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Human and Donor Milk Use Post NICU Discharge

Elaine Ellis, MD, Christine Aune, MD, Mario Fierro, MD, Cathleen Roberts, DO, Mary Allare, MD, Bradlee Drabant, MD, Amy S. Kelleher, MSHS, Christina Sanchez, Cheryl McDuffie, FNP

Abstract:

Background: The health benefits of feeding all infants human milk are well established but the use of human milk after infants are discharged from the Neonatal Intensive Care Unit (NICU) remains low.

Aims: Our aim was to investigate which infants were receiving human milk at discharge from the NICU and at varying times after discharge and to explore factors that foster or inhibit increasing human milk use in NICU graduates.

Methods: We conducted a prospective, observational study and collected data on the use of human milk at hospital discharge and during follow-up visits in five developmental follow-up programs. These follow up programs were in 5 different large cities in 3 different states in the United States.

Results: The overall rate of use of any human milk decreased from 841/1160 (72.5%) at discharge to 233/791 (29.5%) in participants who were followed for >4 and ≤7 months after birth and this trend continued with later follow-up. In a multivariate logistic analysis, the factors found to be independently associated with the use of human milk at follow-up were: use of human milk at discharge (AOR=39.3, 14-162); White race compared to all other races/ethnicity (AOR= 2.97, 2.1-4.2); being reported preterm at birth (<32 weeks) compared to more mature gestational age infants (AOR= 2.02, 1.4-2.9); and mother having received a breast pump within 12 hours of the birth of her infant (AOR=1.90, 1.2-3).

Conclusions: Health care practices within the NICU affect the continued use of human milk after infants are discharged from the hospital. These practices could be enhanced to increase human milk usage in NICU graduates.

Short title: Human and Donor Milk Feeding Use Post NICU Discharge

Keywords: Infant, neonate, premature, prematurity, human milk, breastmilk, follow-up

Clinical Trial Registration: ClinicalTrials.gov, NCT02692521, https://www.clinicaltrials.gov/ct2/show/NCT02692521?cond=NCT02692521&rank=1


Key Points

1. Human milk use drops dramatically after NICU discharge
2. NICU health care process impacts use of human milk at home
3. Important opportunities exist to improve human milk use

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Introduction

Feeding of human milk in the NICU and after discharge is associated with improved outcomes, but rates of human milk provision after infants are discharged from the NICU remain low(1) despite the fact that the American Academy of Pediatrics endorses exclusive breastfeeding for the first 6 months with the recommendation that, ideally, breastfeeding continues for the first year of life. (2) The World Health Organization and UNICEF recommend initiation of breastfeeding within the first hour after birth, exclusive breastfeeding for the first six months, and continued breastfeeding for two years or more, together with safe, nutritionally adequate, age-appropriate, responsive complementary feeding starting in the sixth month. (https://www.who.int/elena/titles/early_breastfeeding/en/) Benefits to low birth weight infants have been demonstrated to include fewer re-hospitalizations, higher Bayley scores and better emotional regulation at 30 months. (3-5) Even though there are established benefits for providing human milk to infants requiring admission for intensive care, mothers face real challenges to accomplish this goal. (6;7)

NICUs have implemented programs to increase the use of human milk, and in some units, as many as 80 percent or more of infants receive at least some human milk at discharge. (8) Various studies have identified early milk expression, lactation support, kangaroo care, and breastfeeding as factors that contribute to increased human milk use after NICU discharge. (6;9-14)

A MEDNAX Continuous Quality Improvement survey done in three NICU, follow-up clinic sites found that about 40-50 percent of NICU graduates were still receiving human milk at 1-3 months after discharge. As a result of the MEDNAX CQI survey, we designed a prospective study to investigate further factors influencing the use of human milk at the time of NICU discharge and during follow-up after discharge from the NICU. Our aim was to investigate which infants were receiving human milk, either expressed or breastfed at varying times after discharge, and explore NICU factors that foster or inhibit increasing human milk use in NICU graduates.

“Our aim was to investigate which infants were receiving human milk, either expressed or breastfed at varying times after discharge, and explore NICU factors that foster or inhibit increasing human milk use in NICU graduates.”

Methods

Design

This is a prospective, observational study from the first follow up visit through 2 years post-discharge to capture information on infants after discharge in a variety of locations to determine factors...
contributing to longer human milk consumption. We prospectively collected data on a convenience sample of discharged infants seen in 5 developmental follow-up clinics. Our developmental teams participate in discharge planning and had access to the discharge summary of infants enrolled in the study. Participating clinics provided care to high-risk infants discharged from 20 NICUs and referred to a developmental follow-up program. The timing of this first recommended visit varied among sites, as did the timing that the family actually kept the visit. All patients who kept their first visit were included in our follow-up study cohort. Ongoing follow-up visit timing was individualized to the needs of each infant.

“We prospectively collected data on a convenience sample of discharged infants seen in 5 developmental follow-up clinics. Our developmental teams participate in discharge planning and had access to the discharge summary of infants enrolled in the study. Participating clinics provided care to high-risk infants discharged from 20 NICUs and referred to a developmental follow-up program.”

Our study was a part of our ongoing quality improvement efforts, and signed consent and authorization forms were waived by the Western Institutional Review Board (WIRB). The WIRB required that an information sheet about our study be provided to the parents of each child seen in follow-up because we were prospectively collecting data and asking study specific questions. The information sheet was used to discuss our research efforts with the parent regarding the collection of routine care information on their child during follow-up. If the parent declined our request to collect prospective data, their child was not enrolled in the study.

Sample
Follow-up of infants after hospital discharge from the NICU is the standard of care. The NICUs included in this study are in 5 different metroplex locations in 3 different states. The majority of study participants were receiving Medicaid insurance. After discharge, office visits were coordinated by the developmental team and took place at individualized intervals at each site for up to two years corrected age. As the timing of visits was variable, we included ranges of follow up times as data points (Discharge; >1 and <=4 months; >4 and <=7 months; >7 and <=10 months; and >10 and <=13 months).

Measurement
Our primary outcome measure was family reported use of any human milk at NICU discharge and at specific time points after discharge from the hospital. We collected data on weight, length, and head circumference at each follow-up visit to assess the impact of breast milk use on growth. We recorded growth measurements at each follow-up visit and collected data regarding specific therapies and interventions that each child was utilizing (e.g., speech and physical therapy, state versus private). New medical diagnoses were recorded, and any case positive for cerebral palsy was documented as to type and severity. Clinical Research Associates, independent of the developmental team, monitored each site for adherence to the protocol, data accuracy, and ensured that each site’s conduct was in accordance with the International Conference on Harmonization Good Clinical Practice Guidelines and HIPPA Regulations.

Data Analysis
Our primary outcome measure was family reported use of any human milk at NICU discharge and at specific time points after discharge from the hospital. Our analytical approach to these data had two goals. The first was descriptive, and we report the changes over time in the use of human milk in our study cohort. The second was to better understand the factors associated with the use of human milk after discharge from the NICU. All statistical analyses were performed using JMP v. 11 (SAS Institute, Cary, NC). The available literature was reviewed to pinpoint factors associated with the use of human and/or donor milk, and these factors were included in the electronic case report form. We compared infants who received human/donor milk to those who did not receive human/donor milk using bivariate and multivariate analysis.

During the bivariate analysis, all of the numeric data (birth weight, estimated gestational age, APGAR score, and length of hospital stay) were evaluated using both parametric (analysis of variance or two-sample t-test) and non-parametric tests (Kruskal–Wallis non-parametric test and Mann–Whitney test). When the data were non-parametric, we used the Kruskal–Wallis non-parametric test to make more than two comparisons and the Mann–Whitney test for two-sample comparisons. After bivariate analysis, multivariate
Our analytical approach to these data had two goals. The first was descriptive, and we report the changes over time in the use of human milk in our study cohort. The second was to better understand the factors associated with the use of human milk after discharge from the NICU.”

Results

Study cohort

We enrolled 1160 infants at five high-risk follow-up clinics; these infants had survived to discharge and kept at least one follow up visit. The first patient was enrolled in September of 2015, and the last patient was enrolled in June of 2017. The median gestational age was 33 weeks with a 10-90\textsuperscript{th} percentile of 26 to 38 weeks and the median birth weight was 1830 grams (10-90\textsuperscript{th} percentile was 860-2988 grams). Eighty-six percent of the infants were preterm, and 48\% were female infants (Table 1). The median age at discharge from the hospital was 30 days (10-90\textsuperscript{th} percentile was 9 to 100 days).

Use of human milk at discharge

Of 1160 participants, 841 (72.5\%) were being fed at least some human milk at discharge, while eighty (10.1\%) participants never received any human milk during hospitalization. The use of human milk at discharge from the hospital was similar for each of the follow-up clinics, with a range of 67 to 76\% (Table 1). Factors associated with use of human milk at discharge from the hospital were: more mature gestational age at birth; heavier birth weight; earlier discharge from the hospital; non-Hispanic white (White-Hispanic participants were less likely to be sent home on human milk); any reported use of Kangaroo care (and when it was reported it was used more frequently and started at an earlier age; Table 1); and any reported use of a human milk pump. Participants who were on human milk at discharge and whose mothers received a human milk pump received a pump sooner after birth than those not on human milk at discharge. The use of human milk at discharge increased with increasing gestational age through 36 weeks and then dropped to lower levels for infants of 37-40 weeks gestation (Figure 1). The participants with the highest rate of human milk use at discharge were those born at 33, 34, and 35 weeks (all were above 80\%; Figure 1). Infants born between 33, 34, and 35 weeks (10-90\textsuperscript{th} percentile was 9 to 100 days).
<table>
<thead>
<tr>
<th>Table 1</th>
<th>Human milk At Discharge</th>
<th>All</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Numbers of Patients</td>
<td>319</td>
<td>841</td>
<td>1160</td>
</tr>
<tr>
<td>Gestational Age at Birth, median (10-90th percentile)</td>
<td>31 (24-38)</td>
<td>33 (28-37)</td>
<td>33 (26-37.9)</td>
</tr>
<tr>
<td>EGA 3 Groups, n (%)</td>
<td>0.0001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=32 weeks</td>
<td>203 (63.6)</td>
<td>353 (42)</td>
<td>556 (47.9)</td>
</tr>
<tr>
<td>33 to 36</td>
<td>61 (19.1)</td>
<td>384 (45.7)</td>
<td>445 (38.4)</td>
</tr>
<tr>
<td>&gt;=37 weeks</td>
<td>55 (17.2)</td>
<td>104 (12.4)</td>
<td>159 (13.7)</td>
</tr>
<tr>
<td>Birth Weight (grams), median (10-90th percentile)</td>
<td>1500 (664-3145)</td>
<td>1920 (1044-2866)</td>
<td>1830 (860-2988)</td>
</tr>
<tr>
<td>Age at DC days, median (10-90th percentile)</td>
<td>48 (12-125)</td>
<td>25 (9-73)</td>
<td>30 (9-99.9)</td>
</tr>
<tr>
<td>Discharge Weight (grams), median (10-90th percentile)</td>
<td>2880 (2177-4342)</td>
<td>2495 (2005-3581)</td>
<td>2583 (2035-3814)</td>
</tr>
<tr>
<td>Sites, n (%)</td>
<td>0.1806</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FTCT</td>
<td>57 (17.9)</td>
<td>142 (16.9)</td>
<td>199 (17.2)</td>
</tr>
<tr>
<td>KID2</td>
<td>76 (23.8)</td>
<td>174 (20.7)</td>
<td>250 (21.6)</td>
</tr>
<tr>
<td>MPDS</td>
<td>21 (6.6)</td>
<td>45 (5.4)</td>
<td>66 (5.7)</td>
</tr>
<tr>
<td>PNSA</td>
<td>132 (41.4)</td>
<td>413 (49.1)</td>
<td>545 (47)</td>
</tr>
<tr>
<td>PPHR</td>
<td>33 (10.3)</td>
<td>67 (8)</td>
<td>100 (8.6)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>0.9724</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>53 (16.6)</td>
<td>85 (10.1)</td>
<td>138 (11.9)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (1.3)</td>
<td>32 (3.8)</td>
<td>36 (3.1)</td>
</tr>
<tr>
<td>Black Hispanic</td>
<td>2 (0.6)</td>
<td>17 (2)</td>
<td>19 (1.6)</td>
</tr>
<tr>
<td>Native American</td>
<td>8 (2.5)</td>
<td>11 (1.3)</td>
<td>19 (1.6)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (4.7)</td>
<td>31 (3.7)</td>
<td>46 (4)</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>1 (0.3)</td>
<td>5 (0.6)</td>
<td>6 (0.5)</td>
</tr>
<tr>
<td>White</td>
<td>84 (26.3)</td>
<td>321 (38.2)</td>
<td>405 (34.9)</td>
</tr>
<tr>
<td>White Hispanic</td>
<td>152 (47.6)</td>
<td>339 (40.3)</td>
<td>491 (42.3)</td>
</tr>
<tr>
<td>Breast pump provided, n (%)</td>
<td>0.0001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>By 6 hours</td>
<td>106 (33.2)</td>
<td>518 (61.6)</td>
<td>624 (53.8)</td>
</tr>
<tr>
<td>By 12 hours</td>
<td>36 (11.3)</td>
<td>116 (13.8)</td>
<td>152 (13.1)</td>
</tr>
<tr>
<td>By 24 hours</td>
<td>29 (9.1)</td>
<td>99 (11.8)</td>
<td>128 (11)</td>
</tr>
<tr>
<td>By 48 hours</td>
<td>22 (6.9)</td>
<td>62 (7.4)</td>
<td>84 (7.2)</td>
</tr>
<tr>
<td>&gt;48 Hours</td>
<td>17 (5.3)</td>
<td>23 (2.7)</td>
<td>40 (3.5)</td>
</tr>
<tr>
<td>Kangaroo care at any time, n (%)</td>
<td>237 (74.3)</td>
<td>740 (88)</td>
<td>977 (84.2)</td>
</tr>
<tr>
<td>Age at Kangaroo care &lt;48 hours, median (10-90th percentile)</td>
<td>56 (17.6)</td>
<td>340 (40.5)</td>
<td>396 (34.2)</td>
</tr>
<tr>
<td>Frequency of Kangaroo care almost daily, n (%)</td>
<td>149 (46.7)</td>
<td>603 (71.7)</td>
<td>752 (64.8)</td>
</tr>
<tr>
<td>Type of human milk feeding during hospitalization, n (%)</td>
<td>0.0001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor milk only</td>
<td>9 (2.8)</td>
<td>0</td>
<td>9 (0.8)</td>
</tr>
<tr>
<td>Donor’s milk with formula supplement</td>
<td>17 (5.3)</td>
<td>0</td>
<td>17 (1.5)</td>
</tr>
<tr>
<td>Mother’s milk only</td>
<td>26 (8.2)</td>
<td>111 (13.2)</td>
<td>137 (11.8)</td>
</tr>
<tr>
<td>Mother’s milk with formula supplement</td>
<td>143 (44.8)</td>
<td>657 (78.1)</td>
<td>800 (69)</td>
</tr>
<tr>
<td>Mother’s milk/Donor milk</td>
<td>45 (14.1)</td>
<td>72 (8.6)</td>
<td>117 (10.1)</td>
</tr>
<tr>
<td>Surgical Procedures, n (%)</td>
<td>0.0001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diuretics</td>
<td>15 (4.7)</td>
<td>10 (1.2)</td>
<td>25 (2.2)</td>
</tr>
<tr>
<td>Steroids</td>
<td>4 (1.3)</td>
<td>3 (0.4)</td>
<td>7 (0.6)</td>
</tr>
</tbody>
</table>
Inhalers: 14 (4.4) 10 (1.2) 24 (2.1) 0.0017
Anticonvulsants: 5 (1.6) 11 (1.3) 16 (1.4) 0.7791
Gastrointestinal medication: 16 (5) 27 (3.2) 43 (3.7) 0.1637
Discharge equipment, n (%): 58 (18.2) 66 (7.9) 124 (10.7) 0.0001
Apnea Monitor: 6 (1.9) 8 (1) 14 (1.2) 0.2282
Feeding pump: 19 (6) 18 (2.1) 37 (3.2) 0.0022
Pulse ox: 36 (11.3) 28 (3.3) 64 (5.5) 0.0001
Home on oxygen: 41 (12.9) 31 (3.7) 72 (6.2) 0.0001
Any report of readmission, n (%): 65 (20.4) 118 (14) 183 (15.8) 0.009
<=32: 43 (21.2) 53 (15) 96 (17.3) 0.0799
33-36: 14 (23) 41 (10.7) 55 (12.4) 0.0112

Table 1. Characteristics of patients sent home on human milk

weeks gestational age were more likely to receive human milk at discharge than infants born at earlier or later gestational ages (based on Chi-square means of proportion test p<0.01).

In the 841 participants being fed some human milk at discharge, the most common feedings were breastfeeding with some bottle supplementation (504, 60%) and bottle feeding of expressed maternal milk (284, 34%). Only 27 (3%) of 841 were exclusively breastfeeding. Twenty-six (3%) were on tube feedings with maternal human milk (15 with gastrostomy tubes and 11 with nasogastric feedings). None of the 26 participants who were fed only donor milk (none of their mother’s own milk) during hospitalization went home on human milk.

In the multivariate logistic analysis that includes data on all 1160 enrolled infants, the factors found to be independently associated with the use of human milk at discharge were: Non-Hispanic White race compared to all other races/ethnicity (AOR= 1.95, 1.52-2.51; p<0.0001); no report of surgical procedures (AOR= 1.96, 1.32-2.94; p=0.0007); any report of kangaroo care (AOR= 1.42, 1.0-2.01; p=0.0468) and being reported preterm compare to term (AOR= 1.86, 1.19-2.94; p=0.0066).

Participants sent home on human milk were healthier at discharge and less often were admitted during the first year of follow-up (Table 1). Participants fed human milk at discharge less often had a report of a surgical procedure and less often went home on diuretics, inhalers, feeding pumps, pulse oximeters, and home oxygen than participants who were not receiving human milk.

Reported use of Human Milk in Follow-Up for >4 and ≤7 months after birth.

There were 1160 participants referred for follow-up between September 2015 and June 2017 and kept one follow up visit, and 791 were followed for >4 and ≤7 months after birth (Table 2). The overall rate of use of any human milk decreased from 841/1160 (72.5%) at discharge to 233/791 (29.5%, p<0.0001), who were
Table 2. Characteristics of patients on breast milk at follow up between 4 and 7 months.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No</th>
<th>Yes</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>558</td>
<td>233</td>
<td></td>
</tr>
<tr>
<td>Gestational Age at birth</td>
<td>33 (27-38)</td>
<td>32 (27-36)</td>
<td>0.0352</td>
</tr>
<tr>
<td>&lt;=32 weeks</td>
<td>244 (43.7)</td>
<td>124 (53.2)</td>
<td></td>
</tr>
<tr>
<td>33 to 36</td>
<td>232 (41.6)</td>
<td>89 (38.2)</td>
<td></td>
</tr>
<tr>
<td>&gt;=37 weeks</td>
<td>82 (14.7)</td>
<td>20 (8.6)</td>
<td></td>
</tr>
<tr>
<td>Birth Weight (grams)</td>
<td>1870 (900-2992)</td>
<td>1780 (862-2700)</td>
<td>0.0691</td>
</tr>
<tr>
<td>Age at DC days</td>
<td>29 (9-92)</td>
<td>30 (9-91.4)</td>
<td>0.3648</td>
</tr>
<tr>
<td>Female</td>
<td>268 (48)</td>
<td>119 (51.1)</td>
<td>0.4367</td>
</tr>
<tr>
<td>Congenital anomalies</td>
<td>112 (20.1)</td>
<td>44 (18.9)</td>
<td>0.7689</td>
</tr>
<tr>
<td>Race Group</td>
<td></td>
<td></td>
<td>0.0001</td>
</tr>
<tr>
<td>African American</td>
<td>58 (10.4)</td>
<td>18 (7.7)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>12 (2.2)</td>
<td>10 (4.3)</td>
<td></td>
</tr>
<tr>
<td>Black Hispanic</td>
<td>11 (2)</td>
<td>3 (1.3)</td>
<td></td>
</tr>
<tr>
<td>Native American</td>
<td>11 (2)</td>
<td>2 (0.9)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>28 (5)</td>
<td>10 (4.3)</td>
<td></td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>1 (0.2)</td>
<td>3 (1.3)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>153 (27.4)</td>
<td>127 (54.5)</td>
<td>0.0001</td>
</tr>
<tr>
<td>White Hispanic</td>
<td>284 (50.9)</td>
<td>60 (25.8)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Surgical Procedures</td>
<td>65 (11.6)</td>
<td>25 (10.7)</td>
<td>0.8061</td>
</tr>
<tr>
<td>Mother breastfed in NICU</td>
<td>348 (62.4)</td>
<td>207 (88.8)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Breast pump provided</td>
<td>480 (86)</td>
<td>229 (98.3)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Kangaroo care</td>
<td>456 (81.7)</td>
<td>209 (89.7)</td>
<td>0.0054</td>
</tr>
<tr>
<td>Frequency of Kangaroo care almost daily</td>
<td>342 (61.3)</td>
<td>176 (75.5)</td>
<td>0.0149</td>
</tr>
</tbody>
</table>

Figure 3. Changes in use of human milk within Gestational Age Groups
Factors associated with the use of human milk at discharge and discharge follow-up (Table 2) and having had a human milk pump provided. The decrease in reported use of any human milk was independent of the site of care and gestational age group (Figures 3 and 4 Supplement). In the multivariate logistic analysis that included only the 791 patients seen in follow-up, the factors found to be independently associated with the use of human milk at discharge and included: more immature gestational age at birth; non-Hispanic white (White-Hispanic participants were less likely to be on human milk at follow-up); any reported use of Kangaroo care (Table 2) and having had a human milk pump provided. The decrease in reported use of any human milk was independent of the site of care and gestational age group (Figures 3 and 4 Supplement).

In the multivariate logistic analysis that include only the 791 patients seen in follow-up, the factors found to be independently associated with the use of human milk at follow-up (>4 and ≤7 months) from the hospital were similar to those associated with the use of human milk at discharge and included: more immature gestational age at birth; non-Hispanic white (White-Hispanic participants were less likely to be on human milk at follow-up); any reported use of Kangaroo care (Table 2) and having had a human milk pump provided. The decrease in reported use of any human milk was independent of the site of care and gestational age group (Figures 3 and 4 Supplement).

