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Prognostic Uncertainty During Therapeutic Hypothermia and Hemodynamic Instability- the Link between Vasoactive Therapies and Adverse Outcomes in the Neonatal Intensive Care Unit

Sirisha Perugu, MBBS, FAAP, HEC-C, John Patrick Cleary, MD, FAAP

"Evaluate whether hemodynamic instability, defined as the need for vasoactive support, predicts vital signs, cerebral near-infrared spectroscopy (cNIRS), mechanical ventilator support, biochemical parameters, and neurodiagnostics in neonates with moderate-severe Hypoxic Ischemic Encephalopathy (HIE). "

Abstract:

BACKGROUND: Evaluate whether hemodynamic instability, defined as the need for vasoactive support, predicts vital signs, cerebral near-infrared spectroscopy (cNIRS), mechanical ventilator support, biochemical parameters, and neurodiagnostics in neonates with moderate-severe Hypoxic Ischemic Encephalopathy (HIE).

METHODS: A retrospective cohort study of thirty-four newborns diagnosed with moderate-severe HIE from 2010 to 2013 at a quaternary NICU with neurodevelopmental assessments until 2016. Data points were extracted from electronic medical records and chart review. The dataset was analyzed to compare primary and secondary outcomes between two groups, patients with vasoactive agents (n=18) and without vasoactive agents (n=16). The primary outcome compared primary hemodynamic parameters (heart rate, blood pressures) and cerebral NIRS. Secondary outcomes were differences in mechanical ventilation, laboratory indices, and neurodiagnostics.

RESULTS: There were no statistically significant differences between heart rate, blood pressure, or oxygen delivery as measured by cerebral NIRS (6,12, 24, 48, and 72 hours time points after birth) in babies with and without vasoactive support. Neonates with vasoactive requirements during therapeutic hypothermia had higher hypoxemia severity, higher blood lactate, lower albumin, and hemoglobin, and required prolonged ventilation (P=0.027). Additionally, they were 30% more likely to have abnormal background EEG with a low voltage pattern (p <0.05). Moderate or severe brain injury on MRI at 10-12 days was seen in almost 50% of the patients exposed to vasoactive support. Despite these important differences at NICU discharge, neurodevelopmental delays (Bay- ley III scaled and composite scores) at six months were not significantly worse in the newborns exposed to vasoactive medications during cooling.

CONCLUSION: It is critical to study the benefits and risks of medical interventions for hemodynamic instability and assess for feedback on whether therapy is meeting the intended goal of appropriate oxygen delivery. Vasoactive medication requirement in neonates with moderate-severe HIE predicts or perhaps contributes to adverse outcomes at NICU discharge. Prognosticating risks for neurocognitive deficits beyond infancy thus remains an important research question in pediatrics.

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***Keywords**: Hypoxic Ischemic Encephalopathy, primary hemodynamic parameters, therapeutic hypothermia, mechanical ventilation, vasoactive therapies*

"Critically ill neonates are at risk for irreversible neurocognitive deficits after a sentinel perinatal event in the setting of moderate-severe Hypoxic Ischemic Encephalopathy. Respiratory failure, life-threatening events requiring cardiopulmonary resuscitation, and shock often occur during the early neonatal period."

Introduction:

Critically ill neonates are at risk for irreversible neurocognitive deficits after a sentinel perinatal event in the setting of moderate-severe Hypoxic Ischemic Encephalopathy. Respiratory failure, life-threatening events requiring cardiopulmonary resuscitation, and shock often occur during the early neonatal period. The serious hemodynamic derangements that can occur in a baby with a high level of illness and moderate-severe HIE are systemic hypotension, myocardial dysfunction, and shock (1-4). In current neonatal critical care practice, there is heterogeneity in the management of early hemodynamic instability, and vasoconstrictors are commonly utilized despite evidence of a paradoxical reduction in

Time In hours	Blood gas	No Vasoactives group				Vasoactives group				P Value
		Mean (SD)	**Min**	**Med**	**Max**	**Mean (SD)**	**Min**	**Med**	**Max**	
6	Mean pH	7.23 (0.13)	6.89	7.25	7.41	7.17(0.13)	6.85	7.19	7.33	0.251
	Min pH	7.23(0.14)	6.88	7.25	7.41	7.14(0.19)	6.61	7.19	7.33	0.205
	Mean pCO2	41.34(20.33)	19.10	36.70	91.90	35.58(14.71)	13.40	36.70	63.00	0.416
	Min pCO2	40.48 (20.57)	19.10	33.10	91.90	34.11(15.17)	9.00	34.20	63.00	0.377
12	Mean pH	7.15(0.19)	7.00	7.02	7.46	7.20(0.12)	7.00	7.19	7.35	0.426
	Min pH	7.14(0.19)	7.00	7.00	7.46	7.18(0.14)	7.00	7.18	7.35	0.502
	Mean pCO2	36.05(7.53)	24.00	35.95	52.40	41.72(14.69)	19.00	42.03	78.70	0.189
	Min pCO2	34.39(8.88)	19.00	35.20	52.40	38.83(13.61)	17.90	38.50	78.70	0.306
24	Mean pH	7.19(0.14)	7.00	7.19	7.42	7.22(0.10)	7.00	7.22	7.41	0.544
	Min pH	7.10(0.16)	7.00	7.00	7.41	7.11(0.14)	7.00	7.00	7.39	0.767
	Mean pCO2	34.10(7.69)	22.70	32.30	50.67	41.87(10.03)	26.88	38.70	56.75	0.032
	Min pCO2	31.78(6.16)	22.00	29.00	44.10	38.06(8.5)	24.20	36.70	55.00	0.036
48	Mean pH	7.24(0.14)	7.00	7.23	7.54	7.19(0.11)	7.00	7.19	7.42	0.234
	Min pH	7.10(0.2)	7.00	7.00	7.54	7.02(0.06)	7.00	7.00	7.26	0.151
	Mean pCO2	36.82(6.46)	23.70	37.88	48.70	40.25(7.51)	24.57	41.55	51.03	0.211
	Min pCO2	33.15(7.68)	21.20	33.20	48.40	34.77(8.25)	16.00	34.40	50.00	0.597
72	Mean pH	7.17(0.19)	7.00	7.13	7.47	7.27(0.13)	7.06	7.30	7.47	0.122
	Min pH	7.11(0.19)	7.00	7.00	7.47	7.11(0.18)	7.00	7.00	7.45	0.971
	Mean pCO2	42.11(8.45)	30.80	40.00	55.80	40.38(5.97)	34.03	38.18	54.43	0.556
	Min pCO2	39.75(6.34)	29.40	39.00	49.00	36.91(7.64)	20.70	36.00	51.70	0.330

Table 1. Mean and minimum blood gas pH and pCO_2 mm Hg mm(mmHg)

cardiac output.

In addition to immediate injury, HIE can be associated with impaired oxygen delivery, systemic hypotension, and cerebral ischemia followed by reperfusion injury to the brain. Cerebral ischemia has been linked to adverse perinatal events and impaired cerebrovascular autoregulation in neonates (4, 5). However, it is complicated to estimate the fluctuations of cerebral blood flow that occur during the acute stages of shock, hemodynamic instability, and respiratory illness (6-9). We investigated whether predictive factors were hidden within the large amount of data generated, concomitantly with the variable medical therapies utilized for infants with HIE in the first seventy-two hours after birth. Our primary hypothesis was that cerebral NIRS and hemodynamic parameters would predict brain injury. The study's secondary outcome was that babies receiving vasoactive infusions during cooling would have more adverse outcomes either correlating or perhaps exacerbated by treatment.

Time Point	Variable	All (N = 34)		No Vasoactives		Vasoactives		P Value
		N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	
0-24 hours	Platelet Count (*10^9/L)	34	176.06 (70.00)	16	213.22 (69.36)	18	143.04 (53.04)	0.0022
	Lactic Acid (mmol/L)	30	7.37 (4.40)	14	5.78 (3.94)	16	8.77 (4.41)	0.0622
	Albumin (g/dL)	34	2.35 (0.46)	16	2.60 (0.38)	18	2.13 (0.42)	0.0017
	Hemoglobin (g/dL)	34	15.25 (2.83)	16	16.68 (2.00)	18	13.98 (2.89)	0.0037
	Troponin (ng/ml)	33	1.50 (3.48)	15	1.20 (3.84)	18	1.75 (3.24)	0.6551
	Sodium (mEq/L)	34	135.37 (3.26)	16	134.78 (2.86)	18	135.89 (3.58)	0.3308
	Glucose (mg/dL)	34	131.93 (62.49)	16	118.04 (45.41)	18	144.27 (73.62)	0.2273
	ANC # (manual)	32	11540.28 (5613.90)	15	14062.30 (5522.37)	17	9314.96 (4811.75)	0.0143
	Creatinine (mg/dL)	34	1.18 (0.44)	16	1.18 (0.57)	18	1.18 (0.29)	0.9972
	Calcium (mg/dL)	34	8.57 (0.62)	16	8.74 (0.66)	18	8.42 (0.55)	0.1287
	Prothrombin time (sec)	21	21.01 (10.73)	8	16.52 (3.51)	13	23.77 (12.77)	0.0727
24-48 hours	Platelet Count	29	151.08 (55.70)	13	164.12 (70.33)	16	140.49 (39.60)	0.2943
	Lactic Acid	27	3.88 (3.11)	10	2.34 (1.27)	17	4.79 (3.53)	0.0164
	Albumin	26	2.18 (0.41)	10	2.48 (0.47)	16	1.99 (0.23)	0.0107
	Hemoglobin	29	15.89 (2.44)	13	17.34 (2.30)	16	14.71 (1.89)	0.0022
	Troponin	7	1.04 (1.92)	2	0.08 (0.11)	5	1.42 (2.21)	0.4554
	Sodium	29	135.52 (5.44)	14	136.26 (4.83)	15	134.83 (6.04)	0.4897
	Glucose	32	89.32 (25.42)	15	93.32 (22.73)	17	85.79 (27.77)	0.412
	ANC # (manual)	25	10291.75 (6147.53)	10	13137.45 (5837.85)	15	8394.62 (5765.16)	0.0568
	Creatinine	32	1.20 (0.73)	15	1.15 (0.71)	17	1.25 (0.76)	0.7299
	Calcium	32	8.68 (0.61)	15	8.68 (0.54)	17	8.67 (0.68)	0.9842
	Prothrombin time	24	21.96 (5.40)	8	20.18 (5.71)	16	22.85 (5.20)	0.2622
48-72 hours	Platelet Count	26	129.54 (60.91)	12	159.13 (73.21)	14	104.18 (33.16)	0.0301
	Lactic Acid	22	2.84 (2.34)	8	1.64 (0.92)	14	3.52 (2.65)	0.0266
	Albumin	23	2.31 (0.48)	12	2.53 (0.49)	11	2.08 (0.34)	0.0201
	Hemoglobin	25	15.95 (3.14)	11	17.97 (2.12)	14	14.36 (2.93)	0.0023
	Sodium	29	135.52 (5.44)	14	136.26 (4.83)	15	134.83 (6.04)	0.4897
	Glucose	29	88.64 (22.79)	14	88.1 (14.95)	15	89.16 (28.82)	0.9013
	ANC # (manual)	21	6699.25(3444.86)	8	7435.50 (2125.63)	13	6246.17 (4069.27)	0.4565
	Creatinine	29	1.12 (0.96)	14	0.86 (0.78)	15	1.37 (1.07)	0.1577
	Calcium	29	9.03 (0.82)	14	9.19 (0.78)	15	8.88 (0.85)	0.3204
	Prothrombin time	34	26.18 (11.64)	16	21.93 (8.36)	18	29.95 (13.01)	0.0429

Table 2. Laboratory diagnostics references in sections

Equipoise is beneficial to research in this field as the links between comprehensive vasopressor indications, and blood pressure thresholds that represent the individualized limits of cerebral autoregulation are unclear (10-12). The hemodynamic parameters chosen in our study are currently being researched as possible indicators of newborn cerebrovascular pressure autoregulation, i.e., heart rate, systolic, diastolic, mean blood pressure, and cerebral NIRS (12-15). We explain the relevance of our findings in context to currently available research for newborn cerebrovascular autoregulation in full-term babies with moderate-severe brain injury.

Objectives: To evaluate whether hemodynamic instability, defined as the need for vasoactive support, predicts vital signs, cerebral NIRS, mechanical ventilator support, laboratory indices, EEG, brain MRI findings, and early neurodevelopmental indices in neonates with moderate-severe HIE. The primary aim was to study the differences between primary hemodynamic parameters and cerebral NIRS in patients with and without exposure to continuous vasoactive medications during their seventy-two hours after birth. The clinically relevant data included in this study were, selected medications (analgesics, anti-seizure therapies, postnatal steroids, inhaled nitric oxide), cardiac troponin I, the established biomarker of myocardial injury, laboratory test results, and neurodiagnostic assessments deemed as a standard of care for therapeutic hypothermia at the study center.

"Only a few neonatal research centers in the USA have correlated cerebral NIRS with blood pressure (16). The secondary aim was to analyze the differences in mechanical ventilator support, biochemical parameters, and neurodiagnostic assessments between the newborns requiring and not requiring vasoactive support during their first seventy-two hours in the NICU. "

Only a few neonatal research centers in the USA have correlated cerebral NIRS with blood pressure (16). The secondary aim was to analyze the differences in mechanical ventilator support, biochemical parameters, and neurodiagnostic assessments between the newborns requiring and not requiring vasoactive support during their first seventy-two hours in the NICU.

Study methods

Design and Data sources: A retrospective cohort study of thirty-four neonates diagnosed with

moderate-severe Hypoxic Ischemic Encephalopathy from 2010 to 2013 at a regional children's hospital with neurodevelopmental follow-ups until 2016. This period was chosen as cerebral NIRS was a routinely used diagnostic tool in infants receiving TH, allowing time for early neurodevelopmental follow-up. Data points were extracted from electronic medical records and supplemented by a chart review.

Setting: All the study subjects were out-born and transferred to the quaternary NICU to receive therapeutic hypothermia and any inhaled Nitric oxide or ECMO.

Participants: The study was approved by the deidentified study center, Institutional Review Board. Patients were excluded if EMR data was unavailable. A data analyst, with the guidance of the principal investigator, designed and executed the search strategy for the EMR, including relevant laboratory results, bedside monitoring data, and patient demographics. This data was augmented through chart review to generate a vasoactive score and extract EEG background and brain MRI findings. ICD codes were searched through medical records for the code HIE, cooling, and therapeutic hypothermia. An initial thirty-seven patients in the NICU at the study center were screened as potential subjects. Three patients were excluded as they did not meet the criteria for cooling at the time. Thirty-four patients were included as they had computerized documentation of receiving therapeutic hypothermia for moderate-severe HIE in the study period. Moderate and Severe encephalopathy was defined based on the 2003 AAP and ACOG criteria (17). An Olympic cool cap was utilized for administering therapeutic hypothermia during the selected time period at the study center. All the patients had their rectal temperatures maintained at 34.5°C ± 0.5°C (34.0-35.0°C) for the duration of hypothermia. Primary hemodynamic data, vasoactive medication dosages, and relevant clinical data were available for all the subjects. The primary outcomes (Heart rate, Blood Pressure, and cNIRS) were analyzed at five-time points.

The respiratory components of the secondary outcomes included the duration of mechanical ventilator support and oxygenation index. Biochemical parameters were trended across three-time points (0-24 hours, 24-48 hours, and 48-72 hours). EEG during cooling was reported either as an evolving pattern or finalized across seventy-two hours. Brain MRI was obtained 10-12 days after birth and included in the data analysis as normal, mild, or moderate to severe injury based on the radiologist's report. Neurodevelopmental assessments after NICU discharge were conducted at the study center and included Bayley III scaled and composite scores from 6 months to 24 months. The number of patients limited statistical power in the review period. The sample size was not calculated as the study design was planned as a retrospective cohort to clarify selected physiologic aspects of clinical decision-making.

Primary hemodynamic data, vasoactive medication information, and relevant clinical information were available for all subjects. Approximately 65% of patients had cerebral NIRS recordings during cooling. One patient did not have an EEG, and five died without brain MRI before their demise. Seven patients expired in the NICU, and one patient died at two years of age.

Neurodevelopmental outcomes were analyzed for the twenty-three patients with high-risk infant follow-up clinic visits at the study center from 6 months to 2 years of age. The median birth weight was 3.15 kilograms (IQ 2.6–3.56), 68% of the patients were male, and there were four late preterm infants in the cohort between 35-36 weeks of gestational age.

"Neurodevelopmental outcomes were analyzed for the twenty-three patients with high-risk infant follow-up clinic visits at the study center from 6 months to 2 years of age."

Vasoactive score/index: Vasoactive medication information was available in the chart review for all the study subjects. The study subjects were categorized into two groups, exposed or not exposed to continuous vasoactive medications at the time of statistical analysis due to limited variation in the pressor score.

Variable	Category	All (N = 34) Mean (SD)/ Frequency (Percent)	No Vasoactives (N = 16) Mean (SD)/ Frequency (Percent)	Vasoactives (N = 18) Mean (SD)/ Frequency (Percent)	P Value
Ventilator Duration (days)		5.00 (4.35)	3.31 (2.68)	6.50 (5.03)	0.027
EEG Background	Missing/Not Done	4 (11.76)	2 (12.50)	2 (11.11)	0.045
Burst suppression		9 (26.47)	7 (43.75)	2 (11.11)	
Continuous low voltage		20 (58.82)	7 (43.75)	13 (72.22)	
Flat		1 (2.94)	0 (0.00)	1 (5.56)	
EEG Seizure	Missing/Not Done	1 (2.94)	0 (0.00)	1 (5.56)	0.708
	Absence	23 (67.65)	12 (75.00)	11 (61.11)	
	Presence	10 (29.41)	4 (25.00)	6 (33.33)	
Sarnat Stage	Missing	2 (5.88)	1 (6.25)	1 (5.56)	0.450
	2	10 (29.41)	6 (37.50)	4 (22.22)	
	3	22 (64.71)	9 (56.25)	13 (72.22)	
Mortality Before NICU Discharge	Alive	27 (79.41)	14 (87.50)	13 (72.22)	0.405
	Death	7 (20.59)	2 (12.50)	5 (27.78)	
MRI(A/B)	Not Done	5 (14.71)	2 (12.50)	3 (16.67)	0.108
Normal MRI-Mild injury		20 (58.82)	12 (75.00)	8 (44.44)	
Moderate-Severe injury		9 (26.47)	2 (12.50)	7 (38.89)	
EEG evolution	Not Done	1 (2.94)	0 (0.00)	1 (5.56)	1.00
	Only Seizures	3 (8.82)	2 (12.50)	1 (5.56)	
Normal -Mild		7 (20.59)	3 (18.75)	4 (22.22)	
Moderate- Severe		23 (67.65)	11 (68.75)	12 (66.67)	

Table 3. Exploratory Outcomes- Mechanical ventilation duration and NICU neurodiagnostics

The abbreviation VAS denotes patients in the vasoactive exposed group, and non-VAS denotes patients with a vasoactive score of 0/no exposure to vasoactive infusions. Each baby was assigned a Vasoactive score/index that accounted for the vasoactive medications considered clinically indicated by the treating team for hypotension and cardiorespiratory illness in the transitional period, i.e., the first seventy-two hours after birth. A score of 0 denoted no utilization of vasoactive infusions, 1-Dopamine less than 10 mcg/kg/min or Epinephrine less than 0.1 mcg/kg/min; Score 2-Dopamine 10-20 mcg/kg/mt, Epinephrine 0.1-0.2 mcg/kg/mt, more than one vasoactive infusion; Score 3-Milrinone (M), Vasopressin (VP) or ECMO/ECLS.

Eighteen patients with a score of 1, 2, or 3 were assigned to the vasoactive group for the analysis. Sixteen patients with a vasoactive index score of 0 were in the group of newborns not exposed to vasoactive medications. Seven neonates expired before NICU discharge, and the criterion for their inclusion was either exposure or no exposure to vasoactive medications in the first seventy-two hours after birth.

STATISTICAL ANALYSIS: Mean with standard deviation (SD) were presented for each primary outcome at each time point on the entire population. Mean with SD were also presented for each group separately. Primary outcomes were compared between two groups by a two-sample two-sided t-test at each time point.

The false discovery rate (FDR) was used to adjust for multiple comparisons. Variables with

consistent significant p values across all three time periods were highlighted. Secondary outcomes were compared between two groups by a two-sample two-sided t-test at each time point except oxygenation index. Wilcoxon's two-sample test was utilized to compare the oxygenation index due to the severe skewness. MRI grade and ventilator duration were compared between two groups for exploratory outcomes by a two-sample two-sided t-test. Comparisons of EEG background (A/B/C), EEG seizure presence, Sarnat stage, and mortality before NICU discharge were by Fisher exact test.

MISSING DATA AND MORTALITY DATA:

Seven neonates admitted to the study center's NICU for cooling died before discharge. One baby died after CPR in the NICU, and six patients died after redirection to exclusive palliative care. One patient died at two years of age after NICU discharge. Cerebral

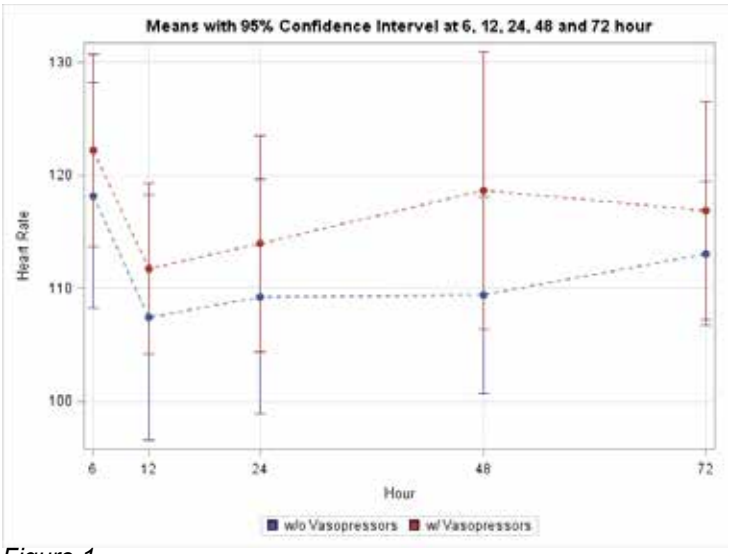
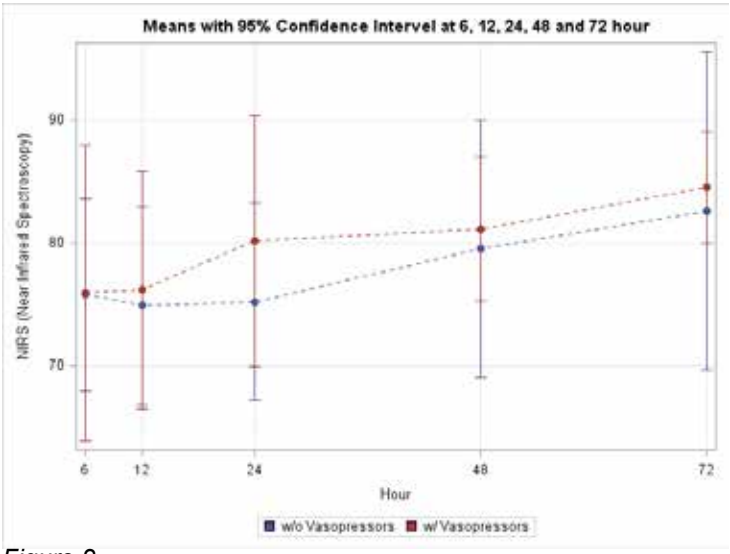


Figure 1



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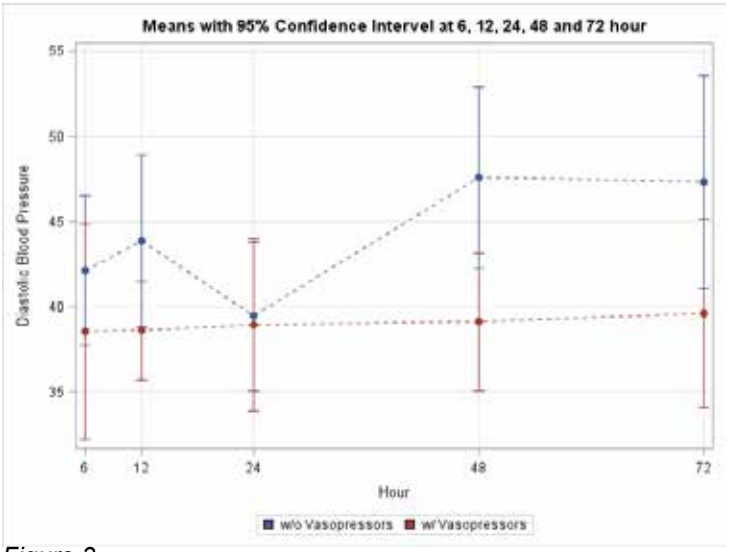

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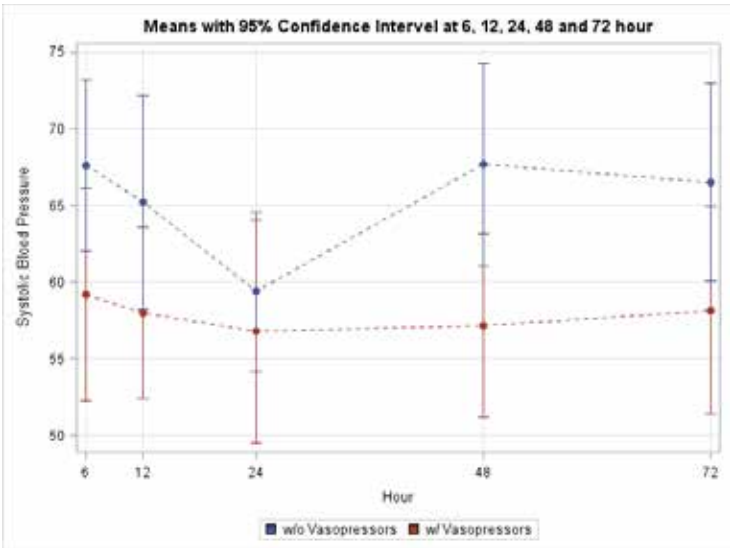

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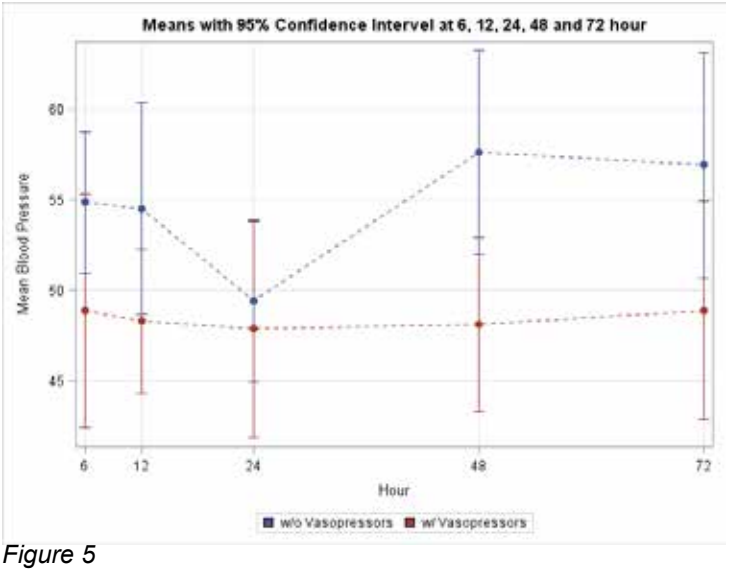

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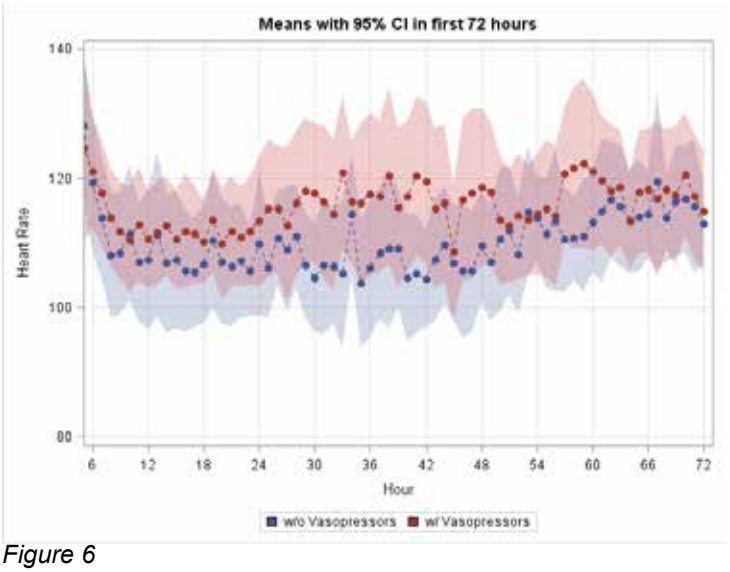

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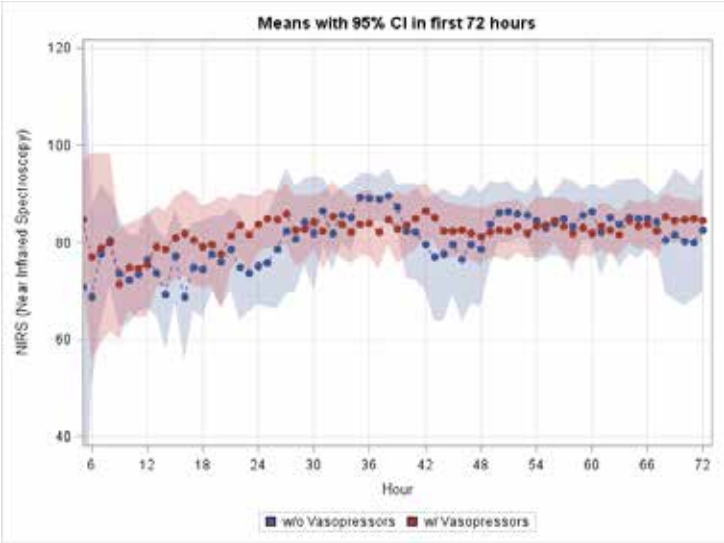

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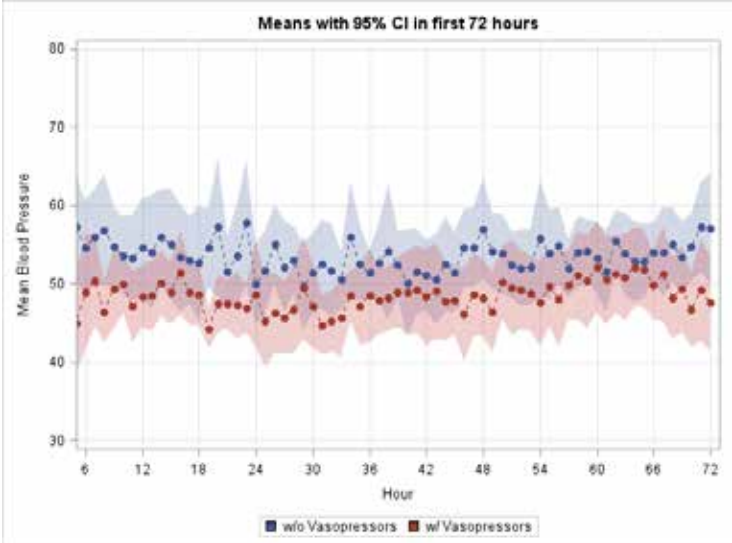

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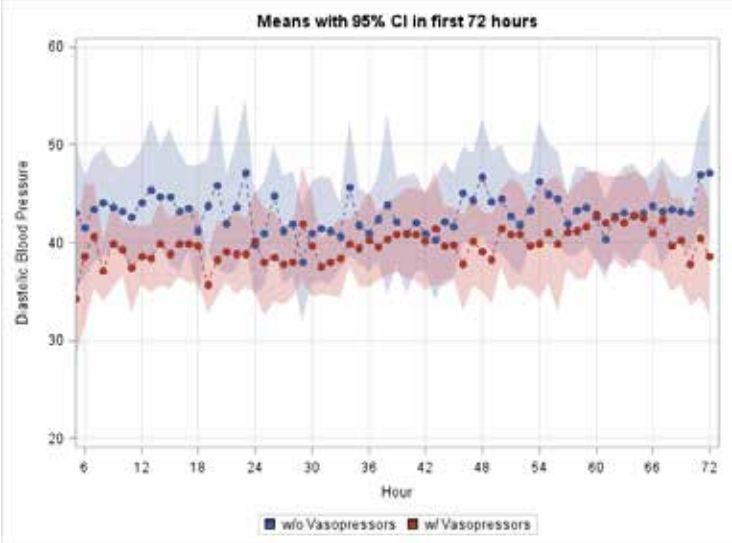

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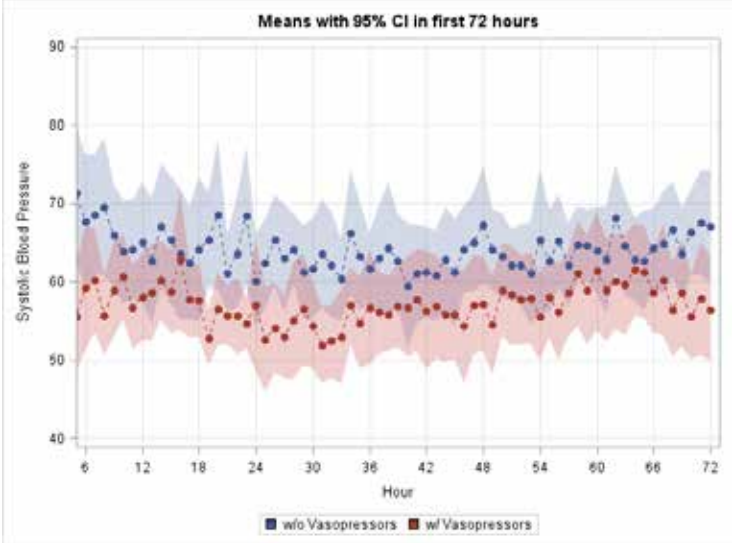

Figure 10

Figure Legends: Blue graph is non -VAS group and red graph is VAS group for each figure.
Figure 1- The trend of mean heart rate with 95% confidence interval (CI) at 6, 12, 24, 48 and 72-hours.
Figure 2- The trend of mean C-NIRS with 95% confidence interval (CI) at 6, 12, 24, 48 and 72-hours.
Figure 3- The trend of mean diastolic blood pressure with 95% confidence interval (CI) at 6, 12, 24, 48 and 72-hours.
Figure 4- The trend of mean with 95% confidence interval (CI) at 6, 12, 24, 48 and 72-hour for systolic blood pressure.
Figure 5- The trend of mean with 95% confidence interval (CI) at 6, 12, 24, 48 and 72-hour for mean blood pressure.
Figure 6- The trend of continuous hourly heart rate mean values within the first seventy-two hours.
Figure 7- The trend of continuous hourly mean values for C-NIRS.
Figure 8- The trend of continuous hourly mean values for mean blood pressure.
Figure 9- The trend of continuous hourly mean values for diastolic blood pressure.
Figure 10- The trend of continuous hourly mean values for systolic blood pressure.
Figure 11- The trend of mean with confidence intervals for oxygenation index (OI) within the first seventy-two hours.

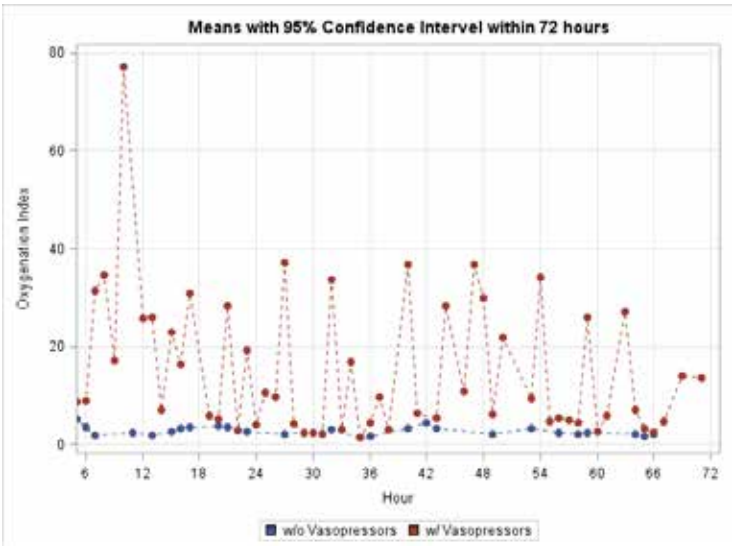

Figure 11

NIRS recordings were available for twenty-four patients during cooling, fourteen in the VAS group and ten in the non-VAS group. EEG was done in thirty-three of the thirty-four patients.

One baby in the vasoactive group required ECLS/VA-ECMO and survived to NICU discharge. In regard to the mortality data for patients requiring vasoactive agents, two patients, each with vasoactive scores of 1 and 3, and one patient with a VAS score of 2, died in the NICU. In the group without exposure to vasoactive therapies, two patients died before NICU discharge.

Among the twenty-seven patients surviving to NICU discharge, twenty-three patients had early neurodevelopmental assessments at the study center. While the majority of the babies had their six months Bayley III ND assessments, by two years of age, only 1/3 of the children followed up at the high-risk infant follow-up clinic. Thirteen patients had HRIF assessments at 24-28 months of age, five patients at 14-16 months and five patients had only one visit at 6.5 months of age. The recorded information included chronologic age, age equivalent data, scaled scores, and composite scores for 1. Cognitive 2. Composite language 3. Receptive language 4. Expressive language 5. Composite motor 6. Fine motor, 7. Gross motor. Developmental milestones were described as advanced, normal, and delays-mild, moderate, and severe.

RESOLUTION OF INCOMPLETE DATA: Any missing or unclear data points from computer extraction were resolved by chart review, and all ventilator and blood gas values were validated by secondary review. If the hemodynamic or laboratory measurements were missing for a targeted hour, the value at the closest hour was used within a (-4, +4) hour range. If there was no measurement collected within the 8-hour range, that was treated as missing data. Non-invasive blood pressure was used only if arterial blood pressure (umbilical or peripheral arterial line) was missing. 38% of babies had missing NIRS at all five timepoints in the non-VAS group (after the imputation with the closest time point). The missing rate of NIRS was 22-28% (22% for the 24th and 48th hour and 28% for the rest three timepoints) in the VAS group. The missing rate of the other primary outcomes ranges from 0-9% across the five timepoints.

"There were no significant differences in primary outcomes between the two groups at all five timepoints after FDR adjustment."

Study results:

PRIMARY OUTCOMES: There were no significant differences in primary outcomes between the two groups at all five timepoints after FDR adjustment. Figures 1-5 illustrate 1. The trend of mean with 95% confidence interval (CI) at 6, 12, 24, 48, and 72-hour for each primary outcome, i.e., Heart rate, Blood pressure (systolic, diastolic, mean), and c-NIRS and, Figures 6-10 illustrate 2. The trend of continuous hourly mean values within the first seventy-two hours for each

primary outcome.

SECONDARY OUTCOMES

Respiratory support, laboratory measurements, and neurodiagnostics:

Mean, minimum, and maximum for mechanical ventilator support were generated during the following time period, 0-6/6-12/12-24/24-48/48-72 hours. Respiratory support measurements: Oxygenation Index (OI) was not collected in the original data set. OI was manually calculated as 100*FiO2*MAP/PaO2. Blood pH was generated from Arterial/Venous/Capillary blood pH. If multiple blood pH types were collected simultaneously, we chose the type based on the following preference: 1. Arterial; 2. Venous; 3. Capillary. Blood partial pressure CO2 (pCO2) and blood arterial partial pressure O2 (pa02) were also generated similarly to blood pH with the same order of preference.

We analyzed the median (with 25 Th. -75 Th. tiles) number of available raw data points per subject during each time period for each outcome. Most summary measurement statistics (mean, minimum, and maximum) were generated on only 1-2 data points in each subject per time period, especially for laboratory tests. The biochemical parameters included albumin, cardiac troponin (nTnI), calcium, creatinine, hemoglobin, hepatic enzymes (ALT/SGPT, AST/SGOT), lactic acid-blood gas, magnesium, phosphorus, platelet count, prothrombin time (PT), random blood glucose, sodium, and absolute neutrophil count (ANC). Exploratory outcomes included MRI grade, ventilator duration, EEG background (A/B/C), EEG seizure presence, Sarnat stage, and Bayley III scaled and composite scores. Similarly, for the laboratory measurements, each subject's mean, minimum, and maximum were calculated during 0-24/24-48/48-72 hours. All of the below analysis was based on these summary statistics.

"Neonates with moderate to severe HIE and vasoactive requirements were more likely to have a higher burden of hypoxemic illness and require prolonged ventilation, approximately two additional days (P=0.027). The oxygenation index was significantly higher during 6-24 hours (p<0.05) (Figure 11)."

Neonates with moderate to severe HIE and vasoactive requirements were more likely to have a higher burden of hypoxemic illness and require prolonged ventilation, approximately two additional days (P=0.027). The oxygenation index was significantly higher during 6-24 hours (p<0.05) (Figure 11). The two groups had no consistent differences in blood pH and blood partial pressure CO2 (pCO2) (Table 1). In the first three days, the group treated with vasoactive agents had higher lactic acid, lower hemoglobin, and lower albumin (Table 2).

The patients exposed to vasoactive agents were also 30% more likely to have abnormal background EEG with low voltage patterns during therapeutic hypothermia and showed either moderate or severe brain injury on MRI at 10-12 days after birth. Before their demise, three patients had moderate-severe brain injury on MRI, and one had moderate-severe brain injury per head ultra-

Month	Variable	All (N = 34)		No Vasoactives		Vasoactives		P Value
		N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	
6	Cognitive Composite	21	96.43 (15.42)	11	94.09 (20.47)	10	99.00 (6.99)	0.4679
	Cognitive scaled	21	9.29 (3.08)	11	8.82 (4.09)	10	9.80 (1.40)	0.4679
	Language Composite	21	91.86 (11.99)	11	88.36 (14.89)	10	95.70 (6.48)	0.1594
	Receptive Language Scaled	21	8.90 (2.64)	11	8.27 (3.04)	10	9.60 (2.07)	0.2609
	Expressive Language Scaled	21	8.29 (1.95)	11	7.73 (2.33)	10	8.90 (1.29)	0.1754
	Motor Composite	20	84.70 (19.24)	10	87.70 (19.41)	10	81.70 (19.62)	0.5006
	Fine Motor Scaled	21	8.43 (3.59)	11	8.36 (3.93)	10	8.50 (3.37)	0.9333
	Gross Motor Scaled	20	6.10 (3.70)	10	6.80 (3.88)	10	5.40 (3.57)	0.4119
14	Cognitive Composite	17	90.88 (16.61)	8	86.88 (20.34)	9	94.44 (12.61)	0.3649
	Cognitive scaled	17	8.00 (3.41)	8	7.38 (4.07)	9	8.56 (2.83)	0.4939
	Language Composite	17	86.29 (15.43)	8	82.63 (18.98)	9	89.56 (11.64)	0.3722
	Receptive Language Scaled	17	8.18 (2.96)	8	7.13 (3.23)	9	9.11 (2.52)	0.1752
	Expressive Language Scaled	17	7.06 (2.86)	8	6.88 (3.56)	9	7.22 (2.28)	0.8118
	Motor Composite	17	85.41 (31.01)	8	75.75 (35.14)	9	94.00 (25.83)	0.2375
	Fine Motor Scaled	17	8.65 (4.37)	8	7.25 (4.13)	9	9.89 (4.43)	0.2251
	Gross Motor Scaled	17	7.41 (4.08)	8	6.50 (3.89)	9	8.22 (4.29)	0.4022
24	Cognitive Composite	12	87.08 (18.76)	5	84.00 (16.73)	7	89.29 (21.10)	0.6529
	Cognitive scaled	12	7.42 (3.75)	5	6.80 (3.35)	7	7.86 (4.22)	0.6529
	Language Composite	12	87.42 (15.42)	5	88.40 (22.12)	7	86.71 (10.42)	0.8621
	Receptive Language Scaled	12	8.58 (2.39)	5	8.20 (3.49)	7	8.86 (1.46)	0.6609
	Expressive Language Scaled	12	7.08 (3.23)	5	7.80 (4.09)	7	6.57 (2.70)	0.5421
	Motor Composite	12	88.92 (22.15)	5	90.80 (26.63)	7	87.57 (20.53)	0.8166
	Fine Motor Scaled	12	8.17 (4.00)	5	8.20 (4.76)	7	8.14 (3.76)	0.9819
	Gross Motor Scaled	12	8.08 (3.78)	5	8.60 (4.51)	7	7.71 (3.50)	0.7085

Table 4. Neurodevelopmental Indices- Mean and SD values

sound. Amongst the three patients without brain MRI prior to their death in the NICU, one 39-week EGA baby with IUGR was determined to have suffered brain death. In context to the severity of EEG findings in the babies who died before NICU discharge, two patients had a burst suppression pattern, and one had a flat line/ isoelectric pattern (Table 3). One patient in the non-VAS group died at two days of age from respiratory failure and had persistent metabolic acidosis with a pH of less than 7.0. Brain MRI was not done for this neonate, and a burst suppression pattern was noted on the EEG along with clinical assessments of a devastating neurologic exam. The means of Bayley III composite cognitive and language scores were 99 (CI 6.99; n=10) and 95.7 (SD 6.48) in the VAS group; in the non-VAS group, 94.09 (SD 20.47; n=11) and 88.36 (CI SD=14.89) respectively. The motor composite scores were 87.7 (CI 19.4; n=11) and 81.7 (CI 19.62; n=10) in non-VAS and VAS respectively. At six months, the majority of the patients had normal to mild developmental delays, and there were no statistically significant differences in between the two groups (Table 4).

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DISCUSSION:

1. PRIMARY HEMODYNAMIC PARAMETERS:

The influence of vasopressors' positive chronotropic effects on cerebral blood flow and cerebrovascular autoregulation during cooling is unclear. In our study, the babies exposed to vasoactive medications had lesser systolic, diastolic, and mean BPs, albeit this was not statistically significant between the two groups

(Figures 3-5, 8-10). Additionally, the VAS group's diastolic BP was lowest at twenty-four to forty-eight hours but did not reach statistical significance (Figures 3 and 9). It is uncertain whether these findings were impacted either by the sample size, transient vasoactive effects, or the clinical practice of titrating dosages in response to the observed alterations of vasopressors on the systemic vasculature. Our observation of lower mean BP is similar to a recent publication that the mean arterial BP in neonates with moderate/severe HIE treated with dopamine during cooling was significantly lower than controls (18).

