such that, in practice, a CPAP level of 8 cmH_2O was its practical operational limit. Given that this most commonly occurred when treating patients needing a high level of support and who were on the verge of requiring intubation it was, to say the least, frustrating.

High Flow Nasal Canulae (HF)

HF is one of the simplest ways to deliver CPAP. Nasal cannulae are connected to a humidified source of gas flow, and the flow rate is adjusted to deliver desired support. The cannulae must be capable of delivering high enough flow rates. The RAM® canulae are likely the most widely used interface for HF delivery. The Wilkinson formula (9) has been used to estimate delivered CPAP pressure, but many units simply adjust the flow rate to clinical effect in practice. Many infants respond quite well to this modality, and an added benefit is patient comfort since the prongs do not have to be tightly fitted for effect.

"he RAM® canulae are likely the most widely used interface for HF delivery. The Wilkinson formula (9) has been used to estimate delivered CPAP pressure, but many units simply adjust the flow rate to clinical effect in practice."

Ventilators

Early neonatal ventilators such as the Sechrist® were used to provide CPAP (and NIPPV) via a nasopharyngeal tube (NPT). This is a regular ETT cut to a length either as determined by direct laryngoscopy to sit just behind the soft palate, or, as was the practice in the unit I practice in, just over 4 cm. (The "P" of Portex on a Portex ETT). With no leak compensation or synchronization, this was rudimentary but did allow for a backup rate and inspiratory time (Ti). A problem associated with these systems is how pressure was typically set: circuit was occluded, pressure(s) set, and the device attached to the NPT. Delivered pressure(s) were invariably lower than set, compounded by CPAP levels of 5 cmH_2O were rarely exceeded. In addition, the resistance of the NPT increased WOB, especially with a longer length.

Third-generation ventilators now include NIV modes. Leak compensation, when available, greatly improves the consistency of delivered pressure in the presence of air leak but in NIPPV mode, maintaining peak inspiratory pressure remains a challenge. Decreasing the slope or increasing inspiratory flow (if inspiratory and expiratory flows can be adjusted independently) may help. If HFO mode is available, these machines may also be used to deliver NIHFO, although the mode has not been validated. Some machines can also provide "oxygen therapy," a constant flow delivered through the inspiratory limb of the circuit that can be used for HF. This eliminates the need for additional equipment and circuits (other than the NIV interface); however, backpressure from nasal prongs may cause the machine to dump pressure. (I have performed bench testing that seemed to indicate 12 lpm was a maximum flow rate with the Drager® VN500, although I have seen the machine dumping pressure at lower flows).

NIV Failure

The surest way to fail our patients on NIV is by failing to establish what represents failure. May I suggest several?

FiO_2

Increasing O_2 requirements usually indicate pulmonary derecruitment. Increasing CPAP support or use of early NIPPV may reverse or mitigate increased FiO_2; however, once derecruitment occurs, re-recruitment is very difficult using NIV. In addition, lungs are very prone to damage during recruitment on top of the damage caused by derecruitment. I suggest an increase of >10% in O_2 requirements should put NIV failure on the radar, combined with other criteria doubly so.

Leaks

Even the most modern NIV devices and interfaces are rendered less effective in the face of leaks, be they around the interface itself or from an open mouth. Chin straps may be used to reduce leakage from the mouth (and may be necessary with higher support pressures), and interfaces should be snug but not tight (with the exception of the RAM® canulae). Nasal prongs should be sized such that they just occlude the nares, and the nasal septum should be visible and not blanched. Nasal masks are sometimes better tolerated, but care must also be taken to avoid undue pressure on the nasal bridge and upper lip. Overtightening of nasal prongs can result in catastrophic damage to the nasal septum, whereas with nasal masks, the bridge of the nose can be excoriated, or the entire centre of the face may be caved in.

Pressure and the Law of Diminishing Return

As NIV support pressure increases, so does the amount of gastric air. Ensuring oral gastric tubes are in situ and vented to air helps, as does routine aspiration of air from the stomach. Eventually, even with due diligence, there may be so much air accumulation in the stomach that it compromises lung volume. This results in increased WOB, tachypnea, and eventually complete derecruitment. From a practical bedside perspective, I find CPAP pressures or NIVHFO MAP of ≥12 cmH_2O are likely to result in excessive gastric distention and/or nasal damage from efforts to maintain pressure if used for an extended period. As such, the requirement for this level of pressure should be considered a failure.

"As NIV support pressure increases, so does the amount of gastric air. Ensuring oral gastric tubes are in situ and vented to air helps, as does routine aspiration of air from the stomach. Eventually, even with due diligence, there may be so much air accumulation in the stomach that it compromises lung volume."

PEEPAPHOBIA

I have bolded this sub-heading because it may be the factor most likely to lead to NIV failure. Infants extubated to NIV should be placed on a CPAP level equal to the **MAP** prior to extubations, **not** PEEP. This may be weaned as indicated, but failure to provide sufficient distending pressure post-extubation is a sure path to failure. Similarly, when NIV is the first intention, pressure must be adequate to aid in recruitment. Initially, this may be 10 – 15 cmH_2O or more. PEEPaphobia on the admission table is likely to buy the patient an ETT.

Other Considerations

The need to vent gastric air as well as feed necessitates the placement of an OGT. In some infants, the existence of an OGT may

decrease vagal tone leading to bradycardic or apneic episodes. One might be tempted to place the tube nasally to avoid this when problematic. This should not be done as notching the nare from pressure required to maintain a seal can occur quickly with an NIV interface.

"One might be tempted to place the tube nasally to avoid this when problematic. This should not be done as notching the nare from pressure required to maintain a seal can occur quickly with an NIV interface."

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Summary

NIV is a universally accepted form of respiratory support in the NICU, and its use will only increase as technology improves. In our desire to avoid the pitfalls of intubation and mechanical ventilation, failing to recognize that NIV is not meeting the patient's needs is not the patient's failure; it's the clinician's.

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

NT

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.

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

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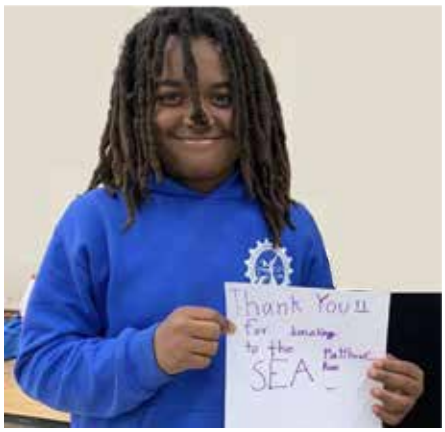

1 session	$15
1 week	$30
1 month	$120
1 semester	$540
1 year	$1,080
Middle School	$3,240

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

Neonatal Intensive Care Unit Awareness Month

JaNeen Cross, DSW, MSW, MBA

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

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

National Perinatal Association

Educate. Advocate. Integrate.

"September is Neonatal Intensive Care Unit Awareness Month. As awareness is vital this month, this article will discuss the preliminary findings from a qualitative study to improve awareness about the experiences of women of color in the NICU."

September is Neonatal Intensive Care Unit Awareness Month. As awareness is vital this month, this article will discuss the preliminary findings from a qualitative study to improve awareness about the experiences of women of color in the NICU. Health disparities, social determinants, and concerns for provider bias are key themes in this study. Recommendations are offered to help support the needs of minority parents in the NICU.

"Many women struggle with healing post-delivery while adjusting to the physical, mental, and emotional toll of having their infant in the NICU."

Health Disparities

Many women struggle with healing post-delivery while adjusting to the physical, mental, and emotional toll of having their infant in the NICU. In this study, women reported poorly controlled/managed chronic health conditions prior to and during the perinatal period. These mothers identified high blood pressure, diabetes, and prolonged hospitalizations prior to delivery. African Americans are disproportionately affected by diabetes, high blood pressure, and heart disease. (1) These conditions can worsen in pregnancy and jeopardize the health of mother and infant. (1) Struggling with chronic health conditions can contribute to further exhaustion, mental and emotional challenges while providing daily care and breastfeeding to a NICU infant.

Social Determinants

In this study, the experience of minority mothers in the NICU deviates from most women in that the experience has an implication for life goals. Women in this study talked about how the NICU experiences fostered reflection on their life goals. In this way, they want to improve their circumstances in life and commit to meeting life goals. These goals include establishing independent housing, furthering educational goals, and improving their credit. Many of these women alluded to less-than-ideal life circumstances and awareness that housing, education, and financial (social determinants) improvements are needed to improve their life. Social determinants provide an accurate understanding of the disparities (1) and the experiences of study participants.

Healthy People 2030 define social determinants of health (SDOH) as environmental conditions where people live, learn, and work that affect outcomes and risks to health, functioning, and quality of life. (2) The five domains of SDOH include economic stability, education access and quality; health care access and quality; neighborhood environment, social and community context. (2) The areas of the desired improvement expressed by study participants align with the domains for SDOH. Study participants' reaffirmation of these goals stems from a desire to provide a better life to their NICU infant than what they currently experience.

NICU Rollercoaster

Like the experiences of all mothers with infants in the NICU, women of color highlight the rollercoaster of emotions. Women disclose antithetical feelings when expressing the experience of having an infant in the NICU. These feelings include happy/sad, comfortable/uncomfortable, bond/loneliness, and closeness/rejection. Mothers in a NICU also cite feelings of exhaustion, fear, surprise, and confusion. Study participants identified sadness and worry during the NICU course; however, it is unknown if they experienced or met full criteria for depression, anxiety, stress, or trauma disorders. It is important to note that in the first post-partum year, an estimated 20-30% of NICU parents have a diagnosable mental disorder. (3) It is recommended that NICU mental health professionals (NMHP) inter-

act with all parents to provide screenings for emotional distress, antenatal screenings, layered levels of support, and telemedicine support. (3)

" Although the emotions associated with having an infant in the NICU can vary throughout a NICU stay (days, weeks, or months), two common factors that influence the experiences of minority women are the health status of the infant and the type of interactions with NICU providers."

Study participants also have very positive experiences in the NICU and express feeling thankful, heightened mood, and amazement with the NICU experience. Although the emotions associated with having an infant in the NICU can vary throughout a NICU stay (days, weeks, or months), two common factors that influence the experiences of minority women are the health status of the infant and the type of interactions with NICU providers.

Provider Bias

Study participants expressed concerns about trust and worries about the safety of their infant during the NICU course. The concern and worry expressed by study participants are warranted. Race and insurance status increases the potential for implicit bias. (4) When implicit bias occurs, patients receive less attention to medical needs, postponed medical care, and insufficient quality of care. (4) In the NICU, parents should function as healthcare team members, and their feedback incorporated into the treatment plan. (5) NICU providers' communication and teaching activities were pathways for establishing trust and assurance of infant safety for study participants. Participants evaluated their ability to trust the NICU providers through communication, teaching, and education activities.

The study showed a correlation between positive experiences in the NICU, quality, and quantity of provider communication, teaching and education, and perceptions of a welcoming environment. It is widely known that NICU provider communication and parent education are standards of care and essential components in the NICU journey. The quality of provider communication with minority populations can increase their involvement in family-centered care. (6) NICU staff education should focus on methods for involving parents in the care of the infant, enhancing and expanding family-centered developmental care. (6) In addition, NICU staff education needs to include awareness and methods for delivering culturally effective care, which includes diversity (i.e., race, gender, sexual orientation, ethnicity, spirituality, socioeconomic status), cultural traditions, and care preferences. (6)

Conclusion

It is essential to bring awareness to the experiences of all mothers and families who experience the NICU. Although there are some shared experiences of having an infant in the NICU, unique experiences occur for minority women. There is a burden of care-related social determinants of health, health disparities, implicit (and explicit) bias. These concerns require NICU providers to make concerted efforts to establish therapeutic relationships. NICU providers must prioritize and offer targeted support for biopsychosocial needs and ensure an environment of trust and safety. The latter is stressed as it is sometimes assumed that provider position and title imply trust and safety, where, in the case of minority populations, this role may strain and challenge the provider/parent relationship. Regarding NICU provider awareness, the Interdisciplinary Recommendations for the Psychological Support of NICU Parents provide standards of care and a starting point in bridging the disparity gap.

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

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NE6 2PA
United Kingdom

admin@cambridgescholars.com
www.cambridgescholars.com

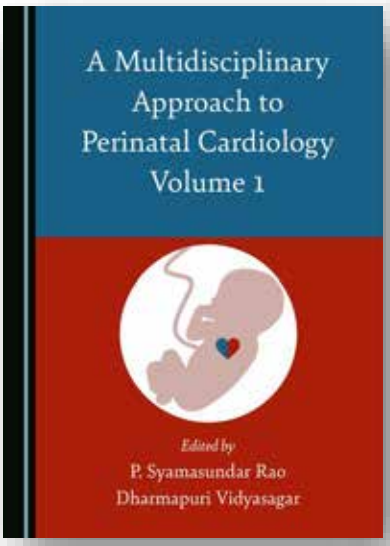
Fax +44 (0)191 265 2056

Cambridge Scholars Publishing is registered in the United Kingdom.

Companies House Reg. Number: 4333775.
VAT Number: 108280727.

A Multidisciplinary Approach to Perinatal Cardiology *Volume 1*

Edited by P. Syamasundar Rao and Dharmapuri Vidyasagar



Hardback

ISBN-13:
978-1-5275-6722-1

ISBN-10:
1-5275-6722-2

Date of Publication:
24/04/2021

Pages / Size:
794 / A5

Price:
£99.99

Book Description

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

About the Editors

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

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

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

My NICU Network
My Perinatal Network

National Perinatal Association + NICU Parent Network

Online L&D Staff Education Program

Caring for Pregnant Patients & Their Families:

Providing Psychosocial Support During Pregnancy, Labor and Delivery

WWW.MYPERINATALNETWORK.ORG

Continuing education credits provided by

pac-lac

About the Program

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

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

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

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

Program Objectives

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

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

PROGRAM CONTENT

COMMUNICATION SKILLS CEUs offered: 1

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

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

PERINATAL MOOD AND ANXIETY DISORDERS CEUs offered: 1

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

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

PROVIDING ANTEPARTUM SUPPORT CEUs offered: 1

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

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

PROVIDING INTRAPARTUM SUPPORT CEUs offered: 1

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

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

PROVIDING POSTPARTUM SUPPORT CEUs offered: 1

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

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

SUPPORTING STAFF AS THEY SUPPORT FAMILIES CEUs offered: 1

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

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

Cost

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

Contact help@myperinatalnetwork.org to learn more.

Faculty

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

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

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

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

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

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

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

Parent/Patient Contributers:

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

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

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

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

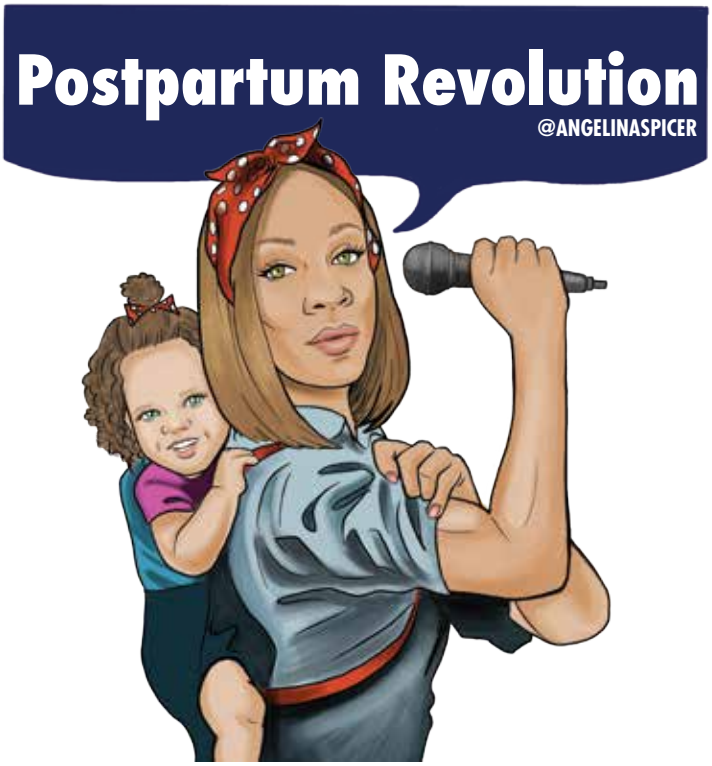
CANCELLATIONS AND REFUNDS

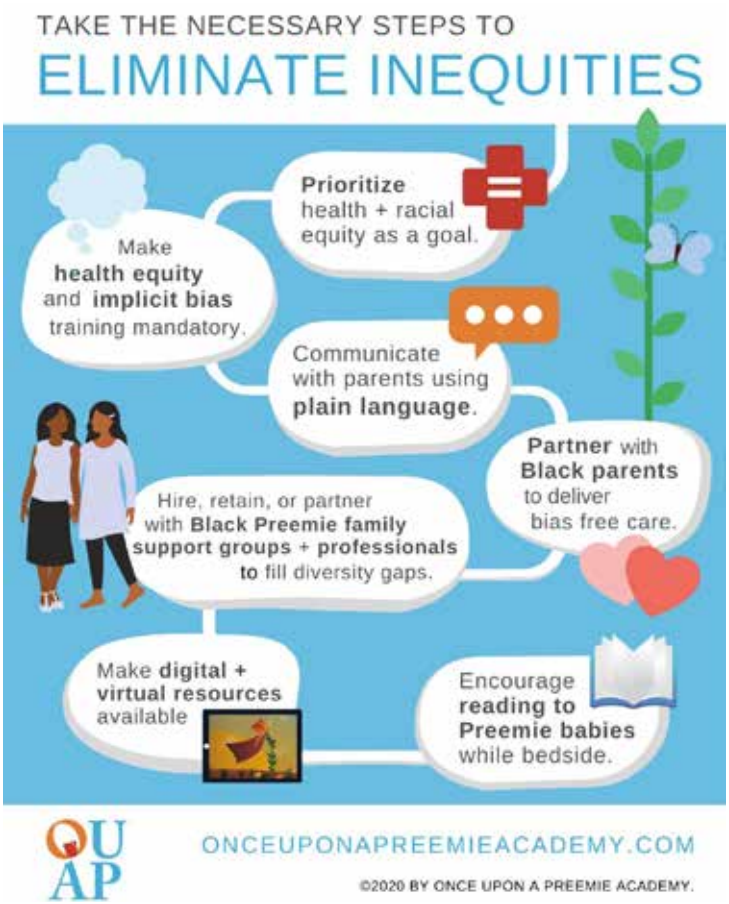
- For Individual Subscribers:
  - If you elect to take only one course, there will be no cancellations or refunds after you have started the course.
  - If you elect to take more than one course and pay in advance, there will be no cancellations or refunds after payment has been made unless a written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

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

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

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





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

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

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

EVIDENCE

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

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

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

TRAUMA-INFORMED

Both parents and providers are confronting significant...

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

LONGITUDINAL DATA

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

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

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

Partnering for patient-centered care when it matters most.

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National Association of Neonatal Nurses

National Perinatal Association

FREE ONLINE EDUCATION

Coping with COVID-19

A viral pandemic

A racial pandemic within a viral pandemic

Will mental illness be the next inevitable pandemic?

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and

National Perinatal Association
NICU Parent Network

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

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

What Will It Take to Increase Maternal Vaccination Rates?

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

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

AfPA
Alliance for Patient Access

"Maternal vaccines can protect pregnant moms and vulnerable babies. So why aren't more women getting them? A new white paper, Improving Maternal Immunization Status, sheds light on this important question. (1)"

Maternal vaccines can protect pregnant moms and vulnerable babies. So why aren't more women getting them? A new white paper, *Improving Maternal Immunization Status,* sheds light on this important question. (1)

Maternal Vaccination Challenges

The white paper highlights two challenges related to vaccination and expectant moms.

1) **Inadequate data.** Determining which women experience gaps in vaccination is difficult because a comprehensive record of vaccinated pregnant women does not exist in the United States. Establishing a widely used vaccine registry or an immunization information system could help identify coverage gaps. Once armed with this information, health care professionals and policymakers could direct targeted campaigns to reach the communities with the lowest rates.

2) **Poor coordination and implementation of maternal immunization programs.** The people developing programs at the federal level and the health care professionals implementing those programs in the states are not communicating well with one another. Greater collaboration is necessary for overcoming on-the-ground challenges and testing solution-driven approaches. California, for example, is piloting a program that provides clinics with Tdap starter doses so providers will have vaccines on site. This negates having pregnant women return for a subsequent appointment once the vaccine is stocked or go elsewhere to get vaccinated.

"Overcoming low maternal vaccine rates also requires education. Expectant moms may be unaware that getting these shots protects their baby during the "window of vulnerability" – before newborns can receive their own vaccinations."

Educating Expectant Moms

Overcoming low maternal vaccine rates also requires education. Expectant moms may be unaware that getting these shots protects their baby during the "window of vulnerability" – before newborns can receive their own vaccinations.

Newborns whose mothers receive both shots during pregnancy are 81% less likely to be hospitalized with flu before six months old. They are also 78% less likely to get pertussis – whooping cough – in their first two months of life, as compared to newborns whose moms did not receive the shots.

"Newborns whose mothers receive both shots during pregnancy are 81% less likely to be hospitalized with flu before six months old. They are also 78% less likely to get pertussis – whooping cough – in their first two months of life, as compared to newborns whose moms did not receive the shots."

Despite the benefits, just 40% of expectant moms got the recommended flu and Tdap – the combination of tetanus, diphtheria, and pertussis – vaccines in 2019. Rates were even lower among Black and Hispanic expectant moms. (2,3)

An Essential Part of Prenatal Care

Overcoming the challenges outlined in the paper will take time and resources. But the data supporting maternal immunization vaccine recommendations are compelling, and as the authors note, the shots are "an essential part of prenatal care."

Fifteen prominent public health, professional and maternal health organizations contributed to the paper. Read more about the challenges and solutions in *Improving Maternal Immunization Status*.

This content article was also published at InstituteforPatientAccess.org

References:

1. https://roar-assets-auto.rbl.ms/documents/11382/Improving%20Maternal%20Immunization%20Status%20White%20Paper%5B2%5D.pdf
2. https://www.cdc.gov/flu/prevent/flushot.htm
3. https://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html

Disclosures: Michelle Winokur, DrPH, is the Policy Communications Director for the Alliance for Patient Access.