Table 3. Supplement (z scores)

Based on Use of Human Milk at Discharge

<table>
<thead>
<tr>
<th>EGA</th>
<th>Age group</th>
<th>No</th>
<th>Yes</th>
<th>P Value</th>
<th>z HC</th>
<th>&gt;4 and &lt;=7 months</th>
<th>z HC</th>
</tr>
</thead>
<tbody>
<tr>
<td>z weight &lt;=32 wks Birth</td>
<td>0.18 (-1.42-1.45)</td>
<td>0.14 (-1.5-1.42)</td>
<td>0.345</td>
<td>0.2 (-1.41-1.45)</td>
<td>0.08 (-1.52-1.5)</td>
<td>0.415</td>
<td></td>
</tr>
<tr>
<td>z weight &lt;=32 wks Discharge</td>
<td>-0.61 (-1.87-0.45)</td>
<td>-0.63 (-1.66-0.36)</td>
<td>0.460</td>
<td>-0.6 (-1.78-0.33)</td>
<td>-0.48 (-1.81-0.52)</td>
<td>0.130</td>
<td></td>
</tr>
<tr>
<td>z weight &gt;4 and &lt;=7 months Birth</td>
<td>-0.75 (-2.19-0.66)</td>
<td>-0.39 (-1.6-0.87)</td>
<td>0.003</td>
<td>-0.43 (-1.91-0.78)</td>
<td>-0.61 (-1.89-0.74)</td>
<td>0.183</td>
<td></td>
</tr>
<tr>
<td>z weight 33 to 36 Birth</td>
<td>0.17 (-1.33-2.31)</td>
<td>-0.18 (-1.58-1.07)</td>
<td>0.113</td>
<td>-0.24 (-1.55-1.04)</td>
<td>-0.03 (-1.31-1.3)</td>
<td>0.120</td>
<td></td>
</tr>
<tr>
<td>z weight 33 to 36 Discharge</td>
<td>-0.46 (-1.7-1.03)</td>
<td>-0.85 (-1.95-0.12)</td>
<td>0.005</td>
<td>-0.85 (-1.93-0.11)</td>
<td>-0.83 (-1.77-0.33)</td>
<td>0.240</td>
<td></td>
</tr>
<tr>
<td>z weight &gt;4 and &lt;=7 months Birth</td>
<td>-0.29 (-1.41-0.93)</td>
<td>-0.32 (-1.54-1)</td>
<td>0.851</td>
<td>-0.31 (-1.39-0.95)</td>
<td>-0.32 (-1.74-1.05)</td>
<td>0.911</td>
<td></td>
</tr>
<tr>
<td>z weight &gt;37 wks Birth</td>
<td>-0.5 (-1.6-1.2)</td>
<td>-0.24 (-1.78-1.38)</td>
<td>0.479</td>
<td>-0.29 (-1.63-1.67)</td>
<td>-0.33 (-2.32-1.34)</td>
<td>0.909</td>
<td></td>
</tr>
<tr>
<td>z weight &gt;37 wks Discharge</td>
<td>-0.75 (-1.77-0.78)</td>
<td>-0.77 (-2.07-0.78)</td>
<td>0.648</td>
<td>-0.75 (-2.02-1.02)</td>
<td>-1.3 (-2.6-0.83)</td>
<td>0.300</td>
<td></td>
</tr>
<tr>
<td>z weight &gt;37 wks &gt;4 and &lt;=7 months Birth</td>
<td>-0.24 (-1.73-1.41)</td>
<td>-0.72 (-2.16-0.84)</td>
<td>0.185</td>
<td>-0.29 (-1.76-0.86)</td>
<td>-1.03 (-2.41-0.3)</td>
<td>0.199</td>
<td></td>
</tr>
<tr>
<td>z length &lt;=32 wks Birth</td>
<td>0 (-1.49-1.09)</td>
<td>0.14 (-1.44-1.11)</td>
<td>0.238</td>
<td>0.12 (-1.37-1.14)</td>
<td>0.14 (-1.46-1.1)</td>
<td>0.905</td>
<td></td>
</tr>
<tr>
<td>z length &lt;=32 wks Discharge</td>
<td>-1.19 (-2.96-0.28)</td>
<td>-0.85 (-2.52-0.32)</td>
<td>0.001</td>
<td>-0.96 (-2.85-0.32)</td>
<td>-0.83 (-2.32-0.49)</td>
<td>0.288</td>
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</tr>
<tr>
<td>z length &gt;37 wks &gt;4 and &lt;=7 months Birth</td>
<td>-0.67 (-2.12-1.02)</td>
<td>-0.37 (-2.01-1.07)</td>
<td>0.256</td>
<td>-0.45 (-2.12-1.09)</td>
<td>-0.44 (-1.91-0.9)</td>
<td>0.923</td>
<td></td>
</tr>
<tr>
<td>z length &gt;37 wks &gt;4 and &lt;=7 months Birth</td>
<td>-0.44 (-1.68-1.38)</td>
<td>0 (-1.73-1.91)</td>
<td>0.063</td>
<td>0 (-1.43-1.75)</td>
<td>-0.25 (-2.2-2.11)</td>
<td>0.461</td>
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</tr>
<tr>
<td>z length &gt;37 wks &gt;4 and &lt;=7 months Birth</td>
<td>-0.63 (-2.4-1.47)</td>
<td>-0.59 (-2.57-1.65)</td>
<td>0.780</td>
<td>-0.34 (-2.38-1.6)</td>
<td>-0.79 (2.84-2.04)</td>
<td>0.331</td>
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</tr>
<tr>
<td>z length &gt;37 wks &gt;4 and &lt;=7 months Birth</td>
<td>-0.66 (-2.82-0.58)</td>
<td>-0.68 (-2.13-0.76)</td>
<td>0.512</td>
<td>-0.56 (-2.39-0.58)</td>
<td>-1.28 (-2.25-1.56)</td>
<td>0.322</td>
<td></td>
</tr>
<tr>
<td>z HC &lt;=32 wks Birth</td>
<td>0 (-1.46-1.4)</td>
<td>0.07 (-1.33-1.33)</td>
<td>0.993</td>
<td>0.07 (-1.33-1.35)</td>
<td>0 (-1.54-1.3)</td>
<td>0.616</td>
<td></td>
</tr>
<tr>
<td>z HC &lt;=32 wks Discharge</td>
<td>-0.71 (-2.06-0.56)</td>
<td>-0.56 (-1.73-0.38)</td>
<td>0.361</td>
<td>-0.71 (-1.94-0.47)</td>
<td>-0.53 (-1.62-0.41)</td>
<td>0.511</td>
<td></td>
</tr>
<tr>
<td>z HC &lt;=32 wks &gt;4 and &lt;=7 months Birth</td>
<td>-0.13 (-1.92-1.31)</td>
<td>0.14 (1.23-1.58)</td>
<td>0.010</td>
<td>0.17 (-1.77-1.55)</td>
<td>-0.11 (-1.54-1.38)</td>
<td>0.107</td>
<td></td>
</tr>
<tr>
<td>z HC &lt;=32 wks Birth</td>
<td>-0.06 (-1.37-1.63)</td>
<td>-0.06 (-1.3-1.19)</td>
<td>0.847</td>
<td>-0.06 (-1.18-0.99)</td>
<td>-0.06 (-1.19-1.36)</td>
<td>0.516</td>
<td></td>
</tr>
<tr>
<td>z HC &lt;=32 wks Discharge</td>
<td>-0.26 (-1.68-0.7)</td>
<td>-0.71 (-1.69-0.2)</td>
<td>0.010</td>
<td>-0.56 (-1.62-0.38)</td>
<td>-0.53 (-1.56-0.38)</td>
<td>0.558</td>
<td></td>
</tr>
<tr>
<td>z HC &lt;=32 wks &gt;4 and &lt;=7 months Birth</td>
<td>0.35 (-1.08-1.49)</td>
<td>0.38 (-0.99-1.78)</td>
<td>0.567</td>
<td>0.38 (0.82-1.76)</td>
<td>0.32 (1.38-1.86)</td>
<td>0.344</td>
<td></td>
</tr>
<tr>
<td>z HC &gt;37 wks Birth</td>
<td>-0.6 (-1.7-0.86)</td>
<td>-0.44 (-1.71-1.21)</td>
<td>0.279</td>
<td>-0.53 (-1.69-0.96)</td>
<td>-0.13 (2.63-1.37)</td>
<td>0.960</td>
<td></td>
</tr>
<tr>
<td>z HC &gt;37 wks Discharge</td>
<td>-0.56 (-2.17-1.03)</td>
<td>-0.87 (-2.53-0.66)</td>
<td>0.188</td>
<td>-0.47 (-2.25-0.83)</td>
<td>-1.17 (-2.85-1.1)</td>
<td>0.090</td>
<td></td>
</tr>
<tr>
<td>z HC &gt;37 wks &gt;4 and &lt;=7 months Birth</td>
<td>0.15 (-1.74-1.96)</td>
<td>-0.22 (-1.89-1.91)</td>
<td>0.300</td>
<td>-0.01 (-1.73-1.94)</td>
<td>-0.58 (-2.74-2.39)</td>
<td>0.051</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Factors associated with continued use of human milk at follow-up (>4 and ≤7 months) from the hospital were similar to those associated with the use of human milk at discharge and included: more immature gestational age at birth; non-Hispanic white (White-Hispanic participants were less likely to be on human milk at follow-up); any reported use of Kangaroo care (Table 2) and having had a human milk pump provided. The decrease in reported use of any human milk was independent of the site of care and gestational age group (Figures 3 and 4 Supplement).
"However, using multivariate analysis, the provision of a human milk pump was not independently associated with the use of human milk at discharge, but it was associated with continued use of human milk at follow-up between 4-7 months.

Growth Data

There were no consistent trends in growth patterns for participants discharged home on human milk compared to those who were not sent home on human milk (Table 3 Supplement). Birth z-scores for weight, length, and head circumferences were not different for any subgroup we evaluated. At discharge, participants with a gestational age between 33 and 36 weeks who were sent home on human milk had slightly lower z scores for weight and head circumference but no differences in z scores for length. At follow-up, these differences were no longer significant. At follow-up (4-7 months), participants with gestational age < 32 weeks who were sent home on human milk had slightly higher z scores for weight, length, and head circumference than participants in the same gestational age group who were not sent home on human milk and there was a suggestion of higher z scores in the lowest gestational ages.

"There were no consistent trends in growth patterns for participants who remained on human milk at follow-up compared to those who were not on human milk at follow-up."

Discussion

In our study of high-risk participants seen in follow-up after NICU discharge, the most important factor associated with the continued use of human milk was being discharged on human or donor milk. We identified Kangaroo care as an important independent factor associated with human milk use. This has been emphasized in a recent randomized Kangaroo care trial, which found...
Supplemental Table showing site demographics

<table>
<thead>
<tr>
<th>Site</th>
<th>FTCT</th>
<th>KID2</th>
<th>MPDS</th>
<th>PNSA</th>
<th>PPHR</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total enrolled</td>
<td>199</td>
<td>250</td>
<td>66</td>
<td>545</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>EGA group, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm &lt;37 weeks</td>
<td>178 (89.4)</td>
<td>208 (83.2)</td>
<td>60 (90.9)</td>
<td>472 (86.6)</td>
<td>83 (83)</td>
<td>0.2109</td>
</tr>
<tr>
<td>Term &gt;=37 weeks</td>
<td>21 (10.6)</td>
<td>42 (16.8)</td>
<td>6 (9.1)</td>
<td>73 (13.4)</td>
<td>17 (17)</td>
<td></td>
</tr>
<tr>
<td>Gestational Age at Birth, median (10-90th %tile)</td>
<td>31 (25-37)</td>
<td>32 (25-38)</td>
<td>32 (26.7-36.6)</td>
<td>33 (28-37)</td>
<td>33 (25-38)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Birth Weight (grams), median (10-90th %tile)</td>
<td>1490 (700-2920)</td>
<td>1610 (766-3126)</td>
<td>1720 (972-2728)</td>
<td>2013 (1076-2928)</td>
<td>2060 (812-3378)</td>
<td></td>
</tr>
<tr>
<td>Race Group, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>52 (26.1)</td>
<td>22 (8.8)</td>
<td>15 (22.7)</td>
<td>36 (6.6)</td>
<td>13 (13)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Asian</td>
<td>12 (6)</td>
<td>9 (3.6)</td>
<td>5 (7.6)</td>
<td>8 (1.5)</td>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td>Black Hispanic</td>
<td>1 (0.5)</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td>16 (2.9)</td>
<td>1 (1)</td>
<td></td>
</tr>
<tr>
<td>Native American</td>
<td>1 (0.5)</td>
<td>14 (5.6)</td>
<td>0 (0)</td>
<td>4 (0.7)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>10 (5)</td>
<td>18 (7.2)</td>
<td>0 (0)</td>
<td>13 (2.4)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>2 (1)</td>
<td>2 (0.8)</td>
<td>2 (3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>78 (39.2)</td>
<td>112 (44.8)</td>
<td>31 (47)</td>
<td>128 (23.5)</td>
<td>56 (56)</td>
<td></td>
</tr>
<tr>
<td>White Hispanic</td>
<td>43 (21.6)</td>
<td>72 (28.8)</td>
<td>13 (19.7)</td>
<td>340 (62.4)</td>
<td>23 (23)</td>
<td></td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>103 (51.8)</td>
<td>136 (54.4)</td>
<td>32 (48.5)</td>
<td>283 (51.9)</td>
<td>48 (48)</td>
<td>0.8</td>
</tr>
<tr>
<td>Receiving human milk at discharge, n (%)</td>
<td>142 (71.4)</td>
<td>174 (69.6)</td>
<td>45 (68.2)</td>
<td>413 (75.8)</td>
<td>67 (67)</td>
<td>0.1806</td>
</tr>
</tbody>
</table>

higher exclusive human milk feedings and direct breastfeeding at both discharge and one-month post-discharge in the earlier, more frequent Kangaroo care group (16). While the provision of a human milk pump was not independently associated with the use of human milk at discharge, it was associated with continued use of human milk at follow-up between 4-7 months. These data are encouraging in that they imply that attention and commitment to many health care practices may be associated with higher rates of long-term human/donor milk use. This study, which included diverse NICU graduates, not just preterm or infants below specific weight limits, reinforces information that kangaroo care, access to human milk pumps, and going home on human milk all contributed to participants receiving human/donor milk longer after discharge. We were encouraged that there were no clinically meaningful differences in growth between infants on human milk compared to those on formula, and there was a suggestion that in lowest gestational ages, being discharged home on human milk was associated with higher z-scores at 4-7 months follow-up. In contrast, infants >37 weeks gestational age who were still on breast milk at 4-7 month follow-up had lower z-scores for weight at follow-up, but the length and head growth were not different.

We showed that continued use of human milk after discharge from the NICU is low and decreases rapidly in all gestational age groups. In all of our sites, it appears that sicker infants—having surgery, going home on medications other than vitamins—were less likely to be on human milk at discharge. A quality improvement project targeting mothers of infants with complex cardiac and congenital anomalies utilized the strategy of human milk pumping (early and often) and were able to show some increases in human milk feedings at discharge.(17) Infants from our sites who did not receive their own mother’s milk but were only receiving donor milk in the NICU were unlikely to go home on human milk at discharge. Thus a strategy to promote health while inpatient actually decreased support to this same health intervention after discharge.

With the information we report, there are potential opportunities for change. Higher human milk use among white mothers indicates that focusing information and developing more culturally specific and culturally sensitive education both prenatally and during NICU stay towards non-white mothers may have benefit, however, other studies have continued to document struggles in impacting rates of human milk feeding in Hispanic and non-Hispanic black mothers (18,19) Other target populations for focus during the NICU stay are mothers whose infants go home on more medications, have surgery and those mothers whose infants receive donor milk only. Implementing, promoting, and strengthening evidenced-based strategies and developing additional strategies based on the identification of ongoing barriers to these strategies will continue to increase human milk use in this vulnerable population. (20,21)

“We did not have information about absolute amounts of human milk as a proportion of total feedings, either total volume or total calories, only whether an infant was receiving any human milk at discharge, which could have impacted growth data.”

**Limitations**

We did not have information about absolute amounts of human milk as a proportion of total feedings, either total volume or total calories.
moving forward, we plan to investigate our data regarding utilization of intervention (therapies), both state-supported and private, and changes in medications between discharge and various follow-up times to work to identify gaps between inpatient care and post-discharge care.”

Moving forward, we plan to investigate our data regarding utilization of intervention (therapies), both state-supported and private, and changes in medications between discharge and various follow-up times to work to identify gaps between inpatient care and post-discharge care. We also plan to analyze the 2-year follow-up data.

References:

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com
Contributors’ Statements

Dr. Ellis conceptualized and designed the study, collected the data, drafted the initial manuscript, and critically analyzed, reviewed, and revised the manuscript for important intellectual content.

Drs. Aune, Fierro, Roberts, Allare, Drabant, Ms. McDuffie, and Christina Sanchez conceptualized and designed the study, collected the data, and critically analyzed, reviewed, and revised the manuscript for important intellectual content.

Mrs. Kelleher conceptualized and designed the study, drafted the initial manuscript, and critically analyzed, reviewed and revised the manuscript for important intellectual content.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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(fish oil triglycerides) injectable emulsion

The first and only fish oil emulsion for pediatric patients with parenteral nutrition-associated cholestasis (PNAC) in the U.S.¹

A source of calories and fatty acids in pediatric patients with PNAC

Patients receiving Omegaven achieved age-appropriate growth

Omegaven-treated patients experienced improvement in liver function parameters

Limitations of Use
• Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients.
• It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6: omega-3 fatty acid ratio of the product.

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

Learn more about our PN portfolio: www.freseniuskabinutrition.com

Please see Brief Summary of Prescribing Information for Omegaven on the reverse side.
OMEGAven (fish oil triglycerides) injectable emulsion, for intravenous use

BRIEF SUMMARY OF PRESCRIBING INFORMATION
This brief summary does not include all the information needed to use Omevagen safely and effectively. Please see full Prescribing Information for Omevagen (fish oil triglycerides) injectable emulsion for intravenous use at www.fresenius-kabi.com/us.

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

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

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

DOSEAGE AND ADMINISTRATION
Prior to administration, correct severe fluid and electrolyte disorders and measure serum triglycerides to establish a baseline level. Initiate dosing in PN-dependent pediatric patients as soon as direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires PN.

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

WARNINGS AND PRECAUTIONS
• Risk of Death in Preterm Infants due to Pulmonary Lipid Accumulation: Deaths in preterm infants have been reported following the use of soybean oil based intravenous lipid emulsions that 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 Omevagen is unknown. Preterm infants that survive may have poor clearance of intravenously administered 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 Omevagen for signs and symptoms of pleural or pericardial effusion.

• Hypersensitivity Reactions: Omevagen containsfish oil and egg phospholipids, which may cause hypersensitivity reactions. Signs or symptoms of a hypersensitivity reaction may include: tachycardia, 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 Omevagen immediately and initiate appropriate treatment and supportive measures.

• Risk of Infections: The infection risk 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 Omevagen. Monitor for signs and symptoms of early infections including fever and/or chills, laboratory blood tests (e.g., hemoglobin, lactate dehydrogenase, bilirubin, and oxygen saturation) and effectively. Please see full prescribing information for Omevagen (fish oil triglycerides) injectable emulsion for intravenous use at www.fresenius-kabi.com/us.

• 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 the rate of administration as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop.

• 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 1000 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 Omevagen for 4 hours and obtain a repeat serum triglyceride level. Resume Omevagen based on new result as indicated.

• Aluminum Toxicity: Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Pretreatments are not protective 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 aluminum at greater than 4 to 5 mg/kg/day accumulate aluminum at levels associated with central nervous 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 evidence of essential fatty acid deficiency (ETAD) 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 Omevagen 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 Omevagen 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 Omevagen and with a higher incidence than the comparator group are: vomiting, agitation, bradycardia, apnea, viral infection, erythema, rash, abscess, neutropenia, hypotension and incision site erythema. Patients had a complicated medical and surgical history prior to receiving Omevagen treatment and the mortality was 13%. Underlying clinical conditions prior to the initiation of Omevagen therapy included prematurity, liver disease, right ventricular function, fetal bowel syndrome, ventilator dependence, coagulopathy, intraventricular hemorrhage, and sepsis. Twelve (6%) Omevagen-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 cholesterol resolved. One hundred thirteen (60%) Omevagen-treated patients reached D-dimer 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 Omevagen-treated patients at 89 and 65 U/L, respectively, at the end of the study. Median hemoglobin levels and platelet counts for Omevagen-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 Omevagen-treated patients.

Median glucose levels at baseline and the end of the study were 86 and 87 mg/dL for Omevagen-treated patients, respectively. Hyperglycemia was experienced by 13 (7%) Omevagen-treated patients. Median triglyceride levels at baseline and the end of the study were 121 mg/dL and 72 mg/dL for Omevagen-treated patients respectively. Hypertriglyceridemia was experienced by 5 (3%) Omevagen-treated patients.

The triene:tetraene ratio (Mead acid arachidonic acid ratio) was used to monitor essential fatty acid status in Omevagen-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 Omevagen in another country. Life-threatening hypoglycemia following a central venous catheter change was reported in a 9-month-old infant with intestinal failure who received PN with Omevagen 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 who received omega-3 fatty acids. Close monitoring of bleeding time in patients receiving Omevagen and concomitant antiplatelet agents or anticoagulants.

USE IN SPECIFIC POPULATIONS
• Pregnancy: There are no available data on Omevagen 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 Omevagen 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 Omevagen, and any potential adverse effects of Omevagen on the breastfed infant.

• Pediatric Use: The safety of Omevagen was established in 189 pediatric patients (19 days to 15 years of age). The most common adverse reactions in Omevagen-treated patients were vomiting, agitation, bradycardia, apnea and viral infection.

• Geriatric Use: Clinical trials of Omevagen did not include patients 65 years of age and older.

OVERDOSEx
In the event of an overdose, fat overload syndrome may occur. Stop the infusion of Omevagen 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.

REFERENCES:
1. Omevagen Prescribing Information, Fresenius Kabi USA, LLC. 2018.
Thirteen-year-old Emily Rose Shane was tragically murdered on April 3, 2010 on Pacific Coast Highway in Malibu, CA. Our foundation exists to honor her memory.

In Loving Memory
August 9, 1996 - April 3, 2010

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

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### Sponsor a Child in the SEA Program
The average cost for the program to provide a mentor/tutor for one child is listed below.

<table>
<thead>
<tr>
<th>Duration</th>
<th>Cost</th>
</tr>
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<tbody>
<tr>
<td>1 session</td>
<td>$15</td>
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<tr>
<td>1 week</td>
<td>$30</td>
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<tr>
<td>1 month</td>
<td>$120</td>
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<tr>
<td>1 semester</td>
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<tr>
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<td>$1,080</td>
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<tr>
<td>Middle School</td>
<td>$3,240</td>
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</table>

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.
Iranian village to a university professor in the United States of America in this memoir. As a boy, his unruly behavior was sedated by scholastic challenges as a remedy. At age twelve, he left home for junior high school in a provincial capital. At first, a lack of self-esteem led him to stumble, but he soon found the courage to tackle his subjects with vigor. He became more curious about the world around him and began to yearn for a new life despite his financial limitations. Against all odds, he became one of the top students in Iran and earned a scholarship to study medicine in Europe. Even though he was culturally and socially naïve by European standards, an Italian family in Rome helped him thrive. The author never shied away from the challenges of learning Italian, and the generosity of Italy and its people became part and parcel of his formative years. By the time he left for the United States of America, he knew he could accomplish whatever he imagined.
Fellow Column: An Unbalanced Translocation Involving Partial Duplication of Chromosome 6 and Partial Deletion of Chromosome 10 in a Premature Infant with Tetralogy of Fallot

Kevin Mo, Teagan Tran, Arjina Boodaghian, John Wear, John Ho, MD, Robin Clark MD, Mitchell Goldstein MD

Abstract

Purpose: To report a case of simultaneous chromosome 10 partial deletion and chromosome 6 partial duplication in a preterm infant.

Methods: This is a retrospective case report followed with clinical observation, echocardiogram, and genetic testing.

Results: A neonate with Tetralogy of Fallot, clubbed feet, low set ears, and webbed neck was found to have chromosomal abnormalities that are consistent with unbalanced translocation between chromosomes 6 and 10, resulting in a partial duplication of chromosome 6 and partial deletion of chromosome 10.

Discussion: Chromosome microarray testing in a patient with multiple congenital anomalies can facilitate rapid diagnosis and treatment with the potential to improve the management of complications and subsequent development.

