NEONATOLOGY TODAY

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

NT

Volume 18 / Issue 4 April 2023

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
11175 Campus Street, Suite #11121
Loma Linda, CA 92354
Tel: +1 (302) 313-9984
LomaLindaPublishingCompany@gmail.com

Sheraton Sand Key Resort in
Clearwater Beach, FL

The Gravens Conference

March 6-9, 2024

2024 THEME:
THE POWER OF VOICE:
USING YOUR VOICE FOR BABIES, FAMILY, STAFF AND BEYOND.

Connect & Learn

https://www.neonatologytoday.net/

LOMA LINDA

LLPC

PUBLISHING COMPANY

EST 2018

Peer Reviewed

Associations of an Exclusive Human Milk Diet with Morbidity and Mortality in ELBW Infants Born ≤750 Grams: an Individual Participant Data Meta-Analysis

Sarah M. Reyes, PhD, Jamie R. Strott-Moore, NNP-BBC, MSN, Sarah L. Brooker, PhD, Martin L. Lee, PhD, Jenelle Ferry, MD, Robert K. Huston, MD, Melinda J. Elliott, MD

Abstract

Background: Survival without major comorbidities remains low among extremely low birthweight (ELBW) infants. An exclusive human milk diet (EHMD) has shown clinical benefits among infants born weighing ≤1,250 g.

Methods: Our objective was to determine the associations between an exclusive human milk diet (EHMD) or a diet containing cow milk-based products (CMBD) and common morbidities and mortality among infants born weighing ≤750 g. We conducted a systematic review with individual participant data meta-analysis. After a PubMed search (Jan 2000 to Feb 2022), authors from eligible RCT and observational studies were invited to contribute their data. EHMD was compared to a CMBD, including formula (CMBD+f). Sensitivity analyses compared an EHMD and a base diet of human milk fortified with cow milk-based fortifiers (CMBD-f). Adjusted odds ratios (aOR) reported are from complete cases.

Results: Six studies were included, totaling 879 infants born between 2007-2015 and weighing ≤750 g. Infants fed an EHMD (n=449) had reduced odds of developing necrotizing enterocolitis (NEC), surgical NEC, and bronchopulmonary dysplasia (BPD) compared to those fed a CMBD+f (n=430). Similar reductions were observed when an EHMD was compared with CMBD-f (n=78). Additionally, an EHMD was associated with 50% lower odds of scoring affirmatively on a mortality and morbidity index (MMI) compared to CMBD+f.

Conclusions: In this study, infants born ≤750 g have reduced odds of developing several major comorbidities than those fed cows milk-based nutritional products, even with a base diet of human milk.

Registry Number: PROSPERO, identifier: CRD42022319031

Keywords: extremely low birth weight infant; human milk; infant, premature*; bronchopulmonary dysplasia; retinopathy of prematurity; necrotizing enterocolitis; exclusive human milk diet; sepsis; meta-analysis

KEY POINTS

Question: Does an exclusive human milk diet (EHMD) provide more benefit than diets containing cow milk products for infants born weighing ≤750 g?

Findings: Among six included studies, infants born between 2007-2015 and weighing ≤750 g (*n*=879) had reduced odds of developing several major comorbidities than those fed cow milk-based nutritional products even with a base diet of human milk. Results were strongest for death, NEC, and BPD.

Meaning: Avoiding cow milk-based fortifiers may be important in reducing mortality and major comorbidities, such as NEC and BPD, in infants weighing ≤750 g.

Introduction

Advances in medical interventions have lowered the viability age to include extremely low birthweight (ELBW) infants born as early as 22 weeks gestational age and ≤500 g. (1-3) Even so, survival without major comorbidities among these infants remains low. (4, 5) Many ELBW infants require longer hospital stays and high-cost health care interventions during early life and long term compared to infants born at higher birthweights. (6-10) Moreover, children born ELBW are more likely to suffer from parent-reported inattention, hyperactivity, and autistic symptoms and require additional resources such as special education. (11, 12) This creates a financial and emotional burden for families, hospitals, and society. Interventions to reduce major comorbidities are needed to improve the long-term quality of life for surviving ELBW infants.

"Total parenteral nutrition (TPN) is started soon after birth to ensure sufficient nutrient intake. However, long-term exposure to TPN without enteral feeding can delay the maturation of the GI tract and can lead to liver dysfunction. (14)"

One of the main challenges in caring for ELBW infants is providing optimal nutrition. ELBW infants rely on the less efficient premature infant gastrointestinal tract instead of the placenta for nutrient transfer. (13) Total parenteral nutrition (TPN) is started soon after birth to ensure sufficient nutrient intake. However, long-term exposure to TPN without enteral feeding can delay the maturation of the GI tract and can lead to liver dysfunction. (14) Thus, achieving full enteral feeds promptly and safely is a primary goal of the healthcare team. (15)

ELBW newborns also require additional nutrients beyond what human milk, the preferred source of nutrition, can provide. (13, 16, 17) Fortifiers are added to the mother's own milk (MOM) or donor human milk (DHM) To provide these required nutrients. (16, 17) These fortifiers have traditionally been made from cow milk. Cow milk-based fortifiers, however, are not always well tolerated and have been associated with NEC, one of the primary causes of death among ELBW infants. (1, 2, 18) Thus, attaining full enteral feeding is a delicate balance between the risk of liver dysfunction and NEC or other morbidities.

Avoiding cow milk-based products using human milk-based versions allows exclusive human milk feeding, which is recommended for all infants with few exceptions. (16) An exclusive human milk

diet [(EHMD), MOM or DHM with added human milk-based human milk fortification] has shown promising results in clinical trials to reduce health complications of prematurity in infants weighing ≤1,250 g compared to diets containing cow milk products, including reduced incidences of NEC and feeding intolerance. (18-23) Given that infants weighing ≤750 g have a higher mortality and morbidity incidence than those born larger and more mature,(24) we hypothesized that the benefits of an EHMD were extended to these smallest ELBW infants, born weighing ≤750 g.

"Given that infants weighing ≤750 g have a higher mortality and morbidity incidence than those born larger and more mature,(24) we hypothesized that the benefits of an EHMD were extended to these smallest ELBW infants, born weighing ≤750 g."

To test our hypothesis, we conducted an individual participant data meta-analysis from existing EHMD clinical trials involving premature infants of any weight category, analyzing only data from those born weighing ≤750 g. We aimed to determine the associations between an EHMD or a diet containing cow milk-based products and common morbidities and mortality among infants weighing ≤750 g. Additional sensitivity analyses compared an EHMD with infants with a diet of MOM and/or DHM with cow milk-based fortifiers and excluded preterm infant formula.

Methods

All studies received hospital-specific ethical reviews that adhered to the Declaration of Helsinki (25), and parents or legal guardians provided written informed consent for all patients before enrollment. For this individual participant data (IPD) meta-analysis, we followed reporting guidelines established by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) for IPD. (26) This systematic review and IPD meta-analysis were prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) under ID: CRD42022319031.

Search Strategy and Study Selection:

Search strategy:

We identified 34 EHMD studies using existing internal databases. We also performed a PubMed search to ensure that a comprehensive list of EHMD studies was captured (**Supplemental Table 1**). The search strategy included a combination of controlled vocabulary and keywords to create search concepts for HM, premature infants, clinical outcomes, and study designs of interest. Records were limited to articles published in 2000 or later as human milk-based human milk fortifiers were not commercially available before this time. For practical reasons, only articles published in English were included. Search results were transferred to Covidence (Veritas Health Innovation, Melbourne, Australia) and screened in duplicate by SMR and JRSM for relevance and eligibility. Conflicts were resolved through consensus.

Inclusion criteria:

All randomized, controlled trials and observational cohort studies with any design (e.g., prospective, retrospective, cross-sectional, or case-control) were eligible for inclusion. All cohorts were required to include infants weighing ≤1,500 g; compare an EHMD intervention diet to cow milk-based diets including cow milk-based fortifier with a base diet of human milk and/or preterm infant formula; and assess clinical outcomes of interest: mortality, bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), necrotizing enterocolitis (NEC), surgical NEC, mortality and morbidity index (MMI), and sepsis, as defined by the study authors. Unpublished data from relevant RCTs and observational cohorts were also eligible for inclusion. Authors from eligible studies provided and consented to use their individual participant data.

"All cohorts were required to include infants weighing ≤1,500 g; compare an EHMD intervention diet to cow milk-based diets including cow milk-based fortifier with a base diet of human milk and/or preterm infant formula; and assess clinical outcomes of interest: mortality, bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), necrotizing enterocolitis (NEC), surgical NEC, mortality and morbidity index (MMI), and sepsis, as defined by the study authors. "

Non-human and preclinical studies were excluded, as were all other published articles (e.g., commentaries, reviews, and case studies). Also excluded were linked studies which would have resulted in duplicate entries per infant. For example, we did not include secondary analyses of trials already included. Finally, studies were excluded if they did not include infants born weighing ≤750 g or if data were not available after contact with study authors.

IPD Integrity, Outcome Measures, and Data Harmonization

Data were assessed for consistency with previously published articles of the included studies, with any discrepancies resolved by communication with the respective study investigators. The primary outcomes of interest were mortality, BPD, ROP, NEC, NEC requiring surgery (surgical NEC), sepsis, and MMI. MMI was examined because individual morbidities with low prevalence limit the power to declare group differences statistically significant and because it has been used in at least one relevant study. (27) Additionally, neonatal morbidities often occur simultaneously. Thus using an MMI allows for a more comprehensive evaluation of nutritional interventions. (28, 29)

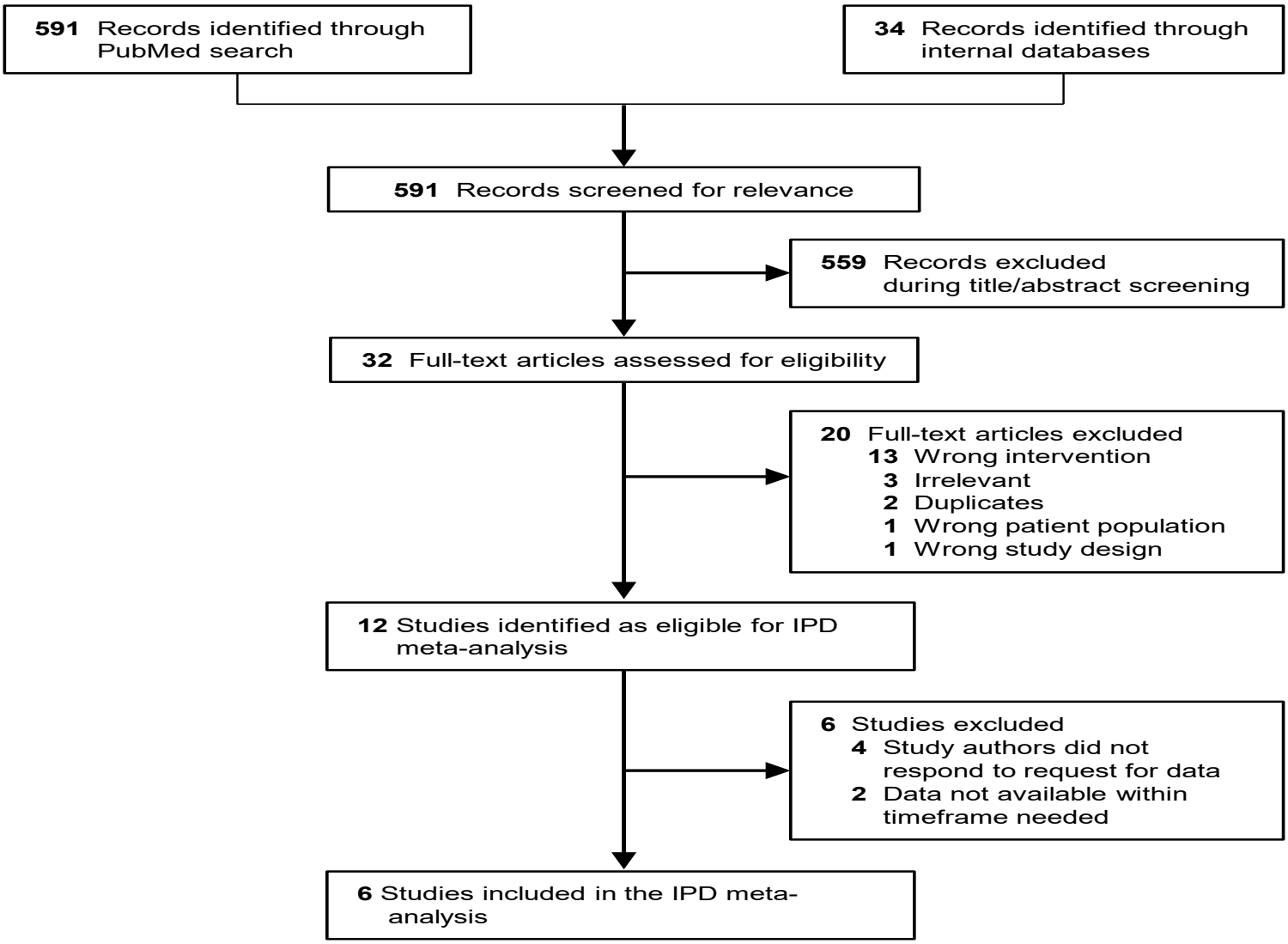


Figure 1. Flow diagram of studies included in the IPD meta-analysis. IPD, individual participant data.

"Outcome variables were re-coded as indicator variables to harmonize results. The definitions of ROP varied, with some studies defining ROP at any stage and some capturing all stages of ROP while others still only documented severe ROP (stage ≥3)."

Outcome variables were re-coded as indicator variables to harmonize results. The definitions of ROP varied, with some studies defining ROP at any stage and some capturing all stages of ROP while others still only documented severe ROP (stage ≥3). Primary analyses included all definitions of ROP (all ROP). Sensitivity analyses were conducted on the subset of cohorts for which severe ROP was reported. Similarly, the definitions of sepsis varied, with one study reporting only late-onset sepsis(30) and the rest reporting all episodes of sepsis. Although individual datasets classified NEC as "any NEC" or "medical NEC," the definitions of each of these variables were the same (Bell Stage ≥2) and were collapsed into one variable, defined as "NEC." NEC requiring surgery was a separate variable, defined as surgical NEC. No studies of interest reported an MMI, and one was calculated for this study, given the available information. Therefore, MMI was a binary outcome defined as an affirmative response for any of the following outcomes: death, severe ROP, sepsis, NEC, or BPD.

Neonatal data captured across studies included gestational age, birth weight, and infant sex. Additional data in a subset of studies included a 5-minute APGAR score, antenatal steroid use, and maternal race and ethnicity. Due to varied reporting practices, maternal race and ethnicity were harmonized using the latest recommendations from the *AMA Manual of Style* Committee(31) into White, Black, and Other.

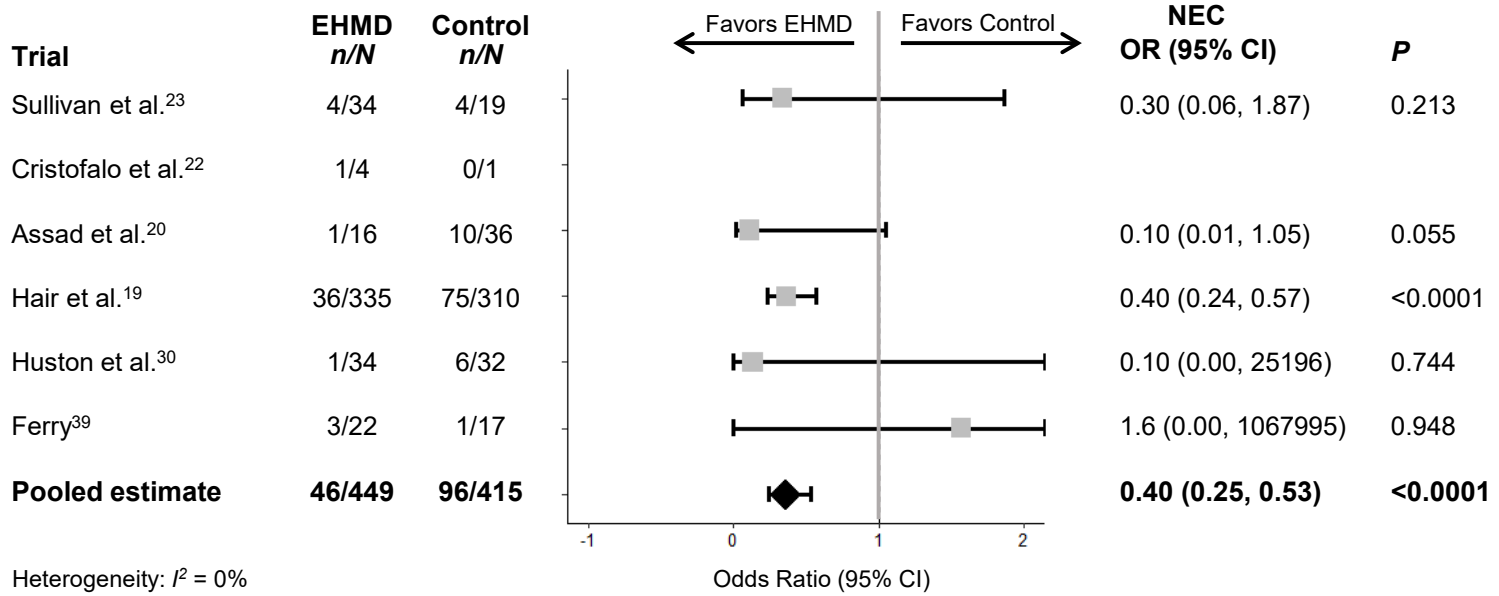


Figure 2. Associations of an EHMD with NEC among infants born ≤ 750 g (N = 860). Forest plots were generated using logistic mixed effects models—CI, confidence interval; EHMD, exclusive human milk diet; NEC, necrotizing enterocolitis.

"Included published studies were assessed for quality using a modified Newcastle-Ottawa scale (32) with a maximum possible score of 9."

Quality Assessment

Included published studies were assessed for quality using a modified Newcastle-Ottawa scale (32) with a maximum possible score of 9. We designated 4 points for *diet exposure assessment*, including diet fed (e.g., MOM, DHM, formula) (1 point), fortification start (e.g., day of life) (1 point), fortification end (1 point), and days to full enteral feeds (1 point); 2 points for *consideration of confounders and potential effect modifiers* including protocol for holding feeds and/or withdrawals (1 point) and control for participant characteristics (e.g., gestational age, sex, race, congenital abnormalities, APGAR score, antenatal steroids, etc.) (1 point); and 3 points for *outcome assessment*, including assessment of the outcome (e.g., diagnosed by trained staff, collection from records) (1 point), the same method of ascertainment in all groups (1 point), and whether follow-ups were long enough for the outcome to occur (1 point). Articles scored >7 were considered high quality; 4-7 moderate quality; <4 low quality. Each article was assessed for quality in duplicate by SMR and JRSM. Conflicts were resolved through consensus.

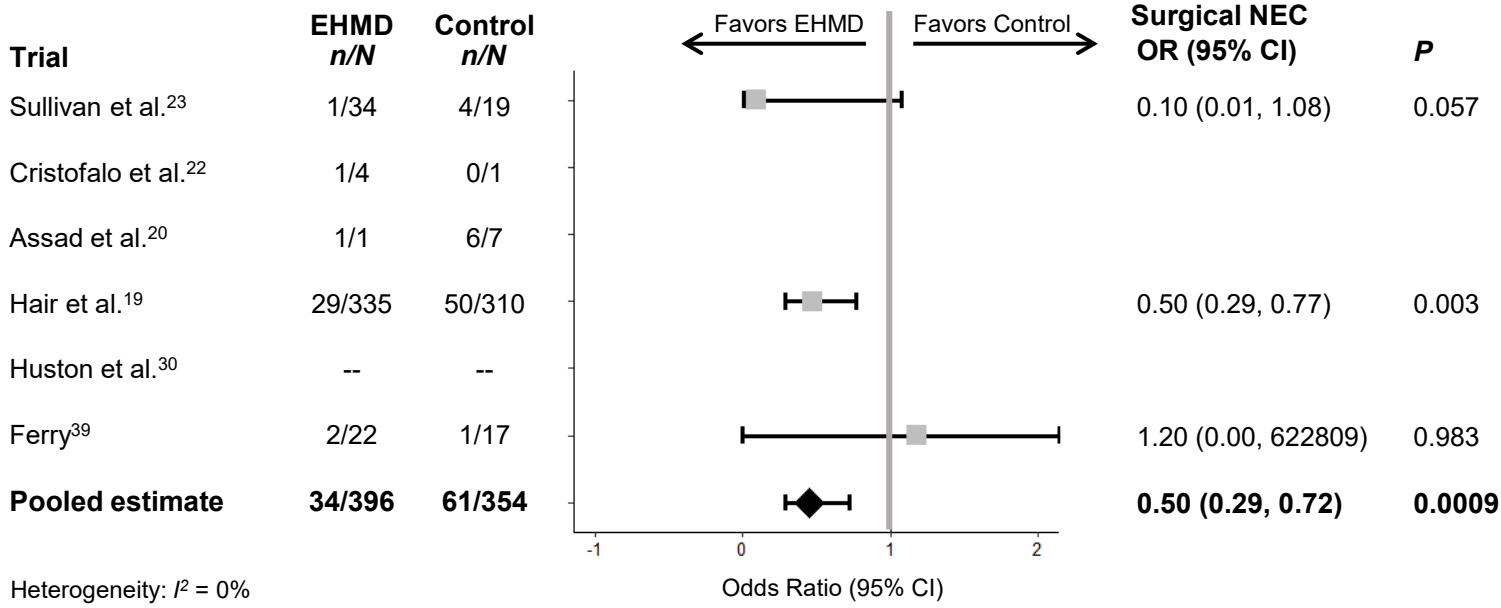
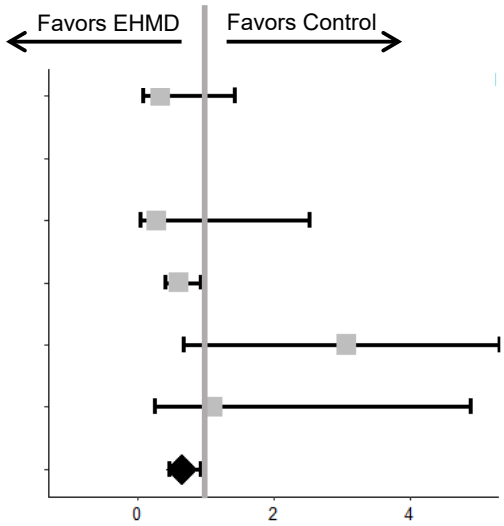


Figure 3. Associations of an EHMD with surgical NEC among infants born ≤ 750 g (N = 860). Forest plots were generated using logistic mixed effects models—CI, confidence interval; EHMD, exclusive human milk diet; NEC, necrotizing enterocolitis.

Trial	EHMD *n/N*	Control *n/N*	BPD OR (95% CI)	*P*
Sullivan et al.[23]	19/34	15/19	0.30 (0.08, 1.42)	0.137
Cristofalo et al.[22]	0/4	1/1		
Assad et al.[20]	8/16	21/36	0.30 (0.03, 2.52)	0.258
Hair et al.[19]	202/279	203/256	0.60 (0.40, 0.92)	0.018
Huston et al.[30]	26/32	16/28	3.10 (0.66, 14.14)	0.152
Ferry[39]	7/22	5/17	1.10 (0.25, 4.88)	0.898
Pooled estimate	**262/387**	**261/357**	**0.60 (0.46, 0.92)**	**0.015**



Heterogeneity: I^2 = 50%

Figure 4. Associations of an EHMD with BPD among infants born ≤ 750 g (N = 860). Forest plots were generated using logistic mixed effects models. BPD, bronchopulmonary dysplasia; CI, confidence interval; EHMD, exclusive human milk diet.

"Unpublished studies were evaluated using the Accuracy, Authority, Coverage, Objectivity, Date, Significance (AACODS) tool. (33) Each domain was assessed using and recorded with "Yes," "No," or "N/A" as applicable. Recording of 4 or more "Yes" responses were considered high quality."

U*npublished* studies were evaluated using the Accuracy, Authority, Coverage, Objectivity, Date, Significance (AACODS) tool. (33) Each domain was assessed using and recorded with "Yes," "No," or "N/A" as applicable. Recording of 4 or more "Yes" responses were considered high quality. The recording of 3 or more "Yes" responses was considered moderate quality, and two or fewer "Yes" responses were considered low quality.

Statistical Analyses

All analyses were conducted following a complete-case, intention-to-treat framework between July 20 and September 29, 2022. (34) We used a two-stage approach. First, we harmonized all outcome variables to be binary, then calculated within-study estimates using logistic mixed effects models with gestational age and birthweight

Trial	EHMD *n/N*	Control *n/N*	MMI OR (95% CI)	*P*
Sullivan et al.[23]	30/34	19/19		
Cristofalo et al.[22]	1/4	1/1		
Assad et al.[20]	11/16	28/36	0.30 (0.05, 2.45)	0.283
Hair et al.[19]	282/339	296/325	0.40 (0.25, 0.69)	0.0007
Huston et al.[30]	29/34	24/32	1.00 (0.00, 769)	0.999
Ferry[39]	17/22	11/17	1.30 (0.27, 6.69)	0.728
Pooled estimate	**370/449**	**379/430**	**0.50 (0.33, 0.75)**	**0.001**

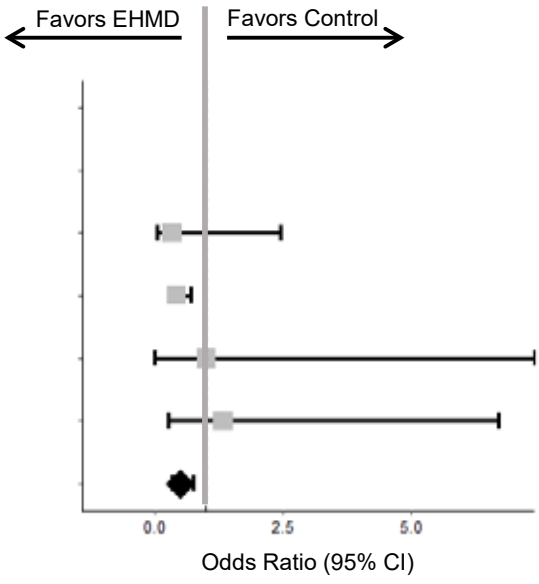


Figure 5. Associations of an EHMD with MMI among infants born ≤ 750 g (N = 860). Forest plots were generated using logistic mixed effects models—CI, confidence interval; EHMD, exclusive human milk diet; MMI, mortality, and morbidity index.

Table 1. Summary of studies included in the individual participant data meta-analysis and percentage of infants born ≤750 g

Publication	Location	Study Design	Participants Birth Year	Initial eligibility criteria	EHMD Fortification	Control Diet	Infants born ≤750 g No. / total No. (%)			Quality Score[a]
							EHMD	Control	Total	
Sullivan et al., 2009[23,b]	US, Austria	Multicenter RCT	2007-2008	BW 500 to 1250 g PN <48 h after birth EN <21 d after birth	Prolact+ $H_2MF^{®}$ @ 40 mL/kg/d or 100 mL/kg/d*	MOM + cow milk-based fortifier @ 100 mL/kg/d or preterm infant formula[c]	34/138 (24.6)	19/69 (27.5)	53/207 (25.6)	7
Cristofalo et al., 2013[22,b]	US, Austria	Multicenter RCT	2007-2008	BW 500 to 1250 g PN <48 h after birth EN <21 d after birth	Prolact+ $H_2MF^{®}$ @ 40 mL/kg/d or 100 mL/kg/d*[3]	Preterm infant formula[d]	4/29 (13.8)	1/24 (4.2)	5/53 (9.4)	6.5
Assad et al., 2015[20]	US	Single center retrospective cohort study	2009-2012 (Controls) 2012-2014 (Intervention)	GA ≤28 wk or BW ≤1500 g	Prolact+ $H_2MF^{®}$ @ 120-150 mL/kg/d	MOM + cow milk-based fortifier and/or preterm infant formula[c]	16/87 (18.4)	36/206 (7.8)	52/293 (17.7)	8
Hair et al., 2016[19]	US	Multicenter retrospective cohort study	2006-2008 (Control) 2009-2012 (Intervention)	BW <1250 g	Prolact+ $H_2MF^{®}$ @ 60 mL/kg/d or 100-120 mL/kg/d*	MOM+ cow milk-based fortifier and/or preterm infant formula[c]	339/819 (41.4)	325/768 (42.3)	664/1587 (41.8)	7
Huston et al., 2018[30]	US	Single center retrospective cohort study	2007-2015	BW 500 to 1250 g	Prolact+ $H_2MF^{®}$ @ 40-50 mL/kg/d	MOM+ cow milk-based fortifier and/or preterm infant formula[c]	34/127 (26.8)	32/252 (12.7)	66/379 (17.4)	7
Ferry et al., (unpublished)[39]	US	Single center retrospective cohort study	2012-2014	BW 440 to 2722 g	Prolact+ $H_2MF^{®}$ @ 40-80 mL/kg/d	MOM + cow milk-based fortifier @ 80-100 mL/kg/d[c]	22/138 (15.9)	17/113 (15)	39/251 (15.5)	--

*Pasteurized donor human milk–based HMF (Prolact+ H2MF®; Prolacta Bioscience)
[a]Study quality was assessed using a modified Newcastle-Ottawa Scale [32], maximum score of 9. See Supplemental Table 2 for detailed quality assessment results.
[b]Trial registered with ClinicalTrials.gov under study ID: NCT00506584. Note Sullivan et al., 2009 [23] and Cristofalo et al., 2013 [22] used the same protocol defined in this trial registry, but were separate studies.
[c]Infants in the control group received MOM + cow milk-based fortifier preferentially over preterm infant formula
[d]Study included only infants whose mothers did not intend on providing their own milk. Consequently, in this study, EHMD consisted of vat pasteurized donor human milk (20 kcal/oz Neo20; Prolacta Bioscience) and vat pasteurized donor human milk-based human milk fortifier (Prolact+ H^2MF; Prolacta Bioscience)
BW, birthweight; EHMD, exclusive human milk diet; GA, gestational age

Table 2. Participant characteristics at baseline according to infant diet (N=879)[a]

Factor	All participants (N=879)	Intervention	Controls		*P* value	
		EHMD (n=449)	(All controls) CMBD+f (n=430)	(No formula controls) CMBD-f (n=78)	EHMD vs. CMBD+f	EHMD vs. CMBD-f
Gestational age, wk	24.6 (3.2)*	24.4 (1.4)*	25.0 (2)*	25.0 (2.3)*	**0.019**	0.066
Birthweight (g)	650 (180)*	660 (115)*	645.0 (130)*	646.5 (101)*	0.055	0.594
Female sex	459 (52.2)*	238 (53.0)*	221 (51.4)*	38 (48.7)*	0.681	0.564
Antenatal steroids[b]	563 (64.1)	299 (66.6)	264 (61.4)	34 (43.6)	0.248	**0.007**
Race[c]					0.645	**<0.001**
Black	316 (35.9)	153 (34.1)	163 (37.9)	4 (5.1)		
White	249 (28.3)	133 (29.6)	116 (27.0)	2 (2.6)		
Other	198 (22.5)	102 (22.7)	96 (22.3)	27 (34.6)		

[a]Values are median (IQR)* for non-normally distributed continuous variables or n (%) for categorical variables. Student's *t* test and chi-squared tests were used to compare continuous and categorical variables, respectively. All tests were run with R (v. 4.1.3) package finalfit (v. 1.0.4).[37,38]
[b]Data available for 3 cohorts,[19,22,23] N=701
[c]Data available for 4 cohorts,[19,20,22,23] N=763
CMBD+f, cow milk-based diet including cow milk-based fortifier with base diet of human milk and/or preterm infant formula; CMBD-f, cow milk-based diet including cow milk-based fortifier with base diet of human milk, excluding preterm infant formula; EHMD, exclusive human milk diet.

as fixed effects and participant as the random effect. Second, pooled estimates were also calculated using logistic mixed effects models adjusted for gestational age and birthweight (fixed effects). Pooled models used the study as the random effect. These models were used to test the association between an EHMD and morbidity and mortality outcomes compared to CMBD+f. Sensitivity analyses evaluated these associations, comparing an EHMD and no formula controls (CMBD-f). We conducted analyses in R (v. 4.1.3). (35-38) Results were considered statistically significant at $p<0.05$. Study heterogeneity was measured using the I^2 statistic. We assessed publication bias using funnel plots with the trim and fill method.

Results

Description of Included Studies

In total, 591 unique records were identified and screened. Of these, 559 were excluded during the title and abstract screening, with 32 full-text articles screened for eligibility (**Figure 1**). After excluding 20 studies that did not meet eligibility criteria, 12 were identified as eligible for IPD meta-analysis, and authors were invited to contribute their data. Six of these 12 studies were excluded due to no response from authors (n=4) or the data being unavailable within the timeframe needed (n=2).

Overall, data from six unique studies were analyzed, totaling 879 infants born weighing ≤750 g between 2007-2015. (19, 20, 22, 23, 30, 39) Of these, 449 infants received an EHMD; 430 received a cow milk-based diet, including cow milk-based fortifier with a base diet of human milk and/or preterm infant formula (CMBD+f). Due to varied reporting practices related to formula feeding in some cohorts, medical records were reviewed as needed. A curated list was created, including only infants who, from their medical records, were confirmed not to have received any preterm infant formula. Consequently, of the 430 CMBD+f infants, only 78 were confirmed to have received a cow milk-based diet including cow milk-based fortifier with a base diet of human milk excluding preterm infant formula (CMBD-f).

Cohort-level characteristics

All included studies were based in the US, with two studies having a study center in Austria (**Table 1**). Included studies were a mix of multicenter RCTs and single or multicenter retrospective cohorts.

Each included study had an EHMD intervention group. In all studies, the EHMD intervention consisted of a base diet of human milk with added vat pasteurized human milk-based human milk fortifiers (Prolact+ H2MF; Prolacta Bioscience). For the base diet of human milk, MOM was almost always preferentially used over DHM. The only exception was Cristofalo et al., 2013 (22) because they only included infants whose mothers did not provide their own milk. Thus, in this study, all infants received vat pasteurized donor human milk (20 kcal/oz Prolacta Bioscience). (22)

Fortification initiation and advancement in the EHMD interventions varied greatly within and across studies (**Table 1**). The earliest initiation of fortification was 40 mL/kg/d. Additionally, weaning from the EHMD varied, with some studies transitioning to a diet including cow milk at 32 weeks and others at 34 weeks.

Most published studies were rated as moderate (4-7 score on the modified Newcastle-Ottawa scale; maximum 9 points), with only 1 study being rated as high quality (>7) and no studies rated as low quality (<4) (**Table 1; Supplementary Figure 1**).

The only *unpublished* study included was rated as high quality. Four of the 5 AACODS criteria were recorded as "Yes," with the criteria for "Coverage" being deemed "Not Applicable" (**Supplementary Table 2**).

Participant characteristics

Among the included studies, infants born ≤750 g represented between 9.4% and 42.3% of the total infants enrolled in original study cohorts (**Table 1**). Overall, these ≤750 g infants were born at a median (IQR) of 24.6 (3.2) weeks gestational age with a birthweight of 650 (180) g (**Table 2**). About 52% of infants were female, ~64% were exposed to antenatal steroids, and nearly 36% were Black. These characteristics were similar across intervention and control groups, except that compared to all controls (CMBD+f), infants in the EHMD group were born slightly younger [gestational age at a birth median (IQR): 24.4 (1.4) vs. 25.0 (2.0), EHMD vs. CMBD+f, respectively; p=0.019, **Table 2**]. Additionally, compared to no formula controls (CMBD-f), more infants in the EHMD group were exposed to antenatal steroids, and a lower percentage was reported to be a race other than Black or White (p≤0.007 for both, **Table 2**).

Associations of an EHMD with Infant Morbidity and Mortality

Mortality

Five studies reported infant mortality. Although adjusted OR in all five studies indicated that an EHMD lowered the odds of death, none of these associations were statistically significant in primary analyses (**Table 3**). Similarly, the pooled estimate indicated a 20.6% reduction in odds of death (aOR: 0.79, 95% CI, 0.56, 1.13, p=0.20; I^2 22%; 838 participants). Although not statistically significant, these results are clinically meaningful.

In subgroup analyses, however, an EHMD was associated with a statistically significant reduction in the odds of death compared to CMBD-f (aOR: 0.39, 95% CI, 0.15, 0.997; p=0.049).

NEC and Surgical NEC

NEC was reported in all 6 included studies. In these cohorts, the incidence of NEC ranged from 10-21% and averaged 17% in pooled data (**Table 3**). The average incidence of NEC in infants fed an EHMD was 10% compared to 23% in those fed cows milk-based nutritional products (CMBD+f). This reduction attributed to an EHMD equated to a 60% decrease in the odds of developing NEC in pooled analyses (aOR: 0.40, 95% CI, 0.25, 0.53; p<0.0001; I^2 0%; 860 participants, **Figure 2, Table 3**). Subgroup analysis showed a similar significant reduction in an EHMD compared to CMBD-f (527 participants, **Table 4**).

NEC requiring surgery (surgical NEC) was reported in 5 studies. In pooled analyses, an EHMD was associated with a 54% decrease in the odds of developing surgical NEC compared to CMBD+f (aOR: 0.50, 95% CI 0.29, 0.73; p=0.0009; I^2 0%; 750 participants, **Figure 3, Table 3**). Subgroup analysis showed a 61% reduction in surgical NEC attributed to an EHMD compared to CMBD-f, though likely due to the small sample size in the control group, this was not statistically significant (aOR: 0.39, 95% CI 0.13, 1.16; p=0.09, 446 participants, **Table 4**).

Table 3. Associations between an EHMD and clinical outcomes among all infants born ≤750 g (N=879)[a]

		Intervention	All Controls	EHMD vs. All controls (CMBD+f)	
Outcomes	All Participants	EHMD n/N (%)	CMBD+f n/N (%)	Adjusted Odds Ratio (95% CI)	*P* value
Mortality					
Sullivan et al.[23]	5/53 (9.4)	2/34 (6)	3/19 (16)	0.30 (0.04, 2.30)	0.242
Cristofalo et al.[22]	0/5 (0)	0/4 (0)	0/1 (0)	--[b]	--[b]
Assad et al.[20]	5/52 (9.6)	1/16 (6)	4/36 (11)	0.62 (0.06, 6.48)	0.691
Hair et al.[29]	150/664 (22.6)	73/339 (22)	77/323 (24)	0.91 (0.63, 0.91)	0.634
Huston et al.[30]	7/66 (23)	1/34 (3)	6/32 (19)	0.09 (0, 16430)	0.697
Ferry et al.[39]	--[c]	--[c]	--[c]	--[c]	
Pooled estimate	167/838 (20)	77/427 (18)	90/411 (22)	0.79 (0.56, 1.13)	0.195
NEC					
Sullivan et al.[23]	8/53 (15)	4/34 (12)	4/19 (21)	0.30 (0.06, 1.87)	0.213
Cristofalo et al.[22]	1/5 (20)	1/4 (75)	0/1 (0)	--[b]	--[b]
Assad et al.[20]	11/52 (21)	1/16 (6.3)	10/36 (2.8)	0.10 (0.01, 1.05)	0.055
Hair et al.[29]	111/645 (17)	36/335(11)	75/310(23)	0.40 (0.24, 0.57)	<0.0001
Huston et al.[30]	7/66 (11)	1/34 (2.9)	6/32 (19)	0.10 (0, 25206)	0.744
Ferry et al.[39]	4/39 (10)	3/22 (14)	1/17 (5.9)	1.60 (0, 1067995)	0.948
Pooled estimate	**142/860 (17)**	**46/449 445 (10)**	**96/415 (23)**	**0.40 (0.25, 0.53)**	**<0.0001**
Surgical NEC					
Sullivan et al.[23]	5/53 (9)	1/34 (2.9)	4/19 (21)	0.10 (0.01, 1.08)	0.057
Cristofalo et al.[22]	1/5 (20)	1/4 (25)	0/1 (0)	--[b]	--[b]
Assad et al.[20]	7/8 (88)	1/1 (100)	6/7 (86)	--[b]	--[b]
Hair et al.[29]	79/645 (12)	29/335 (8.7)	50/310 (16)	0.50 (0.29, 0.77)	0.003
Huston et al.[30]	--[c]	--[c]	--[c]	--[c]	--[c]
Ferry et al.[39]	3/39 (8)	2/22 (9.1)	1/17 (5.9)	1.20 (0, 6228088)	0.983

Pooled estimate	**95/750 (13)**	**34/396 (9)**	**61/354 (17)**	**0.50 (0.29, 0.72)**	**0.0009**
BPD					
Sullivan et al.[23]	34/53 (64)	19/34 (56)	15/19 (26)	0.30 (0.08, 1.42)	0.137
Cristofalo et al.[22]	1/5 (20)	0/4 (0)	1/1 (100)	--[b]	--[b]
Assad et al.[20]	29/52 (56)	8/16 (50)	21/36 (58)	0.30 (0.03, 2.52)	0.258
Hair et al.[29]	405/535 (76)	202/279 (73)	203/256 (79)	0.60 (0.40, 0.92)	0.018
Huston et al.[30]	42/60 (70)	26/32 (81)	16/28 (57)	3.10 (0.662 14.14)	0.152
Ferry et al.[39]	12/39 (31)	7/22 (32)	5/17 (29)	1.10 (0.25, 4.88)	0.898
Pooled estimate	**523/744 (70)**	**262/387 (68)**	**261/357 (73)**	**0.60 (0.46, 0.92)**	**0.015**
All ROP					
Sullivan et al.[23]	35/53 (66)	22/34 (65)	13/19 (68)	0.69 (0.19, 2.48)	0.574
Cristofalo et al.[22]	3/4 (75)	2/4 (50)	1/1 (100)	--[b]	--[b]
Assad et al.[20]	27/52 (52)	5/16 (31)	22/36 (61)	0.23 (0.05, 1.05)	0.574
Hair et al.[29]	80/635 (13)	34/329 (10)	46/306 (14)	0.61 (0.60, 0.61)	<0.0001
Huston et al.[30]	41/60 (68)	25/32 (74)	16/28 (50)	2.41 (0.63, 9.30)	0.200
Ferry et al.[39]	20/39 (51)	13/22 (59)	7/17 (41)	1.89 (0.45, 7.92)	0.386
Pooled estimate	206/844 (24)	101/437 (23)	105/407 (26)	0.69 (0.47, 0.70)	0.055
Severe ROP					
Sullivan et al.[23]	10/53 (19)	7/34 (21)	3/19 (16)	0.90 (0.01, 3687)	0.981
Cristofalo et al.[22]	0/5 (0)	0/4 (0)	0/1 (0)	--[b]	--[b]
Assad et al.[20]	--[c]	--[c]	--[c]	--[c]	
Hair et al.[29]	80/635 (13)	34/329 (10)	46/306 (15)	0.61 (0.60, 0.61)	<0.0001
Huston et al.[30]	3/63 (4.8)	2/32 (6.3)	1/31 (3.1)	1.76 (1.75, 1.78)	<0.0001
Ferry et al.[39]	18/39 (46)	12/22 (55)	6/17 (35)	2.15 (0.50, 9.20)	0.301
Pooled estimate	111/684 (16)	55/421 (13)	56/374 (15)	0.71 (0.46, 1.09)	0.120
Sepsis					
Sullivan et al.[23]	21/53 (40)	15/34 (44)	6/19 (32)	1.66 (0.43, 6.38)	0.458

Cristofalo et al.[22]	1/5 (20)	1/4 (25)	0/1 (0)	--[b]	--[b]
Assad et al.[20]	22/52 (42)	7/16 (43)	15/36 (42)	0.90 (0.26, 3.14)	0.862
Hair et al.[29]	138/664 (21)	69/339 (20)	69/325 (21)	0.96 (0.65, 1.41)	0.822
Huston et al.[30]	10/66 (15)	7/34 (21)	3/32 (9.3)	2.52 (0.56, 11.2)	0.227
Ferry et al.[39]	10/39 (26)	2/22 (9.1)	8/17 (47)	0.05 (0.01, 0.44)	0.007
Pooled estimate	202/879 (23)	101/449 (22)	101/430 (23)	0.94 (0.68, 1.30)	0.694
MMI					
Sullivan et al.[23]	49/53 (92)	30/34 (88)	19/19 (100)	--[b]	--[b]
Cristofalo et al.[22]	2/5 (40)	1/4 (25)	1/1 (100)	--[b]	--[b]
Assad et al.[20]	39/52 (75)	11/16 (69)	28/36 (78)	0.30 (0.05, 2.45)	0.283
Hair et al.[29]	578/664 (87)	282/339 (83)	296/325 (91)	0.40 (0.25, 0.69)	0.0007
Huston et al.[30]	53/66 (80)	29/34 (85)	24/32 (75)	1.00 (0.00, 769.22)	0.999
Ferry et al.[39]	28/39 (72)	17/22 (77)	11/17 (65)	1.30 (0.27, 6.69)	0.728
Pooled estimate	**749/879 (85)**	**370/449 (82)**	**379/430 (88)**	**0.50 (0.33, 0.75)**	**0.001**

[a]Values are means ± SD for continuous variables or n (%) for categorical variables. CMBD+f, cow milk-based diet including cow milk-based fortifier with base diet of human milk and/or preterm infant formula; EHMD, exclusive human milk diet. Within-study estimates were calculated using logistic mixed effects models with gestational age and birthweight as fixed effects and participant as the random effect. Pooled estimates were also calculated using logistic mixed effects models adjusted for gestational age and birthweight (fixed effects), and study as the random effect. All tests were run with R (v4.1.3) package lme4 (v1.1-30) and emmeans (v.1.8.1-1).[35-37]

[b]Model did not converge due to low sample size

[c]Outcome was not measured

Table 4. Pooled associations between an EHMD cow milk-based diet without formula supplementation clinical outcomes among infants born ≤750 g (N=527)

		Intervention	Cow milk-based diet: no formula	EHMD vs. CMBD-f	
Outcomes	Total n/N (%)	EHMD n/N (%)	CMBD-f n/N (%)	Odds Ratio (95% CI)	p-value
Mortality	**89/428 (21)**	**77/427 (18)**	**12/61 (20)**	**0.39 (0.15, 1.00)**	**0.049**
NEC	**62/527 (12)**	**46/445 (10)**	**16/78 (21)**	**0.41 (0.22, 0.78)**	**0.006**
Surgical NEC	45/446 (10)	34/396 (9)	11/50 (22)	0.39 (0.13, 1.16)	0.09
BPD	309/459 (67)	262/387 (68)	47/72 (65)	0.64 (0.33, 1.23)	0.18
Severe ROP	72/483 (15)	55/421 (13)	17/62 (27)	0.47 (0.19, 1.13)	0.091
Sepsis	120/527 (23)	101/449 (22)	19/78 (24)	0.94 (0.48, 1.82)	0.851
MMI	406/496 (82)	370/449 (82)	36/47 (77)	0.89 (0.41, 1.94)	0.765

CMBD-f, cow milk-based diet including cow milk-based fortifier with base diet of human milk, excluding preterm infant formula, EHMD, exclusive human milk diet. Pooled estimates were calculated using logistic mixed effects models adjusted for gestational age and birthweight (fixed effects), and study as the random effect. All tests were run with R (v4.1.3) package lme4 (v1.1-30) and emmeans (v.1.8.1-1).[35-37]

"BPD was reported in all six studies included. The odds of developing BPD attributed to an EHMD compared to a cow milk-based diet (CMBD+f) varied across individual studies. In pooled analyses, we found that an EHMD was associated with a significant (40%) reduction in odds of developing BPD compared to a CMBD+f (aOR: 0.60; 95% CI, 0.46, 0.92; p=0.02; I2 50%; 744 participants, Figure 4, Table 3)."

Bronchopulmonary Dysplasia

BPD was reported in all six studies included. The odds of developing BPD attributed to an EHMD compared to a cow milk-based diet (CMBD+f) varied across individual studies. In pooled analyses, we found that an EHMD was associated with a significant (40%) reduction in odds of developing BPD compared to a CMBD+f (aOR: 0.60; 95% CI, 0.46, 0.92; *p*=0.02; I^2 50%; 744 participants, **Figure 4, Table 3**). Subgroup analysis showed a similar reduction attributed to an EHMD compared to no formula controls (CMBD-f), though again likely due to the small sample size in the control group, this was not statistically significant (aOR: 0.64; 95% CI, 0.33, 1.23; *p*=0.18, 459 participants, **Table 4**).

"An EHMD was associated with a 31% decrease in the odds of developing any ROP and a 29% decrease in the odds of developing severe ROP compared to CMBD+f (Table 3). Although these reductions were not statistically significant, the reduction in any ROP attributed to an EHMD bordered on significance (aOR: 0.69, 95% CI, 0.47, 0.70; p=0.055, 844 participants,Table 4). "

Retinopathy of Prematurity

Five studies reported stages of ROP or only reported severe ROP (stages ≥3). The remaining study reported any ROP without information about the stage. Consequently, we analyzed ROP data in two ways: *all ROP*, representing all incidences of ROP, regardless of the stage using all available information, and *severe ROP,* which only included stages ≥3. An EHMD was associated with a 31% decrease in the odds of developing *any ROP* and a 29% decrease in the odds of developing *severe ROP* compared to CMBD+f (**Table 3**). Although these reductions were not statistically significant, the reduction in *any ROP* attributed to an EHMD bordered on significance (aOR: 0.69, 95% CI, 0.47, 0.70; *p*=0.055, 844 participants, **Table 4**).

The effect size of an EHMD on *severe ROP* was even greater when compared against no formula controls (CMBD-f). That is, compared to infants fed a base diet of human milk with added cow milk-based fortifier (CMBD-f), those fed an EHMD had a 53% decrease in the odds of developing *severe ROP* (aOR: 0.47, 95% CI, 0.19, 1.13; *p*=0.09, 483 participants, **Table 4**).

Sepsis

Sepsis was reported in all 6 included studies. There was no consistent direction of association between an EHMD and the odds of developing sepsis compared to CMBD+f across studies. Pooled estimates indicated that an EHMD slightly reduced the odds of developing sepsis compared to CMBD+f (aOR: 0.94, 95% CI, 0.68, 1.30; *p*=0.69; I^2 41%; 879 participants, **Table 3**). Subgroup analyses excluding the formula showed a similar result associated with an EHMD diet. Compared to no formula controls (CMBD-f), infants fed an EHMD had 6.1% decreased odds of developing sepsis (aOR: 0.94, 95% CI 0.48, 1.82; *p*=0.85, 527 participants, **Table 4**).

Mortality and Morbidity Index

As commonly conducted due to the low prevalence of individual comorbidities, we evaluated the association between infant enteral feeding strategy and the binary mortality and morbidity index (MMI), representing death and/or development of severe ROP, sepsis, NEC, or BPD. We found that the odds of scoring affirmatively on the MMI were reduced by 50% in infants fed an EHMD compared to those fed a CMBD+f (aOR: 0.50, 95% CI, 0.33, 0.75; *p*=0.001; 879 participants, **Figure 5, Table 3**). In subgroup analyses, the odds of scoring affirmatively on the MMI were also reduced with an EHMD vs. no formula controls; however, likely due to the small number of patients in the control group, these results were no longer statistically significant (aOR: 0.89, 95% CI, 0.41, 1.94; *p*=0.77, 496 participants, **Table 4**).

Publication bias

Publication bias could not be conducted for all outcomes because of the limited number of studies. For example, MMI is not reported in all studies, and the definitions of MMI vary based on outcomes investigated in individual cohorts. Funnel plots indicated no publication bias for other outcomes (**Supplementary Figure 2**).

Discussion

This IPD meta-analysis examined the associations between an exclusive human milk diet (EHMD) or a diet containing cow milk-based products (CMBD) and mortality and morbidity among infants at highest risk for mortality or morbidity, those born weighing ≤750 g. Among the six contributing cohorts with a total sample size of 879 infants (19, 20, 22, 23, 30, 39), those fed an EHMD had 60% reduced odds of developing NEC and 50% reduced odds of developing surgical NEC compared to infants fed a CMBD. These reductions in NEC and surgical NEC were similar to those reported in previous EHMD studies conducted among larger preterm infants born weighing ≤1,250 g. (19, 20, 22, 23, 27, 30) NEC is one of the primary causes of death in extremely premature infants. (1) Mounting evidence suggests that cow milk protein may cause intestinal inflammation, leading to feeding intolerance and NEC.(18, 20, 40-43) Considering that infants in the EHMD group

Figure S1. Quality Assessment of studies included in IPD meta-analysis

Study	Quality Score[1] (Max 9)	Exposure Assessment (Max 4)	Comparability (Max 2)	Outcome Assessment (Max 3)
Sullivan et al., 2009[1]	7	***	*	***
Cristofalo et al., 2013[2]	6.5	**	*ǂ	***
Assad et al., 2015[3]	8	***	**	***
Hair et al., 2016[4]	7	***	*	***
Huston et al., 2018[5]	7			
Ferry et al., (unpublished)[6]	--			

Yellow = moderate quality (4-7); Green = high quality (8-9); Grey = no score assessed
*represents 1 point; ǂ represents 0.5 points

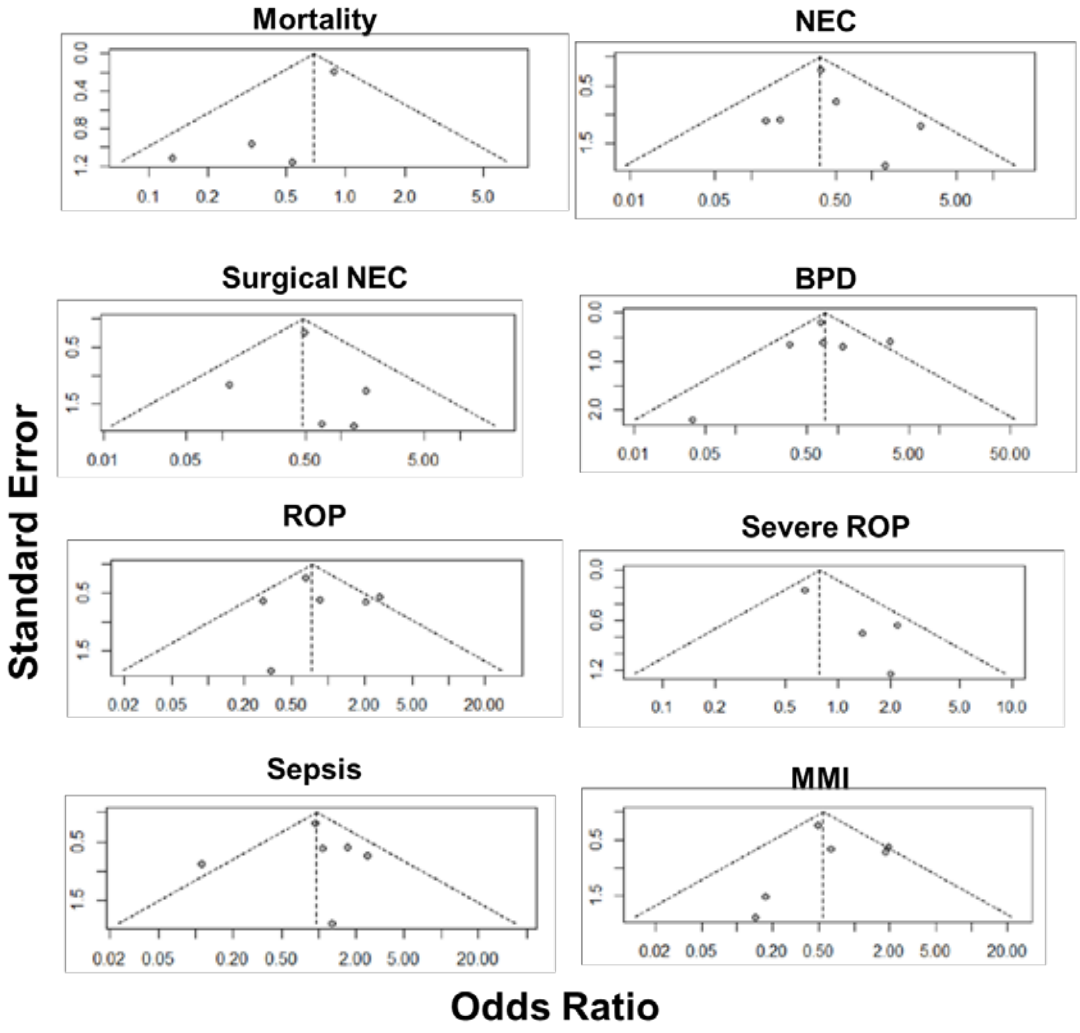


Figure S2. Funnel plots of studies included in the IPD meta-analysis. BPD, bronchopulmonary dysplasia; MMI, mortality and morbidity index; NEC, necrotizing enterocolitis; ROP, retinopathy of prematurity

Table S1. Search Strategy for PubMed

Number	Search terms	Filters	Results
1	"Milk*"[Mesh] OR "Milk, Human"[Mesh] OR "Infant Food"[Mesh] OR "Infant Formula"[Mesh] OR "Food, Fortified*"[Mesh] OR "human milk"[tiab] OR "breast milk"[tiab] OR breastmilk[tiab] OR "donor human milk"[tiab] OR "human milk fortifier"[tiab] OR "exclusive human milk*"[tiab] OR "enteral feeding"[tw]		152,498
2	"Infant, Premature, Diseases"[Mesh] OR "Mortality"[Mesh]" OR "Lung Diseases/epidemiology"[Mesh]" OR "Lung Diseases/diet therapy"[Mesh] OR "Retinopathy of Prematurity"[Mesh] OR "Ductus Arteriosus, Patent"[Mesh] OR "Enterocolitis, Necrotizing"[Mesh] OR "Neonatal Sepsis"[Mesh] OR "mortality"[tiab], "bronchopulmonary dysplasia"[tiab] OR "retinopathy of prematurity"[tiab] OR "patent ductus arteriosus"[tiab] OR "necrotizing enterocolitis" OR "surgical NEC" OR "mortality/morbidity index" OR "sepsis"[tiab] OR "late onset sepsis"[tw]		131,879
3	"Humans"[Mesh] OR "Female"[Mesh] OR "Male"[Mesh] OR "Infant, Premature"[Mesh] OR "Infant, Extremely Low Birth Weight"[Mesh] OR "Infant, Very Low Birth Weight"[Mesh] OR "Infant, Newborn"[Mesh] OR "premature infant*"[tw] OR "preterm infant*"[tw] OR "low birthweight"[tw]		22,372,934
4	#1 AND #3 AND #2		2,114
5	#1 AND #3 AND #2	from 2000 - 3000/12/12	1,813
6	"Retrospective Studies"[Mesh] OR "Epidemiologic Studies"[Mesh] OR "Clinical Trial" [Publication Type] OR "Randomized Controlled Trial" [Publication Type] OR "Published Erratum" [Publication Type] OR "retrospective stud*"[tiab] OR "controlled trial"[tiab] OR "randomized clinical trial"[tiab] OR "observational study"[tiab] OR "multi-center retrospective cohort study"[tiab]		3,822,783
7	#1 AND #3 AND #2 AND #6		667
8	#1 AND #3 AND #2 AND #6	from 2000 - 3000/12/12	591

Search strategy conducted in PubMed on February 22, 2022

Table S2. Quality Assessment of unpublished studies included in IPD meta-analysis.

AACODS		Ferry et al., [6]		
		Yes	No	?
Authority	Identifying who is responsible for the intellectual content Individual author: • Associated with a reputable organization? • Professional qualifications or considerable experience? • Produced/published other work (grey/black) in the field? • Recognised expert, identified in other sources? • Cited by others? (use Google Scholar as a quick check) • Higher degree student under "expert" supervision? Organization or group: • Is the organization reputable? (e.g., WHO) • Is the organization an authority in the field? In all cases: • Does the item have a detailed reference list or bibliography?	X		
Accuracy	Does the item have a clearly stated aim or brief? • If so, is this met? • Does it have a stated methodology? • If so, is it adhered to? • Has it been peer-reviewed? • Has it been edited by a reputable authority? • Supported by authoritative, documented references or credible sources? • Is it representative of work in the field? • If No, is it a valid counterbalance? • Is any data collection explicit and appropriate for the research? • If an item is secondary material (e.g., a policy brief of a technical report) refer to the original. Is it an accurate, unbiased interpretation or analysis?	Yes		
Coverage	All items have parameters that define their content coverage. These limits might mean that a work refers to a particular population group or excludes certain types of publication. A report could be designed to answer a particular question or be based on statistics from a particular survey. • Are any limits clearly stated?			N/A
Date	For the item to inform your research, it needs to have a date that confirms The relevance • Does the item have a clearly stated date related to the content? No easily discernible date is a strong concern. • If no date is given but can be closely ascertained, is there a valid reason for its absence? • Check the bibliography: have key contemporary material been Included?	X		
Significance	This is a value judgment of the item in the context of the relevant research area • Is the item meaningful? (this incorporates feasibility, utility, and relevance) • Does it add context? • Does it enrich or add something unique to the research? • Does it strengthen or refute a current position? • Would the research area be lesser without it? • Is it integral, representative, or typical? • Does it have an impact? (in the sense of influencing the work or behavior of others)	Yes		

were not exposed to cow milk proteins, our findings support this hypothesis. Our findings suggest that an EHMD is better tolerated in ≤750 g infants than a CMBD, as shown previously in larger preterm infants. (20, 40, 44, 45)

"For subgroup analyses, we observed nearly the same magnitude of reduction in NEC (59% lower odds) when an EHMD was compared to a base diet of only human milk with added cow milk-based fortifiers (no formula controls, CMBD-f, p=0.006)."

For subgroup analyses, we observed nearly the same magnitude of reduction in NEC (59% lower odds) when an EHMD was compared to a base diet of only human milk with added cow milk-based fortifiers (no formula controls, CMBD-f, *p*=0.006). Due to the small sample size of infants, we could confirm through medical records did not receive formula, this comparison did not reach statistical significance for surgical NEC (*p*=0.09), but the magnitude of the decrease was similar to infants who received some formula (61% lower odds). These findings serve as an important reminder that effect sizes and measures of association cannot be interpreted by their *P* values alone. (46) The clinical meaningfulness of effect sizes should be considered when evaluating the results of nutrition interventions.

BPD is one of the major comorbidities affecting ELBW infants (5, 47), and BPD severity is linked to their long-term health. (48, 49) Our results attributed an EHMD to a 35% reduction in the odds of developing BPD among infants born weighing ≤750 g. Due to differences in analytical techniques, it is difficult to directly compare our results to those reported previously for larger preterm infants born weighing ≤1,250 g. (19-21)

Nevertheless, the percent difference in incidences of BPD between an EHMD and CMBD was smaller in our study than previously reported, suggesting that an EHMD has a larger effect size in larger infants. One potential reason for this is that the overall incidence of BPD is inversely correlated with birthweight and gestational age at birth; moreover, younger infants are more likely to suffer from more severe forms of BPD than infants born later and with higher birthweights. (28, 47, 50) It is plausible that BPD severity may be differentially impacted based on enteral nutrition. BPD severity should be investigated in future research on the enteral nutrition of ELBW infants.

Research on the effectiveness of small baby units (SBUs) in reducing mortality and comorbidities supports the assertion that standardized care is important for ELBW infants. (51-53) Optimizing nutrition is one of the core tenants used in SBUs that have adopted an infant-driven model of care. (54) We found a 10% lower incidence of death (*p*=0.049) in infants receiving an EHMD than those receiving cow milk-based fortifier without formula. We also found significant reductions in many of the most common major comorbidities, including NEC, BPD, and MMI. These findings suggest that feeding an EHMD to these smallest babies may be safer than feeding cow milk-based products.

Strengths and Limitations:

This study had several strengths. Data harmonization and IPD meta-analysis allow for reliable comparison across cohorts and improved statistical power to declare observed differences statistically significant compared to what aggregate meta-analysis would have allowed. In addition, many of the outcomes reported here have not been previously published. Thus, IPD allowed for a more comprehensive analysis than only existing published data.

"This study also had some limitations. The first is related to availability bias. Importantly, although all authors were invited to contribute their data, 33% did not respond to our request. Not all the data from all eligible studies were able to be collected. In some cases, this was due to timing issues. However, some authors did not respond to our invitation to contribute their data."

This study also had some limitations. The first is related to availability bias. Importantly, although all authors were invited to contribute their data, 33% did not respond to our request. Not all the data from all eligible studies were able to be collected. In some cases, this was due to timing issues. However, some authors did not respond to our invitation to contribute their data. Another limitation was that we could not fully adjust models for all clinically meaningful covariates, including antenatal steroid use, because these data were unavailable in all cohorts. There is also some potential misclassification bias because some cohorts lacked sufficient nutrition data to confirm formula intake. Consequently, we may have underrepresented the number of infants who did not receive formula. However, we remain confident in our findings because undercounting infants would bias estimates toward the null. Additionally, data on the quantity of cow milk-based vs. human milk-based fortifiers consumed in each group were unavailable for analysis. Nevertheless, our results suggest the control group received relatively great amounts of cow milk-based fortifier, and the EHMD group received none. Previous research has shown that for every 10% increase in the volume of milk containing cow milk protein, the increased risk of developing NEC is 12%, surgical NEC is 21%, and sepsis is 18%. (18) Finally, our results may have underestimated the measures of association attributed to an EHMD because the EHMD group was analyzed as a homogeneous group. This is potentially problematic because EHMD feeding protocols varied greatly within studies (e.g., across study sites) and between studies. Previous research has suggested that earlier EHMD fortification protocols may be advantageous in reducing several comorbidities in infants born weighing ≤1250 g (55) and should be the subject of research for smaller ELBW infants. Future studies should carefully consider standardized feeding protocols, including the timing of feeding, the timing of fortifi-

cation, feed advancement rates, and the timing of transitioning off fortifiers. (30, 55)

"Our findings improve the scientific premise that an EHMD reduces the odds of developing several major comorbidities, including a 60% reduction in NEC, a 50% reduction in surgical NEC, and a 40% reduction in BPD, compared to a CMBD in the smallest preterm infants born weighing ≤750 g. These results support our hypothesis that compared to a CMBD, an EHMD reduces comorbidities in ELBW infants born weighing ≤750 g."

