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Changes in Electrical Activity of the Diaphragm in Response to Painful Procedures in Neonates

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Abstract

Background: Premature neonates are exposed to numerous painful procedures. Physiologic fluctuations in heart rate (HR), respiratory rate, and oxygen saturation are typically used to determine the response to pain. Neurally assisted ventilatory assist (NAVA) delivers inspiratory pressure in proportion to the electrical activity of the diaphragm (Edi). Since NAVA allows self-regulation of peak inspiratory pressures (PIP), there is apprehension that painful stimulus may increase respiratory drive and result in excessive PIP. This study evaluated changes in respiratory drive, measured by Edi, in response to a painful procedure (heel stick) to determine if there was excessive PIP delivered from the ventilator.

Methods: Prospective, single-center study; subjects <32 weeks on NAVA/NIV NAVA requiring routine blood work via heel sticks. Vital signs were measured every 10 seconds for the first 2 minutes. PIP, Edi peak, and min were collected for the first ten breaths and then averaged at 1 and 2 minutes. Statistics were repeated measures ANOVA.

Results: Fourteen subjects with gestational age 26.9+2 weeks and birth weight 994+318 grams. At study, the average age was 4.6+5 days, and weight was 948+305 grams. Following the heel stick, the first breath showed an increase in PIP and Edi peak but returned to baseline by the second breath. PIP increased again by the10th breath and at 1 and 2 minutes. HR increased after heel stick and remained elevated through the remainder of the study. There were no changes in tonic Edi, Edi min or other vital signs.

Conclusion: Although the increase in PIP and Edi peak in response to heel stick pain was brief and limited, it is important always to set the PIP alarm limit appropriately to protect the lung from excessive pressures that may be generated during painful procedures.

Keywords: Neurally Adjust Ventilatory Assist (NAVA), Pain, Premature Infants, Neural trigger. Peak Inspiratory Pressure.

Introduction:

Premature neonates experience recurrent painful procedures during their treatment course in the Neonatal Intensive Care Unit. Repeated invasive procedures occur routinely in these neonates, causing pain at a time when it is developmentally unexpected. (1) They can experience an average of 141 procedures during hospitalization with an average of 16 procedures per day, predominantly heel sticks. (2) Heel sticks have been shown to be more painful compared to traditional venous blood sampling (3) The neonatal physiologic response to pain consists of changes in endocrine (cortisol and catecholamine release), autonomic (increases in heart rate (HR), respiratory rate (RR), blood pressure, oxygen saturation (Sat)), and/or behavioral responses (facial action, body movement, and cry). (1,4,5) Neonates are hypersensitive to pain and touch, and their behavioral response is altered compared to older infants. (6,7) Although both facial responses and body movement increase with gestational age, neonates at younger gestational ages display more body movement and less facial responses. (4,8) Endocrine responses to pain, especially catecholamine release, contribute to the autonomic pain response observed in neonates. This is evident through increases in HR and blood pressure Sat and RR. (5,9-13)

" It is, therefore, possible that an increase in the respiratory drive from a non-respiratory cause (such as pain) may result in excessively high Edi signals and subsequent inappropriate PIP delivery while on NAVA. "

Despite alterations in RR and Sat, it is unknown what effect painful stimuli have on the respiratory drive. It is possible to measure the respiratory drive through the electrical activity of the diaphragm (Edi). Neurally adjusted ventilatory assist (NAVA) uses the respiratory drive (Edi peak) and tonic activity of the diaphragm (Edi min) to provide synchronized proportional assist ventilation. (14) A specialized nasogastric catheter is positioned at the level of the diaphragm, and embedded electrodes continuously detect the Edi. The instantaneous tonic Edi (Edi peak – min) is multiplied by a proportionality constant, the NAVA level, to calculate the delivered peak inspiratory pressure (PIP) every 16 milliseconds. Patients can, therefore, determine the amount of PIP delivered by the ventilator, breath to breath, by varying the size of the Edi signal. (15) Various authors have expressed apprehensions about premature neonates' ability to safely and appropriately direct their own ventilation.(16-18) It is, therefore, possible that an increase in the respiratory drive from a non-respiratory cause (such as pain) may result in excessively high Edi signals and subsequent inappropriate PIP delivery while on NAVA.

The purpose of this study was to correlate the change in respiratory drive, as measured by Edi peak, in response to a painful procedure, such as a heel stick, in preterm neonates.

Methods:

This was a prospective, single-center observational study. The study size was a convenience sample enrolling subjects <32 weeks on NIV NAVA (Servo-I ventilator, Getinge, Germany) who required routine blood work via heel sticks. IRB approval and informed consent were obtained. Exclusion criteria for this study

included the use of analgesia, sedation, or the presence of brain injury (HIE, IVH grade 3 & 4).

Baseline measurements were taken 5 minutes before the heel stick prior to the subject being disturbed. HR, Sat, and RR were measured every 10 seconds for the first 2 minutes after the heel stick. PIP, Edi peak, and min were recorded and downloaded from the ventilator 5 minutes before the heel stick as a baseline, at the time of the heel stick, for the first ten breaths after the heel stick, and then averaged over a minute at 1 minute and at 2 minutes. Tonic Edi was calculated (Edi peak minus Edi min) as this is how the ventilator calculates the amount of PIP to deliver.

Statistics:

The dependent variables were HR, Sat, RR, PIP, Edi peak and min, and Tonic Edi. The independent variable was the heel stick event. The examination of data included the calculation of summary statistics for continuous data for each group. Based on the clinical rationale, each observation was viewed as independent; therefore, the statistical analysis was conducted on the full set of observations. The repeated measure ANOVA was conducted to assess if there is any difference across time points for each of the groups and, if found, a post hoc analysis, using Bonferroni correction, was carried out to check which time point was significantly different to the baseline. Data were log-transformed to achieve better normality and constant variance. Statistical analyses were completed using "lmertest" package of R-version R-3.4.4 (GNU General Public License, Free Software Foundation, Inc.). All testing was two-tailed and evaluated at the Type I Error Rate of alpha=0.05 level of statistical significance.

Results:

Fourteen study subjects (10 females) were enrolled. The gestational age was 26.9±2 weeks (range 24-31 weeks), and birth weight was 994±318 grams (range 500-1340 grams). At the time of the study, the age was 4.6±5 days (range 0-17 days), and weight was 948±305 grams (range 450-1690 grams). All subjects received prenatal steroids, and 93% received surfactant. Median Apgar scores were 4 and 7 at 1 and 5 minutes, respectively. Median ventilator settings at the time of the studies were: NAVA level of 1 (range 0-2) cmH_2O/mcV, peak pressure limit 35 (range 30-35) cmH_2O, apnea time 2 seconds, peep 8 (range 6-10) cmH_2O, backup pressure control 20 (range 18-23) cmH_2O, RR 40 (range 30-50) breaths per minute. All subjects were in various stages of resolving RDS, treated with caffeine, and used the RAM cannula as the interface system (Neotech, California).

Table 1 shows the repeated measure ANOVA which demonstrated significant difference over time for Edi peak and PIP ($p < 0.05$) but no changes for tonic Edi or Edi min. Tables 2 and 3 show the post hoc analysis, using Bonferroni correction, to determine which time points were different from baseline for Edi peak and PIP. Both Edi peak and PIP showed significant increases with the first breath after the heel stick, but only PIP continued to show these increases at the 10th breath and at 1 and 2 minutes after the heel stick.

Figure 1 demonstrates the breath-to-breath responses to the heel stick for PIP, tonic Edi, and Edi peak and min. The data was not normally distributed, so it is shown as mean, median, interquar-

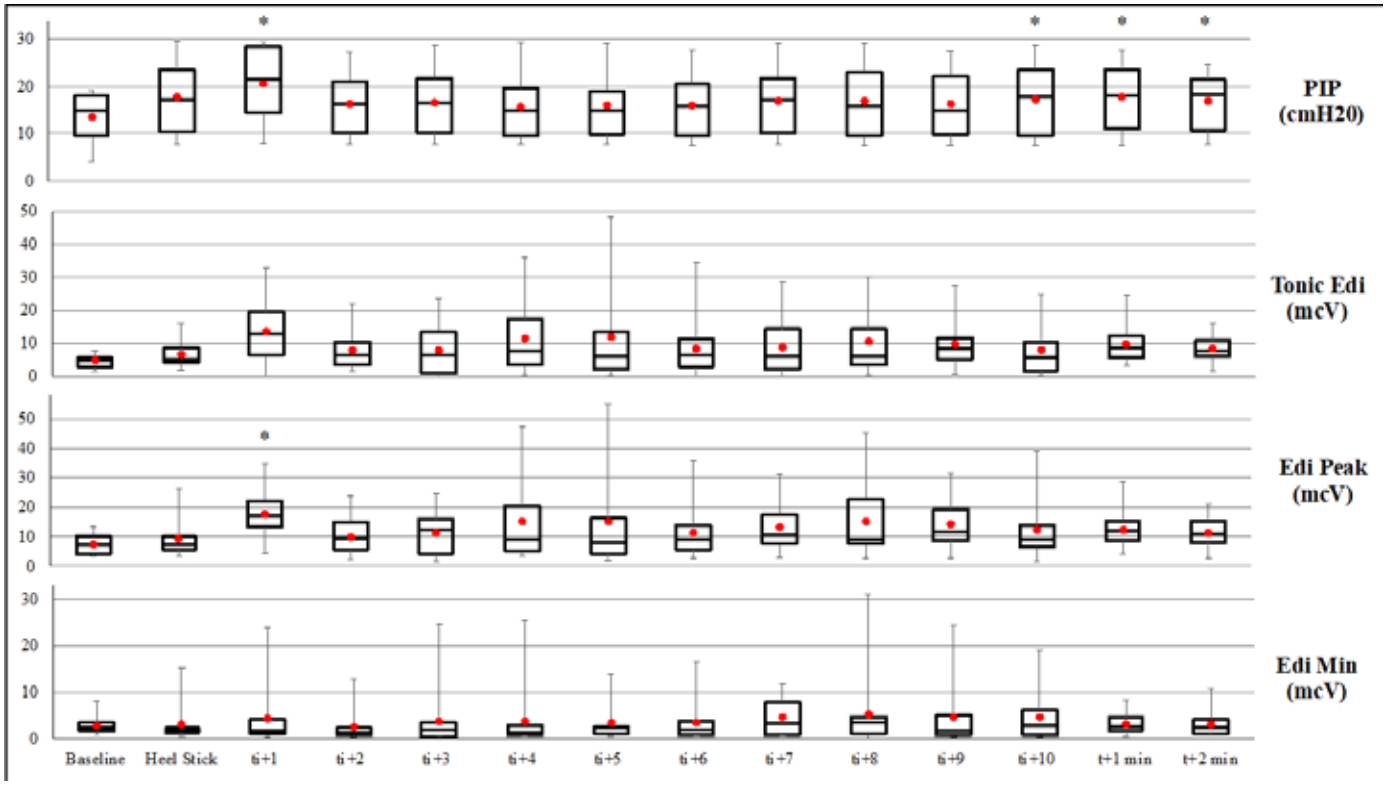

Figure 1: *Respiratory response to pain (heel stick). The first 10 breaths after the heel stick are designated as ti+1 to ti+10, t+1 and t+5 min refers to 1 and 5 minutes after the heel stick. The red solid circles are the mean values. The boxplots show the median and first and third quartiles. The whiskers are the minimum and maximum values. The first breath following the heel increased for PIP and Edi peak followed by a return to baseline. PIP increased again at breath 10 and at 1 and 2 minutes. There were no changes in tonic Edi and Edi min throughout the study. * = p <0.05 compared to baseline.*

	Sum of Squares	**Mean Sum of Sq.**	**Numerator DF**	**Denominator DF**	**F Value**	**P-value**
PIP	1.4906	0.12421	12	156	2.9596	0.000969
Edi Peak	7.3157	0.60964	12	156	1.9744	0.0299
Edi Min	6.3877	0.53231	12	156	0.8154	0.6343
Tonic Edi	6.6484	0.55403	12	156	1.0767	0.3833

Table 1: *Repeated Measure ANOVA results. Type III Analysis of Variance Table with Satterthwaite's method. Only PIP and Edi peak showed significant differences over the study period ($p < 0.05$).*

Edi Peak	Estimate	Standard Error	Z Value	P-value	CI Estimate	Lower	Upper
Baseline-ti+1	-0.8295	0.21	-3.95	**0.00094**	0.436	0.244	0.78
Baseline-ti+2	-0.1977	0.21	-0.941	1.00	0.821	0.459	1.467
Baseline-ti+3	-0.1702	0.21	-0.811	1.00	0.843	0.472	1.508
Baseline-ti+4	-0.4504	0.21	-2.144	0.3841	0.637	0.356	1.14
Baseline-ti+5	-0.2784	0.21	-1.326	1.00	0.757	0.423	1.354
Baseline-ti+6	-0.2552	0.21	-1.215	1.00	0.775	0.433	1.385
Baseline-ti+7	-0.4624	0.21	-2.202	0.3323	0.63	0.352	1.126
Baseline-ti+8	-0.5167	0.21	-2.460	0.1666	0.596	0.334	1.067
Baseline-ti+9	-0.5082	0.21	-2.420	0.1864	0.602	0.336	1.076
Baseline-ti+10	-0.29	0.21	-1.381	1.00	0.748	0.418	1.338
Baseline-t+1 min	-0.5093	0.21	-2.425	0.1838	0.601	0.336	1.075
Baseline-t+2 min	-0.4185	0.21	-1.993	0.5558	0.658	0.368	1.177

Table 2: *Post hoc analysis for Edi peak using Bonferroni correction. Significant increases are bolded*

PIP	Estimate	Standard Error	Z Value	P-value	CI Estimate	Lower	Upper
Baseline-ti+1	-0.42975	0.07743	-5.55	**3.43e-07**	0.651	0.525	0.806
Baseline-ti+2	-0.19987	0.07743	-2.581	0.11816	0.819	0.661	1.015
Baseline-ti+3	-0.20430	0.07743	-2.638	0.09994	0.815	0.658	1.01
Baseline-ti+4	-0.14637	0.07743	-1.89	0.70458	0.864	0.697	1.07
Baseline-ti+5	-0.16142	0.07743	-2.085	0.44522	0.851	0.687	1.054
Baseline-ti+6	-0.15687	0.07743	-2.026	0.51339	0.855	0.69	1.059
Baseline-ti+7	-0.2135	0.07743	-2.757	0.06995	0.808	0.652	1.001
Baseline-ti+8	-0.19953	0.07743	-2.577	0.11966	0.819	0.661	1.015
Baseline-ti+9	-0.16765	0.07743	-2.165	0.36452	0.846	0.683	1.048
Baseline-ti+10	-0.22639	0.07743	-2.924	**0.04151**	0.797	0.644	0.988
Baseline-t+1 min	-0.26334	0.07743	-3.401	**0.00806**	0.768	0.62	0.952
Baseline-t+2 min	-0.23884	0.07743	-3.085	**0.02446**	0.788	0.636	0.976

Table 3: *Post hoc analysis for PIP using Bonferroni correction. Significant increases are bolded*

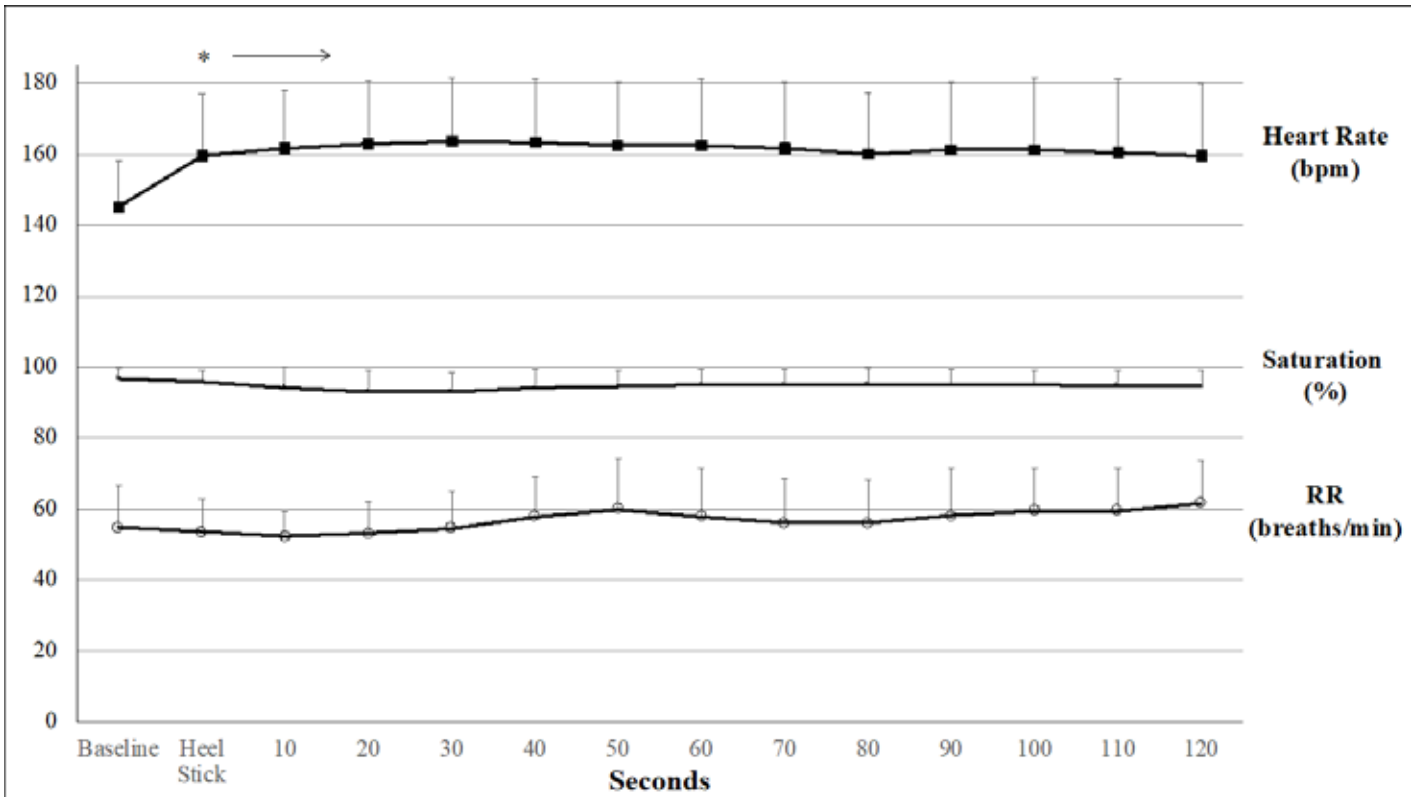

Figure 2: *Response of RR (breaths/min), HR (bpm), and Sat (%) to the heel stick stimuli. Following the heel stick, HR increased within 10 seconds from baseline and remained elevated for the remainder of the two minutes (* = p<0.05). There were no significant changes seen in either RR or Sat in response to the heel stick. Data were normally distributed and shown as mean ± SD.*

tile ranges, maximum and minimum. Following the heel stick, the first breath showed an immediate increase in both Edi peak and PIP, but both decreased by the second breath. Only PIP increased again by the tenth breath and at 1 and 2 minutes after the painful stimulus. There were no significant changes in tonic Edi or Edi min throughout the study.

Vital sign response to the heel stick is shown in Figure 2. Following the heel stick, HR immediately increased and remained elevated for the remainder of the study. There were no changes in either RR or Sat in response to the heel stick.

Although there were some increases in PIP and Edi peak, the majority of the values were within the acceptable clinical range. However, there were some extreme values, as noted by the maximum values. Because of the potential harm from excessive PIP, the percent increase of the maximal value from the mean baseline of each variable was calculated. Figure 3 demonstrates the percent increase above baseline for these extreme values. Although tonic Edi, Edi peak and min had percent increases up to 900% over baseline, the peak pressure limit (set at 35 cmH_2O to limit the PIP to 30 cmH_2O) restricted PIP increases to just over 100% increase from mean baseline PIP (13.5 cmH2O).

Discussion:

This is the first study to examine changes in respiratory drive, as measured by Edi, and PIP in response to a painful stimulus (heel stick) in premature neonates. There was an increase in the Edi peak and PIP with the first breath after the painful stimulus and then a return to baseline until PIP increased again at 1 and 2 minutes after the heel stick. The neonates also responded to the painful stimulus with an increased HR consistent with previous reports of physiological responses to pain. (10,11,13,19,20) There was, however, no increase in the respiratory rate for the two minutes following the stimulus contrary to previously described pain responses in neonates. (11)

"This is the first study to examine changes in respiratory drive, as measured by Edi, and PIP in response to a painful stimulus (heel stick) in premature neonates."

We chose to look at the first ten breaths because previous bedside observations suggested that Edi responded rapidly within 1-2 breaths to various stimuli. We chose to record the variables out to 2 minutes because the painful part of the procedure was complete, and the neonate most likely had returned to baseline. However, both heart rate and PIP continued to be increased at the end of the study.

The increase in HR suggests that neonates responded to the heel stick with catecholamine release and resultant tachycardia. Neonates on ventilators, or with increased illness severity scores or prior painful procedures, were perceived to have lower pain intensity scores and may explain why there was no increase in RR or Sat.(21,22) In addition, premature infants exhibit less behavioral responses to pain with younger postmenstrual age at birth, lower birthweight, mechanical ventilation, and longer length of stay in the NICU. The behavioral indicators that typically increased dur-

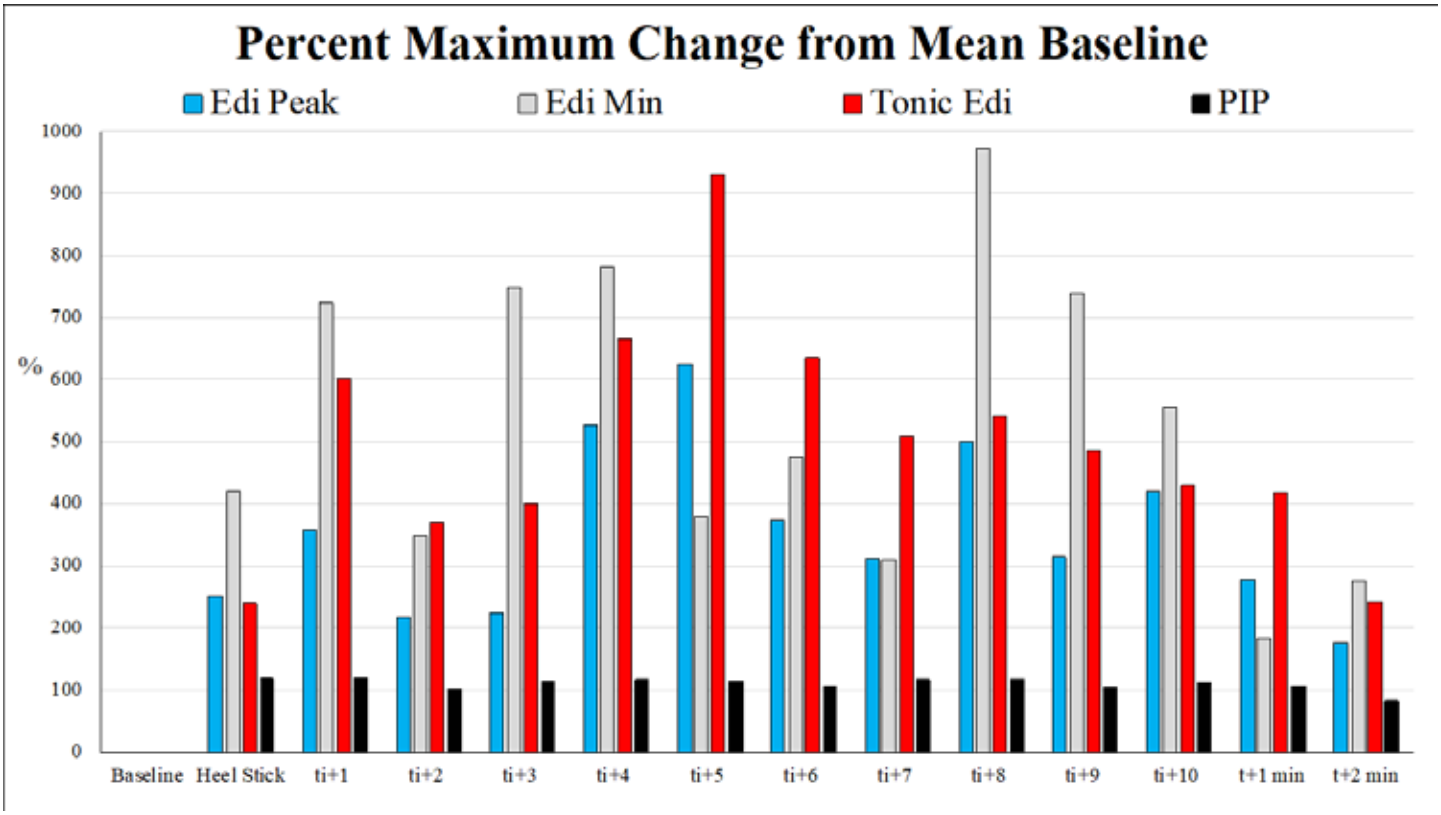

Figure 3: Percent maximum increase from mean baseline for PIP, tonic Edi, Edi peak and min. Despite large increases in tonic Edi, the peak pressure limit prevented excessive PIP increases.

ing heel stick procedure, including crying, arousal state, and facial grimace and were not measured in this study. (23)

NAVA allows self-regulation of PIP raising the concern that painful stimuli may increase respiratory drive and result in excessive PIP being delivered to the neonate. This study showed that there was an increase in Edi peak and the resultant increase in PIP, but this lasted for one breath only and then decreased back to baseline. The sustained increase in HR and the increased PIP at 1 and 2 minutes after the heel stick most likely reflects ongoing stimuli from the bedside provider completing the blood collection from the heel stick.

Although PIP did have increases over the study period, the mean, median, and upper quartile values were all within clinically acceptable ranges, especially for non-invasive ventilation. The ventilator determines the amount of PIP to deliver based on the instantaneous tonic Edi (Edi peak – min). Therefore, large increases in Edi peak and min can result in normal tonic Edi but can also result in excessively high values. Edi peak increase was above the normal Edi peak ranges of 5-15 mcV noted for premature neonates but well within previously observed normal ranges, (24) Edi min were variable and, at times, were significantly elevated. To protect the neonate from excessively high PIP, the ventilator has a peak pressure limit that controls the maximum amount of PIP delivered. The peak pressure limit, found in the alarm screen of the Servo I ventilator, is the essential setting to protect the lung from potential baro or volu-trauma but still allow recruitment of lung for effective ventilation when needed. (15). If this pressure limit is set appropriately during physiologic ventilation, any excessive increase in Edi secondary to the response to pain will result in the pressure popping off 5 cmH_2O below the set pressure limit and should protect the lung from excessive pressures. This was shown in Figure 3, where there were 3-10 fold increase in maximum tonic Edi but only a two fold increase in maximum PIP. Setting the peak limit at 35 cmH_2O limited the maximum PIP to 30 cmH_2O.

This study was limited by the inability to control for variations in bedside comforting techniques while administering heel sticks, although the NICU nurses were all taught similar calming techniques. In addition, pain from the heel stick itself could not be differentiated from the response from being stimulated and/or the heel being squeezed during the subsequent blood draw. However, of practical relevance, none of the above issues resulted in sustained increases PIP, most likely due to the appropriate setting of the peak pressure limit. Future studies would include evaluating the effectiveness of various pain mitigation techniques on the Edi response.

"This study adds to the safety profile of NAVA by suggesting that although premature neonates respond to pain with increases in their respiratory drive, these increases do not trigger sustained, excessive PIPs. "

Conclusion:

NAVA ventilation is gaining wider acceptance as a mode of ventilation in neonates, but apprehension exists concerning the premature neonates' ability to safely and appropriately direct their own ventilation.(16-18) This study adds to the safety profile of NAVA

by suggesting that although premature neonates respond to pain with increases in their respiratory drive, these increases do not trigger sustained, excessive PIPs. Bedside clinical management of neonates on NIV NAVA must always include appropriate safety settings by setting the pressure limit high enough during physiologic ventilation to allow adequate lung recruitment while protecting the lungs from excessive PIP.