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Sinus bradycardia is commonly observed during therapeutic hypothermia and is discussed as protective against evolving ischemic stress (2, 19, 20). Our study showed no differences in the heart rate measured between VAS and non-VAS patients across each time point (Figures 1, 6). Heart rate and Blood Pressure are included in the Neonatal Pain, Agitation, and Sedation Scale (N-PASS). Nursing staff in the study center referenced N-PASS, and physicians prescribed pharmacologic analgesia as needed. It was impossible to extrapolate the effect of seizure activity on heart rate retrospectively.

"Our data showed that babies exposed to vasoactive therapies had an early and sustained improvement in hypotension, as evidenced by the comparable blood pressures at the measured time points separated by 6-12 hours."

Ascertaining if the burden of cardiovascular illness in a severely asphyxiated newborn is predominantly hypovolemic shock, cardiogenic shock, or septic shock can be challenging in retrospective clinical research. Our data showed that babies exposed to vasoactive therapies had an early and sustained improvement in hypotension, as evidenced by the comparable blood pressures at the measured time points separated by 6-12 hours. Importantly, babies requiring vasoactive agents had lower hemoglobin, particularly in the first twenty-four hours, suggesting that a perinatal sentinel event that led to blood loss in the maternal-fetal unit could have been a diagnostic consideration retrospectively. Low albumin indicates that our cohort of patients had a hemodynamic compromise with endothelial injury. Aberrations of vasculature permeability and function could have placed these babies more at risk for systemic hypotension requiring vasopressor therapies. Cardiac troponin I is considered a reliable biomarker of myocardial dysfunction (21-23). In a retrospective study on babies with perinatal asphyxia, the optimal cTnI cutoff value for mortality was 8.1 ng/ml; the median cTnI concentration was 3.1 ng /ml among the twenty-one non-surviving infants, significantly higher compared with the median 0.18 ng/ml observed in the 157 overall survivors (24).

Cardiac troponin levels were measured in 78% of our entire cohort, and the highest cTnI values were in the first 24 hours among the VAS patients. These findings were higher than previously published ranges suggested as cutoff, for 1. Perinatal hypoxia (0.15 microgram/L) predicts myocardial damage but is lower for 2 - predicting the risk of early mortality (4.6 microgram/L), albeit not statistically significant (Table 2). Our results should be interpreted with the limitation that thirty-three patients had troponin measurements for the first 24 hours, and less than one-third of these patients had recorded troponin measurements at the 48 and 72-hour's timepoints. Peripartum onset of myocardial dysfunction and cardiopulmonary resuscitation in the delivery room could have been important factors that influenced the first set of troponin measurements (25).

Delineating which babies were born in the setting of intraamniotic inflammation was not possible. However, none of the babies had confirmed early onset neonatal sepsis. The ANC count was not statistically significant between the two groups. This may suggest that our cohort's pathophysiologic cascade of multi-systemic illness could have been attributed to an abrupt vascular perinatal event rather than sepsis. Serum sodium and serum creatinine were not significantly different between the two groups (Table 2). The hourly clinical management decisions included not administering excess crystalloid boluses and adjusting sodium intake in the intravenous hydration fluids carefully. The indications for echocardiograms were: 1. Vasoactive requirement, 2. Prior to initiating inhaled nitric oxide, 3. Escalating ventilator or vasopressor requirements, or 4. Refractory/worsening metabolic acidosis. During the study period, the standard of clinical care for babies with a hemodynamic crisis at this regional neonatal ECLS center involved a 1-2 ECMO doctor decision-making process to ensure consistency in the treatment of hypotension and cardiorespiratory illnesses.

"The seven babies who expired prior to NICU discharge had devastating brain injuries on clinical assessments, and their early disease trajectory was complicated by either hypoxemic respiratory failure or no meaningful response to escalating vasopressor support along with postnatal steroid therapies."

The seven babies who expired prior to NICU discharge had devastating brain injuries on clinical assessments, and their early disease trajectory was complicated by either hypoxemic respiratory failure or no meaningful response to escalating vasopressor support along with postnatal steroid therapies. ECMO was deemed a

potentially inappropriate therapy and not in the baby's best interest on a case-by-case basis in conjunction with structured family meetings (26).

2. BURDEN OF HYPOXEMIC ILLNESS AND pCO2 DYSREGULATION in HIE:

Oxygen supply and transport are the critical components of medical therapies that optimize tissue level functions and recovery in neonatal cardiorespiratory illnesses and shock. The burden of hypoxemic illness indicated by oxygenation index (OI) in our patients was higher in the VAS group, especially during the first 6-24 hours after birth ($p<0.05$) (figure 11). Oxygen carrying capacity may also have been impacted during the acute phases of respiratory failure in the babies with hemodynamic instability as indicated by lesser hemoglobin in the first twenty-four hours postnatally (Table 2).

Persistent pulmonary hypertension is an important morbidity in patients after perinatal injury (27). Four babies in this study required inhaled nitric oxide for persistent pulmonary hypertension (n=3 in the VAS group). It was impossible to clarify how a combination of a pulmonary vasodilator (iNO) and vasoactive impacted oxygen delivery to the myocardial tissue and brain. The pCO2 measurements (Table 1) were not significantly different between the two groups, even though babies exposed to vasoactive agents had higher hemodynamic instability and stayed longer on mechanical ventilation. Isolated recordings of hypocapnia (pCO2 lesser than 30 mm Hg) for individual patients did not contribute to a statistically significant factor to explain differences either in MRI findings or predicting risks of early neurodevelopmental delays be- tween the two groups in our cohort. However, it is plausible that the risk of ischemic brain injury in the VAS group was increased by higher lactate levels altering cerebral tissue oxygen extraction and pCO2 vasoreactivity.

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3. DIAGNOSTIC CONSIDERATIONS OF THE MONITORING MODALITIES AND BIOCHEMICAL INDICES:

3.A. CEREBRAL NIRS: The standard of neuroprotective care for moderate-severe HIE at the time of this study was initiating therapeutic hypothermia within six hours after birth. There was no established time point or clinical parameter for informing medical providers regarding the evolution of ischemia-reperfusion phases into the irreversible process of apoptotic brain injury during cooling. Reperfusion is an injurious pathophysiologic process, often described as the phase of cerebral hyperperfusion that follows a latent or hypoperfusion phase in newborns impacted by a sentinel hypoxic ischemic perinatal event. It is uncertain if luxury perfusion is the trigger or the unavoidable effect of hyperperfusion and hyperoxia in the cascade of cellular derangements and worsening neurological injury (28).

Cerebral NIRS can be utilized as a non-invasive diagnostic tool for oxygen delivery and possibly identify if a baby is at risk for cerebral injury. The widespread practical application of this modality has been hindered by the lack of defined lower and upper limits for neonates and insufficient research data (29). A commonly referenced range of c-NIRS is 55-85%, based on studies in preterm infants (30). A well-appearing newborn born at term gestational age after an uncomplicated delivery can have a c-NIRS trajectory of 40-50% at birth to almost 78% in the first two days, followed by a plateau to 55-85% by 3-6 weeks of age (31). The neonatal research studies regarding neonatal brain injury and CrSO2 have explicated aspects such as higher values associated with adverse outcomes and multiple factors affecting cerebral blood flow such as heart rate, mean blood pressure, pC02, systemic oxygen saturation, and B. Glucose (31-37). Previous research in infants with severe HIE and worse outcomes has demonstrated CrSO2 values in the range of 77-84% (34). Consistently elevated rScO2 levels during the seventy-two hours of cooling can be attributed to decreased oxygen consumption, lower metabolic rate either from cooling or pathologic, secondary neuronal loss from apoptosis, and any unintended effects of sedative medications (8).

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Systematic consideration of multiple etiologies and interventions can benefit the setting of significant disturbances in the C-NIRS baseline values or cutoff values of <60% and >90%. The timeframe for observing rising c-NIRS values in selected publications ranged be- tween 4-72 hours post birth in neonates with moderate-severe HIE (34, 35). In our study, there was no difference in the c-NIRS values between the patients not exposed to vasoactive agents and those exposed to vasoactive therapies (Figures 2, 7). The location of the c-NIRS optode monitor on an infant's scalp can influence the recorded values by measuring selected regional oxygen saturations. Extending the breadth of the actual probe to the occipital-temporal areas could hypothetically enhance prognostic information regarding which areas of the newborn brain are at the most risk for evolving injury. Reperfusion injury is vital for evaluating the risks of irreversible neurological deficits after a sentinel perinatal event that deprived the newborn's brain of oxygen and essential metabolites. The pathophysiologic cascade of biochemical and vascular responses in the setting of moderate-severe HIE can contribute to the evolution of significant brain injury. The existing clinical evidence that investigates the utility of C-NIRS as a prognostic marker for severity of MRI findings in cooled infants is limited due to the small numbers of patients and the absence of an integrated diagnostic profile with co-existing data such as mean BP, respiratory support, and biochemical indices (36, 37).

Time-trended measurements of cerebral NIRS across seventy-

two hours did not independently correlate either with the severity of brain injury on MRI or exposure to vasoactive medications in our study. The abnormal neurodiagnostics, as evidenced by low voltage EEG background patterns and moderate-severely abnormal brain MRIs in the VAS group along with clinical observations of higher oxygenation index, initial lower hematocrits, and elevated lactate levels in may suggest that those infants indeed suffered some of the sequelae of secondary cellular injury and luxury cerebral perfusion. EEG and brain MRI are important tools of a clinician's neurodiagnostic approach while caring for this vulnerable population.

"The abnormal neurodiagnostics, as evidenced by low voltage EEG background patterns and moderate-severely abnormal brain MRIs in the VAS group along with clinical observations of higher oxygenation index, initial lower hematocrits, and elevated lactate levels in may suggest that those infants indeed suffered some of the sequelae of secondary cellular injury and luxury cerebral perfusion."

3. B. EEG: We described the EEG features in our study population by the following descriptions (38)-1. Background activity-a. burst suppression (discontinuous activity throughout and with or without reactivity), b. continuous low voltage and c. flat trace; 2. Seizures; 3. Evolution of EEG over 72 hours normal or mildly abnormal; moderately abnormal; severely abnormal

A new piece of neurodiagnostic information from our study is finding a continuous low voltage pattern that was moderately severely abnormal in babies exposed to vasoactive therapies. EEG evidence of seizures was not significantly different in the two groups. All the subjects were documented as Sarnat stage 3 or Sarnat stage 2, changing to Sarnat stage 3 during the first seventy-two hours of postnatal life (Table 3). Anti-epileptic drug therapy was prescribed for 50% of the patients in the entire cohort with almost 90% phenobarbital exclusively, and two patients required a combination of phenobarbital and levetiracetam. A few of the confounding factors with EEG patterns of brain activity in our study population could be the utilization of opiates for analgesia, or/and diazepam for agitation, and the effects of hypothermia. Per the symptom-based-needs assessment approach at the time of clinical care, 32% of the neonates were exposed to Opiate (Fentanyl or Morphine Sulfate), and 24% received Diazepam continuous infusion for the following indications-analgesia, agitation, PPHN crisis, or achieve better synchrony with mechanical ventilation for babies with a high level of respiratory illness. An empiric continuous intravenous opiate infusion was not the standard of analgesic care for neonates undergoing therapeutic hypothermia in the study center during 2010-2013. Our research suggests that empiric anti-seizure therapy may not be indicated at the beginning of therapeutic hypothermia for every neonate with moderate-severe HIE. In conjunction with the pediatric neurologist's recommendations, a judicious case-by-case approach can help neonatologists choose the beneficial and appropriately indicated medical therapies for these infants.

3.C. MRI**:** Hypoxia-ischemia in newborns typically results in one of two characteristic patterns of brain injury: (1) Watershed-distribution pattern involving inter-vascular boundary-zone white matter, plus cortical gray matter when severe, and (2) Basal ganglia-distribution pattern involving deep grey nuclei, hippocampi, and perirolandic cortex, with further cortical involvement when severe. The neuropathology of brain injury in moderate-severe HIE can be summarized as 1. Selective neuronal necrosis may occur from cerebral ischemia, with deprivation of oxygen and glucose followed by reperfusion and the cascade of metabolic events. This can be caused by a severe and abrupt injury that diffusely affects the cerebral cortex, deep nuclei, and brain stem. Moderately severe asphyxia can be seen in the situation with slowly evolving hypoxia, acidosis followed by late deceleration of the fetal heart rate, diminished cardiac output, hypotension, and the cerebral ischemic pattern of injury in the cerebral cortex. 2. Parasagittal brain injury that has been known to occur in 40-60% of asphyxiated term infants. In addition to border zones/watersheds or end-fields of major arteries, other distal fields, like the posterior occipital region, can get affected (5).

Brain MRI was done 10-12 days after birth and reviewed by the pediatric radiologists at the study center. In this retrospective analysis of MRI reports, the extent of brain injury was described as either A. normal MRI and mild injury and B-Moderate-severe white matter injury, stroke, intraparenchymal hemorrhage, or presence of cerebral sinovenous thrombosis and sagittal sinus thrombosis. Normal to mild injury was predominantly seen in the non-VAS group (86%; n=12/14). Almost 50% of the patients in the VAS group had moderate-severe MRI evidence of brain injury (n=7/15) (Table 3). Previous research has demonstrated both increased incidence of MRI brain injury and no significantly elevated risk of severe brain injury in babies with HIE requiring vasopressors (3,18).

"Almost 50% of the patients in the VAS group had moderate-severe MRI evidence of brain injury (n=7/15) (Table 3). Previous research has demonstrated both increased incidence of MRI brain injury and no significantly elevated risk of severe brain injury in babies with HIE requiring vasopressors (3,18)."

Five neonates expired without brain MRI. Two patients had a head ultrasound prior to their demise in the NICU. Their early neonatal illness course was complicated by devastating neurologic clinical assessments, hemodynamic instability (despite escalating vasoactives), or persistent hypoxemic respiratory failure refractory to maximally dosed inhaled nitric oxide. Shared decision-making with the goal of exclusive palliative care was the main step toward compassionate extubation in those patients (26).

4. EXTENDING THE CLINICAL TRAJECTORY TO EARLY NEURODEVELOPMENTAL OUTCOMES

A comprehensive way of addressing the implications of moderate-severe HIE will include respiratory and cardiovascular disease trajectories, neurodiagnostics, and early childhood neurodevelopmental outcomes (39-41). Moderate or severe disabilities can occur in approximately 30% of patients, mostly with severe HIE, along with significant cognitive deficits restricting a child's ability to function independently (40, 41). The first study integrating neurodevelopmental outcomes at eighteen months of age and school age for children who received TH with cool cap showed that favorable neurodevelopmental outcomes assessed at eighteen months of age had a predictive value for normal functional assessments at 7-8 years (42). The largest data set (CHND) to date of developmental outcomes analyzed in infants after hypothermia for HIE described two models for predicting death or neurodevelopmental impairment as early as the first few hours after birth. The severity of HIE and specific patterns of EEG and MRI brain injury were associated with death and neurodevelopment impairment. The important caveat was that a composite outcome of death or NDI assumed that the babies who died after withdrawal of artificial life support would most likely suffer from later death or NDI (43).

Our study discussed early neurodevelopmental outcomes (motor, receptive language and expressive language) from six months to two years to better understand the clinical trajectory. Normal to mild delays were the predominant descriptive assessments for the entire cohort. Neurodevelopmental delays at six months were not significantly different in the VAS and non-VAS groups (Table 4).

Limitations:

Fluid resuscitation and volume challenge details were not included in the data extraction. This avoided the confounding effects of inaccurate data entry as all the neonates in our study center were outborn. However, early neonatal sodium and creatinine levels were not significantly different in the two groups of this cohort. Platelet levels significantly differed between the two groups for the first 0-24 and the last 48-72 hours. This study was not designed to extract information on blood product administration or delayed cord clamping. The observation of lower platelets in the vasoactive exposed group could have been either a false positive or that those patients received a platelet transfusion between 24 and 48-hour time points. A recent systematic review and meta-analysis for predicting neurodevelopmental outcomes in moderate and severe HIE showed that early MRI was more predictive than MRI performed after the first week of postnatal life (39). As mentioned previously, our study described brain MRI findings at 10-12 days; perhaps an earlier MRI may have had different findings regarding the extent of brain injury. The other limitations of this retrospective study were the lack of general adaptive and socioemotional components and almost 60% fewer follow-up assessments at two years.

"Cerebral hemodynamics and neurovascular coupling (cerebrovascular responses to brain metabolism) are important concepts to elucidate in the newborn brain."

Conclusions:

Cerebral hemodynamics and neurovascular coupling (cerebrovascular responses to brain metabolism) are important concepts to elucidate in the newborn brain. Derangements in metabolic processes at both intracellular and extracellular levels can potentially affect cerebral hemodynamics and autoregulatory thresholds after acute perinatal injury. During the acute phases of neonatal illnesses, thoughtful and compassionate communication regarding a family's values and individualized perspectives on life and childhood are essential. Concurrently, exploring better ways to understand the closely linked physiologic factors after birth may enhance prognosticating outcomes (41). The physiology of newborn cerebral autoregulation can be clarified by analyzing multiple factors with pathophysiologic relevance, i.e., alterations in primary hemodynamic parameters, changes in cerebral perfusion pressure, and biochemical and hematological parameters. Targeted neonatal echocardiograms, time and frequency domain heart rate variability, continuous cerebral NIRS recordings, key biomarkers, and neurodevelopmental data beyond infancy are a few examples of the precision medicine-based research tools that may improve prognostication challenges for neonatal brain injury and hemodynamic instability.

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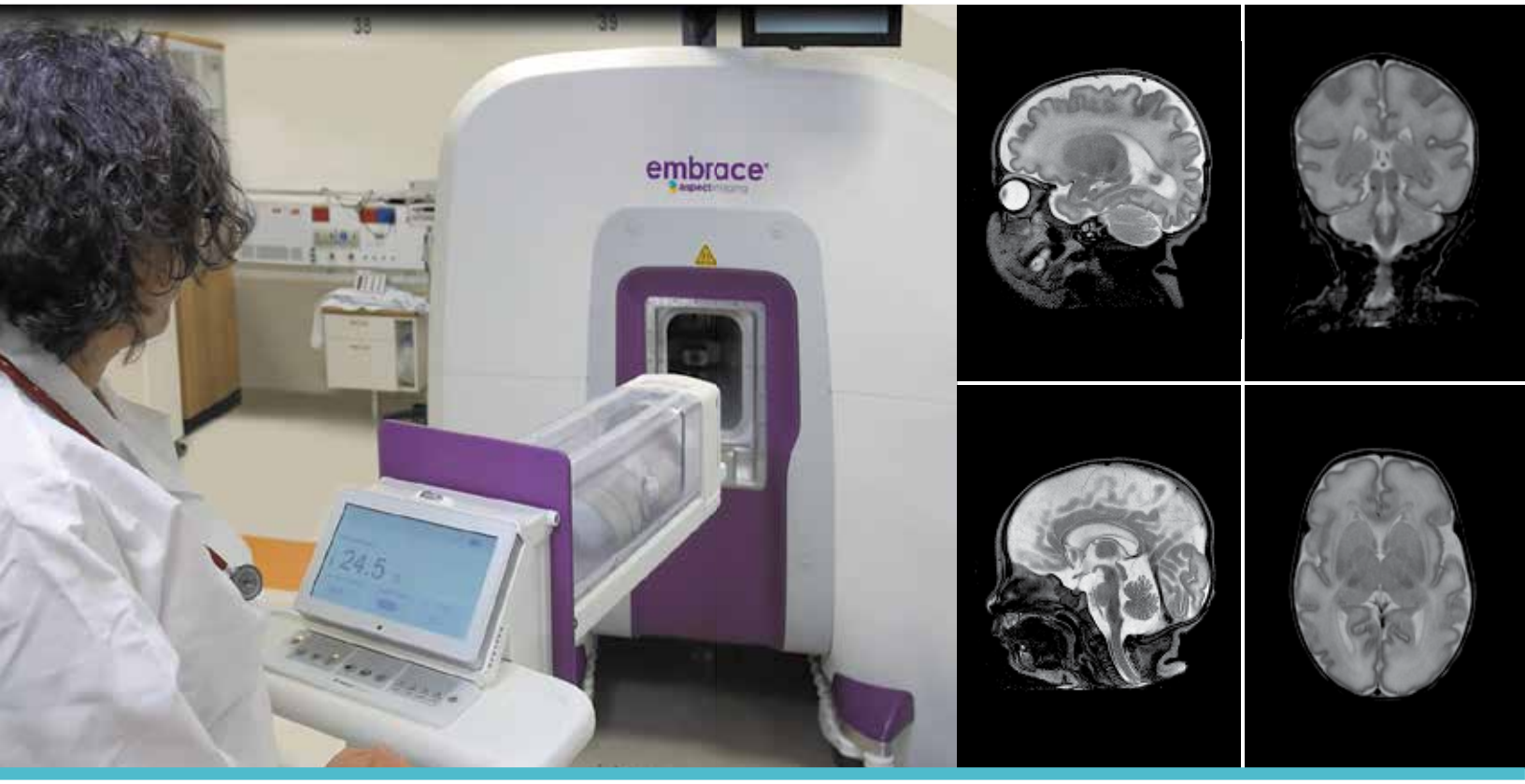

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Letters to the Editor

Physicians Against Drug Shortages (PADS): End Chronic Shortages & Skyrocketing Prices of Generic Drugs, Devices & Supplies, Repeal the 1987 Medicare Anti-Kickback "Safe Harbor" for Hospital Group Purchasing Organizations (GPOs)

Physicians Against Drug Shortages (PADS)

July 18, 2022

The Honorable Patty Murray, Chair
Committee on Health, Education, Labor and Pensions (HELP)
U.S. Senate
Washington, DC 20510

The Honorable Richard Burr, Ranking Member
Committee on Health, Education, Labor and Pensions (HELP)
U.S. Senate
Washington, DC 20510

Re: To End Chronic Shortages & Skyrocketing Prices of Generic Drugs, Devices & Supplies, Repeal the 1987 Medicare Anti-Kickback "Safe Harbor" for Hospital Group Purchasing Organizations (GPOs)

Dear Chair Murray and Ranking Member Burr,

On behalf of Physicians Against Drug Shortages and other organizations representing thousands of physicians who care for millions of Americans, we urge your Committee to end the unprecedented chronic shortages and inflated prices of drugs, devices, and medical supplies by repealing the ill-conceived 1987 Medicare anti-kickback "safe harbor" provision, (1) which exempted GPOs from criminal prosecution for taking kickbacks from suppliers.

"Besides inflating costs for patients and payors, including Medicare and Medicaid, GPO and PBM abuses have undermined our ability as physicians to provide quality care for our patients, especially the most vulnerable."

We greatly appreciate your Committee's efforts to highlight and reform the anti-competitive practices of pharmacy benefit managers (PBMs). But reform of the GPO industry is long overdue. PBMs utilize the GPO safe harbor business model to raise prices on drugs sold to individuals. Besides inflating costs for patients and payors, including Medicare and Medicaid, GPO and PBM abuses have undermined our ability as physicians to provide quality care for our patients, especially the most vulnerable. Indeed, infants who depend on Abbott baby formula are among the latest casualties of GPO sole-source contracting—-not to mention patients of all ages who need diagnostic scans requiring now-scarce contrast dye.

" Indeed, infants who depend on Abbott baby formula are among the latest casualties of GPO sole-source contracting—-not to mention patients of all ages who need diagnostic scans requiring now-scarce contrast dye."

The unsafe safe harbor gave rise to a "legalized" pay-to-play scheme in which for-profit buying cartels sell sole-source contracts to suppliers in return for "fees" (aka kickbacks/rebates) that have sometimes exceeded half of a manufacturer's annual revenue for a single product. It undermined the original and sole purpose of GPOs: saving money for hospitals by purchasing supplies in bulk. Instead, under the perverse safe harbor business model, they exist only to enrich top executives of GPOs and their shareholder hospitals. They are the glue that keeps this travesty in place. Many receive "share backs" as a percentage of the kickbacks paid to the GPOs. (2) Frankly, Congress awarded GPOs a "Get out of jail free card," becoming the only industry we know of to achieve this dubious distinction.

"The evidence of the deadly consequences of GPO anti-competitive contracting, pricing practices, and self-dealing, and their role in causing the shortages, is overwhelming."

The evidence of the deadly consequences of GPO anti-competitive contracting, pricing practices, and self-dealing, and their role in causing the shortages, is overwhelming. It comprises multiple federal and state investigations, including four Senate Antitrust Subcommittee hearings from 2002 to 2006 ; (3) studies by the Government Accountability Office (GAO), (4) the Dept. of Health & Human Services (HHS), and other federal agencies; multiple media exposes; (5) numerous successful federal antitrust lawsuits filed by entrepreneurial device makers against GPOs and/or their dominant supplier "partners"; independent scholarly research, even a 2009 book entitled "Group Purchasing Organizations: An Undisclosed Scandal in the U.S. Healthcare Industry." (6) For this

documentation and much more, visit www.physiciansagainstdrugshortages.com.

Two 2014 GAO reports are particularly relevant to the role of GPOs in causing the ongoing shortages. Congress mandated the first in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). It cited GPOs as a potential "underlying cause." (7) The second, which focused on the GPO funding structure, stated that "repealing the safe harbor could eliminate misaligned incentives." (8)

"Moreover, despite an estimated $300 billion in annual GPO contract volume, there is virtually no disclosure, oversight, transparency, or regulation of this industry."

Moreover, despite an estimated $300 *billion* in annual GPO contract volume, there is virtually no disclosure, oversight, transparency, or regulation of this industry. Although the Inspector General of HHS is charged with ensuring that GPOs comply with the safe harbor, it has rarely exercised its oversight authority, as documented in a March 30, 2012, GAO report. (9)

For an overview, read "How a Cabal Keeps Generics Scarce" (New *York Times,* September 3, 2013) (10) and "Where Does the Law Against Kickbacks Not Apply? Your Hospital" (*Wall Street Journal*, May 8, 2018), (11) and "Hospital Group Purchasing Organizations, Health Care Costs, and Drug Shortages," (*JAMA*, November 13, 2018). (12)

"Most recently, 60 Minutes revealed how outrageous secret "fees" demanded by GPOs had squeezed generic drug makers' margins to the point where they can no longer safely manufacture hundreds of drugs, from sterile saline to vincristine and other generics used to treat childhood cancers. (13)"

Most recently, *60 Minutes* revealed how outrageous secret "fees" demanded by GPOs had squeezed generic drug makers' margins to the point where they can no longer safely manufacture hundreds of drugs, from sterile saline to vincristine and other generics used to treat childhood cancers. (13) The segment featured California neonatologist Mitchell Goldstein, M.D., who had testified before the Antitrust panel in 2002 on how GPO contracting practices prevented clinicians from obtaining the most accurate and cost-effective pulse oximeters, which are crucial for monitoring blood oxygen levels in newborns. (14)

In short, the supply chain is broken. It has been rigged by buying groups solely for the personal enrichment of insiders. Patients are dying. We implore you to exercise your duty of care to all Americans to end this pernicious system. The bipartisan bill that would accomplish that has already been written. In 2005, Senators Mike DeWine (R-OH) and Herb Kohl (D-WI), who presided over the Antitrust panel hearings, drafted the "Ensuring Competition in Hospital Purchasing Act." (15) Unfortunately, it was never introduced because of intense lobbying by the GPO trade group and its cohorts. If it had been enacted, the shortage crisis would have never happened.

COVID-19 has exacerbated the deadly impact of GPO middlemen on the supply chain. The same corrupt practices that caused the drug shortages triggered shortages of masks and other personal protection equipment (PPE), devices, and supplies. Mike Bowen, the now-retired executive vice president of Texas-based Prestige Ameritech, one of a handful of domestic mask makers, had been warning for years that the U. S. was unprepared for a pandemic because GPOs had driven mask production offshore. (16) He told *Infection Control Today* on October 4, 2008, that GPOs had a "chokehold" on the hospital market, adding that "Selling individual products to individual hospitals became impossible over a decade ago." (17)

"COVID-19 has exacerbated the deadly impact of GPO middlemen on the supply chain. The same corrupt practices that caused the drug shortages triggered shortages of masks and other personal protection equipment (PPE), devices, and supplies."

Concerned about the failure of critical supply chains during the pandemic, including drugs and other medical supplies, and the threat to national security posed by America's heavy reliance on China for these goods, President Biden issued an executive order in early 2021 requiring a report 100 days later on the causes and potential solutions.

Released in June 2021, the White House report underscored our findings: "GPO contracting practices may lead to limits in the diversification of supply," it concluded. "GPOs may contract with certain manufacturers that are willing to pay to become a sole supplier. GPOs may also further link discounts to hospitals to sole supplier contractual arrangements. These two practices can lead to one or two manufacturers serving an entire regional or national supply chain." (18)

"Zweig estimated in 2021 that by repealing the safe harbor, "the savings to Medicare and Medicaid would amount to about $37 billion per year." (20)"

Besides the lethal human consequences of this arrangement, its

cost is staggering. As any first-year economics student knows, cartels raise prices, whereas competition lowers them. The current system "may inflate costs by 30% or more," as Zweig and Frederick Blum M.D. explained in a 2018 *Wall Street Journal* oped. (19) Zweig estimated in 2021 that by repealing the safe harbor, "the savings to Medicare and Medicaid would amount to about $37 billion per year." (20)

Physicians Against Drug Shortages (PADS) was the first organization to call for repeal to address the shortages and skyrocketing prices of hospital goods. Since 2012, PADS has published many articles and has been cited extensively for its leadership on this issue. In 2017, the American College of Emergency Medicine adopted a resolution calling for repeal. (21) Other physician organizations have also advocated for repeal.

Thank you for considering our urgent request. We would welcome the opportunity to meet with Committee members and staff to discuss our request further.

Respectfully,

Mitchell Goldstein, M.D., M.B.A.

Chair, PADS
Professor of Pediatrics

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Erratum (Neonatology Today June, 2022

Neonatology Today is not aware of any erratum affecting the June, 2022 edition.

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Should Infants Be Separated from Mothers with COVID-19?

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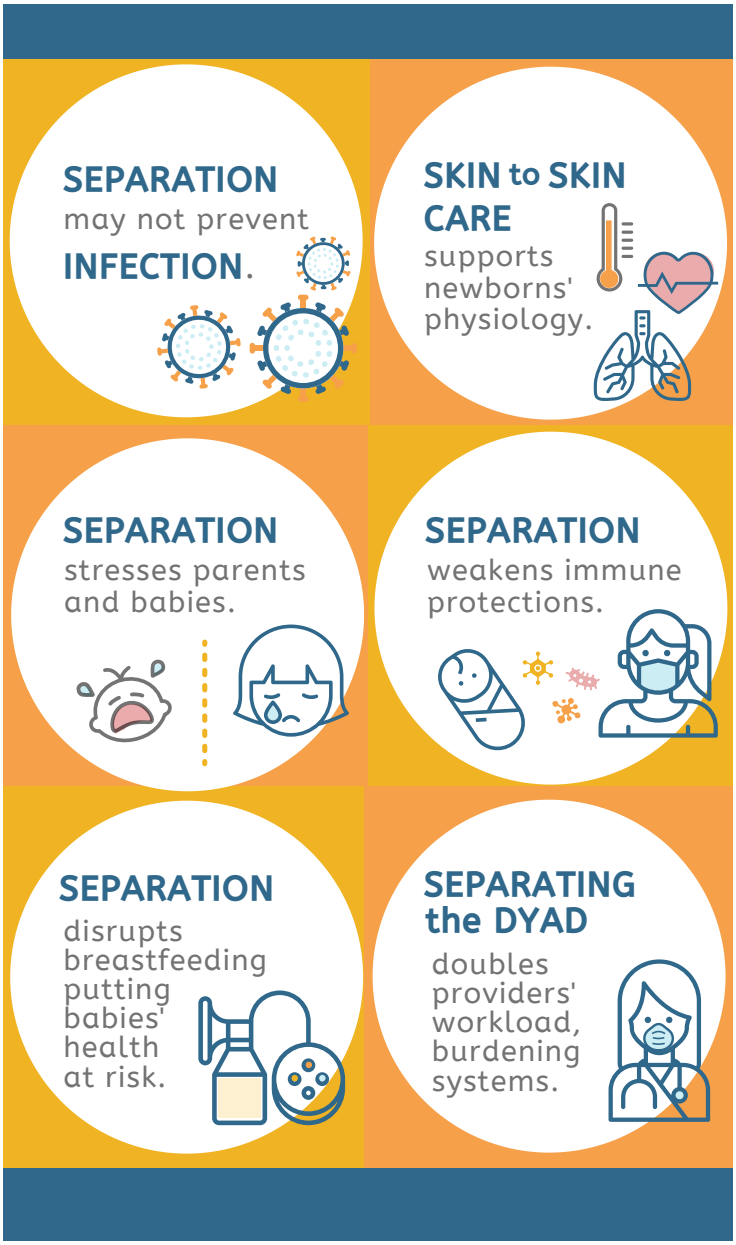

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NT Behind the Scenes: When All Becomes New

Kimberly Hillyer, DNP, NNP-BC

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"The following is an amended transcript for Neonatology Today Media of Dr. Kimberly Hillyer and Dr. Benjamin Rattray, author of When All Becomes New. "

Introduction

Thank you for joining us on today's broadcast. I'm Dr. Kimberly Hillyer, a Nurse Practitioner and the Media Correspondent for Neonatology Today. This segment features Dr. Benjamin Rattray. Dr. Rattray is the author of "When All Becomes New," a compilation of his experiences and reflections over years of doing what we all do every day in the world of neonatology.

Dr. Hillyer: Thank you for joining us on today's segment of Neonatology Today Media; I'm here today with Dr. Benjamin Rattray. Thank you for joining us today, Ben. How are you doing?

Dr. Rattray: I'm great. Thanks so much for having me.

Dr. Hillyer: Thank you so much. You wrote a book that was very inspiring to me because it's an area that I'm working in. It's a story of not just you but individual families and the babies that you come in contact with throughout your career. Can you tell me a little bit about your journey to becoming a Neonatologist?

Dr. Rattray: Yeah, so the story really starts for me in college when I started as a Psychology major. I was actually a Psychology and English major. I took an abnormal psychology class and really got interested in Medicine and the sort of physiology behind everything. Funny enough, it's funny how these things come full circle because my mom was actually a district nurse in New Zealand and, before that, a midwife in England. So, I had some exposure to Medicine through her as a kid. Sometimes that exposure kind of scares you a little bit, but it also, I think, fascinated me and intrigued me. Looking back now, I think that that was probably a big part of it. Every once in a while, when I had a day off school, and she was working, I was able to go around with her. She drove to each patient's house to see them and check up on them. I don't think it happened very often, but it definitely made a big impact on me. That started my interest in Medicine. I always loved kids, was excited to look into Pediatrics, and was also really interested in neurosurgery for a while. I thought that was going to be my residency path, but [I] ended up choosing Pediatrics. Then going through the different rotations, I really fell in love with Pediatric intensive care, neonatology and then ended up in neonatology.

"I always loved kids, was excited to look into Pediatrics, and was also really interested in neurosurgery for a while. I thought that was going to be my residency path, but [I] ended up choosing Pediatrics. Then going through the different rotations, I really fell in love with Pediatric intensive care, neonatology and then ended up in neonatology"

Dr. Hillyer: Now, your book is, like I said, your life story. In a sense, because it goes from your introduction into Medicine in the world of neonatology, being a Fellow, and then going on to becoming an Attending. Can you tell me why you felt that it was very important to see the growth and progression of you as a Physician through these stories?

Dr. Rattray: There are those two elements of the book. One: each chapter is a different patient story, but it also really follows my arc of training. Sort of that young idealistic way that we kind of come at things. Then, sort of reckoning with some of the difficulties as some babies don't make it, and we do have some really difficult outcomes. Also, a faith struggle as I'm kind of going through all of this. So, it seemed like the logical thing to do as I was laying out the chapters was to do it chronologically as I'm moving through my training, as I'm maturing in my journey.

Dr. Hillyer: What did you feel was the biggest difference as you

were putting these stories together as you moved from, let's say, the fellowship to becoming an Attending?

Dr. Rattray: One of the biggest things, and I'm not sure, to be honest, that this part of it comes through as much in the book, but one of the things I think for most people when you're in training, certainly myself you're really so focused on the Medicine. You're just trying to get your medical care to be right. You're trying to get the right diagnosis and the right medications. You're learning your skills, putting in umbilical lines, doing intubations. That's really, I think it is where the focus is, and I think it should be. I mean, that's such an important part of this step, but I think as time has gone on, I'm probably more focused on the families. The relationship that I have with the families, I hope that comes through in the book, but I don't know that I necessarily spelled that out exactly.

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Dr. Hillyer: I think through some of the stories, you could definitely tell it is. I remember one of the stories you were standing behind, kind of an outside observer. Watching this family as they mourned the loss of the child, I think you really were able to show that in those moments.

So, you have some ups, and you have some downs. As you said, it is a roller coaster in the NICU. Can you tell me about one of the ups that you've found helps really get you through some of the lows of the NICU?

Dr. Rattray: Yeah, so one of the ups. There's a story about a baby girl called Faith. She was born really early, about 24 weeks, and like a lot of 24-weekers, had a really rough NICU course. Her parents were amazing; they were like the light of the unit. They would come in and hug everybody, really upbeat, really encouraging. It was like, you felt like we should be trying to encourage them, not the other way around. They were just amazing parents, but they certainly had some really difficult times.

"I was there in the delivery room when she gave birth, and then I actually got to be there on the day that she went home. She did great. She's just like this beautiful girl now. In the book, I talk about that."

I was there in the delivery room when she gave birth, and then I actually got to be there on the day that she went home. She did great. She's just like this beautiful girl now. In the book, I talk about that. Actually, I was at my daughter's preschool graduation, and Faith was there too. She just happened to go to the same school, so it's one of those really great stories that you go through a lot together, but the outcome is really great.

"Because anything that can foster emotions and stir up feelings, and make people feel better is something that's needed right now. There's just so much pain and so much suffering anything that can make people feel better is welcomed."

Dr. Hillyer: I know for me, that was definitely one of the stories that I enjoyed because you're right; you need to have some of those very positive heartfelt moments that remind you once again of the positive aspects of why you do some of these things. Now we are also experiencing very low, lows. Can you tell me about one of yours and how you were able to adjust and move forward?

Dr. Rattray: Yeah, one of the other stories is called "The Sniper's Son," and the reason for that is because the father was a sniper in the army. I met him several weeks into his son's NICU stay. I had met the mother and kind of formed a relationship with her by talking with her each day. Then one day, the dad came in, and we kind of struck up a conversation. He was in army fatigues, and he kind of ended up telling me what he did; I just remember thinking at the time how we were in such different worlds. But his son was doing pretty well, until all of a sudden, he got sick with necrotizing enterocolitis; it just happened so fast. It happened, it really started overnight. I came in the next morning and saw the x-ray. I just couldn't believe it; it was awful. I did anesthesia for the case, and the surgeon opened him up, and essentially it was just black necrotic bowel, all the way through.

"So, we had to make that really difficult decision with the parents to withdraw support. When we did that, the father showed up. He was with the mother, and a lot of the men from his unit showed up in their full military dress uniform and stood with the mom and the dad. They supported them."

So, we had to make that really difficult decision with the parents to withdraw support. When we did that, the father showed up. He was with the mother, and a lot of the men from his unit showed up in their full military dress uniform and stood with the mom and the dad. They supported them. It was really difficult because I was still in training, and it was just that feeling of total helplessness. There was just nothing that we could do, I mean, we could keep his son alive for a little bit longer if we had needed to, but we couldn't ultimately save him. He had no bowel and was too small for an intestinal transplant. There just wasn't anything that we could do. It was really difficult.

"It is the right thing to do, but I just remember thinking about how we didn't talk at all about any of the other parts, kind of that interpersonal part of the case. Nobody in M&M really knew that this guy's regimen had come in and stood there with him. "

I remember we talked about the case at the M&M conference that next week, and it really struck me how we talked about the medical part of it. How quickly did we start an anti-fungal? Which antibiotic did we use? We looked at those initial films, and we dug through the whole case, which was appropriate. It is the right thing to do, but I just remember thinking about how we didn't talk at all about any of the other parts, kind of that interpersonal part of the case. Nobody in M&M really knew that this guy's regimen had come in and stood there with him.

I just remember walking outside. At the end of the day, in the North Carolina sunshine, it was still summer, and walking back to the car, trying to take it all in. I definitely remember that one.

Dr. Hillyer: Now, I know that that is definitely one of the hardest parts of our job, for sure. As you're trying to come up with words to comfort the family during these most difficult times in their lives. have you found anything you feel based on your Faith or your belief that helps you to find that connection with the families?

"As you're trying to come up with words to comfort the family during these most difficult times in their lives. have you found anything you feel based on your Faith or your belief that helps you to find that connection with the families?"

Dr. Rattray: I think one of the things is getting back to that early training. I think that what I thought at the start was that I needed to have that distance, that emotional distance from the parents. I needed to be so professional that the only thing that I was communicating was the medical information. So, what I think I've found is there's more power in just sitting there and being quiet and not even saying anything. I think there's more power in that than trying to say a lot of words. I think that, to be honest, there really isn't anything that we can say that really makes it better; perhaps other than just saying, I'm so sorry that this is happening to you. Sometimes I'll give the mom a hug, depending on if that seems appropriate. I think the biggest thing is to just show how much we care. I think if a tear slips out, it's okay. I think that as long as the family knows that we truly care, certainly, I think anything else can come across as trite. It's interesting because I do take comfort in believing that God makes all new for these babies. At the same time, it's not something that I would say out loud to the parents because I don't think that there's comfort in that. Certainly not at the time, maybe at some point in the future. It's not something I feel can really be expressed, certainly not at that moment.

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Dr. Hillyer: Absolutely. As we are seeing more and more premature babies, extremely immature, extremely low birth weight babies, I feel we have this opportunity more so. Maybe it's just me, where you have these extremely long courses. Sometimes you think you're out of the woods, then something like NEC happens. Then you're having to readjust and re-connect with the family. Sometimes you have to go through these moments with them, but you're not doing it alone as just the physician provider. You have this whole team that you're working with.

You were just speaking about the M&M conference and talked about the technical aspect. How can we, as a full team in the NICU, deal better with these kinds of situations? Do we just let palliative care be a part of it? How do we incorporate that into our field? How do you suggest that we work as a team together?

Dr. Rattray: Yeah, I mean, I think part of it is exactly what you said, we work as a team together. This is really something that always is a team activity. You just can't stress that enough in terms of the bedside nurse, the nurse practitioner, respiratory therapists, and all the people that are involved in the care of the baby. I do think that we definitely should incorporate palliative care. That's something that we do at our hospital because for some babies like you were referring to that are born so early. It is a trial of life, and we often do get to a place where palliative care is the right thing for a baby. Having the resources and the best setup to guide parents through that, I think, is really the best thing to do.

Dr. Hillyer: Now, as you were telling these stories, it's not just your story, but it's someone else's story, families. Were there any concerns that you had when bringing these stories to life for the reader?

Dr. Rattray: Yeah, so there are huge concerns when doing this. Part of it is that I feel like I'm just tasked with the hugest responsibility to get it right because I'm remembering babies' lives. I'm remembering families. So, that's perhaps the biggest weight that I felt. I really felt compelled to tell their stories too. Sort of both feelings compelled to tell the stories and really wanting it to truly portray what happened the right way.

The other part of it, of course, is privacy and protecting family privacy, so I changed a lot of details to make sure that I was providing that level of privacy for families. There's one family that actually asked when I ended up interviewing the mom to get a little bit more of a story from her perspective. She wanted me to keep her babies' names the same and keep the story the same. So, there's one chapter where I actually didn't change anything, and that was based on her request.

Then there's a reunion chapter where I use the baby's name again because the mother asked me to, but everything else, I've changed things. The essential part of the story is exactly the same, but enough has changed so that you can't tell which baby it was.

Dr. Hillyer: As we go through this book, we're seeing your growth, as you said, but what kind of growth or direction do you think this book can help others?

"Well, my hope is that it helps us with the connection. I've had a lot of nurses read the book who says, I didn't know that you felt this way; we feel this way too. I think that speaks to the way that we practice. You know, we can have a pretty rough day, and at the end of the day, everybody goes home."

Dr. Rattray: Well, my hope is that it helps us with the connection. I've had a lot of nurses read the book who says, I didn't know that you felt this way; we feel this way too. I think that speaks to the way that we practice. You know, we can have a pretty rough day, and at the end of the day, everybody goes home. We talk during the day about medical care, and here are the orders that are changing; here's the plan of care. Asking the bedside nurse, what they think about certain things, but we're really not talking about the emotional part of these situations at all. I think partly a book can really help bridge that gap. I mean, I think we should be talking to each other as well, but I think sometimes you can express things in a book that you can't always say, and sometimes you know, especially for me, it takes me a long time to figure out what I'm feeling and thinking. A book allows me to do that.

Dr. Hillyer: So, with this book coming out, you've said nurses come to you and reflect on some of the stories that you told. Seeing themselves in it. Has it changed your practice and your interaction today?

"Certainly, doing all the right medical things, but also being just more human, more down to earth. That's the goal. Just more connection with the parents and also with all of us in the NICU, the staff."

Dr. Rattray: I think it's changed; in that, I feel even more comfortable with parents in terms of trying to interact with them where they are. Just trying to be more personable. Certainly, doing all the right medical things, but also being just more human, more down to earth. That's the goal. Just more connection with the parents and also with all of us in the NICU, the staff.

Dr. Hillyer: As I remember reading through some of the different stories, some of the different chapters. Things like the Sniper story that was extremely powerful to me. Was there a story that didn't quite make the cut of the book? That you really felt was also powerful and may have changed the direction in which you viewed things.

Dr. Rattray: Yeah, so the interesting thing is there are actually chapters that didn't make it into the book. The hard part, I think about a book like this, is that you end up with some cases that just aren't that dramatic. You have a baby who's maybe delivered early and has a really significant course from a parental standpoint, but it's just not something that you can write down in a way that's compelling. Or really, sometimes the stories just don't go anywhere. So, I definitely had some chapters like that that I really wanted to make work because I had a strong interaction with the parents. I really cared about the babies and wanted to tell their stories, but every time I rewrote the chapter, it just didn't go anywhere. I don't know that it really changed the book, necessarily.

" So, I definitely had some chapters like that that I really wanted to make work because I had a strong interaction with the parents. I really cared about the babies and wanted to tell their stories, but every time I rewrote the chapter, it just didn't go anywhere."