Conclusions:

Feeding the smallest infants remains a critical challenge for healthcare teams, who must balance providing the appropriate nutrition while avoiding feeding intolerance and other common feeding-related issues. Our findings improve the scientific premise that an EHMD reduces the odds of developing several major comorbidities, including a 60% reduction in NEC, a 50% reduction in surgical NEC, and a 40% reduction in BPD, compared to a CMBD in the smallest preterm infants born weighing ≤750 g. These results support our hypothesis that compared to a CMBD, an EHMD reduces comorbidities in ELBW infants born weighing ≤750 g. Our results build upon previous findings that human milk has significant clinical advantages over a CMBD when taken together (15, 56-59) and provide new evidence that replacing cow milk-based fortifiers with human milk-based fortifiers reduces mortality and morbidity in ELBW infants born weighing ≤750 g.

References

1. Juul SE, Wood TR, Comstock BA, Perez K, Gogcu S, Puia-Dumitrescu M, et al. Deaths in a modern cohort of extremely preterm infants from the Preterm Erythropoietin Neuroprotection Trial. JAMA Netw Open. 2022;5(2):e2146404. Epub 2022/02/08. doi: 10.1001/jamanetworkopen.2021.46404. PubMed PMID: 35129596; PubMed Central PMCID: PMCPMC8822378.

2. Patel RM, Kandefer S, Walsh MC, Bell EF, Carlo WA, Laptook AR, et al. Causes and timing of death in extremely premature infants from 2000 through 2011. N Engl J Med. 2015;372(4):331-40. Epub 2015/01/22. doi: 10.1056/NEJMoa1403489. PubMed PMID: 25607427; PubMed Central PMCID: PMCPMC4349362.

3. Glass HC, Costarino AT, Stayer SA, Brett CM, Cladis F, Davis PJ. Outcomes for extremely premature infants. Anesth Analg. 2015;120(6):1337-51. doi: 10.1213/ANE.0000000000000705.

4. Jiang S, Huang X, Zhang L, Han J, Yang Y, Wang W, et al. Estimated Survival and Major Comorbidities of Very Preterm Infants Discharged Against Medical Advice vs Treated With Intensive Care in China. JAMA Netw Open. 2021;4(6):e2113197. Epub 2021/06/18. doi: 10.1001/jamanetworkopen.2021.13197. PubMed PMID: 34137828.

5. Zayegh AM, Doyle LW, Boland RA, Mainzer R, Spittle AJ, Roberts G, et al. Trends in survival, perinatal morbidities and two-year neurodevelopmental outcomes in extremely low-birthweight infants over four decades. Paediatr Perinat Epidemiol. 2022;36(5):594-602. Epub 2022/04/20. doi: 10.1111/ppe.12879. PubMed PMID: 35437828.

6. Ganapathy V, Hay JW, Kim JH. Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. Breastfeed Med. 2012;7(1):29-37. Epub 2011/07/02. doi: 10.1089/bfm.2011.0002. PubMed PMID: 21718117.

7. Beam AL, Fried I, Palmer N, Agniel D, Brat G, Fox K, et al. Estimates of healthcare spending for preterm and low-birthweight infants in a commercially insured population: 2008-2016. J Perinatol. 2020;40(7):1091-9. Epub 2020/02/28. doi: 10.1038/s41372-020-0635-z. PubMed PMID: 32103158; PubMed Central PMCID: PMCPMC7314662.

8. Petrou S, Yiu HH, Kwon J. Economic consequences of preterm birth: a systematic review of the recent literature (2009-2017). Arch Dis Child. 2019;104(5):456-65. Epub 2018/11/11. doi: 10.1136/archdischild-2018-315778. PubMed PMID: 30413489.

9. Johnson TJ, Patel AL, Bigger HR, Engstrom JL, Meier PP. Economic benefits and costs of human milk feedings: a strategy to reduce the risk of prematurity-related morbidities in very-low-birth-weight infants. Adv Nutr. 2014;5(2):207-12. Epub 2014/03/13. doi: 10.3945/an.113.004788. PubMed PMID: 24618763; PubMed Central PMCID: PMCPMC3951804.

10. Patel AL, Johnson TJ, Engstrom JL, Fogg LF, Jegier BJ, Bigger HR, et al. Impact of early human milk on sepsis and healthcare costs in very low birth weight infants. J Perinatol. 2013;33(7):514-9. doi: 10.1038/jp.2013.2.

11. van Beek PE, van de Par K, van der Horst IE, van Baar AL, Vugs B, Andriessen P. The Need for Special Education Among ELBW and SGA Preterm Children: A Cohort Study. Front Pediatr. 2021;9:719048. Epub 2021/11/09. doi: 10.3389/fped.2021.719048. PubMed PMID: 34746053; PubMed Central PMCID: PMCPMC8564376.

12. Mathewson KJ, Chow CH, Dobson KG, Pope EI, Schmidt LA, Van Lieshout RJ. Mental health of extremely low birth weight survivors: A systematic review and meta-analysis. Psychol Bull. 2017;143(4):347-83. Epub 2017/02/14. doi: 10.1037/bul0000091. PubMed PMID: 28191983.

13. Abrams SA. In utero physiology: role in nutrient delivery and fetal development for calcium, phosphorus, and vitamin D. Am J Clin Nutr. 2007;85(2):604S-7S. doi: 10.1093/ajcn/85.2.604S.

14. Gleason CA, Juul SE. Avery's Diseases of the Newborn.

10th ed. Philadelphia, PA: Elsevier; 2018.

15. Elliott MJ, Golombek SG. Evolution of preterm infant nutrition from breastfeeding to an exclusive human milk diet: a review. NeoReviews. 2022;23(8):e558-e71. doi: 10.1542/neo.23-8-e558.

16. Meek JY, Noble L. Technical Report: Breastfeeding and the Use of Human Milk. Pediatrics. 2022;150(1). doi: 10.1542/peds.2022-057989.

17. Agostoni C, Buonocore G, Carnielli VP, De Curtis M, Darmaun D, Decsi T, et al. Enteral nutrient supply for preterm infants: commentary from the European Society of Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition. J Pediatr Gastroenterol Nutr. 2010;50(1):85-91. Epub 2009/11/03. doi: 10.1097/MPG.0b013e3181adaee0. PubMed PMID: 19881390.

18. Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. Breastfeed Med. 2014;9(6):281-5. Epub 2014/05/29. doi: 10.1089/bfm.2014.0024. PubMed PMID: 24867268; PubMed Central PMCID: PMCPMC4074755.

19. Hair AB, Peluso AM, Hawthorne KM, Perez J, Smith DP, Khan JY, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet. Breastfeed Med. 2016;11(2):70-4. Epub 2016/01/21. doi: 10.1089/bfm.2015.0134. PubMed PMID: 26789484; PubMed Central PMCID: PMCPMC4782036.

20. Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. J Perinatol. 2016;36(3):216-20. Epub 2015/11/13. doi: 10.1038/jp.2015.168. PubMed PMID: 26562370.

21. Delaney Manthe E, Perks PH, Swanson JR. Team-based implementation of an exclusive human milk diet. Adv Neonatal Care. 2019;19(6):460-7. Epub 2019/11/26. doi: 10.1097/ANC.0000000000000676. PubMed PMID: 31764134.

22. Cristofalo EA, Schanler RJ, Blanco CL, Sullivan S, Trawoeger R, Kiechl-Kohlendorfer U, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. J Pediatr. 2013;163(6):1592-5.e1. Epub 2013/08/24. doi: 10.1016/j.jpeds.2013.07.011. PubMed PMID: 23968744.

23. Sullivan S, Schanler RJ, Kim JH, Patel AL, Trawöger R, Kiechl-Kohlendorfer U, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. J Pediatr. 2010;156:562-7.e1. doi: 10.1016/j.jpeds.2009.10.040.

24. Jeschke E, Biermann A, Gunster C, Bohler T, Heller G, Hummler HD, et al. Mortality and major morbidity of very-low-birth-weight infants in Germany 2008-2012: a report based on administrative data. Front Pediatr. 2016;4:23. Epub 2016/04/06. doi: 10.3389/fped.2016.00023. PubMed PMID: 27047906; PubMed Central PMCID: PMCPMC4801886.

25. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-4. doi: 10.1001/jama.2013.281053.

26. Stewart LA, Clarke M, Rovers M, Riley RD, Simmonds M, Stewart G, et al. Preferred Reporting Items for Systematic Review and Meta-Analyses of individual participant data: the PRISMA-IPD Statement. JAMA. 2015;313(16):1657-65. Epub 2015/04/29. doi: 10.1001/jama.2015.3656. PubMed PMID: 25919529.

27. O'Connor DL, Kiss A, Tomlinson C, Bando N, Bayliss A, Campbell DM, et al. Nutrient enrichment of human milk with human and bovine milk-based fortifiers for infants born weighing <1250 g: a randomized clinical trial. Am J Clin Nutr. 2018;108(1):108-16. Epub 2018/06/08. doi: 10.1093/ajcn/nqy067. PubMed PMID: 29878061.

28. Jensen EA, Edwards EM, Greenberg LT, Soll RF, Ehret DEY, Horbar JD. Severity of bronchopulmonary dysplasia among very preterm infants in the United States. Pediatrics. 2021;148(1). Epub 2021/06/04. doi: 10.1542/peds.2020-030007. PubMed PMID: 34078747; PubMed Central PMCID: PMCPMC8290972 conflicts of interest to disclose.

29. Bassler D, Stoll BJ, Schmidt B, Asztalos EV, Roberts RS, Robertson CM, et al. Using a count of neonatal morbidities to predict poor outcome in extremely low birth weight infants: added role of neonatal infection. Pediatrics. 2009;123(1):313-8. Epub 2009/01/02. doi: 10.1542/peds.2008-0377. PubMed PMID: 19117897; PubMed Central PMCID: PMCPMC2829863.

30. Huston RK, Markell AM, McCulley EA, Gardiner SK, Sweeney SL. Improving growth for infants </=1250 grams receiving an exclusive human milk diet. Nutr Clin Pract. 2018;33(5):671-8. Epub 2018/02/17. doi: 10.1002/ncp.10054. PubMed PMID: 29451716.

31. Flanagin A, Frey T, Christiansen SL, for the AMA Manual of Style Committee. Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals. JAMA. 2021;326(7):621-7. doi: 10.1001/jama.2021.13304.

32. Wells GA, Shea D, O'Connell J, Peterson V, Welch M, Losos M, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. The Ottawa Hospital Research Institute, 2013.

33. Tyndall J. AACODS checklist. Adelaide, Australia: Flinders University2010.

34. Johnston BC, Guyatt GH. Best (but oft-forgotten) practices: intention-to-treat, treatment adherence, and missing participant outcome data in the nutrition literature. Am J Clin Nutr. 2016;104(5):1197-201. Epub 2016/11/03. doi: 10.3945/ajcn.115.123315. PubMed PMID: 27733397.

35. Bates D, Mächler M, Bolker B, Walker S. Fitting linear mixed-effects models using lme4. Journal of Statistical Software. 2015;67(1):1-48. doi: 10.18637/jss.v067.i01.

36. Lenth RV. emmeans: estimated marginal means, aka least-squares means. 1.8.1-1 ed2022. p. R package version.

37. The R Project for Statistical Computing. [September 30 2022]. Available from: https://www.R-project.org/.

38. Dritsakou K, Liosis G, Valsami G, Polychronopoulos E, Souliotis K, Skouroliakou M. Mother's breast milk supplemented with donor milk reduces hospital and health service usage costs in low-birthweight infants. Midwifery. 2016;40:109-13. doi: 10.1016/j.midw.2016.06.015.

39. Ferry J. Comparing an EHMD and cow milk-based nutritional products in a single center retrospective cohort study. Unpublished. 2015.

40. Dogra S, Mukhopadhyay K, Narang A. Feed intolerance and necrotizing enterocolitis in preterm small-for-gestational age neonates with normal umbilical artery Doppler flow. J Trop Pediatr. 2012;58(6):513-6. Epub 2012/07/04. doi: 10.1093/tropej/fms026. PubMed PMID: 22752419.

41. Bertino E, Giribaldi M, Cester EA, Coscia A, Trapani BM, Peila C, et al. New human milk fortifiers for the preterm infant. Journal of Pediatric and Neonatal Individualized Medicine. 2018;6(1):e060124. doi: 10.7363/060124.

42. Clark DA, Munshi UK. Feeding associated neonatal necrotizing enterocolitis (Primary NEC) is an inflammatory bowel disease. Pathophysiology. 2014;21(1):29-34. Epub 2014/01/11. doi: 10.1016/j.pathophys.2013.11.006. PubMed PMID: 24406172; PubMed Central PMCID: PMCPMC7126559.

43. Abdelhamid AE, Chuang SL, Hayes P, Fell JM. In vitro cow's milk protein-specific inflammatory and regulatory cytokine responses in preterm infants with necrotizing enterocolitis and sepsis. Pediatr Res. 2011;69(2):165-9. doi: 10.1203/PDR.0b013e31820263e7.

44. El-Fadeel H, Velumula P, Lulic-Botica M, Natarajan G, Thomas R, Botica G, et al. Effect of an exclusive human milk diet on feeding tolerance in preterm infants. J Perinatol. 2022;42(8):1070-5. Epub 2022/02/21. doi: 10.1038/s41372-022-01348-y. PubMed PMID: 35184144.

45. Sandhu A, Fast S, Bonnar K, Baier RJ, Narvey M. Human-Based Human Milk Fortifier as Rescue Therapy in Very Low Birth Weight Infants Demonstrating Intolerance to Bovine-Based Human Milk Fortifier. Breastfeed Med. 2017;12(9):570-3. doi: 10.1089/bfm.2017.0017.

46. Sullivan GM FR. Using Effect Size-or Why the P Value Is Not Enough. J Grad Med Educ. 2012;4(3):279-82. doi: 10.4300/JGME-D-12-00156.1.

47. Jensen EA, Schmidt B. Epidemiology of bronchopulmonary dysplasia. Birth Defects Res A Clin Mol Teratol. 2014;100(3):145-57. Epub 2014/03/19. doi: 10.1002/bdra.23235. PubMed PMID: 24639412; PubMed Central PMCID: PMCPMC8604158.

48. Manti S, Galdo F, Parisi GF, Napolitano M, Decimo F, Leonardi S, et al. Long-term effects of bronchopulmonary dysplasia on lung function: a pilot study in preschool children's cohort. J Asthma. 2021;58(9):1186-93. Epub 2020/06/09. doi: 10.1080/02770903.2020.1779289. PubMed PMID: 32508174.

49. Schmidt AR, Ramamoorthy C. Bronchopulmonary dysplasia. Paediatr Anaesth. 2022;32(2):174-80. Epub 2021/12/09. doi: 10.1111/pan.14365. PubMed PMID: 34877749.

50. Jensen EA, Dysart K, Gantz MG, McDonald S, Bamat NA, Keszler M, et al. The Diagnosis of Bronchopulmonary Dysplasia in Very Preterm Infants. An Evidence-based Approach. Am J Respir Crit Care Med. 2019;200(6):751-9. Epub 2019/04/18. doi: 10.1164/rccm.201812-2348OC. PubMed PMID: 30995069; PubMed Central PMCID: PMCPMC6775872.

51. Morris M, Cleary JP, Soliman A. Small Baby Unit Improves Quality and Outcomes in Extremely Low Birth Weight Infants. Pediatrics. 2015;136(4):e1007-15. Epub 2015/09/09. doi: 10.1542/peds.2014-3918. PubMed PMID: 26347427.

52. Varga P, Berecz B, Pete B, Kollár T, Magyar Z, Jeager J, et al. Trends in mortality and morbidity in infants under 500 grams birthweight: observations from our neonatal intensive care unit (NICU). Med Sci Monit. 2018;24:4474-80. doi: 10.12659/MSM.907652.

53. Fathi O, Nelin LD, Shepherd EG, Reber KM. Development of a small baby unit to improve outcomes for the extremely premature infant. J Perinatol. 2022;42(2):157-64. Epub 2021/03/14. doi: 10.1038/s41372-021-00984-0. PubMed PMID: 33712714; PubMed Central PMCID: PMCPMC7952830.

54. Altimier L, Phillips R. The Neonatal Integrative Developmental Care Model: Advanced Clinical Applications of the Seven Core Measures for Neuroprotective Family-centered Developmental Care. Newborn and Infant Nursing Reviews. 2016;16(4):230-44. doi: 10.1053/j.nainr.2016.09.030.

55. Huston R, Lee M, Rider E, Stawarz M, Hedstrom D, Pence M, et al. Early fortification of enteral feedings for infants <1250 grams birth weight receiving a human milk diet including human milk based fortifier. J Neonatal Perinatal Med. 2020;13(2):215-21. Epub 2019/11/11. doi: 10.3233/NPM-190300. PubMed PMID: 31707377; PubMed Central PMCID: PMCPMC7369034.

56. Spiegler J, Preuss M, Gebauer C, Bendiks M, Herting E, Gopel W, et al. Does Breastmilk Influence the Development of Bronchopulmonary Dysplasia? J Pediatr. 2016;169:76-80 e4. Epub 2015/12/02. doi: 10.1016/j.jpeds.2015.10.080. PubMed PMID: 26621048.

57. Fang L, Zhang M, Wu L, Wang R, Lin B, Yao J, et al. Is preterm donor milk better than preterm formula for very-low-birthweight infants? Food Nutr Res. 2021;65. Epub 2021/10/16. doi: 10.29219/fnr.v65.5346. PubMed PMID: 34650391; PubMed Central PMCID: PMCPMC8494261.

58. Fleig L, Hagan J, Lee ML, Abrams SA, Hawthorne KM, Hair AB. Growth outcomes of small for gestational age preterm infants before and after implementation of an exclusive human milk-based diet. J Perinatol. 2021;41(8):1859-64. Epub 2021/05/21. doi: 10.1038/s41372-021-01082-x. PubMed PMID: 34012050; PubMed Central PMCID: PMCPMC8342303.

59. Hair AB, Patel AL, Kiechl-Kohlendorfer U, Kim JH, Schanler RJ, Hawthorne KM, et al. Neurodevelopmental outcomes of extremely preterm infants fed an exclusive human milk-based diet versus a mixed human milk + bovine milk-based diet: a multicenter study. J Perinatol. 2022;42(11):1485-8. Epub 2022/09/29. doi: 10.1038/s41372-022-01513-3. PubMed PMID: 36171356.

Supplement References:

1. Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. J Pediatr. 2010;156:562-567.e1. doi: 10.1016/j.jpeds.2009.10.040.

2. Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. J Pediatr. 2013;163(6):1592-1595.e1. doi: 10.1016/j.jpeds.2013.07.011.

3. Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in vlbw infants fed an exclusive human milk diet. J Perinatol. 2016;36(3):216-220. doi: 10.1038/jp.2015.168.

4. Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet. Breastfeed Med. 2016;11(2):70-74. doi: 10.1089/bfm.2015.0137. Erratum in: Breastfeed Med. 2017;12(10):663.

5. Huston RK, Markell AM, McCulley EA, Gardiner SK, Sweeney SL. Improving growth for infants ≤1250 grams receiving an exclusive human milk diet. Nutr Clin Pract. 2018;33(5):671-678. doi: 10.1002/ncp.10074.

6. Ferry J. Comparing an ehmd and cow milk-based nutritional products in a single center retrospective cohort study. Unpublished. 2015.

Disclosures: *The investigators are employees of Prolacta Bioscience (S. M. Reyes, J. R. Strott-Moore, S. L. Brooker, M. L. Lee, M. J. Elliott) or have received past research funding from Prolacta Bioscience (J. Ferry, R. K. Huston). Prolacta Bioscience manufactures human milk-based human milk fortifiers.*

Acknowledgments: *We thank the study authors who contributed their individual participant data for these analyses.*

NT

Corresponding Author

Jamie R. Strott-Moore, NNP-BBC, MSN
Prolacta Bioscience®, Duarte, California

Sarah L. Brooker, PhD
Prolacta Bioscience®, Duarte, California

Corresponding Author

Sarah M. Reyes, PhD
Scientific Liaison, Human Milk & Clinical Research
Prolacta Bioscience, Inc., 1800 Highland Avenue, Duarte, CA 91010
Phone: 888•776•5228 • Fax: 626•599•9269
Email: info@prolacta.com

Martin L. Lee, PhD
Prolacta Bioscience®, Duarte, California;
Department of Biostatistics, Fielding School of Public Health, University of California, Los Angeles, Los Angeles, California

Jenelle Ferry, MD
Pediatrix Medical Group Tampa Regional Practices, St. Joseph's Women's Hospital, Tampa, Florida

Robert K. Huston, MD
4Northwest Newborn Specialists, PC and Pediatrix Medical Group Portland, Oregon

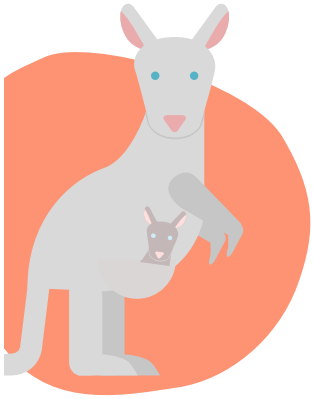
Melinda J. Elliott, MD
Prolacta Bioscience®,
Duarte, California
Department of Neonatology, Pediatrix Medical Group of Maryland, Rockville, MD

Reference: Suh M, et al. *J Infect Dis*. 2022;226(Suppl 2):S154-S163.

MAT-US-2300724 V1.0 January 2023

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

Which Infants are More Vulnerable to Respiratory Syncytial Virus?

RSV is a respiratory virus with cold-like symptoms that causes 90,000 hospitalizations and 4,500 deaths per year in children 5 and younger. It's 10 times more deadly than the flu. For premature babies with fragile immune systems and underdeveloped lungs, RSV proves especially dangerous.

But risk factors associated with RSV don't touch all infants equally.*

*Source: Respirator Syncytial Virus and African Americans

Caucasian Babies	Risk Factor	African American Babies
11.6%	Prematurity	18.3%
58.1%	Breastfeeding	50.2%
7.3%	Low Birth Weight	11.8%
60.1%	Siblings	71.6%
1%	Crowded Living Conditions	3%

AFRICAN AMERICAN BABIES bear the brunt of RSV. Yet the American Academy of Pediatrics' restrictive new guidlines limit their access to RSV preventative treatment, increasing these babies' risk.

AfPA Alliance for Patient Access

Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY

Letters to the Editor

Letter to the Editor: "Response to 'Addressing Structural Racism in Infant Safe Sleep Education: HHS to Fund First Candle Community-Based Project"

Dear Dr. Goldstein,

We read "Addressing Structural Racism in Infant Safe Sleep Education: HHS to Fund First Candle Community-Based Project" with great enthusiasm (Jacobson, A. Addressing Structural Racism in Infant Safe Sleep Education: HHS to Fund First Candle Community-Based Project. Neonatology Today. 2022;17(11):63-64.). This article discusses First Candle's upcoming project in partnership with Healthy Mothers, Healthy Babies Coalition of Georgia (HMHBGA), to assess how current policies effectively circumvent Sudden Unexpected Infant Death (SUID) and address structural racism. The First Candle organization was one of ten to receive grant funding from the US Department of Health and Human Services (HSS)–specifically through the Office of Minority Health (OMH)–to create and propose new policies and community-oriented standards of care to decrease mortality in black infants in Atlanta, Georgia.

"The First Candle organization was one of ten to receive grant funding from the US Department of Health and Human Services (HSS)–specifically through the Office of Minority Health (OMH)–to create and propose new policies and community-oriented standards of care to decrease mortality in black infants in Atlanta, Georgia."

We look forward to the results of this project and its impact on maternal and infant care. In the meantime, we would like to delve deeper into the prevalence of racial and social disparities found in SUIDS to illuminate the importance of this project.

According to the Centers for Disease Control and Prevention (CDC), SUID is the unexpected death of an infant under one year old due to unidentifiable causes. This can encompass a range of events, from Sudden Infant Death Syndrome (SIDS) to accidental suffocation in sleeping environments and deaths of unknown causes (1). In the United States, SUID is the third leading cause of infant mortality, accounting for 3,400 deaths per year (2). Although SUID rates have declined significantly since the 1990s, a significant discrepancy exists between races. For instance, data shows more than twice higher SUID rates in American Indian/Alaska Native, Black, and Native Hawaiian/Other Pacific Islander communities than in Non-Hispanic Whites (1). Moreover, according to a 2019 statistical report, infants of non-hispanic black women had a mortality rate of 10.62, compared to 4.49 non-Hispanic white women (3).

" Moreover, according to a 2019 statistical report, infants of non-hispanic black women had a mortality rate of 10.62, compared to 4.49 non-Hispanic white women (3)."

In addition, race is not the only factor affecting infant health and mortality. Babies sleeping in a prone position, household smoking, low birth weight, and overwrapping infants have all correlated with increased rates of SUIDS. Each risk factor listed above has been associated with "the pathway of" low socioeconomic status, making education in these communities critical (4). We advocate for both First Candle and HMHBGA to focus on designing policies to target education in the African American population regarding SUID and bring heightened awareness to mortality prevention through local media, social media, and the like.

"From 1994 to 2006, we saw a decline in the SIDS rate, primarily due to the Back to Sleep campaign. It is time to focus on the striking differences in mortality rates of infants born to African American mothers compared to their white counterparts. We again appreciate and endorse both the First Candle and HMHBGA organization for investigating the demographic discrepancy through the perspective of structural racism."

From 1994 to 2006, we saw a decline in the SIDS rate, primarily due to the Back to Sleep campaign. It is time to focus on the striking differences in mortality rates of infants born to African American mothers compared to their white counterparts. We again appreciate and endorse both the First Candle and HMHBGA organization for investigating the demographic discrepancy through the perspective of structural racism. This project may help inform policy changes to provide more effective and tailored care to at-risk communities.

References:

1. "About Sids and Suid." *Centers for Disease Control and Prevention*, Centers for Disease Control and Preven-

tion, 28 June 2022, https://www.cdc.gov/sids/about/index.htm#:~:text=Sudden%20unexpected%20infant%20death%20(SUID,the%20problem%20and%20CDC%20activities.

2. Boyer BT, Lowell GS, Roehler DR, Quinlan KP. Racial and ethnic disparities of sudden unexpected infant death in large US cities: a descriptive epidemiological study. Inj Epidemiol. 2022 Mar 25;9(1):12. doi: 10.1186/s40621-022-00377-7. PMID: 35337375; PMCID: PMC8957171.

3. Ely, Danielle, and Anne Driscoll. "Infant Mortality in the United States, 2019: Data from the Period Linked Birth/Infant Death File." *National Vital Statistics Reports*, vol. 70, no. 14, 2021, https://doi.org/10.15620/cdc:111053.

4. Spencer, N. (2004). Sudden unexpected death in infancy and socioeconomic status: A systematic review. *Journal of Epidemiology & Community Health*, *58*(5), 366–373. https://doi.org/10.1136/jech.2003.011551.

Sincerely,

Anh-Tram Bui OMS III, Patric Maehler OMS III, Violet Quann OMS III, Rostam Vohoumani OMS III

Dear Physicians to be Anh-Tram Bui OMS III, Patric Maehler OMS III, Violet Quann OMS III, and Rostam Vohoumani OMS III,

The disturbing persistence of elevated SIDS rates in specific populations at risk for disparity is a significant concern. Although the association with structural racism may be difficult to appreciate at first glance, it must be remembered that perceptions and assumptions drive the vehicle that produces the factors that result in this disparate rate. The socioeconomic factors are at once apparent, but it does not stop there. Less vigilant enforcement of housing codes, "red line" associated goods and services, and access issues are associated co-factors. Even differences in school performance matter; anticipatory guidance must be read and understood to be effective. Smoking in the household, diet, and obesity also matter, as does the incidence of co-sleeping.

"Although the association with structural racism may be difficult to appreciate at first glance, it must be remembered that perceptions and assumptions drive the vehicle that produces the factors that result in this disparate rate. The socioeconomic factors are at once apparent, but it does not stop there."

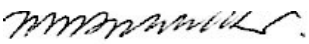
However, how do we combat these issues? How do we effectuate change when many of these factors are related to generational practices that, again, are related to structural racism? These behaviors are set within these individuals, poverty is rooted in these communities, and these unsafe practices are now part of a tradition that will not disappear. The answer is that we must. It goes beyond advocacy; it defines caring. These statistics can only improve if we all do our part to be part of the positive change process. Casting blame perpetuates stereotypes and does not help those most impacted. Rather than argue the point, we must fix the problem.

"These statistics can only improve if we all do our part to be part of the positive change process. Casting blame perpetuates stereotypes and does not help those most impacted. Rather than argue the point, we must fix the problem."

The partnership with HMHBGA which has been supported by grant funding will help find specific solutions that are mindful of the considerations that might otherwise be overlooked and further perpetuate these issues. First Candle is part of that solution, and they deserve our attention, sincere support, and utmost respect.

Sincerely,

Mitchell Goldstein, MD, MBA, CML



Editor in Chief

NEONATOLOGY TODAY

Loma Linda Publishing Company

A Delaware "not for profit" 501(c) 3 Corporation.

c/o Mitchell Goldstein, MD

11175 Campus Street, Suite #11121

Loma Linda, CA 92354

Tel: +1 (302) 313-9984

LomaLindaPublishingCompany@gmail.com

Published monthly.

www.NeonatologyToday.net

Twitter: www.Twitter.com/NeoToday

NT

Envision is built for your career in neonatology — wherever it takes you.

With Envision Physician Services, you'll find opportunities that fit your needs, schedule and goals no matter where you are in your career journey.

We are currently featuring leadership and staff opportunities across the nation, so there's never been a better time to find your perfect fit.

WHY NEONATOLOGISTS CHOOSE ENVISION

- Diverse practice environments in attractive locations nationwide
- Competitive compensation and benefits
- Physician- and clinician-led practices with collaborative work environments
- Flexible and equitable scheduling
- Career development and leadership opportunities
- Comprehensive clinician wellness support

Full-Time, Part-Time, Per Diem and ENVOY Ambassador Team Opportunities.

Featured Neonatology Opportunities

- Baptist Medical Center East
  Montgomery, AL
- HCA Florida Fort Walton–Destin Hospital
  Fort Walton Beach, FL
- Medical City Arlington
  Arlington, TX
- Medical City Las Colinas
  Las Colinas, TX

Contact our experienced recruiters today at 855.367.3650 to learn more about our featured opportunities and see how you can advance your neonatology career with us.

Envision
PHYSICIAN SERVICES

LEARN MORE NOW

Erratum (Neonatology Today March, 2023

Neonatology Today is not aware of the erratum affecting the March, 2023 edition.

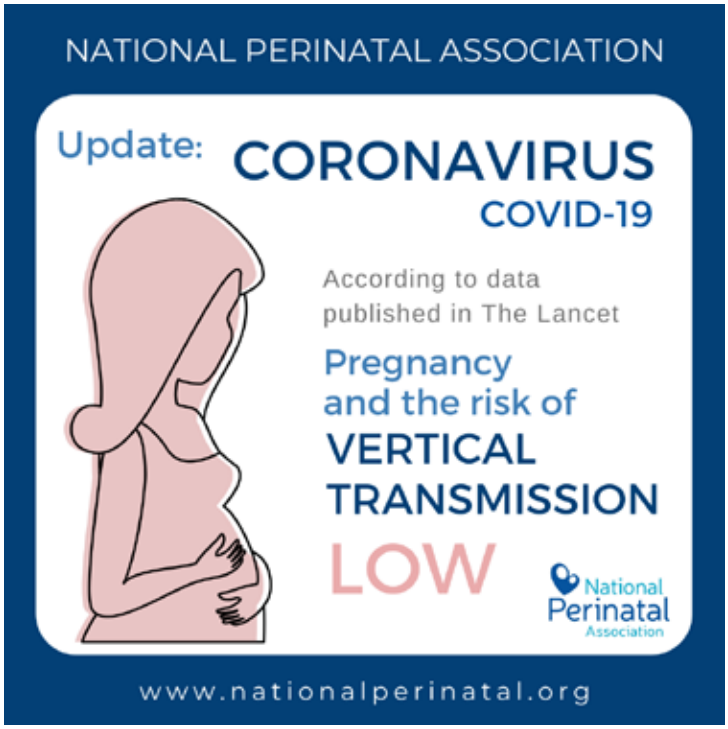
Corrections can be sent directly to LomaLindaPublishingCompany@gmail.com. The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from www.neonatologytoday.net.

NT

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

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

NT



BASED ON THE ARTICLE:

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

Fellow's Column: Co-Occurrence of Hyperleukocytosis and Candidemia in a Neonate: A Case Report

Violet Quann, OMS3; Anh-Tram Bui, OMS3; Mitchell Goldstein, MD, MBA, CML

"Normal white blood cell (WBC) count in neonates ranges from 9,000 - 30,000 cells/mcL. Leukocytosis, in which white blood cells increase up to 30,000 cells/mcL, is a well-documented and often physiological finding in neonates. Cases of hyperleukocytosis, however, are exceedingly rare, especially in extremely preterm infants."

Introduction:

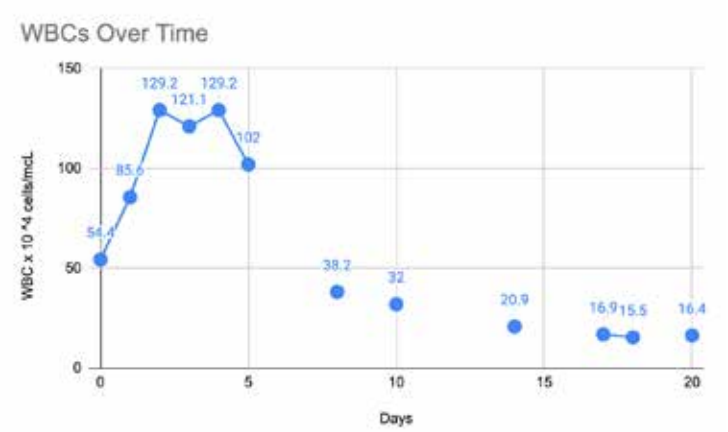
Normal white blood cell (WBC) count in neonates ranges from 9,000 - 30,000 cells/mcL. Leukocytosis, in which white blood cells increase up to 30,000 cells/mcL, is a well-documented and often physiological finding in neonates. Cases of hyperleukocytosis, however, are exceedingly rare, especially in extremely preterm infants. A WBC count of 100,000 cells/mcL or greater is cause for concern, as only a few differentials could be the cause. One must rule out congenital leukemia, transient abnormal myelopoiesis, leukocyte adhesion deficiency, and sepsis-induced leukemoid reaction (1). Only after they have been excluded can the diagnosis of neonatal leukemoid reaction be established. Complications of hyperleukocytosis are related to increased blood viscosity, including intracranial hemorrhage and renal and respiratory failure.

Candida is one of the most common organisms in the United States to cause a bloodstream infection (2). This infection is acquired from the environment, with risk factors including intubation, catheter placement, and those receiving total parenteral nutrition (TPN). In the neonatal population, additional risk factors include prematurity and low birth weight (<1000g). Some of the most severe complications of candidemia are meningitis, endophthalmitis, osteomyelitis, and endocarditis (3).

We present a co-occurring hyperleukocytosis and candidemia case in a preterm infant with favorable outcomes.

Case Presentation:

A 25-week-old baby girl was born at 740g to a G7P5 mother that received prenatal care and antenatal steroid therapy. APGAR scores were 5 at one minute and 9 at five minutes. However, the baby required respiratory support soon after birth and was intubated. The baby was admitted to the NICU for apnea of prematurity. On day zero, a routine sepsis workup showed her WBCs to be 54.4 cells/mcL, but her blood culture had no growth. On day two, her WBCs were 85.6 cells/mcL. On day four, the WBCs had risen to 129.9 cells/mcL, and the blood culture grew *Candida albicans*. The next day, her WBCs were down to 102 cells/mcL, which started a steep downward slope until the WBC count was within normal range by day fourteen, at 20.9 cells/mcL.



Management and Outcome:

In light of the high WBC count and risk for sepsis, given her prematurity and low birth weight, the baby was started on ampicillin, gentamicin, and azithromycin in the first few days of life. On day four, Vancomycin and Cefepime were started. Soon after, when the culture grew Candida, Fluconazole was added. Sensitivity came back on the culture on day fifteen, showing *Candida* resistant to Fluconazole, and the infant was switched to Micafungin, at which point the WBC was already within normal range.

"Soon after, when the culture grew Candida, Fluconazole was added. Sensitivity came back on the culture on day fifteen, showing Candida resistant to Fluconazole, and the infant was switched to Micafungin, at which point the WBC was already within normal range."

On day two, a head ultrasound revealed a grade two germinal matrix hemorrhage with mild ventriculomegaly, resolved by day nineteen. Serial chest x-rays were consistent with neonatal respiratory distress syndrome with the potential to develop into bronchopulmonary dysplasia. Both of these complications were consistent with hyperleukocytosis. Detection of possible complications from the candidemia included an eye exam and an echocardiogram, which revealed no intraocular fungal infection or endocarditis, respectively. The baby had a suspected seizure on day seventeen, received one dose of phenobarbital, and the EEG returned normal

shortly thereafter.

"The baby had no physical exam findings of congenital leukemia, including hepatomegaly, splenomegaly, papilledema, or skin lesions (5). The baby also did not present with delayed umbilical cord separation, bacterial infections, or absent pus formation, making leukocyte adhesion deficiency less likely (6)."

Discussion:

In cases of hyperleukocytosis, it is crucial to conduct a thorough investigation to rule out troubling diagnoses. The baby did not have Down Syndrome, which removes transient abnormal myelopoiesis from the differentials (4). The baby had no physical exam findings of congenital leukemia, including hepatomegaly, splenomegaly, papilledema, or skin lesions (5). The baby also did not present with delayed umbilical cord separation, bacterial infections, or absent pus formation, making leukocyte adhesion deficiency less likely (6). Considering the WBC count was within range before the *Candida* was known to be resistant and an effective antifungal administered, we can safely rule out sepsis as the cause of the hyperleukocytosis. Neonatal hyperleukocytosis is an extremely high WBC count that resolves spontaneously without an identifiable cause (7). The rate at which this patient's WBCs increased from birth to day four of life and re-normalized by day fourteen indicated neonatal hyperleukocytosis. The timeline of the blood culture growing *Candida* was consistent with late-onset sepsis. Late onset is defined as occurring >3 days after birth (8), and it affects 10-20% of extremely low birth weight babies (9). This baby had multiple risk factors for developing candidemia.

With the separation of these two disease processes, it is clear that this was a rare case of co-occurring candidemia and neonatal hyperleukocytosis.

References:

1. Parvez Y, Mathew AG. Hyperleukocytosis in Newborn: A Diagnosis of Concern. Indian Journal of Hematology & Blood Transfusion [Internet]. 2014 Sep [cited 2023 Apr 22];30(Suppl 1):131. Available from: https://doi.org/10.1007/s12288-013-0305-5
2. Greenberg RG, Benjamin DK Jr. Neonatal candidiasis: diagnosis, prevention, and treatment. J Infect. 2014 Nov;69 Suppl 1:S19-22. doi: 10.1016/j.jinf.2014.07.012. PMID: 25448311.
3. Kauffman CA. Complications of candidemia in ICU patients: endophthalmitis, osteomyelitis, endocarditis. Semin Respir Crit Care Med. 2015 Oct;36(5):641-9. doi: 10.1055/s-0035-1562891. Epub 2015 Oct 5. PMID: 26437407.
4. Bhatnagar N, Nizery L, Tunstall O, Vyas P, Roberts I. Transient abnormal myelopoiesis and AML in Down syndrome: An update. Curr Hematol Malig Rep. 2016 Oct;11(5):333-341. doi: 10.1007/s11899-016-0338-x. PMID: 27435308.
5. Calvo C, Fenneteau O, Leverger G, Petit A, Baruchel A, Méchinaud F. Infant acute myeloid leukemia: A unique clinical and biological entity. Cancers (Basel). 2021 Apr 8;13(4):777. doi: 10.3390/cancers13040777. PMID: 33917962; PMCID: PMC8066802.
6. Justiz Vaillant AA, Ahmad F. Leukocyte Adhesion Deficiency. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470537/
7. Duran R. The relationship between leukemoid reaction and perinatal morbidity, mortality, and chorioamnionitis in low birth weight infants. Int J Infect Dis. 2010 Nov;14(11):998-1001. doi: 10.1016/j.ijid.2010.06.012. Epub 2010 Sep 8. PMID: 20825929.
8. Flannery DD, Edwards EM, Coggins SA, Horbar JD, Puopolo KM. Late-onset sepsis among very preterm infants. Pediatrics. 2022 Dec;150(6):e2022058813. doi: 10.1542/peds.2022-058813. Epub 2022 Nov 16. PMID: 34786767.
9. Fu J, Ding Y, Jiang Y, Mo S, Xu S, Qin P. Persistent candidemia in very low birth weight neonates: Risk factors and clinical significance. BMC Infect Dis. 2018 Sep 3;18(1):439. doi: 10.1186/s12879-018-3487-9. PMID: 30176802; PMCID: PMC6121286.

Disclosures: *Authors have no competing interests to declare.*

NT

Corresponding Author

Violet Quann, OMS III
3rd Year Medical Student
College of Osteopathic edicine of the Pacific
Western University of Health Sciences
Pomona, CA
Email: violet.quann@westernu.edu

Anh-Tram Bui OMS III
3rd Year Medical Student
College of Osteopathic edicine of the Pacific
Western University of Health Sciences
Pomona, CA

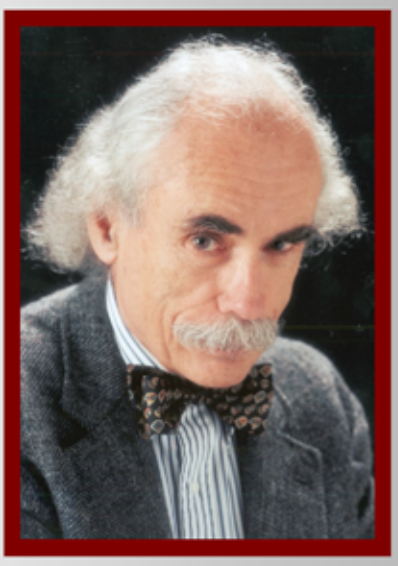
Fellow's Column is published monthly.

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

Elba Fayard, MD, Interim Fellowship Column Editor
or Saba Saleem, OMS IV Fellowship Column Assistant Editor
LomaLindaPublishingCompany@gmail.com

Mitchell Goldstein, MD, MBA, CML
Professor of Pediatrics
Loma Linda University School of Medicine
Division of Neonatology
Department of Pediatrics
Email: mgoldstein@llu.edu

LAWRENCE D. LONGO, MD
CENTER FOR PERINATAL BIOLOGY



Fifth Annual

Longo Symposium

Keynote Address

Mana Parast, MD, PhD

Professor, Department of Pathology
Director, Perinatal Pathology Service
Co-Director, Center for Perinatal Discovery
University of California San Diego

Invited Speakers Include:

Yalda Afshar, MD, PhD
University of California
Los Angeles

Laura Brown, MD
University of Colorado
Anschutz Medical Campus

Brian Cox, PhD
University of Toronto

Elizabeth Enninga, PhD
Mayo Clinic

Terrie Inder, MD
Children's Hospital of
Orange County (CHOC)

TUESDAY,
APRIL 25, 2023

UNIVERSITY CHURCH FELLOWSHIP HALL

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

LOMA LINDA UNIVERSITY
School of Medicine

ACCREDITATION STATEMENT

The Loma Linda University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.
The Loma Linda University School of Medicine designates this Live Activity for a maximum of **4.75** *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

DISCLOSURE STATEMENT

This program has been planned and implemented in accordance with ACCME essentials and standards. The Loma Linda University School of Medicine Office of Continuing Medical Education relies on its CME faculty to provide program content that is free of commercial bias. Therefore, in accordance with ACCME standards, any faculty and/or provider industry relationships will be disclosed and resolved.

DRINKS, WI-FI AND GRATUITY INCLUDED

7-Night Pacific Coastal CME AWAY® Cruise
October 8-15, 2023
On board Celebrity Eclipse

COMPANION CRUISES FREE!

NEONATAL CARE CONFERENCE AND WORKSHOP 2023

SCAN FOR DETAILS

IN PARTNERSHIP WITH

CME away CRUISE

ACADEMY OF NEONATAL CARE

Celebrity Cruises

Prices shown are CME AWAY® group rates. Additional stateroom categories and promotions may be available. Please ask your CME AWAY® Advisor.

Rates as of June 15, 2022		PASS. 1	PASS. 2
I3 – Prime Insider	Sitting area w/ sofa, LCD TV, vanity	$1,698	FREE
I2 – Oceanview	Large window, sitting area w/ sofa, LCD TV, vanity	$2,298	FREE
V3 – Veranda—Partial View	Floor-ceiling sliding glass door, sitting area w/ sofa, LCD TV, vanity	$2,598	FREE
V2 – Veranda	Floor-ceiling sliding glass door, sitting area w/ sofa, LCD TV, vanity	$2,708	FREE
C2 – Concierge Class	Floor-ceiling sliding glass door, sitting area w/ sofa, LCD TV, vanity	$3,108	FREE
A2 – Aqua Class	Floor-ceiling sliding glass door, Sitting area with sofa, LCD TV, vanity (max. 2 people / room)	$3,508	FREE

*Price staterooms are located in preferable areas of the ship—i.e. high deck and/or midship.

CONFERENCE TUITION	$ USD
Family Physician	$ 1,100
Specialist	$ 1,100
Resident or Retired, Respiratory Therapists, CNS's, RN, NP, PA, Other	$ 500

Frequent Traveller With CME AWAY® by Sea Courses? Ask your Advisor about tuition discounts!

FLEXPAY

Ask us about FlexPay, which allows you to fully customize up to 10 automatic payments that can be arranged by date and amount. No fees, ever.

Peer Reviewed

Impaired Engagement in High-Reliability Organizing (HRO): 2. Information Impairs Engagement

Daved van Stralen, MD, FAAP, Sean D. McKay, , Errol van Stralen, Thomas A. Mercer, RAdm, USN (Retired)

Abstract

Information has specific qualities that adapt it for engagement. Correlation as a descriptive term strengthens engagement, while causation as an explanatory term can mislead engagement. Information flows and has a contextual range of values and can combine with local experience. Information is stored as revisable (belief) versus not revisable (knowledge). Information reduces uncertainty, except in the flux of rapidly changing events. Disturbances and disruptions make the gap between stable and unstable situations and between theory and practice visible. Theories, classifications, and the standards necessary for high-risk operations can become idealized, impairing information and engagement. The belief that more data illuminates the problem and directs us toward the solution will occupy valuable assets. Data collection in these 'reddened' environments increases information variance, disintegrating reliability during the flux of events.

"Theories, classifications, and the standards necessary for high-risk operations can become idealized, impairing information and engagement... Data collection in these 'reddened' environments increases information variance, disintegrating reliability during the flux of events."

Introduction

Information combined with our emotions feeds our imagination. Our imagination can help us or hurt us. It is not information that drives action; it is the inferences we make from that information that drives action. Logic is a structured method to generate inferences from the information. The inferences we generate from classical logic do not drive action.

We assume an orderly, white-noise, logical, information-sensitive world (information-reducing variance). We see ourselves as logical and not swayed by emotion, stress, or fear. Nevertheless, it is a reddened and pink noise world with forcing functions and abrupt events that are information insensitive (more information increases variance). We follow modal and paraconsistent logic and use emotion to give value and meaning to information. Stress and fear make us more effective.

We will wait for more information and process it as it arrives. Our efforts to deny stress and fear counterintuitively worsen stress responses and fear-circuit behaviors. We become susceptible to their inherent vice. Therefore, the reliance on the information, particularly precise digital data, and the use of classical logic impair engagement.

"We will wait for more information and process it as it arrives. Our efforts to deny stress and fear counterintuitively worsen stress responses and fear-circuit behaviors...Therefore, the reliance on the information, particularly precise digital data, and the use of classical logic impair engagement."

Information

"Information is like a hot potato. Don't hold onto it. Toss it to someone else." Los Angeles City Firefighter.

In early descriptions of their experience with High-Reliability Organizing, the authors described HRO as the basic characteristics of *information flow* and *authority migration* (the authority to make decisions). Information flows to those who need or might need to know. Authority migrates to those who need to make decisions. This forms a topological network that overlays the organization's hierarchy.

"Information flows to those who need or might need to know. Authority migrates to those who need to make decisions."

There are many uses for the term "information." A useful description of information, one that avoids confusion between information and data or knowledge, is that *information reduces uncertainty*. Information and data support models of leadership and management, the evaluation and management of patients, and healthcare professional education and training. This is the objective, decontextualized normative stance for theory and *scientific rationality* (1).

Scientific theory and rationality aim to represent an "outside" view of the world, a dispassionate, objective representation disinterested in personal experience and practical concerns. Academicians

make theories without practice to create the *scientific subject domain* (2).

Theories and standards can become idealized, developing their inertia to insinuate themselves into the environment. This inertia can give the appearance of stability, or it may occur during calm periods of very long period red noise environments. New descriptions of reality are repeated until they become true. The origins and functions of HRO become washed out as it begins to resemble conventional business and organizational science models.

"Theories and standards can become idealized, developing their inertia to insinuate themselves into the environment. This inertia can give the appearance of stability, or it may occur during calm periods of very long period red noise environments."

People introduced to HRO then have a new baseline, but one that has shifted (3). However, the contingencies of the actual world cannot change. Such contingencies create gaps between information from idealized theories and information found in actual events. Common sense accommodates the slips that occur between ideal theories and the contingencies of practice (4, 5).

The world of practice has regular disturbances and disruptions. Operations occur in the context of an environment that can unexpectedly change. Transient information must be constantly evaluated and judged if not local and ephemeral. Operators in the field develop their logic of practice built upon contextual relations entwined with people and work (6). This subjective contextualized pragmatic stance aligns with personal, affective judgment to form *practical rationality* (1).

Disturbances and disruptions make visible the gap between stable and unstable situations and between theory and practice. We prevent the consequences that develop from the uncertainties in these gaps. Reliability is more assured when practical engagement dominates, when practice adjusts to the flux of circumstances. HRO supports engagement to reduce consequences (1). A theory of engagement as practice will move theory into the practical world, closing the gap between theory and practice (2).

> "Moreover, we have highlighted that engaged activity is characterized by [an] interplay of practical, non-deliberate coping and instances in which we encounter the world as 'present' in moments of breakdown. In such instances, things stand out and matter to us in terms of our particular situation and our projected ends…Breakdowns may thus resemble what Weick (7) refers to as 'vantage points,' which allow for the discovery and interpretation of relevancies that had previously been invisible" (2).

Increasing information will decrease variance and uncertainty in white noise environments where no event or energy frequencies dominate (Table 1). This is a property of the Gaussian distribution, descriptive statistics, and event probabilities—more information improves statistical values and refines probability predictions. These information-sensitive systems match the decontextualized normative stance of theory and scientific rationality.

However, increasing information will increase variance in an environment with reddened noise, described by power functions (Table 1). The counterintuitive consequence is that more information *increases* uncertainty. These information-insensitive systems respond better to a contextualized pragmatic stance with personal, affective judgment and practical rationality.

"However, increasing information will increase variance in an environment with reddened noise. The counterintuitive consequence is that more information increases uncertainty."

Paradoxically, we engage a system moving toward thermodynamic disorder—increasing entropy. For that reason, we subscribe to Claude Shannon's information entropy theory—information is the change from certainty to uncertainty. Information is uncertain because if you know something for certain, it is not information while moving from uncertainty to certainty-generated information (8).

Shannon presented a mathematical demonstration that information behaves similarly to energy in thermodynamics—the entropy of information measurably increases as uncertainty (randomness) increases during communication (8). Shannon founded the field of information theory, and his work forms the basis of today's digital information systems. (Shannon also coined the computer term "bit," short for binary digit.)

"The problems of communication in a stable environment by similar operators are the most basic, encoding, transmitting, and decoding. In the environment of an HRO, both the context and the operators are likely different. Varying contexts impart heterogeneity to the information."

Communicating Information

Communication organizes and transfers information across time and space. The problems of communication in a stable environment by similar operators are the most basic, identified by Shannon as encoding, transmitting, and decoding (8). In the environment of an HRO, both the context and the operators are likely different. Varying contexts impart heterogeneity to the information (4).

In Communication Theory, information becomes corrupted (information is lost) as it is transmitted, similar to the entropy of any system moving toward disorder of its elements (8). *Communication corrupts information.* Karl Weick adds HRO to this phrase (personal communication, DvS), "Communication *without calibration* corrupts information."

Besides corrupting information, the transmission increases the

Table 1. Patterns and Characteristics of Noise (9)

Color	Structure	Variance	Distribution
White	No frequencies dominate Flattened spectrum Environmental stability	Information *sensitive* Data *decreases* variance	Gaussian distribution - Elements fully independent - No autocorrelation
Red	Low frequencies dominate Long-period cycles Infrequent events carry more power = forcing functions	Information *insensitive* Data *increases* variance	Power law distribution - Elements *not* independent - Mutual/reciprocal relations
Pink	Midpoint of red noise Slope lies *exactly* midway between white noise and brown (random) noise Events are abrupt and catastrophic	Information *insensitive* Data *continuously increases* variance (*Continuous* increase distinguishes pink noise from reddened spectra)	Power law distribution - No well-defined long-term mean - No well-defined value at a single point

heterogeneity of the information by moving information from one context to another. The information resides in more than one context, and it is that context that gives information its meaning and relevance. Information is situated within contexts. To maintain the continuity of contexts, we use representations such as classifications and standardization (4). Communication across contexts, without shared classifications, will also corrupt information. We see this in the vertical hierarchy of a hospital. Administrators and legal counsel may lack the necessary experience from intimate patient contact. The lack of such experience impairs their ability to appreciate the practical classifications used for disease evaluation, management, and patient care. However, they control the funds and make or influence the policies.

"Besides corrupting information, the transmission increases the heterogeneity of the information by moving information from one context to another. The information resides in more than one context, and it is that context that gives information its meaning and relevance."

Corrupted, heterogeneous information looks like valid, reliable information. While this impairs effective engagement, a veteran operator treats all information with a rapid, investigative process like the inductive process described by Leonhard Euler (10) in George Pólya (11):

> "The kind of knowledge which is supported only by observations and is not yet proved must be carefully distinguished from the truth; it is gained by induction as we usually say…Indeed, 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."

"Corrupted, heterogeneous information looks like valid, reliable information."

The Assumptions of Data

The allure of data comes from the Gaussian distribution—more data *decreases* the variance of information, which increases the reliability of that information. Reliable information improves our ability to find solutions operating within *information-sensitive* systems. Gathering information becomes a legitimate focus for problem-solving and operations.

"... more data decreases the variance of information, which increases the reliability of that information. Reliable information improves our ability to find solutions operating within information-sensitive systems."

On the other hand, more data in a red or pink noise environment increases variance. Collecting more data, thus, creates confusion and is counterproductive. Red and pink noise environments are *information-insensitive but* not feedback insensitive. Engagement generates information through feedback in real-time despite any rapid change in human performance or flux within the environment.

Ventilator management for awake, breathing patients demonstrates the different conclusions derived from data (the

blood gas) versus engagement (hand ventilation). The blood gas delineates the current situation, guiding the physician's choice of settings. *The situation drives decisions*. Hand ventilation, on the other hand, identifies the ventilation characteristics that calm the patient, which can prevent patient-ventilator asynchrony and reduce unintended loss of the airway. *Consequences drive action.*

"On the other hand, more data in a red or pink noise environment increases variance. Collecting more data, thus, creates confusion and is counterproductive. Red and pink noise environments are information-insensitive but not feedback insensitive."

While both data-driven and engagement approaches maintain similar oxygen levels, they use information differently (Table 2). Information for the quantitative, data-driven approach favors precise (digital is more trusted) objective measurements, primarily pH and carbon dioxide levels. Information from qualitative engagement comes from the operator's interaction with the problem and environment, favoring feedback, subjective interpretations, and subjective evaluations. The focus is on the operator's actions and the patient's physical and mental response.

Through blood gas analysis, we fit the situation of the patient's respiratory status into our understanding of respiratory physiology and ventilator mechanics. We extend our understanding of respiratory physiology through hand ventilation into the brain. We can primarily fit the situation into our understanding—a data analytical approach. Alternatively, we can use what we learn from engaging in the situation to extend our understanding—synthesis through engagement (12).

Managing a mechanical ventilator for comfort is not new. The effect of respiratory rate on comfort was described in a 1947 curare study (16). It also demonstrates how engagement bridges the gap between theory and practice. The volunteer subject received curare stepwise. Despite the usual ventilation rate of 18–20 breaths per minute, he described shortness of breath with adequate ventilation and oxygenation. A ventilation rate of 24 breaths per minute relieved the dyspnea. (This study was the first to prove thinking occurred in the central, rather than the peripheral, nervous system.)

More recently, in 2000 and 2002, researchers found that restricting tidal volume caused air hunger from vagal afferents from the lung to the anterior insula (17, 18). *Higher* tidal volumes transmit to the insula by the dorsal vagus nerve, inhibiting the amygdala and sympathetic nervous system activity (19, 20). This supports the use by veteran operators of the command, "Take a deep breath." They had observed shallow breathing by the novice and knew from experience that a deep breath could break the fear or anxiety experienced by the novice.

Through engagement, one author (DvS) worked with a team of RCPs to initiate and manage mechanical ventilators in a free-standing pediatric subacute facility (21, 22). They initially used patient calm as the endpoint. With experience, they learned to use mechanical ventilation to enhance the child's life—they used a smile as the endpoint (23). The tension between approaches, blood gas analysis, and smile/sensation results from philosophies favoring the predictability of data or the uncertainty of engagement.

Physicians accustomed to intensive care ventilation relied on blood gas analysis and a well-controlled airway to protect the lungs from damage. These patients are closely monitored in a controlled environment. Physicians supporting patients with long-term mechanical ventilation monitor the patient's cognition and affect in a healthcare facility, the home, or public spaces. A calm, comfortable patient assures safety. Long-term mechanical ventilation occurs in a different context, a new vantage point "for the discovery and interpretation of relevancies that had previously been invisible" (7). Disagreements in the different approaches are a false debate created by arguing across different levels of analysis.

The belief that more data illuminates the problem and directs us toward the solution will occupy valuable assets. Within the constrained spectrum of a closed system, data analysis can fill in the spaces of missing information—puzzle solving (15). In a reddened noise environment, we recommend prudence when generating information rather than at the expense of achieving control or building structure. Data collection in these 'reddened' environments increases information variance, disintegrating reliability during the flux of events. Keep in mind that even slow-moving events are the result of reddened noise. Information as data will not fill gaps when we are "mystery solving" (15). This is the "I Am Data Driven" Fallacy.

"The belief that more data illuminates the problem and directs us toward the solution will occupy valuable assets... In a reddened noise environment, we recommend prudence when generating information rather than at the expense of achieving control or building structure. Data collection in these 'reddened' environments increases information variance, disintegrating reliability during the flux of events...Information as data will not fill gaps when we are 'mystery solving.' This is the "I Am Data Driven" Fallacy."

Information Usage

Information has specific qualities that adapt it for engagement. Information flows and has a contextual range of values and can combine with local experience (24).

Information Has a Range

Information has a range of possibilities or configurations compatible with the information available in the system at any given state or time. This allows information to adapt to local circumstances, be revised during an engagement, and be updated over time. Information can be supported and not

Table 2: Information Usage for Data and Engagement

Method	Blood Gas	Hand Ventilation
Information	Data-driven	Engagement
Objective	pH and CO_2 level	Calm patient
Flow Specifications	Whole field view External, fixed point Quantitative	Local groupings Within flow Qualitative
Quality	Precision	Accuracy
Reasoning	Deduction Facts *guarantee* the conclusion	Induction Evidence *supports* the conclusion
Decision-making	Analysis Confirms knowledge	Synthesis Creates knowledge
Problem Structure (13)	Well-structured problem Algorithm, Protocol	Ill-structured problem Heuristics
Decision-Problem Condition (14)	Trivial problem The situation dictates interventions	Undefined problem The objective guides interventions
Full Spectrum Analysis (15)	Puzzle Solving	Mystery Solving

supported by local possibilities (the "information range") (24). This at first seems trite, but in classical logic and deductive reasoning, propositions must be true or false, and new information does not change a hypothesis once it is logically proven or after a deductive conclusion is reached.

"Factive and non-revisable information is considered hard information, corresponding to knowledge. Information that may or may not be factive, therefore revisable with new information, is considered soft information, corresponding to belief."

Factive and non-revisable information is considered hard information, corresponding to knowledge. Information that may or may not be factive, therefore revisable with new information, is considered soft information, corresponding to belief. These differences develop from how the information is stored rather than the type of information: revisable (belief) versus not revisable (knowledge) (24). This has a bearing on the logic operators that act on information. Epistemic logic is the logic of knowledge, while doxastic logic is the logic of belief.

Classical logic does not allow us to use incoming, contradictory information for inference (25). Motivated reasoning (26, 27) is an example of over-scrutinizing information inconsistent with one's knowledge or belief.

"Trustworthiness reflects one's experience, ability to manage shifting information, and capability to identify and correct wrong information rapidly."

Adjusting to new information involves the reliability or trustworthiness of the incoming information and our attitude toward new or disconfirming information. Trustworthiness reflects one's experience, ability to manage shifting information, and capability to identify and correct wrong information (25) rapidly. One of the authors (DvS) would offer a factive statement unfamiliar to the team to evaluate inexperienced PICU staff and residents. Reactions ranged from anger at the provocation, quizzical to interested. The reactions also mirrored how the individual would later respond to an evolving, novel, and unexpected crisis—would the individual evaluate or reject information that disconfirms their initial assumption?

What makes this important is that epistemic and doxastic logics are *nonmonotonic logics.* That is, classical logic is monotonic logic. It does not allow revision of the conclusion even in the presence of disconfirming facts. Many in healthcare use the principles of classical logic without appreciating that the conclusion cannot be revised. The inferences from adaptive, nonmonotonic logic

change as information becomes available and premises expand the external dynamic. The internal dynamic describes withdrawing the inference rule should we encounter a contradiction (28).

Belief change, rather than knowledge change, can be static or dynamic. Static belief change refers to a fixed, unchangeable truth or principle. While the principle does not change, our belief *about* the principle does. That is, the situation is *unchanging*. Dynamic belief change refers to the principle and belief changes—each or both can change. The situation is *changing* (25).

"We collect contradictory data, accumulate inconsistent information, and find that increasing information increases the variance... 'Handling contradictory data is one of the most complex and important problems in reasoning under uncertainty.'"

We collect contradictory data, accumulate inconsistent information, and find that increasing information increases the variance (29–31). We invalidate and change our conclusions and derived solutions, processes not permitted in monotonic classical logic (32, 33). "Handling contradictory data is one of the most complex and important problems in reasoning under uncertainty" (30). These are the paraconsistent logics. Formalized modes of *nonmonotonic reasoning* give "rules of conjecture" rather than "rules of inference." Adding new assumptions can disconfirm conclusions appropriate in one set of assumptions (34).

Information as Correlation

Correlation allows a part of a structured information environment to carry information *about* another part. This is not trivial, as described in the corruption of communication by its transmission. Information is contextual but also situated in locales. Lack of familiarity with a different locale changes the meaning and relevance of information.

One of the authors acted as a *pro bono* expert witness for a team of EMS medics about to lose their paramedic certification for failure to communicate from a major traffic collision. The base station nurse reported their failure to respond to queries from the base hospital physician. The author made a short investigation with the pro bono attorney, James O. Page, the LA County Fire Battalion Chief who helped create the California paramedic program. The collision occurred on a mountain pass where mountains interfered with radio communication. They placed their radio 100 yards from the collision to contact the hospital. The delays occurred because of the distance the medics had to traverse between the radio and the collision site. As simple as this seemed, the government agency and hospital base station staff maintained that the medics should have responded promptly. Shortly before the hearing, the agency dropped the charges. The information did not correlate between the field and the hospital.

Classification and standardization can solve the problem of information correlation in a white-noise environment. Precision supports distinct classifications, while standardization gives meaning to precision. Precision is reliable in white noise systems as we see repeated or similar actions which produce predictable results. That reliance on precision, such as ICD-10 or DSM codes, leads to loss of information while classifying a situation.

"Classification and standardization can solve the problem of information correlation in a white-noise environment. Precision supports distinct classifications, while standardization gives meaning to precision. Precision is reliable in white noise systems as we see repeated or similar actions which produce predictable results. That reliance on precision, such as ICD-10 or DSM codes, leads to loss of information while classifying a situation."

The problem arises from who sets the standards. Making sense in one context does not necessarily make sense in another, even between a physician and nurse standing by the same neonate. "One person's standard is another's confusion and mess," Leigh Star (4)—standardization and communicating across contexts also corrupt information.

Information flow

Information flows through correlated elements in a system. This occurs through organizational design, customarily hierarchical, and by the strength of relations between individuals and groups, forming topological patterns. Information is situated and accessible. That is, one part of a system carries information about another part or is constrained to the information that can be carried (24). Information flow, therefore, reflects the organization's culture through cooperation, decision-making, and quality of life (35, 36).

"Information flow, therefore, reflects the organization's culture through cooperation, decision-making, and quality of life."