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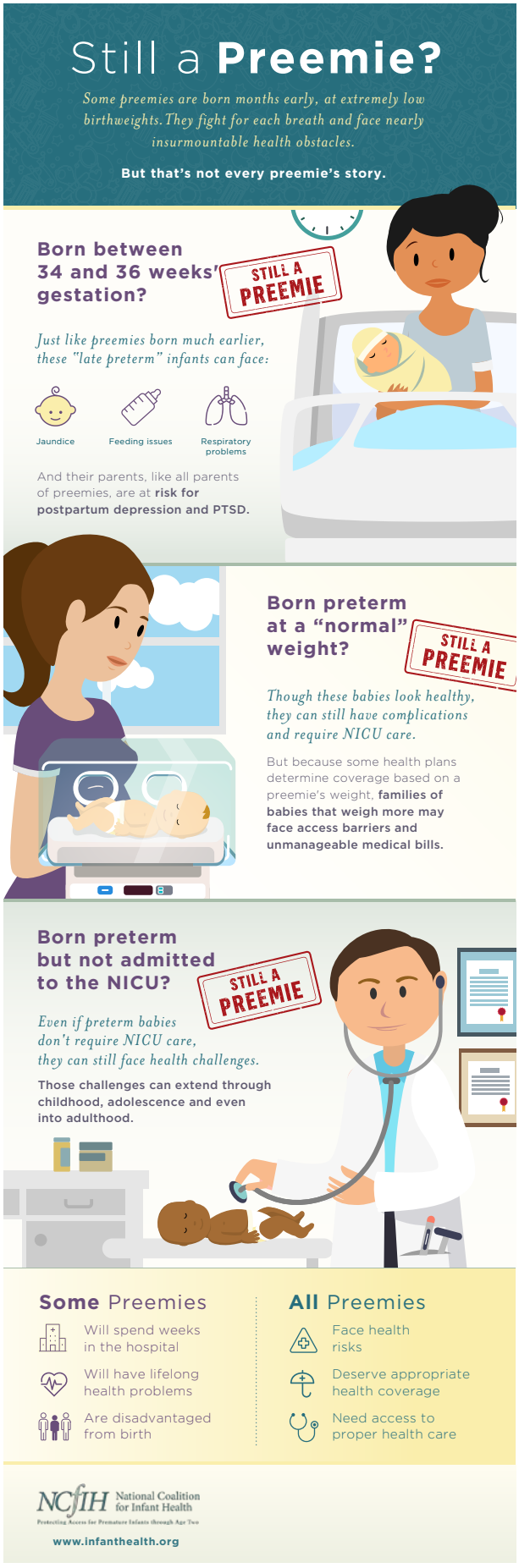

Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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

Limit Contact with Others

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

Provide Protective Immunity

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

Take Care of Yourself

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

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

WARNING

Never Put a Mask on Your Baby

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

If you are positive for COVID-19

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

We can help protect each other.

Learn more

www.nationalperinatal.org/COVID-19

National Perinatal Association

The Gap Baby: An RSV Story

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

The National Coalition for Infant Health advocates for:

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

www.infanthealth.org

Peer Reviewed

I CAN Digitally Involved (I CANDI): Engage within Pediatric Healthcare, Science, Research, and Innovation

Amy Ohmer

iCAN
International Children's Advisory Network

"Autumn greetings from iCAN! This is a great time to think about indoor activities as the seasons begin to change, and for our young people, iCAN offers a multitude of fun ways to engage within pediatric healthcare, science, research, and innovation. "

Autumn greetings from iCAN! This is a great time to think about indoor activities as the seasons begin to change, and for our young people, iCAN offers a multitude of fun ways to engage within pediatric healthcare, science, research, and innovation. If you have not had a chance to visit our unique and informative iCAN educational materials, we invite you to do so now. The newest learning module for kids, families, and the community is freely available and has been designed BY KIDS - FOR KIDS to teach the basics of Pediatric Clinical Research Trials. To check it out, visit iCAN at https://www.icanresearch.org/ican-curriculum.

For nearly a decade, PEDS 2040 has been the leading conference on pediatric innovation. On September 22-24, The Society of Pediatric Innovation, founded by Dr. Anthony Chang, along with an amazing line-up of partners, including the International Children's Advisory Network, Inc. (iCAN), are gathering virtually to continue our mission to shape the future of pediatrics, featuring a diverse group of industry leaders, dynamic panels, and networking opportunities.

To support PEDS2040, iCAN is seeking youth members and parents to help provide insight into their journey with iCAN through participation in a virtual panel session. The panel will be held on September 22nd and moderated by iCAN President Leanne West from 12:15 - 12:45 EDT. To see all of the speakers during this three-day event, head over to https://www.ispi4kids.org/peds2040/. Check frequently as more exciting details will be unveiled.

Registration for this innovative event is open at visit https://www.ispi4kids.org/peds2040/.

Are you looking for ways to better engage patients within your projects? iCAN is helping to support the pediatric voice by sharing recordings of youth members and experts during our monthly ASK THE EXPERTS series led by Dr. Anthony Chang, CHOC, AIMED, iSPI. If you would like to be an expert for our monthly sessions, please email Amy Ohmer at amyohmer@icanresearch.org.

Because of our supportive partnerships,

#iCANMakeADifference

You can too! Pledge to be a SPONSOR for the

2022 iCAN Summit

Email us at info@iCANResearch.org

The International Children's Advisory Network, Inc., (iCAN) is a tax exempt organization as described in Section 501(c)3 of the Internal Revenue Code.

2022 SUMMIT

iCAN
International Children's Advisory Network

SAVE THE DATE

July 13th through July 17th, 2022

To be held in-person at the University of Lyon, Franc

Hosted by iCAN KIDS France

Registration Opens May 15th, 2022

PROVIDING CHILDREN AND FAMILIES A VOICE IN MEDICINE, RESEARCH AND INNOVATION
around the world

Sign up for for updates at www.iCANResearch.org

iCAN is continuing the effort to get all kids to where they need to be to share their own expert experiences through our continued Community Patient Partnership with the FDA and through collaborative partnerships with MRCT, PFMD, and AIMed. Each session is recorded, and all recordings may be found of our youth member sessions sharing support of medical device wear, insight to health conditions, and more on https://www.icanresearch.org/videos.

"Coming up this fall, iCAN's Director, Amy Ohmer, will partner once again with Theresa Shalaby, Senior Regulatory Services Manager, Functional Plain Language Summaries, Synchrogenix, a Certara Company, to share in support for how to involve young people throughout the lay summary review."

Coming up this fall, iCAN's Director, Amy Ohmer, will partner once again with Theresa Shalaby, Senior Regulatory Services Manager, Functional Plain Language Summaries, Synchrogenix, a Certara Company, to share in support for how to involve young people throughout the lay summary review. Certara, the global leader in biosimulation, will host the inaugural "New Horizons in Pediatric Drug Development Symposium," taking place October 28-29, 2021. The two-day virtual symposium is being held to bring together thought leaders and innovators in pediatric drug development to share new developments in the field and to collaborate on new ideas to advance pediatric drug development into a new era.

Do you have an iCAN chapter at your hospital? There is no cost to create a chapter or for a child to participate, as iCAN is supported through sponsoring partnerships. Starting a chapter is free and easy, as iCAN helps each group get started and up and running. If you would like to start a chapter, often, the best place to start is through your hospital's ChildLife center. We are happy to meet with your ChildLife team to help share how iCAN is making a difference in patients' lives around the world. To set up a meeting, please contact us by email at info@icanresearch.org or visit www.icanresearch.org. If any interested kids are not involved in an iCAN chapter but would still like to participate, iCAN offers a Virtual Chapter to accommodate any child, anywhere in the world. All children are welcome and are encouraged to join us!

"In 2022, for the second week of July, iCAN and their KIDS France Chapter will be hosting the 8th Annual iCAN Summit, June 11th - June 15th, 2022."

In 2022, for the second week of July, iCAN and their KIDS France Chapter will be hosting the 8th Annual iCAN Summit, June 11th - June 15th, 2022. iCAN will offer an interactive series of in-person sessions at the University of Lyon, France, to support learnings through the pediatric patient perspective as well as industry learnings on innovation, science, and pediatric research. Children from ages 8-18 will meet with stakeholders to share their knowledge and expertise as kids, many of whom are living with rare, complicated, and complex conditions. Registration opens March 15th, 2022, and everyone is invited through www.icanresearch.org. Check us out and learn from the kids!

Looking ahead to 2022, iCAN is busy creating the Summit 2022 agenda. Check out our BRAND NEW 2022 Summit video to better understand what iCAN is all about. Get ready for the iCAN 2022 Summit Lyon, France!

To keep track of all of the new content being added for the Summit, be sure to check out https://www.icanresearch.org/2022-summit and add a bookmark to connect easily.

Through this endeavor, iCAN will be seeking sponsorship for our kids to attend the iCAN Summit and continue supporting the pediatric voice by including children in research, science, innovation, and medicine/medical device development. To help us by sponsoring a youth member, please email Amy Ohmer, Director, amyohmer@icanresearch.org. All donations support iCAN, a tax-exempt organization described in Section 501(c)3 of the Internal Revenue Code. All donations are welcome and appreciated. https://www.icanresearch.org/sponsoring

#iCANMakeADifference #iCAN #iCANBeDigitallyInvolved #iCAN-2022Summit

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

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Respiratory Syncytial Virus is a

Really Serious Virus

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

Coughing that gets worse and worse

Breathing that causes their ribcage to "cave-in"

Rapid breathing and wheezing

Bluish skin, lips, or fingertips

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

Call your doctor and meet them at the hospital.

If you baby isn't breathing call 911.

Thick yellow, green, or grey mucus

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

Fever that is higher than 101° Fahrenheit

101°

which is especially dangerous for babies younger that 3 months

National Perinatal Association

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PROTECT YOUR FAMILY FROM

RESPIRATORY VIRUSES

flu coronavirus pertussis RSV

WASH YOUR HANDS
often with soap and warm water.

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

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

USE AN ALCOHOL-BASED HAND SANITIZER.

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Inductive Processes, Heuristics, and Biases Modulated by High-Reliability Organizing (HRO) for COVID-19 and Disasters

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

Abstract

We view and understand the world through our internal logic, both public and private internal logic. The logic of practice differs by the frame of reference – a fixed point or within the flux of events, which can have "cosmology episodes" that collapse sensemaking. We have different perceptions and capabilities from the different reference frames, Eulerian and Lagrangian specificities, Euclidean, and topological spaces. When approaching a situation, all we have is observation, induction, and the capability to learn through action. Because people have limited time and knowledge, they must make inferences from the information they have available. We almost universally use heuristic, subjective approaches for better decision-making for complex, interactive problems and processes. Heuristics work through the nearness of information between the old problem-solution and the new problem, a topological space. In routine operations, we are susceptible to heuristic bias, yet error corrects this heuristic bias counterintuitively. We have found four predominant heuristics that cause consequential bias and interfere with effective decision-making: availability, representativeness, confirmation bias, and over-conservative revision. Motivated reasoning, a fifth bias but not from a heuristic, overly scrutinizes information that conflicts with closely held beliefs. Unless we assume that every word and behavior could instantly be wrong, we can too easily begin treating our treatments.

"Interviewing people for After Action Reports or following a serious event, the authors initially hear stories that don't match how people act in threatening circumstances (1). The stories only make sense through publicly accepted beliefs, heuristics, and logic. A supportive challenge to the description of their actions, while the authors let the person know they had been in similar situations, quickly changes the narrative to one more consistent with human experience."

Introduction

Interviewing people for After Action Reports or following a serious event, the authors initially hear stories that don't match how people act in threatening circumstances (1). The stories only make sense through publicly accepted beliefs, heuristics, and logic. A supportive challenge to the description of their actions, while the authors let the person know they had been in similar situations, quickly changes the narrative to one more consistent with human experience.

Several areas that a person transforms for acceptability are their private logic, how they learn through action, sensemaking shortcuts, and reason.

We view and understand the world through our internal logic, both public and private internal logic. Our public logic informs our stories and what we openly expect in a situation. Our intimate explanations to ourselves and a few trusted others come from our private logic.

"This is not a trivial distinction; private logic is quite visible in the first minutes or hours after a tragedy as events expose the raw beliefs of each person. Because we otherwise have no access to people's intimate internal logic, some behaviors and beliefs may not make sense to us unless we appreciate this private internal logic."

This is not a trivial distinction; private logic is quite visible in the first minutes or hours after a tragedy as events expose the raw beliefs of each person. Because we otherwise have no access to people's intimate internal logic, some behaviors and beliefs may not make sense to us unless we appreciate this private internal logic. One author (DvS) has extensive experience as the first person to arrive at an emergency, observing this change in behaviors and words as family or friends arrive.

We more easily observe this in the hospital following an accident, such as near-drowning when one parent had sole custody of the child. Within several days a narrative develops faulting the custodial parent. Leigh Aveling, the hospital chaplain, explained how this shatters the family's dynamics. During the first several days, family or friends enter and gain greater influence. Aveling and the author approached the next drowning admission differently. Within the PICU, they isolated the parents from family and friends, with the chaplain offering spiritual counseling and the intensivists explaining childhood behaviors and accidents.

After 48 hours, the extended family could visit in the presence of parents. The paternal grandparents openly blamed the mother.

The father tenderly placed his arm around her and said it was an accident; no one intended it to happen. He continued defending the mother throughout the PICU admission. The child survived.

The rules of their narrative affect their understanding of the event as it unfolds, how they interpret the results, and how they tell their story. This is how they explain but also how they understand. We will hear this internal logic and the shift from private to the public when we listen to their description or during an interview immediately after events have occurred. First, they make sense to themselves; then, the story seems to change as they begin to make sense to others. This is not falsity; listen for their internal logic, as it will help explain their actions and how they will act next time. "It is after the fact that we retrospectively begin to attribute specific reasons for the decisions that we made," Capt. Chesley "Sully" Sullenberger (personal communication).

Academicians studying the logic of practice from outside the flux and trajectory of events attempt to normalize cognition and behaviors without the necessary access to inner mental states impaired by stress and threat that are manifested as contingently linked behaviors (2-4). Detached observation and identification of abstract properties, necessary for scientific objectivity, conceal the situational reasoning and intent of the operator (4-6). The internal logic of operations that individuals utilize becomes unrecognized and inaccessible (7).

"Detached observation and identification of abstract properties, necessary for scientific objectivity, conceal the situational reasoning and intent of the operator (4-6). The internal logic of operations that individuals utilize becomes unrecognized and inaccessible (7)."

When unrecognized within a system, this concealment impedes the development of experts (6). The academic focus on abstract properties diminishes or further conceals the development of expert performance which, paradoxically, comes from experience in particular situations rather than abstractions (6, 8).

Renaud Vidal (9), research engineer, Aix Marseille University, observed the "presumption of logic becomes a presumption of control." HRO decentralization and distribution of autonomy to field operators can undermine the necessary presumption logic and control. The loss of confidence in the system destabilizes the confidence–cautiousness balance. Bob Bea, Professor Emeritus, Civil Engineering, University of California, Berkeley, maintains a database of over 600 engineering failures and has studied some of the largest engineering disasters in recent U.S. history (10). Bea has also had the experience of a novice placed in a dangerous context.

> "Some of the work we have done has been able to reach [field operators] and capture their perceptions and ideas for improvements = worker/operator empowerment. However, many of my colleagues have used methods and approaches that have depowered the worker/operators because of the dramatic differences in 'language' and 'motives.'"
>
> Bob Bea, 8/30/2005, personal communication

The unsupported belief that objectivity and distance from practice outweigh subjectivity and proximity can lead researchers, leaders, and managers to consider operators as biased, imprecise, and nonrational. The organization and human practices can then be made more rigorous through scientific knowledge with scientific rationality (4). Rejection of the logic of practice used by operators enacts unrecognized restraints that become visible in a crisis (11, 12), a dangerous form of latent failure.

Yet within the NICU, the environment can become unpredictable from time compression and abrupt changes in structure. The Neonatologist must work with imperfect information in flux—the internal logic of events changes. Threats impair the mind, which, if unmodulated, can easily become unrecognized and even normalized (13).

Karl Weick (14) described how these "cosmology episodes" collapse sensemaking and leadership. This occurred even with seasoned wildland firefighters during the 1949 Mann Gulch Fire. Such abrupt breaches in the environment involve the entire group or organization. What is rational and logical in structured, predictable environments becomes harmful during a cosmology episode. Actions or events may appear irrational solely because we do not recognize the system's internal logic. We likely continue our use of classical, scientific logic even as the system's internal logic changes.

This forms a gap between what executives and administrators expect based on concepts and plans developed from public logic and the actual behaviors that emerge from private logic.

"Our presence in or out of a system is more than a different frame of reference. We have different perceptions and capabilities. For Newtonian mechanics, physicists must make specific the frame of reference when they study natural phenomena."

Private logic

Our presence in or out of a system is more than a different frame of reference. We have different perceptions and capabilities. For Newtonian mechanics, physicists must make specific the frame of reference when they study natural phenomena. There is an assumption of Euclidean space, yet more likely, the operator is in a topological space. For our purposes, we shall identify the space we describe.

Time is integral to emergencies and crises. For example, removing the time component from stress and the stressor makes them uncontrollable and inescapable. Uncontrollability is a recognized cause of stress and inescapability; the inability to maintain 'safety distance' is a recognized cause of fear (2, 15). The metaphors we use for stress come from physics and the study of solids. Stress in colloids and fluids differ in response to pressure, solids deform or break while many fluids are incompressible, and shear stress, solids deform, and fluids flow. (Compressible fluids develop discontinuities called shocks.) We limit our use of metaphor and analogy, staying close to the inductive principles for using an analogy.

There are two specifications for fluid flow that align with experience (Table 1), Eulerian and Lagrangian specifications. Eulerian specifications align with business management studies, while La-

grangian specifications align with psychological studies.

	Eulerian, quantitative	Langrangian, qualitative
Frame	External, fixed point Focus on the specific location	Within flow Focus on the individual moving parcel
Properties	Flow	Trajectory
Flow analysis	Fluid velocity, volume, rate Multiple, fixed positions	Continuous measure Parcel velocity with position, pressure
Characteristics	Rate of change of system Variables fixed at a point	Individual parcels Along individual trajectories

Table 1: Eulerian and Lagrangian Specifications (16)

The specific relation between the operator and the particular situation constitutes the logic of underlying practice (4, 17). The purpose of logic for the operator in an HRO is to update mental patterns of observed reality for an accurate representation to guide actions in the world (4, 7, 18), reasoning in transition to develop expert performance (19), open up a universe of possibilities (20), and to grasp ambiguity to sustain ongoing projects (21).

"When the logic of practice is made visible, other factors lead to its suppression. Leaders and managers may believe field operators cannot grasp the necessary content or exercise the necessary judgment. This becomes self-fulfilling when the organization maintains operators at the competence skill level, the level of abstract learning, and below the practice of the particular situation. "

When the logic of practice is made visible, other factors lead to its suppression. Leaders and managers may believe field operators cannot grasp the necessary content or exercise the necessary judgment. This becomes self-fulfilling when the organization maintains operators at the competence skill level, the level of abstract learning, and below the practice of the particular situation. There is little need for rationality or logic of practice at the competence level because procedures become routines and standards. A high-turnover workforce becomes interchangeable (22).

Epistemic logic is concerned with logical approaches to knowledge and belief, how operators perceive and understand the actual world. People may have believed as a conviction that everything they believe is true, or only believe what is objectively true, that is, independent of their subjectivity. There are small but conceptually important differences between the frames of view.

Knowledge of the situation depends on the frame of reference (3, 23): the perfect (objective) external, the imperfect external, and the subjective internal points of view. The external views compare to Eulerian specifications, while the internal point of view is more akin to the Lagrangian view.

The perfect external view represents assumptions of omniscience and perfect knowledge of the situation, uninvolved with events. This view also assumes access to how operators are feeling and thinking. We believe the models developed cannot be wrong.

The imperfect external view represents someone outside the situation but without full knowledge of the situation. This models leadership more closely from a distance. We assume these operational models could be wrong.

"The imperfect external view represents someone outside the situation but without full knowledge of the situation. This models leadership more closely from a distance. We assume these operational models could be wrong."

Inductive processes

Induction is to learn through action. To approach any situation or to experience a situation that abruptly envelopes us, at first, all we have for learning is observation. It is the observation that begins the inductive process and how we gain knowledge. Leonhard Euler (24) described this, "We should use such a discovery as an opportunity to investigate more than exactly the properties discovered and to prove or disprove them; in both cases, we may learn something useful." Through induction and common sense, we find the regularity and coherence behind the visible surface; we discover the "engine" driving the problem (25-27).

John Boyd, an influential U.S. Air Force military tactician, described straightforward mental approaches for us to "act relatively free or independent of any debilitating external influences" when our mental patterns may not represent observed reality. "Creativity is related to induction, synthesis, and integration since we proceed from unstructured bits and pieces to a new general pattern or concept. We call such action a creative or *constructive induction*…this creative induction is the separation of the particulars from their previous domains by the *destructive deduction*. Without this un-structuring, creating a new structure cannot proceed—since the bits and pieces are still tied together as meaning within unchallenged domains or concepts, John Boyd (18).

Boyd's response to a disruption of observed reality parallels Weick's sensemaking perspective that operators create what they focus on through repeated cycles. For Weick's sensemaking, the operator distinguishes cues within an ambiguous event to use for enactment toward a resolution that restores the disrupted activity (28, 29). Both authors describe the rapidity of inductive and deductive processes as responses to disrupted cosmology. John Dewey describes the same functions of inductive and deductive processes but over a longer time period of discovery:

"When pains are taken to make each aspect of the movement as accurate as possible, the movement toward building up the idea is known as inductive discovery (induction, for short); the movement toward developing, applying, and testing, as deductive proof

(deduction, for short). While induction moves from fragmentary details (or particulars) to a connected view of a situation (universal), the deduction begins with the latter and works back again to particulars, connecting them and binding them together. The inductive movement is toward discovering a binding principle; the deductive is toward testing, confirming, refuting, and modifying it based on its ability to interpret isolated details into a unified experience. So far as we conduct each of these processes in the light of the other, we get valid discovery or verified critical thinking, John Dewey (30).

Induction ensures safety and reliability. Knowledge from observation "must be carefully distinguished from the truth; it is gained by induction," Leonhard Euler (24). Inductive processes are the chance to "correct our ideas when they are wrong, to adapt them to reality," George Pólya (31). These creative inductive processes move the system from disorder toward order and a goal-oriented system (18, 32).

"A disaster or pandemic COVID 19 brings the environment into our medical work area. We experience complexity, loss of structure, and lose definability – characteristics of the ill-structured problem (33). Business management and medical decision-making approaches support computational routines such as algorithms for decisions and actions. Such computational routines, however, do not support learning."