Then there's another story that I wish I could have put in, which was actually the backstory for the baby that I saw at the reunion. He actually had hydrops, but it happened so far in the past. Probably when I was so sleep-deprived as a Fellow. I just could not make it come alive on the page, so I ended up putting him into the reunions

chapter. The thing that's really interesting about that, though, is I realized that's actually where he belongs in my story because, as significant as his story was in the NICU. He's more significant in a way to me now out of the NICU because his mom has texted me pictures and sent me photos as he's grown up, and getting to see him like grow up has just been amazing. So, he's really significant to me more in that reunion way. It's not to say that he wasn't significant in the NICU because he was, and I remembered. I remember that time really vividly; I just couldn't make it come alive the way I could once he was out of the NICU.

"Were there any times during your fellowship or as an Attending where you felt that one of these stories, whether one that's made it in the book or one that wasn't able to make it in the book, really had you re-evaluate the direction in which you were going as a physician?"

Dr. Hillyer: That's understandable, and I really think that, like you said, that reunion part is very powerful. Also, it's one of those factors that keep us moving forward and driving forward. Were there any times during your fellowship or as an Attending where you felt that one of these stories, whether one that's made it in the book or one that wasn't able to make it in the book, really had you re-evaluate the direction in which you were going as a physician?

Dr. Rattray: That's a great question. I mean, I think I've always been pretty steadfast in my direction; I don't think that I've ever really hit that place where I thought, you know, I'm going to throw in the towel. I'm not doing this anymore. I certainly have had times where I've really had self-doubt and really worried.

In one of the stories, we have twins, and one of the babies ends up having sepsis and dies. The other one, because of the other twin getting sick, alerted us. We did a CBC and early screening for infection, and it was flagged as high risk. We got a blood culture, started antibiotics, and sure enough, the other baby was also getting bacteremic and getting septic. That was a really difficult time, where I wondered have we started the right antibiotics on the sibling who died. Was there more that we could have done? As it turns out, we did start the right antibiotics, and we did everything we could. It definitely was a stressful time and really made me wonder if we'd made the right choices.

Dr. Hillyer: Now that stress, the continued questioning of whether or not you ordered the right antibiotics, ordered the right labs. It doesn't just stop as soon as you walk out of the Neonatal Intensive Care Unit. How do you deal with that going home?

Dr. Rattray: So, you're right about that. You just bring it right home; I mean, I try and have that decompression time as I'm driving in the car, but the truth is you bring it home. I think I even wrote in that story; I was periodically going to my laptop and logging into the electronic health record just to see how the baby was doing. What the blood culture was, seeing what the sensitivities were. So yeah, I mean, I think the main thing is to try and stay grounded as much as possible. I really try and be in the moment with the kids, be in the moment when I'm at home. Really focus on those things, and sometimes I do a better job than other times. Even the administrative part of work can get the better of me sometimes. I'm checking my cell phone and checking my work emails at nine o'clock at night. I think, why am I doing this right now? This email can wait until tomorrow. I think there's that weird mix of administrative and leadership responsibilities and clinical responsibilities that sometimes it's really hard to walk away from.

"I'm checking my cell phone and checking my work emails at nine o'clock at night. I think, why am I doing this right now? This email can wait until tomorrow. I think there's that weird mix of administrative and leadership responsibilities and clinical responsibilities that sometimes it's really hard to walk away from."

Dr. Hillyer: Absolutely, and I can understand that this has been something that you've just started to realize, especially during the pandemic, where we've really had to put a mirror in front of us. Being in the healthcare field, learning how to decompress. To step away, to find that healing for yourself. Was this something that you've been working on throughout your progression? Or is this something that during this pandemic really has made you, kind of, focus on?

Dr. Rattray: I think both. I think I go through these cycles where I'm not very good at my work-life balance, and things feel really out of kilter. Then I'll set some guard rails. I'll say that there's no more logging in at night, no

more checking my email past six or seven at night. I put those guard rails in. But then something will come up, and I'll end up kind of falling back into it a little bit. So, I think to keep recalibrating. I think the pandemic definitely puts the pressure on us to draw those boundaries in a way because, you know, it's been such an intense time. Even for us in neonatology, I mean, I can't imagine, for our colleagues in Adult Intensive Care. I think certainly we really have to remember kind of who we are as people and do things that help us to decompress.

"Even for us in neonatology, I mean, I can't imagine, for our colleagues in Adult Intensive Care. I think certainly we really have to remember kind of who we are as people and do things that help us to decompress."

Dr. Hillyer: Absolutely, and as we've now gone through this pandemic. We're also going through a time where politics is once again becoming a factor. Especially in the neonatal world, it may become a factor as our legal system looks at Roe vs. Wade. Do you have any kind of thought process as far as how you think this may affect us in the neonatal world?

"Especially in the neonatal world, it may become a factor as our legal system looks at Roe vs. Wade. Do you have any kind of thought process as far as how you think this may affect us in the neonatal world?"

Dr. Rattray: That's a great question. One of the interesting things is this morning, I was just listening to a podcast that was really focusing on the nuance of everything. Right now, as you're alluding to, everything is so incredibly polarized, and the reality is there's so much more nuance to everything than I think the politicians at least can really allow for. I think, more than anything, if we can care for and love the people around us, my opinion is that that's what we're called to do. It's interesting to wonder how these changes might affect us. Certainly, something that I've been thinking about, and it's tough to say right now. It's so difficult to predict how things will be in the future. I think, especially in healthcare, I think we're called to serve the people around us. So, I think that that's where our focus should be.

Dr. Hillyer: I know that in our neonatal world, there is this balance with ethics. Especially when it comes to the extremely low birth weight infants between the bounds of 24, 23, to 22 weeks, is there a point in time where you think healthcare and Medicine won't be able to push anymore? That it will cause a direct conflict with what's going on with the rest of our society?

Dr. Rattray: It's a great question because it feels like it always changes. If you talk to people that are older than us, for example, they'll say, "Wow, I remember when 28 weeks was just the earliest that we could save a baby." Yet, here we are; we're wrestling right now, in our center, with 22 weeks trying to decide how ethical it is for us, given our outcomes, to really push that boundary. I think a lot of centers around us we're really struggling with that. It certainly feels right now like 20 weeks. I just can't imagine going lower than 22 weeks without a massive change in technology; in the way that we practice. That would be a completely different paradigm. So, it's interesting because you wonder if anyone ever looking back on this interview in 10 years or 20 years could potentially be so different at that point.

"I think a lot of centers around us we're really struggling with that. It certainly feels right now like 20 weeks. I just can't imagine going lower than 22 weeks without a massive change in technology; in the way that we practice. That would be a completely different paradigm."

Dr. Hillyer: You're right. Technology changes consistently, and Medicine keeps pushing the boundaries. It's been amazing to see that neonatology is still considered a very young part of Medicine.

Dr. Rattray: Yeah, but kind of like you're pointing out, though, at what point are we doing families a disservice. If you get to that point where the outcomes are so poor, then we're really doing a disservice. On the other hand, though, this is the tension. There's always so much tension here because we want to help families; we want to save babies. Some babies have really wonderful outcomes like we were talking about baby Faith, who was born so early and had such an amazing outcome. Then you don't want to pull these kinds of kids. Sometimes you can pull an outlier case and then base your whole prac-

tice on that; that doesn't seem like the right thing to do either. So, there's a very real tension. As it happened to me last week, it happened at two o'clock in the morning very, very quickly with a baby who was approaching 23 weeks. I had five minutes to talk to mom; dad was out of state. You know, five minutes, two o'clock in the morning to make these really big decisions. So yeah, these things are never, never easy.

"Now, these decisions aren't just NICU to parent, but we also bring in our OB colleagues. They're also struggling during this time with maternal death rates. Is there a way that we are able to collaborate with them?"

Dr. Hillyer: Now, these decisions aren't just NICU to parent, but we also bring in our OB colleagues. They're also struggling during this time with maternal death rates. Is there a way that we are able to collaborate with them? Dealing with the holistic care of a family when there may be issues with maternal mortality and morbidity and then the neonatal side of mortality and morbidities.

Dr. Rattray: Right. Yeah, I mean, I think that's the most important thing is having that collaboration. Sometimes everything happens so quickly that it's hard to have a good conversation, but it's the ideal case when we can. I had a case where I was working closely with Maternal-Fetal Medicine and the OB over the course of two weeks. We had a baby that was actually too growth-restricted for us to be able to intubate if they delivered. That was a case where even though the chance of intrauterine demise was fairly high since it was essentially 100 if they delivered. We just tracked everything really closely, but that was a good situation where we had really good collaboration, and we had a great outcome. I think that's the key because you're pointing out that we're not just balancing the baby. We're balancing the mom as well and the mom's health. So, we really have to keep everything in mind and hopefully have really good discussions.

Dr. Hillyer: As we talked earlier also about the technological advances that we've seen, we also see advances when it comes to the human genome. How do you see that play an effect on our medical management and care?

Dr. Rattray: That's a great question and one that I don't think I can answer right now. Certainly, it looks like there is technology for isolated diseases to modify. Once again, it seems like there's so many ethical questions that come up both for the obstetricians and for us. Because you can certainly see situations where you know, modifying something to get rid of a lethal disease could be very beneficial or a disease that's a lifelong impairing disease. You could certainly see the benefit there, but then it's also easy to quickly see how that can become a very dangerous situation. Where you're no longer just modifying single diseases, but you're modifying all sorts of things and really tailoring, which could be a very big problem.

Dr. Hillyer: One of the things that you talked about was what you hoped your colleagues would get out of this book. What if a parent was to read your book? What would you hope that they would get out of it?

"A lot of them actually just said it really helped them to know how much the medical community cares about their babies because they can see we're thinking about their babies as we're driving home, we're thinking about their babies at home. We really, really care. We're not just punching the clock from eight to five. This is our life, and we really care, and so I think it really helps them to know that."

Dr. Rattray: It's interesting because I have; I've told a number of parents do not read the book because I'm afraid that it might cause some sort of PTSD for them. Or, at least if you read it, please wait until you're out of the NICU. I mean, that's definitely important, but I've actually had a number of parents who have read it and have given me feedback. A lot of them actually just said it really helped them to know how much the medical community cares about their babies because they can see we're thinking about their babies as we're driving home, we're thinking about their babies at home. We really, really care. We're not just punching the clock from eight to five. This is our life, and we really care, and so I think it really helps them to know that. I've actually had really good feedback from parents, but in terms of the target audience, I wouldn't say that that's really my target audience. It's been surprising. I thought, talking about target audiences; I thought that maybe then the nurses wouldn't be that interested in the book because it's kind of like reading about what you do at work all day. It's like,

maybe you just want to come home and watch a legal thing or something totally removed from work, but they have been my biggest supporters. So, there's sort of surprises, I think, along the way about who wants to read the book, I should say.

Dr. Hillyer: Well, it definitely hit home for me, and I enjoyed reading it. As a nurse, I could definitely see your thoughts as far as what it's like for the parents to read it and why you might not want to have them read it. But also, for those parents that do read it, letting them get that sense that we do care, even after, like you said, we're not just punching the clock. If you were to write another book, what do you think that book would be a reflection of?

"I think my writing at the moment is more articles talking about reflection, talking about drawing near, and observing. I'd like to try my hand at a novel, and I've got a rough draft. I'm not sure if it's going to go anywhere. It's all up in the air right now."

Dr. Rattray: I think I'm done with the NICU stories for now. It's hard to imagine writing another book because I feel like it would just be too similar. I think my writing at the moment is more articles talking about reflection, talking about drawing near, and observing. I'd like to try my hand at a novel, and I've got a rough draft. I'm not sure if it's going to go anywhere. It's all up in the air right now.

Dr. Hillyer: Well, you were able to put together some really compelling stories, some heart-wrenching stories. So whatever direction you choose to go for your next book. I'm sure it is going to be just fascinating. Is there any other work that you're doing out there that you would like us and my audience to know about?

Dr. Rattray: I think the biggest thing right now is I'm mainly involved in local leadership in our NICU. I do have a website, which is my name benjaminrattray.com. Where I'm putting some blog posts and also some links to media, definitely, each blog takes me a very, very long time to put up on the website. It's just, I'm a very kind of slow writer. Some people I know can put out a blog a week or a blog a day, and it turns out that's not me. But I do have some blog posts up there, so that's where I can be found online.

Dr. Hillyer: I look forward to going to that website and checking out some of those blogs. I don't write a lot, I talked to someone, and they said within their first day, they just wrote pages and pages, and I was just amazed.

Dr. Rattray: Oh, I know that is not me. I mean, Hemingway said, "writing is easy. You just sit there and bleed." That is me; it's like I could spend an entire morning changing two words around and then put them back the way they were. Or, like, one sentence could take me an hour. So, it's a pretty slow, sometimes painful process, but it's also very rewarding when I feel like I've been able to express some of the things that I've been thinking and feeling.

Dr. Hillyer: Well, I think this book really did grasp some of those things that you were feeling as you processed and went through your journey into neonatology. I hope that you continue to find that balance. That work-life balance and find the pleasure in writing your next book, and then I look forward to seeing the blogs and anything else.

Dr. Rattray: Thank you. I appreciate that.

Dr. Hillyer: I want to thank you for joining us on today's segment of Neonatology Today with Dr. Benjamin Rattray.

Thank you for joining us.

Dr. Rattray: Thanks so much for having me.

NT

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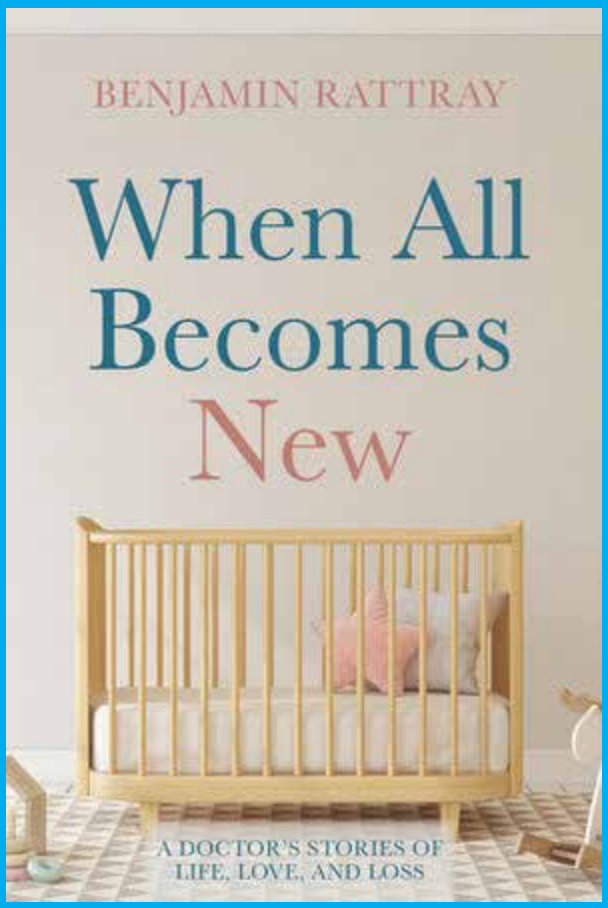

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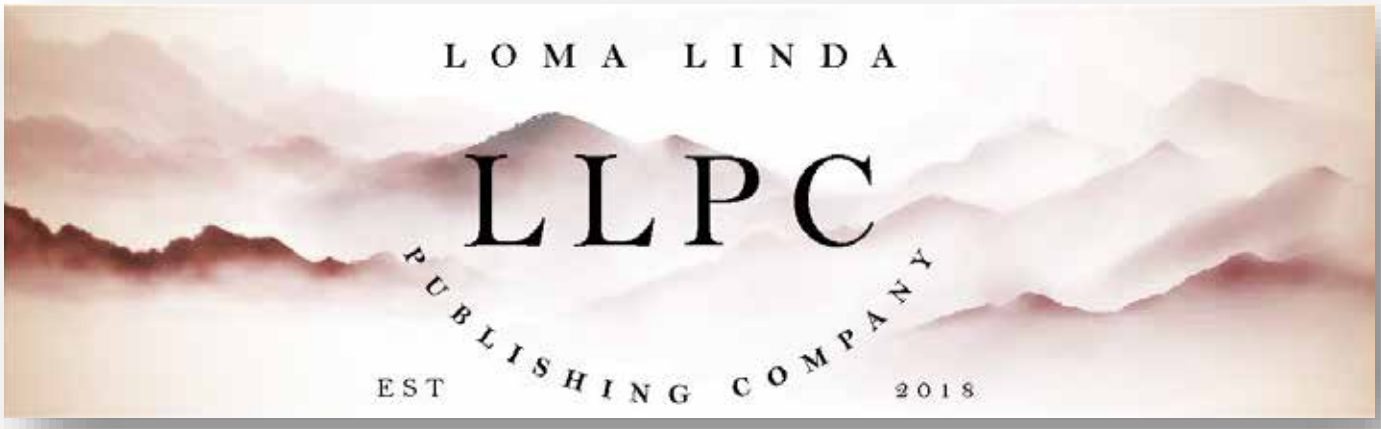

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High-Reliability Organizing (HRO) is Contextual

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

Abstract:

HRO emerged from engagement with a flux of contingencies to make them more orderly. We cannot treat these environments as isolated systems with demarcated boundaries. Instead, the environment comprises of open, contextual systems always in flux. These sequential events are better viewed as 'state vectors' acting like arrows in time, rather than discrete, sequential events. Rational ('top down') and heuristic ('bottom up') cognitive approaches have limits when engaging these dynamic, open systems. We propose that context-focused engagement reduces the error of "engaged abstraction" and that quantum cognition contains elements used by HRO operators.

"These sequential events are better viewed as 'state vectors' acting like arrows in time, rather than discrete, sequential events. Rational ('top down') and heuristic ('bottom up') cognitive approaches have limits when engaging these dynamic, open systems. "

Introduction:

When we understand the origins of HRO, we can better understand the driving forces of HRO. From WWII through the Vietnam War, the US Navy's Pacific Fleet conducted most of the US Navy's combat operations. The exigencies of combat made it imperative for everyone to identify effective actions and retain what they learned. Safety is vital even during wartime, and accidents are investigated. Safety in combat has an additional function because avoidable operational loss causes unaffordable shortages of men and planes and increases vulnerability to enemy activity. The introduction of the first *nuclear* aircraft carriers in the Pacific Fleet brought together three independent, otherwise disparate domains within a single individual: 1) aerial warfare experience with initiative, improvisation, and flexibility, 2) nuclear propulsion engineering experience with rigor, detail, and conformity to procedures; and 3) previous aircraft squadron and large ship command of complex organizations in demanding circumstances (1). HRO, codified by the UC Berkeley HRO (High-Reliability Organizing) Project, emerged from the Nimitz class nuclear aircraft carriers, US Navy's Pacific Fleet (2, 3).

In the medical world, practitioners engage with a flux of contingencies to make them more orderly and safer. Efforts to enact order sometimes succeed, sometimes fail, but most often, they produce both. Unfortunately, that mixing can threaten reliable functioning. The healthcare community has translated HRO to enact order in the flux of contingencies, support safety, and achieve reliability in the performance of healthcare (4-6).

"When operations, in the context of combat, are translated into more abstract normative statements, this can lead to nuances, fine-tuning, and subtle yet essential cues getting lost. Nuances can get restored by engagement and action."

When operations, in the context of combat, are translated into more abstract normative statements, this can lead to nuances, fine-tuning, and subtle yet essential cues getting lost. Nuances can get restored by engagement and action. However, the context, which is a powerful component, is missed when translating HRO from a combat to a healthcare setting. Sensemaking is created from the context. Then subsequently, action emerges from this sensemaking in context. Thus, the incomplete translation of HRO will risk the loss of vital nuances in sensemaking, which are only found through the contextual engagement of the embedded, ill-structured problem (7).

Karl Weick (8) used the sinking of the El Faro, a 90-foot container ship, to describe the consequence of using abstractions to interpret contextual circumstances. The captain abstracted his experience with Alaskan winter storms to the context of a Caribbean hurricane. However, Alaskan storms demonstrate strong winds from one direction, while Caribbean hurricanes have strong winds that gradually change directions. This error resulted in him taking the ship into the eye of a Category 3 hurricane.

"Abstractions can help make the situation more understandable but also result in the loss of unique details from the original context of the circumstance. Concepts then become a definite "form" we treat as fixed and absolute rather than abstractions that are the farthest removed from our original perceptions. "

Abstractions can help make the situation more understandable but also result in the loss of unique details from the original context of the circumstance. Concepts then become a definite "form" we treat as fixed and absolute rather than abstractions that are the farthest removed from our original perceptions. When we convert our perceptions into abstractions, the experience flow is interrupted, and we lose alternative insights (8). When we use abstractions to make the situation more comprehensible, we develop "engaged abstraction" – sensemaking is no longer sufficiently contextualized (9). We break our present-at-hand existence into parts. As Karl Weick states, "Actions always occur in a specific context" (personal communication).

"When we witness an event as spectators from the outside, we can focus on specific locations in space or time. We independently observe the flow of events and the rate of change as separable sequences. We can then also readily decontextualize events and experiences, enabling us to think with abstractions. "

When we witness an event as spectators from the *outside*, we can focus on specific locations in space or time. We independently observe the flow of events and the rate of change as separable sequences. We can then also readily decontextualize events and experiences, enabling us to think with abstractions. We may prefer to call the spectator's observations 'objective evaluations.' However, there is a purpose in choosing such an external framework: we can form abstractions that are harder to disconfirm and fit easier into our understanding without changing that understanding. The selection of an *external* framework becomes a subjective selection of experience to fit our understanding. We risk developing Sanberg and Tsoukas's "engaged abstraction."

When viewed from *within* the flow of events, our observations are made with context and later become perceptions that influence our actions. Actions emerging from within the context of events become experiences (10). Abstractions quickly lose their function and become dangerous if they do not. From this *internal* framework, we respond to continuous local changes in position and pressure. We have less concern for the general flow of the event and more interest in changing its trajectory. By focusing on the flux of our *individual* segment, the "flow" that we experience the event reveals the constraints that the environment places on perception. Our understanding must fit our contextual experience.

A crisis has flux, and how the spectator or operator experiences that change influences their system information and communication. Contextual experience is unnoticeable from a fixed, external point of observation distant from events. Even within an event, our experience will differ from those around us or even working alongside us. The operator responds to local threats within the event space by creating a trajectory toward stabilization and recovery.

The academic and management science literature commonly uses the 'top-down' perspective from a fixed point outside the flux of events. The benefit is more precise information and quantitative data that produces a normal distribution for statistical analysis and probability predictions.

The operator within the flux of events, the 'bottom-up' perspective, is personally at risk during changing contexts, necessitating rapid updating of less reliable and evolving information. The internal frame relies on accurate information and communication for practical descriptions, vital characteristics when novel demands appear or rapidly increase, and unrecognized shifts in resource availability.

Operators within a crisis focus on context and what they can learn; spectators focus on what they already know.

Notions of high reliability will emphasize this difference. The high-reliability theory relies partially on how the outside view depends on codifying a framework of guiding principles. However, if those principles are seen as the essence of producing reliability, then the importance gets misplaced. Reliability is more assured when practical engagement dominates practice because this allows adjustment to the flux of circumstances. The constituents of that engagement make "higher reliability" a property of work.

This becomes the difficulty of HRO implementation – principles understood at the executive level do not support the practical engagement of disruptions. The expectation arises for operators to fit their experience into institutional understanding. Institutional expectations affect documentation, reinforcing institutional knowledge to ensure homeostatic stability, no matter how brittle.

Open Systems Create Context

We cannot treat the environment as an isolated system with demarcated boundaries. System behavior is generated by its openness, *not* a complication of openness (11). Environmental factors influence the activity and behavior of the elements and the people in this environment. Open systems are contextual.

Like the world around us, healthcare is an open system exchanging resources, energy, and information with the environment. This is like the biotic and abiotic ecological processes that interact to stabilize and sustain an ecological system. Information from the environment shapes the system's activities, while participants within the system alter the environment. This is also a form of information. This flow of information between the system and participants creates complex feedback relationships. Feedback loops can be short, long, indirect, delayed, etcetera.

"Like the world around us, healthcare is an open system exchanging resources, energy, and information with the environment. This is like the biotic and abiotic ecological processes that interact to stabilize and sustain an ecological system. Information from the environment shapes the system's activities, "

Neonatologists effectively merge the subjective into the objective – the process of contextualization. Opacity, ethical uncertainties, physiologic instability, shifting probabilities, and changing trajectories are inherent to the work of a Neonatologist. The Neonatologist becomes acquainted with the neonate's parents, family, and culture during great stress and distraction. The NICU is a microenvironment of the hospital in a healthcare system supported by other systems. This is not unlike other sciences that do not have pure objectivity: biologists, ecologists, psychologists, and sociologists.

The Logic for Contextuality

Research on human cognition is based on probabilistic models from probability theory. Quantum models of cognition are based on contextuality, how conditions of uncertainty interfere with a person's inferences and decisions (12).

Probability theory formalizes probability as a 'probability space,' specified as a measurable space with measurable subsets (a subset is an event) and a 'probability measure' between 0 and 1. Central to probability theory are random variables, probability distributions, and stochastic processes. From probability theory, we have both the law of large numbers and the central limit theorem. The Kolmogorov axioms (Andrey Kolmogorov) are the foundations of probability theory and mainstays for psychology and cognitive science.

"For entangled quantum systems, this operation may not be valid. Random variables from different distributions do not always have joint probability distributions. In quantum theory, the inability to combine different probability distributions into a joint probability distribution is known as contextuality (13)."

Observed data allowed us to combine the probability distributions of two random variables using probability theory. The data must come from the same probability space to create such a joint probability distribution. For entangled quantum systems, this operation may not be valid. Random variables from different distributions do not always have joint probability distributions. In quantum theory, the inability to combine different probability distributions into a joint probability distribution is known as *contextuality* (13).

It may seem as though the subjective character of context and contextuality would corrupt the objective nature of science. A significant source for this misconception is the inability to utilize probability theory in an open system. Kolmogorov recognized contextuality at the classical level, stating that all probability measures needed to be linked to specific contexts ((14) in (11)). Failure to consider contextuality leads to the misapplication of Kolmogorov probability theory at the classical level (11).

Some abstract principles in quantum theory are relevant to cognitive phenomena: superposition, compatibility, and complementarity.

Superposition is the sequential placement of system interactions.

In classical probability theory, the system is in a definite state with respect to possible states. When the state changes across time, it is a definite state at each moment, and the system produces a definite path. In Boolean logic, events can be combined in any order, 'A and B' equals 'B and A,' the logical conjunction is commutative.

In quantum probability theory, a system is in an indefinite (dispersed) superposition state *until a measurement is performed* on the system. All possible definite states have the potential to be actualized, but only one of them will become actual *upon measurement*. In Boolean logic, the order of combining events will change the system. 'A and B' does *not* equal 'B and A,' making the logical conjunction non-commutative.

Processes are a series of time-based steps. For continuous time as experienced, there are no gaps in the temporal order. A dense sequence always has a discrete element between any two sequential elements. In a continuous sequence, there are an infinite number of elements between any two such elements. This is for "instant-based" models. We use "interval-based" models for reasoning about events with duration [15]. The difference is whether we talk in terms of time "instants" or time "intervals." Classical logic assumes discrete elements and time measures. Logics used in HROs or quantum theory allow for partial truths (modal logics) and accept conflicting information (paraconsistent logics) (15).

This may seem a trivial distinction. Operations occur in "instant-based" time. The operator experiences continuous, smoothly changing elements but must communicate with other operators as though the elements are dense and changing as discretely different elements. Spectators observe "interval-based" time, which is also used for planning and algorithms. "Response to therapy guides further therapy as a "different" patient is created each time. The "sensed" patient, or the patient we evaluate for purposes of management, does not exist later for review. Only the "monitored" patient does; this patient is the patient reconstructed later from monitored and recorded data and caregiver notes for diagnosis, heuristics, or legal reasons. The two patients are not identical" (16).

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Our actions in an ambiguous or uncertain situation, even when we arrive or take a measurement, change the situation. The following action has a different value and response than had the action occurred first. Karl Weick (17) described superposition as a property of enactment:

> "The explorer cannot know what he is facing until he faces it and then looks back over the episode to sort out what happened, a sequence that involves retrospective sensemaking. But the act of exploring itself impacts what is being explored, which means that parts of what the explorer discovers retrospectively are consequences of his own making… Action precedes cognition and focuses cognition."

Compatibility, whether two questions can be answered simultaneously or sequentially.

The questions are compatible if two questions can be answered simultaneously or if the order does not matter. In classical probability models, we can describe all events within a single, compatible collection of events. If the two questions must be answered sequentially, and the order matters, the questions are incompatible.

Principle of complementarity, some questions are incompatible

(the effect of sequence)

Incompatible questions provide different perspectives of an event, perspectives we need to understand the world (13). The Heisenberg Uncertainty Principle is a product of the principle of complementarity. We can be certain about the particle's position or momentum, but not both simultaneously.

This is relevant for us to know a person's understanding of two events, such as their understanding of the beliefs or experiences of two different people or processing two different perspectives of the same matter. We must switch between points of view, and the points of view may not be compatible. Presenting two perspectives or points of view can imply incompatibility; the person cannot process both perspectives simultaneously. Superposition means one cannot decide a matter from more than one perspective – to choose from one perspective; you are making your cognitive state dispersed (making indefinite) for the other perspective (13).

"Presenting two perspectives or points of view can imply incompatibility; the person cannot process both perspectives simultaneously. Superposition means one cannot decide a matter from more than one perspective – to choose from one perspective; you are making your cognitive state dispersed (making indefinite) for the other perspective (13)."

Inherent Vice

Compatibility and complementarity explain the dictum of fire rescue ambulance personnel who trained one of the authors: "What helps us now can hurt us later; what hurts us now can help us later."

Compatibility and complementarity help us understand the inherent vice of stress and fear. The activation sequence of the locus coeruleus versus the hypothalamus-pituitary-adrenal axis can affect dominance during a stress response of norepinephrine or cortisol. The sequence for the ability to escape or gain control of the situation compared to the presentation of the position (context) of the threat can determine flight versus fight fear responses (18).

We borrow the insurance term "inherent vice" to describe how the desired qualities of a commodity can damage the commodity. For example, stress disables the executive functions for rapid adaptive response to novel, uncertain, or uncontrollable situations. Stress also impairs cognition and memory recall, confounding efforts to develop a solution.

Events: States or Vectors

In quantum probability theory, events are treated as vector spaces rather than subsets of a universal set. Within the circumstances, an element or person is not a subset of a larger set. Instead, they are elements as vectors with potential directions. We do not know the direction, and the person does not know until they move or act. This better fits our experience in abrupt crises: things do not go as we expect, and people do not necessarily behave as we expect.

A state vector acts like an arrow in time, replacing probability values used in classical logic (13). Concepts change continuously under the influence of context. The change is 'the change of state of the concept.' Concepts, then, can be modeled as a quantum entities influenced by the contexts of measurement (19). HRO is the dynamic, physical enactment of the contextual. It is not a state variable to achieve,

"Academic studies of decision-making fall into two distinct approaches, a decontextualized rational approach and a heuristic approach using 'bounded rationality' that recognizes the contextual limits of human cognition (20, 21). Operators in dangerous contexts find that these two approaches neither describe nor prescribe how operators make decisions in dangerous contexts (22-27)."

Decisions within Context

Academic studies of decision-making fall into two distinct approaches, a decontextualized rational approach and a heuristic approach using 'bounded rationality' that recognizes the contextual limits of human cognition (20, 21). Operators in dangerous contexts find that these two approaches neither describe nor prescribe how operators make decisions in dangerous contexts (22-27). 'Quantum cognition,' derived from quantum theory, adopted mathematical approaches developed to address contextual influences encountered in quantum physics (11, 13).

Rational approaches comprising 'top-down' deductive approaches will incorporate subjective probability and expected utility. Models assume people are rational actors whose decisions meet an expected utility. Fundamental axioms to derive inferences are independent of context (28). Rational approaches to decision-making use Bayes Theorem and are found in game theory and decision theory. Scientific rationality and classical logic work well with what Herbert Simon calls the well-structured problem (29) but fail in the VUCA-2T environment or when experiencing liminality (15) [Table 1].

"Rational approaches to decision-making use Bayes Theorem and are found in game theory and decision theory. Scientific rationality and classical logic work well with what Herbert Simon calls the well-structured problem (29) but fail in the VUCA-2T environment or when experiencing liminality (15) [Table 1]."

Heuristic approaches are bottom-up inductive processes that incorporate contextuality for Simon's ill-structured problem. Simon acknowledged the limits of human cognition with his concept of

'bounded rationality.' Heuristics, rather than algorithms, would overcome the limitations posed by both the problem and cognition (20, 29-31). Heuristic approaches support operations in the VUCA-2T environment [Table 1].

Table 1. VUCA-2T (3)

Volatility	Rapid, abrupt changes in events
Uncertainty	Lack of precise knowledge, need for more information, unavailability of the necessary information
Complexity	A large number of interconnected, changing parts
Ambiguity	Multiple interpretations, causes, or outcomes
Threat	Impaired cognition and decision-making
Time Compression	Limitations acquiring information, deciding or acting before consequential changes

Quantum cognition accepts the limits of human cognition and bounded rationality with a heuristic approach. In common with the rational approach are inferences from a defined probability theory derived from basic axioms (11, 13), described in "The Logic of Contextuality" above.

Superposition

In the superposition state, there is no single trajectory or algorithm for a decision, leaving the individual conflicted until the moment of decision (12). Irving Janis and Leon Mann identified the effects of such conflict on decision-making (32) [Table 2]. Cognitive decision-making models assume that we can immediately know the antecedent state of mind before the inquiry. In quantum cognition, the act of deciding *creates* the cognitive state. This is like Niko Tinbergen's approach to animal behavior – we do not investigate until we see the behavior, and antecedents cannot be identified. Quantum cognition would investigate the 'function' of a decision like Tinbergen investigated the 'function' of behavior (see "Contextuality and the Function of Behavior," below). Deciding can also create the emotional state of fear or gastric distress (tonic immobility), strongly influencing social interactions and collaborative decision-making (33).

"Cognitive decision-making models assume that we can immediately know the antecedent state of mind before the inquiry. In quantum cognition, the act of deciding creates the cognitive state. This is like Niko Tinbergen's approach to animal behavior – we do not investigate until we see the behavior, and antecedents cannot be identified. Quantum cognition would investigate the 'function' of a decision like Tinbergen investigated the 'function' of behavior (see "Contextuality and the Function of Behavior," below)."

Table 2: Conflicted Decision-Making (32)

Decision Strategy	Characteristics
Vigilance	"A thorough information search, unbiased assimilation of new information and other qualities of high-quality decision-making" Awareness of serious risks for *no* protective action taken and when protective actions *are* taken Compare the risk of acting and the risk of doing nothing.
Hypervigilance	A nonselective search for information and a rapid, cursory evaluation of data Only consider limited alternatives; do not review the decisions Thought processes are simplistic and easily disrupted. If an action is not fruitful, then develop a new action plan, continuing this cycle in response to local successes and failures
Unconflicted inertia	A decision raises little emotional arousal Maintain the status quo – no decision process, no decision made ["no decision" *is* a decision]
Unconflicted change	After considering other courses of action, choose an alternative that offers no serious risks
Defensive avoidance	Belief there are no good alternatives Give up the search Minimize threat cues Develop "fatalistic beliefs that support a precariously optimistic outcome."

Inquiry can also create a cognitive state when the individual's state is ambiguous. Asking if the person is afraid creates fear ("Should I be?") (13). This is like workers in dangerous contexts; while they can feel fear, they cannot show fear (3).

The answer to a question causes one to respond differently because the question and answer create a new context. One behavior of leadership follows "The questions the leader asks and the answers the leader accepts ((34), 404-405). Questions can be directed to move people, identify discrepancies, or appreciate complexity and ambiguity. Subordinates can develop alternative explanations for events and circumstances.

> William J. Corr, Captain, Los Angeles City Fire Department, would ask firefighters to describe or explain what they were doing. He would compliment them on their skill, expertise, and ingenuity. Over time he began to talk to the firefighters, not to offer suggestions but to ask if they had considered anything else since they'd last spoken. Within a few months, the culture of the fire station had changed.
>
> —Daved van Stralen

Self-Organization is Contextual

In an open system, fluctuations and noise frequencies became contextually dependent. Consequently, context affects which measurements can be observed and what values can be obtained

(11). Interactions in an open system can induce change in the state of the involved processes, if not the process itself. Process algebra, based on Alfred North Whitehead's process theory (35), is a framework for processes that become a sequence of generated events ("actual occasions"). There is a coherent temporal structure, but the generated events in the sequence have a transient existence. Information plays a fundamental role in the unfolding of reality, and the meaning of that information gives coherence to events. Reality emerges out of a series of actual occasions (11).

"There is a coherent temporal structure, but the generated events in the sequence have a transient existence. Information plays a fundamental role in the unfolding of reality, and the meaning of that information gives coherence to events. Reality emerges out of a series of actual occasions (11)."

Local, nonlinear feedback develops order and stabilizes systems through self-organization. Positive feedback contributes to growth and structure, while negative feedback restricts growth. Through self-organization, order comes out of chaos (36), but nonlinear interactions degrade our ability to predict trajectories. Self-organization, then, is contextual.

External environmental fluctuations can correlate on different time and space scales, forming processes with unstable frequencies (37). Internal fluctuations, like self-organization and multiple degrees of freedom, can generate a nonequilibrium dynamical system that regains the lost stability (38). Because red and pink noise ["Context Influences Noise" below] do not form a Gaussian curve, collecting more data does not produce a better norm or stochastic model. Instead, more data increases the variance of the system (39).

In self-organizing systems, structure emerges through nonlinear kinetics. Such dynamic systems require continual flux of energy and matter in an open system, as noted above. The continuous flux of energy supports reactions far away from the equilibrium state. These are termed dissipative structures from their continuous dissipation of energy. Patterns then arise from energy dissipation into the environment (40).

Context Influences the Color of Noise

Random fluctuations of energy without a predominant energy frequency and uncorrelated in time form 'white noise' with a Gaussian distribution. However, feedback, or autocorrelation, increases the power spectrum in the lower frequencies. This creates a long period of 'reddened' noise frequencies discussed below. The Gaussian distribution of white noise is the basis for *objective* classical science and Newtonian physics. Reddened noise creates a power distribution contextual in time and space, introducing complexity and *subjectivity* into science (Table 3).

The order of sequence of interactions between frequencies influences their summation, "incompatibility" in quantum terms. The principle of complementarity describes this incompatibility and the uncertainty principles that derive from them. An accurate or precise prediction of a forcing function is not possible.

In a red noise environment or during a pink noise event, using beliefs derived from probability theory contributes to mistranslations of scientific principles while corrupting the necessary flow of information. The noise process is independent of timescale or magnitude. We need not characterize normal environmental variation differently from catastrophes (39).

The long periods of red noise frequencies carry greater energy, becoming a 'forcing function' that forces a system or population to respond. "External forcing by environmental noise alters the qualitative nature of the dynamics" (37), driving environmental influences into the organization and destabilizing the organization's internal environment. In systems dominated by lower frequencies, that is, increased redness, contextual and ecological processes predominate.

"In these situations, the internal environment becomes ecological – diversity and variation maintain equilibrium (42). Problems become contextual and amenable to pragmatic engagement and solutions."

In these situations, the internal environment becomes ecological – diversity and variation maintain equilibrium (42). Problems become contextual and amenable to pragmatic engagement and solutions.

Color	Structure	Variance	Distribution
White	No frequencies dominate Flattened spectrum	Data *decreases* variance	Gaussian distribution - Elements fully independent - No autocorrelation
Red	Low frequencies dominate Long-period cycles	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	Data *continuously increases* variance Distinguishes pink noise from reddened spectra	Power law distribution - No well-defined long-term mean - No well-defined value at a single point

Table 3. Patterns and Characteristics of Noise (41)

Forcing functions experienced by the individual illuminate the stress response functions and reveal weaknesses in leadership and the social fabric of the organization or culture. Novelty, uncertainty, and uncontrollability, elements that are inherent to red noise, cause stress. (43, 44).

- *Novelty* comes from the emergence of new properties during the nonlinear interactions of self-organization.
- *Uncertainty* is an inherent principle of linear, time-variant systems, a product of the stochastic frequencies in red noise. (Heisenberg's Uncertainty Principle is an example from quantum mechanics.)
- *Unpredictability* develops from stochastic frequencies and the rate of change in the logistic equation that can develop into deterministic chaos (45).

"This quandary of subjective wisdom versus objective knowledge was well known to the Greeks. Aristotle distinguished wisdom from the knowledge within the context – the particulars of a situation. Virtue emphasizes acting for the community values necessary for the common good rather than working in self-interest."

Contextuality as Phronesis

This quandary of subjective wisdom versus objective knowledge was well known to the Greeks. Aristotle distinguished wisdom from the knowledge within the context – the particulars of a situation. Virtue emphasizes acting for the community values necessary for the common good rather than working in self-interest.

In Aristotle's words, *phronesis* (prudence) is an intellectual virtue or characteristic that is "bound up with action, accompanied by reason, and concerned with things good and bad for a human being" (46). Those with prudent judgment consider the good of the community, which makes this one of Aristotle's four cardinal virtues (the others are justice, temperance, and fortitude). The three elements of phronesis are:

- The person (as an actor who possesses character)
- The particular (situation and context)
- Values (a vision of the good of the community, phronesis is a virtue)

Phronesis is acquired by both practice and observation: practice creates the experience, while observation of elders who model this virtue leads to phronesis. The Neonatologist continuously acquires and models phronesis.

"Providence of foresight" is the source for our word "prudence"; the Romans translated *phronesis* as "prudence." Phronesis is now more commonly translated as "practical wisdom."

Contextuality is Irreversible

Feedback loops in self-organizing processes can amplify or dampen long periods in red or pink noise frequencies, affecting, but not preventing, the presentation of forcing functions. A dissipative structure emerges from local, nonlinear reactions (contextuality) supported by the flow of energy (entropy). These dissipative structures are irreversible without adding some form of energy from outside the system. *Contextuality is irreversible*.

"To understand the dynamics of complex systems confronting us, we need a conceptual model that *embraces fundamental irreversible change.* This requires nothing less than a major shift in our interpretation of physical reality," William Sulis, McMaster University, Ontario, Canada (11) [emphasis from the authors]. Karl Weick, while reviewing the HRO Series published in *Neonatology Today*, observed, "The common notion of enactment is wrongly indifferent to materiality. You add that in as it should be."

Each interaction in the system induces a change in the involved process, if not the process itself. These transitions may be transiently irreversible, but the irreversibility of transitions ensures a non-commutative operation (11). Actions that influence the process, no matter how minor, can thus have sustained effects on the system. For decision-making, on the other hand, such irreversible transitions ensure that the consequences of decisions by individuals persist, enabling a collective transition to form.

The transition is not only to a new state or process but to a new probability distribution. Therefore, these systems cannot be represented by a single probability distribution. Irreversibility also means the systems are history-dependent and different histories will have different probabilities for subsequent behaviors. The resulting autocorrelation reddens the noise frequency for that system.

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Context Is from the Hippocampus

Context is hierarchical and critical for episodic memory storage and retrieval. The cognitive map in the hippocampus is the physiological basis for the context (47). Spatial and episodic contexts are formed in the hippocampus as maps, providing representations of context to the brain and tracking changes over time. Recognition of a novel context may lead to exploration, while a familiar context may elicit a past experience in that context. Discrepant or disrupted predictions formed from past experience in the context could lead to a new or modified context representation (48, 49). Different maps for a physical area can be represented if the behavioral or sensory information differs between encounters. An episodic context can change from spatial representation to temporal (chunks of time) defined by the behavioral goal (49).

The hippocampus seems to have four computational functions (49):

- Recognize return to a familiar context and where one is within that context
- Provide a map associating internal (self-motion, dead reck-

oning) and external (sensory) cues
- Map a search to a plan, deliberate, and identify novel paths and connections
- Provide a resource for consolidation

With active behavior or attentive processes, cells in the hippocampus fire in sequential order: cells with place fields behind the animal fire first and cells with place fields farther ahead of the animal fire later. This forms an ensemble representation of spatial trajectories near the animal. Sequences play a more active and complex role in information processing than encoding experience (50).

"With active behavior or attentive processes, cells in the hippocampus fire in sequential order: cells with place fields behind the animal fire first and cells with place fields farther ahead of the animal fire later. "

The hippocampus is part of deliberative decision-making. Hippocampal disruption shifts decision systems away from deliberative planning systems. Transient disruptions of the hippocampus impair working memory (49). Stress also impairs working memory.

The anterior (ventral) hippocampus identifies a change in context, and a significant change is signaled to areas in the cortex concerned with context and the ventromedial prefrontal cortex (vmPFC). Uncertainty and ambiguity in decision-making occur in the vmPFC, incorporating contextual factors into this process. We maintain "flight distance" for safety, behaviorally or emotionally. The flight distance is an animal's security distance from a threat (51). Proximity measured in the hippocampus increases activity in the ventromedial prefrontal cortex (vmPFC), which connects to the amygdala for the determination of the motivational importance of the threat (52).

Contextuality and the Function of Behavior

People and organizations must defend against hostile environments and adverse situations. Outside the flux of events, management science addresses adverse situations through risk and risk management strategies. The HRO operates within the flux of events to engage the situation through capability and the suppression of fear (3, 18).

Fixed constitutive defenses, such as spines or shells for animals or a well-developed hierarchy for an organization, make sense when risks are consistently high or defensive costs are low. Proactive defenses such as rules and protocols are most effective when risks are predictable and controllable (53). The HRO, however, operates where risks vary by location and time, and defenses carry costs. Reactive defenses are more effective and reliable with these increasingly unpredictable or uncontrollable risks (53).

"Every animal has to cope in numerous ways with a hostile, at least uncooperative environment," Nobel laureate Niko Tinbergen. Behavior is the most immediately adaptive method for surviving hostile environments (54).

The spectator, however, does not notice the behavior until it happens, and the spectator doesn't know the individual's mind. Observing behaviors only when they come to attention confounds cause-and-effect reasoning – the event as the arbitrary cause in the flow of time and *the observed behavior as the effect*. The spectator looks backward in time from the behavior to seek the cause. The spectator cannot know the antecedents of the behavior nor the cognitive-affective processes of the individual (54).

Tinbergen (54) treated behaviors as a process, tracing the ever-changing effects of the behavior *forward* in time – *the observed behavior as the cause*, not the effect. Does the observed behavior promote better achievement and survival? Describing how a behavior achieves better survival is to describe the *function* of the behavior. That is, observe the effect of behavior to identify its function. Raymond Novaco changed his focus on studying anger from the *cause* of anger to the *function* of anger after Tinbergen's reasoning (personal communication, DvS).