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Disclosures:

HS and KF are on the speakers' bureau for Getinge and Chiesi.

DL and RM have no conflicts to disclose.

HS and KF contributed to study design, data collection, analysis and writing the manuscript.

DL and RM contributed to data analysis and writing the manuscript.

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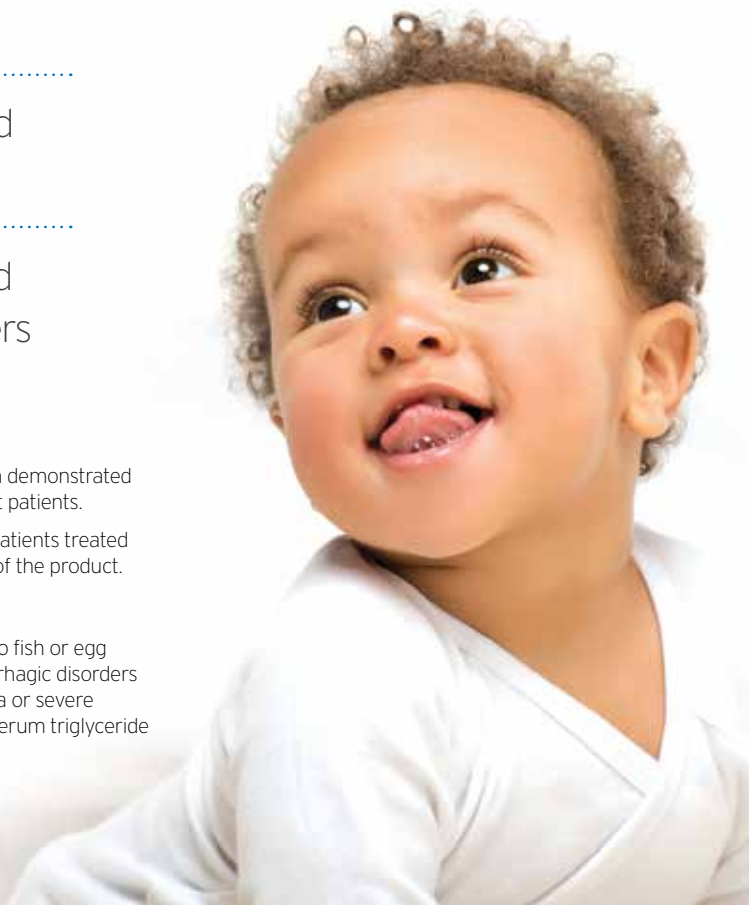

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- Risk of Death in Preterm Infants due to Pulmonary Lipid Accumulation: Deaths in preterm infants after infusion of soybean oil-based intravenous lipid emulsions have been reported in medical literature. Autopsy findings in these preterm infants included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

ADVERSE REACTIONS

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

Clinical Trials Experience

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

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

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

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

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

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

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

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

Postmarketing Experience

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

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

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

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

OVERDOSE

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

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Peer Reviewed

Case of a Preterm Newborn with the Nosocomial Acquisition of COVID-19 Infection in the Neonatal Intensive Care Unit and Contact Tracing

William Liu MD, FAAP, Stephanie Stovall MD, FAAP

This is a case report of a preterm newborn with the nosocomial acquisition of COVID-19 in the neonatal intensive unit setting, with symptoms of low-grade temperature elevation, mild upper respiratory tract symptoms, and transient leucopenia and neutropenia. We also describe the ensuing contact tracing process.

"This is a case report of a preterm newborn with the nosocomial acquisition of COVID-19 in the neonatal intensive unit setting, with symptoms of low-grade temperature elevation, mild upper respiratory tract symptoms, and transient leucopenia and neutropenia. We also describe the ensuing contact tracing process."

Baby Girl was born a 1.66 kilogram 33-week preterm appropriate for gestational age female; Weight (27%); head circumference: 29 cm (31%); length: 40 cm (16%) Fenton growth curve, delivered by vertex presentation cesarean section due to maternal indications with worsening chronic hypertension to a 26-year-old Gravida 2 para 1 with one spontaneous abortion, Black Haitian mother who did have prenatal care. The mother was an insulin-dependent diabetes mellitus class F, with a diagnosis of type diabetes at ten years old. Her medical history was also remarkable for chronic hypertension and thalassemia trait. Hepatitis B, serology, HIV nonreactive; Rubella immune. GC and Chlamydia screen were negative; she denied a history of drugs, EtOH, or cigarettes. Maternal medications during antepartum care included Insulin, Labetalol, and Procardia. She received betamethasone prior to birth. Antepartum GBS screen was negative; ROM occurred at delivery, no meconium-stained amniotic fluid was present; no maternal fever or any noted maternal respiratory symptoms including dyspnea, shortness of breath, malaise, cough or coryza was noted.

Delivery room: Infant noted to have poor respiratory effort, responding to bag and mask positive pressure ventilation, placed on nasal CPAP, and brought to the neonatal intensive care unit (NICU). Apgar 3 and 8 at one and five minutes.

Hospital Course:

The infant did have mild respiratory distress syndrome with a minimal reticular granular pattern or normal chest x-ray at birth, transient supplemental oxygen requirement, and requiring maximal support of bubble CPAP +6. The infant was weaned to room air by day of life (DOL) 5. Shortly after birth, the infant was normotensive with a transient initial mixed acidosis, received 10 ml/kg 0.9 normal saline. A repeat capillary blood gas was normal by 6 hours of life. Initial CBC and differential were not suggestive of infection. Ampicillin and gentamicin were started at birth and discontinued after 36 hours of treatment with negative blood culture results. The infant was initially placed exclusively on intravenous fluids and was normoglycemic. Expressed breast milk or donor breast milk feeds were initiated at DOL 1 and advanced without problems. She did have some bradycardia and desaturation events and was started on caffeine citrate on DOL 3, and did have mild physiologic jaundice managed with early phototherapy. By DOL 5, the infant was in room air, on oral maintenance dosing of caffeine citrate, tolerating full enteral feeds, and without need for parenteral fluids.

The NICU is comprised of 64 single family rooms clustered in seven 8-10 room hallways. NICU visitation during this time period was unrestricted for parents. The mother was visiting, holding her baby, and bottle feeding with expressed or donor breast milk.

DOL 6: While visiting her baby, the mother was found to have a possible syncopal episode, found poorly arousable, lethargic, and dizzy, and taken to the emergency room for evaluation. She was reportedly inconsistent with the administration of her insulin dosing and was admitted for hypoglycemia. At that time, the mother denied any shortness of breath, congestion, or cough. There was no fever noted, nor any reported respiratory symptoms, and no COVID-19 testing was done. The mother was hospitalized for one day, had readjustment in her insulin dosing, and then discharged.

DOL 8-DOL 16: She continued to visit her baby in the NICU. The baby remained in room air and in an incubator.

DOL 19, the mother was admitted to the hospital for fever, cough, and hyperglycemia. Her SARS-CoV-2 RNA test was positive. She was maintained on airborne and contact isolation but did not require positive pressure support or supplemental oxygen. She was treated with a course of doxycycline and ceftriaxone for possible pneumonia. She was also managed for diabetic ketoacidosis as well as chronic kidney disease due to diabetic nephropathy. She required hospitalization from DOL 19 to DOL 28. She maintained self-quarantine at home until her baby was discharged on DOL 31.

DOL 20: The NICU staff were notified of the mother's admission. The infant at this time was a 2.094-kilogram 35+6-week postmenstrual age infant in room air, off caffeine citrate, on full cue-based enteral feeds, taking about 60-70% of feeds by nipple. The

	DOL 5	DOL 19	DOL 20	DOL 21	DOL 22	DOL 26
WBC (x 10^3/uL)	6.8	7.0	3.6		6.4	6.4
Neutrophils (%)	30		25		19	10
Lymphocytes (%)	48		56		74	66
Monocytes (%)	17		10		2	8
Eos (%)	4		1		2	
Hemoglobin (gm/dL)	20.2	13.1	13.1		12.9	
Hematocrit (%)	57.7	38.1	36.3		37.2	
Platelet (x 10^3/uL)	256	185	249		255	
CRP (mg/dl)			<0.5		<0.5	0.6
AST (U/L)				24	27	36
ALT (U/L)				7	7	10
SARS CoV-2 RNA, Qualitative (Abbott Diagnostics Scarborough, Inc)			Positive		Positive	

infant had weaned off donor breast milk and was on the mother's expressed breast milk or 24-cal premature formula. The baby was moved to a negative pressure room, placed on airborne and contact isolation, and tested SARS CoV-2 RNA positive. CBC: WBC 3.6; ANC 900.

DOL 21: T 37.2 centigrade (99 Fahrenheit) and T 37.6 centigrade (99.6 Fahrenheit)

DOL 22: Infant's repeat SARS CoV-2 RNA was positive.

DOL 23-24: The infant was noted to have mild nasal congestion, occasional sneezing, and cough. The neonatal nurse practitioner and neonatologist rounding elected to follow the baby clinically and did not order a viral respiratory panel or chest x-ray. The infant was not noted to have any persistent symptoms by the end of the day.

DOL 24-31: There were no additional symptoms reported. The infant gradually advanced to full nipple feedings and was discharged to his mother on DOL 31. The mother received the baby at the hospital entry, and follow-up was arranged with the pediatrician on DOL 34, 14 days from diagnosis of the infant. Both the mother and the infant remain well on outpatient follow-up on DOL 47, 17 days post-discharge.

Contact Tracing:

On DOL 20 of the baby's hospitalization, the hospital infection prevention team and the NICU nursing leadership initiated contact tracing, in compliance with the hospital employee exposure algorithm (see below), reviewing potential exposures to both mother and baby during the period 14 days prior to the mother's COVID-19 positive testing to the day of COVID positive testing on the baby (DOL 3-20). This review was extended to DOL 3, due to the uncertainty of onset of mother's symptoms on DOL 19. During this time, the NICU had unrestricted parental visitation, and there were no masking requirements for visitors. The mother was documented to have visited 15 times, roomed in twice, and held the baby seven times with or without feeding (her last visit was on DOL 16). She used expressed breast milk or donor breast milk feeds. Seventy-four separate potential exposures were identified based upon schedule and location of assignment, and 30 were found to have some level of exposure.

NICU staff adopted mandatory masking on 3/30 (DOL 12), and mandatory parent masking started on 4/2 (DOL 15). Staff were not required to wear eye protection until 4/7 (DOL 20). Risk assessment was based upon direct or phone interviews; each exposure was classified as low, moderate, or high risk.

Contact tracing required dedicated time from the quality and safety director, nursing director, nursing manager, several nursing supervisors, and infection prevention specialist, as well as system-level employee health interviewers. Steps in contact tracing were: (1): Identify the period of risk; (2) Identify the primary exposures; (3) Conduct a risk assessment of exposures; (4) define who should receive testing; (4) assess for secondary exposure risk based upon testing.

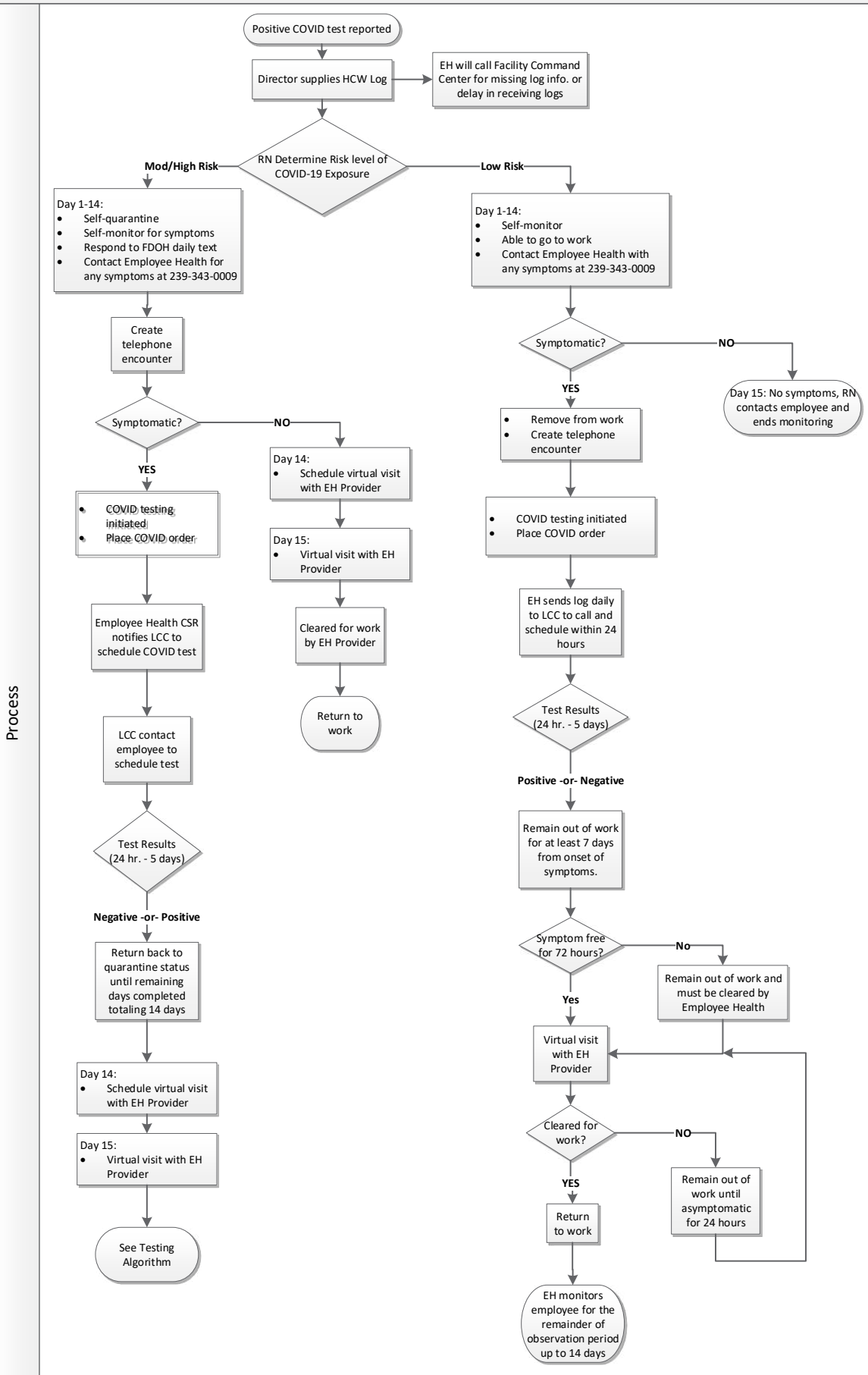
Potential candidates for review included the routine NICU staff-nurses (permanent as well as staffing resource center staff-"floater" who rotates through several departments, as well as some nursing staff who rotate from pediatric intensive care unit to NICU), respiratory therapists (permanent and "floaters"), clinical nurse assistants, patient care liaison, occupational therapy, social workers, pharmacists, dieticians, neonatologists and neonatal nurse practitioners, as well as housekeeping staff. It was also necessary to consider ancillary staff that had more variable exposure times, including milk lab personnel, ultrasonography, echocardiogram and radiology technicians, as well as medical-surgical consultants.

Risk Assessment Findings:

There were 15 high-risk, two moderate, and 12 low-risk exposures, and one medical provider was also identified to have moderate-risk exposure. There were 16 healthcare workers in the moderate or high-risk category who were placed on home quarantine for 14 days from date of potential exposure and received COVID-19 testing (one staff member with two exposures). Although our existing Employee Exposure Algorithm recommended testing of medium-high-risk exposures only if symptomatic, due to the NICU setting,

Lee Health COVID-19 EH: Employee Exposures Algorithm

Final Version 6



COVID-19_EH Employee Exposures algorithm — Version 6, Last Updated 04/23/2020

Adapted from CDC guidance documents in early April 2020, which have undergone subsequent revisions. https://cdc.gov/coronavirus/2019-ncov/guidance-risk-assesment-hcp.html

infection prevention elected to test all moderate and high-risk exposures for SARS-CoV-2 RNA testing. All testing was negative. All medium-high risk employees were required to self-quarantine for 14 days. One low-risk employee was also tested due to some respiratory symptoms and was negative. Otherwise, low-risk staff continued to work but were asked to self-monitor for 14 days, and none developed signs or symptoms of COVID-19 infection.

Secondary exposure risk was deemed to be low, with no positive testing. There were a total of eight potential newborn exposures. Six newborns remained hospitalized, with exposure to staff categorized as moderate or high-risk. The two who were discharged were doing well in a follow-up contact. The six babies remaining in the NICU showed no signs of COVID-19 infection and were negative on SARS-CoV-2 RNA testing.

"There were a total of eight potential newborn exposures. Six newborns remained hospitalized, with exposure to staff categorized as moderate or high-risk. The two who were discharged were doing well in a follow-up contact. The six babies remaining in the NICU showed no signs of COVID-19 infection and were negative on SARS-CoV-2 RNA testing."

Risk Assessment: Mother never wore a mask during her exposures in the NICU

- **High Risk:** Exposure to Mother: any contact within 6 ft for >5 minutes, without mask, gown, or face shield. If no eye protection only- moderate. Contact with baby through portals for > 5 minutes if the baby is in an incubator, or any direct contact outside of incubator > 5 minutes (holding, feeding), without a gown, face shield, or surgical mask. (face shields did not start until 4/7 DOL 20)
- **Medium Risk**: Exposure to Mother: any contact within 6 ft for >5 minutes, with mask, gown, and face shield. Contact with baby through portals for > 5minutes if the baby is in an incubator, or any direct contact outside of incubator > 5 minutes (holding, feeding), with a gown, face shield, and a surgical mask.
- **Low Risk:** Exposure to Mother: any contact > 6 ft for <5 minutes. Contact with baby through portals for < 5minutes if the baby is in an incubator, or any direct contact outside of incubator < 5 minutes.

Discussion:

This is a report of a preterm newborn with nosocomial acquisition of COVID-19 from exposure to mother, as well as consequences of contact tracing following diagnosis.

Although pediatric patients and newborns have been reported in the literature, there isn't much in the way of detailed clinical descriptions of disease, especially in premature babies. Looking at nine recent published reports with a pediatric focus, as of May 3, 2020, there were 560 infants <1 year of age with confirmed SARS-CoV-2 testing.(1-8) Zhu reported ten newborns born to mothers with COVID-19 pneumonia. Still, none of these were SARS-CoV-2 positive. (7) There were five newborn cases with confirmed SARS-CoV-2 testing positive, with some clinical description of the disease, of which two were preterm. (4,5,7) This is a third case report.

"There were five newborn cases with confirmed SARS-CoV-2 testing positive, with some clinical description of the disease, of which two were preterm. (4,5,7) This is a third case report."

Even though this infant had only minimal symptoms, co-infections have been reported,(10) and, given the novelty of a COVID-19 positive baby, documentation of a normal chest x-ray and a viral respiratory panel would have been useful. We also did not follow serial testing to demonstrate when the PCR-based test became negative. Of interest, Zeng had reported three positive newborns where positive testing was noted on day of life 2 and 4 but became negative in all three newborns by day of life 6 or 7.5

We also describe the repercussions of this late-onset maternal exposure. Fortunately, no one was found to be positive, but many staff needed to be quarantined. The lack of any positive testing for all healthcare workers with exposure to the mother or baby also strongly implicates the mother as the primary vector for nosocomial acquisition and eliminates the likelihood of primary maternal acquisition from the identified NICU exposures.

The CDC has general guidelines for contact tracing. (10) Contact tracing in the NICU involves many potential exposures, those who are primarily based in the NICU, as well as multiple ancillary staff who will travel to other areas of the hospital. Immediate action is critical. The baby was placed under airborne and contact isolation and tested when we became aware of the exposure. Systematic and timely contact interviews and testing were implemented. If our contact tracing had yielded positive staff members, it would have necessitated a secondary level tracing that might extend outside the NICU area, and introduce many more potential exposures and increased infectivity risk throughout the hospital.

Following this event, we moved to limited visitation allowing only one parent for up to 2 hours/day, with paper screen/ attestation and physical exam assessment (temperature and targeted exam) of the parent by an APRN at the front desk, as well as enhanced video visitation for parents.

We will continue to face ongoing and evolving challenges as it relates to developing rational screening strategies- statewide and nationally, and for NICU workers, on a unit and institutional level.

Acknowledgments:

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Disclosure: The authors have no disclosures.

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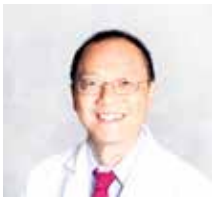

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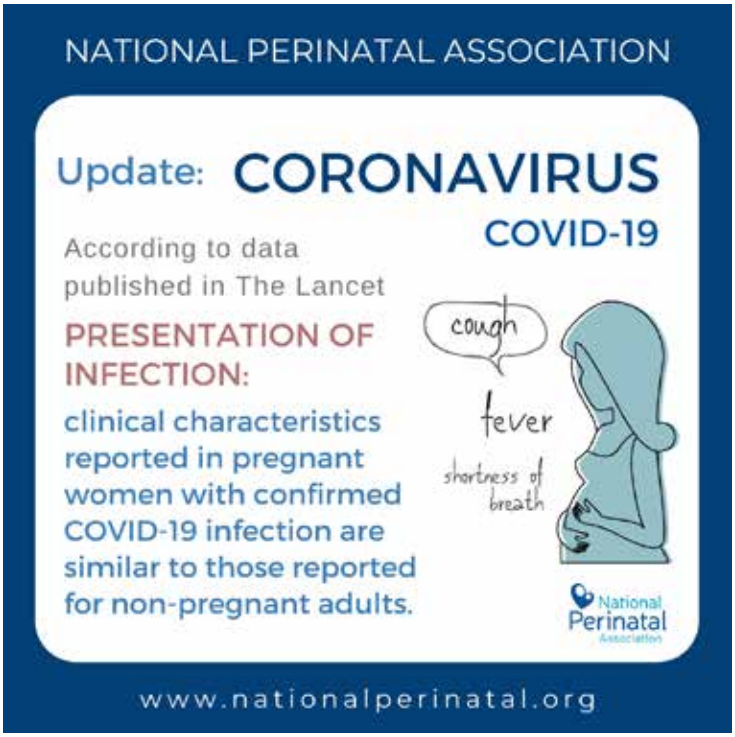

Fellow Column: COVID-19 Clinical Quick Guide for the Neonatologist

Anna G. Smith, MD, Abhineet Monti Sharma, MD

Case:

A 30-year-old gravida three mother presents to triage at 32 6/7 weeks gestational age after feeling a gush of clear fluid overnight. Her obstetrics team admits her for further monitoring and administration of betamethasone due to the risk of prematurity. On admission, her temperature is 98.7F, heart rate is 80-90 (sinus), her respiratory rate is 25, her blood pressure is 110/60, and she is saturating 100% on room air. To date, her pregnancy has been uncomplicated, and she has no significant past medical history. Her serologies at the time of admission are normal except for a pending GBS swab and SARS-CoV-2 nasal-pharyngeal swab. She does not report drug, tobacco, or current alcohol use. She is a nurse in an adult intermediate care unit. Her previous pregnancies have been uncomplicated and resulted in the delivery of two healthy, term neonates. The following day, she reports contractions of increasing frequency. On her assessment, she is febrile to 102.3F and saturating 89%. She is tachycardic with a sinus heart rate of 100 and visibly diaphoretic. Her blood pressure is 130/80. Her SARS-CoV-2 is still pending. Three hours after onset of developing symptoms, she delivers a male infant with APGAR scores of 8-9, weighing 1800 grams, and an initial temperature of 99.7F. The infant maintains age-appropriate saturations initially but eventually placed on CPAP +5 for tachypnea and drifting saturations. Following delivery, he is admitted to the neonatal intensive care unit due to gestational age, weight, and need for respiratory support. An X-ray obtained on admission shows findings consistent with respiratory distress syndrome of the newborn. Four hours following the infant's admission, the mother's SARS-CoV-2 swab returns positive. She is admitted to the adult Intensive Care Unit due to worsening respiratory status.

"Four hours following the infant's admission, the mother's SARS-CoV-2 swab returns positive. She is admitted to the adult Intensive Care Unit due to worsening respiratory status."

Background:

Severe acute respiratory syndrome coronavirus (2) (SARS-CoV-2) is the virus that causes coronavirus disease 2019 (COVID-19). As of April 2, 2020, 1.7% of infections were among children aged < 18 years. Within this pediatric category, 23% of affected children were below age 2.(1) Understanding of COVID-19, along with recommendations for neonatologists and their patients, is evolving. The following is a summary of the literature available during April 2020 on select topics.

Prenatal Counseling:

Pregnant women should follow the same recommendations as non-pregnant persons for avoiding exposure to SARS-CoV-2. Current literature suggests that pregnancy does not appear to increase susceptibility to infection or worsen the clinical course. In areas of high incidence, a high percentage of mothers are reported to be asymptomatic. (2,3) Data from New York City showed that with universal screening, 15% of pregnant mothers tested positive (33/215). 87% of these women had no symptoms at the time of presentation (29/215). In some centers, 33% of women were found to be positive during admission due to symptoms or implementation of universal screening. Among these women, 71% developed symptoms during their hospital stay. (2,3) As a provider, consider telemedicine via phone or video for prenatal counseling services in order to minimize the risk of exposure. (4)

Delivery Considerations:

To reduce the risk of exposure, consider minimizing the number of providers only to include essential staff for delivery. In institutions without universal screening, keep in mind that the second stage of labor is considered an aerosol-generating procedure, which may require additional personal protective equipment (PPE). (5) Currently, there are no recommendations regarding cesarean section or vaginal delivery for SARS-CoV-2 positive mothers. (4,6)

Resuscitation Considerations:

For newborns who require resuscitation, the standard Neonatal Resuscitation Program (NRP) pathways can be followed. Intubation and airway considerations include the use of viral and bacterial filters on ventilator circuits to decrease aerosolization. (7) At this time, consider N-95 or equivalent protection for all vaginal and cesarean section deliveries for Person of Interest (PUI) and known positive mothers.

Transmission and Newborn Testing:

There is limited evidence of vertical transmission to neonates. Current studies cite a range from 11% (3/33) in the most extensive retrospective study to 14% (1/7) in another retrospective study.(8) 9 There is increasing evidence that neonates are positive for IgM and IgG suggesting that antibodies either pass from the mother (IgG) or are produced by the infant (IgM). (10) A review of bodily fluids, including amniotic fluid, cord blood, neonate nasopharyngeal swab, and breast milk, have all tested negative to date. (11) Newborns can still acquire COVID-19 through close contact with infected mothers as SARS-CoV-2 main routes of transmission are respiratory droplets, via contact and aerosol, and contaminated objects like toys and baby bottles. (12) At this time, infants born to SARS-CoV-2 positive mothers should be considered PUIs initially, and appropriate PPE should be used. Current recommendations suggest testing vertically exposed newborns at 24 hours of life to increase the likelihood of capturing replicating viral RNA as opposed to contaminating RNA and repeat testing at 48 hours of life. (6) If the infant is determined to be negative on both tests, no additional PPE is required. Labs of neonates who test positive for SARS-CoV-2 are nonspecific. Positive neonates are more likely to have elevated WBC compared to negative neonates. (10) No lymphopenia has been noted in neonates, as compared to literature cited for older children and adults. A review of computed tomography and X-ray findings among infected neonates has demonstrated no specific findings. (10,13)

"Current recommendations suggest testing vertically exposed newborns at 24 hours of life to increase the likelihood of capturing replicating viral RNA as opposed to contaminating RNA and repeat testing at 48 hours of life. (6)"

Outcomes in Neonates:

To date, there is a relatively low incidence of poor outcomes in neonates. (14) Primary clinical issues reported in the literature are related to postmenstrual age (PMA) at birth as opposed to symptoms of SARS-CoV-2. There is a higher instance of preterm births and preterm labor in patients who test positive for COVID-19, but this seems to be related to maternal factors as opposed to neonatal factors. Current data suggests that 14% of newborns born to SARS-CoV-2 positive mothers were born before 36 weeks' gestation. (14) The youngest positive infant described in the literature was born at 31 weeks PMA and had complications related to prematurity. (8) The average APGAR scores cited in present literature for these newborns have been 8-9. (10,14) Clinical features of symptomatic newborns born to mothers with confirmed COVID-19 may include fever, pneumonia, respiratory distress syndrome, cyanosis, lethargy, feeding intolerance, emesis, diarrhea, and abdominal distention. Sepsis, DIC, and death have been rare complications cited in a single case report. (10,14,15) The youngest infant born to a SARS-CoV-2 mother who died was born at 34 weeks' gestation and died at 8 days of life. The patient's demise was due to multisystem organ failure without a clear etiology. The infant was found to be PCR negative on multiple tests throughout the hospitalization. (14) The average length of NICU stay has not been found to vary from the average length of stay for neonates who are otherwise well. (8,10) Postnatal management of neonates born to SARS-CoV-2 positive mothers depends on the institution. The variation highlights the importance of identifying a second caregiver in the event of worsening maternal illness.