Cooperation. Trust breeds cooperation, increasing the sharing of information. Internal consulting, for learning, increases technical knowledge and familiarity with dangers. When information becomes a political commodity, helping friends while harming enemies, the flow of information stops or becomes directed for personal gain rather than to fulfill the organization's mission. Using information as a weapon degrades the quality of available information and impairs the desire to engage and the quality of that engagement (35).

The quality of decision-making. Complete information and transparent processes are integral to decision-making but

also for review as information flows through the organization. Decisions are made in a closed environment from a lack of Trust in subordinates or when others attack decisions. These decisions do not carry reliable information, impairing the ability to engage effectively (35).

"Trust breeds cooperation, increasing the sharing of information. Internal consulting, for learning, increases technical knowledge and familiarity with dangers. When information becomes a political commodity, helping friends while harming enemies, the flow of information stops or becomes directed for personal gain rather than to fulfill the organization's mission. Using information as a weapon degrades the quality of available information and impairs the desire to engage and the quality of that engagement."

The quality of life. An organization with efficient information flow also does better with its people. Knowing superiors receive and share information increases the participation and creativity of its members (35).

The drive for efficiency in an organization can unintentionally block information flow. Minimal environmental change occurs when a red noise environment has long frequencies. Because this mimics the stability of white noise, leaders can successfully develop a structured, rule-driven system. All major thinking occurs in the central part of the organization. Over time, the flow of information diminishes as the periphery becomes marginalized and the central part comes to the protection of its status (37).

"Bureaucratic organizations use standard channels or procedures for information flow, often inefficient during a crisis. Departments have their own rules and protect themselves. Work is done by the book."

The patterns of information flow in an organization can also be used to describe a typology of organizational culture (36):

- *Pathologica*l. A preoccupation with personal power, needs, and glory.
- *Bureaucratic*. A preoccupation with rules, positions, and departmental turf.
- *Generative*. Concentration on the mission of the organization.

"Generative organizations freely move needed information on time—'Who needs the information now?' The most important goal is accomplishing the mission; everything is subordinated to good performance. Information and decision-making will cross departmental lines if necessary. These organizations tend to be proactive."

Generative organizations freely move needed information on time—"Who needs the information now?" The most important goal is accomplishing the mission; everything is subordinated to good performance. Information and decision-making will cross departmental lines if necessary. These organizations tend to be proactive (35, 36).

"Pathological organizations have large amounts of fear and threat that create the ecology of fear. People may distort information to make themselves look better or use it to embarrass and hurt individuals."

Bureaucratic organizations use standard channels or procedures for information flow, often inefficient during a crisis. Departments have their own rules and protect themselves. Work is done by the book (35, 36), which is also a means to sabotage a factory (38, 39).

Pathological organizations have large amounts of fear and threat that create the ecology of fear (40). People may distort information to make themselves look better or use it to embarrass and hurt individuals (35, 36).

The "Correlation of Causation" Paradox

In the 1970s, two street gangs were moving into South Los Angeles—the Crips and the Pirus (later becoming the Bloods). Serving on a fire rescue ambulance (RA), one of the co-authors (DvS) would encounter individuals dressed or acting like a gang members. This was before gangs began to wear common clothing and colors. Whether the clothes, attitudes, or behaviors were related, gang membership did not matter. At the time, it was sufficient for the medics to know the correlation to protect the patient and bystanders. Law enforcement and fire companies did not respond to these calls unless the RA called in a request.

That correlation did not mean causation was common sense to the fire rescue ambulance medics. The correlation between gang attire and attitudes made one think of the gang. However, the individual may be a young initiate full of posture, an outsider

wanting the attention of gang membership, or a more innocent individual dressing in the local gang's manner for protection or being left alone. Each scenario necessitated a different approach, even in a mix of these individuals. Choosing wrong could affect the way other medics would be treated. We also considered the individual, subtly guiding them away from the gang.

When engaging uncertainty, we are vigilant for findings that indicate unrecognized threats. These observed entities do not necessarily cause threats but correlate with them. Observing one prepares you for the other. Interventions are based on these correlations without consideration of cause. It, therefore, seemed odd to one co-author that EMS physicians would quote, "Correlation does not mean causation" during discussions with paramedics wanting to understand on-scene medical care better.

"That correlation did not mean causation was common sense to the fire rescue ambulance medics."

An early form of cliché-as-argument was a pipe-smoking statistician discussing early findings that correlated smoking with cancer. "Such results suggest that an error has been made, of an old kind, in arguing from correlation to causation; we cannot argue from Correlation to causation" (41). "The association observable between the practice of cigarette smoking and the incidence of cancer of the lung…has been interpreted…as though it demonstrated a causal connexion between these variables" and "Dr. Bradford Hill while admitting that the evidence of association found by his Unit did not amount to proof of causation" (42). These cited quotations are from Ronald A. Fisher, the statistician who developed the Analysis of variance (ANOVA), introduced the null hypothesis, proposed the level of $p = 0.05$, and developed a modern experimental design. In dangerous contexts, sometimes association or correlation is all you have…and it saves your life.

"Correlation does not mean causation" is a "thought-terminating cliché," a phrase used to depreciate information or block analytical thinking. Once someone uses such a phrase, the speaker requires no further argumentation, and no argumentation is allowed by others. It is a form of "loading the language" used during indoctrination processes. Complex problems are compressed into brief, definitive-sounding phrases that can be easily memorized and expressed. To others, these phrases cause constriction and linguistic deprivation (43). This is "cliché-as-information."

"'Correlation does not mean causation' is a 'thought-terminating cliché,' a phrase used to depreciate information or block analytical thinking."

However, there is a relationship between correlation and causation. "*Correlation* is a descriptive term with empirical relevance, while *causation* is an explanatory term associated with theoretical attempts to understand correlations" (44).

Perhaps the priority of causation over correlation derives from the idea that all knowledge derives from Immanuel Kant's (1724–1804) idea of concepts. Kant presented concepts from specified delimited categories. The fundamental principle within a concept is causation. Refined since Kant's original work, concepts have become a foundation of modern science (45). Causation is fundamental to scientific theories.

Discarding information because it correlates with, rather than causes, events creates new openings for unexpected failure.

Correlation and causation also influence the type of information used: *description* versus *explanation*. "Causation implies correlations between cause and effect, but this does not always apply the other way around: correlations between two systems can result from a common cause in their history rather than from a direct causal interaction" (44). Causal relations are interactions that explain observed correlations.

"However, there is a relationship between correlation and causation. 'Correlation is a descriptive term with empirical relevance, while causation is an explanatory term associated with theoretical attempts to understand correlations.'"

Both correlation and causation can initiate engagement. Identifying correlations for information use while proving and disproving various correlations can drive engagement past what is known. This is the language of description. On the other hand, searching for causes or relying on causation is fraught with danger:

- Emergent properties occur from nonlinear interactions at the local level. Though scientific principles do not change, emergent properties are often novel and may not fit into conventional schemes of description or action. Causation can be nonlinear.
- Unrecognized influences or limitations of performance may become apparent through "errors" or "mistakes" (39). Correcting errors or rectifying mistakes distract from the investigation of unrecognized influences and will change the value of information. Causation can be occult.
- The representativeness heuristic, what is seen represents what is happening, biases us to regard partial information as complete information (46). Causation may not represent events.

Describing plans and events by cause and causation changes the information used for planning, education, and training. The formed language will direct people to identify the situation, search for an occult cause or treat the representative cause. Engagement focuses on reducing consequences by engaging before the situation can be fully identified.

Information as Code

To work with information, whether for computation or transmission, we must encode it. This gives definitions and syntax that novices must learn. Reason and logical inference are how we handle information as a cognitive act. One of the authors (DvS) was present at a discussion with a newly graduated Nurse Practitioner. One physician asked about the most challenging part of becoming an NP. "Learning to present a patient to a physician." Nurses

present patients by the physiologic system, giving each system's assessment, treatment, and plan. Physicians ask for all the information first, then the assessment, followed by the plan. The plan coming last was the most difficult part.

The author began listening to staff presenting a patient to a physician and observed the subtle conflict as the staff member would present a system and then stop, waiting for the physician to respond. Meanwhile, the physician would stand mute, waiting for the staff member to finish the presentation. We see this when a staff member approaches a physician, states the problem, then asks for orders. The physician stands, waiting for more information.

"Describing plans and events by cause and causation changes the information used for planning, education, and training. The formed language will direct people to identify the situation, search for an occult cause or treat the representative cause. Engagement focuses on reducing consequences by engaging before the situation can be fully identified."

Descriptions

Engagement is the empirical act of learning by doing. We do not engage with the randomness of trial and error. When we engage, we perceive details, utilize correlations, and communicate through descriptions. We act through correlations.

"Engagement is the empirical act of learning by doing. We do not engage with the randomness of trial and error. When we engage, we perceive details, utilize correlations, and communicate through descriptions. We act through correlations."

Explanations utilize causation, "why," or "how" an event occurred. When we explain an event, we use concepts and cause-and-effect (causation) (47, 48). Understanding through explanation forms the basis of formal education and the cognitive domain of learning. We understand through causation. Explanation as information may hint at causes or be treated with certitude because explanations are often privileged over descriptions.

In the turmoil of the liminal space, descriptions of how something is used, an action performed, or a situation experienced all carry meaning. Nothing is learned when we analyze with definitions. Too easily, labeling and defining things, rather than describing, becomes an unconscious act (49).

Rather, the *conscious* act of experience as a "cooperation of internal needs and external materials" converts 'cause-and-effect' into 'means-and-end' (Charles Sanders Peirce (50)). The "conscious intentions of a human being can influence the activities of his brain," which correlates intent with the outcome (51, 52). These *intent-outcome* correlations can constrain the individual's interactions with events (44), reducing unrestrained actions. Simple interactions can then transform into more complex participation (49). This is observation as cause-and-effect, used in the inductive processes described by George Pólya (53).

"Explanations utilize causation, "why," or "how" an event occurred. When we explain an event, we use concepts and cause-and-effect (causation). Understanding through explanation forms the basis of formal education and the cognitive domain of learning. We understand through causation."

In any new situation, we rapidly search for the familiar. We can use metaphors for description and analogies for reasoning. When the person using the metaphor has experience with the word or phrase, metaphors carry meaning and assist interpretation. Analogies have greater applicability to support interpretation and reasoning when the comparison has plausibility, increased similarities, and correspondences between domains.

Distance from the event, however, interferes with forming accurate descriptions, correlations, or causations. Individuals, instead, rely on rationalizations and the abstraction of clichés and metaphors to support and explain their judgments, interpretations, and actions (40). Without analogical strength, the metaphors and analogies become thought-terminating cliches (43). We cannot describe or argue against a metaphor or cliché.

Veteran operators can identify experience despite the use of cliché, slang, or jargon. One of the authors (DvS) listened in as a Los Angeles Fire Department captain described his experience on a promotion board for a large Midwest fire department. He remarked on the differences in operations and slang. Despite his unfamiliarity with their operations, he described the interviewees who knew their job but had difficulty discussing it. He could recognize their capabilities despite their constrained fluency. The interviewees who scored lower had all the right words in the right order, but they did not seem to have the wherewithal to operate their rig or command a fire company. That discussion regularly comes to the author when evaluating people for emergency operations. It most likely represents the difference between practical engagement and well-structured theory.

Responding to forcing functions, operators form *local groupings* (Lagrangian specifications, Table 3) and rely on *functional descriptions* for accuracy and relevance (54, 55). The operator moves within the event, continually influenced by the changing context. Unable to discern causation, these operators focus on context, identify correlations, and learn through engagement.

From the fixed-point *whole field view* (Eulerian specifications, Table 3) that lies outside the flux of events, the involved veteran operator uses *structural definitions* for precision and clarity. Leaders with less experience with the entire field view risk treating knowledge as

certitude, relying on normative standards, focusing on a precision-based error in the red noise environment, and micromanaging. Karl Weick (personal communication, DvS) observed that details could work against them. "The use of details without context is micromanagement," he warned. Micromanagement too easily gives a sense of participation.

"The risk of treating knowledge as certitude and reliance on normative standards is the greatest for spectators far from events, such as executives, academicians, or uninvolved observers. Information paradoxically becomes more confident with distance ."

Table 3: Specifications for the Flow of Events (56)

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

The risk of treating knowledge as certitude and reliance on normative standards is the greatest for spectators far from events, such as executives, academicians, or uninvolved observers. Information paradoxically becomes more confident with distance (57). "A story always sounds clear enough at a distance, but the nearer you get to the scene of events, the vaguer it becomes"—George Orwell describing shooting an elephant (58). Executives, administrators, and managers readily become spectators without realizing it.

Spectators will focus on what they already know. Unfortunately, this influences language and the form of information that is passed along. When micromanagement creates the ecology of fear, information becomes defensive for subordinates. It has been the experience of the authors that a reliable method to identify 'low reliability' in an organization is defensiveness in the use of information that leads to deference from engagement. In an ICU or ward setting, staff may report a medical problem in terms they believe will initiate a response from the attending. In one of the author's (DVS) numerous experiences, the staff member's choice of story was less than severe, alerting the author to the leadership culture of the unit.

Distance breeds not only certitude but expectations of precision in information. Reliance on causation, precision, definitions, diagnostic testing, and diagnoses becomes normative. The ostensible drive for clarity then usurps the "accuracy of ambiguity."

The Drive for Precision

Precision measures reduced variance necessary for smooth hardware functioning or operations in a white-noise environment. Structures that must *not* deviate from specifications require precision. That is, the system cannot tolerate variance from the specified value. These systems have no autocorrelation, meaning that measurements are independent and random. For precision, the error is a value that exceeds a threshold of what can be accepted. Compare precision to accuracy (Table 4), the proximity to the desired value or state. Accuracy improves with feedback, a form of autocorrelation. In a thinking, self-organizing system, internal feedback improves accuracy and operates toward allostasis.

The privileged nature of precision over accuracy supports the assumption that centralized authority reduces variance through well-developed rules and protocols. That is, precise methods of acting and operating will increase the reliability of operations. This belief has consequences for the interpretation of error. Precision relies on conforming to standards and following rules—the cultural values of *conformity* and *obedience*. Nonconformance becomes associated with disobedience and error rather than a sign of adaptability. Leaders and auditors become at risk of developing guard-like attitudes that protect patients and the organization from the actions of healthcare professionals.

Table 4: Precision versus Accuracy

Precision	Accuracy
Hardware	Human behavior
Obedience and Conformity	Initiative and Creativity
Assures our understanding	Extends our understanding
Applicable to white noise Gaussian distribution ("Six Sigma")	Applicable for red and pink noise Power distribution
Error identifies a structural defect.	Error generates information An error ensures safety by identifying boundaries of knowledge and performance.
Assures homeostasis	Supports allostasis

However, natural and expected fluctuations of events within the environment create gaps between these rules and fluctuating events. These gaps can confuse the selection of a rule or disagreement between operators in selecting the "correct" rule. The fear of error this creates can become widespread within the organization to create an organizational *ecology of fear* (40). In these organizations, the *fear* of error causes more harm than the errors themselves.

"The privileged nature of precision over accuracy supports the assumption that centralized authority reduces variance through well-developed rules and protocols. That is, precise methods of acting and operating will increase the reliability of operations. This belief has consequences for the interpretation of error. Precision relies on conforming to standards and following rules—the cultural values of conformity and obedience. Nonconformance becomes associated with disobedience and error rather than a sign of adaptability."

Precise information, such as digital measurements, often influences engagement actions more than analog measurements and vague or ambiguous information. Rather than being depreciated for difficulty or relegated to the "gray zone," the latter should drive inquiry. Vague or ambiguous information is more likely to be disregarded, while precise information often seems to stop the inquiry.

"Vague or ambiguous information is more likely to be disregarded, while precise information often seems to stop the inquiry."."

The Outlier as Information

Considering an uncommon or unexpected finding as random and independent contributes to valuing the observation as insignificant. Too far from the norm (expected) by multiple standard deviations (sigma), the observation is difficult to connect to an influence of current affairs. Hence, the phrase "RUN—Repeat Until Normal."

The meaning of an outlier differs between the consistency and predictability of white noise environments and reddened noise in the NICU. Operators classify outliers as signs of a developing process or a revelation of unknown structures. Outliers carry information.

Outliers in statistics are tiny populations of random, independent values. Outliers in probability are infrequent outcomes. Information of a developing problem, when presented as a slight extension of normal, readily becomes disregarded, decreasing the drive to engage.

"The meaning of an outlier differs between the consistency and predictability of white noise environments and reddened noise in the NICU. Operators classify outliers as signs of a developing process or a revelation of unknown structures. Outliers carry information."

Hearing hoofbeats, medical educators counsel that we should think of horses, not zebras. (Monty Python fans may think of coconuts.) However, zebras are the more dangerous, aggressive equines. For HROs and operators in dangerous contexts, the outlier, like the zebra, is the dangerous element. The outlier may represent an occult process, a singular event from a covert, compensated state. This is vigilance for discrepancies and early heralds of disruptions. What distinguishes vigilance from paranoia is information. Understanding the structure of events in a process, a slow wave of change that may or may not stop, informs vigilance. Ignorance of how a process might occur can create paranoia. We can influence a process if we know something about it and ourselves.

"Classifications and standards influence the descriptions, the presentation and sharing of information, and social knowledge. The formulation of categories and standards cannot help but favor one point of view over another, information is lost, and organizational values shift. This is not benign, as social knowledge will change, and some people will be harmed. There is an ethical component to structuring classifications and standards. Facts, reason, and causation influence classifications and standards more than correlations, values, and moral action. Classifications, standards, and causation too quickly diminish the salience, meaning, and relevance of the outlier, whether the outlier is a person, thing, event, or information."

Standards, including protocols and algorithms, make things work together across distance and time. Standards support reliability and predictability.

Concepts are a select type of classification and standards. Immanuel Kant developed the idea that knowledge as facts and concepts are included in preformed (a priori) categories and linked rigorously by laws of formal logic (47, 48). Something cannot exist except for its inclusion in a category that limits what knowledge is. Concepts provide the elements for comparison, standardization, and quantification.

Classifications and standards influence the descriptions, the presentation and sharing of information, and social knowledge. The formulation of categories and standards cannot help but favor one point of view over another, information is lost, and organizational values shift. This is not benign, as social knowledge will change, and some people will be harmed. There is an ethical component to structuring classifications and standards (4).

Facts, reason, and causation influence classifications and standards more than correlations, values, and moral action. Classifications, standards, and causation too quickly diminish the salience, meaning, and relevance of the outlier, whether the outlier is a person, thing, event, or information.

The formulation of "social knowledge" is how Kant mediated between objective facts and reason and subjective values and moral action (59). For anthropologist James P. Spradley (60), "Culture is the acquired knowledge people use to interpret experience and generate behavior." What was essential to Spradley was the *insider's view* of how people use social knowledge to interpret the world, generate social behavior, and interpret the behavior of others. As people learn their culture, they acquire new ways to interpret experience.

Classifications and standards, as social knowledge, shape culture and influence information and communication.

Conclusion

All information is not equal. Knowledge information is factive and tends not to be revisable. Nevertheless, belief information is revisable. The fundamental problem with information during engagement is the mental inability of the operator to update and revise beliefs. This creates a gap between belief and the environment, which is not visible to the individuals holding the firm belief.

"Information is lost through theories, classifications, and standards. While necessary for high-risk operations, they develop their own inertia when they become idealized. This affects the generation, handling, and communication of information. The result is impaired, if not inhibited, engagement."

The commonly repeated cliché, "Correlation does not mean causation," misleads those new to HRO. During a disruptive event, it is not possible to have effective knowledge of causation. Veteran operators use correlation as a descriptive agent, part of a vigilant approach, treating correlated information as imperfect, transient information. That is, correlated information has investigative value.

Information is lost through theories, classifications, and standards. While necessary for high-risk operations, they develop their own inertia when they become idealized. This affects the generation, handling, and communication of information. The result is impaired, if not inhibited, engagement.

Emphasizing engagement as mystery-solving acknowledges that uncertainty is integral to any high-reliability situation. A function of engagement is converting uncertainty to certainty and information generation. In full-spectrum analysis, the operator knows multiple possibilities and outcomes (15). The full spectrum includes contextual details, identification of influential factors, and vigilance for correlations that can be investigated.

That the uncertainty of information can impair engagement is part of engagement in full-spectrum analysis.

References:

1. van Stralen D. Pragmatic High-Reliability Organization (HRO) During Pandemic COVID-19. Neonatology Today. 2020;15(4):3–9.
2. Zundel M, Kokkalis P. Theorizing as engaged practice. Organization Studies. 2010;31(9–10):1209–27.
3. Pauly D. Anecdotes and the shifting baseline syndrome of fisheries. Trends in Ecology & Evolution. 1995;10(10):430.
4. Bowker GC, Star SL. Sorting things out: Classification and its consequences. Cambridge, MA: MIT Press; 1999.
5. van Stralen D, Mercer TA. Common Sense High Reliability Organizing (HRO) in the Response to COVID-19. Neonatology Today. 2021;16(7):90–102. doi: 10.51362/neonatology.today/2021716790102.
6. Sandberg J, Tsoukas H. Grasping the logic of practice: Theorizing through practical rationality. Academy of management review. 2011;36(2):338–60.
7. Weick KE. Theory and practice in the real world. In: Tsoukas H, Knudsen C, editors. The Oxford handbook of organization theory. New York: Oxford University Press; 2003. p. 453–75.
8. Shannon CE. A Mathematical Theory of Communication. Bell System Technical Journal. 1948;27(3):379–423. doi: 10.1002/j.1538–7305.1948.tb01338.x.
9. van Stralen D, McKay SD, Mercer TA. Disaster Series: High Reliability Organizing for (HRO) Disasters–Disaster Ecology and the Color of Noise. Neonatology Today. 2021;16(12):96–109. doi: https://doi.org/10.51362/neonatology.today/2021161296108.
10. Euler L. Opera Omnia, ser. 1, vol. 2. In: Pólya G, editor. Mathematics and plausible reasoning: Induction and analogy in mathematics. 1. Princeton, NJ: Princeton University Press; 1761.
11. Pólya G. Mathematics and plausible reasoning: Induction

and analogy in mathematics. Princeton, NJ: Princeton University Press; 1954.

12. van Stralen D, McKay SD, Mercer TA. Engagement in High Reliability Organizing (HRO): The Individual Matters. Neonatology Today. 2023;18(2):30–45.

13. Simon HA. The structure of ill structured problems. Artificial Intelligence. 1973;4(3–4):181–201. doi: 10.1016/0004-3702(73)90011-8.

14. Dieterly DL. Problem Solving and Decision-making: An Integration. Moffett Field, California: NASA Ames Research Center, 1980 Contract No.: NASA Technical Memorandum 81191.

15. Wolfberg A. Full-spectrum analysis: A new way of thinking for a new world. Military Review. 2006;86(4):35–42.

16. Smith SM, Brown HO, Toman JEP, Goodman LS. The Lack of Cerebral Effects of d-Tubocurarine. Anesthesiology. 1947;8(1):1–14.

17. Banzett RB, Mulnier HE, Murphy K, Rosen SD, Wise RJ, Adams L. Breathlessness in humans activates insular cortex. Neuroreport. 2000;11(10):2117–20.

18. Evans KC, Banzett RB, Adams L, Mckay L, Frackowiak RS, Corfield DR. BOLD fMRI identifies limbic, paralimbic, and cerebellar activation during air hunger. Journal of neurophysiology. 2002;88(3):1500–11.

19. Jerath R, Edry JW, Barnes VA, Jerath V. Physiology of long pranayamic breathing: neural respiratory elements may provide a mechanism that explains how slow deep breathing shifts the autonomic nervous system. Medical hypotheses 2006;67(3):566–71.

20. Jerath R, Crawford MW, Barnes VA, Harden K. Self-Regulation of Breathing as a Primary Treatment for Anxiety. Applied Psychophysiologic Biofeedback. 2015:1–9. doi: 10.1007/s10484-015-9279-8.

21. van Stralen D, Calderon RM, Clements P, Padgett J, Kausen B, Roberts KH. High Reliability Organzaton Methods Facilitate Initiation of Mechanical Ventilation in a Pediatric Nursing home. Society of Critical Care Medicine's 35th Critical Care Congress; January 7–11, 2006; San Francisco, CA: Society of Critical Care Medicine; 2006.

22. van Stralen D, Calderon RM, King P, Padgett D, Lewis J, Rao R. Initiation of Mechanical Ventilation (MV) in a Pediatric Subacute Care Facility (SCF) v. ICU: Cost Avoidance CHEST; 11/2–8/2002; San Diego, CA: American College of Chest Physicians; 2002.

23. van Stralen D, Calderon R, Padgett J, Clements P, Eachus T. Smile and Laughter During Mechanical Ventilation in Children. Mastering the Challenges Across the Spectrum of Long Term Care; March 16–29, 2006; Dallas, Texas: America Medical Directors Association, 29th Annual Symposium; 2006.

24. Martinez M, Sequoiah-Grayson S. Logic and Information. In: Zalta EN, editor. The Stanford Encyclopedia of Philosophy. Spring 2019 ed. Online: Metaphysics Research Lab, Stanford University; 2019.

25. Baltag A, Renne B. Dynamic Epistemic Logic. In: Zalta EN, editor. The Stanford Encyclopedia of Philosophy. Winter 2016 ed. Online: Metaphysics Research Lab, Stanford University; 2016.

26. Kraft PW, Lodge M, Taber CS. Why people "don't trust the evidence" motivated reasoning and scientific beliefs. The ANNALS of the American Academy of Political and Social Science. 2015;658(1):121–33.

27. Kunda Z. The case for motivated reasoning. Psychological bulletin. 1990;108(3):480.

28. Priest G, Tanaka K, Weber Z. Paraconsistent logic. In: Zalta EN, editor. The Stanford Encyclopedia of Philosophy Summer 2018 Edition ed: Metaphysics Research Lab, Stanford University; 2018.

29. Hunter A. Paraconsistent logics. Reasoning with Actual and Potential Contradictions: Springer; 1998. p. 11–36.

30. Arieli O, Avron A, Zamansky A. Ideal paraconsistent logics. Studia Logica. 2011;99(1):31–60.

31. Halley JM. Ecology, evolution and 1/f-noise. Trends in ecology & evolution. 1996;11(1):33–7.

32. McCarthy J. Artificial intelligence, logic and formalizing common sense. In: R.H. T, editor. Philosophical logic and artificial intelligence. Berlin, Germany: Springer, Dordrecht; 1989. p. 161–90.

33. Minsky M. A framework for representing knowledge. In: Winston PH, editor. The Psychology of Computer Vision. New York, NY: 211–277; 1975.

34. McCarthy J. Some expert systems need common sense. Ann N Y Acad Sci. 1984;426:129–37. Epub 1984/01/01. doi: 10.1111/j.1749-6632.1984.tb16516.x. PubMed PMID: 6391331.

35. Westrum R. The study of information flow: A personal journey. Safety Science 2014;67:58–63. doi: http://dx.doi.org/10.1016/j.ssci.2014.01.009.

36. Westrum R. A typology of organisational cultures. Quality and Safety in Health Care. 2004;13(suppl_2):ii22–ii7. doi: 10.1136/qshc.2003.009522.

37. Westrum R. Management strategies and information failure. In: Wise JA, Debons A, editors. Information systems: Failure analysis. Proceedings of the NATO Advanced Research Workshop on Failure Analysis of Information Systems. Berlin, Germany: Springer-Verlag; 1987. p. 109–27.

38. OSS OoSS. Simple Sabotage Field Manual — Strategic Services (Provisional) [DECLASSIFIED]. Washington, DC: Office of Strategic Services; 1944.

39. van Stralen D, Gambino W. Error as a Faulty Failure Sigtology.today/20209159114117.

40. van Stralen D, Mercer TA. Pandemic COVID-19, the High-

Reliability Organization (HRO), and the Ecology of Fear. Neonatology Today. 2020;15(12):129–38. doi: 10.51362/neonatology.today/2020121512129138.

41. Fisher RA. Cancer and smoking. 1958;182(4635):596–.

42. Fisher RA. Lung cancer and cigarettes? Nature. 1958;182(4628):108.

43. Lifton RJ. Thought Reform and the Psychology of Totalism: A study of brainwashing in China. New York, NY: W. W. Nor17. Banzett RB, Mulnier HE, Murphy K, Rosen SD, Wise RJ, Adams L. Breathlessness in humans activates insular cortex. Neuroreport. 2000;11(10):2117–20.

44. Atmanspacher H. Quantum Approaches to Consciousness. In: Zalta EN, editor. The Stanford Encyclopedia of Philosophy. Summer 2020 ed. Online: Metaphysics Research Lab, Stanford University; 2020.

45. van Stralen D, Mercer TA. The Nature of Neonatal Experience during Pandemic COVID-19. Neonatology Today. 2021;16(3):87–97. doi: 10.51362/neonatology.today/202131638797.

46. Kahneman D, Tversky A. On the psychology of prediction. Psychological Review. 1973;80(4):237–51. doi: 10.1037/h0034747.

47. Kulyk O. Chaos in Heinrich Rickert's philosophy. Scientific and theoretical almanac «Grani». 2019;22(8):37–46.

48. Sloan PR. Performing the Categories: Eighteenth-Century Generation Theory and the Biological Roots of Kant's A Priori. Journal of the History of Philosophy. 2002;40(2):229–53.

49. Leddy T. Dewey's Aesthetics. In: Zalta EN, editor. The Stanford Encyclopedia of Philosophy Stanford University Press; 2020.

50. Legg C, Hookway C. Pragmatism. In: Zalta EN, editor. The Stanford Encyclopedia of Philosophy: Stanford University Press; 2020.

51. Stapp HP. Attention, intention, and will in quantum physics. Journal of Consciousness Studies. 1999;6(8–9):143–64.

52. Stapp HP. Quantum approaches to consciousness. In: Zelazo PD, Moscovitch M, Thompson E, editors. David, Morris. nal. Neonatology Today. 2020;15(9):114–7. doi: 10.51362/neonaMoscovitch, and Evan Thompson, eds The Cambridge: Cambridge University Press; 2007. p. 881–908.

53. Pólya G. Induction and analogy in mathematics. Princeton, NJ: Princeton University Press; 1954.

54. van Stralen D, Mercer TA. High Altitude Climbing, High Reliability, COVID-19, and the Power of Observation. Neonatology Today. 2021;16(1):68–79. doi: 10.51362/neonatology.today/20211616879.

55. van Stralen D, Mercer TA. The Art of Neonatology, the Art of High Reliability as a Response to COVID-19. Neonatology Today. 2021;16(2):74–83. doi: 10.51362/neonatology.today/202121627483.

56. Price JF. Lagrangian and eulerian representations of fluid flow: Kinematics and the equations of motion: MIT OpenCourseWare; 2006.

57. Tetlock PE. Expert Political Judgment. Princeton, NJ: Princeton University Press; 2009.

58. Orwell G. Shooting an elephant. In: Packer G, editor. Facing Unpleasant Facts: Narrative essays. Boston, MA: Mariner Books; 2008. p. 29–37.

59. Abbott A. Chaos of disciplines. Chicago, IL: University of Chicago Press; 2010.

60. Spradley JP. Culture and Ethnography. In: Spradley JP, McCurdy DW, editors. Conformity and Conflict: Readings in Cultural Anthropology. 1st ed. Boston, MA: Pearson; 1984. p. 1–13.

Corresponding Author

Daved van Stralen, MD, FAAP
Associate Professor, Pediatrics
Department of Pediatrics
Loma Linda University School of Medicine
11175 Campus Street
CP-A1121
Loma Linda, CA 92350
Email: DVanStra@llu.edu

Sean McKay
Executive Partner / Director, Disruptive Rescue & Austere Medicine
Element Rescue - Response Solutions within Nonlinear Complex Environments
Greenville, South Carolina, United States

Errol van Stralen
Program Director at Ancora Corporate Training
Tuscumbia, Alabama, United States

Thomas A. Mercer
Rear Admiral
United States Navy (Retired)

Acknowledgments

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

William J. Corr, Captain II, Los Angeles City Fire Department (retired)

Adrian Wolfberg, National Academy of Sciences, Defense Intelligence Agency

INFANT AND FAMILY-CENTERED DEVELOPMENTAL CARE (IFCDC)

STANDARDS AND SAMPLE RECOMMENDATIONS FOR INFANTS IN THE INTENSIVE CARE UNIT

SYSTEMS THINKING IN COMPLEX ADAPTIVE SYSTEMS

- Are the baby and family central to the mission, values, environment, practice & care delivery of IFCDC in the unit?
- Are the parents of each baby fully integrated into the team and treated as essential partners in decision-making and care of the infant?
- What are the strategies and measurements used to improve and sustain IFCDC in the unit?

POSITIONING & TOUCH FOR THE NEWBORN

- Are the positioning plans therapeutic and individualized, given the care needs and development of the baby?
- Are the positioning and touch guidelines continually reviewed by the team, including the parents, and adapted to meet the changing comfort needs of the baby?

SLEEP AND AROUSAL INTERVENTIONS FOR THE NEWBORN

- Can the team confidently describe the "voice" or behavioral communication of the baby?
- Are the baby's unique patterns of rest, sleep, and activity documented by the team and protected in the plan of care?

SKIN-TO-SKIN CONTACT WITH INTIMATE FAMILY MEMBERS

- Is the practice of skin-to-skin contact supported and adjusted to the comfort needs of each baby, parent, & family member?
- Are the parents & family members supported to interact with the baby to calm, soothe, & connect?

REDUCING AND MANAGING PAIN AND STRESS IN NEWBORNS AND FAMILIES

- Are parents supported to be present and interactive during stressful procedures to provide non-pharmacologic comfort measures for the baby?
- Are there sufficient specialty professionals to support the wellbeing of the team, including parents, families, and staff? Examples include mental health, social, cultural, & spiritual specialists.

MANAGEMENT OF FEEDING, EATING AND NUTRITION DELIVERY

- Are the desires of the m/other central to the feeding plan? Is this consistently reflected in documentation with input of the m/other?
- Does the feeding management plan demonstrate a feeding & nutrition continuum from in-hospital care through the transition to home & home care?

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

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

2022 William A. Silverman Lecture
Where's the Evidence?

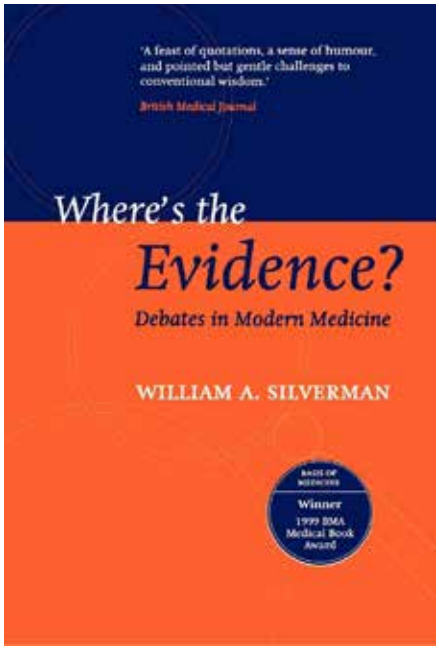
Haresh Kirpalani MD, MSc

Hello. Good afternoon, everyone. First of all, I really want to thank the Section of Neonatal and Perinatal Pediatric Medicine of the AAP and its current Chair, Dr. Lily Lou.

Lily, thank you for the very kind words. Although I'm not physically present at the meeting, she told me what she was going to say. And I'm very touched. I must apologise to both her, to Dr. Silverman, and the whole committee of the perinatal section of the AAP, and to the audience for not being there. I gauged that with my age and my prior asthma that I was over the baseline risk for consequences from COVID. That made it uncomfortable. I think perhaps Dr. Silverman might approve of my attempt at risk stratification. But I want to thank the committee again. I'm very humbled and very conscious of Dr. Silverman's contribution, and this was beyond my expectation.

"This book consists of essays that he wrote under either a 'nom-de-guerre' or 'nom-de-plume.' I'm not sure which title Dr. Silverman would prefer, but he signed himself "Malcontent" when he originally wrote these essays entitled as "Fumes from the Spleen." "

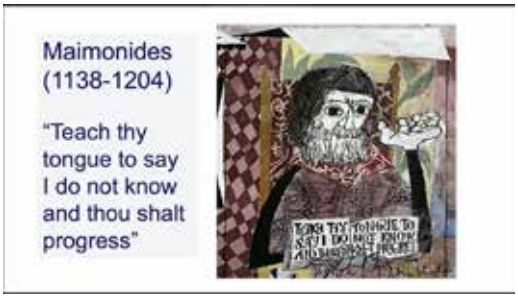
I think it's appropriate to begin with some small vignettes about Dr. Silverman. Even though most of the audience most likely full well know about Dr. Silverman. The title of my talk, "Where's the Evidence?" comes from his book shown here, *Where's the Evidence? Debates in Modern Medicine* (1).



This book consists of essays that he wrote under either a 'nom-de-guerre' or 'nom-de-plume.' I'm not sure which title Dr. Silverman would prefer, but he signed himself "Malcontent" when he originally wrote these essays entitled as "Fumes from the Spleen." He wrote these after he stepped down early from the chair at Columbia. And the reason he stepped down, I think, is quite interesting. He stepped down, he said, because he had become so disillusioned with how people use data from physiological laboratory studies to treat premature babies.

"So what was Dr. Silverman's mission?...'If we respect truth, we must search for it by persistently searching for our errors.'"

So what was Dr. Silverman's mission? I believe that the quotes that he himself used either in his prefaces or in the bodies of his works give us some measure of the man. Here is what he wrote at the end of his preface to a book where he cited Karl Popper, the famous philosopher of science, saying, "If we respect truth, we must search for it by persistently searching for our errors." And that was certainly one leitmotif of Dr. Silverman, one that prompted his friends to commission a piece of art. It was a picture of the Spanish Jewish philosopher, physician Maimonides, of the 12th century. And one of his sayings is depicted on this tablet, "Teach Thine tongue to say, I do not know, and thou shalt progress."



And indeed, Silverman would often cite this. Now, all of this sounds extremely serious. And he was a very serious man. But that doesn't mean to say Dr.Silverman didn't have his moments of mischief. For example, he would insist everyone distrust authority. And when visitors came to his unit in Columbia, he would hand them a badge. And the badge, which he would ask them to wear, would be said—and forgive me, I know no Latin—but it would say "Semper Plangere." (2) Apparently, that means "always complain." Now, despite those mischievous comments, you can see the undertone here. This was that he distrusted prescriptions that were not based on evidence in medicine.

First of all, I should say that I have no financial relationship to disclose or conflicts of interest to resolve. I will also not discuss any unapproved or off-label drug use.

In the next 25 minutes, I will try and discuss some questions or examples that Silverman gave us from which we can profit and learn. And, I'm going to try and explore them in today's context. My outline is as follows: I'll first highlight two questions posed by Dr. Silverman in relation to choosing therapies. He said that

we should always consider the difference between association and causation. Thus, one question he posed was "Is association always causative?" In my view, another question he raised for our attention was "Is the whole notion of all physiological arguments sufficient to warrant a course of therapy?"

I'll then examine these questions using selected neonatal examples to highlight some categories that were used by Dr. Silverman. In addition, I ask how long did it take from the physiological postulate that was raised before the randomised controlled trial, or RCT, verification or refutation of that postulate?

The first question that Dr.Silverman posed to remind us of is the difference between association and causation. This graph (Figure 1) is drawn from his famous book, *Retrolental Fibroplasia—a Modern Parable* (3). We now know that disease as Retinopathy of Prematurity. On the X-axis are the years from 1938 through to 1946, and the solid black line on the Y-axis is the incidence of Retrolental fibroplasia (RLF). This is the same disease we know as Retinopathy of Prematurity. You see the horrifying spike as neonatal intensive care took hold.

"... two questions posed by Dr. Silverman in relation to choosing therapies. He said that we should always consider the difference between association and causation. Thus, one question he posed was 'Is association always causative?' In my view, another question he raised for our attention was 'Is the whole notion of all physiological arguments sufficient to warrant a course of therapy?'" "

Around the same time, you also see the rise in three therapies, inhaled oxygen, water-soluble vitamins, and iron. Now, at the time, people came to a premature conclusion that iron was the causative agent in RLF by extrapolating from its physiological relationship to vitamin E. But as we now know, the culprit was actually oxygen. Clearly, iron was only an association.

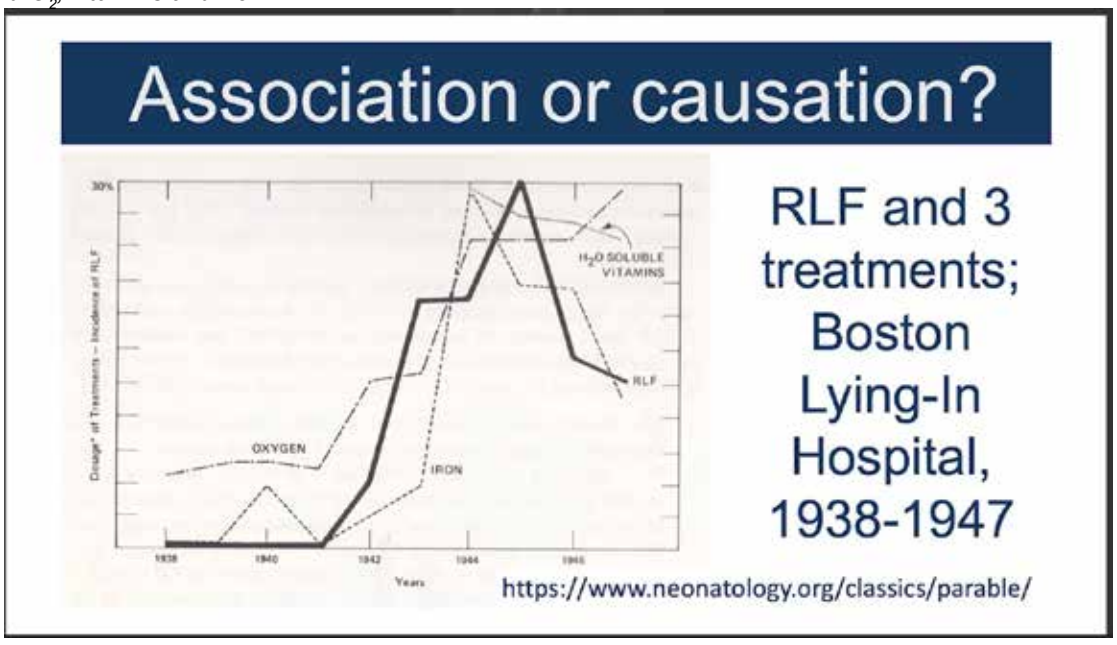
"You see the horrifying spike (in ROP) as neonatal intensive care took hold. Around the same time, you also see the rise in three therapies, inhaled oxygen, water-soluble vitamins, and iron. Now, at the time, people came to a premature conclusion that iron was the causative agent in RLF by extrapolating from its physiological relationship to vitamin E. But as we now know, the culprit was actually oxygen. Clearly, iron was only an association.""

The second question I'm going to take from Silverman as a model for us is whether physiology is sufficient to warrant a line of therapy. This quotation comes directly from his book on RLF, where he records what he wrote in a baby's chart the following:

"It has been decided to try ACTH (Adrenocorticotropic Hormone). On the rationale that 1) it is a connective tissue disease; 2) prematures are maybe deficient in ACTH; and 3) no other agent has given any indication of beneficial effect." (4)

You can hear the note of anxiety about writing this in the chart. I think we can see the dilemma that he was in as the physician of this baby. He wrote about his patient that she was:

Figure 1. RLF and O_2, vitamins and Fe



"the prematurely born daughter of (a colleague)…after six miscarriages. (This infant) proceeded to 29 weeks…following definite signs of RLF...the treatment was started more in desperation than conviction."

Her eyes were "almost normal" when she was sent home. Now, the story did't end there while this was a satisfactory ending, of course, for this child and this family. But "we were puzzled about two infants" who recovered without treatment.

"This quotation comes directly from his book on RLF, where he records what he wrote in a baby's chart the following: 'It has been decided to try ACTH. On the rationale that 1) it is a connective tissue disease; 2) prematures are maybe deficient in ACTH; and 3) no other agent has given any indication of beneficial effect.'"

I think all of us have, at times, been in such a dilemma, and as physicians, we recognise this dynamic. But the quandary was posed to him, and the experience led him to do a randomised trial. In that randomised trial, ACTH was found to be ineffective. This was a "parable," in his words, and in a nutshell, the story behind his most famous book. This copy on my slide looks a bit battered. It's quite old and was lent out on several occasions, but thankfully the whole book now is available free of charge at the website *https://www.neonatology.org/classics/parable/*. I strongly urge particularly young people who don't know about Silverman to read this book. It reads like a detective story.

"I think all of us have, at times, been in such a dilemma, and as physicians, we recognise this dynamic. But the quandary was posed to him, and the experience led him to do a randomised trial. In that randomised trial, ACTH was found to be ineffective."

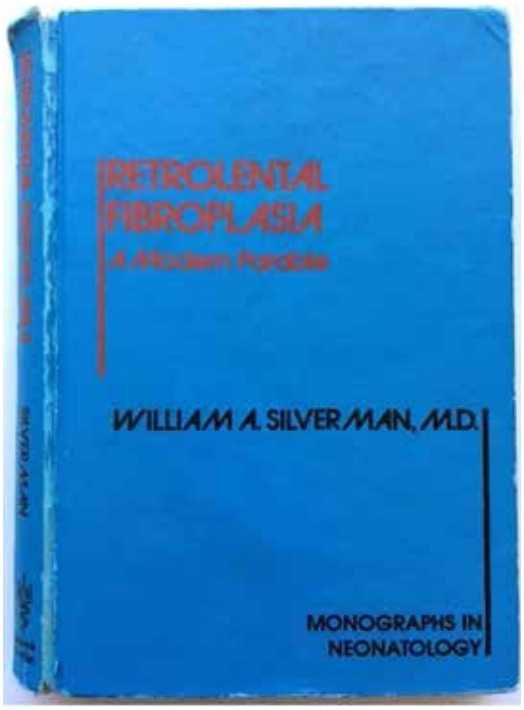


Figure 2. Results of some "Proclaimed" Therapies in the Development of Perinatal Medicine

Gradual Changes in Therapy	Consequences* Led to Sounder Practice	Led to Disaster	Misled into Fruitless Byways
Testosterone to stimulate growth of prematures		?	
Thyroid hormone . . ibid . . .			×
DES to prevent miscarriage		×	
Progestins to prevent miscarriage		×	
Exchange transfusion	×		
Supplemental oxygen for periodic breathing		×	
Initial thirsting and starving		× (?)	
Synthetic vitamin K prophylaxis		×	
Low-fat, high-protein feedings		?	
Sulfisoxazole prophylaxis		×	
Chloramphenicol prophylaxis		×	
Gastric emptying to prevent RDS**			×
Sternal traction for RDS			×

"The example that I picked to illustrate 'disaster' was oxygen for periodic breathing. As you can see..., certainly unrestricted oxygen ablated the periodic breathing seen in air and led to a more regular breathing. But as Silverman pointed out, unrestricted oxygen had led to harm or disaster with retinopathy."

He placed his thoughts about proclaimed therapies in a very famous table, which showed three categories about various "putative therapies." (5) I've expanded that in the next slide (Figure 2) to emphasise that sometimes the physiology-based intervention led to "sounder practice" or to "disaster" or to "fruitless byways."

Here is one example for each of these categories from Silverman's famous table. The first was CPAP (continuous positive airway pressure) for RDS, showing a picture of one of the babies in Dr. Gregory's first cohort in 1971. (6) At the time that Silverman wrote the book, he still placed a question mark by CPAP, although he thought this had led to sound the practice. It took until 2008 before Colin Morley published the COIN trial (7) and shortly after Neil Finer and Wally Carlo (8) evaluated the benefits of CPAP in a much more systematic way to avert intubation.

The example that I picked to illustrate "disaster" was oxygen for periodic breathing. As you can see in the slide, certainly unrestricted oxygen ablated the periodic breathing seen in air and led to a more regular breathing. But as Silverman pointed out, unrestricted oxygen had led to harm or disaster with retinopathy.

Finally, the example I've chosen from Silverman as being a fruitless byway is sternal traction. And you can see there that there's a stitch under the surface sternum moving up to some weights, which counter-balances the tendency of the chest wall to collapse the very compliant preterm chest wall. This was supposed to avert a sternal and pulmonary collapse. Of course, it didn't work but didn't overtly lead to harm except perhaps the pain. And this was a "fruitless byway."

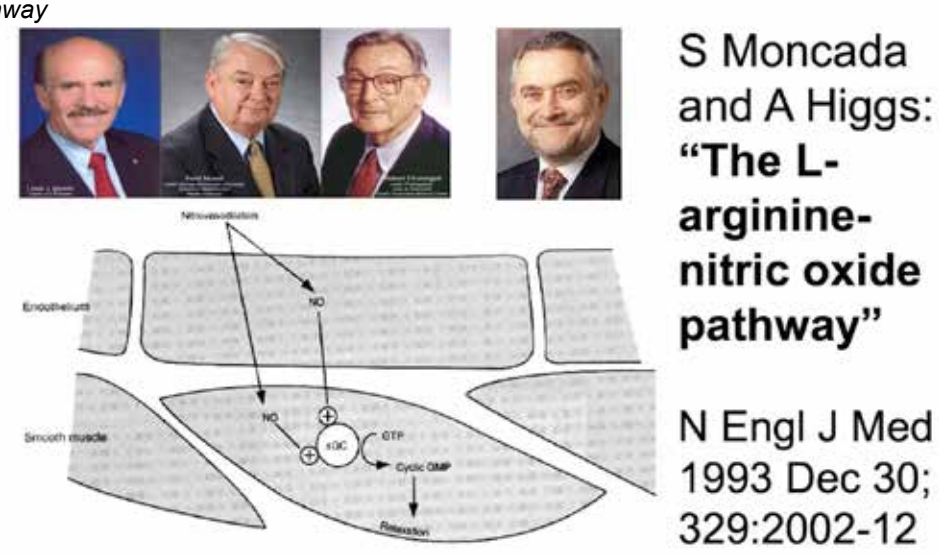
What about in a more modern era? I'm going to depict an example for each of the three of these categories. In the first example, I've asked if randomised controlled trials (RCT) verified that indeed the intervention had led to sound practice.

This was the case for inhaled nitric oxide for term infants with persistent pulmonary hypertension of the newborn. And in fact, the gap here from hypothesis to RCT verification or refutation was rather short and accomplished in ten years. This slide (Figure 3) shows four gentlemen at the top and relates a rather controversial story because the three gentlemen on the left were acknowledged by the Nobel Prize. Dr. Moncada on the right, although he had participated in all of the same work and had developed the story of nitric oxide, he was not so credited. But in a poetic form of justice perhaps, his article (9) is probably far more quoted than the articles by the Nobel Prize winners. So perhaps a small justice for Moncada. Or perhaps the message here is that the merit lies in the work itself without any consideration of prizes.

"...randomised controlled trials (RCT) verified that indeed the intervention had led to sound practice.This was the case for inhaled nitric oxide for term infants with persistent pulmonary hypertension of the newborn. And in fact, the gap here from hypothesis to RCT verification or refutation was rather short and accomplished in ten years."

These gentlemen had collectively displayed that in order for vasodilators to exert a relaxation of smooth muscles and arterial vessels in all the vascular compartments of the body, the endothelium was a necessary component. Because it elaborated what they called the endogenous relaxation factor, or the RF, this was later shown to be nitric oxide, which diffused from the endothelium to the smooth muscle cells, where through the cyclic

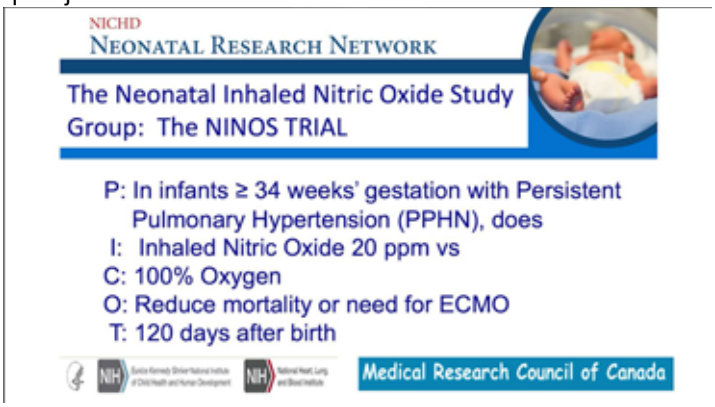
Figure 3. The Nitric Oxide Pathway



GMP pathway, it induced relaxation.

Very quickly, our colleagues in the 1990s extrapolated this to infants in observational studies. Dr. Neil Finer in Canada obtained funding from the Medical Research Council of Canada and initiated a trial. Very shortly thereafter, the Neonatal Research Network in the USA, with Richard Ehrenkrantz and Linda Wright, joined the NINOS trial.

That asked this question: "In a population of infants who are greater than 34 weeks gestational age with PPHN (persistent pulmonary hypertension), does inhaled nitric oxide (NO) at 20 parts, as opposed to a control of 100% oxygen, reduce the outcome of mortality or the need for ECMO (Extracorporeal Membrane Oxygenation), by 120 days after birth?" Neil and Richard showed their results of their trial in 1997 (10). I was very fortunate that Neil had put me on the executive committee of that trial when I was quite junior.



The primary composite outcome was convincingly positive for inhaled NO. Death or ECMO was reduced from the Control group rate (77/121 [63.6%]) with inhaled NO (52/114 [45.6%], p=0.006). The trial was closed early for benefit, but only about 20 babies away from target sample size. This cohort of infants with hypoxic respiratory failure had not responded to aggressive conventional therapy. But, as you can see, if we separate out the components of the primary outcome, there was no reduction in death alone.

"My second example is in the category of "disaster" or harm and sustained inflation (SI) at birth for extremely preterm infants who have a poor respiratory effort. I believe that you can trace the gap from hypothesis to randomised trial verification or refutation to just under 40 years."

My second example is in the category of "disaster" or harm and sustained inflation (SI) at birth for extremely preterm infants who have a poor respiratory effort. I believe that you can trace the gap from hypothesis to randomised trial verification or refutation to just under 40 years. The story starts in Nottingham, England, where the group of Dr. Milner with Dr. Vyas displayed that babies requiring resuscitation could establish a functional residual capacity quicker if a sustained inflation of about 5 seconds, as opposed to the standard inflation time, usually less than one second. That was regardless of either a slow waveform, a square wave, or a slow rising form. (11)

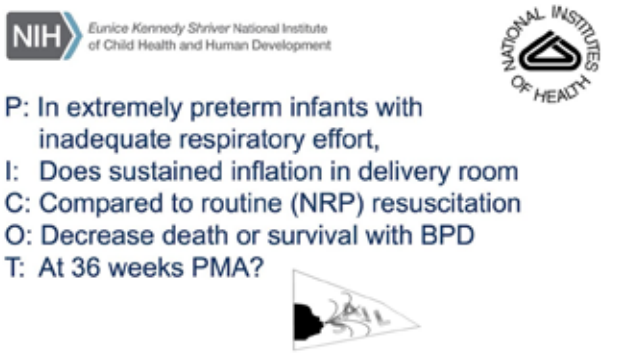
It took a few years, but in the 2000s, the group, led by Stuart Hooper in Melbourne, explored this further, using a slightly longer sustained inflation using a synchrotron. (12) A synchrotron is simply an X-ray where the subject is placed an extremely long way away from the X-ray generation plant. This narrows the X-rays into a parallel beam to you give extremely high resolution. What I want to show you are two videos of rabbit pups from the above paper by Dr. te Pas. The first is of a rabbit pup trying to establish a spontaneous breath. You can see the rabbit pup is breathing and does open the main conducting airway opening, but the lung itself is only minimally opening.

If we move over to the second video, a sustained inflation of about 20 seconds was delivered to this rabbit pup through an endotracheal tube. Now the same initial pattern with the conducting airways opening is seen. However, then you see this beautiful appearance of small round circles coalescing into the lung. Now the rabbit is performing its own respiratory manoeuvres. The difference is very vivid.

"This was extrapolated into human physiology and further extrapolated away from using an endotracheal tube. That was because, by this stage, we knew that intubation was not good. So people were trying to avoid this and tried to deliver sustained inflation with a mask. And some smaller trials were done that indicated some benefit.."

This was extrapolated into human physiology and further extrapolated away from using an endotracheal tube. That was because, by this stage, we knew that intubation was not good. So people were trying to avoid this and tried to deliver sustained inflation with a mask. And some smaller trials were done that indicated some benefit. Two in particular led by Arjan Te Pas in Holland (13) and another led by Dr. Lista in Italy (14). However, the benefits that were being described were short-term.

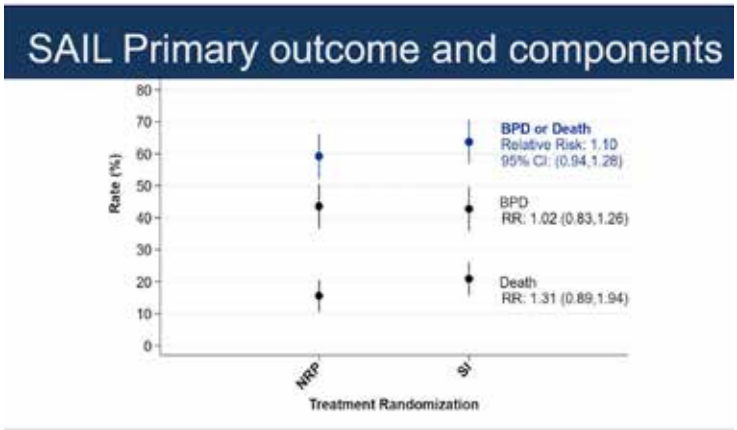
Nobody had yet asked in an adequately sized trial this primary PICOT (patient, intervention, comparison, outcome and time) question: "In a population of extremely preterm infants with inadequate respiratory effort, does sustained inflation in the delivery room as compared to a control arm of routine (or neonatal



resuscitation program, NRP) control resuscitation decrease the outcome of death or survival with BPD (bronchopulmonary dysplasia) at 36 weeks postmenstrual age?"

A group of international workers combined forces to answer that question. We calculated a sample size of about 600 babies was needed to answer that question (15). The primary outcome of death or BPD, when the trial was stopped on the Y axis, was no different (RR 1.10 [95%CI 0.94, 1.28]).

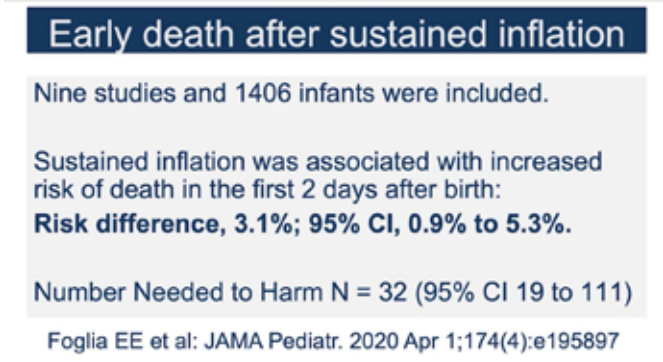
Figure 4. Sustained Inflation Outcome



When examined by either BPD or death alone, there still was no difference. Now I said that the sample size was 600, but the trial was prematurely stopped at just over 400. It was stopped after the independent DSMB (Data and Safety Monitoring Board), led by Dr. A. Jobe, had reviewed the data up to 400 babies.

When we designed the trial, we were careful to ensure to pick up signals of harm. One signal we were looking for was early death. That is death within the first two days of life. There was an excess mortality in the sustained inflation group (adjusted risk difference 5.6 [2.1, 9.1]).

Figure 5. Early Death After Sustained Inflation



But because the trial was stopped early, correctly, I would argue there remained a potential for bias. To that end, we were fortunate that Foglia conducted a meta-analysis including about 1400 babies. (16) That analysis confirmed that sustained inflation was associated with an increased risk of death in the first two days of after birth (Figure 5). The risk differences shown the number needed to harm was a mean of 32, with a 95% confidence interval of 19 to about 111.

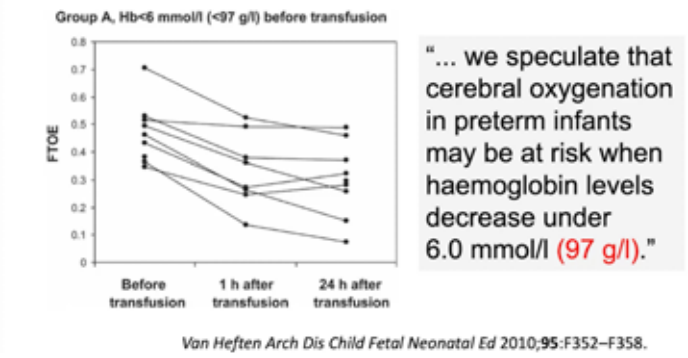
This was important because the practice of sustained inflation was passing into a standard of care in several parts of the world, particularly, I think it's fair to say, in Europe. So before this became a much more generalised therapy, at least we indicated some evidence to suggest SI required more study before entering standard practice.

"When examined by either BPD or death alone, there still was no difference... When we designed the trial, we were careful to ensure to pick up signals of harm. One signal we were looking for was early death. That is death within the first two days of life. There was an excess mortality in the sustained inflation group (adjusted risk difference 5.6 [2.1, 9.1])."

The last example I'm going to suggest—following Silverman's paradigm—is one where RCTs suggested a "fruitless byway." This example is on the notion of a liberal red blood cell (RBC) transfusion strategy with higher hemoglobins will improve brain development in preterm infants. Here the interval from hypothesis to RCT was actually just over 40 years. I submit the story can be traced to the late 1970s. This is illustrated by this quote from some authoritative workers: "We have demonstrated a highly physiological phenomenon, a defect in oxygen supply which correlates with the clinical syndrome of anaemia, most commonly seen an incidence of shorter gestation. This occurs during the period of maximum brain growth and could prejudice the child's chances of achieving full potential later in life." (17)

Some small studies tried to evaluate this, but not very many in a randomised way. However, newer observational data led to indirect support for the above statement. This shows data from the newer technology of near-infrared spectroscopy, or NIRoscopy, for cerebral oxygenation (18). This graph (Figure 6) shows the fractional oxygen extraction (FTOE) of blood from the brain before, immediately after, and 24 hours after transfusion. I draw your attention to the haemoglobin level at which these babies were transfused, of 97 grams per litre (9.7 grams per decilitre). There was a decrease after RBC transfusion in the FTOE. The authors speculated that cerebral oxygenation and preterm may be at risk when haemoglobin levels decrease under 97 grams per litre.

Figure 6. Effect of RBC Transfusion on FTOE



As I say, there were some randomised studies looking at this, but they were relatively small. It's only recently that two large

studies were able to address this question, and that included the Transfusion of Prematurity (TOP) trial conducted by the Neonatal Research Network (NRN) of the NICHD (19); and also a German network trial led by Dr. Axel Franz (20).

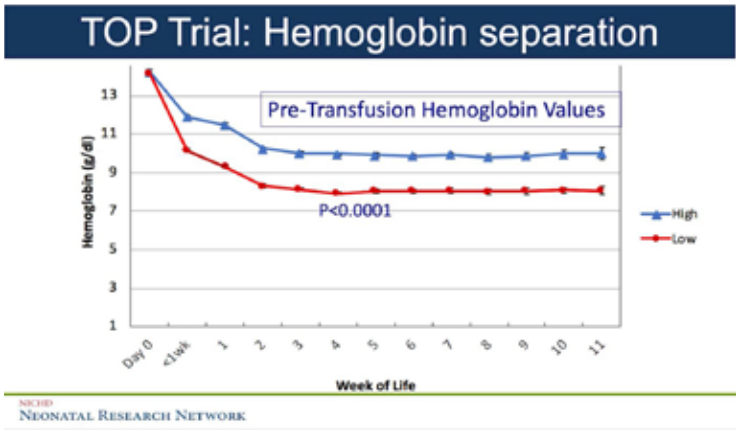
Both trials asked the following PICOT question:

"In ELBW (extremely low birthweight) infants, does randomisation to a liberal RBC transfusion strategy—as compared to a restrictive RBC transfusion strategy—show a reduced death or impairment at 22-24 months corrected age?" The largest trial was the TOP trial.

This summary (Figure 7) displays haemoglobin levels in infants by randomised group in grams per decilitre.

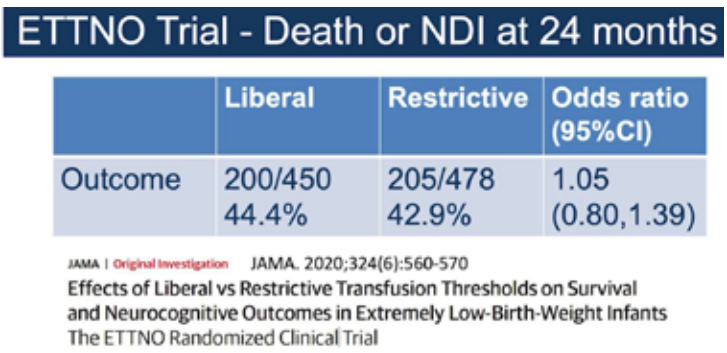
Figure 7. Haemoglobin Levels in Infants

Haemoglobin was about two grams per decilitre higher in the



liberal transfusion strategy group above infants randomised to the low arm, and that difference was maintained through hospital stay. Importantly that level in the high group was above that speculative level of 9.7 grams per decilitre we noted earlier. However, at two years of outcome, the total primary outcome of death, or MDI, in the population with 93% follow-up showed no difference (RR 1.00 [95% CI 0.92, 1.10]). It's always good to have replicated data. The German group had reported just a month before we did, and although a smaller study, had almost exactly the same findings (OR 1.05 [95%CI 0.80, 1.39]). So I think we can be confident that transfusing infants to a high transfusion level within the ranges of the top algorithm does not confer benefits for death or long-term neurodevelopmental outcome.