Behavior is more than a physical act. We couple perception and action, adjusting our actions to changing situations and learning through physical actions (55). Motor cognition, combined with somatic and cognitive knowledge, enhances thinking while acting (17). We use motor cognition when we are actively engaged in an uncertain situation.

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Contextuality and the Ecology of Fear

A predator has greater influence through its absence than its presence; this is the ecology of fear (56). Not only do prey populations decrease, but the ensuing trophic cascade changes the landscape to become a "landscape of fear" (57). The focus of management science on risk and the management of risk rather than increased capabilities and the suppression of fear contributes to the organizational ecology of fear (58). Defense patterns differ if the risk is unpredictable, uncontrollable, variable, and the defense costs are high (53).

Vigilance in the absence of the predator, a defense cost, sustains the stress response with chronically elevated glucocorticoid levels and reduced reproduction (59, 60). Inducible antipredator responses allow selecting antipredator behaviors with variable expression, increasing behaviors for elevated risks and decreasing their expression as the threat abates (53).

Stress. Novelty, uncertainty, and uncontrollability, in the domain of executive functions, cause stress responses (43, 44). Uncontrollability causes minor stress to impair executive functions (61).

Novelty. In any new situation, we can find something familiar; then, we start at that point. We can use metaphors for description and analogies for analogical reasoning. Metaphors carry meaning and assist interpretation when the person using the metaphor has to experience the word or phrase. Analogies have greater applicability to support interpretation and reasoning when the comparison has plausibility, high similarities, and correspondences between domains. Without analogical strength, the metaphors and analo-

gies become thought-terminating cliches (62). We cannot describe or argue against a metaphor or cliché.

Uncertainty. Collecting more data and information to reduce variance is counterproductive in a red noise environment. On the contrary, more information increases variance and uncertainty.

Controllability. The sense of control comes from how we choose and interpret our actions. When people used pencils for examinations, one of the authors (DvS) asked the residents why they brought five sharp pencils to the exam when one dull pencil would suffice. The degree of stress experienced by consulting physicians in an ICU room could be observed by how often they turned the display knob on a mechanical ventilator. They would observe the chest, turn the knob, read the numbers, observe the test, and repeat. What they saw on the ventilator was not a new setting but different displays.

Predictability. Inference to know if therapy will succeed or the course of a disease commonly follows scientific logic and probability statistics. Modal and paraconsistent logics replace scientific logic (15, 63). We cannot develop probabilities because we do not have a Gaussian distribution in red noise environments.

Fear. Proximity in time or space of a threat or an approaching threat. We use Joseph LeDoux and Daniel Pine's (64) description of "fear" as a conscious, subjective feeling generated in *cortical regions* of the brain. Therefore, fear is amenable to conscious interpretation, and consequently, the individual can modulate what we call "fear reactions."

Fear reactions are conscious sensations experienced when exposed to an imminent threat (64, 65). The amygdala sends signals to the brain's unconscious (subcortical) and conscious (prefrontal cortex) regions, accounting for the uncontrolled fear responses and the feeling of fear. The emotional response of fear is to diminish danger (66), creating the drive to avoid or escape, generally focusing on self-interest, self-protection, or the protection of others.

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Response to Thinking and Acting

The human brain will release corticotropin-releasing factor (CRF), which goes to the hypothalamic-pituitary-adrenal axis (HPA). The HPA terminates ongoing activity, suppresses executive functions, and impairs abstract cognition. Concurrently, CRF enters the locus coeruleus-norepinephrine system (LC-NE) to reorient cognition for attention and arousal – adaptive cognition is started, the individual focuses on behaviors, and engagement follows.

The amygdala responds to a perceived threat by causing the periventricular nucleus of the hypothalamus to secrete corticotropin-releasing factor (CRF). CRF simultaneously stimulates two systems: 1) the hypothalamic-pituitary-adrenal axis (HPA) to inhibit abstract thinking and memory and 2) the locus coeruleus-norepinephrine (LC-NE) system for adaptive thinking and behaviors. This initiates the adaptive cognitive shift necessary for survival.

Norepinephrine, an amino acid hormone, has binding sites on the membrane of specific cells and rapid, specific actions (50 milliseconds). Steroid hormones are fat soluble, so they cross the cell membrane into the cytoplasm and affect cell function with less specificity and a more delayed response – slower, organ-specific (5 minutes).

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Lack of Contextual Information

During interviews with participants following a terrorist shooting, the authors identified misunderstandings due to the lack of contextual information (67).

Unexpected Helicopter Transport

A trauma center received two patients by helicopter. They had not been notified of the patients. Some individuals in the administration of the trauma center and EMS agency believed the helicopter was ordered to fly to a non-trauma hospital.

The context: The scene transportation manager took advantage of a pause in the flow of ambulances Triage A. He rapidly selected two patients for helicopter transport to move some patients to trauma centers away from the two local trauma centers and to transport two patients rather than wait for another ambulance. One patient began to deteriorate at altitude. The treating medic requested the dispatcher to notify the trauma center, but the dispatcher was preoccupied with activities surrounding the shooting.

Wandering Evacuees

Medics at the triage site observed people walking away from the buildings and crossing a major street. Complaints came in about the unplanned creation of a second triage site while the triage medics were trying to manage arriving victims.

The context: A call came for an ambulance and field supervisor to respond to a home north of the triage site. Even though the call was heard in the field, no one responded. It appeared the call was to respond to a nearby abandoned house. Law enforcement officers had selected the abandoned house for a secondary triage site to collect possible injured people evacuating from a nearby office building. The abandoned house had a metal fence useful for protection from a possible sniper, and the site could contain people from nearby buildings, keeping the main triage site clear.

Less Serious Patients Transported First

An ambulance crew was prepared to transport a seriously wounded patient shot in the chest. Instead, they were given a less critical patient with multiple wounds in the extremities.

The context: A patient with a chest wound was in the ambulance receiving area. As the ambulance arrived, the patient showed signs of developing pneumothorax. Ambulances were backed up. The treating medic did not want to waste time, so he sent the

patient with multiple gunshot wounds who was less sick. This allowed him to stabilize the patient with the chest wound by completing the thoracentesis.

Under-triage Shooting Victims

Nurses at a community hospital heavily criticized medics for transporting shooting victims to a community emergency department rather than a trauma center. These criticisms continued, interfering with the completion of the medic's paperwork.

The context. All area trauma centers were receiving critically injured victims. It was explained to the nurses with some effort that a major shooting had occurred. Trauma centers should not be inundated with minor patients simply because of the type of trauma.

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Ambulance Self-dispatch

Ambulances from a private ambulance service arrived at a fire station near the triage area—the self-dispatched of several ambulances to the scene confused within the system.

The context. The regional EMS authority contacted the ambulance service, requesting two ambulance strike teams to respond to the site.

Case Studies

The following stories illustrate the effect of disregarding context. The actors are all successful; their decision-making is typical. What is different is the lack of context in their problem-solving.

The El Faro (8)

The captain of the container ship El Faro had 15 years of experience sailing through arctic winter storms between Tacoma, Washington, and Anchorage, Alaska. As captain of the El Faro in the Caribbean, he sailed the ship into a Category 3 hurricane. The wind, waves, and list of the ship were, the captain would repeat, a typical winter day in Alaska. The ship turned over and sank.

The shipping route off Alaska was close to a shoreline that buffered winds. The winds of arctic storms blow north to south. The wind direction is circular in a hurricane. Winds blowing against the port side (left) confused the captain.

The captain misattributes the ship's list to the wind hitting the large sail of the ship. Thirty minutes later, the captain and crew realize the list is due to flooding.

The captain never called them a "hurricane." Instead, the storm was a "system," "low," "disturbance," or "storm."

By describing this as a 'typical winter day in Alaska,' the captain was looking for a similar situation. The hippocampus creates context by identifying what is different. This may be the mechanism for the brain moving toward abstractions versus contextualizing the circumstance – interpreting the situation similarly reduces stress (no novelty) and fear (distance from threat).

Interpreting the situation, like his experience in Alaska, lifts events out of the environment to connect them to abstract concepts. The captain's substitution of other words for "hurricane" furthered his shift in thought. The supposition of a "typical" storm substituted an abstract conceptual order for the current perceptual order of the storm. Concepts in this new conceptual order became converted into discontinuous "facts." The captain developed "engaged abstraction" (9).

Mount Everest (68). After 30 years of attempts, climbers failed to reach the summit of Mount Everest. In the 1920s, George Finch, a mountaineer, and scientist with engineering skills developed portable oxygen equipment and advocated better sleep and diet (69). Finch was excluded from the 1924 expedition and had been denied membership to the London Alpine Club because of conflicting personalities. His ideas did not match the high-altitude science at the time; science developed in pressure chambers for aeronautics (69, 70).

International pressure forced the London Alpine Club to use science. In 1952, they brought in Gifford Pugh, a physiologist, experienced climber., and mountain warfare instructor. He focused on diet, oxygen, fatigue, and acclimatization (71). In 1953, Sir Edmund Hillary and Tenzing Norgay reached the summit of Everest, smiled, removed their oxygen set, and took photos (70).

Cholera. The scientific theory of cholera pathology was the poison of the sodium pump by cholera toxin. This disabled the active transport of glucose in the intestinal mucosa. In South Asia, for hundreds of years, treatments for cholera included fluids with salt and a form of sugar. Robert A. Phillips (72), a medical researcher, gained extensive clinical experience with cholera in South Asia during the 1950s and '60s. He led a team that, by 1970, overturned that theory of cholera pathology. A solution consisting of sugar, salts, and water now saves countless lives of severely dehydrated adults, children, and infants.

Assisted ventilation. Physicians through the 19th Century considered mouth-to-mouth resuscitation a futile method to save lives. "This practice has been objected to. It has been urged that inflating the lungs with air so charged with carbonic acid gas is more likely to destroy than restore life" (73). The physician writing those words resuscitated several newborn babies, starting in 1814.

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Mechanical ventilation causes extreme distress in patients unless the patient is sedated. Otherwise, the ventilator causes ventilator-patient asynchrony in the breathing patient. One of the authors (DvS), serving on a fire rescue ambulance, had administered mouth-to-mouth breathing in the field to an infant, adolescent, and

adult. We used that experience to teach bag-valve-mask (BVM) resuscitation for breathing patients, a technique used in a pediatric subacute care facility and some elite army special operations forces. When used for ventilator-dependent children, they smile and laugh, some for the first time (74).

For children with cognitive disabilities, unfamiliar faces or touch cause them to withdraw mentally and emotionally. This state of "hypoactive delirium" is a reversible decrease in mental state. Healthcare and public safety professionals routinely interpret this as a severely blunted mental state, if not a vegetative state, though these children smile in response to family and familiar healthcare providers. The likely cause is the change in social context processed by the hippocampus as a significant contextual change. The hippocampus becomes disabled for memory retrieval, except motor memory, while signaling to the ventromedial prefrontal cortex (vmPFC) about uncertainty or the proximity of a threat within the safety distance. Healthcare professionals outside the context of familiarity do not understand the bond formed by the child who can smile, while families lose some of their trust in healthcare professionals. It is not uncommon for families to report that healthcare professionals tell the parents that the child cannot smile. Instead, the Duchenne emotional smile involving the eyes is a reflex or grimace; the child does not feel happy or pleasure—this is from a simple change in context.

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Military combat. Academicians criticized a study of soldiers in the operational area (75) because problems in its design and execution would limit any attempt to conclude it. The authors did not indicate that the quotes used were statistically representative. The study's findings would challenge the conventional wisdom about military unit cohesion. The authors found that, contrary to the consensus findings of the vast literature, the distinction between social and task cohesion is irrelevant in the operational area.

The authors of the critiqued publication had deployed into an active war zone. Soldiers were assigned to the authors for force protection. However, the first duty of the soldiers in the operational area was to defend the area by engaging the enemy rather than standing by the authors.

> "Is [it] scientifically appropriate to assume that the extensive work done in peaceful settings will necessarily generalize to combat?"
>
> "Research involving human participants conducted in safe, peaceful settings will not necessarily generalize to combat; combat findings may differ from those developed elsewhere."
>
> Thomas A. Kolditz (76)

Implementation of HRO, Patient-Centered Care

Referring to an article about HRO in a medical setting, a patient safety officer wrote, "The article seemed descriptive rather than numbers driven. Unless there is some specific data, it will be met with skeptical responses" from members of the quality improvement committee.

Classical logic and Kolmogorov probability theory are deeply embedded in medical science. The familiarity and trust that develop influence the beliefs of healthcare professionals and their understanding of how they think. The risk is reliance on abstract concepts, even extracting abstract concepts from operating concepts. As Weick describes the captain of the El Faro: The captain substituted an abstract conceptual order for the current perceptual order of the storm. Concepts in this new conceptual order became converted into discontinuous "facts." The captain developed "engaged abstraction."

The authors have implemented HRO into their various programs, but it was through appreciation of contextual details and decision-making as reciprocal feedback. This drives operations deeper into the situation.

The lack of contextualization in HRO implementation impairs operations and washes out the function of HRO. The organization does not develop the capability to withstand environmental forcing functions, let alone develop adaptive allostatic growth.

As described in our disaster series, bedside staff repeatedly resolved daunting circumstances without a plan or outside direction. In each disaster setting, self-organization against the environment created improvisation, and self-organization with colleagues made teams. Success emerged from their focus on context, influenced by their acceptance that each of them was a participant.

Directing care to our patients too quickly becomes a 'substituted abstract conceptual order' for evaluation and management. Adjusting care to the patient's circumstances becomes 'patient-centered care.' Perhaps we could consider a quantum approach of continuous change and different perspectives. We could also examine the realization that uncertainty is the state in which we operate rather than the result of ineffective operations. We work within the patient's context rather than a medical context.

In the 1970s, one of the authors (DvS) served on a fire rescue ambulance that responded with two medics but no fire companies or law enforcement officers. Approaching the scene meant entering the patient's territory, whether that was the home, vehicle, office, or vacant field. The patient did not adapt to us. Instead, we adapted to the patient, which meant their language, culture, family and friends, and local furniture and belongings. You cannot tell people to leave when it is their grandparent's bedroom.

This gave a different tenor of care compared to a medical setting and revealed the power of role theory. Patients and their families are intruders into our abode in the medical setting. This is good as they more readily take on the role of patient. In their home, they forget this and continue their role as human beings. The author learned through experiencing failures and successes that we treat the family, friends, and home, regardless of patient privacy. That is not to say personal details are shared, but that the patient and parents benefit if they can learn how to explain their changed circumstances with varying levels of prudence.

"That is not to say personal details are shared, but that the patient and parents benefit if they can learn how to explain their changed circumstances with varying levels of prudence."

Patient-centered care, like all medical care, has the danger of becoming "engaged abstraction" when we want it to be "engaged context."

"Consequently, stress and fear responses may become naturalized in our behavioral responses. We then engage the changing contextual order, but with the error of "engaged abstraction." Accepting uncertainty and flux and understanding that our presence alone changes the situation can reduce the emergence of stress and fear responses."

Conclusion:

HRO emerges when our perceptual order is contextual. Context develops when environmental changes come to our attention through the hippocampus. The hippocampus is linked to brain regions that respond to uncertainty and fear. Consequently, stress and fear responses may become naturalized in our behavioral responses. We then engage the changing contextual order, but with the error of "engaged abstraction." Accepting uncertainty and flux and understanding that our presence alone changes the situation can reduce the emergence of stress and fear responses. But more critical is the understanding that their history does not predetermine the trajectory of events, the act of measuring changes events, and asking questions and the answers we accept can be sufficient to move in a better direction

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Peer Reviewed

Fellow's Column:Spontaneous Intestinal Perforation or Necrotizing Enterocolitis

Kristie Searcy, MD, Shabih Manzar, MD

Summary:

Confusion and overlap exist with the definition of necrotizing enterocolitis (NEC) and spontaneous intestinal perforation (SIP). Although clinically significant NEC and SIP may present similarly, the confirmation requires exploratory laparotomy. The article describes a working algorithm to differentiate between the SIP and NEC. This draft aims to stimulate the neonatology practicing community about this topic. Further discussion is needed to reach some consensus.

Abbreviations:

SIP/FIP- Spontaneous/Focal Intestinal Perforation, NEC- Necrotizing Enterocolitis

> ***"The article describes a working algorithm to differentiate between the SIP and NEC. This draft aims to stimulate the neonatology practicing community about this topic. Further discussion is needed to reach some consensus."***

Cost:

The estimated annual cost of caring for infants with Necrotizing Enterocolitis (NEC) is about $500 million to $1 billion. [1] NEC is used as one of the NICU's key performance indicators. (2,3) A high-performer institution is the one that has the lowest incidence of NEC. However, the data could be influenced by how the institution defines NEC.

> ***"Recently, Nue (4) questioned Bell's criteria for diagnosing NEC, which was developed in the late 1970s. The author believed this staging system is outdated and suggested using the terms' medical NEC' or 'surgical NEC' depending on the clinical symptoms, radiologic signs, and surgical findings."***

Controversy:

Recently, Nue (4) questioned Bell's criteria for diagnosing NEC, which was developed in the late 1970s. The author believed this staging system is outdated and suggested using the terms' medical NEC' or 'surgical NEC' depending on the clinical symptoms, radiologic signs, and surgical findings. Similarly, Berrington and Embleton (5) expressed concerns about differentiating NEC with focal intestinal perforation (FIP). Swanson et al. (6) reported the published data from a US national data set from 2002 to 2017, showing a decreasing trend in NEC while an increasing trend of spontaneous intestinal perforation (SIP). They also encountered and acknowledged the overlap and misdiagnosis between the two. In a Canadian study, Shah et al. (7) studied a cohort study of 17,426 infants and found higher odds of a composite outcome of mortality or morbidity with NEC than with SIP. In their report, the diagnosis of FIP/SIP was made according to the local practices based on the lack of clinical features of NEC. Studies from Fisher et al. (8) showed that neonates with laparotomy-confirmed SIP had significantly lower mortality than those with laparotomy-confirmed NEC.

So, this brings us to two questions: Why do we use NEC as a quality indicator if we cannot define it unanimously? Second, should we redefine NEC?

> ***"So, this brings us to two questions: Why do we use NEC as a quality indicator if we cannot define it unanimously? Second, should we redefine NEC? "***

Diagnostic issues:

Diagnostic-related groups (DRGs) have been used to measure the complexity of inpatients using a case mix index (CMI). (9)Defining diseases is challenging in neonatal medicine. For example, hyaline membrane disease is also labeled as respiratory distress syndrome. One is a pathological diagnosis, while the other is a clinical one. To diagnose diseases, clinicians rely on clinical presentation supported by radiological, laboratory, and pathological findings. A retrospective case-control study of 114 infants where 48 infants had SPI and 66 had NEC showed that a transient increase in serum alkaline phosphatase level is independently associated with SIP compared to NEC, suggesting utility in using serum alkaline phosphatase levels to differential infants with these conditions. (10)

Labeling a condition with a diagnosis is required for management, data monitoring, and billing. NEC impacts the neurodevelopmental outcome and may persist long term; therefore, data on NEC is essential. For instance, studies suggest that preterm infants diagnosed with surgical NEC had slower catchup head growth at four months and were more likely to experience developmental delay at 36 months compared to preterm infants with surgical SIP. (11) The question is: why we do not create a single clinical diagnosis for conditions with similar clinical presentation. Once the clinician has all the data and evidence, the final diagnosis could be labeled as NEC, SIP/FIP.

***Proposed solution*:**

For example, high bilirubin is entered into the medical record as hyperbilirubinemia. Some clinicians prefer jaundice. Once the fractionated bilirubin information is available, the diagnosis

Figure 1

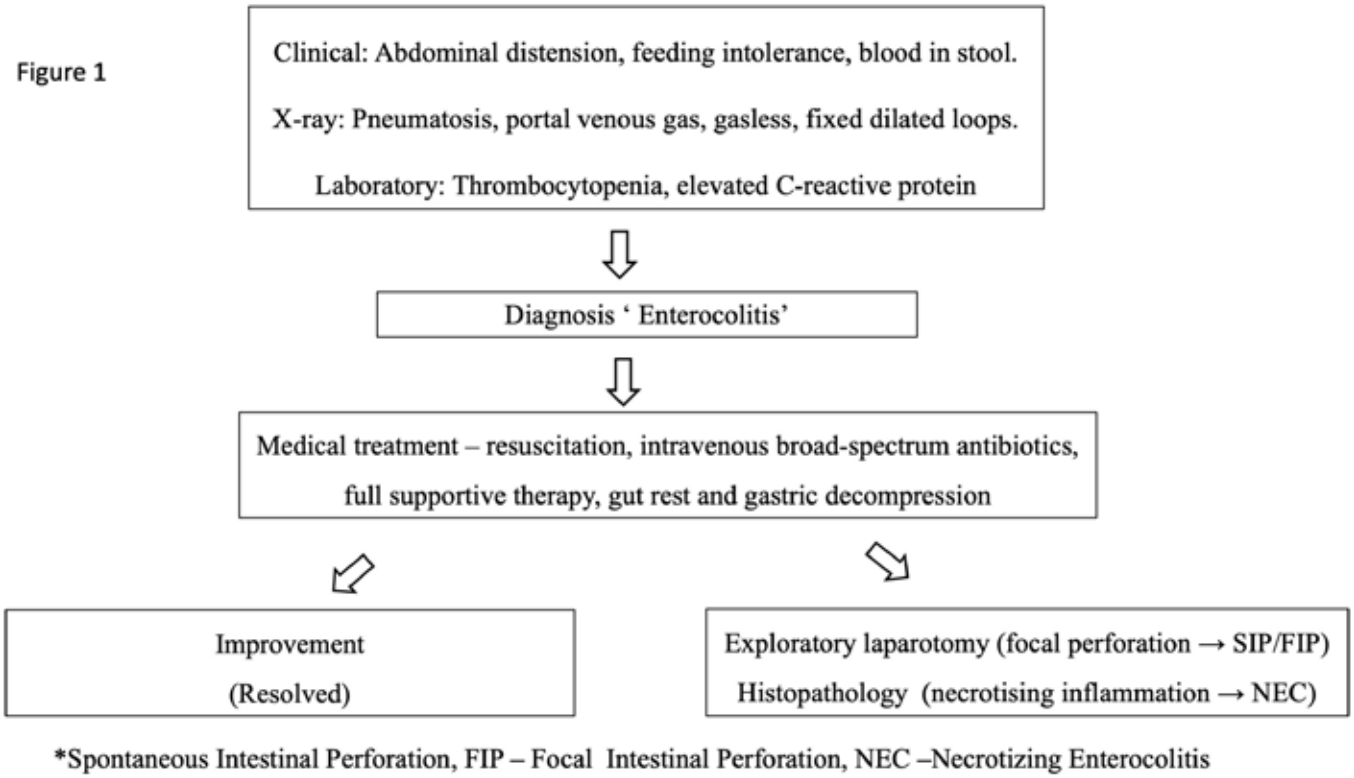

Figure 1: The diagnostic flow chart for diagnosis of Enterocolitis to SIP/FIP-NEC

is modified to unconjugated (indirect) or conjugated (direct) hyperbilirubinemia. Further, it could be classified as physiological or pathological jaundice. Using the same analogy, the name for a clinical presentation for SIP/FIP and NEC could be a common nomenclature.

To diagnose NEC or SIP/FIP, clinicians should look at clinical, ra-

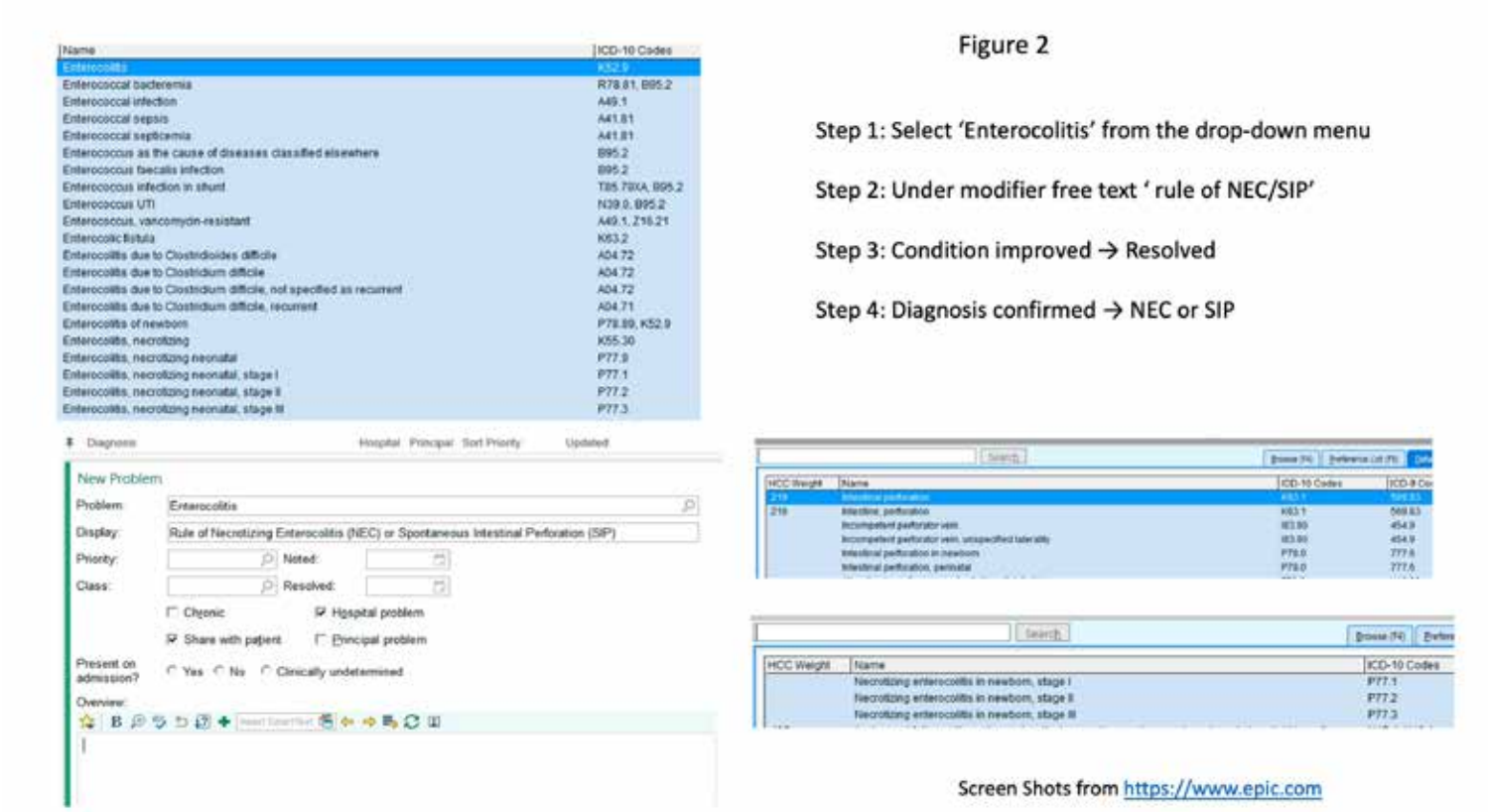

Figure 2: Steps of working on the electronic chart with a diagnosis of Enterocolitis to SIP/FIP-NEC

diological, and laboratory evidence (abdominal distension, feeding intolerance, blood in stool, pneumatosis, portal venous gas, gasless, fixed dilated loops, abnormal laboratory indices).

"Based on this information, a diagnosis of 'enterocolitis' could be entertained as, at this point, SIP/NEC could not be ruled out. The caveat with the diagnosis of SIP/FIP and NEC is the need for exploratory laparotomy. Perforation can only be confirmed after surgical intervention, and necrotizing is a histopathological diagnosis."

Based on this information, a diagnosis of 'enterocolitis' could be entertained as, at this point, SIP/NEC could not be ruled out. The caveat with the diagnosis of SIP/FIP and NEC is the need for exploratory laparotomy. Perforation can only be confirmed after surgical intervention, and necrotizing is a histopathological diagnosis. Therefore, starting with a diagnosis of enterocolitis could be justified. Once confirmation is done, the final diagnosis could be changed to FIP or NEC (Figures 1 and 2). As the medical treatment for both conditions is the same (resuscitation, intravenous broad-spectrum antibiotics, full supportive therapy, gut rest, and gastric decompression), differentiating both at the time of occurrence is not that important.

This draft aims to stimulate the neonatology practicing community to get some consensus. Views and comments from colleagues would be appreciated.

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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?

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Peer Reviewed

Briefly Legal: Extreme Prematurity Complicated by Trauma after Delivery

Maureen E. Sims, MD, Barry Schifrin, MD

Clinical History

A 29-year-old pregnant woman, G4P3, developed vaginal bleeding and preterm labor and gave birth to an extremely premature male baby. The mother was unsure of her dates, but at 18 weeks gestation, ultrasound dating placed the pregnancy at 24 5/7 weeks gestation at the time of birth.

The mother had become pregnant about six weeks after the prior term delivery.

A fetal ultrasound was performed upon arrival to the hospital and found a biophysical profile of 8/8, representing normal fetal activity (breathing, moving, tone) and normal amniotic fluid volume. The fetus was in breech presentation, and the estimated gestational age (EGA) was 23 3/7 weeks, eight days younger than the EGA assigned by the 2nd-trimester ultrasound.

Upon admission, magnesium sulfate for tocolysis, antibiotic prophylaxis against group B streptococcus, and corticosteroids for fetal lung maturation were administered. The fetal tracings were of poor quality. The mother had consented to a vaginal delivery on admission. Still, her deposition stated that she expressed to the obstetrician her desire that everything be done for this baby to optimize its outcome - including cesarean section if needed. No discussion about the prospects of morbidity and mortality in this extremely premature baby or the options for cesarean section were documented in the medical records or in deposition testimony. Severe variable decelerations began about 2 hours prior to birth. The mother was not informed of a change of circumstances in terms of delivery route and was not reconsented despite the deteriorating FHR patterns.

"Severe variable decelerations began about 2 hours prior to birth. The mother was not informed of a change of circumstances in terms of delivery route and was not reconsented despite the deteriorating FHR patterns."

The patient progressed rapidly in labor with spontaneous rupture of the membranes occurring 2 minutes before the breech delivery. The obstetrician, called to the delivery a few minutes before the birth, attended the birth. The umbilical cord was found between the legs of the delivering breech fetus. At delivery, the baby fell out of the hands of the obstetrician, falling about 3 ½ feet and striking his head on the wheellock of the delivery table before hitting the floor. After the event, the obstetrician wrote that the cord was short and the placenta had abrupted. He charted that the eyes were fused and that the baby did not breathe immediately at birth.

A cord gas was sent, but not until 6 hours after the birth, making it invalid. The baby was intubated in the delivery room and given positive pressure ventilation. Apgar scores were $1^{1},4^{5},5^{10.}$ The baby weighed 670 grams on admission, and his head circumference was 21 cm. He had a 2-2.5 cm laceration on the left parietal area, which was actively bleeding. His eyes were fused, and he had multiple bruises. A Ballard examination placed the infant at 24 weeks.

"On admission to the NICU, his blood pressure was undetectable and could not be measured even after blood products and several pressors were provided. Initially, he was placed on a conventional ventilator at 100% inspired oxygen but needed high-frequency oscillatory ventilation."

On admission to the NICU, his blood pressure was undetectable and could not be measured even after blood products and several pressors were provided. Initially, he was placed on a conventional ventilator at 100% inspired oxygen but needed high-frequency oscillatory ventilation. His complete blood count (CBC) showed a hematocrit of 30%, a white blood count of 6.5 x10 ^{3} u/L, and a platelet count of 116 x10^{3} u/L. The first blood gas (venous) at 1.5 hours of life showed a pH of 6.7, a pC02 of 45 mmHg, a p02 of 26mmHg, and a base excess of -26 – a severe metabolic acidosis. Despite maximum support with pressors and blood products, the baby died at 12 hours, having never achieved a detectable blood pressure

Discovery

The Coroner's report affirmed that the cause of death was a traumatic brain injury. The findings documented in the Coroner's records included: subgaleal, subdural, and grade 4 IVH (intraventricular hemorrhage, specifically hematoma in the brain parenchyma), multiple bruises, mild chorioamnionitis, absent funisitis, and an umbilical cord length that was normal for 24-week infant (when all of the pieces of cord were accounted for.).

In his deposition, the obstetrician stated that the placenta shot out of the vagina because of the short cord pulling the baby out of his hands onto the floor.

"Despite maximum support with pressors and blood products, the baby died at 12 hours, having never achieved a detectable blood pressure"

Allegations

The case was adjudicated in court. The Plaintiff averred that:

1. There was a failure to obtain proper informed consent. It violated reasonable standards of care by not informing the mother of the change in fetal status about 2 hours before delivery to discuss or recommend a cesarean section. The fail-

ure to properly discuss the risks, benefits, and alternatives to vaginal delivery in the face of the deteriorating fetal condition, meant that the caregivers had NOT obtained proper informed consent from the patient. Despite defense arguments to the contrary, Plaintiff pointed out that the obstetrician was responsible for explaining what is known in terms of morbidity and mortality given the uncertainty of the true EGA (23, 24, and 25 weeks). Such conduct by the obstetrician, however, was consistent with the notion that the care providers had decided, without the agreement of the mother, not to intervene for fetal distress in this extremely premature fetus, despite the mother's expressed view that everything be done to enhance the outcome of the baby. Plaintiff explained that such a paternalistic approach was inappropriate and violated reasonable standards of care.

" Such conduct by the obstetrician, however, was consistent with the notion that the care providers had decided, without the agreement of the mother, not to intervene for fetal distress in this extremely premature fetus, despite the mother's expressed view that everything be done to enhance the outcome of the baby."

Indeed, the statistics from the NICHD (National Institute Child Health and Development) and VON (Vermont Oxford Network) relevant to the year of birth for this baby (male, singleton, exposure to antenatal steroids, birth weight of 670 grams, 24 weeks) should have been discussed with the mother. Those statistics showed a survival to be 63% (NICHD) and 70% by VON for the year the baby was born. The NICHD outcome for profound neurodevelopment impairment was 3-5%, for moderate-severe neurodevelopment impairment to be 32-37%, for blindness <15%, for deafness 1-2%, for moderate-severe cerebral palsy 6-9%, and cognitive developmental delay 31-35%. Ultimately, all predictive tools (National Institute of Child Health and Development and Vermont Oxford Network) and published papers, including babies for the 2016 birth year, far exceed >50% survival, being 63%-70% survival for 24 weeks gestation and >>50% have good outcomes.

2. Plaintiff alleged that the care providers were obliged to operate based on the gestational age of at least 24 5/7 weeks from an 18-week ultrasound. This was required by the standard of care, notwithstanding that 2nd-trimester ultrasounds, while superior for dating compared to later ultrasounds, are still associated with a range of errors. Also, the biparietal diameter and femur length, which tend to be the most reliable of the various parameters for estimating gestational age, are consistent with 26-27 weeks if used alone. The Ballard exam, where EGA measurements are rounded to weeks, excluding days, estimated the gestational age at 24 weeks. The Coroner placed the baby at 24 5/7 weeks. Brain gyral patterns are very accurate concerning dating.

3. The newborn died from suffering severe trauma at delivery due to the physician's negligent conduct during the delivery that permitted the baby to fall to the floor. The plaintiff experts pointed out that the obstetrician's description of the events leading to the dropped baby was not credible, that they were self-serving and not validated in the medical chart. Placentas, especially those that are separated, are not delivered with force, and the cord was not short for 24 weeks gestation (per the Coroner's report)

   Notwithstanding the change in the Coroner's assessment of the cause of death, as shown in his initial assessment, the baby died of hypovolemic shock secondary to blood loss in his subgaleal and subdural spaces and the grade 4 IVH – all documented on postmortem examination. The combination of birth trauma (the fall) superimposed on fetal distress was responsible for the extra- / intracranial bleeding, his hypovolemia and anemia, and the cause of death. There was obvious hypovolemic shock from the acute blood loss in the subgaleal and subdural spaces, IVH, and multiple bruises. Subgaleal and subdural hemorrhages were pathognomonic of head trauma in a newborn delivered from a breech presentation when the head is significantly larger, proportionally than the torso.

"There was obvious hypovolemic shock from the acute blood loss in the subgaleal and subdural spaces, IVH, and multiple bruises. Subgaleal and subdural hemorrhages were pathognomonic of head trauma in a newborn delivered from a breech presentation when the head is significantly larger, proportionally than the torso."

4. While there was no evidence of abruption in the Coroner's report, that diagnosis is clinical, not pathological, and one of the most common discernible causes of preterm labor and delivery. It was below the standard of care to fail to include abruption in the differential diagnosis of preterm labor with frequent contractions and deteriorating fetal condition.

5. In response to the assertion of the Defense, plaintiff experts pointed out that the Ballard examination does not account for fractions of the week: it rounds off gestational age to weeks. Additionally, the birth weight was higher than 670 grams since some blood was on the floor and wheellock. Similarly, when delivered a few hours after this ultrasound, a direct examination of the newborn assessed him as more mature than 23 weeks gestation, as stated by the Defense.

6. In response to the assertions of the Defense, plaintiff experts averred that the clinical presentation of GBS could not reasonably explain the trauma or other clinical features given the brief time of ruptured membranes, the treatment of the mother with antibiotics three hours prior to birth, the absence of clinical signs of maternal or neonatal infection, and the negative blood cultures on the baby. As for the allegation that the negative culture in the baby resulted from the mother having received antibiotics, Plaintiff pointed out that the laboratory accounts for the prior antibiotic administration in the culture media.

7. In response to the Defense expert's assertion that respiratory distress syndrome was a significant contributing cause

of the morbidity, Plaintiff explained that the baby had shock lung.

But for these negligent actions that fell below a reasonable standard of care, given appropriate care, the newborn would have survived had he not been dropped.

"But for these negligent actions that fell below a reasonable standard of care, given appropriate care, the newborn would have survived had he not been dropped."

Defense arguments

1. The Defense argued that even though ultrasounds during the 2nd trimester are accurate for dating, a standard deviation of 10 days would put the baby at 23 weeks at birth – they failed to point out that adding ten days on the upper end of the estimate meant that it was 27 weeks at birth.
2. The Defense contended that the short intervals between conceptions were a significant comorbidity that decreased the chances of survival for this baby. Plaintiff experts disagreed.
3. The Defense further asserted that the baby had a<50% chance of survival and >50% chance of poor outcome regardless of delivery mode and head trauma from being dropped. Plaintiff experts disagreed.
4. They attributed the cause of death to GBS sepsis and other comorbidities impacting the baby's survival, including RDS, histologic chorioamnionitis, abruption of the placenta, short cord, prolapsed cord, GBS sepsis, and pregnancies that were too close together. Further, IVH grade 4 is very common at this gestation. Had the baby survived, he would have been very disabled. Plaintiff experts disagreed.
5. The Defense also maintained that IVHs were very common in premature babies of this gestation but neglected to point out that that risk increased with increasing evidence of decelerations during labor. Further, contemporary statistics showed that severe IVH was present in <6% at < 32 weeks' gestation. Plaintiff experts disagreed.

"The case went to court. On the stand during his testimony to the jury, the Coroner recanted his original opinion, now stating that the baby died because of extreme prematurity. After some deliberation, the jury decided for the Defense, explaining later that they felt sorry for the obstetrician."

Disposition

The case went to court. On the stand during his testimony to the jury, the Coroner recanted his original opinion, now stating that the baby died because of extreme prematurity. After some deliberation, the jury decided for the Defense, explaining later that they felt sorry for the obstetrician.

"The Neonatal Research Network (NRN) was established in 1986 to address the critical need for rigorous research in babies admitted to the Neonatal Intensive Care Units (NICUs), so that solid evidence generated by such research could be used to improve the treatment and enhance the options for health outcomes of critically ill newborn babies."

Discussion

The Neonatal Research Network (NRN) was established in 1986 to address the critical need for rigorous research in babies admitted to the Neonatal Intensive Care Units (NICUs), so that solid evidence generated by such research could be used to improve the treatment and enhance the options for health outcomes of critically ill newborn babies. The National Institutes of Child Health and Human Development (NICHD) funded the NRN.

The debate in the case calls attention to the 2008 article by Jon Tyson et al. in the New England Journal of Medicine, "*Intensive care for extreme prematurity—moving beyond gestational age*." This study of 4,446 infants born at 22-25 weeks' gestation between January 1, 1998 and December 31, 2003, reported survival and neurodevelopmental outcome statistics at 18-22 months according to gestational age, birthweight, and gender of the infant. They also considered whether the birth was a singleton or multiple, whether steroids had been administered, as well as the hospital's approach to active treatment of these babies in the delivery room. The findings of this study challenged the widespread use of using gestational-age thresholds alone in deciding whether to administer intensive care to extremely premature infants. This study showed that each 100-gram increase in birth weight reduced the risk of death or disability for infants, similar to the risk reduction from a one-week increase in gestational age. Other factors enhancing outcome included: female gender, singleton birth, exposure to antenatal steroids, and active intervention in the delivery room. Based on the paper's findings, an "NICHD calculator" was devised to provide estimates of possible outcomes based on patient and hospital characteristics. In many respects, the more aggressive the approach, the better the outcome.

This original predictive tool of 2008 was updated and validated by cohorts of patients from the NICHD-NRN in 2012 (enrollment 2006-2012) and by cohorts of patients from the VON in 2006-2012 and 2013-2016. As one might expect, the survival rates and favorable outcomes were improved compared to the original publication. The VON 2013-2016 survival for 24 weeks gestation was 70%. The latest NICHD-NRN tool (2012) is now ten years old and is available: https://www.nichd.nih.gov/research/supported/EPBO/use

In the VON cohort for 24 weeks gestation, the survival in 2006-2012 was 66% (slightly better than the NICHD of 63%), and in VON, the 2013-2016 survival for 24 weeks gestation was 70%.

The baby, in this case, was born in 2016. The neurodevelopmental outcomes were very similar. Another predictive study published in Pediatrics in 2012 entitled: *"Outcome Trajectories in Extremely Preterm Infants"* evaluated infants with birth weight <1.0 kg admitted to 18 large academic tertiary NICUs during 1998-2005. The authors found that the prediction of death or neurodevelopmental impairment improved using information available during the clinical course, specifically delivery room treatment, at 7-days, 28-days, and 36 weeks postmenstrual age. This study confirmed that:

1. The predictive ability was improved by adding gender and birthweight, as Tyson et al. had shown.
2. The 5-minute Apgar score was an additional predictor of mortality, which reflects not only the condition at birth but also whether and how effectively resuscitation was provided.
3. The importance of birth weight declines, whereas that of respiratory illness severity increases with advancing postnatal age. Surprisingly, the ability to predict death and impairment did not improve with increasing postnatal age among infants who avoided early death.

"Thus, the study showed that the ability to predict long-term morbidity and death in extremely low birth weight infants did not improve significantly after the first week of life, probably because most of the commonly used variables are predictors of early mortality and not a longer-term outcome. "

Thus, the study showed that the ability to predict long-term morbidity and death in extremely low birth weight infants did not improve significantly after the first week of life, probably because most of the commonly used variables are predictors of early mortality and not a longer-term outcome. However, the effects of different variables varied with postnatal age.

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

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA

EVIDENCE

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

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

- **S** EEK PARTICIPATION
- **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.

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Gravens By Design: Supporting Fathers in the NICU

Tiffany Willis, PsyD

The NICU can be an incredibly stressful environment for both the infant and its parents. Unlike many traumatic events, the NICU experience can often feel like an ongoing trauma, with the stay often involving highs and lows, new diagnoses, changes in prognosis, multiple procedures, and a rollercoaster of emotions. This chronic stress directly impacts the brain and can cause challenges with memory, emotional regulation, hypersensitivity, weakened immune system, and mental health problems. (1) The NICU can also trigger trauma responses for parents with previous traumatic experiences. NICU triggers can include alarms, interaction with authority, loss of control, physical exposure of breast/chest for feeding, prior loss, or negative hospital experiences. When a parent is triggered, their stress response system is activated, causing them to go into fight, freeze, or flee mode. In the NICU setting, this may look like a family who rarely visits, parents who shut down and do not engage with the infant or ask questions to the medical team, or parents who appear to be overly aggressive or involved in infant care.

"In the NICU setting, this may look like a family who rarely visits, parents who shut down and do not engage with the infant or ask questions to the medical team, or parents who appear to be overly aggressive or involved in infant care."

When working with families in the NICU, it is essential to use a Trauma Informed Care lens to ensure that the families' behaviors are being viewed from a place of understanding rather than judgment. (2) Perinatal Mood and Anxiety Disorders (PMAD) can result from prolonged stress related to the trauma of the NICU experience. Both parents are susceptible to developing PMADs. Often, much of the attention from medical professionals, friends, and family is on the well-being of the infant and birthing parent; however, this article will focus on the father's experience.

"Both parents are susceptible to developing PMADs. Often, much of the attention from medical professionals, friends, and family is on the well-being of the infant and birthing parent; however, this article will focus on the father's experience."

Paternal Depression:

Paternal Depression is often characterized by irritability, emotional detachment, withdrawal from the family, and increased substance use. (3) Research shows that 10-20% of fathers experience a diagnosable PMAD, with depression and anxiety being the most prevalent. (4) Paternal depression occurs in 10% of fathers and increases to 12% as children approach toddler age. (3, 5) For Headstart families, mostly minoritized, low socioeconomic families, the rate of paternal depression is 18%. (3, 5) Fathers are at increased risk for developing depression when the birthing parent experiences depression. (6) There is a known correlation between paternal depression and the father's use of corporal punishment, as well as emotional problems in the child at the age of 3. (7) Also, fathers with depression are less likely to read to their children, which is vital for future cognitive and language development. Black fathers' experience of depression is often complicated by racism and cultural norms, which often do not promote emotional expression or involve formal therapy or psychiatric medication. Fathers in the United Stated tend to have greater rates of depression than fathers internationally, which some contribute to the lack of adequate paternal leave.

"Fathers in the United Stated tend to have greater rates of depression than fathers internationally, which some contribute to the lack of adequate paternal leave."