Heuristics

A disaster or pandemic COVID 19 brings the environment into our medical work area. We experience complexity, loss of structure, and lose definability – characteristics of the ill-structured problem (33). Business management and medical decision-making approaches support computational routines such as algorithms for decisions and actions. Such computational routines, however, do not support learning. On the other hand, heuristics can search the complex or poorly structured environments of a disaster to increase accuracy in decision-making and make our working model more detailed (34, 35). Heuristics are how we learn while solving ill-structured problems (36).

Heuristics and ambiguity

During a disaster, Bayes' Theorem can update the probabilities of events from updated information. This assumes we have sufficient time and that we can generate the information. Bob Bea, Professor Emeritus, Civil Engineering, University of California, Berkeley (8/8/2007, personal communication), (37) underscored that Bayes' Theorem "should only be used to update *epistemic* or model-parameter uncertainties." These uncertainties occur from the model's imperfections and are fundamentally 'information sensitive,' that is, increasing information reduces the uncertainty. Claude Shannon's Information Entropy describes how choice, acting to change uncertainty to certainty, creates information (38).

Heuristics operate outside this system by making the model more accurate in real-time (34). In a disaster, we work with "inherent or natural uncertainties that are fundamentally information insensitive" (Bob Bea, 8/8/2007, personal communication). Acquiring more information does not necessarily reduce uncertainty. Nevertheless, heuristics can increase accuracy and add detail (34).

Ambiguity corrupts accuracy and detail. "Ambiguity may lead us to construct a world that, while supported by evidence, is not true. We select evidence and interpretations for their plausibility, but later events show we were wrong" (39). However, Karl Weick (21) embraces ambiguity – to reduce ambiguity, you must initially increase it. Through the engagement of the complex and ambiguous environment, we then organize the situation. The active engagement of ambiguity creates understanding, organization, and communication, like Shannon's statement that when we make choices in uncertainty, we create information (38). From our experience and the use of heuristics, we learn through engagement and can then manage the ambiguity and complexity of a disaster.

Heuristic problem solving

For complex, interactive problems and processes, we almost universally use heuristic, subjective approaches for better decision-making (36, 40). Heuristics are the mental operations we use to learn how to solve problems, improve our performance, make use of our intuition and insight (25, 36), make inferences about the environment (31), and identify and correct errors (41). Heuristics are built from our experience and modeling, watching other people solve problems (25, 41).

Heuristics work through the nearness of information between the old problem-solution and the new problem (42). *Thinking while acting* and *learning by doing* utilize this topological information while trial and error occur when the distance between experience and the situation is too great or non-existent. Topological distances are relational rather than hierarchical.

We cannot equate the rapidity of making a connection with the presence, utility, or effectiveness of a heuristic. Speed of connection does come from a heuristic, but it is the availability heuristic discussed below. However, practical, common-sense decision-making evaluates the consequences of actions, tempering the speed of association (27). For innovative decision making, "a major part of the decision-making task [is] to discover what consequences will follow" (43).

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Heuristic, "serving to discover or find out," describes *provisional* reasoning to discover the problem's solution and is often based on induction or analogy (25). Heuristics would be specific to a situation and, for the embedded problem, derive rationality from the structure of the environment (44, 45). We use heuristics when we don't know. Acting when we do not know relies on error identifica-

tion and correction to maneuver through events (27, 32, 46).

Herbert Simon and Allen Newell (36) recognized that people have limited time and knowledge; therefore, they must make inferences from the available information. This means contingently ignoring part of the information while using partially relevant information when we don't know which part is relevant (27, 47). Heuristics are a large part of practical, common-sense problem solving (27).

Heuristic Bias

Heuristics are the rules we use for intuitive predictions, like the more statistically based Bayes' Theorem. Daniel Kahneman and Amos Tversky studied heuristic rules and subsequent biases by comparing them to Bayes' Theorem's statistical prediction. Specifically, they evaluated category and numerical prediction (48).

But what if we wanted to predict influence. "What action can I take to influence the situation?" The uncertainties within a disaster are not 'information sensitive," imperfections that can be reduced with Bayes' Theorem. The uncertainties in a disaster are inherent to entropy in an open system. Such uncertainties are fundamentally "information insensitive." Information is less to create a better model than it is to guide actions.

Heuristics, when they don't take us to a satisfactory result (33), can keep us trapped in a failed bias (48). For example, when we learn a dynamic skill, moving from novice to proficient, we use the new information to extend our performance (6, 49). Failures will increase as we gain motor and cognitive control. Once our performance becomes stable, our instructor takes us to a higher level of training. The cyclic increase and decrease in performance as we add skills is regression to the mean. An indirect consequence comes when the instructor complements the student for improvement; the student pushes the skill and begins to fail. The instructor interprets the new failure because of the complement. The opposite occurs with improved performance after criticism (48). A teaching culture develops where complements are not given, and criticism is good teaching technique.

"Decision-making in academic studies is to decide for the answer, a normative result. Too great a distance from the normative value is an error (35, 48)."

Decision-making in academic studies is to decide for the answer, a normative result. Too great a distance from the normative value is an error (35, 48).

Decision-making in a volatile situation is to move toward safety, bring control, generate information, give meaning, and reduce ambiguity. Decision-making works through reciprocal feedback; response to an action is interpreted and guides the next action, much like John Boyd's OODA Loop (50). In uncertainty and volatility, accuracy drives our beliefs and decisions and leads to more accurate inferences (35). Algorithmic strategies for normative outcomes use information and computation (26, 33) while relying on a stable model of an actual world

Heuristics as psychological bias, normative with a singular decision, can favor algorithmic approaches such as protocols and rules. Heuristics for decisions to increase accuracy bring about engagement and sharing of freshly generated information. Reciprocal decision-making relies on heuristics for decisions, error for correction, and consequences for guidance (21, 33, 35, 46). The decision doesn't end until the threat has abated.

Heuristics and psychology

Heuristics are also understood to be mental operations for prediction and judgment under uncertainty. Heuristics are economical and effective in these situations but lead to systematic and predictable errors and biases (51, 52). Academic studies measure single or 'final' decisions made from beliefs and predictions, using probability as a standard. For example, the representativeness heuristic measures the bias that what you see represents what is actual. The bias comes from connecting what you see to a stereotype that you have. Acting during a dynamic, complex situation, you would use representativeness as a starting point, then use inductive processes to distinguish bias from the truth (24), probing the situation and your hypothesis in the form of the OODA loop (53). Also, the prediction has a different meaning in preparation for and responding to an abrupt event. While heuristic reasoning is good, Pólya underscores that heuristic reasoning is not rigorous proof (25). Like much of our experience in dangerous situations, you use it without fully trusting it.

In training novices, we have found four predominant heuristics (Table 2) that cause consequential bias and interfere with effective decision-making: availability, representativeness, confirmation bias, and over-conservative revision. Motivated reasoning, a fifth bias but not from a heuristic, prevents accepting information that contradicts a strongly held belief. This is not confirmation bias.

"In training novices, we have found four predominant heuristics (Table 2) that cause consequential bias and interfere with effective decision-making: availability, representativeness, confirmation bias, and over-conservative revision. Motivated reasoning, a fifth bias but not from a heuristic, prevents accepting information that contradicts a strongly held belief. This is not confirmation bias."

Heuristic	Bias
Availability	What you think of first is most important
Representativeness	What you see represents events
Confirmation bias	Seek supporting evidence
Overconservative revision	More information to stop than start
Motivated reasoning	Overly scrutinize evidence against strongly held beliefs

Table 2: Heuristics and biases

Availability, also called frequency bias, leads us to accept our first impression. Availability bias also occurs when redundant measurements of variables influence our perceptions. Availability also biases us toward precision and the use of numbers as quantitative information over qualitative values.

Amos Tversky and Daniel Kahneman (51) described the impor-

tant role 'imaginability' has toward our view of the risks of an adventurous expedition. Imagine the contingencies with which you are not equipped to cope. Although this is more of a frame problem, it represents how a new frame can lead to inordinate concern from staff. "If many [contingencies] are vividly portrayed, the expedition can be made to appear exceedingly dangerous, although the ease with which disasters are imagined need not reflect their actual likelihood. Conversely, the risk involved in an undertaking may be grossly underestimated if some possible dangers are either difficult to conceive or simply do not come to mind." We see this in inexperienced staff and families.

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Tversky and Kahneman, however, focused decision-making on threats one could conjure, or even worse, worry of not conjuring enough threats. Operators in dangerous contexts seek capabilities for threats, particularly capabilities they can generalize to unforeseen threats or that extend operations into novel situations (41, 54, 55).

We can demonstrate availability by asking someone to spell the word "folk." Then ask, "What is the white of an egg called?" The answer you had made available to the brain is "yolk." We experience availability with consultants because the information from their specialty is more available to them. Acceptance of our first impression simplifies the situation. We, too easily, stop developing more structure. Mentally listing 3-4 causes of the situation helps discipline the mind to continue thinking after the first acceptable answer.

"Acceptance of the suggestion in its first form is prevented by looking into it more thoroughly. Conjectures that seem plausible at first sight are often found unfit or even absurd when their full consequences are traced out. Even when reasoning out the bearings of a supposition does not lead to rejection, it develops the idea into a form in which it is more [apt] to the problem," John Dewey (30).

Representativeness, closely tied in with complexity and "reluctance to simplify," leads us to regard partial information as if it were complete information: what you see represents what is happening. This is a difficult one to break because practical, commonsense problem solving uses partial information (27), which is also all we have when we begin to engage. When we recognize the bias of representativeness, we can reevaluate the situation and update and revise our beliefs.

Confirmation bias derives from cognitive dissonance. To reduce dissonance, we search for confirming information. We look for evidence that will support our conclusions while ignoring disconfirming, discrepant data. Confirmation and availability biases are insidiously dangerous; an individual stops considering alternatives.

Overconservative revision biases us to require more information to stop an action than we initially required to start. We continue treatments long past the point when we would not have initiated the treatment. Once we start a treatment, we find it hard to stop, even when the reason to treat is gone.

The author (DvS) assumed care for a child with a 'do not resuscitate order' due to failure of cardiovascular support. The treating and consulting teams supported the withdrawal of medical support from the patient. Vascular access was lost, effectively terminating support. The author placed a central venous catheter from a supraclavicular approach and confirmed placement by chest x-ray. In the early-morning hours, the child went into abrupt respiratory distress. A chest x-ray showed fluid in the chest on the side with the catheter. Further studies revealed that the catheter was alongside, rather than inside, the vein. All the required fluids and medications were entering the chest cavity rather than the bloodstream. Oddly, the child had improved. The author discontinued all medications under the assumption that the medications were not necessary. The child continued to improve.

Medication to strengthen the heart had constricted blood vessels and caused kidney failure. This led to medications to dilate the blood vessels and to improve kidney function. Other medications also became involved to help maintain physiological balance. We had been treating our treatments.

It is easier to identify the symptoms of "treating the treatment" in others rather than in your own care. The author resolved "treating the treatments" on several patients during evaluation for an organ transplant. Consultants and second opinions play an important role in high-risk environments since they bring new points of view.

" Error corrects heuristic bias. Though counterintuitive, the individual in these situations considers every action could be wrong. The author (DvS) served on a fire rescue ambulance in South Los Angeles ten years after the Watts Riots. The Crips and Pirus (later the Bloods) were moving north. Recognizing a gang member by clothing, behavior, stance, and countenance influenced our approach."

Error corrects heuristic bias. Though counterintuitive, the individual in these situations considers every action could be wrong. The author (DvS) served on a fire rescue ambulance in South Los Angeles ten years after the Watts Riots. The Crips and Pirus (later the Bloods) were moving north. Recognizing a gang member by clothing, behavior, stance, and countenance influenced our approach. The gang 'uniform' had yet to form. However, we had to discern the gang member from the 'wannabe' attempting to join or the youth adopting the gang appearance for their protection. Each needed to be treated differently. It was the feedback during our interactions that guided us. To stick with the wrong approach could lead to our injury or mistreating a youth trying to get by and stay in school. Every word and behavior could instantly be wrong.

Cognitive science

Artificial intelligence was modeled from human cognition. Herbert Simon differentiated human thinking between well-structured problems that humans and computers could solve with algorithms and ill-structured problems that humans could solve with heuristics but computers could not (36). Artificial intelligence worked to make computers operate like human thinking. From this research, the field of cognitive psychology developed (56). Computers then

became a metaphor for cognitive scientists to understand human thinking (57), bringing along easily understood algorithms as thinking models. As a result, algorithms are often the method proffered to work with complex situations and with a large amount of information for decisions.

We urge caution regarding the reliance on algorithms and the over-scrutiny of heuristics for operations during a disaster.

Motivated reasoning

Motivated reasoning is the spontaneous default mechanism for defending their prior attitudes and actively challenging arguments incongruent with their strongly held beliefs. People are unaware of their use of motivated reasoning, which comes from motives to achieve an accurate conclusion or maintain a specific conclusion (58).

A person firmly holds their desired conclusion even if it involves rejecting disconfirming evidence (58-60). Rather than emotion or identity, this is reasoning toward a preferred conclusion affecting forming impressions, determining beliefs and attitudes, evaluating evidence, and making decisions (58, 61). Analytical sophistication and education do not reduce the presence of motivated reasoning (62).

Motivated beliefs are unconsciously directed toward a goal (62). Protecting a self-serving conclusion comes from their prior beliefs; the conclusions seem more plausible. Motivation appears to have its effects through cognitive processes rather than emotion (58). The individual will attempt to be rational, constructing an "objective" justification persuasive to a dispassionate observer. This can involve creatively combining knowledge to construct new, logical beliefs supporting their desired conclusion. They do not realize their reasoning processes have biased their thinking (58).

We commonly find this in lay science and medical issues, that once they formed an impression, they have motivated reasoning to keep it. Scientific and health literacy then fail (63). It is difficult to counter their arguments. They may be receptive when the message is congruent with their preexisting goals or when their motivation comes from a deep existential need (60). Still, the direct challenge can evoke strong emotions, even physical anger, and outrage (58, 62). This is a clear sign you have infringed on a protected, cherished belief.

Individuals protect cherished beliefs for several reasons (58, 62). Motivated reasoning enhances self-efficacy against a problem of self-control or gives utility for beliefs to counter a perceived weakness in a desired trait. Motivated reasoning also protects personal and social identity. Selective updating by information avoidance and asymmetric processing of good and bad information protects these beliefs (62).

This is the danger of motivated reasoning to over-scrutinize new information that disconfirms cherished beliefs. Abrupt threats, Weick's loss of cosmology, do not respond to cherished beliefs. In the search for solutions, heuristics help *if* we calibrate our decisions through early error detection and correction. We must rapidly distinguish ambiguous cues calibrated to actual events (28, 29), not beliefs. We gain accuracy through inductive processes and heuristics.

Motivation for accuracy takes greater cognitive effort for reasoning, attending to relevant information, deeper processing, and more complex rules (58). This is similar to the approach described by Simon for the ill-structured problem (36), where greater accuracy is achieved through heuristics and reciprocal (50) decision making (35, 36). The concern of avoiding a wrong judgment and drawing the wrong conclusion while more careful cognitive processing parallels HRO reasoning. A consequence is the reduction of cognitive biases (58).

Conclusion

We do not give up our judgment and creativity in a dangerous context or lose our thinking under time compression. We can use inductive processes to learn from the environment as we act. We can use heuristics to develop solutions for the embedded, ill-defined problem through vigilance toward error, using error to define our operational envelope (46). Anomalies and disconfirming evidence are valuable; we search for them. Counterintuitively, by constantly proving ourselves wrong, we become closer to being right.

"We do not do this through speed or shortcuts but by increasing our tempo. Boyd described the methods and benefits of a faster tempo: the ability to transition more rapidly than events change, develop more repertoires of action, free and open communication, interactive support, increased information sources to select from, and generation of new ideas that can be rapidly tested (64). Our private logic can then become our public logic. "

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"Morally, we interact with others by avoiding mismatches between what we say we are, what we are, and the world we have to deal with," John Boyd (64).

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Disclosures: The authors have no relevant disclosures

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Acknowledgments

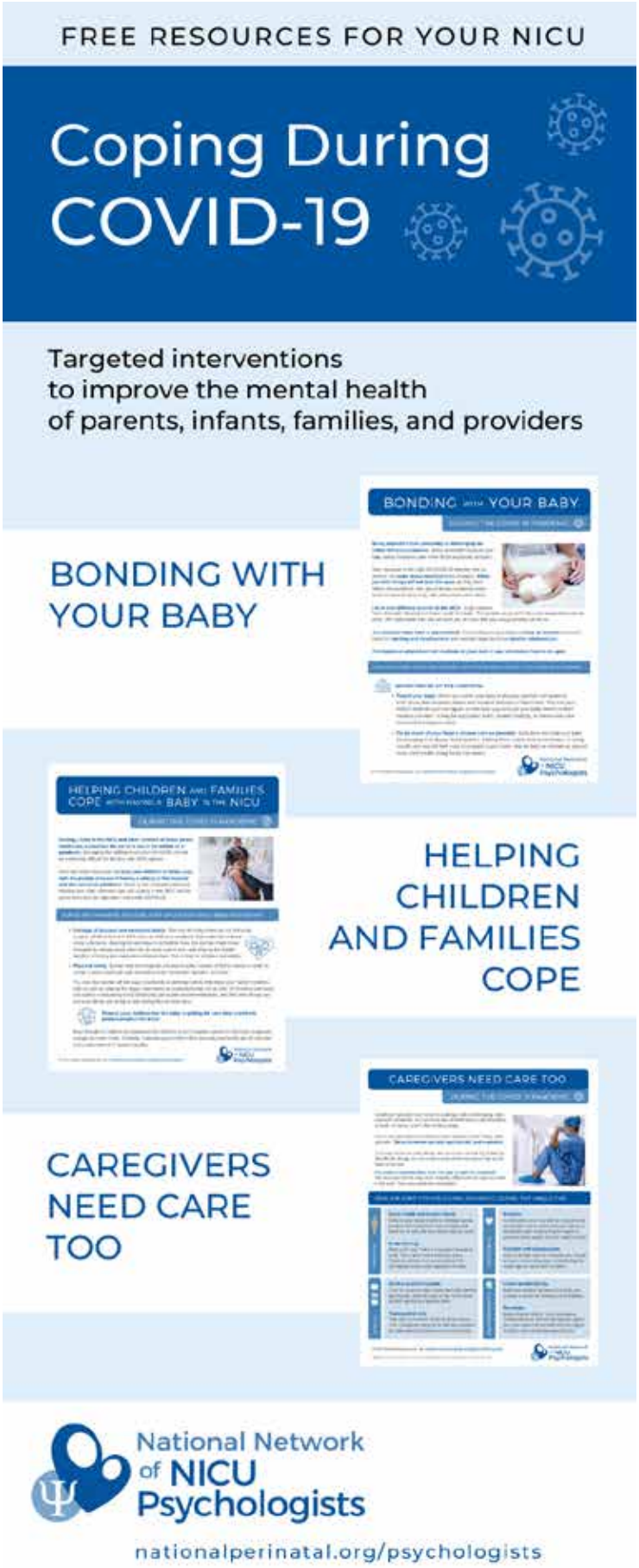
Karl Weick, Rensis Likert Distinguished University Professor of Organizational Behavior and Psychology, Emeritus, University of Michigan

Sean D. McKay, Element Rescue, LLC

Errol van Stralen, Ancora Education

William Gambino, CIV, DoD

William J. Corr, formerly with the Los Angeles City Fire Department, now deceased



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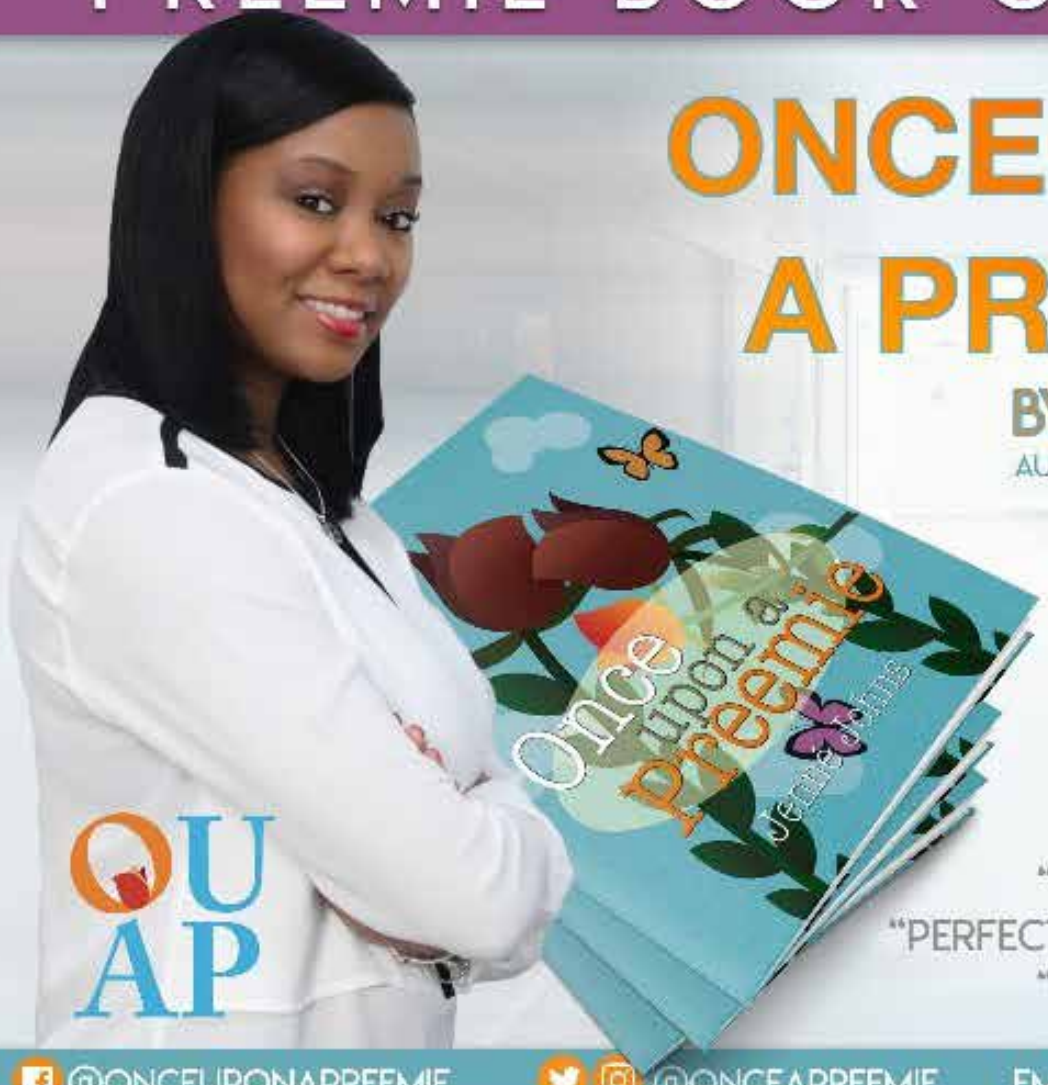

ONCE UPON A PREEMIE

BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE

QUAP

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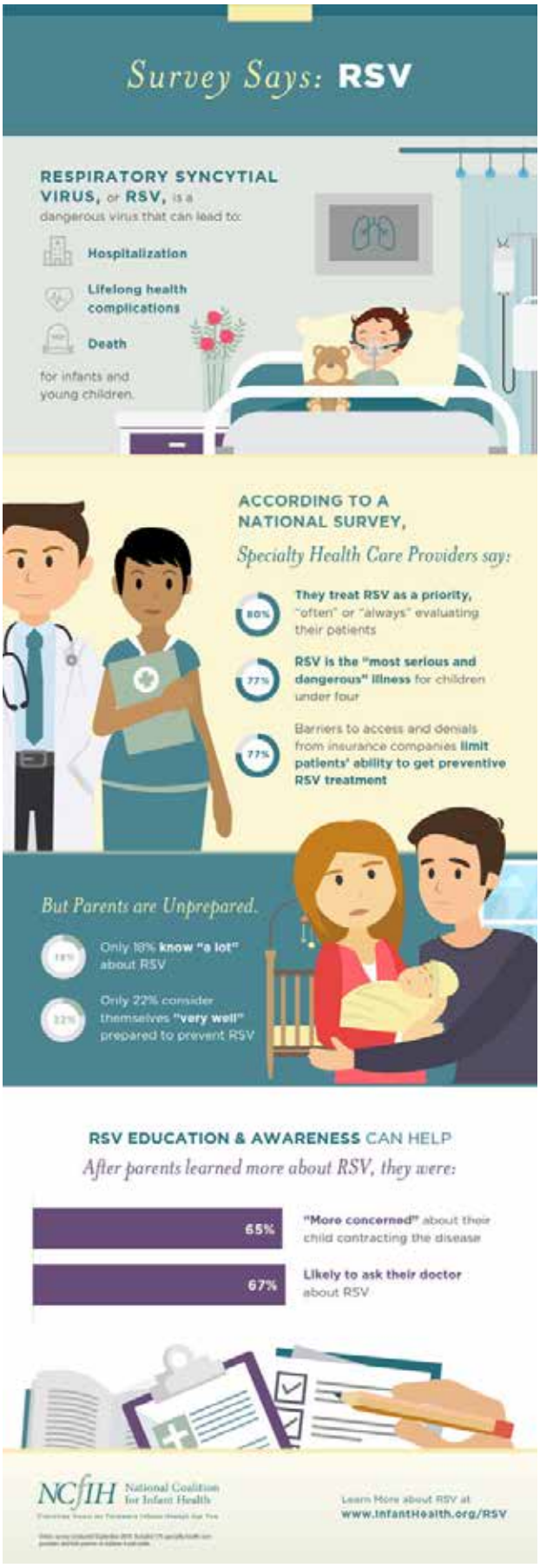

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Compiled and Reviewed by David Vasconcellos, MS IV

CDC: Delta variant causing increase in pediatric COVID-19 cases, not severity

Alyson Sulaski Wyckoff, Associate Editor

September 07, 2021

Two new studies found COVID-19 cases in children and adolescents have been increasing in number but not severity since the delta variant became predominant.