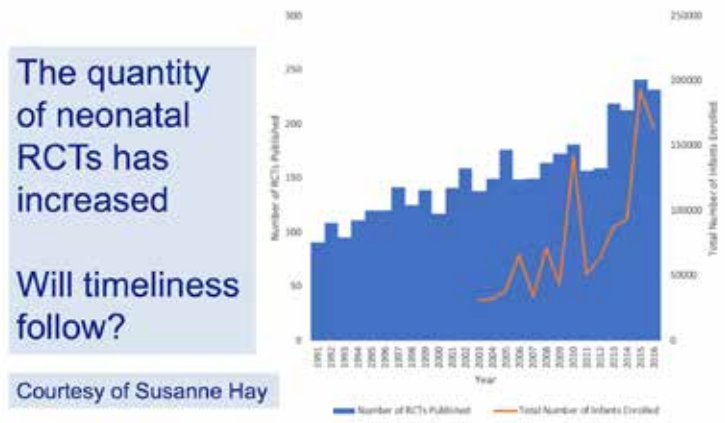
Figure 8. Outcome of Liberal v. Restrictive RBC Transfusion



Now, I think I've displayed (to) you that the three categories that Silverman used are still pertinent, but perhaps I may have been a bit gloomy. I've suggested that we're being rather slow. Perhaps I shouldn't be so gloomy. This data (Figure 9) from Susanne Hay and John Zupancic from Boston shows the cumulative number of babies and the number of trials from 1991 to 2016. You can see that the quantity of neonatal randomised trials has increased from <100 per year to just under 250 per year. I'm confident that the timeliness will follow, as will the quality and the size of trials.

"However, at two years of outcome, the total primary outcome of death, or MDI, in the population with 93% follow-up showed no difference...The German group had reported just a month before we did, and although a smaller study, had almost exactly the same findings. So I think we can be confident that transfusing infants to a high transfusion level within the ranges of the top algorithm does not confer benefits for death or long-term neurodevelopmental outcome."

Figure 9 Number of Trials and Infants



"This data from Susanne Hay and John Zupancic from Boston shows the cumulative number of babies and the number of trials from 1991 to 2016. You can see that the quantity of neonatal randomised trials has increased from <100 per year to just under 250 per year. I'm confident that the timeliness will follow, as will the quality and the size of trials."

In my final three slides, I must thank some people. First of all, I was privileged to be the student of some outstanding clinicians and scientists who helped me. In the UK, initially, there were Edmund Hey, Cyril Noble, and Malcolm Coulthard. In the Hospital for Sick Children in Toronto Paul Swyer, Karen Pape, and Mex Perlman. Then in McMaster Medical School Gordon Guyatt and Robin Roberts.

Throughout my Canadian and Philadelphia years, I was fortunate to have outstanding research fellows, including Tai Fai-Fok, John Zupancic, Mazen Al-Essa, Chad Anderson, Connie Williams, David Millar, Elaine Boyle, Sara De Mauro, Fliz Foglia, Eric Jensen, Maky Fraga, Ursula Guillen, Li Ma, Clyde Wright, and Nic Bamat.

I was fortunate to be in the Children's Hospital of Philadelphia (CHOP) for the last 15 years of my career.

I was very fortunate to have two outstanding division chiefs, first Phyllis Dennery, who brought me to CHOP. Then Eric Eichenwald was a second amazing division chief. I was very fortunate. Both Phyllis and Eric (were) incredibly supportive. The environment in which one is so important.

I must, of course, thank my wife, Barbara, together with whom I had a great many friends in academic life,

And I end by thanking the AAP and all of those people—the nurses, all at the bedside, the babies, and their parents, This is a painting by the German expressionist Otto Dix (that) displays one of these babies.

Thank you.

References:

1. Silverman WA. Where's the Evidence? Debates in Modern Medicine. Oxford University Press; 1999.
2. Oransky I. Obituary. Lancet. 2005 Jan 8.
3. Silverman WA. Retrolental Fibroplasia— a Modern Parable. New York: Grune & Stratton, 1980 p. 20. Also at https://www.neonatology.org/classics/parable/
4. Ibid. p.22
5. Ibid. p.85
6. Gregory GA et al. Treatment of the idiopathic respiratory-distress

syndrome with CPAP. N Engl J Med. 1971; 284: 1333–1340.

7. Morley CJ, Davis PG, Doyle LW, and COIN Trial Investigators. Nasal CPAP or intubation at birth for very preterm infants. N Engl J Med. 2008 Feb 14; 358(7):700–708.

8. Finer NN, Carlo WA, Walsh MC, SUPPORT Study Group of the Eunice Kennedy Shriver NICHD Neonatal Research Network. Early CPAP versus surfactant in extremely preterm infants. N Engl J Med. 2010 May 27; 362(21):1970–1979.

9. S Moncada and A Higgs. The L-arginine-nitric oxide pathway. N Engl J Med. 1993 Dec 30; 329:2002–2012.

10. The Neonatal Inhaled Nitric Oxide Study Group. Inhaled Nitric Oxide in full term and nearly full-term infants with hypoxic respiratory failure. N Engl J Med. 1997 Feb 27; 336:597–604.

11. Vyas H, Milner AD, Hopkin IE, and Boon AW. Physiologic response to prolonged and slow rise inflation in the resuscitation of the asphyxiated newborn infant. J Pediatr. 1981 Oct; 99(4):635–9.

12. te Pas AB, Siew M, Wallace MJ et al. Establishing FRC at birth: effect of sustained inflation and positive end-expiratory pressure Pediatr Res. 2009 May;65:537–541.

13. te Pas AB, Walther FJ. A randomized, controlled trial of delivery-room respiratory management in very preterm infants. Pediatr 2007; 120 (2):322–329. doi.org/10.1542/peds.2007-0114

14. Lista G, Boni L, Scopesi F, et al., SLI Trial Investigators. Sustained lung inflation at birth for preterm infants: a randomized clinical trial. Pediatr. 2015 Feb 1;135(2):e457–e464. doi.org/10.1542/peds.2014-1692

15. Kirpalani H, Ratcliffe SJ, Keszler M, et al. Effect of Sustained inflations vs. Intermittent Positive Pressure ventilation on BPD or death among extremely Preterm Infants. The SAIL randomized clinical trial. JAMA. 2019; 321(12):1165–1175.

16. Foglia EE, Te Pas AB, Kirpalani H, et al. Sustained Inflation vs. Standard Resuscitation for Preterm Infants: A Systematic Review and Meta-analysis. JAMA Pediatr. 2020 Apr 1;174(4):e195897

17. Wardrop CA, Holland BM, Veale KE, Jones JG, Gray OP "Non-physiological anaemia of prematurity. Arch Dis Child. 1978 Nov;53(11):855-60.

18. van Hoften JCR, Verhagen EA, Keating P, ter Horst HJ, Bos AF. Cerebral tissue oxygen saturation and extraction in preterm infants before and after blood transfusion. Arch Dis Child Fetal Neonatal Ed. 2010 Sep; 95(5):F352–F358. doi: 10.1136/adc.2009.163592

19. H. Kirpalani, E.F.Bell, S.R.Hintz, et al. Higher or lower hemoglobin transfusion thresholds for preterm infants. N Eng J Med. 2020 Dec 31; 383:2639-51. doi: 10.1056/NEJMoa2020248

20. Franz AR, Engel C, Bassler D, et al. Effects of liberal vs. restrictive transfusion thresholds on survival and neurocognitive outcomes in extremely low-birth-weight infants: the ETTNO randomized clinical trial. JAMA 2020 Aug 11; 324(6):560–70. doi:10.1001/jama.2020.10690

Disclosures: No significant disclosures were noted.

NT

Haresh Kirpalani, MD, MSc
Emeritus Professor CE of Pediatrics
Department: Pediatrics
Perelman School of Medicine
University of Pennsylvania
Contact information
6103 Cedar Grove
Burlington, ON L7P 0N1

Brilliant! Dr. Bell bridges the journey from grief to growth. This is classic wisdom on healing from our heartbreaks and ultimately enjoying a fulfilling life.

– Christine Theard, M.D.

Post-Traumatic Thriving

The Art, Science, & Stories of Resilience

Randall Bell, Ph.D.

Peer Reviewed

Briefly Legal: Failure to Diagnose a Classic Case of Spontaneous Intestinal Perforation (SIP)

Maureen Sims, MD, Barry S. Schifrin, MD

"A 23 1/7 weeks' gestation, she presented to the hospital having developed vaginal bleeding and abdominal cramping after using cocaine the night before. The presumptive cause of the bleeding and cramping was placental abruption associated with cocaine use. Although there was unlikely sufficient time for obtaining a therapeutic benefit, soon after admission, the mother was given terbutaline, magnesium sulfate, and betamethasone."

At the time of her pregnancy, the patient was a 43-year-old G50P4 woman with two prior cesarean sections, whose prenatal course was complicated by active cocaine use, heavy smoking, and the consumption of several beers daily. She had a history of syphilis and chlamydia, both treated six years earlier. She was group B Streptococcus (GBS) negative. A 23 1/7 weeks' gestation, she presented to the hospital having developed vaginal bleeding and abdominal cramping after using cocaine the night before. The presumptive cause of the bleeding and cramping was placental abruption associated with cocaine use. Although there was unlikely sufficient time for obtaining a therapeutic benefit, soon after admission, the mother was given terbutaline, magnesium sulfate, and betamethasone. Shortly after that, however, she developed a fever of 101^{0}F and spontaneous rupture of membranes with the production of malodorous amniotic fluid. Because of the presumptive diagnoses of chorioamnionitis and placental abruption, and the four prior cesarean sections (uterine rupture could not be excluded), the decision was made to deliver the baby by repeat cesarean section.

At birth, the 570-g male infant received Apgar scores of 4^{1},5^{5},5^{10}. The arterial cord gas pH was 7.14, the pCO_2 was 56 mmHg, the pO_2 was 23 mmHg, and the base deficit (BD) was 10.7. Still in the delivery room, the baby was placed in a plastic bag to maintain his temperature and immediately intubated. He was given positive pressure ventilation and surfactant replacement therapy before being brought to the Newborn Intensive Care Unit (NICU). The placenta revealed a 25% abruption with histological evidence of chorioamnionitis.

In the NICU, his physical examination was normal, though immature. A CBC revealed a marked anemia with a hematocrit of 30%. The remainder of the CBC was unremarkable. The infant required moderately high ventilator settings and 100% inspired oxygen. Antibiotics were started, and several hours after admission, a second dose of surfactant replacement was administered for respiratory distress syndrome. Because of mildly low blood pressure, normal saline boluses were given, and dopamine was begun, followed by packed red blood cell transfusions. On DOL 1, a cranial ultrasound showed intraventricular hemorrhages, grade 3 on the right and grade 4 on the left. Over the next week and a half, the infant followed a stormy course with the development of a tension pneumothorax relieved by a chest tube, a patent ductus arteriosus treated with indomethacin, seizures controlled by phenobarbital, hyperglycemia controlled by insulin and posthemorrhagic ventriculomegaly. Because of the child's instability related to these conditions, feeding was withheld. He was fed parenterally via a percutaneous intravenous catheter with \increasing amounts of nutrients. On DOL 10, greenish fluid began draining from his orogastric tube. His abdominal girth had suddenly increased from 16 cm to 18.5 cm, despite a 15% weight loss from birth. On examination, the abdomen was tense and bluish.

"Because of the child's instability related to these conditions, feeding was withheld. He was fed parenterally via a percutaneous intravenous catheter with \ increasing amounts of nutrients. On DOL 10, greenish fluid began draining from his orogastric tube. His abdominal girth had suddenly increased from 16 cm to 18.5 cm, despite a 15% weight loss from birth. On examination, the abdomen was tense and bluish."

A single, flat-plate radiograph revealed a paucity of gas in the bowel but no intramural gas to suggest necrotizing enterocolitis. The blood culture taken after birth was negative, but the one repeated on DOL 14 showed ***coagulase-negative staphylococcus*** (CONS). The green output and abdominal findings on examination continued. Despite daily "abdominal radiographs," no cross-table lateral or left lateral decubitus radiographs were obtained to determine the presence of abdominal free air better. Indeed, some of the radiographs included only the chest. These radiographs were consistently interpreted as showing a paucity of intestinal gas, with no portal venous gas or free air. The differential diagnosis of the treating neonatologist included necrotizing enterocolitis and ileus from sepsis. It did not include intestinal perforation. Inexplicably, the neonatologist did not reorder the abdominal radiographs when the abdomen was not included in the radiograph, nor was a cross

Issue	SIP	NEC
Pathophysiology	-localized to the area of perforation characterized as isolated mucosal ulceration with submucosal thinning -focal intestinal perforation, generally in the watershed area of the terminal ileum, without gross findings elsewhere -ischemia, reperfusion, or thromboembolism -operative findings typically involve a single subcentimeter perforation, usually on the antimesenteric border of the small intestine, with minimal peritoneal contamination and healthy appearing surrounding intestine	-primarily driven by ischemia and initiation of enteral feeds resulting in full-thickness hemorrhagic necrosis of the intestinal mucosa. -characterized by inflammation, invasion of enteric gas-forming organisms, and dissection of gas into the muscularis and portal venous system -depending on the progression of the disease and the presence of underlying pathogenic factors, it may move into gangrenous necrosis and perforation -as the intestine heals, bowel wall thickening, fibrinous adhesions, and areas of stenosis may appear
Incidence and population affected	-mainly 25-27 weeks	-peaks at 29 -32 w -90% preterm -10% term with a strong association with congenital heart disease, gastroschisis, hypoxic-ischemic events
Gender	M>F	M=F
Timing	-preterm infant, usually within the first ten days	-typically presents after the first week and after the infant has begun to feed.
Presentation	-abdominal distension, classical bluish discoloration of the abdominal wall in the absence of abdominal wall erythema -if diagnosis missed, progression to instability	-a usually vague, nonspecific, slight change in vital signs, new onset or increase in apnea, feeding intolerance, increased gastric residuals, emesis -with the progression of disease; cardiovascular instability, lethargy, distension, tenderness, lack of bowel sounds
Radiologic Imaging	- gasless abdomen, absence of pneumatosis intestinalis and portal venous air. Cross-table lateral view or lateral decubitus with the left side down shows free air 2/3 time - 1/3 of the time, free air is not found because perforation is walled off or has been resorbed	-pneumatosis intestinalis, portal venous air, transient thickening of the intestinal wall, fixed dilated small bowel loops -free air if perforation occurs -significant bowel distension or fixed bowel loops
Associated infection	-concomitant sepsis with CONS	-30% cultures positive, probably reflecting a breakdown in the mucosal barrier leading to bacterial translocation
Laboratory	-may have: high or low white blood cell counts, thrombocytopenia, low hct	
Diagnosis	-operative findings of isolated bowel perforation in otherwise normal bowel	-pneumatosis intestinalis and/or portal venous gas

Management	-gastric decompression -withholding feedings -correction of acidosis, anemia, and thrombocytopenia. -blood pressure support -antibiotic coverage: 2 broad-spectrum agents that cover intestinal microorganisms, typically ampicillin, and an aminoglycoside or third-generation cephalosporin, although occasionally *Staphylococcal* species are heavy colonizers of the intestinal tract, Furthermore, nafcillin or vancomycin should be considered. In situations with suspected or proven intestinal perforation, aggressive anaerobic coverage with clindamycin is often added -surgical repair (bedside drain, especially in cases of instability)	
Differential Dx	NEC, malrotation, intestinal atresia, intussusception, aganglionosis, and volvulus	SIP, malrotation, intestinal atresia, intussusception, aganglionosis, and volvulus
Morbidity	-similar risk for neurodevelopmental impairment as surgical NEC	-strictures post NEC -depends on gestational age, BW, the extent of bowel involvement, & need for surgical intervention.
Mortality	Infants diagnosed with SIP had higher mortality than controls. In bivariate analyses, SIP had higher mortality than NEC in the overall population. That could be explained by SIP occurring more frequently in infants with younger GA and smaller BW. In fact, in infants with BW 1000–1499, the mortality from NEC was greater than SIP, and within the group of infants with BW <1000 g, mortality from SIP and NEC did not differ. After controlling for confounding variables in regression analysis, NEC had a higher adjusted odds ratio for mortality than SIP. Therefore, it is plausible to hypothesize that SIP is a sign of severe immaturity, making them more vulnerable to increased mortality and other complications.	

Discussion

Pathology

Spontaneous intestinal perforation (SIP), also called isolated intestinal perforation and focal intestinal perforation, is a disease entity first appreciated in the late 1980s as more immature infants survived. Over the years, there have been increasing reports of SIP in VLBW and ELBW neonates. SIP is localized to the perforation area generally in the watershed areas of the terminal ileum, without gross findings elsewhere, and is characterized as isolated mucosal ulceration with submucosal thinning. SIP usually occurs before the initiation of enteral feeds. In patients with SIP, operative findings typically include a single, small (<1 cm diameter) perforation, usually on the antimesenteric border of the small intestine, with minimal peritoneal contamination and a healthy appearance surrounding the intestine. The predominant pathophysiologic feature is circulatory, namely, ischemia, reperfusion, or thromboembolism.

Population affected

The median gestation age for SIP ranges from 25-27 weeks, and the median birth weight ranges from 670 to 973 grams. Some studies have found that SIP appears more frequently in male than female infants. Severe chorioamnionitis (as present in this case) is an antenatal risk factor for SIP.

Cocaine, Steroids, and Indomethacin

Indomethacin has been used antenatally for tocolysis and prophylactically in high-risk neonates to help close the ductus in premature fetuses. It is well known that cocaine use during pregnancy has adverse consequences for both the mother and fetus. Among 17,466 non-Asian singleton deliveries in 1988 from the University of Illinois Perinatal Network database in the metropolitan Chicago area, Handler et al. found elevated adjusted relative risks (RR) of SGA births (RR = 2.8, 95% (CI) 2.2-3.7), prematurity (RR = 2.4, 95% CI 1.9-3.1), abruptio placentae (RR = 4.5, 95% CI 2.4-8.5), and perinatal death (RR = 2.1, 95% CI 1.1-4.0) for "any" cocaine users (n = 408) compared with non-using women cocaine, other drugs or alcohol) Paradoxically, cocaine use decreases neonatal morbidity in patients with preterm premature rupture of membranes compared to those where rupture occurs without cocaine. After birth, prophylactic indomethacin is used by over a quarter of neonatologists because of its short-term benefits in closing the ductus arteriosus. While brief antenatal exposure to indomethacin (≤ 2 days) is not associated with SIP, randomized controlled trials (RCTs) have found that infants exposed to both indomethacin and corticosteroids after birth are at increased risk of SIP. Paradoxically, antenatal glucocorticoids may be somewhat protective, while neonatal steroids alone may increase the risk of SIP. Trials of prophylactic indomethacin alone have not been shown to predispose to SIP. Whether prophylactic neonatal indomethacin alone or combined with antenatal steroids increases the rate of SIP has led to contrary conclusions.

table or lateral view requested.

"On DOL 15, the surgical consult, finally obtained, requested a cross-table lateral view, revealing a pneumoperitoneum. The baby was transferred to a regional children's hospital for surgical care. A Penrose drain was inserted into the abdomen at the referral hospital, which drained stool and blood."

On DOL 15, the surgical consult, finally obtained, requested a cross-table lateral view, revealing a pneumoperitoneum. The baby was transferred to a regional children's hospital for surgical care. A Penrose drain was inserted into the abdomen at the referral hospital, which drained stool and blood. Following this intervention, the infant's abdominal exam and clinical findings improved. He did develop a partial small bowel obstruction that responded to conservative care without surgery. Neurosurgical interventions included a reservoir placed and multiple taps until he was large enough to tolerate the placement of a ventricular-peritoneal (VP) shunt. The multiple taps prior to the VP shunt caused hyponatremia, requiring boluses of normal saline after the procedures. He was diagnosed with retinopathy of prematurity, for which he underwent laser treatment.

He was discharged from the hospital at three months of age. His discharge diagnoses included: BPD, posthemorrhagic obstructive hydrocephalus s/p VP shunt, retinopathy of prematurity s/p laser, and osteopenia. On-up examination, he had profound cognitive deficits, cerebral palsy, and visual impairment.

"Both the birthing hospital and the neonatologist were sued. In deposition testimony, the plaintiff neonatology expert was critical of the treating neonatologist for 1) Failing to consider SIP in the differential diagnoses. 2) Not ordering a left lateral decubitus or cross-table view to look for free air in the peritoneal space. 3) Not obtaining a surgical consult. 4) not reordering abdominal radiographs when they failed to include the abdomen. "

Both the birthing hospital and the neonatologist were sued. In deposition testimony, ***the plaintiff neonatology expert was critical of the treating neonatologist for 1) Failing to consider SIP in the differential diagnoses. 2) Not ordering a left lateral decubitus or cross-table view to look for free air in the peritoneal space. 3) Not obtaining a surgical consult. 4) not reordering abdominal radiographs when they failed to include the abdomen.***

The defense claimed that the problems with the baby were those related exclusively to the severe prematurity and the mother's use of cocaine. The birthing hospital and the defendant neonatologist settled the matter out of court.

When steroids are administered prenatally, the physiological surge in bioactivity in the fetus/newborn lasts approximately 72 h after the last betamethasone dose. Indeed, several studies have identified that the combination of recent (< 7 days, <3 days) antenatal glucocorticoids and prophylactic neonatal indomethacin was associated with SIP. In an intent to treat, a multi-epoch study of the role of prophylactic indomethacin (PINDO) on rates of death or bronchopulmonary dysplasia, grades 2 and 3 (death/BPD) in newborns <25 weeks, Clyman et al. found no significant differences in the incidence of death/BPD or of secondary outcomes (necrotizing enterocolitis/spontaneous perforations, or intraventricular hemorrhage (grades 3 or 4) in various comparisons between infants born in a PINDO epoch and those born in the Expectant Management epoch. They concluded that despite being at high risk for PDA-related morbidities, PINDO did not appear to alter the rates of intestinal perforation or any secondary outcomes in infants <25 weeks. They did find that PINDO treatment resulted in far more frequent closure of the ductus by 7-8 days (85% v. 24%).

"If early diagnosis is followed by timely resection, the morbidity and mortality statistics with SIP are better than those with surgically treated NEC. Thus, co-management or prompt consultation with a pediatric surgeon is vital to timely and appropriate care. "

Clinical features

The signs and symptoms of SIP usually develop suddenly without prior clinical evidence of intestinal inflammation. Since an intestinal perforation has occurred, affected infants often appear deceptively better than expected. The infants are initially fairly stable, then suddenly develop abdominal wall distension, which is classically blue. The most common organism associated with SIP is CONS. The differential diagnosis of abdominal distention includes ileus from sepsis and NEC. Less common causes include malrotation, intestinal atresia, intussusception, aganglionosis, and volvulus. Radiographic findings are nonspecific and often include a paucity of gas or "a gasless abdomen." Pneumoperitoneum is present about two-thirds of the time. When the perforation has been rapidly walled off or the free air resorbed, pneumoperitoneum may not be found. Careful abdominal examinations, close attention to the clinical course, and undertaking proper radiography are the keys to diagnosing SIP and providing timely intervention. If early diagnosis is followed by timely resection, the morbidity and mortality statistics with SIP are better than those with surgically treated NEC. Thus, co-management or prompt consultation with a pediatric surgeon is vital to timely and appropriate care. Many infants do very well with localized resection and primary

anastomosis, although some evidence focuses on peritoneal drainage as a definitive, non-surgical treatment.

Suggested Reading

1. Ang JL, Rath CP, Tan H, Patole S, Rao SC. Mortality and neurodevelopmental outcomes of infants with spontaneous intestinal perforation: a systematic review and meta-analysis. Arch Dis Child Fetal Neonatal Ed. 2022;[Epub ahead of print]. doi: 10.1136/archdischild-2022-324157. PMID: 34507935.

2. Arnautovic TI, Longo JL, Trail-Burns EJ, Tucker R, Keszler M, Laptook AR. Antenatal receiving postnatal indomethacin. J Pediatr. 2021;232:59-64.e1. doi: 10.1016/j.jpeds.2020.08.063. PMID: 33010998.

3. Attridge JT, Clark R, Gordon PV. New insights into spontaneous intestinal perforation using a national data set (3): antenatal steroids have no adverse association with spontaneous intestinal perforation. J Perinatol. 2006;26(11):667-670. doi: 10.1038/sj.jp.7211607. PMID: 16977372.

4. Aviles-Otero N, Kumar R, Khalsa DD, et al. Caffeine exposure and acute kidney injury in premature infants with necrotizing enterocolitis and spontaneous intestinal perforation. Pediatr Nephrol. 2019;34(4):729-736. doi: 10.1007/s00467-018-4123-3. PMID: 30415418.

5. Chawla S, Natarajan G, Laptook AR, Chowdhury D, Bell EF, Ambalavanan N, et al. Model for severe intracranial hemorrhage and role of early indomethacin in extreme preterm infants. Pediatr Res. 2022;92(3):1648-1656. doi: 10.1038/s41390-021-01771-2. PMID: 34706917.

6. Clyman RI, Hills NK. Prophylactic indomethacin, antenatal betamethasone, and the risk of intestinal perforation in infants <28 weeks' gestation. J Perinatol. 2022;[Epub ahead of print]. doi: 10.1038/s41372-023-01653-0. PMID: 35147533.

7. de Waal K, Phad N, Stubbs M, Chen Y, Kluckow M. A randomized placebo-controlled pilot trial of early targeted nonsteroidal anti-inflammatory drugs in preterm infants with a patent ductus arteriosus. J Pediatr. 2021;228:82-86.e1. doi: 10.1016/j.jpeds.2020.08.054. PMID: 33010992.

8. Elgendy MM, Othman HF, Heis F, et al. Spontaneous intestinal perforation in premature infants: a national study. J Perinatol. 2021;41(5):1122-1128. doi: 10.1038/s41372-021-00946-9. PMID: 33837303.

9. Fatemizadeh R, Mandal S, Gollins L, et al. Incidence of spontaneous intestinal perforations exceeds necrotizing enterocolitis in extremely low birth weight infants fed an exclusive human milk-based diet: a single center experience. J Pediatr Surg. 2021 May;56(5):1051-1056. doi: 10.1016/j.jpedsurg.2021.01.057. PMID: 33637480.

10. Handler A, Kistin N, Davis F, et al. Cocaine use during pregnancy: perinatal outcomes. Am J Epidemiol. 1991 Apr 1;133(8):818-825. doi: 10.1093/oxfordjournals.aje.a115959. PMID: 1850255.

11. Hall TR, Zanivovic A, Lewin D. Neonatal Intestinal Ischemia with Bowel Perforation: an in utero complication of maternal cocaine abuse. AJR Am J Roentgenol. 1992 Jun;158(6):1303-1304. doi: 10.2214/ajr.158.6.1590121. PMID: 1590121.

12. Härtel C, Hartz A, Pagel J, et al. NOD2 loss-of-function mutations and risks of necrotizing enterocolitis or focal intestinal perforation in very low-birth-weight infants. Inflamm Bowel Dis. 2016 Feb;22(2):249-256. doi: 10.1097/MIB.0000000000000627. PMID: 26716903.

13. Kandraju H, Kanungo J, Lee KS, et al. Association of co-exposure of antenatal steroid and prophylactic indomethacin with spontaneous intestinal perforation. J Pediatr. 2021 Jan;235:34-41.e4. doi: 10.1016/j.jpeds.2020.09.055. PMID: 33038617.

14. Kelleher J, Salas AA, Bhat R, et al. Prophylactic indomethacin and intestinal perforation in extremely low birth weight infants. Pediatrics. 2014 Dec;134(6):e1369-e1377. doi: 10.1542/peds.2014-1154. PMID: 25422012.

15. McGoldrick E, Stewart F, Parker R, Dalziel SR. Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth. Cochrane Database Syst Rev. 2020 Dec 17;12(12):CD004454. doi: 10.1002/14651858.CD004454.pub3. PMID: 33331071.

16. Ragouilliaux CJ, Keeney SE, Hawkins HK, Rowen JL. Maternal factors in extremely low birth weight infants who develop spontaneous intestinal perforation. Pediatrics. 2007 Nov;120(5):e1458-e1464. doi: 10.1542/peds.2006-3505. PMID: 17998314.

17. Refuerzo JS, Sokol RJ, Blackwell SC, et al. Cocaine use and preterm premature rupture of membranes: improvement in neonatal outcome. Am J Obstet Gynecol. 2002 Jun;186(6):1150-1154. doi: 10.1067/mob.2002.122986. PMID: 12066134.

18. Renolleau C, Toumazi A, Bourmaud A, Benoist JF, Chevenne D, Mohamed D, et al. Association between baseline cortisol serum concentrations and the effect of prophylactic hydrocortisone in extremely preterm infants. J Pediatr. 2021;234:65-70. doi: 10.1016/j.jpeds.2020.10.035. PMID: 33248427.

19. Sims ME. Was this case of necrotizing enterocolitis preventable? NeoReviews. 2018;19:e422-e425. doi: 10.1542/neo.19-8-e422.

20. Sims ME. Failure to diagnose spontaneous intestinal perforation. NeoReviews. 2014;15:e498-e501. doi: 10.1542/neo.15-11-e498.

21. Shaffer ML, Baud O, Lacaze-Masmonteil T, Peltoniemi OM, Bonsante F, Watterberg KL. Effect of prophylaxis for early adrenal insufficiency using low-dose hydrocortisone in very preterm infants: an individual patient data meta-analysis. J Pediatr. 2019;207:136-142.e8. doi: 10.1016/j.jpeds.2018.11.044. PMID: 30638990.

22. Slaughter JL, Reagan PB, Bapat RV, Newman TB, Klebanoff MA. Nonsteroidal anti-inflammatory administration and patent ductus arteriosus ligation, a survey of practice preferences at US children's hospitals. Eur J Pediatr. 2016;175:775-783. doi: 10.1007/s00431-015-2676-7. PMID: 26728681.

23. Swanson JR, Hair A, Clark RH, et al. Spontaneous intestinal perforation (SIP) will soon become the most common form of surgical bowel disease in the extremely low birth weight (ELBW) infant. J Perinatol. 2022;42(3):589-594. doi: 10.1038/s41372-022-01347-z. PMID: 34700022.

24. The' TG, Young M, Rosser S. In-utero cocaine exposure and neonatal intestinal perforation: a case report. J Natl Med Assoc. 1995;87(12):889-891. PMID: 8540508; PMCID: PMC2607946.

25. Wadhawan R, Oh W, Hintz SR, et al. Neurodevelopmental outcomes of extremely low birth weight infants with spontaneous intestinal perforation or surgical necrotizing enterocolitis. J Perinatol. 2014;34(1):64-70. doi: 10.1038/jp.2013.132. PMID: 24135709; PMCID: PMC3877634.

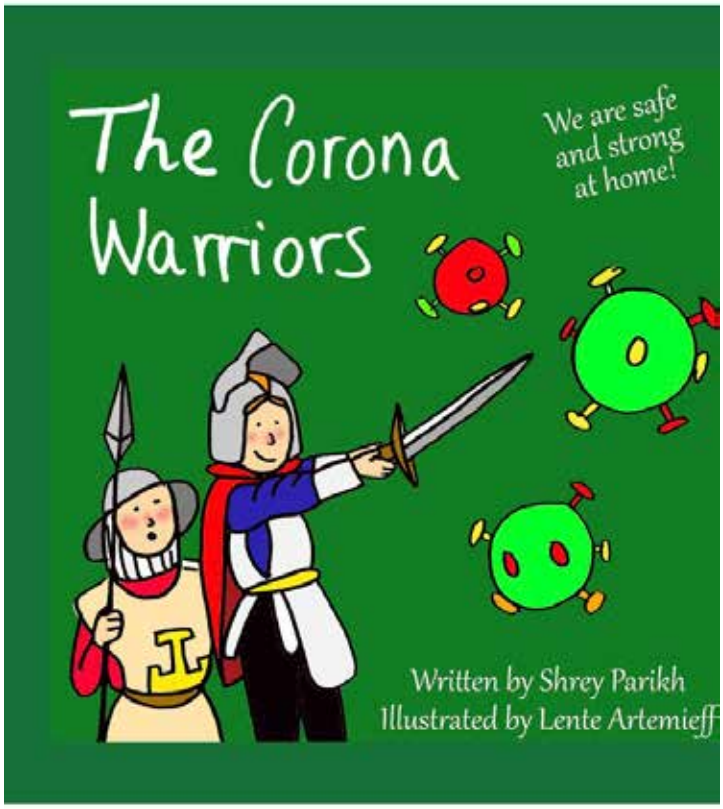
Disclosures: The authors have no disclosures

NT

Corresponding Author:

Maureen E. Sims, M.D.
Professor of Pediatrics
Geffen School of Medicine,
University of California, Los Angeles
Los Angeles, California
email: mes@g.ucla.edu

Barry Schifrin, M.D,
Western University of Health Sciences, Pomona, California
Formerly, Professor of Obstetrics & Gynecology
Keck School of Medicine, University of Southern California, Los Angeles



ONCE UPON A PREEMIE ACADEMY

eLearning Courses

Health and Racial Equity Continuing Education Courses

+ An Intro to Health and Racial Equity and Implicit Bias
+ Solutions for Addressing Inequities and Implicit Bias In the NICU
+ Black NICU Mother's Mental and Emotional Health
+ Black Preemie Parents as Partners in Preemie Care

Register at OnceUponAPreemieAcademy.com

$150
physicians
$175

equity-focused solutions for healthcare professionals

The first and only virtual training academy focused on delivering health and racial equity educational programs for perinatal and neonatal healthcare professionals. Our purpose is to raise awareness and offer real-time solutions for addressing health and racial equity.

+ Earn Continuing Education Credits
+ Learn from nationally recognized perinatal and neonatal professionals and preemie parents
+ Gain actionable tools to drive health and racial equity solutions in your organization!

pac-lac Continuing Education Partner, paclac.org/continuing-education

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.

nann.org nationalperinatal.org

National Association of Neonatal Nurses

National Perinatal Association

Gravens By Design: The Gravens Conference – Advancing The Science and Methods of Caring in the NICU With a New Standard of Care

Robert White, MD

From its inception in the early days of NICU care, the Gravens Conference has focused on the human component needed to achieve excellent neonatal care and optimal outcomes. Over the nearly 40 years of this meeting, compelling evidence has emerged to show that to achieve optimal outcomes; we must address not only the physiological challenges of ill newborns but also their developmental needs. These needs are not easily evaluated by looking at a lab test or treated by writing an order, nor are they achieved only by protecting babies from noxious stimuli; we must also consistently provide nurturing stimuli, which has been more challenging.

"At the recently concluded 2023 Gravens Conference, several formal programs were designed to assure that each newborn is given the development support often lacking, even in NICUs offering the most advanced medical and surgical treatments. The evidence basis for these programs is now more than sufficient to affirm that using such a structured program should be considered the standard of care for NICU care going forward."

At the recently concluded 2023 Gravens Conference, several formal programs were designed to assure that each newborn is given the development support often lacking, even in NICUs offering the most advanced medical and surgical treatments. The evidence basis for these programs is now more than sufficient to affirm that using such a structured program should be considered the standard of care for NICU care going forward.

When a decision has been reached to adopt a formal program of developmental support that incorporates staff and family, the next step is to choose a system that best fits the personnel and resources of a given NICU. To this end, the 2023 Gravens Conference presentations will be reviewed in Neonatology Today articles in the upcoming months. Hopefully, all those who provide care in the NICU will consider these carefully and find one they can embrace.

"To this end, the 2023 Gravens Conference presentations will be reviewed in Neonatology Today articles in the upcoming months. Hopefully, all those who provide care in the NICU will consider these carefully and find one they can embrace."

We are at the end of the era where developmental care was considered turning down the lights, reducing noise, eliminating unnecessary painful procedures, and leaving babies undisturbed except for a few minutes each time vital signs and feedings were due. Developmental care involves comprehensive nurturing of human interactions, even in the sickest or most premature infants, and NICUs now have several choices of evidence-based programs that can be adopted. Going forward, what should not be an option is retaining the disproven notion that babies' brains will optimally develop if we protect them from harm and watch them grow.

"Developmental care involves comprehensive nurturing of human interactions, even in the sickest or most premature infants, and NICUs now have several choices of evidence-based programs that can be adopted. Going forward, what should not be an option is retaining the disproven notion that babies' brains will optimally develop if we protect them from harm and watch them grow."

Disclosure: The author has no conflicts of interest

NT

Corresponding Author

Robert D. White, MD
Director, Regional Newborn Program
Beacon Children's Hospital
615 N. Michigan St.
South Bend, IN 46601
Phone: 574-647-7141
Fax: 574-647-3672
Email: Robert_White@pediatrix.com

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.

WEAR A MASK

PROTECT PARENTS + BABIES

COVID-19

When we all wear masks...

We protect parents and babies.

Project Sweet Peas + National Perinatal Association

USA UNA MASCARILLA

PROTEGER A LOS PADRES Y BEBÉS

COVID-19

Cuando todos usamos mascarillas ...

Protegemos a los padres y los bebés.

Project Sweet Peas + National Perinatal Association

Fragile Infant Forums for Implementation of IFCDC Standards: Reflections from Gravens 2023

Geert Lingier, Dale Garton, RN, BHSc, MN, Raylene Phillips, MD, MA, FAAP, FABM, IBCLC, Joy V. Browne, Ph.D., PCNS, IMH-E

"….the message and interaction of the baby and parents can no longer be viewed as "additional" or "optional," but should be integrated as an essential part of medical management, and caregiving for babies and their families."

Background and purpose of the Gravens workshop on IFCDC Standards implementation:

The recommended Standards, Competencies, and Best Practices for Infant and Family Developmental Care in Intensive Care (IFCDC) are based on the mounting evidence of the neuroprotective aspects of care and the importance of supporting infant and parent mental health. The standards provide essential evidence for achieving excellence in practice, including responsiveness to the baby's behavioral communication and keeping the nurturing relationship of the parent(s)/family as central to managing and delivering care.

"….the message and interaction of the baby and parents can no longer be viewed as "additional" or "optional," but should be integrated as an essential part of medical management, and caregiving for babies and their families." https://nicudesign.nd.edu/nicu-care-standards/introduction/

IFCDC principles cannot be operationalized without integrating systems thinking, as all policies and practices are only effective with supportive policies, procedures, and values. For every practice change, attention to how the system develops strategies to support and monitor healthy physiological and neurodevelopmental outcomes is necessary.

Increasing interest in implementing the IFCDC Standards has prompted efforts to integrate evidence-based practices nationally and internationally in NICUs. The Gravens 2023 workshop held in March offered an opportunity to examine several exemplars of IFCDC standard implementation using systems thinking.

"The following three national and international exemplars demonstrate many challenges in implementing standards, particularly during the recent pandemic."

The following three national and international exemplars demonstrate many challenges in implementing standards, particularly during the recent pandemic. They also describe opportunities for systems-level collaborative work.

Exemplar: Ghent Belgium NICU, Geert Lingier, Head Nurse

The NICU in the University Hospital of Ghent - Belgium, is a level III-IV unit operating in a ward model with limited bedside space. Despite the limited area per bedspace, parents and siblings are always welcome. A subunit was recently put into operation where parents can be permanently present and actively involved in care according to IFCDC principles. The service will be integrated into a new hospital, and couplet care will be implemented.

"During the pandemic, policies and practices included having parents consistently welcomed in the department with kangaroo care and breastfeeding continuing unabated."

Implementation practices and outcomes during the COVID pandemic: When the COVID pandemic erupted in March 2020, our unit, like many other centers, faced many questions regarding babies and families being together. A task force was quickly developed and charged with addressing the frequently changing pandemic conditions. Many internal task force members represented pediatric, intensive care, and government settings. As guidelines

changed regularly, at least eight different internal versions of the recommendations were published, each based on evidence and in close consultation with the hospital's infection prevention department.

During the pandemic, policies and practices included having parents consistently welcomed in the department with kangaroo care and breastfeeding continuing unabated. For siblings and other visitors, especially during the peaks of the COVID waves, there were periodically some restrictions.

"The COVID screening policy consisted of testing all outborn babies or if the mother, who was systematically screened at delivery, had a positive COVID PCR test. Parents were only required to be tested in case of COVID symptoms, and there were no requirements for vaccination."

The COVID screening policy consisted of testing all outborn babies or if the mother, who was systematically screened at delivery, had a positive COVID PCR test. Parents were only required to be tested in case of COVID symptoms, and there were no requirements for vaccination. There was a vaccination rate of more than 95% among staff members, and there were COVID outbreaks consistent with the pandemic surges.

Since the start of the pandemic, 1800 patients have been admitted to the NICU at UH Ghent with years with positive COVID PCR tests in only eight patients. Seven positive samples were detected in outborn babies and children outside the unit. Only one patient acquired the infection on the unit, linked to a positive test of his mother, who was also symptomatic. The baby who tested positive was born at 25 weeks and required some respiratory support (CPAP) to be restarted; however, not necessarily linked to the COVID infection.

Evidence versus emotion:

Not all neonatal units in Belgium followed a similar policy. Very often, strict rules were imposed on parents on the advice of infection prevention services; reduction in being with their baby, less frequent kangaroo care, and restrictions on breastfeeding. These rules were often motivated by emotion, general global panic, and less by evidence. The results of these policies implemented IFCDC principles at a low priority during the pandemic.

Based on our experience, frequent adjustments to the available COVID evidence resulted in minimal COVID-positive PCR testing in our patients. It resulted in the continued application of IFCDC principles, where parents were continuously involved in caring for their babies in much the same way as before the pandemic. Our approach consistently puts evidence at the forefront, as the IFCDC Standards describe. Our practice appeared to have been correct.

Among many other lessons, the COVID pandemic taught us that the maximum pursuit of scientific evidence in our care is the optimal approach. The IFCDC standards can be seen as a handhold in the permanent search for evidence-based practice, particularly emphasizing seeing parents as primary caregivers for their babies.

"Among many other lessons, the COVID pandemic taught us that the maximum pursuit of scientific evidence in our care is the optimal approach. The IFCDC standards can be seen as a handhold in the permanent search for evidence-based practice, particularly emphasizing seeing parents as primary caregivers for their babies."

Exemplar: New Zealand NICU, Dale Garton, Nurse Manager

To achieve a persistent change in the culture of care in the Auckland, New Zealand NICU toward implementing the IFCDC standards, the multidisciplinary NICU team and the organizational 'system' needed to improve family integration into their baby's care. Developmental care (DC) practices already employed by staff and therapists could be termed, at best, as a *generalist approach.* The approach depended on individuals' skills and knowledge rather than agreed standards of care supported by Clinical Guidelines, audits, and outcomes. In the past few years, there have been no real efforts towards significant change despite a core staff experiencing educational approaches such as the Family and Infant Neurodevelopmental Education (FINE).

"The healthcare climate was demanding during this time, as there was a global pandemic, and staff turnover was at an all-time high. However, during the demands of COVID responsiveness, staff were challenged to become more resourceful, resilient, and agile resulting in opportunities to introduce change."

Implementation during the COVID-19 pandemic:

The healthcare climate was demanding during this time, as there was a global pandemic, and staff turnover was at an all-time high. However, during the demands of COVID responsiveness, staff were challenged to become more resourceful, resilient, and agile resulting in opportunities to introduce change.

In 2021 there was also a momentous overhaul to the New Zealand Healthcare system, providing a solid foundation for integrat-

ing whānau into NICUs. The healthcare changes meant that all 20 District Health Boards throughout New Zealand (regional) were abolished and replaced with one healthcare entity called - Te Whatu Ora, which partnered with Te Aka Whai Ora **(**Maori Health Authority)**.** Te whatu ora in the Maori language interprets as '***the weaving of wellness.'*** This new system in healthcare demanded actions to be delivered as agreed in Te Tiriti o Waitangi, a founding document signed between the British crown and Maori people in 1840.

Culturally appropriate systems-level changes:

Using the IFCDC principles, particularly Recommendations for Best Practices in Systems Thinking https://nicudesign.nd.edu/nicu-care-standards/ifcdc--recommendation-for-best-practices-in-systems-thinking/, we developed an approach titled "Whānau Haumaru Kotahi (Family Integrated Care)." The word whānau is Māori, the indigenous peoples of Aotearoa (New Zealand). Whānau translates as 'family,' but its meaning is more complex. It includes physical, emotional, and spiritual dimensions and is based on whakapapa (descendants).

"The Te Tiriti o Waitangi underpinning principles of partnership, participation and protection are sustained by the IFCDC standards and competencies. This synergy enabled us to translate the importance of integrating whānau in a way that made sense in Te Whatu Ora (New Zealand healthcare system)."

The Te Tiriti o Waitangi underpinning principles of partnership, participation and protection are sustained by the IFCDC standards and competencies. This synergy enabled us to translate the importance of integrating whānau in a way that made sense in Te Whatu Ora (New Zealand healthcare system). Our collaboration with whānau can be best described using the Māori word whanaungatanga. This word is defined in the Māori dictionary as "a relationship through shared experiences and working together which provides people with a shared sense of belonging."'

Implementation of IFCDC practices and progress:

To implement Whānau Haumaru Kotahi (Family Integrated Care), we reviewed the IFCDC standards and competencies--well supported by strong evidence-based references. Most research was carried out in other parts of the world and different healthcare systems, so we needed to find a way to adapt and translate them for NICU whānau in New Zealand.

Implementing Whānau Haumaru Kotahi has included in-house orientation and staff training and supporting them financially to participate in the online FINE training. Quality cycles have been initiated to measure success or to re-evaluate. Progress has been slow but consistent, hampered by the ongoing challenge of staff turnover and the necessary COVID response in New Zealand that had a significant impact in 2022. To date, the IFCDC standards and competencies are utilized and include Te Tiriti o Waitangi principles to measure progress.

Exemplar: Loma Linda University Raylene Phillips, Medical Director NICU, Loma Linda University Hospital, Murrieta

Our experience has taught us that the level of support from NICU and hospital administration is directly related to the success of our Neuroprotective Infant and Family-Centered Developmental Care (IFCDC) program. Strong NICU Director support protected time for a developmental care nurse and encouraged an active committee of nurses, therapists, and physicians who worked on QI projects to improve IFCDC.

Systems and management change:

Effects on implementation:

Without administrative support for IFCDC and when nursing management changed, the developmental care nurse no longer had protected time, NICU nurses were assigned to general pediatrics, and pediatric nurses unfamiliar with the importance of IFCDC were assigned to the NICU. The IFCDC program was heavily impacted as many gains in positioning and handling, infant-led feeding, parent-infant interactions, and other important aspects of IFCDC were lost.

The impact of COVID-19 on IFCDC implementation:

The COVID-19 pandemic brought another blow to IFCDC when parental presence was severely limited in the large Level 4 NICU of our regional children's hospital. The administration chose to ignore a recommendation by our state Public Health Department that during the pandemic, parents of NICU and PICU patients be allowed to be present at their child's bedside together, allowing support to each other during the family's NICU crisis. However, administration at the small Level 2 NICU community hospital, never restricted parents from being with their babies.

"Administrators' and managers' decisions affect financial resources for space and equipment, time given to NICU staff for education, and appropriate staffing. More importantly, their decisions ultimately affect the rights of parents to be present in the NICU with their babies and the rights of babies to be with their parents."

During the pandemic, the World Health Organization identified the danger in separating newborns from their parents and the safety of keeping them together under most circumstances https://news.un.org/en/story/2021/03/1087442#:~:text=The%20UN%20World%20Health%20Organization%20%28WHO%29%20on%20Tuesday%2C,by%20keeping%20them%20together%20to%20ensure%20skin-to-skin%20contact. In our larger NICU, only one parent was allowed at their baby's bedside for a short time each day. If they left the unit for any reason (for food or restroom), they

were not allowed to return that day. The cost to babies deprived of their parent's presence during this time is incalculable, and the trauma for parents was significant.

Support for IFCDC Before and During the Pandemic

Both before and during the pandemic, an important strategy for effective change has become apparent. Implementing any change towards IFCDC must not only focus on the NICU but should incorporate the people making decisions that affect how we care for babies and families in intensive care. Administrators' and managers' decisions affect financial resources for space and equipment, time given to NICU staff for education, and appropriate staffing. More importantly, their decisions ultimately affect the rights of parents to be present in the NICU with their babies and the rights of babies to be with their parents.

Implementing guidelines and practices must include strategies to engage leadership and hospital officials, including how to explain in evidence-based ways why IFCDC is so important for the short-term and long-term outcomes of the preterm and sick babies in our care.

Integration of the IFCDC Standards: Next Steps

We thank these national and international contributors for our understanding of the intricacies of implementing the standards, reminding us that considerations for cultural, epidemiologic, and financial influences will influence their application. It also reminds us that the best implementation involves not only staff and managers but also administrative and policy experts.

In the future, the IFCDC panel will address two significant efforts:

- The IFCDC Standards request that clinical providers, caregivers, parents, family members, and administrators, nationally and internationally, send feedback, recommendations, and potential revisions. Please see the "Proposal to Revise" form at the website https://nicudesign.nd.edu/nicu-care-standards/ .
- Ongoing Fragile Infant Forums for the Implementation of Standards (FIFI-S) will assist intensive care leaders and teams develop theoretical and applied approaches to assuring systems thinking, practice change, and better baby and family outcomes. The next FIFI-S virtual Forum will be held on September 28 and 29, 2023. For more information, please contact Joy Browne joy.browne@cuanschutz.edu.

Acknowledgment: *Thanks to Carol Jaeger, DNP, RN, NNP-BC, for her excellent organization and direction of the Gravens 2023 workshop and her ongoing commitment to the Consensus Panel.*

Disclosures: *No author has professional or financial relationships with any companies that are relevant to this study. There are no conflicts of interest or sources of funding to declare.*

NT

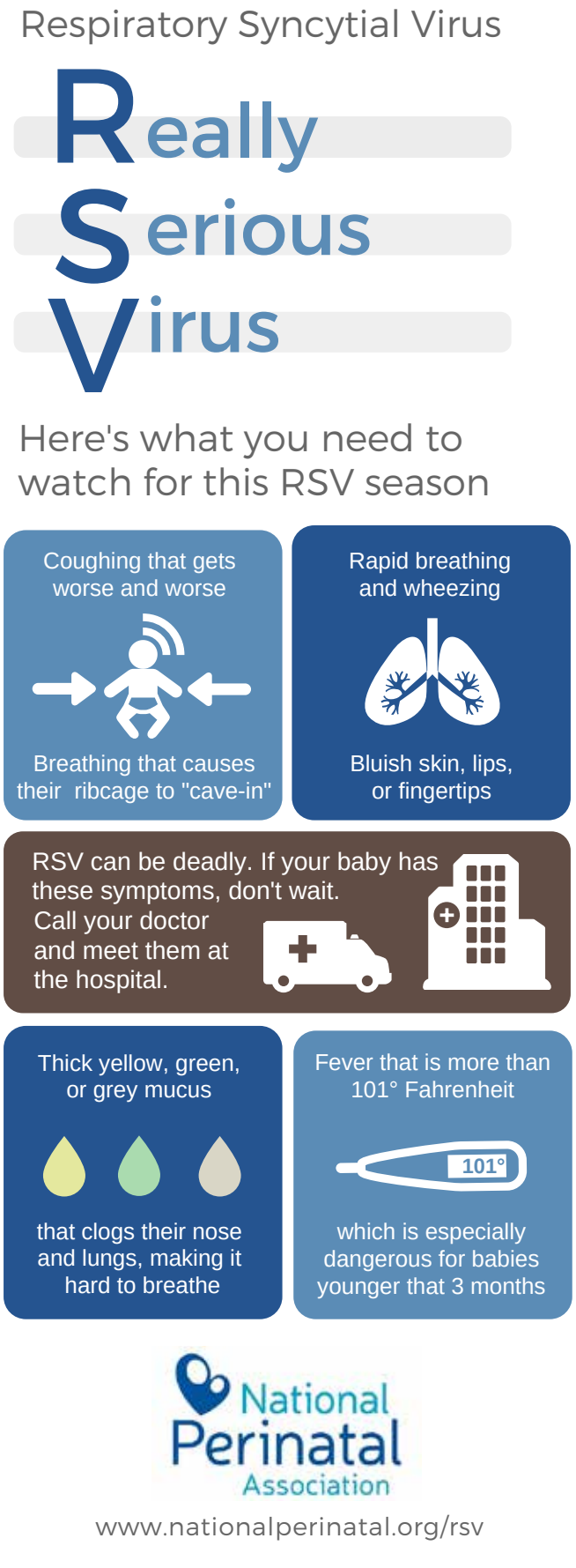
Geert Lingier
Hear Nurse Neonatl Intensive Care Unit
Universitair Ziekenhuis Gent

Dale Garton, RN, BHSc, MN,
Nurse Unit Manager, NICU, Starship Child Health
Auckland District Health Board
Grafton Auckland
New Zealand

Raylene Phillips, MD, MA, FAAP, FABM, IBCLC
Medical Director, Neonatal Services
Pediatric Department Chair
Loma Linda University Medical Center - Murrieta
Associate Professor, Pediatrics/Neonatology
Director, Breastfeeding/Lactation
Loma Linda University School of Medicine
Loma Linda University Children's Hospital
Loma Linda, CA

Corresponding Author

Joy Browne, Ph.D., PCNS, IMH-E(IV)
Clinical Professor of Pediatrics and Psychiatry
University of Colorado School of Medicine
Aurora, Colorado
Telephone: 303-875-0585
Email: Joy.browne@childrenscolorado.org



FCC TASKFORCE

FCC Core Team

Co-Chairs
Malathi Balasundaram, MD
Colby Day, MD
Keira Sorrells

Program Manager
Caroline Toney-Noland, MSc

Mission Statement

We exist to equip and support NICUs as they seek to begin or strengthen family-centered care in their unit.

What is family-centered care?

Family-Centered Care (FCC) ensures that caregivers are active, engaged team members throughout their NICU journey and is a key factor in improving infant health and family mental health outcomes.

Be sure to visit our new website, fcctaskforce.org, to view all past and upcoming webinars as well as shared resources.

Want to strengthen FCC in your NICU? Click this link or scan the QR code to join the FCC Taskforce.

@FCCTaskforce

Upcoming Webinars

May 11, 11am-12:30pm PT

- "Family Engagement and QI" Dr. Meg Parker & Molly Wylie
- "VON Family Engagement QI Work Examples" Marybeth Fry & Lelis Vernon

July 20, 11am-12:30pm PT

- "The I-Rainbow: A flexible, evidence-based care path for providing developmental care in the NICU" Dr. Melissa Scala & Dr. Eilish Byrne
- "Social Media: A Tool for Connecting with Families" Dr. Daphna Barbeau
- "How Mammha is Closing Gaps in Maternal Mental Health Care in NICUs" Maureen Fura, MPA, Mamma CEO & Founder


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 ™

Peer Reviewed

Non-invasive Ventilation (NIV) in the Micropremature Infant: Proceed With Caution

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.

"Although evidence incontrovertibly supports the use of NIV to decrease the incidence of chronic lung disease, evidence to support its use in the extremely premature population is lacking. In a previous column in NT, I have identified "practice creep" in this regard, with NIV being used with smaller and smaller babies utilising increasing pressures."

Although evidence incontrovertibly supports the use of NIV to decrease the incidence of chronic lung disease, evidence to support its use in the extremely premature population is lacking. In a previous column in NT, I have identified "practice creep" in this regard, with NIV being used with smaller and smaller babies utilising increasing pressures.

"CPAP belly" is a ubiquitous phenomenon in the NICU and is typically viewed as CPAP's benign companion. Just how benign this condition has not been investigated sufficiently, in the writer's opinion, nor have other common occurrences that accompany NIV, namely bradycardic and apneic episodes.

A study of 343 infants published in 2009 did not find any correlation between the use of CPAP and necrotising enterocolitis (NEC) (1), although it must be noted that at that time, NIV was not commonly used in the micro-premature population. In addition, not so long ago, a CPAP level of 7 cmH_2O was considered high, and this must be contrasted against much higher levels, i.e., 12 cmH_2O or more, as well as newer modalities such as NIV using high-frequency oscillation.

Every body system is underdeveloped in the premature infant, especially with decreasing post-menstrual age (PMA). While the pulmonary system is most susceptible to damage from medical interventions, the gastrointestinal system is as well. We are obsessed (often rightfully so) with pulmonary over-distention, but distended bowel resulting from CPAP belly stretches the intestinal wall. While the aforementioned study found this to be of no consequence, is this true with much smaller infants of lower PMA? Since the use of NIV on extremely small babies is a recent (and largely unsupported) phenomenon, evidence of its safety is lacking. It also takes time to reveal associations with treatment, especially in the case of something as pervasive as NEC.

"There are several reasons apneas and bradycardias (A&Bs) are common occurrences in premature infants. The immature respiratory centre is the primary culprit, but they are also the hallmark of more serious factors such as infection. A common causation in a tiny infant on NIV is their tiring out and failing the modality. "

There are several reasons apneas and bradycardias (A&Bs) are common occurrences in premature infants. The immature respiratory centre is the primary culprit, but they are also the hallmark of more serious factors such as infection. A common causation in a tiny infant on NIV is their tiring out and failing the modality. Because of the possibility of more serious etiology, clinicians often perform a full or partial septic workup to rule out sepsis. This is not benign; it represents an additional (and often unnecessary) procedure(s) and requires a significant volume of blood. The lab at my workplace requires 1.5 mL of blood for culture and CBC. This contributes to iatrogenic anemia, which may be more detrimental to the extremely premature than those of greater PMA.

The PINT study was conducted between 2001 and 2005 (2). 23-week PMA infants were not routinely offered resuscitation at that time. Thus, no conclusions regarding the safety of accepting low hemoglobin in these infants can be drawn. The PENUT study also did not include infants of less than 24 weeks PMA but did raise a flag regarding transfusions: each transfusion negatively affected cognitive and motor outcomes (3). Erythropoietin (EPO) was given in this study, and interestingly, those infants who received EPO did not suffer deficits in BDSI-III scores, but those who did not receive EPO did (3). The takeaway was to reduce the need for transfusion wherever possible. Unnecessary blood withdrawals do not fit that narrative. Since CPAP belly and associated abdominal distention may obfuscate more serious conditions like NEC (4), clinicians can hardly be faulted for being cautious.

" The takeaway was to reduce the need for transfusion wherever possible. Unnecessary blood withdrawals do not fit that narrative. Since CPAP belly and associated abdominal distention may obfuscate more serious conditions like NEC (4), clinicians can hardly be faulted for being cautious."

Another consequence of A&Bs is decreased perfusion and oxygen saturation. The premature gut is very susceptible to injury from under-perfusion and tissue hypoxia. One meta-analysis showed a significant increase in severe NEC in infants managed with lower SpO_2 targets (85-89%) c.f. those whose SpO_2 was targeted at 91-95% (5). More recently, transfusion re-perfusion injury to the gut has been suggested (6), leading to the withholding of feeds during transfusion in some units; the practice is the subject of an ongoing study (7) and debate. A patent ductus arteriosus, a risk factor for NEC (8), may amplify the effect of periodic A&B-related gut hypoperfusion.

While relatively low CPAP pressure may not result in rising intragastric pressure (9), this cannot be assumed with higher pressure. Intra-thoracic pressure results in increased intra-abdominal pressure (4). This delays gastric emptying time, which is already increased in the premature infant, decreases intestinal blood flow and slows intestinal motility resulting in feeding intolerance (4). Furthermore, increased abdominal distention exerts upward pressure on the diaphragm, necessitating further increases in CPAP distending pressure to maintain adequate lung inflation (4). This is a perfect picture of a vicious circle.

The relationship between the pulmonary and gastrointestinal systems is complex. One affects the other; "how?" is a topic of an ongoing investigation. Remembering this when using ever-higher pressures on increasingly smaller babies behooves us. There are many factors in which one system affects the other and vice-versa. Intestinal inflammation contributes to pulmonary inflammation, and pulmonary inflammation contributes to intestinal inflammation (10). Indeed, pulmonary pathology increases the risk of NEC, and NEC increases the risk of pulmonary pathology (10).

Assessing tissue oxygenation via pulse oximetry does not necessarily reflect tissue (i.e., gut) oxygenation in and of itself, and intestinal hypoperfusion/hypoxia increases NEC risk (10). More accurate means of assessing oxygenation are needed, i.e., near-infrared spectroscopy (10).

"Assessing tissue oxygenation via pulse oximetry does not necessarily reflect tissue (i.e., gut) oxygenation in and of itself, and intestinal hypoperfusion/ hypoxia increases NEC risk (10). More accurate means of assessing oxygenation are needed, i.e., near-infrared spectroscopy (10)."

Other factors, including antibiotics, severe anemia, and hypotension, impact the bowel. Of interest, spontaneous breathing improves intestinal perfusion. This adds further weight to avoiding paralysis, and although many bedside caregivers conflate spontaneous breathing superimposed on high-frequency oscillation or jet ventilation as "fighting the ventilator." This is not the case; it is desirable (10).

Pulmonary/intestinal interactions are too numerous to expand here, but reference 10 is an excellent primer.

A&Bs may require vigorous stimulation to resolve. During the neurologically sensitive first 72 hours, is it prudent to regularly stimulate an infant to breathe when the goal is to minimise handling?

"Given the probability of failure and the lack of evidence supporting its safety (and other sequelae such as nasal damage from prolonged use of NIV interfaces), is it prudent to use this mode in the sub-25-week PMA population?"

The likelihood of failing NIV increases with decreasing birthweight and PMA, particularly below 25 weeks. Given the probability of failure and the lack of evidence supporting its safety (and other sequelae such as nasal damage from prolonged use of NIV interfaces), is it prudent to use this mode in the sub-25-week PMA population? It is not, particularly during the first 72 hours of life.

Finally, the fact that chronic lung disease can develop, despite using NIV is lost on many. This is particularly true if mode failure

is not recognised and the appropriate action is taken. Increasing FiO2 often reflects pulmonary derecruitment, which may lead to "atelectrauma." In the face of severe CPAP belly/abdominal distention, increasing pressure is likely, not helpful. It may make things worse. The increasing frequency and severity of A&Bs indicate that things are not going well.

As stated in a previous column, "With NIV, failure is not a four-letter word." Failing to recognise it should be.

References:

1. https://pubmed.ncbi.nlm.nih.gov/19564301/#:~:text=The%20impact%20of%20CPAP%20and%20oxygen%20on%20gut,necrotizing%20enterocolitis%20%28NEC%29%20has%20not%20been%20adequately%20addressed
2. https://clinicaltrials.gov/ct2/show/NCT00182390
3. https://www.nature.com/articles/s41390-020-01273-
4. https://www.scilit.net/article/a38b328b4b873992b7f9509d-8426b34e
5. https://www.sciencedirect.com/science/article/abs/pii/S0146000521000689?fr=RR-2&ref=pdf_download&rr=7b8aa11439f20fb5
6. https://www.liebertpub.com/doi/pdf/10.1089/bfm.2018.29082.efl#:~:text=gut%20injury%28TRAGI%29%20refersto%20the%20temporal%20association%20%28%3C48%20hours%29,opposed%20to%20the%20luminalside%2C%20of%20the%20mucosal%20barrier.
7. https://pubmed.ncbi.nlm.nih.gov/30890001/
8. https://link.springer.com/article/10.1007/s12098-014-1545-x
9. https://journals.lww.com/jpgn/Fulltext/2005/02000/Patent_Ductus_Arteriosus,_Indomethacin_and.19.aspx
10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8440476/

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

Corresponding Author

Rob Graham, R.R.T./N.R.C.P.
Advanced Practice Neonatal RRT
Sunnybrook Health Science Centre
43 Wellesley St. East
Toronto, ON
Canada M4Y 1H1
Email: rcgnrcp57@yahoo.ca
Telephone: 416-967-8500

pac-lac

Perinatal Advisory Council:
Leadership, Advocacy and Consultation

Continuing Medical Education

The Continuing Education Department at PAC/LAC is pleased to consider requests to be a joint provider of your CME activity. PAC/LAC is actively involved in direct and joint-providership of multiple continuing education activities and programs and works with our partners to ensure the highest standards of content and design. PAC/LAC is the recipient of the 2018 Cultural & Linguistic Competency Award. This award recognizes a CME provider that exemplifies the goal of integrating cultural and linguistic competency into overall program and individual activities and/or a physician who provides leadership, mentorship, vision, and commitment to reducing health care disparities

PAC/LAC is an accredited provider of continuing education by Accreditation Council for Continuing Medical Education / Institute for Medical Quality, the California Board of Registered Nursing, the California Association of Marriage and Family Therapists, the National Commission for Health Education Credentialing, and the American Association for Respiratory Care.

To inquire about Continuing Education Joint-Providership opportunities for your event please visit our website and complete the online request form.

PAC/LAC offers continuing education for:

- Continuing Medical Education (CME)
- California Registered Nurses (CEU)
- Licensed Clinical Social Workers (LCSW)
- Licensed Marriage and Family Therapists (LMFT)
- Licensed Professional Clinical Counselors (LPCC)
- Licensed Educational Psychologists (LEP)
- Certified Health Education Specialists (CHES)
- Continuing Respiratory Care Education (CRCE)

www.paclac.org

PAC/LAC's core values for improving maternal and child health have remained constant for over 30 years – a promise to lead, advocate and consult with others.

Leadership

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

Advocacy

Providing a voice for healthcare professionals and healthcare systems to improve public policy and state legislation on issues that impact the maternal, child and adolescent population.

Consultation

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

The Golden Hour in the Neonatal Intensive Care Unit

Bernadette Mercado BSRT, NPS

"[Golden Hour] is the first 60 minutes of life, where extensive preparation, assessment, and care are administered to a preterm or term infant upon delivery."