Introduction

Prematurity is commonly associated with respiratory distress syndrome, patent ductus arteriosus, apnea of prematurity, hypoglycemia, and fetal exposure to drugs of abuse. Prematurity is also common in neonates with structural cardiac anomalies, limb abnormalities, and facial dysmorphism. We report a preterm infant treated in the neonatal intensive care unit with chromosome 6 and 10 abnormalities.

Methods

A retrospective chart review was performed on a patient who presented to the Emanate Health Queen of the Valley Neonatology Intensive Care Unit (West Covina, CA) following the preterm delivery of a twin gestation. Subsequent growth, developmental, cardiac, and musculoskeletal anomalies were monitored in the NICU.

Case Report

Baby M is a 36 week and 1-day gestation infant born to a 20-year-old Hispanic G2P1 woman who is blood type O positive. The mother’s first pregnancy led to premature delivery and rapid demise of an infant with multiple congenital abnormalities. In the second pregnancy, dichorionic diamniotic fraternal twins with intrauterine growth restriction (smaller twin B; Baby M) were diagnosed with club feet and congenital heart disease on prenatal ultrasound. There was persistent absent end-diastolic flow in twin B. Due to suspected fetal anomaly and fetal distress; a cesarean section was performed.

“In the second pregnancy, dichorionic diamniotic fraternal twins with intrauterine growth restriction (smaller twin B; Baby M) were diagnosed with club feet and congenital heart disease on prenatal ultrasound. There was persistent absent end-diastolic flow in twin B.”

The mother underwent general anesthesia, and amniotic fluid was clear. The presentation of this patient was breech. The baby had poor respiratory effort and required supplemental O2 with positive pressure ventilation. APGAR scores were 5 and 9 and 1 min
and 5 min, respectively. Following delivery, the mother and the patient's twin were stable and were discharged without any significant complications.

This 36 weeks gestation female was small for gestational age for all growth parameters: birth weight was 1255 g (<3%tile), head circumference was 26.5 cm (<3%tile), the length was 38 cm (<3%tile). The temperature was 36.1, the heart rate was 152, the respiratory rate was 79, and the blood pressure was 57/25. The chest had mild to moderate retractions in the substernal and intercostal areas consistent with prematurity. Breath sounds were clear and equal bilaterally. There was a 4/6 systolic murmur throughout the precordium. Other significant features were micrognathia, webbed neck, contracted fingers, club feet, low set ears, and epicanthal folds. The abdomen was soft and flat with normal external genitalia. The baby had bilateral club feet. Her hips were stable. She responded to tactile stimulation with diminished tone and decreased spontaneous activity. The skin was pink and adequately perfused. The infant was managed on non-invasive ventilation. She was placed on NPO on admission and started on IV D10 at 100ml/kg/day. The baby had initial hypoglycemia that resolved with IV therapy. The baby advanced to full cycled feeds of PE 24hp. There were no known maternal risk factors for infection. The baby had hyperbilirubinemia of prematurity and received phototherapy. The infant had no unusual movements or seizure-like activity.

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Echocardiograms on day of life 3 and 19 revealed Tetralogy of Fallo\textit{t} with large outlet VSD and overriding aortic root, PFO, ASD, PDA, aortic stenosis, bicuspid aortic valve, pulmonic stenosis, and thick and doming pulmonic valve. The infant was started on Furosemide at 13 days. She underwent routine chromosome analysis with a “re\textit{flex}” chromosome microarray. Abdominal ultrasound and retinal exams were within normal limits. Serology negative for HIV, Rubella, and Hepatitis B. When the baby reached 2 kg, she was transferred to a tertiary center for further evaluation and heart surgery.

Initial chromosome analysis (LabCorp) microarray analysis identified a terminal duplication of chromosome 6q and a terminal deletion of chromosome 10p. Microarray testing found a 28.5 MB duplication on chromosome 6 6q24.1 → q27 and a 3.8 MB deletion on chromosome 10 at 10p15.3→p15.2, consistent with an unbalanced translocation. Chromosome 6 duplication involved genes \textit{PITRM1} and \textit{ZMYND11}. The chromosome 10 deletion involved \textit{NMBR} g. The presence of a terminal gain and terminal loss of different chromosomes in the same analysis suggests that the proband may have inherited a single unbalanced derivative chromosome 10 from a parent with the balanced translocation between the two chromosomes. The lab recommended specific FISH analyses for the parents to investigate possible familial genetic rearrangements.

**Discussion**

Parents who have balanced chromosome translocations may be asymptomatic, while their offspring with unbalanced translocations may have complex congenital anomalies. Unbalanced translocations can also lead to infertility, miscarriage, or life-threatening congenital anomalies. Baby M’s mother had a previous stillbirth, which raises concerns that this translocation is familial, and the mother may carry a balanced version of the t(6;10) translocation. There have been reported cases of chromosome 6;10 translocations, resulting in miscarriage, suggesting that the stillbirth before baby M may have been a result of an inherited unbalanced translocation. [1]

The twin gestation with Baby M was dichorionic and diamniotic, suggesting that these were fraternal twins, conceived from different gametes. While baby M had a birth weight of 1255g, twin A was born at almost twice her birth weight and was discharged without any significant anomalies. Because the mother may have had a balanced translocation, further testing was recommended in her. If a familial translocation can be confirmed in one of the parents, further testing is warranted for the asymptomatic twin A who is also at risk to carry a balanced version of the familial translocation. Understanding the results of the microarray analysis can help explain the features of this patient and can potentially help predict future development.

Deletions in chromosome 10p yield a range of variable symptoms and findings. Associated features include severe intellectual disability, growth delays, short neck, and congenital heart defects. [2] Several cases have also been reported in patients with features...
of DiGeorge syndrome. DiGeorge syndrome, which is a common feature of the 22q11.2 deletion syndrome, presents with the triad of conotruncal heart defects, hypocalcemia, and absent thymus. While the genetic origins of this patient’s condition are distinct from DiGeorge syndrome, cardiac anomalies, epicanthal folds, short necks, and widely spaced nipples are similar and point to possible common pathophysiology. Absent thymus, absent parathyroid glands, and possible hypocalcemia in other patients with similar genetic abnormalities have been described.

Specifically, this patient’s 10p15.3→p15.2 deletion includes the genes PITRM1 and ZMYND11. PITRM1 codes for an ATP-dependent metalloprotease that degrades post-cleavage mitochondrial transit peptides. [4] The protein binds zinc and can also degrade amyloid beta A4 protein, which suggests a possible link to Alzheimer’s disease. ZMYND11 codes for a zinc finger protein that localizes to the nucleus and functions as a transcriptional repressor. [5] Specifically, it is known to bind the adenovirus E1A protein. Deletion of these genes, causing haploinsufficiency for the gene products, could contribute to manifestations related to Alzheimer’s and Adenovirus infection in this patient.

References
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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*
THE VIRTUAL NEONATAL UPDATE 2020

2-20 November 2020

On 2 November 2020, talks by twenty eminent speakers on topics from nutrition to heart and lung diseases, and from cystic fibrosis to blood-born viruses will be posted on our site.

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Enquiries: judy.gowing@imperial.ac.uk
The Covid-19 pandemic has triggered a decline in pediatric vaccination rates across the country, as parents avoid taking their children into clinics or hospitals for fear of coming into contact with the coronavirus. This raises concerns of increased risk for outbreaks of infectious diseases and loss of herd immunity, especially when the day comes that wearing masks, social distancing, and sanitizing measures become less common and unvaccinated populations become exposed.

There is also the concern that this reluctance to get their children vaccinated could heighten the normal worry some parents have about the safety of vaccines themselves and their side effects on infants and children. Anti-vaccine bias has been persistent in a segment of the population, especially around vaccines and autism, despite multiple studies showing no link.

Parents’ reasons for vaccine hesitancy have been reported to include religious practices, personal beliefs or philosophical reasons, safety concerns, and a need for more information from healthcare providers. Since in some cases, the safety concern could be around a perceived link between vaccines and Sudden Infant Death Syndrome (SIDS), this may be a good time to review what we know about vaccines and SIDS.

SIDS is part of the sleep-related infant death classifications of Sudden Unexpected Infant Death (SUID), which also includes accidental suffocation and strangulation in bed (ASSB). The CDC reports that SUID is the leading cause of death for infants one month to one year of age, currently resulting in an average of 3,600 infant deaths annually in the U.S., and the mortality rates within this are higher for Black, Hispanic, and Native American infants than for white babies. At First Candle, our mission is to reduce the rate of SUID through family adoption of the infant safe sleep practices developed by the American Academy of Pediatrics (AAP), which have contributed to a more than 50 percent reduction in SIDS deaths between 1994 and 1999, following the launch of the Back to Sleep (now Safe to Sleep) campaign.

Although SIDS can strike at any age during the first year of life, the majority of cases occur during the first six months. Since this time frame coincides with the administration of several scheduled vaccines, it has led to some parents to fear that SIDS is linked to the vaccines. Since (in normal times) the majority of U.S. children receive these multiple vaccinations during their first year, it is statistically possible that some number of SIDS cases could occur shortly after a vaccine has been administered. However, there has been ongoing research, including population-based studies and analyses of data from the Vaccine Adverse Event Reporting System (VAERS), that indicate no increased risk of SIDS from vaccinations.

To every NICU nurse who has cared for these precious babies we say….. "Thank you."
What parents should also know is that there is evidence that suggests vaccines can decrease the risk of SIDS. In addition to recommending that babies sleep supine on a firm surface with no extraneous bedding, and that breastfeeding can reduce the risk of SIDS since 2016, the AAP guidelines have also recommended keeping to the schedule of well-child care visits and the immunizations that go with them. This is not only for the benefits of each specific vaccine, but because vaccinations may help reduce the risk of SIDS. (7-9).

Parents may also have concerns about additives, and so should be reassured that mercury-based thimerosal has been removed from nearly all vaccines and that thimerosal-free versions of the multi-dose flu vaccines are available.

However, we know from our own educational work with healthcare providers who counsel families about practicing infant safe sleep practices that habits and fears may not be changed by reading fact sheets, so it is critical for practitioners to listen and learn about parents’ viewpoints and generational cultures and to combine evidence-based information with empathy and real-world understanding of what their lives may be like. Are there barriers to their compliance with the wellness visits, and can they be addressed? Are there personal histories that have shaped their decisions, which should be openly and constructively discussed?

These challenging times may also present new solutions; some health programs have been exploring options such as mobile or curbside clinics, having patients wait in their cars, and designating separate areas for sick and wellness visits, in order to bring vaccination rates up. These remedies could help parents of newborns keep their scheduled visits.

In short, the current situation gives rise to fears and worries, but it can also be an opportunity to discuss with parents immunization benefits, reviewing the normal side effects that may occur – but also the effects of the diseases the vaccines prevent. It may be difficult to be concerned about things we no longer see, such as annual polio outbreaks, but the recent rise in measles cases is a reminder of our vulnerability and what vaccines keep at bay.

References

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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Wes Gifford, M.D., Ph.D.
Wednesday, October 7, 2020
4:00pm – 5:00pm Eastern Time

**Ethical Considerations for the Periviable Birth**
John Lantos, M.D.
Wednesday, November 4, 2020
4:00pm – 5:00pm Eastern Time

**Improving the Nutrition of the Extreme Premature Infant**
Camilia Martin, M.D.
Wednesday, December 2, 2020
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The Survey says RSV

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

www.nicuawareness.org
www.nationalperinatal.org/NICU_Awareness
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.
Balancing the Needs of the Patient and the Needs of the System

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

I learned to drive long ago. The process began with me sitting on my maternal grandfather’s knee behind the wheel of a half-ton truck or his ’58 Oldsmobile. This progressed to the mowing down small trees in a vacant field in my uncle’s jalopy, then driving a tractor pulling a hay wagon on my grandmother’s farm at age 9. When 16 finally arrived, I took driver’s while education in a ’73 Oldsmobile Cutlass.

Our family had two vehicles: a ’66 Ford ½ ton, and a ’67 Meteor Rideau 500. (Note to car buffs: Meteor was the Canadian brand of Mercury). The truck had the standard “3 on the tree” transmission, and the other was an automatic. No one was permitted to drive the automatic until they had mastered the standard. This was no small feat! If the shift between first gear to second was precisely done, the entire transmission would lock up, bringing the truck to a screeching stop. What, you may be asking about now, does this have to do with the subject at hand. There are, it seems, a few parallels.

“With fewer and fewer babies being intubated for invasive ventilation or even resuscitation, and the advent of “minimally invasive” surfactant administration, there are fewer and fewer opportunities for trainees to learn this very basic yet essential skill.”

Technology has improved the care and outcomes of all patients, be they young or old. Graphics give us information about lung compliance and over-distention; transilluminators make finding and cannulating veins and arteries easier; fiber-optic laryngoscopes provide brighter light, and fiber optic laryngoscopes aid in the visualisation of the airway and placement of the endotracheal tube. There are many more aids and adjuncts available to modern clinicians that were not available when many of us were training.

These and other devices constitute a double-edged sword. In the adult world, “old school” anesthetists complain the skill of laryngoscopy is quickly becoming a lost art. With the relatively recent availability of video laryngoscopy devices in the N.I.C.U., there is fear the same may happen in the world of neonatology. This fear is justified, although experience with the video laryngoscope recently purchased for teaching purposes by the unit in which I work has demonstrated that new devices also have a learning curve. Just how steep that learning curve is, and whether video laryngoscopy becomes standard practice in the N.I.C.U., remains to be seen.

With fewer and fewer babies being intubated for invasive ventilation or even resuscitation, and the advent of “minimally invasive” surfactant administration, there are fewer and fewer opportunities for trainees to learn this very basic yet essential skill.

In many NICUs, respiratory therapists (RRTs) are the ones doing most of the intubations; thus, RRT trainees are also in the training queue. This would not be such a problem were it not for the fact that many of our fellows in training will never again work in a level 3 or 4 facility, but rather a level 2 facility or even a hospital with only a well-baby unit. Why does this present a problem?

In a world experiencing increasingly shrinking health care budgets, it is unlikely that a facility without higher-level neonatal care will invest in the technology we find commonplace in our level 3 and 4 units. Should a patient in one of these facilities require intubation, the ability of the clinician to perform this procedure, “the old-fashioned way” is essential. That clinician may be the only person with neonatal intubation skills available. As well, there are
As real as simulations are, there is no substitute for the adrenalin-fidelity simulations do not necessarily improve learning objectives, including neonatal resuscitation program learning. It is also interesting that there is some evidence that higher-cost simulators and simulators do not substitute for the real thing, nor are they a complete substitute for clinical practice. These devices are a great opportunity the N.I.C.U. affords trainees to learn intubation skills. Perhaps it is neonatology that poses a bigger challenge to simulations. There are situations that cannot be adequately taught in a simulation setting.

Simulators ranging from 25-weeks (“micro-preemie”) are available. These offer a chance to practice oral intubation, umbilical line placement, IV placement, nasogastric tube placement, and can present a variety of birth defects. To the best of my knowledge, these devices do not offer experience with false-tracking umbilical lines or femoral artery or hepatic catheterisation. There are clinical signs of these occurrences in real life that a simulator can’t simulate. These devices are a great start, but they are not a true substitute for a real patient, nor are they a complete substitute for clinical practice.

This is of concern as simulation sessions become an increasingly large part of basic training and substitution for real-life experience for trainees. Anecdotally, there is a subtle difference observed in students with extensive simulator training; however, literature does not support these observations. It is worth noting that the amount of clinical time replaced by simulation in this study was limited to 50%. While there was no difference in pass rates or educational outcomes, passing does not always equate to real-world competence. Every trainee I have worked with has passed their didactic and clinical programs. The real test might be how many of the simulator group actually pass orientation in a critical care setting. It is also interesting that there is some evidence that higher-fidelity simulations do not necessarily improve learning objectives, including neonatal resuscitation program learning.

As real as simulations are, there is no substitute for the adrenalin-fueled panic that can ensue in real life (although I have witnessed just that during simulations). There is no “time out” function in the resuscitation room. Simulators do offer opportunities to experience a variety of clinical situations that a trainee may never see during a typical rotation. Whatever one’s personal views are, it is undeniable that simulation training has become an integral part of medical education and is here to stay.

I recall attending a lab session during my training, where we practiced intubating anesthetized cats. I learned two things: cats are easy to intubate, and cats are not babies. While in my adult training program, we were also encouraged, where possible, to practice laryngoscopy on cadavers post unsuccessful resuscitation to improve competency. The ethics of doing this today may be called into question, but the experience gained cannot be disputed.

The micro-premature infant presents another quandary. It is generally accepted where I practice that the most experienced person present at resuscitation is the one who manages the airway. Compounding the problem in the unit in which I practice is we intubate nasally wherever and whenever possible. I have yet to find a mannequin that allows for nasal endotracheal tube placement. How then are trainees to learn these skills? Clearly, when it comes to patient care, we want what is best for our babies, and the needs of trainees are secondary. The question here is, how does this philosophy serve future patients and those destined to be treated by those trainees? Where is the balance? What are the ethical implications? Perhaps it is time that we, as practitioners, should be addressing these issues to improve training as a whole.

Perhaps the same technology creating these problems will, with evolution and innovation, create needed solutions. Some high-end mannequins have anatomy with a range of adjustments (the size of the palate, for instance). While I have faith in the ability of technology to save us from technology, it comes with a price and a very high one at that. The cost of furnishing a complete simulation suite is steep. The question of whether cash strapped institutions will be amenable to this investment remains. Until that time, we must make do with what is available to us as teachers.

The one place where endotracheal intubation is still commonplace is the operating room. This could be the ideal venue for learning laryngoscopy and intubation in a controlled environment and under the watchful eyes of a skilled, experienced pediatric anesthetist.

The one place where endotracheal intubation is still commonplace is the operating room. This could be the ideal venue for learning laryngoscopy and intubation in a controlled environment and under the watchful eyes of a skilled, experienced pediatric anesthetist. This would require liaising with our anesthesia colleagues but could also have an impact on the training of new anesthetists who also must have excellent intubation skills. There are only so many trainee vacancies on their roster and only so many patients for neonatology trainees on whom to practice. Therefore, the limited opportunity the N.I.C.U. affords trainees to learn intubation skills...
could, at present, leave us with no choice but simulation.

Finally, I believe that neonatal fellowship programs should offer a respiratory rotation. While RRTs are the primary drivers of ventilation in some units, outside North America, this is a profession that does not exist. When foreign trainees return to their native lands, it is they who must run the ventilators. Who better to learn the intricacies of ventilators and mechanical ventilation from than those who have made it their life’s work? A four-week rotation acting as an RRT orientee could prove invaluable, especially to our foreign trainees.

To use the driving analogy, we all should learn standard before availing ourselves of the luxury of an automatic. By the way, to this day, my vehicles have standard transmissions. I also intubate the “standard” way. When Armageddon comes, I will be doing it the “old fashioned way.” How about you?

References:
1. https://ojin.nursingworld.org/MainMenuCategories/ANAPeriodicals/OJIN/TableofContents/Vol-23-2018/No2-May-2018/Articles-Previous-Topics/Simulation-Based-Learning-Undergraduate-Education.html#:~:text=The%20control%20group%20could%20have,who%20had%20more%20clinical%20time.
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3195067/

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

In Loving Memory
August 9, 1996 - April 3, 2010

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

**Make a Difference in the Life of a Student in Need Today!**
Please visit [emilyshane.org](http://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.

<table>
<thead>
<tr>
<th>Duration</th>
<th>Cost</th>
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<tbody>
<tr>
<td>1 session</td>
<td>$15</td>
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<tr>
<td>1 week</td>
<td>$30</td>
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<td>1 month</td>
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<td>1 semester</td>
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<tr>
<td>1 year</td>
<td>$1,080</td>
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<tr>
<td>Middle School</td>
<td>$3,240</td>
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</tbody>
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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.
Congenital hypothyroidism (CH) is the most common neonatal endocrine disorder affecting 1 out of every 2000 newborns. (1) Prior to 1976, when the American Thyroid Association recommended the inclusion of CH as part of the newborn screen (NBS). (2) CH was the leading cause of severe intellectual disabilities in children. With neonatal screening, CH can be diagnosed and treated in the newborn period, which significantly decreases the damaging effects of this disorder. Because of the continued support for NBS programs by the American Thyroid Association and the American Academy of Pediatrics, CH is now known as the most preventable cause of intellectual disabilities in children.

Best practices and guidelines have evolved as science has advanced. Unfortunately, national guidelines and standardization of best practices based on empirical evidence are lacking, and current NBS programs vary among states. Kilberg and colleagues (3) reviewed current practices for all NBS programs in the United States (n=51). The authors reported that regardless of the initial screening approach of measuring thyroxine (T-4) or thyroid-stimulating hormone (TSH), or both, all 51 programs did have TSH level, initiating immediate follow-up and further testing. However, the authors highlighted current variations among the states that result in potential limitations for CH screening protocols in some NBS programs. Specifically, if the TSH is borderline or the NBS is late, states vary on follow-up procedures. The concerning finding the authors presented was the lack of age-adjusted TSH thresholds for late initial screens and follow-up tests. Keeping the TSH threshold at higher levels consistent with the initial NBS (>40 mU/L) may result in false-negative reports. In 2006, the American Academy of Pediatrics reported that 10% of CH cases have TSH values <40mU/L and emphasized the need for age-adjusted values (4). According to the 2018 publication by Kilberg and colleagues (3), most programs do not adjust their TSH thresholds based on age. The authors provide a poignant example of an NBS collected at day of life 4 with a TSH of 24mU/L. Under their current practices, 28 out of 51 state programs (55%) would report this case as a false negative and miss the identification of CH.

Another strategy to be considered for reducing false negatives is the implementation of a second metabolic screening at 2-6 weeks of age. Few NBS programs in the United States have reported on the benefits of this additional neonatal screen. An eight-year review in Colorado revealed a false negative rate for CH on the initial NBS of 15.6%, and an additional 46 CH cases were identified using the second metabolic screening method. (5) Forty-six additional newborns received therapeutic medication to reduce the effects of hypothyroidism and decrease the risk and severity of intellectual disabilities. A more recent eight-year review in Alabama followed 146 newborns who were identified on the first or second NBS as having abnormal thyroid levels. Permanent CH was confirmed in 92 of the 121 newborns identified on the initial NBS (75%) and 5 of the 25 newborns identified from the second NBS (20%). (6) Five newborns would not have been able to receive medication for the prevention and reduction of severe intellectual disabilities if there was not a second NBS. In Utah, a four-year retrospective review revealed 20% of CH cases were missed on the initial NBS resulting in 25 additional cases detected because of the second NBS. (7)

There is the science. Now here is the reality. $38.50 saved my son’s life. He was 6 days old. I finished a feeding, rocked him to sleep, and checked my phone. I noticed three missed phone calls from my pediatrician. My heart sank. Something was wrong. I quickly called the pediatrician. “Your son has an abnormal newborn screen.” My mind raced through the list of congenital diseases included on the NBS that I had collected many times as a newborn intensive care nurse. “Your son’s thyroid levels are abnormal. Can you come to the hospital to run some more tests today?”

In 2018, 1 out of 1300 newborns in Nebraska were diagnosed with a form of hypothyroidism because of abnormal results identified on their NBS. (8) Seventeen babies that year were potentially saved from a known developmentally devastating disease. The cost of a newborn screen in Nebraska for 2018 was $38.50. (9) A price tag of $38.50 saved my son’s life.

Tiffany Moore, RN, PhD

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

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

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NEONATOLOGY TODAY www.NeonatologyToday.net

September2020 36
In 2018, 1 out of 1300 newborns in Nebraska were diagnosed with a form of hypothyroidism because of abnormal results identified on their NBS. (8) Seventeen babies that year were potentially saved from a known developmentally devastating disease.