The studies from the Centers for Disease Control and Prevention (CDC) also showed adolescent COVID-19 hospitalization rates are highest among those who are not vaccinated and in communities with low vaccine coverage.

"What is clear from these data is community level vaccination coverage protects our children," CDC Director Rochelle P. Walensky, M.D., M.P.H., said at a news conference. "As the number of COVID-19 cases increase in the community, the number of children getting sick, presenting to the emergency room and being admitted to the hospital will also increase."

Both studies in the *Morbidity and Mortality Report* looked at COVID-19 among children and adolescents ages 0-17 years and compared data from July and August when the highly transmissible delta variant was dominant to earlier periods in the pandemic.

A study of national data on COVID-19 cases among children and adolescents in 2021 found they peaked in January, dropped in June and spiked in August. The weekly COVID-19 hospitalization rate followed a similar pattern.

During the week ending Aug. 14, about 1.4 of every 100,000 children and adolescents were hospitalized for COVID-19, nearly five times the weekly rate in late June and close to the peak in January, according to another study of 14 states.

Children ages 0-4 years have had the highest pediatric hospitalization rates since the start of the pandemic, and their weekly rate of 1.9 per 100,000 children in mid-August was nearly 10 times that of late June.

Researchers looked for signs if delta is causing more severe disease. Both studies found statistically similar levels of severity before and after delta was dominant. For instance, about 23% of those hospitalized were admitted to the intensive care unit in the delta period compared to 27% pre-delta. Likewise, 10% required invasive mechanical ventilation and 2% died in the delta period compared to 6% and 1%, respectively, before delta.

"Although we are seeing more cases in children and more overall cases, these studies demonstrated that there was not increased disease severity in children," Dr. Walensky said. "Instead, more children have COVID-19 because there is more disease in the community."

The increased hospitalizations are coming at the same time as a spike in respiratory syncytial virus, causing many children's hospitals to report intensive care units at or near capacity.

Impact of vaccination

Both studies showed vaccination has a significant impact on COVID-19 hospitalizations. One foundunvaccinated adolescents were hospitalized in July at a rate 10 times higher than fully vaccinated adolescents.

The other showed emergency department visits and hospitalizations for COVID-19 were 3.4 and 3.7 times higher in states with the lowest vaccination coverage compared to states with the highest vaccination coverage.

About 53% of adults, 46% of adolescents ages 16-17 years and 37% of those ages 12-15 years are fully vaccinated, according to CDC data and an AAP analysis. About 404,000 adolescents received their first dose this past week, a rate that has declined for three weeks.

"We know what we need to do to protect our children," Dr. Walensky said. "Get vaccinated, wear masks and follow CDC guidance. We must come together to ensure that our children, indeed our future, remain safe and healthy during this time."

Associate Editor Alyson Sulaski Wyckoff contributed to this report.

Resources

- Information from the CDC on clinical considerations for COVID-19 vaccines
- CDC COVID vaccination toolkit for pediatricians
- AAP guidance on providing COVID-19 vaccines to adoles-

cents

- Information for parents from HealthyChildren.org on preparing children and adolescents for COVID-19 vaccination
- CDC COVID-19 guidance for schools
- AAP COVID-19 guidance for schools

Contact information for AAP headquarters

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

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

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

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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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AAP flu recommendations allow for coadministration with COVID-19 vaccine

Melissa Jenco, News Content Editor

September 03, 2021

Editor's note:*For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Influenza vaccine and COVID-19

Influenza vaccine can be administered simultaneously with or any time before or after administration of the currently available COVID-19 vaccines. Because it is unknown whether reactogenicity of COVID-19 vaccines will be increased with coadministration of flu vaccine, the reactogenicity profile of the vaccines should be considered. Clinicians should consult current guidance on coadministration of COVID-19 vaccines with influenza vaccines from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) (https://bit.ly/3AGBwS0) and the AAP (https://bit.ly/3yTsLnd).

Children who have acute moderate or severe COVID-19 should not receive influenza vaccine until they have recovered. Those with mild illness can be vaccinated.

"As we continue to face another year of the COVID-19 pandemic, timely influenza vaccination of all persons 6 months of age and older, is a priority this year," said Flor M. Munoz, M.D., M.Sc., FAAP, a lead author of the policy statement. "This is particularly important for anyone who has medical conditions that increase the risk for complications for both influenza and COVID-19, including children."

Additional updates for 2021-'22

Composition: For the first time, all pediatric and adult influenza vaccines are quadrivalent. Viral strain components influenza A(H1N1) pdm09 and A(H3N2) components are new, while influenza B components are unchanged from last season.

Vaccine formulations for children 6 through 35 months of age also are the same as last season. Afluria Quadrivalent is the only vaccine for children in this age group available in a dosing volume of 0.25 mL prefilled syringe. Fluzone Quadrivalent, which previously was available in a 0.25-mL and a 0.5-mL prefilled syringe, is available only in a 0.5-mL dose for this group. *However, a 0.25-mL dose still is an approved option if drawn from a multidose vial.* The presentation and approved dose for the two other vaccines available for this age group, Fluarix and FluLaval, is 0.5mL.

The **age indication** for the cell culture-based inactivated influenza vaccine, Flucelvax Quadrivalent, has been extended to ages 2 years and older (previously 4 years and older).

Doses, timing: *All* influenza immunization doses should be completed by the end of October, if possible. Children ages 6 months through 8 years who are receiving flu vaccine for the first time, who have had only one dose ever prior to July 1, 2021, or whose vaccination status is unknown should be vaccinated as soon as vaccines become available so they can receive two doses four weeks apart by the end of October. *Data available to date on waning immunity do not support delaying vaccination in children.*

The language in the policy statement on **contraindications** for IIV and LAIV has been updated to harmonize with ACIP recommendations and package inserts. A documented previous severe reaction to any IIV or LAIV is a contraindication to vaccination.

Other recommendations

- Children 6 through 35 months of age can receive any licensed, age-appropriate IIV available this season, at the dose indicated for the vaccine. Children 36 months (3 years) and older should receive a 0.5-mL dose of any available, licensed, age-appropriate vaccine.
- Efforts should be made to ensure vaccination of children in high-risk groups and their contacts, unless contraindicated.
- Product-specific contraindications must be considered when selecting the type of vaccine to administer. Children who have had an allergic reaction after a previous dose of any influenza vaccine should be evaluated by an allergist to determine whether receipt of the vaccine is appropriate.

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- Children with egg allergy can receive IIV or LAIV without any additional precautions beyond those recommended for all vaccines.
- Pregnant women should receive IIV at any time during pregnancy to protect themselves and their infants. Women in the postpartum period who did not receive vaccination during pregnancy should receive influenza vaccine before hospital discharge. Influenza vaccination during breastfeeding is safe for mothers and their infants.
- The AAP supports mandatory influenza vaccination of health care personnel.

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New AAP main number**:** 630-626-6000

NT

Continued support of telehealth services urged to address disparities: AAP

Trisha Korioth, Staff Writer

September 01, 2021

Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Updated AAP interim guidance strongly urges continued use of telehealth and in-person services so that all children and adolescents have access to health care during and after the pandemic. The interim guidance parallels recommendations in a new AAP policy statement to continue use and sustain integration of telehealth into future models of pediatric care. The policy is published in the September *Pediatrics*.

Care by pediatricians, pediatric medical subspecialists and pediatric surgical specialists should not be delayed due to difficulties with in-person access, according to the AAP. However, many communities have not been able to access care through telehealth due to lack of infrastructure, such as high-speed broadband, and lack of culturally appropriate information, support and resources.

"These inequities can result in worsening existing health disparities, rather than reducing them," according to the AAP. "This critical mode of health care access will continue in post-pandemic settings."

The AAP said continued use of telehealth visits is part of the matrix of care options and provides "the right care in the right place at the right time."

The updated interim guidance comes as COVID-19 cases have been rising sharply. From Aug. 12-26, the cumulated number of child COVID-19 cases increased 9% (384,137 cases were added), according to a report from the AAP and Children's Hospital Association. Children represent 14.8% of all cases in the U.S.

The interim guidance also recommends the following:

- All pediatric health care services, including telehealth, should be coordinated through the medical home.
- Well-child care should be consistent with Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, fourth edition, and the corresponding AAP/Bright Futures periodicity schedule.
- Disparities in under-resourced populations' access to telehealth should be monitored and addressed.
- Quality metrics data collection and analysis measures should be supported across institutions so that disparities in telehealth access can be monitored, evaluated and responded to quickly.
- Payment should be provided for

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voice-only (telephonic) services when infrastructure does not support full telehealth services.

- Graduate medical education program curriculum should be designed to educate trainees on how to provide high-quality telehealth services.

Updates also were made to the Guidance Related to Early Care and Education/Child Care During COVID-19 and Guidance on Providing Pediatric Well-Care During COVID-19. Visit http://bit.ly/AAPcovid-19guidance.

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NT

COVID-19 town hall: Experts address schools, testing, quarantine, therapies

Trisha Korioth, Staff Writer

September 03, 2021

Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Pediatrician experts at an AAP virtual COVID-19 town hall shared information on mitigating risks as school resumes, testing and quarantine, monoclonal antibody therapy and combating misinformation. Following are highlights.

Monoclonal antibody therapy

Vaccination should be the primary way to avoid severe illness from COVID-19, but pediatricians also may have questions about use of monoclonal antibody therapy for COVID-19 treatment and post-exposure prophylaxis, said Yvonne A. Maldonado, M.D., FAAP, chair of the AAP Committee on Infectious Diseases.

The Food and Drug Administration has approved monoclonal antibody therapy for emergency use in children over age 12.

For treatment, a patient receives an hour-long infusion and is kept for observation. Facilities must be capable of accommodating a patient for several hours. Although it has high efficacy in reducing hospitalizations from COVID-19, Dr. Maldonado said therapy can be expensive.

Post-exposure prophylaxis requires a shorter visit. A monoclonal cocktail is given subcutaneously in a smaller amount than infusion therapy. It has been successful in reducing infections by about 80% if given within 96 hours of exposure, according to Dr. Maldonado.

Effectiveness of mitigation measures

During the 2020-'21 school year, COVID-19 transmission levels in a community played a large role in decisions to stay open or to close. This school year is different, with the availability of vaccines and improved understanding of effective mitigations (e.g., masking, 3 to 6 feet of distance, staying home when sick).

Preliminary data show mitigation measures can prevent significant spread of the virus, including the delta variant, within classrooms, said Sara Bode, M.D., FAAP, chair-elect of the AAP Council on School Health Executive Committee.

Dr. Maldonado pointed to a recent study that showed during a surge of SARS-CoV-2 in North Carolina, outbreaks were uncommon within schools where masking was routine. "The risk of infection in them was really very low," she said.

Joelle Simpson, M.D., M.P.H., FAAP, a member of the AAP Council on Children and Disasters Executive Committee, said patients she sees in the emergency department (ED) are a "pulse check of what's going on in the community." EDs are seeing a surge of critical care patients, mostly from other viral illnesses such as respiratory syncytial virus.

Dr. Simpson also has noticed an increase in anxiety and uncertainty among families regarding school-related decisions on testing and quarantine. This has prompted them to reach out to their primary care pediatrician or come to the ED.

Pediatricians in communities where schools aren't using mitigation measures are answering more calls from families and helping to guide them through exposure, testing and return to school. "Navigating all of that complexity is still a challenge for many communities right now," Dr. Bode said.

Consistent communication

Clear communication across an entire pediatric group or institution is crucial, Dr. Simpson said. This includes knowing what is recommended regarding testing, quarantine and other common topics. When there is a disconnect in the institution, she said, it contributes to misinformation. She suggested posting guidelines online and regularly communicating across teams to ensure that consistent information is carried throughout the organization.

"There's already so much divisive news and misinformation going on, even for us as trained providers … I found that virus of misinformation is one of the most challenging things to tackle through all of this," Dr. Simpson said.

Dr. Bode agreed and urged pediatricians to be creative in starting conversations with parents to provide accurate information. "At any point that they're coming in, if you can start that conversation, it's a good time to start it."

Dr. Maldonado encouraged pediatricians to keep communicating with each another. "We're well past the time when we thought this pandemic would be over," she said. "The hardest part is to really remember to practice self-care because it's hard to feel like you can stop because (the pandemic) hasn't stopped." She reminded everyone to support each other, "not only for the

good of your patients, but your own well-being."

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NT

Improving Understanding of Bronchopulmonary Dysplasia to Optimize Childhood Outcomes

Published on Sep 02, 2021 in Neonatology Update

Preterm infants with bronchopulmonary dysplasia (BPD), particularly those who require prolonged mechanical ventilation during the neonatal period, are at high risk for poor medical and developmental outcomes throughout childhood. Today, about half of extremely preterm infants who survive to 36 weeks post-menstrual age (PMA) have BPD. Infants with BPD have increased risk for poor respiratory health, developmental delay, and cerebral palsy. As children with BPD mature beyond infancy, they continue to demonstrate important developmental sequelae. BPD is associated with approximately one-standard deviation decrease in childhood intelligence and significantly increased risk for cerebral palsy. In addition, children and adolescents with BPD have poorer performance than other children across multiple domains, including academic skills, visual-motor integration, executive function, motor coordination, and social function.

Our team of investigators in the Children's Hospital of Philadelphia Chronic Lung Disease Program, in collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network, developed a treatment-based classification of BPD disease severity. This new definition of BPD is based on the level of respiratory support at 36 weeks PMA, regardless of oxygen administration. This definition has high predictive accuracy for both death or serious respiratory morbidity and death or moderate to severe neurodevelopmental impairment at 18-26 months corrected age. A higher grade of BPD is associated with more severe developmental impairment.

Impact of strategies to prevent or treat BPD

Over the past several decades, many therapies and care strategies—including prenatal therapies, immediate postnatal medications, and respiratory strategies to prevent BPD and later approaches to treat or decrease severity of BPD—have been rigorously evaluated and introduced into the bedside armamentarium. The hope is that by preventing or treating BPD, these strategies will also improve longer-term outcomes.

The key perinatal strategy to prevent BPD is administration of antenatal corticoste-

roids, which reduce mortality, respiratory distress syndrome, and several other important neonatal morbidities. Unfortunately, however, antenatal steroid treatment does not reduce the incidence of BPD or improve the developmental outcomes of survivors. In the immediate postnatal period, noninvasive respiratory support as an alternative to routine intubation in the delivery room, early surfactant treatment of intubated infants, and vitamin A all lead to reductions in the combined endpoint of death or BPD in very preterm infants. However, none of these approaches has been demonstrated to improve developmental outcomes at 2 years.

The impact of postnatal corticosteroids on both BPD and longer-term developmental outcomes is uncertain due to heterogeneity in existing research as well as in clinical practice, including the type of steroid used, timing of administration, dosing regimen, route of administration, and baseline risk for adverse outcomes in the treated children. When given during the second week or beyond, this therapy may reduce risk for adverse developmental sequelae. However, much remains to be learned about how to best use postnatal steroids to reduce BPD while protecting neurodevelopment. Lastly, inhaled steroids have also been studied both for prevention and treatment of BPD. When initiated in the first 2 weeks of life, inhaled steroids reduce BPD but may increase mortality without clear developmental benefits or harms. Later initiation of inhaled steroids does not reduce BPD and longer-term impacts are unknown.

In the neonatal intensive care unit, caffeine is standard of care for infants at risk for apnea. Caffeine is the only neonatal intervention that has been clearly proven to reduce BPD and provide lasting developmental benefits, with particular benefit for motor outcomes. Importantly, at least half of the improvement in motor impairment that is observed until 11 years in children treated with caffeine is attributed directly to shorter duration of mechanical ventilation.

As BPD progresses, it becomes increasingly difficult to differentiate the impact of the lung disease itself from the impact of therapies to manage or treat the lung disease. The relative risks and benefits of available therapies must be weighed against one another to determine the best care plan for each individual infant.

Next steps for BPD research and clinical care

New strategies for prevention and treatment of BPD are always being evaluated. For example, budesonide instilled with surfactant is likely to significantly reduce BPD, and effects on longer term outcomes are currently under investigation. State-of-the-art approaches, such as the artificial placenta, stem cell therapies, and liquid ventilation, all have the potential to alter the landscape of BPD epidemiology and, hopefully, the subsequent adverse sequalae of BPD.

After discharge, intensive developmental interventions and comprehensive multidisciplinary care are essential for improving medical and neurodevelopmental outcomes for this high-risk population. Yet much remains to be learned about how best to support infants with BPD and their families throughout childhood, in order to help them obtain their maximum developmental potential and reduce childhood functional impairments.

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To access our Inpatient and ICU Clinical Pathway for Pulmonary Hypertension (PH) Screenings in Patients with Bronchopulmonary Dysplasia (BPD) visit www.chop.edu/bpdpathwayph.

Contributed by: Sara B. DeMauro, MD, MSCE

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NT

Improving Understanding of Bronchopulmonary Dysplasia to Optimize Childhood Outcomes

Father's Health Can Affect Child's Hospital, Emergency Visits

Marcia Frellick

September 12, 2021

The more comorbidities a father has before his child's conception, the higher the risk that the child will require an emergency department visit or inpatient care in the first 2 years of life, new data indicate.

It is not clear whether the association is related to biology, lifestyle, or both, but the findings represent an opportunity to engage men in preconception counseling, said Tony Chen, MD, clinical assistant professor in urology at Stanford Health Care in California, who presented his team's findings at the American Urological Association 2021 Annual Meeting.

"Previous studies show that only 10% of men seek preconception counseling," Chen said, noting that it is much more common for women to do so. "If you combine that fact with what we see in our data, this presents a significant chance to motivate men to improve their lives and their offspring's lives," he said.

Previous studies have largely focused on the effect of the mother's preconception health on her child, so little is known about the influence of the father's preconception health.

Chen's team used 2009 to 2016 data from the IBM MarketScan Research database, which collects information on inpatient and outpatient healthcare claims from private, employer-insured people. Of the 295,355 boys and 278,735 girls born during the study period, 34.9% had at least one visit to the emergency department, and 6.0% had an inpatient admission.

Diagnostic codes were used to determine how many components of the metabolic syndrome (MetS) — hypertension, diabetes, hyperlipidemia, and obesity — each mother and father had.

The odds of an inpatient admission or emergency department visit increased as the number of the father's comorbidities increased, after adjustment for birth year, region, offspring sex, age of mother, maternal MetS, prematurity, admission to the newborn intensive care unit, low birth weight, time of follow-up, and parental smoking status.

For example, the child of a father with two MetS components was 13% more likely to require hospitalization in the first 2 years of life than the child of a father with no MetS components (95% CI, 1.08 - 1.19). And the child of a father with three or more MetS components was 22% more likely to have at least one emergency department visit (95% CI, 1.15 - 1.29), and 48% more likely to have at least three visits than the child of a father with no components (95% CI, 1.36 - 1.61).

"The rate of hospitalization was highest in the 0- to 6-month age group, and was lowest in the 18- to 24-month age group," Chen reported. The same was true for the rate of emergency department visits.

It is possible that men with health issues might see a doctor frequently before conception and, therefore, might be more comfortable taking their child to the emergency department than someone who does not frequently see doctors, suggested Petar Bajic, MD, a urologist at the Cleveland Clinic and the Center for Men's Health at the Glickman Urological & Kidney Institute in Cleveland.