Routine Care:

Current recommendations for routine newborn care in the setting of SARS-CoV-2 positive testing for mother and/or baby are based on evolving expert guidelines. (4,6) Infants should be bathed as soon as possible to facilitate the removal of viral particles. Mothers should be encouraged to pump early to establish supply. Currently, no data suggesting that SARS-CoV-2 is present in breastmilk exists. (11) Thus, mothers should pump and feed, if possible. Breastmilk may contain protective immunologic factors against SARS-CoV-2. If it is not feasible to separate mother and infant or if the mother chooses to room with her infant, it is recommended that she maintain six feet distance unless caring for her infant. Well appearing newborns should receive all indicated care, including timely administration of vaccines and circumcision. At discharge, it is recommended to maintain separation of mother and infant for at least 14 days if the mother is positive and the baby is negative. In such cases, the infant should be discharged home with a caregiver who has tested negative, and the mother should maintain distance when possible. At a minimum, a mother should use hand hygiene and wear a face mask until she is free of fevers for 72 hours, remains asymptomatic for at least seven days, or she has a negative repeat SARS-CoV-2 test. Positive infants may be discharged with close follow up through the first 14 days. Methods of follow up include telemedicine or in-office visits with the pediatrician. All caregivers should follow proper hand hygiene and wear appropriate PPE.

"Positive infants may be discharged with close follow up through the first 14 days. Methods of follow up include telemedicine or in-office visits with the pediatrician. All caregivers should follow proper hand hygiene and wear appropriate PPE. "

Case Continued:

Given the maternal fever and neonatal requirement for respiratory support, blood cultures were obtained, and the infant was started on antibiotics. The infant did not develop an oxygen requirement and was weaned from respiratory support the following day. Nasopharyngeal swabs for SARS-CoV-2 from the infant remained negative at 24 and 48 hours of life screens. Antibiotics were discontinued at 48 hours, and PPE precautions were removed at the same time. The infant required nasogastric gavage feeds and remained in the NICU until 36 weeks PMA. He was discharged home with his grandmother and father while his mother remained in the hospital. She was discharged a month after delivery. At the time of discharge, her SARS-CoV-2 swabs were negative. She was otherwise asymptomatic at the time of discharge.

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- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
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Next-Level Perinatal/Neonatal Comfort Care Training

Creating an Interdisciplinary Palliative Care Plan for Each Baby and Their Family

A 3-day intensive training of seminars and hands-on activity sessions to provide an overview of the methods, elements, and strategies needed to create a comprehensive neonatal comfort care plan for the entire perinatal team.

Perinatal detection of congenital anomalies leads to the identification of infants who are affected by life-limiting conditions with a short life expectancy. Moreover, a significant number of newborns admitted to the neonatal ICU in critical condition face potentially adverse prognoses. Perinatal palliative care offers a plan for improving quality of life of the infant and the family, when extending the baby's life is no longer the goal of care or the complexity of the medical condition is associated with uncertain prognosis. The evidence base for perinatal palliative care continues to grow. However, there is no consensus about best clinical practice in promoting support for the family or comfort for the neonate. Support for the family is achieved through appropriate pre- and postnatal consults, shared-decision making, and advance care planning. A state of comfort for the neonate is achieved when basic needs such as bonding, maintenance of body temperature, relief of hunger/thirst, and alleviation of pain/discomfort are met.

This three-day training will cover virtually all aspects of perinatal palliative care, including information about the successful experiences of the Neonatal Comfort Care Program in providing perinatal palliative care for over a decade at Columbia University Irving Medical Center (CUIMC). Faculty will discuss evidence-based rationale, practical aspects and strategies for implementing and applying aspects of comfort care to provide support for families and achieve a state of comfort for newborns with limiting or life-threatening conditions. Additional mphasis will be given to hands-on simulations and case studies. Health professionals at all career stages are welcome to attend. Registration is required.

Elvira Parravicini, MD, Columbia University and New York Presbyterian/Morgan Stanley Children's Hospital, Director of Columbia University's Neonatal Comfort Care Program

Brian Carter, MD, University of Missouri-Kansas City and Children's Mercy Hospital

Alexandra Mancini, RN, Chelsea & Westminster Foundation Trust & True Colour Trust, London, UK

Charlotte Wool, PhD, RN, York College of Pennsylvania; Perinatal Palliative Care Consultant

See site for full instructor list.

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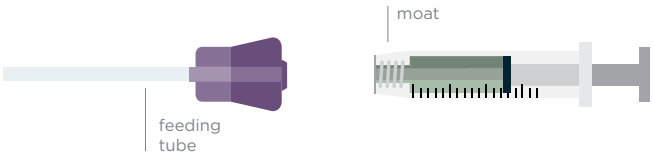
More details and registration: mailman.columbia.edu/comfort-care

SAFETY IN THE NICU

New tubes, new problems?

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



DOSING ACCURACY

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

INFECTION RISK

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

WORKFLOW ISSUES

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

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

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

ENFit® is a registered trademark of GEDSA

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

A collaborative of professional, clinical, community health, and family support organizations focused on the health and safety of premature infants.

infanthealth.org

The Straight Talk for Infant Safe Sleep Program in Support of American Academy of Pediatrics Safe Sleep Guidelines

Barb Himes, IBCLC

Saving babies. Supporting families.

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

First Candle is a longstanding member of the resource pool available to families and the postpartum health care community, but there are also others – Title V partners -- that could have a place on the resource list for neonatology and perinatology professionals.

"First Candle is a longstanding member of the resource pool available to families and the postpartum health care community, but there are also others – Title V partners -- that could have a place on the resource list for neonatology and perinatology professionals."

Our work focuses on reducing infant mortality through our Straight Talk for Infant Safe Sleep program, a constructive and collaborative training for health care professionals that enables them to help families understand the importance of and adopt the infant Safe Sleep Guidelines last updated by the American Academy of Pediatrics (AAP) in 2016. We also provide bereavement support for families coping with the loss of an infant.

Continuous Improvement, Title V and National Performance Measures

We recently took part in a webinar series hosted by the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA), designed to help Maternal and Child Health divisions in state and jurisdiction health departments improve services and make evidence-based decisions when developing their five-year state action plans. The subject matter expert-led sessions were designed to help Title V program staff identify evidence-based strategies that address the 15 National Performance Measures (NPMs) that focus on public health and are relevant to Title V (The Maternal and Child Health Block Grant Program) services.

Selected Areas of Focus

Our particular focus during this series of sessions was on NPMs around breastfeeding. The AAP recommends that all infants (including premature and sick newborns) exclusively breastfeed for about six months, as human milk supports optimal growth and development by providing all required nutrients during that time. Breastfeeding strengthens the immune system, improves normal immune response to certain vaccines, offers possible protection from allergies, and reduces the probability of SIDS.

Breastfeeding has been shown to extend benefits to the mother, including improved confidence and bonding with the baby and a reduction in anxiety and postnatal depression, as well as increased release of oxytocin while breastfeeding, leading to a reduction in postpartum hemorrhage and quicker return to a normal-sized uterus over time. There are also indications the mother may be less likely to develop breast, uterine, and ovarian cancer, and have a reduced risk of osteoporosis. (1)

Research indicates, however, that there is a gap between the percentage of infants who are ever breastfed and those breastfed exclusively through six months (83.2% ever breastfed; 24% exclusively for six months) (2) . We were able to suggest proven strategies that health departments can implement to help improve breastfeeding outcomes, such as lactation consultants and fatherhood engagement programs. Also worth noting was the full range of NPMs covered by the MCHB sessions, including:

- NPM 1: Well-Woman Visit
- NPM 2: Low-Risk Cesarean
- NPM 3: Perinatal Regionalization
- NPM 4: Breastfeeding
- NPM 5: Safe Sleep
- NPM 6: Developmental Screening
- NPM 7: Child Safety/Injury
- NPM 8: Physical Activity
- NPM 9: Bullying
- NPM 10: Adolescent Well-Visit
- NPM 11: Medical Home
- NPM 12: Health Care Transition
- NPM 13: Oral Health
- NPM 14: Smoking
- NPM 15: Adequate Insurance Coverage

"The goal of regional perinatal care, for example, is to ensure that mothers and newborns at the highest risk for morbidity and mortality deliver at birthing facilities equipped with appropriate personnel, resources, and capabilities to meet their needs."

The goal of regional perinatal care, for example, is to ensure that mothers and newborns at the highest risk for morbidity and mortality deliver at birthing facilities equipped with appropriate personnel, resources, and capabilities to meet their needs. Proven strategies in addressing this include adoption of standard definitions for hospital level of care and statewide assessment of personnel, resources, and capabilities of birthing facilities.

In this area, Title V agencies can design, fund, and manage the implementation of perinatal systems in partnership with hospitals and perinatal professionals, and fund and manage the implementation of maternity facility assessment in partnership with hospitals and perinatal professionals.

With regard to safe sleep, strategies presented at the session included implementing a multicomponent strategy (systems approach) that targets caregivers, childcare providers, health care providers, and hospital systems, and providing training to professionals who interact with expecting and new mothers and families that emphasizes nuanced approaches, taking into account family needs, beliefs, and context.

In these areas, Title V agencies can build systems by engaging appropriate programs and partners across functions (such as hospitals, healthcare provider organizations, community-based programs, etc.) and utilizing train-the-trainer programs.

Awareness of Available Resources

These examples serve as a reminder of the range of disciplines intrinsic to Title V agencies, which could be a part of the prenatal, perinatal, and postpartum health care professional's inventory of support services.

It may be worthwhile to identify resources at the community, health department, and hospital-level that can be available to provide support for parents of newborns. This new era of novel coronavirus presents us with a renewed commitment to maintaining effective and high-quality levels of care, while at the same time facing known and as yet-unfolding challenges.

At such a time, being aware of what resources are available and partnering to take advantage of areas of expertise can be effective strategies toward continued excellence in maternal and infant health care.

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

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At First Candle we provide bereavement support to the over 27,000 families who will experience the loss of a baby every year.
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The Survey says RSV

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5 THINGS YOU CAN DO TO CELEBRATE NICU AWARENESS

1 Educate Yourself

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

2 Post on Social Media

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

3 Recognize NICU Staff

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

4 Share Your Story

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

5 Join Our Community

Get involved. Become a member of our organizations and share your talents.

This project is a collaboration between

Project Sweet Peas + National Perinatal Association

www.nicuawareness.org

www.nationalperinatal.org/NICU_Awareness

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

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

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

Laura will be greatly missed.

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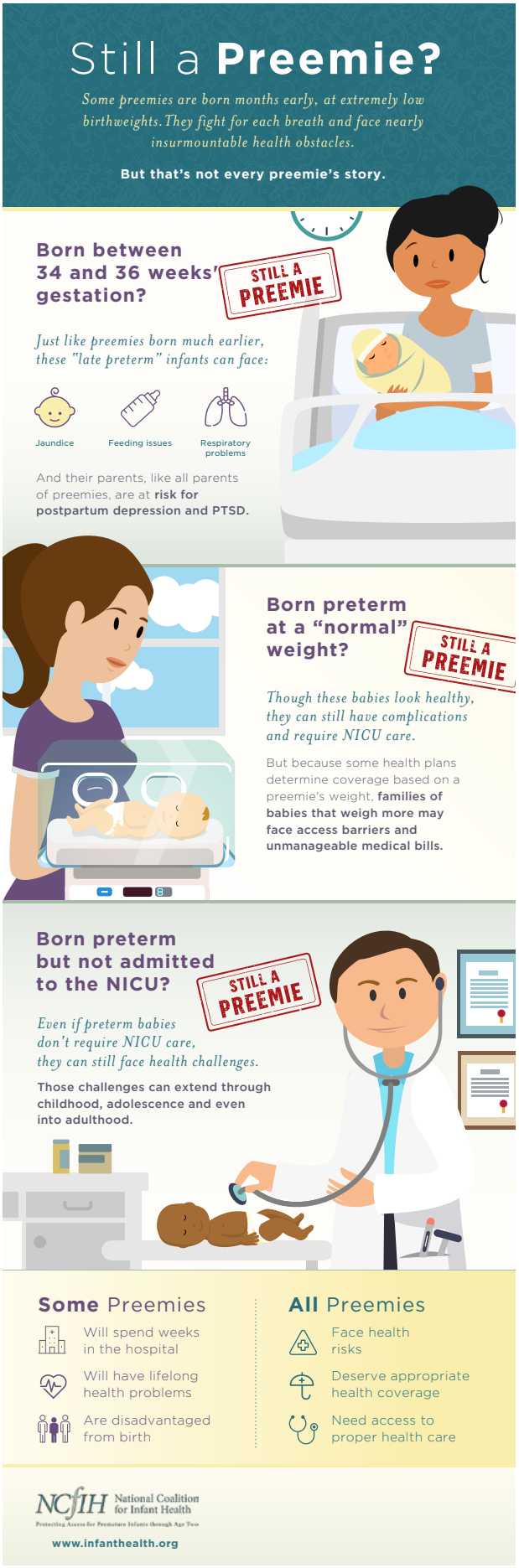

Raising Global Awareness of RSV

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

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

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

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

Respiratory Potpourri: Recruitment Maneuvers During High-Frequency Jet Ventilation (HFJV): High, Low, Long, or Short?

Rob Graham, R.R.T./N.R.C.P.

I dedicate this column to the late Dr. Andrew (Andy) Shennan, the founder of the perinatal program at Women's College Hospital (now at Sunnybrook Health Sciences Centre). To my teacher, my mentor and the man I owe my career as it is to, thank you. You have earned your place where there are no hospitals and no NICUs, where all the babies do is laugh and giggle and sleep.

Those who have been utilising high-frequency jet ventilation (HFJV) for some time have most likely used conventional breaths (CMV)) superimposed on HFJV either to reverse atelectasis or for initial lung recruitment. Traditionally the term conventional breath was an apt description as their parameters were just that; relatively high peak inspiratory pressure (PIP) of 20 cmH_2O (or higher) and inspiratory time (Ti) of 0.5 seconds or so.

"Traditionally the term conventional breath was an apt description as their parameters were just that; relatively high peak inspiratory pressure (PIP) of 20 cmH2O (or higher) and inspiratory time (Ti) of 0.5 seconds or so."

The past debate has revolved around whether to set CMV PIP below HFJV PIP, or above. The difference between the two, aside from the obvious difference in pressure, is with the jet itself. CMV PIP set higher than HFVJ PIP will cause the jet ventilator to pause for the duration of the CMV breath, while CMV PIP set below HFJV PIP will not; HFJV breaths will be superimposed on CMV breaths.

PIP differences aside, clinicians were instructed to use CMV during initial HFJV to recruit the lungs since the low PIP and short Ti of HFJV are not powerful enough to do so on their own. These were started at rates of 5-10 and were reduced as FiO_2 improved with the aim to stop them entirely and run HJFV in CPAP mode. CMV breaths were (and still are) advised to help determine optimal PEEP settings. If FiO_2 increases when CMV rate is reduced or CMV breaths are discontinued, PEEP is increased until FiO_2/SpO_2 is stable when CMV is discontinued. This approach seems to work, and it is still the standard practice in many NICUs.

The burning question behind the use of CMV with HFJV is "why?". After all, if the benefit of HFJV is its gentleness, why use high PIP CMV breaths at all? This strategy works in the short term, but there are known sequelae associated with CMV, mainly inflammatory response and lung injury stemming from sheer forces, volutrauma, and conducting airway/alveolar duct rupture or tears. The short-term gain from the use of CMV may come at the cost of pulmonary damage later.

I do not use the traditional style CMV breaths in my personal practice. Initially, rather than use CMV to recruit the lung, I prefer to start with higher PEEP instead. This has worked well for me and is how HFJV is done in the NICU I practice in. I believe it is one of the reasons our CLD rates are remarkably low.

There are clinical situations, however, which do not respond well enough to increasing PEEP. Regional atelectasis is one, and unilateral collapse is another. The question is how to manage these pathologies clinically without causing further damage to the lung, and without over-distending well -functioning areas of higher compliance.

Physics dictate that gas takes the path of least resistance; compliant areas accept volume more readily, and gas will preferentially fill these areas until they become less compliant from over-distention. Once this happens, gas will begin to enter less compliant/higher resistance areas.

There is an inherent problem with the standard CMV breath in this situation: time. Time constants dictate how long it takes for gas to fill a space, and the most compliant areas of the lung take the longest to fill; a standard Ti of 0.5 seconds likely does not afford enough time for this to happen, let alone time for pendelluft to redistribute volume within the lung. The result is areas of higher compliance being over-distended, resulting in volutrauma, and collapsed/atelectatic areas suffering damage from the inflammatory response with surfactant impairment that follows atelectasis. (1,2) The clinical response may be good, but it comes at a cost.

Contrast this with a different form of CMV, one which ostensibly protects compliant areas while gently opening up areas of collapse. How is this accomplished? A combination of relatively low CMV PIP combined with a longer CMV Ti.

Limiting PIP reduces the volume that enters compliant areas, thus giving some protection against volutrauma while increasing the CMV Ti gives more time for pendelluft to occur once compliant areas have accepted as much volume as they will at a given PIP. The lower PIP also slowly and gently exerts a force against collapsed areas and eventually recruits them. I refer to these breaths as recruitment maneuvers (RMs) to differentiate from the standard CMV breaths of old.

"Ti gives more time for pendelluft to occur once compliant areas have accepted as much volume as they will at a given PIP. The lower PIP also slowly and gently exerts a force against collapsed areas and eventually recruits them. "

We know that the lung is at greatest risk of damage when being recruited, be it on the admission table or after de-recruitment. Appropriate PEEP/MAP should prevent atelectasis; however, what that level is may not be provided by clinicians suffering from "PEEPaphobia" or "MAPaphobia." The modified CMV breath (I prefer to

use the term “recruitment maneuver” (RM)) may offer gentler recruitment and be less apt to damage or further damage the lungs.

Not to be confused with sustained inflations (there is evidence these are not a good idea) (3), RMs have shorter Ti and usually lower PIP, and have been gaining favour within the unit I work in, and have been a personal standard of practice for over ten years. From a clinical perspective, they can work “like magic” or produce less dramatic results. The goal is to decrease FiO_2 and provide more lung volume to work with. Similar to CMV breaths, RMs should be used only when necessary for as short a period as possible. PEEP should be increased when they are discontinued to prevent derecruitment.

“Similar to CMV breaths, RMs should be used only when necessary for as short a period as possible. PEEP should be increased when they are discontinued to prevent derecruitment."

One scenario in which RMs work very well is complete unilateral collapse. Whether from a mainstem intubation or surfactant being inadvertently given to one lung only, initiating RMs while positioning the baby collapsed side up has, in my experience, worked very well, and generally within 8-12 hours. Regional atelectasis is more challenging to treat, and RMs may take longer to work, but they too respond to this treatment.

Settings:

There is some variation within the clinical practice when it comes to RMs. Some use slightly shorter Ti, some longer; some use a respiratory rate of 5 while some use more; some use slightly higher PIP and some less.

It is my practice to use PIP of 5-6 above PEEP, a rate of 10, and Ti of 2 seconds. PIP settings on most ventilators are limited to a minimum delta P, although the utility of pressures below 5 above is limited though there may be situations where lower delta P may succeed. The slave ventilator used with most of the jets in my NICU has a maximum Ti of 2 seconds. I do not believe it prudent to exceed Ti of more than 3 seconds. If these settings do not achieve positive results within an hour or so, then PIP may be increased; a PIP 5-6 above PEEP may be insufficient to re-inflate non-compliant areas. The goal is to use as low a PIP as will do the job, though it stands to reason the higher the PIP, the less protective the RM is. The use of a rate of 5 is likely adequate for most situations; higher rates should be reflective of the urgency of improving clinical status. If inspiratory and expiratory flow rates are independently adjustable, I will decrease inspiratory flow rate to soften the waveform of the RM, otherwise lengthening slope or rise time will have a similar effect.

Management:

Once the desired effect is achieved RMs may be discontinued, or their frequency decreased if a more cautious approach is taken. Either way, the goal is the same: the discontinuation of RMs.

As the lung is recruited, ventilation may improve as well as oxygenation. Initially, CO_2 may rise, followed by a precipitous drop as the recruitment occurs, and ventilation-perfusion matching (VQ) improves. Conversely, ventilation may decrease as the RM decreases HFJV ΔP for the duration of the RM; increasing HFJV PIP may be required temporarily. Either way, the dynamics of ventilation change during RMs and must be accommodated. The monitoring of $PaCO_2$ during RMs is de rigueur.

Caveats:

This style of RM is relatively new. As such, there is anecdotal evidence of their effectiveness but no proper clinical trials. I have never seen a baby suffer a pneumothorax as a result of RM use, but higher Ti has been associated with an increase of pneumothorax4. The chance of air leak is always present and should be high on the clinician’s troubleshooting list should acute deterioration occur. In my workplace, there is a needle aspiration kit attached to each ventilator.

As a final note on the subject, it is worth noting that third-generation ventilators providing oscillation along with conventional modes may also give the option of sigh breaths during oscillation (HFO) This style RM may benefit some patients on HFO as well.

2.0 ETT: A way to buy time?

The use of 2.0 mm ETT’s is controversial, to say the least. The unit where I work stocks them, but they are not meant to be used for ventilation. Rather, they are used (rarely) in emergent situations involving post extubations edema to buy time for dexamethasone to do its job. There is no way at present to ventilate through this small an ETT, partially because the resistance is too high for conventional ventilators to work. The small lumen leads to severe gas trapping, and there is no way to properly suction. Although it is possible to pass a 6 Fr suction catheter through a 2.0 ETT (with some difficulty) straight from the package, once the tube is in situ and secured, this becomes impossible. The tape securing the ETT creates a stricture preventing passage. Even if it were possible, the catheter completely occludes the airway, and suctioning results in removal of lung volume along with whatever secretions the small catheter is capable of removing. Even if 5 Fr catheters are available, their inherent high resistance makes them useless for tracheal toilet.

I recently cared for a 23+5-week gestation infant weighing 499 grams. The resuscitation team was unable to intubate with a 2.5 ETT. The decision was made to place a 2.0 ETT orally. Initially, the infant did very well on oscillation with volume guarantee (HFO/VG) using remarkably low amplitude and was in 21% O2 post-surfactant.

Initial settings were frequency of 10 Hz, maximum amplitude of 20 cmH_2O (using 15), mean airway pressure (MAP) of 10 cmH_2O, I:E ratio of 1:2, and volume targeted at 1 mL. The frequency was decreased to 8 Hz, and I:E ratio increased to 1:3, both in an attempt to mitigate presumed gas trapping. Volumes were weaned as low as 0.6 mLs, but rising CO_2 necessitated increasing back to 1 mL. At 15 hours of life, the baby was placed on HFJV as FiO_2 was increasing, as was CO_2. (This should have been the initial mode of ventilation in my opinion). Initial settings were a rate of 240, PIP of 20, PEEP of 9, and Ti 0.02 seconds. Prior to the switch, monitoring HFO/VG with the jet on standby mode showed a higher MAP than set on the ventilator, confirming the presence of inadvertent PEEP. PEEP, as measured on the jet ventilator in operation, was 9.2. Shortly thereafter, the decision was made to reintubate with a 2.5 ETT under rapid sequence induction.

Previously, a 2.5 ETT was passed through the left nare using a small amount of lubricating jelly, and a 6 Fr suction catheter as an introducer. Initially, the nose blanched but pinked up nicely in a short time. A 6 Fr suction catheter was passed through the ETT using a small amount of lubricating jelly and used as an introducer as previously. The suction catheter was then passed through the vocal cords using Magill forceps under direct laryngoscopy and advanced as deeply as possible. The ETT was then passed through the vocal cords over the catheter with gentle pressure while rotating the ETT. The patient was then placed back on HFJV. Once the ETT was up-sized, FiO_2 returned to 0.21.

Having the 2.0 ETT in situ for approximately 15 hours may have dilated the glottis making it possible to pass the larger tube. Lesson? A tiny baby may be successfully ventilated for a short time with a 2.0 ETT in order to buy time for inflammation to subside and possible dilation of the glottis.

Life Pulse® Play:

Please note any modification of the Life Pulse® circuit is not sanctioned by Bunnell Inc., and this "investigation" is purely academic.

Colleagues have mused about the suitability of HFJV for the treatment of COVID-19 refractive to traditional ventilation options. The ability of HFJV to overcome airway resistance and the double-helical bidirectional flow characteristics of the mode also facilitates clearance of secretions. The question of whether or not the Life Pulse® has enough driving pressure to accomplish this task in a larger patient is the biggest question.

The maximum servo pressure (the driving pressure required to achieve set PIP) available on the machine is 20 psi; however, the accumulator inside holds 500 mls of gas under pressure. This may not be sufficient to keep up with the demands of larger patients depending on rate, Ti, and PIP.

Modifying the circuit, I have been able to achieve PIP of up to 107 cmH_2O (using a Sechrist® Airway Pressure Monitor Model 400) and a servo pressure just over 20 psi using a jet rate of 240 and Ti 0.034. This may be sufficient for a small adult; however, the largest LifePort® adaptor is a 5 mm, smaller than a typical adult endotracheal tube. This may not be an insurmountable problem as I am quite sure a resourceful clinician could figure out a way to make it fit. My next exercise will be to determine if there is a way to estimate pressure delivered by the machine with the modification made. Stay tuned.

While on the topic of unorthodox use of the Life Pulse® I should mention I have not had the opportunity to investigate further "NINJA" (Non-Invasive Nasal Jet Assisted ventilation). I look forward to updating readers on this mode.

"As with the rest of the world, ensuring PPE availability is still a challenge, and the first wave of this pandemic is not yet over. How any of us fair with the predicted second wave is at this point unknown and will largely depend on our collective ability to ramp up production of PPE to ensure all involved in the care of COVID-19 patients are properly protected."

It is fortunate that here in Ontario as in California, closing down non-essential businesses and institutions as well as social distancing and stay at home advisories have thus far prevented our system from being overwhelmed. Knock wood, but at this point, we in Ontario have a surplus of adult ICU bed capacity and no shortage of ventilators. As with the rest of the world, ensuring PPE availability is still a challenge, and the first wave of this pandemic is not yet over. How any of us fair with the predicted second wave is at this point unknown and will largely depend on our collective ability to ramp up production of PPE to ensure all involved in the care of COVID-19 patients are properly protected.

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

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first candle

Saving babies. Supporting families.

Virtual
Mother's Day - Father's Day Walk/Run Challenge
May 10th - June 21st

#everybabycounts

Does running a marathon seem impossible? Here's an easy way to do it - over 6 weeks!