Golden Hour captures photographers and social media influencers because of the cinematography of the sun in this last hour before sunset, and the first hour before sunrise is spectacular by the beach or up the mountain. It is a sign of hope and a new day on posters or social media posts. Golden Hour is about something other than capturing a great photo opportunity in the NICU. It is the first 60 minutes of life, where extensive preparation, assessment, and care are administered to a preterm or term infant upon delivery.

According to research, the term Golden Hour started in adult trauma, wherein the first hour is dedicated solely to trauma management.

"Evidence-based practice has proven that the golden hour approach decreases patient mortality with better outcomes, whether in stabilizing a patient that needs to be transferred to a higher level of care or in patient outcomes in general."

Evidence-based practice has proven that the golden hour approach decreases patient mortality with better outcomes, whether in stabilizing a patient that needs to be transferred to a higher level of care or in patient outcomes in general.

The primary goal of the golden hour is to use evidence-based interventions and treatments to achieve better neonatal outcomes, especially in extremely low gestational age neonates (ELGAN).

The second goal was to use the best evidence-based practice available, beginning with non-invasive procedures like gentle stimulation depending on age, CPAP, and thermoregulation, followed by invasive procedures such as IV lines, Umbilical catheters.

What are the elements that we focus on during this hour?

The NICU team should:

- Start with gathering labs from blood samples.
- Perform temperature regulation.
- Determine Delayed or Early Cord Clamping.
- Monitor basic vitals like the BP and O2 sat %.
- Assess the need for surfactants based on gestation and clinical manifestation of the baby.
- The Neonatologist assesses the baby's body systems. If, within Golden Hour, a baby has been admitted to the NICU, each team member assumes a role. The Respiratory Therapist monitors the respiratory status and works with the nurse to ensure temperature regulation and infection control measures are performed. Not every baby in this golden hour gets CBG or receives Oxygen or CPAP. However, babies admitted just for observation should be closely monitored by a Respiratory therapist, even for one documented respiratory assessment.

"Not every baby in this golden hour gets CBG or receives Oxygen or CPAP. However, babies admitted just for observation should be closely monitored by a Respiratory therapist, even for one documented respiratory assessment."

The Components of the Golden Hour

Component 1: *Antenatal Counseling:*

- The Antenatal period is the minutes immediately post–delivery.
- The Neonatologist will first counsel the parents on the estimated gestational age and the associated risk factors.
- Studies show that preterm infants, especially very low birth weight babies, have a high mortality rate and high occurrence of neurodevelopmental disabilities.
- This component aims to inform parents of the baby's condition and assist them in decision-making, for example, if the team will provide full code or comfort care.

Component 2: *Neonatal Team*

A team leader should be the Neonatologist or Pediatrician, and every team member should be assigned a role before delivering the Neonate to avoid any confusion and chaos.

"A team leader should be the Neonatologist or Pediatrician, and every team member should be assigned a role before delivering the Neonate to avoid any confusion and chaos. "

The respiratory is responsible for the airway; RN receives the baby and checks HR, performing stimulation and drying. A person that could intubate should be present in high-risk deliveries. Depending on Hospital protocol, everyone

Every team member should be NRP certified and attend high-risk or term delivery.

The What, WHY, and How before Delivery Or "Heads-up"

- Everyone should be Informed of the expected neonatal admission, especially if the team will attend the birth of any preterm neonate or high-risk term neonate.

  (https://mhnpjournal.biomedcentral.com/articles/10.1186/s40748-017-0057-x)

- Pre-check all equipment needed during resuscitation. Using a pre-resuscitation check-off list is ideal and speeds up the process.

- Prepare for multiple births, from twins to octuplets. Know the maternal history in detail from the maternal records and shared with the team leader. Usually, the OB will debrief the team on the latest before proceeding with a procedure like a c-section.

"Delayed cord clamping (DCC) is clamping of the cord after the stoppage of placental circulation, within 30 seconds to 3 min after neonatal birth. DCC for one minute led to the transfer of 80 ml of extra blood, and a delay of three minutes led to a total transfer of 100 ml of blood to the Neonate."

Component 3: *Delayed VS Early Cord Clamping*

- Delayed cord clamping (DCC) is clamping of the cord after the stoppage of placental circulation, within 30 seconds to 3 min after neonatal birth. DCC for one minute led to the transfer of 80 ml of extra blood, and a delay of three minutes led to a total transfer of 100 ml of blood to the Neonate.

- The candidates for DCC are term and stable infants. For Preterm babies that need resuscitation, ECC is necessary.

- Early Cord clamping (ECC) is the method of cord clamping when blood circulation is still present from the placenta to the newborn. The cord is clamped immediately after birth or Within 15 seconds of birth.

Studies showed that delayed cord clamping is associated with:

- Fewer infants requiring transfusions for anemia (RR 0.61, 95% CI 0.46 - 0.81),

- Less intraventricular hemorrhages (IVH) (ultrasound diagnosis all grades) (RR 0.59, 95% CI 0.41- 0.85) and

- Lower risk for necrotizing enterocolitis (NEC) (RR 0.62, 95% CI 0.43 - 0.90)

- One thing to note: Bilirubin concentration was significantly higher in neonates allocated to DCC compared with ECC (mean difference 15.01 mmol/L, 95% CI 5.62 - 24.40). It resulted in increased Jaundice and the use of phototherapy for DCC babies. (Rabe H, Diaz-Rossello JL, Duley L, Dowswell T. 2019 Sep)

"Bilirubin concentration was significantly higher in neonates allocated to DCC compared with ECC (mean difference 15.01 mmol/L, 95% CI 5.62 - 24.40). It resulted in increased Jaundice and the use of phototherapy for DCC babies."

Component 4: *Prevention of Hypothermia*

Temperatures < 36.5 °C are a dangerous problem in newborns, especially for preterm infants. There are several ways to keep the baby warm, such as:

- Prewarming the isolette

- Using plastic wrap or bag, caps, or thermal mattress.

- Transporters must be pre-warmed and ready for transport.

- Pre-Warm, humidified gas should be prepared in equipment such as Ventilators or non-invasive like CPAP.

- Possible skin-to-skin contact with the mom is one way to keep the infant warm.

- The delivery room temperature is preferred to be from 26 to 28 °C, which may keep the babies warmer.

Component 5: *Respiratory Support*

- Think NRP when it comes to Respiratory and Cardiac support.

- We have learned that term and preterm infants are prone to respiratory distress, a priority when attending a high-risk delivery.
- Everyone in the delivery room needs to Follow current NRP guidelines in resuscitation.
- Determine the need for respiratory support, such as intubation, or a non-invasive method like Mask CPAP or NIV, based on the baby's respiratory condition and the doctor's order.
- Be ready to administer surfactant.

"Manifestations of cardiac anomalies will surface in PDA, PFO, and PPHN. Look at pre- and post-ductal oxygenation, perfusion, auscultation, and X-ray results. "

Component 6: *Cardiac Support*

- The first step is to check the baby's heart rate. The team member can count the number of beats in 6 seconds and multiply it by 10. A more accurate method is to have the team member tap out the heartbeat with their finger. The assigned person will state the heart rate to the team. The Initial HR determines the next step of intervention based on the current NRP guidelines.
- Manifestations of cardiac anomalies will surface in PDA, PFO, and PPHN. Look at pre- and post-ductal oxygenation, perfusion, auscultation, and X-ray results.
- UA UV and IV Lines are best placed in the golden hour for immediate fluid access.

Component 7: *Nutrition*

- The placenta is the source of nutrients for the fetus, and once delivered and the umbilical cord is disconnected, the food supply for the baby stops.
- On-term babies, breastfeeding should be introduced within the first half-hour following birth.
- On ELBW, feeding will be evaluated, by the Neonatologist will determine a strict nutritional requirement.
- The nurse will closely monitor the infant's Fluid intake. Stable preterm infants with no complications can start on feeds.
- Glucose levels are checked on term and preterm infants.

Component 8: *Sepsis Prevention*

- Neonatal sepsis and prematurity are the two most common causes of neonatal mortality and morbidity.
- Hand washing and using an aseptic technique are essential to preventing neonatal sepsis.
- All invasive procedures like umbilical lines, IV lines, and surfactant administration should be done using asepsis techniques.
- The bundled care approach between RT and RN should be made and planned accordingly.
- Respiratory therapists should keep
- CPAP and ventilator circuits should be clean, and sterile distilled water should be used for humidification.

"Depending on hospital policy, Prophylactic Antibiotics will be started by the team to prevent the Early Onset of Sepsis or EOS. Antibiotic therapy like IV Ampicillin for GBS coverage and gram-negative organisms are usually used. "

Component 9: *Continuation of sepsis*

Depending on hospital policy, Prophylactic Antibiotics will be started by the team to prevent the Early Onset of Sepsis or EOS.

Antibiotic therapy like IV Ampicillin for GBS coverage and gram-negative organisms are usually used.

Depending on the mother's prenatal history and status, antibiotics and antifungal medications are given based on the hospital policy.

Blood culture is also collected by the nurse for further diagnosis of sepsis.

Possible cause of sepsis in a newborn are:

- If a Mother is Hep B positive, their babies should receive Hepatitis B immunoglobulin and single-antigen hepatitis B vaccine within 12 hours of birth.
- HIV+ moms' babies are started on Antiretroviral for prophylaxis.
- Mom with syphilis, those babies are considered to start on penicillin.
- Vaginal deliveries can spread bacteria that can pass to the babies' skin, eyes, and mouth.

Component 10: *Cooling/Therapeutic Hypothermia for Asphyxia*

The cooling method, also called newborn therapeutic hypothermia, lowers the baby's body temperature to treat hypoxic-ischemic encephalopathy (HIE). HIE is a neonatal brain injury that occurs if your baby's brain does not receive enough oxygen. The baby's body temp is purposely lowered to around 89°F to 93°F (32°C to 34°C).

Sample of a Cooling Protocol (refer to hospital policy or discuss with Neonatologist):

- Evidence of fetal distress or neonatal distress as evidenced

by one of the following: i., history of the acute perinatal event (e.g., placental abruption, cord prolapse, severe fetal heart rate abnormality);

- pH ≤7.0 or base deficit ≥16 mmol/L in a cord or postnatal blood gas obtained within the first hour of life.
- 10-minute Apgar score of ≤5; iv. Assisted ventilation should be initiated at birth and continued for at least 10 minutes; c) evidence of moderate to severe neonatal encephalopathy by examination.
- Lactate level- high levels indicate HIE. Normal for 0 – 90 days is 1.1-3.5 mmol/L

Component 11: *Labs and Monitoring*

Laboratory results are essential in the golden hour. Standard testing for babies exhibiting distress may include:

- Complete blood count,
- Blood culture, glucose,
- Arterial blood gas (ABG) analysis/capillary blood gas, and
- Chest X-ray (CXR)

Component 12: *Monitoring Vitals*

Monitoring and recording are a critical factor in the Golden Hour. Some important measurements include:

- Heart rate,
- Respiratory rate,
- Capillary refill time,
- Invasive or non-invasive blood pressure
- Saturation

"For a stable-term newborn, Golden Hour still is a necessary time to observe with the help of the parents, especially the mother."

For a stable-term newborn, Golden Hour still is a necessary time to observe with the help of the parents, especially the mother.

Pediatrician or RN counsels the mother regarding maintaining temperature and frequency of breastfeeding, emphasizing starting early feeding and maintenance of asepsis in newborn care.

For unstable babies admitted to NICU, neonatologists discuss the baby's present status with the parents, interventions made until that time, and further management plans.

The Neonatologist should explain all necessary consents obtained by the RN from the parents, like admission, procedure, transportation, and starting of hypothermia or other protocols.

Competent 13: *Pre-Transport*

The NICU team should first stabilize Neonate. When shifting to a tertiary health care center and the receiving hospital should be informed regarding this transport so that the Neonate receives the required care on reaching the center.

In summary, the Benefits of Golden Hour Care are the following:

- Increase the number of infants with an admission temperature of 36.5 °C – 37.4 °C.
- Decrease in the incidence of ROP and BPD
- Significant improvement in time of surfactant administration
- Improvements in time to start dextrose and amino acids infusion.
- Decrease in time to give antibiotics.
- Decrease in the incidence of IVH.
- Faster placement of umbilical catheters
- Significant reduction of the time to reach NICU after delivery.
- Glucose greater than 50 mg/dL.

References:

1. Sharma, D. (2016). The golden hour of neonatal life: Need of the hour. Maternal Health, Neonatology and Perinatology, 3, https://doi.org/10.1186/s40748-017-0057-x
2. Rajaratnam, J. K., Marcus, J. R., Flaxman, A. D., Wang, H., Levin-Rector, A., Dwyer, L., Costa, M., Lopez, A. D., & Murray, C. J. (2010). Neonatal, postneonatal, childhood, and under-5 mortality for 187 countries, 1970-2010: A systematic analysis of progress towards Millennium Development Goal 4. Lancet, 375(9730), 1988-2008. doi: 10.1016/S0140-6736(10)60703-9. Erratum in: Lancet. 2010 Aug 28;376(9742):686. Erratum in: Lancet. 2010 Jun 19;375(9732):2142. PMID: 20546887.
3. Joseph, R. M., Korzeniewski, S. J., Allred, E. N., O'Shea, T. M., Heeren, T., Frazier, J. A., Ware, J., Hirtz, D., Leviton, A., & Kuban, K.; ELGAN Study Investigators. (2017). Extremely low gestational age and very low birthweight for gestational age are risk factors for autism spectrum disorder in a large cohort study of 10-year-old children born at 23-27 weeks' gestation. American Journal of Obstetrics and Gynecology, 216(3), 304.e1-304.e16. doi: 10.1016/j.ajog.2016.11.1009. PMID: 27847193; PMCID: PMC5334372.
4. Rabe, H., Diaz-Rossello, J. L., Duley, L., & Dowswell, T. (2012). Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes. Cochrane Database of Systematic Reviews, (8), CD003248. doi: 10.1002/14651858.CD003248.pub3. Update in: Cochrane Database Syst Rev. 2019 Sep 17;9:CD003248. PMID: 22895933.
5. American Academy of Pediatrics. (2021). NRP, 8th Edition.

Disclosures: The authors have no disclosures

NT

Bernadette Mercado BS RRT
Instructor
Academy of Neonatal Care
Email: beme715@gmail.com

99nicu

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

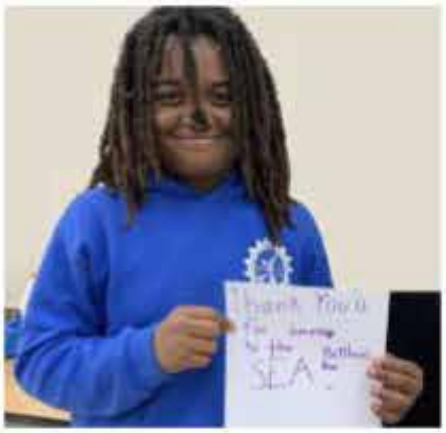
August 9, 1996 - April 3, 2010

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.

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

Eye to Eye, Hand in Hand: Countering SUID Rate Increases in Non-Hispanic Black Populations Through Community-Based Education

Alison Jacobson

first candle

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.

" According to a Centers for Disease Control (CDC) study (1) released in March on Sudden Unexpected Infant Death (SUID) and Sudden Infant Death Syndrome (SIDS) rates in the U.S. from 2015-2020, 2019-2020, the SIDS rate went up 15%, to become the third leading cause of infant death."

According to a Centers for Disease Control (CDC) study (1) released in March on Sudden Unexpected Infant Death (SUID) and Sudden Infant Death Syndrome (SIDS) rates in the U.S. from 2015-2020, 2019-2020, the SIDS rate went up 15%, to become the third leading cause of infant death.

Study authors suggested this may likely be due to changes in classification and noted that the overall SUID rate during this period did not change significantly – except for non-Hispanic Black infants. In 2020, the SUID rate per 100,000 live births was the highest among this group, at 214, nearly three times the rate for non-Hispanic White infants (75.6) and higher than at any time during 2017 – 2019. This widens a disparity; the non-Hispanic Black infant mortality rate is now 2.8 times higher than for non-Hispanic White infants.

" This widens a disparity; the non-Hispanic Black infant mortality rate is now 2.8 times higher than for non-Hispanic White infants."

This finding of significantly higher rates of SUID from 2019 to 2020 among non-Hispanic Black infants but not for other single-race or Hispanic infant groups was unexpected.

The study put forward that the COVID-19 pandemic disproportionately exacerbated social determinants of health for this group, including pandemic-related changes to employment, healthcare access, childcare, and caregiver stressors, and noted that reducing risk should include "increased clinical training and quality improvement efforts for safe sleep education, and identification of methods for removing barriers to implementing safe sleep practices."

First Candle supports all efforts to advance education around infant safe sleep. However, we also know that "quality improvement efforts" for this education must include community-level interaction with families considering their lived experiences and real-world circumstances.

During the community listening sessions we conducted in 2019, we heard the challenges felt by parents and family members in these communities concerning compliance with the American Academy of Pediatrics (AAP) guidelines for infant safe sleep. This led to our white paper (2) identifying the everyday barriers to infant safe sleep practice and the very real cultural beliefs and social norms affecting family decisions. Education that does not look at how the message is delivered and by whom is ineffective.

"First Candle recognizes the power of these social norms, and we are increasingly aware that no "one size fits all" teaching model for families and the healthcare providers who serve them will be successful. "

The Full Scope of the Issue

In a simultaneously released commentary (3) on the CDC study, the AAP stated that the SUID rate disparity is likely due to multiple factors, reflecting poverty levels, health care access, and education around infant safe sleep and human-milk feeding, which can reduce SUID risk. They also recognized "social norms related to these practices that vary between communities."

First Candle recognizes the power of these social norms, and we are increasingly aware that no "one size fits all" teaching model for families and the healthcare providers who serve them will be successful. Safe sleep messaging has to respect the cultural practices and real-life challenges families face and acknowledge the part structural racism has played in supporting and educating them.

"The CDC study and the AAP commentary highlight the "multifactorial" nature of the forces behind disparities in infant mortality in the U.S. We realize that addressing this many-faceted issue requires consistent effort and focus from many groups on many levels, and First Candle is part of that."

The CDC study and the AAP commentary highlight the "multifactorial" nature of the forces behind disparities in infant mortality in the U.S. We realize that addressing this many-faceted issue requires consistent effort and focus from many groups on many levels, and First Candle is part of that.

This understanding has led to the launch of our Let's Talk Community Chat program, a partnership with local organizations, doulas, and fathers to educate them about safe sleep practices, breastfeeding, and the proper use of infant products. These individuals and groups then go into their communities to sit down monthly and talk with all members of a family or gathering of families, meeting them "where they're at" concerning their existing beliefs and challenges.

The program was piloted in Harlem last year and has been so successful that we have received grants and private donations to expand into Atlanta and Philadelphia this year.

We look forward to expanding our community-led education program to cities nationwide. We know that providing assistance to these local organizations, listening to the specific challenges within each community, and allowing them to lead the way on safe sleep education, breastfeeding, and other supports families need will finally change the trajectory of SUID.

References:

1. Shapiro-Mendoza CK, Woodworth KR, Cottengim CR, et al. Sudden Unexpected Infant Deaths: 2015–2020. Pediatrics. 2023;151(4):e2022058820
2. Jacobson, Alison, Himes, Barb. Understanding the Obstacles and Influences in Adopting Infant Safe Sleep Practices. Neonatology Today, 2021; Vol. 16, Issue 10
3. Rebecca F. Carlin, MD; Fern R. Hauck, MD, MS; Rachel Y. Moon, MD. Increasing Disparities in Sudden Unexpected Infant Deaths Reflect Societal Failures. https://doi.org/10.1542/peds.2022-060798

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

NT

Corresponding Author

Alison Jacobson
Executive Director
Chief Executive Officer
First Candle
21 Locust Avenue, Suite 2B
New Canaan, CT 06840
Telephone: 1-203-966-1300
For Grief Support: 1-800-221-7437
Email: Alison@firstcandle.org
www.firstcandle.org

About First Candle

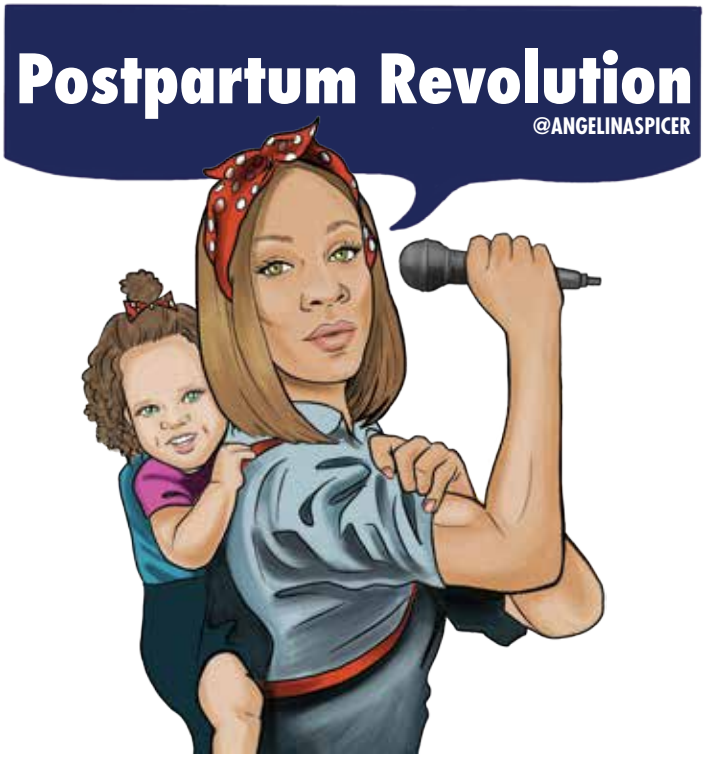
First Candle, based in New Canaan, CT, is a 501c (3) committed to eliminating Sudden Unexpected Infant Death while providing bereavement support for families who have suffered a loss. Sudden Unexpected Infant Death (SUID), which includes SIDS and Accidental Suffocation and Strangulation in Bed (ASSB), remains the leading cause of death for babies one month to one year of age, resulting in 3,500 infant deaths nationwide per year.

Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY



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

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."

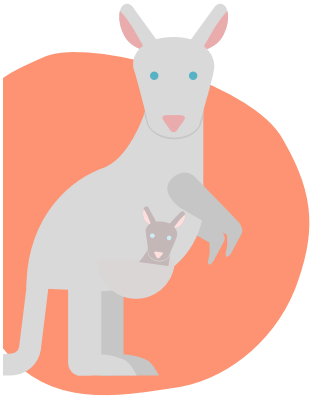
10 HELP US HEAL

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

Position available for Neonatal Nurse Pretensioner (NNP)

Excellent practice opportunity for a NNP in an established Los Angeles neonatal practice. The Neonatal Hospitalist Group (NHG) is interviewing for an NNP to join the practice. The practice includes four NICU's in the Burbank and Glendale area. Call is from home with excellent work life balance. If you are interested, please email Robert Gall, MD, at robertgallmd@gmail.com.

Protecting your baby from

Respiratory Viruses:

What parents need to know this RSV and flu season

RSV (Respiratory Syncytial Virus) and flu infections affect the lungs and can cause serious breathing problems for children and babies.

Certain diagnoses can make children and babies more vulnerable for serious complications - including prematurity, chronic lung disease, heart conditions.

You can limit the spread of viruses by wearing a mask, washing your hands with soap & water, and using alcohol-based hand sanitizer.

The fewer germs your baby is exposed to, the less likely they are to get sick. Limit visitors. Avoid crowds. Stay away from sick people.

Immunizations save lives. Stay up-to-date with your family's flu and COVID-19 vaccinations. This helps stop the spread of deadly viruses.

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

National Perinatal Association

www.nationalperinatal.org/rsv

ONCE UPON A PREEMIE ACADEMY

eLearning Courses

Health and Racial in the NICU

Meet Our Faculty

+ Jenné Johns, MPH
Once Upon A Preemie Academy

+ Dawn Godbolt, Ph.D.
National Birth Equity Collaborative

+ Chavis A. Patterson, Ph.D.
Children's Hospital of Philadelphia

+ Shanté Nixon
Connect2NICU

+ Deidre McDaniel, MSW, LCSW
Health Equity Resources and Strategies

+ Dalia Feltman, MD, MA, FAAP
Univ. of Chicago Pritzker School of Medicine

+ Terri Major- Kincade, MD, MPH
Pediatrician and Neonatologist

+ Ashley Randolph
Glo Preemies

REGISTER TODAY
OnceUponAPreemieAcademy.com

Health and Racial Equity + On-Demand Continuing Education

The first and only virtual training academy focused on delivering health and racial equity educational programs for perinatal and neonatal healthcare professionals. Our purpose is to raise awareness and offer real-time solutions for addressing health and racial equity.

pac-lac

Continuing Education Partner, paclac.org/continuing-education

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

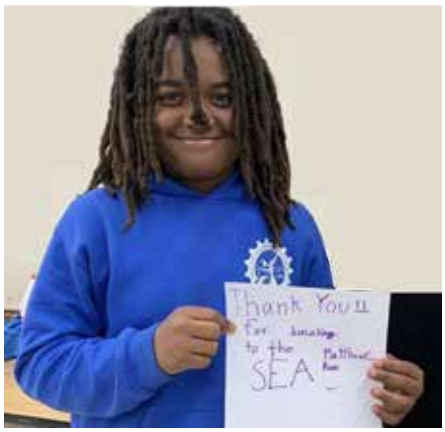
Thirteen-year-old Emily Rose Shane was tragically murdered on April 3, 2010 on Pacific Coast Highway in Malibu, CA. Our foundation exists to honor her memory.

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.**

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.

National Perinatal Association: The Hidden Side of Maternal Mental Health

Cristal Grogan

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.

"Robin Williams once said, 'All it takes is a beautiful smile to hide an injured soul, and they will never notice how broken you really are.'"

Robin Williams once said, "All it takes is a beautiful smile to hide an injured soul, and they will never notice how broken you really are."

It has been debated that there are over 27 categories of emotions that the human population experiences over their lifetime. Unlike islands that operate individually, these categories of emotions interweave and overlap as we move throughout our day and experience all life throws at us. As we all know, emotions are a natural and necessary part of life, but when emotions become too intense or difficult to manage, they can lead to mental health issues such as depression and anxiety. Research has begun to highlight that a mother's emotional wellbeing is vital for their child's healthy development. Nevertheless, discussions surrounding maternal mental health remain a topic that is tiptoed around and often ignored until an outburst or breakdown is experienced that forces intervention by a care team.

"Research has begun to highlight that a mother's emotional wellbeing is vital for their child's healthy development. Nevertheless, discussions surrounding maternal mental health remain a topic that is tiptoed around and often ignored until an outburst or breakdown is experienced that forces intervention by a care team."

However, public breakdowns do not always happen. In our society, mental health concerns are often hidden and swept under the rug out of fear, shame, embarrassment, and so much more. The topic of mental health has historically been stigmatized and taboo in many cultures and societies. This can be attributed to various reasons, including cultural and social beliefs, lack of understanding and education about mental health, fear of discrimination, and a tendency to view mental illness as a sign of weakness or personal failing. We need to start talking about maternal mental health openly and honestly. We must show understanding and empathy if we want to create a more supportive and accepting society for those struggling with mental health challenges. There has to be a better way.

"As a mother who has experienced two high-risk pregnancies, two premature births, the death of one child, and the raising of a child with complex medical needs, it is safe to say that I have faced a tornado of emotions head-on during my journey."

As a mother who has experienced two high-risk pregnancies, two premature births, the death of one child, and the raising of a child with complex medical needs, it is safe to say that I have faced a tornado of emotions head-on during my journey. I have celebrated the highs, been brought to my knees with the lows, and have swum through the waters of the in-betweens; never quite knowing what I will face next. Throughout my journey, maternal mental health has remained a topic that is often overlooked and often unacknowledged. I am a parent who has always presented themselves as educated, emotionally stable, organized, and able to research and process information accordingly. Moreover, although I have been able to carry myself well, I am also the parent who has silently cried in more showers than I can count, who has dealt with suicidal ideation, crippling anxiety, depression, and more private mental breakdowns than I will ever be brave enough to admit.

One of the most significant challenges mothers like me face is the lack of mental health resources. Many women struggle to access affordable and appropriate mental health services, especially for marginalized communities, such as low-income and rural populations. This lack of resources can severely affect mothers and their child (ren). It is becoming increasingly clear that addressing mental health concerns follow-

ing a diagnosis and early on is crucial to prevent long-term adverse effects for both mother and child. This brings yet another level of need, making this a next-to-impossible endeavor to address alone without systematic change.

It is also vital to note that the impact of maternal mental health issues may be vastly different depending on the person's social, economic, and financial circumstances. So, although everyone is experiencing the same storm, some are in vastly different boats than others. Furthermore, our greatest strengths often become our most significant weaknesses in those boats. Resilience can turn into stubbornness. Independence can turn into isolation. Perfectionism can turn into burnout.

"On the other hand, mothers who are resilient and able to adapt to change may be better equipped to handle the challenges of motherhood, but they may also feel pressure always to be strong and not ask for help when needed. "

For example, mothers highly dedicated to their children's wellbeing may become so focused on their parenting role that they neglect their self-care and mental health needs. This can lead to burnout, exhaustion, etc. On the other hand, mothers who are resilient and able to adapt to change may be better equipped to handle the challenges of motherhood, but they may also feel pressure always to be strong and not ask for help when needed.

"It is important to keep working towards reducing the stigma surrounding maternal mental health and increasing access to resources and support to help people feel comfortable seeking help when needed. Meaningful progress and care transformation can only be achieved through proactive and intentional behavior, processes, or systems changes."

So, what can we do? How do we begin to change such a broken system? It is essential to increase access to mental health resources for mothers. To address this issue. This can include:

- Funding for research and treatment programs
- Improving insurance coverage
- Increasing awareness and education
- Involving and supporting partners and families
- Addressing systemic inequalities
- Screening for mental health issues during and after pregnancy

It is important to keep working towards reducing the stigma surrounding maternal mental health and increasing access to resources and support to help people feel comfortable seeking help when needed. Meaningful progress and care transformation can only be achieved through proactive and intentional behavior, processes, or systems changes. Remember that mothers' wellbeing is the foundation of healthy families, strong communities, and a prosperous society. By prioritizing maternal mental health, we are investing in the present and securing a brighter future for future generations.

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

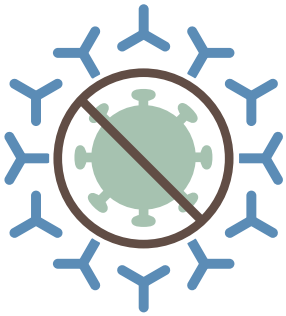
NT

Corresponding Author

Cristal Grogan
Secretary
National Perrinatal Association
Email: Cristalgrogan@gmail.com

Protecting your baby and family from

Respiratory Viruses:



What parents need to know this RSV and flu season

Like COVID-19, RSV (Respiratory Syncytial Virus) and flu affect the lungs and can cause serious breathing problems for children and babies. Talk to your family about the risks.

Certain diagnoses can make children and babies more vulnerable for serious complications from respiratory viruses - including prematurity, chronic lung disease, and heart conditions.

You can limit the spread of viruses by wearing a mask, washing your hands with soap & water, using an alcohol-based hand sanitizer, and getting vaccinated.

The fewer germs your baby is exposed to, the less likely they are to get sick. Let people know you need their help to stay well. Limit visitors. Avoid crowds. Stay away from sick people.

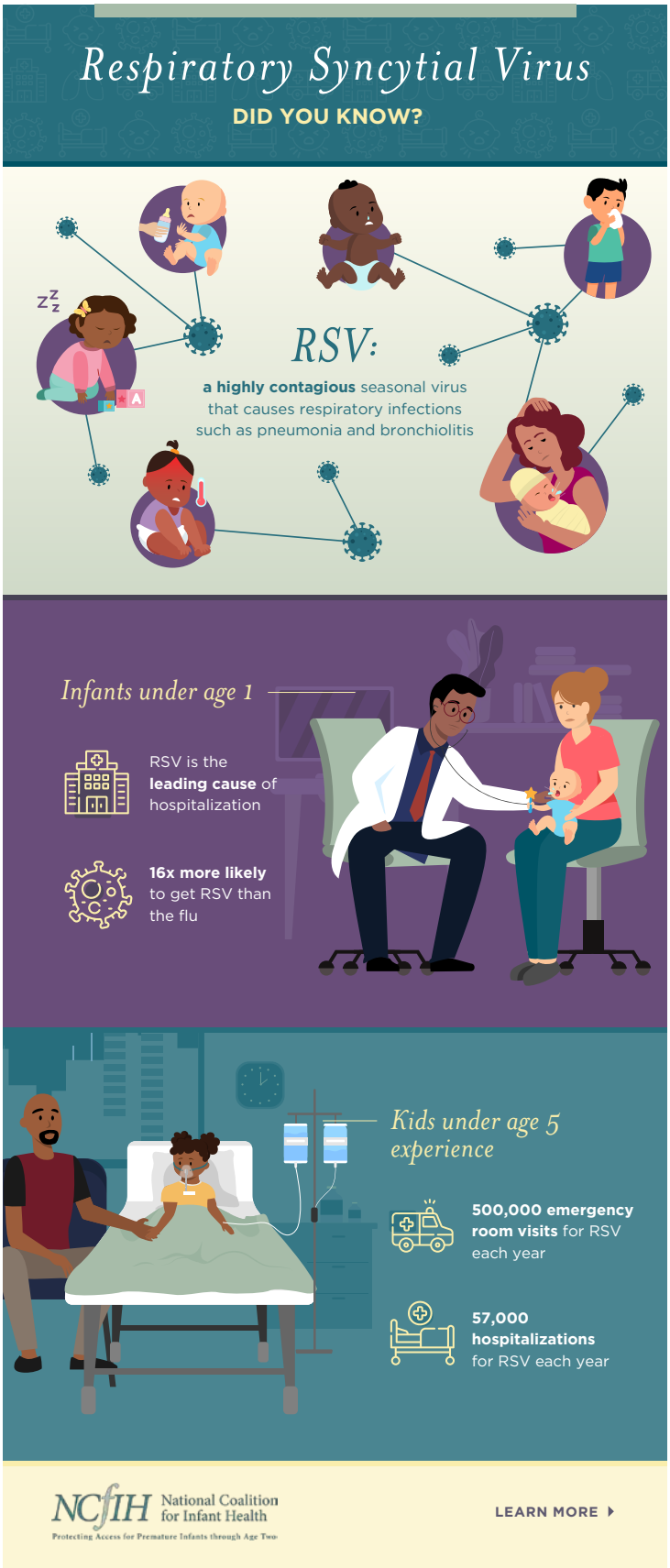
Immunizations save lives. Stay up-to-date with your family's flu vaccinations and COVID-19 boosters. This helps our community stay safe by stopping the spread of deadly viruses.

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

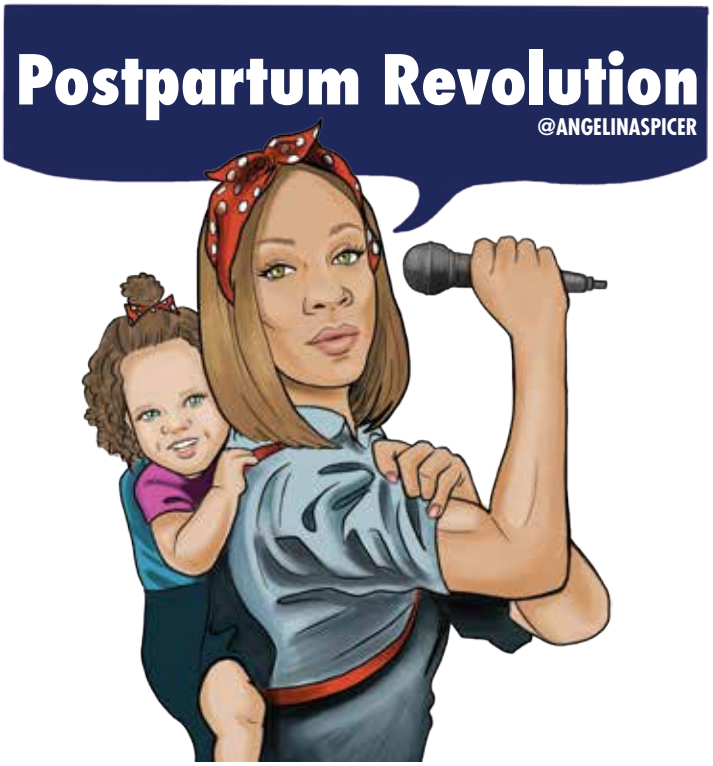
WE CAN HELP PROTECT EACH OTHER.

National Perinatal Association

www.nationalperinatal.org/rsv



The Gap Baby: An RSV Story



Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY

Family Centered Care Taskforce March Webinar: Improving Discharge Planning

Vincent Smith MD, MPH, Malathi Balasundaram MD, Colby Day MD, Caroline Toney Noland MSc, Kari McCallie MD, Kristy Love

Colby Day: I think if you advance, it shows our core team. Caroline, who we could not do any of this without. We have Malathi and myself, and then we also have quite a few partners. Now, as you can see, the slide has grown over time, which is pretty exciting. And so we're very grateful to have such wonderful partners as we start to grow this Family Centered Taskforce even further. And we also have a few grants that we're very grateful for as well. We're supported by Genentech and ProLacta, and then we also had a Gravens lunch session sponsored. And today we have 2 exciting presentations that you'll get to hear from Dr. Smith and Kristy Love initially, and I will speak in a little more detail about that in a couple of minutes to introduce them, and then our very own, Dr. Balasundaram, is going to be able to give us a talk as well. We will have specific questions and answers after each of these sessions, and so please definitely chat in questions and comments as our speakers are presenting, and then we will have some time set aside after each presentation to be able to talk through some of those questions.

We could not do this without our family partners. We have 17 family partners who are very active with our organization, and then we also have our health care partners as well that we see on the next slide, who are 16 very dedicated individuals that are contributing to the task force. And we have a couple of exciting updates to tell you since our last webinar. Most of these are related to the recent Gravens Conference that was in Florida. I hope that many of you were able to attend it either in person or virtually. We were able to support five Family Partners to attend the Gravens Conference virtually and four Family Partner Small Group Leaders, as well as three Health Care Partners Small Group Leaders to attend the conference in person. In collaboration with the National NICU Parent Network, we are able to hold a Taskforce luncheon that had 70 Gravens attendees and provide CME/CEUs for this attendance. And we also shared a much of our taskforce work with the general attendees at Gravens on Friday in the form of a workshop, which was very interactive and a great way to hear how other people are doing things in their institutions, and to share what our actual members are doing as well. And this last bullet point is really exciting. So, a year ago we have 50 individuals that were involved in this taskforce, and over the last year, we've been able to expand to over 415 individuals, who represent over 200 NICUs from 36 states and 14 countries, all of whom are committed to learning more about family-centered care, and really trying to advance this culture in their units and globally.

"So, a year ago we have 50 individuals that were involved in this taskforce, and over the last year, we've been able to expand to over 415 individuals, who represent over 200 NICUs from 36 states and 14 countries, all of whom are committed to learning more about family-centered care, and really trying to advance this culture in their units and globally."

And so now, it is my pleasure to introduce our first two speakers. Dr. Vincent Smith is the Division Chief of Newborn Medicine at Boston Medical Center and a Professor of Pediatrics. He's a graduate of Texas A&M University, Stanford University School of Medicine, and the Harvard School of Public Health. He trained in pediatrics at Children's Hospital and Boston Medical Center in the Boston Combined Pediatric Residency program. He then completed a fellowship in Neonatal-Perinatal Medicine

through the Harvard-wide program, a collaboration of Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Massachusetts General Hospital, and Boston Children's Hospital.

He completed a fellowship and health services research at Children's Hospital and serves as the medical director for the AAP Fetal Alcohol Spectrum Disorders Program. He is an active member of the Massachusetts Medical Society and Society for Pediatric Research. And he is also a former member of the National Perinatal Association Board of Directors. In addition to parental NICU discharge readiness, his professional interests include families affected by substance use and medical care for LGBTQIA-headed families.

"Dr. Vincent Smith is the Division Chief of Newborn Medicine at Boston Medical Center and a Professor of Pediatrics... Kristy Love...is a mother of two premies. For over 20 years, Kristy has worked in the nonprofit community, providing health education, advocating for NICU families and the high-risk population."

Along with Dr. Smith, we have Kristy Love, who is a mother of two premies. For over 20 years, Kristy has worked in the nonprofit community, providing health education, advocating for NICU families and the high-risk population. She's collaborated with community groups, corporations, national organizations, and universities to improve outcomes for families of premature infants, babies formed with special needs and developmental needs. So please join me in welcoming our speakers and remember to chat in your questions.

Vincent Smith: Excellent. All right. So, first of all, thank you all for having us, and for your interest in this topic, because it's pretty near and dear to my heart and to Christy's heart. It's hard for me to see the chat while I'm sharing my screen, so somebody else will have to kind of keep an eye on the chat for me.

I'm going to do most of the talking for the presentation part, and Christy is going to jump in to add extra detail and also when there are questions that come up.

And I also want to acknowledge Erika Goyer from National Perinatal Association who helped make all of our slides look so much more beautiful than the slides that I initially created. So, thank you for that.

I have no financial disclosures that are relevant, and Kristy has no financial disclosures that are relevant.

We would like to acknowledge that the publication of the discharge guidelines supplements was sponsored by the National Perinatal Association, and the funding for the publication was provided to the National Perinatal Association by private donations and supported by an educational grant by Sobi. The funding for the implementation portion of the project was provided to National Perinatal Association by our partners and AngelEye, who've been helping us on the second part of our journey.

So, during our time together a couple of things I want to kind of explain the importance of discharge preparation, which I'm not going to spend too much time on, because I feel like I'm preaching to the choir when it comes to that. I do want to spend it describing the creation of the guidelines and what the guidelines cover. And then I also want to talk a little bit about some steps for a successful implementation of the guidelines. I want to spend just a little bit of time and give a kind of high-level view of that. And then if you want more information about the successful implementation, we're going to have to invite Cuyler (Romeo) back because she's amazing, and she does a great presentation for those who were at Gravens, you kind of heard it.

So, this is going to be kind of the flow of the talk for today. We're going to start off with some definitions and the creation of the guidelines. And then we're going to review the topics that the guidelines cover, and there are like 200 plus guidelines. We're not going to be able to go through each individual guideline in that kind of way. So, what I want to give you is more of kind of a bit of a flavor for what the guidelines cover as opposed to specific guidelines themselves. And I'll tell you how you can get the guidelines and then also about some supporting material that goes with the guidelines. Then the last piece we'll talk a little bit about implementation, and hopefully, we'll make it not seem quite as scary or as a big of a task, as it sometimes can seem when you're trying to implement something new.

So, the importance of NICU discharge preparation and transition planning. Normally, I spend a good amount of this part of the time convincing you that it's really important to have discharge planning for the families and for providers. But given the audience, we're going to skip that part, and we're going to just jump right into assuming we all agree that it's an important thing.

So, we will start off talking with two kinds of related concepts, and the first one is discharge readiness, which is the desired outcome, and then discharge preparation, which is a process for our families to get discharge ready.

"So, we will start off talking with two kinds of related concepts, and the first one is discharge readiness, which is the desired outcome, and then discharge preparation, which is a process for our families to get discharge ready."

And if we're talking about discharge readiness specifically, what we're talking about is the attainment of technical skills and knowledge, emotional comfort, and confidence with infant care. And this is by the primary caregivers at the time of discharge, and anybody who's ever heard a talk from me in the last 10 years knows that I use this definition all the time. I think this is really important. Discharge readiness is the goal. Discharge preparation is the process, and so it's the process of facilitating discharge readiness to successfully make the transition for home. So, with that in mind, we're going to transition to the discharge preparation guidelines. When we start to think about the guidelines where they came from in the ether and all of this, the original guidance came from the AAP. And what the AAP (the American Academy of Pediatrics) did was they described basically infant physiological maturity in pretty reasonable detail. What they said was that in order for an infant to transition from the NICU to home, the infant needs to achieve physiologic maturity, meaning that they can coordinate breathing and oral feedings; they can ingest adequate volumes and gain weight; and they can maintain normal body temperature; and thus they demonstrate stability. And so that's

all pretty clear and pretty straightforward. And then the AAP said the parents should participate in a program for care of the infant at home. But what the AAP didn't do was give more detail about what the program should involve, how it should be implemented, or any of (those) things. They just said this needs to happen, and then they just left it kind of open. And the AAP suggested that former NICU infants need to be followed in a medical home that is familiar with taking care of former NICU infants. And they said in this medical home, they need to be followed by a pediatric provider, and they need a program that's going to track the infant's growth and development. And so all of that is actually really good, but they don't talk about the transition from the NICU piece to this medical home piece or any support services that come around the families after they're already discharged.

"But what the AAP didn't do was give more detail about what the program should involve, how it should be implemented, or any of (those) things. They just said this needs to happen, and then they just left it kind of open. And the AAP suggested that former NICU infants need to be followed in a medical home that is familiar with taking care of former NICU infants. And they said in this medical home, they need to be followed by a pediatric provider, and they need a program that's going to track the infant's growth and development."

So with that in mind, that's kind of what brings us to how the National Perinatal Association got into the discharge planning game. The National Perinatal Association developed these guidelines over many years, and they were using the best available evidence. I think everybody's familiar with the National Perinatal Association. But for those who don't know, NPA is an interdisciplinary organization and is one of the leading voices in perinatal care, and one of their missions is to bring parents and professionals together to advocate for better policies and care practices. The way the guidelines came about is around 2017, the NPA convened a work group with the goal of creating a comprehensive set of guidelines that reflected the best available evidence from across disciplines. And it's also informed by families' experiences, and so families were always a part of this process from the very beginning all the way through.

And so the process of creating these guidelines started with what's called an environmental scan, which is basically reviewing all existing standards and literature, and also the work group collected and collated existing standards and had a literature review of published medical and nursing literature that were related to this particular topic. And then, using that environmental scan, that became the basis for the first draft of the evidence-based, multidisciplinary consensus guidelines. And then the work group determined where consensus existed, recognizing that there were some differences in practices, and then they also tried to identify gaps with no guidelines available and then created a course of action to be able to address what the gaps were.

Then, in 2019, the National Perinatal Association hosted a summit of content experts whose express purpose was to review the draft of the guidelines that the work group had created. Prior to the conference, the content experts were divided into 4 groups based on topics—family and home assessment, special circumstances, support systems, and/or transfer and/or coordination of care. And each of those groups was given the questions: is this content appropriate; is this content complete; or is there missing information; and also are the recommendations appropriate, practical and actionable? Are the recommendations clear and concise, and are the recommendations comprehensive and complete? So that was the pre-work that folks had to do coming into the summit. During the summit, which consisted of 16 multidisciplinary experts, representing 14 different organizations, they reviewed their assigned sections of the guidelines At the end of the summit, each of the groups produced a report and devised next steps for their draft of the guidelines. Then a select group of content experts went back and verified each of the references associated with the guidelines from the original article or guidance and assessed the level of evidence for each of the items.

And then in January of 2021, NPA hosted a second national summit. After all the work was done between the first summit and the second summit, and this national summit consisted of experts that reviewed the revised version of the guidelines. That summit consisted of 22 multidisciplinary experts that represented 19 different organizations. Similar to the first summit, the content experts were assigned this time 5 different topic areas instead of 4, and during the summit, the content experts reviewed their assigned sections of the guidelines with the same questions that we have from the first summit. At the end of the summit, the group of experts produced a report and devised next steps for the draft of the guidelines. So that report is what was used to make the final form of the guidelines which were created and published. And that's where we are today.

"The National Perinatal Association is an interdisciplinary organization and is one of the leading voices in perinatal care, and one of its missions is to bring parents and professionals together to advocate for better policies and care practices."

So, the goal of these guidelines is to support the families and to assure that they have the skills, knowledge, and confidence that they need to be able to transition successfully from the NICU to home. You should know that these guidelines are free, and they're open access. You can just come and claim them. You can use them. And in addition to the guidelines themselves, there is a companion website which we're going to talk about. But you'll notice on the slides, NICUtohome.org, and we're going to talk a little bit about that after I run you through the guidelines.

So, when we're thinking about the guidelines, they're divided up into the topic areas: basic information, anticipatory guidance,

family and home needs assessment, and the transition and coordination of care. And as I mentioned a couple of times, there are over 200 of these guidelines, so there's no way we're going to be able to go through all of them, and I'm not sure it'd be worth your time for us to sit here and do that together, and so instead, what I'm going to try to do is give you a flavor for what each of the sections cover, and then from there we can talk a little bit more about how to use these guidelines.

The first section of the guidelines is what we call basic information, and what we covered in this particular area are things that every family in the NICU should know, regardless of if they're in the NICU for 3 days or 3 months, And so it covers things like goals and timelines, like when things need to happen during the course of your NICU journey and a curriculum for what the skills and the knowledge that the families need to acquire to help them make the transition. Then it discusses discharge education, strategy, which is going to be your approach to helping the family with the education curriculum. And then it also talks a little bit about supplemental material, because in most instances, bedside teaching is going to be the number one method of commanding information. But then, in addition to the bedside teaching, there's going to be potential websites. There can be digital teaching. There can be videos. Sometimes there are papers, folders, binders. So, there are a lot of other ways to get supplemental material to reinforce the information that's given right at the bedside. And then, in addition, basic information also covers infant care, skills, demonstration, and that goes into a little bit of detail when you're actually doing the teaching and the teach back and confirming understanding, and it discusses safer sleep practices, car seat/car bed installation and safety. And then, understanding what some typical and atypical infant behaviors are because sometimes, especially former premies—their behaviors may be slightly different than what you'd expect for term babies that are the same age.

The next section of the guidelines covers home and family needs assessment, and this gives individuals an idea about the family structure, the family support, the family's learning, style, and other factors that could impact how your discharge preparation process is going to go. In this section they look at family assessment, which is looking at who's in the family, who are going to be the care providers, who are going to be the primary providers, who are going to be the other support systems. It looks at caregiver mental health, both at the time of discharge planning, taking into account past mental health issues, and also raising awareness that potential mental health issues for both the caregivers and for the infant that may come up later, and also it has a little bit of anticipatory guidance. But there's a whole anticipatory guidance section that we're going to talk about independent of this particular section.

"...bedside teaching is going to be the number one method of commanding information. But then, in addition to the bedside teaching, there are going to be potential websites. There can be digital teaching. There can be videos. Sometimes there are papers, folders, binders. So, there are a lot of other ways to get supplemental material to reinforce the information that's given right at the bedside."

The next section of the guidelines. We talk a little bit about, transfer and coordination of care, and what we found in our in our work is that traditionally, this has been an area of really pretty significant weakness and or challenge when it comes to the discharge planning process because oftentimes people think, okay, when they leave the NICU, you cut the cord, the end, and our work here is all done. For a family, though, that's not how they experience any of this. What we strive for is to have basically a continuum from NICU to home and have it be a seamless transition between both the providers that are taking care of the infant and the family, and for the family, so that they don't feel like they're just dumped by the NICU, which is often how families feel.

"We talk a little bit about transfer and coordination of care, and what we found in our work is that traditionally, this has been an area of really pretty significant weakness and or challenge when it comes to the discharge planning process..."

And so in this section, we talk a little bit about the importance of primary care, pediatric primary care providers and the medical home, and we also help the family to understand the role that the medical home will play—kind of an ongoing care and with care coordination. And we talk a little bit about use of navigators and navigating the hospital system for appointments and things that follow up after NICU discharge. In this section, we make some recommendations about communication among NICU providers and community providers, as well as communication between families after discharge and the NICU.

We strongly encourage more integration of the NICU and community providers in ongoing care together. In this section here, we also explain the potential for subspecialty needs and how to talk with families about that. We talk about things like routine home visiting. We talk about follow up problems, like early intervention, and then we talk about ways to communicate information to the medical home and to subspecialty providers, and one of those methods is the discharge summary where we talk about some specific components that the discharge summary should include for clarity and for the sake of transition.

"The next section of the guidelines talks a little bit about understanding what the family support systems are, so you can help the families to get in place any types of support that they're going to need to be able to successfully make this transition."

The next section of the guidelines talks a little bit of understanding what the family support systems are, so you can help the families to get in place any types of support that they're going to need to be able to successfully make this transition. Some of the systems that we look at are peer to peer programs and how to safely use technology. So the role of social worker and potential social worker involvement, because for some families, social work is almost like a bad word, and we try to not have it be framed in that kind of way and not have social work interaction be in that kind of way. We talk a little bit about mental health support because sometimes mental health issues can arise, especially for fathers and partners in a very different way than what they would for postpartum birthing people. And we talk about communication, post-discharge, mostly communication between families and NICU providers. And then we talk about use of community programs for potential support for families.

And then the next section of the guidelines—we talk about anticipatory guidance, and the goal for this whole section is to give the families a more realistic idea of what their life is going to be like with their new addition—and this is both in the short term, like in the days and weeks that follow discharge, and more in the long term over the course of the next couple of years as the infant grows and develops—the kind of things that they look for. And part of the goal of this section of the guidelines is to help families understand how they parent the NICU graduate, and it may be slightly different than parenting a non-NICU graduate. We talk about helping them to understand their baby's development and when they're going to reach their milestones and what their baby's follow-up care will look like. How many appointments are they going to have? And are there going to be providers coming to the house? Are they going to have to go to our offices? And then we really stress the importance of a medical home to help the families, not just with the direct medical care but also with coordination of care, especially if subspecialties are involved, if the baby has any kind of complex medical needs or any kind of ongoing medical needs or any medical equipment.

"And then we really stress the importance of a medical home to help the families, not just with direct medical care but also with coordination of care, especially if subspecialties are involved, if the baby has any kind of complex medical needs or any kind of ongoing medical needs or any medical equipment."

And so those things sometimes people don't understand the role that medical homes can play and the help the medical homes can provide. And then the last part we also want families to understand and address their own psychosocial needs, because many times these things never actually get addressed, or even mentioned, and especially for husbands or partners or for fathers or partners, regardless of the marital status. Sometimes this isn't even addressed.

In addition to all of these big pillars that we've just talked about, there are also some other circumstances that have to be taken into account as part of your discharge planning process.

"One of the first ones is families who prefer speaking other languages. And in this section of the guidelines, we talk a little bit about interpreter use. We specifically address when it's appropriate to use family members as interpreters and when it's not. We talk about using computers..."

And so, because these things you need to be aware of and because they may affect what you do during the discharge planning process. One of the first ones is families who prefer speaking other languages. And in this section of the guidelines, we talk a little bit about interpreter use. We specifically address when it's appropriate to use family members as interpreters and when it's not. We talk about using computer and things like Google translator without specifically naming Google. And then we talk about in-hospital navigation when the preferred language for the family is not the prevailing language of the area that they're in. And then we talk about the importance of social support and also primary care options for families with limited English proficiency.

And then for military families, we talk a little bit in this section about follow up considerations. How follow up happens? We talk about the moves that are often inherently part of being a military family. We talk about Tricare insurances and some of the pros and cons that come with that, considering a lot of military families, or the majority of military families, are on the Tricare insurance. We talk about home visitation and what that looks like for military families compared to non-military families, and then we talk about information sharing because it matters quite a bit if you're a military family in a military hospital, or a military family in a civilian hospital, or if you go back and forth between different types of facilities, which oftentimes military families do.

"So, all of those are important considerations that you need to take into account when you're doing your kind of discharge planning. What the ultimate goal for the guidelines is—because we cover a lot of territory and there's kind of 200 of them—it really boils down to what every family is going to need to know, what families are going to need to be ready for having an idea what their day-to-day life will look like, and who's going to be part of the team."

And then for LGBTQIA plus-headed families, we talk about the importance of designating who the caregivers are, understanding what parental roles are, and understanding parental rights and acceptable terminology and acceptable questions versus non-acceptable questions.

Then for parents with disabilities, in this section we talk a little bit about some family literacy, accessibility issues, both in the hospital and in the NICU and home as well as home environment preparation, meaning getting the home ready to be able to successfully parent an infant at home and some factors that need to be taken into account, like possibly an OT assessment of the home to make sure that it's appropriate, and then also an assessment of caregiver ability.

And then in the section where we talk about families with distinct cultural and or philosophical expectations, we talk a little bit about family belief systems. We talk about family support people. We talk about cultural practices and then community resources and how community resources may interact in a way that's culturally sensitive.

So, all of those are important considerations that you need to take into account when you're doing your kind of discharge planning. What the ultimate goal for the guidelines is—because we cover a lot of territory and there's kind of 200 of them—it really boils down to what every family is going to need to know, what families are going to need to be ready for having an idea what their day-to-day life will look like, and who's going to be part of the team. And so that's a summary of what all the guidelines cover without specifically looking at the individual guidelines.

"There is also a companion website. So, you can write this down and check it out. It's the nicutohome.org....created by the National Perinatal Association. It's kind of a living place, and it's intended to be a place, a repository for tools and resources and a community of experts, who are all interested in NICU discharge planning and discharge preparation.."

Alright, so this is what I promised you earlier in the talk. There is also a companion website. So, you can write this down and check it out. It's the nicutohome.org. And what's really cool about this website is it's created by the National Perinatal Association. It's kind of a living place, and it's intended to be a place, a repository for tools and resources and a community of experts, who are all interested in NICU discharge planning and discharge preparation. It's a place where you can come and look for information. Or if you have some suggestions or ideas or things that work for you, you can come and share those, so then they become available to other people. It's our way of making this whole implementation of the guidelines a little bit easier because if one person has figured out one part, they can help with, and then another person figures out another part, and you put them all together, then it makes it easier for the next group to come along and to be able to implement what these guidelines say. There's no reason to reinvent the wheel every single time.

But what do we do next? So the guidelines were finished, the guidelines were published. The website was created, tools were put up on the website, and then, as one of our work group members, Julia E., says, "We did not create these guidelines so

they can sit on a shelf." And so what we really want is for people to be able to get these guidelines into the hands of people who actually have an ability to make a difference in the lives of families because we really do believe that these guidelines can help, and for anyone who's been through the NICU who didn't have really specific guidelines, the journey, probably the transition, probably wasn't as ideal as it could be.

"And so what we really want is for people to be able to get these guidelines into the hands of people who actually have an ability to make a difference in the lives of families because we really do believe that these guidelines can help, and for anyone who's been through the NICU who didn't have really specific guidelines,... the transition, probably wasn't as ideal as it could be."

And so that leads us to talking about implementation of the guidelines. And so, when we think about this, what do we do to turn these recommendations into actions? And what do we do next?

And this can be a pretty daunting task, and we acknowledge that. So, our work group, once the guidelines were created, turned to focusing on how we can help with the implementation and understanding. The guidelines are written in such a way that they're general, meaning that they can apply to a bunch of different circumstances because the personnel available in any given NICU, the patient population, and the types of providers, and the types of patients, the number of patients—those are going to vary quite a bit across NICUs, and there's no way we could do just one stop shopping, like push the "if this, then do this." So, what's going to be required in order to be able to implement these guidelines locally, you're going to have to look at and adapt them for whatever your resources are available to you. But that can seem scary. And so anybody at Gravens, there was a mom there named Mia Malcolm, and one of her quotes was "We're not asking you to boil the ocean. We just want you to start with the pot."

"'We're not asking you to boil the ocean. We just want you to start with the pot.'"

And so the truth is, everybody has a pot that they can start with. For these guidelines, even though there's a bunch of them, you can pick one that you're passionate about, one that you care about, and start with that. And then, once you're able to successfully and sustainably implement that, move on to the next, and move on to the next, and before you know it, you have a whole package of discharge planning that you've kind of kind of built up. I'm going to talk a little bit about just one person's implementation journey, and it's Cuyler Romeo, and she's just an excellent of the work group, and she's just an excellent example of what one person who's motivated can do. She's an OT (Occupational Therapist), and she works with feeding, feeding matters, and she's at Banner in Arizona. I want to talk a little bit about that.

"For these guidelines, even though there's a bunch of them, you can pick one that you're passionate about, one that you care about, and start with that. And then, once you're able to successfully and sustainably implement that, move on to the next, and move on to the next, and before you know it, you have a whole package of discharge planning that you've kind of kind of built up."

And so a couple of important pieces about her. You know she's a former NICU mom. She's an OT, a feeding specialist, and has years of working in the NICU. But what she didn't have is a background in implementation, science, or health care, quality and improvement. And so she was a motivated person who thought that this was a really good idea and thought there was potential benefit to her unit in doing this and to the families that she takes care of. So she relied on open access tools for health care quality and improvement, and dissemination science, and she was able to do quite a bit with just those open access tools.

And so, just before we jump into to what exactly she did and how she did it. Let's talk a little bit about what her unit is like. She's at Banner, in Arizona, which I told you before is a community hospital. It's a level 3. It's got 42 beds at present, and it serves Southern Arizona and several rural communities, and she describes her population way better than I'm ever going to be able to describe it, but you name it, they have it in that unit. People travel for hours sometimes to get there. They have really complex patients. And so all of those things are kind of really important. And the way she kind of began this was she put together a group of invested stakeholders, and she used already existing infrastructure and relationships, meaning that she didn't come in and try to create something brand new. She had a parent group who was already interested in (being) active. She had a group of nurses and therapists who are already interested in (being) active. She found a neonatologist who was willing to come on board and believed in what she was trying to accomplish. She pulled all of these people together, and they form kind of a think tank.

And then she said, okay, with this group of stakeholders, with this group of guidelines, can we pick one, maybe two things which are really important to our patient population, maybe something that we're not doing as well as what we would like to do, and let's try to focus on those, and what things would make a meaningful difference to our population. And then what kind of metrics will we use to measure our success so that we can know, not just for ourselves, but for others and people who are clinically at the

bedside, people who are in administration, people who are going through the program who are experiencing it as families. And so, what kind of outcomes are going to be important? What kind of metrics are going to be important for us to be able to show that we're being successful with these things?

"And then she said, okay, with this group of stakeholders, with this group of guidelines, can we pick one, maybe two things which are really important to our patient population, maybe something that we're not doing as well as what we would like to do, and let's try to focus on those, and what things would make a meaningful difference to our population."

What she chose was access to early intervention services because what she was finding—as a place to start with—a lot of families are leaving the NICU but not connecting with early intervention services. And it's including people who would qualify for early intervention services. Then given that she's an OT and feeding matters in her organization, identify feeding needs and risk factors. And she chose to implement these things because they're related to topics that her unit cared about, and they had metrics that they could measure, that they could track for success with early intervention, referral and assessing services and assessing feeding risk and documenting the assessment of the feeding risk and using that for early intervention. Just to prove the power that one person can have—when she decided that these were the things that she was going to focus on. She was able to make a few phone calls to local agencies, and it's amazing how making one phone call suddenly removes barriers. She discovered that there was an individual who could help with referrals to earlier intervention, both making them and following them up, and that person wasn't getting the referrals, and so just connecting her unit with that particular individual, referrals went up from like 10% to maybe 40%. It was an order of magnitude of change to that huge degree. And then she found out that many kids who met requirements for services—meaning they've been evaluated by a therapist and found to have a challenge that they would qualify for early intervention services—they just weren't getting referred because people weren't aware that the feeding challenges that were coming up qualify people for services. So, I'm not saying that this is what you need to do in your specific unit, but I said sometimes just having one person making one phone call and having one discussion can really change outcomes in a huge way for folks and for individuals.

So then, what Cuyler was able to do was to go online—again, I told you she didn't have any training in dissemination or implementation models—but she was able to go to this website dissemination-implementation.org. And what she found was that there are a bunch of free tools that she could put in the things that she was trying to measure, what she was trying to do, and it, in a really simple and straightforward way, walked her through the processes that she would need for a successful implementation and use to be able to assess how the implementation is going, thus helping to maintain a sustainable program.

"What she chose was access to early intervention services because what she was finding...a lot of families are leaving the NICU but not connecting with early intervention services...including people who would qualify for early intervention services...She discovered that there was an individual who could help with referrals to earlier intervention, both making them and following them up, and that person wasn't getting the referrals, and so just connecting her unit with that particular individual, referrals went up from like 10% to maybe 40%."

And so, this is an example of some of the tools that she was able to access that help with the planning. This was one of her challenges. Infants are referred to community services NICU developmental clinic, (which) could follow, but the service is often not rendered. And why? Using these tools, she could kind of help trouble-(shoot). Why this? Even if the referrals are happening—not that all the referrals were happening—but first to get the referral to happen, and then, when they did happen, how come the services are not getting rendered? And then there are tools to understand the needs. And in this particular instance, the tools were divided up into three different categories—processes, providers and parents. And we'll talk about those on this slide.

"Cuyler was able to do was to go online...to this website dissemination-implementation.org. And what she found was that there are a bunch of free tools that she could put in the things that she was trying to measure, what she was trying to do, and it, in a really simple and straightforward way, walked her through the processes that she would need for a successful implementation and use to be able to assess how the implementation is going, thus helping to maintain a sustainable program."

So in relation to what the guidelines were and what their goals were, processes were things like discharge summary, approved assessments, and education. Provider information were things

like medical records, point of contact, referral pathways, and follow up. And then the parent piece was parent education and advocacy with education, integration, and advocacy. And so those are ways that they kind of translated the guidelines that they were working with into these tools that they were using and how they could help with their implementation.

So what was your greatest worry? I think that in starting this work that they were really intimidated because it was doing something new, and they were worried about what was going to be their ability to be successful. And then in doing this, they were, I think, pleasantly surprised at how much one person could actually do and how much change could come about with one particular person. This again was a pilot study, meaning that they decided they were going to pick one or two guidelines to start with, using these resources that are already available, and then supplementing with the online materials that were free and readily available to them, and working towards goals that were already kind of important to them.