Paternal Anxiety:

Paternal anxiety is often related to worry about their child having adverse developmental outcomes. (7) It ranges from 4.1% to 16% prenatally but can range from 2.4% to 18% postnatally. (7) A systematic review of 43 papers showed that fathers experience anxiety at a rate much greater than depression, which is also true for the birthing parent. (7) Under the umbrella of anxiety is paternal postpartum Posttraumatic Stress Disorder (PTSD), which occurs at a rate of 33% for NICU fathers. This rate is slightly lower than for the birthing parent. However, fathers are likely to continue endorsing severe PTSD symptoms at six months postdelivery. For fathers, postpartum PTSD can look like avoidance or a protective need to be constantly present. Intrusive thoughts and increased irritability are also common symptoms. Fathers with a trauma history are at increased risk for developing postpartum PTSD. (1)

Screening:

Screening for PMADs is vital for both parents. Fathers are rarely screened for PMADs but are at equal risk. In 2018, the National Perinatal Association (NPA) released a position statement recommending that fathers be screened for PMADs at least twice during the perinatal period and at 2, 4, and 6-month pediatric visits. Pediatricians see the child and its parents multiple times within the first

year of life and are best positioned to detect maladjustment. (8) In one study, fathers assessed for PMADs in the pediatric setting screened positive at a rate of 4.4%, (9) which allowed for intervention that may not have otherwise been provided. The Edinburgh Postnatal Depression Scale is the standard assessment tool for PMADs. It is in 18 different languages, has ten questions, and assesses for anxiety, depression, and suicidality. When using with fathers, it is best to use a cutoff score of 5 or 6 to ensure detection of distress, as gender typical men are often less expressive about their feeling, and distress could go undetected if using the general 12 cutoff score. (10)

"In one study, fathers assessed for PMADs in the pediatric setting screened positive at a rate of 4.4%, (9) which allowed for intervention that may not have otherwise been provided. "

It is important to remember that fathers are valuable members of the family system. During a NICU experience, they often take on much more responsibility than they are used to by ensuring that older children are cared for, chauffeuring the birthing parent during the first several weeks when they are unable to drive, being the liaison for medical updates with families and friends, cleaning the home, going back to work, all while trying to "be strong" or "hold it together" for their partner, all while experiencing their grief. This responsibility is a lot to manage and add to this stress. Fathers are often ignored or not addressed at the bedside or in family meetings, are less likely to be asked to hold or participate in infant care, and often witness intense scenes during the delivery. In order to care for the whole family, fathers' well-being must be a priority.

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COVID-19

STOP THE SPREAD AT HOME

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

HYGIENE TIPS

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

EYES
Wear protective eye gear (glasses)

HANDS
ALWAYS wash your hands

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

BATHROOM

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

PROTECT

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

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

SELF ISOLATION

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

6 FT

Practice social distancing

KITCHEN

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

TRACK COVID-19 NEAR YOU BY VISITING COVIDNEARYOU.ORG

#STOPTHESPREAD

MIORA

Visit Miora.org

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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

Peer Reviewed

Fragile Infant and Family-Centered Developmental Care Evidence-Based Standards: The Value of Systems Thinking

Carol Jaeger, DNP, RN, NNP-BC, Carole Kenner, PhD, RN, FAAN, FNAP, ANEF

Abstract:

Infant and Family-Centered Developmental Care (IFCDC) requires systems thinking – a re-examination of all the factors that interact to create/support the implementation of these care practices. This article will explore what systems thinking means and how it must be considered a cornerstone for implementing IFCDC.

"Systems thinking is a way to make sense of an institution's or unit's component parts, their intra- and interrelationship, and their function over time. (1) It provides a process to explore those elements that contribute to an outcome."

Background

Systems thinking is a way to make sense of an institution's or unit's component parts, their intra- and interrelationship, and their function over time. (1) It provides a process to explore those elements that contribute to an outcome.

In healthcare organizations, systems thinking is the big-picture view of the relationship between values, mission, infrastructure, education, practice, innovation, change, evaluation, and the sustainment of care over time. (2) Further, systems thinking shows the factors that influence culture –the attitudes, relationships, and behavior - of the interprofessional staff, parents, and families. Consequently, the articulated values, mission, evidence-based education, practice, and change process guide the culture and, ultimately, the organization's or unit's operational practice. (3)

"The Infant and Family Centered Developmental Care (IFCDC) Consensus Committee has been using systems thinking to guide the implementation of IFCDC within the Intensive Care Unit. (4) Assimilating the principles in the mission, vision, values, professional performance, education, clinical practice, continuous improvement process, and sustainment over the continuum of care and time is challenging in intensive hospital settings, at best."

The Infant and Family Centered Developmental Care (IFCDC) Consensus Committee has been using systems thinking to guide the implementation of IFCDC within the Intensive Care Unit. (4) Assimilating the principles in the mission, vision, values, professional performance, education, clinical practice, continuous improvement process, and sustainment over the continuum of care and time is challenging in intensive hospital settings, at best. Since the onset of the pandemic, systems and systems thinking were, by necessity, interrupted. Implementing strict infection control practices has put limitations on staff, parents, and families access to the intensive care unit (ICU) and the associated disruption of consistent system-wide care practices. Parent and family member presence was severely restricted, personal contact and voice recognition was inadequate, appropriate communication with families was intermittent, and education for continuing care was limited. (5) Relationships between staff and among staff and parents/family members were affected. The "normal" flow of activity was altered, and healthcare team members became siloed in their respective specialty roles and functions. Their interactions with each other and families were done individually and not as a team approach to care. The result was fragmented, often disjointed care approaches, where disciplinary views took precedence over a "big picture" holistic care effort. (6)

The principles of Infant and Family-Centered Developmental Care: in which Systems' thinking in complex adaptive systems is essential to implementation, including:

- Baby as a competent Interactor
- Neuroprotection of developing brain
- Individualized care
- Family involvement
- Environmental protection
- Infant mental health

The evidence-based practice sections of Infant and Family-Centered Developmental Care are accomplished with Systems thinking in complex adaptive systems.

- Reducing and managing pain & stress in newborns and families
- Positioning and touch for the newborn
- Sleep and arousal interventions for the newborn
- Skin-to-skin contact with intimate family members
- Management of feeding, eating, and nutrition delivery

Consensus Committee on Infant Family-Centered Developmental Care. Report of the First Consensus Conference on Standards, Competencies and Best Practices for Infant and Family Centered Care in the Intensive Care Unit. https://nicudesign.nd.edu/nicu-care-standards/ ; February 2020.

In many, if not most, ICUs, the workforce was evaluated and limited to "essential staff" and practice. Continuous improvement processes were focused on safety occurrences; thus, practice improvement was curtailed. Consequently, operational budgets were reduced. Medical, nursing, and interprofessional student access to clinical experiences was eliminated in exchange for a simulation experience, or if clinical rotations did occur, the hospital staff acted as a preceptor instead of the usual clinical faculty. Healthcare interprofessional students graduated with limited patient/family contact.

"Medical, nursing, and interprofessional student access to clinical experiences was eliminated in exchange for a simulation experience, or if clinical rotations did occur, the hospital staff acted as a preceptor instead of the usual clinical faculty. Healthcare interprofessional students graduated with limited patient/family contact. "

Why are these changes important to IFCDC implementation from a systems perspective? Because these factors impact the unit's system and culture of how care is provided. The focal point for care decisions moved from family-centered or baby-focused to one of staff availability and infection thwarting. The worst of the pandemic is over, yet the ramifications from a systems' thinking view are not.

As the restrictions of the pandemic are released, the unit operational budgets are not as quick to rebound to pre-pandemic levels, and staff shortages across all healthcare professions are common. As new hires enter the workforce, they begin to practice with limited specialized clinical skills and likely little knowledge of IFCDC. They may have never experienced the family as an essential caregiver since entering the workforce. So, their worldview of what is "usual practice" is altered. Care is probably focused more on physical needs and not developmental support. Igniting the excitement for IFCDC practice – often viewed as "fluff" or nice but not necessary to care – is like starting over with the reluctance that comes with fear, apathy, and inertia. With the development of evidence-based standards, IFCDC is essential to care for the baby and family in intensive care, yet with the impact of the pandemic, there have been policy and practice changes that have impeded progress in their implementation. (7)

Regardless of the experience and sensitive approach to the baby's needs, healthcare staff cannot provide the connection of a parent. The baby's need for neurophysiological and psychosocial support in the nurturing care of his/her parents is still essential. However, most importantly, staff need to comprehend and demonstrate competence in the skill of connecting and supporting the baby, parents, and family members. This relationship is the sustaining factor throughout the lifespan, and the foundation is established in intensive care.

Systems thinking is essential to a leader's assessment, planning, implementation, improvement, and continual monitoring of the mission, values, practice, outcome, and sustainment of a healthcare organization, an ICU, and thus is instrumental in affecting clinical care for babies and their families. As the pandemic recedes to an endemic, the interprofessional team and parents need to use systems thinking and a trusting, collaborative relationship to re-invest in the essential practice of infant and family-centered developmental care.

"As the pandemic recedes to an endemic, the interprofessional team and parents need to use systems thinking and a trusting, collaborative relationship to re-invest in the essential practice of infant and family-centered developmental care. "

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Fragile Infant Forums for Implementation of Standards (FIFI S)
Formerly Fragile Infant Feeding Institute
July 13-15, 2022

Rationale: The FIFI S initiative is to promote, facilitate and provide strategies for implementation of the published standards of care for Infant and Family Centered Developmental Care in intensive hospital units in the US. Each of the forums will focus on one of the established sets of standards, competencies and best practices (feeding and nutrition, handling and positioning, promotion of states and arousal, pain and stress, skin to skin care and systems issues) with the goal of:

1. Raising awareness of availability of and need for implementation of current evidence based standards into practice.

2. Developing effective and reproducible strategies for assuring implementation of the competencies and best practices into intensive care and

3. Assuring that systems integration will lead to permanent changes in clinical practice.

The first of the forums will focus on the evidence based section of Feeding, Eating and Nutrition Delivery. Faculty will include influencers and researchers in the field. Audience participants will include professionals who will benefit from current research and systems implementation approaches to clinical care and contribute to discussion of best practices.

Hospitals will be encouraged to send their team of professionals who are leaders, influencers and those who have been selected to support change in their hospitals. A letter of support/commitment from the administration will be required for participation.

The two day intensive forum will bring together thought influencers, researchers, clinical professionals and parents who are invested in assuring practice excellence by implementing the IFCDC Standards, Competencies and Best Practices into baby and family intensive care systems.

Objecives:

- Discuss current best evidence based infant feeding practices
- Establish essential systems issues that guarantee implementation of best practices
- Determine best practice implementation strategies for the Feeding and Nutrition standards in national NICUs

Organizing Committee:

- Joy Browne
- Carol Jaeger
- Erin Ross
- Mitchell Goldstein

Program Consultants:

- Joan Arvedson
- Jacqueline McGrath
- Kelly McGlothen-Bell

Proposed Faculty:

- Suzanne Thoyre
- Barbara Medoff-Cooper
- Erin Ross
- Carol Jaeger
- Kelly McGlothen-Bell
- Carol Kenner
- Pamela Dodrill
- Britt Pados

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You are invited to register for the First Fragile Infant Forum for Integration of Standards—FIFI-S Hybrid Conference July 13-15, 2022

The initial Forum will address the Standards, Competencies, and Best Practices for Infant and Family-Centered Developmental Care, focusing on the *Best Practices for FEEDING, EATING, and NUTRITION* developed by the Gravens interprofessional consensus panel.

https://nicudesign.nd.edu/nicu-care-standards/

Registration: https://fifi_s.eventbrite.com

Registration: Hotel Reservations

The Forum allows discourse on current research and implantation of the Standards into intensive care practice. Scholars, administrators, and clinicians are invited to attend to develop a series of recommendations for implementing these competencies and best practices. An emphasis on evidence, system change, and adaptation to a new way of practicing will be the focus of workgroups. Dissemination of implementation recommendations will follow.

Supported by Loma Linda Publishing Company,
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Objectives:

- Discuss current best evidence-based infant feeding practices
- Establish essential systems issues that guarantee the implementation of best practices
- Determine best practice implementation strategies for the Feeding and Nutrition standards in intensive care

Organizing Committee:

- Joy Browne
- Carol Jaeger
- Erin Ross
- Mitchell Goldstein

Faculty:

- Erin Ross PhD, SLP
- Carol Jaeger DNP, NNP
- Kelly McGlothen-Bell IBCLC, DNP
- Carole Kenner PhD, RN
- Pamela Dodrill PhD, SLP
- Britt Pados SLP
- Joy Browne PhD
- Debra Paul, OTR
- Joan Arvedson, PhD, SLP

AGENDA (subject to change without notice)

Date/time	Topic	Speaker/Facilitator
July 13	**FORUM DAY 1**	TBD
Afternoon	Optional visit to Prolacta	
6:00-7:00	Gathering/networking/ happy hour	Faculty
7:00-8:00	Keynote on Systems Change	TBD
July 14	**FORUM DAY 2**	
8:30-9:00 am	Welcome, introductions, instructions, and goals for the Forum	Browne
9:00-9:30 am	Overview of Feeding, Eating, and Nutrition Delivery standards development and current evidence	Ross Arvedson
9:30-10:30 am	2 Research presentations of current best practices in Feeding, Eating, and Nutrition delivery. 20-minute presentation, 10-minute discussion each	Ross Pados
10:30-11:00	Break	
11:00-12:00	Research presentations of current best practices in Feeding, Eating, and Nutrition Delivery: 20-minute presentation, 10-minute discussion each	Thoyre Dodrill

12:00-12:30	Discussion across speakers with generalities of the barriers they faced, who they included, and what they forgot	All am speakers Moderator: Browne
12:30-1:15	Lunch	
1:15 – 1:45	Systems thinking 20-minute presentation 10-minute discussion	Jaeger Kenner
1:45-2:00	Instructions and assigned to workgroups to develop strategies for implementation	Browne
2:00 – 2:45	Workgroup discussion of potential strategies for implementation (systems and eating integrated)	Faculty member to each group
2:45-3:15	Strategies for implementation workgroup feedback	Designated facilitator and recorder
3:15-3:30	Break	
3:30-4:15	Workgroups: Identifying barriers to clinical implementation	Faculty assigned to each workgroup
4:15-4:45	Reports from workgroups	Designated facilitator and recorder
4:45-5:00	Synthesis of Day 1 topics	Paul
5:00	Adjourn	

Day/time	**Content/Topics**	**Presenter/facilitator**
July 15	**FORUM DAY 3**	
8:30-9:00	Continued discussion, review of the previous day, and goals for the second day.	Browne
9:00 -9:30	System implementation: Realistic strategies	Kenner Jaeger
9:30-10:00	Clinical implementation approaches including how to address barriers	Paul
10:00-10:15	Break	
10:15-11:00	The importance of and how to measure progress (metrics)	Jaeger/Ross
11:00-11:45	Open forum discussion: Integration of standards into systems and clinical practice	Moderators Paul Kenner
11:45-12:30	Lunch	
12:30-12:45	Assign to workgroups	Browne

12:45-1:30	Workgroups: Recommendations for implementation of standards to include systems thinking	Faculty assigned to each workgroup
1:30-2:00	Reports from workgroups	Designated facilitator and recorder
2:00 – 2:45	Summary and discussion of recommendations from workgroups to include recommendations, system and clinical implementation strategies, barriers	Browne Ross
2:45-3:00	Break	
3:00-3:30	How to use systems thinking to address recommendations, implementation, and barriers (full circle)	Kenner Jaeger
3:30-3:45	What have we forgotten? Check-in with group	Arvedson
3:45-4:00	Next steps, action plan development and statement of accountability	Browne
4:00	Adjourn	

Location: Courtyard by Marriott Los Angeles Pasadena/Monrovia
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Costs for both in-person and virtual:

$395 for MDs
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"Storyteller" painting by Sharron Montague Loree, 1982

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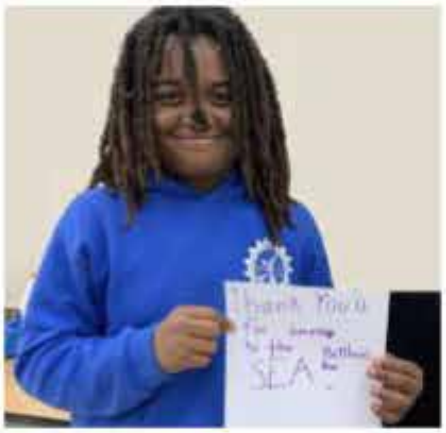

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Middle School	$3,240

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Unplanned Extubation in the NICU

Bernadette Mercado BS RRT

Unplanned or unintended extubation can lead to neonatal morbidity, and there is an increase in unplanned extubation (UE) in the Neonatal Intensive Care Unit (1) It can occur when handling babies, especially during care or when parents perform skin-to-skin or kangaroo care. Outdated protocols, ineffective tube holders or improper use of securement devices, and no standardization of care in the NICU can result in Unplanned extubation. UE is associated with poorer hospital outcomes, including increased mechanical ventilator time, increased length of hospital stays, and death. (2)

"Outdated protocols, ineffective tube holders or improper use of securement devices, and no standardization of care in the NICU can result in Unplanned extubation. UE is associated with poorer hospital outcomes, including increased mechanical ventilator time, increased length of hospital stays, and death. (2)"

Background of Problem

The downstream financial impacts of unplanned extubation, several potential costs extend up to $50,000 per incident and double the length of stay, adding up to 5.9 billion in healthcare costs. (3) The financial impact is one of the issues and the long-term effects it can cause on the infant and the family. An extended lack of training and focus on care and ways to prevent unplanned extubation needs to be addressed in the Neonatal Intensive care Unit. Like any high-risk profession, there is no room for error when a life is at stake. We can compare it to aviation; pilots are highly trained to transport passengers from one destination to another. They are highly trained not just to fly a plane but to troubleshoot mechanical issues. This research emphasized the need for specialized personnel in a specialized unit. Respiratory therapists need to be part of a team of experts who can discuss and focus on premature infants. It showed in the research that extensive training and protocol should be emphasized. (4)

Possible Solution One - Importance of Designated special: ized RT in a NICU team implementing protocols.

An article in RT magazine talked about the vital role of a Respiratory Therapist striving to improve. This study found that the execution of respiratory-based protocols would be one of the solutions for the intubated population of the NICU, which will prevent or reduce incidents. (Rafidi, A., & Rozansky, C. 2021, February 26). This research will reduce Unplanned extubation by having a standardized approach to care for ventilated neonates. Bundle care was also one effective practice to reduce UE incidence. It takes two to tango is one of the methods we can adapt and continue to implement in the NICU, always two at the bedside during procedures. Having respiratory therapist-driven protocols is part of quality improvement measurements applied to facilities. It was also seen in the research that the overall scoring for patient care should be overseen by nursing and respiratory managers for close auditing and analysis. Managing what next steps are needed for specific patients will ensure suitable treatment plans based on respiratory therapist-driven protocols and team member communications.

Healthcare will always be constantly inclined toward improving care and increasing positive patient outcomes. Reflecting on these facts, we can see that an evidence-based approach of standardized protocols would decrease unnecessary reintubations by reducing the root causes of a UE and complying with a benchmark targeted goal of a UE rate of 1-2 per 100 ventilator days (Rafidi, A., & Rozansky, C. February 2021)

" A comparison was made with airlines saying there are few crashes or errors because pilots and airlines follow protocols and training to prevent tragedies. Same with the RT in the NICU unit same goes for patients trusting the physicians and staff members and the hospital. The medical field strives to advance and improve the quality of care, close to perfect or minimal errors. "

A comparison was made with airlines saying there are few crashes or errors because pilots and airlines follow protocols and training to prevent tragedies. Same with the RT in the NICU unit same goes for patients trusting the physicians and staff members and the hospital. The medical field strives to advance and improve the quality of care, close to perfect or minimal errors. Newer stan-

dards are being created to maintain and enhance quality patient care; According to the article, the medical field has continuously strived to advance the quality of care by minimizing medical errors. As technology developed, patient-driven healthcare began. Healthcare strives to be error-free like the airline industry because lives are at stake. (4)

"Data collected over a ten-year duration showed that GBS was the most commonly occurring EOS organism, followed by E. coli. Of note, none of the infants' mothers received prophylactic antibiotics in all four cases of GBS sepsis."

Research has proved that training in a specialty like a ventilator troubleshooting is essential and saves lives. This research confirmed that specific training is needed, and a "Bootcamp" benefited Respiratory therapists in improving skills in performing competency assessments. The study described the five-team characteristics: membership, interdependence, shared goals, and dynamics. Teams have been the structure for conducting business or work for most of history. Research has proven that development is essential in a dedicated unit to explore possibilities for obtaining a healthy work environment and completing a project. (5)

"The study aims to create and sustain UE rates below the published standard of 1 per 100 ventilator days. (6) It was concluded that standardization and interventions should be implemented to reduce unplanned extubation."

Possible Solution Two – Standardization

The study aims to create and sustain UE rates below the published standard of 1 per 100 ventilator days. (6) It was concluded that standardization and interventions should be implemented to reduce unplanned extubation. Standardization correlates with the decline of UE, A drop in ETT tube placement should be confirmed by chest X-ray. This is a cost-cutting inpatient procedure and requires less radiation exposure. Implementations include standardization of patient care, recording, patient re-positioning, movement, shift event reporting, and patient handoff. Having a protocol and set policy in a specialized unit will decrease Unplanned extubations. (7)

Result if No Change is Made

Unplanned extubation is associated with increased costs and adverse outcomes, complications, and death. During mechanical ventilation, the most common adverse events were. 14% to 41% of infants go through a UE during their NICU. (3) Short-term trauma from reintubation, deoxygenation, and hemodynamic instability lead to CPR. UE is associated with poorer hospital outcomes, including increased mechanical ventilator (MV)time, hospital stay, and thus increased hospital costs. Some studies have indicated that these poor clinical outcomes are primarily driven by patients who require reintubation after UE. (1) Caregiver error is always associated with UE.

Some adult restraints can help prevent UE. When it comes to NICU babies, restraints are not an option. That is why the caregivers are responsible for the endotracheal tubes. The standardization and implementation of specific protocols should be implemented, enforced, and followed. According to the data in this study, the average cost of mechanical ventilation is approximately $1,522 per day in hospital costs. The average price is $59,206 for an ICU stay for a mechanically ventilated patient without unplanned extubation. Due to an increased ICU length of stay (18 vs. nine days) for patients who go through accidental extubation, the average cost of an ICU stays and complications doubles to $100K. Due to the increased length of stay and complications due to accidental extubation, the additional cost per unplanned extubation is $40,992. (1)

"Due to an increased ICU length of stay (18 vs. nine days) for patients who go through accidental extubation, the average cost of an ICU stays and complications doubles to $100K. Due to the increased length of stay and complications due to accidental extubation, the additional cost per unplanned extubation is $40,992."

A study factored in complications such as nosocomial infection. It increased length of stay (LOS)in pediatric patients who experienced accidental extubation in the ICU and found that costs increased by $36,692 per UE incident. In the United States, the overall cost burden in the ICU from unplanned extubation totals nearly $5 billion. If incidents of accidental extubation in the NICU are included, this event adds $500 million in hospital costs. (1)

Best Option to the Resolve the Problem

The first option is implementing RT-driven protocols, acknowledging the importance of designated specialized RT in a NICU. Many researchers and healthcare organizations have successfully proven and implemented improvements and reduced death and complications from UE. According to the Actionable Patient Safety Solution, a blueprint outlines actionable steps organizations should take to reduce UE. The goal is to eliminate all preventable harm caused by unplanned extubation. The key players in these safety protocols are Respiratory Therapists. Their specialty in airway protection and mechanical ventilation can help prevent UE, tube migration, and mechanical ventilation.

Challenges to Implementing the Solution

The main concern in the solutions mentioned is staffing issues; The RTs must attend a 3-day NICU training course. That will pull RTs away from bedside care while in training. Not all RT will go simultaneously; some must wait for their turn. Usually, it causes a conflict among employees, thinking one is more favored or trusted. Seniority should be implemented to eliminate these is-

sues. The employees who have been there the longest should be trained first and for a year, mentor new employees who are stepping up in the NICU, and be the resource for others who have not gone through training.

No incentive should be given for working in a specialized unit. These will not entice staff to work in a high acuity unit without encouragement. A manager can reach out to administration and union to see what we can do to provide specialty pay to RT who would like to work in the NICU. Advocating for the staff and the NICU should be the highest priority of a leader in the department.

Risks and Dependencies

Work-force Risk

With training comes the risk of staff turnover. It is not a secret that the more education, training, and experience employees gain, the more they become an asset to the department. On the other hand, they have become more marketable in the healthcare industry. A respiratory therapist can branch out to other hospitals or fields with higher pay. With specialty, training staff can be more marketable to other hospitals.

Operational Risk

During training, this will take staff away from bedside patient care for two weeks. The department will experience staffing issues. But this is just a temporary issue that can be prepared in advance for coverage.

Another operational risk is new equipment; failure can be anticipated that specific new equipment without proper training will not work as well as expected. New machines designed to stay connected to the patient's ventilator circuit have increased mechanical dead space that affects ventilation. It can also be a hazard for the weight it adds to the circuit.

"In conclusion, the first step is increasing the awareness that unplanned extubation is an issue in the Neonatal Unit that needs to be addressed. Going back to basics like retraining and extensive Neonatal training should be offered to the Respiratory therapist working closely with babies."

Conclusion

In conclusion, the first step is increasing the awareness that unplanned extubation is an issue in the Neonatal Unit that needs to be addressed. Going back to basics like retraining and extensive Neonatal training should be offered to the Respiratory therapist working closely with babies. New revised protocols and standardization should be implemented, enforced, and followed. Evaluating new technologies and different devices in the market should be considered. A waveform capnography monitor is out on the market and should be considered for monitoring babies' endotracheal tubes while having skin-to-skin care with the parents; it is a valuable tool for regular baby care. It can also be used when babies have procedures performed on mechanical ventilation. Staffing and equipment cost less than the cost of accidental extubation of 5 million a year and the priceless lives that can be saved.

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Disclosures: The author has no conflicts noted.

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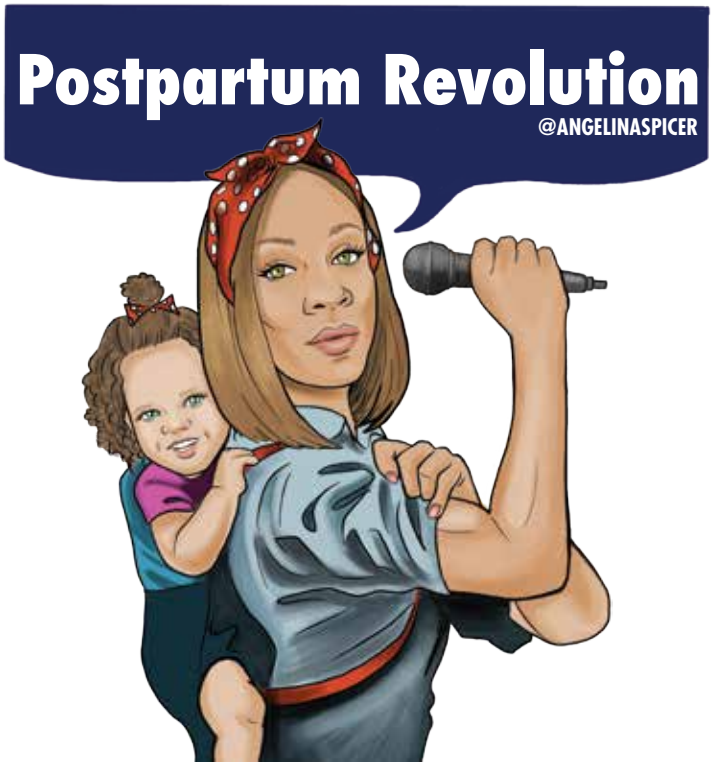
The Village Son

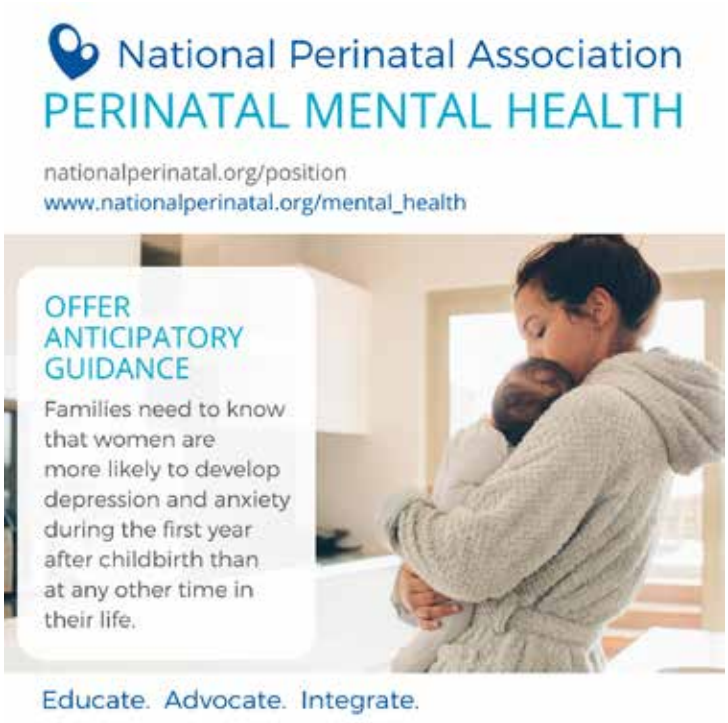
A Life's Journey

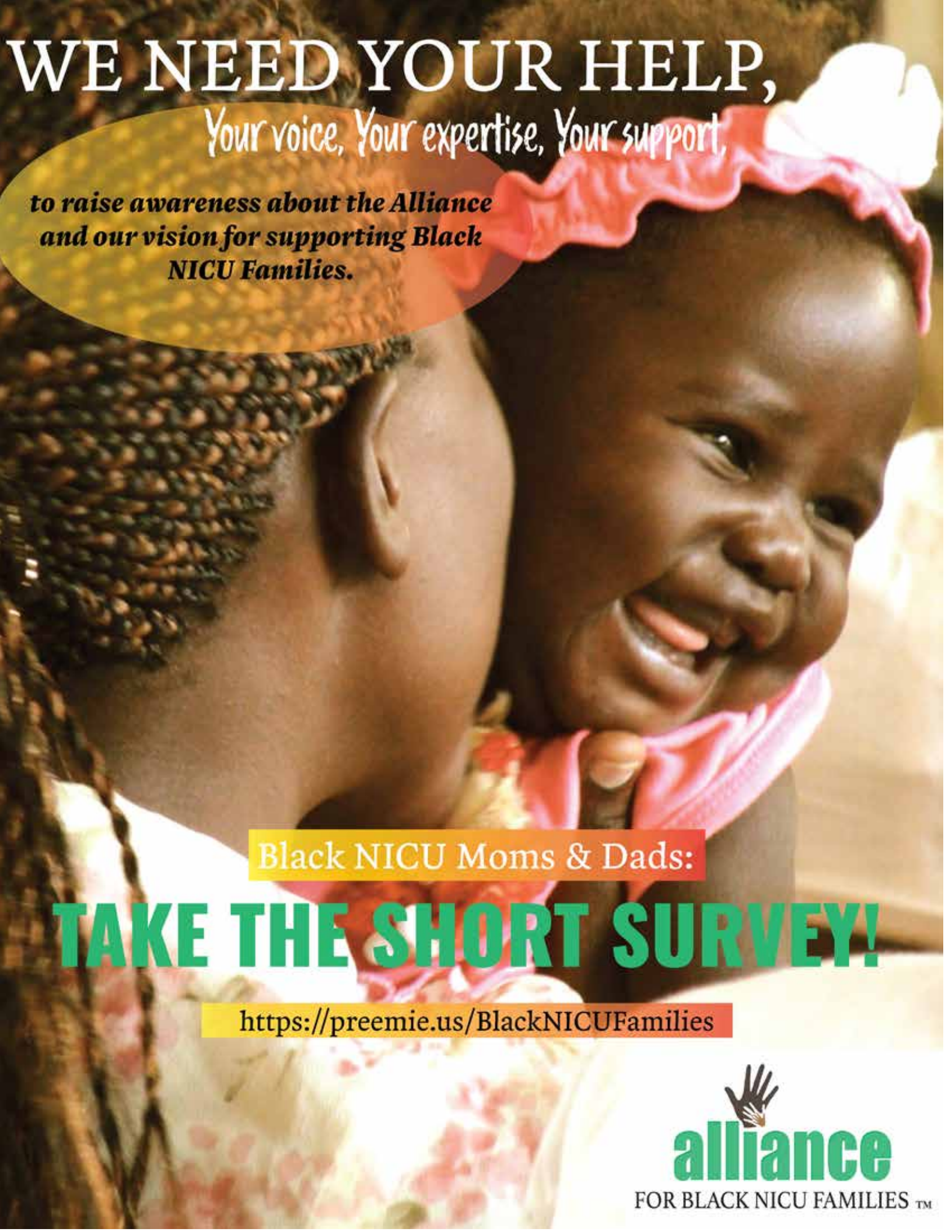
Iranian village to a university professor in the United States of America in this memoir. As a boy, his unruly behavior was sedated by scholastic challenges as a remedy. At age twelve, he left home for junior high school in a provincial capital. At first, a lack of self-esteem led him to stumble, but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

Houchang D. Modanlou

Alvin Goldberg
December 25, 1936 - July 5, 2022
May his memory be a blessing to those who knew him.






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 ™

Examining What the Revised AAP Infant Safe Sleep Guidelines Mean for Families

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.

"In the past two months, a great deal of information and legislation has come out about safe sleep and products that are not appropriate for infant sleep."

In the past two months, a great deal of information and legislation has come out about safe sleep and products that are not appropriate for infant sleep.

The Safe Sleep for Babies Act makes it unlawful to manufacture, sell, or distribute crib bumpers or inclined sleepers for infants, and the Consumer Products Safety Commission has ruled that the only products that can be marketed for infant sleep are cribs, bassinets, play yards, and bedside sleepers.

In addition, the updated American Academy of Pediatrics (AAP) Guidelines have been released and are being published in the July issue of *Pediatrics*.

All this new information can be confusing to families as they consider what they should and should not do. From our decades of work with care providers and families, we recognize the real-world challenges confronting parents as they care for their babies.

We also realize that the language of the revised guidelines is appropriately drafted for AAP members and not necessarily for families and caregivers. We support the guidelines and want to ensure that parents, caregivers, and community members understand them and how to use infant products safely and as intended.

" We also realize that the language of the revised guidelines is appropriately drafted for AAP members and not necessarily for families and caregivers. We support the guidelines and want to ensure that parents, caregivers, and community members understand them and how to use infant products safely and as intended."

The revised set of guidelines retains recommendations outlined in the initial Back to Sleep campaign, which contributed to a 50 percent decrease in SIDS deaths after its launch in the 1990s, and introduced new or updated actions parents and caregivers can take to reduce the risk of sleep-related infant death. First Candle, known as the SIDS Alliance, was a collaborator in the original campaign.

Some may recognize previously known advice in the revised guidelines and wonder what is new. While the revision retains the basic evidence-based tenets for safe infant sleep, it references data that may have been compiled since the last revision in 2016, expands language on breastfeeding/human milk feeding, sleep surfaces, bedding, and swaddling, and provides information regarding infant safe sleep products and recent actions taken by the Consumer Product Safety Commission (CPSC).

Among the guidelines left in place are placing babies on their backs for night and nap, sleeping on their firm, flat surface, with

no loose bedding or other items; room sharing during the first six months, breastfeeding; and healthcare guidance for the mother and infant pre- and post-natal.

The revised guidelines also address risky infant sleep environments, including bed-sharing. While the revised document acknowledges that parents may decide to share a bed with their infant to help with breastfeeding or for cultural norms, the AAP cannot support bed-sharing under any circumstances.

Indeed, the rate of bed-sharing is high. The Centers for Disease Control and Prevention (CDC) analyzed 2009–2015 Pregnancy Risk Assessment Monitoring System (PRAMS) data. They found that more than half of families (61.4 percent) reported infant bed sharing, with higher rates among American Indians/Alaska Natives, non-Hispanic Blacks, or Asians/Pacific Islanders than non-Hispanic whites or Hispanics.

"Parents are exhausted, and while they may know the guidelines are against adult bed-sharing, it often happens for practicality while the mother is breastfeeding, and she may fall asleep. For others, it is due to socioeconomic factors, cultural beliefs, traditions, or personal choices."

Parents are exhausted, and while they may know the guidelines are against adult bed-sharing, it often happens for practicality while the mother is breastfeeding, and she may fall asleep. For others, it is due to socioeconomic factors, cultural beliefs, traditions, or personal choices.

We are disappointed that the rates of SUID have not decreased in more than two decades despite the safe sleep guidelines. That means we must change how these messages are delivered and by whom. Trusted community providers such as doulas, social service agencies, and faith-based leaders must lead the way in having authentic conversations with families, educating and supporting them in ways that respect their lived experiences.

First Candle incorporates its "common language" approach to the safe sleep guidelines through its website and materials and its professional- and family-targeted outreach programs. It draws on the AAP guidelines in its Straight Talk for Infant Safe Sleep program, which trains health care providers, including nurses, doulas, and social workers, on safe sleep and explores how implicit bias impacts the education of families.

The guidelines are also central to its Let's Talk Community Chats initiative, which partners with community leaders and advocates to address racial disparities in SUID rates through extended conversations with families about safe sleep, breastfeeding, and the proper use of infant products. The chats are held monthly, free of charge, at local gathering places such as churches, community centers, laundromats, and retail establishments.

Both of these programs are opportunities to discuss the applications of each guideline, the "why" behind each in everyday language, free of bias, and to help parents understand how to safely and properly use infant products.

"The results of First Candle's review of the revised guidelines and the "why" information can be found on its website at https://firstcandle.org/safesleep/. Additional graphics, video, and other media assets are available at www.firstcandle.org/media."

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***Disclosure**: The author is the Executive Director of First Candle, a 501c (3) non-profit organization.*

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About First Candle

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

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:

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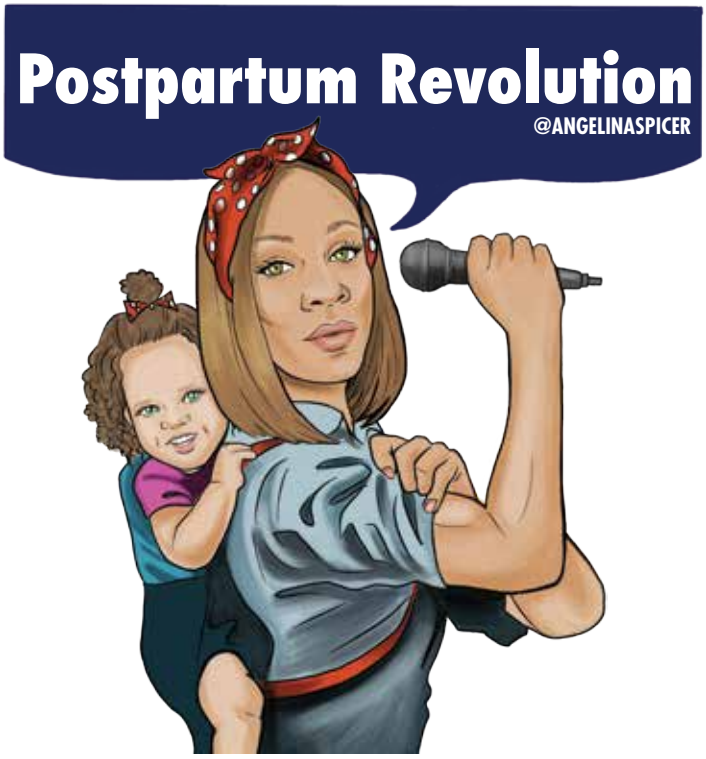
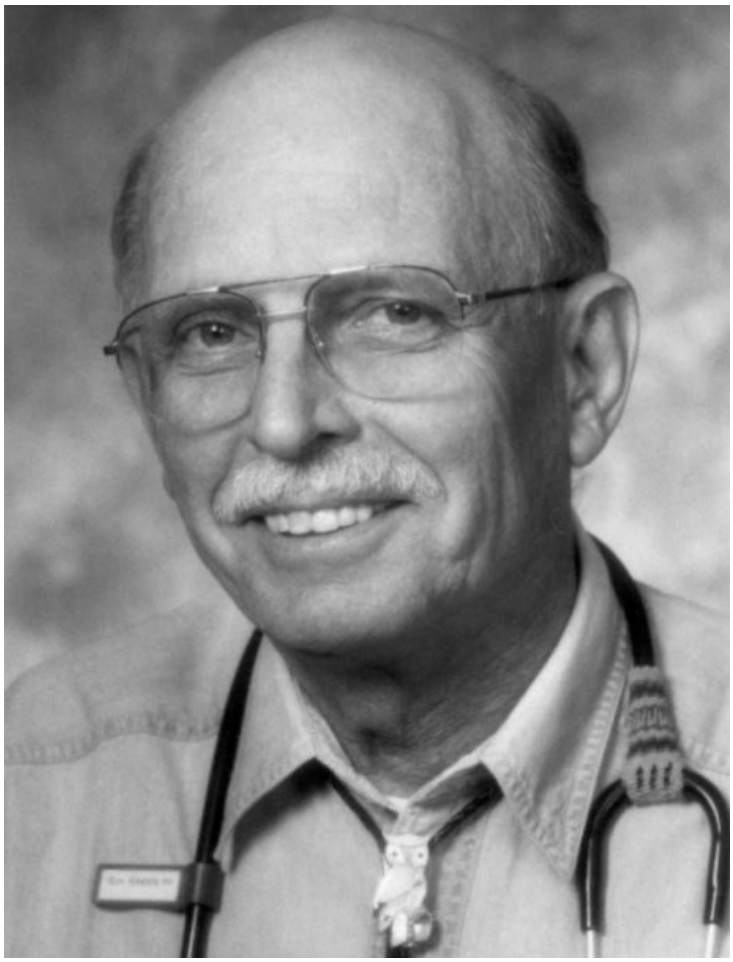


In Memory of Thomas Richmond Harris, MD

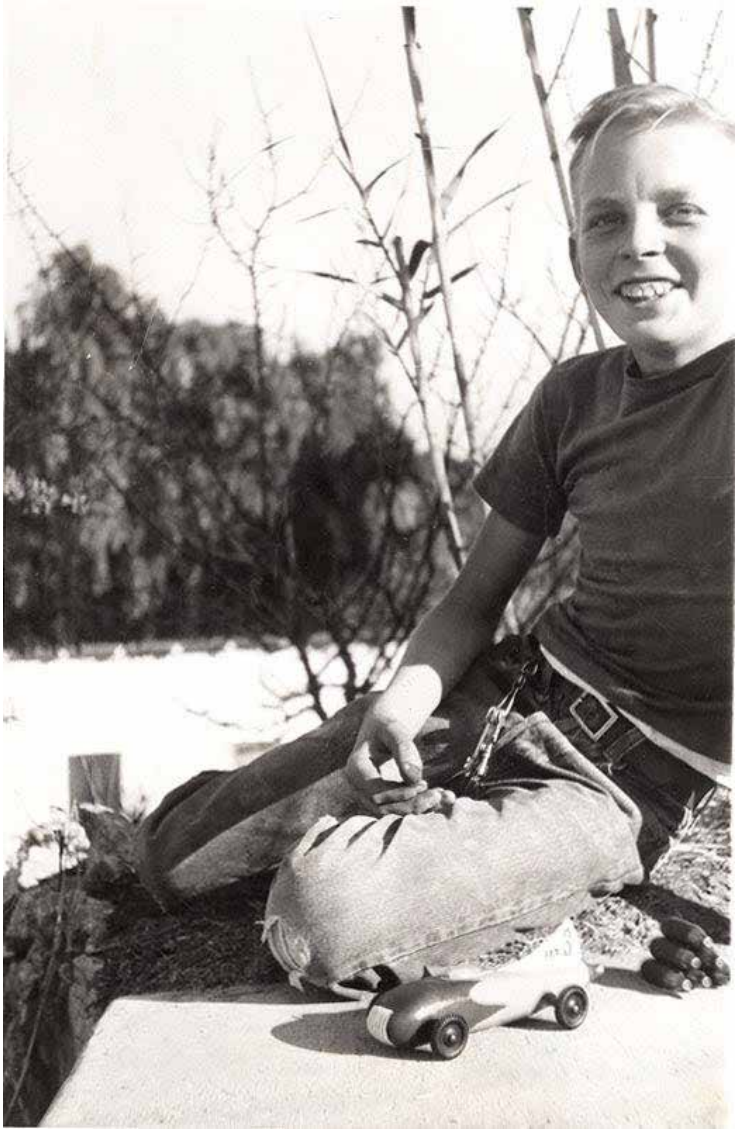
Jill Koster



Dr. Thomas Richmond Harris, 88, passed away on May 19, 2022, while undergoing a surgical procedure in Riverside, California. He was surrounded by his family before the surgery.

Tom was born in Long Beach, CA, on September 21, 1933, to **Richmond Ralph Harris** (born 1909 in Long Beach, CA) and **Ellen Crandell** (born 1911 in Ann Arbor, MI). As a young boy, he was diagnosed with severe asthma and a cat allergy, so his mother, a cat lover, sent him to a boarding school. Unable to return home on weekends or holidays, Tom was prone to self-pity and had a deep-seated fear of abandonment. But he channeled that energy into his activities; he learned camping and survival skills, could identify birds and plants by their species, took up building model airplanes and woodworking, and became an excellent swimmer.

A local newspaper once wrote about young Tom putting peanut butter on trees to lure animals near him on Christmas. As he matured, Tom became self-reliant and was a natural leader among his peers. In applying himself academically, Tom found that he excelled, building the confidence that would later propel him to success as a doctor and educator.



Tom obtained his BA in History in 1955 from Pomona College in Claremont, CA. While there, he spent a formative semester as an exchange student at the historically black Fisk University at the start of the Civil Rights Movement. In the summers, he worked as a firefighter and came to know the Southern Californian mountains and valleys like the back of his hand.

Primarily to please his mother, Tom attended Union Theological Seminary in New York City on a Rockefeller brother's fellowship from 1955 to 1957. But ultimately, Tom found the answers to his religious questions wanting, and so he left the seminary to pursue pre-med courses at Columbia University.

"Tom obtained his BA in History in 1955 from Pomona College in Claremont, CA. While there, he spent a formative semester as an exchange student at the historically black Fisk University at the start of the Civil Rights Movement."

Tom was drafted into the Army in 1957 and served until his honorable discharge as a "Specialist 4" in 1963. While stationed in Germany, Tom learned German well enough to continue his pre-med studies at the University of the Saar in Saarbrücken and to obtain his MD magna cum laude in 1965 from the Free University of Berlin. The Berlin wall was erected shortly after he moved to the American sector of West Berlin, and Tom would later fondly recount helping smuggle personal items in and out of Communist-controlled East Berlin.

Tom interned in medicine in Augsburg, Germany, and Tucson,

AZ, from 1965 to 1968, before undertaking a pediatrics residency and a neonatology fellowship at Stanford University Hospital from 1968 to 1971.