We're excited to announce our first Virtual Walk/Run Challenge! From Mother's Day - Father's Day sign up to walk or run 26 miles - less than 1 mile per day - and help raise fund to help parents who need our support after the loss of their precious baby.

You can join at any time during the 6 weeks and walk/run as much or as little as you'd like.

Sign up at www.firstcandle.org

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

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

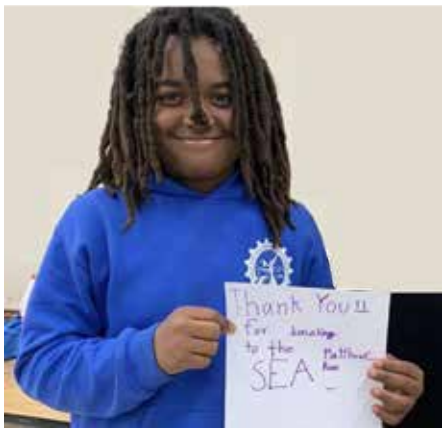
Thirteen-year-old Emily Rose Shane was tragically murdered on April 3, 2010 on Pacific Coast Highway in Malibu, CA. Our foundation exists to honor her memory.

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.

Mothers with COVID-19 and Their Newborn Infants: A Joint Position Statement on Shared Decision-Making

Joan Rikli, MBA, MSN, RN, Jerasimos Ballas, MD, MPH, Dionne WIlson, CAE, Kristy Love

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 Association of Neonatal Nurses

National Perinatal Association
Educate. Advocate. Integrate.

As the Covid-19 pandemic continues to shape all our lives, those who provide care to pregnant patients, their families, and newborns face a challenging task. We are entrusted with the responsibility of formulating new policies for childbirth and newborn care in the midst of a dynamic public health crisis. So how do you create evidence-based guidelines when the evidence is evolving?

Parents and providers get new data every day and the information we need to make informed decisions is ever-changing. This not only poses significant challenges in creating a safe environment for patients and first line healthcare workers, but also in maintaining the highest standards of ethical and compassionate care at such a potentially vulnerable time for both parents and newborns.

The National Perinatal Association (NPA) and National Association of Neonatal Nurses (NANN) recognize these unique challenges and offer guidance in creating a culture of shared decision-making when providers must deliver the newborn of a Covid-19+ mother or when the mother is a Patient Under Investigation (PUI).

Drawing from the multidisciplinary experience of our organizations, we have created a Joint Position Statement addressing the need to balance evidence-based practices for both infection control and protection of healthcare providers with the established benefit of newborn bonding and breastfeeding in the 4th trimester.

With information changing rapidly as more data is collected, we acknowledge the potential for policy changes based on institutional constraints and regional developments. However, any policy must start with the dignity of the patient at its core and aspire to do no harm as we all navigate these challenging and uncertain times.

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

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FOR IMMEDIATE RELEASE

National Association of Neonatal Nurses

National Perinatal Association

Mothers with COVID-19 and Their Newborn Infants

A Joint Position Statement on Shared Decision-Making

Chicago, IL May 11

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www.nationalperinatal.org/COVID-19
www.nann.org/about/position-statements

Joint Position Statement
May 2020

Mothers with COVID-19 and Their Newborn Infants

Issue: Shared Decision Making

The National Association of Neonatal Nurses (NANN) and the National Perinatal Association (NPA) fully support the **incorporation of a shared-decision model between the mother and the clinical team** to determine the best care for the mother-newborn dyad.

NANN and NPA **encourage the ideal scenario**, which is to keep mother and newborn together **while respecting the unique challenges** individual institutions may encounter.

While we recognize the myriad uncertainties in understanding the best evidence-based practice for the mother-newborn dyad during the postpartum period, we encourage families and clinicians to remain diligent in learning **up-to-date evidence** and ultimately **working in partnership** for the safest and best practice for all parties involved.

NANN and NPA acknowledge the **potential trauma** and exacerbation of **postpartum mental health issues** that may negatively impact the fourth trimester.

We encourage healthcare providers to assist the mother to **recognize the ideal versus realistic scenarios**, **acknowledge the uncertainty and grief** over changing expectations, and **consider higher-touch care** in the weeks following delivery.

Discussion

NANN and NPA have reviewed the recommendations from the American Academy of Pediatrics (AAP) [1], Centers for Disease Control and Prevention (CDC)[2], and the World Health Organization (WHO) [3] regarding mother-newborn infant postpartum care in the hospital if a mother is COVID-19+. **All statements support and emphasize the importance of a shared-decision model** between mother and the healthcare provider team to determine the need for postpartum separation of the mother-newborn dyad while they are in the hospital.

What Is Known

- Empirical evidence to date has **not shown vertical transmission** of the virus through the placenta, amniotic fluid, or breastmilk.[4-9]
- **Mortality rates for neonates specific for COVID-19 are minimal**. Seven reports from China,[4,-7;10-12] one multicenter report from Italy,[13] and one multicenter report from New York City [14] have published data on pregnant women who are COVID-19+ delivering newborns during this pandemic. A total of 127 neonates born to mothers who are COVID-19+ were reviewed from the nine published studies. One preterm infant death was noted.[12] However, this preterm neonate did not test positive for COVID-19 on day of life. [9] No other fatalities were reported.

Challenges

- **Small sample sizes** and mother-infant separation practices varied between the institutions.
- Vertical transmission **cannot yet be ruled out**.
- **Horizontal transmission** from mother to newborn may occur, thereby increasing exposure risk to additional clinicians caring for the newborn.
- **Limited resources.** Necessary resources such as personnel, physical space, personal protective equipment (PPE), and medical technologies – including additional isolettes – must be available to safely care for the emergent medical needs of mother-baby dyads.

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**.

We appreciate WHO's recommendation to **keep mother-newborn dyads together** and emphasize using **good respiratory and hand hygiene** at all times.

We support this recommendation so long as it is a **shared decision between mother and clinical team**, which includes all affected care providers (e.g., nursing, obstetric, and pediatric clinicians), and is feasible for the institution at that time.

We affirm the importance of neonatal attachment during the first days of life as discussed by WHO [3] and recognize the unknown risk of exposure to the COVID-19 virus as expressed by AAP[1] and CDC. [2]

Another important consideration is that these **mother-infant dyads are discharged from postpartum care to a same home environment**. Therefore, we recommend clinicians and researchers working with this population to **collect data throughout the entire neonatal period and publish timely reports** to help us further understand longitudinal outcomes of neonates exposed to COVID-19, which will help inform and guide the evidence for postpartum care during this pandemic and future pandemics.

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Resources:

www.nationalperinatal.org/NPAandNANN

www.nationalperinatal.org

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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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NICU Awareness

National Perinatal Association

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Did You Know?

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

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

Special Health Needs

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

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

Who Can Help

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

Special Developmental Needs

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

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

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

Who Can Help

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

Special Educational Needs

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

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

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

Who Can Help

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

Find more resources at nationalperinatal.org/NICU_Awareness

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Providing Psychosocial Support in the NICU

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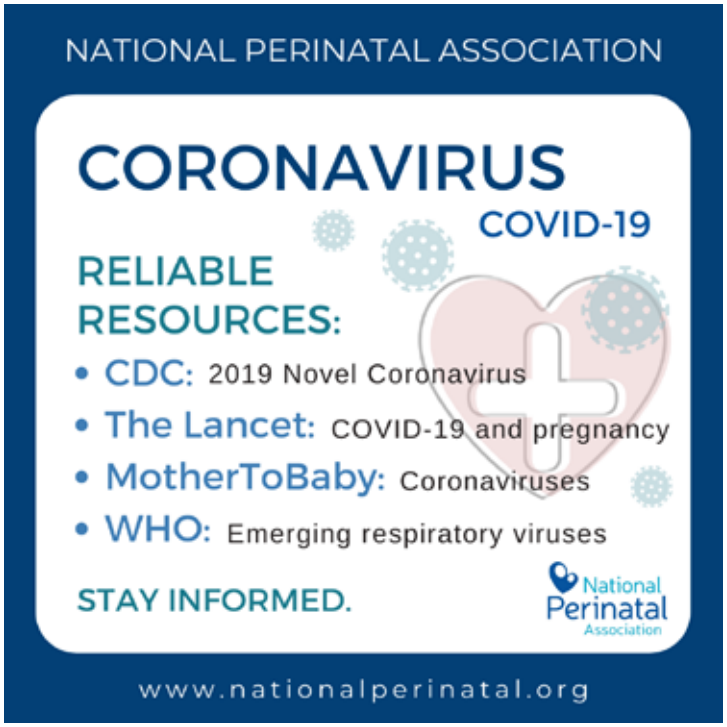

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COVID-19: Care for Infants and Children & Competition for Resources

Darby O'Donnell, JD and the AfPA Governmental Affairs Team
Alliance for Patient Access (AfPA)

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

Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act - a bipartisan, $2 trillion COVID-19 relief package for U.S. families, physicians, health care providers, job seekers, employers, and small business owners alike - at the end of March.

The aim was both economic and public health-related in light of the damage already done and to come from the coronavirus pandemic. Despite its magnitude - notably the largest rescue package in U.S. history - not every patient or health care provider was an immediate beneficiary of the congressional relief funds.

Physicians, Family Practices and Children's Hospitals

Those who treat children and infants as their primary source of income - physicians, family practices and children's hospitals - fell largely just beyond the scope of CARES Act relief funding, round one (so-called CARES tranche 1) because those early funds were geared towards Medicare beneficiaries and distributed based on Medicare revenues.

As the Children's Hospital Association (CHA) explained it, "Children's hospitals were not supported from this distribution as they do not serve Medicare patients (65 years and older) yet are among the highest Medicaid providers in the country, with Medicaid accounting for over 50% of their patients." (1)

> ***"It is critical that frontline physicians who may not participate in Medicare fee-for-service, in whole or in part, including obstetrician-gynecologists, pediatricians, and family physicians, have the resources they need to continue providing essential health care to patients amid the pandemic and in the months to come," they wrote."***

The New York Times acknowledged in a recent article pediatric practices have the most to lose. For starters, pediatricians are among the lowest paid of the medical specialties. And they could be the "hardest hit" of the health practice areas; since they "don't generally treat Medicare patients, they were not compensated for the decline in visits as parents chose not to take their children to the doctor and skipped their regular checkups." (2)

In late April, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists joined forces to write to the U.S. Department of Health and Human Services Secretary Alex Azar asking him to address non-Medicare patients and their providers.

"It is critical that frontline physicians who may not participate in Medicare fee-for-service, in whole or in part, including obstetrician-gynecologists, pediatricians, and family physicians, have the resources they need to continue providing essential health care to patients amid the pandemic and in the months to come," they wrote. (3)

CARES Act Funding, Round 2

On April 24th, about two weeks after the Department of Health and Human Services (HHS) released a first batch of funding to hospitals and physicians, a second tranche of the CARES Act COVID-19 relief funding was released for providers to include those left out of the previous allocation. HHS's action was lauded by

many as relief reached a broader range of health care providers, with less restrictions to their relief based on the age or insurance enrollment of their patients.

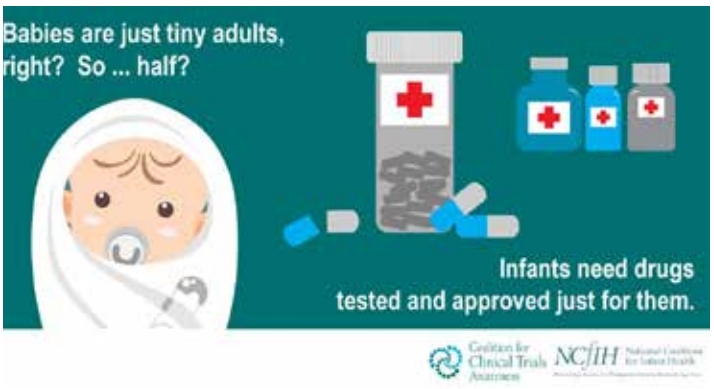
The pediatric community was quick to respond.

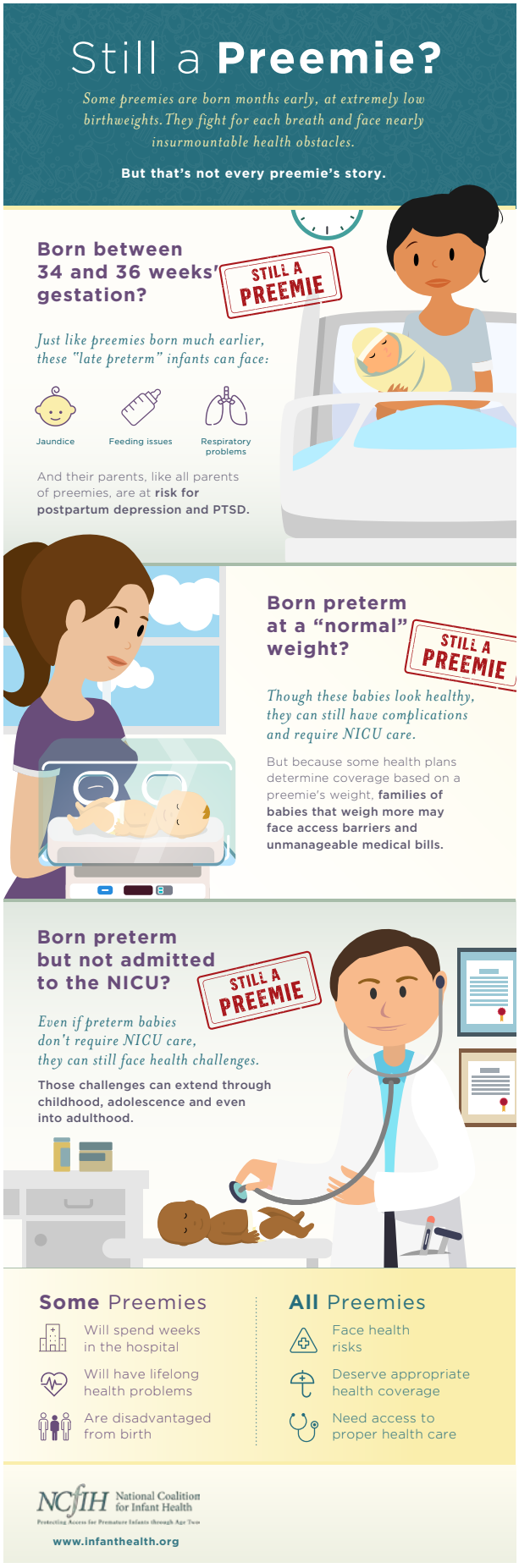
CHA noted that while "children's hospitals represent only 2% of all the nation's hospitals, they serve 25% of the U.S. population," and in the midst of COVID-19 "children's hospitals deferred pediatric care and experienced significant drops in volumes related to local and federal stay-at-home guidance." CHA claimed that their affiliated hospitals' patient care revenues fell roughly 40-50%, which equated to an operating loss in excess of $2 billion each month across the nation's children's hospitals. The late allocation of CARES Act funding had "mitigated only a fraction" of the damage to the operating costs of children's hospitals across the country.

Meanwhile, the coalition which included the American Academy of Pediatrics and the American Academy of Family Physicians raised the consequences of pediatric and family-centered practices losing income and closing their doors without "urgently needed financial relief" via HHS. One critical concern with these physicians shuttering their doors would be lose of access to infant and childhood immunizations - which would be put off or less frequently administered, resulting potentially in future outbreaks of vaccine-preventable diseases and creating an uphill battle for families and public schools that require these immunizations.

"One critical concern with these physicians shuttering their doors would be lose of access to infant and childhood immunizations - which would be put off or less frequently administered, resulting potentially in future outbreaks of vaccine-preventable diseases and creating an uphill battle for families and public schools that require these immunizations."

Hospitals and family-centered care facilities are navigating new





waters when it comes to pediatric care. With employee furloughs, reduced outpatient and inpatient services, previously bustling pediatric units and clinics are now ghost towns. The emotional impact to nurses, staff, and other providers, when not seeing their patients, cannot be overstated.

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

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

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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

Interpreting Umbilical Cord Blood Gases: Technical Issues: Part II

Jeffrey Pomerance, MD, MPH

Case 4: Blood Gas Samples Drawn from the Same Vessel

The mother was a 31-year-old, gravida 4, para 0, aborta 3, with an intrauterine pregnancy at 42 0/7 weeks by fair dates (20-week sonographic scan with uncertain last menstrual period). (1)

She presented in active labor with ruptured membranes. The fetus was in a breech position. The patient was taken for a primary cesarean section. At delivery, there was a problem delivering the aftercoming head. Apgar scores were 3 and 8 at one and five minutes, respectively.

Cord blood gas results were as follows:

	Umbilical Vein	Umbilical Artery
pH	7.19	7.18
Pco_2 (mmHg) *(kPa)*	66 *8.80*	68 *9.07*
Po_2 (mmHg) *(kPa)*	14 *1.87*	13 *1.73*
HCO_3^- (mmol/L)	25	25
BD (mmol/L)	5	5

Interpretation

The umbilical vein sample's pH is mildly depressed, the PCO_2 moderately elevated, the PO_2 mildly decreased, and the base deficit is normal. The umbilical artery sample pH is normal, the PCO_2 mildly elevated, and the PO_2 and base deficit are normal. Therefore, there is moderate respiratory acidosis in the venous sample and a mild respiratory acidosis in the arterial sample. All the "rules" of the relationship between umbilical venous and arterial samples are met (the venous sample *always* has a higher pH, a lower PCO_2, and a higher PO_2). Yet, it seems obvious that these two samples cannot represent samples of both the umbilical vein and the umbilical artery because the values are almost identical. The only additional finding that could have made this conclusion even more apparent would be if one of the three measured parameters (pH, PCO_2, PO_2) disobeyed the "rules" of relationship. One does not need any formula or additional evaluation process to interpret this set of cord blood gases correctly. However, there are times that the correct interpretation is not as clear (see next case).

"One does not need any formula or additional evaluation process to interpret this set of cord blood gases correctly. However, there are times that the correct interpretation is not as clear (see next case)."

Whenever umbilical venous and arterial pH values are close, but not identical, one also must consider the possibility that one sample consists of mixed venous and arterial blood (most commonly, the needle sampling the artery slips through into the vein behind it). However, the interpretation remains the same, i.e., and two vessels have not been successfully sampled.

In the example above, either an umbilical vein or an umbilical artery was sampled twice. As it is much easier to sample blood from the umbilical vein, it is more likely that both samples are venous, although the values are closer to normal for an umbilical artery sample. The question really becomes, "Was the easier to sample vessel sampled twice, or was the more difficult to sample vessel sampled twice?" The betting odds are with the vein.

In some hospitals, in a cost-containment effort, only an umbilical artery sample is obtained. However, *unless both umbilical venous and umbilical arterial samples are obtained, one cannot be certain that the only sample obtained is indeed from an umbilical artery.* Riley and Johnson (2) suggest looking at the color of the blood samples to ascertain that both venous and arterial samples have been obtained. If the color looks the same, the samples have probably been drawn from the same vessel.

"In some hospitals, in a cost-containment effort, only an umbilical artery sample is obtained. However, unless both umbilical venous and umbilical arterial samples are obtained, one cannot be certain that the only sample obtained is indeed from an umbilical artery."

It has been suggested that an umbilical venous sample is a good proxy for an umbilical arterial sample as the relationship between these two samples is known and is within a certain range. For example, one would expect the umbilical arterial pH to be between 0.04 and 0.10 lower than the pH in the umbilical venous sample, (3,4) (see next case). This is true in normal, non-asphyxiated newborns and even in those newborns who are depressed secondary to uteroplacental insufficiency. However, when the fetus/newborn has issues with cord occlusion and associated terminal bradycardia (5-9) (a relatively common problem … cord occlusion with terminal fetal bradycardia), or with fetal heart failure (10) (a relatively rare problem … fetal circulatory failure), an umbilical arterial sample may have values that are much worse than those in the umbilical venous sample.

Key Points

- When umbilical venous and arterial blood gas samples are almost identical, or if some, but not all of the matched pHs, PCO_2s or PO_2s do not obey the "rules" of relationship, it is clear that the samples come from the same vessel. If all of the matched parameters are opposite to the "rules" of relationship, suspect the samples have been mislabeled (see Case 6). As the umbilical vein is much easier to sample than the umbilical artery, usually, the umbilical vein is the vessel that has been sampled twice.
- Unless both umbilical venous and umbilical arterial samples are obtained, one cannot be certain that a single sample is from an umbilical artery.
- An umbilical venous sample may be a reasonable proxy for an umbilical arterial sample in normal, non-asphyxiated newborns or in newborns depressed secondary to uteroplacental insufficiency.
- In newborns depressed secondary to cord occlusion with terminal fetal bradycardia or fetal heart failure with terminal fetal bradycardia, the umbilical arterial cord gas values may be much worse than those in the venous sample.

Case 5: Blood Gas Samples from One Vessel or Two?

The mother was a 24-year-old, gravida 2, para 0, aborta 1, with an intrauterine pregnancy at 38 1/7 weeks. (1) The mother had spontaneous rupture of membranes with egress of clear fluid and was in labor at the time of admission. The FHR showed non-repetitive, moderate variable decelerations with an occasional severe variable deceleration. After one hour, the mother was completely dilated, completely effaced, with the vertex at +3 station. She pushed for one hour and was taken to the delivery room where the fetus had a deceleration to 60 bpm lasting for one minute. The infant delivered one minute later with Apgar scores of 8 and 9 at one and five minutes, respectively.

Cord blood gas results were as follows:

	Umbilical Vein	Umbilical Artery
pH	7.28	7.25
Pco_2 (mmHg) *(kPa)*	47 *6.27*	52 *6.93*
Po_2 (mmHg) *(kPa)*	29 *3.87*	18 *2.40*
HCO_3(mmol/L)	22	22
BD (mmol/L)	5	5

Interpretation

Both cord blood samples are entirely normal. The issue is, "Are these two blood gas samples from the same vessel or from two different vessels?" Making this decision correctly is a vetting process.

Initial evidence suggests the two samples came from different vessels. All of the measured venoarterial differences are in the "correct" direction (pH higher in the vein, PCO_2 lower in the vein, and PO_2 higher in the vein).

Data published by Yeomans, Hauth, Gilstrap, and Strickland, (11) based on "uncomplicated term vaginal deliveries," is a good data set with which to establish a normal range of pH and PCO_2 differences in cord gas analyses. As pH is the most reproducible of the measured parameters, it is taken as the primary determinant, and PCO_2 is used as the backup determinant. Using this data, assuming the differences between umbilical venous and arterial pH and PCO_2 have normal distributions, the 95th percentile range of differences for pH is from 0.04 to 0.10, and the 95th percentile range of differences for PCO_2 is from 4 to 18 mmHg, (3,4) (see Table 1 below). This suggests that when the pH difference is less than 0.04, the samples are probably from the same vessel. When the pH difference is borderline, i.e., 0.03, before concluding the umbilical venous and arterial samples came from the same vessel, check the PCO_2 difference. If the PCO_2 difference is less than 4 mmol/L, it is safe to conclude that the samples came from the same vessel.

In this case, the pH is borderline, 0.03. However, the PCO_2 difference is 5 mmHg, towards the lower end of the normal range, but normal nonetheless. Therefore, one should conclude that these samples came from different vessels, i.e., an umbilical vein and an umbilical artery. White et al.(12) and Westgate et al. (13) have suggested similar cutoff criteria for establishing samples from the same vessel.

Apgar scores were quite normal, further suggesting that cord blood gas samples would be normal. All of these findings lead to the conclusion that different vessels were sampled.

Umbilical Cord Venoarterial pH and P_{CO_2} Differences

	pH			Pco_2 (mmHg) *(kPa)*		
	Vein	**Artery**	**Delta***	**Vein**	**Artery**	**Delta***
	7.35	7.28	0.07	38 *5.07*	49 *6.53*	11 *1.46*
SD	0.05	0.05	0.0156	5.6 *0.75*	8.4 *1.12*	3.54 *0.47*
± 2 SD Range			0.039-0.101 (~0.04-0.10)			3.9-18.1 *0.52-2.41*
Borderline low delta*			0.03			

Table 1
Derived (3,4) in part from data published by Yeomans ER, Hauth JC, Gilstrap LC III, Strickland DM. Umbilical cord pH, PCO_2, and bicarbonate following uncomplicated term vaginal deliveries (146 infants). Am J Obstet Gynecol 1985;151:798-800.(11)
**Delta (the difference between umbilical venous and arterial values)*

For a discussion of widened umbilical cord venoarterial pH and PCO_2 differences, please see up-coming sections on cord occlusion with terminal fetal bradycardia and cases of fetal circulatory failure.

Key Points

- The normal range of pH differences between umbilical cord venous (higher) and arterial (lower) blood samples is 0.04 to 0.10. Larger differences may be seen under certain conditions.

- The normal range of PCO2 differences between umbilical cord venous (lower) and arterial (higher) blood samples is approximately 4 to 18 mmHg (0.52 to 2.41 kPa).
- A pH difference between umbilical cord venous and arterial samples of less than 0.03 signifies that both samples came from either an artery or a vein.
- A pH difference of 0.03 should be considered borderline. If, in addition, the umbilical venoarterial PCO2 difference is less than 4 mmHg, both samples should be considered to have come from either an artery or a vein.
- As the umbilical vein is much easier to sample than the artery when one concludes that both samples came from the same vessel, more likely it is the vein.

Case 6: Mislabeled Samples

The mother was a 19-year-old, gravida 1, para 0, aborta 0, with an intrauterine pregnancy at 38 3/7 weeks. Membranes had ruptured spontaneously with egress of clear fluid. She was in labor at the time of admission. The amniotic fluid was clear at the time of admission. The FHR showed intermittent variable decelerations that became more severe over time. After three hours, the mother was completely dilated, completely effaced, with the vertex at +2 station. The mother pushed for 90 minutes and was taken to the delivery room. Amniotic fluid was now lightly stained with meconium. The infant delivered 15 minutes later with Apgar scores of 6 and 8 at one and five minutes, respectively.

Cord blood gas results were as follows:

	Umbilical Vein	Umbilical Artery
pH	7.25	7.29
Pco_2 (mmHg) *(kPa)*	65 *8.67*	55 *7.33*
Po_2 (mmHg) *(kPa)*	14 *1.87*	21 *2.80*
HCO_3(mmol/L)	28	26
BD (mmol/L)	1	1

Interpretation

The venous pH and base deficit are normal, while the PCO_2 is mildly elevated, and the PO_2 depressed. The arterial sample is entirely within normal limits. However, the relationships between the "venous" and "arterial" blood gas samples, except for the base deficits, which are the same, are physiologically impossible. The first three "rules" of the relationship between pH, PCO_2, and PO_2 have been broken. The umbilical venous pH is not higher, the PCO_2 is not lower, and the PO_2 is not higher than the umbilical artery pH, PCO_2, and PO_2, respectively. Therefore, the results have been mislabeled. The correct labeling is as follows:

	Umbilical Vein	Umbilical Artery
pH	7.29	7.25
Pco_2 (mmHg) *(kPa)*	55 *7.33*	65 *8.67*
Po_2 (mmHg) *(kPa)*	21 *2.80*	14 *1.87*
HCO_3(mmol/L)	26	28
BD (mmol/L)	1	1

Now, one can see that the venous values are all normal, except for a mildly elevated PCO_2. The arterial sample results are all entirely normal.

"The base deficits in the umbilical venous and arterial samples are usually approximately equal, but if one base deficit is significantly worse than the other, it must be the arterial sample."

Key Points

- The umbilical venous blood gas always has a higher pH, a lower PCO_2 and a higher PO_2 than the umbilical arterial blood gas.
- The base deficits in the umbilical venous and arterial samples are usually approximately equal, but if one base deficit is significantly worse than the other, it must be the arterial sample.
- When the data reported are in the opposite (non-physiological) direction, suspect that the samples have been mislabeled.