For them, their next step is they're going to refine the pilot a little bit more. They're going to continue to collect data with the pilot, and then they want to expand the pilot. Because again, as I said, they started with two things, and there are over 200 guidelines, and they want to expand it because, as they noted, they were able to make success and make measurable, meaningful success with the things that they were doing. Then, people became excited about the success, and people became excited about the potential success, and so that got people on board to want to do more, and then they want to assess what their outcomes look like and to make sure that what they're doing really is as sustainable as what they hope it is. And then, they made the one partnership which was hugely key to being able to connect with outpatient services, which was one of their goals. And so, they're looking for other partnerships in other ways and making use of other resources which could be underutilized because people may not be aware of them or know how to use them.

So anyway that was not meant to be a course on how to do implementation but just an example of what the power of one person who's motivated can do, and I say that so you could feel empowered to do things and know that you aren't alone in necessarily doing this. There are other ways to help, and National Perinatal Association is one of those.

"And so, they're looking for other partnerships in other ways and making use of other resources which could be underutilized because people may not be aware of them or know how to use them."

So I'm going to stop talking because I was supposed to only talk for 30 minutes, and I think I went over just a little bit, and I want to thank all of the steering committee who worked on these guidelines, who produced the guidelines and all the content experts who contributed to being able to make this work happen. And I want to thank you for listening for your attention, and Kristy and I are happy to take some questions.

Colby Day: Thank you so much for that fantastic talk. We have had a few things in the chat that have come up while you've been showing us your slides and talking through Zoom. One of the things that has come up is when is the correct time to measure parental readiness for discharge and whether parents really know that they're ready for discharge prior to going home, or whether it might be a better idea to evaluate that after they've been home and are able to actually assess that they've been made ready. I love to hear your thoughts on that.

Vincent Smith: So, I love how they frame a question as being simple when it's actually really, really complicated. I would say, there are a couple of ways to do it, and I'm going to preface it. Kristy, you should unmute and jump in here too if I'm messing up or leaving something out. I don't know that there is a magic correct time or a magic incorrect time, I think, for sake of ease, oftentimes it's easier to assess their discharge readiness right before they go home while they're still in the NICU—and ideally, after all the discharge teaching has been done, which means that you can't wait till the last minute to do all the discharge teaching, otherwise there's no time to get it in and assess and have them leave.

And so ideally, you'll have a timeline. You'll get the discharge education pieces done early enough and skills demonstrations done early enough and signed off on all these things early enough that you get assessed right before they go home, because that's the time when you're most likely get most of them. But it is true that, at the moment, right before they go home, they're probably at a bit of a high. They're excited. They're nervous because they're leaving, but they're also excited because they're going to be going home, and it's really kind of a mixed thing. But they haven't been at home primarily providing all the care for the infant. Yeah. And so sometimes how you feel in the moment and how you feel after a week of doing that is a little different. And in that regard, assessing what the discharge readiness is like a week or two after discharge, then you probably get a more realistic idea of how people feel about their discharge preparation at that time. The problem is people are really busy at that time taking care of their infant, adjusting to the addition to the family. And so your response rate is probably going to be a little bit lower, and you could make the argument that if you assessed 4 to 6 weeks after discharge after people get over the initial shock and awe of being at home and like oh, I can't believe I'm actually home and I'm doing it. And so, I think that then they've had a chance to kind of settle in, re-establish a routine, and they kind of figured out a lot of the initial challenges that are kind of a little bumpy a few days right after discharge, and so that could give you a better idea of long term what it meant. And then, if you assess them at 6 to 8 months afterwards, you can get an idea of what the retention of the information really is like.

And so that was a really, really, really, really really long answer to say there's not really a magic number, and there's pluses and minuses with whichever way you decide to do the assessment. I think it's probably more important to do an assessment in a consistent way. And that way you get relative comparisons again and again and again. And whichever time period you pick, there are good arguments for either time period. So, Kristy, did you want to add anything to that?

Kristin Love: I think you covered the majority of it, I will just share as a NICU parent. No matter how much education and preparation we have, or we think that, or the staff feels that we have, we really don't. Because once we walk out those doors, we're leaving our support system and knowledge back in the NICU. So, community resources is a huge piece that I think a lot of institutions are missing, communities are missing, because

having your community resources is going to help that transition.

"I will just share as a NICU parent. No matter how much education and preparation we have, or we think that, or the staff feels that we have, we really don't. Because once we walk out those doors, we're leaving our support system and knowledge back in the NICU. So, community resources is a huge piece that I think a lot of institutions are missing, communities are missing, because having your community resources is going to help that transition."

Colby Day: And I would definitely recommend to those of you that haven't been reading through the chat, and we'll make this available as well. We had some really great examples and stories that have been shared from our family partners that are on the call, and at least in perusing them as they've been coming through, I have to say there are probably a lot of areas we can improve. There's been a few that have stated they had a good experience but maybe still had some issues with things like feeding supply companies and whatnot, but certainly sounds like we have some room for improvement with discharge readiness.

Another thing I would love for you to speak about is you really emphasize that medical home. And I wonder if you could define a little bit what you mean by that because I feel like medical home could be a different group of individuals, depending on resources in the community and where people are being discharged and how maybe they could bridge this support gap that we're talking about of parents leaving the NICU and kind of feeling that they are addressed at that point.

Vincent Smith: Alright, so when we're thinking about medical home, we're thinking about a place that serves kind of multi functions. I mean, it's a place that you have to feel comfortable asking just general questions because especially when you're home with a former NICU baby, there are some things that you're just not sure if they're going to be normal or abnormal, and it's going to take a while to know that. So, you do need a place that you can get that baseline level of "is this okay," "is this not okay?" And then you want to have a place that's going to consistently monitor your growth and development of the infant and be able to know when they need to do interventions. And so, because there can be ongoing issues, specifically feeding issues and specifically growth-related issues. And then, as the kid gets a little bit older, sometimes there are behavioral challenges and learning difficulties to come along.

And so you want a place that's going to kind of understand that and be your partner and working with that and can also help with you if you need that for advocacy for services—whether it's early intervention services or if the kid is a little bit older, school system services, and then also a lot of former NICU babies have complex medical care, meaning it's not just their primary care that they're seeing. They see Endocrine, or they see Renal, or they see Cardiology, or they see Infectious, or speech and OT—they see all these other litany of services, and as a parent, it can be kind of hard to keep track of all of those things and to make sure that all the referrals are in place and that all the recommendations are being implemented. In theory, your medical home should be able to help you with that, because you shouldn't have to kind of manage all of that stuff by yourself. They should help you track appointments, and when there's feedback from the appointments, how to implement that and make sure that that's getting taken care of and making sure that all of the infant and the family's needs are getting met. And so sometimes, a new need will come up that hadn't been anticipated, and you'll need referrals, and the medical home should in theory be able to help you make the referrals and help follow the recommendations from the referral.

"...when we're thinking about medical home, we're thinking about a place that... you have to feel comfortable asking just general questions because...there are some things that you're just not sure if they're going to be normal or abnormal, and it's going to take a while to know that. So, you do need a place that you can get that baseline level of "is this okay," "is this not okay?" And then you want to have a place that's going to consistently monitor your growth and development of the infant and be able to know when they need to do interventions...And so you want a place that's going to kind of understand that and be your partner and working with that and can also help with you if you need that for advocacy for services"

And so the whole point with the medical home is what that looks like can vary a little bit. There's no like this is only what a medical home looks like. I mean it can be a pediatric provider. It can be a pediatric practice. It can be oftentimes, though it's more than just the pediatrician, because sometimes you have some of the nurses who are discharge coordinators or case managers or social workers or psychologists or therapists or all these other people who can help with some of the other health heavy lifting and help when questions or challenges arise. And so it could just be your pediatrician. But sometimes it's more than just the pediatrician. I feel like I'm giving really long answers to these questions.

Colby Day: Well, it's because we aren't asking simple questions. Right? No, that answered my portion of the

question definitely. We have about 2 minutes before we're going to go to Dr. Balasundaram. And we just had a question come through on how we build out a medical home for underserved areas and rural areas. So, I'm going to challenge you to try to answer that because it's important.

"I think whether it's an underserved area, whether it's a rural area, whether it's an affluent area, realistically, what you'll have to do is an assessment of what the resources are that are available at that given (area),"

Vincent Smith: So, I think whether it's an underserved area, whether it's a rural area, whether it's an affluent area, realistically, what you'll have to do is an assessment of what the resources are that are available at that given (area), and that's going to vary quite a bit—like a lot, depending on where you are and what that place is. And then you have to map that out to what the specific needs are, and then, regardless of what's available, if it's not going to be available to you locally, then you have to look at what are other ways through maybe telemedicine or remote health, that you can get some of these other needs met and what are the supports that are available to you. And I say that because sometimes there are national things that are available and accessible to supplement, and it may not be as robust as being able to go to a place that's right across the street from you, but if that place is not available to you, it's better than nothing. That makes sense, like consultation with the developmental pediatrician 200 miles away over telemedicine is probably better than not having any consultation at all. I mean, although it'd be preferable for you to be able to go across the street to your developmental pediatrician and have them see you and your baby and to make the assessments and form a natural relationship with you that way. Sometimes it's not going to be available.

I think the thing that matters the most is having somebody who really cares and who's willing to get in there and help. Because I think that makes a huge difference.

Colby Day: Absolutely. Well, thank you so much, Dr. Smith, and also Kristy for this talk, and I'm going to pass things over to Dr. Balasundaram.

Vincent Smith: Thank you so much for having us.

Malathi Balasundaram: Hi, everyone. Thanks, Vincent and Kristy, for sharing your wonderful resources to our community. And Vince and I use many of your publications while building this program. So thank you for all your work and the discharge planning and the preparation. So that's wonderful. I'm going to talk about our local unit-based program that we have built for our NICU families… I'm going to start from our journey, which began in 2017, and we completed our journey in 2019 and (show) how we are sustaining the program, and I can give you a demo of our education activities under the MyChart Bedside. Okay. So this is the picture of me. I'm with Doctor Kari McCallie, and she is my partner at the time, and so she is a neonatologist, an Epic Physician Builder, and she is supposed to be on sabbatical. And she said she wouldn't make it to this meeting, but lucky for us she joined. And so, if you have any specific questions related to the Epic (an electronic health record system) and MyChart Bedside, here is our contact information, and she is available for you to ask any questions if you are thinking of implementing this program in your unit.

El Camino Health is the 20-bed community level 3 NICU, and we provide care for any infants 23 weeks and on, and we are an open bay unit with approximate delivery volume of 4,500 newborns that average 400 NICU admissions per year.

We are staffed by Stanford neonatologists and nurses and ancillary staff, and we do have Stanford residents and medical students there (going) through our unit. We don't have any fellows or advanced practice providers in our unit.

So I don't want to spend more time here, and I think Dr. Smith clearly described why we needed to focus on this, and we heard about our multiple family partners, about how they felt about the discharge planning and post discharge. I just wanted to briefly talk about if you are not adequately preparing families, that contributes to poor infant outcomes and heightened family anxiety and increase in the healthcare utilization after discharge.

As Dr. Smith mentioned in his talk, quality of discharge teaching is the strongest predictor of discharge readiness. With this in mind, this will be built into our program as a part of the Family Center Care committee. So we built our family-centered care program in 2016, and in the beginning phase, we actually looked at improving the discharge education. So we looked at our Press-Ganey (patient satisfaction surveys), and some of you are familiar with this. But if you have international colleagues, I just wanted to share what is the Press-Ganey. So this is the patient satisfaction survey the families usually get after discharge, and we have our really specific survey that goes out to the families by mail, and we are actually working on making that an electronic form. So (in) this survey, we looked at our Prepare for Discharge top box responses—that is the response that reflects the highest possible rating. So we looked at (it), and our rating was 47% in 2017, so we looked at the other categories. We were scoring (around) 70%. So, this is the lowest of 47%. So, we wanted to improve by using technology and providing consistent discharge teaching, and the goal is to start this process closer to the admission time and not waiting until the last few days of hospitalization.

So this is just a screenshot of our NICU survey (Figure 1). We used a four page document in the beginning of the journey, and then I consolidated, worked with the present patient experience. We consolidated this into 2 pages. It focuses on different categories—nurses, doctors, and discharge, an overall assessment, some specific to our center. So this survey is usually sent out within a month time period to the NICU families.

So this is a flow diagram (Figure 2). And it focuses on multiple interventions that we followed in this incremental journey. The first intervention we formed a committee—we formed the task force—it's called, a comprehensive discharge teaching task force.

We have a wide range of providers—bedside nurses, nurse practitioners, nurse manager, neonatologists—and families are members of this task force. Once we formed the committee, we wanted to work on the unit-specific discharge teaching. So, the team members actually wrote a unit-specific discharge teaching. We have some old discharge teaching also, so we just modified that, and we created a video for important discharge teaching sections, like how to use the bulb syringe and how to measure the temperature and (using the) car seat and mixing the formula. So, we just to ask the families what they wanted to hear from us. We included their feedback, and we created a video, and we created the El Camino NICU gmail account, and we uploaded that into YouTube, and we linked that YouTube into the e-book content. So we've been through several revisions, and we accommodated the Family Advisory Board that we are now calling a Family Partnership Council.

"The first intervention, we formed the task force—it's called a comprehensive discharge teaching task force. We have a wide range of providers—bedside nurses, nurse practitioners, nurse manager, neonatologists—and families are members of this task force. "

Originally we thought, we can build this as a Word document, and then with the Word document, it's not easy to navigate the table of contents. So I just converted that into an e-book using a iBook author application. Now it's called the Apple Pages. So in this day it has a table of content, and parents can review this, and then so they can go back and review the content at their own pace. So we had a 3 iPads donated by our family advisory board. That's how we started this project in the beginning, using the three iPads.

The next intervention. Once we wrote that e-book, then we wanted to implement that e-book, and then how (to) make sure it reaches every family—we focused on that as a second intervention.

"Once we wrote that e-book, then we wanted to implement that e-book, and then how (to) make sure it reaches every family—we focused on that as a second intervention."

So here you can see the content (Figure 3). On the picture on the left is the discharge teaching on the e-book and iPad. So it does (have) a table of contents. We matched the content to the electronic health record (of) what the nurses are looking on their end. So, we match the content with the order (of) how it appears, and we created a paper checklist. So the paper checklist was based at the bedside, and it matched the content of the e-book, too. So whenever the parents review this information, they can actually sign off on the paper checklist, and the nursing staff kind of add that information into electronic health record. So it was manually transferred by nursing staff into Epic.

So the next intervention is like, okay, (with) the previous one, the nursing staff manually needed to input that information. (With) a paper checklist, we did an audit, making sure it (was) reaching every patient. But still we were not able to achieve that. So the next intervention.

We had only 3 iPads in the unit, and (there are) 20 patients there. We don't have access for (all of) them to use it. So, what we did is we actually created the PDF of our discharge education and uploaded it into our hospital website, and so that way, the patients' families can have access to this information, so they can review this information at their home.

So when they are here, they can just focus on providing care to the babies, and instead of sitting and then reading the information, we uploaded that on the website with the help of our marketing team. And so, they can review that information and come to the unit and then check off on the paper checklist.

Figure 1. Press-Ganey Survey

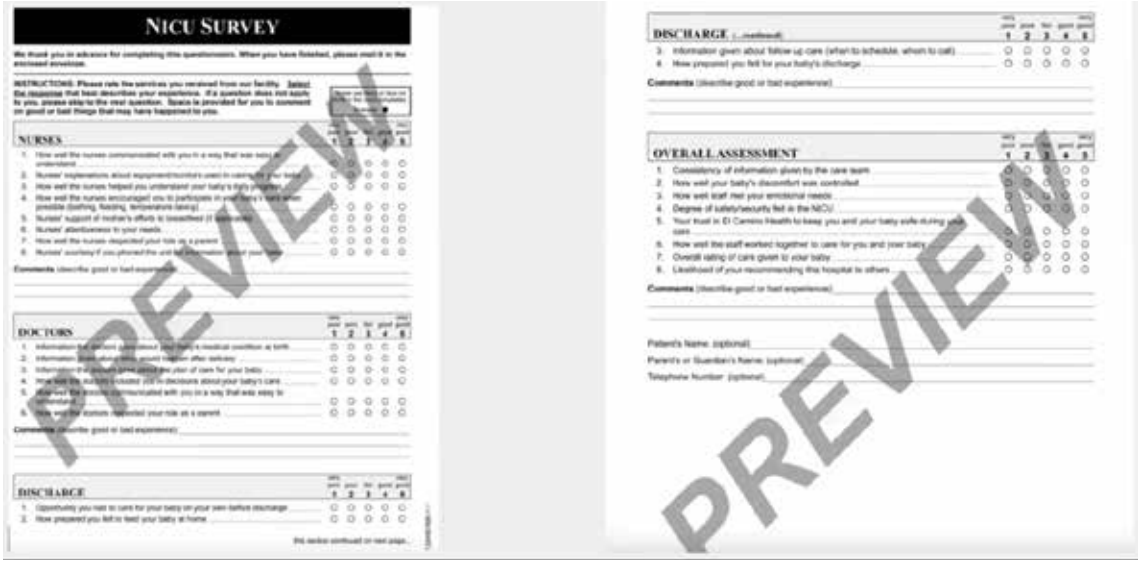
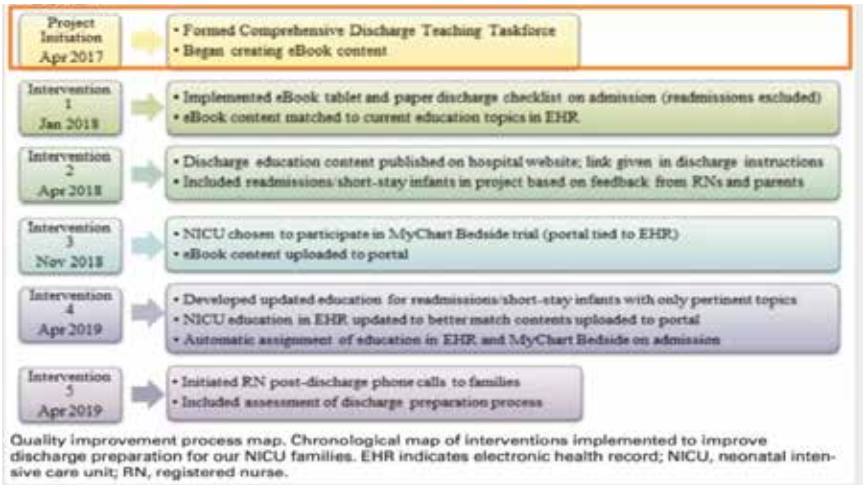


Figure 2 Flow Diagram of Interventions



Quality improvement process map. Chronological map of interventions implemented to improve discharge preparation for our NICU families. EHR indicates electronic health record; NICU, neonatal intensive care unit; RN, registered nurse.

"we actually created the PDF of our discharge education and uploaded it into our hospital website, and so that way, the patients' families can have access to this information, so they can review this information at their home... also, we created a Homecoming Checklist"

And during this intervention also, we created a Homecoming Checklist. So what it is—we usually give this information a few days before the discharge. It has a checklist for the families to go through. What are the things they need to buy or bring in on the day of discharge. So just to help them prepare, bring in the car seat and installing the car seat, information and all those things. It was created by one of our nurses, Michelle Ranch. It's really useful to give this information just a few days before the discharge so the parents can prepare.

So, the next intervention is—so there's always room for improvement, right? From the previous intervention, the nursing staff has to manually enter into Epic, and it's only the three iPads at the bedside, so the iPads are not available frequently for some of the families. So lucky for us at our hospital—actually, I did the pilot study to include the MyChart Bedside as a part of the pilot to the NICU—we received 20 iPads, so each baby gets their own iPad.

So we actually pilot that MyChart Bedside, integrating the

Figure 3 E-book on Tablets

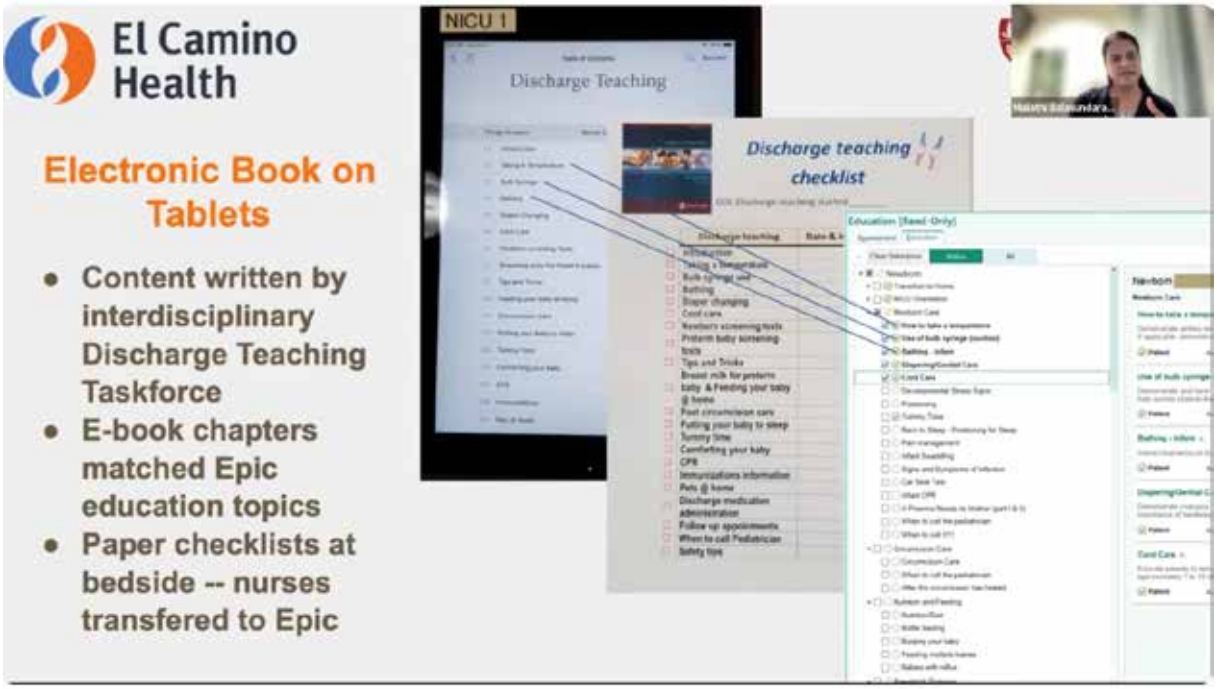


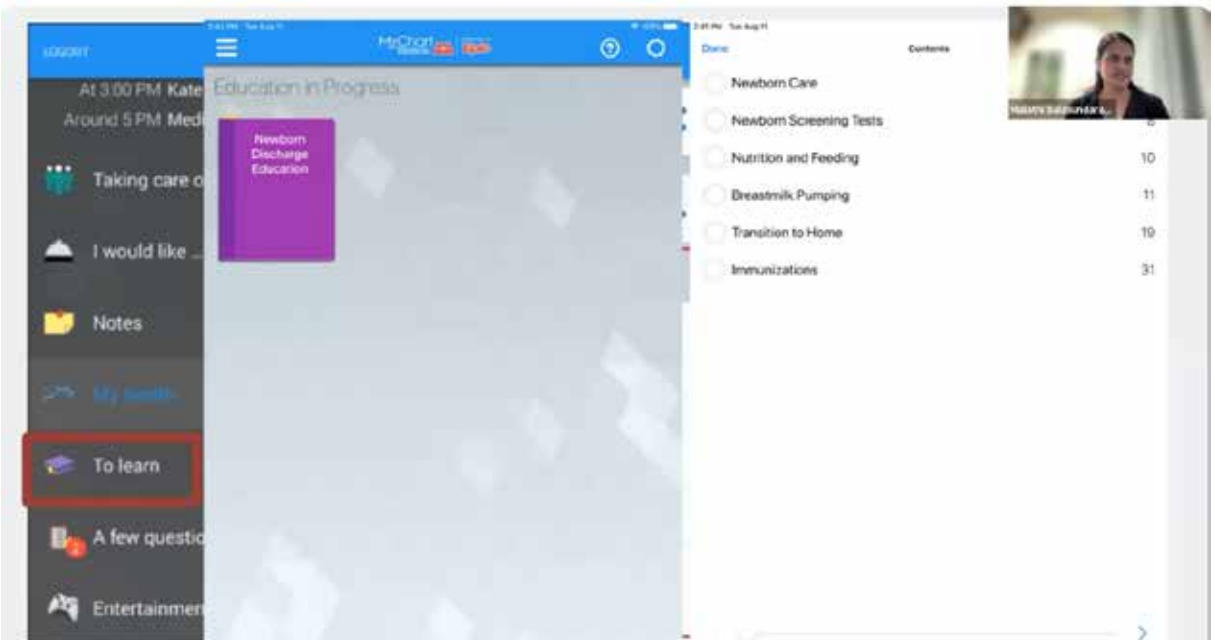
Figure 4. MyChart Bedside

e-book content to the MyChart portal. This is a MyChart Bedside screenshot (Figure 4). Basically it's a tablet-based application that gives the admitted patients and their families more information about the patient's condition and hospital stay. As you can see, they can review their treatment team, who's taking care of their babies, and they can look at the vital signs and lab work and problem list and what medications the baby's on. All this information is available on their iPad and the MyChart Bedside.

Under MyChart Bedside, there's a section called "To Learn" (Figure 5). That's where we uploaded all of our e-book discharge education into that To Learn section.

So this is where the families look at this information on the iPad, and under To Learn, it opens as a e-book. It's a newborn discharge education. It has different chapters, divided into 6 categories, and the page opens (like) this for each chapter. Once they open the chapter, this is what they are seeing on their end. So, each chapter has the reading material, and also if applicable, there is some picture. And also, there's a video incorporated. I can just play this video hopefully. [video does not play in this article]

Figure 5. MyChart Bedside Newborn Discharge Education Interface - "To Learn"



Nurse (on video): To bulb section your baby, you're going to take your bulb suction, gently press down with your thumb, put it in your baby's mouth on the side, release, and then put any mucus or secretions on a cloth to the side. You're always going to do the mouth before you do the nose. So, to do the nose, you'll do the same thing, one nostril at a time. Gently insert the bulb suction, release, and then put any mucus or secretions to the side.

Malathi Balasundaram: Okay. (The parents are looking at) MyChart Bedside while they are in the NICU because they can't take that iPad home. But if they wanted to see this information on their own mobile, they can use this as a MyChart mobile app (through) the app store. They can download the MyChart app, and they can pick the organization, and ours is El Camino Health, and they can log into the mother's MyCare account, and it's a proxy. Then switch to the baby. They can select the menu and type education so they can just look at the education. All the material that is on their MyChart Bedside is available for them to review on their phone. That way, if they wanted to review this on their phone, they can do that, and they don't have to use bedside MyChart Bedside. If they have an iPad or laptop, they can bring that, and we can actually use their device to scan the QR code and activate the MyChart Bedside so they can keep that account active even after the discharge, so all the information will be saved. And they have full access to their baby's information, labs, vital signs and everything, and now they can even look at our notes. Once we sign it, it just flows to MyChart Bedside, and so they can review and read our notes.

Once we received these 20 iPads, we wanted to take this as a pilot project. So, what we did is (take) the e-book content and transfer to the "To Learn" section of the MyChart Bedside. The discharge education checklist (Figure 6) was manually assigned to patients by nurses, so you could have imagined that…it was time consuming for nurses. I can show the data on how we did this pilot phase, and so we wanted to make it better. We wanted to improve. So this is how it works. What they do is the patient reviews this information, (for) example, taking a temperature. (There are) two boxes on the bottom. One is "I understand"; the other one is "I have a question." So, if they understand the concept, they can just click "I understand." So that flows directly to the Epic electronic health record, and the nurses can review that information. And if they have any questions, they can put "I have questions," so that it flows, and then it's (recorded as) not complete. (The orange circles turn green when the concept is completed.)

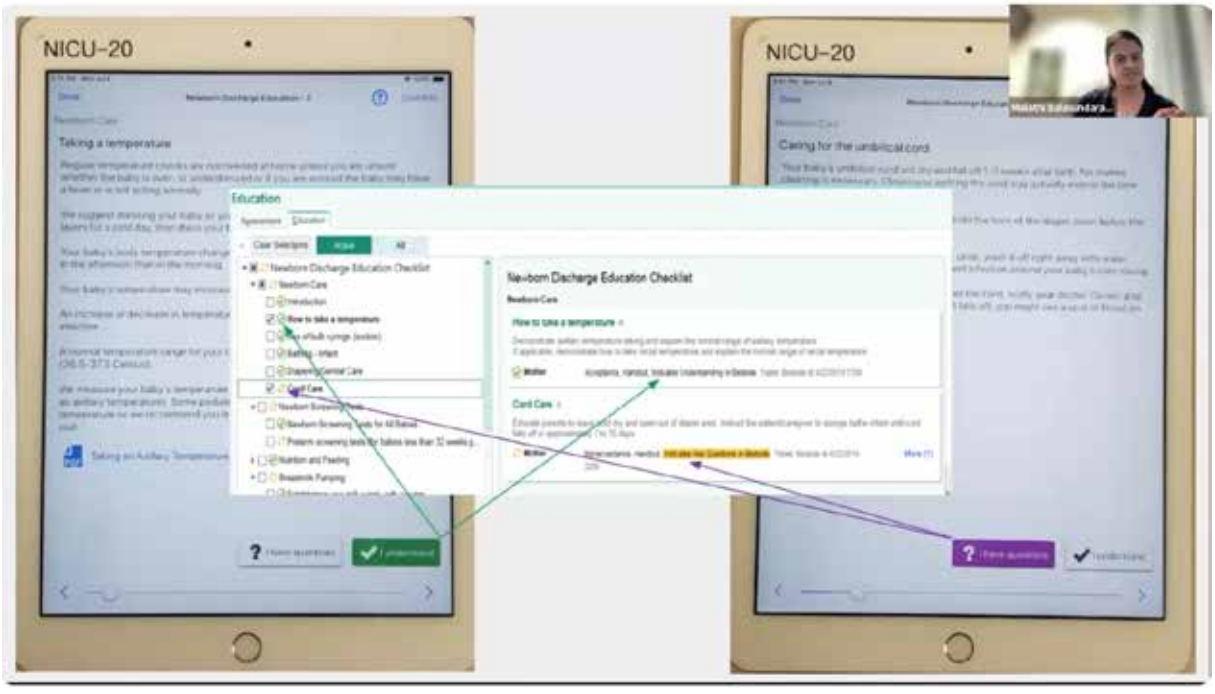
So, (to) this day the nurses can see whether this family participated in the education, how far they are behind or how far they (have) completed, and so they can just gently remind them to complete that education to be in advance and so not on the day of discharge. That's the beauty of this space that they are able to look at this and then communicate with the families.

So the next intervention, as I mentioned, the nurses actually need to assign the checklist in order for them to get the families to see this information on the MyChart Bedside, which is just painful, so we just wanted to get it better, so we optimized that MyChart Bedside portal.

This optimization is where our Epic Physician Builder, Dr. McCallie, did a beautiful job of creating this content of what are the information (written) in the e-book. So, each education section (was) given a point, and so we have full discharge education points.

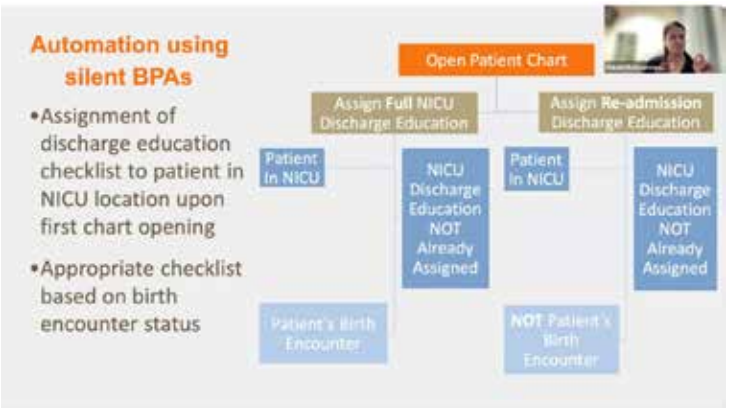
There's a separate section for the readmission discharge education points (since) we don't want the readmission families

Figure 6. MyChart Bedside Newborn Discharge Education Checklist Interface



or short stay families to look at the entire discharge education. So we created a consolidated version for the readmission families.

So this way, using the BPA, the Best Practice Advisory, (the discharge education is) actually automatically assigned to the patient at the time of any NICU admission. So this is what the flow diagram is showing.



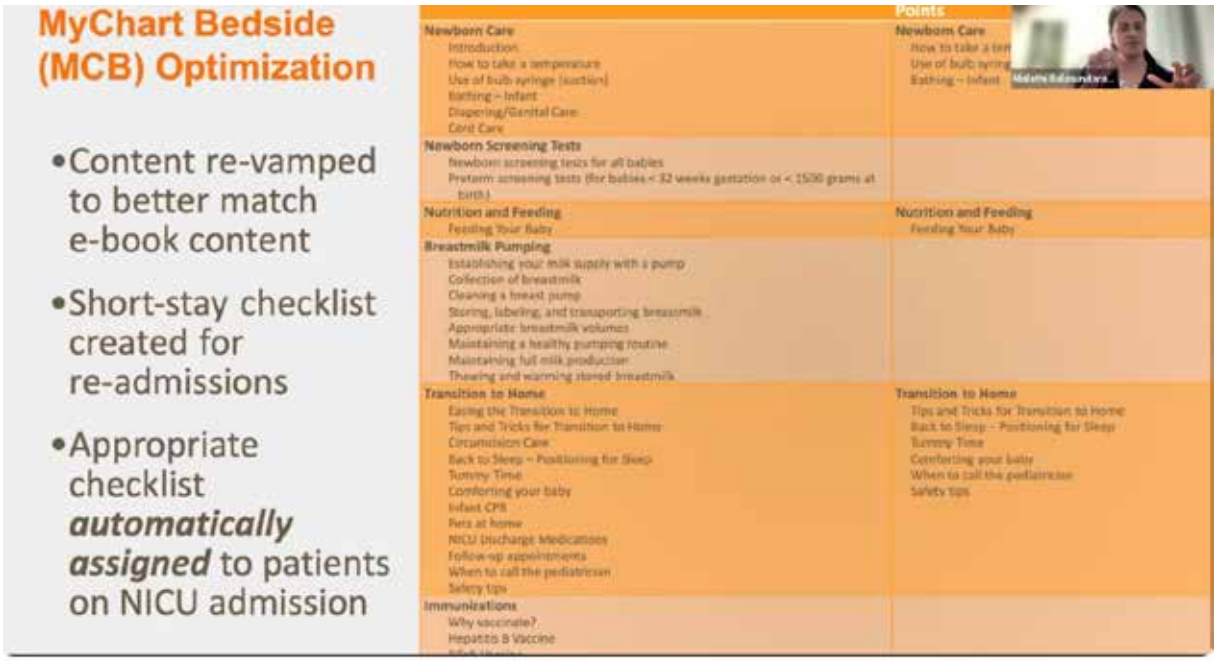
The silent Best Practice Advisory you can use. But if you open the patient chart based on their birth encounter—if the baby was born to that encounter, they actually get this full discharge education. But if they are re-admitted, it's not a birth encounter, then they will get this small version of the re-admission discharge education (instead of the full discharge education)… So then we focused on this. We focused on the full education. Then we had a consolidation education version.

This slide actually shows our demographics of maternal language, and what proportion we have of non-English language preference families, and, as you can see, we have a majority 89% who speak English and 4% Spanish.

But we wanted to include everyone, so we actually included a specific for the Spanish speaking families. So in this version, the Spanish-speaking doctors with the help of a unit clerk and Google Translator translated all the material into Spanish. Then we can

"All the material that is on their MyChart Bedside is available for them to review on their phone. That way, if they wanted to review this on their phone, they can do that, and they don't have to use bedside MyChart Bedside. If they have an iPad or laptop, they can bring that, and we can actually use their device to scan the QR code and activate the MyChart Bedside so they can keep that account active even after the discharge, so all the information will be saved. And they have full access to their baby's information, labs, vital signs and everything, and now they can even look at our notes. Once we sign it, it just flows to MyChart Bedside, and so they can review and read our notes."

Figure 7. Full NICU Discharge Education Points



assign this based on the family's language preference. If they speak Spanish, they will be assigned to the Spanish discharge education. I will show you the screenshot of how the families review that information in the next few slides.

So this is what the family sees.

So they actually see this information in Spanish, and they have a e-book, and then they have a chapter, and then each chapter has the same information and videos. We actually have a subtitle, and the subtitle will be translated into Spanish, so they can just read that subtitle. And so that's the one modification we did. And so then they can check off the same way that the other families do—to understand or they have a question.

The nurses, and on the other end of Epic, they actually see the information as Spanish in parentheses, and then they just (see) all the information in English (Figure 8). But once they try and sign off, they can see all the completion, everything, all the circles are completed and green. That gives us the information that education was completed for this family.

We do have a PDF printout for the families If they don't have any electronic access, or they don't know how to download on their phone…so they can take this home and then review that information and come to the bedside, and then they can check off that they understand or they have a question.

So we try to capture every level as possible as we can.

"...we actually asked 159 families how they feel about the MyChart Bedside education, and 70% used it...(and of those) 92% said they liked it, and 6%... preferred one-on-one education with the nurses"

So this is how (we continued) the optimization then—we created this Consolidated Education point, and we translated into Spanish, and then we automatically assigned the education based on their birth encounter or readmission.

Then we wanted to hear from the families. Okay, so is it really working, or how we are doing? Lucky for us, we actually have the follow up phone call. As a part of the family centered care program, you have a follow up a phone call program for nurses. Right now we have four nurses. They actually call the families within a week or two after discharge and check in with them—how the home transition went and how we can improve and is there any way that we can provide better care for the future families. And so that's the way we wanted to hear from them.

So, during that implementation phase, we actually asked 159 families how they feel about the MyChart Bedside education, and 70% used it, and 30% haven't used it, and because they were short stay—they stayed only less than 48 h, like admitted for rule out sepsis—and so they are not able to access those MyChart Bedside. But whoever had access to that, 92% said they liked it, and in 6%, they preferred one-on-one education with the nurses, and 2% declined to rate. The MyChart Bedside Education—a majority of them actually like this program, and they wanted this to continue; they actually gave it good feedback. I just want to read a couple of them: "It's very good informative material, and it answered most of our questions"; "appreciated the simplicity of the iPad"; very convenient refresher for experienced parents"; and "smooth, easy to navigate and self-paced."

Figure 8. The Nurse Sees Progress in English of Spanish-language Discharge Education Checklist

"We wanted to hear from the nurses also because it's a workflow change. So we asked them how they feel about this program, and the majority of them, 92%, actually liked it—'improved the workflow on the day of discharge'; 'making teaching easier for parents, as they had seen content previously and were able to ask better informed questions'; consistent teaching content'; 'and easy to keep track.'"

We wanted to hear from the nurses also because it's a workflow change. So we asked them how they feel about this program, and the majority of them, 92%, actually liked it—"improved the workflow on the day of discharge"; and "making teaching easier for parents, as they had seen content previously and were able to ask better informed questions"; consistent teaching content"; "and easy to keep track."

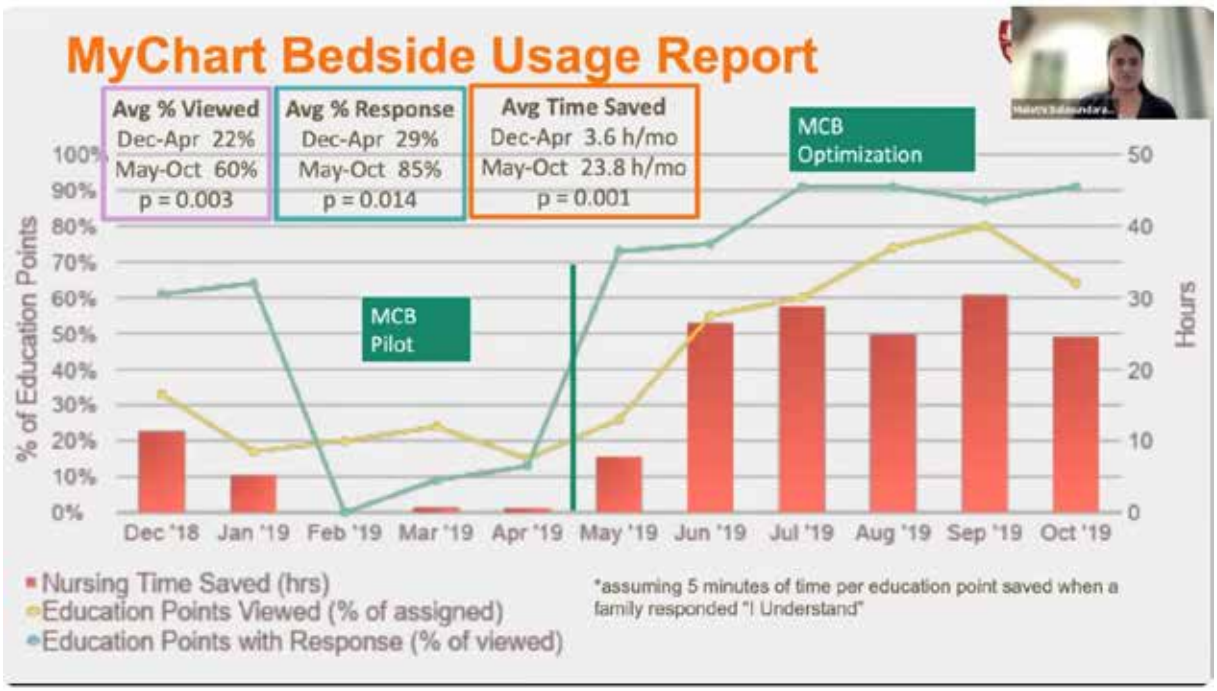
So any quality improvement work that we do, along with the process, we have to look at the outcome, and so the next slide shows our outcome focused on MyChart Bedside usage (Figure 9). As you can see, the yellow line is usage. We separated into two different time periods. The pilot period is the one where the nursing staff had to manually enter the checklist. As you can see, the usage is very, very, very low, so it's 22% average in the pilot phase, the yellow bar. But then you see the optimization where automatically everything is assigned. So, it improved to 60%. The parents viewed the MyChart Bedside more frequently and then responded, improving from 29% to 85% on the green line. The Red Bar is actually the nursing time. So we assumed 5 min of nursing time per education point. So then, how much saved by using MyChart Bedside when a family responded "I understand"? You can see from 3 h per month average, you're able to increase to 24 h per month average, and in the sustainability period, we are actually doing a fantastic job of saving 55 h per month. So, it's better response from the families and nursing staff and decreases the burnout. There's a lot of advantages of using this platform, and it's not easy and is time consuming, but we can make it work.

"...how much saved by using MyChart Bedside when a family responded "I understand"? You can see from 3 h per month average, you're able to increase to 24 h per month average, and in the sustainability period, we are actually doing a fantastic job of saving 55 h per month."

So then as you may recall what our original aim was. We looked at the Prepared for Discharge Press-Ganey survey, and the top box for analysis. So our average was 47% pre-intervention, and we are able to improve that to 70% (after optimization). So, our return response rate for our Press-Ganey is around 20%. I actually look at this quarterly prior to feedback to the leadership team. With that return rate, we were able to show the improvement Just fantastic. Thank you.

So the sustainability period. Yes, we've completed this intervention in 2019, and so we wanted to see how we are doing. So, this is two years later, and, as you can see the amazing unit clerks—they are the one to actually activate the iPad at the time after the admission, they actually activate scanning the QR code and then leave it at the bedside. The parents need to put in the PIN. So then they can have full access to their account, and we were able to improve our average view and our average response. And so our average is around 83 to 94%. Last year we looked at our

Figure 9. MyChart Bedside Usage Report with Time and Optimization



data, still we are consistently doing a 92 to 95% of the time they were able to review and then answer the question they are able to understand.

Also, we looked at our report for discharge top box responses, and then we were still consistently in the 70s and so, which is great.

So, we were able to show that the impact with this project is the family receive(s) consistent information. So, it's not based on who's on and who's discharging the baby. If some nurses are really good with the discharge education, they do a great job. It's not like that. So consistent information was given and prepared well before discharge, and (families) ask the questions based on the knowledge that they received or read.

And you've saved the nurses time, and I've also included the family satisfaction scores about (being) "prepared for discharge." Also, it's easy to update the content. It's kind of easy, and with the help of Epic Physician Builder, we can just update the content and the Epic. We actually did that in the division twice, and we changed our breast pump from one company to another one, so we had to update everything. So it's just a little bit easy to update the content based on feedback and changes in the unit. And we included every disciplinary staff wanting to provide better care—nurses, MDs, Lactation consultant, unit clerk, marketing, IT and families. So it's just a multidisciplinary way of showing that improvement. And the families have access to this education post discharge by accessing the website, or if they activated the MyChart Bedside on their iPad, then they have a full access to that.

"And what if the families are technologically challenged? It could be that everyone uses a smartphone, and it's easy to teach them, so they can overcome all those barriers."

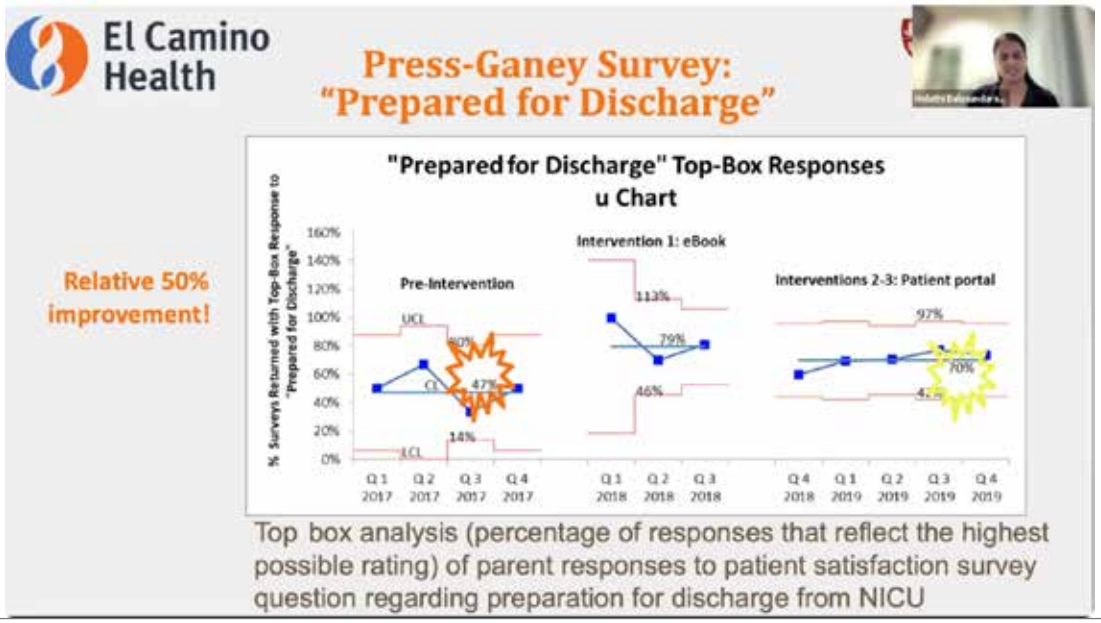
Every project has challenges, and I share some potential solutions here. Physician time commitment—so we did volunteer, and I wrote the e-book, formatted and uploaded in the iPad all those things. And then Epic Physician Builder affected my colleague the same way, building the EHR BPA—all those things is a time commitment, but we are proud to do that because we were able to show this big impact.

IT (Information Technology) security—the original meeting with IT wass that they were concerned about security issues on losing the iPads, and we actually shared the family voices on how stressful the discharge planning (was), and they were able to change their mind. (Now,) they (the families) were able to have full access. And in this, 6–7 years now, they haven't lost a single iPad.

So, we have all of our 20 iPads and 5 iPads that were donated from the family advisory board—we still have it in every unit. As the staff are rotating trainings and education, we have several travelers, and then we have new trainees and new hires in the nursing staff. So what I did is we had a yearly refresher FCC (Family Centered Care) Orientation list. So, I actually do the one-on-one orientation with the trainees. It's just to go through the FCC Activities. Same goes with the early refresher for our nursing staff, the orientation list.

The other challenge is website content updating. So it (has to)

Figure 10. Press-Ganey Survey Results after Implementation and Opimization of MyChart Bedside



go through Marketing. So there's a delay in updating. We still have the old version on our website, and it's time to update that information.

> **"And in this, 6–7 years now, they haven't lost a single iPad"**

This is the screenshot of our FCC Orientation checklist (Figure 11). It just covers the entire topic under the FCC umbrella, so we include the discharge teaching as a part of that. So all the nursing staff get their training.

So, the limitation of this project: I know it was done in the 20-bed community NICU. So, you may have a concern about taking this to the Children's Hospital, or an acute unit and all those things, but it's still possible they can once the baby is stable. You're not giving this information when they're on ECMO, but maybe when they come off of it…or when they are stable, you can still assign this education.

> **"It's not a replacement for direct bedside teaching. We still want bedside teaching to happen, so we included that as a part of the education as well."**

Finding champions to run the program, and if you already have the unit specific content, you can just translate or just convert them into the e-book or maybe it's a great medical student project, so they can, or you can, use the NPA Guidelines or whatever you want to use. So, you can just to change the cover and then use the e-book as a platform.

These (are) not available in other languages, so we have only English and Spanish, but you can request a fund, and you can translate the material on your own. And iPads—you can make sure if someone is willing to give a foundation funds or something, so you can add this: the MyChart website pilot project, or you can use the MyCare on Mom's phone as a proxy to access this education.

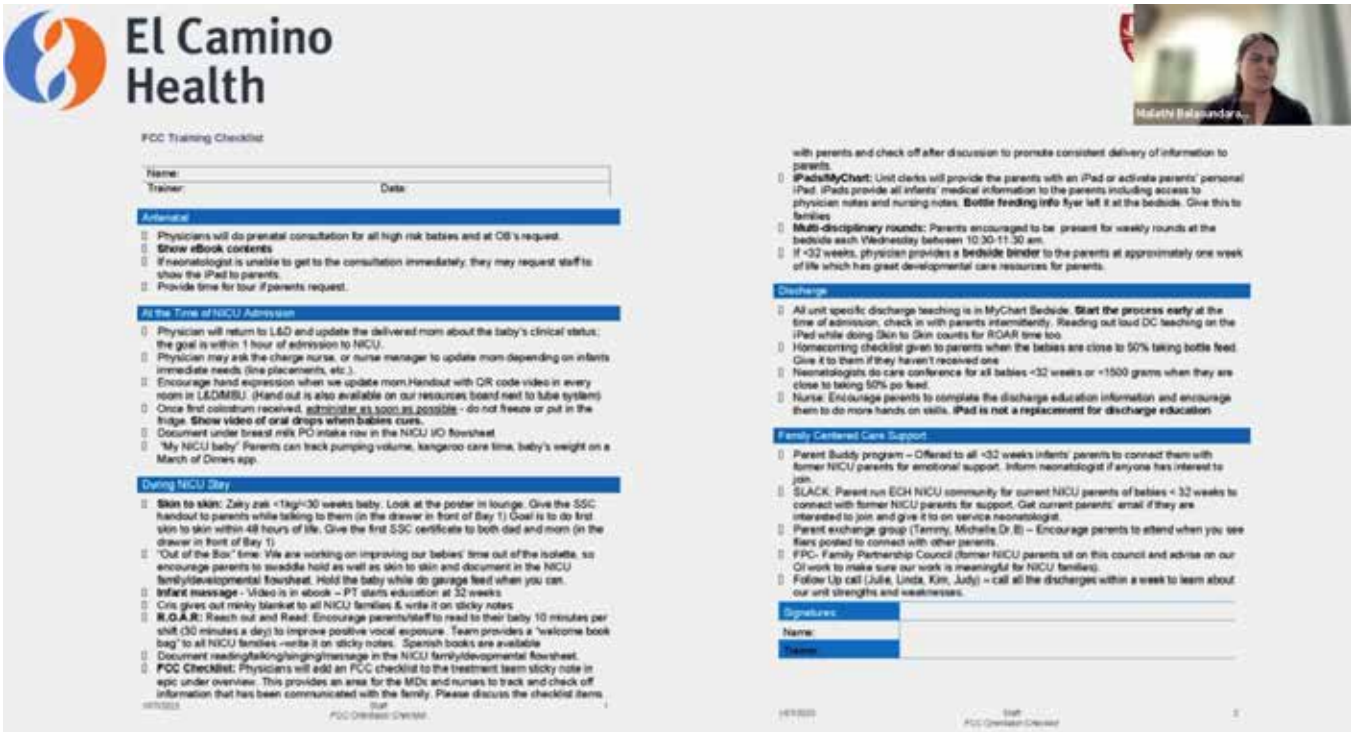
And what if the families are technologically challenged? It could be that everyone uses a smartphone, and it's easy to teach them, so they can overcome all those barriers.

It's not a replacement for direct bedside teaching. We still want bedside teaching to happen, so we included that as a part of the education as well.

> **"That was an e-book for discharge education. We have an e-book for diagnoses, and what it does is it pulls directly from the patient's problem list. So, if the patient has jaundice on their problem (list), it assigns them the handout for jaundice from the NICU PET website. It's also nice because it will assign it. It gives the handouts in all of the languages, so English, Spanish, and Chinese."**

We added the Spanish discharge education, as I mentioned. But you can go and then actually change the preferred language on your own. So that's why the instruction lists are here. You can

Figure 11. Family Centered Care (FCC)Orientation Checklist



do it under demographics. And once you do that, then you can delete all the English discharge education, and then you can just add the Spanish.

We added infant massage into this part of the discharge education, so they will get this information at 32 weeks. It's just a video and then a short description of benefits. And then families can review this information (about) it.

We added the new Breast Milk Pumping e-book because we changed our breast milk pumping company. So we just added that information.

This is my acknowledgment slide, and I think this is the end of our talk, so I just wanted to acknowledge everyone, and there's three references. That's it.

Caroline Toney-Noland: Great. Thank you so much for sharing it. There was a lot of good chatter happening in the chat. So someone asked, and Carrie started to answer, how much of the discharge teaching is child- as well as NICU unit-specific? Could these be used in different locations across the country or the world?

"We did want to show you our new website. So, if you go to FCCTaskforce.org, you'll be taken here. You've seen our padlet in the past. This is our brand new websiite. So, you can see under webinars all of their recordings and slide decks under resources. These are things that we've linked to or that presenters have linked to, or that things that you all have shared, that you have found really valuable as part of the listserve."

Malathi Balasundaram: Oh, I think they could if they have their discharge education unique for their population, so they can just convert this into whatever format they want. They just start with the e-book. They can do it. They can just convert that in the format, or if they want it to go to MyChart, but they can have full access. They can. It's just they need content. Kari, just jump in if you have any thoughts about this.

Caroline Toney-Noland: …to answer questions people with just wonderful questions. So keep them coming.

Caroline Toney-Noland: I think Betsy had mentioned this in Vincent's presentation about the importance of diagnosis-specific discharge education. It seems like you've automatically sent most of these to NICU families. Do you have videos or education that are more diagnosis-specific yet? Or is that perhaps in the next intervention?

Malathi Balasundaram: We actually have it. We don't, we don't cool the babies in our units, so we actually transfer them out. But if you are a cooling center, you can actually add a problem-specific discharge education. So we actually have three problem-specific information for the families using the NICU PET, the parent education material website. So, we actually put that information on our education area. So, for ROP and RDS—and there's one more diagnosis—we actually have the parent and our chart link to that education section. Yes, so you can make it diagnosis-specific. That's easy to make if you have the material. Yes.

Kari McCallie: Yeah, we have just like you saw (for) the e-book. That was an e-book for discharge education. We have an e-book for diagnoses, and what it does is it pulls directly from the patient's problem list. So, if the patient has jaundice on their problem (list), it assigns them the handout for jaundice from the NICU PET website. It's also nice because it will assign it. It gives the handouts in all of the languages, so English, Spanish, and Chinese. So we don't even have to know what the parents preferred languages, necessarily. We can just go ahead and give them all the handouts.

Caroline Toney-Noland: That's fantastic. Thank you so much. Thank you, Malathi. I know that it's really encouraging to hear from someone, especially since you didn't have funding, and so to have this, I think, is a really wonderful opportunity that you asked for what you needed, and your family Partnership council was able to help you with that and your administration. So thank you so much for sharing that. In our last couple of minutes, if you have other questions, drop them in the chat and Malathi can respond. We did want to show you our new website. So, if you go to FCCTaskforce.org, you'll be taken here. You've seen our padlet in the past. This is our brand new website. So, you can see under webinars all of their recordings and slide decks under resources. These are things that we've linked to or that presenters have linked to, or that things that you all have shared, that you have found really valuable as part of the listserve. So please make sure you check that out. If you have any feedback, let us know. And then I want to just sort of show you a wonderful video that features some of our family partners, and we can have this to end our session today.

Video (Mother 1): I came into my premie experience already having gone through the trauma of infertility, and already having that, you know. At first, I thought it was guilt, but it was shame. It was I am not a good mother—I am not. I can't even get pregnant first of all. Now I can't stay pregnant. Now I don't know my babies.

Video (Mother 2): You know the trauma. It begins at delivery, and then it just continues throughout until you get to discharge. And then you're processing.

Video (NICU provider): As NICU providers, you know, to take on all that emotion, you know. You just be fried by the end of the day, right? But leave it absent and not addressing it does not allow for very good family-centered care, and I think a lot of it relies on communication.

Video (Mother 3): Personally, after I gave birth at 24 weeks, I felt such a guilt that I failed with the voice that I was like "Now they're in the NICU—that's where they belong. They're with the people who know how to treat them, and they don't need me." I was lucky enough to be in a hospital that had a very strong family-centered care plan, who, before I could even verbalize that, said to me, "You're going to change diapers. You're going to take the temperature. You're going to feed them. You're going to hold them. They need you." And I needed that—to know that, you know, I was supposed to be there.

Video (Mom 4): After that first month, one of the nurses— she said I was going to hold Avery today, and I haven't held Avery ever. And she said, "Oh, well, we're just going to make that happen today," and I was like "Oh, I don't know if I can do that." But she said, "We can do it. We're going to do it together."

Video (Mom 5): Simply asking how my day was or having a conversation with me that has nothing to do with the NICU or

babies or monitors meant the world to me.

Video (Mom 6): In any kind of an ICU situation, your relationship with your partner is—that is the most fragile, because you're both going from the hardest time of your life, together with your child, that you both love more than anything.

Video (Mom 7): and I think another concrete thing that's super important that often gets left out that our family experienced is not having adequate discharge planning. You go from having this like super high intensity experience to sometimes from having had a one-on-one nurse to be with your child to just saying, "Okay, it's a big change to go home. If you have questions, this is where you call. You're going to have questions. That's okay. You know how to do this, and it's scary." So I think you know just kind of naming that for families involving people understand that you can be a good parent and be scared.

Video (NICU Provider): For NICU parents, you know, this is again a life altering event—that in the NICU, we are there because we have to because that's our kid. We are resilient, not because we want to, but because we have to. At the end of the day as NICU providers, you and your teams could go home. You could change jobs. You could do whatever you can. And again, not to say you don't care, because I know you absolutely care about your families and you and your kid. For us, that's our full life.

Caroline Toney-Noland: Thank you so much to all of the family partners who are part of that video for allowing us to share it to hopefully amplify your voice in this. We do have a couple of upcoming webinars. You'll be receiving calendar invites for these if you're part of the listserve.

We have some amazing content coming at you, and this is all a reflection of things that you have named, or that our family partners or health care partners have named, are absolutely vital to providing this work, and so thank you so much for all that you do. You know we've all been inspired to say, I think, by so many different wonderful options and resources. Start small. Pick something that you're going to work on in the next week and try to find a way to make it happen.

So thank you so much, and we will see you all in May.

Bibliography

1. Balasundaram et al. "Increasing Parent Satisfaction with Discharge Planning: An Improvement Project Using Technology in a Level 3 NICU." Adv Neonatal Care. 2021 Feb 4.
2. AAP Committee on Fetus and Newborn. "Hospital discharge of the high-risk neonate." Pediatrics. 2008 Nov; 122(5): 1 119-1126
3. Smith VC, Hwang SS, Dukhovny D, Young S, Pursley DM. "Neonatal intensive care unit discharge preparation, family readiness and infant outcomes: connecting the dots." J Perinatol. 2013;33(6):415-421.

Disclosures: *There are no reported disclosures*

NT

Vincent Smith, MD, MPH
Division Chief of Newborn Medicine
Professor of Pediatrics
Boston Medical Center
Boston, Massachusetts, United States

Malathi Balasundaram, MD
Clinical Associate Professor
Stanford School of Medicine
FCC Committee Chair
El Camino Hospital
Mountain View, CA, United States

Colby Day Richardson
Associate Medical Director of Golisano Children's Hospital NICU
Assistant Professor of Pediatrics
Division of Neonatology
University of Rochester School of Medicine
Rochester, NY, United States

Caroline Toney-Noland, MSc
Program Manager
CPQCC (California Perinatal Quality Care Collaborative)

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

Kari McCallie
Clinical Associate Professor of Pediatrics
Lucille Packard Children's Hospital
Stanford University
Palo Alto, CA, United States

Kristy Love
Director of Operations
National Perinatal Association

Cambridge Scholars Publishing

Lady Stephenson Library
Newcastle upon Tyne
NE6 2PA
United Kingdom

admin@cambridgescholars.com
www.cambridgescholars.com

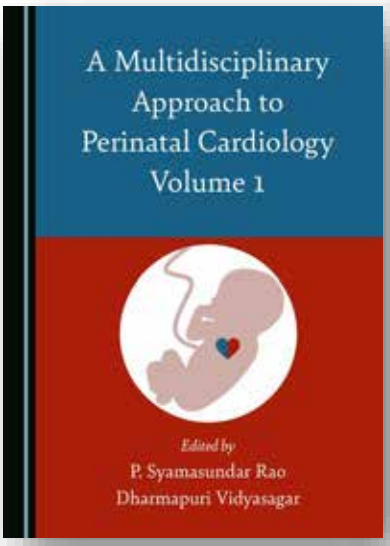
Fax +44 (0)191 265 2056

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.

Amanda Brown, CNM, MSN, MPH
University of North Carolina-Chapel Hill Hospitals, Chapel Hill, NC.

Sara Detlefs, MD
Fellow in Maternal-Fetal Medicine, Baylor College of Medicine, Houston, TX.

Sue L. Hall, MD, MSW, FAAP
Neonatologist, Ventura, CA.

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:

Brittany Boet
Founder, Bryce's NICU Project, San Antonio, TX.

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

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

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

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

CANCELLATIONS AND REFUNDS

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

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

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

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

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.

nann.org nationalperinatal.org

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?

WWW.MYNICUNETWORK.ORG

and

National Perinatal Association
NICU Parent Network

RSV Vaccine to Get Priority Review by the FDA

Michelle Winokur, DrPH

The Alliance for Patient Access, founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing 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 di[1]rectors. Its physician leadership is supported by policy advocacy management and public affairs consultants.

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

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

"The Food and Drug Administration will give priority review to a first-of-its-kind maternal vaccine against respiratory syncytial virus via the breakthrough therapy program. (1,2)"

The Food and Drug Administration will give priority review to a first-of-its-kind maternal vaccine against respiratory syncytial virus via the breakthrough therapy program. (1,2)

RSVpreF, which is administered to pregnant mothers, reduced infants' chances of needing to see a doctor for lower respiratory infections by 81% in Phase 3 clinical testing last year. (3,4)

This follows the FDA's December 2023 decision to expedite the review of an RSV vaccine for older adults. (5) European regulators have already approved one RSV immunization for infants and are giving multiple candidates expedited assessment. (6,7,8)

"This follows the FDA's December 2023 decision to expedite the review of an RSV vaccine for older adults. (5) European regulators have already approved one RSV immunization for infants and are giving multiple candidates expedited assessment. (6,7,8)"

RSV's Global Toll

And just in time. RSV is a highly contagious virus that causes cold-like symptoms in millions of patients yearly. (9) Moreover, severe cases can lead to bronchiolitis, pneumonia, or death. (9)

Almost all children contract an RSV infection by age two. (10) Globally, more than 100,000 young children die from it every year. (11) It accounts for over 2 million doctor visits and 58,000 hospitalizations annually among children under five. (12) It is also the leading cause of hospitalization among children under one.

"RSV is dangerous for older patients, too. It kills between 6,000 and 10,000 American seniors every year and hospitalizes ten times as many. (13)"

RSV is dangerous for older patients, too. It kills between 6,000 and 10,000 American seniors every year and hospitalizes ten times as many. (13)

The physical, financial, and emotional burdens RSV imposes on children, parents and families, and the elderly are enormous. (14, 15, 16, 17) These new immunizations represent a potential breakthrough.

Relieving Burdens

"The impact would be huge," Dr. Janet Englund, a respiratory virus specialist at Seattle Children's Hospital, told the Wall Street Journal last year. (18) "It would change hospitalization rates. Young babies wouldn't have to come to the hospital so much."