Reviewing the literature identifies potential major gaps in NBS programs related to CH. The risks of parental distress from a false positive and the minimal additional funding required for a second NBS or lowering the TSH threshold seem insignificant compared to the potential developmental consequences of delayed diagnosis and treatment for CH. In a world with so many unknowns and uncertainties, very few diseases can be identified early and, with simple treatment, drastically alter outcomes. A few things to consider as a neonatal provider:

- Does your state use age-appropriate thresholds for TSH levels? Why not?
- What is the process for follow-up on NBS abnormal values? Is there someone dedicated to ensuring 100% follow-up rates?
- Has your state considered a second metabolic screen? Why not?
- Does your program have sufficient lab support and adequate funding? If not, advocate for change. Lawmakers listen to you.

For more information and resources, please visit the Centers for Disease Control and Prevention [https://www.cdc.gov/newborn-screening/index.html](https://www.cdc.gov/newborn-screening/index.html) or the National Newborn Screening and Global Resource Center [http://genes-r-us.uthscsa.edu/](http://genes-r-us.uthscsa.edu/)

References:

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

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Postpartum Revolution
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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

Seek Participation
Help Explore Options
Assess Preferences
Each a Decision
Evaluate 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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**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.

<table>
<thead>
<tr>
<th>Special Health Needs</th>
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<tbody>
<tr>
<td>Babies who have had a NICU stay are more likely to need specialized care after they go home.</td>
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<tr>
<td><strong>Timely follow-up care is important.</strong></td>
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<tr>
<td>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.</td>
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<th>Special Developmental Needs</th>
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<td><strong>Any NICU stay can interrupt a baby’s growth and development.</strong></td>
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<tr>
<td>Needing specialized medical care often means that they are separated from their parents and from normal nurturing.</td>
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<td>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 &quot;catching up&quot; and should be understood to be developing at their &quot;adjusted age.&quot;</td>
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<tr>
<th>Special Educational Needs</th>
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<td><strong>Every child has their own unique developmental needs and every student has their own unique and special educational needs.</strong></td>
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<tr>
<td>Take advantage of the services and support that can meet your child where that are and help them reach their future educational goals.</td>
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<tr>
<td>Call your local school district to request a free educational evaluation. Learn about all the available programs and support.</td>
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<th>Who Can Help</th>
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<td>• pediatricians</td>
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<td>• neonatal therapists</td>
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<td>• pulmonologists</td>
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<td>• neurologists</td>
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<td>• gastroenterologists</td>
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<td>• cardiologists</td>
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<td>• nutritionists</td>
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<td>• CSHCN - Programs for Children with Special Health Care Needs</td>
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<tr>
<td>Who Can Help</td>
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<tr>
<td>• IBCLCs and lactation consultants</td>
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<td>• Early Childhood Interventionists</td>
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<td>• developmental pediatricians</td>
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<td>• physical therapists (PTs)</td>
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<td>• speech therapists (SLPs)</td>
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<td>• WIC - Special Supplemental Nutrition Program for Women, Infants, and Children</td>
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<td>• social workers and case managers</td>
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<td>Who Can Help</td>
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<tr>
<td>• Preschool Program for Children with Disabilities (PPCD)</td>
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<tr>
<td>• Special Education programs under the Individuals with Disabilities Education Act (IDEA)</td>
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<td>• educational psychologists</td>
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<td>• speech therapists (SLPs)</td>
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<tr>
<td>• occupational therapists (OTs)</td>
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<tr>
<td>• reading specialists</td>
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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.

Did You Know?

**Special Developmental Needs**
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- neonatal therapists
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- neurologists
- gastroenterologists
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- nutritionists

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Who Can Help?

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."

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 they 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.

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.

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

www.infanthealth.org
Precluding Pregnant Women from COVID-19 Vaccine Trials is Cause for Concern

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

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

It is normal to test vaccines in healthy adults first. They have the lowest risk should a side effect occur. It is the same reason older adults, young children, and people with certain health conditions are typically not included in early trials. However, people in each of these groups have already been included in COVID-19 vaccine trials, while one group is notably missing: pregnant women. (1)

"However, people in each of these groups have already been included in COVID-19 vaccine trials, while one group is notably missing: pregnant women. (1)"

Researchers would do well to find a way to safely include pregnant women – and soon. Having a vaccine that hundreds of millions of people worldwide cannot take should be concerning.

Women of reproductive age comprise a sizable portion of the workforce, and they are overrepresented in many professions that are less likely to be able to work remotely. They are first responders, health and child care providers, and educators, among other front-line jobs. Vaccinating pregnant women will not only protect them from serious COVID-19 complications, but it also will benefit their communities and those they serve.

The Food and Drug Administration recognized the necessity of testing vaccines in pregnant women. In June, the agency issued guidance that called upon vaccine developers to include not just diverse populations, elderly individuals and those with medical comorbidities, but also to “provide data to support [vaccine] use during pregnancy.” (2)

From influenza to the zika virus to Ebola, pregnant women experience more severe health outcomes, up to and including maternal death and fetal loss. (3) Data released earlier this month from the Centers for Disease Control and Prevention show similar trends are likely for pregnant women with confirmed SARS-CoV-2 infection.

“The surveillance data representing the experience of more than 20,000 pregnant women suggest they are more likely to be hospitalized due to COVID-19-related complications than non-pregnant women. (4)”

The surveillance data representing the experience of more than 20,000 pregnant women suggest they are more likely to be hospitalized due to COVID-19-related complications than non-pregnant women. (4) Additionally, pregnant women appear to be at increased risk of needing intensive care-level treatment and ventilator support.

While the more recent data seem to validate early trends that show pregnant woman are not more likely to die from COVID-19, just knowing they are more vulnerable to severe COVID-19 should be reason enough to work toward an effective vaccine for them. (5)

Additionally, vaccinating pregnant women against COVID-19 could benefit their unborn babies. Research has proven that pregnant women who are vaccinated against certain diseases, flu, and whooping cough, for example, pass along antibodies to their babies. (6) These antibodies give babies some immunity until they are old enough to be vaccinated themselves. The question as to whether or not unborn babies are similarly protected from COVID-19 will remain until pregnant women are included in clinical trials.

As the months toward the January 2021 target date for delivering a safe, effective COVID-19 vaccine wind down, those involved in the effort should pause to reflect on the effect of their omission, then retool their approach to include pregnant women in COV-
ID-19 testing.

References

The author has not indicated any disclosures.

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NATIONAL PERINATAL ASSOCIATION

CORONAVIRUS COVID-19

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

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December 2 - 4, Hyatt Regency Aurora-Denver

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Respiratory Syncytial Virus is a Really Serious Virus

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

- Coughing that gets worse and worse
- Rapid breathing and wheezing
- Breathing that causes their ribcage to "cave-in"
- Bluish skin, lips, or fingertips
- Thick yellow, green, or grey mucus that clogs their nose and lungs, making it hard to breathe
- Fever that is higher than 101° Fahrenheit which is especially dangerous for babies younger than 3 months

RSV can be deadly. If your baby has these symptoms, don't wait. Call your doctor and meet them at the hospital. If your baby isn’t breathing, call 911.

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

- **flu**
- **coronavirus**
- **pertussis**
- **RSV**

WASH YOUR HANDS often with soap and warm water.

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

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

USE AN ALCOHOL-BASED HAND SANITIZER.

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

www.nationalperinatal.org/rsv
Williams-Beuren Syndrome Presenting as Pulmonary Edema with Pleural Effusion: A New Pulmonary Manifestation of Elastin Vasculopathy

Fadi Al Khazzam, Ashraf Gad, Muhammad Dilawar

Abstract

Introduction: Williams-Beuren syndrome (WBS) is a gene deletion disorder characterized by distinct facial features, cardiovascular anomalies, and intellectual disability. Many genes are involved in WBS, of which the elastin (ELN) gene deletion is almost present in all cases. Limited data exist about pulmonary diseases in children with WBS. Furthermore, pleural effusion (PE) has not been reported in these patients.

Case Presentation: A term, small-for-gestational-age (SGA) male Caucasian newborn presented with respiratory distress shortly after vaginal birth. A chest radiograph showed significant pulmonary edema with bilateral pleural effusion. A 2D Echocardiogram demonstrated supravalvular aortic stenosis and branch pulmonary stenosis suspecting WBS. A genetic evaluation revealed an interstitial 1.5Mb deletion in the long arm of chromosome 7 involving band q11.23 confirming the diagnosis of WBS. The child underwent surgical repair at 4 months for age due to cardiac disease progression.

Conclusions: An unexplained finding of pulmonary edema and PE in a newborn can be associated with genetic disorders and warrants investigation for WBS, especially in SGA newborns.

Key words

Williams-Beuren syndrome, ELN, Elastin, Williams syndrome, pleural effusion, microdeletion, supravalvular aortic stenosis, and branch pulmonary artery stenosis

Background:

Williams-Beuren Syndrome (WBS) is a contiguous gene deletion disorder that involves the chromosomal region 7q11.23 (1). WBS affects about 1 in 10000 to 23500 live births, depending on the population (2,3). The deleted chromosomal region in WBS involves many genes, particularly the elastin (ELN) gene, which is present in the majority of cases of WBS (1).

The clinical manifestations of WBS are quite variable and comprise distinct facial features, cardiovascular anomalies, growth failure, transient hypercalcemia, hypothyroidism, musculoskeletal defects, genitourinary, stellate iris pattern, hypotonia, and peculiar neurodevelopmental and behavioral profile (2-10). Early diagnosis of patients with WBS, especially in the neonatal period, can be challenging due to the sporadic nature of the disorder; also important physical features can be overlooked, resulting in devastating outcomes including sudden death (11).

Pleural effusion (PE) results from disruption of the pleural liquid turnover in the pleural space. Although PE is a clinical feature of some genetic syndromes and chromosomal abnormalities (12-14), it is not associated with WBS. Additionally, limited data have been published on the involvement of pulmonary disease in patients with WBS (15,16).

“The clinical manifestations of WBS are quite variable and comprise distinct facial features, cardiovascular anomalies, growth failure, transient hypercalcemia, hypothyroidism, musculoskeletal defects, genitourinary, stellate iris pattern, hypotonia, and peculiar neurodevelopmental and behavioral profile (2-10).”

In this report, we present a case of a male infant with WBS born with pulmonary edema with PE and progressive supravalvular aortic stenosis (SVAS) and branch pulmonary artery stenosis (PAS). We review the relevant literature concerning the presentation of WBS in the neonatal period, mainly due to pulmonary disease. To our knowledge, there have been no other published reports similar to this unusual presentation.

Case Presentation:

A Serbian male infant was born at 37 weeks’ gestation via induced vaginal delivery to a 31-year-old caucasian mother. The mother is otherwise healthy; her firstborn female child was 4 kg at term birth. Antenatal laboratory screening was unremarkable except for a positive GBS on the vaginal swab for which she received adequate treatment with Penicillin G. In the third trimester, fetal ultrasonography indicated fetal growth restriction with a low end-diastolic flow and abnormal pulsatility index on the umbilical artery Doppler. On admission, her membranes were intact, and the fetal heart rate tracing was category-1. After 20 hours of labor induction, including a 9-hour second stage, a healthy baby was born vigorous, the amniotic fluid was clear. The baby required only routine care. Apgar scores were 9 and 10 at 1 and 5 minutes, respectively. Birth weight was 2.35 kg (5th percentile), head circumference 33 cm (35th percentile), and length 45 cm (5th percentile). The newborn was transferred to the postnatal ward to room in with his mother. The placental histopathologic examination revealed a small placenta, weight 350 g (<3rd percentile), and a marginally inserted 3-vessel umbilical cord.
Genetic consultation was sought because of the unexplained finding of pulmonary edema and PE. Microarray analyses revealed an interstitial deletion of the long arm of chromosome 7 involving band q11.23. In the postnatal ward, the baby developed tachypnea and circumoral cyanosis at four hours of age; therefore, he was transferred to the neonatal intensive care unit (NICU) for further management.

Physical examination upon admission to the NICU revealed tachypnea with subcostal retractions. The cardiac exam revealed a grade 2/6 systolic ejection murmur at the left lower sternal border. Other features included epicanthal folds, upturned nose, and wide mouth; the rest of the clinical examination was unremarkable. Chest X-ray (Figure 1a) revealed significant bilateral lung opacification indicating alveolar and interstitial edema, hyperinflation, and bilateral pleural effusion.

The baby required continuous positive airway pressure (CPAP) support for two days and a nasal cannula for an additional day. He was started on ampicillin and amikacin antibiotic on admission for suspected sepsis and continued for 7 days, provided the chest x-ray findings. Chest X-ray (Figure 1b) repeated after two days demonstrated persistent hyperinflation (on CPAP), interstitial edema, and appearance of fluid in the interlobar fissure, and resolution of the pleural effusion.

Sepsis evaluation revealed normal results, including a negative blood culture. Serum electrolytes showed a corrected serum calcium level of 2.41 mmol/L (9.7 mg/dl).

A 2D echocardiogram (echo) done on the second day of life revealed an aneurysmal atrial septum with a small fenestrated atrial septal defect with left-to-right shunting, a small-mid muscular ventricular septal defect with left-to-right shunting, patent descending aorta with a peak gradient of 14 mmHg.

Genetic consultation was sought because of the unexplained finding of pulmonary edema and PE. Microarray analyses revealed an interstitial deletion of the long arm of chromosome 7 involving band q11.23. The deleted region is ~1.5Mb in size and includes 24 genes, including ELN, LIMK1, BAZ1B, CLIP2, GTF2IRD, NSUN5, CLDN4, EIF4H, LAT2, MLXIPL, TBL2, WBSCR18, WBSCR22, WBSCR27, confirming the diagnosis of WBS. The chromosomal microarray study done on both parents was normal. The baby was discharged home at one week of age in a stable condition.

A follow-up echo study done at 4 weeks of age revealed mild SVAS with a peak gradient of 34 mmHg, and moderate bilateral branch PAS, peak gradients 40 to 50 mmHg, and normal biventricular size and function. The study was repeated at 10 weeks of age (Figure 2a & 2b) revealed progression of the SVAS; diameter 5.1mm, Z score -3.2, and branch PAS, right pulmonary artery; diameter 2.9mm, Z score -2.8, and left pulmonary artery; 4.6mm, Z score -0.43, with a peak gradient of 81 mmHg, and 56 mmHg, respectively. The descending aorta with flow acceleration showed a peak gradient of 30 mmHg and moderate left ventricular hyper-

(Figure 1a and 1b): Chest x-ray on admission (Figure 1a) demonstrates mild lung hyperinflation, diffuse interstitial edema and opacification, and bilateral pleural effusion (arrowheads). Chest x-ray 2 days later (Figure 1b) while on CPAP demonstrates inflated lungs, interstitial edema with fluid in the interlobar fissure, and resolution of the pleural effusion.
The exact cause of pulmonary edema and PE in our patient is unclear; however, it is notable that the disruption of the pleural liquid turnover process of any etiology results in pleural fluid accumulation.

At 4 months of age, the infant underwent open-heart surgery for Brom aortoplasty of the SAVS with pulmonary homograft patch augmentation of both PAs. Postoperatively, the baby developed reactive hypertension requiring treatment with multiple antihypertensives medications; he was discharged home on oral furosemide and propranolol. He was also started on levothyroxine treatment for hypothyroidism.

Discussion

WBS is a gene deletion disorder that involves the 7q11.23 regions (1). Although up to 28 deleted genes have been described in this disorder, the ELN gene mutation is the most predominant one. This particular gene deletion results in elastin vasculopathy characterized by elastosis and disorganization of the elastic lamellae in the affected tissue (6,17). Although ELN gene deletion is peculiarly related to the cardiovascular disease often described in patients with WBS, the role other deleted genes play in the pathology and clinical manifestations of WBS is hardly defined (18).

Elastin is expressed in multiple cell types in the lung, including pleural mesothelial cells, smooth muscle cells in airways and blood vessels, endothelial cells, and interstitial fibroblasts (19). Elastin protein integrates with fibrillin-containing microfibrils in the extracellular matrix to form the elastic fibers that contribute to the physical property of these tissues (19).

The exact cause of pulmonary edema and PE in our patient is unclear; however, it is notable that the disruption of the pleural liquid turnover process of any etiology results in pleural fluid accumulation. pleural liquid normally originates from the high-pressure systemic blood vessels in the parietal pleural membranes and drains into the lymphatic stomata located in the submesothelial connective tissue of the parietal pleura. We hypothesize that elastosis in the submesothelial connective tissue or in the vascular
wall increases the microvascular pressure and results in either altered pleural liquid secretion or impaired drainage, or both (20). Additionally, blockage of the lymphatic stomata by a similar mechanism affects liquid absorption. Alveolar and interstitial edema, consequently, PE can also arise if the elastin layer in the visceral pleura, and the alveolar or vascular wall is defective. Speculatively, this can result in either leakage of the fetal alveolar fluid into the pleural space, impaired clearance of the fetal fluid from the alveoli and the interstitium, or through both mechanisms (21). Although PE due to congenital lymphatic malformation (chylothorax) is associated with specific genetic and chromosomal disorders such as Gorham-Stout, Optiz G/BBB, Hennekam, Milroy syndromes, Trisomy 21, Turner, and noon syndrome (12-14), our patient is the first reported description of PE in a case of WBS.

Other respiratory conditions reported in patients with WBS are congenital lobar emphysema (CLE). Walsh et al. published the case of a preterm male infant who had suffered respiratory distress syndrome until day 25 of life when he developed CLE, requiring left upper lobectomy at six weeks of age. Wong et al. also reported a 2-month-old infant found to have CLE in the right middle lobe during his preoperative cardiac workup for surgical repair; a bronchoscopy demonstrated a small, collapsed right middle lobe bronchial orifice. Impaired lung elastin production has been suggested to play the primary role in the pathogenesis of CLE in both patients (15,16).

Studies have shown that loss of elastin fiber integrity is a trigger of inflammation and tissue injury in certain diseases such as chronic obstructive pulmonary disease, emphysema, and cutis laxa (21-24). In the adult literature, Wojcik et al. reported a case of severe bullous emphysema in a male adult who was later confirmed to have WBS (26). Another case of WBS for a young adult man who had paraseptal emphysema incidentally found on chest CT. To further assess the association of pulmonary manifestations in WBS, Wan et al. studied a cohort of 16 nonsmoker adolescents and young adults with WBS. They found higher respiratory symptoms in WBS subjects despite nonsignificant spirometric abnormalities compared to controls (26).

The penetrance and severity of SVAS and total cardiovascular disease in WBS subjects are more common among male subjects, as described by Sadler et al., possibly due to hormonal effect (27). In her study, male gender and a low body mass index increased the likelihood of an earlier diagnosis of WBS (27). Consistent with the previous study conclusion, the abnormal finding of chest X-ray in our patient, in addition to growth restriction, led us to entertain a genetic diagnosis. Although chest CT did not delineate a discrete coarctation in our patient, the subisthmus narrowing of the aorta is usually regarded as an atypical form of coarctation, particularly in this disorder, resulting in the so-called middle aortic syndrome. Such a syndrome can rapidly progress to a severe form of focal coarctation or diffuse narrowing, as describe by Kammache et al. and Hall et al. (28,29). Moreover, lifelong cardiac follow up is essential in the patient because of the risk of developing vasculopathy or arterial hypertension (8).

Finally, the upper respiratory features of this disorder include changed quality of voice, which may advance to upper airway obstruction. Stridor associated with subglottic cyst has been reported in WBS (30). Koren et al. and Vaux et al. published the cases of bilateral vocal cord paralysis revealed on an endoscopic exam.

Figure 2b. A 2D echo with color Doppler depicting pulmonary artery (PA), right pulmonary artery (RPA), and left pulmonary artery (LPA) in high parasternal view. AO; Aorta, RA; right atrium, LA; left atrium
of 2 separate newborns who later required tracheostomy (31, 32). A third infant presented with noisy breathing in the neonatal period and developed significant stridor in the second year of life (32). The findings of harsh, hoarse, or brassy quality of voice changes in WBS patients can be explained by impaired elastogenesis in the lamina propria of the vocal cords, as illustrated by heterozygous ElN deletions (ElN +/−) experiment in mice (33). However, the mechanism of paralysis of the vocal cords in these children needs further explanation.

**Conclusion:**

WBS is associated with severe short and long term morbidity and mortality in children. Unexplained findings of PE after birth can be a manifestation of elastin vasculopathy disorder such as WBS, especially in the presence of additional abnormal features such as growth restriction and cardiac murmur. Therefore, it is imperative to exercise vigilance in order to diagnose WBS in the neonatal period.

**Authors’ Contributions:**

Dr. Al Khzzam and Dr. Gad have an equal share in drafting this manuscript. They both reviewed the literature and equally contributed to drafting, reviewing, and editing the final version.

**References**


The authors have no conflicts of interests to disclose.
Respiratory Syncytial Virus: How you can advocate for babies this RSV season

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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
ONCE UPON A PREEMIE

By Jenné Johns
Author | Speaker | Advocate

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Neonatology Today – Reflection on the Past and Future

Mikko Hallman, MD, PhD

History helps to understand the future. Nordic countries – Sweden, Denmark, Norway, Finland, Estonia, Latvia, Lithuania – have smaller total populations than California, and they currently form a somewhat heterogeneous group of independent nations. As an example of development, in the late 19th century, Finland had no hospital beds for newborns, and infant mortality was nearly two orders of magnitude higher than today. In 1910 Finnish physician Arvo Ylppö led the first neonatal care unit for the premature, established in Berlin (1). Premature newborns were fed with fresh breast milk instead of fasting. This practice remained controversial for a very long time. During the next tumultuous decades, progress in neonatal medicine was slow.

“In 1910 Finnish physician Arvo Ylppö led the first neonatal care unit for the premature, established in Berlin (1). Premature newborns were fed with fresh breast milk instead of fasting. This practice remained controversial for a very long time.”

The rapid development of modern neonatology started in the 1960s. In 1963, premature Patrick Kennedy, born at 34.5 wk, died of RDS. This sad event elevated RDS as a medical challenge. Progress in neonatal-perinatal medicine was made by, among others, Louis Gluck, Abraham Rudolph, Kurt Benirschke, and Edward Hon in California and by Roberto Caldeyro-Barcia (Uruguay), Peter Karlberg (Sweden), Graham Liggins (New Zealand). They broadened the early findings on lung surfactant by John Clements and Mary-Ellen Avery. Next-generation investigators managed to accomplish satisfactory treatment and prevention of RDS by the end 1980s, i.e., about 20 years later than the US-Astronauts landing on the moon in 1969. Great success is nearly always followed by slower progress as the focus of public support shifts.

Pharmacologic support for medicines in children started to advance after 2002 when new legislation encouraged pediatric drug studies (2). This policy is beneficial, particularly for diseases in adolescents and older children. Regardless, neonatology maintained academic activities in the 2000s, and modern neonatal practices started to benefit transitional economies. However, great medical investments have mainly benefited adults and the elderly. The progress in the prevention of both premature births and poor intrauterine growth has been slow and antenatal research has focused on infertility (3). The blastocyst and its precursors undergo “therapies,” whereas, after the development of the embryo, any drug trials are rare; previous spectacular adverse effects are still in mind. However, intrauterine tissues and newborn undergo investigations, using sophisticated visualization techniques, genomics, and other non-invasive ‘omics’ methods. Progress in identification of the risk of premature birth has been made (4). An increase in research support, seamless interaction between fertility and antenatal prevention projects, and merging of neonatal-perinatal diagnostics/intervention programs are required for a breakthrough.