Case 7: pH Alone versus Complete Blood Gas Analysis

The mother was a 35-year-old, gravida 4, para 1, aborta 2, with an intrauterine pregnancy at 34 weeks' gestation by poor dates. (14) Two years prior, the mother delivered an infant with intrauterine growth restriction. She was seen for the first time during this pregnancy when she came to the hospital with uterine contractions occurring every five minutes. The fundal height was 27 cm. The cervix was long and closed. Ultrasound examination revealed an infant with an estimated fetal weight of 960 grams, a grade III placenta, and markedly decreased amniotic fluid volume. No fetal breathing or body movements were noted. The FHR monitor revealed moderate recurrent late decelerations. The mother was taken for an urgent primary cesarean section. A male infant was

delivered with Apgar scores of 1, 5, and 7 at one, five, and 10 minutes, respectively. The birth weight was 920 g.

Cord blood gas results were as follows:

	Umbilical Vein or Artery
pH	7.22
Pco_2 (mmHg) *(kPa)*	Not Available
Po_2 (mmHg) *(kPa)*	Not Available
HCO_3^- (mmol/L)	Not Available
BD (mmol/L)	Not Available

Interpretation

The information provided is inadequate. A pH of 7.22 is low if from an umbilical vein and normal if from an umbilical artery. When a single sample is drawn from an umbilical cord, without instruction as to the vessel from which it is to be obtained, the sample is frequently venous, as the vein is much larger and easier to sample. Even when the goal is to sample the umbilical artery, some specimens may still come from the umbilical vein. In this case, without paired samples, there is no reliable way to know which vessel was sampled.

As stated above, if the sample is from the umbilical vein, the pH is slightly low. Is the pH low on a respiratory basis, on a metabolic basis, or a combination of both? Without a PCO_2, a base deficit cannot be calculated.

Cord occlusion with terminal bradycardia may result in a venous cord sample that is substantially better than its arterial counterpart. Was that the situation in this case? We do know that the FHR decelerations were described as "late" in configuration. Variable decelerations, suggestive of cord compression, were not reported. This suggests uteroplacental insufficiency rather than cord compression. Therefore, umbilical venous and arterial derangements should be similar. Additionally, this infant was extremely small for dates (probably asymmetric) with associated decreased amniotic fluid volume, conditions that frequently result from nutritional and respiratory uteroplacental insufficiency. (15) The decreased amniotic fluid volume further predisposes to cord compression (16) and prolonged decelerations. (17)

"Cord occlusion with terminal bradycardia may result in a venous cord sample that is substantially better than its arterial counterpart. Was that the situation in this case?"

Measuring only the pH leaves so many unanswered questions that the information is of very limited value. In the infant described above, the clinical presentation at least suggests the infant may have been more acidotic than reported. To assist in management, it would be appropriate to obtain a blood gas directly from the infant soon after transfer to the neonatal special care unit.

When umbilical cord blood is analyzed for pH, both PCO_2 and PO_2 should be measured as well, and bicarbonate and base deficit calculated from these results. This permits a much more meaningful analysis. Additionally, analyzing both umbilical venous and umbilical arterial blood provides the best basis for correct interpretation.

Key Points

- When only a single pH measurement is obtained from either an umbilical vein or artery sample, one cannot determine:
  - Whether the sample is from the vein or artery, or
  - Whether any acidosis present is respiratory, metabolic or mixed.

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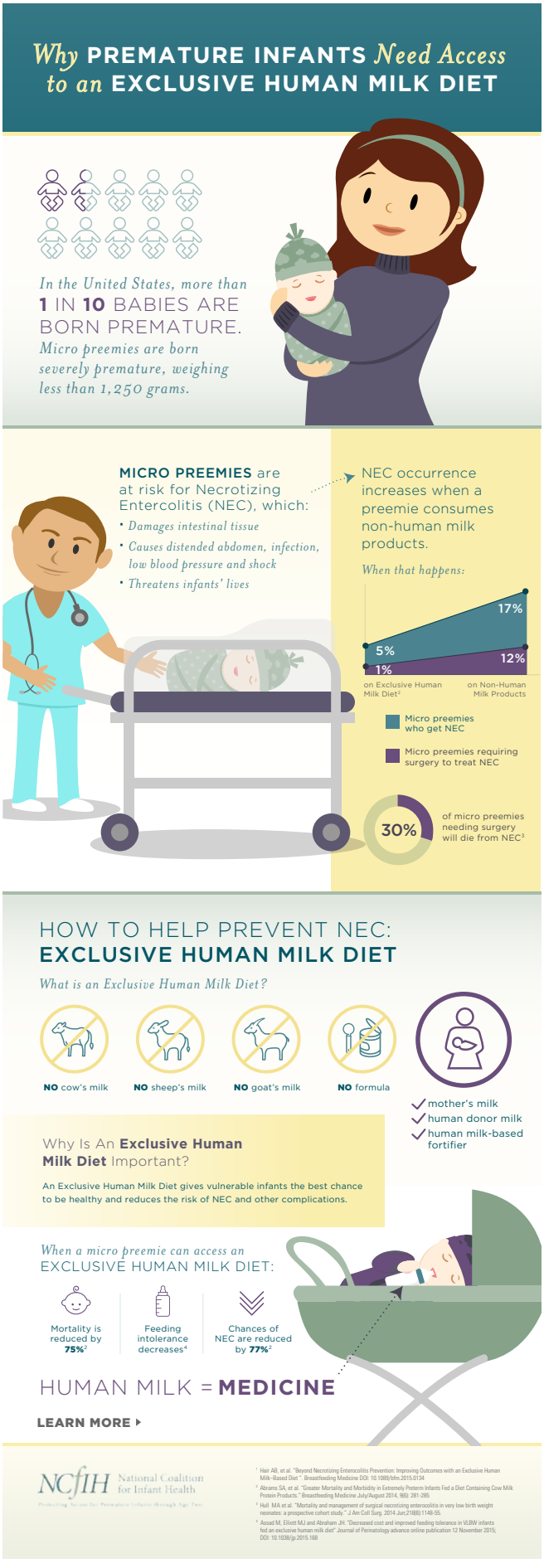

Peer Reviewed

The Bundled Neonate: Neonatal Coding and Common Procedures

Scott D. Duncan, MD, MHA

Neonatal intensive care requires a combination of medical management and procedural skills. Care can occur within several different settings, ranging from the delivery room to the intensive care unit. Reimbursement is based upon proper documentation, supporting the (Current Procedural Terminology (CPT®), and International Classification of Disease, Tenth Revision, Clinical Modification (ICD-10) codes.

The astute neonatologist and/or advanced practice provider (APP) should understand common CPT® code sets and their appropriate use. Many practices expect the provider to enter the correct CPT® code into a charge capture system, which is ultimately transmitted to the payor. Yet many physicians and APPs do not understand the nuances of the daily code in combination with procedural coding.

In an effort to encourage correct coding and reduce inappropriate payments, the Centers for Medicare & Medicaid Services (CMS) instituted a National Correct Coding Initiative (NCCI) .1 Procedure-To-Procedure (PTP) edits were first implemented in 1996 and consists of incorrect code combinations.1 This information is updated quarterly and available via CMS at https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/NCCI-Coding-Edits. Billing software should incorporate a transaction edit system, highlighting errors in the claim prior to submission and integrating NCCI edits. Billing for several services that should be incorporated into a single service is considered fraud!

Typical CPT® codes used in the daily management of the ill neonate include the critical care code set (99468-99472) and the intensive care code set (99477-99480). The critical care and intensive care CPT® codes are considered global codes, that is "most services provided throughout the day in the usual cases of neonatal care are factored into the value of those codes and therefore are bundled or not billed separately."2 A partial list of procedures which are considered bundled can be found in Table 1.

Procedure	CPT® Code
Endotracheal Intubation	31500
Surfactant Administration	34610
Umbilical artery catheterization	36660
Umbilical venous catheterization	36510
Peripheral arterial catheterization	
Lumbar puncture	62270
Suprapubic bladder aspiration	21100

Table 1 Common Procedures Bundled in Global Codes

"How can the medical provider ensure they are accurately documenting the patient's condition? First, determine if the patient's diagnoses "MEAT"s criteria: if a condition is Measured, Evaluated, Assessed, or Treated, it is the clinical significance that is documented in the medical record."

There are limited procedures that are not considered part of the global critical care or intensive care codes. Most of these procedures require additional work beyond that of the daily management of the neonate. An abbreviated list of procedures that may be billed in addition to the global codes is found in Table 2.

Procedure	CPT® Code
Thoracentesis	32554
Thoracostomy tube	32551
Exchange Transfusion	36450
Abdominal Paracentesis	49082

Table 2 Common Procedures Not Bundled in Global Codes

Two unique situations exist where procedures are not bundled into the CPT® code set. These include the use of time-based (hourly) critical care codes (99291-99292) and the delivery room resuscitation code (99465). The typical use of a time-based code occurs in the scenario where a critically ill neonate is being transferred to a NICU in the care of a different group of physicians, or critical care is being provided by a second physician of a different specialty. None of the common procedures found in Table 1 are considered bundled when using time-based critical care codes; however, the time for the procedure must be subtracted from the total time in which critical care was provided. Please refer to the latest NCCI edits and/or guidance from the payor for a comprehensive list of procedural codes that may be billed separately when using time-based critical care codes.

Within the delivery room, common procedures associated with resuscitative efforts may include intubation, surfactant administration, thoracentesis, paracentesis, and umbilical vein catheterization. In the event that a neonate requires resuscitation, the appropriate CPT® code would be 99465. Other procedures performed in the delivery room should be reported separately; however, the procedure must be performed as an essential component of the resuscitation. These procedures may include emergency endotracheal intubation

(31500), catheterization of the umbilical vein (36510), catheterization of the umbilical artery (36660), and surfactant administration (34610).

Correct coding and documentation support the business aspects of the practice of neonatology, in all its variations and employment models. The neonatal care practitioner should have knowledge of correct coding, selecting the correct code(s) for the care provided. Further, the practitioner should know when to bundle or unbundle the baby!

Question

You are asked to attend an emergency cesarean delivery of a 24-week estimated gestational age neonate with a concerning fetal heart rate tracing and preterm rupture of membranes. The neonate is born limp, with poor respiratory effort, low heart rate, and cyanosis. Following NRP guidelines, you provide bag-mask ventilation. Subsequently, the neonate requires intubation and positive pressure ventilation. Heart rate is less than 60 beats per minute, and cardiac compressions are started. An umbilical venous catheter is placed, and the neonate is given epinephrine. The infant was slow to recover, and surfactant is given as part of the resuscitative effort. Once stabilized, the infant is moved to the NICU, where an umbilical arterial catheter is placed. What is the correct code(s) for the delivery room?

A. 99465

B. 99465, 31500, 36510

C. 99465, 31500, 36510, 36660

The correct answer is B.

99465 represents the code for delivery or birthing room resuscitation, provision of positive pressure ventilation and/or chest compressions in the presence of acute inadequate ventilation and/or cardiac output.

31500 represents the code for endotracheal intubation, emergency procedure.

36510 represents the code for catheterization of the umbilical vein for diagnosis or therapy in the newborn.

36660 represents the code for catheterization of the umbilical artery for diagnosis or therapy in the newborn. As this procedure was performed in the NICU, this procedure is not billable as part of the resuscitation, nor as part of the initial day of critical care.

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Peer Reviewed

Reflections on Another Pandemic

Gail Levine, MD

As we are faced with the Covid-19 pandemic, we reflect back to another pandemic disease with devastating consequences, fearful to the population, without treatment, and with the population looking hopefully towards the development of a vaccine.

Poliomyelitis infections have likely been with humankind since antiquity, as described in images and historical accounts. Polio was an endemic pathogen until the 1900s when the United States and Europe began to see epidemics. (1) Jakob Heine published the first medical article about polio in 1840. In 1890 Karl Oskar Medin was the first to study a poliomyelitis epidemic. The disease was, therefore, then called Heine-Medin disease. (2,3)

Before 1900, polio infections mostly occurred in children six months to four years of age. (4) Only mild symptoms generally resulted from infection in this age group and resulted in immunity. (5) Around the turn of the century, there were improvements in clean water and sewage disposal, and this younger age group had less exposure to poliovirus. Poliovirus exposure was thereby delayed until later childhood and adulthood. At these ages, we are more at risk for the paralytic form. (4)

"1952 brought the nation's most severe epidemic, with over 57,000 cases, over 21,000 with mild to severe paralysis, and 3145 deaths. (7,8)"

Epidemics caused widespread fear, closure of movie theatres, and cancellation of meetings and public gatherings. Children were told not to drink from water fountains; pools were closed. People stayed home. (6) 1952 brought the nation's most severe epidemic, with over 57,000 cases, over 21,000 with mild to severe paralysis, and 3145 deaths. (7,8)

John Enders, Thomas H. Weller, and Frederick C Robbins successfully cultured the poliovirus in human tissue and were awarded the Nobel Prize in 1954. (9) This work enabled the development of the Salk vaccine, the inactivated polio vaccine. Testing took place in 1954. Vaccine campaigns followed licensing, promoted by the March of Dimes. In the US, the annual number of cases fell from a peak of 58,000 cases to 5600 cases. (3) Albert Sabin developed the oral polio vaccine with an attenuated live virus. It was licensed in 1962. Mass immunization with this vaccine further reduced cases to 161 in 1961. (10)

Franklin D Roosevelt became paralyzed from the waist down by polio in 1921. In 1938 he helped to found the National Foundation for Infantile Paralysis, now known as the March of Dimes. The March of Dimes raised funds for rehabilitation of those with paralysis and contributed to funding the development and testing of the polio vaccines. The March of Dimes transformed philanthropy by soliciting small donations from individuals rather than only large contributions from the wealthy. A dime in 1950 was equivalent to $1.06 in 2020. (11)

Poliovirus is a human enterovirus C species, a single positive-strand RNA virus. (12) Poliovirus serotypes 1, 2, and 3 can all produce motor neuron disease. Most paralytic disease is due to Poliovirus 1. Wild poliovirus serotypes 2 and 3 no longer circulate. Pakistan and Afghanistan continue to report cases of wild poliovirus 1 poliomyelitis. (13)

Poliovirus is transmitted by fecal-oral spread, and in epidemics, by pharyngeal spread. (14) 90-95% of poliovirus infections are asymptomatic. In less than 10%, a minor illness known as abortive polio follows an incubation period of 4-10 days. It can include symptoms of common viral infections. In some, there is a symptom-free interval of a few days, followed by CNS involvement. There are meningitic symptoms and signs, which may be followed by the destruction of anterior horn cell motor neurons and motor weakness. Only 0.1% of poliovirus infections lead to paralysis. (15, 16)

Viral replication in spinal motor neurons leads to cell death and paralysis of the muscle tissue supplied by the motor neurons. Cranial nerve involvement can lead to dysphagia, and thoracic muscle involvement can lead to respiratory insufficiency. (17)

The polio pandemic led to advances in vaccine science and the transformation of philanthropy, as well as to developments in rehabilitation medicine. Many of its survivors became leaders in the disability rights movement.

"We can be hopeful that similarly beneficial outcomes result from our current COVID-19 pandemic, whether that be an acceleration of research into therapeutics and vaccines, or improved preparedness for the next pandemic yet to emerge."

We can be hopeful that similarly beneficial outcomes result from our current COVID-19 pandemic, whether that be an acceleration of research into therapeutics and vaccines, or improved preparedness for the next pandemic yet to emerge.

Philip Zweig, a friend of Neonatology Today, has shared with us his Polio Pioneer card. He took part in a trial of a polio vaccine in 1954. In 1954, this would have been the trial of the Salk inactivated polio vaccine.

THE NATIONAL FOUNDATION FOR INFANTILE PARALYSIS

CERTIFIES THAT

Philip Zweig

HAS BEEN ENROLLED AS A

POLIO PIONEER

and this certificate of membership is
hereby presented for taking part in the first national tests
of a trial polio vaccine conducted during 1954.

Basil O'Connor PRESIDENT

ATTESTED

SCHOOL Woodbury

TOWN OR CITY Woodbury COUNTY Nassau STATE N. Y.

DATE 6/8/54 CHAIRMAN Carl Shapiro

THE NATIONAL FOUNDATION FOR INFANTILE PARALYSIS

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OPIOIDS and NAS
When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

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

I was exposed to opioids.

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

NAS is a temporary and treatable condition.

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

My mother may have a SUD.

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

My potential is limitless.

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

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National Perinatal Association

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NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

SAFE TO SLEEP®

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Unlocking Complexities of the Microbiome in the War on Viruses: Progenabiome and Colleagues Push Innovation in Combating COVID-19

Implications for COVID-19 and its relationship to the microbiome.

MALIBU, Calif., May 4, 2020 /PRNewswire/ -- Progenabiome is sharing gut microbiome research findings by next generation shotgun sequencing utilizing Kraken metagenomic analysis at the Digestive Disease Week (DDW) 2020 virtual meeting May 2-5. The California-based research lab was scheduled to present at DDW, the world's largest gathering of digestive disease health professionals with 14,000+ attending each year, however the meeting was cancelled due to the coronavirus pandemic. Data will now be shared on the DDW ePosters and ePapers site, available to access at no charge.

"Finding non-toxigenic Clostridium difficile (C.diff) in the gut flora of all 119 subjects tested by genetic sequencing raises the question whether C.diff is an innocent bystander or villain and if antibiotics should be used to kill something that is part of our microbial fingerprint," says Progenabiome CEO Sabine Hazan, MD, "this breakthrough in research challenges us to look beyond the traditional protocols to treat bacteria and viruses automatically with drugs. It also forces us to understand the balance of the microbiome that allows for immunity to occur."

Hazan has been a solo practice gastroenterologist and clinical trials investigator for 25+ years. She has participated in over 150 clinical trials for the pharmaceutical and nutrition industries and launched Progenabiome in 2018 to investigate the role of the gut microbiome in various diseases and conditions.

Strategically placed as a genetic sequencing lab, site, CRO, and now sponsor, Progenabiome has 39 ongoing clinical trials, including three COVID-19 studies through which the lab is validating testing, prophylaxis, and at-home treatment protocols for the novel coronavirus.

"A one-pill-solution is rarely the answer for everyone," argues Hazan, who believes medicine is as much an art as it is a science. She argues that physicians and patients need multiple options given the complexity of the interactions taking place inside us.

Progenabiome is also leading COVID-19 research with several innovative clinical trials in the pipeline. Having worked with Gilead as an investigator for their Harvoni treatment, she sees the approval of Remdesivir for COVID-19 as a step in the right direction, however she maintains that intravenously administered medication "is not a panacea." She argues, "this virus requires a solution for all" so further research of alternate options remains necessary. Like Hazan, many physicians maintain that more studies are needed for effective and accessible COVID-19 solutions, including further investigation of hydroxychloroquine (HCQ) and azithromycin (AZM) which have shown promise in COVID studies globally.

Dr. Alan Miller, president and CEO of Alta Pharmaceutical Research Center reiterates the need for more clinical research, saying, "We currently have only one FDA-approved medication for COVID-19 and that isn't enough." Dr. Miller has participated in 110 FDA-approved clinical trials and has helped bring several drugs to market including: Crestor, Zetia, Januvia, Uloric, Cialis, Repatha, Victoza, Trulicity, various insulins, and others.

However, concern over the extension of the QT interval has been highlighted as a potential cardiac side effect of HCQ, albeit azithromycin has a similar effect. Physician experts maintain that long-established HCQ, which has been approved for medical use in the U.S. since 1955, is very safe for the vast majority of patients, subject of course to utilizing the drugs within agreed parameters. Dr. Ami Ben-Artzi has treated thousands of patients with HCQ and says the rheumatology community considers HCQ safe with minimal side effects and concerns only in long-term use. He has 15 years experience at multiple institutions including NYU, UCLA, and presently, Cedars-Sinai Medical Center.

Dr. John Goldman, former Emory University professor and author of 50 articles, 35 chapters and 89 abstracts, has over 50 years experience treating patients with HCQ. He has prescribed tens of thousands of doses and has not evidenced adverse effects for G6PD or EKG. He describes HCQ as "a very safe drug"

Dr. Alon Steinberg, Progenabiome's Chief Medical Officer, argues "More data is needed to evaluate the risks and benefits of HCQ and AZM for COVID." As a leading cardiologist, he is particularly interested in visualizing EKG strips of COVID patients who receive treatment at home.

This seems to be backed up by the recent publication by Ehud Chorin and 12 other cardiologists on the QT interval in 84 patients treated with HCQ and azithromycin, which demonstrated that "there were no torsades de pointes events recorded, including in patients with severely prolonged QTc… Four patients died from multi-organ failure, without evidence of arrhythmia."

Dr. Thomas Borody, world-renowned leader in the clinical microbiota says, "I see these as important trials to enable us to determine whether we can stem the tide of infection, protect our frontline staff and start using the drugs we have to protect our global community. Time is of the essence." Borody is the founder of the Centre for Digestive Diseases, reviewer for several leading medical journals, and holds over 160 patents in areas including treatment of H.pylori, Crohn's, IBS, FMT and more.

Dr. Hazan and Dr. Borody are collaborating on several innovative studies including COVID-19 therapy protocols.

The two microbiome experts were previously set to present groundbreaking microbiome data at the Malibu Microbiome Meeting (MMM), originally scheduled for March 28-29. Now, they hope to share their research and COVID findings at the rescheduled MMM event on August 22-23 along with fellow leading physicians and academicians from around the world. Other MMM speakers include Drs. Paul Feuerstadt (Yale), Colleen Kelly (Brown), Sahil Khanna (Mayo Clinic), Jessica Allegretti (Harvard), Neil Stollman (UCSF), Scott Jackson (NIST), Howard Young (NIH), and more.
For more, visit
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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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- Invitation for special programming by the Section at the AAP's National Conference.
- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

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

The Section also accepts affiliate members (those holding masters or doctoral degrees or the equivalent in pharmacy

or other health science concentrations that contribute toward the discovery and advancement of pediatrics and who do not otherwise qualify for membership in the AAP). Membership application for affiliates: http://shop.aap.org/aap-membership/ then click on "Other Allied Health Providers" at the bottom of the page.

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

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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

CDC launches national viral genomics consortium to better map SARS-CoV-2 transmission

Rapid release of open coronavirus sequence data will help guide COVID-19 public health response, drive innovation and discovery, and advance understanding of this and future pandemics

Press Release

For Immediate Release: Friday, May 1, 2020
Contact: Media Relations
(404) 639-3286

CDC has kicked off the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) consortium, which will greatly expand the use of whole genome sequencing (WGS) of the COVID-19 virus.

This national network of sequencing laboratories will speed the release of SARS-CoV-2 sequence data into the public domain.

SPHERES will provide consistent, real-time sequence data to the public health response teams investigating cases and clusters of COVID-19 across the country. It will help them better understand how the virus is spreading, both nationally and in their local communities. Better data, in turn, will help public health officials interrupt chains of transmission, prevent new cases of illness, and protect and save lives.

"The U.S. is the world's leader in advanced rapid genome sequencing. This coordinated effort across our public, private, clinical, and academic public health laboratories will play a vital role in understanding the transmission, evolution, and treatment of SARS-CoV-2. I am confident that our finest, most skilled minds are working together to help us save lives today and tomorrow," said CDC Director Robert Redfield, M.D.

Tracking the COVID-19 virus as it evolves

Genomic sequence data can give unprecedented insight into the biology of SARS-CoV-2, the virus that causes COVID-19, and help define the changing landscape of the pandemic. By sequencing viruses from across the United States, CDC and other public health authorities can monitor important changes in the virus and use this information to guide contact tracing, public health mitigation efforts, and infection control strategies.

The SPHERES consortium is an ambitious effort to coordinate SARS-CoV-2 genome sequencing nationally, organizing dozens of smaller, individual efforts into a single, distributed network of laboratories, institutions and corporations. The consortium combines the expertise, technology, and resources of 40 state and local public health departments, several large clinical laboratories, and over two dozen collaborating institutions across the federal government, academia, and the private sector.

SPHERES will establish best practices and consensus data standards, acceler-

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first candle

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ate open data sharing, and establish a pool of resources and expertise to help bring cutting-edge technology to the national COVID-19 response.

SPHERES data open, shared

Consortium members share a commitment to rapid open sequence sharing. They plan to submit all useful sequence data into public repositories at the National Library of Medicine's National Center for Biotechnology Information (NLM/NCBI), the Global Initiative on Sharing Avian Influenza Data (GISAID), and other public sequence repositories. This will help ensure that that viral sequence data from across the United States is rapidly available for public health decision making and freely accessible to researchers everywhere.

Consortium members include:

Federal agencies and laboratories

Centers for Disease Control and Prevention, Office of Advanced Molecular Detections

Argonne National Laboratory

National Institute of Allergy and Infectious Diseases, Office of Genomics and Advanced Technology

National Institute of Standards and Technology

National Library of Medicine's National Center for Biotechnology Information

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

*Names of corporations are provided for information purposes only, and their inclusion here does not constitute an endorsement of the corporations or any of their commercial products or services by the U.S. Centers for Disease Control and Prevention.

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Walder Foundation

For the past six years, CDC's Office of Advanced Molecular Detection program has invested in federal and state public health laboratories to expand the use of pathogen genomics and other advanced laboratory technologies for infectious disease surveillance and outbreak response. The current consortium investment aims to save lives in the SARS-CoV-2 pandemic and prepare the United States and the world for future pandemic response.

To learn more about genomic sequencing or CDC's work in advanced molecular detection, visit https://www.cdc.gov/amd/

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

NT

NIH-supported research survey to examine impact of COVID-19 on rare diseases communityU.S. Funding for WHO

There is a unique impact on those afflicted by rare diseases

Thursday, May 7, 2020

For the millions of people living with a rare disease, the novel coronavirus disease COVID-19 presents challenges, from potential reduced access to needed medical care to possible heightened anxiety and stress. A new online survey launched by the *National Institutes of Health-supported Rare Diseases Clinical Research Network (RDCRN)* aims to find out how the COVID-19 pandemic is impacting individuals with rare diseases, their families and their caregivers. Results will help the rare disease research community shed light on the needs of people with rare diseases during the COVID-19 pandemic and other potential health crises, in addition to informing future research efforts.

The RDCRN, led by NIH's National Center for Advancing Translational Sciences (NCATS), in collaboration with nine other NIH Institutes and Centers, currently is made up of 20 recently funded clinical research consortia focused on better understanding how rare diseases progress and developing improved approaches for diagnosis and treatment. Scientists from different disciplines at hundreds of clinical sites around the world work together with about 140 patient advocacy groups to study more than 200 rare diseases, including immune system disorders, heart, lung and kidney disorders, brain development diseases and more.

"As a leader in fostering innovative, collaborative clinical research to improve the lives of individuals with rare diseases, the RDCRN is uniquely positioned to carry out a survey like this," said Anne Pariser, M.D., director of the NCATS Office of Rare Diseases Research, which oversees the RDCRN. "The network has the necessary infrastructure, disease expertise, and access to patients through patient organizations to find answers to important questions."

Though individually rare, affecting only a few hundred to several thousand people, rare diseases collectively affect an estimated 30 million people in the United States. Many rare diseases are life-threatening, and about half of those affected are children.

The research survey, developed and led by the RDCRN Data Management and Coordinating Center at Cincinnati Children's Hospital Medical Center, is one of the first efforts nationwide to quantify the impact of a health crisis on the rare disease community. It is seeking responses from at least 5,000 people with a rare disease or caring for someone who has a rare disease. The survey will be distributed online to participants. In addition, some RDCRN-funded scientists plan to incorporate survey results into natural history studies, which follow patients to chart the progression and course of a disease. The survey is open to anyone with a rare disease, along with family and caregivers, and is not limited to the diseases studied within the RDCRN.

The impetus for the survey began through conversations among network researchers and patient advocacy organizations. Patients, families and caregivers were worried about how COVID-19 might affect them.

"People affected by a rare disease, and families and caregivers, initially asked how to avoid the virus," said RDCRN Program Director Tiina Urv, Ph.D. "Then they became concerned about access to medicines and maintaining medical care during the pandemic, and the status of clinical trials. They were concerned about meeting the medical challenges that they face every day. We were hearing enough anecdotally that we wanted to get a clearer picture of the problem."