During his lengthy career as a neonatologist, Tom taught and worked at the following institutions of higher education and medicine:

• **In Tucson, AZ**: Arizona Health Sciences Center, University Medical Center, The University of Arizona School of Medicine, and Tucson Medical Center (1971-1980);

• **In Salt Lake City, UT**: University of Utah College of Medicine, Primary Children's Medical Center, and University of Utah College of Nursing (1980-1985);

• **In Philadelphia, PA**: Temple University School of Medicine and University Hospital (1985-1987);

• **In Denver and Grand Junction, CO**: University of Colorado School of Medicine and St. Mary's Hospital (1987-1992); and

• **In Phoenix and Yuma, AZ**: various hospitals serviced by Neonatology Associates, Ltd., and Yuma Regional Medical Center (1992-2004).

Tom is credited with many innovative ways of saving babies, including the transport to tertiary care centers of high-risk pregnant mothers and sick babies in rural areas. He gave hundreds of lectures on neonatal critical care and pulmonary physiology, and his talks received awards for their inventive use of visual aids consisting of diagrams Tom meticulously drew, photographs he took, and tables and charts illustrating data he painstakingly collected. Tom also published 28 scientific articles and five book chapters and served as editor or reviewer of many more.

In 1983 Tom wrote an open letter to then-Surgeon General C. Everett Koop, MD, on the proposed "Baby Doe Law" to defend and protect medical practitioners. From then on, Tom was frequently called on as a source for comment by journalists and medical publications addressing the subject. Tom also served as an expert witness in numerous malpractice and criminal cases involving the untimely death of newborns, usually in support of medical caregivers.

"In 1983 Tom wrote an open letter to then-Surgeon General C. Everett Koop, MD, on the proposed "Baby Doe Law" to defend and protect medical practitioners. From then on, Tom was frequently called on as a source for comment by journalists and medical publications addressing the subject."

Tom was dedicated to improving neonatal nurse practitioner programs wherever he worked. He was also instrumental in the development and FDA approval of the Bunnell high-frequency jet ventilator; his tireless efforts in gathering data, developing treatment strategies, and founding an annual international conference to exchange ideas for improving this ground-breaking technology have helped save over 200,000 infants to date.

As the recipient of numerous awards and honors, Tom will be remembered at Primary Children's Hospital in Salt Lake City as the namesake for the "Harris Care Team" in their Neonatal Critical Care program. He also received a "Lifetime Achievement Award" from the Children's Health and St. Joseph's Medical Centers in Phoenix, AZ.

Although medicine was his first love and prioritized above all else, Tom's personal life was notable too.

While stationed in Germany with the Army in 1959, he met and married a local pediatric nurse, **Irmgard Maria Harris** (nee: Sporer). Tom and Irmgard traveled Europe extensively: rolling their little VW bug through Italy, attending bullfights in Spain, and smuggling artwork out of Russia. Together they shared two children: **Michelle Elizabeth Goetz** (nee: Harris), who was born in Tucson, AZ, in 1967 and still resides there with her two children (**Aaron James Goetz**, 31, and **Tyler Mark Goetz**, 28); and **Mark Richmond Harris**, who was born in Tucson, AZ in 1972 and resides there as well.

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Tom later met **Susan Louise Dennerly** (nee: Ammon), a pediatric nurse in the ICU Nursery at Tucson Medical Center. Susan shared Tom's love of children, camping, and fishing. Together they had two children: **Jared Thomas Harris**, born in 1973 in Tucson, AZ, who resides in Denver, CO, with his wife **Rene Lynn Harris** (nee: Seiler) and their three children (**Joshua Jared Harris**, 25, **Hunter Michael Harris**, 21, and **Taylor Rene Harris**, 19) and grandchildren; and **Jill Rochelle Koster** (nee: Trumbull-Harris), born in 1975 in Tucson, AZ, who resides in the US Virgin Islands with her husband **Scott Allan Koster**.

After relocating to Utah, Tom met and married **Dr. Claudia Stevens Harris** (nee: Harris), a professor of graduate-level business management classes who minored in mathematics. Claudia shared Tom's love of academia, scholarship, and classical music. Together they shared two children: **Alexis Stevens Harris**, born in 1975 in Salt Lake City, UT, who resides in Chapel Hill, NC; and **Jessica Anne Harris**, born in 1981 in Salt Lake City, UT, who resides in New York City.

When that marriage ended, Tom reconnected with **Patricia Ann Jensen**, an executive secretary who had worked with him in Salt Lake City, UT. Pat had since lost her long-time husband to a protracted illness. With their subsequent union, Tom became the fill-in patriarch of a large and loving Mormon family. Tom and Pat enjoyed many peaceful years together, traveling between Arizona and Utah and overseas, including Germany, Denmark, and New Zealand. When Pat was diagnosed with Alzheimer's disease, Tom spent years studying the illness and lovingly caring for her.

Not one to give up on romance, Tom later married **Kimhuor Tieng**, mother to **Vitou Tieng**, born in 1981 in Phnom Penh, Cambodia, and two other children whom she lost to starvation while working in the killing fields of Pol Pot and the Khmer Rouge. Kimhuor came to America in 1994 and worked for many years as a chef. When videotaping and photographing Kimhuor cooking, Tom and she hit it off. Their union in 2015 enabled Tom to immerse himself in an entirely new culture surrounded by another large and loving family. In addition to becoming stepfather to Kimhuor's son Vitou and his wife **Yun Kil Khounphithack**, Tom became a grandfather to their three young children (**Kanchnatevi Weiran Tieng**, 14, **Vi-**

tou Chen Tieng, 12, and **Amrita Tieng**, 6) who reside with their parents in Las Vegas, NV.

Together Tom and Kimhuor bought a house in Riverside, CA, with a large gravel pit of a yard and devoted the last seven years of Tom's life to rehabbing the house and planting hundreds of trees, bushes, plants, and flowers, turning it into a lush garden oasis from the hot Southern California sun.

In his spare time, Tom enjoyed traveling to visit family and going sailing or fishing. He helped his kids with their home improvement and building projects. And Kimhuor introduced Tom to meditation, which, although challenging, brought Tom solace. Tom and Kimhuor frequently hosted family and friends at home until the Covid-19 pandemic began.

Tom's final project in life was transcribing the over 750 pages of Civil War diary, and letters home written by his great, great grandfather Francis B. Harris while serving in the Union Army. Tom proudly donated the original diary and letters, as well as his thorough transcriptions, to the Huntington Library in San Marino, CA.

In addition to his life-long struggle with asthma, in 2004, Tom underwent a triple bypass and aortic valve replacement. In 2020, he began coughing up blood periodically due to intermittent bouts of pneumonia. This past December, Tom fell while gardening, causing a gash in his head and significant blood loss, revealing his need for a pacemaker. Tom seemed to be on the mend this Spring until the coughing resurfaced and worsened. Strong antibiotics were prescribed to clear up what appeared to be a lung infection, but on May 17, 2022, Tom began coughing up copious amounts of blood, and a bronchoscopy was scheduled for the following day. That procedure led to discovery of a vascular tumor blocking Tom's right ventricle. With his heart and kidneys slowly failing, Tom chose surgery to have the tumor removed, knowing full well the risks involved. He insisted that if he were to go on living, it would be only with the full use of his body and intellect. While sedated in surgery, Tom's lungs collapsed, his blood pressure dropped, and doctors honored his medical directives, allowing him to pass away peacefully on May 19, 2022.

Tom was preceded in death by his parents and former wives, **Irmgard Maria Harris**, **Claudia Stevens Harris**, and **Patricia Ann Jensen**. He is survived by everyone else named herein as well as his older sister **Betty Salinas** (nee: Harris).

Tom's loved ones describe him as driven, ambitious, and incredibly disciplined. He was perpetually intellectually curious up to his final hour. An adventurer at heart, he deeply loved and appreciated wildlife and nature. He enjoyed traveling, camping, hiking, skiing, sailing, and birdwatching and was an excellent photographer. He was an avid fly-fisherman and a true artist when it came to fly-tying and the building of custom fly rods. And surprisingly (given his profession), Tom's penmanship was impeccable, which was greatly appreciated by his clinical colleagues.

No matter the project—whether in his workshop, his garden, writing a letter, or preparing a lecture—Tom took great pride in his work and gave every task his absolute all.

Tom was also honest to a fault, which made him a comically bad poker player but an incredibly accurate historian. Those who knew him well also knew that Tom sometimes did not react well to adversity and could succumb to his temper, though he directed most of his frustration inward and rarely lashed out at others. Thankfully Tom also had a great sense of humor and could laugh about his failings. Tom was deeply intellectual and never shied away from a difficult or complicated subject. On the contrary, he had a knack for spurring meaningful discussions. An ardent Democrat, Tom followed politics closely, volunteered for local and national political campaigns later in life, and was passionate about a woman's right to choose and other socially liberal causes.

Tom was also a passionate, caring, and sentimental man. Upon his passing, he left each of his six children a box containing the important cards and letters they had exchanged, their school photographs and drawings, school reports and essays, newspaper clippings, and various other childhood mementos. Tom also saved every "thank you" card or letter he received. Since his passing, the letters written by parents of premature or sick babies Tom treated but could not save are particularly moving to his children. Even in the face of unspeakable loss, tens of bereaved parents took the time to praise his heroic effort to provide around-the-clock and fastidious care while keeping a direct, honest, and sincere line of communication and steadfast emotional support and professional guidance.

In sum, **Dr. Thomas Richmond Harris** loved fiercely, lived independently, and worked tirelessly to build a long and successful career and a diverse and vibrant family. He lived a fascinating and full life and did so his way up until the very end. He was deeply loved and will be sorely missed.

Tom's ashes will be interred at Riverside National Cemetery on Thursday, June 9, 2022, at 11:30 am. His family and friends are planning a virtual memorial ceremony for what would have been Tom's 89th birthday: September 21, 2022, beginning at 8 pm Eastern. If you would like to participate in either event, sign up here, and we will be in touch with details.

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https://drtomharris.com/

The Dr. Thomas R. Harris Memorial is scheduled for Wednesday, September 21, 2022, 8 pm EST on Zoom

Tom Harris Tribute

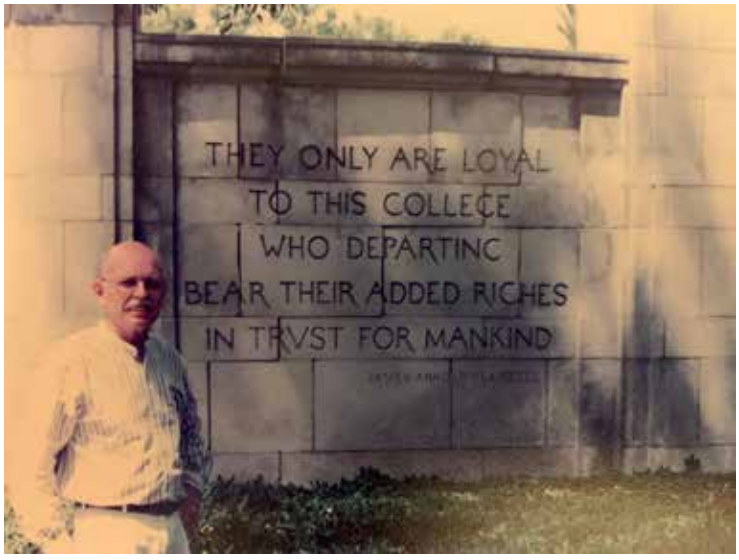
My friend, Dr. Tom Harris, left us on May 19, 2022, while undergoing a surgical procedure in Riverside, California. I urge you to read the dedicated website detailing his extraordinary life his daughters created at drtomharris.com.

To my knowledge, Tom was the first person to use a high-frequency ventilator to treat newborn infants using a fluidic device created by Dr. Jerry Calkins at the University of Arizona Medical Center in 1980. That device utilized two Suave shampoo bottles housed in a shoe box. When he moved to Salt Lake City not long after that, he was instrumental in the development of the first FDA-approved HFV, for which over 200,000 infants to date are eternally grateful.

Tom was passionate, caring, incredibly disciplined, and adventurous. He taught me how to fly fish, and we both broke our arms at a conference we co-founded at the Snowbird ski resort in Utah.

I miss him terribly.

Bert Bunnell, ScD



A Tribute to Dr. Tom Harris

I first met Tom Harris in 1995. Relative to other neonatologists here, I was a latecomer. Tom was a fixture at the Snowbird High-Frequency Conference. For someone like me, a brand new Neonatologist in 1995, he represented the voice of reason, experience, and bedside acumen. He was a mix of the practical bedside clinician and academician. Tom knew his physiology well and how to translate it into clinical effects. We missed having him at Snowbird these past few years. With our moving the conference to Ontario, CA, we hoped that Tom might be able to attend. This coming year, we plan to hold a memorial lecture to honor his life and contribution to our knowledge. He truly made a difference.

Mitchell Goldstein, MD

Professor of Pediatrics

Loma Linda University Children's Hospital

A Tribute to Dr. Tom Harris

Tom Harris; I met Tom at the first High Frequency Conference. We toured the Nursery at the old Primary Children's Hospital where he showed me the jet ventilator. Tom was a great clinician and physiologist for neonates.He was responsible with Burt for its use in preterm critically ill newborns. I agreed to assist Tom with the High Frequency meetings and when Tom moved to Philadelphia at his request I took it over. Tom continued to support the meeting. He was always a resource and a friend. I will miss him.

Don Null, MD

A Tribute to Dr. Tom Harris

It is with great pleasure I write this tribute to Tom. I met Tom in December 1976 when I moved from the University of Cincinnati to join the faculty at the University of Arizona, where he was the medical director of the Neonatal Intensive Care Units and the transport services. Although we both left Tucson in 1980, we continued to be in touch and exchanged personal and professional stories. We chatted for long periods on his birthdays during the last decade.

A great **Clinician**- Tom was passionate about providing the best care to every baby. He earned the respect of nurses, parents, and other staff (note: we did not have respiratory therapists and nurse practitioners then). I want to share several stories which come to mind: (1) During the early 'dark days' of Neonatal care, he taught me how to use negative-pressure ventilators. Nurses disliked this ventilation mode because these babies developed neck ulcers resulting from the cuff around the neck. (2) Use of the inverse inspiratory -expiratory ratio popularized by Dr. Reynold (Oxford) led to air leaks. This gave him the impetus to develop 'high-frequency Jet ventilation' in conjunction with our Anesthesiology faculty and subsequently Bert Bunnell; the rest is history! (3) A baby with Ectopia Cordis (1 in 5.5 million births with poor prognosis) was ventilated for more than a year at Tucson Medical Center, raising ethical discussions! In conjunction with Dr. Harlan Giles, he started the joint maternal-Fetal medicine Neonatology Care program.

An articulate **Teacher**- He was excited to teach physiology to our residents, nurses, and Neonatologists. This provided an insight into the changing pathophysiology we often see in many disease states and incorporated strategies to improve their outcome. He started the Neonatal Nurse Practitioner program in conjunction with the College of nursing.

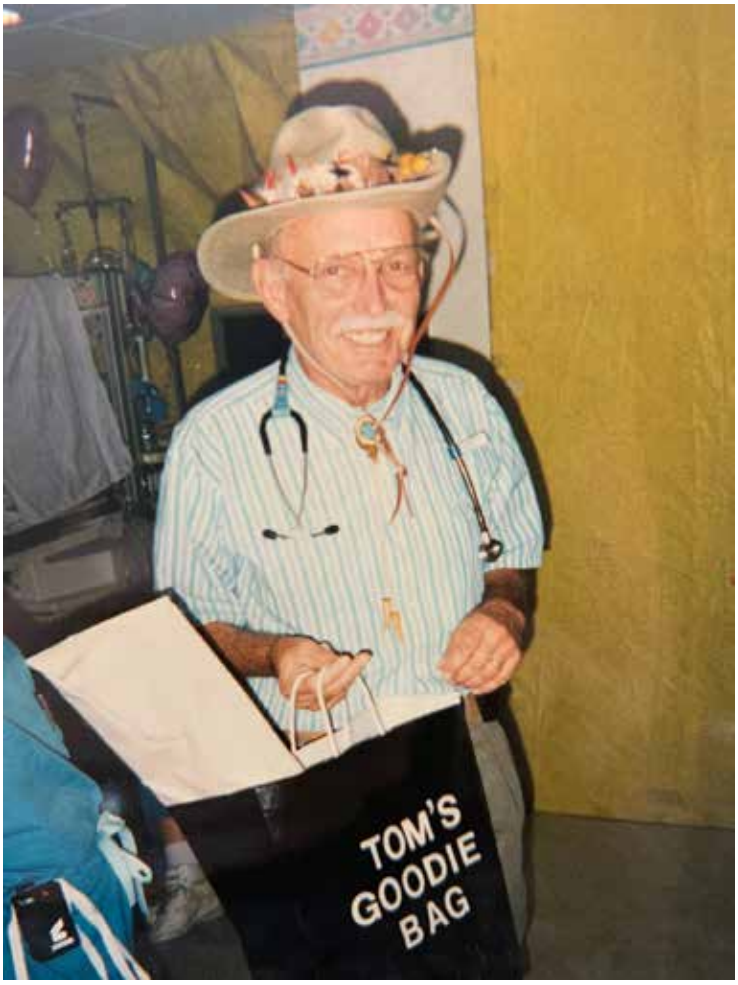
A great **PERSON**- He went out of his way to help others. I remember when he installed skylights in our house in Tucson. He taught me how to fly fish, and ski. Our children would later interact with him at the slopes at Alta and Snowbird, Utah. They enjoyed his company, and he shared the stories of his early college days with my daughter; his wife Patricia was fond of her.

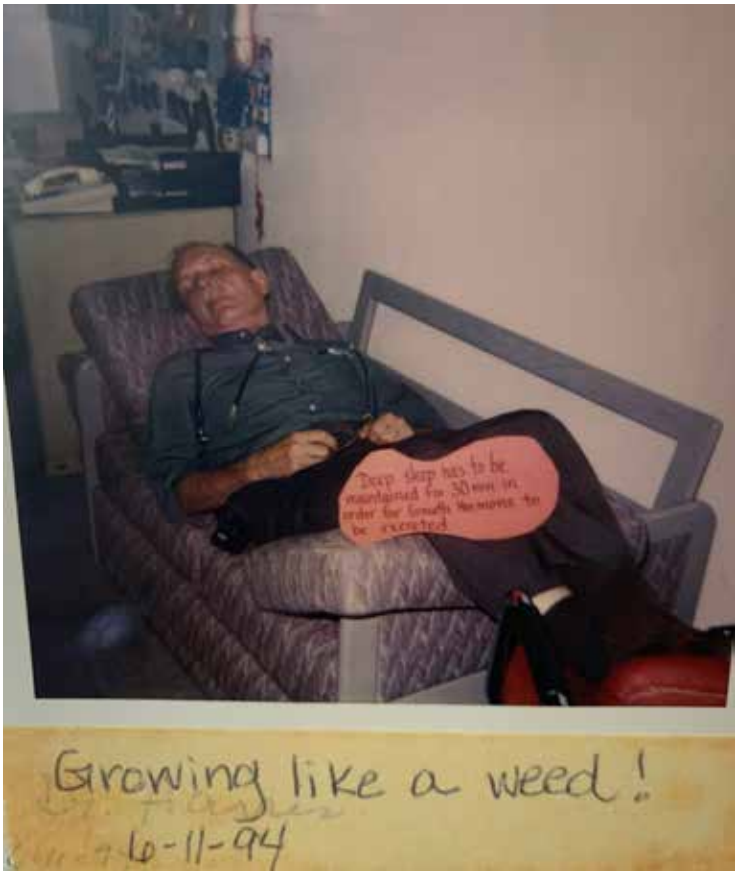
In summary, Tom has been a role model and an inspiration to many, including me. He instilled the importance of providing good patient care with compassion and balanced that with self-care, love of nature, and family.

Arun Pramanik, MD., DCH, FAAP, FIAP.

Professor of Pediatrics

LSU Health, Shreveport, LA.





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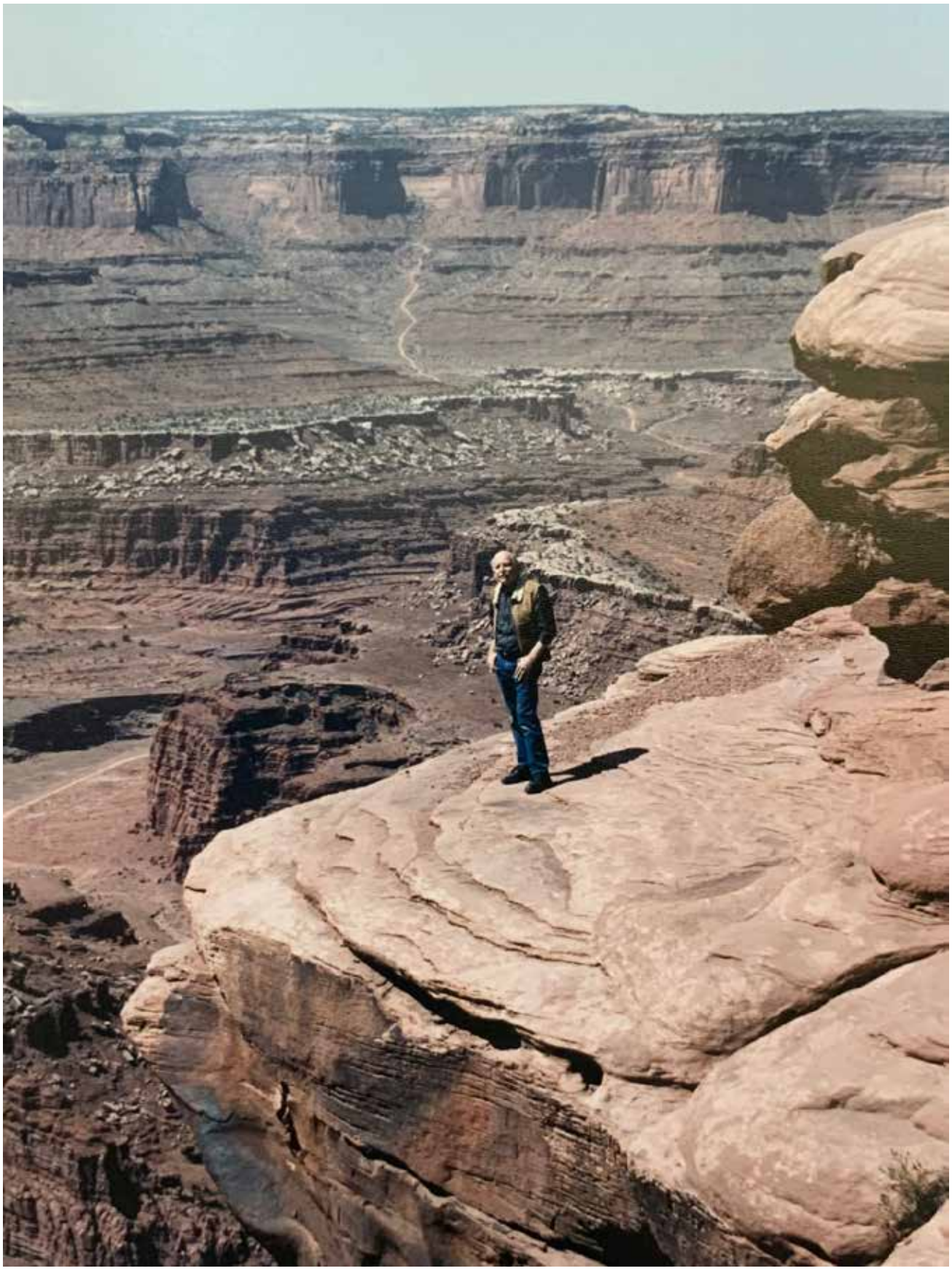

https://drtomharris.com/

Dr. Thomas R. Harris Memorial
Wednesday, September 21, 2022,
8 pm EST on Zoom

NT

Corresponding Author

Jill Koster
Daughter of Tom Harris
Email: Jill_TH@hotmail.com
Website: https://DrTomHarris.com

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COPING WITH COVID-19

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

Provide culturally-informed and respectful care.

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

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

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."

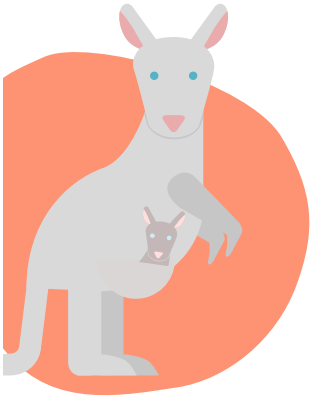
10 HELP US HEAL

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

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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
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Raising Global Awareness of RSV

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

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

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

RSV GOLD

A Global Mortality Database for Children with RSV Infection

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

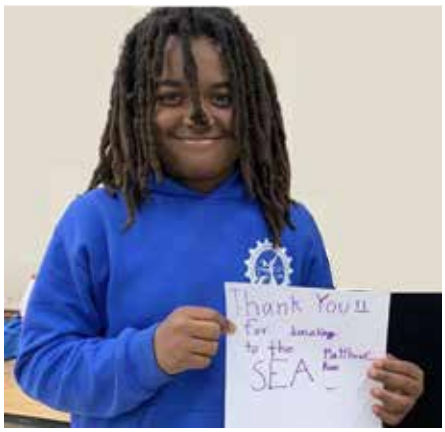
Thirteen-year-old Emily Rose Shane was tragically murdered on April 3, 2010 on Pacific Coast Highway in Malibu, CA. Our foundation exists to honor her memory.

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.

Occupational Therapy and Infancy: Supporting Families During the Earliest Occupations

Alexis Ferko, B.A., OTS

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

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

National Perinatal Association

Educate. Advocate. Integrate.

"Occupational therapy (OT) is a holistic, client-centered, occupation-based profession focused on assisting individuals to independently participate in daily activities to the best of their ability (1)."

Occupational Therapy and Infancy:

Occupational therapy (OT) is a holistic, client-centered, occupation-based profession focused on assisting individuals to independently participate in daily activities to the best of their ability (1). Occupational therapy practitioners (OTP) are board certified, have extensive academic training and clinical experience and treat individuals across the lifespan in various settings (2) while considering the "biological, developmental, and social-emotional aspects of human function in the context of daily occupations" (3). OTPs utilize the power of occupation to support families and infants in achieving positive outcomes (4). The first year of an infant's life is a rapid period of growth; infants are learning how to actively interact with their environment and family system (5). Occupations of infancy are defined as "any activity or task of value in which the family or setting expects the infant to engage" (4) including activities of daily living (ADL) like feeding and bathing, health management including social and emotional health promotion and maintenance, rest and sleep, play and social participation (1). Infants also participate in co-occupations, meaning infants share an occupation with their caregiver; examples such as play and breastfeeding (1). OTPs also assist families with adapting to new performance patterns including habits, roles, routines, and client factors. OTPs treat infants in settings including hospitals or NICU's, early intervention (EI), outpatient, and community-based settings. Infants may be referred to OT for concerns with maintaining homeostasis or bonding in the NICU, feeding or sensory concerns, physical development, social-emotional skills, and sleep (1).

" Infants also participate in co-occupations, meaning infants share an occupation with their caregiver; examples such as play and breastfeeding (1). OTPs also assist families with adapting to new performance patterns including habits, roles, routines, and client factors."

"Many infants and families have their first experience with OT in the NICU setting. NICU OTPs have extensive knowledge in neonatal medical conditions, development and understand the complex medical needs of infants in this setting (3). "

OT in the NICU:

Many infants and families have their first experience with OT in the NICU setting. NICU OTPs have extensive knowledge in neonatal medical conditions, development and understand the complex medical needs of infants in this setting (3). OTPs are members of an interdisciplinary team of professionals including pediatricians, physical therapists (PT), speech-language pathologists (SLP), lactation consultants, respiratory therapists, nurses, midwives, neonatologists, among others. OTPs administer assessments related to sensory processing, motor function, social-emotional development, pain, activities of daily living (ADL), neurobehavioral organization, and environmental screenings (3) to identify and create an appropriate infant and family-centered intervention plan. The primary functions of an OT in the NICU is to focus on developmentally appropriate occupations, maintaining homeostasis (stable vitals, feeding, breathing), self-regulation, sensory development, feeding, motor function, coping and attachment skills, bathing and dressing, and nurturing interactions with caregivers including skin-to-skin contact (3). OTPs utilize various interventions including sensory integration, neurodevelopmental techniques, positioning/handling, infant massage, feed-

ing, bonding, and environmental modifications to minimize stress and overstimulation while in this setting. Therapists must also address the family system by forming a therapeutic relationship with the family. The NICU can cause separation between infant and caregivers especially if there are maternal complications after delivery which can increase stress and instability within the family system (3). Parent-infant attachments and occupations must be prioritized, including bonding such as skin-to-skin contact, or kangaroo care. Kangaroo care is an essential intervention to support infants in the NICU by having the infant lay on the caregiver's bare skin. Benefits to this intervention include more stable heart rate, breathing patterns and temperatures, faster weight gain, more successful feeding, and increased bonding (6). OTPs also consider the Neonatal Integrative Developmental Care Model, meaning therapists are fostering a healing environment in the NICU setting – a setting known to be stressful and overstimulating for infants and their families. Core measures of this model include skin protection, optimizing nutrition, positioning/handling to promote breathing and stability, safeguarding sleep, optimizing nutrition, minimizing stress and pain through environmental and sensory modifications, and partnering with families (7). Research shows that interventionists who follow this model have better growth development outcomes (7).

"As of 2020, over 83% of infants are breastfed at some point in their young life (9). 60% of mothers stop breastfeeding before they intend to stop due to various reasons including latching difficulties, infant weight concerns, lack of work and family support, and concerns with medication while breastfeeding (9)."

Breastfeeding and Feeding:

As of 2020, over 83% of infants are breastfed at some point in their young life (9). 60% of mothers stop breastfeeding before they intend to stop due to various reasons including latching difficulties, infant weight concerns, lack of work and family support, and concerns with medication while breastfeeding (9). OT can assist with facilitating breastfeeding which improves parent-infant attachment and bonding and can also reduce postpartum depression (2). OTPs must consider various aspects of the infant-caregiver dyad during breastfeeding including infant arousal state, respiratory ability, overall stability, oral reflexes, oral strength and endurance and caregiver arousal, attention, posture and upper extremity strength, cognition, and cultural values/beliefs related to feeding (10). It is also important to consider sensory and environmental stimulation, social supports, and bottle/nipple type if the infant is not being breastfed. OTPs can assist breastfeeding caregivers with developing routines and habits to promote breastfeeding and education related to their infant's hunger and stress cues, positioning, ergonomics, self-regulation, and environmental modifications (10). Infant interventions include suck training, positioning, and various sensory strategies to promote arousal levels (10). Environmental and activity modifications include changing the position of feeds, adapting the lighting, touch, sound and using supportive equipment during feeding and adapting the type, thickness or volume of milk and feeding schedule (10). Feeding is a very important occupation for an infant as it takes up much of their early life and helps facilitate secure attachments to their caregiver as well as promoting self-regulation (11).

OT's Role in Transitioning Home:

OT also plays a role in assisting families with the transition from NICU to home. Transition planning begins at NICU admission with OTPs educating families on various interventions and considerations for the infant's unique medical needs. Upon discharge from the NICU, OTPs may recommend follow-up with EI, outpatient OT or PT, or a feeding clinic to address various concerns including feeding, global developmental delay, ROM or joint limitations, tone management, among others (8). OTPs also educate families on general infant care like signs of stress and how to relax or calm an infant, feeding strategies, home environment set-up and safe sleep strategies. OTPs also work with lactation consultants to address any concerns or strategies related to breastfeeding.

Early Intervention and Infancy:

Infant occupations vary based on family, contextual and cultural factors. OT is a primary service under IDEA Part C and delivers services related to the infant's individualized family service plan (IFSP) outcomes (12). Gorga (1989) identified seven areas of occupational therapy treatment practices for infants in EI including motor control, sensory modulation, adaptive coping, sensorimotor development, social-emotional development, daily living skills and play (11). OT interventions include handling, positioning, adapting the environment, sensory registration, arousal, attention, emotional regulation, cognition, feeding and play activities like reach and grasp (11). The American Occupational Therapy Association (AOTA) elaborated on various interventions in early intervention including promoting healthy bonding and attachment, family education and training, adapting tasks and the environment, participation in ADLs, rest and sleep and play related to the infant's IFSP outcomes (12).

"Occupational therapy practitioners are client-centered, occupation-based and address the infant and their family holistically. Various occupations OTPs can address include feeding, bathing, rest and sleep, health management, play and social participation, among others (1)."

Conclusion:

Occupational therapy practitioners are client-centered, occupation-based and address the infant and their family holistically. Various occupations OTPs can address include feeding, bathing, rest and sleep, health management, play and social participation, among others (1). Breastfeeding is also an important co-occupation OTPs can address in this setting. OT can also work with the family to promote carryover of strategies, encourage developmental care, and optimize infant well-being in the NICU, EI and home setting. Various professions work with occupational therapists on multidisciplinary, transdisciplinary, and interdisciplinary teams including PT, SLP, pediatricians, lactation consultants, nursing, midwives, neonatologists, and other specialists. These

professions would benefit from working with OT to help increase independence, improve overall well-being and participation in infant and family occupations all of which leads to a greater quality of life for both the infant and family. Occupational therapists serve a unique role in the neonatal intenseive care setting by identifying, promoting, and adovacating for developmental care practices that aim to support families in participating in these early occupations.

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

NT

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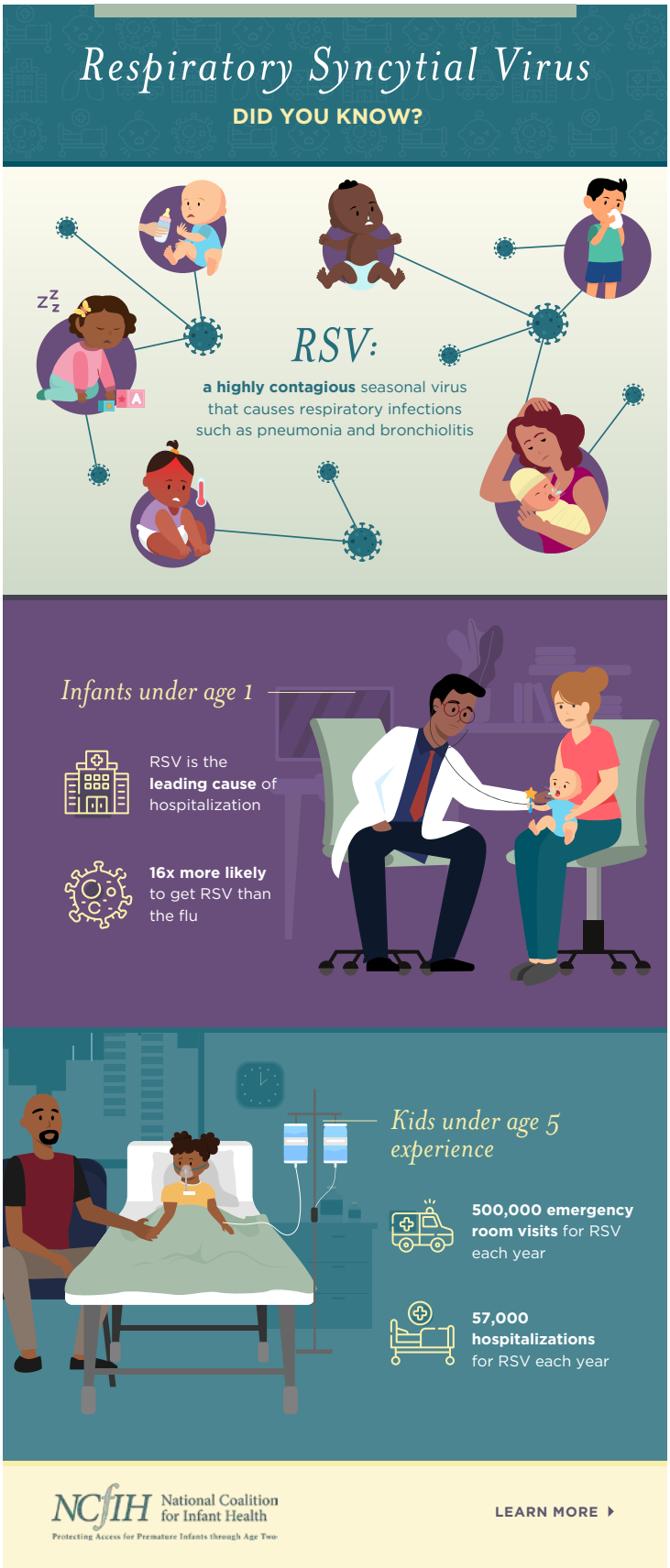
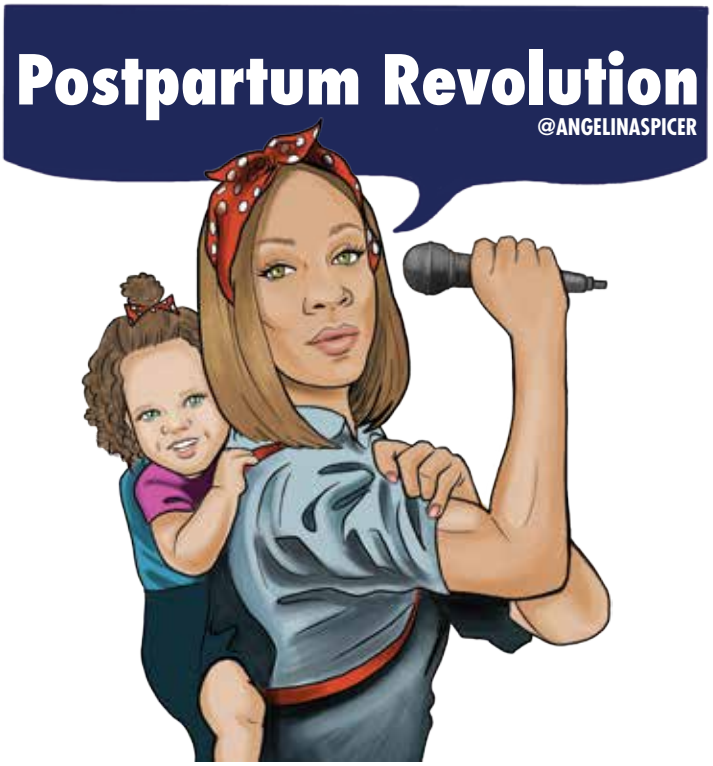


The Gap Baby: An RSV Story



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Including, But Not Limited To…

Kelly Welton, BA, RRT-NPS

Just when we thought we were nearing the end of the CoVid crisis, new details emerged.

"Many RTs, RNs, and others did the money grab, never looking back. And they don't need to; travel contracts are still alive and well, although the salary has come down."

Many RTs, RNs, and others did the money grab, never looking back. And they don't need to; travel contracts are still alive and well, although the salary has come down. Even with the horror stories of staff RTs and RNs letting travelers do all of their work, the opportunities to branch out, learn more and explore what other hospitals do and how they do it provide just enough gravitational pull to keep staff moving through the maze of States and licensure requirements. And although I'd love to go on (and on) about how absurd it is that we have a NATIONAL Board for Respiratory Care that administers the exams that we must pass to work, the individual licensure is by State. I'm reminded of people who make a living doing expedited Passport and Visa services. For a price, you can get someone to jump through all those hoops for you and get you a valid passport in record time. Why not start a business expediting State RT licenses? It's all a bunch of hoops and money, no more. The delays in care due to licensure constraints state-to-state during the pandemic are unconscionable. But that's not what today's article is about.

"Why not start a business expediting State RT licenses? It's all a bunch of hoops and money, no more. The delays in care due to licensure constraints state-to-state during the pandemic are unconscionable. But that's not what today's article is about. "

Another more subtle shift is occurring at a more critical level- Neonatologists. I recently read a letter to the editor of a small newspaper about a local hospital spending millions on building a new NICU. "We don't' need another NICU!" the author states, "We need social services for the homeless and better access to care for the disadvantaged." And although I don't disagree, I can't think of one hospital that went to the expense to build more NICU beds just for show. Since building more NICUs means the need for more NICU staff, this is where it gets scary. A new grad Neonatologist with many school bills to pay is faced with several choices when taking their first job. Major medical center? Or rural setting? What is the cost of living for each? What will their schedule and co-coverage look like? In Southern California, where housing is expensive no matter where you go, the top offer for the least amount of call is usually the winner.

"A new grad Neonatologist with many school bills to pay is faced with several choices when taking their first job. Major medical center? Or rural setting? What is the cost of living for each? What will their schedule and co-coverage look like? In Southern California, where housing is expensive no matter where you go, the top offer for the least amount of call is usually the winner. "

This leaves smaller hospitals with less Neonatology staff holding the bag for 24-hour call and coverage, often several days a week. The pay may be less and the call even longer in rural areas. Who needs inexpensive housing if you're never going to see it? New grad neonatologists may not want to bring their large medical center training down a few levels by staffing a level II NICU. They've been trained for action, for all kinds of emergencies that befall the offspring of a nation that can't stop growing. As such, large center NICUs will likely continue to be built, while smaller NICUs will bear the brunt of what shows up for them, prepared or not. How can we even this out? A NICU with top RNs, RTs, and ancillary staff still can't run without an MD. But it's the same song being sung again.

"As such, large center NICUs will likely continue to be built, while smaller NICUs will bear the brunt of what shows up for them, prepared or not."

Attracting and keeping top talent requires more than just money and prestigious titles. No one in healthcare should be made to care for so many patients a week that they crash and burn. We did this during CoVid out of necessity. But even if Covid disappeared tomorrow, the patients, large and small, will not. It took the pandemic to pay RTs and RNs what we are worth at the expense of exhausting us all. Let's do the same for Doctors, not just with money, but by leveling the playing field so that no one MD is working twice as many hours as a colleague at the next hospital down the road. Because if we have a mass exodus of Neonatologists the same way we just had a mass retirement of RTs and RNs, where does that leave those families in need of NICU care?

"Let's do the same for Doctors, not just with money, but by leveling the playing field so that no one MD is working twice as many hours as a colleague at the next hospital down the road. Because if we have a mass exodus of Neonatologists the same way we just had a mass retirement of RTs and RNs, where does that leave those families in need of NICU care?"

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

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I WANT TO LEARN TO WORK IN THE NICU...BUT HOW?

ACADEMY OF NEONATAL CARE OFFERS LIVE AND ONLINE CLASSES. ALL COURSES ARE APPROVED FOR CONTINUED CREDIT UNITS.

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ACADEMY OF NEONATAL CARE

NICU LIVE COURSE AND WORKSHOP

August 25, 26, and 27 @ Ventura County Hospital
300 Hillmont Ave, Ventura, CA 93003

SESSION 1

HIGH RISK PREGNANCIES
FETAL LUNG DEVELOPMENT
FETAL CIRCULATION
CBG'S, CORD GASES, AND TCOMS
NEONATAL ASSESSMENT
SURFACTANTS
NICU VENTILATORS
HIGH FLOW NASAL CANNULA
INFECTION CONTROL -
HANDS-ON WORKSHOP

SESSION 2

PNEUMONIA/SEPSIS
HFOV BASICS
CHEST XRAYS
APNEAS AND BRADYCARDIAS
IVH
RDS
NON-INVASIVE VENTILATION
PROVE YOURSELF IN THE NICU
HANDS-ON WORKSHOP

SESSION 3

VENTILATOR
WAVEFORMS
ECMO-INO UPDATE -JET
VENTILATOR
PSYCH-SOCIAL ASPECTS IN
NICU CARE
TRANSPORTS
HANDS-ON WORKSHOP



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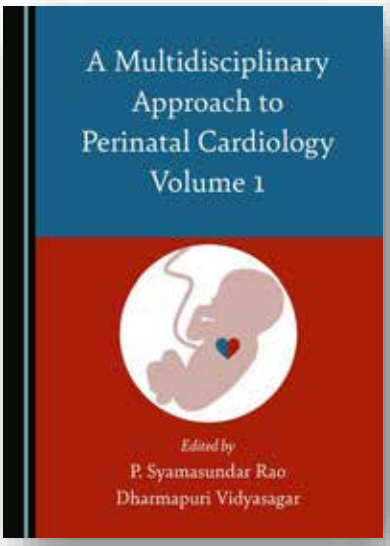
A Multidisciplinary Approach to Perinatal Cardiology *Volume 1*

Edited by P. Syamasundar Rao and Dharmapuri Vidyasagar



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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.

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National Association of Neonatal Nurses

National Perinatal Association

FREE ONLINE EDUCATION

Coping with COVID-19

A viral pandemic

A racial pandemic within a viral pandemic

Will mental illness be the next inevitable pandemic?

WWW.MYNICUNETWORK.ORG

and

National Perinatal Association
NICU Parent Network

More States Extend Postpartum Medicaid Coverage

Michelle Winokur, DrPH

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

"Nineteen. That is the number of Medicaid programs extending postpartum coverage to one year. That number jumped by four in June, with the federal government approving requests from Maine, Minnesota, New Mexico, and the District of Columbia."

Nineteen. That is the number of Medicaid programs extending postpartum coverage to one year. That number jumped by four in June, with the federal government approving requests from Maine, Minnesota, New Mexico, and the District of Columbia.

Postpartum coverage for new moms who lived in these locales ended after 60 days.

All four extensions were approved under provisions from the American Rescue Plan. The Biden administration proposed the package to quicken the country's economic recovery from COVID-19. The 2021 plan is most commonly known for its economic stimulus components, but it also made way for new health programs and expansions of others.

"The 2021 plan is most commonly known for its economic stimulus components, but it also made way for new health programs and expansions of others."

Extended Eligibility and More Benefits

States that elect to lengthen new moms' eligibility via the American Rescue Plan must provide them full Medicaid benefits. This means new moms will also get health care services like inpatient hospital stays and doctor visits that are not directly related to their pregnancy or postpartum care covered.

Currently, states are permitted to offer a narrower set of benefits to those who qualify for Medicaid when they become pregnant. It is called "pregnancy Medicaid." Coverage can be limited to only those services that relate directly to prenatal care, labor, and delivery.

Medicaid finances over 1.5 million births. That is about 42% of all births in America.

More Extensions on the Way

Until Congresses passes legislation requiring all Medicaid programs to provide one year of coverage postpartum – a policy pushed by the Biden administration – coverage extensions are handled on a case-by-case basis.

"Until Congresses passes legislation requiring all Medicaid programs to provide one year of coverage postpartum – a policy pushed by the Biden administration – coverage extensions are handled on a case-by-case basis."

Twelve-month postpartum extensions exist in California, Florida, Illinois, Kentucky, Louisiana, Maryland, Michigan, New Jersey, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, and Virginia. Some of these extensions were provided

under the American Rescue Plan and others through an "1115 waiver," which allows Medicaid programs to provide coverage that varies in duration, location, or scope from the federal rules.

Additional state extension requests are being reviewed. As many as 720,000 pregnant women and new moms could be eligible for expanded coverage if all states adopted this option.