But more work needs to be done to raise awareness about the availability of preconception counseling and its benefits for both men and women, he told Medscape Medical News. Such counseling can happen in many different medical settings.

"There are a number of opportunities for improving the quality of counseling we're giving to couples," Bajic said. "We also need to increase the amount of information online, because we know a lot of couples are getting their educational information on the internet and we need to make sure there are reliable sources backed by evidence."

Chen and Bajic have disclosed no relevant financial relationships.

American Urological Association (AUA) 2021 Annual Meeting: Abstract PD29-02. Presented September 11, 2021.

Marcia Frellick is a freelance journalist based in Chicago. She has previously written for the Chicago Tribune, Science News, and Nurse.com, and was an editor at the Chicago Sun-Times, the Cincinnati Enquirer, and the St. Cloud (Minnesota) Times. Follow her on Twitter at @mfrellick.

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212-301-6700 infants born between 22 weeks' and 34 weeks' gestation.

In one of the study datasets that included admissions to over 350 NICUs in the U.S., they found that mechanical ventilation utilization in preterm infants decreased from 29.4% in 2008 to 18.5% in 2018. Nationally, the study authors wrote, the changes were associated with about 30,000 fewer infants receiving mechanical ventilation during the study period. As the number of infants on mechanical ventilation went down, the duration of time that ventilated babies spent on mechanical ventilators also went down.

Also, in their findings, researchers discovered that the total number of days on non-invasive respiratory support went up across all gestational ages from 13.8 days to 15.4 days. Hatch said more research is needed to understand the implications of spending more time on non-invasive respiratory support therapies.

"We need to figure out if the increase in duration of respiratory support is a good thing, and what does that do to NICU length of stay and overall resource utilization for preterm infants in the U.S. It raises more questions," he said.

Additionally, they saw an increase in the number of extremely preterm infants, 22 to 24 weeks' gestation, being placed on mechanical ventilation as there has been increased intervention and improved survival for this age group. Hatch notes that the respiratory support strategies for this particular population of infants needs more examination.

"The field of neonatology has worked really hard to examine our practices and get better. I am proud of how quickly some of the landmark respiratory care studies have penetrated our clinical care," said Hatch. "Care in the NICU is becoming less invasive and gentler because it is the right thing to do for babies' long-term outcomes."

Journal reference:

Dupree Hatch III, L., *et al.* (2021) Changes in Use of Respiratory Support for Preterm Infants in the US, 2008-2018. *JAMA Pediatrics.* doi.org/10.1001/jamapediatrics.2021.1921.

Source:

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NT

Keeping Your Baby Safe

during the COVID-19 pandemic

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- 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.
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Take Care of Yourself

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- Seek mental health support.

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- Because babies have smaller airways, a mask makes it hard for them to breathe.
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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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Genetic Corner: Diaphragmatic Hernia in an Infant with a Type II Distal Deletion of 22q11.2 (LCR22E-F)

Robin Dawn Clark, MD

Case summary:

A 34-day old female with a left-sided congenital diaphragmatic hernia (CDH) was born at 33w 3d gestation to an obese 18-year old G1P0 mother by vaginal delivery. The mother was admitted for preterm labor at 32w. During that admission, polyhydramnios, mild ventriculomegaly, CDH, and pre-eclampsia were diagnosed. Amniotic reduction was performed four times. The baby was delivered nine days after the mother was admitted. The mother denied teratogenic exposures, diabetes, or trauma. Her BMI was 58.82 kg/m². She had mild spotting for two days at 26 w. Apgar scores were 6 and 7. BW was 2.225 g (Z-score 0.58), BL 43 cm (Z-score -0.08), HC 31 cm (Z-score 0.58). Her diaphragmatic hernia was repaired with mesh on day 18. An echocardiogram after surgery showed a moderate to large patent ductus arteriosus, L>R, patent foramen ovale, mild dilation of the left ventricle, and mild elevation of pulmonary pressures. She is currently tolerating the slow advancement of feedings.

"Minor dysmorphic features were appreciated on the physical exam but did not suggest a particular syndrome. The forehead was square and prominent. The ear lobes were uplifted. The philtrum was long, and the upper lip was thin. The nose was broad with upturned nasal tip and anteverted nares. There was clinodactyly of the little fingers."

Minor dysmorphic features were appreciated on the physical exam but did not suggest a particular syndrome. The forehead was square and prominent. The ear lobes were uplifted. The philtrum was long, and the upper lip was thin. The nose was broad with upturned nasal tip and anteverted nares. There was clinodactyly of the little fingers. The baby responded to light touch and was jittery during the exam.

Family history:

The mother is 18 years old, and the father is 19. The parents are from Mexico and deny consanguinity. The family history was negative for other relatives with diaphragmatic hernia or other congenital anomalies.

Laboratory tests:

An amniocentesis had been performed nine days prior to delivery, but the normal prenatal microarray results, arr(1-22,X)x2, did not return until after delivery. By that time, a postnatal microarray had been sent to the same laboratory. That study, interpreted with postnatal reporting criteria, revealed a 655 kb deletion from 22q11.22 to 22q11.23, spanning low copy repeat regions LCR22-E and LCR22-F (distal type II deletion). The deleted interval involved eight known genes (*MIR650, MIR5571, IGLL5, RSPH14, GNAZ, RAB36, BCR, FBXW4P1*), none of which are known to be associated with diaphragmatic hernia.

Parental follow-up testing for this variant is in progress.

"That study, interpreted with postnatal reporting criteria, revealed a 655 kb deletion from 22q11.22 to 22q11.23, spanning low copy repeat regions LCR22-E and LCR22-F (distal type II deletion). The deleted interval involved eight known genes (MIR650, MIR5571, IGLL5, RSPH14, GNAZ, RAB36, BCR, FBXW4P1), none of which are known to be associated with diaphragmatic hernia."

Discussion:

In reviewing this case, I was struck by these three points:

1. A pathogenic deletion was detected on the postnatal microarray, but the prenatal microarray had been normal
2. This child has an atypical, distal, smaller 22q11.2 deletion that is distinct from the more common deletion associated with DiGeorge syndrome
3. Congenital diaphragmatic hernia is a feature, albeit an uncommon one, of 22q11.2 deletion syndrome.

Taking the first point, first: it is worth considering that these normal prenatal microarray results, had they been available prior to delivery, might have discouraged the baby's physicians from ordering a chromosome microarray after delivery. In that scenario, a postnatal chromosome microarray might have been considered unnecessary at best and even redundant and wasteful. In retrospect, it is a good thing that the prenatal microarray results and the postnatal blood sample passed like ships in the night; otherwise, this copy number variant might not have been detected. When laboratories

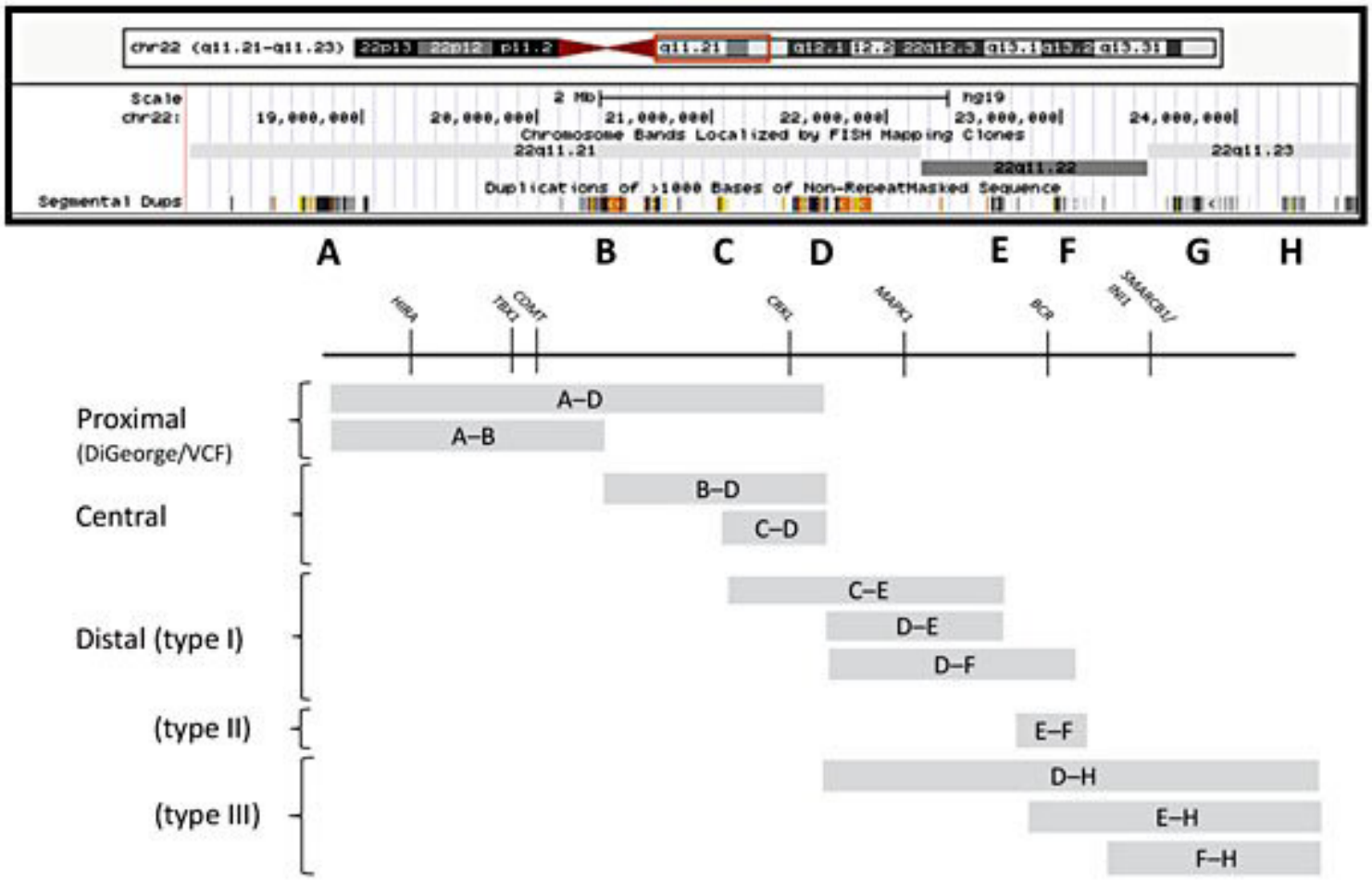

Figure 1: *The proximal, central and distal 22q11.2 deletions are defined by their low copy repeat breakpoints. LCR22A-H and key genes are noted. (Adapted from Burnside, 2015)*

have different reporting standards for prenatal and postnatal microarrays, and many do, a normal prenatal microarray result must carry less diagnostic weight. At the reference laboratory that processed this sample, and at others, deletions smaller than 1 Mb are not reported on prenatal samples. This instance is not the first time that a postnatal microarray provided a diagnosis when the prenatal microarray was normal. After several such experiences, I no longer regard a normal prenatal microarray as a definitive test. Now I do not hesitate to order a postnatal microarray after a normal prenatal microarray when I suspect a chromosome anomaly.

Second, this child has one of the less commonly described 22q11.2 deletion types, which are varied and numerous. 22q11.2 deletion syndrome (22q11.2DS) is the most common recurrent chromosome microdeletion syndrome with a prevalence of 1/2000-1/4000 live births. The chromosome region around 22q11.2 is predisposed to genomic instability because it is enriched with repetitive DNA sequences, called low copy repeats (LCR). A cluster of 8 LCRs, known as LCR22A-H, is responsible for chromosomal misalignment during meiotic recombination (nonallelic homologous recombination), which predisposes this region to recurrent deletions and duplications.

About 90% of patients with 22q11.2DS have a classic ~3 Mb deletion flanked by breakpoints in the two larger regions of repetition, LCR22A and LCR22D. Individuals with this 22q11.2 deletion commonly present with a recognizable facial phenotype, conotruncal heart defects, cleft palate, and features of DiGeorge syndrome or velocardiofacial syndrome.

The more distal 22q11.2 deletions that lie farther from the centromere, with breakpoints from LCR22D to LCR22-H, are less common and have different phenotypes. Although these three distal 22q11.2 deletions have been lumped together (OMIM 611867), each probably represents a distinct clinical entity. They have been classified into three types: type I (LCR22C-F), type II (LCR22E-

F), and type III (deletions that include *SMARCB1*, LCR22D-H). Our patient has a type II distal deletion, which is the smallest and possibly mildest of the 22q11.2 deletions. It does not share breakpoints with the classic LCR22A-D deletion and does not have many overlapping features other than intellectual disability.

The type II distal deletion is rare, with few reports in the literature. Mikhail *et al*. (2014) described 13 unrelated patients with various distal 22q11.2 deletions, who were ascertained by intellectual handicap, autism, dysmorphic features, or congenital anomalies. Of these, four patients had the smallest, type II, LCR22E-F deletion, similar to our patient. These individuals had a milder phenotype that did not include growth deficiency or cardiac defects. Burnside (2015) reviewed eight patients with type II distal deletions, including the four previously reported by Mikhail *et al.* in 2014. Seven of the eight individuals (88%) had developmental delay and dysmorphic features (abnormal ears, prominent forehead, or deep-set eyes). She described intellectual disability (4/8), CNS anomalies/seizures (2/8), hypotonia (1/8), and cardiovascular defect (1/8).

As for the last point, CDH is a less common but recognized feature of 22q11.2DS. In their report of 28 fetuses with 22q11.2DS, Volpe *et al.* (2003) described 2/28 with diaphragmatic hernia. In their cohort of 1246 patients with 22q11.2DS from Children's Hospital of Philadelphia, Unolt *et al.* (2017) reported a prevalence of CDH of 0.8% (10/1246). All 10 of these children had other major malformations. All of the five in whom the breakpoints could be defined had the classic larger deletion flanked by LCR22 A-D. However, not all individuals with CDH have the classic 22q11.2 deletion. Stark *et al.* (2015) identified two different atypical 22q11.2 deletions that did not include *TBX1* among 28 individuals with CDH: one deletion was proximal to LCR22-B, and one was bordered by LCR22 C-D. Tan *et al*. (2011) reported CDH in a patient with a type I (LCR22D-E) distal 22q11.2 deletion. Although a candidate gene or critical region for diaphragmatic hernia has not been identified in the 22q11.2 region, our case may help narrow the region of interest.

"Although a candidate gene or critical region for diaphragmatic hernia has not been identified in the 22q11.2 region, our case may help narrow the region of interest."

Practical Applications:

1. Appreciate that 22q11.2 copy number variants (deletions and duplications) can be flanked by any two of the eight low copy repeats (LCR22A-H) that predispose this region to genomic instability.
2. Recognize that the most common (90%) of the 22q11.2 deletions is the classic 3 Mb 22q11.2 deletion (LCR22A-D) that presents with typical facial features, cardiac and palatal defects. However, expect about 10% of 22q11.2 deletions to be atypical.
3. Appreciate that the three distal 22q11.2 deletions are distinct entities with phenotypes that differ from the proximal classic deletion (LCR22A-D) associated with DiGeorge syndrome.
4. Be aware that prenatal and postnatal microarrays have different reporting standards, and small deletions or duplications may be missed prenatally.
5. Order a postnatal chromosome microarray when you suspect a copy number variant, regardless of normal prenatal microarray results.
6. Consider the 22q11.2 deletion syndromes in the differential diagnosis of infants with a congenital diaphragmatic hernia, especially when there are other anomalies and/or dysmorphic features.

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Disclosures: The authors have no relevant disclosures.

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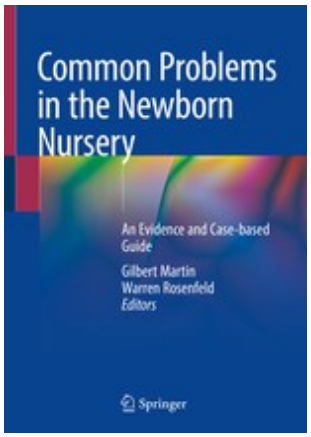

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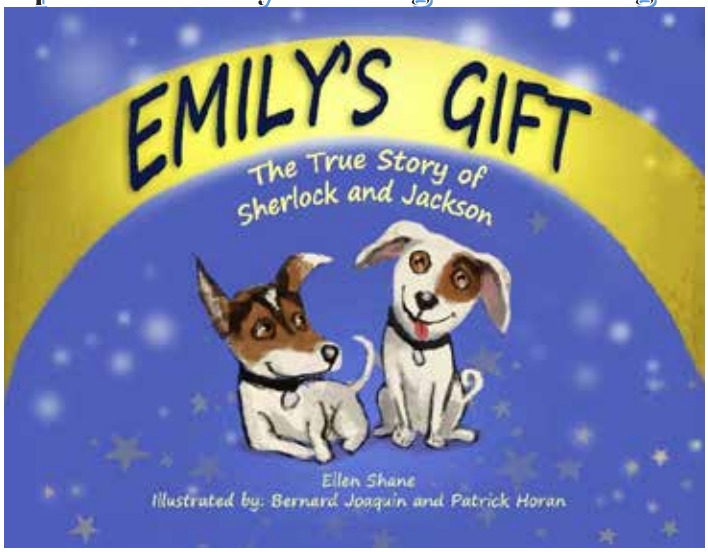

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Infant Health Matters

Susan Hepworth, Mitchell Goldstein, MD, MBA, CML

National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

The National Coalition for Infant Health is a collaborative of more than 200 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCfIH prioritizes safety of this vulnerable population and access to approved therapies.

Q:Why is it important that medications and devices be developed specifically for infants?

When it comes to medical innovation, not all patients are the same. The preterm babies I care for in the NICU, for example, need the highest level of care. They are not "tiny adults." Yet, they are often subjected to smaller doses of "adult" medication or smaller versions of adult devices. This can be dangerous. Measurement errors and inaccurate device readings can lead to poor health outcomes. I know firsthand that we need innovative technologies tailored to their size and weight for the health and safety of my tiny patients.

Q: What is one example of innovation improving infant health care?

The pulse oximeter. Today, most people know it as a tiny device that slides over your finger and uses light to measure blood oxygen levels. But as recently as the early 1990s, neonatologists had to treat newborn patients using a conventional oximeter, which was developed for adults. These monitors were unreliable and inadvertently led to some preterm babies receiving too much oxygen, causing blindness in some cases. There were other issues as well. Infants' motion and decreased perfusion sometimes prevented these monitors from reading. When the first pulse oximeter adapted for neonates was developed, a patient I was caring for became the first life of many saved.

Tiny patients need innovative technologies tailored to their size and weight. Other medical devices, such as ventilators and tubing designed for infants, also prevent avoidable illness and death.

Q: Do you recall a time when safety was critical for a patient's survival?

Yes, on numerous occasions. I think about this patient who became the first life saved by a pulse oximeter designed for infants. Back then, the oximeter was part of a study, not yet widely accepted and distributed in hospitals. My patient was in critical condition, and the conventional pulse oximeter my team and I were using repeatedly failed to provide an accurate reading of blood oxygen levels. I made a crucial decision to use the "experimental" monitor, which had important modifications to enhance infant safety, and it worked, ultimately saving the infant's life.

Q: How can policymakers encourage the development of more medications and devices for infants?

Policymakers have a lot of options for incentivizing drug development in areas of high need. That includes research grants, patent extensions, tax credits, or regulatory incentives like priority review vouchers. We need policymakers to use these tools to encourage optimal infant care and protection. But policies also have to allow for infants to access these drugs and devices once they are developed. For example, at some hospitals, administrators are mandated to purchase medical products from specific manufacturers without considering performance and outcomes data. This can limit access and discourage smaller companies from innovating for infants especially those at greatest risk for disparity.

" For example, at some hospitals, administrators are mandated to purchase medical products from specific manufacturers without considering performance and outcomes data. This can limit access and discourage smaller companies from innovating for infants especially those at greatest risk for disparity."

Encouraging competition, promoting innovation, and ensuring access can go a long way toward furthering devices and medications for infants—and saving lives.