As consortia scientists and clinicians engaged with patient groups and patients, sharing information and advice, a plan came together over several weeks to conduct a scientific research study to gauge the impact of COVID-19 on those in the rare disease community.

Questions in the research survey focus on a range of topics, from a patient's ability to get proper care for a rare disease or condition to mental and emotional health. The survey asks what their concerns are as a person with a rare disease, or as family members and caregivers. Groups of people with different rare diseases and the community will have different needs and concerns, whether it is how to get needed medications or physical therapy to navigating an emergency room in a medical crisis.

"We hope the study questionnaire will help us better estimate the proportion of rare disease patients who have been diagnosed with COVID-19, and find out how they are affected whether or not they had COVID-19," said project principal investigator Maurizio Macaluso, M.D., Dr.P.H. at Cincinnati Children's. "This survey provides an opportunity for the rare disease community to get timely data on the challenges they face."

The researchers also think the survey data may help them tease out answers to many other questions. For example, do some subgroups of people with rare disease fare better or worse with the virus? Are certain individuals more prone to infection because of their underlying rare condition or disease?

Ultimately, the researchers hope the survey will help determine how the RDCRN can respond to the rare disease community's concerns by providing information and advice through its network of medical experts and patient advocacy groups.

"This survey is a great example of how the consortia and patient groups are working together as a network to make a difference for the entire rare disease community," Urv said.

For more information on the RDCRN COVID-19 survey, including how to participate, go to https://www.rarediseasesnetwork.org/COVIDsurvey(link is external). To learn more about the RDCRN, see https://ncats.nih.gov/rdcrn.

In addition to NCATS, other NIH funding for the RDCRN comes from the National Institute of Allergy and Infectious Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute of Neurological Disorders and Stroke, the National Heart, Lung, and Blood Institute, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Dental and Craniofacial Research, the National Institute of Mental Health and the Office of Dietary Supplements.

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About the National Center for Advancing Translational Sciences (NCATS): NCATS conducts and supports research on the science and operation of translation — the process by which interventions to improve health are developed and implemented—to allow more treatments to get to more patients more quickly. For more information about NCATS and its programs, visit https://ncats.nih.gov.

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

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###

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NT

Investigational ChAdOx1 nCoV-19 vaccine protects monkeys against COVID-19 pneumonia

Study provided data for clinical testing to commence.

Media Advisory

Friday, May 15, 2020

What

A single dose of ChAdOx1 nCoV-19, an investigational vaccine against SARS-CoV-2, has protected six rhesus macaques from pneumonia caused by the virus, according to National Institutes of Health scientists and University of Oxford collaborators. SARS-CoV-2 is the virus that causes COVID-19. The researchers posted their data to the preprint server bioRxiv(link is external). The findings are not yet peer-reviewed but are being shared to assist the public health response to COVID-19. Based on these data, a Phase 1 trial of the candidate vaccine began on April 23 in healthy volunteers in the United Kingdom.

The vaccine was developed at the University of Oxford Jenner Institute. It uses a replication-deficient chimpanzee adenovirus to deliver a SARS-CoV-2 protein to induce a protective immune response. ChAdOx1 has been used to develop investigational vaccines against several pathogens, *including a closely related coronavirus that causes Middle East respiratory syndrome* (MERS). The scientists quickly adapted the platform to SARS-CoV-2 when the first cases of COVID-19 emerged. They showed that the vaccine rapidly induced immune responses against SARS-CoV-2 in mice and rhesus macaques. They then conducted vaccine efficacy testing on the macaques at NIAID's Rocky Mountain Laboratories (RML) in Hamilton, Montana. Six animals that received the investigational vaccine 28 days before being infected with SARS-CoV-2 were compared with three control animals that did not receive the vaccine. The vaccinated animals showed no signs of virus replication in the lungs, significantly lower levels of respiratory disease and no lung damage compared to control animals.

Oxford University has entered into a partnership with UK-based global biopharmaceutical company AstraZeneca for the further development, large-scale manufacture and potential distribution of the vaccine.

Article

N van Doremalen et al. Single dose ChAdOx1 nCoV-19 vaccination reduces SARS-CoV-2 replication and prevents pneumonia in rhesus macaques(link is external).

Who

Vincent Munster, Ph.D., chief of the Virus Ecology Unit in NIAID's Laboratory of Virology, is available to comment on this study.

Contact

To schedule interviews, please contact Ken Pekoc, (301) 402-1663, *kpekoc@niaid.nih.gov*(link sends e-mail).

This press release describes a basic research finding. Basic research increases our understanding of human behavior and biology, which is foundational to advancing new and better ways to prevent, diagnose, and treat disease. Science is an unpredictable and incremental process — each research advance builds on past discoveries, often in unexpected ways. Most clinical advances would not be possible without the knowledge of fundamental basic research.

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

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NT

Coordinated strategy to accelerate multiple COVID-19 vaccine candidates is key, NIH experts say

Parallel development is key to the multiple

development of vaccine candidates.

Media Advisory

Monday, May 11, 2020

What

A harmonized and collaborative approach to the clinical testing, scale-up and distribution of candidate vaccines to prevent COVID-19 is essential, scientific leaders write in a perspective published today in Science. As the COVID-19 pandemic continues, government, industry and academia have introduced a variety of vaccine candidates. The authors note that more than one effective vaccine approach likely will be required to successfully protect the global community from SARS-CoV-2, the virus that causes COVID-19. They describe a strategic approach to research and development that would generate essential data for multiple vaccine candidates in parallel.

National Institutes of Health Director Francis S. Collins, M.D., Ph.D., National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony S. Fauci, M.D., Lawrence Corey, M.D., professor in the Vaccine and Infectious Disease Division at the Fred Hutchinson Cancer Research Center in Seattle, and John R. Mascola, M.D., director of NIAID's Vaccine Research Center are the co-authors of the commentary.

The perspective discusses diverse vaccine candidates and key considerations for development, including the characteristics of various vaccine platforms in terms of prior commercial experience, scalability, and the types of immune responses generated. It also emphasizes that no single vaccine or vaccine platform is likely to meet the global need, highlighting the need for a coordinated strategic approach to vaccine development.

The authors stress that researchers need to learn more about what constitutes a durable protective immune response against COVID-19. They review considerations for vaccine efficacy trials, explaining how trials for several candidate vaccines can be conducted in parallel to generate essential safety and efficacy data and accelerate the licensure and distribution of COVID-19 vaccines. The authors propose specific approaches to harmonizing the clinical testing of multiple vaccine products, including using common clinical trials designs, clinical endpoints, standardized immune assays and a common Data Safety and Monitoring Board.

The authors emphasize that developing COVID-19 vaccines will require unprecedented cooperation from governments, academic institutions, industry, and global philanthropic partners. The ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) public-private partnership spearheaded by NIH aims to facilitate such collaboration with discussions and collaborations on trial designs and data sharing.

Protecting the entire global community from COVID-19 through vaccination will require significant manufacturing capacity, according to the authors. They emphasize the need to fund the necessary biomanufacturing infrastructure and note possible hurdles in the eventual delivery of vaccines, including cost, distribution systems and cold chain requirements. The authors conclude that strategic collaboration among public and private sectors to effectively accelerate COVID-19 vaccine development is essential.

Article

Corey et al. A Strategic Approach to COVID-19 Vaccine R&D. Science. DOI: 10.1126/science.abc5312 (2020).

Who

NIH Director Francis S. Collins, M.D., Ph.D., NIAID Director Anthony S. Fauci, M.D., and NIAID Vaccine Research Center Director John Mascola, M.D., are available to provide comment.

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301-402-1663

To schedule interviews with Dr. Collins NIH - News Media Branch*(link sends e-mail)*
301-496-5787

NT

Study to determine incidence of novel coronavirus infection in U.S. children begins

NIH-funded study also will ascertain percentage of infected children who develop COVID-19.

Monday, May 4, 2020

A study to help determine the rate of novel coronavirus infection in children and their family members in the United States has begun enrolling participants. The study, called Human Epidemiology and Response to SARS-CoV-2 (HEROS), also will help determine what percentage of children in-

fected with SARS-CoV-2, the virus that causes COVID-19, develop symptoms of the disease. In addition, the HEROS study will examine whether rates of SARS-CoV-2 infection differ between children who have asthma or other allergic conditions and children who do not. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is sponsoring and funding the HEROS study.

"One interesting feature of this novel coronavirus pandemic is that very few children have become sick with COVID-19 compared to adults," said NIAID Director Anthony S. Fauci, M.D. "Is this because children are resistant to infection with SARS-CoV-2, or because they are infected but do not develop symptoms? The HEROS study will help us begin to answer these and other key questions."

The HEROS study team will rapidly enroll 6,000 people from 2,000 U.S. families already participating in NIH-funded pediatric research studies in 11 cities. Study participants will include both healthy children and children with asthma or other allergic conditions. The study team will prospectively follow these children and their families for six months to determine who gets infected with SARS-CoV-2, whether the virus is transmitted to other family members, and which family members with the virus develop COVID-19.

Leading the HEROS study is Tina V. Hartert, M.D., M.P.H. Dr. Hartert is director of the Center for Asthma and Environmental Sciences Research, vice president for translational research, the Lulu H. Owen Chair in Medicine and a professor of medicine at the Vanderbilt University School of Medicine in Nashville.

"So far, data on the extent of SARS-CoV-2 infection in the U.S. population have been limited to people who physically interact with the healthcare system: those who are tested—especially those who test positive—and those with severe disease," said Dr. Hartert. "These data provide real-time guidance in a setting of limited test availability, but they don't enable us to understand the full extent of SARS-CoV-2 infection in the entire population. The HEROS study will help fill this knowledge gap and inform public health interventions."

Preliminary evidence suggests that having an allergic condition paradoxically may reduce a person's susceptibility to SARS-CoV-2 infection and severe COVID-19 disease. A NIAID-funded study(link is external) recently examined upper and lower airway cells for the expression of ACE2, the gene that codes for the receptor that the coronavirus uses to infect cells. ACE2 expression is necessary for a cell to make this receptor, but additional steps also are involved. In both children and adults, respiratory allergy, asthma and controlled allergen exposure were associated with significantly reduced ACE2 expression. The expression of ACE2 was lowest in people with high levels of both asthma and sensitivity to allergens.

The HEROS study will further clarify whether reduced ACE2 gene expression in airway cells of children with allergic diseases correlates with a lower rate of SARS-CoV-2 infection and COVID-19.

The study will be conducted completely remotely. Every two weeks, a caregiver in participating families will collect nasal swabs from the child who is the primary study participant and all other family members who are enrolled in the study, and will mail the samples to a laboratory for analysis. On the same day as the nasal swab, the caregiver will complete online questionnaires about each participant's current symptoms, social distancing practices, recent activities outside the home, and recent exposure to people who are sick.

In addition, if any member of the household develops symptoms of a viral illness, the caregiver will fill out another online questionnaire designed to determine the likelihood that the illness is COVID-19.

If COVID-19 is likely, the caregiver will collect nasal swabs from all study participants and a stool sample from the symptomatic participant within 24 hours.

Laboratory analyses of nasal swabs will test for SARS-CoV-2 and assess gene expression in the collected airway-surface cells. Investigators hope that these gene expression studies will reveal patterns that correlate with higher or lower risk of infection, COVID-19 symptom development and SARS-CoV-2 transmission.

A caregiver also will collect a blood sample from each study participant two weeks, 18 weeks and 24 weeks after enrollment as well as three weeks after the family's first likely case of COVID-19, if there is one. The blood will be collected using a new, nearly painless device that extracts a small quantity of blood through the surface of the skin. The blood will be analyzed for antibodies to SARS-CoV-2 once an appropriate antibody test becomes available.

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Reference

DJ Jackson, et al. Association of Respiratory Allergy, Asthma and Expression of the SARS-CoV-2 Receptor, ACE2(link is external). Journal of Allergy and Clinical Immunology DOI: 10.1016/j.jaci.2020.04.009 (2020)

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NT

Commemorating Smallpox Eradication – a legacy of hope, for COVID-19 and other diseases

WHO commerates the erradication of Smallpox

8 May 2020 News release

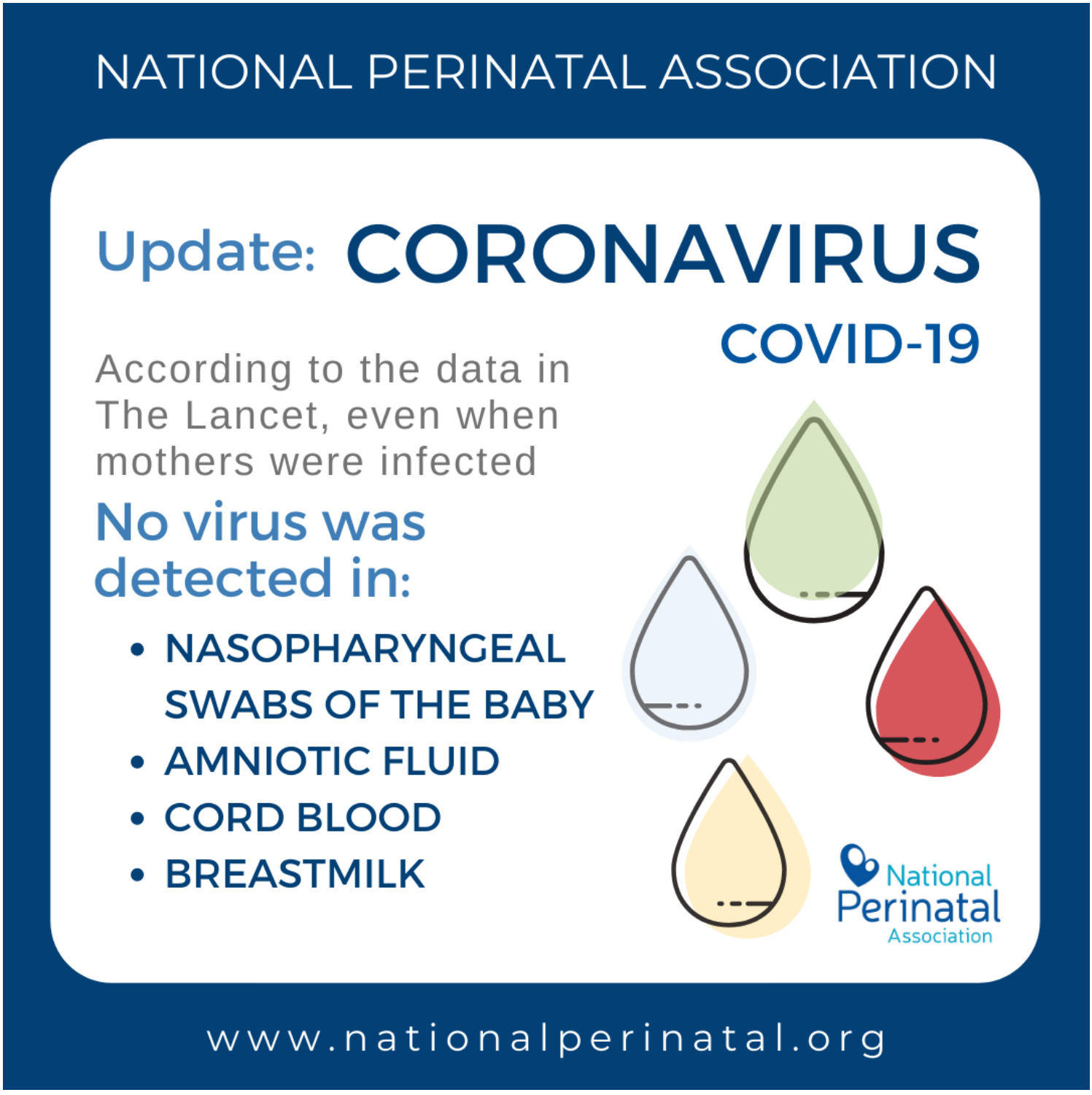
On 8 May 1980, the 33rd World Health Assembly officially declared: 'The world and all its peoples have won freedom from smallpox.'

The declaration marked the end of a disease that had plagued humanity for at least 3 000 years, killing 300 million people in the 20th century alone.

It was ended, thanks to a 10-year global effort, spearheaded by the World Health Organization, that involved thousands of health workers around the world to administer half a billion vaccinations to stamp out smallpox.

The US$ 300m price-tag to eradicate smallpox saves the world well over US$ 1 billion every year since 1980.

Speaking at a virtual event hosted at WHO-HQ, involving key players in the eradication effort, WHO Director-General, Dr Tedros Adhanom Ghebreyesus said, "As the world confronts the COVID-19 pandemic, humanity's victory over smallpox is a reminder of what is possible when nations come together to fight a common health threat."



The world got rid of smallpox thanks to an incredible demonstration of global solidarity, and because it had a safe and effective vaccine. Solidarity plus science equalled solution!

Dr Tedros highlighted that smallpox eradication also offers hope for efforts to eliminate other infectious diseases, including polio, which is now endemic in just two countries. To date, 187 countries, territories and areas have been certified free of Guinea worm disease, with seven more to go. And the fight against malaria has so far resulted in 38 countries and territories certified as malaria-free. In the case of Tuberculosis (TB), 57 countries and territories with low TB incidence are on track to reach TB elimination.

At the event, Dr Tedros unveiled a commemorative postal stamp to recognize the global solidarity that drove the initiative and honour the efforts of health workers who ensured its success.

The stamp, developed by the United Nations Postal Administration (UNPA), in collaboration with WHO, signifies what national unity and global solidary can achieve. Numerous countries, such as Guinea, India, Nigeria, Philippines, Togo and others issued smallpox stamps to show support for, and raise awareness about WHO's Intensified Smallpox Eradication Programme launched in 1967.

WHO Regional Director for Africa, Dr Matshidiso Moeti's earliest memories of smallpox is of her father. "I was visiting WHO headquarters, and I saw a photo of my Dad, standing with the other experts on the Global Commission. I remember him going out, doing follow-up visits with patients. He often would go with a driver and disappear into the bush for days. I felt in awe of his tireless work. The strategies used to eradicate smallpox still apply today."

"Lessons learned from smallpox are used today to respond to disease outbreaks. For example, house-to-house active case-finding underpins the polio eradication programme, and ring vaccination of contacts is helping to combat the spread of the Ebola virus disease. Similarly, surveillance, case-finding, testing, contact-tracing, quarantine, and communication campaigns to dispel misinformation are central to controlling COVID-19, " explained David Heymann, Professor of Infectious Disease Epidemiology at The London School of Hygiene & Tropical Medicine (LSHTM) and Distinguished Fellow, Global Health Security at Chatham House, London.

Following smallpox eradication, WHO and UNICEF launched the Expanded Programme on Immunization, under which 85% of the world's children are vaccinated and protected from debilitating diseases.

With the potential of a COVID-19 vaccine ahead, ensuring sufficient supplies and reaching people in hard to reach places is a high priority. Addressing vaccine hesitancy poses a significant challenge to stop the virus. Access to accurate public health information and education is critical to ensure that the public has the facts to keep themselves and others safe.

To permanently commemorate the eradication of smallpox and the lessons learned on a global scale, rather than every 10-years, WHO is calling museums, exhibition companies, designers, curators and associations to develop an immersive, interactive and educational exhibition on smallpox and its relevance for COVID-19 and global health security. The exhibition, which will be unveiled later this year, will promote a better understanding of public health and empower people to keep informed and safe during a pandemic.

Notes to the media

Smallpox stamp

The smallpox stamp is in the denomination of CHF 1,70. It was designed by Sergio Baradat (United Nations) in collaboration with the World Health Organization and is available for purchase at unstamps.org. The stamp can be used to mail postcards and letters around the world, provided that they are sent from the UN headquarters in New York, Geneva or Vienna respectively.

Smallpox Eradication dates

On 9 December 1979, a global commission certified that smallpox had been eradicated, and this certification was officially accepted by the 33rd World Health Assembly in 1980.

Museum Exhibition

Exhibition design companies, museums, curators and other companies/organizations in this field are invited to express their interest to develop an immersive, educational exhibition on smallpox and its relevance for COVID-19 and global health security by writing to *privatesectorpartners@who.int*

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Neonatology Solutions NICU Directory: The Directory is finally completed!

Scott Snyder, MD

After many months of data compilation, we are pleased to announce that the Neonatology Solutions U.S. NICU Directory is finally complete! To our knowledge, this is the only online resource to list all Level 2, 3, and 4 NICUs in the United States. The final tally is 1,359 NICUs from sea to shining sea. State summaries are also now included, which contain not only NICU information but also Neonatology Practice Groups and Fellowship programs. Additional resource links provide connections to state-based websites, including medical associations, collaboratives, and public health sites. Where known, we have included contact information for medical and nursing directors, as well as current job openings for Neonatologist positions, for which there are presently 86 listed on the site.

Whenever possible, we have attempted to classify NICUs according to the Leveling Criteria outlined in the AAP Guidelines for Perinatal Care, 8th Edition (2017). In our discovery and data collection process, it was noted that some state registries and NICUs utilize a slightly different criterion and leveling process. While we have attempted to rectify this with the information available within various program websites, we recognize that we may not have characterized every NICU based on their true capabilities. As such, we encourage medical directors or practicing neonatologists to visit the site to check the completeness and accuracy of the data. The total number of NICUs may fluctuate if we receive differing information. As always, we appreciate your help by notifying us of any errors or omissions via the easy-to-use links on the website or email me directly at Scott@NeonatologySolutions.com.

"After many months of data compilation, we are pleased to announce that the Neonatology Solutions U.S. NICU Directory is finally complete! To our knowledge, this is the only online resource to list all Level 2, 3, and 4 NICUs in the United States. "

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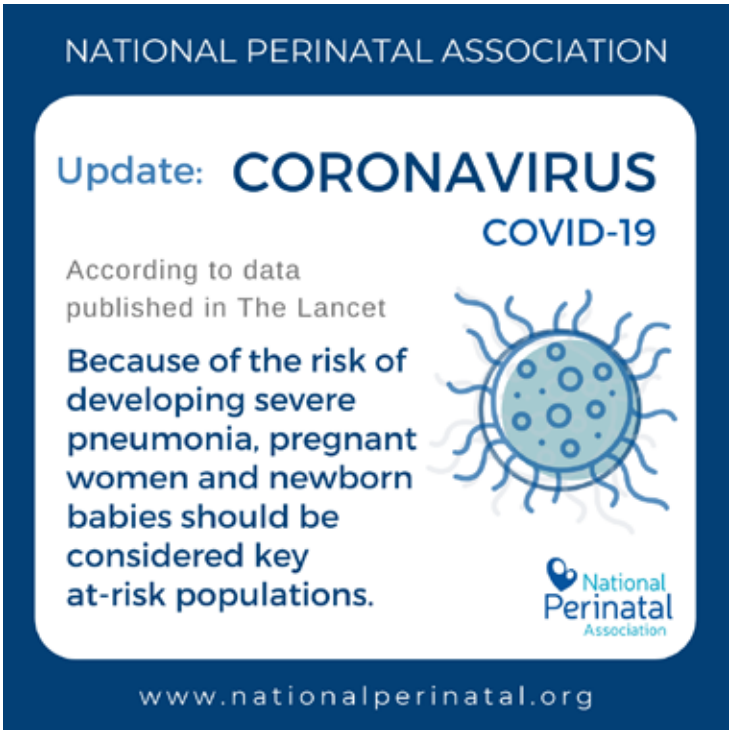


We sincerely hope this information is useful to colleagues in our field. Please do not hesitate to reach out if you have ideas for additional information that we can include to make this a valuable and FREE resource. Your feedback is welcome!

Stay healthy!"

https://neonatologysolutions.com/explore-nicus-and-programs/

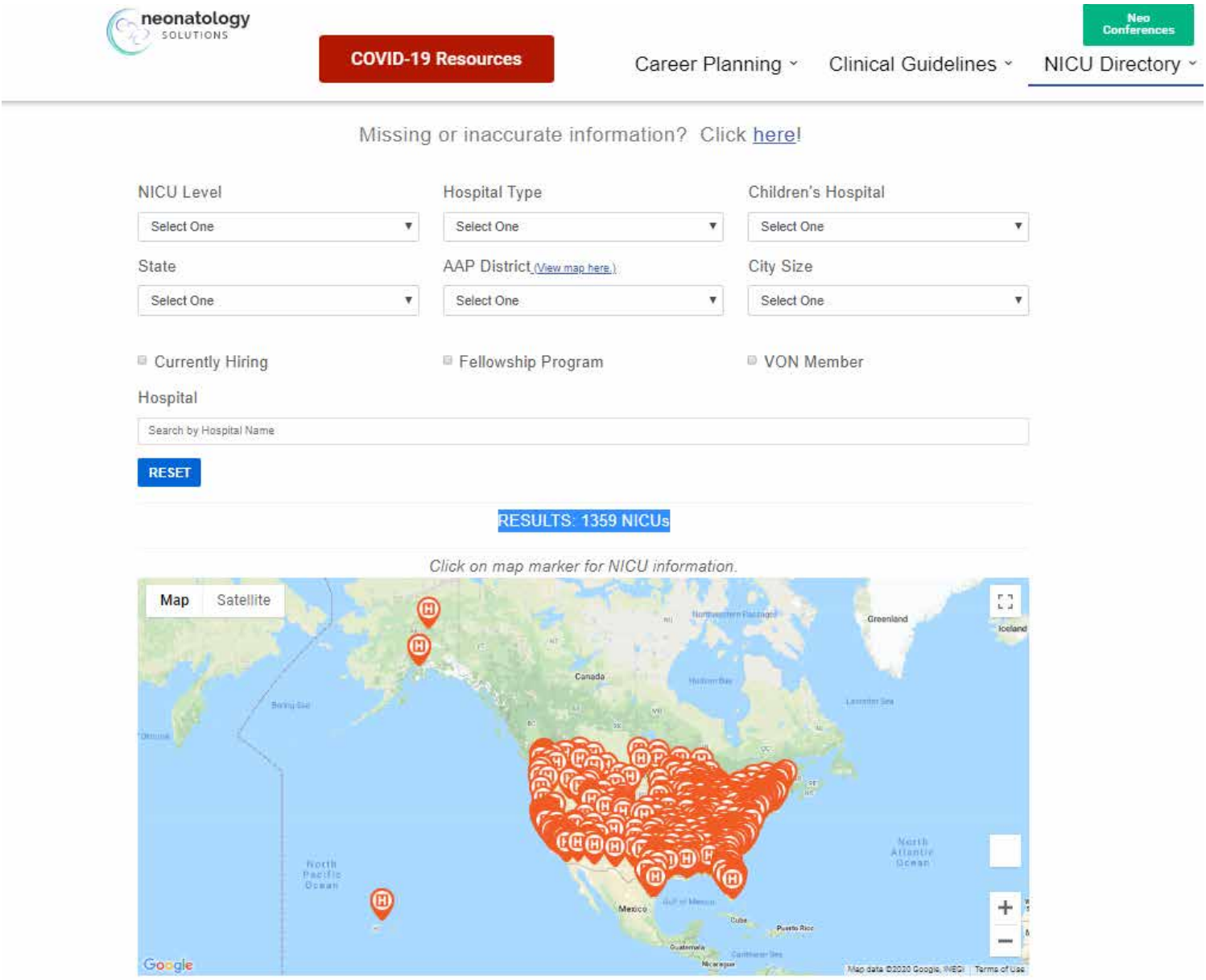
Thank you!!

References:

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

The author is a principal of Neonatology Solutions, LLC.

NT



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NCfIH National Coalition for Infant Health

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- **Clear, science-based nutrition guidelines** for pregnant and breastfeeding mothers
- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

www.infanthealth.org

Peer Reviewed

The Genetics Corner: A Consultation for Neonatal Diabetes Mellitus Reveals Uniparental Disomy 6

Subhadra Ramanathan MS, MSc, Matthew Wood MD, Robin Dawn Clark MD

Case History:

A small for gestational age female infant was transferred to the NICU at Loma Linda University Children's Hospital at seven days of age for persistent hyperglycemia and neonatal diabetes mellitus. Persistent maternal vaginal bleeding was reported from 2 months' gestation. The mother reported nausea and hyperemesis throughout the pregnancy and a poor gestational weight gain of 11 lbs. Intra-uterine growth retardation (IUGR) was recognized late in the third trimester.