Some feel that the intact survival of more and more immature infants is the future goal. Others argue that prolonging the extremely short gestations and decreasing IUGR are the challenges (4,5). These aims are not exclusive. The long-term outcome of preterm infants, regardless of the length of pregnancy, has started to improve gradually. However, the burden of prematurity for families and society continues to be high.

How do we advance our unique field? Continuous education and quality improvements are admirable goals. Networking, participation in data collection, and trials advance the field. Some institutes maintain anonymous, voluntary medical data banks on pregnancies, newborns, children, and adults. This may enable sophisticated analyses of population-wide clinical and ‘omics’ data (6). Anonymity and voluntary participation are key issues that must be maintained. We may anticipate new discoveries, like the expansion of less-invasive management practices and new targeted biological drugs for high-risk pregnancies and immature infants. We encourage our talented young colleagues to proceed with research that eventually may revolutionize neonatal-perinatal medicine.

References:

The author indicates no conflict of interest
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THE BRETT TASHMAN FOUNDATION

The Brett Tashman Foundation is a 501©(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to “TheBrettTashmanFoundation.org” or phone (909) 981-1530.
I was exposed to opioids. I am not an addict. Addiction is a set of behaviors associated with having a Substance Use Disorder (SUD).

I was exposed to substances in utero. I am not addicted. 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.

My mother may have a SUD.

My potential is limitless.

When reporting on mothers, babies, and substance use NAS is a temporary and treatable condition. There are evidence-based pharmacological and non-pharmacological treatments for Neonatal Abstinence Syndrome.

My mother 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.

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!
Coping With COVID-19: An Online Educational Course

Sue Hall, MD

A viral pandemic. A racial pandemic within the viral pandemic. Is mental illness the next inevitable pandemic? Many think so.

The COVID-19 pandemic has heaped a variety of psychosocial stresses on pregnant people, new parents, and frontline medical providers, and has had a disproportionate effect on disadvantaged communities and people of color.

The National Perinatal Association has joined with the NICU Parent Network to create My NICU Network—My Perinatal Network to provide online continuing education on the topic of providing psychosocial support to parents, patients, and staff. The newest offering, “Coping with COVID-19,” which is “just in time” education, is a short (3-course) program of educational courses to give NICU providers more knowledge and skills about how to support patients’ and NICU staff’s emotional well-being during the COVID-19 pandemic. As stated in the New England Journal of Medicine: “Given that most COVID-19 cases will be identified and treated in health care settings by workers with little to no mental health training, it is imperative that assessment and intervention for psychosocial concerns be administered in those settings” (Pfefferbaum and North, 2020). Our goal, therefore, is to provide frontline NICU and maternity providers with an understanding of trauma-informed care, how to identify patient populations at greatest risk of experiencing adverse effects such as Perinatal Mood and Anxiety Disorders as a result of the pandemic, and how to provide psychosocial supports to mitigate the potential that these stresses could evolve into more serious problems.

“The courses are available for free (no-credit) thanks to a grant that the National Perinatal Association has been awarded from the Health Resources and Services Administration of the US Department of Health and Human Services, through the University of North Carolina at Chapel Hill.”

The COVID-19 course reviews the impact that societal disruptions and social determinants of health have had on families’ well-being and on the pronounced racial disparities that the pandemic has brought to light. It explores the anxieties which practitioners may expect to see among pregnant patients and new parents, including the distress parents are feeling about the potential and sometimes required separation from their babies after birth. The topic of staff distress related to working during the pandemic is also addressed in detail, with mitigation strategies proposed.

“This program for NICU providers (physicians, nurses, nurse practitioners, social workers, educators, therapists, etc.) consists of 3 courses:

1- Giving Birth During the COVID-19 Pandemic: Trauma-informed Care to Support Patients, Families, and Staff;

2- Communication Skills for NICU Staff; and

3- Providing Emotional Support to NICU Parents.

Interested learners can also choose to take our more extensive program of 7 courses for NICU staff called “Caring for Babies and Their Families: Providing Psychosocial Support in the NICU;” maternity providers can take the new 6-course program called ’Caring for Patients and Their Families: Providing Psychosocial Support During Pregnancy, Labor & Delivery.’”
rich, and family-centered, and include the patient/parent “voice.”

Interested learners can also choose to take our more extensive program of 7 courses for NICU staff called “Caring for Babies and Their Families: Providing Psychosocial Support in the NICU;” maternity providers can take the new 6-course program called “Caring for Patients and Their Families: Providing Psychosocial Support During Pregnancy, Labor & Delivery.” Information about all programs, and all included courses (which can be taken individually), are available on our websites at www.myperinatalnetwork.org or www.myperinatalnetwork.com.

Reference:

The author has no conflicts to disclose

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The Brett Tashman Foundation is a 501©(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to “TheBrettTashmanFoundation.org” or phone (909) 981-1530.
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“I've interviewed Deb Discenza, Co-Founder of the Alliance for Black NICU Families for an inside look at the power of standing in solidarity and leading solutions that address health and racial equity in the NICU and beyond.”

Q: What is the Alliance for Black NICU Families?

A: These are like-minded organizations that have come together along with partner organizations, to create long-needed change in the African American community of NICU families. Too long we have seen systemic racism play its part in healthcare and the NICU is no different. Any professional that says that their NICU is not prone to systemic racism doesn’t realize what implicit bias is and that it can feed into narratives behind curtains, behind closed doors. It can be as simple as not providing a family resources that would be given to anyone else in the same situation. We have to do better. We must do better.

Q: Who are the members of this newly formed Alliance?

A: We have members that span the African American leadership of NICU and preemie support groups nationwide as well as organizations that see the importance of being a part of our movement. We have also had industry representation. We are also proud to have our first international member. Racism does not know a state boundary, it does not know a country boundary either. Our members are as follows:

- GLO Preemies: https://www.glopreemies.com
- Connect to NICU: http://connect2nicu.com
- Eli Collins Foundation for Premature Babies: http://www.elibabies.org
- Families Blossoming: https://familiesblossoming.com
- Once Upon a Preemie: www.OnceUponAPreemie.com
- Pebbles of Hope: http://www.pebblesofhope.org
- Saul’s Light: https://www.saulslight.org
- Mended Little Hearts: https://mendedhearts.org
- PreemieWorld: https://preemieworld.com
- Prolacta Bioscience: https://www.prolacta.com
- Sage Therapeutics: https://www.sagerx.com/
- Sobi Therapeutics: https://www.sobi.com/en

Q: What does the formation of this Alliance mean to the neonatal community at this time?

A: This Alliance came about because I saw what was happening with the Black Lives Matter Movement and reached out to many of the people you see listed as members that are African American. I simply sent them messages of love and support during this turbulent time.

This Alliance came about because I saw what was happening with the Black Lives Matter Movement and reached out to many of the people you see listed as members that are African American. I simply sent them messages of love and support during this turbulent time.”

Jenné Johns, MPH

In this month’s Health Equity Column, I welcome the readers of Neonatology Today to journey with me, as we take a deeper look into health and racial equity issues plaguing our society and impacting Black NICU and Preemie families. In recognition of NICU Awareness Month (a time designated to honor families experiencing a stay in the neonatal intensive care unit and the health professionals that care for them), I’ve interviewed Deb Discenza, Co-Founder of the Alliance for Black NICU Families for an inside look at the power of standing in solidarity and leading solutions that address health and racial equity in the NICU and beyond.
Founder of the Alliance for Black NICU Families and President of Glo Preemies stood in complete alignment and agreement with the importance of charge of this Alliance. As an African American led NICU support organization, Ashley knew instantly that this Alliance would move our country beyond a moment to support Black NICU Lives to a movement. Through our early outreach and awareness-raising efforts, everyone was literally onboard without much convincing. They understood the goals immediately. Same with the industry folks. They were really excited and wanted to help. And so here we are.

Q: What personal and professional experiences led you and the Co-Founder to co-create the Alliance?

A: As for me, I am not African American. I am coming from a different background as a Jewish woman that grew up with extremely dark olive-toned skin. I was picked on, I was bullied and I was treated as if I were not human. After the 2016 elections when the white supremacy movement appeared to see its moment in the sun, I had my first official hate-crime occur as an adult. While my skin tone has lightened a lot as an adult, I still look ethnic. If that is what happened to me in a single instance, I fear for the African American community that is just trying to go about their lives like every other human being on earth. The Black Lives Matters Movement is about police brutality but it shines a light on so many other inequities. Hearing Ashley and others members of the Alliance talk about this is so enlightening. Too many times and in too many ways, our country has let down the African American community and that has to stop. Ashley Randolph and I, formed this Alliance to focus on the tiniest of community members and their families- the NICU community (one in which we both experienced). We hope to plant seeds of education and advocacy and support in a very powerful way. Our first effort is health and racial equity education for the neonatal professional sector.

Q: What does the Alliance want to accomplish and what is the call to action?

A: We are hoping to garner an annual mandate for continuing education on racial and health equity for gaining and maintaining licensing for NICU and pediatric professionals. Our current goal is to get that change instituted in at least 10 states that have a significant African American populations and significant racial and ethnic disparities. We will uplift our founding member, the Once Upon A Preemie Academy as the gold standard for this continuing education.

In addition, we are asking the community at large to share this Racial and Health Equity survey with Black families that have been or are currently in the Neonatal Intensive Care Unit (NICU): https://preemie.us/BlackNICUfamilies. For organizations interested in partnering with us we ask 1) to include their organization’s name as a partner on our letterhead going out to state licensing boards and 2) Encourage Black NICU families to complete the above survey.

Q: Where can we find more information about the Alliance?

A: We have a website at https://blacknicufamilies.org. For addi-
ONCE UPON A PREEMIE ACADEMY

2020 SPONSORSHIP PROSPECTUS

"DELIVERING HEALTH AND RACIAL EQUITY TRAININGS FOR THE PREEMIE/NICU COMMUNITY"
The Once Upon A Preemie Academy TM is the first and only virtual training academy focused on delivering health and racial equity educational programs for healthcare professionals who support the Neonatal Intensive Care Unit (NICU) and Premature Baby community. Our purpose is simple, to raise awareness and offer real-time solutions for addressing health and racial equity.

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

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

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

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

- 50% prefer either web-based and or live
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The monograph below was originally penned in 1986. Although this concept is tongue-in-cheek, the issue of malpractice (not valpractice) remains very real in today’s world. I do not believe that the number of cases that have the potential for litigation has decreased. On the other hand, case reviews, depositions, court trials, and arbitrations are fewer because they are so expensive. Over the years, a “cottage industry” was born. Expert witnesses in all fields, economists, and attorneys with specific expertise in medical malpractice proliferated. The judgments were often excessive and had to be modified in order to be appropriate in dealing with economic principles. The following illustrative scenario describes some of the aspects of both malpractice and valpractice.

“And so, members of the jury, I want you to look again at two-year-old Jason Carroll who, although born prematurely at 32 weeks of pregnancy, is perfectly normal today. This accomplishment was part of the team effort demonstrated by both the perinatal and neonatal health care network, but Jason’s recovery from the most serious part of his illness was the result of the better care offered by Dr. Fairchild compared with that by Dr. Heller. Now, look into your hearts…your souls…and render a VALPRACTICE judgment in favor of Dr. Fairchild.”

Allen Washington turned slowly away from the jury. His movements were well-practiced. Taking small steps, he passed the bench, nodded to me, and gracefully sat down.

I stifled a yawn, trying to appear professional, but was bored out of my mind. Today’s schedule was full of these VALPRACTICE cases. The pendulum was making full circle, and things would finally get back to normal…but when” The malpractice crisis reached its peak in 1987 when after three judgments of over 30 million dollars, all the insurance carriers quit. Doctors converted their assets; hospitals set up trusts and foundations; and suddenly there was no money for the patient or the lawyer. The most litigious law firms in the country began experiencing financial problems, and the public complained about “due process.” They were right. For a period of time, there was “no process.” Finally, in 1988, someone—to this day I can’t remember who—coined the term VALPRACTICE. The expression was an abbreviation for “value in practice,” and it rewarded the individual for the extra effort, the correct decision. In simple terms, it substituted a “val” for a “mal.” Before long, the rules became extremely complicated. A panel in each hospital was created to determine whether “your care was better than my care.” Points were offered for better judgment, extra time spent with families, quality and penmanship of patient notes, use of medications, and so forth.

This initial group of criteria soon expanded as nurses, social workers, and respiratory therapists became involved. A “point guard” was added to each hospital unit to assist in the judgment process.

The snowball continued. Doctors and nurses no longer had time to use handwritten notes, for the entries in the charts were voluminous. The medical record office soon ran out of room and personnel. Typing pools were enlarged immediately, and in fact, TPI (Typing Pools International), a small company that went public on the over-the-counter exchange on June 27 at six dollars a share, had split twice and was still 12 dollars a share by September 18. Hospitals changed their building plans and converted patient rooms into storage facilities for charts, typewritten reports, and copying machines. A new industry was formed.

The competition was fierce. Doctors wanted to work extra hours in order to spend more time with the patient and the family and rack up valpractice points. Nurses took double shifts, and one ICN nurse in San Jose broke the nursing work record by doing a “triple-double.”
The library and research staff were overwhelmed with requests for literature searches as doctors proved their extra value with references and more references. The lawyers loved it. The insurance companies reappeared, quoting VALPRACTICE insurance and offering a part of the judgment to the family if something occurred that was of lesser value. That is, nothing was described in terms of malpractice or poor care any longer. If an error occurred, it was thought of in terms of being of “lesser value” than someone else’s care.

Before long, the inevitable occurred. The court calendar became overcrowded, and it often took two to three years for a case to come to trial. The competition between self-interest groups eroded the team effort, and perinatal and neonatal mortality rates increased. It was obvious that a new type of tort reform was needed.

My reverie was broken as the jury returned to the courtroom.

“Thank you, ladies and gentlemen,” I began. “Have you reached a verdict?”

“We have, your Honor,” replied the foreperson, a heavyset woman with thick, red eyeglasses. “The jury would especially like to thank the respiratory therapist expert witness provided by both doctors for clearly explaining the basic functions of the current equipment available.” “In fact…” she continued. On with it, I thought…

“Several members of the jury are considering leaving their present fields of work and returning to school to become respiratory therapists.”

“Please, please,” I interrupted. “May the count have the verdict?”

“Of course. I am sorry, your Honor.”

The jury felt that Dr. Fairchild demonstrated great value to the patient on the third day when oxygenation failed, and all respirator changes produced no improvement in the blood gases or clinical status. He changed to the Ultrasonic Cabal Company Friction Ventilator, and Jason suddenly improved. For this reason, we find Dr. Fairchild guilty of VALPRACTICE. In addition, we believe that Dr. Heller should be remanded for additional education courses focusing on the Ultrasonic Cabal Company ventilator.”

“Thank you for your time and effort. The jury is dismissed, and this case is closed.”

As the reporters scurried out of the courtroom to call in the stories, I wondered if a call to my broker about Cabal and Company would be considered as inside information.

I picked up the phone……..

Disclosure: Dr. Martin indicates no relevant disclosure.

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com
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Neonatology Solutions has updated and refined content for residents, fellows, and practicing Neonatologists who are searching for information about neonatology fellowship training programs. Within the NICU Directory page, users can select the Neonatology Fellowship Programs tab, which will open a map-based search function as well as all fellowship programs listed by state. Information regarding the number of fellow positions, program directors, division directors, and affiliated NICUs and training sites are all included.

"Within the NICU Directory page, users can select the Neonatology Fellowship Programs tab, which will open a map-based search function as well as all fellowship programs listed by state. Information regarding the number of fellow positions, program directors, division directors, and affiliated NICUs and training sites are all included."

We hope this resource helps trainees to efficiently find the information they need when searching for a future fellowship program or while networking and collaborating during training. As always, we appreciate any feedback regarding how to make this site the most valuable free Neonatology resource on the web.

References:

The author is a principal of Neonatology Solutions, LLC.
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Level III | 20 Beds

Texas Children’s Hospital
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The CE activity explains safe infant sleep recommendations from the American Academy of Pediatrics and is approved by the Maryland Nurses Association, an accredited approver of the American Nurses Credentialing Center’s Commission on Accreditation.
The National Urea Cycle Disorders Foundation

NIH-supported study to track prevalence and impact of SARS-CoV-2 among pregnant women in low- and middle-income countries

The impact of SARS-CoV-2 in low and middle income countries is being studied by NIH.

Tuesday, September 1, 2020

WHAT:

The National Institutes of Health has launched a study to track the prevalence and impact of SARS-CoV-2 infection among approximately 16,000 pregnant women in seven low- and middle-income countries. The study will follow women through pregnancy and 12 months after childbirth to compare maternal, fetal and newborn outcomes of participants who have been infected with the virus to those of pregnant women who have not been infected.

At delivery, women enrolled in the study will receive an antibody test to determine if they have been exposed to SARS-CoV-2. Researchers hope to determine if infection increases the risk of complications such as preterm birth, fetal growth restriction, stillbirth, newborn death and birth defects. They also hope to assess participants' knowledge and attitudes of COVID-19 during pregnancy, including safety, protective practices and prenatal care. Women in the study will also be invited to participate in a follow-up analysis to determine if maternal SARS-CoV-2 infection influences infant outcomes such as cerebral palsy, developmental delays and hearing and vision abnormalities.

The study is being conducted by the Global Network for Women's and Children's Health Research, a group of clinical sites funded by NIH’s Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). The participating countries are Guatemala, Bangladesh, India, Pakistan, Kenya, Democratic Republic of Congo and Zambia.

WHO:

NICHD Director Diana W. Bianchi, M.D., is available for comment.

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

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

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Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Contact
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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:

Mitchell Goldstein, MD, FAAP, Section Chairperson, MGoldstein@llu.edu and
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Dedicated to the Health of All Children

# # #

The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit www.aap.org. Reporters can access the meeting program and other relevant meeting information through the AAP meeting website at http://www.aapexperience.org/
Scientists at NIAID’s Rocky Mountain Laboratories (RML), based in Hamilton, Montana, conducted a preclinical study of AZD1222. Their findings — recently published in Nature — indicate the candidate vaccine rapidly induced immune responses against SARS-CoV-2 in mice and rhesus macaques. A single dose of the vaccine protected six rhesus macaques from pneumonia caused by the virus. Based on the RML data, a Phase 1 trial of the candidate vaccine began on April 23 in healthy volunteers in the U.K. Investigators recently reported promising results in The Lancet. Currently, the vaccine candidate is being evaluated in Phase 2/3 trials in the U.K. and Brazil and in a Phase 1/2 trial in South Africa.

The NIAID COVID-19 Prevention Network (CoVPN) will participate in the Phase 3 clinical trial of AZD1222 in the U.S. The CoVPN is composed of existing NIAID-supported clinical research networks with infectious disease expertise and is designed for efficient and thorough evaluation of vaccine candidates and monoclonal antibodies for the prevention of COVID-19.

Ann R. Falsey, M.D., professor of medicine, University of Rochester School of Medicine in New York, and Magdalena E. Sobieszczyn, M.D., associate professor of medicine at Columbia University Medical Center in New York, will serve as coordinating investigators for the trial.

Volunteers 18 years and older are eligible and must provide informed consent to participate in the trial. Participants will be randomly assigned to the investigational vaccine group or the placebo group, and neither the investigators nor the participants will know who is assigned to which group. After an initial screening, participants will receive two injections of either the investigational vaccine or a saline placebo approximately four weeks apart. One person will receive a placebo injection for every two people who receive AZD1222, which will result in approximately 20,000 people receiving the investigational vaccine and 10,000 people receiving a placebo.

The trial primarily is designed to determine if AZD1222 can prevent symptomatic COVID-19 after two doses. The trial also will evaluate if the vaccine candidate can prevent SARS-CoV-2 infection regardless of symptoms and if it can prevent severe COVID-19. It also will assess if the experimental vaccine can reduce the incidence of emergency department visits due to COVID-19.

Participants will be closely monitored, particularly after injections, for safety and reactogenicity, which refers to symptoms — usually mild and self-limiting — that can occur after vaccination. Investigators will evaluate participants after each vaccination and will ask participants to record any symptoms after returning home as well. An independent Data and Safety Monitoring Board (DSMB) will provide oversight to ensure the safe and ethical conduct of the study.

Participants will be followed for two years after their second vaccination. They will be asked to provide blood and nasopharyngeal samples at their initial visit and will be asked to provide blood samples periodically for the duration of the trial. Scientists will examine the blood samples in the laboratory to measure and characterize immune responses. The severity of the disease observed will be measured and used to assess the activity of the investigational vaccine and the placebo.

“Safe and effective vaccines will be essential to meet the global need for widespread protection against COVID-19,” said NIAID Director Anthony S. Fauci, M.D. “Positive results from preclinical research led by NIH scientists supported the rapid development of this vaccine candidate, which has also showed promise in early-stage clinical trials.”

The Phase 3 trial is being implemented as part of Operation Warp Speed, a multi-agency collaboration led by HHS that aims to accelerate the development, manufacturing and distribution of medical countermeasures for COVID-19. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership also guided the development of the trial protocol to ensure a coordinated approach across multiple vaccine efficacy trials. NIH experts have emphasized the importance of a harmonized process to generate data for multiple investigational vaccines in parallel to assess the relative effectiveness of each.

“NIH is committed to supporting several Phase 3 vaccine trials to increase the odds that one or more will be effective in preventing COVID-19 and put us on the road to recovery from this devastating pandemic,” said NIH Director Francis S. Collins, M.D., Ph.D. “We also know that preventing this disease could require multiple vaccines and we’re investing in those that we believe have the greatest potential for success.”

Oxford University’s Jenner Institute and Oxford Vaccine Group developed AZD1222. The candidate vaccine was licensed to AstraZeneca for further development. The vaccine uses a non-replicating chimpanzee adenovirus to deliver a SARS-CoV-2 spike protein to induce an immune response. SARS-CoV-2 is the virus that causes COVID-19.

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vestigational vaccine.

Participants suspected to have COVID-19 will be asked to undergo a nasal and nasopharyngeal swab for testing. Participants who test positive for SARS-CoV-2 infection will be followed closely and referred for medical care if symptoms worsen.

Adults who are interested in joining this study can visit Coronaviruspreventionnetwork.org or ClinicalTrials.gov and search identifier NCT04516746.

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.

About the COVID-19 Prevention Network: The COVID-19 Prevention Network (CoVPN) was formed by the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health to respond to the global pandemic. Through the CoVPN, NIAID is leveraging the infectious disease expertise of its existing research networks and global partners to address the pressing need for vaccines and antibodies against SARS-CoV-2. CoVPN will work to develop and conduct studies to ensure rapid and thorough evaluation of vaccines and antibodies for the prevention of COVID-19. The CoVPN is headquartered at the Fred Hutchinson Cancer Research Center. For more information about the CoVPN, visit: coronaviruspreventionnetwork.org.

About HHS, ASPR, and BARDA: HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures — vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, BARDA-supported products have achieved 55 FDA approvals, licensures or clearances. To learn more about federal support for the nationwide COVID-19 response, visit https://www.coronavirus.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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Probiotic skin therapy improves eczema in children, NIH study suggests

Effect noted in children as young as three years of age and persists for up to eight months..

Wednesday, September 9, 2020
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An experimental treatment for eczema that aims to modify the skin microbiome safely reduced disease severity and increased quality of life for children as young as 3 years of age, a National Institutes of Health study has found. These improvements persisted for up to eight months after treatment stopped, researchers report Sept. 9 in Science Translational Medicine.