RSV has been a focus of medical research and development for years. (19) The FDA's expedited review of potential immunizations

indicates that regulators know the situation's urgency. If these immunizations are approved, they could dramatically reduce RSV infections in the United States and allow international health organizations to distribute the vaccine in the developing world, where RSV patients are at even greater risk. (20)

References:

1. https://www.scientificamerican.com/article/rsv-is-spreading-what-we-know-about-this-common-and-surprisingly-dangerous-virus/
2. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-granted-fda-breakthrough-therapy-designation
3. https://www.wsj.com/articles/rsv-vaccine-pfizer-infants-study-11667251540
4. https://www.yahoo.com/now/pfizer-announces-positive-top-line-103000293.html
5. https://www.cnbc.com/2022/12/07/rsv-fda-to-decide-on-pfizer-vaccine-for-older-adults-by-may-2023.html
6. https://www.astrazeneca.com/media-centre/press-releases/2022/beyfortus-approved-in-the-eu-for-the-prevention-of-rsv-lower-respiratory-tract-disease-in-infants.html
7. https://www.pmlive.com/pharma_news/gsks_application_for_its_rsv_vaccine_accepted_by_ema_under_accelerated_assessment_1480016
8. https://www.thepharmaletter.com/article/fda-follows-ema-in-accepting-pfizer-s-rsv-vaccine-filing
9. https://www.cdc.gov/rsv/about/transmission.html
10. https://www.cdc.gov/rsv/high-risk/infants-young-children.html
11. https://www.medscape.com/viewarticle/974323
12. https://www.cdc.gov/rsv/research/index.html
13. https://www.nytimes.com/2023/03/01/health/rsv-vaccine-fda.html
14. https://healthpolicytoday.org/2019/06/13/infants-arent-the-only-ones-hurt-by-rsv/
15. https://healthpolicytoday.org/2022/03/31/alleviating-the-burden-of-rsv-for-infants-and-children/
16. https://healthpolicytoday.org/2022/06/15/respiratory-syncytial-virus-takes-a-toll-on-families/
17. https://www.cdc.gov/rsv/high-risk/older-adults.html
18. https://www.wsj.com/articles/pfizer-moderna-j-j-see-respiratory-virus-rsv-as-next-vaccine-target-11650015001
19. https://www.washingtonpost.com/health/2022/10/10/rsv-vaccine/
20. https://www.nytimes.com/2022/11/01/health/rsv-children-vaccines.html

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

NT

Corresponding Author

Michelle Winokur, DrPH
Executive Director
Institute for Patient Access
2020 K Street NW, Suite 505
Washington, DC 20006
Telephone: (202) 951-7095
Email: mwinokur@instituteforpatientaccess.org

Immunizing Yourself Against **COVID-19**

COVID-19 vaccines have been shown to:

- Lessen the severity of symptoms[1]
- Reduce disease transmission[3]
- Reduce risk of mortality[2]
- Make communities healthier and safer[4]

Understanding the Options

COVID-19 vaccines are available for children, adolescents and adults. There are 3 types to choose from.

mRNA VACCINES

New to market, but research has been ongoing since the 1990s.

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

PROTEIN SUBUNIT VACCINES

Used for three decades against the flu, whooping cough and hepatitis B.

Deliver harmless versions of the COVID protein that train the immune system to fight the virus.

VECTOR VACCINES

Used for decades against chickenpox, malaria and tuberculosis.

Use a modified virus, such as a common cold, to teach the body to fight off COVID.

COVID vaccines are recommended for everyone ages 6 months and older, and boosters for everyone ages 5 years and older, if eligible.[5]

Safe and Sound

COVID vaccines have been:

- **Thoroughly tested** through multi-phase trials with tens of thousands of participants[6]
- **Proven safe and effective** for adults as well as children[7]
- **Vetted and approved** by the US FDA and EMA and endorsed by the WHO[8-10]

Get Your Jab

Vaccines are available at your:

- **Doctor's office**
- **Neighborhood pharmacy**
- **Community health center**

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

1. https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8782520/
3. https://www.nejm.org/doi/full/10.1056/nejmc2107717
4. https://royalsocietypublishing.org/doi/full/10.1098/rsif.2020.0683
5. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
6. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-and-effectiveness
7. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-and-effectiveness
8. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
9. https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised
10. http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/WHO-EUA-qualified-covid-vaccines.pdf

GAfPA Global Alliance for Patient Access

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Save the Date!
May 25, 2023

26th Annual Conference
Quality of Life for Families XXVI

Keynote Speaker: Dr. Diana Ramos
California Surgeon General

pac-Lac
Perinatal Advisory Council:
Leadership, Advocacy and Consultation

Where: **Hilton Los Angeles North/Glendale**
100 West Glenoaks Blvd,
Glendale, CA 91202

You can attend In-Person or Hybrid

LOMA LINDA
LLPC
PUBLISHING COMPANY
EST 2018

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

iCAN: The International Children's Advisory Network! "Mark Your Calendars"

Sabina Schmidt Goldstein-Becerra

iCAN
International Children's Advisory Network

Get involved today and Join the iCAN Parent Council!

"The International Children's Advisory Network, Inc. (iCAN) provides the pediatric community with many opportunities to come together to hear and learn from the most crucial stakeholder, the patient. "

The International Children's Advisory Network, Inc. (iCAN) provides the pediatric community with many opportunities to come together to hear and learn from the most crucial stakeholder, the patient. If you are unfamiliar with iCAN and would like to learn more about how to join us in our quest to ensure that every patient has a voice in medicine, research, and innovation, please visit our website at **www.iCAN.health.**

Pfizer, Jumohealth, LabCorp, Pediatric Trials Network, Advances in Therapeutics and Technology, Georgia Institute of Technology, Everylife Foundation for Rare Diseases, and Global Center for Medical Innovation are just a few of the organizations that iCAN is proud to partner with for our programs.

We are still seeking sponsors and donations for our 2023 Summit Presented by Jumo Health. We are working with the International Society for Pediatric Innovation (iSPI), our sister organization. This annual Summit allows our members to network with top healthcare experts while learning from one another's distinctive experiences as children living with chronic and/or unusual diseases. The iCAN summit offers the scientific community a chance to interact directly with kids, teenagers, and families to educate them on the significance and relevance of the perspective of pediatric patients in research, medicine, and innovation. We are now accepting registrations!

Mark Your Calendars! iCAN's Annual Advocacy and Research Summit presented by Jumo Health is July 10 - 14, 2023 in San Diego, California

"We are still seeking sponsors and donations for our 2023 Summit Presented by Jumo Health. We are working with the International Society for Pediatric Innovation (iSPI), our sister organization."

For more information, visit **www.icanresearch.org/summit**

Sponsor a child to go to the 2023 iCAN Summit!

Each year, the Summit is attended by children from all over the globe thanks to sponsorship from iCAN. This summer, we would love to welcome children from around the world to San Diego!

Kids Uganda sharing their voice at the 2022 Summit in France

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

Learn How to Support iCAN Youth:

https://www.icanresearch.org/donate

Stress Awareness Month is in April. Because of this, we had two incredible speakers-Aaron Blacker and Joshua Wayne- on our Ask the Experts (ATE) segment on April 15th. They discussed the value of having access to mental health care and the relationship between stress and rising levels of technology. Every month at 10:00 AM EST, we host ATE. To learn more about the topics and dates, visit our Instagram account, @icanresearch. All are welcome.

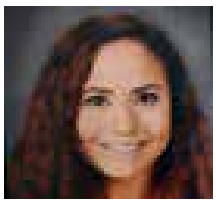
Please register: WWW.ICANRESEARCH.ORG/EVENTS

Please email us if you are interested in speaking at ATE **abbyclark@icanresearch.org**

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

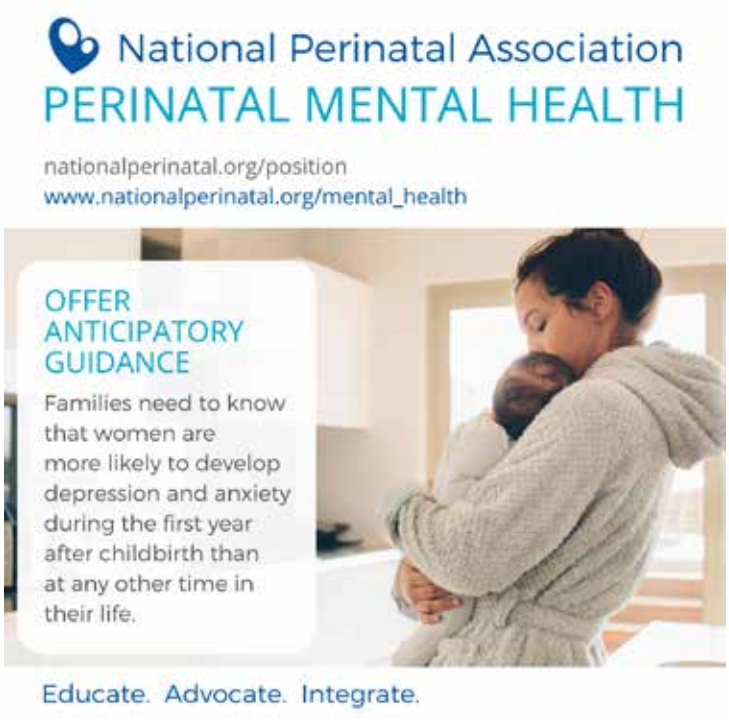
NT

Corresponding Author



Sabina Schmidt Goldstein-Becerra

Website: www.icanresearch.org
Phone: (+1) 818-256-7120
Email: sabina.goldstein@icanresearch.org



Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY

2023 iCAN SUMMIT

to be held July 10-14th in Southern California

iCAN
International Children's Advisory Network

Learn more:

www.iCANResearch.org

Registration opens March 1st, 2023

iCAN is not responsible or liable for any and all travel arrangements (including but not limited to flights, trains, cars, transport of any kind, accommodations, meals, reservations or other rental / vacation services acquired) by/for participants for any reason. iCAN is not responsible for any attendee medical needs. iCAN advises attendees to purchase travel insurance for the iCAN Summit.

Join Us In-Person for 2023

Kids - Make Your Summer Count!

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

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

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing...

EVIDENCE

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

PARTNERSHIP

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

Your Pregnancy and Substance Use

4 Things you can do to improve your health and lower your risk for complications

Get Prenatal Care

Start early. Go to all your visits. Empower yourself with information so you can make smart decisions. Build relationships with providers who understand Substance Use Disorders (SUDs) and know how to help. Partner with them to reach your goals. But remember, you do not need to be abstinent from substance use to get care. Go now.

Reduce Your Use

There are simple things you can do to limit the harm substances might do.

- Use fewer substances
- Use smaller amounts
- Use less often
- Learn how to use safer

Reducing or quitting smoking is a good place to start. Set your goals, then ask for help.
One of the best things you can do is to stop using alcohol. We know that even small amounts are risky. And when combined with benzos and opioids, alcohol can kill.

Use Medications for Opioid Use Disorder (MOUD) if you are opioid dependent

Methadone and Buprenorphine (Subutex® or Suboxone®) are the "Standard of Care" during pregnancy because they:

- Eliminate the risks of illicit use
- Reduce your risk for relapse
- Can be a positive step towards recovery

Take Good Care of Yourself

You deserve a healthy pregnancy & childbirth.

- Eat healthy and take your prenatal vitamins
- Find the right balance of rest and exercise
- Surround yourself with people who care

Your Health Matters

Academy of Perinatal Harm Reduction
www.perinatalharmreduction.org

National Perinatal Association
www.nationalperinatal.org

Education. Anytime, Anywhere.

Academy of Neonatal Care

The Academy of Neonatal Care serves to educate Respiratory Therapists, Nurses, and Doctors in current and best practices in Neonatal ICU care. We prepare RT's new to NICU to fully function as a bedside NICU RT. Our goal is to enrich NICU care at all levels. Beginner to Advanced Practice, there is something for you at:

www.AcademyofNeonatalCare.org.

Keeping Your Baby Safe
from respiratory infections

RSV
COVID-19
colds
flu

How to protect your little ones from germs and viruses

This year is an especially dangerous cold and flu season - especially for vulnerable infants and children. Fortunately, there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

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

Limit Contact with Others

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

Provide Protective Immunity

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

Take Care of Yourself

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

Get Immunized

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

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 feel sick or are positive for COVID-19

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

We can help protect each other.
www.nationalperinatal.org/rsv

National Perinatal Association

PROTECT YOUR FAMILY FROM
RESPIRATORY VIRUSES

flu coronavirus pertussis RSV

WASH YOUR HANDS
often with soap and warm water.

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

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

USE AN ALCOHOL-BASED HAND SANITIZER.

STAY AWAY FROM SICK PEOPLE
Avoid crowds. Protect vulnerable babies and children.

National Perinatal Association

www.nationalperinatal.org

FREE RESOURCES FOR YOUR NICU

Coping During COVID-19

Targeted interventions to improve the mental health of parents, infants, families, and providers

BONDING WITH YOUR BABY

HELPING CHILDREN AND FAMILIES COPE

CAREGIVERS NEED CARE TOO

National Network of NICU Psychologists

nationalperinatal.org/psychologists

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

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

Identify babies at greatest risk

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

Teach families how to protect

their babies from respiratory infections

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

Use your best clinical judgement

when prescribing RSV prophylaxis

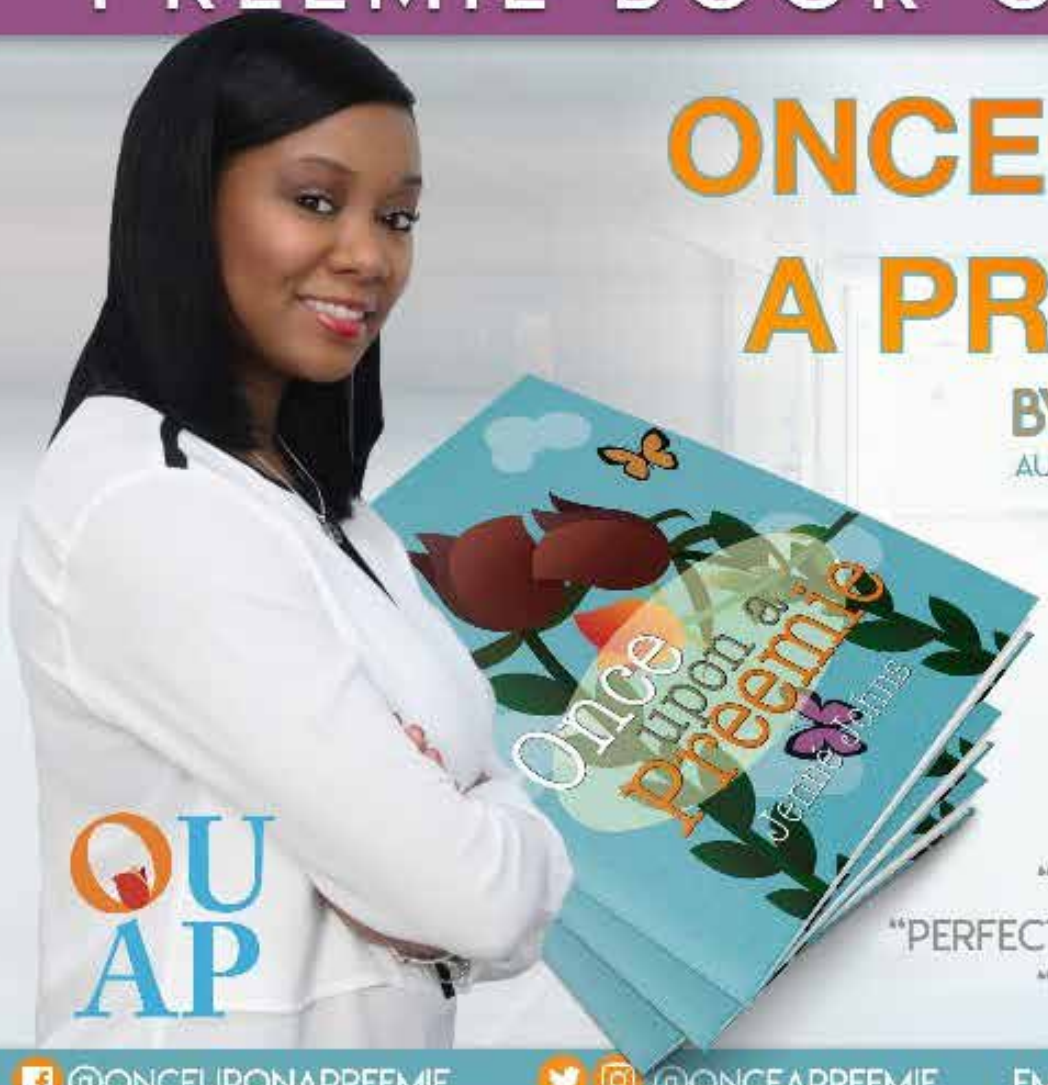
Tell insurers what families need

and provide the supporting evidence

National Perinatal Association

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

PREEMIE BOOK ON SALE



ONCE UPON A PREEMIE

BY JENNÉ JOHNS

AUTHOR | SPEAKER | ADVOCATE

QUAP

"ONE OF A KIND"
"PERFECT FOR PREEMIE FAMILIES"
"ENCOURAGING"

@ONCEUPONAPREEMIE @ONCEAPREEMIE EMAIL: HI@ONCEUPONAPREEMIE

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

SPEAKING ENGAGEMENTS

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

MEDIA APPEARANCES

Preemie Family

The Joyner Report

PEBBLES of Hope

WDAS 105.3 FM

CBS RADIO

wgts 91.9 Washington, D.C.

MAJIC 102.3 92.7 The Real Sound of the DMV

AVAILABLE FOR $12.99 ON AMAZON OR ONCEUPONAPREEMIE.COM

Still a **Preemie?**

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

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation?

STILL A PREEMIE

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

Jaundice | Feeding issues | Respiratory problems

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

Born preterm at a "normal" weight?

STILL A PREEMIE

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

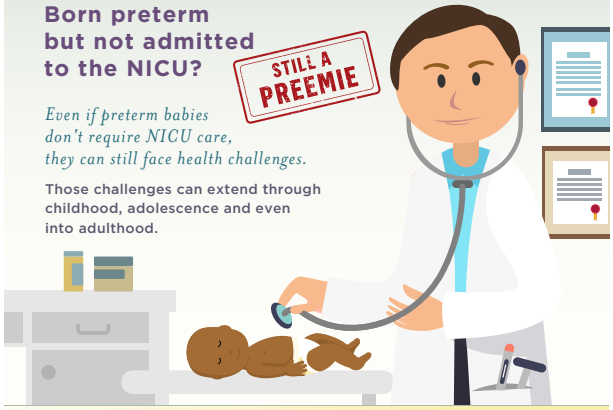
But because some health plans determine coverage based on a preemie's weight, **families of babies that weigh more may face access barriers and unmanageable medical bills.**

Born preterm but not admitted to the NICU?

STILL A PREEMIE

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

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



Some Preemies

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

All Preemies

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

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

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

I was exposed to opioids.

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

NAS is a temporary and treatable condition.

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

My mother may have a SUD.

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

My potential is limitless.

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

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

National Perinatal Association

FREE Online CE Activity

Nurses: parents trust you.

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

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

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

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

SAFE TO SLEEP®

Compiled and Reviewed by Saba Saleem, BS, OMS 4

Preterm Birth, Small for Gestational Age, and Large for Gestational Age and the Risk of Atrial Fibrillation Up to Middle Age

NEWS PROVIDED BY

JAMA Pediatrics

Fen Yang, MD, MSc[1]; Imre Janszky, MD, PhD[2]; Mika Gissler, Dr-Phil[3,4,5]; et al

April 24, 2023

Key Points

Question Are preterm birth, small for gestational age, and large for gestational age associated with increased risks of atrial fibrillation (AF) up to age 49 years?

Findings In this multinational cohort study with 8 million participants, preterm birth and large for gestational age were associated with increased risks of AF in childhood and up to age 49 years in adulthood, while an association between small for gestational age and an increased risk of AF was observed only in childhood. Similar findings were observed in sibling analyses.

Meaning Preterm birth, excessive fetal growth, and reduced fetal growth may increase the risk of AF up to age 49 years.

Abstract

Importance Adverse birth outcomes, including preterm birth, small for gestational age (SGA), and large for gestational age (LGA) are associated with increased risks of hypertension, ischemic heart disease, stroke, and heart failure, but knowledge regarding their associations with atrial fibrillation (AF) is limited and inconsistent.

Objective To investigate whether preterm birth, SGA, or LGA are associated with increased risks of AF later in life.

Design, Setting, and Participants This multinational cohort study included Danish, Swedish, and Finnish national health registries. Live singleton births in Denmark from 1978 through 2016, in Sweden from 1973 through 2014, and in Finland from 1987 through 2014, who were followed up until December 31, 2016, in Denmark, December 31, 2021, in Sweden, and December 31, 2014, in Finland were included. Data analyses were performed between January 2021 and August 2022.

Exposures Preterm birth (less than 37 gestational weeks), SGA (less than 10th percentile birth weight for gestational age), and LGA (more than 90th percentile birth weight for gestational age) identified from medical birth registers.

Main Outcomes and Measures Diagnosis of AF obtained from nationwide inpatient and outpatient registers. The study team ran multivariable Cox proportional hazard models and flexible parametric survival models to estimate hazard ratios (HRs) and 95% CIs for AF according to preterm birth, SGA, and LGA. Sibling analyses were conducted to control for unmeasured familial factors.

Results The cohort included 8 012 433 study participants (maximum age, 49 years; median age, 21 years; male, 51.3%). In 174.4 million person-years of follow-up, 11 464 participants had a diagnosis of AF (0.14%; median age, 29.3 years). Preterm birth and LGA were associated with increased AF risk in both the full population cohort and in the sibling analyses; the multivariate HRs from the cohort analyses were 1.30 (95% CI, 1.18-1.42) and 1.55 (95% CI, 1.46-1.63), respectively. Preterm birth was more strongly associated with AF in childhood than in adulthood. Children born SGA had an increased risk of AF in the first 18 years of life but not afterwards.

Conclusions and Relevance Preterm births and LGA births were associated with increased risks of AF up to middle age independently of familial confounding factors. Individuals born SGA had an increased AF risk only during childhood.

Reference

JAMA Pediatr. Published online April 24, 2023. doi:10.1001/jamapediatrics.2023.0083

NT

COVID during pregnancy may alter brain development in boys

NEWS PROVIDED BY

NPR Health News

Jon Hamilton

April 18, 2023

A COVID infection during pregnancy could raise baby boys' risk of some neurodevelopmental delays, study finds.

Boys born to mothers who got COVID-19 while pregnant appear nearly twice as likely as other boys to be diagnosed with subtle delays in brain development.

That's the conclusion of a study of more than 18,000 children born at eight hospitals in Eastern Massachusetts. Nearly 900 of the children were born to mothers who had COVID during their pregnancy.

In the study, boys, but not girls, were more likely to be diagnosed with a range of developmental disorders in the first 18 months of life. These included delays in speech and language, psychological development and motor function, as well as intellectual disabilities.

Spinal stimulation can improve arm and hand movement years after a stroke

In older children, these differences are often associated with autism spectrum disorder, says Dr. Roy Perlis, a co-author of the study and a psychiatrist at Massachusetts General Hospital.

But for the young children in this study, "it's way too soon to reliably diagnose autism," Perlis says. "All we can hope to detect at this point are more subtle sorts of things like delays in language and speech, and delays in motor milestones."

Meet the 'glass-half-full girl' whose brain rewired after losing a hemisphere

The study, which relied on an analysis of electronic health records, was published in March in the journal *JAMA Network Open*.

The finding is just the latest to suggest that a range of maternal infections can alter fetal brain development, especially in male offspring. For example, studies have found links between infections like influenza and cytomegalovirus, and disorders like autism and schizophrenia.

"Male fetuses are known to be more vulnerable to maternal infectious exposures during pregnancy," says Dr. Andrea Edlow, the study's lead author and a maternal-fetal medicine specialist at Massachusetts General Hospital.

But the effect from COVID-19 appears to be modest, Perlis says. "Most children of moms who have COVID during pregnancy won't have neurodevelopmental consequences even if there is some increase in risk."

A research opportunity

The study came about because Perlis and Edlow — both of whom are on the faculty at Harvard Medical School — saw an opportunity when COVID-19 arrived.

They had been looking for ways to use electronic health records to study factors that might affect the brain development of a fetus. That meant identifying pregnancies involving diabetes, high blood pres-

sure, or an infection like influenza, then following the offspring as they grew up.

"When the COVID pandemic started, we pivoted to try to look at fetal brain development and how it might be impacted by SARS-CoV-2 infection," Edlow says.

Building a better brain through music, dance and poetry

So the team began comparing the offspring of infected and uninfected mothers. And when they had a large enough group to look for sex differences, they found one.

"If a mom had SARS-CoV-2 infection in pregnancy and had a male child, her 12-month-old was 94% more likely to have any neurodevelopmental diagnosis," Edlow says.

Keep in mind that the virus that causes COVID-19 rarely infects a fetus, Edlow says. That makes it similar to influenza viruses, but very different from Zika virus, which directly attacks a developing brain.

With influenza or COVID-19, the risk to a fetus appears to come primarily from the mother's immune response to an infection, not the infection itself.

As part of the body's effort to fight the virus, it produces proteins known as cytokines, which regulate the immune system.

"These are cytokines that are really important for that initial immune response," says Kim McAllister, a professor at the University of California, Davis and director of the school's Center for Neuroscience. "They make you feel really bad. And that's a good thing because that's your immune system fighting off the pathogen."

But cytokines, unlike most pathogens, can cross the placenta and cause inflammation in a fetal brain. And animal studies suggest that this inflammation has a greater impact on the brains of male fetuses than female fetuses, and results in different behavioral abnormalities after birth.

"There's no doubt from the animal models that there is a link between maternal immune activation, changes in gene expression in the brain, changes in brain development, and long-lasting changes in behaviors," McAllister says.

The Harvard researchers plan to continue assessing the children in their study for several more years. That will allow them to see whether the early delays in boys persist or result in a diagnosis like autism spectrum disorder.

"I hope these effects go away," Perlis says. "I would be far happier if at the two-year and three-year follow-up there's no effect."

SOURCE NPR

NT

Loud Incubators Might Damage Preemie Babies' Hearing

NEWS PROVIDED BY

US NEWS

By Cara Murez

March 27, 2023

While an incubator can save the life of a premature baby, it may be contributing to hearing loss in these vulnerable infants.

A new study published March 27 in *Frontiers in Pediatrics* assessed the sounds in the neonatal intensive care unit, evaluating the impact on newborns.

"The motivation of our multidisciplinary research team concerns the question: why many more premature babies suffer hearing impairments," said study author Christoph Reuter, of the University of Vienna in Austria.

"We believe that what we have measured in our studies could be a leading cause," he said in a journal news release. "However, to understand how to protect premature infants from such noise levels, precise environment information is needed."

In the womb, the fetus hears low-frequency sound muffled by amniotic fluid, and no abrupt noises.

Sounds in incubators are much less muffled. There are many high-frequency components and abrupt noises. Recommended noise limits have been established, but these are often exceeded, especially when incubators are handled or opened, researchers said.

"Our study focused on various real-life noises and their levels as well as on their timbral characteristics, with two main purposes," said co-author Matthias Bertsch from the University of Music and Performing Arts Vienna. "Firstly, describing the NICU and incubator environment; secondly, providing awareness by presenting interactive material of real-life situations."

The study used a mannequin placed in an incubator equipped with measurement microphones.

Researchers recorded different sounds both inside and outside the incubator. Then they analyzed decibel levels to determine how sounds had been modified by the incubator.

While the incubator dampened most sounds, it caused certain ones to resonate within its cavity. This created a booming effect and raised the noise level by up to 28 decibels.

While sound inside the incubator was much louder than sound outside it, individuals outside the incubator didn't perceive it as loud.

"As closed boxes, incubators usually have an inherent resonance at around 100 Hz," meaning sounds inside are "exceptionally loud," said senior author Vito Giordano of the Medical University of Vienna. "Noises from the outside sound more tonal inside the incubator, booming and muffled as well as less rough or noisy, because of this resonance."

Both weighted decibel levels (which are

adjusted to account for the range of human hearing) and unweighted decibel levels were assessed.

The authors said the unweighted levels measured were much higher than the weighted ones, which significantly underestimated the noise preemies were exposed to.

Weighting is only an accurate reflection of sounds at lower levels, and is designed for adult ears, which are sensitive at different frequencies, they noted.

"Our results are not generalizable to all incubators available on the market," Reuter said. "Moreover, we measured in a simulation room under ideal conditions and not under everyday conditions, where the sound generated by the environment would be even louder."

The aim is not to deprive babies of all sound, the authors said. For their own development, it's good for infants to be able to hear things happening around them.

They said, however, that there is a need to take sound into account when designing and using incubators.

Hearing impairment can lead to delays in infants' language development.

More information

The March of Dimes has more on hearing loss in infants.

SOURCE: *Frontiers in Pediatrics*, news release, March 27, 2023

NT

ROP Incidence Increased in Premature Infants

NEWS PROVIDED BY

The American Journal of Managed Care

April 17, 2023

By Julia Bonavitacola

Retinopathy of prematurity (ROP) was found to have increased from 2003 to 2019, especially in Black and Hispanic children.

Black and Hispanic children were found to be especially vulnerable to retinopathy of prematurity (ROP), which has increased in infants from 2003 to 2019, according to a new study published in JAMA Ophthalmology. Researchers also found that infants in the areas of lowest income in the country had the highest proportional incidence of ROP.

ROP affects premature and low-birthweight infants, which can lead to vision impairment and blindness in the child. Abnormal development of retinal blood vessels is the primary cause of ROP. Its incidence has increased due to unmonitored supplemental oxygen, neonatal care advancements, and higher survival rates for premature infants. This current study used the National Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Databases (KIDs) to analyze the incidence of ROP in the United States from 2003 to 2019 across racial groups, income groups, and geographic regions.

Data for this study were taken from the KIDs, which contained data on pediatric patients in the United States and are meant to estimate health care trends. The KIDS database is produced every 3 years, which gave the researchers data from 2003, 2006, 2009, 2012, 2016, and 2019 to work with.

Patients who were important to this study were identified using International Classification of Diseases, Ninth Revision (ICD-9) and Tenth Revision (ICD-10) codes. Newborns who had low birth weight or were premature were considered ROP candidates in this study. Infants with ROP who were younger than 1 year were also identified using ICD codes. Racial and ethnic categories, median household income (MHI), and region were all taken from the KIDS database.

There were 125,212 discharges identified in the database, of which 48.3% were female. A total of 36.4% were White, 24.1% were Black, 16.5% were Hispanic, 3.3% were Asian/Pacific Islander, 0.5% were Native American, and 6.7% identified as other. Most of the patients with ROP were from urban hospitals, with 42.0% located in the urban South and 15.1% located in the urban North. A total of 32.6% were born in areas with the lowest MHI quartile and 18.3% were born to parents living in areas of the highest MHI quartile.

Infants with ROP were found to more likely be female (odds ratio [OR], 1.05; 95% CI, 1.03-1.07), be Black (OR, 1.72; 95% CI, 1.70-1.74) or Hispanic (OR, 1.05; 95% CI, 1.03-1.07), or live in the urban South (OR, 1.21; 95% CI, 1.20-1.23) or urban Midwest (OR, 1.18; 95% CI, 1.16-1.20). Infants from areas with lower MHIs also had higher odds of being diagnosed with ROP.

Incidence of ROP increased from 0.3% in 2003 to 0.76% in 2019 in all newborn infants. ROP candidates also had an increase in ROP incidence, from 4.4% in 2003 to 8.1% in 2019. This increase was seen across all races and ethnicities, but Black, Hispanic, and other infants had higher incidences. Incidence of ROP in Black infants increased from 5.8% in 2003 to 11.6% in 2019. Incidence of ROP in Hispanic infants increased from 4.6% in 2003 to 8.2% in 2019; White infants saw an increase from 3.8% to 6.7%.

ROP incidence also increased in all geographic regions. Incidence of ROP increased from 3.7% to 8.3% in the South, 4.9% to 8.9% in the Midwest, 5.4% to 8.2% in the North, and 4.6% to 6.8% in the West. All urban regions saw an increase in incidence rate whereas rural areas saw a decrease. The Northeastern, Midwestern, Southern, and Western urban areas had increases in ROP incidence of 50%, 91%, 123%, and 46%, respectively, whereas the corresponding rural areas had decreases of 18%, 73%, 32%, and 36%.

The lowest MHI quartile saw an increase in the rate of ROP, going from 4.9% in 2003 to 9.0% in 2019. The second-lowest quartile also had an increase from 4.6% to 8.2%.

The study is limited to the data available in KIDs, which do not include data from outside of the hospital setting. These databases track discharges rather than patients, which could lead to counting a child more than once. Databases are also subject to missing data, which could influence the results.

The researchers concluded that the overall incidence of ROP had doubled from 2003 to 2019 in premature infants, which

pac-lac

Perinatal Advisory Council:
Leadership, Advocacy and Consultation

Continuing Medical Education

The Continuing Education Department at PAC/LAC is pleased to consider requests to be a joint provider of your CME activity. PAC/LAC is actively involved in direct and joint-providership of multiple continuing education activities and programs and works with our partners to ensure the highest standards of content and design. PAC/LAC is the recipient of the 2018 Cultural & Linguistic Competency Award. This award recognizes a CME provider that exemplifies the goal of integrating cultural and linguistic competency into overall program and individual activities and/or a physician who provides leadership, mentorship, vision, and commitment to reducing health care disparities

PAC/LAC is an accredited provider of continuing education by Accreditation Council for Continuing Medical Education / Institute for Medical Quality, the California Board of Registered Nursing, the California Association of Marriage and Family Therapists, the National Commission for Health Education Credentialing, and the American Association for Respiratory Care.

To inquire about Continuing Education Joint-Providership opportunities for your event please visit our website and complete the online request form.

PAC/LAC offers continuing education for:

- Continuing Medical Education (CME)
- California Registered Nurses (CEU)
- Licensed Clinical Social Workers (LCSW)
- Licensed Marriage and Family Therapists (LMFT)
- Licensed Professional Clinical Counselors (LPCC)
- Licensed Educational Psychologists (LEP)
- Certified Health Education Specialists (CHES)
- Continuing Respiratory Care Education (CRCE)

www.paclac.org

PAC/LAC's core values for improving maternal and child health have remained constant for over 30 years – a promise to lead, advocate and consult with others.

Leadership

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

Advocacy

Providing a voice for healthcare professionals and healthcare systems to improve public policy and state legislation on issues that impact the maternal, child and adolescent population.

Consultation

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

could lead to medical and economic consequences for the health care system in the United States.

Reference

Bhatnagar A, Skrehot HC, Bhatt A, Herce H, Weng CY. Epidemiology of retinopathy of prematurity in the US from 2003 to 2009. JAMA Ophthalmol. Published online April 13, 2023. doi:10.1001/jamaophthalmol.2023.0809

SOURCE AJMC

NT

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:

- Connect with other AAP members who share your interests in improving effective drug therapies and devices in children.
- Receive the SOATT newsletter containing AAP and Section news.
- Access the Section's Website and Collaboration page – with current happenings and opportunities to get involved.
- Network with other pediatricians, pharmacists, and other health care providers to be stronger advocates for children.
- Invitation for special programming by the Section at the AAP's National Conference.
- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

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

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

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

Christopher Rizzo, MD, FAAP, Chair, crizzo624@gmail.com

Mitchell Goldstein, MD, FAAP, Immediate Past Chair, MGoldstein@llu.edu and

Jackie Burke

Sections Manager

AAP Division of Pediatric Practice

Department of Primary Care and Subspecialty Pediatrics

630.626.6759

jburke@aap.org

Dedicated to the Health of All Children

###

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

NT

Maternal SARS-CoV-2, Placental Changes and Brain Injury in 2 Neonates

NEWS PROVIDED BY

American Academy of Pediatrics

Merline Benny, MD; Emmalee S. Bandstra, MD; Ali G. Saad, MD; Roberto Lopez-Alberola, MD; Gaurav Saigal, MD; Michael J. Paidas, MD; Arumugam R. Jayakumar, PhD; Shahnaz Duara, MD

April 6, 2023

Long-term neurodevelopmental sequelae are a potential concern in neonates following in utero exposure to severe acute re-

spiratory syndrome coronavirus disease 2 (SARS-CoV-2). We report 2 neonates born to SARS-CoV-2 positive mothers, who displayed early-onset (day 1) seizures, acquired microcephaly, and significant developmental delay over time. Sequential MRI showed severe parenchymal atrophy and cystic encephalomalacia. At birth, neither infant was SARS-CoV-2 positive (nasopharyngeal swab, reverse transcription polymerase chain reaction), but both had detectable SARS-CoV-2 antibodies and increased blood inflammatory markers. Placentas from both mothers showed SARS-CoV-2- nucleocapsid protein and spike glycoprotein 1 in the syncytiotrophoblast, fetal vascular malperfusion, and significantly increased inflammatory and oxidative stress markers pyrin domain containing 1 protein, macrophage inflammatory protein 1 bh, stromal cell-derived factor 1, interleukin 13, and interleukin 10, whereas human chorionic gonadotropin was markedly decreased. One infant (case 1) experienced sudden unexpected infant death at 13 months of age. The deceased infant's brain showed evidence of SARS-CoV-2 by immunofluorescence, with colocalization of the nucleocapsid protein and spike glycoprotein around the nucleus as well as within the cytoplasm. The constellation of clinical findings, placental pathology, and immunohistochemical changes strongly suggests that second-trimester maternal SARS-CoV-2 infection with placentitis triggered an inflammatory response and oxidative stress injury to the fetoplacental unit that affected the fetal brain. The demonstration of SARS-CoV-2 in the deceased infant's brain also raises the possibility that SARS-CoV-2 infection of the fetal brain directly contributed to ongoing brain injury. In both infants, the neurologic findings at birth mimicked the presentation of hypoxic-ischemic encephalopathy of newborn and neurologic sequelae progressed well beyond the neonatal period.

The outbreak caused by severe acute respiratory syndrome coronavirus disease 2 (SARS-CoV-2) has had a profound effect on global health and worsened maternal and fetal outcomes.1,2 This report summarizes severe neurologic injury in 2 infants born in the third trimester, whose mothers tested SARS-CoV-2 positive several weeks before delivery. Both infants displayed ongoing neurologic injury and developmental deficits. One infant, with sudden death at 13 months of age, had extensive loss of brain white matter, gliosis, and vacuolization at autopsy.

Reference

Merline Benny, Emmalee S. Bandstra, Ali G. Saad, Roberto Lopez-Alberola, Gaurav Saigal, Michael J. Paidas, Arumugam R. Jayakumar, Shahnaz Duara; Maternal SARS-CoV-2, Placental Changes and Brain Injury in 2 Neonates. *Pediatrics* 2023; e2022058271. 10.1542/peds.2022-058271

SOURCE AAP

NT

Diagnosing early-onset neonatal sepsis in low-resource settings: development of a multivariable prediction model

NEWS PROVIDED BY

British Medical Journal

Samuel R Neal[1], Felicity Fitzgerald[2], Sim-

ba Chimhuya[3], Michelle Heys[1], Mario Cortina-Borja[1], Gwendoline Chimhini[3]

April 27, 2023

Abstract

Objective To develop a clinical prediction model to diagnose neonatal sepsis in low-resource settings.

Design Secondary analysis of data collected by the Neotree digital health system from 1 February 2019 to 31 March 2020. We used multivariable logistic regression with candidate predictors identified from expert opinion and literature review. Missing data were imputed using multivariate imputation and model performance was evaluated in the derivation cohort.

Setting A tertiary neonatal unit at Sally Mugabe Central Hospital, Zimbabwe.

Patients We included 2628 neonates aged <72 hours, gestation ≥32+0 weeks and birth weight ≥1500 g.

Interventions Participants received standard care as no specific interventions were dictated by the study protocol.

Main outcome measures Clinical early-onset neonatal sepsis (within the first 72 hours of life), defined by the treating consultant neonatologist.

Results Clinical early-onset sepsis was diagnosed in 297 neonates (11%). The optimal model included eight predictors: maternal fever, offensive liquor, prolonged rupture of membranes, neonatal temperature, respiratory rate, activity, chest retractions and grunting. Receiver operating characteristic analysis gave an area under the curve of 0.74 (95% CI 0.70–0.77). For a sensitivity of 95% (92%–97%), corresponding specificity was 11% (10%–13%), positive predictive value 12% (11%–13%), negative predictive value 95% (92%–97%), positive likelihood ratio 1.1 (95% CI 1.0–1.1) and negative likelihood ratio 0.4 (95% CI 0.3–0.6).

Conclusions Our clinical prediction model achieved high sensitivity with low specificity, suggesting it may be suited to excluding early-onset sepsis. Future work will validate and update this model before considering implementation within the Neotree.

Correspondence to Dr Michelle Heys, Population, Policy and Practice, UCL Great Ormond Street Institute of Child Health, London WC1N 1EH, UK; m.heys@ucl.ac.uk

http://dx.doi.org/10.1136/archdischild-2022-325158

SOURCE THE BMJ

NT

Exposure of preterm neonates receiving total parenteral nutrition to phthalates and its impact on neurodevelopment at the age of 2 months

NEWS PROVIDED BY

Nature

Iman Al-Saleh, Rola Elkhatib, Hissah Alnuwaysir, Hesham Aldhalaan, Eiman Alismail, Abdulaziz Binmanee, Amal Hawari, Fahad Alhazzani, Mohammad Bin Jabr & Gamal Mohamed

April 28, 2023

Abstract

This prospective study assessed the exposure to phthalates of preterm neonates who received total parenteral nutrition (TPN) during their stay in the neonatal intensive care unit (NICU) and the risk of neurodevelopment delays at the age of 2 months. Our study recruited 33 preterm neonates who required TPN upon NICU admission. Urine samples for analyzing phthalate metabolites were obtained at admission and then daily until the last day of receiving TPN. Phthalates in the daily TPN received by the preterm neonates were analyzed. The neurodevelopment of the neonates was assessed using the Ages and Stages Questionnaire Edition 3 (ASQ-3). Diethyl phthalate and butyl benzyl phthalate were found in all TPN samples, while 27% and 83% contained dibutyl phthalate and di-(2-ethylhexyl) phthalate (DEHP), respectively. Yet, the daily dose of each phthalate that our preterm neonates received from TPN was much lower than the recommended tolerable limit. Urinary levels of monobenzyl phthalate and four metabolites of DEHP [i.e., mono-(2-ethylhexyl) phthalate (MEHP), mono-(2-ethyl-5-hydroxyhexyl) phthalate, mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP), and mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP)] and the sum of four DEHP metabolites ($\sum_4$DEHP) increased significantly in preterm neonates before discharge. However, these levels were not correlated with their phthalate parent compounds in TPN, suggesting other sources of exposure in the NICU. At 2 months, we found that urinary levels of mono-iso-butyl phthalate (M*i*BP), MECPP, MEHP, and $\sum_4$DEHP were inversely related to fine motor skills. After adjusting for head circumference, the inverse relationships remained significant, suggesting direct effects from phthalates. Given the extreme vulnerability of our population, it is critical to minimize exposure to phthalates during their NICU stay.

SOURCE NATURE

NT

Tranexamic acid does not appear to prevent maternal hemorrhage after cesarean delivery

Thursday, April 13, 2023

Tranexamic acid appears no more effec-

tive than placebo in reducing the need for blood transfusion or preventing maternal death in patients with increased risk for excessive bleeding because of cesarean delivery, according to a study funded by the National Institutes of Health. Tranexamic acid slows the natural breakdown of blood clots and was considered promising for reducing the risk of excessive bleeding after giving birth—known as postpartum hemorrhage—after cesarean delivery.

In addition, patients who received tranexamic acid had slightly less need for additional medical or surgical interventions to treat postpartum hemorrhage and a slightly lower drop in red blood cell count.

The study was led by Luis D. Pacheco, M.D., of the University of Texas Medical Branch at Galveston, and colleagues. It appears in the New England Journal of Medicine. Funding was provided by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

"Our findings differ from those of previous trials, which were smaller and therefore did not have the statistical power to detect a difference in the need for blood transfusion between groups," said study author Monica Longo, M.D., of the NICHD Pregnancy and Perinatology Branch. "The current study included participants from 31 birthing centers across the United States and found no benefit of the drug, compared to placebo."

Previously, researchers have theorized that since tranexamic acid prevents the breakdown of blood clots, the drug might slow blood loss and reduce the risk of postpartum hemorrhage. Tranexamic acid has been found to be effective among women experiencing postpartum hemorrhage. Researchers sought to determine the effectiveness of the drug for patients undergoing cesarean delivery who did not have hemorrhaging at the time of treatment.

Researchers assigned 11,000 patients to receive either intravenous tranexamic acid or placebo after umbilical cord clamping at the time of cesarean delivery. The study included women who had undergone scheduled and unscheduled cesarean delivery.

The researchers reported the results as a single primary outcome of events that might be expected with postpartum hemorrhage, the need for a transfusion of red blood cells or death. These events occurred in 201 patients (3.6%) in the tranexamic acid group and 233 (4.3%) in the placebo group, a difference that was not statistically significant. For the placebo group, one death occurred. There were no deaths in the tranexamic acid group. There was no significant difference between the groups for the secondary outcome of estimated blood loss of more than 1 liter during the procedure: 7.3% in the tranexamic acid group, 8% in the placebo group.

However, the study found that patients who received tranexamic acid had less need for additional medical or surgical interventions to treat postpartum hemorrhage, compared to the placebo group (16.1% versus 18%), and a lower drop in red blood cell count after cesarean delivery (1.8 grams per deciliter versus 1.9 grams per deciliter).

The tranexamic acid group was more likely to have an infection after giving birth, 3.2% to 2.5%. The authors noted that previous trials had not seen a difference in infection rates between the groups and added that the finding would need to be confirmed by additional research.

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

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

NIH…Turning Discovery Into Health®

References

Pacheco LD, et al. Tranexamic acid to prevent obstetrical hemorrhage after cesarean delivery. The New England Journal of Medicine(link is external). 2023.

###

Institute/Center

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

Contact

Linda Huynh or Robert Bock(link sends e-mail)

301-496-5133

NT

FDA-approved drug shows promise in lab models for blinding childhood disease

Wednesday, March 29, 2023

Strategy may speed delivery of therapeutic options relative to time it would take to develop gene therapies.

Illustration of treated vs. untreated LCA10

In LCA10, CEP290 mutations lead to defects in the photoreceptor outer segment. Consequently, the building blocks of the primary cilium accumulate in the photoreceptors, which activates autophagy (shown left, untreated). Reserpine restores the balance between autophagy and the ubiquitin-proteasome system histone deacetylase 6 and improves primary cilium assembly. Holly Y. Chen, Ph.D., NEI

What

A National Institutes of Health team has identified a compound already approved by the U.S. Food and Drug Administration that keeps light-sensitive photoreceptors alive in three models of Leber congenital amaurosis type 10 (LCA 10), an inherited retinal ciliopathy disease that often results in severe visual impairment or blindness in early childhood.

LCA 10 is caused by mutations of the ciliacentrosomal gene (CEP290). Such mutations account for 20% to 25% of all LCA – more than any other gene. In addition to LCA, CEP290 mutations can cause multiple syndromic diseases involving a range of organ systems.

Using a mouse model of LCA10 and

two types of lab-created tissues from stem cells known as organoids, the team screened more than 6,000 FDA-approved compounds to identify ones that promoted survival of photoreceptors, the types of cells that die in LCA, leading to vision loss. The high-throughput screening identified five potential drug candidates, including Reserpine, an old medication previously used to treat high blood pressure.

Observation of the LCA models treated with Reserpine shed light on the underlying biology of retinal ciliopathies, suggesting new targets for future exploration. Specifically, the models showed a dysregulation of autophagy, the process by which cells break down old or abnormal proteins, which in this case resulted in abnormal primary cilia, a microtubule organelle that protrudes from the surface of most cell types. In LCA10, CEP290 gene mutations cause dysfunction of the primary cilium in retinal cells. Reserpine appeared to partially restore autophagy, resulting in improved primary cilium assembly.

Reserpine targets dysregulated intracellular signaling pathways downstream of the primary cilium. Such a treatment strategy could potentially address retinal ciliopathies caused by many of the more than 160 disease-causing genes, regardless of the specific gene involved. That's in contrast to gene therapy, which requires a very expensive and labor-intensive process to tailor an individual gene-based therapeutic approach for each mutation.

This work was supported by the NEI Intramural Research Program (ZIAEY000450 and ZIAEY000546) and the National Center for Advancing Translational Sciences Intramural Research Program (ZIATR000018-06)

NEI Spokesperson

Anand Swaroop, Ph.D., senior investigator and chief of the NEI Neurobiology Neurodegeneration and Repair Laboratory

To schedule interviews with Dr. Swaroop, contact NEI at neinews@nei.nih.gov(link sends e-mail)

Reference

Chen HY, Swaroop M, Papal S, Mondal AK, Song HB, Campello L, Tawa GJ, Regent F, Shimada H, Nagashima K, de Val N, Jacobson SG, Zheng W, Swaroop A. "Reserpine maintains photoreceptor survival in retinal ciliopathy by resolving proteostasis imbalance and ciliogenesis defects," eLife March 28, 2023, https://doi.org/10.7554/eLife.83205

About the NEI: NEI leads the federal government's efforts to eliminate vision loss and improve quality of life through vision research…driving innovation, fostering collaboration, expanding the vision workforce, and educating the public and key stakeholders. NEI supports basic and clinical science programs to develop sight-saving treatments and to broaden opportunities for people with vision impairment. For more information, visit https://www.nei.nih.gov.

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

NIH…Turning Discovery Into Health®

###

Institute/Center

National Eye Institute (NEI)

Contact

Kathryn DeMott or Claudia Costabile(link sends e-mail)

301-496-5248

Connect with Us

Subscribe to news releases

RSS Feed

NT

NIH-supported trial shows artificial pancreas improves blood glucose control in young children

Wednesday, March 15, 2023

What

Artificial pancreas technology improved blood glucose control in young children between ages 2 and 5 with type 1 diabetes, according to the results of the Pediatric Artificial Pancreas (PEDAP) Trial, a 13-week randomized controlled trial conducted at three pediatric diabetes centers across the United States. The study was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, and results were published in the New England Journal of Medicine(link is external).

The artificial pancreas, also known as closed-loop control, is an "all-in-one" diabetes management system that tracks blood glucose levels using a continuous glucose monitor (CGM) and automatically delivers the insulin when needed using an insulin pump. The system replaces reliance on testing by fingerstick or CGM with delivery of insulin by multiple daily injections or a pump controlled by the patient or caregiver.

The trial enrolled 102 participants between ages 2 and 5, a particularly challenging population when it comes to glycemic control, and randomly assigned them to

either the artificial pancreas group or the standard care comparison group. The artificial pancreas group received training on how to use the study device — an insulin pump programmed with Control-IQ insulin dosing technology — and a CGM. The standard care group continued to use their pre-study method of blood glucose management and were trained to use the study CGM.

During the 13 weeks, participants in the artificial pancreas group spent 12% more time — approximately three hours per day — within their target blood glucose range compared to the standard care group. The greatest difference in blood glucose control was seen at nighttime, between 10 p.m. and 6 a.m., with artificial pancreas participants spending 18% more time in range than the standard care group. Nighttime control is especially challenging to maintain in children with type 1 diabetes.

Additional measurements of blood glucose control also improved, similar to findings seen in previous artificial pancreas trials in older children and adults.

The trial was conducted at the Center for Diabetes Technology at the University of Virginia, Charlottesville; the Barbara Davis Center for Diabetes at the University of Colorado, Aurora; and Stanford University, Palo Alto, California. Due to emergency pandemic restrictions at the time of the study, more than 80% of the device trainings, and 90% of the study visits overall occurred virtually, suggesting the suitability of the technology for use in remote and underserved areas.

The study also assessed safety of using the artificial pancreas device in young children. Similar numbers of severe hypoglycemia occurred among both study groups. One instance of diabetic ketoacidosis occurred in the artificial pancreas group due to a problem with the insulin pump tubing called infusion set failure.

Study funding was provided by the National Institute of Diabetes and Digestive and Kidney Diseases (grant # U01DK127551). Tandem Diabetes Care provided the investigational closed-loop insulin pumps and infusion supplies and Dexcom Inc. provided the CGM supplies used in the trial.

Who

Guillermo Arreaza-Rubin, M.D., program director in NIH's National Institute of Diabetes and Digestive and Kidney Diseases, the study's lead funder, is available to comment on this study.

Reference

Wadwa, R.P., et al. Randomized, controlled trial of automated insulin delivery with virtual visits in young children with type 1 diabetes. New England Journal of Medicine. March 16, 2023. DOI: 10.1056/NEJMoa2210834(link is external).

The NIDDK, a component of the National Institutes of Health (NIH), conducts and supports research on diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition and obesity; and kidney, urologic and hematologic diseases. Spanning the full spectrum of medicine and afflicting people of all ages and ethnic groups, these diseases encompass some of the most common, severe, and disabling conditions affecting Americans. For more information about the NIDDK and its programs, see http://www.niddk.nih.gov.

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

NIH…Turning Discovery Into Health®

###

Institute/Center

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Contact

Alyssa Voss(link sends e-mail)

301-496-3583

NT

8th World Congress of Pediatric Cardiology *and* Cardiac Surgery

WASHINGTON D.C.

In 2023, for the first time ever, the World Congress of Pediatric Cardiology and Cardiac Surgery will be held in the continental United States of America. The 2023 WCPCCS promises to be the most comprehensive, up-to-date and technologically advanced meeting ever designed for Pediatric and Congenital Heart Disease.

AUGUST 27 – SEPTEMBER 1, 2023

SUBSPECIALTY TRACKS

• Cardiac Surgery • Ambulatory Cardiology •
• Cardiac Catheterization • Multimodal Imaging •
• Cardiovascular Nursing • Rheumatic Heart Disease •
• Fetal Cardiology • Adult Congenital Heart Disease •
• Cardiovascular Disease in the Neonate •
• Basic and Translational Science • Neurodevelopment •
• Heart Failure and Transplantation • Echocardiography •
• Administration & Leadership • Cardiac Anesthesia •
• Pulmonary Hypertension • Global Cardiac Health •
• Electrophysiology • Quality Improvement •
• Special Sessions for Trainees and Junior Faculty •
• Big Data, New Technology & Artificial Intelligence •
• Cardiac Intensive Care Advocacy • Cardiopulmonary Bypass, ECMO & Mechanical Circulatory Support •

Please subscribe to our mailing list and visit the website for the latest information on abstract submission, registration, lodging and more details to help you prepare for #WCPCSS2023

Join our mailing list at
WCPCCS2023.org

Connect and learn
#WCPCCS2023

Abstract Submission is Now Open

Peer Reviewed

Genetics Corner:
Genetics Corner: PHACES Syndrome in an Infant with Segmental Facial Hemangiomas and Stridor

Robin Dawn Clark, M.D.

"A 34-day-old female infant was admitted to the Pediatric Intensive Care Unit for hypoxic respiratory insufficiency and worsening biphasic stridor. She was born at 34 weeks gestation but had no problems at birth and was discharged home with her mother."

Case History:

A 34-day-old female infant was admitted to the Pediatric Intensive Care Unit for hypoxic respiratory insufficiency and worsening biphasic stridor. She was born at 34 weeks gestation but had no problems at birth and was discharged home with her mother. Although not present at birth, by a few days of age, the parents noted several small, nonconfluent facial hemangiomas on the lower lip, chin, sublingual area, and preauricular region on the left. Stridor began at about ten days of age, and the baby was diagnosed with laryngomalacia at the first pediatric visit at about two weeks of age. She was admitted to a community hospital for stridor for one day and discharged with oral prednisone. She failed to improve and was admitted to the PICU from the emergency department of another hospital at four weeks of age. Laryngoscopy and bronchoscopy demonstrated a subglottic hemangioma. The infant was initially treated with CPAP in the ED, NIMV in the PICU, and then intubated in the OR on day 2 of her hospital course. She remained intubated and mechanically ventilated for ten days while she was treated with propranolol and decadron. When a supraglottoplasty was performed on day 11, there was an improvement in the subglottic hemangioma, and she was extubated. The sublingual hemangioma had also resolved.

"The consultant diagnosed PHACES syndrome based on the presence of segmental facial hemangiomas in the mandibular distribution with two major criteria affecting the midline chest and abdominal wall."

A genetics consultation was requested on day 13. She had facial hemangiomas as above, a supraumbilical raphe, widely spaced nipples, bifid xiphoid, an area of skin hypoplasia over the midsternum, and a superior sternal cleft, most evident on inspiration, tightly adducted thumbs, fisted hands and moderately increased tone in the lower extremities. The consultant diagnosed PHACES syndrome based on the presence of segmental facial hemangiomas in the mandibular distribution with two major criteria affecting the midline chest and abdominal wall. A chromosome microarray was normal. An echocardiogram revealed a patent foramen ovale. A fundal exam was normal. A brain MRI was considered to be within normal limits: "mild prominence of the bilateral frontotemporal extra-axial spaces, likely related to benign enlargement of the extra-axial spaces in infancy (BESSI)." However, a brain magnetic imaging angiogram revealed neurovascular abnormalities: "markedly decreased caliber/diminutive appearance of the right middle cerebral artery including the distal vessels, which remain patent; subtle caliber change of the right ICA terminus, which may represent possible ectasia/small fusiform aneurysm." In addition, the right A1 segment of the ICA was absent, and the left posterior communicating artery was not visualized. MRA of cervical vessels was considered essentially normal although: "possible diminutive/hypoplastic right brachiocephalic artery versus imaging artifact was documented. Neurosurgical and interventional radiology consultations did not recommend intervention. The infant was discharged on day 21 on propranolol, 1.9 mg/kg/day divided BID.

"In addition, the right A1 segment of the ICA was absent, and the left posterior communicating artery was not visualized. MRA of cervical vessels was considered essentially normal although: "possible diminutive/hypoplastic right brachiocephalic artery versus imaging artifact was documented. "

Discussion:

Infantile hemangiomas are benign, common, isolated, and usually self-limited vascular tumors. However, as this patient illustrates, 2-3% of children with infantile hemangiomas have PHACES syndrome (OMIM #60519), a neurocutaneous disorder characterized by typically large (>5cm) segmental infantile hemangiomas, usually on the face, scalp or cervical region, and extracutaneous anomalies. This disorder of unknown etiology is an acronym for its most common features: ***p***osterior fossa malformation, segmental infantile ***h***emangiomas, ***a***rterial anomalies, ***c***ardiac defects, ***e***ye abnormalities, and ***s***ternal defect or ***s***upraumbilical raphe. (1) In early literature, it was referred to as PHACE syndrome before the sternal elements were recognized as part of the condition. Most patients with PHACES syndrome are female, with a skewed distribution of up to 9F:1M. Segmental facial hemangiomas usually occur shortly after birth in areas that correspond to facial developmental fields: frontotemporal (S1), maxillary (S2), mandibular (S3), and frontonasal (S4). (2) Facial hemangiomas typically re-

spond rapidly to propranolol. (3)

"Airway infantile hemangiomas (AIH) present with hoarseness and stridor from birth to 4 months. Up to 50% of AIH occur in association with PHACES syndrome."

Airway infantile hemangiomas (AIH) present with hoarseness and stridor from birth to 4 months. Up to 50% of AIH occur in association with PHACES syndrome. Although AIH can occur without cutaneous manifestations, most are associated with facial hemangiomas in the mandibular or "beard" (S3) distribution that, as in the patient described above, includes the lower lip, chin, mandible, and preauricular area. Biphasic stridor is typical of subglottic AIH. Steroids are ineffective, but most AIH responds rapidly to propranolol, 1-3 mg/kg/d. In a retrospective review of 36 patients with AIH successfully treated with oral propranolol, the median length of propranolol treatment was 15 months. Relapses occurred in 15% of this cohort. (4)

"Revised diagnostic criteria for PHACES syndrome allows a definite diagnosis of the syndrome when a segmental hemangioma of 5 cm or greater occurs with one major or two minor criteria or a hemangioma of less than 5 cm occurs with two major criteria. (5)"

Revised diagnostic criteria for PHACES syndrome allows a definite diagnosis of the syndrome when a segmental hemangioma of 5 cm or greater occurs with one major or two minor criteria or a hemangioma of less than 5 cm occurs with two major criteria. (5) Airway infantile hemangiomas (AIH) present with hoarseness and stridor from birth to 4 months. Up to 50% of AIH occur in association with PHACES syndrome. The brain and cervical arteriopathy of PHACES syndrome commonly involve the internal carotid artery and its embryonic branches, ipsilateral to the cutaneous hemangioma. In one study, dysgenesis was the most common intracranial vascular anomaly, seen in 39/70 cases of PHACES syndrome. Aneurysms were frequently encountered within the dysplastic segments. Three of the 70 patients had remote infarcts on imaging. Among those with conventional brain MR imaging, structural abnormalities were present in 41% (24/59). (6)

LUMBAR syndrome is a similar disorder with a different distribution of anomalies. This acronym is for ***l***ower body hemangiomas, ***u***rogenital anomalies, ***m***yelopathy, ***b***one deformities, ***a***norectal malformations/***a***rterial anomalies, and ***r***enal anomalies. There is speculation that, as yet, uncharacterized somatic gene mutations cause both PHACES and LUMBAR syndromes. (7)

The evaluation of an infant with suspected PHACES syndrome should include an echocardiogram, ophthalmologic exam, brain MRI and MRA. In a retrospective review of infantile segmental or periorbital hemangiomas, the hemangioma size (>5 mc or not) did not correlate with extracutaneous anomalies. (8) The authors concluded that infants with small, <5 cm segmental hemangiomas should be evaluated for other anomalies, a conclusion that this case also supports.

Figure 1: (A, B): Facial hemangiomas of the lower lip, chin (Figure 1A), and preauricular area (Figure 1B) are within the mandibular or S3 distribution, but they are small and discontiguous, measuring less than 5 cm.

Practical applications:

1. Consider the diagnosis of PHACES syndrome in infants with segmental facial infantile hemangiomas, especially when accompanied by cardiac, brain, ocular, and sternal defects or a supraumbilical raphe.

2. When PHACES syndrome is suspected, regardless of the hemangioma size, evaluate for extracutaneous anomalies of the heart, eyes, and brain by ordering an echocardiogram, ophthalmology consult, and brain MRI and MRA. Appreci-

Figure 2: (A, B)These two views of the chest illustrate the supra-umbilical raphe (Figure 2A), widely spaced nipples, bifid xiphoid process (Figure 2B), and midline region of dermal hypoplasia over the sternum. There is a subtle cleft of the superior sternum, more evident on inspiration (Figure 2A).

ate that neurovascular anomalies increase the risk for infantile stroke.

3. Appreciate that airway hemangiomas are more frequent in the presence of segmental facial infantile hemangiomas in the S3, mandibular, or "beard" distribution. Specifically, understand that biphasic stridor is a sign of subglottic infantile hemangioma.

4. Recall that propranolol is the treatment of choice in infantile hemangiomas, and that relapse can occur after treatment is discontinued.

References:

1. Rotter A, *et al.* PHACE syndrome: clinical manifestations, diagnostic criteria, and management. An Bras Dermatol. 2018 Jun;93(3):405-411. PMID: 29924216

2. Endicott AA, *et al.* Mapping of Segmental and Partial Segmental Infantile Hemangiomas of the Face and Scalp. JAMA Dermatol. 2021 Nov 1;157(11):1328-1334. PMID: 34550297.

3. Disse SC, *et al.* PHACE Syndrome-before and after Propranolol Therapy. J Pediatr. 2018 Feb;193:275. PMID: 29221694.

4. Corbeddu M, *et al.* Management of Upper Airway Infantile Hemangiomas: Experience of One Italian Multidisciplinary Center. Front Pediatr. 2021 Dec 7;9:717232. PMID: 34950613

5. Garzon MC, *et al*. PHACE Syndrome: Consensus-Derived Diagnosis and Care Recommendations. J Pediatr. 2016 Nov;178:24-33.e2. PMID: 27659028

6. Hess CP, *et al.* Cervical and intracranial arterial anomalies in 70 patients with PHACE syndrome. AJNR Am J Neuroradiol. 2010 Nov;31(10):1980-6. PMID: 20705698.

7. Siegel DH. PHACE syndrome: Infantile hemangiomas associated with multiple congenital anomalies: Clues to the cause. Am J Med Genet C Semin Med Genet. 2018 Dec;178(4):407-413. PMID: 30580483.

8. Proisy M, *et al.* PHACES Syndrome and Associated Anomalies: Risk Associated With Small and Large Facial Hemangiomas. AJR Am J Roentgenol. 2021 Aug;217(2):507-514. PMID: 34036811.