"The mother reported nausea and hyperemesis throughout the pregnancy and a poor gestational weight gain of 11 lbs. Intra-uterine growth retardation (IUGR) was recognized late in the third trimester. "

The baby was delivered by induced vaginal delivery at 37w 3d for IUGR to a 28-year-old G6 P2-3 SAb1 TAb2 mother.

Birth weight:	4 lb 11.1 oz (2130 g) (3rd percentile)
Birth length:	17.5" (44.5 cm) (8th percentile)
Birth head circumference	31.8 cm (31.8 cm) (15th percentile)

After delivery at an outside hospital, blood glucose values were initially stable in the 70s, but repeat checks showed elevated blood sugars trending up above 200. A continuous insulin infusion did not control the hyperglycemia. Blood glucose values ranged from >500 to <70 in spite of frequent adjustments to insulin infusion. C-peptide was undetectable while on an insulin infusion. The patient was transferred to our facility for endocrinology consult and further management.

Under endocrinology direction, insulin infusion therapy transitioned to oral glyburide. After discontinuation of insulin infusion and prior to initiation of glyburide, the C-peptide level was detectable but low, in spite of rising blood sugar levels. There was no evidence of multiple common diabetes-related autoantibodies. Due to elevated blood sugars, glyburide dosing was increased, and subcutaneous insulin glargine was started. While on both insulin glargine and glyburide, blood sugars remained labile, with both high and low blood sugar values. Insulin glargine was discontinued, and glyburide was increased further under endocrinology direction. At this time, blood glucose is more stable but elevated at 100-300.

Genetics Evaluation:

Because of restrictions due to the coronavirus pandemic, this evaluation was done at a distance. The NICU team uploaded photos of the baby into the Media tab of her electronic medical record. Examination of these photographs revealed a thin infant with deep infraorbital creases, macroglossia with a long, protruding tongue, mild micrognathia, thin upper lip, and incomplete helical folds of the right external ear. She had redundant periumbilical skin, which gave the impression that a small umbilical hernia had recently been reduced. She had asymmetric growth retardation with decreased subcutaneous tissue, wrinkled skin, and a relatively preserved head circumference. An echocardiogram was normal; an ultrasound of the abdomen showed normal pancreas.

The clinical history and physical findings suggested transient neonatal diabetes mellitus caused by paternal uniparental disomy for chromosome 6 (patUPD6). Chromosome microarray analysis was pending at that time, and requests for other genetic tests were put on hold until the microarray results were available. In a few days, the microarray results confirmed uniparental isodisomy 6: arr(X)x2,(6)x2 hmz. Methylation studies were not done, but the phenotype was consistent with UPD6 of paternal origin. No further genetic testing was ordered.

"The clinical history and physical findings suggested transient neonatal diabetes mellitus caused by paternal uniparental disomy for chromosome 6 (patUPD6)."

Discussion and Counseling:

The diagnosis of transient neonatal diabetes mellitus due to paternal uniparental disomy 6 (6q24-TNDM) explains this child's low birth weight and macroglossia as well as her neonatal diabetes. The cardinal features of 6q24-TNDM are severe intrauterine growth retardation, neonatal hyperglycemia, which usually starts in the first week of life in a term infant, dehydration, and absence of ketoacidosis. The low birth weight is likely caused by the lack of insulin in utero. Insulin is a major growth factor during fetal life. Macroglossia and umbilical hernia are common. Our patient's clinical presentation and chromosome microarray test results are consistent with 6q24-TNDM due to paternal isodisomy for chromosome 6.

The "transient" neonatal diabetes mellitus associated with 6q24-TNDM lasts three months on average but can persist until 18 months. Insulin is usually required initially, but the need for it gradually declines over time. Intermittent episodes of hyperglycemia may occur in childhood, particularly during illnesses, during which the child should be closely monitored. Diabetes mellitus may recur in adolescence or later in adulthood. Intelligence and growth

are usually normal. However, the long-term outcomes are still not completely known

Neonatal or congenital diabetes mellitus (NDM) is rare, with an incidence of about 1/90,000-160,000 live births. There are over 20 known causes for NDM, which can be classified into transient, permanent, and syndromic forms. In a recently published study from the United Kingdom involving 1020 patients, genetic testing detected a causal genetic etiology in more than 80% of infants diagnosed with diabetes before six months of age (de Franco E et al., 2015). Mutations in the potassium channel genes are the most common cause of permanent neonatal diabetes mellitus.

A genetic aberration usually causes transient neonatal diabetes mellitus at the imprinted locus on chromosome 6q24 (6q24-TNDM). Genomic imprinting refers to the differential expression of genes based on parent-of-origin, usually mediated by DNA methylation, which silences gene expression in one of the alleles.

Three distinct mechanisms cause 6q24-TNDM by overexpression of the imprinted genes PLAGL1 and HYMAI at chr6q24, which are normally expressed only on the paternally derived chromosome 6

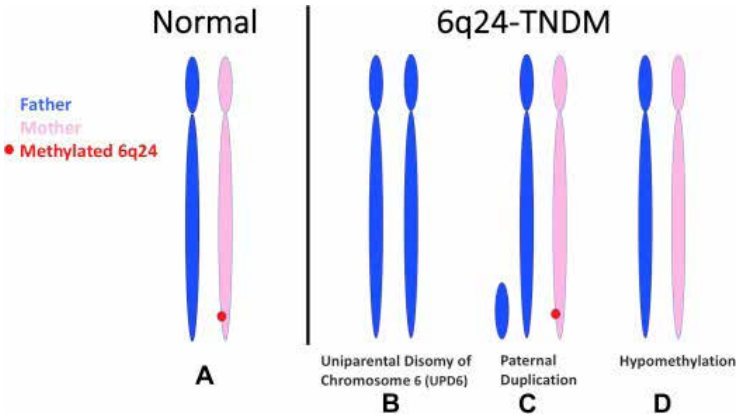

Figure 1 from Lemelman MB, Letourneau L, Greely SAW, 2018).

A- Normal biparental disomy of chromosome 6: active genes are expressed on the paternal copy of chromosome 6, silenced (imprinted) genes are not expressed on the maternal copy of chromosome 6

B- Uniparental disomy of chromosome 6: both copies of chromosome 6 are derived from the father, which produces two active copies of these genes without a maternally derived copy of chromosome 6.

C- Duplication of the paternal allele of the imprinted region on chr 6q24: two active copies of these genes on the paternal chromosomes, one inactive (imprinted) copy on the maternally derived copy.

D- Loss of maternal methylation (hypomethylation) of the imprinted region on chr 6q24: the maternally derived copy is active rather than silenced.

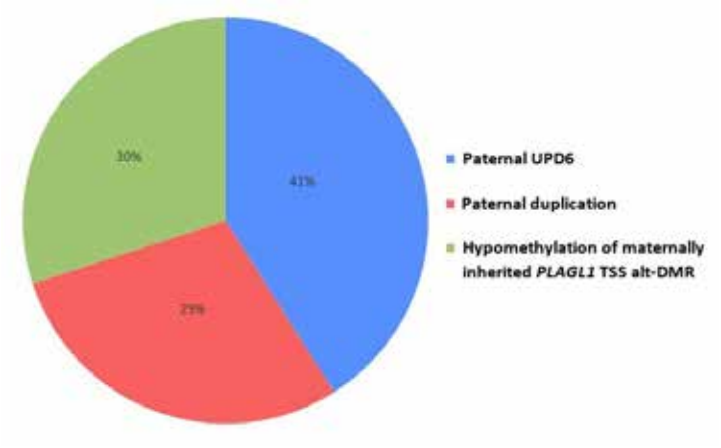

Figure 2: Distribution of the different genetic mechanisms causing 6q24-TNDM, from GeneReviews on 6q24-TNDM

Chromosome microarray analysis using SNP (single nucleotide polymorphism) genotyping can detect uniparental isodisomy as well as a duplication of 6q24.

The microarray test detected isodisomy of chromosome 6 in our patient. The likely mechanism was "monosomy rescue," in which monosomy for chr 6 in the egg was compensated for by post-zygotic mitotic duplication of the paternal chr 6, leading to complete isodisomy of the paternal chr 6. Monosomy 6 is not compatible with life, but after diploidy has been restored, the embryo can continue to develop. Therefore, paternal UPD "rescues" an embryo that would not have been viable otherwise (Figure 3).

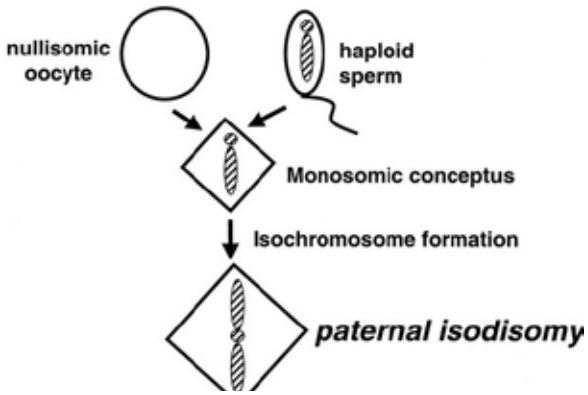

Figure 3: Monosomy rescue through isochromosome formation (adapted from Shaffer LG et al., 2001)

Practical applications:

1. Consider 6q24-TNDM when a small for gestational age infant presents with macroglossia and neonatal diabetes.
2. Recognize that the "transient" nature of TNDM, may still take

months to resolve.

3. A chromosome microarray can identify most cases of 6q24-TNDM. However, methylation studies of chromosome 6, which may require parental blood samples, can identify all three major causes.
4. Genetic testing informs the treatment of the various subtypes of NDM. A clear etiology and diagnosis clarifies the natural history, prognosis, and risks for developing related disorders.

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Your Pregnancy and Substance Use

4 Things you can do to improve your health and lower your risk for complications

Get Prenatal Care

Start early. Go to all your visits. Empower yourself with information so you can make smart decisions. Build relationships with providers who understand Substance Use Disorders (SUDs) and know how to help. Partner with them to reach your goals. But remember, you do not need to be abstinent from substance use to get care. Go now.

Reduce Your Use

There are simple things you can do to limit the harm substances might do.

- Use fewer substances
- Use smaller amounts
- Use less often
- Learn how to use safer

Reducing or quitting smoking is a good place to start. Set your goals, then ask for help.
One of the best things you can do is to stop using alcohol. We know that even small amounts are risky. And when combined with benzos and opioids, alcohol can kill.

Use Opioid Agonist Therapy (OAT) if you are opioid dependent

Methadone and Buprenorphine (Subutex® or Suboxone®) are the "Standard of Care" during pregnancy because they:

- Eliminate the risks of illicit use
- Reduce your risk for relapse
- Can be a positive step towards recovery

Take Good Care of Yourself

You deserve a healthy pregnancy & childbirth.

- Eat healthy and take your prenatal vitamins
- Find the right balance of rest and exercise
- Surround yourself with people who care

Your Health Matters

Academy of Perinatal Harm Reduction
www.perinatalharmreduction.org

National Perinatal Association
www.nationalperinatal.org

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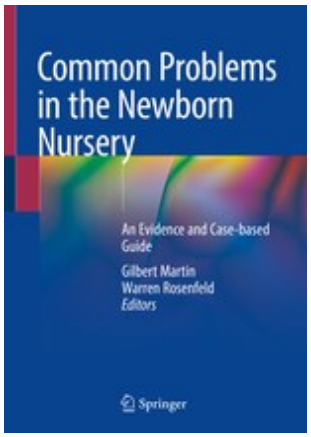
Editors: **Martin**, Gilbert, **Rosenfeld**, Warren (Eds.)



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COVID-19 & Infant Health

Susan Hepworth, Suzanne Staebler, DNP, APRN, NNP-BC

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

Susan Hepworth interviews Suzanne Staebler on the reality of proviing care during the pandemic.

A: How are infants affected by COVID-19?

Dr. S: NICUs are starting to see babies born to COVID-positive mothers. Some of these babies may also test positive. The mothers are sick, but many times the babies have no symptoms. These babies still require isolation and one-on-one staffing. No visitors.

"Some of these babies may also test positive. The mothers are sick, but many times the babies have no symptoms. These babies still require isolation and one-on-one staffing. No visitors."

Generally, you see infants and children contracting COVID less frequently and not having as difficult a time with it as older adults do. One theory says that may be because of all the vaccinations young children receive. Their immune systems are bolstered.

How is work in the neonatal intensive care unit different now?

Dr. S: We wear masks in the unit, of course, but also anywhere inside the building now. We could come in contact with another provider who's been in a COVID room and may have the disease on their scrubs or lab coat. We can't risk exposing the infants.

Every night I'm at home putting my N95 in the oven at 350 de-

grees to sterilize it for the next day.

Then there are the shortages you hear about. I was in the middle of the newborn nursery the other day and went to sanitize my hands—no hand gel. So I had to leave the unit, go down the hall and wash my hands, then come back.

What is the link between COVID-19 & RSV?

Dr. S: We're talking about respiratory syncytial virus, the leading cause of hospitalization for children under age one. The same babies at risk for RSV are vulnerable to severe COVID. That includes infants with underlying conditions, especially respiratory conditions. If they contract COVID, they struggle more than other infants.

COVID precautions are the same steps families take to protect their premature or at-risk infant from RSV. Limiting visitors, not taking the baby in public places, religiously washing hands, and sterilizing.

Even then, it's hard. You can't put a face mask on a preemie. The rest of the world now has a glimpse of what preemie parents go through during RSV season.

"Even then, it's hard. You can't put a face mask on a preemie. The rest of the world now has a glimpse of what preemie parents go through during RSV season."

What can policymakers do to protect infants and their families right now?

Dr. S: They can prevent what's preventable. The last place you want to take a preemie right now is an ER.

Specifically, I mean improving access to preventive RSV treatment. That could limit avoidable hospitalizations and conserve hospital resources needed for COVID. And they can increase the availability of donor breastmilk to boost babies' immunities. That way, if infants are exposed, the severity of disease won't land them in the hospital.

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Disclosures: The author does not have any relevant disclosures.

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National Coalition for Infant Health Values (SANE)

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

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

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

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

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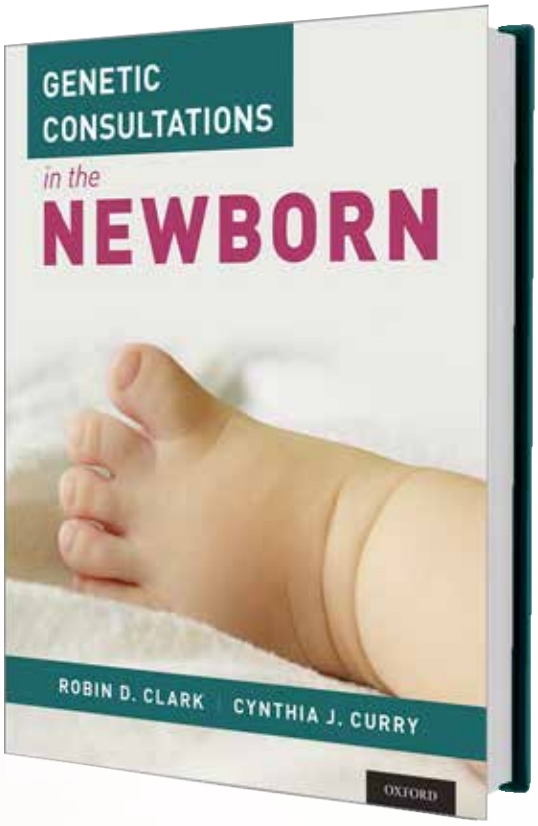

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OXFORD

RSV AWARENESS:
A National Poll of Parents & Health Care Providers

Respiratory syncytial virus, or RSV, is far from the common cold. It can lead to hospitalization, lifelong health complications or even death for infants and young children. **In fact, it is the leading cause of hospitalization in children younger than one.**

Yet a national poll of parents and specialty health care providers reveals a startling divide in attitudes toward the virus. While both groups acknowledge RSV as a significant concern, the two populations vary widely in their reported ability to meet RSV's threat head-on. Health care providers vigilantly monitor for the virus, which they report seeing regularly in their practices. Parents, however, feel unequipped to protect their young children.

Meanwhile, specialty health care providers overwhelmingly report that health plan rules and insurance denials block vulnerable infants' access to preventive RSV treatment. Such barriers can put unprepared parents at a double disadvantage. The survey does suggest, however, that education can embolden parents to seek more information about RSV and take steps to protect their children.

KEY FINDINGS

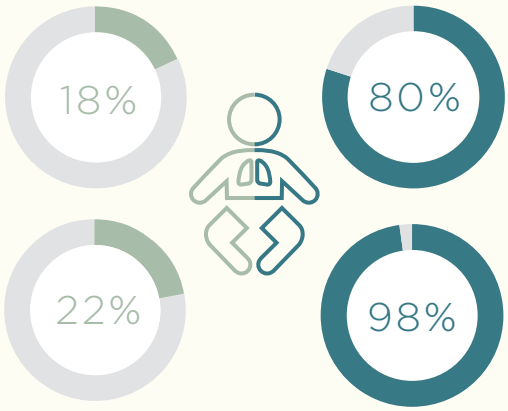
Preparedness

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

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

PARENTS

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



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

SPECIALTY HEALTH CARE PROVIDERS

They treat RSV as a priority, "often" or "always" evaluating their patients (80% doctors; 78% nurses)

During RSV season, they are especially vigilant about monitoring patients for symptoms or risk factors for RSV (98%).

Peer Reviewed

Coronavirus-19 Pandemic: Mothers and Infants

Joseph R. Hageman, MD

Every time I think I have a final version of an editorial about the Coronavirus-19 (COViD-19) pandemic, another new paper pops up from the New England Journal of Medicine, JAMA, or JAMA Pediatrics! I have published 2 COViD-19 editorials in Pediatric Annals (1,2), the second of which was just published as an update a couple of days ago. (2) I sensed that mothers and babies are definitely at risk for the acquisition of the COViD-19 virus. Still, in general, the literature has suggested that the vast majority of them were relatively spared from severe illness and death.

In order to provide the most up to date recommendations for the management of newborns and mothers, we have an excellent fellow column by Smith and Sharma in this issue. (3) In addition, I have a few thoughts to add in this pearl about aspects of COViD-19 infection in mothers and newborns.

"In order to provide the most up to date recommendations for the management of newborns and mothers, we have an excellent fellow column by Smith and Sharma in this issue. (3) In addition, I have a few thoughts to add in this pearl about aspects of COViD-19 infection in mothers and newborns."

Let's talk about pregnant mothers and their infants. On the positive side, there is a new article by Iqbal and colleagues just published in the New England Journal of Medicine about "an uncomplicated delivery in a patient with COViD-19 in the United States" in which a pregnant woman presented at 39 weeks' gestation with clinical symptoms and signs of COViD-19 with a positive PCR and was delivered on hospital day 3. (4) The infant had Apgar scores of 8 and 9 at one of five minutes of age and had no evidence of clinical COViD-19 infection. The neonate was separated from the mother and nourished with formula and expressed breast milk. Mother and baby were discharged on day 6, with the mother feeling better. (3) Care was taken from the time of admission through discharge to keep from infecting hospital staff. The father also tested positive for COViD-19 (4). The follow up was uneventful for the infant, mother, and father. (4)

On the negative side, "maternal death due to COVID-19 disease" was published the day before by Hantoushzadeh, Shamshirsaz, and colleagues in a collaborative effort with clinicians in Iran and with Baylor College of Medicine and Texas Children's Hospital in the American Journal of Obstetrics and Gynecology(5). In this case series which summarizes the clinical courses of 9 pregnant women diagnosed with SARS-CoV-2 infection during their latter second and third trimester. All nine women were diagnosed with rRT-PCR nucleic acid testing (NAT): 7 of 9 died, 1 of 9 remains critically ill, and one recovered after a prolonged hospitalization (5). The authors provide an excellent summary of the current literature about maternal COViD-19 infection, which both reinforces the fact that the vast majority of pregnant women who acquire COViD-19 infection have a mild illness, but also that severe illness with acute respiratory distress syndrome is also possible. (5) The authors also report the level of illness of household contacts of these women, which was mild and the outcomes of their infants: five infants including a set of twins were intrauterine fetal deaths (IUFD), a set of 28-week gestation twins who died on day of life 3 from respiratory complications, one 30 5/7 week premature infant who acquired COViD-19 infection on hospital day 3, remains intubated in the neonatal intensive care unit, three other infants who are alive and doing well. (5) There was also a research letter by Baud and colleagues about a pregnant woman who had COViD-19 or SARS-CoV-2 infection and had a miscarriage in her second trimester. (6) The mother had a positive nasopharyngeal swab for COViD-19. The stillborn infant was delivered vaginally after ten hours of labor, and swabs from the axillae, mouth, meconium, and fetal blood were all negative. The fetal autopsy revealed no malformations, and fetal lung, liver, and thymus biopsies were also negative. Within minutes of expulsion, the fetal surface of the placenta was disinfected and incised, and two swabs and biopsies close to the umbilical cord and margin were obtained, all were negative for bacterial infection, but were positive for SARS-CoV-2. The placental histology showed mixed inflammatory infiltrates composed of neutrophils and monocytes in the subchorial space, and evidence of inflammation of the umbilical cord (funisitis) was also noted. (6) These findings suggest COViD-19 related placental infection. There was no evidence of vertical transmission of COViD-19; however, no other cause for the fetal demise was demonstrated. (6) The authors suggest that further investigation of whether SARS-CoV-2 crossed the placenta is warranted. (6)

"The authors provide an excellent summary of the current literature about maternal COViD-19 infection, which both reinforces the fact that the vast majority of pregnant women who acquire COViD-19 infection have a mild illness, but also that severe illness with acute respiratory distress syndrome is also possible. (5)"

The combination of the up to date summary by Smith and Sharma and these findings provide obstetrical providers, neonatologists, and pediatric providers' guidelines for the care of mothers with

COViD-19 infection and their infants as well as their family/ household members.

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The author has no conflicts to disclose

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Summarize the pearl for emphasis.

No more than 7 references.

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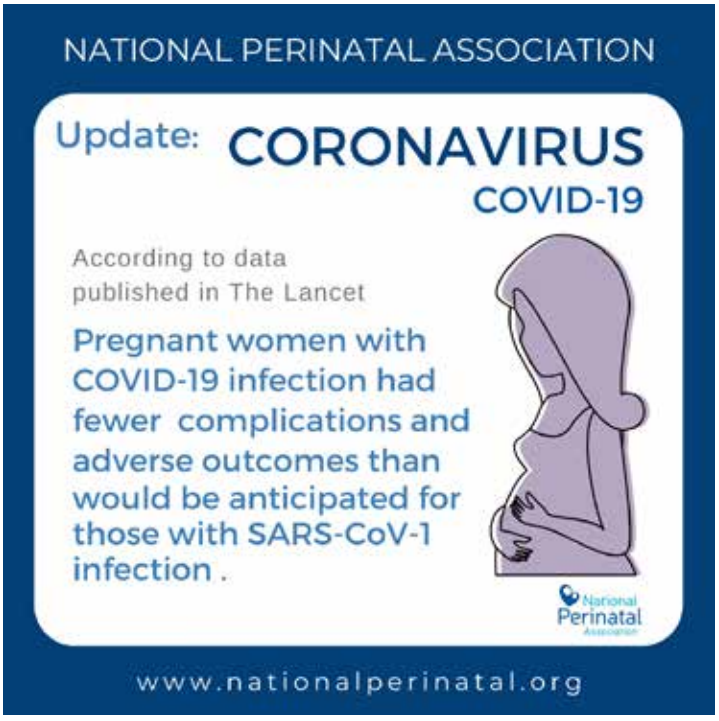
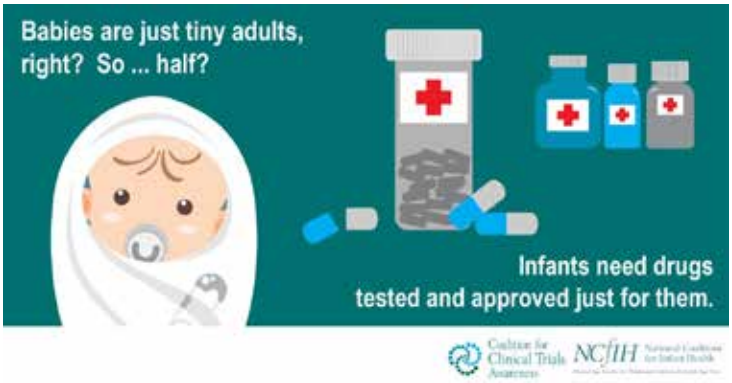
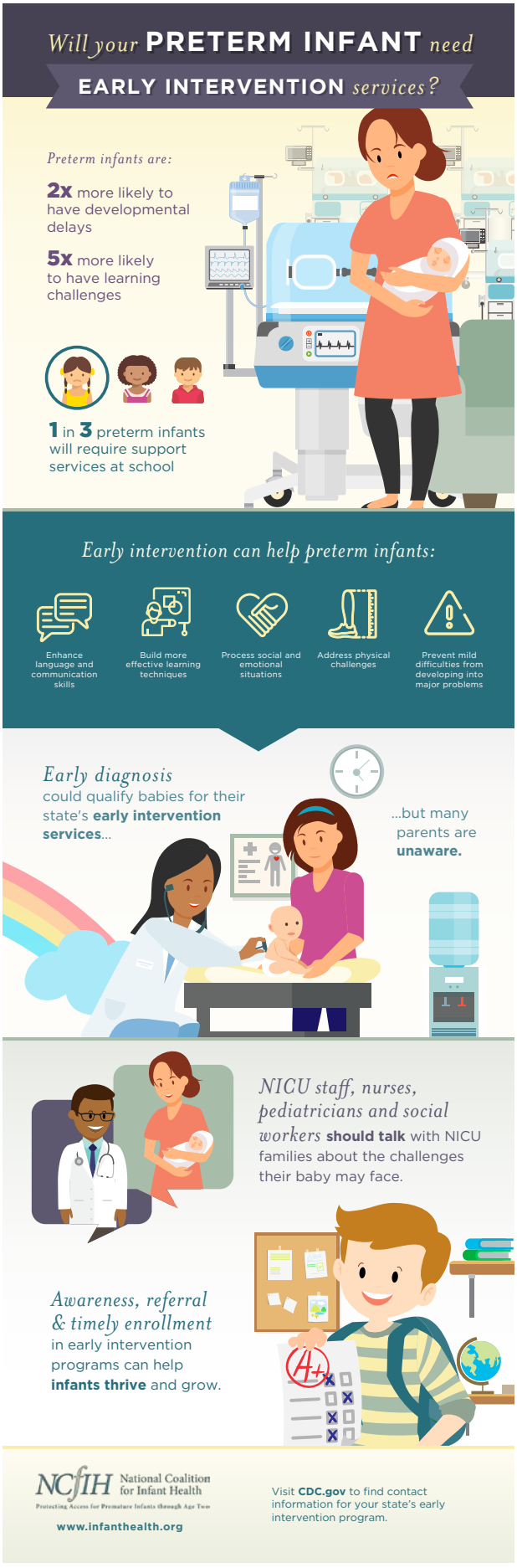





Will your PRETERM INFANT need
EARLY INTERVENTION services?
Preterm infants are:
2x more likely to have developmental delays
5x more likely to have learning challenges
1 in 3 preterm infants will require support services at school
Early intervention can help preterm infants:
Enhance language and communication skills
Build more effective learning techniques
Process social and emotional situations
Address physical challenges
Prevent mild difficulties from developing into major problems
Early diagnosis could qualify babies for their state's early intervention services...
...but many parents are unaware.
NICU staff, nurses, pediatricians and social workers should talk with NICU families about the challenges their baby may face.
Awareness, referral & timely enrollment in early intervention programs can help infants thrive and grow.
NCfIH National Coalition for Infant Health
Protecting Access for Premature Infants through Age Two
www.infanthealth.org
Visit CDC.gov to find contact information for your state's early intervention program.