Advantages of Consistent Coverage

Extended Medicaid coverage will likely reduce "churn" for new moms who move between being insured and uninsured.

Data show that approximately one-third of women experience a coverage disruption between conception and postpartum. As expected, that can mean gaps in care, increased emergency department use, and worse health outcomes.

" Increasing access to and coverage of high-quality maternal health services is the first of five goals in the Biden administration's recently released blueprint for addressing the maternal health crisis. The plan's other goals are better data collection and diversifying the perinatal workforce. All are aimed at improving maternal health outcomes."

Increasing access to and coverage of high-quality maternal health services is the first of five goals in the Biden administration's recently released blueprint for addressing the maternal health crisis. The plan's other goals are better data collection and diversifying the perinatal workforce. All are aimed at improving maternal health outcomes.

Michelle Winokur, DrPH, is the Executive Director of the Institute for Patient Access.

This content article was also published at InstituteforPatientAccess.org

NT

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Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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

Limit Contact with Others

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

Provide Protective Immunity

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

Take Care of Yourself

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

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

WARNING

Never Put a Mask on Your Baby

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

If you are positive for COVID-19

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

We can help protect each other.

Learn more

www.nationalperinatal.org/COVID-19

National Perinatal Association

The Gap Baby: An RSV Story

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

The National Coalition for Infant Health advocates for:

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

www.infanthealth.org

I CAN Digitally Involved (I CANDI): 2022 Summit Wrap Up

Amy Ohmer

"The International Children's Advisory Network, Inc. (iCAN) is pleased to share our excitement for the 2022 iCAN Summit presented by Jumo Health from July 11th - July 15th, 2022, in Lyon, France."

The International Children's Advisory Network, Inc. (iCAN) is pleased to share our excitement for the 2022 iCAN Summit presented by Jumo Health from July 11th - July 15th, 2022, in Lyon, France.

"The EJP is in its sixth year of funding through the EU and provides several tools and initiatives to promote research and education in rare diseases. The program is a six-year EU-funded project that provides several tools and initiatives to promote research and education in rare diseases."

To kick off the global summit experience, iCAN presented on July 7th, 2022, through the European Joint Programme on Rare Diseases (https://www.ejprarediseases.org/). (1) The EJP is in its sixth year of funding through the EU and provides several tools and initiatives to promote research and education in rare diseases. The program is a six-year EU-funded project that provides several tools and initiatives to promote research and education in rare diseases. It is coordinated by INSERM (https://www.inserm.fr/) and involves the most relevant European research organizations. (2) Speaking on behalf of iCAN is Christine Woods, iCAN Board of Directors and parent of KIDS Georgia youth members. Christine spoke in the 'Activities to Empower Children's Collective or Group' session about learning to create young people's groups.

The iCAN Call for Poster/Abstract Submissions was completed on June 1st, and this year, iCAN received 31 submissions from around the world. Tune in to iCAN at www.icanresearch.org/2022-summit to view the posters starting the week of July 11th, 2022. (3)

"The iCAN Call for Poster/Abstract Submissions was completed on June 1st, and this year, iCAN received 31 submissions from around the world."

Additionally, for all interested, there were events from July 11th - July 15th, 2022, where attendees (both virtual and in-person) participated and experienced throughout the week.

Highlights included:

- Sessions were held in partnership with Jumo Health, Pfizer, Eli Lilly, Labcorp, Pediatric Trials Network, and more.
- Introduction of Amelia Williams, Rare Disease Patient and Youth Advocate
- Serious Games development project with participation from all iCAN Youth Members
- Launch of the 2022 iCAN Curriculum - Becoming a Leader
- Announcement of winners for the 2022 iCAN Anthology Book designed in partnership with Duke Clinical Research Institute
- A newly released Poster Session video and each poster submission were featured on iCAN's website to help inspire and educate on the work of our Youth Members.
- Interviews with Gambino Gesu Pediatric Hospital in Rome, Italy, to share insights of patient voice through an iCAN Young Adult Professional (YAP) summer internship with Dr. Alberto Tozzi, President of the International Society of Pediatric Innovation (iSPI). This unique opportunity allowed four YAP members to practice clinical research skills to understand youth perception of vaccines better. With more to come, this project will benefit all through pediatric healthcare in learning how to communicate with patients and families better.
- Cultural events, learning activities, and much, much more!

Joining forces with our community partner, Rareartist.org, iCAN is pleased to share that the 2022-23 Rare Artist Advocacy Event is

2022 SUMMIT

iCAN
International Children's Advisory Network

SAVE THE DATE

July 13th through July 17th, 2022

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

Hosted by iCAN KIDS France

Registration Opens May 15th, 2022

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

Sign up for for updates at
www.iCANResearch.org

open. To learn more, visit www.icanresearch.org to learn how to submit your art to help spotlight rare and orphan diseases. (4) All ages are welcome to participate.

iCAN Chapter Startups: iCAN welcomes interested hospitals to join at no cost. Chapter groups can be as small or large - with the emphasis on helping to spotlight the youth voice. To learn more, check out https://www.icanresearch.org/chapters. (5)

iCAN Youth Council: The next leadership level is available for youth members interested in supporting iCAN in a more significant way. The iCAN Youth Council is active in creating, overseeing, executing, and disseminating pediatric issues/topics through the unique perspective of youth throughout research, science, advocacy, technology, and medicine. Interested young people can learn more at https://www.icanresearch.org/our-youth. (6)

iCAN Young Adult Professionals: This dedicated group of young adults ages 18+ helps to support iCAN at a professional and higher educational level. iCAN offers internships and greater leadership roles to help retain and engage young adults as they begin their careers. To learn more about this group, head over to https://www.icanresearch.org/ican-young-adult-professionals. (7)

iCAN Parents: All parents (and family members) are welcome to join iCAN to participate as advisors for the littlest patients (0-7 years old). Joining is free and can be done by visiting www.icanresearch.org or emailing iCANparent@icanresearch.org. (3) To learn more, check out this page at https://www.icanresearch.org/parents-families. (8)

The 'I CAN' Book is now available at www.icanresearch.org for $25.00 using our unique PayPal link on the home page under donations. (4) After payment, to receive your copy, please contact us at info@icanresearch.org with your name and mailing address - this beautiful hard-bound book is created by iCAN Youth Members from around the world and filled with positive statements about overcoming challenges to be the best you can be. Fully illustrated by our KIDS Bari chapter, this beautiful book is a treasure you and your family will treasure for years to come.

"The next leadership level provides for youth members interested in supporting iCAN in a more significant way. The iCAN Youth Council is active in creating, overseeing, executing, and disseminating pediatric issues/topics through the unique perspective of youth throughout research, science, advocacy, technology, and medicine. Interested young people can learn more at https://www.icanresearch.org/our-youth. (6)"

Save the Date:

- iCAN's own unique youth series **'Ask the Experts'** has a new session planned for **August 20th, at 10:00 a.m. EST**. To join this fun and free event, please register at www.icanresearch.org/events. (9) All are welcome to attend, and kids of all ages are invited to join. Additional sessions are open for registration, and we welcome all doctors, researchers, and community leaders to join us. Due to the iCAN Summit, July has no 'Ask the Experts' for July.
- **Join iCAN and the American Academy of Pediatrics National Conference and Exhibition from October 7th - 11th, 2022,** at the Anaheim Convention Center, Anaheim, California. We cannot wait to see you at our booth #2034! Look for the iCAN colors and stop by and say hello!

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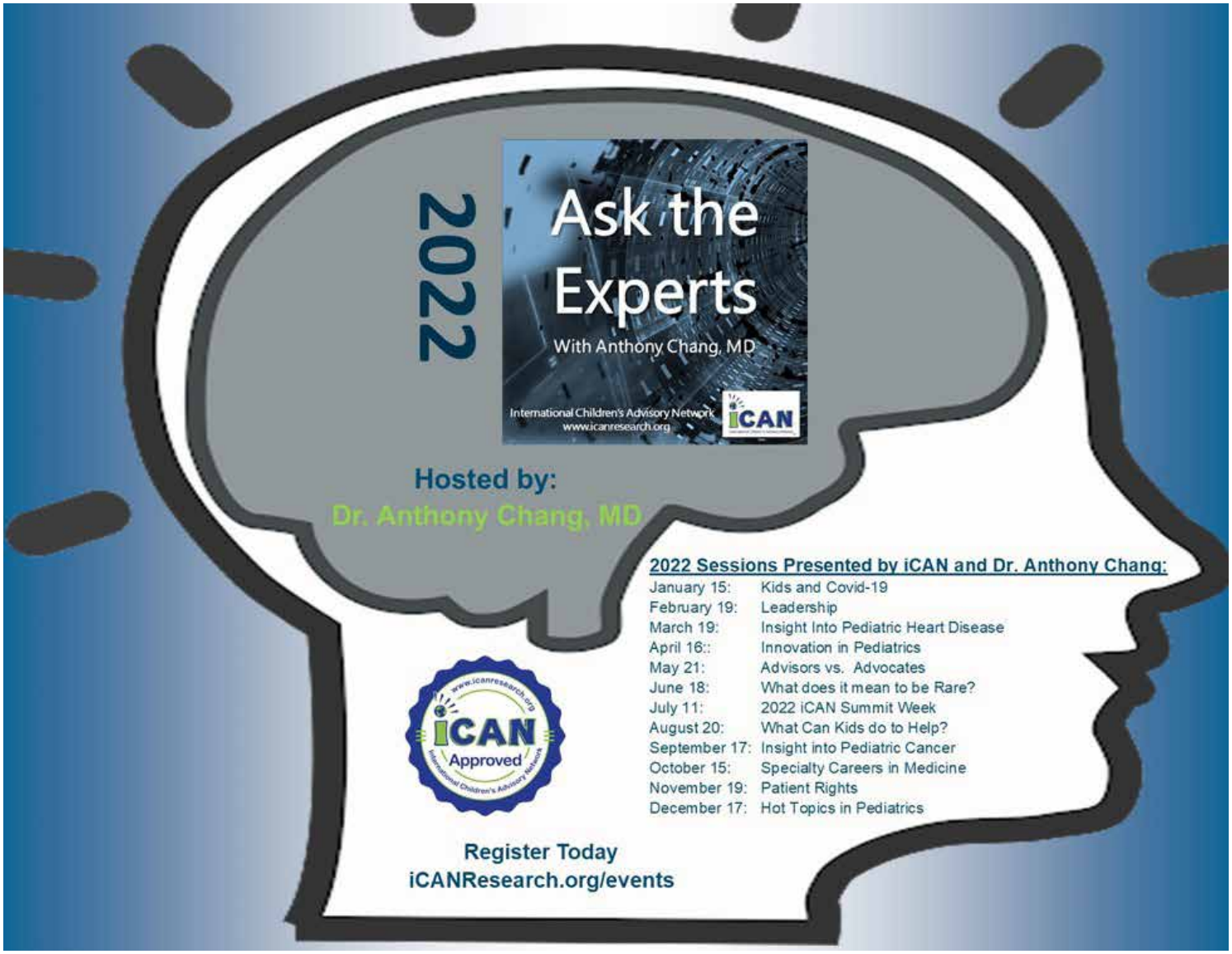

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6. https://www.icanresearch.org/our-youth
7. https://www.icanresearch.org/ican-young-adult-professionals
8. https://www.icanresearch.org/parents-families
9. www.icanresearch.org/events

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

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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:

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PROTECT YOUR FAMILY FROM

RESPIRATORY VIRUSES

flu coronavirus pertussis RSV

WASH YOUR HANDS
often with soap and warm water.

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

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

USE AN ALCOHOL-BASED HAND SANITIZER.

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

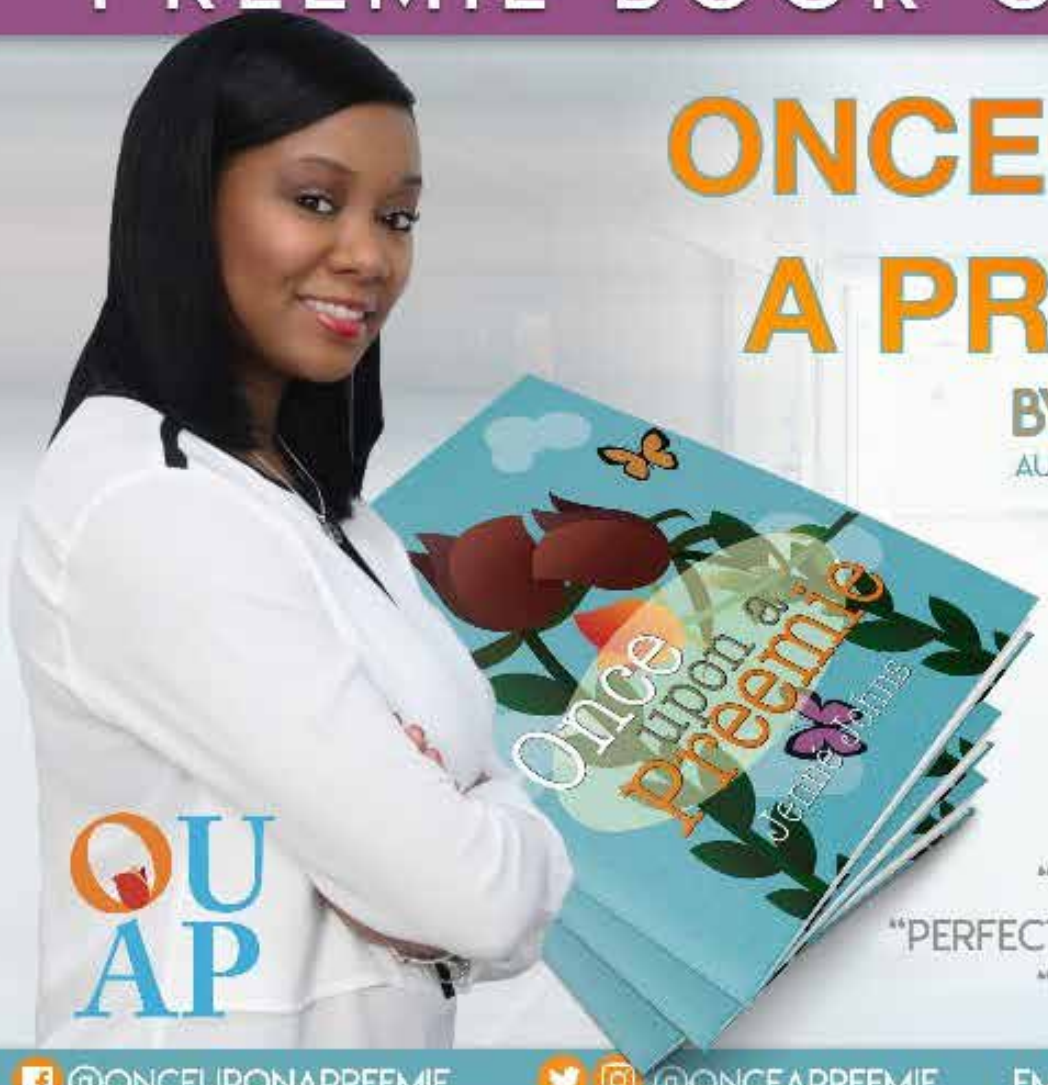
Tell insurers what families need

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.

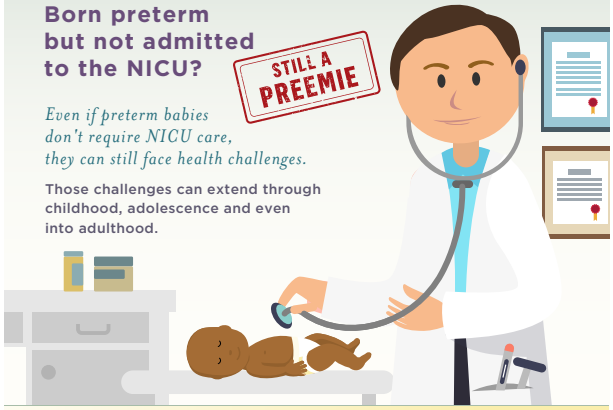
But because some health plans determine coverage based on a preemie's weight, **families of babies that weigh more may face access barriers and unmanageable medical bills.**

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 David Vasconcellos, MS IV

Prolacta Bioscience Introduces Its First Evidence-Based Feeding Protocol for an Exclusive Human Milk Diet in the NICU

Jun 14, 2022, 09:03 ET

Nutritional Guidance Sets Premature Infants on Track for Healthy Growth and Improved Outcomes

DUARTE, Calif., June 14, 2022 /PRNewswire/ -- Prolacta Bioscience®, the world's leading hospital provider of 100% human milk-based nutritional products for critically ill, premature infants, today announced the introduction of the first evidence-based feeding protocol for the use of an Exclusive Human Milk Diet including Prolacta's products (Prolacta's EHMD) in the neonatal intensive care unit (NICU). Prolacta's EHMD Protocol™ addresses the nutritional risks of late and inadequate nutrition facing low birth weight premature infants and is the first nutritional guidance issued for the use of the company's human milk-based nutritional products.

To help meet each patient's unique needs, Prolacta's EHMD Protocol is designed to provide flexible feeding advancement based on each premature infant's weight, clinical status, and health risk factors.

Developed in conjunction with independent clinicians, registered dieticians, nurses, and neonatologists, Prolacta's EHMD Protocol is backed by 15 years of clinical experience and more than 20 clinical studies.1 The protocol presents additional perspective on the standard of care in NICUs that can help premature infants avoid complications and reach key growth goals.

"This protocol provides best-practice guidance to members of the NICU team as we tailor nutrition to each infant's needs and risk factors," said Rangasamy Ramanathan, MD, professor of pediatrics, division chief, Division of Neonatal Medicine, LAC+USC Medical Center. "A standardized feeding approach for an EHMD with human milk-based products helps eliminate the uncertainty in meeting infants' protein goals to achieve adequate growth with fewer complications."

Prolacta's EHMD Protocol guides decision-making in the NICU as clinicians work to:

- Achieve healthier growth with fewer complications
- Fortify safely and confidently in the first week of life
- Tailor nutrition to each infant's individual needs and risk factors
- Account for variability of mother's own milk/unanalyzed donor milk
- Supplement for fat loss in tubing
- Meet protein goals while staying on-label

Prolacta's EHMD Protocol supports clinicians in delivering the optimal nutrients to fragile infants at the optimal time — helping as they work to achieve better health outcomes, (2-4) lower hospital costs, (5,6) and significantly reduce the risk of complications and feeding intolerance associated with cow milk-based fortifiers. (2-5,7-9)

Over the past 15 years, more than 20 clinical studies involving more than 5,000 premature infants have shown that hospitals with the best outcomes followed similar feeding practices with the use of Prolacta's fortifiers. (1) Inversely, it is proven that delayed fortification leads to less-optimal results in critically ill, premature infants. (10)

An EHMD is achieved when 100% of the protein, fat, and carbohydrate in an infant's diet are derived from human milk. An EHMD with Prolacta's 100% human milk-based fortifiers, compared with the use of cow milk-based fortifiers or formula, is known to reduce the risk of severe complications and feeding intolerance in preterm infants. (7)

Fortify Early for the Best Outcomes

For years, the risks associated with cow milk-based fortifiers left healthcare professionals in the NICU cautious about starting fortification too early. With Prolacta's EHMD Protocol, clinicians can safely begin fortification as early as the first week of an infant's life, confident that issues such as feeding intolerance and other complications have been shown to be significantly reduced.

(2,3,5,11)

"Prolacta's EHMD Protocol can reduce the incidence of comorbidities, support adequate growth, and improve mortality rates, offering groundbreaking benefits for this fragile patient population," said Melinda Elliott, MD, FAAP, and chief medical officer at Prolacta. "Even the most vulnerable infants born weighing less than 750 g have been shown to greatly benefit from an EHMD, giving them the best chance for a healthy, bright future." (2-5,7-9,11-15)

Proven Safety; Flexible Feeding Advancement

To help meet each patient's unique needs, Prolacta's EHMD Protocol is designed to provide flexible feeding advancement based on each premature infant's weight, clinical status, and health risk factors.

Improved Short- and Long-Term Outcomes

Prolacta's EHMD Protocol supports adequate growth with fewer complications as measured by increases in length, head circumference, and weight. (11) These gains lower the risk of long-term metabolic morbidities including obesity, diabetes, and cardiovascular disease.16 Research has shown that Prolacta's fortifiers, when used as part of an EHMD, support healthy body composition with improvements in lean body mass, normal total body fat, and adequate bone mineralization.16 Furthermore, for premature infants fed an EHMD, the benefits of appropriate nutrition extend to long-term neurocognitive development. (14)

Compared to cow milk-based fortifiers, an EHMD with Prolacta's 100% human milk-based nutritional fortifiers has been clinically proven in more than 20 peer-reviewed clinical studies to:

- Lower mortality and morbidity (3,5,8,17)
- Reduce incidence of feeding intolerance (3,5)
- Achieve adequate growth (2,11,17)
- Reduce incidence of bronchopulmonary dysplasia (BPD) (2,4,5,8)
- Reduce incidence of retinopathy of prematurity (ROP) (3,5,8)
- Reduce late-onset sepsis incidence and evaluations8
- Reduce risk of necrotizing enterocolitis (NEC) (3,5,7,8,18)
- Improve long-term outcomes such as neurodevelopment (14,19)
- Shorten stays in the NICU (5)
- Reduce hospital costs (5,6)

For a copy of Prolacta's EHMD Protocol, email info@prolacta.com.

About Human Milk-Based Products

The major difference between cow milk-based and human milk-based products is the composition — notably, the bioactive components that are unique to human milk. These include immunoglobulins, lactoferrin, milk fat globule membranes, and the wide spectrum of prebiotics known as human milk oligosaccharides (HMOs), which are not easily manufactured and thus are greatly decreased or missing from cow milk-based nutritional products. (20) Bioactivity is thought to support infants' immunity, development, growth, and long-term health. (21)

Prolacta's 100% human milk-based nutritional products have the highest bioactivity in the human milk industry. (1) Prolacta's nutritional products are vat pasteurized using profiles defined by the U.S. Food and Drug Administration (FDA) to ensure pathogen inactivation and the highest level

of safety while retaining as much of the natural bioactivity of the milk as possible.1 Prolacta's vat pasteurized products retain higher bioactivity than products processed using other methods, including retort sterilization and ultra-high-temperature (UHT) processing. (22,23)

About Prolacta Bioscience

Prolacta Bioscience® Inc. is a privately held, global life sciences company dedicated to Advancing the Science of Human Milk® to improve the health of critically ill, premature infants. Prolacta's 100% human milk-based nutritional products have been evaluated in more than 20 clinical studies published in peer-reviewed journals. More than 80,000 premature infants have benefited from Prolacta's nutritional products worldwide to date.* Established in 1999, Prolacta is the world's leading provider of human milk-based nutritional products for hospital use and is also exploring the therapeutic potential of human milk across a wide spectrum of diseases. Prolacta maintains the industry's strictest quality and safety standards for screening, testing, and processing human donor milk. Operating the world's first pharmaceutical-grade human milk processing facilities, Prolacta uses vat pasteurization and a patented, FDA-reviewed manufacturing process to ensure pathogen inactivation while protecting the nutritional composition and bioactivity of its human milk-based products. Prolacta is a global company with headquarters in Duarte, California, and can be found online at www.prolacta.com, and on Twitter, Instagram, Facebook, and LinkedIn.

*Estimated number of premature infants fed Prolacta's products from January 2007 to December 2021; data on file.

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310-721-9444

SOURCE Prolacta Bioscience

NT

CDC issues advisory on parechovirus infections in infants

July 12, 2022

Health officials are asking clinicians to be on the lookout for infants with parechovirus (PeV) infection following reports of infections in multiple states.

PeV should be considered in infants with fever, sepsis-like syndrome or neurological illness such as seizures or meningitis without another known cause, according to a health advisory from the Centers for Disease Control and Prevention (CDC).

PeVs are part of the same taxonomic family as enteroviruses, and PeV infections are common in childhood. PeV positive specimens tested by the CDC this year all have been type PeV-A3, which most often is associated with severe disease. The CDC did not release a case count and could not say how cases this year compare to previous years because there is no systematic surveillance for PeVs.

Common symptoms of PeV infections in children ages 6 months to 5 years include upper respiratory tract infection, fever and rash. Severe illness can occur in children under 3 months and may include sepsis-like illness, seizures and meningitis or meningoencephalitis. Clinicians should test for PeV in children with symptoms. Testing is available at commercial clinical laboratories and state public health laboratories. Hospitals also may use multiplex meningitis and encephalitis panels for cerebrospinal fluid testing that include PeV. The CDC can test samples in some cases, but clinicians should work with their state officials and email PicornaLab@cdc.gov before submitting specimens.

PeV is transmitted via fecal-oral and respiratory routes by both symptomatic and asymptomatic individuals. Shedding can occur for one to three weeks from the upper respiratory tract and as long as six months from the gastrointestinal tract, according to the CDC. There is no specific treatment for PeV infections.

Officials recommend cohorting hospitalized infants with PeV infection with other affected infants. Clinicians also should use contact, droplet and standard precautions. Alcohol-based hand sanitizer with at least 60% alcohol content is preferred for cleaning hands in most clinical situations. However, soap and water are preferred after patient care involving diapering or toileting, before eating or feeding and if hands are visibly soiled.

Resources

- Information from the AAP *Red Book* on parechovirus
- Information from the CDC on non-polio enterovirus
- Information from the CDC on specimen collection, storage and shipment

Melissa Jenco, News Content Editor

New AAP main number: 630-626-6000

NT

CHILD Registry expands pilot program; primary care organizations encouraged to apply

July 1, 2022

The AAP Child Health Improvement through Longitudinal Data (CHILD) Registry is seeking additional primary care organizations to join its pilot program.

Over about six to nine months, pilot sites will validate electronic health record (EHR) data, review and test content, and provide feedback that will help shape and improve the CHILD Registry.

The CHILD Registry is the only longitudinal clinical data registry for all infants, chil-

pac-lac

Perinatal Advisory Council:
Leadership, Advocacy and Consultation

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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.

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- 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.

dren and adolescents in the United States. Pediatricians and others who care for children will be able to use the data to improve child health and well-being.

The pilot program is being expanded to include a wider range of EHRs used in pediatrics and expand the diversity of patient populations and geographic locations.

Pilot program participants will receive several benefits. Their cost to participate in the registry will be covered for three years. It is anticipated that participating in the pilot program will qualify for American Board of Pediatrics Maintenance of Certification Part 4 credit due to the continuous quality improvement process.

Also, "pioneer" practices participating in the CHILD Registry pilot will help lay the groundwork for all subsequent practices and have a significant impact on the trajectory of this important AAP initiative.

AAP members interested in participating as a pilot site should complete the form at https://www.surveymonkey.com/r/CHILDRegistryPilotForm by Aug. 1. Selection criteria include EHR system used, patient population, organization size and geographic location.

For more information regarding pilot participation, visit http://www.aap.org/CHILDRegistry or email childregistry@aap.org.

Contact information for AAP headquarters

American Academy of Pediatrics

345 Park Blvd, Itasca, IL 60143

The AAP Department of Quality

New AAP main number: 630-626-6000

NT

Erythropoietin Does Not Add Benefit to Standard Cooling Therapy for Birth Asphyxia

Results Contrast with Earlier, Smaller Trials

Adding erythropoietin to cooling therapy for newborns with birth asphyxia has no benefit over cooling therapy alone, reports a new study led by UC San Francisco.

The findings, publishing July 13th, 2022 in the New England Journal of Medicine, contrast with results from small trials in which erythropoietin appeared safe and effective. The current multicenter trial of 500 infants with moderate or severe hypoxic ischemic encephalopathy (HIE) found an equal risk of death or neurodevelopmental impairment at 2 to 3 years of age for the hypothermia-only (placebo) group and the hypothermia plus erythropoietin group. However, the erythropoietin group had more serious adverse events during the newborn period than the placebo group.

"These results show the importance of large clinical trials," said Yvonne Wu, MD, UCSF professor of neurology and pediatrics and the study's lead author. "Previous research indicated a protective effect from erythropoietin, but with 500 babies instead of 50, there was enough statistical power to reveal a different outcome, as well as an unexpected effect."

Hospitals in the U.S. and abroad that currently use erythropoietin with cooling therapy for infants born with HIE should reconsider the practice, said Wu.

The double-blind, placebo-controlled trial randomized infants to receive 1000 U per kilogram of erythropoietin or an equal volume of saline placebo intravenously prior to 26 hours of age and at 2, 3, 4 and 7 days of age. Death or neurodevelopmental impairment at age 22-36 months occurred in about half of infants in both groups.

"This well-executed trial provides essential information for clinicians, even though the findings were negative. Although erythropoietin may have some clinical benefits, these findings suggest that caution may be warranted when combining the drug with cooling to treat infants with hypoxic–ischemic encephalopathy," said Adam Hartman, MD, program director at the National Institute of Neurological Disorders and Stroke.

HIE affects more than 10,000 infants each year, and accounts for 22% of neonatal deaths worldwide. Large trials indicate therapeutic hypothermia improves neurodevelopmental outcomes, yet up to 40% of infants who receive this therapy still die or have long-term disabilities such as cerebral palsy.

The current study doesn't address whether erythropoietin could benefit infants with HIE in countries where therapeutic cooling is unavailable, the authors wrote, or infants with a milder form of HIE for whom hypothermia isn't yet proven.

Authors: UCSF co-authors are Fernando Gonzalez, MD and Elizabeth Rogers, MD of the Department of Pediatrics; Amy Goodman, PhD, of the Department of Neurology; and Hannah Glass, MD, Departments of Neurology and Pediatrics. Additional authors and affiliations can be found in the paper.

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About UCSF: The University of California, San Francisco (UCSF) is exclusively focused on the health sciences and is dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care. UCSF Health, which serves as UCSF's primary academic medical center, includes top-ranked specialty hospitals and other clinical programs, and has affiliations throughout the Bay Area. UCSF School of Medicine also has a regional campus in Fresno. Learn more at https://www.ucsf.edu, or see our Fact Sheet.

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NT

FDA, AAP offer resources to help families using imported infant formula

July 14, 2022

The Food and Drug Administration (FDA) is stressing that the imported infant formulas it has approved for use in the U.S. are safe and nutritious.

Parents and caregivers can learn about where to find comparable products, how to read the labels and how to prepare these formulas through new FDA tip sheets and videos as well as answers to frequently asked questions on the AAP's HealthyChildren.org website.

The HealthyChildren.org FAQ has additional information on understanding imported formula labels, using goat's milk formula, the dangers of families importing their own formula and eligibility with Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) benefits.

"Consumers should have confidence that the infant formula being imported to the U.S. through FDA's flexibilities involved a thorough review of the information provided by the company, including details about the products' nutritional adequacy and safety, microbiological testing results, labeling information and importantly details about the manufacturing facilities' foods safety production practices and inspection history," said Susan T. Mayne, Ph.D., director of the FDA's Center for Food Safety and Applied Nutrition.

Formulas for more than 524 million 8-ounce bottles are being imported from nine countries and include brands that may be unfamiliar to U.S. consumers such as Bubs Australia and Kendamil.

Because some labels have metric measurements, the FDA has created a tip sheet showing conversions from milliliters

to fluid ounces and Celsius to Fahrenheit. It also has videos answering parents' questions and pictures of imported labels parents and caregivers may see on store shelves.

Dr. Mayne encouraged families to try different brands if they can't find their usual formula but also recommended talking to their pediatrician about feeding changes, especially if their baby has a medical condition. Pediatricians also can help families request specialty formula from Abbott Nutrition.

The infant formula shortage has been ongoing for months due to supply chain issues and the shutdown of an Abbott Nutrition plant following complaints of bacterial infections among several infants who had consumed the formula. Dr. Mayne said U.S. manufacturers have been ramping up production to make up for the shortage. The FDA also is making plans to allow expanded access to formula to avoid future shortages.

Resources

- Information for parents from HealthyChildren.org on imported formula, what to do if they can't find formulaand the risks of homemade formula
- FDA imported infant formula resources for parents and caregivers
- *AAP News* story "AAP experts offer advice on how pediatricians can help parents through formula shortage"
- Health and Human Services infant formula resources
- Information on the FDA investigation into powdered infant formula
- Information for WIC participants from the Department of Agriculture
- Information on submitting an urgent request for specialized formula

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New AAP main number: 630-626-6000

NT

New JAMA Pediatrics study shows simple bundle reduces ped cardiac arrest by 30%

In case you missed it, UCSF Benioff Children's Hospital was one of 15 centers across the country that implemented a prevention-based bundle that reduced cardiac arrest in children by 30%. Results were published Tuesday in JAMA Pediatrics, and we're happy to offer as expert sources UCSF co-authors Dr. Sarah Tabbutt, a pediatric cardiac intensive care physician at UCSF Benioff Children's Hospital and the Executive Director of the practice collaborative, and Dr. Amy McCammond, medical director of UCSF Benioff Children's Hospital Cardiac ICU.

The groundbreaking Pediatric Cardiac Critical Consortium (PC4) study showed a reduction in cardiac arrest in children suffering from heart disease thanks to PC4's Cardiac Arrest Prevention 'practice bundle'. PC4 investigators report that implementing a low-technology cardiac arrest prevention strategy (or bedside bundle) reduced cardiac arrests in the cardiac intensive care unit by an average of 30% across the 15 participating centers.

"PC4 analyzed cardiac arrest across all collaborative hospitals to find those with the lowest cardiac arrest rates. We then implemented their practices as a patient care bundle across centers with amazing results. The success of this project is a result of collaboration, which is the fundamental principle of not only, PC4 but also of the overarching organization of Cardiac Networks United", said Dr. Sarah Tabbutt.

The cardiac arrest prevention bundle was designed to promote situational awareness and communication to recognize and mitigate deterioration in high-risk patients. Each element of the bundle was specifically chosen to be minimal in cost and technology independent. The bundles comprised several elements, including a mandatory twice-daily safety huddle. "The UCSF Benioff Children's Hospital's Cardiac Intensive Care Unit team enthusiastically embraced implementing the bundle" says Dr. Amy McCammond, the institutional lead and Director of the Cardiac Intensive Care Unit. "It was a team approach including bedside nurses, respiratory therapists, frontline providers, and ICU physicians. I am proud of the substantial reduction in cardiac arrests achieved by our team at UCSF and all of the teams at participating centers."

Heart disease affects nearly 1 in every 100 children, and about 25% of those children need heart surgery. Cardiac arrest occurs when the heart stops functioning, and chest compressions are required to provide adequate blood flow to the body. Many experts in the field considered cardiac arrests when in the hospital largely unavoidable, but the PC4 cardiac arrest prevention bundle challenges that notion.

"Pediatric cardiac patients are at the highest risk of suffering in-hospital cardiac arrest with very high morbidity and mortality following the arrest event," says Tia Raymond, MD, pediatric cardiologist at Medical City Children's Hospital in Dallas, a lead consultant for the American Heart Association Resuscitation Guidelines and an Executive Committee member of PC4. "High quality cardiopulmonary resuscitation during cardiac arrest combined with post-resuscitation care has been the focus, yet preventing a cardiac arrest all together in this high-risk population should be the priority. Our results from this multicenter collaborative among PC4 sites have demonstrated that identification of high-risk

cardiac populations is possible, and that with implementation of a simple bedside cardiac arrest prevention bundle can result in significant reduction of cardiac arrest in this population."

The national project analyzed over 2,500 patients for which the Cardiac Arrest Prevention bundle was applied. In these patients, there was a 30% relative reduction in intensive care unit cardiac arrests, which translated to an average of 11 fewer intensive care unit cardiac arrests per month at participating hospitals.

Please let me know if you are interested in speaking with our experts about this exciting new development!

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

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

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- 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.

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

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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

Study: Childhood obesity increasing, starting earlier

July 5, 2022

Childhood obesity among primary school children is increasing and starting at earlier ages, according to a new study.

"With more children experiencing severe obesity in the recent cohort, we can expect higher risks of … co-morbidities in today's high-schoolers and future adults," authors wrote in "Changes in the Incidence of Childhood Obesity," (Cunningham SA, et al. *Pediatrics*. July 5, 2022).

Researchers followed two nationally representative groups of children from kindergarten through fifth grade. One group entered kindergarten in 1998 and the other in 2010.

About 15.3% of the children had obesity when they entered kindergarten in 2010 compared to 12% in the earlier cohort, and a higher proportion of the recent group had severe obesity, the study found.

Among children who did not have obesity when they entered kindergarten, 16.2% of the later cohort had obesity by the end of fifth grade compared to 15.5% of the earlier group. This difference was driven largely by those who were overweight in kindergarten and progressed. There was no change in the risk of developing obesity among those with a normal body mass index (BMI) in kindergarten.

The risk of developing obesity was greater among boys than girls in both groups. Authors also noted differences by race. The risk of new onset obesity by fifth grade was 29% higher for Black students in the recent group compared to the earlier group, the only racial group to see an increase.

Looking at socioeconomic data, the greatest risk of developing obesity was among the lowest and highest groups while staying steady for those in the middle. Authors said the finding is "a reminder that children of all walks of life are at risk for obesity."

They expressed concern about the impact of rising obesity on rates of diabetes and cardiovascular issues and a wider array of health issues for those with severe obesity. Authors also called for more research on biological factors such as maternal obesity in addition to social determinants and interventions for young children.

"We speculate that prevention programs need to look beyond simple solutions to obesity, including addressing the substantial changes in physical activity and in food environments that have progressed in recent decades, as well as the epigenetic and neuro-psycho-behavioral pathways to obesity," they wrote. "Ongoing surveillance is required to monitor changes in health at population levels."

Authors of a related commentary noted Hispanic children have higher obesity rates by age 2 years compared to children of other races.

"This finding supports the American Academy of Pediatrics recommendation of a life-course approach to identify children 'early on the path to obesity' for primary prevention of obesity," they wrote.

Resources

- AAP interim guidance *Obesity Management and Treatment During COVID-19*
- AAP clinical report *The Role of the Pediatrician in Primary Prevention of Obesity*
- AAP Institute for Healthy Childhood Weight
- Bright Futures health initiative
- Information for parents from HealthyChildren.org on obesity

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New AAP main number: 630-626-6000

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Keeping Your Baby Safe

during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

Wash Your Hands

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

Limit Contact with Others

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

Provide Protective Immunity

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

Take Care of Yourself

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

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

WARNING

Never Put a Mask on Your Baby

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

If you are positive for COVID-19

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

We can help protect each other.
Learn more
www.nationalperinatal.org/COVID-19

National Perinatal Association

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu coronavirus pertussis RSV

WASH YOUR HANDS
often with soap and warm water.

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

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

USE AN ALCOHOL-BASED HAND SANITIZER.

STAY AWAY FROM SICK PEOPLE
Avoid crowds. Protect vulnerable babies and children.

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National Perinatal Association

Peer Reviewed

Genetics Corner: Diabetic Embryopathy with Prominent Bone Anomalies in an infant of a Diabetic mother

Heidi Duarte, M.D, Curtis Grossheim, BS, Hua Wang, M.D., Ph.D, Robin Clark, M.D

Case History

A female baby was born at a gestational age of 35 weeks, AGA, to a 25-year-old mother with a history of type I diabetes (DM1) for 10 years, chronic hypertension, and a known history of 2 previous spontaneous abortions (G3P1). The pregnancy was complicated by maternal COVID infection two months before delivery. Prenatal care was initiated towards the end of the first trimester. The mother was induced due to worsening hypertension, but due to failure to progress, a cesarean section was performed. The mother's DM1 was poorly controlled, and she did not know she was pregnant initially. Only near the end of her first trimester was she able to control her blood sugars better. Her first prenatal ultrasound was performed at 11 weeks of gestation. Her prenatal ultrasound report at 20 weeks gestational age showed congenital right femoral deficiency. After birth, multiple congenital anomalies were identified, including left club foot, absent right femur, tethered cord, and butterfly vertebra. *A genetics consultation was requested. The clinical phenotype is highly suggestive of Diabetic Embryopathy (DE).*

" After birth, multiple congenital anomalies were identified, including left club foot, absent right femur, tethered cord, and butterfly vertebra. A genetics consultation was requested. The clinical phenotype is highly suggestive of Diabetic Embryopathy (DE)."

Genetic Evaluation

The baby was seen by pediatric genetics for multiple congenital anomalies and the mother's history of multiple spontaneous abortions.

Her physical exam was notable for poor coordination of suck, identified as mostly tongue thrusting, which can be normal with this level of prematurity of 35 weeks but is not as common. It was noted that she had posteriorly rotated ears with an abnormal fold and pointed helix on the right (Fig. 1b), folded and interrupted helix on the left ear (Fig. 1a), and no pits or tags present. She did have a mostly flat philtrum, mild retrognathia, and full face. There was a shortened nasal bridge, which altogether presented as dysmorphic facies (Fig. 1c). In relation to her extremities, she did have adequate tone in all extremities (Fig. 2a) except her right leg, which had minimal spontaneous movement, the sensation of the right foot is intact, the right leg which is missing the femur (Fig. 2a, Fig. 3b) has abnormal toe placement (overlapping toes) (Fig. 3c), and both lower extremities had a certain degree of club foot (Fig. 2b, Fig. 3a, Fig. 3b). Her hips were asymmetric due to poor development of the right acetabulum (Fig. 2a). Her right hand was hypoplastic when compared to the left side (Fig. 2a). On her back a deep sacral dimple/pit with visible base was noted and it was positioned much lower than usual (Fig. 2c). She developed hyperbilirubinemia. She required triple phototherapy while in the NICU.

"She had multiple imaging studies done to identify if any internal malformations were present. The Ultrasound (US) of her spine showed an abnormally low termination of the conus medullaris at the lower portion of L3 with borderline prominent cauda equina."

She had multiple imaging studies done to identify if any internal malformations were present. The Ultrasound (US) of her spine showed an abnormally low termination of the conus medullaris at the lower portion of L3 with borderline prominent cauda equina. With these findings, she was diagnosed with a presumed tethered cord until an MRI could be performed in the future. No evidence of germinal matrix hemorrhage was found on her head US. The pelvic US could not identify ovaries, but the uterus was anatomically normal. The renal US showed small bilateral kidneys, possibly due to prematurity. An echo was done at the referring hospital at 24

Figure 1a: Right ear with normal shape Figure 1b: Left ear with pointed helix Figure 1c: Full face with a short nose, mild retrognathia, flat philtrum

Figure 2a: Good tone in all extremities other than right lower extremity, asymmetry of the pelvis. Figure 2b: Club foot of the left foot Figure 2c: Abnormally low sacral dimple

hours of life and then again on day 4. The initial echocardiogram showed a small mid-septal interatrial communication with a left to right shunt and normal cardiac anatomy with a small PDA with a left to right shunt. On day 4 of life, her echocardiogram was found to have normalized.

The radiographic imaging (XR) of her right lower extremity confirmed the clinical diagnosis of agenesis of the right femur and showed hypoplasia/shortening of the proximal fibula (Fig. 5a, Fig. 5b, Fig. 5c). Suspected dysplasia of the right acetabulum was also noted (Fig. 5a). Her thoracic Spine X-ray showed Butterfly vertebra at T8 and T9 (Fig. 4a, Fig. 4b). An abdominal XR showed soft tissue/fluid convexity occupying the pelvis, which may reflect distended urinary bladder.

A chromosomal microarray was sent out at the request of pediatric genetics, and it was normal.

Multiple congenital anomalies in the setting of maternal history of multiple spontaneous abortions, Chromosome microarray was performed

"The chromosome microarray was negative, which excluded microdeletion or microduplication syndromes."

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Diabetic Embryopathy has various clinical presentations; the severity is associated with uncontrolled maternal glucose levels. A

Figure 3a: Club foot of left foot. Figure 3b: Right club foot. Figure 3c: Abnormal toes on the left foot.

Figure 4a: Butterfly vertebrae noted in radiographic imaging in T8 and T9 Figure 4b: Full spine Xray w/ butterfly vertebrae

careful investigation to exclude other genetic disorders that have overlapping features with diabetic Embryopathy is crucial to making the correct diagnosis.

Discussion

The rate of congenital malformations in children of diabetic mothers is around 5-6%, which is constant between type 1 and type 2 diabetes.

The Clinical Features of Diabetic Embryopathy are Vast.

The most frequent structural deformities in fetuses exposed to pregestational diabetes were congenital cardiac defects followed by genitourinary defects. Together these two categories make up more than 50% of the abnormalities found in diabetic Embryopathy. The central nervous system is also commonly affected, but almost any organ can be affected. Cardiovascular system defects include transposition of the great vessels, ventricular septal defects, single umbilical artery, cardiomyopathy, coarctation of the aorta, and atrial septal defects. CNS malformations include anencephaly, spina bifida, microcephaly, and holoprosencephaly. Skeletal system malformations include caudal regression syndrome, sacral agenesis, and limb defects. Renal system malformations include renal agenesis, hydronephrosis, and ureteral abnormalities. The gastrointestinal system can be affected by malformations of duodenal atresia, anorectal atresia, and small left colon syndrome. Certain organs display increased vulnerability when exposed to the teratological effects of high glucose levels in serum. The research has shown cardiac and nervous system tissue to be the most vulnerable, followed by the skeletal system. Caudal regression, though only partially present in this patient, is identified almost exclusively in infants of diabetic mothers. Lastly, the high frequency of early spontaneous abortions and perinatal death in pre-gestational diabetic mothers is important.

"Caudal regression, though only partially present in this patient, is identified almost exclusively in infants of diabetic mothers. Lastly, the high frequency of early spontaneous abortions and perinatal death in pre-gestational diabetic mothers is important."

Malformation is Strongly Associated with Uncontrolled Diabetes

The risk of malformations was statistically significant in patients

Figure 5a: XR of the right lower extremity with agenesis of the right femur, hypoplasia/shortening of the proximal fibula, and dysplasia of the right acetabulum. Figure 5b: Compares left and right leg with notable agenesis of the right femur and shortened limb. Figure 5c: Visualization of the pelvis, with flexion of the left leg and malformed pelvis on the right side.

with uncontrolled diabetes prior to pregnancy or in their first trimester (when many women still do not know that they are pregnant), with significantly elevated hemoglobin A1c of > 9%. However, malformations can still occur in pregnancies of mothers with diabetes type 1 and 2 where hemoglobin A1C is found to be normal or slightly elevated. Using a developmental, morphologic approach, a time before a defect must have occurred is identified using known embryonic organ development timing. Thus, an organ that is not fully differentiated is vulnerable to malformations, making caudal regression occurring at week three gestational age after ovulation, meaning that a mother would be considered five weeks pregnant if calculated by the last menstrual period (LMP). Situs inversus and anencephaly will occur at gestational age since LMP at week six if we follow this thought process.