Atopic dermatitis, commonly called eczema, is a chronic inflammatory skin disease characterized by dry, itchy skin and rashes. The disease is most common in children and is linked to an increased risk of developing asthma, hay fever and food allergy. While available treatments can help manage eczema symptoms, current options can be costly, and many require multiple daily applications.

The experimental therapy contains strains of live Roseomonas mucosa—a bacterium naturally present on the skin—originally isolated from healthy volunteers and grown under carefully controlled laboratory conditions. For four months, clinical trial participants or their caregivers periodically applied this probiotic therapy to areas of skin affected by eczema.

“A child suffering from eczema, which can be itchy, painful and distracting for the child, also is very difficult for the entire family,” said Anthony S. Fauci, M.D., director of NIH’s National Institute of Allergy and Infectious Diseases (NIAID), which led the study. “These early-stage findings suggest that R. mucosa therapy may help relieve some children of both the burden of eczema symptoms and the need for daily treatment.”

Numerous genetic and environmental factors contribute to eczema, and scientists are learning more about the role that the skin’s microbiome plays in this condition. In 2016, NIAID researchers reported that R. mucosa strains isolated from healthy human skin improved outcomes in cell culture and mouse models of eczema.

To build on these preclinical findings, NIAID launched a Phase 1/2 clinical trial at the NIH Clinical Center in Bethesda, Maryland, to assess the safety and potential benefit of R. mucosa therapy in people with eczema. Interim results reported in 2018 for 10 adults and five children aged 9 to 14 years indicated that the treatment was safe and associated with reduced eczema severity. Since then, the trial has enrolled an additional 15 children, for a total of 20 children with mild to severe eczema ranging in age from 3 to 16 years.

Twice weekly for three months and every other day for an additional month, children or their caregivers sprayed a solution of sugar water containing live R. mucosa onto areas of skin with eczema. For the first 15 children enrolled in the study, the dose of live R. mucosa was gradually increased each month. The last five children to enroll received the same dose throughout the four-month treatment period. Regardless of dosing strategy, no serious adverse events were attributed to the therapy.

“Most children in the study experienced substantial improvements in their skin and overall wellbeing following R. mucosa therapy. Encouragingly, the therapeutic bacteria stayed on the skin and continued to provide benefit after therapy stopped,” said NIAID’s Ian Myles, M.D., principal investigator of the trial. “These results support a larger study to further assess the safety and effectiveness of this experimental treatment by comparing it with a placebo.”

Seventeen of the 20 children experienced a greater than 50% improvement in eczema severity following treatment. Improvement occurred on all treated skin sites, including the inner elbows, inner knees, hands, trunk and neck. The scientists also observed increases in the skin’s barrier function—its ability to seal in moisture and keep out allergens. Additionally, most children needed fewer corticosteroids to manage their eczema, experienced less itching, and reported a better quality of life following the therapy. These benefits persisted after treatment ended, and the therapeutic R. mucosa strains remained on the skin for up to eight months.

The NIAID researchers next set out to better understand how R. mucosa therapy improves eczema symptoms. They found that treated skin had increased microbial diversity and reduced levels of Staphylococcus aureus—a bacterium known to exacerbate eczema.

In addition to imbalances in the microbiome, the skin of people with eczema is deficient in certain lipids, or oils. By conducting experiments in cell and animal models of eczema, the NIAID scientists found that a specific set of lipids produced by R. mucosa strains isolated from healthy skin can induce skin repair processes and promote turnover of skin tissue. Study participants had increased levels of these lipids on their skin after treatment with R. mucosa.

The researchers emphasize that additional studies are needed to further elucidate the mechanism of R. mucosa therapy and to explore whether genetic or other factors may explain why some participants did not benefit from the experimental treatment.

For more information about the completed Phase 1/2 study Beginning Assessment of Cutaneous Treatment Efficacy for Roseomonas in Atopic Dermatitis (BACTERIAD), see ClinicalTrials.gov using identifier NCT03018275.

NIH has exclusively licensed the R. mucosa therapy to Forte Biosciences to advance this potential treatment through further clinical development, and the company plans to begin enrollment in a Phase 2 placebo-controlled trial later this month. For more information about this study, Evaluation of FB-401 in Children, Adolescents and Adults (2 Years and Older) With Mild to Moderate Atopic Dermatitis, see ClinicalTrials.gov using identifier NCT04504279.

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,
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.

References

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Institute/Center
National Institute of Allergy and Infectious Diseases (NIAID)
The study enrolled 101 children between ages 6 and 13 and assigned them to either the experimental group, which used the new artificial pancreas system or to the control group which used a standard CGM and separate insulin pump. Check-ins and data collection were conducted every other week for four months.

Study participants were instructed to continue about their daily lives so that the researchers could best understand how the system works in the typical routines of the children.

The study found that youth using the artificial pancreas system had 7% improvement in keeping blood glucose in range during the daytime, and a 26% improvement in nighttime control compared to the control group. Nighttime control is of particular importance for people with type 1 diabetes, as severe, unchecked hypoglycemia can lead to seizure, coma or even death. The overall time-in-range goal for the artificial pancreas reflected a nearly 11% improvement, which translated to 2.6 more hours per day in range.

“The improvement in blood glucose control in this study was impressive, especially during the overnight hours, letting parents and caregivers sleep better at night knowing their kids are safer,” said protocol chair R. Paul Wadwa, M.D., professor of pediatrics at the Barbara Davis Center for Childhood Diabetes at the University of Colorado, Aurora (CU). “Artificial pancreas technology can mean fewer times children and their families have to stop everything to take care of their diabetes. Instead, kids can focus on being kids.”

Sixteen adverse events, all classified as minor, occurred in the artificial pancreas group during the study, with most due to problems with the insulin pump equipment. Three events occurred in the control group. No cases of severe hypoglycemia or diabetic ketoacidosis occurred during the study.

“For decades, NIDDK has funded research and technology development to create a user-friendly automated device that could ease the constant burden of type 1 diabetes, from the finger sticks and insulin injections, to the insulin dose calculations and constant monitoring while improving diabetes control outcomes and preventing both short- and long-term complications of the disease,” said Arreaza-Rubín. “The artificial pancreas is a culmination of these years of effort, and it’s exciting to see how this technology may benefit children with type 1 diabetes and their families, and hopefully benefit everyone with diabetes in the future.”

The artificial pancreas technology used in this study, the Control-IQ system, has an insulin pump that is programmed with advanced control algorithms based on a mathematical model using the person’s glucose monitoring information to automatically adjust the insulin dose. This technology was derived from a system originally developed at the University of Virginia (UVA), Charlottesville, with funding from NIDDK.

This four-month study was part of a series of trials conducted in the International Diabetes Closed-Loop (iDCL) Study. In addition to CU and UVA, study sites included Stanford University School of Medicine, Palo Alto, California; and Yale University School of Medicine, New Haven, Connecticut. Jaeb Center for Health Research served as the data coordinating center.

Based on data from the iDCL trials, Tandem Diabetes Care has received clearance from the U.S. Food and Drug Administration for use of the Control-IQ system in children as young as age 6 years.

“As we continue to search for a cure for type 1 diabetes, making artificial pancreas technology that is safe and effective, such as the technology used in this study, available to children with type 1 diabetes is a major step in improving the quality of life and disease management in these youth,” said NIDDK Director Dr. Griffin P. Rodgers.

The iDCL Study is one of four major research efforts funded by NIDDK through the Special Statutory Funding Program for Type 1 Diabetes to test and refine advanced artificial pancreas systems. The studies, with additional results forthcoming, are looking at factors including safety, efficacy, user-friendliness, physical and emotional health of participants, and cost.

This study was funded by NIDDK through grant UC4DK108483 and Tandem Diabetes Care, Inc. Tandem also provided the experimental closed-loop systems used in the trial, system-related supplies including the Dexcom CGM and Roche glucometer, and technical expertise.

The NIDDK, part of the NIH, conducts and supports basic and clinical research and research training on some of the most common, severe, and disabling conditions affecting Americans. The Institute’s research interests include diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition, and obesity; and kidney, urologic, and hematologic diseases. For more information, visit https://www.niddk.nih.gov/.

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

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The American Academy of Pediatrics California Chapter 2 Condemns Attacks on Those Protecting Public Health

Attacks on those protecting public health increase.

Pasadena, CA (June 18, 2020)

Our local chapter of the American Academy of Pediatrics, representing over 1,500 pediatricians and pediatric subspecialists in 7 counties in California, strongly condemns recent unfair and uninformed attacks on local health officers and directors who provide evidence-based leadership and guidance to protect their communities from the spread of COVID-19.

A half dozen local public health officers and directors have left or will leave their positions shortly, reportedly driven out by threats and/or political considerations having taken precedence over the public’s health.

This is not typical. This is not acceptable.

Pediatricians and pediatric subspecialists rely on local health officials and partner with them to keep children and communities safe. We urge elected officials at every level to take steps to ensure that health officers feel safe and are empowered to continue in their critically important leadership roles. Children in particular are a vulnerable population and public health departments have always monitored the safety, health and well-being of children in a number of settings. As pediatricians and pediatric subspecialists, we rely on our public health officials to give us recommendations and have partnered with them on a number of occasions related to clean air, immunizations, and vaping. We hope that there is a path forward in which our public health officials feel safe and empowered to continue protecting us and our communities.

The American Academy of Pediatrics

COVID-19 Cases in Children Reach a Grim Milestone, Surpassing a Half-million: American Academy of Pediatrics

Data compiled by the American Academy of Pediatrics and Children’s Hospital Association underscore the need for communities to double-down on efforts to curb the spread of the coronavirus.

For Release: 9/8/2020

More than 513,000 U.S. children have been diagnosed with COVID-19 since the American Academy of Pediatrics and Children’s Hospital Association began tracking cases in the spring, according to the latest weekly report that compiles state-by-state data.

The AAP on Tuesday released a report that found 70,630 new child cases reported from Aug. 20 through Sept. 3, bringing the total to 513,415 cases in children, up from 442,785 -- a 16% increase in child cases over 2 weeks. The data -- while limited because of its reliance on how each state reports its cases -- underscores the urgent need to control the virus in communities before schools and businesses can reopen safely.

“These numbers are a chilling reminder of why we need to take this virus seriously,” said AAP President Sara “Sally” Goza, MD, FAAP. “While much remains unknown about COVID-19, we do know that the spread among children reflects what is happening in the broader communities. A disproportionate number of cases are reported in Black and Hispanic children and in places where there is high poverty. We must work harder to address societal inequities that contribute to these disparities.”

As of Sept. 3, 513,415 children and teens have tested positive for the virus and children represented 9.8% of all reported cases, according to researchers. Throughout the summer surges in the virus have occurred in Southern, Western and Midwestern states.

“This rapid rise in positive cases occurred over the summer, and as the weather cools, we know people will spend more time indoors,” said Sean O’Leary, MD, MPH, FAAP, vice chair of the AAP Committee on Infectious Diseases. “The goal is to get children back into schools for in-person learning, but in many communities, this is not possible as the virus spreads unchecked.

“Now we are heading into flu season. We must take this seriously and implement the public health measures we know can help;
that includes wearing masks, avoiding large crowds, and maintaining social distance. In addition, it will be really important for everyone to get an influenza vaccine this year. These measures will help protect everyone, including children,” he said.

The report is updated every week, usually on Monday.

AAP resources include:

- Children and COVID-19: State-Level Data Report
- Healthy Children.org article for parents: “Can Children Get COVID-19?”

###

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.

Media Contact:
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American Academy of Pediatrics Opposes HHS Action on Childhood Vaccines; Calls It ‘Incredibly Misguided’

**Vaccines can now be routinely administered outside of the medical home.**

For Release:
8/19/2020

The American Academy of Pediatrics (AAP) opposes today’s announcement from the U.S. Department of Health and Human Services (HHS) authorizing state-licensed pharmacists to order and administer all vaccines to children and adolescents ages 3-18 years.

“This move is incredibly misguided. In the middle of a pandemic, what families are looking for is reassurance and clinical guidance from the doctors they trust most to care for their children: pediatricians,” said AAP President Sally Goza, MD, FAAP. “Pediatricians’ offices are open and safe. We have all necessary childhood and adolescent vaccines in stock with trained medical professionals who can administer them. We know that the best, safest place for children to get vaccinated is in their medical home.”

Creating a new vaccine system is not only unnecessary, but it will not provide children with the same level of optimal medical care they receive from the pediatrician who knows the child’s medical history. Most children and adolescents receive vaccines as part of routine well-child check-ups, when other important health care is provided, including developmental and mental health screenings, counseling about nutrition and injury-prevention, and chronic disease manage-

Family Centered Care is trendy, but are providers really meeting parents needs in the NICU?

Consider the following:

Surveys show hospital support groups are being widely underutilized by parents.

And only 10% of NICUs surveyed connect parents with non-hospital support.

Graham’s Foundation, the global support organization for parents going through the journey of prematurity, set out to find the missing piece that would ensure all parents have real access to the support they need.

See what they found by emailing info@grahamsfoundation.org to request a free copy of the 2017 whitepaper, “Reaching Preemie Parents Today” (Heather McKinnis, Director, Preemie Parent Mentor Program, Graham’s Foundation).

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

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

Visit www.GrahamsFoundation.org to learn more.
Keeping Your Baby Safe
during the COVID-19 pandemic

How to protect your little one from germs and viruses

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

Here's what you can do...

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

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

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

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

Never Put a Mask on Your Baby
- Because babies have smaller airways, a mask makes it hard for them to breathe.
- Masks pose a risk of strangulation and suffocation.
- A baby can't remove their mask if they're suffocating.

If you are positive for COVID-19
- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop the virus from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

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

National Perinatal Association

PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

WASH YOUR HANDS
often with soap and warm water.

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

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

USE AN ALCOHOL-BASED HAND SANITIZER.

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

can Indian or Alaska Native - today’s announcement only widens
the health inequities children have faced throughout the COVID-19 pandemic. Data show that the Vaccines for Children program has increased vaccination rates across all races, ethnicities and income groups, and reduced racial and ethnic disparities.

“This unprecedented expansion of pharmacies’ ability to administer vaccines to children is not a solution to the vaccine hesitancy that is driving down rates of childhood immunizations in the U.S.,” Dr. Goza said. “Many parents have questions about their children’s vaccines, and pediatricians are ready to talk with them. It’s what we do, every day, one-on-one with thousands of parents, as part of the long-term trusting relationships that families have with their physicians.”

Today’s action supersedes state laws governing the scope of pharmacists’ ability to administer vaccines, using the COVID-19 pandemic as justification to make policy change that goes well beyond care related to COVID-19. Many states currently restrict pharmacists from administering vaccines to children of any age or limit the age range or type of vaccine that can be administered by a pharmacist.

“Now more than ever, parents trust their children’s pediatrician,” Dr. Goza said. “Rather than create an unnecessary alternative method to deliver immunizations to children, our federal government should invest in the one we have: pediatricians.”

###

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.

Media Contact:
Susan Martin
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The National Coalition for Infant Health advocates for:

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

www.infanthealth.org
The Genetics Corner: DiGeorge Anomaly Associated with Diabetic Embryopathy in an Infant without a Deletion on Chromosome 22q11

Subhadra Ramanathan MS, MSc, Robin Dawn Clark MD

Case History:

A genetics consult was requested for a one-week-old female infant with prenatally diagnosed complete atrioventricular (AV) canal defect. The pregnancy was complicated by maternal pregestational diabetes mellitus, which was poorly controlled in the first trimester, indicated by a maternal hemoglobin A1c level of 11.7.

“This genetics consult was requested for a one-week-old female infant with prenatally diagnosed complete atrioventricular (AV) canal defect.”

The infant was delivered at 37 weeks gestation by emergency C-section for failure to progress after spontaneous rupture of membranes.

Birth weight: 3050 g (6 lb 11.6 oz)
Birth length: 50.5 cm (19.88")
Birth head circumference: 34 cm (13.39")

Apgar scores were:
1 (0 color, 0 reflex, 0 resp, 0 tone, 1 HR) at 1 minute.
8 (1 color, 2 reflex, 2 resp, 1 tone, 2 HR) at 5 minutes

The congenital heart defect was confirmed postnatally with an unbalanced right-dominant atrioventricular canal with moderate AV valve regurgitation and aortic arch hypoplasia with coarctation. In addition, the infant had a solitary kidney and vertebral anomalies.

The infant underwent Norwood operation with aortic arch reconstruction at two weeks of age. Chromosome microarray analysis was normal. A G-tube was placed for poor oral intake and concern for aspiration.

Genetics Evaluation:

Because of restrictions due to the coronavirus pandemic, this evaluation was performed remotely by video in the cardiac intensive care unit. The family history was significant for pregestational maternal diabetes mellitus and advanced paternal age (father was 50 at delivery).

The infant was nondysmorphic and did not have the characteristic facial features associated with 22q11.2 deletion syndrome. There was moderate scoliosis with a lower thoracic curve, concavity to the left, corresponding to the vertebral anomalies evident on chest X-ray: T8 butterfly vertebra and right T11 hemivertebra. MRI L-spine showed a tethered cord (terminating at L3-4) with an associated fatty filum that merged with a sacral lipomeningocele. An Ophthalmology evaluation was normal.

She had hypocalcemia, secondary to hypoparathyroidism, and thymic aplasia with absent thymic shadow on chest X-ray. Her newborn screening test was positive for severe combined immunodeficiency (SCID). Lymphocyte subsets showed T- and B-cell deficiency, but not to the degree seen in SCID. Subsequent Immunology evaluation showed low-normal results on the mitogen stimulation test and a normal response to lymphocyte proliferation. Live vaccines are contraindicated in this patient.

Her chromosome microarray analysis was normal, which ruled out a deletion in 22q11.2 or other copy number variant/microdeletion or microduplication. Nevertheless, a repeat consult was requested to confirm these results with FISH analysis for 22q11.2. FISH testing would have been redundant given the normal chromosome microarray analysis, and it was not performed. The pattern of anomalies in this infant, which can be described as DiGeorge anomaly (rather than syndrome) were best explained by diabetic embryopathy due to the mother’s preconceptional diabetes mellitus, which was poorly controlled in the first trimester.

Discussion and Counseling:

“The pattern of anomalies in this infant, which can be described as DiGeorge anomaly (rather than syndrome) were best explained by diabetic embryopathy due to the mother’s preconceptional diabetes mellitus, which was poorly controlled in the first trimester.”

The infant’s constellation of clinical findings is best characterized as the DiGeorge anomaly (DGA). DGA is characterized by the presence of at least 2 of the following: (1) symptomatic hypocalcemia and/or parathyroid deficiency. Hypocalcemia is generally secondary to the absence or hypoplasia of the parathyroid glands (2) cellular immune deficiency or absence of part or all of the thymus. Diminished humoral immunity has also been reported, particularly in infants with DiGeorge syndrome with 22q11 deletion (3) congenital heart disease (CHD)/cardiovascular malformation, typically conotruncal defects.

Dr. Angelo DiGeorge and colleagues at St. Christopher’s Hospital for Children in Philadelphia first described this eponymous condition in 1965 in infants with hypoparathyroidism, thymic aplasia, and cellular immunodeficiency. DGA is a prototypical field defect caused by defective migration of cephalic neural crest cells into the third and fourth pharyngeal pouches during embryonic de-
development (Kornfeld Sj et al., 2000). This can result in ectopic or absent parathyroid, thymic or parafollicular thyroid tissue:

The clinical features of DiGeorge syndrome were expanded to include congenital heart disease, particularly conotruncal malformations, as well as characteristic facial dysmorphisms by circa 1972. An association between a microdeletion on chromosome 22q11.2 and DiGeorge syndrome was reported in 1981 (de la Chapelle et al., 1981). These patients are now described as having 22q11.2 deletion syndrome, rather than DiGeorge syndrome, indicating the underlying etiology for their clinical features and because not all individuals with 22q11.2 deletion syndrome have all of the elements of DiGeorge syndrome.

However, some patients with DiGeorge anomaly DO NOT have a deletion on chr 22q11. 2. In a study of 64 patients who met at least 2 of the 3 criteria for DGA, the 22q11.2 deletion was detected in 55% (35/64). The other most commonly recognized etiologies for this constellation of clinical features was diabetic embryopathy (5/64) and unbalanced chromosome translocations [which would also be detected on the chromosome microarray analysis] (3/64) (Rope AF, et al., 2009).

Infants of diabetic mothers are at a higher risk of birth defects. The highest window of susceptibility for fetal malformations is in the first four weeks of pregnancy, which is a strong recommendation for counseling diabetic women to optimize their diabetic control prior to conception (Castori, 2013).

The recurrence risk for diabetic embryopathy in a future pregnancy in a mother with pregestational diabetes, who has had a prior affected pregnancy, is increased over 10%. Diabetic women should be encouraged to plan all future pregnancies and to be in excellent diabetic control prior to conception, optimally with a HgbA1c level between 5.7 - 5.9. The greater the level of control, the lower the potential risk to the pregnancy: the lower the risk for miscarriage and infertility as well as congenital anomalies. The diabetic mother-to-be should start prenatal vitamins and supplemental folic acid (4 mg/day) beginning at least a month prior to any future conception. The latter recommendation also addresses the increased risk for open neural tube defects in infants of diabetic mothers (Ramanathan S, Clark RD, 2019)

“...”The diabetic mother-to-be should start prenatal vitamins and supplemental folic acid (4 mg/day) beginning at least a month prior to any future conception. The latter recommendation also addresses the increased risk for open neural tube defects in infants of diabetic mothers (Ramanathan S, Clark RD, 2019)"

Practical Applications:

1. Be aware that poorly controlled maternal diabetes is one of the most potent human teratogens, tripling, or more the chance of birth defects.

2. Consider diabetic embryopathy when you suspect a 22q11.2 deletion, but the microarray is normal. Appreciate that although a microdeletion on chromosome 22q11 is the most common cause of DiGeorge anomaly, it is not the only cause. In the absence of a chr 22q11.2 deletion, maternal diabetes can cause the DiGeorge anomaly.

3. Be confident that a normal chromosome microarray test definitively rules out the deletion of chromosome 22q11.2. A FISH test for chromosome 22q11.2 is unnecessary after a normal microarray. Chromosome microarray analysis offers a higher resolution than FISH testing: it detects both small and large, typical, and atypical microdeletions on chromosome 22q11.2, and it offers more information than FISH testing by documenting the size and position of the deletion and its genomic content.

4. Counsel diabetic mothers to achieve good diabetic control prior to conception to reduce the risk for diabetic embryopathy.
   - Recommend monitoring maternal HgbA1c levels prior to gestation and early in the first trimester.
   - Counsel diabetic women of child-bearing age on the increased risk for congenital anomalies when diabetes is poorly controlled in early preg...
nancy.
- Encourage diabetic mothers to take folic acid daily starting prior to conception.
- Recognize that miscarriage and infertility are associated with gestational diabetes mellitus.

References:

The authors have no relevant disclosures.
Common Problems in the Newborn Nursery
An Evidence and Case-based Guide

- Provides practical, state of the art management guidance for common clinical problems in the newborn nursery
- Written by experts in the field in a clear, easy-to-use format
- Utilizes a case-based approach

This comprehensive book thoroughly addresses common clinical challenges in newborns, providing an evidence-based, step-by-step approach for their diagnosis and management. *Common Problems in the Newborn Nursery* is an easy-to-use, practical guide, covering a full range of clinical dilemmas: bacterial and viral infections, jaundice, hypoglycemia, hypotonia, nursery arrhythmia, developmental dysplasia of the hips, newborn feeding, cardiac problems, late preterm infants, dermatology, anemia, birth injuries, ocular issues, and hearing assessments in the newborn.