Survey Says: RSV
RESPIRATORY SYNCYTIAL VIRUS, or RSV, is a dangerous virus that can lead to:
Hospitalization
Lifelong health complications
Death
for infants and young children
ACCORDING TO A NATIONAL SURVEY,
Specialty Health Care Providers say:
They treat RSV as a priority, "often" or "always" evaluating their patients
RSV is the "most serious and dangerous" illness for children under four
Barriers to access and denials from insurance companies limit patients' ability to get preventive RSV treatment
But Parents are Unprepared.
Only 18% know "a lot" about RSV
Only 22% consider themselves "very well" prepared to prevent RSV
RSV EDUCATION & AWARENESS CAN HELP
After parents learned more about RSV, they were:
65% "More concerned" about their child contracting the disease
67% Likely to ask their doctor about RSV
NCfIH National Coalition for Infant Health
Learn More about RSV at www.infanthealth.org/RSV

OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS

I am not an addict.

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

I was exposed to opioids.

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

NAS is a temporary and treatable condition.

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

My mother may have a SUD.

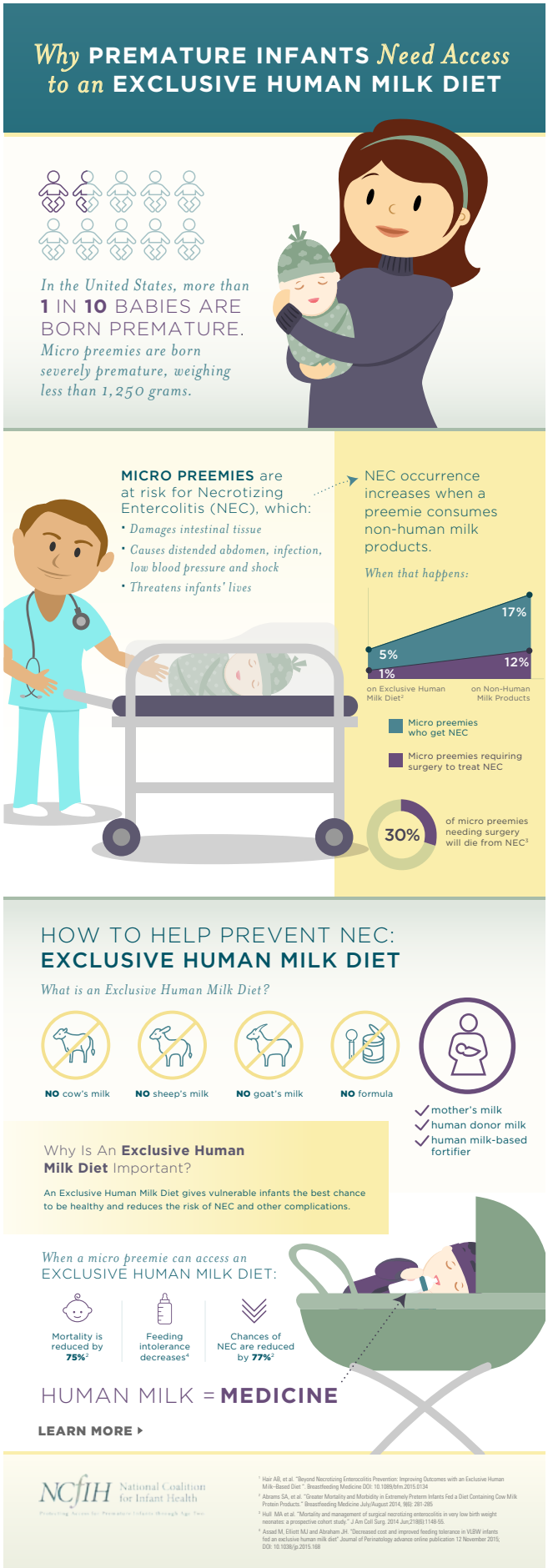
She might be receiving Medication-Assisted Treatment (MAT). My NAS may be a side effect of her appropriate medical care. It is not evidence of abuse or mistreatment.

My potential is limitless.

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

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

National Perinatal Association



SAVE YOUR LIFE:

Get Care for These POST-BIRTH Warning Signs

Most women who give birth recover without problems. **But any woman can have complications after the birth of a baby.** Learning to recognize these POST-BIRTH warning signs and knowing what to do can save your life.

POST-BIRTH WARNING SIGNS

Call 911
if you have:

- ❑ **P**ain in chest
- ❑ **O**bstructed breathing or shortness of breath
- ❑ **S**eizures
- ❑ **T**houghts of hurting yourself or your baby

Call your healthcare provider
if you have:

(If you can't reach your healthcare provider, call 911 or go to an emergency room)

- ❑ **B**leeding, soaking through one pad/hour, or blood clots, the size of an egg or bigger
- ❑ **I**ncision that is not healing
- ❑ **R**ed or swollen leg, that is painful or warm to touch
- ❑ **T**emperature of 100.4°F or higher
- ❑ **H**eadache that does not get better, even after taking medicine, or bad headache with vision changes

Trust your instincts. ALWAYS get medical care if you are not feeling well or have questions or concerns.

Tell 911 or your healthcare provider:

"I had a baby on _____ (Date) and I am having _____ (Specific warning signs)."

These post-birth warning signs can become life-threatening if you don't receive medical care right away because:

- **Pain in chest, obstructed breathing or shortness of breath** (trouble catching your breath) may mean you have a blood clot in your lung or a heart problem
- **Seizures** may mean you have a condition called eclampsia
- **Thoughts or feelings of wanting to hurt yourself or your baby** may mean you have postpartum depression
- **Bleeding (heavy)**, soaking more than one pad in an hour or passing an egg-sized clot or bigger may mean you have an obstetric hemorrhage
- **Incision that is not healing, increased redness or any pus** from episiotomy or C-section site may mean you have an infection
- **Redness, swelling, warmth, or pain** in the calf area of your leg may mean you have a blood clot
- **Temperature of 100.4°F or higher, bad smelling vaginal blood or discharge** may mean you have an infection
- **Headache (very painful), vision changes, or pain in the upper right area of your belly** may mean you have high blood pressure or post birth preeclampsia

GET HELP

My Healthcare Provider/Clinic: _____ Phone Number: _____

Hospital Closest To Me: _____

AWHONN
PROMOTING THE HEALTH OF WOMEN AND NEWBORNS

This program is supported by funding from Merck, through Merck for Mothers, the company's 10-year, $500 million initiative to help create a world where no woman dies giving life. Merck for Mothers is known as MSD for Mothers outside the United States and Canada.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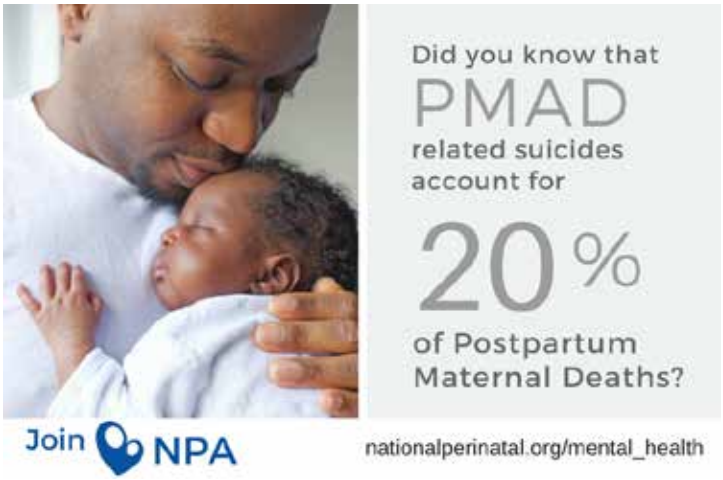
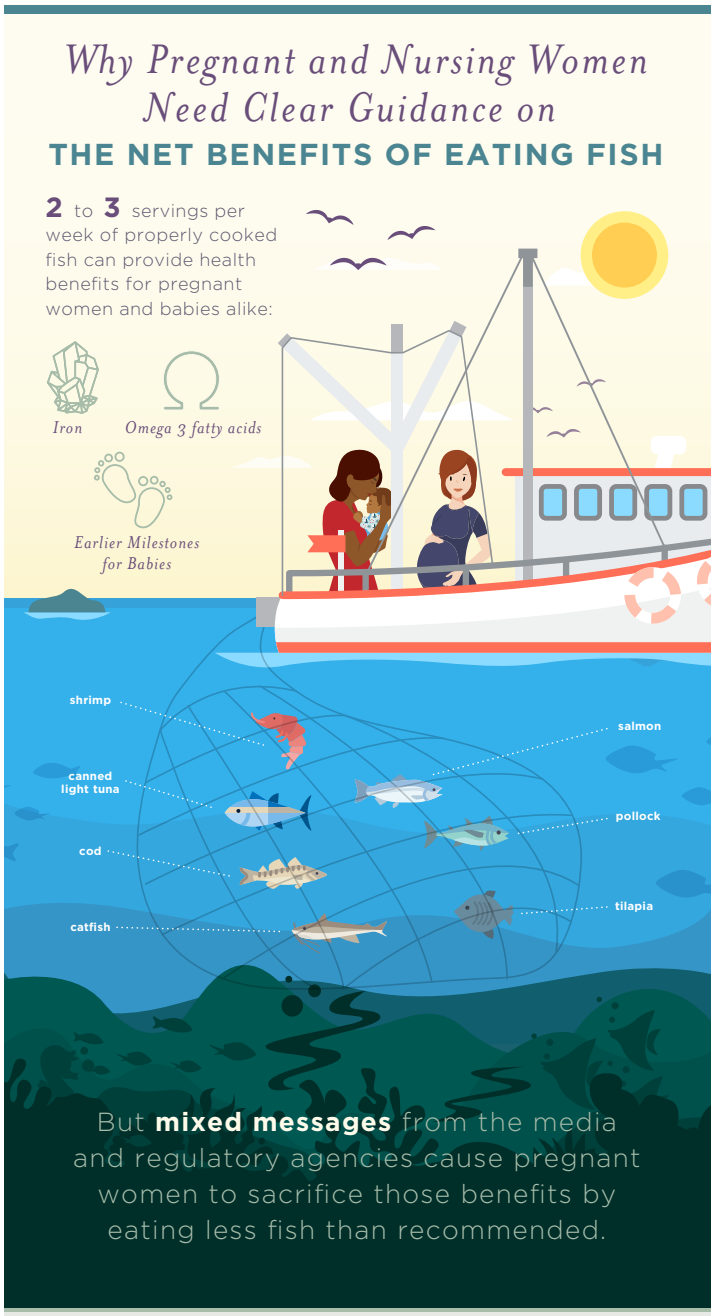

Did you know that
PMAD
related suicides
account for
20%
of Postpartum
Maternal Deaths?
Join NPA
nationalperinatal.org/mental_health


Support the
Open Letter
Breastfeeding
Innovations
Team


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
salmon
canned
light tuna
pollock
cod
tilapia
catfish
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
ON FISH CONSUMPTION
FOR PREGNANT
WOMEN, INFANTS,
AND NURSING MOMS.
NCfIH National Coalition
for Infant Health
LEARN MORE

Letters to the Editor

From: Gail Levine <glevine18@gmail.com>
Sent: Wednesday, May 6, 2020 2:12 PM
To: Goldstein, Mitchell <MGoldstein@llu.edu>
Subject: [EXTERNAL] The current state

To the Editor of Neonatology Today:

Nationally and internationally, we are experiencing community spread of COVID-19. Each hospital has developed its own guidelines and algorithms for the care of patients and the safety of staff. Below are a few evidence-based recommendations for improving safety for mothers and babies, and hospital staff.

`1. We should encourage the testing of all mothers admitted for delivery.

Nationally, more mothers are re-evaluating their in-hospital birth plans and opting for midwife-assisted home births. This is due to fear of encountering COVID-19 in the hospital.

A NEJM report in which all mothers admitted for delivery at an NYC hospital were tested for COVID-19 showed that 29/210 (114%) asymptomatic and afebrile women were positive by PCR for COVID-19. 4 women with symptoms were positive as well. Of these 33 positive women, 29 (88%) were asymptomatic. (1) The degree of community spread in other areas may be lower, but the proportion of asymptomatic/all positives may still hold in this range.

Hospitals should test all mothers admitted for delivery, as testing availability increases. It would reassure the families in the community that every possible risk reduction measure is being undertaken.

2. NICU visiting should be limited to once per day, with one parent only visiting. Many units do have an isolation room for a newborn who is either a PUI or known to be positive.

An article in the NEJM documented infective stability of COVID-19 in aerosols to be at least 3 hours, and on plastic surfaces to be 72 or more hours. (2) Another NEJM article showed that a sneeze generates aerosols which diffuse throughout a room. (3) Aerosols are known to be generated by ordinary speech and singing, as well as coughing and sneezing. A pre-publication article has shown that infective COVID -19 in aerosols may persist in the air for 16 hours (the time limit of the experiment, so potentially longer). (4) Parents should be asked to wear masks, but even N-95 masks can leak around their margins, and as lay people, they may not use these masks expertly, and they may not always be compliant. The longer staff and visitors are in contact with each other, the more risk they may render to each other. For our NICUs, we are not yet able to test all of the visitors, and we do not test asymptomatic staff or the support person for the postpartum mothers. We know that asymptomatic but infected persons can transmit the virus to others. As testing availability and turn around time improves, we should test all of these persons.

An argument for more liberal visiting in the NICU is parent-child bonding and facilitation of breastfeeding. These are clearly important. However, a corollary argument about bonding and family unity can be made for decreasing risk to staff and parents and visitors: If one of these were to contract COVID-19 in the NICU and become critically ill, and not survive themselves or transmit the virus to one of their own family members, that would impact their family very significantly and even permanently. (This has been reported in the media in the NYC area. A woman working as a P.A. in an N.Y. hospital contracted COVID-19 at work, became critically ill, and passed away shortly after being intubated. Her 18-year-old daughter had such profound grief that she continued to text her mother for some time after she had passed away.)

3. E.R. For the duration of the pandemic, admissions of newborns from home to the NICU should be suspended, unless the patient requires specialized or tertiary NICU care, and the NICU has an acceptable isolation room. When we admit a patient, we may be able to test the infant for COVID-19, but we are generally not able to test the parents who accompany the newborn. Exposure to these COVID-19 unknown persons is an unwarranted additional risk to our NICU staff and patients. These patients can often be cared for in a pediatric ward with space to evaluate a PUI infant. NEJM has reported the case of a 3-week old infant admitted from home who had mild symptoms at presentation, but who rapidly became critically ill. (5) Indeed the primary mission of most community hospital NICUs is the provision of safe care to newborns delivered at that L+D service.

Thank you for your consideration,

Gail L. Levine, M.D.
Assistant Professor of Pediatrics
Loma Linda School of Medicine
Division of Neonatology, Department of Pediatrics
"Kindness builds the world" Psalms 89:3

1. Universal Screening for SARS-Cov-2 in women admit-

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4. *Comparative dynamic aerosol efficiencies of three emergent coronaviruses and the unusual persistence of SARS-CoV-2 in aerosol suspensions. Fears, A.C. et al., MedRxiv posted April 18, 2020, DOI: Https://DOI.org/10.1101/2020.04.13 20063784*
5. *Late onset neonatal sepsis in a patient with COVID-19. Correspondence. Munoz, A. et al. DOI 10.1056/NEJM/ Mc2010614 April 22, 2020. NEJM.org*

Dear Dr. Levine:

Thank you for a comprehensive analysis of the issues involved in our new "normal." Many different strategies have been advocated to keep us safe and, at the same time, provide the care necessary to ensure good outcomes for our most at-risk neonates.

Although early reports appeared to suggest that neonates and younger pediatric patients were not at risk of severe disease, a new syndrome that appears to be similar to Kawasaki's disease has been described with multisystem involvement and late mortality in younger pediatric patients that had recovered from COVID-19 infection as long as six weeks prior to relapse.(1-3)

Yes, it seems cruel to separate the mother-infant dyad, but as you have noted, the real risk may come from those who we do not test or who are not our patients. The effects on staff in so far as morbidity and mortality are not inconsequential. And even with appropriate risk reduction techniques and teaching, parents may not comply and inadvertently transmit disease. (4)

Mask utilization is predicated on the effective use of the appropriate mask. Although N-95 masks may offer considerable protection from spread both to and from the parents, all masks are not created equal. The popular "valved" covers may protect the host from viral exposure to some extent but do not protect those in close proximity. They are exposed to the unfiltered droplets passing through the valve. (5)

Efforts that are currently underway are directed towards flattening the curve with the understanding that we may not be able to reduce the area under the curve in terms of total numbers of affected patients. The emphasis is on producing a controlled "pandemic" that does not overwhelm our hospital resources.

Yet, there is hope on the horizon, including an anti-viral cocktail similar to the one used for HIV as well as numerous vaccine candidates. Although our epidemiologists warn that we may not be able to reduce the total number of infections but rather space them out in such a way as to avoid resource shortage, we must still try to protect those at highest risk. For them, it is not sufficient to flatten the curve; we must demolish it. (6-12)

People are not merely numbers, and we simply do not have enough dedicated healthcare providers to put them at excessive risk. Although we must approach the issues involved in maternal-infant bonding with as much humanity as possible, safety comes first.

Sincerely,

Mitchell Goldstein, MD

Editor in Chief

NEONATOLOGY TODAY

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c/o Mitchell Goldstein, MD

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Loma Linda, CA 92354

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Published monthly.

www.NeonatologyToday.net

Twitter: www.Twitter.com/NeoToday

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NT

Erratum (Neonatology Today April, 2020)

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

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

NT

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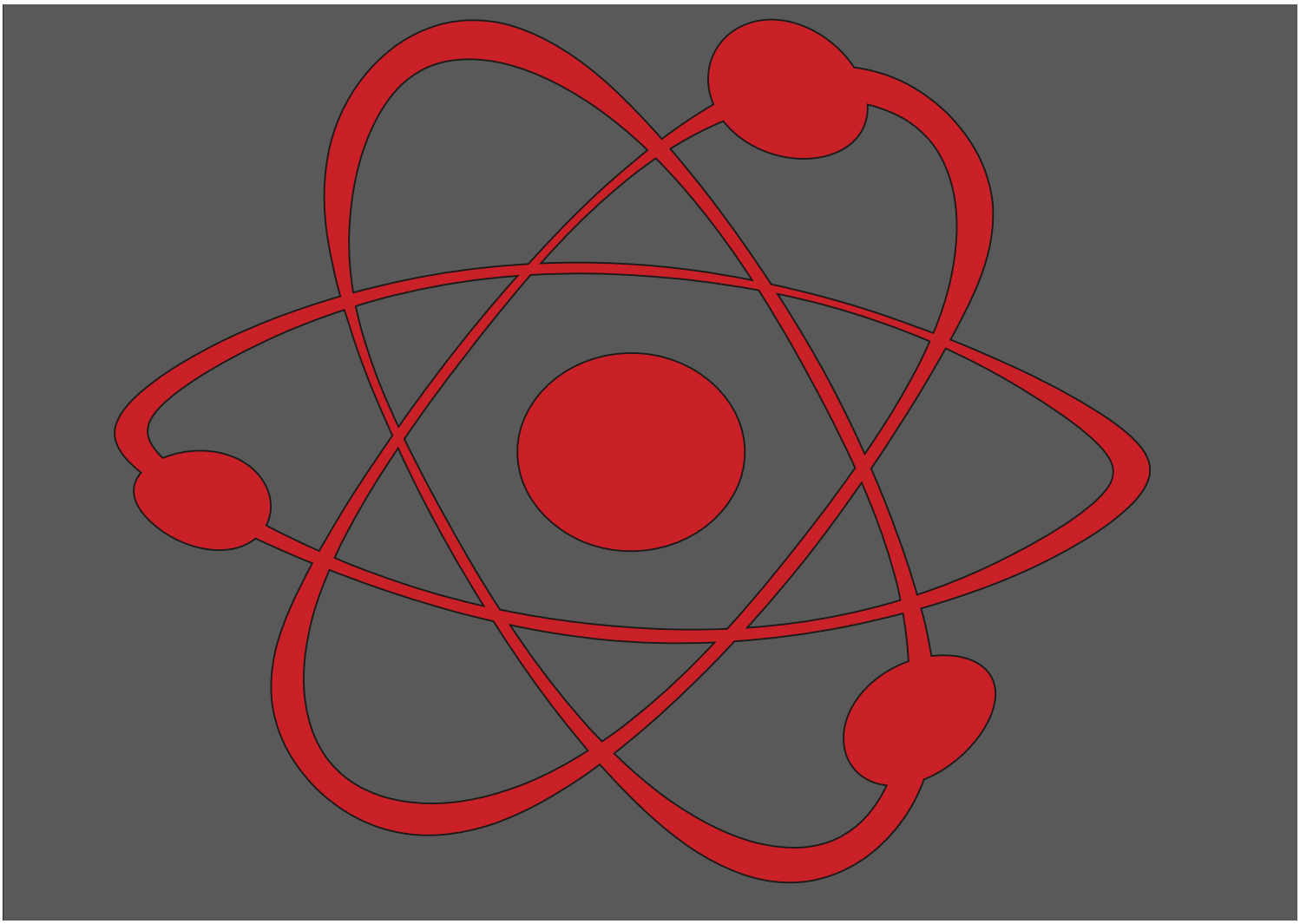

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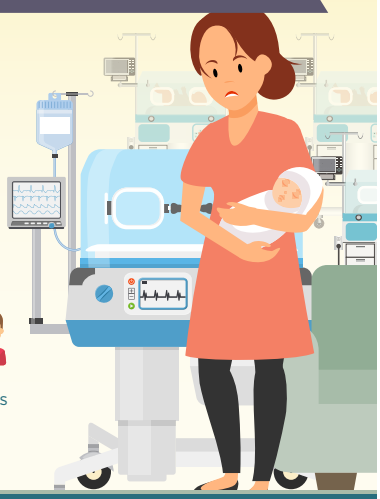
Will your PRETERM INFANT *need* EARLY INTERVENTION *services?*

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



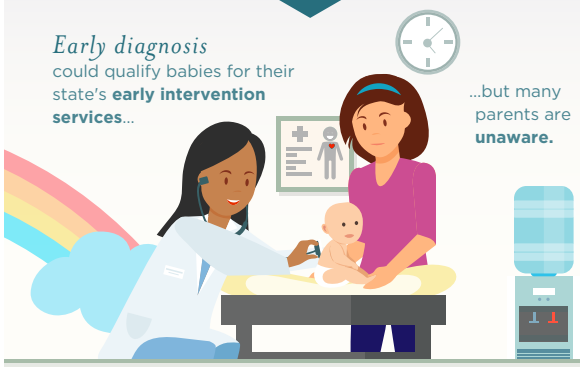
Early intervention can help preterm infants:

- 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

www.infanthealth.org

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

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

1 DE CADA **7** MADRES AFRONTA LA DEPRESIÓN POSPARTO, *experimentando*

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

Sin embargo, sólo el 15% recibe tratamiento[1]

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

La salud de la madre

El sueño, la alimentación y el comportamiento del bebé a medida que crece[2]

La capacidad para cuidar de un bebé y sus hermanos

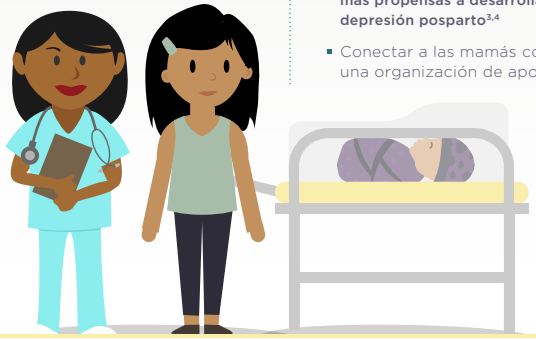
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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

LOS HOSPITALES PUEDEN:

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



NCFIH National Coalition for Infant Health

www.infanthealth.org

[1] American Psychological Association. Accesible en: http://www.apa.org/pi/women/resources/reports/postpartum-depression.aspx

[2] National Institute of Mental Health. Accesible en: https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml

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Upcoming Medical Meetings

19th Annual World Congress on Neonatology
July 20 - 21, 2020
Location: Vancouver, British Columbia
https://neonatal.conferenceseries.com/

Innovations in Neonatal Care
August 10 - 12, 2020
Mednax
Austin, Texas
http://www.innovationsconference.com/

9TH ICCN International Conference on Clinical Neonatology
September 3 - 4, 2020
Turin, Italy
https://www.mcascientificevents.eu/iccn/

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

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

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

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

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

Miami Neonatology 2020: 44th International Conference
November 15 - 18, 2020
University of Miami Miller School of Medicine
Miami Beach, Florida
http://pediatrics.med.miami.edu/neonatology/international-neonatal-conference/

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

Hot Topics in Neonatology
December 6 - 9, 2020
Organization: Nemours
National Harbor, Maryland
http://www.hottopicsinneonatology.org/

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

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Academic Neonatologist Opportunity in Southern California

Loma Linda University Faculty Medical Group, Department of Pediatrics, Division of Neonatology, is seeking board certified or board eligible Neonatologists to join their team.

The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children's Hospital is committed to providing the highest quality of family-centered medical care with our skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill babies. As one of the few level 4 tertiary centers in Southern California, we are equipped to provide the highest level of care for newborns with the most complex disorders. Our facility has the largest Level IV NICU in California, serving approximately 25 percent of the state.

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. Pediatric neurologists work together with us in our NeuroNICU to diagnose, treat and monitor babies with neurologic injury or illness and we focus on providing neuroprotective, developmentally appropriate care for all babies in the NICU. Very specialized care is given in our Small Baby Unit to babies born at less than 30 weeks gestation. Babies at risk for developmental delay are followed up to 3 years in our High-Risk Infant Follow-up Clinic. Genetics specialists are available for evaluation and consultation.

Our Children's Hospital is designated as a Baby Friendly Hospital that supports breastmilk feeding for both term and preterm babies. Neonatal Social Workers and Child Life Specialists are important members of our team. It is our goal to support babies and families in culturally sensitive ways as our patients come from many different ethnic and religious backgrounds.

Loma Linda is located in the center of Southern California. A sunny climate augments the cultural benefits of Los Angeles and Palm Springs and the year-round recreational opportunities of nearby mountains, deserts and beaches.

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Faculty Medical Group

For more information please contact:

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efayard@llu.edu

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Physician Recruitment Coordinator
kswensen@llu.edu

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GREAT MEDICINE.

EOE/AAE

Neonatal Nurse Practitioner

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- Care of high acuity NICU patients
- 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.

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Neonatology Today's policies ensure the protection and responsible use of animals and humans in all research articles under consideration. Authors are encouraged to follow the guidelines developed by the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3R), International Committee of Medical Journal Editors, and the Guide for the Care and Use of Laboratory Animals and U.S. Public Health Service's Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Authors are expected to demonstrate to their institutional review board or suitable proxy that ethical standards are met. If there is doubt whether research conducted was in accordance with ethical standards, then there must be verification that the institutional review body approved the uncertain aspects. Research not following these policies on participating animal and human subjects may be rejected. Researchers have a moral obligation towards the humane treatment of animals and ethical considerations for humans participating in research and are expected to consider their welfare when designing studies.

https://www.nc3rs.org.uk/arrive-guidelines

http://www.icmje.org

https://olaw.nih.gov/policies-laws/phs-policy.htm

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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.

Dr. Larry Tinsley provides May's photograph. These are geese with their new hatchlings near a body of water. Spring is here.

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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 (i.e., open access). There is no charge for your manuscript to be published under open access

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

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

6. An abstract may be submitted.

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

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

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

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

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