NT

Corresponding Author

Robin Clark, MD
Professor, Pediatrics
Loma Linda University School of Medicine
Division of Genetics
Department of Pediatrics
*Email:*rclark@llu.edu

40th Advances in Neonatal and Pediatric Cardiorespiratory Care

This conference is unique because it focuses on physiology based patient care

Attend in person or virtually

January 31-February 2, 2024

Location:
Hilton Hotel
Glendale, CA

Confirmed Guest Speakers

- Frank Ing
- Donald Null
- Colleen Kraft
- Shahab Noori
- Amy B. Hair
- Rangasamy Ram
- Mitch Goldstein
- Kathi Salley Randall
- Valerie Y-L Chock
- Cynthia L. Blanco
- Amy Yeh
- Jennifer Shepard
- Yogen Singh

Hands-on Practice Sessions for FECHO/LUS/aEEG

INTERNATIONAL PDA 2023 SYMPOSIUM

August 26-27, 2023
WASHINGTON, DC
Walter E. Washington Convention Center

The 5th International PDA Symposium in Partnership with the 8th World Congress of Pediatric Cardiology and Cardiac

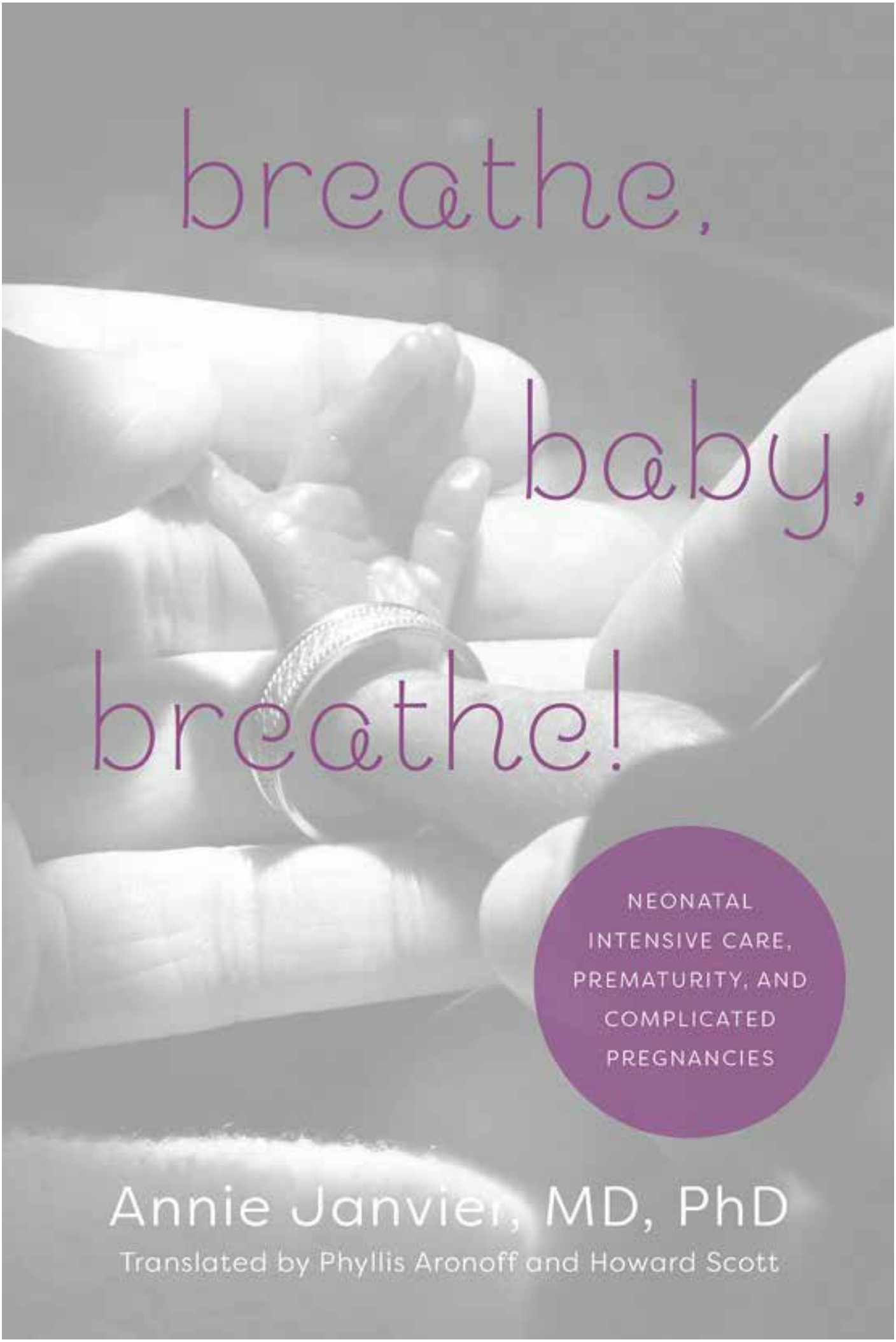
Program highlights

Joint statement on management recommendations for PDA in the extremely premature infants from the International PDA symposium, World Congress of Pediatric Cardiology and Cardiology Surgery and the NeoHeart Society.

- In depth discussion of PDA treatment options in the extremely premature infants, indications, patient selection, follow-up, and outcomes.
- Examination of current evidence and clinical trials.
- Updates on ongoing clinical trials.
- Hands-on workshop on performing echocardiography to image the PDA in the newborn.
- Hands-on workshop on transcatheter device closure of the PDA in the newborn.
- Debates on whether PDA needs to be closed or not, timing of PDA closure, techniques of PDA closure and interventions to keep the PDA patent in the newborn period.
- Case discussions including taped cases of transcatheter PDA closures.
- Meet the experts session.
- Abstract presentations.
- Updates in interventional techniques to treat PDA is in the extremely low birth weight infants.
- Discussion of long-term outcomes of extremely low birth weight infants with PDAs.
- Global trends in PDA management in the extremely premature

Featured Speakers

8th World Congress of Pediatric Cardiology *and* Cardiac Surgery
AUGUST 27 – SEPTEMBER 1, 2023
WASHINGTON D.C.


breathe,
baby,
breathe!
NEONATAL INTENSIVE CARE, PREMATURITY, AND COMPLICATED PREGNANCIES
Annie Janvier, MD, PhD
Translated by Phyllis Aronoff and Howard Scott

Peer Reviewed

The House is on Fire!! Responding to Unexpected Neonatal Events

Lisa Owens, DO

"Like firefighters, neonatologists must be ready to "put out a fire" anytime. While we are clinically prepared for the necessary interventions, we may feel less prepared for coding such events. Understanding what was done, what was submitted before the emergency, and which codes have procedures bundled or when 24-hour global codes apply can help."

Like firefighters, neonatologists must be ready to "put out a fire" anytime. While we are clinically prepared for the necessary interventions, we may feel less prepared for coding such events. Understanding what was done, what was submitted before the emergency, and which codes have procedures bundled or when 24-hour global codes apply can help.

"The hospital delivery team (NICU RN and RT) attends a routine C/Section of a term infant as per hospital policy. At 15 minutes of life, the neonatologist on call receives a call from the RN because she is not comfortable taking the baby to the NBN. The Neo rushes to the DR and finds the infant in mild respiratory distress with oxygen saturations in the mid-80s."

Scenario #1

The hospital delivery team (NICU RN and RT) attends a routine C/Section of a term infant as per hospital policy. At 15 minutes of life, the neonatologist on call receives a call from the RN because she is not comfortable taking the baby to the NBN. The Neo rushes to the DR and finds the infant in mild respiratory distress with oxygen saturations in the mid-80s. The baby does not appear distressed, the heart rate is in the 120s, and the pulses are equal throughout. The Neo applies CPAP and asks the OB about the significant pregnancy complications. The OB states that the mother had gestational DM. The Neo then orders a CXR to evaluate heart size, shape, and lung fields, which is unremarkable. At 25 minutes of life, the infant's oxygen saturations are above 95%, and the CPAP is removed. The infant is observed for another 10 minutes and then cleared for transport to NBN. The Neo updates the parents and documents in the chart—total time 40 minutes.

The best CPT code for this encounter is:

A. 99464 Attendance at delivery

B. 99465 Delivery room resuscitation

C. 99221 Initial hospital care

D. 99252 Inpatient consult, 35 minutes

Correct answer: D. When a consult code is used, the documentation should reflect the request for a consult and the total time spent. CPT 2023 has revised the time requirements.

CPT Code	Time (minutes)
99252	**35**
99253	**45**
99254	**60**
99255	**80**

With the updated CPT, the face-to-face time with the patient does not have to be documented separately, merely the total time.

Because the resuscitation was over, neither delivery room code was appropriate.

Despite the exam and history obtained, this does not meet the requirement for H&P. Therefore; answer C cannot be used.

"The neonatologist on call is requested to come to the Level II nursery. A 5-day-old 33-week infant receiving low flow oxygen via NC, approximately 100 ml/kg enteral feedings, and has a PIV for TPN running at approximately 50 ml/kg. She weighs 1750 grams today. She was seen by a member of the same physician group this morning."

Scenario #2

The neonatologist on call is requested to come to the Level II nursery. A 5-day-old 33-week infant receiving low flow oxygen via NC, approximately 100 ml/kg enteral feedings, and has a PIV for TPN running at approximately 50 ml/kg. She weighs 1750 grams today. She was seen by a member of the same physician group this morning. The nurse at the bedside tells you the baby has had increasing oxygen needs and abdominal distension throughout her shift and has passed a bloody stool. On exam, the abdomen is discolored and grossly distended, and during the exam, the infant has a significant apneic episode. The neonatologist intubates the infant, stops feeds, places a Replogle, and orders an X-ray showing diffuse pneumatosis. Labs are drawn, broad-spectrum antibiotics are ordered, and the infant is transferred to the Level IV nursery across the hall, total time spent 75 minutes.

The best CPT code for the evening encounter is:

A. 99479 intensive care day 1500-2500 grams

B. 99468 Initial critical care < 29 days of life

C. 99469 Subsequent critical care < 29 days of life

D. 99291 Critical care time (99291), 31500 Intubation

Correct answer: B.

This infant was initially admitted to the Level II nursery. All admit codes can only be used once per admission, and since this infant has spent the entire admission in the intensive care unit, this transfer to critical care qualifies for a critical care admission code. The critical care codes are 24-hour global and bundled, meaning most procedures are included and cannot be billed separately. Since critical care had been provided (intubation, PPV,) this code could be used. However, the infant was transferred to Level IV and will be cared for there. Thus, the global code is more appropriate.

"The pediatrician on call is asked to come urgently to the Emergency Department. EMS has dropped off a newly born infant from a birthing center. The infant appears term, is pale, grunting, and is lethargic. Their heart rate is 190's. The dad had accompanied the infant and said there was "a lot of blood" when the baby came out. The pediatrician suspects a cord accident or placental abruption. "

Scenario #3

The pediatrician on call is asked to come urgently to the Emergency Department. EMS has dropped off a newly born infant from a birthing center. The infant appears term, is pale, grunting, and is lethargic. Their heart rate is 190's. The dad had accompanied the infant and said there was "a lot of blood" when the baby came out. The pediatrician suspects a cord accident or placental abruption. She quickly places a UVC (5 minutes), gives a bolus of NS over 10 minutes, and orders emergency blood. The respiratory distress worsens, and the pediatrician intubates the infant (5 minutes). The pediatrician calls the regional NICU (covered by a different group) for transfer. The total time spent was 80 minutes.

The best CPT code for this encounter is:

A. 99291 critical care (30-74 minutes), 99292 critical care (additional 30 minutes)

B. 99291,31500 (intubation), 31560 (UVC), 96360 (administration of IVF, 31-60 min)

C. 99291, 31500, 31560

D. 99468

Corresponding Author:

Lisa Owens, D. O.
Senior Faculty
Baylor College of Medicine, Department of Pediatrics
17600 I 45 South
Ste 402
The Woodlands, TX
Office 440.26
Ph:832-826-1360
Email: Lisa.Owens@bcm.edu

Correct answer C. Procedures are not bundled with critical care time but must be subtracted from total critical care time. After subtracting procedural time, the critical care time does not exceed 74 minutes, and 99292 cannot be added as in answer A. If this infant had been admitted directly to NICU in this facility and the neonatologist and the pediatrician were in the same group, 99468 would be used, and separate codes from ED would not be entered. Since the infant is being transferred to a different facility and covered by a different group, the pediatrician can submit codes reflecting the work done in ED.

Unpredictability is the hallmark of Neonatology. When you think everything is under control, a fire breaks out somewhere, requiring your time and attention. Coding and documentation is the boring part of the job, but even firefighters have boring parts, too. I see them at the grocery store every time I go…

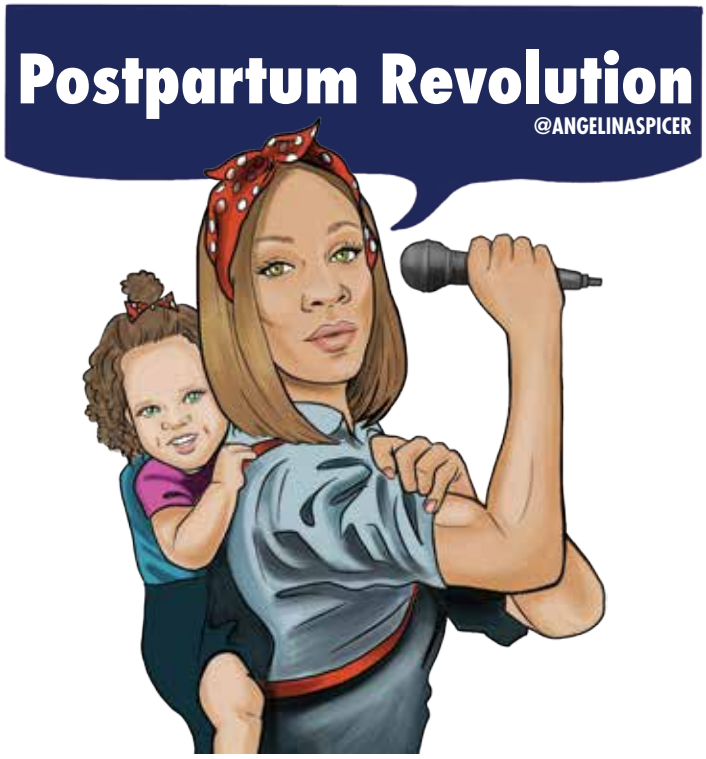
"Unpredictability is the hallmark of Neonatology. When you think everything is under control, a fire breaks out somewhere, requiring your time and attention. Coding and documentation is the boring part of the job,"

Let us be like firefighters: always look on the bright side and approach our work with a burning passion!

References:

1. Coding for Pediatrics 2023, American Academy of Pediatrics
2. CPT 2023, Professional Edition, AMA

Disclosure: The author has no disclosures.



Vaccines and Preventive Monoclonal Antibodies

WHAT'S THE DIFFERENCE?

The Importance of Immunization

Vaccines and preventive monoclonal antibodies are two different types of immunization. While they function differently, they both serve the same purpose: protecting people from serious illnesses and diseases.

Different Technology, Same Protective Value

AfPA

https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work#:~:text=Vaccines%20contain%20weakened%20or%20inactive,rather%20than%20the%20antigen%20itself.

https://static1.squarespace.com/static/5523fcf7e4b0fef011e668e6/t/62445afd0134140ff954f3f6/1648646910485/NCIIH_Monoclonal+Antibodies+Inclusion+in+the+VFC+Program_Position+Paper_Mar+2022.pdf

VACCINES		PREVENTIVE MONOCLONAL ANTIBODIES
Teach the body to create antibodies that fight off a specific disease.		Introduce antibodies that are ready to ward off disease in the body.
By introducing an inactive piece of a disease or proteins that look like the disease, they trigger an immune response, training the body to create antibodies that defeat the disease.	**How does it work?**	Instead of teaching the body to create antibodies and defenses, they provide antibodies that are readily available.
Both support the immune system's defenses.		
Many vaccines are readily and easily available. The technology behind vaccines has been around for decades.	**What are the benefits?**	Preventive monoclonal antibodies can provide protection for diseases where there isn't an existing vaccine or there isn't an existing vaccine for certain patient groups.
Both protect against disease and provide a public health benefit by decreasing the burden of disease.		
Polio Measles COVID-19 And more	**What can this immunization protect against?**	RSV COVID-19
Both can provide tailored protection from a variety of diseases.		
Yes	**Is it safe?**	Yes

Both vaccines and preventive monoclonal antibodies undergo extensive testing for safety and efficacy.

READ NPA's statement: BLACK LIVES MATTER

The Indirect Impact of **RSV**

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

Susan Hepworth, Suzanne Staebler, DNP, APRN, NNP-BC, FAANP, FAAN, Mitchell Goldstein, MD, MBA, CML

OVERVIEW

RSV impacts not only infants and young children, but also entire families.

The National Coalition for Infant Health and the Alliance for Patient Access sought to examine the multifaceted burden that RSV places on families and to identify potential policy solutions.

Two surveys were conducted, one of parents who had at least one child contract RSV and one of health care providers who treat infants and children with RSV.

Both surveys were conducted with YouGov, a global public opinion and data company. Parents and providers were recruited from a pool of pre-selected respondents to ensure they met the survey's requirements. Participants received an honorarium.

RSV PARENT SURVEY

340 parents who had at least 1 child sick with RSV

67% of parents said their child was hospitalized for RSV

RSV HEALTH CARE PROVIDER SURVEY

175 health care providers across various pediatric and neonatal subspecialties

67% worked in an outpatient facility

33% worked in a hospital

RESULTS

FINANCIAL BURDEN

More than ⅔ of parents said the costs of RSV posed a financial burden or financial crisis.

7% of parents said they were fired as a result of caring for their child with RSV.

32% of parents reported losing potential income while their child had RSV.

EMOTIONAL BURDEN

68% of parents said watching their child suffer affected their mental health.

69% of parents felt guilty that they could not do more to prevent their child's RSV.

When parents found out there was no treatment for RSV, only supportive care:

- **48%** felt angry
- **46%** felt helpless

SOCIAL BURDEN

43% of parents had never heard of RSV before finding out their child was sick.

54% of parents had to rely on family and friends for sibling care, transportation and other responsibilities.

42% of parents said they struggled to care for their other children when one faced RSV.

RESULTS

PARENT EDUCATION & AWARENESS

86% of providers said they include RSV education as part of routine care.

99% of providers agreed that parents need more information about RSV.

TREATMENT CHALLENGES

Nearly ⅓ of providers have been reluctant to test for RSV because no treatment exists.

48% of providers said it was difficult to decide whether to send an infant or child with RSV to the emergency room.

92% agreed that if an immunization were available, it should be added to the Vaccines for Children program's list of pediatric vaccines.

MISCONCEPTIONS

A majority of providers (60%) explained that around 50% or more of the babies they see hospitalized for RSV were born healthy, despite many people thinking severe RSV only impacts premature infants or those with preexisting conditions.

CONCLUSION

Both surveys highlighted that the burden of RSV extends well beyond its physical symptoms.

The virus may lead to:

- **Long-lasting health challenges** for babies and young children
- **Financial, social and emotional burdens** for families
- **Frustration for providers,** who lack a cure or viable preventive interventions

This burden is not experienced by the few. Most infants and children contract RSV by the time they are two, and challenges that accompany RSV may impact anyone who has been affected.

Moving forward, the many burdens of RSV demonstrate the need for:

- **More RSV education**
- **Research and innovation** for preventive interventions
- **Access to prevention and treatment** for all babies and children

The challenges caused by RSV can reach far and wide, and its indirect impacts often leave families struggling.

Managing RSV's Indirect Impact

Susan Hepworth, Mitchell Goldstein, MD, MBA, CML

NCfIH 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.

On March 28, the coalition released Managing RSV's Indirect Impact. This video highlights the emotional, financial, and social burdens that fall on RSV patients and their families, hoping to emphasize the many reasons why policy makers should be encouraged to support innovation in RSV care.

The text from the video follows. Please feel free to share this video with your networks.

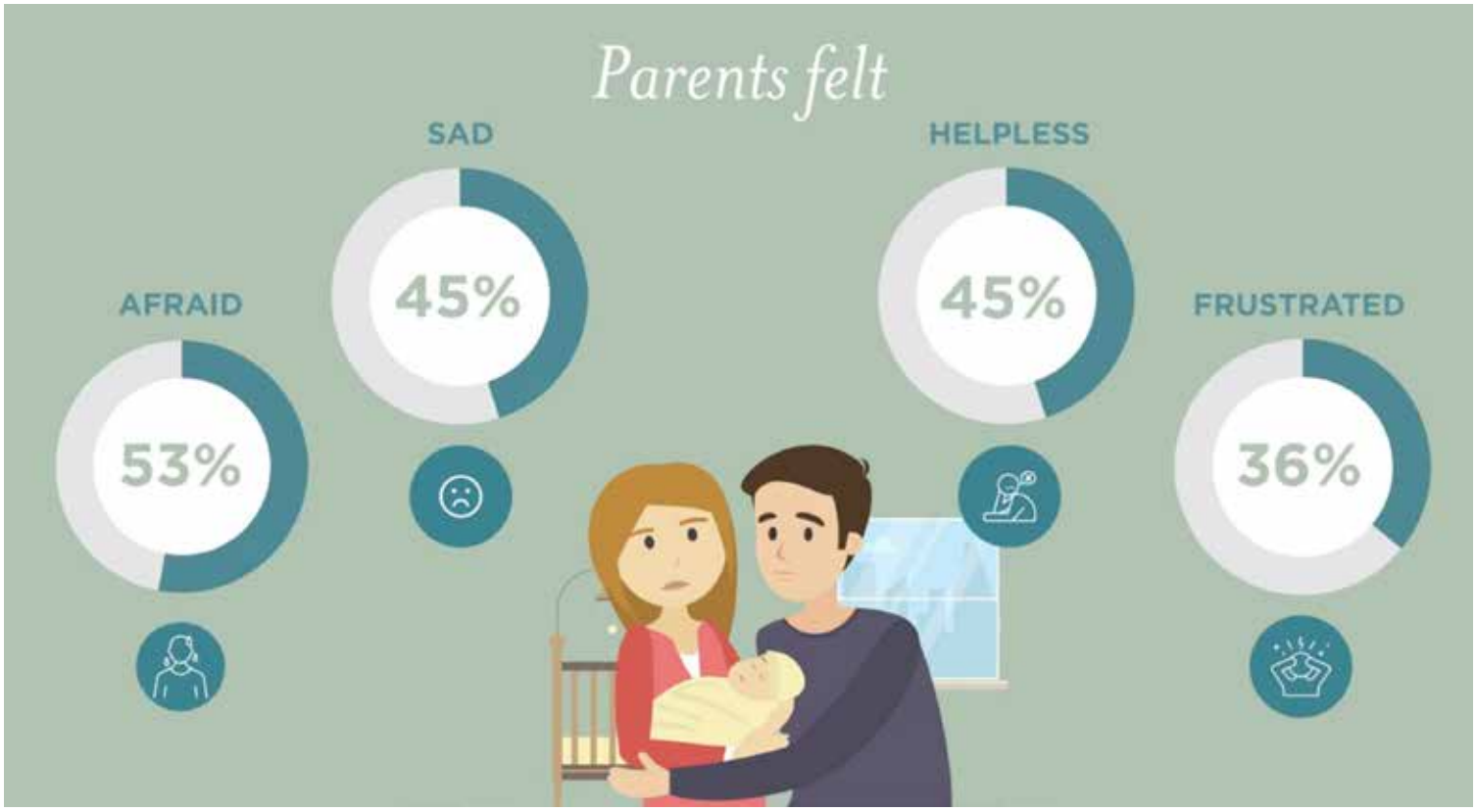
Nearly every child catches RSV by age 2. Respiratory Syncytial Virus affects the lungs and airways and can cause bronchiolitis, pneumonia, coughing, wheezing, or other cold-like symptoms. But for many families, that's only the beginning. A national survey of parents and health care providers found that the disease also levies an emotional, financial, and social burden.

"Some parents have to request paid time off, take unpaid leave, or cut back on work. And nearly 20% left their job or were fired."

Of the 340 parents whose child caught the virus, more than two-thirds said it landed their child in the hospital. 68% of parents reported the experience affected their mental health. While the child was sick, parents felt afraid, sad, helpless, and frustrated. And many felt guilty they couldn't do more to prevent their child's sickness.

"So, how can policy makers help? By supporting innovation and ensuring timely and equitable access to care and preventive interventions."

RSV also dealt a financial blow. Families faced medical bills, loss of potential income, childcare costs for siblings, and transporta-



tion expenses. Meanwhile, some parents have to request paid time off, take unpaid leave, or cut back on work. And nearly 20% left their job or were fired as a result. Perhaps that's why more than two-thirds of surveyed parents described RSV as a financial burden or crisis.

RSV impacted families' social balance, too. More than one-third of parents said the experience strained their relationship with their partner. They had to turn to family members and friends to help with child-care. And, all the while, siblings struggled to understand what was happening.

It's clear that RSV's impact is multifaceted. So, how can policy makers help? By supporting innovation and ensuring timely and equitable access to care and preventive interventions. Surveyed health care providers agree than immunization and vaccine-like interventions could help minimize the burden of RSV. And 82% of parents agreed they'd want their child to receive such an intervention. With good policy and innovation, families and their health care providers can work together to reduce the burden of RSV.

References:

1. Staebler S. The Indirect Impact of RSV: RSV Parent & Provider Survey Results. [2023 Jan 11]. In: NCFIH [Internet]. Alliance for Patient Access and the National Coalition for Infant Health; Available from: https://admin.allianceforpatientaccess.org/wp-content/uploads/2023/01/AfPA-and-NCfIH_The-Indirect-Impact-of-RSV_Survey-Report_Jan-2023.pdf

Disclosures: *The authors have no disclosures*

NT

Policy Recommendations

Health care providers and parents overwhelmingly support greater awareness and improved options to prevent and treat RSV.

97%
of providers said **immunizations and vaccine-like interventions** could help minimize the burden of RSV.

92%
agreed that, if an immunization were available, it should be **added to the Vaccines for Children program's list** of pediatric vaccines.

92%
agreed that **policy should ensure all babies and children get access** to future immunizations or preventive interventions for RSV.

Susan Hepworth
Director
National Coalition for Infant Health
2020 K Street NW
Suite 505
Washington, DC 20006
Email: info@infanthealth.org

Mitchell Goldstein, MD, MBA, CML
Professor of Pediatrics
Loma Linda University School of Medicine
Division of Neonatology
Department of Pediatrics
Email: mgoldstein@llu.edu

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.

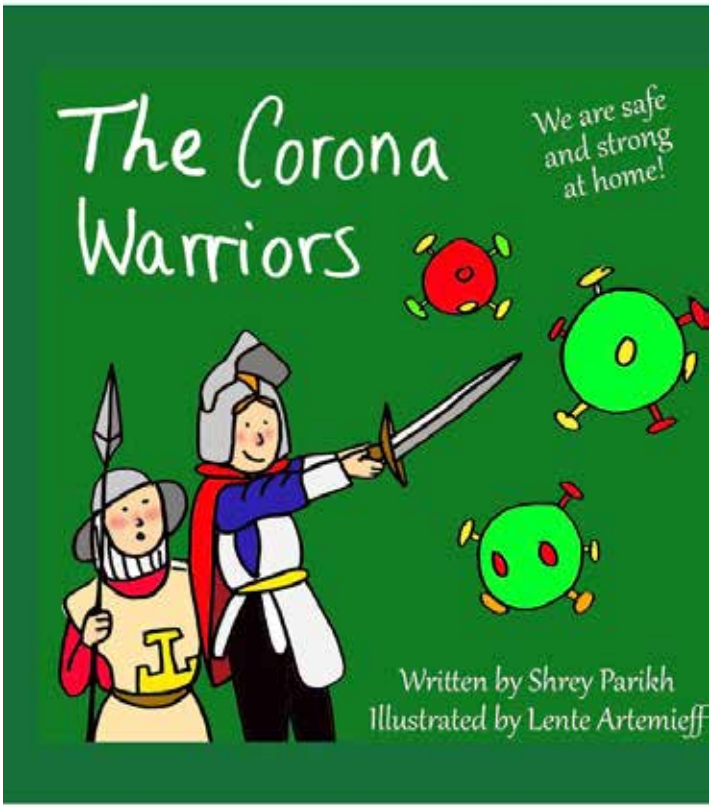
Equality. Prematurity and related vulnerabilities disproportionately impact minority and economically disadvantaged families. Restrictions on care and treatment should not worsen inherent disparities.

Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY



Save the Date!
May 25, 2023

26th Annual Conference
Quality of Life for Families XXVI

Keynote Speaker: Dr. Diana Ramos
California Surgeon General

pac-lac
Perinatal Advisory Council:
Leadership, Advocacy and Consultation

Where: **Hilton Los Angeles North/Glendale**
100 West Glenoaks Blvd,
Glendale, CA 91202

You can attend In-Person or Hybrid

The Signs & Symptoms of RSV

RESPIRATORY SYNCYTIAL VIRUS

Know the Signs & Symptoms of RSV

- Cough
- Runny Nose
- Struggling to Breathe *(breastbone sinks inward when breathing)*
- Difficulty Eating
- Lethargy
- Wheezing

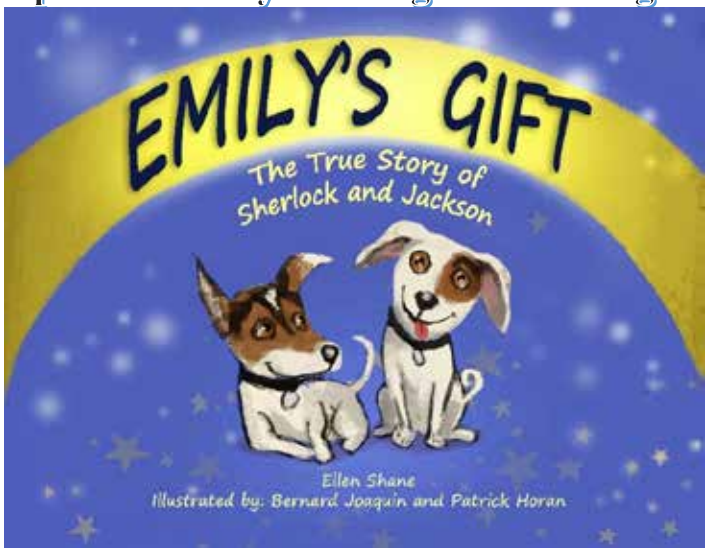
RESPIRATORY SYNCYTIAL VIRUS
is a highly contagious seasonal virus that can lead to hospitalization for some babies and young children.

Know the Signs.

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

LEARN MORE

"Emily's Gift" can be purchased by clicking on the image of the cover below.



Purchases of this engaging **true story** provide disadvantaged middle school students, risking academic failure, the opportunity to attain their best personal and academic potential.

Purchasing options include a limited quantity of signed and numbered books specifically to support the SEA Program, an ebook, soft and hardcover versions, and the option to donate one or more books to support organizations supporting young children.

You can provide both reading entertainment for younger children, and make a difference in the lives of the disadvantaged middle schoolers we support.

Sales support our nonprofit charity's SEA Program. You can make a difference for these children!

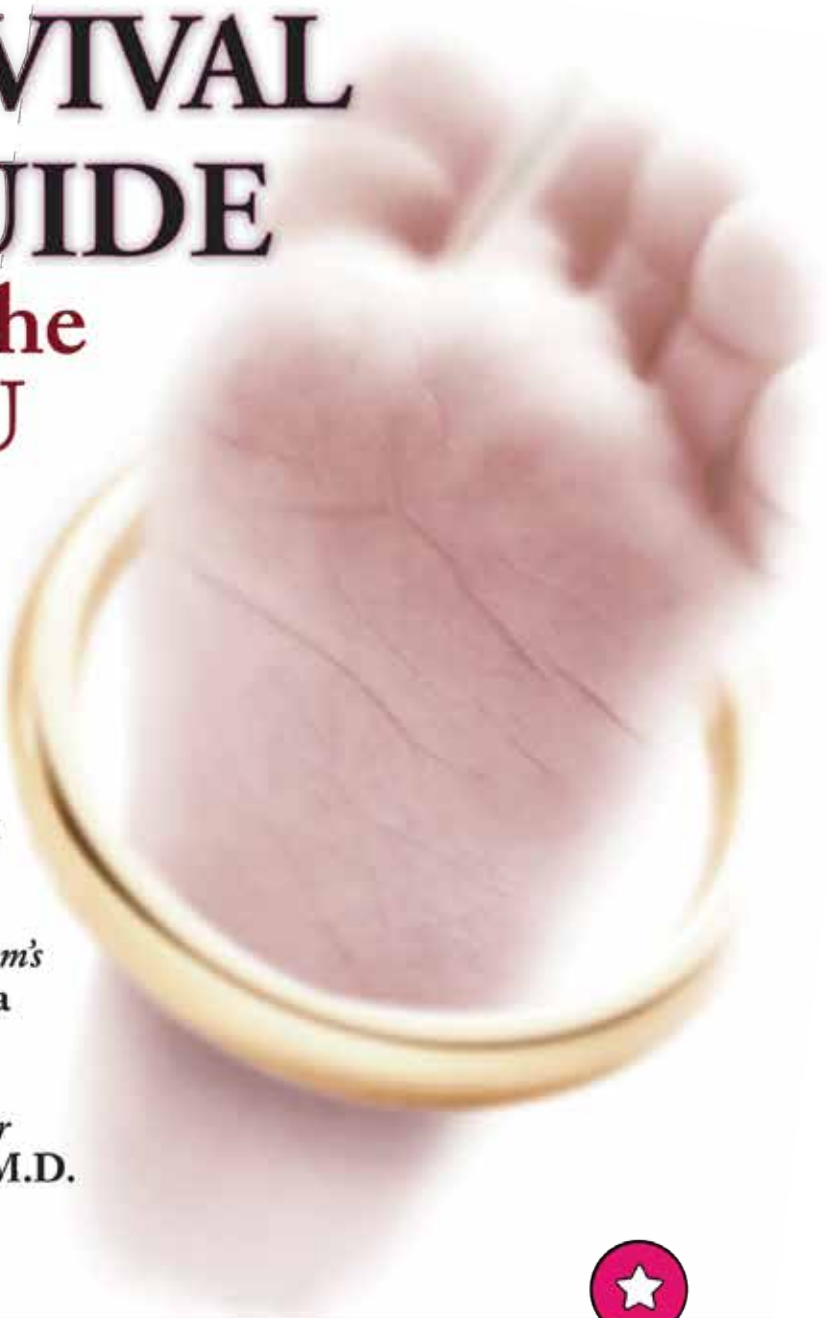
Emily's Gift-Click Here to Buy

Direct SEA Support-Click Here

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

For more information, please visit emilyshane.org.

The Preemie Parent's SURVIVAL GUIDE to the NICU



By

little man's
Nicole Conn

&

PreemieWorld.com's
Deb Discenza

with

Medical Editor
Alan R. Spitzer, M.D.

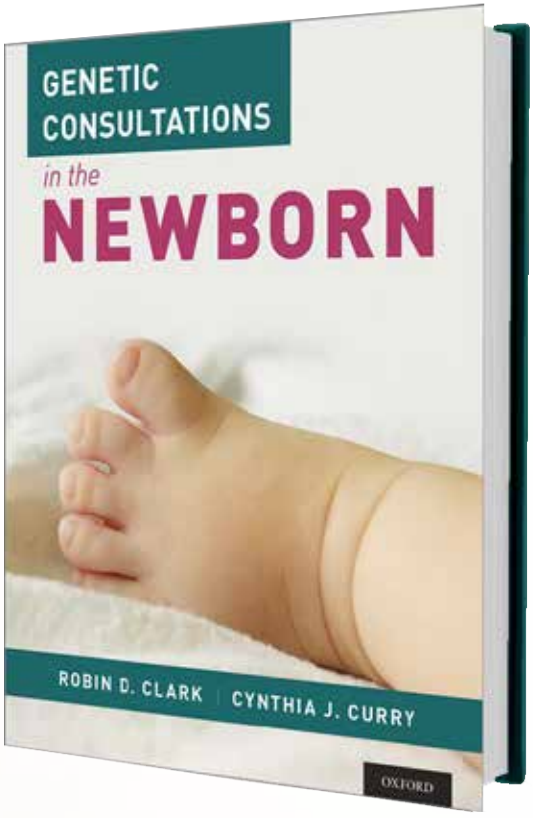
HOW TO MAINTAIN YOUR SANITY & CREATE A NEW NORMAL

second edition

"The definitive work in genetic evaluation of newborns"
- Judith G. Hall

GENETIC CONSULTATIONS *in the* NEWBORN

$99.95
Hardcover



Robin D. Clark | Cynthia J. Curry

- A streamlined diagnostic manual for neonatologists, clinical geneticists, and pediatricians - any clinician who cares for newborns
- Organized by symptom and system, enriched with more than 250 photography and clinical pearls derived from authors' decades of clinical practice
- Includes "Syndromes You Should Know" appendix, distilling the most frequently encountered syndromes and chromosomal abnormalities in newborns
- OMIM numbers for each condition situate authors' practical guidance in the broader genetics literature, connecting readers to the most up-to-date references

Comprising of more than 60 chapters organized by system and symptom, *Genetic Consultations in the Newborn* facilitates fast, expert navigation from recognition to management in syndromes that manifest during the newborn period. Richly illustrated and packed with pearls of practical wisdom from the authors' decades of practice, it empowers readers to recognize the outward signs and symptoms crucial for an effective diagnosis.

Order now by clicking here.

OXFORD

Peer Reviewed

Clinical Pearl: Overestimation of Oxygen Saturation with Pulse Oximetry Compared with Arterial Blood Oxygen Saturation in Infants and Children of Color

Joseph R. Hageman, MD., Mitchell Goldstein, MD

"Recently, several studies have examined the accuracy of oxygen saturation compared with arterial oxygen co-oximetry in infants and children of color with white infants and children (1-4)."

Recently, several studies have examined the accuracy of oxygen saturation compared with arterial oxygen co-oximetry in infants and children of color with white infants and children (1-4). Vesoulis and colleagues compared oxygen saturation with arterial blood gas oxygen values in Black and White preterm infants (124 black, 170 white infants; mean gestational age 25.8 ± 2.1 weeks, mean birth weight 845 ± 265 grams) and demonstrated an overestimation of SpO2 measured by the mean bias of 2.4 greater for Black infants (1). This resulted in greater occult or hidden hypoxemia (SpO2 > 90% when SaO2 < 85% 9.2% vs. 7.7% in Black infants (1). One must remember that the skin color identified as black has considerable variability and may change significantly after birth, especially in premature infants. The range of coloration and increase in pigmentation may lead to results that are incorrectly mapped to lighter skin. The author (MRG) recollects original calibration studies in the 1990s on premature infants where skin color assessment had to be assessed daily because of these changes.

"The range of coloration and increase in pigmentation may lead to results that are incorrectly mapped to lighter skin. The author (MRG) recollects original calibration studies in the 1990s on premature infants where skin color assessment had to be assessed daily because of these changes."

In addition, studies by Foglia and colleagues and Ruppel et al. at Children's Hospital of Philadelphia of infants and children aged 1-17 years with congenital heart disease in cardiac catheterization also demonstrated moderate overestimation of oxygen saturation of pulse oximetry compared with central arterial oxygen saturation in the cath lab (2,3).

An excellent editorial by Gray, Subramaniam, and Huang summarized the issues and questions regarding hidden hypoxemia in infants and children with darker skin tones (4). We, as clinicians, need to be aware of this phenomenon and that, at this point in time, melanin seems to be the reason for this (1-4). Investigators are very active in their technological work to address "the biases of transmissive oximetry (4)".

Two examples of these new technologies are in development to attempt to address this skin-tone bias: photoacoustic imaging and polarized light oximetry (4). With photoacoustic imaging, sound waves are generated when light is absorbed by a material (4). A corrective equation is applied that accounts for the change in oxygen saturation as a function of skin tone (4). Polarized light oximetry uses polarized light for oximetry because polarization can reduce the light-scattering effects of melanin on oxygen saturation readings, yielding more accurate oxygen saturation readings "across diverse patient populations " (4)". The effects of considering functional versus fractional oximetry and individual differences that may lead to more carboxyhemoglobin or methemoglobin must be considered. Non-invasive Co-oximetry (i.e., Rainbow Technology) may ultimately resolve these concerns.

"The effects of considering functional versus fractional oximetry and individual differences that may lead to more carboxyhemoglobin or methemoglobin must be considered. Non-invasive Co-oximetry (i.e., Rainbow Technology) may ultimately resolve these concerns."

I recommend you take some time to review this editorial to understand these new concepts, as I have learned a lot by putting this together for your review.

When I sent this Pearl to Mitchell Goldstein for his thoughtful review, he sent me a letter to the editor from Neonatology Today from Joe Kiani, the Founder, and CEO of Masimo, with Mitchell's response from 2021 (5).

The letter was entitled'Pulse Oximeters are not racist' and described Mr. Kiani (Masi); and his co-inventor Mohammed (Mo) Dian's internal data analysis comparison of oxygen saturation and co-oximetry values in 200 black and 194 caucasian subjects and found a bias of 0.4% (5). The Masimo technology was developed initially in 1989 (5). Joe Kiani's letter and Mitchell Goldstein's response are excellent and provide a historical perspective of this issue for your review(5).

References:

1. Vesoulis Z, Tims A, Lodhi H et al. Racial discrepancy in pulse oximetry accuracy in preterm infants. J Perinatol 2021; 42:79-85.
2. Foglia EE, Whyte RK, Chaudhary A et al.The Effect of skin pigmentation on the accuracy of pulse oximetry in infants with hypoxemia. J Pediatr 2017; 182:375-377.
3. Ruppel HR, Makeneni S, Faerber JA et al.Evaluating the accuracy. E ee of pulse oximetry in children according to race. JAMA Pediatr. 2023:doi:10.1001/jamapediatrics.2023.0071.
4. Gray KD, Subramariam HL, Huang ES. Effects of racial bias in pulse oximetry on children and how to address algorithmic bias in clinical medicine. JAMA Pediatr 2023:doi.10.1001/jamapediatrics.2023.0077.
5. Kiani J, Goldstein M. Letters to the Editor. Neonatology Today 2021;16(4):143-145.

Disclosures: The authors have no disclosures

NT

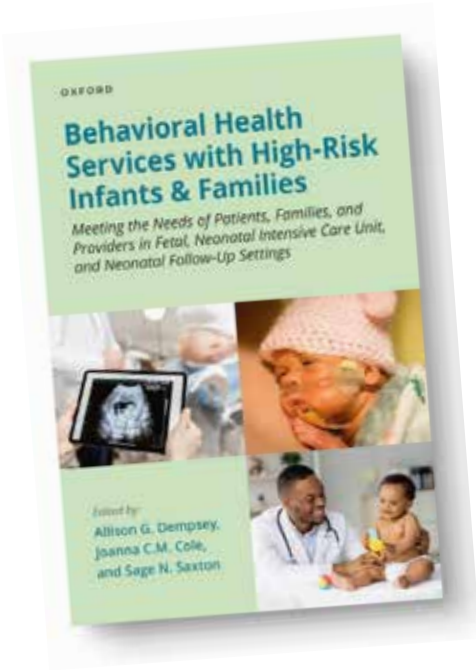
Corresponding Author

Joseph R. Hageman, MD
Senior Clinician Educator
Pritzker School of Medicine
University of Chicago
MC6060
5841 S. Maryland Ave.
Chicago, IL 60637
Phone: 773-702-7794
Fax: 773-732-0764
Email: jhageman@peds.bsd.uchicago.edu

Mitchell Goldstein, MD, MBA, CML
Professor of Pediatrics
Loma Linda University School of Medicine
Division of Neonatology
Department of Pediatrics
Email: mgoldstein@llu.edu

National Network of NICU Psychologists

Education, Resources, and Support for Perinatal Mental Health Professionals



Preorder

Behavioral Health Services with High-Risk Infants and Families

Use discount code **ASPROMP8** and save 33% online at www.oup.com

$56.00

Free Resources

Empower families with the skills they need.

Download our perinatal Mental Health Plan worksheets.

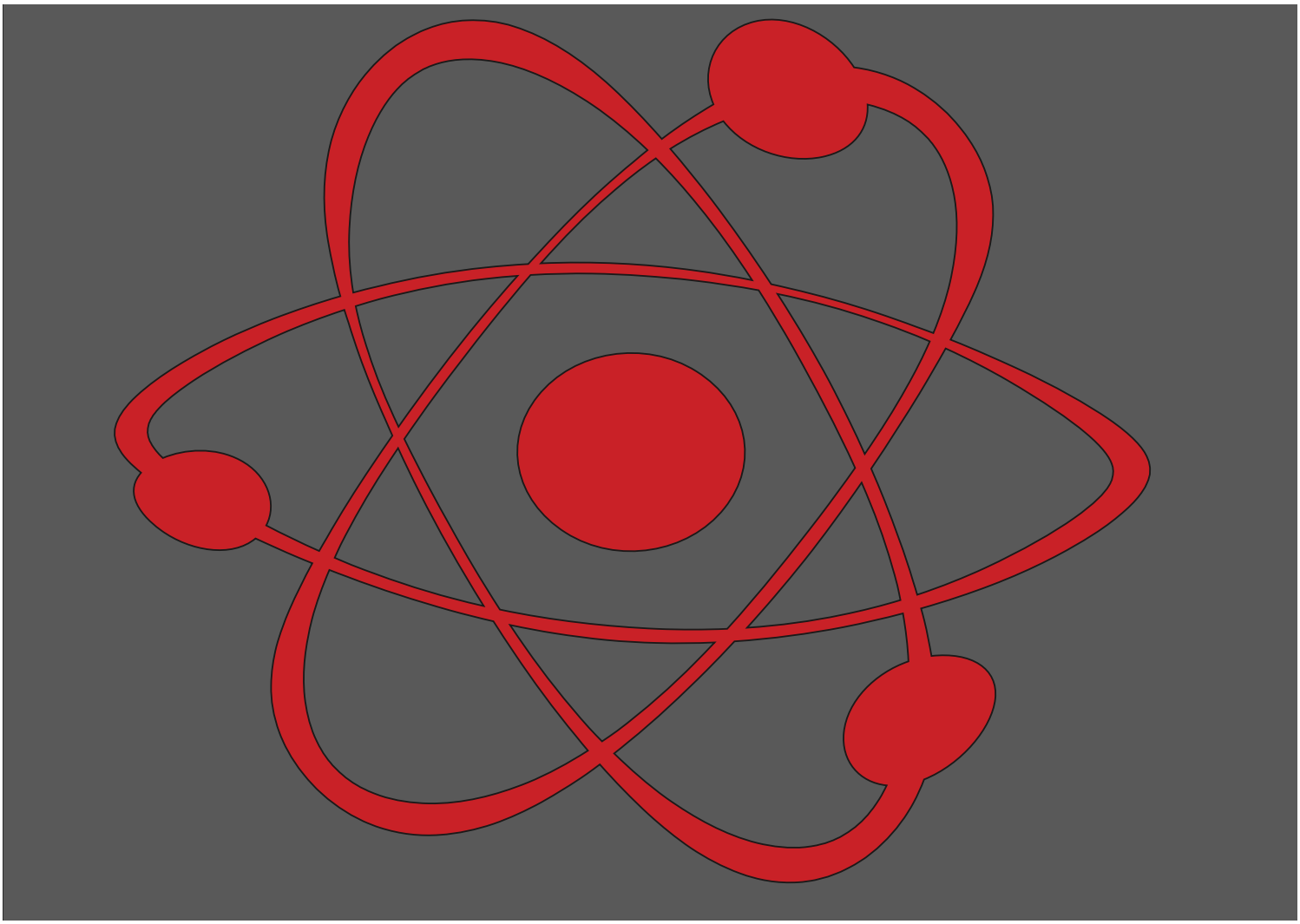
Support NICU families and staff during COVID-19.

See resources created by the National Network of NICU Psychologists.

National Perinatal Association

NATIONALPERINATAL.ORG/PSYCHOLOGISTS

Academic True Open Model (ATOM)



Loma Linda Publishing Company supports the Academic True Open Model (ATOM)

Journals listed support the following principles:

1. Free subscriptions (electronic or paper) to all.
2. Peer review of all submitted manuscripts
3. Timely review of manuscripts
4. Timely response to letters to the editor
5. Listing and correction of erratum
6. Appropriate disclosure of any related conflicts of interest in published manuscripts
7. No charge for submission of manuscripts
8. No charge for review of manuscripts
9. No charge for processing of artwork, color, layout, or length of manuscript
10. No charge for publication of manuscript in electronic or digital form.
11. A commitment to the ethical treatment of humans and animals in research.
12. Documentation of informed consent where indicated.

NT

Any journal that supports the ATOM principles can be listed here, along with their logo and a link back to their site, free of charge. Please contact Loma Linda Publishing Company at LomaLindaPublishingCompany@gmail.com for additional details.

Neonatology Today, a publication of Loma Linda Publishing Company.

ISSN: 1932-7137 (Online), 1932-7129 (Print)

Readers can also follow

NEONATOLOGY TODAY

via our Twitter Feed

@NEOTODAY

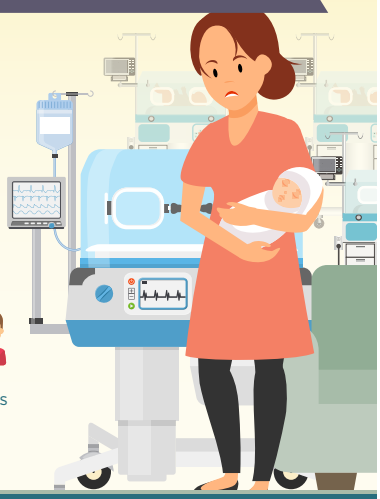
Will your PRETERM INFANT *need* EARLY INTERVENTION *services?*

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



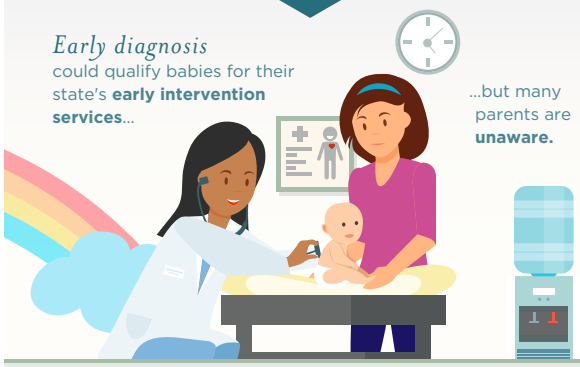
Early intervention can help preterm infants:

- 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*

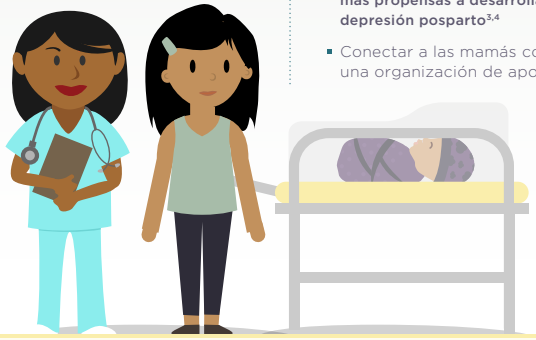
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

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

www.infanthealth.org

[1] American Psychological Association. Accesible en: http://www.apa.org/pi/women/resources/reports/postpartum-depression.aspx

[2] National Institute of Mental Health. Accesible en: 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.

Upcoming Medical Meetings

Pediatric Academic Societies Meeting
April 27-May 3, 2023
Washington, DC
https://www.pas-meeting.org/

Perinatal District 8 Conference
June 1-4, 2023
San Diego, CA
https://district8sonpm.org/

8th World Congress of Pediatric Cardiology and Cardiac Surgery
August 27-September 1, 2023
Washington, DC
http://wcpccs2023.org/

2023 AAP National Conference & Exhibition
October 20-24, 2023
Washington, DC.
https://aapexperience.org

40th Advances in Neonatal and Pediatric Cardiorespiratory Care
January 31-February 2, 2024
Hilton Los Angeles North/Glendale
100 West Glenoaks Blvd.
Glendate, CA 91202
https://paclac.org/advances-in-care-conference/

2024 Gravens Conference: The Power of Voice: Using Your Voice for Babies, Family, Staff and Beyond
March 6-9, 2024
Sheraton Sand Key Resort
Clearwater Beach, FL
https://paclac.org/https-paclac-org-gravens-conference/

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
Loma Linda, CA 92354
www.NeonatologyToday.net
Tel: +1 (302) 313-9984
LomaLindaPublishingCompany@gmail.com

Editorial and Subscription
Mitchell Goldstein, MD
Neonatology Today
11175 Campus Street
Suite #11121
Loma Linda, CA 92354

Sponsorships and Recruitment Advertising
For information on sponsorships or recruitment advertising call Andrea Schwartz Goodman at: +1 (302) 313-9984 or send an email to andrea.schwartzgoodman@neonatologytoday.net

FREE Subscription
Neonatology Today is available free to qualified individuals worldwide interested in neonatology and perinatology. International editions are available in electronic PDF file only; North American edition available in print once a year in February. To receive your free qualified subscription please click here.

Submit a Manuscript:
On case studies, clinical and bench research, hospital news, meeting announcements, book reviews, and "state of the art" meta analysis.
Please submit your manuscript to:
LomaLindaPublishingCompany@gmail.com
We will respond promptly
Twitter Account: @NeoToday

The Emily Shane Foundation
Annual Spring Gala Fundraiser
Wings Over Malibu
Thursday, April 27, 2023 from 6:30 – 8 PM

The Emily Shane Foundation, a 501(c) 3 nonprofit charity based in Malibu, CA, currently serves the Malibu, Oxnard, Thousand Oaks, Santa Monica, Westchester, Culver City, South Los Angeles, and Pico Rivera communities. This school year, we commenced at a new site in Watts. The foundation was created in honor of Emily Rose Shane, following her tragic murder on April 3rd, 2010. She was 13 years old and in eighth grade (middle school).

Our foundation's SEA (Successful Educational Achievement) Program empowers underserved, disadvantaged middle schoolers by providing them with essential academic tutoring and mentorship. The SEA Program serves those identified as being at risk of failure and who could not otherwise afford this essential after-school support. Our objective is to enable these children to be successful students, so they can achieve their goals and dreams. Participants are guided on a path toward success in school and life. The foundation's "Pass it Forward" motto encourages kindness and social consciousness, as each SEA Program participant is encouraged to perform one good deed for every session with their mentor/tutor.

The need for SEA has always been significant. However, as a result of the pandemic, it has only increased. Our comprehensive program includes a mentorship component and a focus on organizational and study skills, offering a complete approach for our students to attain success in the classroom. The SEA Program truly makes a difference in a child's life. Our students face challenges such as being below grade level in one or more subjects; others cope with English language struggles and their academic challenges are often coupled with both home-life and/or social issues.

We are excited to announce our annual spring gala fundraiser, Wings Over Malibu, to take place the evening of April 27, 2023, directly over the waves in the lovely Ocean Room at Duke's Restaurant in Malibu. This event provides the opportunity for those who support our work to learn firsthand of the incredible impact of our SEA Program. Highlights include a live auction, an online silent auction, exclusive wines presented by The Narcissist Wine Company, hearty appetizers, members of the Malibu Middle and High School Orchestras serenading our guests, a featured SEA Program student sharing their experience in the program, and more!

For more information, requests for sponsorship, or donations, please contact us by sending an email to this address: info@emilyshane.org. If you are mailing a donation, please send it to: 2893 Searidge St., Malibu, CA 90265. We must receive all donations by Friday, April 14th, 2023.

Thank you so much for your consideration,

Ellen Shane
Executive Director
The Emily Shane Foundation
www.emilyshane.org
TAX ID # 27-3789582
(213) 290-5441

THE EMILY SHANE FOUNDATION PRESENTS

Wings Over Malibu*

Our Annual Spring Gala Fundraiser

THURSDAY, APRIL 27, 2023

6:00-8:30 PM PST

Click Here: The Emily Shane Foundation was recently featured on CBS KCAL News

THE OCEAN ROOM, DUKE'S RESTAURANT, MALIBU

21150 E PACIFIC COAST HWY, MALIBU, CA 90265

Highlights include:

- *Live auction featuring resort stays, fine jewelry, experiences and more*
- *Online silent auction with fantastic items commencing April 20 -* ***click here to access auction!***
- *A selection of exclusive wines from The Narcissist Wine Company*
- *Beautiful live music by members of the Malibu Middle & High School Orchestras*
- *Hearty appetizers that will be passed around and stationed*
- *And more!*

Click HERE to purchase tickets and for event details!

For more information or to learn about sponsorship opportunities, please contact us at **info@emilyshane.org.**

**All proceeds to help support our foundation's SEA Program, which empowers underserved, disadvantaged middle school students at risk of academic failure at sites across Los Angeles and Ventura Counties.*

EMILY SHANE FOUNDATION

The Gravens Conference
on the Environment of Care for High Risk Newborns

THE VOICES OF ALL PROFESSIONALS WHO WORK WITHIN THE ENVIRONMENT OF CARE FOR HIGH RISK NEWBORNS AND THEIR FAMILIES NEED TO BE HEARD.

WE WANT TO HEAR FROM PROFESSIONALS WHO REPRESENT A BROAD RANGE OF BACKGROUNDS, CULTURES, BELIEFS GENDER AND LIFESTYLE DIFFERENCES.

Please contribute to the Gravens Professional Diversity Fund!

Funds will provide support professionals from diverse backgrounds to attend the Gravens conference.

Send your tax deductible contribution to

Neonatology Today
Division of Neonatology, Department of Pediatrics
Loma Linda University Children's Hospital
11175 Campus Street, CP 11121
Loma Linda, CA 92354

Or PayPal

Save the Date!

January 31- February 2nd, 2024

40th Advances in Neonatal and Pediatric Cardiorespiratory Care

You can attend In-Person or Virtual

pac-lac
Perinatal Advisory Council
Leadership, Advocacy and Consultation

Where: **Hilton Los Angeles North/Glendale**
100 West Glenoaks Blvd,
Glendale, CA 91202

Attractions Distances are displayed to the nearest 0.1 mile and kilometer.

Glendale Galleria - 1.7 km / 1.1 mi
Americana at Brand - 2 km / 1.2 mi
Griffith Park - 3.3 km / 2.1 mi
Los Angeles Zoo - 5.3 km / 3.3 mi
Walt Disney Studios - 7.9 km / 4.9 mi
Nickelodeon Animation Studio - 7.9 km / 4.9 mi
Warner Brothers Studio - 8.2 km / 5.1 mi
Greek Theatre - 9.9 km / 6.1 mi
Descanso Gardens - 9.9 km / 6.2 mi
Hollywood Boulevard - 10.3 km / 6.4 mi
Universal Studios Hollywood - 10.9 km / 6.8 mi
Rose Bowl Stadium - 11.2 km / 7 mi
Pasadena Convention Center - 11.6 km / 7.2 mi

Other Attractions

Disneyland – 35 mi
Santa Monica Pier -26 mi
Venice Beach - 28 mi

The nearest airports are:

Hollywood Burbank Airport (BUR) - 12.8 km / 8 mi
Los Angeles Intl. (LAX) - 43.5 km / 27 mi
Ontario International Airport- 45 mi
Long Beach Airport- 35 mi

Clinical Trial Center (Full-Time, Day Shift) - Research Coordinator

The Loma Linda University Health's Clinical Trial Center is actively seeking and recruiting top clinical research coordinator talent.

Our mission is to participate in Jesus Christ's ministry, bringing health, healing, and wholeness to humanity by Creating a supportive faculty practice framework that allows Loma Linda University School of Medicine physicians and surgeons to educate, conduct research, and deliver quality health care with optimum efficiency, deploying a motivated and competent workforce trained in customer service and whole-person care principles and providing safe, seamless and satisfying health care encounters for patients while upholding the highest standards of fiscal integrity and clinical ethics. Our core values are compassion, integrity, humility, excellence, justice, teamwork, and wholeness.

Able to read, write and speak with professional quality; use computer and software programs necessary to the position, e.g., Word, Excel, PowerPoint, Access; operate/troubleshoot basic office equipment required for the position. Able to relate and communicate positively, effectively, and professionally with others; provide leadership; be assertive and consistent in enforcing policies; work calmly and respond courteously when under pressure; lead, supervise, teach, and collaborate; accept direction. Able to communicate effectively in English in person, in writing, and on the telephone; think critically; work independently; perform basic math and statistical functions; manage multiple assignments; compose written material; work well under pressure; problem solve; organize and prioritize workload; recall information with accuracy; pay close attention to detail. Must have documented successful research administration experience focused on managing clinical trials function. Able to distinguish colors as necessary; hear sufficiently for general conversation in person and on the telephone; identify and distinguish various sounds associated with the workplace; see adequately to read computer screens and written documents necessary to the position. Active California Registered Nurse (RN) licensure preferred. Valid Driver's License required at time of hire.

The Clinical Trial Center is actively involved in many multi-center global pediatric trials, which span different Phases of research to advance health care in children. Please reach out to Jaclyn Lopez at 909-558-5830 or JANLopez@llu.edu with further interest. We would love to discuss the exciting research coordinator opportunities at our Clinical Trials Center.

Additional Information

- Organization: Loma Linda University Health Care
- Employee Status: Regular
- Schedule: Full-time
- Shift: Day Job
- Days of Week: Sunday, Monday, Tuesday, Wednesday, Thursday, Friday, Saturday

LOMA LINDA UNIVERSITY

Loma Linda University Children's Hospital is hiring Neonatal Nurse Practitioners

Children's Hospital, centrally located in Southern California, has earned Magnet Recognition as part of the American Nurses Credentialing Center's (ANCC) Program.

We are looking for experienced or new graduate Neonatal Nurse Practitioners (NNPs) who are excited to join a cohesive team that practices in a collaborative, fast-paced, high-acuity setting.

- Full-time and part-time positions available
- Level IV, 84-bed Neonatal Intensive Care Unit (NICU)
- Regional referral center encompassing Tiny Baby unit, ECMO, Cardiac ICU, Neuro NICU and Surgical services
- Maternity services and delivery center
- 24/7 coverage by NNP team and Fellows
- Competitive employee benefit packages

*Offering a **sign-on bonus** with relocation reimbursement for full-time, direct applicants who meet requirements.

For more information, please contact:

Karin Colunga, MSN, RN, PNP-BC
Director of Advanced Practice Nursing
kecolunga@llu.edu | 909-558-4486

BEST CHILDREN'S HOSPITALS U.S.News & World Report NEONATOLOGY 2022-23

THELEAPFROGGROUP TOP CHILDREN'S HOSPITAL 2021

MAGNET RECOGNIZED AMERICAN NURSES CREDENTIALING CENTER

LOMA LINDA UNIVERSITY CHILDREN'S HOSPITAL

HEALING. HEALTHY. HAPPY.
A Seventh-day Adventist Organization

LLUHNK1#8977-CH-22/1022/TBD

NEONATOLOGY TODAY

News and Information for BC/BE Neonatologists and Perinatologists

We Can Help <u>You</u> Recruit from 1,045 NICUs in the USA & Canada

Your Recruitment Advertising Includes:

- Full color Recruitment Ad in the issue(s)
- Your recruitment listing in the e-mail blast for the issue(s) with a hot link
- 3-Step Special Recruitment Opportunity Website Section on three (3) areas of the website
- *We can create your recruitment ad at no extra charge!*

For more information, contact:

Melissa LaMarca

+1 (302) 313-9984 or

Melissa.LaMarca@neonatologytoday.net

NEONATOLOGY TODAY

Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine
Loma Linda Publishing Company | c/o Mitchell Goldstein, MD | 11175 Campus St, Ste. 11121 | Loma Linda, CA 92354 |
LomaLindaPublishingCompany@gmail.com

Editorial Board

Neonatology Today's Policy on Animal and Human Research

Neonatology Today's policies ensure the protection and responsible use of animals and humans in all research articles under consideration. Authors are encouraged to follow the guidelines developed by the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3R), International Committee of Medical Journal Editors, and the Guide for the Care and Use of Laboratory Animals and U.S. Public Health Service's Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Authors are expected to demonstrate to their institutional review board or suitable proxy that ethical standards are met. If there is doubt whether research conducted was in accordance with ethical standards, then there must be verification that the institutional review body approved the uncertain aspects. Research not following these policies on participating animal and human subjects may be rejected. Researchers have a moral obligation towards the humane treatment of animals and ethical considerations for humans participating in research and are expected to consider their welfare when designing studies.

https://www.nc3rs.org.uk/arrive-guidelines

http://www.icmje.org

https://olaw.nih.gov/policies-laws/phs-policy.htm

NT

Neonatology and the Arts

This section focuses on artistic work which is by those with an interest in Neonatology and Perinatology. The topics may be varied, but preference will be given to those works that focus on topics that are related to the fields of Neonatology, Pediatrics, and Perinatology. Contributions may include drawings, paintings, sketches, and other digital renderings. Photographs and video shorts may also be submitted. In order for the work to be considered, you must have the consent of any person whose photograph appears in the submission.

Works that have been published in another format are eligible for consideration as long as the contributor either owns the copyright or has secured copyright release prior to submission.

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one the next tolast page as well as photographs of birds on rear cover.. For this edition, we have a Fashionable Fish by Dr. Paula Whiteman and a Yellow Parakeet by Dr. Mita Shah.

Mita Shah, MD,
Neonatal Intensive Care Medical Director
Queen of the Valley Campus
Emanate Health, West Covina, CA

NT

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, SVG, or pdf) for each figure. Preferred formats are ai, SVG, psd, or pdf. tif and jpg images with sufficient resolution so as not to have visible pixilation for the intended dimension. In general, if acceptable for publication, submissions will be published within 3 months.

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

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

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

6. An abstract may be submitted.

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

8. References should be included in standard "NLM" format (APA 7th is no longer acceptable). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

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

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

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.

NT

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:

NPN
NICU PARENT NETWORK

NICU Parent Network

Visit nicuparentnetwork.org to identify national, state, and local NICU family support programs.

*** The information provided on the NICU Baby's Bill of Rights does not, and is not intended to, constitute legal or medical advice. Always consult with your NICU care team for all matters concerning the care of your baby.**

NANT 13 - Call for Abstracts

Presented by the National Association of Neonatal Therapists (NANT)

Conference Dates:

Main Conference: April 14-15, 2023

Pre-Conference: April 13

Location: Tucson, AZ USA*

*Barring any restrictions to the contrary, NANT 13 is scheduled to be held in- person. However, in the event such restrictions occur, the event will be hosted online including all accepted sessions/posters.

The theme for NANT 13 is ***Inspiring Competence & Confidence***.

NANT and our Members aim to deliver best practices for NICU babies and parents all over the world. This advanced practice area requires a high level of competence, fueled by interprofessional collaboration and research.

Competence is not finite—it is an ongoing commitment to the pursuit of scientific knowledge and skill proficiency. We never arrive or are experts in all areas of practice. We rely on each other and use our unique professional lenses and experiences to advance the field of neonatal therapy.

We are calling upon you to share your research and clinical expertise. What can you contribute to the standard of care? How can you fill the gaps in neonatal therapy competency?

NANT intends to develop attendees' confidence to serve, lead, and implement collaboratively. We seek the right individuals, research, and tools to make that happen.

Sharing your valuable work in this internationally attended conference is a powerful way to inspire new levels of competence and confidence in this specialty.

We invite you to submit an abstract to present an oral or poster presentation at NANT 13.

Click here to submit an abstract.

Abstract Submission Deadline: Monday, August 15, 2022


GYOTAKU
@drpaulawhitema