Written by experts in their fields, each chapter begins with a clinical case presentation, followed by a discussion of potential treatment and management decisions and various differential diagnosis. Correct responses will then be explained and supported by evidence-based literature, teaching readers how to make decisions concerning diagnosis encountered on a daily basis.

While this guide is directed towards health care providers such as pediatricians, primary care physicians, and nurse practitioners who treat newborns, this book will also serve as a useful resource for anyone interested in working with this vulnerable patient population, from nursing and medical students, to nurses and residents in pediatrics or family practice.

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Common Problems in Newborn Nursery

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

For more information, please visit emilyshane.org.
On September 10, 2020, the National Coalition for Infant Health held its 2020 Virtual Conference. Although it was originally scheduled to be a presence summit, difficulties secondary to the COVID 19 pandemic forced the meeting virtual. The agenda follows:

### Agenda

**11:30 a.m.**

**Welcome**

- **Susan Hepworth**, Executive Director, National Coalition for Infant Health

**11:35 a.m.**

**Opening Remarks**

- **Julian Nixon**, NICU Dad; CAFLS Director of Diversity & Inclusion, Clemson University

**11:45 a.m.**

**The Forgotten Preemies: Late Preterm Infants**

- **Viveka Prakash-Zawisza**, MD, MS, MBA
  
  President-Elect, National Perinatal Association

**12:05 p.m.**

**RSV & COVID-19: Double Trouble**

- **Suzanne Staebler**, DNP, APRN, NNP-BC
  
  Emory University School of Nursing; National Coalition for Infant Health

- **Crystal Baker**, Patient Advocate

**12:25 p.m.**

**Keynote Speaker**

- **Congresswoman Kim Schrier**, MD (WA-08)
  
  Author of the VACCINES Act

**12:50 p.m.**

**Break**

**1:05 p.m.**

**COVID-19 Chaos: Isolation, Disruption, Preterm Birth Reduction?**

- **Rebecca L. Cypher**, MSN, PNNP
  
  2020 AWHONN President

- **Christine Tester**, Mental Health Peer Specialist & Family Advocate, Hand to Hold

- **Mitchell Goldstein**, MD
  
  National Coalition for Infant Health; Loma Linda University Children’s Hospital

**12:50 p.m.**

**High Time: Facing Disparities in Infant Health**

- **Jenné Johns**, MPH
  
  President, Once Upon a Preemie; Founder, Once Upon a

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“They health care providers, parents, regulators, policy makers and advocates attended the virtual 2020 Infant Health Policy Summit on September 10. This year’s summit was held virtually because, in spite of the current public health situation, we must continue the important dialogue about issues facing the infant health community and their families.”

- **Erin Sundseth Ross**, PhD, CCC-SLP
  
  Assistant Clinical Professor, Department of Pediatrics, School of Medicine, University of Colorado

- **Host: Susan Hepworth**, National Coalition for Infant Health

12:05 p.m.

**RSV & COVID-19: Double Trouble**

- **Suzanne Staebler**, DNP, APRN, NNP-BC
  
  Emory University School of Nursing; National Coalition for Infant Health

- **Crystal Baker**, Patient Advocate

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- **Mitchell Goldstein**, MD
  
  National Coalition for Infant Health; Loma Linda University Children’s Hospital

**12:50 p.m.**

**High Time: Facing Disparities in Infant Health**

- **Jenné Johns**, MPH
  
  President, Once Upon a Preemie; Founder, Once Upon a
2020 Infant Health Policy Summit

REGISTER

Thursday, September 10
11:30 a.m. to 2:15 p.m. EDT

FEATURED SPEAKER:
Congresswoman Kim Schrier, MD (WA-08)
Author of the VACCINES Act

TOPICS:
- The Forgotten Preemies: Late Preterm Infants
- RSV & COVID-19: Double Trouble
- COVID-19 Chaos: Isolation, Disruption, Preterm Birth Reduction?
- High Time: Facing Disparities in Infant Health
- Congenital Gut Disorders: Research & Reality

SPEAKERS

Rebecca L. Cypher, MSN, PNPNP 2020 AHONN President
Mitchell Goldstein, MD, National Coalition for Infant Health
Jenné Jeunes, MPH, President, Occu Upon a Preemie
Heidi E. Karpen, MD, Emory University/Children's Healthcare of Atlanta
Martin L. Lee, PhD, CStat, CSci, FIBMS, Prolacta Bioscience®
Viveka Prakash-Zawisza, MD, MS, MBA, President-Elect, National Perinatal Association
Erin Sundseth Ross, PhD, CCC-SLP, University of Colorado
Suzanne Staebler, DNP, APRN, NNP-BC, Emory University School of Nursing
Christine Tester, Hand to Hold
Michel A. Young, MD, FAAP, FABM, Howard University College of Medicine

Advocates:
Crystal Baker
Julian Nixon
Katie Trudo
Preemie Academy

- **Michal A. Young, MD, FAAP, FABM**  
  Associate Professor, Department of Pediatrics and Child Health, Howard University College of Medicine

- **Host: Susan Hepworth**, National Coalition for Infant Health  
  1:40 p.m.  
  Introducing: Alliance for Black NICU Families

- **Ashley Randolph-Cooley**, Patient Advocate

- **Host: Susan Hepworth**, National Coalition for Infant Health  
  1:45 p.m.  
  Congenital Gut Disorders: Research & Reality

- **Martin L. Lee, PhD, CStat, CSci, FIBMS**  
  Vice President, Clinical Research and Development, Prolacta Bioscience®

- **Heidi E. Karpen, MD**  
  Associate Professor of Pediatrics, Associate Director Neonatal-Perinatal Medicine Fellowship Training Program, Emory University/Children's Healthcare of Atlanta

- **Katie Trudo**, NICU Parent

- **Host: Susan Hepworth**, National Coalition for Infant Health  
  2:05 p.m.  
  Closing Remarks

- **Susan Hepworth**, Executive Director, National Coalition for Infant Health

The National Coalition welcomes those interested in our activities as well as organizations interested in protecting access for premature infants through age two to visit our website [www.infanthealth.org](http://www.infanthealth.org).

Disclosures: The authors do not have any relevant disclosures.

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National Coalition for Infant Health Values (SANE)

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

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

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

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

Respiratory syncytial virus, or RSV, is a contagious seasonal respiratory virus that can cause bronchiolitis and pneumonia. It is also the leading cause of hospitalization in babies less than one year old. RSV can be deadly for premature infants and at-risk infants with congenital heart disease or chronic lung disease.

Preventive treatment called palivizumab can protect infants from RSV, but national claims data shows certain babies aren’t getting access to this FDA-indicated therapy.

National Health Plan Coverage & Access

A national data supplier provided palivizumab claims for Medicaid and commercial health plans across the nation from January 2019 through December 2019.

“Gap” Babies

Commercial Plans Denied

40%

Medicaid: 25%

Health plans deny 40% of palivizumab prescriptions for premature infants born between 29 and 36 weeks gestation.

“In-Guidance” Babies

Commercial Plans Denied

25%

Medicaid: 14%

One in every four prescriptions is denied for infants who should qualify for coverage under standard insurance policies.

This includes severely premature infants born before 29 weeks gestation, babies born before 32 weeks gestation who have chronic lung disease, and babies born with congenital heart disease.
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GENETIC CONSULTATIONS in the NEWBORN

Robin D. Clark | Cynthia J. Curry

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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.

**Preparedness**

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

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

- **Parents**
  - Only 18% said parents know “a lot” about RSV, reflecting an awareness level that’s roughly half that of the flu.
  - Only 22% of parents consider themselves “very well prepared” to prevent RSV.

- **Specialty Health Care Providers**
  - They treat RSV as a priority, “often” or “always” evaluating their patients (80% doctors; 78% nurses).
  - During RSV season, they are especially vigilant about monitoring patients for symptoms or risk factors for RSV (98%).
Clinical Pearl: The COVID-19 Vaccine and Viral Variants

Joseph R. Hageman, MD

Once the vaccine is available, our lives, professional and private, will go back to “normal”. The vaccine will be available to pregnant women and children for this SINGLE, UNIQUE virus, and they will be protected. The pregnant women will produce antibodies that will be transferred transplacentally to their fetuses, right? Will it be just like the flu vaccine that is given during pregnancy, where the immune response by the mother helps protect the newborn infant (1)? Here is information from the Center for Disease Control and Prevention (CDC): “Pregnant women who get a flu vaccine also are helping to protect their babies from flu illness for the first several months after their birth, when they are too young to get vaccinated. A list of recent studies on the benefits of flu vaccination for pregnant women is available” (2). Of course, we all are aware that: “only small amounts of maternal IgG are transferred in the first trimester, with an estimated transplacental transfer of approximately 10% of maternal IgG concentrations by 17–22 weeks’ gestation. The concentration of maternal IgG in infant cord blood reaches approximately 50% of the maternal IgG levels by 30 weeks’ gestation, and by 37–40 weeks of gestation, infant cord blood concentrations of maternal IgG often exceed that of maternal serum by the delivery time point in full-term, healthy pregnancies. Thus, while maternal IgG is transferred across the placenta throughout pregnancy, the majority of the transfer occurs in the last trimester of gestation” (3).

However, there is a problem. First of all, the vaccine testing has not included pregnant women and children (4), although Heath and colleagues and Malhotra et al. support their inclusion using very carefully designed studies (5). Lurie, Sharfstein, and Goodman also encourage the involvement of pregnant women, including those who risk exposure as health care workers, and young children, who are at risk for the development of multi-system inflammatory syndrome (MIS-C) (7).

There is another important issue that all of us as providers may be aware of, and that is the fact that there is an amino acid variant of the original SARS-CoV-2 (D614 Spike protein) that is now causing COVID-19 infection/disease around the world: SARS-CoV-2 D614G Spike protein) and may have a “fitness advantage” (8). In infected individuals, G614 is associated with lower RT-PCR cycle thresholds, which is suggestive of higher upper respiratory tract viral loads, but not increased disease severity (8). The fact that this variant is associated with less severe disease is reassuring; however, the question that comes to mind is, are the vaccines being developed taking this new variant, and the possibility that there may be other variants or mutations of the virus into account? If the vaccine involves components of the spike protein, which we realize is the major mechanism involved in the ability of the virus to enter the cell in the human respiratory tract, then the immune response of the patient to the vaccine or other immune-based interventions may be different or attenuated (8). O‘Callaghan, Glatz, and Offit discuss the five core candidate vaccines in development, all of which are aimed at inducing antibodies directed against the receptor-binding domain of the surface spike (S) protein of SARS-CoV-2 (9).

Finally, for this pearl, Lurie et al. note that investigators should be aware of and look for more severe illness in vaccinated individuals who nevertheless develop COVID-19 (7).

As all of us continue to follow the evolution of this COVID-19 pandemic, the most important goal for us as clinicians is to provide evidence-based, scientifically verified, best-practice care for our patients.”

References

“Thus, while maternal IgG is transferred across the placenta throughout pregnancy, the majority of the transfer occurs in the last trimester of gestation” (3).”
2. https://www.cdc.gov/flu/highrisk/pregnant.html#anchor_1571257723

The authors has no conflicts to disclose.

**Clinical Pearls are published monthly.**

Submission guidelines for “Clinical Pearls”:
1250 word limit not including references or title page.
May begin with a brief case summary or example.
Summarize the pearl for emphasis.
No more than 7 references.
Please send your submissions to:
jhageman@peds.bsd.uchicago.edu

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**NATIONAL PERINATAL ASSOCIATION**

**Update: CORONAVIRUS COVID-19**

According to data published in The Lancet

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

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

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!
There is widespread belief that severe fetal acidosis and resultant hypoxic-ischemic encephalopathy are most often associated with late decelerations and absent variability. In my experience, fetal asphyxia, as reflected in severe derangements in umbilical cord blood gases, is often associated with progressively severe variable decelerations that result in terminal, prolonged fetal bradycardia. Cord compression, especially if the umbilical vein continues to be occluded while umbilical arterial blood flow is restored, impedes return of blood from the placenta to the fetus while maintaining outflow from the fetus to the placenta. This may result in fetal hypovolemia and augment the consequences of decreased fetal cardiac output and ischemia. In this situation, the umbilical blood gases may reflect striking differences between the vein and the artery.

“Cord compression, especially if the umbilical vein continues to be occluded while umbilical arterial blood flow is restored, impedes return of blood from the placenta to the fetus while maintaining outflow from the fetus to the placenta. This may result in fetal hypovolemia and augment the consequences of decreased fetal cardiac output and ischemia.”

In addition, ischemia is known to be a much more potent cause of brain injury than hypoxia alone. In experiments with fetal sheep made severely hypoxic for two hours, the added presence of hypotension resulted in marked lactic acidosis and severe brain damage, whereas the presence of severe hypoxia alone did not. Similarly, human fetuses exposed to severe hypoxia and concurrent “blood loss” (to the placenta) as typically occurs during terminal bradycardia following cord compression, are more likely to suffer brain damage than when hypoxia occurs alone.

Be aware that variable decelerations associated with a slow return to baseline, a rise in baseline, or absence of variability in the baseline between decelerations, are not reassuring. Cord compression resulting in terminal bradycardia is a worrisome development and a potential harbinger of both fetal acidosis and neurological injury – irrespective of whether the cause of impaired umbilical cord blood flow is stretch as the baby descends into and through the birth canal or by external compression (see Table below). Accordingly, in order to give appropriate emphasis to the importance of impaired cord blood flow, this section contains ten case histories and is the longest section.

Table: Mechanism of impairment of umbilical cord blood flow

<table>
<thead>
<tr>
<th>Mechanism of Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stretch</td>
</tr>
<tr>
<td>Short cord</td>
</tr>
<tr>
<td>A relatively short cord with fundal implantation</td>
</tr>
<tr>
<td>Cord around the neck or other structure(s) (functionally short cord)</td>
</tr>
<tr>
<td>A true knot in the cord (minimal stretch)</td>
</tr>
<tr>
<td>Descent of fetus</td>
</tr>
<tr>
<td>Shoulder dystocia (possible)</td>
</tr>
<tr>
<td>Breech delivery with a trapped head (stretch and compression)*</td>
</tr>
<tr>
<td>Compression</td>
</tr>
<tr>
<td>Kinking of cord (especially with decreased Wharton’s jelly)</td>
</tr>
<tr>
<td>A true knot in the cord</td>
</tr>
<tr>
<td>Torsion of cord</td>
</tr>
<tr>
<td>Entwining of cords (monoaamniotic twins)</td>
</tr>
<tr>
<td>Hematoma of cord (may also cause vessel spasm)</td>
</tr>
<tr>
<td>Cysts of cord</td>
</tr>
<tr>
<td>Prolapsed cord (overt or occult)</td>
</tr>
<tr>
<td>Breech delivery with a trapped head (stretch and compression)*</td>
</tr>
<tr>
<td>Stricture of cord</td>
</tr>
<tr>
<td>Shoulder dystocia (probable)</td>
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</tbody>
</table>

Whether or not the umbilical cord becomes stretched is determined by a number of factors: absolute cord length, distance of placental implantation from the cervix, location of cord insertion on the placental disc, functional cord shortening by wrapping around one or more fetal structures (most commonly the neck), true knot in the cord (causing minor functional cord shortening and self-compression), and descent of the fetus into and through the birth canal. Delivery of the head, followed by shoulder dystocia, causes functional cord shortening by the length of the fetal head, a length that may be sufficient to cause vascular occlusion by stretching. Breech delivery with a trapped head also causes a sudden and large functional cord shortening by the distance from the fetal breech to the fetal chin.

Stretching of the umbilical cord occludes the umbilical vessels in much the same way as does the simple Chinese finger puzzle in which a finger from each hand is placed in each end of a woven bamboo cylinder. When one attempts to remove their fingers, the result is a tightening of the woven tube. As the cylinder is stretched, thereby increasing its length, its diameter is decreased, trapping the fingers. Another way to think about this is to realize that the umbilical cord has a fixed volume, i.e., a cross-sectional area multiplied by length. If the umbilical cord is stretched, making it longer, the cross-sectional area must be decreased in order to maintain...
The anatomic relationship between the umbilical vein and the umbilical arteries is quite varied. However, looking at the most common configuration (as depicted in an 1870 drawing by Joseph Hyrtl on the front cover of Interpreting Umbilical Cord Blood Gases, 2nd ed.), one can see that if the umbilical cord were to be stretched, the more easily compressed vein would come into juxtaposition with the harder to compress arteries in many locations. In some variants, the arteries are not wound around the vein at all, or only minimally so. In theory, certain configurations should be more resistant to venous occlusion by stretch than others.

External compression of the cord is influenced by the thickness of the cord, which in turn is determined by the amount of Wharton’s jelly. The umbilical venous muscular coat is thinner than that of the umbilical arteries. Typically, infants of diabetic mothers whose diabetes was not well controlled during pregnancy have relatively thick cords, and infants with intrauterine growth restriction have relatively thin cords. It is easier to compress a thin cord. The presence of oligohydramnios (frequently associated with decreased Wharton’s jelly, which is mostly composed of water) also increases the vulnerability of the cord to compression.

In the presence of oligohydramnios, the cord more commonly migrates to a position where it is at increased risk of compression, rather than safely “floating” in amniotic fluid. Classically, external compression of the cord occurs in association with cord prolapse. In this situation, typically, the cord is compressed between the presenting part of the baby and the lower uterine segment. Each subsequent uterine contraction further compresses the cord by wedging the fetus more tightly into the birth canal. External cord compression also occurs in breech presentation with entrapment of the aftercoming head.

Additionally, the cord may be compressed and partially or totally occluded when it doubles back on itself (kinked) or when there is a true knot in the cord. Usually, a true knot remains loose even as the baby descends into the pelvis as the cord is generally not critically short (either anatomically or functionally); however, fetal movement may lead to a “cord accident” by tightening of the knot at any time. This mechanism comes into play more frequently with “thin” cord with decreased Wharton’s jelly. A knot in such a cord is more easily tightened.

Cord compression typically results in variable decelerations. The quick decrease in the FHR is not caused by hypoxemia, but rather is a reflex response to a sudden increase in fetal blood pressure when a major source of blood runoff, the umbilical arteries, is lost by cord compression.

Finally, occlusion of the umbilical arteries by either stretching or external compression becomes easier as fetal arterial pressure falls. As hypoxemia leads to asphyxia, this mechanism further facilitates occlusion of the umbilical arteries.

Case 9: Virtual Total Umbilical Cord Occlusion: A Thought Experiment

The mother was a 21-year-old, gravida 1, para 0, aborta 0, with an intrauterine pregnancy of 39 2/7 weeks’ gestation by good dates. The pregnancy was uncomplicated. Membranes were intact. The FHR pattern was entirely normal with the presence of accelerations, absence of decelerations, and moderate variability. In this thought experiment, the umbilical cord was double clamped (“virtually” without entering the uterus). The clamp instantaneously and entirely interrupted all blood flow in the umbilical cord. The fetus was delivered 40 minutes later.

Questions (1-word answers preferred):
1) Describe the fetus, now newborn.
2) Describe the cord blood gases.

Interpretation:

Answers:
1) Dead
2) Normal

Once the umbilical cord is clamped, no blood flows through it. With no ingress of oxygen from the umbilical vein, the fetus will rapidly develop severe respiratory and metabolic acidosis. Over 40 minutes, the fetus will die. Blood gas values in the stagnant blood in the umbilical cord, however, remain approximately the same as they were prior to umbilical cord clamping. As the fetus had a perfectly normal and reassuring FHR tracing prior to being clamped, one would expect the umbilical cord blood gases to be entirely normal. Over time, probably in excess of one hour, the blood gases will degrade.

Total umbilical cord occlusion has been well studied by Myers in the anesthetized term monkey fetus. In the first 90 seconds following umbilical cord clamping, the FHR decreased rapidly along with an abrupt increase in blood pressure due to the sudden increase in peripheral vascular resistance. After the first 15 to 20 seconds following cord clamping, the elevated fetal blood pressure began to decline, precisely at the time when the first oxygen-poor blood reached the myocardium. Then, at approximately 60 seconds following cord clamping, the beginnings of a “major, long-lived augmentation in blood pressure occurred during which both the systolic and the diastolic pressures were restored to values that, 150 seconds into the asphyxia, compared to values present prior to the asphyxia. After this secondary blood pressure increase reached its zenith at three to four minutes, the pressure again declined slowly until, after 12 to 15 minutes of asphyxia, the pressure recorded within the thoracic aorta approached that of the surrounding tissue. At this time, blood flow through all parts of the fetal body ceased.

Interestingly, although the fetal heart stopped performing mechanical work, it continued to register a QRS complex at 60–70 beats per minute, i.e., electromechanical dissociation, or pulseless electrical activity. Blood sampled from the fetal thoracic aorta demonstrated a linear decrease in pH, a linear increase in the base deficit, and an almost linear increase in Pco₂ over 12.5 minutes. The pH declined from 7.29 to 6.81, or approximately 0.038 per minute. The base deficit increased from 2.8 to 17 mEq/L, or approximately 1.1 mEq/L/minute, and the Pco₂ rose from 52 to 132 mmHg or approximately 6.4 mmHg/minute. It is important to note that further linear trends would not be expected to continue as blood flow to the fetal peripheral tissue had ceased, and peripheral lactic acid
I was exposed to opioids. I am not an addict. Addiction is a set of behaviors associated with having a Substance Use Disorder (SUD). 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. When reporting on mothers, babies, and substance use NAS is a temporary and treatable condition. My mother may have a SUD. My potential is limitless. There are evidence-based pharmacological and non-pharmacological treatments for Neonatal Abstinence Syndrome. 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. 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!

“Almost always in terminal fetal bradycardia resulting from cord occlusion, the vein remains occluded while blood flow in the umbilical arteries is restored for varying periods of time.”

Although Meyers’ model is quite instructive, it does not represent what actually occurs during the great majority of cases of terminal cord occlusion. I have seen only rare instances in which I thought that umbilical venous and arterial occlusion happened almost simultaneously as a terminal event. Almost always in terminal fetal bradycardia resulting from cord occlusion, the vein remains occluded while blood flow in the umbilical arteries is restored for varying periods of time. This combination is more challenging for the fetus, as progressive hypoxia and varying degrees of hypovolemia occur simultaneously. Key Point

- When umbilical blood vessels are occluded during terminal fetal bradycardia, a blood gas sample taken from either an umbilical vein or artery will only reflect the blood gas status prior to the occlusion. Over time, probably in excess of one hour, the blood gas samples will degrade.

References:


Disclosure: The author has no disclosures.
Error as a Faulty Failure Signal

Daved van Stralen, MD, FAAP, William Gambino, MA, MMAS

An organization’s High-Reliability Organization (HRO) attributes can become impediments to generating reliability and safety in ill-structured, dangerous, or life-preservation contexts. To what extent do subjective perceptions of what constitutes “reliability” develop into attack vectors for self-inflicted organizational sabotage? How could internal administrative or external regulatory pressure cause an otherwise reliable organization to focus solely on the strongest failure signals, oversimplify circumstances, centralize decision making authority, vilify error, and disregard outliers? “Preoccupation with failure” becomes “preoccupation with error.” Error, then, loses its leverage for learning and understanding. The resulting fear of, or preoccupation with, error becomes an obstacle to comprehension, learning, and enactment.

We agree with Dr. Turbow (Turbow 2020) that HRO has the potential to improve outcomes (Roberts, Kuo, and van Stralen 2004; Roberts et al. 2005; van Stralen 2008; van Stralen et al. 2008) and engage medical errors beyond what medical experts envisioned for HRO (Nolan et al. 2004; Hines et al. 2008; Chassin and Loeb 2013; Department of Defense 2014). Unfortunately, the incomplete translation from HRO theory into HRO practice (van Stralen 2020) includes misinterpretation of errors as failure signals and the mistranslation of error and failure as exposure to liability.