Multifactorial Effects on the Pathogenesis of diabetic Embryopathy

Both genetic and environmental factors are considered at play in diabetic Embryopathy. Aberrant DNA methylation and cis-sequence variation in the pathogenesis of DE has been reported. The environmental factors include maternal diabetic state and severity and intrauterine conditions. The process of malformation development is multifactorial and is not dependent on just one variable. Other variables include vascular disease, hormone imbalances, ketone, amino acid abnormalities, hypoxia, and glycosylation of proteins, all of which could be teratogenic factors. Though overall, the risk of major birth defects was directly proportional to the control of the maternal blood glucose level, specifically during the first trimester and typically before the seventh week after ovulation, mothers with diabetes type 2, more so that DM1, have been found to develop fetal malformations even with a hemoglobin A1C only mildly elevated. Therefore, good pre-pregnancy care and excellent glycemic control are of the utmost importance in DM1 and DM2.

Characteristics of this Patient

Though cardiac defect is the most commonly seen in DE, our patient here did not find lasting cardiac defects on the postnatal echo that was done on day 4 of life. Our patient developed the syndrome of phocomelic diabetic Embryopathy with abnormalities of the lower extremities and the absence of one femur, along with abnormal development of the pelvis and acetabulum and abnormal vertebrae. There is also a possible tethered cord. Embryonic nervous system development is closely linked with vertebral chondrogenesis, noting that the embryonic spinal cord and notochord play a vital role in the chondrification of surrounding somatic tissues. This is evident clinically with degrees of skeletal malformations correlating with the variance in the neural tube closure.

" Embryonic nervous system development is closely linked with vertebral chondrogenesis, noting that the embryonic spinal cord and notochord play a vital role in the chondrification of surrounding somatic tissues. This is evident clinically with degrees of skeletal malformations correlating with the variance in the neural tube closure."

Differential Diagnosis:

DE has a wide variety of clinic presentations. Abnormalities can present in the organogenesis of any organ system. These dysmorphias are not unique to diabetic Embryopathy, and a careful investigation into each patient's unique abnormalities is crucial in making the correct diagnosis. DE is often made as a diagnosis of exclusion after ruling out other common causes of abnormal organogenesis. The first logical step is a genetic evaluation, as many genetic diseases present with similar symptoms. The most prevalent genetic diagnosis' that need to be ruled out include:

1. DiGeorge Syndrome, with symptoms that mimic diabetic embryopathy complications such as Cardiac anomalies, learning abilities, and facial dysmorphism.

2. VACTRL can present with cardiac abnormalities, anal atresia, vertebral defects, limb defects, and renal abnormalities similar to diabetic Embryopathy.

3. CHARGE Syndrome affects multiple organ systems, growth retardation, and facial dysmorphias.

4. Neural Tube Defects are characteristic of Diabetic Embryopathy but can also be caused by genetic factors, folic acid deficiency, and vitamin B12 deficiency. By combining a detailed history and physical examination with genetic testing results, the diagnosis of DE can confidently be made after ruling out the other conditions on the differential diagnosis.

Practical Application:

1. Diabetic Embryopathy has a wide variety of clinic presentations. Abnormalities can present in the organogenesis of any organ system. The clinical features overlap many genetic disorders.

2. A careful investigation into each patient's unique abnormalities is crucial in making the correct diagnosis.

3. No statistically significant correlation of fetal malformations was identified in neonates born to mothers with gestational diabetes who did not have pregestational diabetes. This has been supported by many strong studies that repeatedly show that gestational diabetes does not cause diabetic Embryopathy. Also, women diagnosed with prediabetes before pregnancy are not at higher risk of having a child with diabetic Embryopathy.

4. Counseling before conception is essential for women with pregestational diabetes mellitus and reasonable metabolic control before conception to decrease the risk of diabetic Embryopathy and maternal morbidity.

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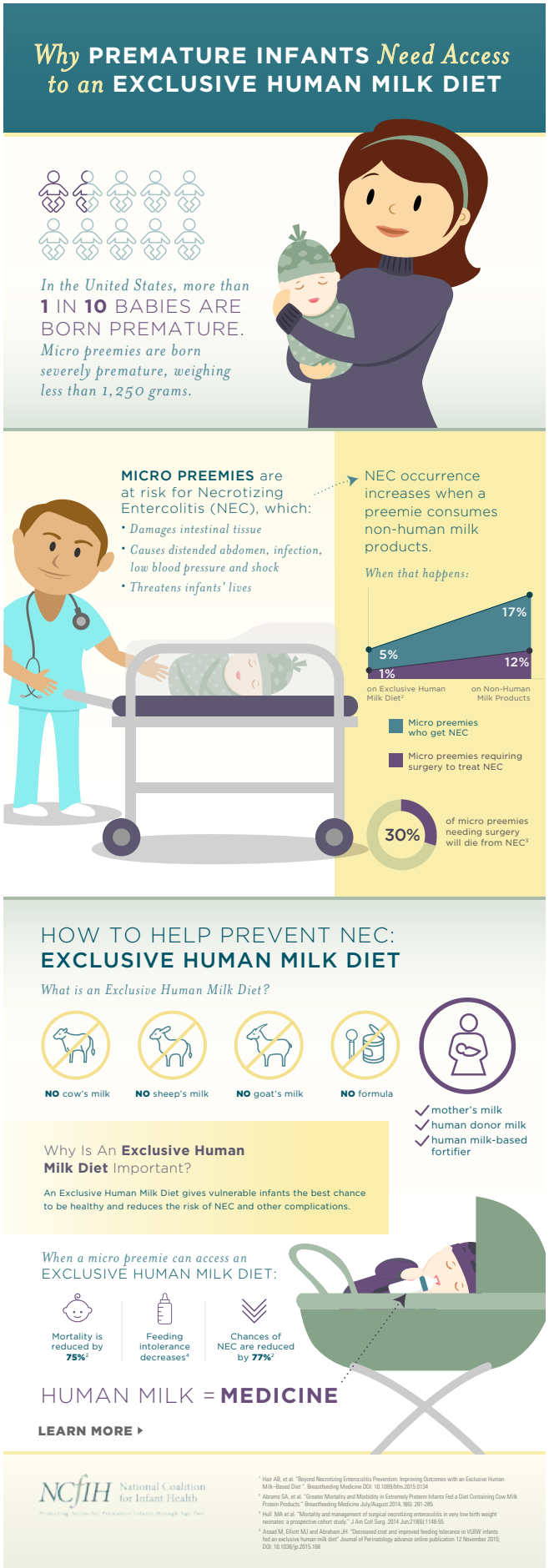


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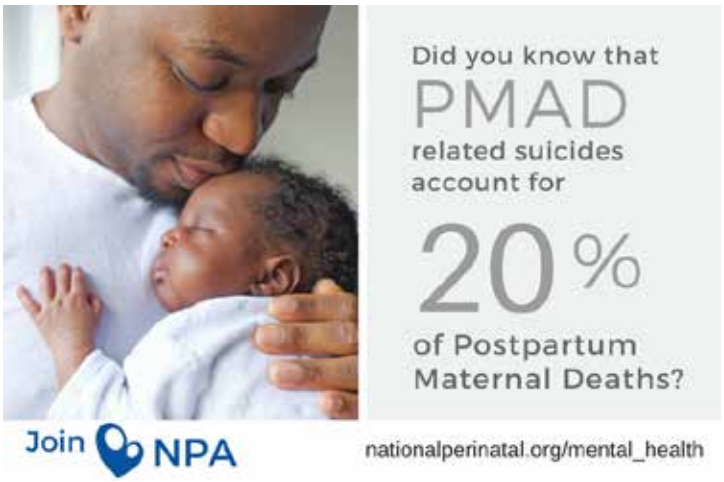
Did you know that
PMAD
related suicides
account for
20%
of Postpartum
Maternal Deaths?
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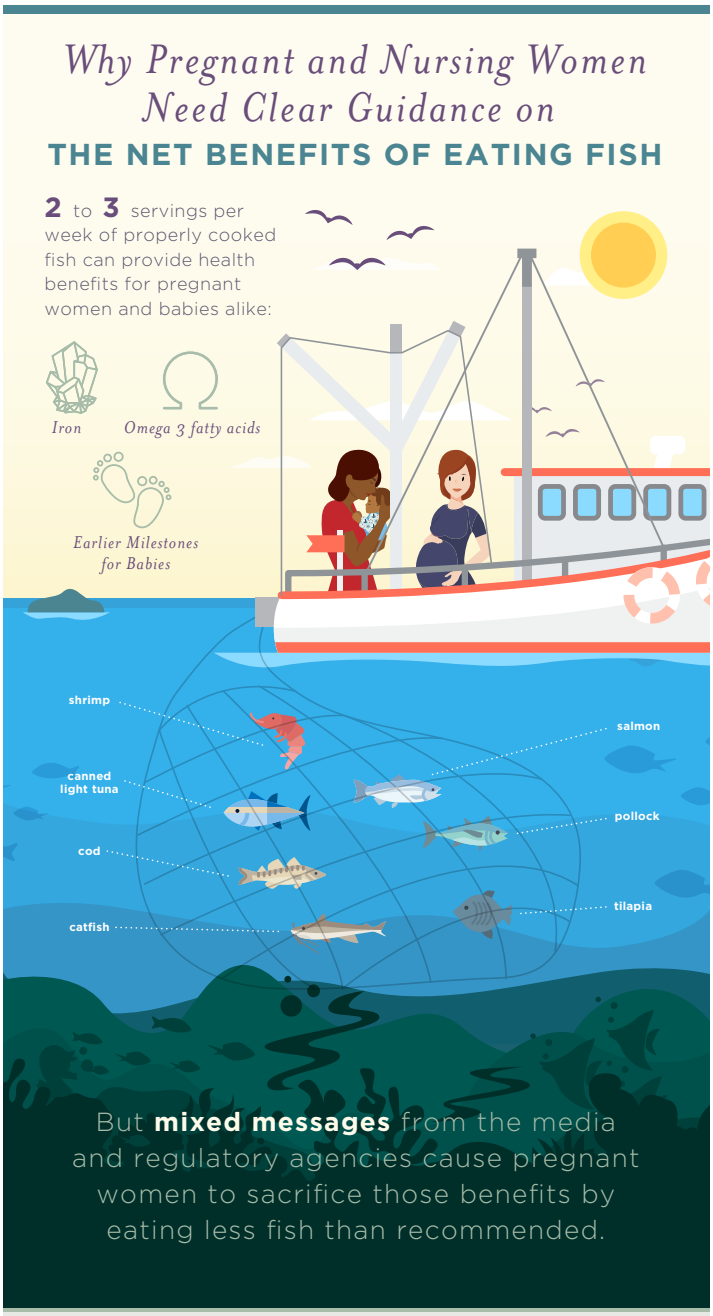
Why Pregnant and Nursing Women
Need Clear Guidance on
THE NET BENEFITS OF EATING FISH
2 to 3 servings per
week of properly cooked
fish can provide health
benefits for pregnant
women and babies alike:
Iron
Omega 3 fatty acids
Earlier Milestones
for Babies
shrimp
canned
light tuna
cod
catfish
salmon
pollock
tilapia
But mixed messages from the media
and regulatory agencies cause pregnant
women to sacrifice those benefits by
eating less fish than recommended.


GET THE FACTS
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FOR PREGNANT
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Medical Legal Forum: Rip Van Winkle and You: Implications of the Statute of Limitations for the Practicing Neonatologist

Jonathan M. Fanaroff, MD, JD

You may recall the story of Rip Van Winkle, a farmer in the Catskill Mountains who falls asleep for twenty years after a magical drink. The short story by Washington Irving, published in 1819, is based on a German folktale. What does this have to do with a medico-legal column? Put simply, neonatologists need to be aware that the statute of limitations for their young patients may exceed the twenty-year slumber of Mr. Van Winkle.

What is the statute of limitations?

"Put simply, neonatologists need to be aware that the statute of limitations for their young patients may exceed the twenty-year slumber of Mr. Van Winkle."

Black's Law Dictionary defines the statute of limitations as the "time frame set by legislation where affected parties need to take action to enforce rights or seek redress after injury or damage." (1) In practical terms, for a baby you care for, it is the time in which the parents (acting on behalf of the baby) or the patient themselves must file a medical malpractice lawsuit.

Why is there a statute of limitations?

The purpose of the statute of limitations is to prompt an injured party to pursue a claim in a reasonable period of time and while evidence is still available to allow a proper disposition of the case. For minors, however, there is also the consideration that they may not be able to testify or fairly represent themselves for several years, so the statute of limitations may need longer.

How long is the statute of limitations?

This is a very important issue. The states generally regulate medicine, and so the statute of limitations is set by state legislatures. Furthermore, almost every state legislature 'tolls' or functionally extends the statute of limitations for minors, with the longest tolling set for newborn patients. This period can range considerably, with the average time to bring a claim for newborns being 12.3 years, ranging from 1 to 23 years. (2) Consequently, in some states, a medical malpractice lawsuit may be filed more than two decades after the alleged malpractice. Often in those states, the statute of limitations does not begin to run until a newborn patient reaches the age of majority.

"Consequently, in some states, a medical malpractice lawsuit may be filed more than two decades after the alleged malpractice. Often in those states, the statute of limitations does not begin to run until a newborn patient reaches the age of majority."

What does this mean for the practicing neonatologist?

It might be surprising to learn that the patient the baby you cared for today may file a lawsuit against you in the year 2042. What are the implications? First, as noted earlier, the statute of limitations varies considerably in different states, and it is advisable to know what it is in the state where you practice. Keep in mind that the legislature can and does sometimes change the statute of limitations in certain circumstances. Second, appropriate documentation is especially important when the care provided is called into question years later. It is often said that "if it was not documented, it was not done." This is not necessarily true, but careful factual, professional documentation can be crucial years later when health care professionals may not recall what occurred. Finally, it is critical to have liability insurance coverage still in effect for the entire period in which you may be held liable. With the proper documentation and liability coverage, you can rest assured even longer than Rip Van Winkle.

"Finally, it is critical to have liability insurance coverage still in effect for the entire period in which you may be held liable. With the proper documentation and liability coverage, you can rest assured even longer than Rip Van Winkle."

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1. https://thelawdictionary.org/statute-of-limitations/. *Accessed July 17, 2022.*
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https://doi.org/10.1097/BPO.0b013e3181653b3d

Disclosure: There are no reported conflicts.

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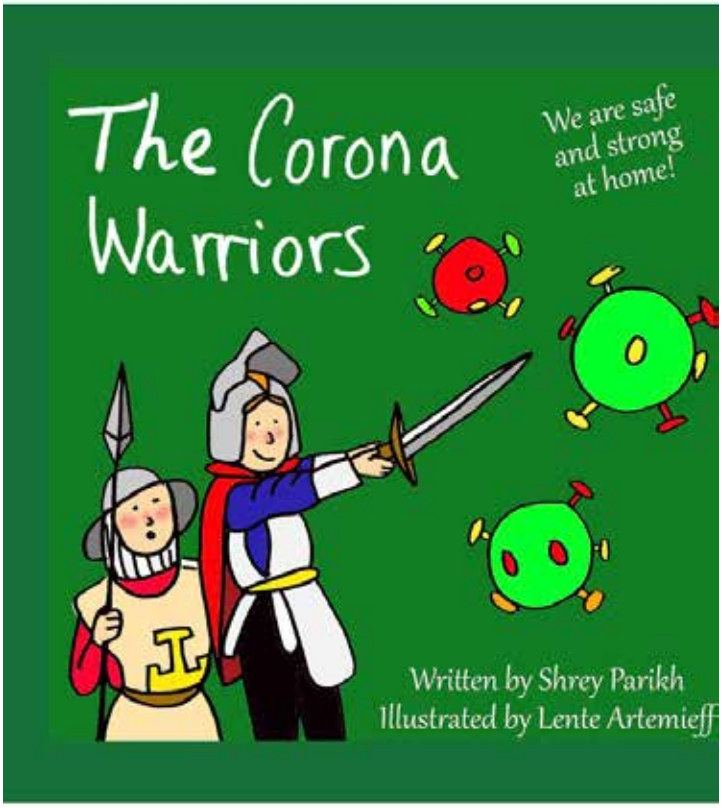

2022

Infant Health Policy Summit

WEDNESDAY, **AUGUST 31**

9:00 A.M. REGISTRATION & BREAKFAST
10:00 A.M. PROGRAM BEGINS

THE WILLARD INTERCONTINENTAL
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TOPICS INCLUDE:

- Black maternal health crisis
- RSV vaccines and interventions
- Parents as partners in their baby's care
- Human donor milk quality and safety
- Drug, formula and product shortages

FEATURING:

The Honorable
ALMA S. ADAMS, PH.D.
U.S. Representative
(NC-12)
Co-founder and Co-chair, Black Maternal Health Caucus

The Honorable
BRUCE WESTERMAN
U.S. Representative
(AR-04)
Republican Healthy Future Task Force Subcommittee on Treatments and Father of a Son Hospitalized with Respiratory Syncytial Virus

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

IfPA | Institute for Patient Access

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Respiratory Syncytial Virus Takes a Toll on Families

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.

It starts with a cough, a wheeze, and a sniffle. For an infant or young child, these symptoms may mark the beginning of a virus that burdens their families and their health for years to come.

So explains "**The Burden of RSV: Impacting All Families**," a recently released white paper from the National Coalition for Infant Health. (1)

While not every child experiences RSV the same, many develop harsh symptoms that can seriously hinder their well-being. And the impact of RSV extends beyond the sick child to their family.

A Burdensome Experience

"While not every child experiences RSV the same, many develop harsh symptoms that can seriously hinder their well-being. And the impact of RSV extends beyond the sick child to their family."

While adults may experience RSV as "just a cold," infants and young children can face serious damage and harsh symptoms from the virus. And RSV is not rare.

- **Nearly all infants catch RSV.** Research shows that nearly all infants catch RSV before the age of 2. It is an illness to which nearly all babies are susceptible.
- **RSV symptoms are painful.** Babies and children may suffer painful symptoms while they have RSV, such as wheezing, coughing, lethargy, and struggling to breathe. These symptoms can cause lasting harm.
- **Supportive care is needed.** In many cases, symptoms may be too much for children to handle on their own. For children under the age of 5, RSV causes more than 500,000 emergency room visits and 58,000 hospital visits each year.

While preemies and infants are particularly vulnerable, children under the age of 5 are still at a high risk of severe RSV.

"Supportive care is needed. In many cases, symptoms may be too much for children to handle on their own. For children under the age of 5, RSV causes more than 500,000 emergency room visits and 58,000 hospital visits each year."

Long-Term Consequences

The impact of RSV does not end when a baby's immune system finally wins out against the virus. Unfortunately, the harm caused by RSV can lead to further difficulties for the baby and their family. RSV can lead to:

- **Emotional strain.** During an RSV hospitalization, families may experience distress or emotional exhaustion. Watching a child struggling with illness is draining, and additional responsibilities such as work and child care for siblings can place even more stress on parents.
- **Financial toll.** Hospitalization and follow-up treatments can generate staggering medical bills. The total cost of supportive care can be devastating for families just trying to care for their children.
- **Health complications.** Children who contract RSV at a young age are more likely to develop asthma or another breathing disorder later in life. While children may overcome the virus, its impact lingers in the form of long-term health consequences.

Despite the harm RSV causes, no cure or vaccine yet exists. There are preventive interventions, but not everyone can access them.

Read "**The Burden of RSV: Impacting All Families**" to learn more about RSV, its impact, and how families and health care providers can work to prevent it. (1)

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1. https://static1.squarespace.com/static/5523fcf7e4b0fef011e668e6/t/62aa3a1421c8377491e06778/1655323159078/NCfIH_The+Burden+of+RSV_White+Paper_June+2022.pdf

Disclosure: No relevant disclosures noted

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National Coalition for Infant Health Values (SANE)

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

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

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

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

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.

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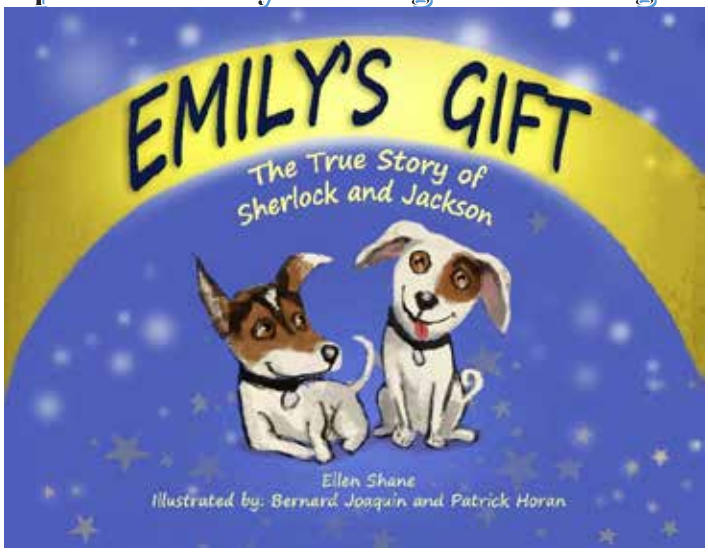

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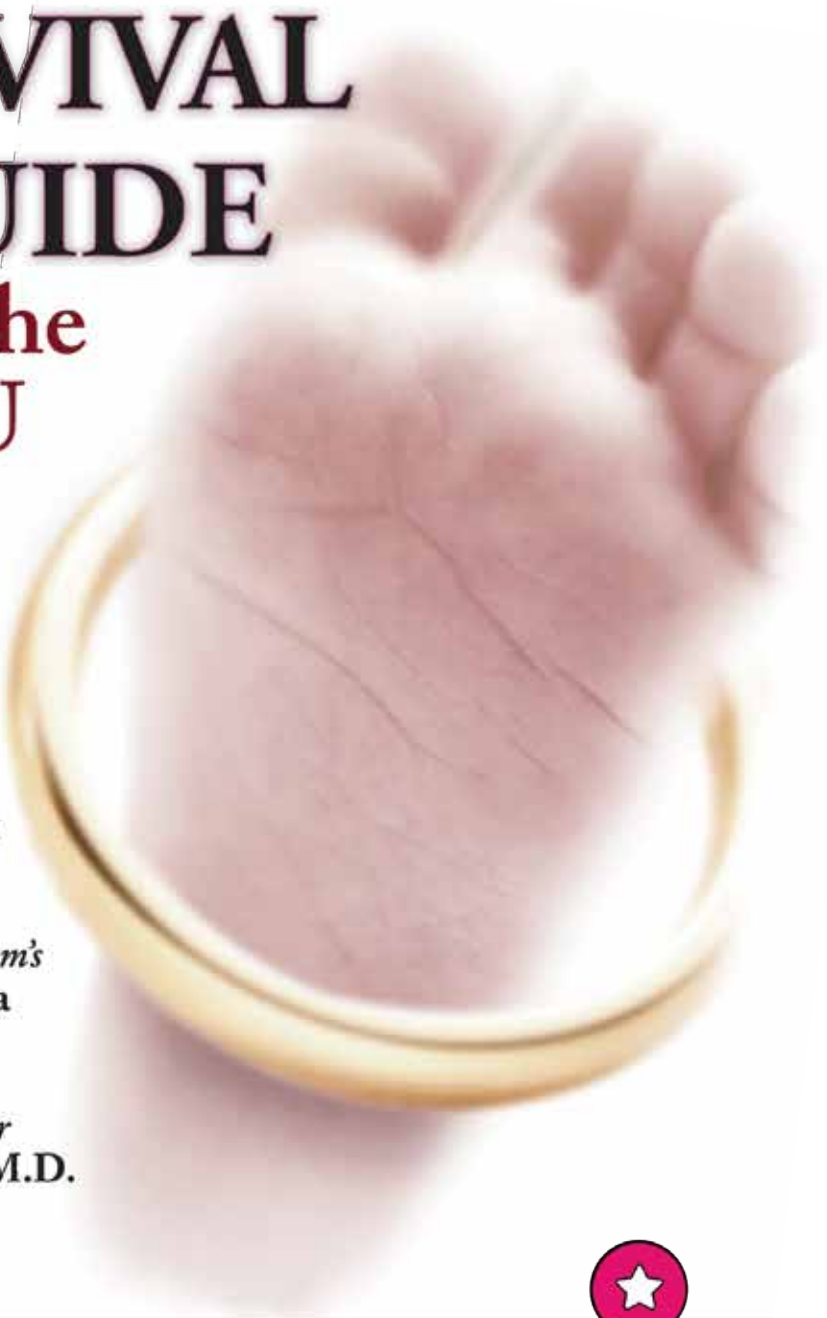

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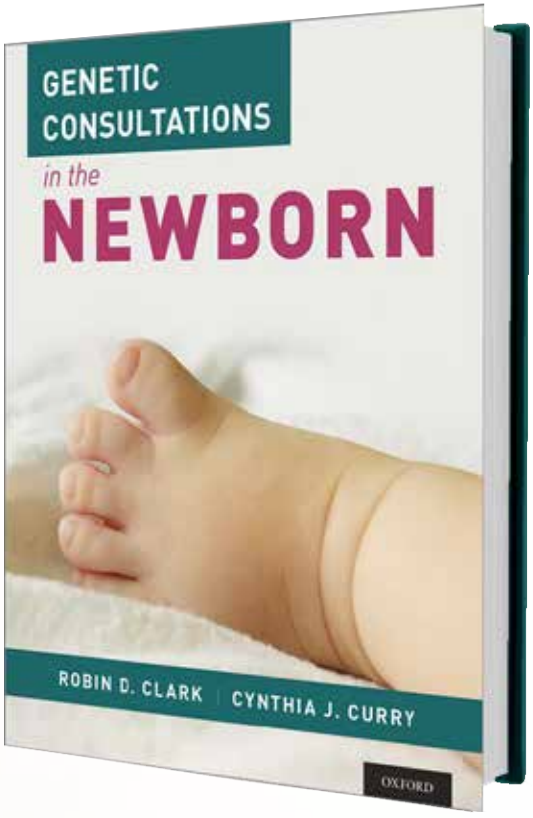

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Clinical Pearl: Persistent Pulmonary Hypertension of the Newborn and Possible Premature Ductal Closure with History of In Utero Exposure to a Selective Serotonin Reuptake Inhibitor

Kendall Ulbrich, MD

***Abstract**::*

Persistent pulmonary hypertension of the newborn more often affects term and near-term infants. It occurs when the anticipated postnatal decrease in pulmonary vascular resistance fails to occur. There is evidence in animal models of premature ductal closure and persistent pulmonary hypertension of the newborn in fetal mice with in-utero exposure to selective serotonin reuptake inhibitors, commonly prescribed antidepressants in pregnancy. This case raises suspicion about an association in a neonate between in-utero exposure to selective serotonin reuptake inhibitors and persistent pulmonary hypertension of the newborn secondary to premature ductal closure.

"This case raises suspicion about an association in a neonate between in-utero exposure to selective serotonin reuptake inhibitors and persistent pulmonary hypertension of the newborn secondary to premature ductal closure."

Introduction:

Pulmonary vascular resistance is high in fetal circulation and characteristically decreases during the transition to neonatal circulation. A failure in this expected drop in pulmonary vascular resistance after birth leads to persistent pulmonary hypertension of the newborn (PPHN). This condition more commonly affects term and near-term infants and occurs in approximately 10-20 in 10,000 live births. (1) PPHN may lead to profound hypoxemia and respiratory failure and is associated with significant morbidity and mortality in affected infants. (1)

"Pulmonary vascular resistance is high in fetal circulation and characteristically decreases during the transition to neonatal circulation. A failure in this expected drop in pulmonary vascular resistance after birth leads to persistent pulmonary hypertension of the newborn (PPHN)."

Case Presentation

An infant was delivered at 39 weeks and 2 days gestation via uncomplicated vaginal delivery to a 35-year-old gravida 4, para 2-0-2-2 mother. Pregnancy was complicated by maternal anxiety treated with sertraline, a selective serotonin reuptake inhibitor (SSRI), 100mg daily throughout pregnancy. Prenatal imaging revealed a thickened nuchal fold at 12 weeks. Noninvasive prenatal screening (NIPS) returned low risk, and chorionic villous sampling returned normal karyotype and microarray. Normal level two ultrasound was performed with a recommendation for a follow-up echocardiogram after birth, given a prenatal finding of a thickened nuchal fold. Delivery was complicated by meconium-stained amniotic fluid. The infant required resuscitation in the delivery room, including continuous positive airway pressure (CPAP) for increased work of breathing, which was resolved in the delivery room. Apgars assigned were 7 and 8 at 1 min and 5 mins, respectively. The infant was left in the delivery room in stable condition and admitted to the newborn nursery. At 9 hours of life, the infant was noted on the exam in the newborn nursery to appear dusky with pre-ductal oxygen saturations in the low 80s. The infant was then transferred to the neonatal intensive care unit (NICU) for further management.

The infant was initially admitted to the NICU on 2 LPM nasal cannula, requiring 35-40% FiO_2. The physical exam was unremarkable, with no respiratory distress and clear, equal breath sounds bilaterally. No murmur was noted, and the infant was well perfused with 2+ femoral pulses bilaterally. On DOL 2, the infant developed increasing FIO_2 requirement with increased respiratory support to CPAP. Physical exam at that time was unremarkable for the respiratory exam though the infant was noted to be hyperalert and jittery. On DOL 3, the infant was intubated due to worsening FiO_2 requirements to 100% and started on inhaled nitric oxide (iNO) with improvements in FiO_2 requirements.

"Initial evaluation included a chest x-ray which revealed no abnormal findings. Echocardiogram on DOL 0 (<24 hours of life) showed a closed ductus arteriosus and mildly dilated and hypertrophied right ventricle. "

Clinical Course:

Initial evaluation included a chest x-ray which revealed no abnormal findings. Echocardiogram on DOL 0 (<24 hours of life) showed a closed ductus arteriosus and mildly dilated and hypertrophied right ventricle. On DOL 2, with worsening FiO_2 requirements noted, arterial blood gas was obtained and notable for low PaO_2 46 mm Hg. After initiation of inhaled iNO, repeat arterial blood gas was notable for a rising PaO_2 of 101 mm Hg. This rise in PaO_2 in response to hyperoxia and iNO in an infant with an otherwise reassuring respiratory exam and unremarkable chest x-ray

is consistent with PPHN. Repeat echocardiogram DOL 6 showed moderate flattening of the interventricular septum consistent with systemic right ventricular pressure, supporting the diagnosis of PPHN. This case was reviewed with cardiology, and premature ductal closure was discussed as a possible etiology of this PPHN, given findings of a closed ductus on an echocardiogram at less than 24 hours of life with significant PPHN. Of note, the infant's jittery and hyperalert state was attributed to *in-utero* SSRI exposure and resolved with time. The mother reported a previous child had also shown similar neurologic symptoms after birth that self-resolved and were also attributed to *in-utero* SSRI exposure. Over two weeks, the infant was weaned off iNO, extubated to room air, and discharged home.

"Of note, the infant's jittery and hyperalert state was attributed to in-utero SSRI exposure and resolved with time. The mother reported a previous child had also shown similar neurologic symptoms after birth that self-resolved and were also attributed to in-utero SSRI exposure. Over two weeks, the infant was weaned off iNO, extubated to room air, and discharged home."

Discussion:

Our recent cohort study found that *in-utero* SSRI exposure was associated with significantly greater odds of resuscitation in the delivery room and NICU admission. (2) While the mechanisms underlying these findings have not yet been elucidated, animal models provide biological plausibility for an association between in-utero SSRI exposure and PPHN. A delay in the usual postnatal decrease in pulmonary vascular resistance has been shown in fetal rats exposed to the SSRI fluoxetine. (3) Histologic evaluation in this animal model also revealed pulmonary artery smooth muscle cell proliferation and pulmonary vascular remodeling. (1) In a large cohort study of publicly insured pregnant women, evidence showed a potential increased risk of PPHN after *in-utero* SSRI exposure. (1) Animal models also provide biological plausibility for a possible association between in-utero SSRI exposure and premature ductal closure. *In vivo*, premature constriction of the ductus arteriosus was observed in SSRI-exposed fetal mice. Serotonin receptors were expressed on ductal tissue isolated from these fetal mice, which constricted in response to both serotonin and SSRI exposure. (4) Isolated ductal cells pretreated with SSRI also demonstrated an attenuated response to a prostaglandin E2-induced vasodilation, which suggested that the ductus arteriosus may default to a constricted state during SSRI exposure, thereby leading to premature constriction with *in-utero* exposure. (4)

"While the mechanisms underlying these findings require further study, and this case does not demonstrate a causal relationship between in-utero SSRI exposure and premature ductal closure or PPHN, it does support a possible association between these findings."

While the mechanisms underlying these findings require further study, and this case does not demonstrate a causal relationship between *in-utero* SSRI exposure and premature ductal closure or PPHN, it does support a possible association between these findings. Further investigation into this relationship is needed, as well as an exploration into the translation from animal models to clinical cases.

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Summarize the pearl for emphasis.

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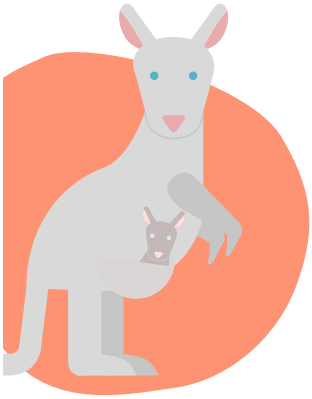

GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

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

PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

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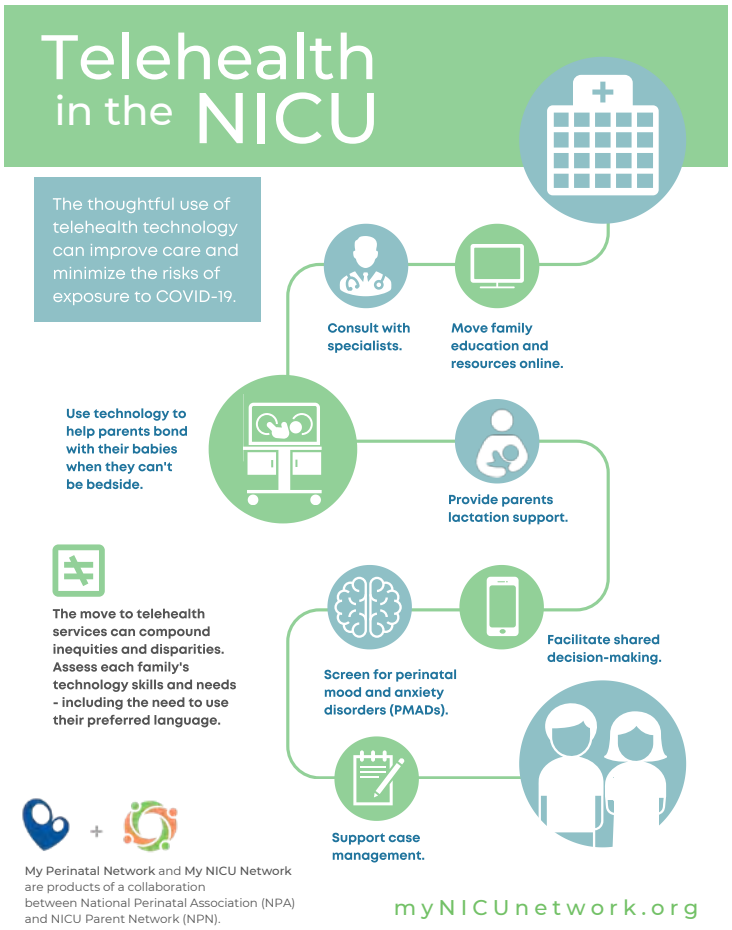

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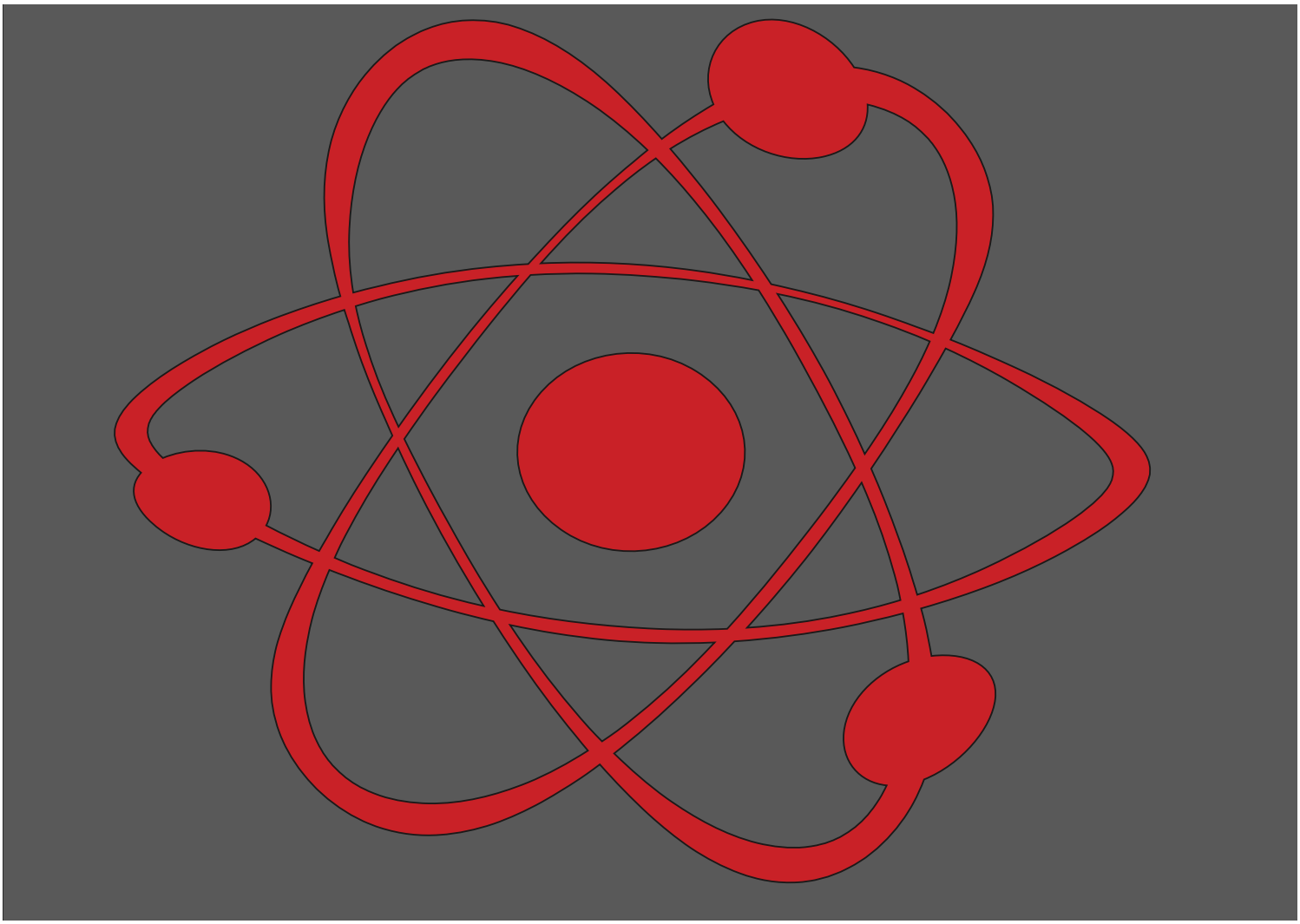

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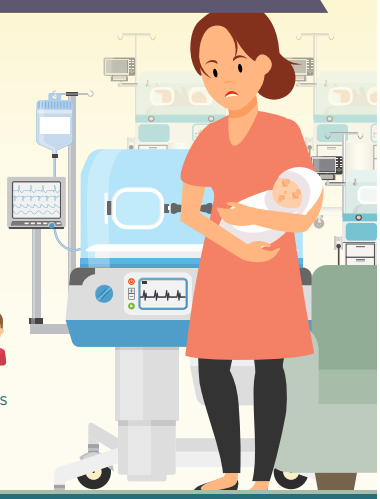
Will your **PRETERM INFANT** *need* **EARLY INTERVENTION** *services?*

Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges

1 in **3** preterm infants will require support services at school

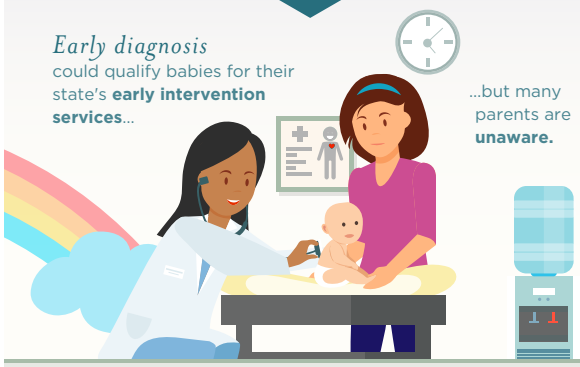


Early intervention can help preterm infants:

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

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

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



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

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

NCFIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

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

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- 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

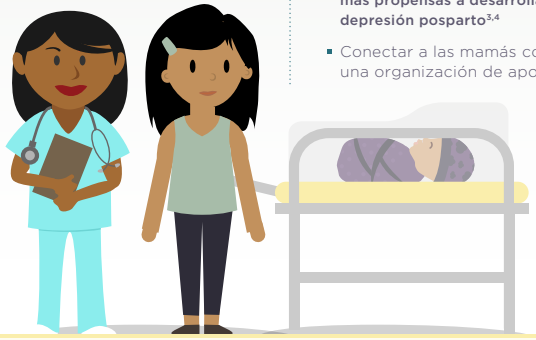
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

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.

Pediatrix® Neonatology Grand Rounds Series: Hot topics in neonatal care

Hosted by the Pediatrix® Center for Research, Education, Quality and Safety (CREQS), our Pediatrix Neonatology Grand Rounds series occur the first Wednesday of every month at 4 p.m. Eastern Time. The monthly hour-long webinars are a great way to earn accredited CE and learn about the latest goings-on in neonatology. Join us as we explore relevant topics such as:

- **May 4** — Neurodevelopmental outcomes in the drug-exposed premature infant.
- **June 1** — Growth assessment and coding for malnutrition in the NICU.

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**Webinar topics and speakers subject to change.*

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Upcoming Medical Meetings

2022 American Academy of Pediatrics National Conference and Exhibition
Anaheim Convention Center
Anaheim, CA
October 7-12, 2022
https://aapexperience.org/conference-event-locations/

Once Upon a Preemie Presents 1st Annual Conference Accelerating the Health and Racial Equity in Maternal and Neonatal Care
University City Science Center
3675 Market Street, 2nd Floor
Philadelphia, PA 19104
November 17th, 2022
Watch for the registration link.

NEO: The Conference for Neonatology
February 22-24, 2023
Las Vegas, NV
https://www.mednax.com/neo-conference/

36th Annual Gravens Conference on the Environment of Care for High Risk Infants
The Future is Now for Babies, Families, and Systems
Sand Key, FL
March 8-11, 2023
Hold the Date

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

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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

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Neonatal Nurse Practitioner

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- State of the art technology
- 24/7 coverage provided by NNP team and Fellows

Who We Are

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

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

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

Contact Us

Please visit our website **http://careers.llu.edu** or contact Jeannine Sharkey, Director of Advanced Practice Services at jsharkey@llu.edu or (909) 558-4486.

LOMA LINDA UNIVERSITY HEALTH

If you are an individual who understands and embraces the mission and purpose of Loma Linda University and its entities as premier Seventh-day Adventist Christian institutions, please visit our website or call 1-800-722-2770. EOE/AA/M/F/D/V

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https://www.nc3rs.org.uk/arrive-guidelines

http://www.icmje.org

https://olaw.nih.gov/policies-laws/phs-policy.htm

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Neonatology and the Arts

This section focuses on artistic work which is by those with an interest in Neonatology and Perinatology. The topics may be varied, but preference will be given to those works that focus on topics that are related to the fields of Neonatology, Pediatrics, and Perinatology. Contributions may include drawings, paintings, sketches, and other digital renderings. Photographs and video shorts may also be submitted. In order for the work to be considered, you must have the consent of any person whose photograph appears in the submission.

Works that have been published in another format are eligible for consideration as long as the contributor either owns the copyright or has secured copyright release prior to submission.

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one page as well as photographs of birds on another. This month's original artwork features Paula Whiteman, MD who graces us with Snapdragons. Our bird of the month is a Candian Goose by Mita Shah, MD.

Herbert Vasquez, MD,
Associate Neonatologist, Queen of the Valley Campus
Emanate Health, West Covina, CA
VasquezH1@gmail.com

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Manuscript Submission: Instructions to Authors

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

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

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

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

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

6. An abstract may be submitted.

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

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

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

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

11. NT recommends reading Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals from ICMJE prior to submission if there is any question regarding the appropriateness of a manuscript. NT follows Principles of Transparency and Best Practice in Scholarly Publishing(a joint statement by COPE, DOAJ, WAME, and OASPA). Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

NICU Baby's Bill of Rights

1- The Right to Advocacy
My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical records, and prognosis, so they celebrate my achievements and support me when things get challenging.

2- The Right to My Parents' Care
In order to meet my unique needs, my parents need to learn about my developmental needs. Be patient with them and teach them well. Make sure hospital policies and protocols, including visiting hours and rounding, are as inclusive as possible.

3- The Right to Bond with My Family
Bonding is crucial for my sleep and neuroprotection. Encourage my parents to practice skin-to-skin contact as soon as and as often as possible and to read, sing, and talk to me each time they visit.

4- The Right to Neuroprotective Care
Protect me from things that startle, stress, or overwhelm me and my brain. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time and faster than it ever will again. The way I am cared for today will help my brain when I grow up. Connect me with my parents for the best opportunities to help my brain develop.

5- The Right to be Nourished
Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Also, let my parents know that donor milk may be an option for me.

6- The Right to Personhood
Address me by my name when possible, communicate with me before touching me, and if I or one of my siblings pass away while in the NICU, continue referring to us as multiples (twin/triplets/quads, and more). It is important to acknowledge our lives.

7- The Right to Confident and Competent Care Giving
The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help educate them about my unique needs, development, diagnoses, and more.

8- The Right to Family-Centered Care
Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9- The Right to Healthy and Supported Parents
My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my parents about resources such as peer-to-peer support programs, support groups, and counseling, which can help reduce PMAD, PPD, PTSD, anxiety and depression, and more.

10- The Right to Inclusion and Belonging
Celebrate my family's diversity and mine; including our religion, race, and culture. Ensure that my parents, grandparents, and siblings feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

Presented by:

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

Save the Date for the Second Fragile Infant Forum for the Implementation of Standards (FIFI-S)

January 18-20, 2023

"Implementing Evidence Based Strategies to Alleviate Stress in the Baby and Family in Intensive Care"

For more information contact

PACLAC.org

"Storyteller" painting by Sharron Montague Loree, 1982


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