Disclosure: No relevant disclosures noted

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National Coalition for Infant Health Values (SANE)

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

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

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

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

READ NPA's statement: **BLACK LIVES MATTER**

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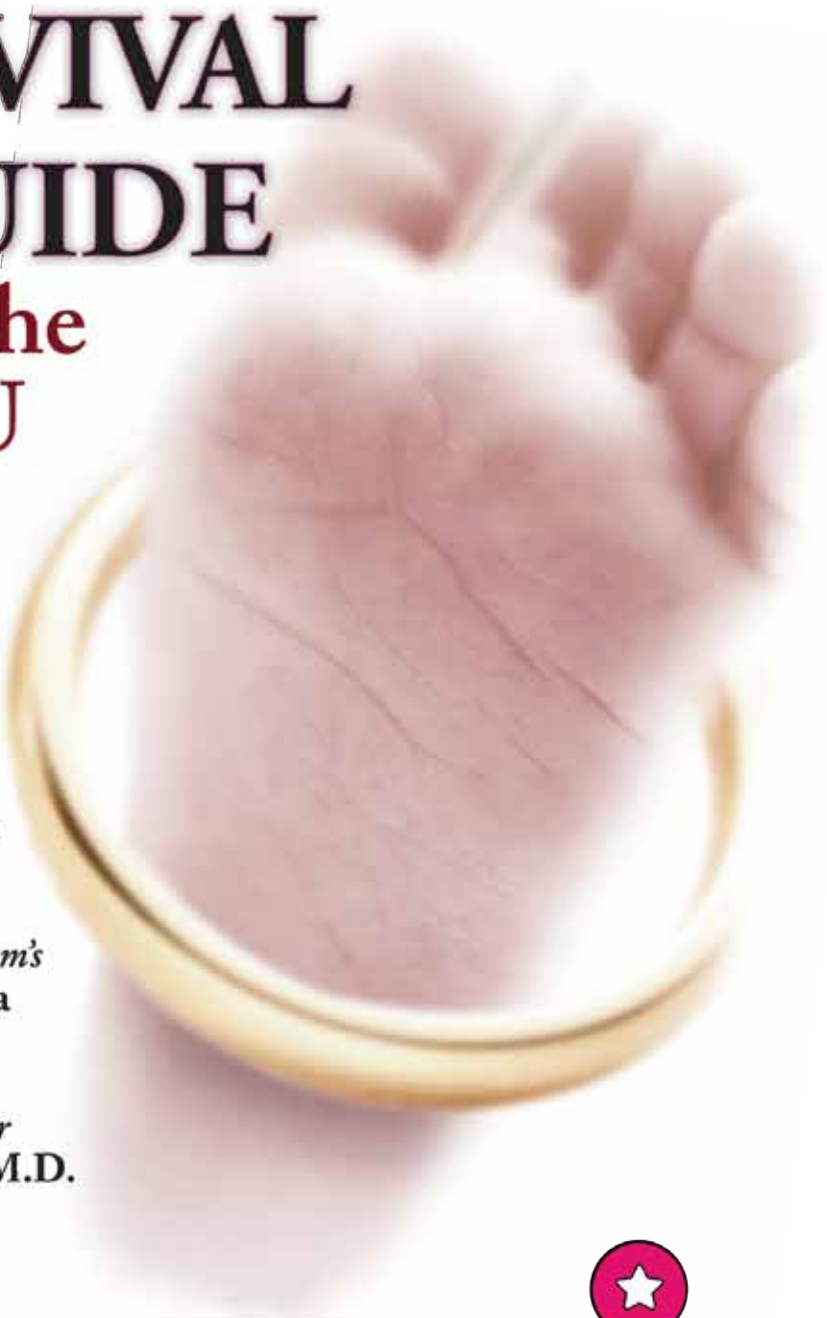
The Preemie Parent's SURVIVAL GUIDE to the NICU



By

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with

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National Statistics

Respiratory Syncytial Virus

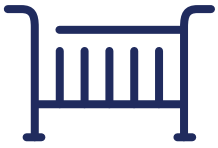
About Respiratory Syncytial Virus

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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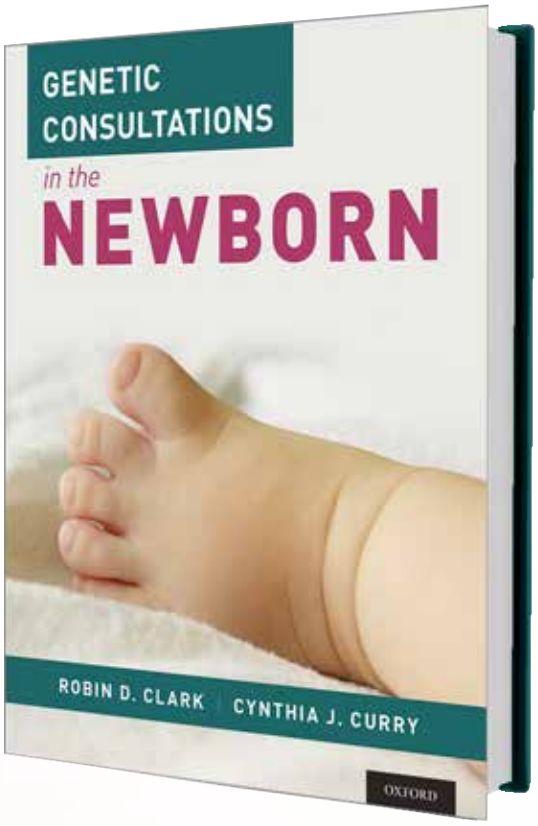

Robin D. Clark | Cynthia J. Curry

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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

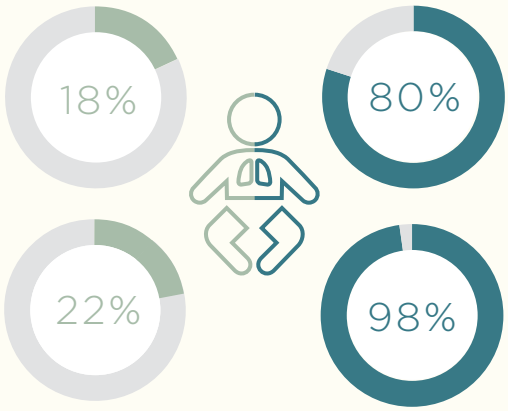
Parents of children age four and under report that understanding of RSV is lacking. That leaves them less than fully prepared to prevent their young children from catching the virus.

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: RSV(P): Will It Be Joining Us this Fall? Interim Guidance from the AAP for the Use of Pavalizumab Prophylaxis During the Delayed RSV Surge

Melanie Wielicka, MD, PhD

"RSV is one of the most common causes of viral childhood illness and constitutes a significant public health burden, on average responsible for approximately 2.1 million outpatient visits and 57,000 hospitalizations annually in children under the age of 5 years (1)."

Every year, respiratory syncytial virus (RSV) infections follow a typical seasonal pattern. Once the new pediatric interns get well acquainted with the pediatric units and emergency rooms over the summer, the cases rapidly increase in the fall, peaking in early February and declining in the spring. RSV is one of the most common causes of viral childhood illness and constitutes a significant public health burden, on average responsible for approximately 2.1 million outpatient visits and 57,000 hospitalizations annually in children under the age of 5 years (1).

However, during the classic RSV season of 2020, with the use of non-pharmacologic interventions, including universal masking and social distancing, it appeared as if we started to not only slow down the spread of COVID-19 but also other common respiratory illnesses (2). Throughout that winter, the pediatric units across the country remained unusually less busy. Based on the available data tracked by the CDC, only 0.037% of RSV PCR tests performed across the country the week of 12/26/20 were positive, compared to 15.639% during the corresponding week in 2019, demonstrating a marked reduction in RSV cases (3, 4).

In the spring of 2020, we observed increased COVID-19 vaccine availability and vaccination rates, with the rates of COVID-19 cases finally starting to decline. As the world cautiously started to return back to its "normal," with more relaxed mask policies, reopening of daycares, schools, and restaurants, pediatricians started to note increased patient volumes in the emergency rooms, as a result of what appears to be a delayed RSV surge, with 16.097% of positive RSV PCR tests nationally in the week of 8/21/21 (4).

Pavilizumab) has been shown to greatly reduce RSV-related hospitalizations and ICU admissions in infants at high risk for a more severe course of the disease. History of prematurity is a well-known risk factor, with increased hospitalization rates and longer hospital stays in these patients (5). As a result, the AAP guidelines from 2014 recommend palivizumab prophylaxis in infants born before 29 weeks 0 days gestation who are younger than 12 months prior to the start of RSV season for a total of 5 monthly doses. Additionally, infants born after 29 weeks gestation can also qualify for Synagis if they suffer from chronic lung disease or congenital heart disease (6).

Given the available data on the current RSV activity in the United States, associated with increased numbers of emergency room visits and hospitalizations, the AAP released an interim guideline on Synagis use during this time, strongly supporting consideration for Synagis use in those patients who meet the eligibility criteria listed in their 2014 guideline. This strategy should be implemented in regions with high rates of RSV infections, consistent with the rates classically seen during the fall-winter RSV season (7).

"This delayed increase in RSV activity leaves some uncertainty as to what we should expect this fall. In light of what we have learned from last year's RSV season, if local authorities re-instate universal masking and strict social distancing policies across the country with the current rise in COVID-19 hospitalizations, we could potentially see these non-pharmacologic measures affect the RSV curve as much as the COVID-19 one."

This delayed increase in RSV activity leaves some uncertainty as to what we should expect this fall. In light of what we have learned from last year's RSV season, if local authorities re-instate universal masking and strict social distancing policies across the country with the current rise in COVID-19 hospitalizations, we could potentially see these non-pharmacologic measures affect the RSV curve as much as the COVID-19 one. Conversely, if the high rates of RSV persist, it might be necessary to expand the course of Synagis to include more than five doses to ensure adequate protection of those with a history of prematurity. With all that in mind, the AAP guideline suggests to re-assess the need for administering Synagis to infants at risk at least monthly, as it appears that the COVID-19 pandemic will continue to play a significant role in the patterns we see in RSV as well as other common infectious diseases.

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Disclosures: The authors have no conflicts to disclose

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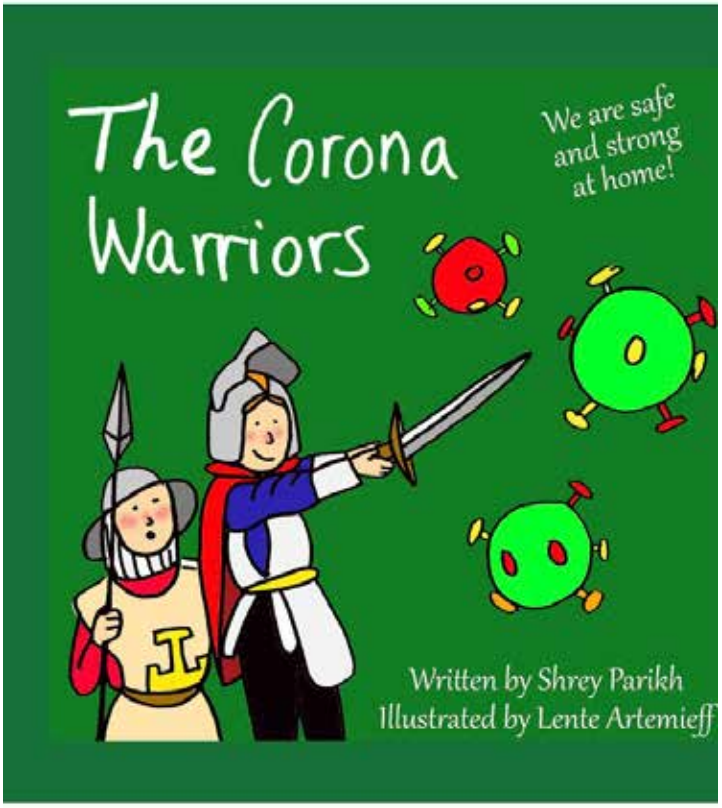

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OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

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

I was exposed to opioids.

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

NAS is a temporary and treatable condition.

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

My mother may have a SUD.

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

My potential is limitless.

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

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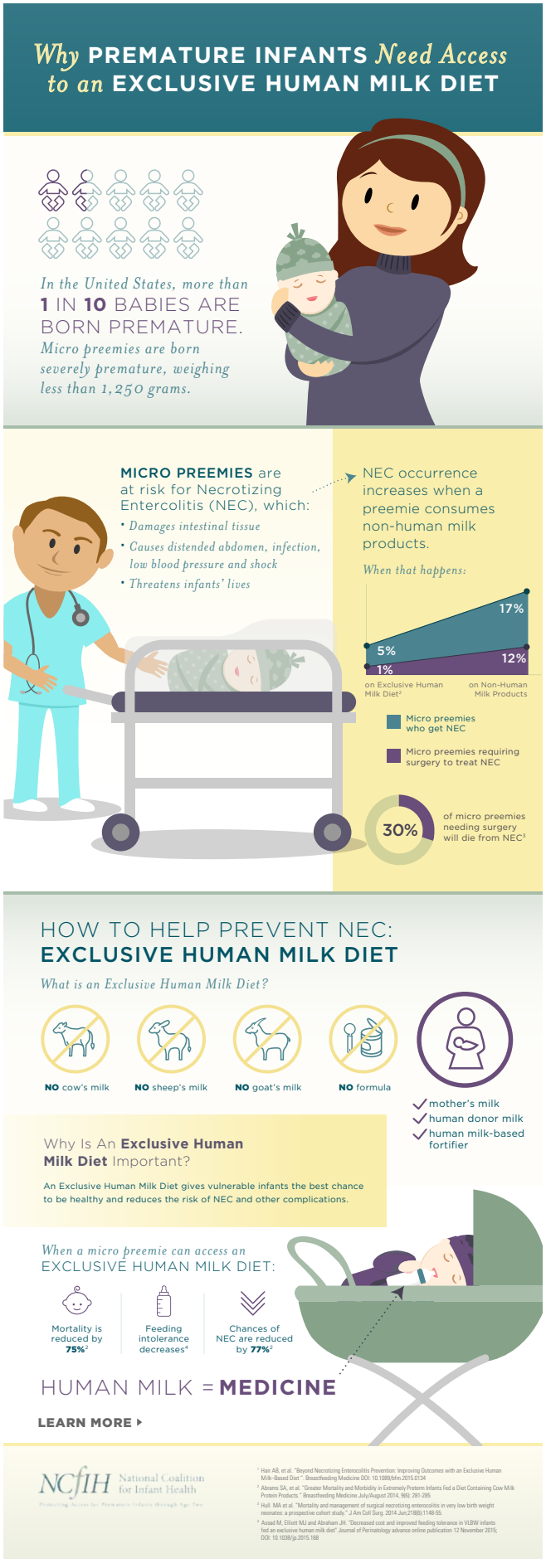
National Perinatal Association



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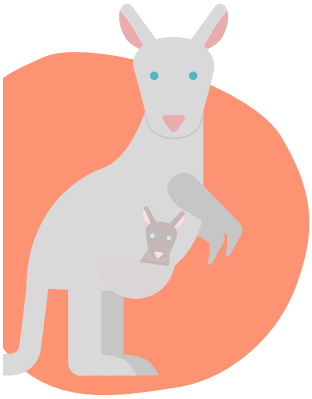

GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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

National Perinatal Association

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Peer Reviewed

Medico-Legal Forum: The Electronic Medical Record: Legal Issues to Consider Part I: Patient Care or Paper Care or Who Cares?

Gilbert I. Martin, MD

Doctors hate to write. Perhaps the accumulation of all those undergraduate courses with small calculus-like equations followed by medical school, where every word seemed so important, set the stage for…poor legibility. The handwriting is terrible…he/she must be a doctor. How many times I have heard this when scribbling a prescription or finishing a progress note. Externs, interns, and residents…as the years progressed, the notes regressed.

"Doctors hate to write. Perhaps the accumulation of all those undergraduate courses with small calculus-like equations followed by medical school, where every word seemed so important, set the stage for…poor legibility. The handwriting is terrible…he/she must be a doctor."

To simplify matters, checklists and templates were designed, and notes became data-filled and less explanatory. However, the information was recorded, and the "medical record" documented care…or did it?

Care…patient care, a term physicians use in everyday conversation. However, in today's era of "documentation," patient care is becoming paper care. Under the 1996 Health Insurance Portability and Accountability Act (the Kennedy-Kasselbaum law), documentation requirements will be used to justify the payment. (1) According to this law, to justify a 25-minute visit with a patient, an incredible amount of documentation is required. The chief complaint, an extended history (with several elements necessary), a review of systems (a complete inventory), pertinent history, a complete physical examination, data evaluation, and plan must be present. Wait, you say. This is the stuff we learned in medical school. True, true, I answer. But the complexity of the visit and its documentation will determine which "code" should be used for billing. More time will be spent in fulfilling the "paperwork" requirement than in working with the patient.

Picture the following scenario: Your obstetrical colleague admits a patient at 24 weeks gestation with premature rupture of membranes. After she is stabilized, the neonatologist is asked to speak to the family regarding prognosis and also attends the delivery three days later. The baby is intubated, given surfactant, and placed on a ventilator, and umbilical access is obtained. The neonatologist spends many hours stabilizing this infant during the first 24-hour period. Only five organ systems are described (instead of six) in the written note, with two elements in four systems noted rather than in all systems. Because of this failure of documentation and recording, the auditor changes the code and reduces the corresponding fee. Suddenly the focus is on the paper and not the patient. The art of medicine, the time we can spend with our patients and their families, is being eroded by the necessity of following all of the rules to receive payment.

What is so important about payment? When my toilet fills up, or the washing machine breaks down, I call the plumber. He comes, does his job, and presents a bill, and I pay it. No discounted "plunging" for service. An hourly fee with additions for nighttime and weekend service. I determined long ago that a cash transaction for a plastic fork enmeshed in the garbage disposal is worth six hours of neonatal intensive care, including intubation and umbilical artery catheterization.

Somewhere in history, the reason for writing a medical note has been forgotten because the written record is used for multiple reasons. We were taught that the information documented in the chart would assist all members of the "health team" in caring for the patient. We have lost sight of our "purpose' and should inform our legal colleagues that there is a difference between completeness and obfuscation.

In today's world, most hospital notes are electronic. The electronic medical record (EMR) enables the healthcare professional to see more patients. But reviewing the EMR from a medical-legal standpoint has many pluses as well as minuses. The EMR often does not present information in a meaningful way so that the reader will understand what is happening to the patient and especially the plan. Fast forward to a medical malpractice scenario where these electronic notes are not clear or meaningful.

"In today's world, most hospital notes are electronic. The electronic medical record (EMR) enables the healthcare professional to see more patients. But reviewing the EMR from a medical-legal standpoint has many pluses as well as minuses. The EMR often does not present information in a meaningful way so that the reader will understand what is happening to the patient and especially the plan."

Part II of this series will discuss the benefits and shortcomings of the electronic medical record and how the author must be aware of the medical-legal consequences.

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Disclosure: There are no reported conflicts.

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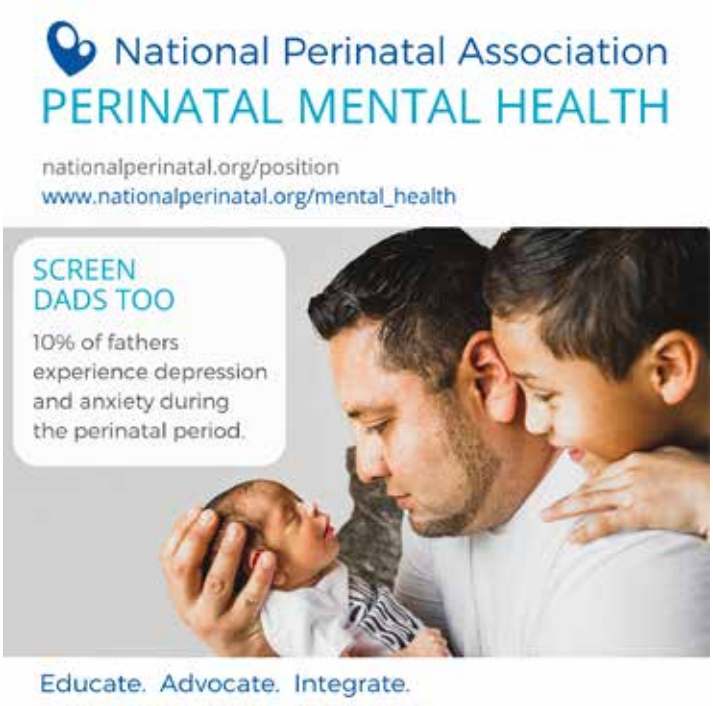

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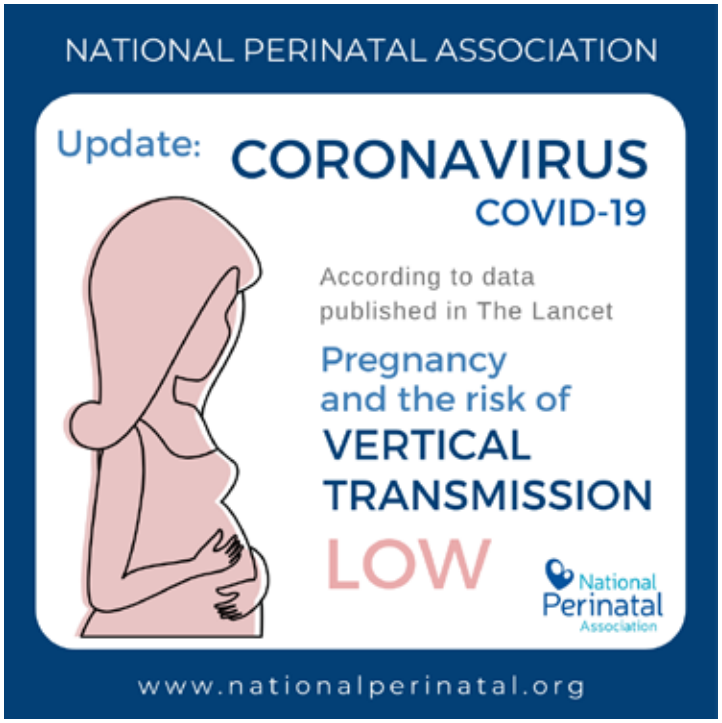


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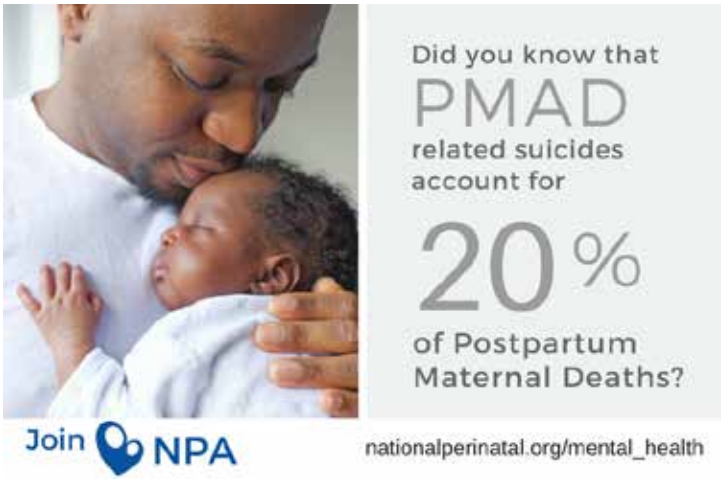
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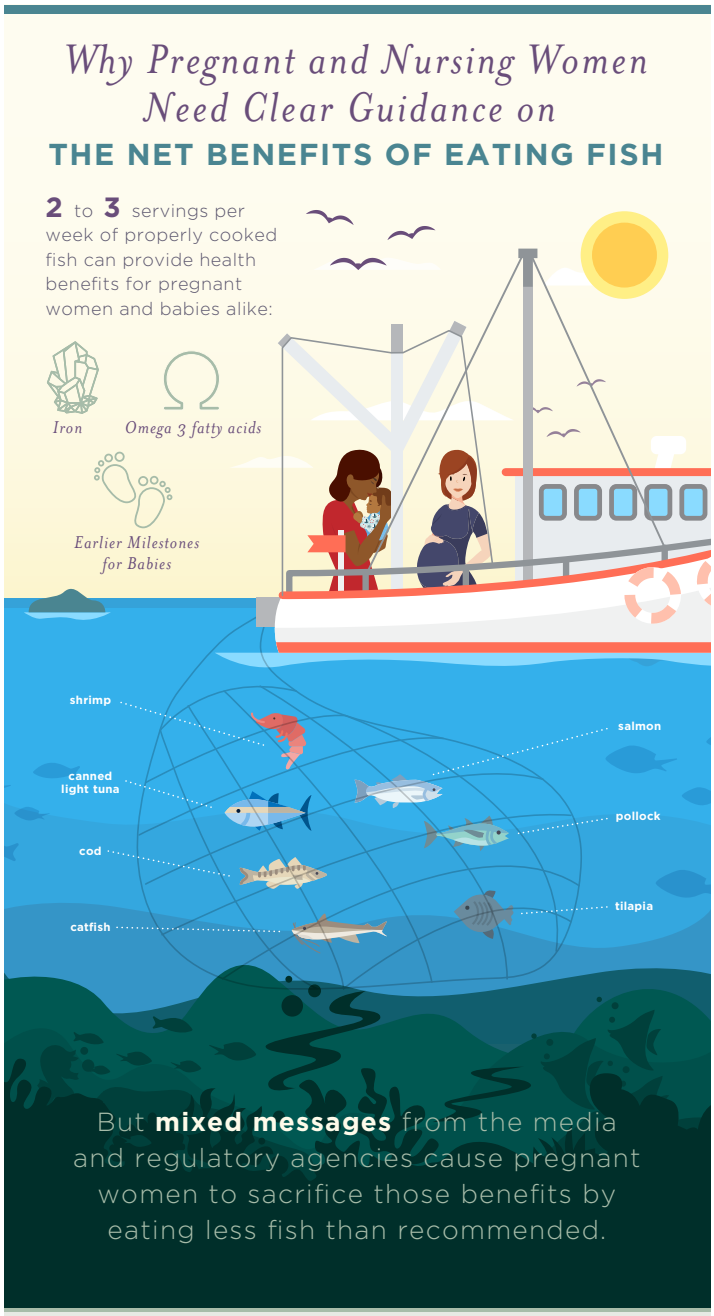
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Interpreting Umbilical Cord Blood Gases: Section 7: Fetal Circulatory Failure

Jeffrey Pomerance, MD, MPH

"The most common mechanisms responsible for fetal asphyxia at delivery are umbilical cord occlusion and uteroplacental insufficiency. Rarely, however, some other problem in the fetus, such as severe anemia or hypovolemia, becomes the operative mechanism."