Pronounced, almost singular, focus on error and liability may appear prudent but misdirects HRO processes, sacrificing responsiveness and adaptability for standardization and compliance with rules and processes. The drive for organizational reliability and safety often results in normative, reductionist, and linear solutions.

“One person’s error is another person’s information. Until we experience something, we don’t know exactly how we would act or what to expect. Acts are not mistakes; they become mistaken late in their development (Paget 1998, 45).”

One person’s error is another person’s information. Until we experience something, we don’t know exactly how we would act or what to expect. Acts are not mistakes; they become mistaken late in their development (Paget 1998, 45). The future branches in time (Goranko and Galton 2015), open to the influence of future contingents the individual may not anticipate. Until something makes it visible, we do not notice the consequences, but by then, the antecedents have become lost to perception, and the actor departed. Organizations achieve High Reliability between the rules, but whether through errors captured by insiders or plans made by spectators, or both, may depend on how you classify actions, errors, and compliance.

We wonder how leadership would classify outliers, situations, actions, and outcomes that do not fit a category or meet a standard. Without classification, we lose sensitivity to exclusions, and the elements become invisible (Bowker and Star. 2000; 300-1), capable of an unexpected appearance and abrupt disruptions. The lack of clear definition and standardization along with outside influences (Grober and Bohnen 2005) makes medical error capable of misclassification or invisible from non-classification. To standardize is to invent error.

“The lack of clear definition and standardization along with outside influences (Grober and Bohnen 2005) makes medical error capable of misclassification or invisible from non-classification. To standardize is to invent error.”

Classification systems have three characteristics, following abstract scientific logic: 1) they are consistent and unique, 2) the categories are mutually exclusive, and 3) the system is complete (Bowker and Star 2000; 10-11). Classification influences thinking and acting. Consider how “error” and the “typology of error” influence whether the team engages a disruption as an error, a novel situation, or emergent circumstances. How one classifies the incident influences actions, communications, and documentation.

But concrete experience and immediate perceptions have degrees of truth and different ways of being true, following modal logics of degree, necessity, and possibility (Garson 2016). We must not allow abstractions of error and liability to substitute for concrete, value-free rendering of fact. Alfred North Whitehead (1926/1967; 64) warns against the “fallacy of misplaced concreteness,” of accepting abstractions as the most concrete rendering of
fact. Error as an abstraction interferes with leveraging error by an individual to make a mistake and, with colleagues, discover what steps to take without suffering other consequences (Rosson and Carroll 2005; 87-8).

Classifying elements makes visible (and surveillance easier) what the dominant domain considers important (Bowker and Star 2000; 30, 44-46), for example, the International Classification of Diseases (ICD-10) classification system and criteria for diagnosis. A premature infant can be classified by diagnoses (limited to ICD-10), physiological derangements (hypoxemia, peripheral perfusion), nursing care (intravenous infusions, medication administration, feeding methods), or technology demands (mechanical ventilation, ECMO). What is important differs from whether we look from top-down versus bottom-up or from the isoselle versus the administration.

Problems interact with the environment creating abrupt, disorienting changes. With rules created independently of context and insistence on compliance, subordinates look for evidence supporting discrete rules rather than generating information to resolve the problem. Rules confound the application of discrete concepts to continuously evolving events. Compliance, in the absence of an identifiable rule or applicable process, inhibits initiative and prevents the experiences of failing from which we learn (van Stralen, McKay, Mercer 2020). Because we cannot identify failures from not acting, we cannot correct such errors, and belief in the value of “not acting” becomes incorporated into cultural knowledge (Weick 1979 148). A pattern of presumed successes then forms gives the illusion of legitimacy, halts learning, and reinforces belief in the value and importance of compliance.

“Standardization through error management, effectively normalizes behaviors, reinforces compliance, and inhibits action outside of organizational norms. Compliance for the purpose of error reduction becomes normative behavior.”

But to what or whom are we compliant? Environments where people must move between ill-structured and well-structured problems confound people anchored in the normative stance. Standardization, enforced by error management, creates the perception of control, thereby reducing this discomfort. As a measurement of not reaching the standard, error does have important functions in education, documentation, recovery of information, or creating common ground between diverse domains, communities of practice, and regulatory agencies (Star and Griesemer 1989; Bowker and Star 2000; 15-16). But standardization’s significant inertia resists change (Bowker and Star 2000; 325), supported by error management, makes standardization an effective mechanism to “control the tacking back-and-forth, and especially, to standardize and make equivalent the ill-structured and well-structured aspects” (Star 2010). Standardization through error management, effectively normalizes behaviors, reinforces compliance, and inhibits action outside of organizational norms. Compliance for the purpose of error reduction becomes normative behavior.

From the top-down normative stance, compliance, readily measurable against idealized standards (Bowker and Star 2000; 15), makes more sense. The inertia of standardization overcomes the HRO characteristic “reluctance to simplify.” Complexification and agility, now circumscribed, can no longer support problem resolution and achievement of an accepted end-state. The pragmatic stance has become an organizational outlier.

From the bottom-up pragmatic stance, error emerges from local, nonlinear interactions, manifesting the environment entwined with human intent. Invisible processes complicate interventions. During contingent circumstances, error avoidance occupies working memory, and, when people most need thought, performance decreases. Error correction, on the other hand, drives engagement, extending operations into adverse conditions and hostile environments.

Elaboration of compliance in this manner reveals the negative side of compliance — detrimental outside interference, error, safety, and liability become failure signals, and security becomes compliance-based. Perhaps we can obtain some understanding when we view error and compliance through the domains of law, business, and sabotage.

For questions of HRO and the law, we have deferred to the late Assistant US Attorney Michael “Mike” A. Johns, who advised us that the decision-making elements of HRO could offer protection from legal action, particularly through understanding and use of heuristics and the consequent biases. For the HRO, error corrects heuristic bias (van Stralen, McKay, and Mercer 2020). As in our opening paragraph, Johns was concerned “whether influences from outside the agency itself might be contributing to decision errors (their attorneys, their court system, etc.)” (personal communication).

HRO, through preoccupation with failure, makes visible safety lapses and the breach of duty in liability. However, acting as outside influences, liability, and safety contribute to decision errors. C. Northcote Parkinson (1955), observed that his eponymic Parkinson’s Law, “work expands so as to fill the time available for its completion,” contributed to economic inefficiency during WWII. Any criticism would likely be met with, “Don’t you know there’s a war on?” (Stevenson 1993). For example, healthcare executives, resistant to a patient safety study out of concern for liability to the hospital, queried a committee about liability. One member asked, “What duty are we breaching?” The executives could not articulate any duty the study would breach. Queries about liability and safety will easily terminate or endanger the extension of operations into ambiguity, adversity, or threat. The hospital did not conduct the aforementioned study.

Physical protection systems (PPS) protect nuclear facilities (high consequence low probability events/incidents) against theft or sabotage. Performance criteria select elements and procedures for overall system performance while feature criteria (also called compliance-based) select elements for the presence of certain items (Garcia 2007; 64-5). “The use of a feature criteria approach in regulations or requirements that apply to a PPS should generally be avoided or handled with extreme care. Unless such care is exercised, the feature criteria approach can lead to use of a checklist method to determine system adequacy, based on the
Preoccupation with failure logically leads to error as a failure signal and liability exposure as a potential failure. Behaviors to prevent failure or reduce liability exposure include “doing everything through channels,” “refer all matters to committees” which should be “as large as possible — never less than five,” “advocate caution,” “urge your fellow-conferencees to be reasonable and avoid haste,” “worry about the propriety of any decision — raise the question of whether such action as is contemplated lies within the jurisdiction of the group or whether it might conflict with the policy of some higher echelon,” and “apply all regulations to the last letter.” The above quotations exemplify a “type of simple sabotage’ that requires “no destructive tools whatsoever and produces physical damage, if any, by highly indirect means.” During World War II, the United States Office of Strategic Services (OSS) contributed to undermining Nazi industrial efforts by teaching these “simple sabotage” methods to civilian workers in occupied Europe (Office of Strategic Services 1944). Yet, leaders commonly accept these methods as a prudent means to prevent error and reduce liability.

Could an otherwise reliable organization be targeted via its own HRO attributes? That is, error, liability, and safety, as singular failure signals distracting support from line staff, sabotages efforts to generate reliability and safety.

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NEONATOLOGY TODAY

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“During the 2nd 99NICU Webinar, we will explore the wider impact of nurse staffing on patient outcomes and review what the evidence suggests are potential strategies for optimising staffing. Supported by the latest research from experts in their field, we encourage you to interact with our speakers with a live Q&A session.”

DATE/TIME
2020-10-14. 16:00-17:00 CET

TITLE
Unpicking the evidence for nurse staffing in the NICU: What is optimal and what is the impact?

SHORT DESCRIPTION
Many of our 99NICU subscribers will have experienced first-hand the challenges of staffing the NICU, being aware of the short-term impact nurse staffing can have both on patient care and staff morale.

During the 2nd 99NICU Webinar, we will explore the wider impact of nurse staffing on patient outcomes and review what the evidence suggests are potential strategies for optimising staffing. Supported by the latest research from experts in their field, we encourage you to interact with our speakers with a live Q&A session.

We look forward to welcoming you to the 2nd 99NICU webinar!

PRESENTERS
This webinar is presented by two leading experts in this field, Chiara Dall’Ora at the University of Southampton / UK, and Eileen T. Lake at the University of Pennsylvania School of Nursing / US.

Chiara Dall’Ora is a lecturer at the University Of Southampton. Her research mainly entails designing and performing large workforce studies using quantitative, routinely collected data, focusing in particular on nurses’ shift patterns and staffing levels. Chiara qualified as a Registered Nurse in Italy and, after pursuing an MSc in Nursing and Midwifery Sciences, she completed her Ph.D. within Health Sciences in 2017.

Eileen Lake has made a significant impact on nursing care practice through research on clinical work environments and nurse staffing levels in hospitals. She is currently a professor of nursing and sociology, Jessie M. Scott Endowed Term Chair in Nursing and Health Policy, and associate director of the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing. Eileen Lake has developed a foundational measure/index of nursing care performance to demonstrate nursing’s impact on patient outcomes. This index provides scientific evidence that health care settings that capitalize on nurses’ education and skills achieve higher quality outcomes.

WEBINAR PLATFORM
Webex though Vienna University

REGISTRATION LINK
https://meduniwien.webex.com/meduniwien/onstage/g.php?MTID=eaaec00a22970d3d60d3566b36166fbed

Timeline
2020-09-08 – pre-announcement (Newsletter)
2020-09-15 – announcement on 99nicu.org + in Newsletter
2020-09-21 – open registration Stefan Johansson

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The authors indicate that they have no disclosures

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Associate Professor, Karolinska Institutet
Stockholm, Sweden
stefan.johansson@99nicu.org

NT
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

2 to 3 servings per week of properly cooked fish can provide health benefits for pregnant women and babies alike:

- shrimp
- canned light tuna
- cod
- catfish
- salmon
- pollock
- tilapia

But mixed messages from the media and regulatory agencies cause pregnant women to sacrifice those benefits by eating less fish than recommended.

Did you know that PMAD related suicides account for 20% of Postpartum Maternal Deaths?

Support the Open Letter
Breastfeeding Innovations Team

Get the Facts on Fish Consumption for Pregnant Women, Infants, and Nursing Moms.

Learn More
Letters to the Editor

September 3, 2020
Neonatology Today

To the editor,

A pregnant mother with a highly infectious disease delivers an infant who does not have the infection. Management of the mother and infant follow published guidelines. The mother and infant are discharged without complications (1). Free of context, the reader could view this case report as trivial. The reader would then miss the influence of pandemic COVID-19 as it brings together uncertainty, ambiguity, threat, stress, and fear, creating tumultuous medical, social, and political environments in which we operate that can, indirectly and unconsciously, drive treatment decisions.

We lack reliable information regarding the behavior of COVID-19 in pregnancy, transmission to an infant, or a newborn infant’s vulnerability to the virus. Mother’s cough and congestion during labor and fetal intolerance of labor produce multiple possible trajectories, from benign to fatal. Uncertainty and ambiguity confound guidelines or protocols (2). Threats emerge from the virus and differences in medical and nursing opinions, requests and expectations of the parents, beliefs of the infant’s family, healthcare givers, and even hospital administrators, and the source of those beliefs from the medical literature, news media, and social media. We do not work in isolation, “exposure to even mild uncontrollable stress can rapidly impair [prefrontal cortical] functions in humans” (3).

The authors presented an “embedded problem” (4), actually a set of problems embedded in different environments. The infant’s problem of COVID-19 exposure in a hospital environment with an infected mother, the mother’s problem of COVID-19 and her refusal of separation in an environment she cannot control, and the physician’s problem of developing knowledge of a disease in an environment with social and medical demands and expectations.

Each change in the problem changes the environment. Each change in the environment changes the problem. The problem and environment are inextricably linked. Decontextualization brings conceptual clarity and tractability to the problem, but we sacrifice realism.

Given an equally likely outcome from treating or not treating, particularly faced with medical uncertainty and social certainty (physicians’ well-considered opinions (5)), we would like to think we would not treat. Hidden in this belief, however, we consider failure from treating to be a complication or expected outcome, while failure from not treating is a medical error.

This has some rationality because failure from acting (treating) is visible, making it correctable if things go wrong. Not acting is more difficult. If we create a straight line from failure-to-treat to a poor outcome, we classify it as an error. But what if failure to treat has no consequence? Failure from not acting, in this sense, is not visible, cannot be corrected, and becomes cultural knowledge (6). To act against this, cultural knowledge is to act against the standards of the group.

The authors of this case report did not treat, but did they act? We must recognize the danger of not acting. Not acting is an action, possibly the most dangerous thing we do. Not acting may communicate to others disregard, dismissal, indifference, or inattention to the problem. On the other hand, not acting may be expectant management, “an attitude of mindful indifference (i.e., the capacity for experienced operators to distinguish problems that could turn into critical ones from problems that can be tolerated on account of the overall system reliability)” (7). Effective mindful indifference relies on staff with the capability to rapidly switch to mindful attention with authority to act.

Within this environment, the authors frame their case report with profound simplicity as a straightforward challenge with minimal actions. The authors indirectly describe the effective use of improvisation (8) and mindful indifference. Could the authors elaborate on their program?

Sincerely,
Daved van Stralen, MD, FAAP
Associate Professor, Pediatrics
Loma Linda University School of Medicine
Cell 909.965.5446

References
The Authors Respond:

Poj Lysouvakon,

I love Dr. van Stralen’s concept of ‘mindful indifference’. In the context of the well-baby nursery, though, I think it shortchanges the thought and hand-wringing that has gone into making care plans for our newborns in the era of COVID. Some may even perceive this ‘mindful indifference’ as just ‘indifference’, intellectual laziness, and/or lack of compassion/concern for the newborn. Rather, this intent of this clinical pearl is to show just how difficult it is to make seemingly simple decisions when there are precious few data points and evidence-based guidelines in these early months of the pandemic. Decisions made now may or may not correlate with the ever-changing recommendations from various organizations and, as such, should be critiqued in the context of those recommendations that were current at the time when the decision was made and not in light of current guidelines.

Joseph R. Hageman

This is what came to mind as part of my initial response to the letter: I like the concept of being mindful (1) in the assessment of the clinical situation and using expectant management...in this era of uncertainty and limited data available to make evidence-based decisions. However, careful observation and ongoing serial assessment is something we used a lot 50 years ago... 50 years ago I was an orderly.

Jaclyn Eisenberg

The large part missing from this clinical pearl is the behind the scenes work. We did not include the reading, the teaching, the meetings about guidelines, the time spent searching for PPE before donning and doffing, the handwashing, and the many discussions with residents, nurses, social workers, lactation consultants, the patient’s pediatrician, and most importantly, the patient’s mother. We did not include the anxious feeling we all shared before walking into the room of a patient whose mother had COVID-19 and wondered if this particular patient could be the one to infect us while hoping that anxiety did not prevent us from providing good patient care. We also did not include the sense of helplessness we felt when we discharged this infant to a home where his mother was his primary caretaker – we did our best to keep him safe in the hospital but knew the best place for him was home with his family.

By condensing this case into a “pearl,” our point was largely that this infant had an unremarkable hospital course in spite of all of the above.

I agree with Poj, though that although mindful indifference is largely what we practice in the MBU - using the word indifference almost undermines what we do on a day to day basis. Observation is not really mindful indifference - it actually is observation. When I choose not to “act,” it’s from a place of serious reflection.

References

tential, opportunity, and ability to lead. Learned helplessness is a quality that represents an adaptation to limited potential and stills self-efficacy.

Emotions play a definite role in leadership. It is the ability to control the natural response to the unfamiliar or seemingly unfavorable that works to the advantage of the leader. The optimist learns to see the "glass half full" as opposed to "half empty." Although the concept is simple, one's followers fall in line with those who favor or can see an outcome that is not predicated to failure (1, 5). Mindfulness allows the leader to look at a situation that a lesser leader might find disconcerting or less advantageous and go beyond traditional logic and predefined notion. Looking at the bright side, opening up new opportunities, defying conventional wisdom is what mindfulness implies (1). The leader imbued with mindfulness is the one who offers hope where others only see failure. It is that leader who radiates optimism: goal setting and performance peaks where there is at least the prospect of success (6). To fall back on preconceived notions is to give up when the situation demands innovation to achieve progress.

To accept a diminished world view, to embrace what is in front or below only, limits interaction, buys into conventional wisdom, and flattens the globe we call earth. Those who willingly imperil themselves by traversing great distances in the name of these limitations only to fall off the edge of their known world in a state of learned helplessness deserve their fate.

Self-efficacy is critically essential to leadership. While this skill does not come naturally, elements of emotional intelligence and mindfulness build a robust platform for the development of this desired ability. The avoidance of preconceived notions, a limited perspective, and the mindfulness that follows is critical in the development of the leader with true self-efficacy (1).

References:

Regards,
MG
Sincerely,
Mitchell Goldstein, MD
Editor in Chief

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

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com
Neonatology Today Readies the Beta Test of its Digital Web Site

Neonatology Today's new web presence, which Dr. Chou supervises, is getting close to production. We teased a graphic preview of the interface in the August edition but are now happy to announce a working beta. The beta can be accessed at https://www.neonatologytoday.org/web/. Although we envision moving the total web presence over to this new format, the PDF version of Neonatology Today will continue in its present form. However, advance search tools will be available to locate individual manuscripts from the current as well as previous editions currently extending back to 2012. Manuscripts can be downloaded in HTML or PDF format. A full download of the journal PDF containing that issue will also be available. We hope that this interface will help us meet the metric for ultimate inclusion in the National Library of Medicine Database (Pub-Med) by facilitating the publication of the specific required file format.

We anticipate that there will be several new features as well.

1. An online submission portal: Submitting a manuscript online will be easier than before. Rather than submitting by email, we will have a devoted online submission portal that will have the ability to handle any size manuscript and any number of graphics and other support files. We will have an online tracking system that will make it easier to track manuscripts in terms of where they are in the review process.

2. Reviewers will be able to review the manuscript online. This portal will shorten the time from receipt of review to getting feedback to the submitting authors.

3. An archive search will be available for journals older than 2012.

4. A new section called news and views will enable the submission of commentary on publications from other journals or news sources. We anticipate that this will be available as soon as the site completes the beta phase.

5. Sponsors will be able to sign up directly on the website and submit content for both the digital and PDF issues of Neonatology Today.

Despite all of these changes, Neonatology Today holds true to our Academic True Open Model (ATOM), never a charge to publish and never a charge to subscribe.

Please find a preview of our new interface just to the right of this column.

If there are any questions about the new website, please email Dr. Chou directly at: fu-sheng.chou@neonatologytoday.net
Erratum (Neonatology Today August, 2020)

Neonatology Today has identified no erratum affecting the August, 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

Which Infants are More Vulnerable to Respiratory Syncytial Virus?

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

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

*Source: Respiratory Syncytial Virus and African Americans

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Caucasian Babies</th>
<th>African American Babies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prematurity</td>
<td>11.6%</td>
<td>18.3%</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>58.1%</td>
<td>50.2%</td>
</tr>
<tr>
<td>Low Birth Weight</td>
<td>7.3%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Siblings</td>
<td>60.1%</td>
<td>71.6%</td>
</tr>
<tr>
<td>Crowded Living Conditions</td>
<td>1%</td>
<td>3%</td>
</tr>
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</table>

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

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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

De cada 15% la salud de la madre, la capacidad para cuidar de un bebé y sus hermanos. Sin embargo, sólo el 15% recibe tratamiento.

Para ayudar a las madres a enfrentar la depresión posparto:
- Los encargados de formular políticas pueden:
  - Financiar los esfuerzos de despistaje y diagnóstico
  - Proteger el acceso al tratamiento
- Los hospitales pueden:
  - Capacitar a los profesionales de la salud para proporcionar apoyo psicosocial a las familias
  - Especialmente aquellas con bebés prematuros, que son 40% más propensas a desarrollar depresión posparto
  - Conectar a las mamás con una organización de apoyo

1 in 3 preterm infants will require support services at school.

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 existing 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.

Visit CDC.gov to find contact information for your state’s early intervention program.
Upcoming Medical Meetings

8th Annual Fall Conference on Current Concepts in Neonatal Care
September 23 - 26, 2020
Napa, California

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

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

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.
Neonatal Nurse Practitioner

- Collaborative work environment
- Care of high acuity NICU patients
- State of the art technology
- 24/7 coverage provided by NNP team and Fellows

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With over 900 beds in four hospitals, we operate some of the largest clinical programs in the nation. We also offer the only Level I Regional Trauma Center and Children’s Hospital in the Inland Empire servicing the largest county in the US. We lead in many areas of excellence; pediatrics, cardiac services, cancer treatment and research, mental health, chemical dependency, and other essential clinical disciplines. All this adds up to endless possibilities for our patients and for you.

The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children’s Hospital is committed to providing high-quality, family-centered care with our highly skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill infants and a new Tiny Baby Program focusing on improving survival and outcomes of extremely low birth weight infants (<1000g at birth). As one of the only level 3 tertiary centers in Southern California, we are equipped to provide the highest level of care for the most complex disorders. We have subspecialists in all medical and surgical areas that are available at all times and are supported by hospital staff with technical, laboratory, and service expertise.

At Loma Linda University Health, we combine the healing power of faith with the practices of modern medicine. We consist of a University, a Medical Center with four hospitals, and a Physicians Group. These resources have helped us become one of the best health systems in the nation.

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- We can create your recruitment ad at no extra charge!

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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.

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Neonatology and the Arts

This section focuses on artistic work which is by those with an interest in Neonatology and Perinatology. The topics may be varied, but preference will be given to those works that focus on topics that are related to the fields of Neonatology, Pediatrics, and Perinatology. Contributions may include drawings, paintings, sketches, and other digital renderings. Photographs and video shorts may also be submitted. In order for the work to be considered, you must have the consent of any person whose photograph appears in the submission.

Works that have been published in another format are eligible for consideration as long as the contributor either owns the copyright or has secured copyright release prior to submission.

Logos and trademarks will usually not qualify for publication.

This month we continue to feature artistic works created by our readers on one page as well as photographs of birds on another. This month’s original artwork is again from Paula Whiteman, MD who has graced Neonatology Today with another stunning graphic. Our bird of the month is provided by Dr. Larry Tinsley, with his update on the endangered plastic flamingo breeding colony.

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