The most common mechanisms responsible for fetal asphyxia at delivery are umbilical cord occlusion and uteroplacental insufficiency. Rarely, however, some other problem in the fetus, such as severe anemia or hypovolemia, becomes the operative mechanism. The following case is such an example.

Case 19: Chronic Fetal-Maternal Transfusion

The mother was a 32-year-old, blood type A positive, gravida 1, para 0, aborta 0, with an intrauterine pregnancy at 36 weeks gestation. Several weeks earlier, an ultrasound to rule out fetal growth restriction was reported as normal. The mother now complained of absent fetal movement from the previous evening. She was not in labor. At the hospital, the FHR tracing demonstrated a rate of 130 bpm but with absent variability. Maternal supplemental oxygen was administered. After 10 minutes, there began a slow decline in FHR to 65 bpm. The infant was delivered approximately 10 minutes later by "crash" cesarean section and was observed to be very pale. Amniotic fluid was clear. Apgar scores were 0, 0, 0, and 0 at one, five, 10, and 13 minutes, respectively.

Cord blood gas results were as follows:

	Umbilical Vein	Umbilical Artery
pH	7.24	6.85
Pco_2 (mmHg) *(kPa)*	48 *6.40*	97 *12.93*
Po_2 (mmHg) *(kPa)*	43 *5.73*	10 *1.33*
BD_{ecf} (mmol/L)	7	17

Resuscitation included intubation, ventilation with 100% oxygen, chest compressions, and ETT epinephrine. Chest movement was good. The ETT was suctioned and was clear. Resuscitation efforts were discontinued at 13 minutes of life when there was no response. The infant's birth weight was appropriate for gestational age at 3125 g. No edema was detected. An autopsy was not performed, although placental pathology was said to be normal except for numerous nucleated fetal RBCs and a very pale maternal side of the placenta (representing fetal blood). (1)

A hematocrit obtained from the umbilical cord at the same time as cord gases was 6% (hemoglobin 2.0 g/dL). A maternal Kleihauer-Betke test was positive for 3.4% fetal RBCs. There was no history of maternal trauma.

Although it was not mentioned, an enlarged liver was almost certainly present.

"Slowed circulation allows a normal placenta to have prolonged transit time and subsequently increased oxygen diffusion across the intervillous space. (3) The application of maternal supplemental oxygen would enhance this effect. (4,5) The umbilical arterial blood gas is extremely acidotic with combined severe respiratory acidosis and very severe metabolic acidosis."

Interpretation

The umbilical venous blood gas is normal, except for a minimally decreased pH, a slightly elevated Po_2, and a slightly elevated base deficit in a fetus who had not been exposed to labor. Minor increases in fetal base deficit normally occur during the second stage of labor. (2) The mildly elevated Po_2 can be explained based on slowed fetal circulation typically seen during heart failure. Slowed circulation allows a normal placenta to have prolonged transit time and subsequently increased oxygen diffusion across the intervillous space. (3)The application of maternal supplemental oxygen would enhance this effect. (4,5) The umbilical arterial blood gas is extremely acidotic with combined severe respiratory acidosis and very severe metabolic acidosis. The umbilical venoarterial pH, Pco_2, and base deficit differences are all much widened.

It is important to realize that a default value of 15.0 g/dL (or 14.3 g/dL) is assumed unless an alternate hemoglobin value is entered into the blood gas analyzer. A corrected hemoglobin value may be entered into the analyzer after a blood gas is analyzed, but it must be before any subsequent blood gas has been run. As an extra-cellular base deficit has no entry for hemoglobin, a blood base deficit will be reported.The corrected cord blood gas base deficits are as follows:

	Umbilical Vein	Umbilical Artery
pH	7.24	6.85
Pco_2 (mmHg) *(kPa)*	48 *6.40*	97 *12.93*
Po_2 (mmHg) *(kPa)*	43 *5.73*	10 *1.33*
BD_b (mmol/L)	6	13

The newly estimated (corrected) base deficit values demonstrate an insignificant change in calculated metabolic acidosis in the umbilical venous sample but a much larger change in the arterial sample. Hemoglobin, oxyhemoglobin, and erythrocyte bicarbonate contained in RBCs are themselves buffers. Indeed, about 53% of the total buffering capacity in whole blood comes from the contents of RBCs (hemoglobin and oxyhemoglobin, 35%; erythrocyte bicarbonate, 18%). (6) As the number of red blood cells and hemoglobin decreases, there is a decreased amount of bicarbonate present. In other words, had the amount of hemoglobin been normal, the pH would have been better.

Why then was this newborn dead with a base deficit of "only" 13? There are at least two likely answers to this question. First, normal placental exchange functions to help maintain normal blood gas values in the fetus until the circulation fails. While carbon dioxide (the respiratory component) equilibrates rapidly across an intact placenta, lactic acid and electrically charged bicarbonate or buffer base can cross the intervillous space relatively slowly. (7)To the extent that these components cross the placenta at all, a fetal umbilical venous blood sample would underestimate the degree of metabolic acidosis present at the fetal tissue level. However, as fetal circulation fails and placental function deteriorates because of inadequate fetal circulation, oxygen debt increases, and metabolic acidosis develops. The fetal kidneys appear to play no role in regulating acid-base balance. (7) Second, as fetal circulation fails, fetal blood pressure falls, eventually approaching zero, and blood ceases flowing in the umbilical arteries. Therefore, an umbilical arterial blood gas only reflects the situation prior to the cessation of arterial blood flow.

"Second, as fetal circulation fails, fetal blood pressure falls, eventually approaching zero, and blood ceases flowing in the umbilical arteries. Therefore, an umbilical arterial blood gas only reflects the situation prior to the cessation of arterial blood flow."

As the fetus is dying, rapidly increasing respiratory and metabolic acidoses occur at the fetal tissue level. Following the complete fetal circulatory failure, tissue status becomes progressively less well represented by the umbilical artery blood gas sample. It is important to appreciate that compensated heart failure is not associated with metabolic acidosis, and it is as compensation fails only, and death is approaching that metabolic acidosis appears. It then will progress rapidly.

In the patient presented above, the umbilical venoarterial blood gas differences are extremely wide. The pH difference is 0.39 (7.24 minus 6.85). Anything wider than 0.10 is abnormal (8, 9) and suggests the umbilical cord blood samples either came from an infant with cord occlusion with terminal fetal bradycardia (common) or, as in this case, chronic fetal heart failure. The perinatologist who delivered this infant found no evidence of umbilical cord occlusion. There was no knot in the cord, nor was the cord around the fetal neck or any other body part. Furthermore, the mother was not in labor. Therefore, the descent of the fetus could not entrap an occult cord or put a stretch on a short cord. Additionally, we have a ready explanation for the infant's demise, namely the extraordinarily severe anemia leading to fetal heart failure. We do not need a cord problem in addition to explain the outcome. The principle of abiding by the simplest solution (Occam's razor) should apply. Widened pH differences have been reported in an *in utero* study of severe fetal anemia secondary to isoimmunization (10) and in a twin with congestive heart failure, possibly secondary to viral myocarditis leading to fibroelastosis. (11)

In severe chronic fetal anemia, initially, the fetus can compensate for the anemia by increasing cardiac output. However, as the anemia worsens, the heart fails, and there is a period of low cardiac output before fetal demise. The dying process is likely more prolonged in a fetus than in a child or adult because the placenta will clear lactic acid (although more slowly than oxygen or carbon dioxide) being produced at the tissue level secondary to hypoxia. (7, 12) In severe fetal anemia, fetal hemoglobin carries the usual amount of oxygen per gram of hemoglobin; however, the hemoglobin level is so critically low that the amount of oxygen delivered to the tissues becomes inadequate to support normal metabolism. When death occurs, it may be quite sudden.

When heart failure occurs in the child or adult, there is also a widening of the pH and Pco_2 differences between arterial and venous blood. However, the differences are in the opposite direction compared with umbilical venous and arterial blood. (13) As heart failure progresses, cardiac output decreases, blood flow slows further, and tissues extract an increasing percentage of oxygen from the blood. Therefore, blood leaving the tissues carries a decreased amount of oxygen and increased carbon dioxide per mL of blood. In other words, the venoarterial difference widens. This phenomenon is explained by the Fick (14) principle, which states, "The amount of a substance taken up or released by an organ is the product of its blood flow rate (referred to as blood flow) and the difference in the concentration of the substance between the organ's arterial and venous blood." (15)

$$\text{Cardiac output (liter/min)} = \frac{O_2 \text{ consumption (mL/min)}}{\text{A-V } O_2 \text{ difference (vol \%)} \times 10}$$

From this equation we can see that if cardiac output decreases and tissue oxygen consumption remains constant, then the venoarterial oxygen difference must increase. Likewise, using the same equation for carbon dioxide production, if cardiac output decreases and carbon dioxide production remains constant, then the venoarterial carbon dioxide difference must also widen. In the absence of a change in the metabolic component of the blood gas, if carbon dioxide increases, pH will fall. Vascular accumulation of lactic acid occurs only in the terminal stage of heart failure, after all other compensation methods have been utilized. What makes this clear is the finding of an absence of metabolic acidosis in the umbilical vein. However, once the tipping point of lactic acid accumulation occurs, death is near. As blood flow from the umbilical arteries through the placenta to the umbilical vein remains intact, one would not expect a widened base deficit between the umbilical vein and the umbilical arteries.

Finding a widened base deficit difference between the umbilical vein and arteries is explained by the following. In the fetus, the pulmonary bed receives less than 10 percent of cardiac output. (16, 17) Therefore, when fetal cardiac failure occurs, essentially, it is right heart failure. Fetal right heart failure leads to increased central venous pressure which, in turn, causes decreased umbilical venous blood flow and, terminally, to complete cessation of blood flow. (18)

This complete cessation of umbilical venous blood flow must occur prior to complete cessation of umbilical arterial flow in order for a substantial base deficit difference to exist, just as typically occurs in cord occlusion with terminal bradycardia. This is precisely why umbilical cord blood gases of newborns with umbilical cord occlusion and terminal bradycardia look so similar to cord blood gases of newborns with chronic fetal heart failure and terminal

bradycardia (see Table 1 below).

Chronic Fetal Heart Failure with Terminal Fetal Bradycardia: Pathophysiology, Duration and Effect on Cord Gases			
Condition	**Changes in Cord Blood Flow**	**Duration**	**Effect on Cord Gases**
Chronic Fetal Heart Failure (compensated)	UV: Slowed UAs: Slowed (↑ time for down/uploading O_2/CO_2 across placenta and at tissue level)	Days to Weeks	UV: ↑ Po_2, ↓ Pco_2, normal BD UA: ↓ Po_2, ↑ Pco_2, normal BD
Chronic Fetal Heart Failure (uncompensated)	UV: Stops (2° ↑ing CVP) UAs: Slows further → Stops	Minutes	UV: No further change UA: ↑ing respiratory and metabolic acidoses

Table 1: Chronic fetal heart failure with terminal fetal bradycardia: Pathophysiology, duration, and effect on umbilical cord blood gases

UV, umbilical vein; UA, umbilical artery; ↑, increased; ↓, decreased; 2°, secondary to

A fetus with cord occlusion and terminal fetal bradycardia has a mechanical obstruction of the umbilical cord followed by a period in which the fetal arterial blood pressure briefly overcomes the obstruction. In contrast, umbilical venous blood flow remains occluded. On the other hand, a fetus with heart failure and terminal bradycardia has right heart failure and elevation of umbilical venous pressure that results in cessation of umbilical venous blood flow while umbilical arterial blood flow continues briefly. Both have a common pathophysiology: a period of cessation of umbilical venous blood flow, but temporarily continuing umbilical arterial blood flow. At birth, how can one distinguish between a newborn with cord occlusion and terminal bradycardia and one with chronic fetal heart failure and terminal fetal bradycardia (see Table 2, this section)?

"A fetus with cord occlusion and terminal fetal bradycardia has a mechanical obstruction of the umbilical cord followed by a period in which the fetal arterial blood pressure briefly overcomes the obstruction. In contrast, umbilical venous blood flow remains occluded."

Why did this infant *not* have any discernable edema? Certainly, with a hematocrit of 6%, hydrops fetalis would be anticipated. Nicolaides et al. (19) studied seven hydropic and ten nonhydropic fetuses at 18 to 25 weeks gestation. All fetuses with sonographic evidence of hydrops had hemoglobin values of 3.8 g/dL (hematocrit approximately 11.4%) or less. All but one nonhydropic fetus had a hemoglobin value greater than 4.0 g/dL (hematocrit approximately 12.0%). Hypoalbuminemia was found in six of the seven hydropic fetuses and in two of the nonhydropic fetuses.

These data suggest that the infant described above had both a chronic and an acute phase of fetal-maternal transfusion. If there had been only an acute phase of blood loss from the fetus to the mother, the infant would have died quite before a hematocrit of 6% was reached. If there had only been a chronic phase of blood loss from the fetus to the mother, hydrops would have been expected. Perhaps the chronic phase brought the fetal hematocrit down to the 12-15% range, a range in which fetal hydrops may not be present, and a superimposed acute phase completed the decrease to six percent. Kohlenberg and Ellwood (20) have reported intermittent fetal-maternal hemorrhage. Asphyxia is not associated with chronic fetal blood loss without superimposed labor until the fetus' hemoglobin falls to less than 4.0 g/dL. (21) During labor, the fetus may deteriorate quickly. When the fetus' hemoglobin is even lower, as in this case, labor does not need to occur for the fetus to be asphyxiated or die.

How can one estimate the extent of fetal blood loss? Conventional methods for calculating fetal blood loss provide only approximations and tend to underestimate. In addition, these methods are more appropriate for calculating acute rather than chronic blood loss.

A look at the issue from the maternal side estimates how much fetal blood is in the maternal circulation. This approach does not consider the fact that fetal RBCs are destroyed gradually (or sometimes not so gradually if the mother is type O and the fetus type A, for example) in the mother's circulation. Therefore, the Kleihauer-Betke test itself also underestimates the amount of fetal-maternal transfer. In the premature between 24 and 28 weeks, fetal hemoglobin (HbF) accounts for more than 90% of fetal blood, while at term, only approximately 75% of hemoglobin is HbF. (22) Fetal RBCs that contain adult hemoglobin rather than HbF are omitted from the estimate.

Assuming a maternal total blood volume of five liters and a maternal hematocrit of 36%, 3.4% fetal RBCs represent approximately 61 mL of packed fetal RBCs in the maternal circulation (5000 x 0.36 x 0.034 = 61). At term, the fetal-placental unit contains approximately 125 mL of blood per kg of infant weight. (23,24) Assuming an initially normal fetal hematocrit of 50% in a 3125 g infant, the total fetal-placental blood volume is 391 mL (125 x 3.125 = 391) with a packed cell volume of 196 mL (391 x 0.50 = 196). Thus, over time, the fetal-placental unit is calculated to have lost approximately 31% (61/196 = 0.31) of the normal, calculated fetal-placental blood volume at term. This assumes that there was no ABO incompatibility between the mother and the fetus, as this would result in a more rapid loss of fetal RBCs from the maternal circulation. (25) In this case, the infant's blood type is unknown, although the mother's A+ blood type makes ABO incompatibility unlikely.

A second approach to estimating the volume of fetal blood loss looks at the issue from the fetal side. This approach does not consider the fact that the fetus continues to produce RBCs, sometimes at a prodigious rate. The placenta demonstrated fetal response (NRBCs) to chronic blood loss. Again, assuming an initial fetal-placental hematocrit of 50%, a hematocrit of 6% at the time of birth suggests a loss of 88% of the fetal-placental blood volume over time (initial Hct minus final Hct, divided by initial hematocrit

((50-6)/50 = 0.88).

These two approaches to estimating fetal-placental blood loss into the mother provide very different estimates. This suggests ABO incompatibility, resulting in more rapid destruction of fetal RBCs in the maternal circulation, although the mother's blood type (A+) argues against this.

These methods of calculating fetal blood loss should be taken with a grain of salt, as results exceeding 100% of fetal blood volume occur fairly often. This points out the problem of differentiating termal fetal bradycardia secondary to cord compression from chronic fetal heart failure secondary to severe fetal anemia.

Differentiating Terminal Fetal Bradycardia Secondary to Cord Compression from Chronic Fetal Heart Failure Secondary to Severe Fetal Anemia

Findings	Cord Compression	Fetal Heart Failure
Abnormal FHR tracing from the time of maternal admission	No	Yes
Preceding late FHR decels	Unlikely	Likely
Cord blood gases with widened pH, Pco_2, and possibly base deficits	Yes	Yes
Maternal placental surface very pale	No	Yes (severe anemia – most common cause of chronic fetal heart failure)
Slow neonatal recovery from metabolic acidosis	Atypical	Common

Table 2 *Differentiating cord compression from chronic fetal heart failure using methods designed for calculating acute blood loss to calculate chronic blood loss.*

It is also of note that this infant had a recorded FHR of approximately 65 bpm 10 minutes prior to delivery. Why was it then that there was no discernable heart rate at the time of birth? Please see discussion of this issue under fetal heart rate present, neonatal heart rate absent, in a prior section.

Key Points

- Cord occlusion and uteroplacental insufficiency account for the great majority of abnormal FHR tracings and abnormal umbilical cord blood gas results.
- Although widened differences between umbilical veno-arterial pH and Pco_2 suggest cord occlusion, they also are typical of a much rarer event, fetal heart failure.
- Cord blood gases of newborns with umbilical cord occlusion and terminal bradycardia look very similar to cord blood gases of newborns with chronic fetal heart failure and terminal bradycardia because they have a common pathophysiology — a period of cessation of umbilical venous blood flow, but with temporarily continuing umbilical arterial blood flow.
- A mildly elevated umbilical venous Po_2 suggests slowed circulation and therefore increased time for oxygen to cross the placenta from the mother to the fetus, prior to the terminal event.
- Widened arterial-venous pH and Pco_2 differences are associated with heart failure in both children and adults, as well as heart failure in the fetus.
- Typically, chronic fetal heart failure is not associated with ongoing metabolic acidosis. What makes this clear is the finding of an absence of metabolic acidosis in the umbilical vein. Therefore, umbilical venous cord gases tend to be normal or near-normal.
- As fetal heart failure becomes terminal, elevated right heart pressures are transmitted to the umbilical vein, resulting in interruption of umbilical venous blood flow prior to cessation of umbilical arterial blood flow and, hence, widened base deficits.
- Once fetal blood pressure falls to a critical level, blood will no longer perfuse the umbilical arteries. After this time, umbilical artery blood no longer reflects continuing change at the fetal tissue level.

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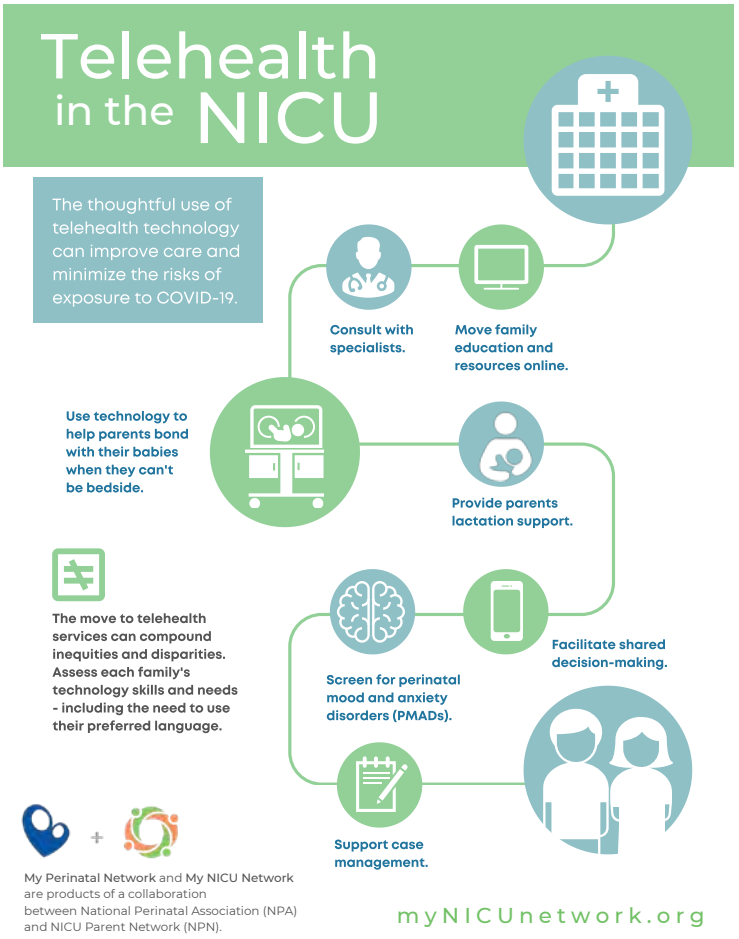
Disclosure: The author has no disclosures.



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Letters to the Editor

Winning the Race to the Bottom -- How to Get a Meaningful Product to Market

Medical Predictive Science Corporation

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Letter to the Editor

August 30th, 2021

To the Editor,

I enjoyed the recent article, "*False Alarms Signal Urgency of Infant-Specific Devices,"* and thought I would share some of my relevant experiences and opinions.

Many years ago, when we were early in the development of HeRO, we went to a large device manufacturer to ask for funding. Across an impressive conference table, one of their executives told me, "Will, it's a lot easier for me to get a check cut for one hundred million dollars to buy a company than to invest one million." I must have looked stunned because he explained that his company did not invest in new, promising technologies or startups based on potential growth. Instead, they bought mature companies based on existing revenues. So, a one million dollar investment in a promising technology could not be justified. But, wait a few years, multiply annual revenues by the correct factor, and that is what the company is worth. And if it is one hundred million dollars, it is one hundred million dollars, and it is well-justified.

So, who then will take promising NICU technologies from the bench to the bedside? NIH SBIR, STTR, and other grants are notoriously slow and only cover R&D expenses. What about sales? What about marketing? This is where venture capitalists are supposed to work, correct? Realizing that many investments that a VC makes will fail, they must focus their early-stage investments on home runs whose potential returns are 10-fold or greater.

Given that it takes about 10 years and $10-$100+ M to bring a new technology to market, products focused in the NICU have some challenging math to overcome. For a $100 M valuation to be achieved, annual revenues of $25 M to $50 M are required, based upon the lowest investment of $10 M. That is between $1,000 and $2,000 for every single NICU bed in the USA, every single year with 100% market share. Effectively, that makes a NICU-focused technology practically unfundable for VCs.

For most companies with a NICU product, angel investors and NIH funding are the best answer. In the case of HeRO, those funding methods provided for the HeRO research, and we have funded our growth organically (a venture capitalist would read that as *slowly*). However, the research results have been the home run. Mortality after infection and mortality in the NICU were improved in the largest RCT ever conducted among VLBWs. Length of stay was reduced among survivors. Mortality at 18-22 months was improved among ELBWs studied, and death-or-NDI was reduced among those that experienced sepsis. There was no increase in testing or antibiotics. It costs about $1000 per QALY or $50,000 to save a life.

But even after ten years of commercializing, the majority of US NICUs do not have HeRO. Should the venture capitalists have funded this project? The fact of the matter is that neonatology is a niche marketplace. And if the largest, most expensive RCT in neonatology had a mortality improvement result, yet most NICUs are slow to adopt the technology, why on earth would a VC invest in any new NICU technology to address the urgent need for infant-specific devices?

In order to supply neonatologists with new infant-specific devices, there needs to be rapid adoption of those proven to work. Certainly, many technologies will not save lives nor improve outcomes. But once technologies have been shown to do so, early adopters need to take ownership and drive proven technologies forward to make them the standard of care as quickly as possible. This is best for the patients and ensures a reward for those investment capital dollars needed to produce the devices. The VCs and medical device companies deciding whether to fund new technologies for the NICU are watching and taking note.

I argue that neonatologists that want the best care for their patients, now and in the future, should have HeRO. The evidence is incontrovertible, and it is a very inexpensive way to save a life. Take your shoe off and bang it on the table if you have to!

Sincerely,

Will King, CEO

Medical Predictive Science Corporation

Dear Mr. King,

I understand your pain. As a practicing neonatologist, many devices could result in quantum improvements in neonatal care, but we will never see them because of myriad product development, capitation, and distribution cycle problems. What you have touched on is just the tip of the iceberg. In addition to medical device manufacturers, pharmaceutical companies and those that produce biologics are also at risk.

Although pharmaceutical companies are now incentivized to perform pediatric clinical trials and develop indications for our at-risk neonates, this grant is not a panacea. By developing a product with a pediatric indication, pharmaceutical manufacturers can receive an additional six months of patent protection on a more highly profitable drug in their portfolio, potentially covering the cost of development, research, and marketing of the pediatric-specific therapy. As we know, most university academic settings are risk-averse and cannot even approach the idea of putting a large investment of endowment funds into the development of a novel therapeutic. Smaller pharmaceutical firms without a significant portfolio gamble on their very existence with every product

they produce. Relatively recently, Medimmune developed an enhanced monoclonal antibody directed against the RSV F protein. It would have reduced cost and potentially improved RSV prophylaxis in our most at-risk population. Despite clinical evidence of efficacy, there was a 1% increase in the development of rash following immunization. The FDA denied the application. An estimated one billion had been spent to develop this therapeutic. The fallout was significant. Medimmune, albeit a wholly-owned subsidiary of AstraZeneca at the time, was folded into the parent company. Palivizumab, or Synagis, was ultimately transferred to Sobi.

Despite the risk in the pharmaceutical and biological pipeline, Medical devices have even less protection. The market sees these devices as widgets until they have been deemed to be essential. ECRI and other organizations provide product evaluation but are not gatekeepers to successful integration in the Neonatal Intensive Care Unit. Although a device may provide significant improvement in care, outcomes, and patient comfort, medical devices are subject to evaluation by Group Purchasing Organizations (GPO). These devices are evaluated not only on their worthiness but also on the ability of their parent company to provide additional cost-efficient discounts on other product lines to the GPO. These discounts are then passed on to the GPO member organizations as end-of-cycle federally sanctioned kickbacks based on the volume and percentage of purchases along the lines of GPO qualified inventories.

Even with substantial angel investor backing, excellent QALY data, and clinician backing, life-altering equipment, critical medical devices, and essential algorithms can be held up by a non-optimal purchasing arrangement. Further, these arrangements cannibalize the sales of potential competitor devices as hospital purchasing is under the gun to achieve the best possible kickback. Physicians often have no say in this process. Certain hospitals depend on this revenue to provide "cost-efficient" patient care. This model can lead to sole-sourcing of various components and a race to the bottom by GPO contractors that favors even lower cost and increasingly "offshore" options. At the depths of this pandemic, we saw this process manifest in shortages of masks, nasal swabs, and other durable goods.

And yet, as you have pointed out, we are leaving some of the more provocative technologies off the table. The value of an infant life, improved neurodevelopmental outcome, a child who has not gone on to develop blindness or cerebral palsy, and future generations that have been enhanced by building on the best of breed technologies that we have developed today cannot be estimated by Qalys. It is not that VCs cannot understand the concept, but their valuation estimation comes from understanding revenue cycles, return on investment, and mitigating risk in a defined investment over a time shorter than that required to see the long-term benefit. Yes, a company with a 100 million dollar valuation is a better buy than a one million dollar valuation – the value chain has been defined.

Although I have done a fair amount of advocating and "shoe banging" for our most at-risk babies, our Internal Revenue Service may provide the best example for a better model. If we could figure a way to reward improvement in extremely long-term outcome measures by exempting the tax on profits from these technologies that offer real cost savings by decreasing reliance on government programs, this process could be done at no net cost to the taxpayers and provide a significant advantage to VC and angel investors. Of course, the predicate of getting these devices into the NICUs to produce this improvement must be met to realize these cost savings.

Sincerely,

Mitchell Goldstein, MD, MBA, CML

Editor in Chief

NEONATOLOGY TODAY

Loma Linda Publishing Company

A Delaware "not for profit" 501(c) 3 Corporation.

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Published monthly.

www.NeonatologyToday.net

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

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

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Erratum (Neonatology Today August 2021

Neonatology Today is not aware of any erratum affecting the August, 2021 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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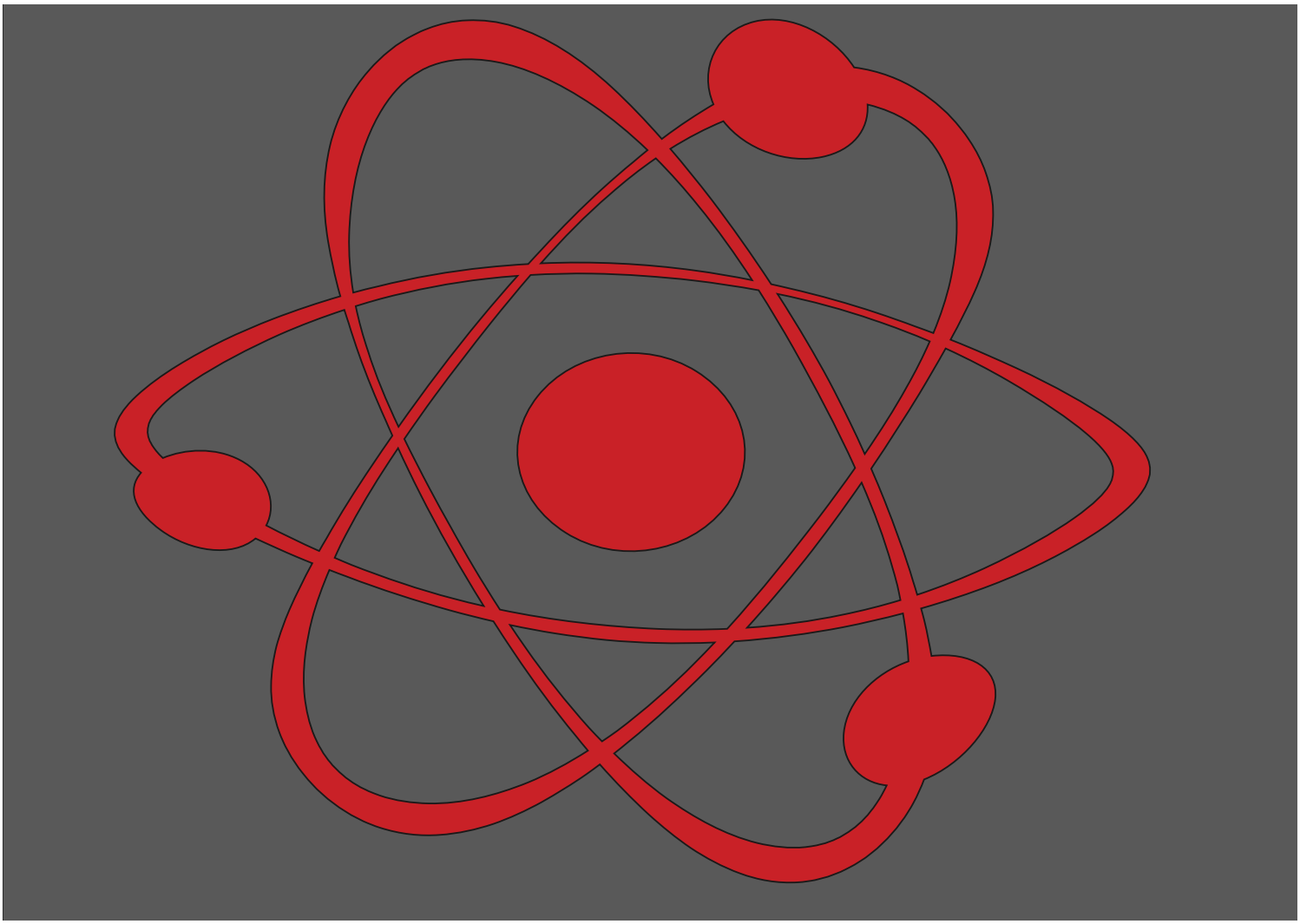
Academic True Open Model (ATOM)



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Neonatology Today, a publication of Loma Linda Publishing Company.

ISSN: 1932-7137 (Online), 1932-7129 (Print)

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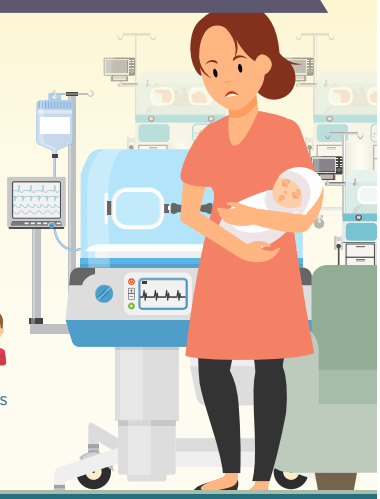
Will your **PRETERM INFANT** *need* **EARLY INTERVENTION** *services?*

Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges

1 in **3** preterm infants will require support services at school



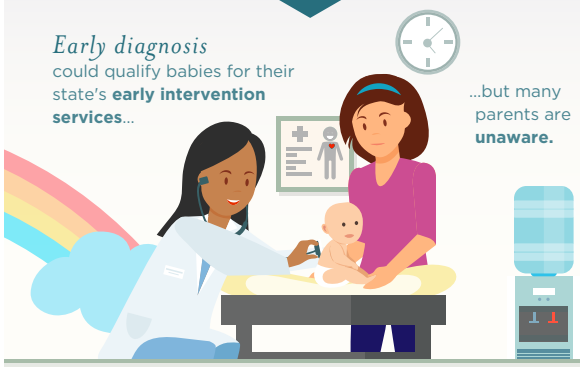
Early intervention can help preterm infants:

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

Early diagnosis

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

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



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

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

NCFIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

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

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

1 DE CADA **7** MADRES AFRONTA LA DEPRESIÓN POSPARTO, *experimentando*

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

Sin embargo, sólo el 15% recibe tratamiento[1]

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

La salud de la madre

El sueño, la alimentación y el comportamiento del bebé a medida que crece[2]

La capacidad para cuidar de un bebé y sus hermanos

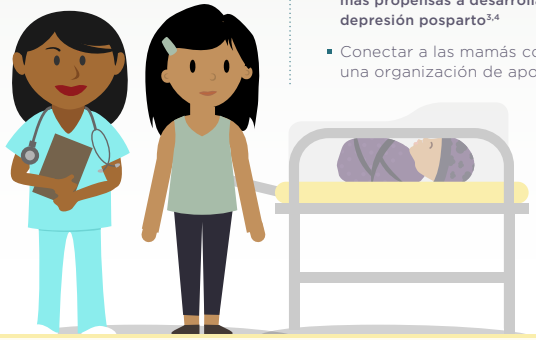
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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

LOS HOSPITALES PUEDEN:

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



NCFIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

[1] American Psychological Association. Accessible on: http://www.apa.org/pi/women/resources/reports/postpartum-depression.aspx

[2] National Institute of Mental Health. Accessible on: https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml

[3] Journal of Perinatology (2015) 35, 529–536; doi:10.1038/jp.2015.147.

[4] Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Villegas L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

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National Perinatal Association

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New York City, New York
Virtual Conference
October 9 & 10, 2021
https://columbiacme.rievent.com/a/QATIWQ

American Academy of Pediatrics National Conference and Exhibition
Philadelphia, PA (now all virtual)
October 8-12, 2021
https://aapexperience.org/

2021 National Perinatal Association Perinatology at the Intersection of Health Equity and Social Justice
Hyatt Regency Aurora-Denver
Denver, CO
December 1-3, 2021
www.NPAconference.org

Hot Topics in Neonatology®
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National Harbor, MD
December 6-8, 2021
http://www.hottopicsinneonatology.org/

2022 NeoPREP®
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January 22-26, 2022
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35th Annual Gravens Conference on the Environment of Care for High Risk Infants
Transformational Change: Making if Happen in the NICU
March 9-12, 2022
Sheraton Sand Key
Clearwater Beach, Fl
Abstract call:
https://neonatologytoday.org/Gravens/Abstract/

38th Annual Advances in Therapeutics and Technology: Critical Care of Neonates, Children, and Adults
March 29-April 2, 2022
Snowbird, UT
https://paclac.org/advances-in-care-conference/

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

NEO: The Conference for Neonatology
March 2-4, 2022
San Diego, CA
www.neoconference.com

Specialty Review in Neonatology
March 1-6, 2022
San Diego, CA
www.specialtyreview.com

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

NEONATOLOGY TODAY

ISSN: 1932-7137 (Online). ISSN:: 1932-7129 (Print). Published monthly. All rights reserved.

Publication
Mitchell Goldstein, MD
Loma Linda Publishing Company
11175 Campus Street
Suite #11121
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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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https://www.nc3rs.org.uk/arrive-guidelines

http://www.icmje.org

https://olaw.nih.gov/policies-laws/phs-policy.htm

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Neonatology and the Arts

This section focuses on artistic work which is by those with an interest in Neonatology and Perinatology. The topics may be varied, but preference will be given to those works that focus on topics that are related to the fields of Neonatology, Pediatrics, and Perinatology. Contributions may include drawings, paintings, sketches, and other digital renderings. Photographs and video shorts may also be submitted. In order for the work to be considered, you must have the consent of any person whose photograph appears in the submission.

Works that have been published in another format are eligible for consideration as long as the contributor either owns the copyright or has secured copyright release prior to submission.

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one page as well as photographs of birds on another. This month's original artwork is called "Airborne" is provided by Nico Akiva Anderson. Our bird of the month is "The Canadian" rendered by is Barbara Strobel-Dellger on a Quilt.(bldellger@gmail.com), the aunt of Katie Strobel, MD (KMStrobel@mednet.ucla.edu) a Neonatal-Perinatal Medicine Fellow PGY-6 at UCLA.

Herbert Vasquez, MD,
Associate Neonatologist, Queen of the Valley Campus
Emanate Health, West Covina, CA
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Manuscript Submission: Instructions to Authors

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

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.

11. NT recommends reading Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals from ICMJE prior to submission if there is any question regarding the appropriateness of a manuscript. NT follows Principles of Transparency and Best Practice in Scholarly Publishing(a joint statement by COPE, DOAJ, WAME, and OASPA). Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

NICU Baby's Bill of Rights

1- The Right to Advocacy
My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical records, and prognosis, so they celebrate my achievements and support me when things get challenging.

2- The Right to My Parents' Care
In order to meet my unique needs, my parents need to learn about my developmental needs. Be patient with them and teach them well. Make sure hospital policies and protocols, including visiting hours and rounding, are as inclusive as possible.

3- The Right to Bond with My Family
Bonding is crucial for my sleep and neuroprotection. Encourage my parents to practice skin-to-skin contact as soon as and as often as possible and to read, sing, and talk to me each time they visit.

4- The Right to Neuroprotective Care
Protect me from things that startle, stress, or overwhelm me and my brain. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time and faster than it ever will again. The way I am cared for today will help my brain when I grow up. Connect me with my parents for the best opportunities to help my brain develop.

5- The Right to be Nourished
Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Also, let my parents know that donor milk may be an option for me.

6- The Right to Personhood
Address me by my name when possible, communicate with me before touching me, and if I or one of my siblings pass away while in the NICU, continue referring to us as multiples (twin/triplets/quads, and more). It is important to acknowledge our lives.

7- The Right to Confident and Competent Care Giving
The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help educate them about my unique needs, development, diagnoses, and more.

8- The Right to Family-Centered Care
Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9- The Right to Healthy and Supported Parents
My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my parents about resources such as peer-to-peer support programs, support groups, and counseling, which can help reduce PMAD, PPD, PTSD, anxiety and depression, and more.

10- The Right to Inclusion and Belonging
Celebrate my family's diversity and mine; including our religion, race, and culture. Ensure that my parents, grandparents, and siblings feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

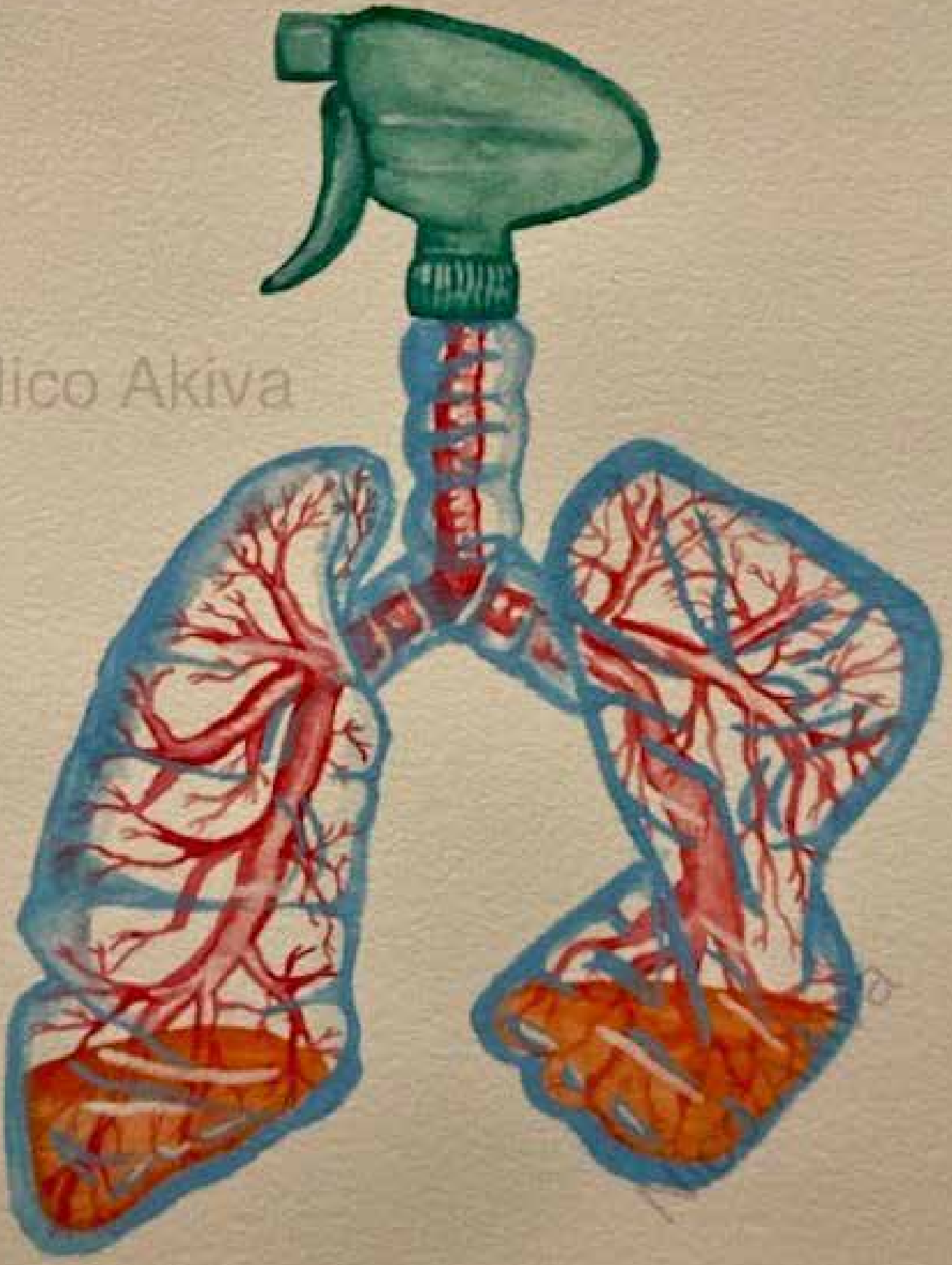
Presented by:

NICU Parent Network

NPN NICU PARENT NETWORK

Visit nicuparentnetwork.org to identify national, state, and local NICU family support programs.

*** The information provided on the NICU Baby's Bill of Rights does not, and is not intended to, constitute legal or medical advice. Always consult with your NICU care team for all matters concerning the care of your baby.**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